POLICY ROUNDTABLES

Competition and Regulation Issues in the Pharmaceutical Industry

2000

Introduction

The OECD Competition Committee debated competition and regulation issues in the pharmaceutical industry in June 2000. This document includes an executive summary and the documents from the meeting: an analytical note by Mr. Darryl Biggar for the OECD, written submissions from Australia, the Czech Republic, the European Commission, France, Hungary, Italy, Japan, Korea, Mexico, the Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, the United States, BIAC, as well as an aide-memoire of the discussion.

Overview

The pharmaceutical sector is a dynamic, research-intensive industry that is fundamentally influenced by a web of regulations designed to: a) promote research and innovation in the design and production of drugs; b) protect consumers from potentially harmful effects of drugs; and c) to control public and private expenditure on drugs. These objectives are sometimes in conflict and may require a balancing of the interests of producers and consumers. Since most consumers have some form of health insurance, their incentives to control their purchases of pharmaceuticals or to purchase from the most efficient pharmacist are limited.

Health insurers seek to control pharmaceutical expenditure through various policies such as co-payments, lists of approved drugs and maximum reimbursement levels for different drugs. If reimbursement levels for pharmacists are set at a national or regional level, incentives for entry by new pharmacists are excessive in certain locations, typically leading to restrictions on the establishment of new pharmacies.

Well thought out reform of this industry has the potential to reduce pharmaceutical expenditures while maintaining the quality of the drugs consumed.

Related Topics

OECD Guiding Principles for Regulatory Quality and Performance (2005)
Intellectual Property Rights (2004)

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COMPETITION AND REGULATION ISSUES IN THE PHARMACEUTICAL INDUSTRY

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FOREWORD

This document comprises proceedings in the original languages of a Roundtable on Competition and Regulation Issues in the Pharmaceutical Industry, which was held by the Committee on Competition Law and Policy in June 2000.

It is published under the responsibility of the Secretary General of the OECD to bring information on this topic to the attention of a wider audience.

This compilation is one of several published in a series entitled "Competition Policy Roundtables".

PRÉFACE

Ce document rassemble la documentation dans la langue d'origine dans laquelle elle a été soumise, relative à une table ronde sur questions de concurrence et de réglementation dans l'industrie pharmaceutique, qui s'est tenue en juin 2000 dans le cadre de la réunion du Comité du droit et de la politique de la concurrence.

Il est publié sous la responsabilité du Secrétaire général de l'OCDE, afin de porter à la connaissance d'un large public les éléments d'information qui ont été réunis à cette occasion.

Cette compilation fait partie de la série intitulée "Les tables rondes sur la politique de la concurrence".

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EXECUTIVE SUMMARY

In the light of the written submissions, the background note and the oral discussion, the following points emerge:

(1) *The pharmaceutical sector is a high-technology and knowledge-intensive industry. The industry has a two-tier structure. The largest firms account for the majority of the R&D investment in the industry and hold the majority of patents. A large number of smaller firms manufacture off-patent products or under license to a patent-holder. The pharmaceutical industry is heavily regulated. Few aspects of the industry are unaffected by regulatory controls.*

The pharmaceutical sector produces and distributes chemicals with therapeutic value. Pharmaceuticals are an important input into health services more generally. Pharmaceutical policies must be closely integrated into wider health policies to avoid inefficient substitution towards or away from pharmaceuticals relative to other health inputs, to the detriment of health cost and quality outcomes. Most OECD countries spend between ten and 20 percent of total health expenditure on pharmaceuticals. Rising per capita expenditure on pharmaceuticals in several OECD countries over the last decade has focused policy attention on the pharmaceutical industry and controls on pharmaceutical expenditure.

The largest pharmaceutical companies have revenues in the billions and tens of thousands of employees. These companies spend heavily on both marketing and R&D. Marketing expenditures exceed expenditure on R&D. An important component of this marketing effort is the practice of "detailing" – i.e., promotional visits to individual prescribing physicians. Although virtually all OECD countries have some domestic production of pharmaceuticals the bulk of pharmaceutical production occurs in Japan, Switzerland, the US and the EU (particularly the UK). Although the largest pharmaceutical companies may produce competing products, the main form of competition between these companies is competition in innovation – in developing new and/or improved therapies. The second tier of manufacturers – who produce generics or products under license, conduct relatively little R&D of their own and compete mainly on the conventional dimensions of price, service and efficiency.

The pharmaceutical industry is heavily regulated. All aspects of the life-cycle of new drugs are regulated, from patent application, to marketing approval, commercial exploitation, patent expiration and competition with generics. All the important actors in the pharmaceutical industry – the manufacturers, wholesalers, retailers and prescribing physicians are also subject to regulatory controls. These regulatory controls pursue three primary objectives:

(a) preserving the incentives for research and development and the flow of new innovative drugs;

(b) ensuring the safety of drugs consumed by the public; and

(c) controlling the quantity and quality of drug expenditures.

(2) *The protection of intellectual property rights, especially patents, is fundamental for ensuring a continuing flow of innovative new drugs. There is evidence that the pharmaceutical industry is more reliant on patent protection for innovation than other industrial sectors. The research and development process for new drugs is costly and risky. Relatively few new chemical entities ever receive marketing approval. Of these, only a few are commercially successful. A sizeable proportion of pharmaceutical manufacturers revenues can come from relatively few products.*

Pharmaceutical companies are unusually heavily reliant on intellectual property right protection (and, in particular, patents) to preserve the income flows necessary to finance research and development. R&D is a risky business. Of 10 000 products patented, only 100 will reach human trials and only ten will be marketed. Research has found that 75 percent of drug company profits come from just ten percent of all drugs. For some major firms, three products account for 70 – 80 percent of total pharmaceutical sales.

All OECD countries are signatories to the TRIPs agreement, which provides for a standard patent life of 20 years from filing. However, the process for obtaining marketing approval can be slow and costly, taking a number of years. This reduces the effective or commercial life of a patent. Most OECD countries therefore allow for an extension of up to five years to the patent life for pharmaceutical products. (New Zealand and Hungary are exceptions to this rule, allowing no extension; Italy allowed a longer extension for a short period). This is often coupled with provisions which enhance and encourage the entry of generic products upon expiration of the patent.

Many countries have adopted a mutual recognition procedure under which drugs approved in another jurisdiction receive expedited (or automatic) approval domestically. The EU also has a centralised procedure which, for successful applicants, grants marketing approval for the whole of the EU. The time required to obtain marketing approval seems to vary widely. While marketing approval can take years in the US, the time limits are 300 days in the case of New Zealand (for high risk medicines), 95 days in the case of Korea and 90 days in Mexico (60 days for drugs which have been patented in other countries).

(3) *The demand for pharmaceuticals is fundamentally influenced by the presence of health insurance (whether public or private). Health insurance often pays for all or part of the costs of some pharmaceuticals (particularly "prescription" pharmaceuticals). Since the insured consumer does not face the full cost, the incentives on the consumer to curtail his or her demand are weakened. As a consequence, health insurers adopt a host of mechanisms to control the quantity and quality of drug expenditures. These mechanisms include the use of co-payments, formularies, controls on the prices paid for drugs, on prescribing physicians and on pharmacists.*

The market for pharmaceuticals in fundamentally influenced by features of pharmaceutical demand and, in particular, by the effects of health insurance. For those pharmaceutical purchases which are covered by health insurance, the health consumer is partially or fully insulated from the cost and therefore has a weakened incentive to trade-off cost and quality, to substitute other treatments or to forego treatment entirely. It is common to distinguish three pharmaceutical markets – (*a*) the market for non-reimbursed or over-the-counter medicines, for which the consumer pays the full price; (*b*) the market for reimbursed, prescription, or "ethical" medicines, for which the demand is affected by health insurance; and (*c*) the market for pharmaceuticals purchased by hospitals. Hospitals often manage their own pharmaceutical expenditures and may have incentives for controlling costs and using pharmaceuticals effectively.

In the case of prescription medicines, since the final consumer has little incentive to control his/her consumption, responsibility falls to the health insurer (which is often closely linked to the government) to control the quality and quantity of drug expenditures. There are a variety of mechanisms that health insurers can use to ensure cost-effective drug consumption, including the use of co-payments, formularies, controls on the prices paid for drugs, on prescribing physicians and on pharmacists (see below).

Many countries have established specialised agencies to take responsibility for managing pharmaceutical expenditure – maintaining the national formulary, setting co-payment policies and establishing regulatory and financial controls on physicians and pharmacists. In the US, with its predominantly private health care system, these activities are primarily the responsibility of private companies known as Pharmacy Benefit Managers. The US experience suggests that this is one area where responsibility for regulatory policies may be efficiently divested to a commercial organisation.

(a) Co-payments and Reimbursement Policies

The incentives on an individual consumer to control his/her expenditure on drugs depends on the marginal expenditure or "co-payment" that he or she faces. The co-payment may depend on the identity of the drug, the identity of the individual or the level of the annual expenditure of that individual on drugs or on health care more generally. It is common for co-payments to be reduced for the poor or chronically sick. Since the bulk of pharmaceutical expenditures is accounted for by a small minority of consumers, some incentives for control of pharmaceutical expenditures can be retained by limiting reimbursement until annual expenditure exceeds a certain threshold (such as occurs in Denmark, Sweden and Norway).

(b) Formularies

Nearly all health insurers maintain a list of drugs which are covered by the insurance, the extent and conditions of that coverage and any conditions on use or prescribing. This list is known as a formulary. Simple techniques, such as excluding from the formulary drugs which do not meet a cost-effectiveness threshold, can have a big impact on pharmaceutical consumption.

(c) Price Controls

Most health insurers also control the prices that they pay for drugs (or limit the price which will be reimbursed for a drug). These prices are set in different ways. Where the products in a therapeutic class are close substitutes, the prices of the drugs in that class are often set equal to the lowest price in that class.

Where a drug has few close substitutes price-setting is more difficult. It is common to set prices based on international price comparisons of equivalent drugs. If almost all countries set prices on the basis of international comparisons, the importance of the price-setting policies in those countries which do not use international comparisons is magnified. A few countries fix prices on the basis of costs (also known as profit controls). These policies are also occasionally complemented with other industry-wide controls such as a limit on annual rate of increase, a broad freeze on prices or an enforced across-the-board price reduction.

From a theoretical perspective pharmaceutical prices should be set on the basis of cost-benefit analysis, also known as pharmaco-economic analysis. This analysis quantifies the

beneficial effects of a drug (e.g., fewer side-effects, fewer hospitalisations – this analysis necessarily involves subjective elements) and compares it with the cost. In principle all those drugs (and other health inputs) with a benefit-to-price ratio above a given threshold, should be accepted. Several countries (including the UK) have adopted a policy of using pharmaco-economic analysis to assess the quality of pharmaceutical and other health care spending.

(d) Controls on Prescribing Physicians and Pharmacists

Most insurers control the prescribing practices of individual physicians, to ensure the most cost-effective treatment of patients. These controls typically take the form of prescribing guidelines or controls on who may prescribe certain medications. Some countries also impose nominal or explicit "budgets" on prescribing physicians or give a financial incentive to doctors who achieve a certain level of generic prescribing (e.g., Spain). In a few cases the payment to the health care provider is fixed, giving strong incentives to economise on pharmaceutical use along with all other health inputs. The clearest example of this is the UK "GP Fundholder" programme under which the local doctor is given responsibility for purchasing health care services on behalf of a group of patients in return for a fixed per-capita payment. Such schemes rely on competition between doctors to ensure incentives to maintain quality are retained.

Many insurers also control the activities of pharmacists. Since pharmacists are typically compensated on the basis of a percentage margin on the products they sell, in the absence of explicit controls they have an incentive to increase rather than reduce the price of the medications they sell. Many countries either allow, encourage or require substitution of cheaper bio-equivalent products. In some cases, pharmacists are allowed to keep some of the cost savings from substituting cheaper equivalent products. Only in Japan and Korea are doctors are allowed to both prescribe and dispense medications. There is currently in a proposal in Korea to separate these two professions to reduce the financial incentive to over-prescribe.

(4) The costs of maintaining a retail distribution network are a substantial component of the total costs of pharmaceuticals. Where consumers are insured against the price of pharmaceuticals they have no incentive to shop for the cheapest pharmacy and competition between pharmacies cannot be relied upon to ensure efficient and effective delivery of pharmacy services. In these cases it is necessary to regulate the margins of pharmacies.

The widespread availability of and access to pharmaceuticals is one component of the quality of health care services. When consumers are insured against the prices of pharmaceuticals it is not possible to rely on competition to ensure the efficient supply of pharmacy services. In this circumstance, efficient supply of pharmacy services requires knowledge of the costs of maintaining each pharmacy (or each network of pharmacies). Instead, most countries simply fix margins for pharmacists on a nation-wide basis, ignoring local variation in costs. This leads to over-compensation in some areas and possibly under-compensation in others (particularly rural areas). Over-compensation leads to inefficiently high prices to consumers and induces inefficient entry. Countries respond by regulating entry and the location of pharmacies. For example, in Australia, pharmacies can be relocated to a site no closer than two kilometres from another pharmacy and can only move closer to existing pharmacies in steps of one kilometre every two years. In Sweden pharmacy services are provided by a government-owned monopoly company.

One alternative is to tender for the right to provide pharmacy services in a location or for the right to provide a network of pharmacies in a region. The tendering process would reveal information

about the costs of pharmacies. Another possibility would be to lessen the requirement that consumers be completely insured. For example, consumers could be insured for the wholesale costs of the pharmaceutical but not the dispensing costs. If consumers paid for (some part of) the pharmacy dispensing costs, competition between pharmacies would be restored, along with competition with other retail outlets such as mail-order or Internet pharmacies. Some countries (e.g., the US and Australia) already permit sale of pharmaceuticals via the Internet. In other countries (e.g., the Czech Republic) mail-order and Internet sales of pharmaceuticals is strictly forbidden. In the US and Mexico, which have little or no public insurance reimbursement of pharmaceuticals, pharmacies are largely unregulated.

Many countries also regulate the prices and services of pharmaceutical wholesalers. The reason for this remains unclear. Many countries noted that the pharmaceutical wholesaling sector was relatively concentrated. Some countries grant pharmacies a monopoly on the sale of non-prescription pharmaceuticals or require that a pharmacy be owned by a pharmacist, or limit the formation of chains of pharmacies. These restrictions also appear unnecessary.

(5) Differences in policies regarding price controls lead to differences in the wholesale prices of pharmaceuticals across different countries. This, in turn, encourages international trade in pharmaceuticals. This trade, although currently small, potentially undermines the ability of pharmaceutical manufacturers, governments and health insurers to pursue different policies across different countries.

Differences in price control policies encourage traders to purchase pharmaceuticals in low-price countries and sell them in high-price countries. This limits the ability of countries to pursue independent pharmaceutical price-fixing policies. This would likely result in higher prices in poorer countries.

(6) Competition law applies in full to the pharmaceutical industry (with possible derogation for "regulated conduct"). It is conventional to base analysis of the relevant product market on standardised systems for classifying pharmaceuticals according to their therapeutic purpose, such as the ATC classification system. Many of these therapeutic classes are concentrated, with one or two firms accounting for the majority of sales. OECD competition authorities have addressed a range of issues including vertical and horizontal mergers and vertical and horizontal arrangements along with cases of abuse of dominance. Some of the most difficult issues involve the handling of mergers or agreements which might have an impact on the incentives for innovation.

In defining the relevant product markets in pharmaceutical products, it is common to start with standardised classification systems such as the Anatomical Therapeutic Classification ("ATC") system which is recognised by the World Health Organisation. The classifications of drugs given by this system (particularly "level 3") are often used as a starting point for market definition, with other drugs excluded (or added) when the ATC classification is too broad (or too narrow) for competition purposes. It may also be necessary to distinguish pharmaceutical product markets according to the mode of administration (an injectable drug may not be considered to be a substitute for an oral drug) or a different distribution methods (a hospital-only drug may not act as a competitive constraint on a widely available prescription drug).

Many studies of concentration in pharmaceutical markets have found relatively high concentration in individual therapeutic classes. In many markets one or two firms account for the bulk of all sales. However, market share information at one point in time may not give an

accurate impression as market shares may change over time as substitute products are developed and as patents expire.

Over the last decade there has been a wave of horizontal mergers between the largest pharmaceutical companies. Competitive analysis of these mergers requires consideration of not only the products that are currently being commercial exploited but also products which are likely to come into the market in the future (i.e., products that are currently in the process of obtaining market approval). In addition, attention must be paid to the effect of the merger on the incentives for innovation. Where there are barriers to the development of a viable research programme in a particular line of research, the merger of two firms with overlapping research programmes has the potential to delay or limit the rate of innovation. In one case the US FTC required divestiture of the research and development programme for a new drug in phase 3 trials. This R&D programme was purchased by a rival and the resulting product subsequently became a viable competitor to the products offered by the merged entity.

Pharmaceutical companies often enter into agreements and joint-venture arrangements at each stage of the manufacturing process – at the research and development phase (for example, to pool patented know-how) and/or at the marketing and promotion phase (for example, to exploit complementary marketing strengths). Often an agreement for co-operation in research, once a successful product emerges, leads to an agreement for co-operation in marketing.

In the case of vertical mergers, OECD competition authorities have addressed mergers between pharmaceutical manufacturers and wholesalers (e.g., Australia) or mergers between pharmaceutical manufacturers and Pharmacy Benefit Managers (e.g., USA). These vertical mergers raise concerns for competition authorities such as favouring the parent companies own products and sharing of information to facilitate upstream collusion.

Abuse of dominance cases appear relatively rare but are not unknown. France addressed a case in which a manufacturer of product A which held a strongly dominant position and another product B which was losing its patent protection, attempted to restore the revenues of product B by requiring purchasers of the product A to also purchase product B. The US reported cases in which groups of pharmacies acted collectively to refuse lower reimbursement rates offered by insurers. In addition, several countries reported actions against associations of pharmacists seeking to co-ordinate pricing or entry to the profession.

SYNTHÈSE

Les principaux points qui se dégagent des contributions écrites, de la note de référence et des débats oraux peuvent être résumés comme suit :

(1) *L'industrie pharmaceutique est un secteur de haute technologie et à forte intensité de savoir. Elle présente une structure à deux niveaux. Les plus grosses entreprises du secteur réalisent la majorité des investissements en recherche-développement et détiennent la plupart des brevets. Un grand nombre de petites entreprises fabriquent soit des produits non brevetés, soit des produits brevetés pour lesquels une licence leur a été délivrée. L'industrie pharmaceutique est fortement réglementée et peu d'aspects de son activité échappent aux mesures réglementaires.*

Le secteur pharmaceutique produit et distribue des substances possédant des propriétés thérapeutiques. Les produits pharmaceutiques sont une composante importante des services de santé dans leur ensemble. Les politiques les concernant doivent être mises en cohérence avec les autres aspects des politiques de santé afin d'éviter des reports inefficients sur d'autres produits ou d'autres services de santé, avec des conséquences préjudiciables sur les coûts et la qualité des résultats. Dans la plupart des pays de l'OCDE, les dépenses de médicaments représentent de dix à 20 pour cent de la dépense totale de santé. La hausse des dépenses de médicaments par habitant enregistrée au cours de la dernière décennie dans plusieurs pays de l'OCDE a conduit les pouvoirs publics à s'intéresser de près à l'industrie pharmaceutique et à la maîtrise des dépenses de médicaments.

Les plus grosses entreprises du secteur réalisent des milliards de dollars de recettes et emploient des dizaines de milliers de personnes. Elles consacrent des sommes considérables à la commercialisation des produits ainsi qu'à la R-D. Les dépenses de commercialisation sont supérieures à celles affectées à la R-D. Les efforts de commercialisation s'appuient en grande partie sur la pratique du "démarchage", c'est-à-dire sur les visites à visée promotionnelle auprès des médecins prescripteurs. Bien que les pays de l'OCDE aient presque tous une production nationale de médicaments, la grande majorité de la production est concentrée au Japon, en Suisse, aux États-Unis et dans l'Union européenne (surtout au R-U). S'il arrive que les plus grosses sociétés pharmaceutiques fabriquent des produits concurrents, c'est essentiellement sur l'innovation (mise au point de nouveaux traitements et/ou amélioration de traitements existants) que s'exerce la concurrence entre ces sociétés. Les entreprises du second niveau -- fabricants de produits génériques ou de produits sous licence -- effectuent assez peu de R-D et la concurrence qu'elles se livrent est de type conventionnel et s'exerce sur les prix, le service et l'efficience.

L'industrie pharmaceutique est fortement réglementée. Chaque étape du cycle de vie d'un nouveau médicament -- demande de brevet, autorisation de mise sur le marché, commercialisation, expiration du brevet et concurrence des génériques – est réglementée. Tous les principaux acteurs du secteur - fabricants, grossistes, détaillants et médecins prescripteurs -

sont eux aussi soumis à des contrôles réglementaires. Ces contrôles visent essentiellement trois objectifs :

(a) encourager les efforts de recherche et de développement afin de garantir un flux continu de nouveaux médicaments ;

(b) garantir la sécurité des médicaments consommés par les patients ;

(c) contrôler le volume et améliorer la qualité des dépenses de médicaments.

(2) *La protection des droits de propriété intellectuelle, en particulier grâce aux brevets, est essentielle pour garantir la continuité de l'innovation dans de nouveaux médicaments. Certains indices montrent que la protection des innovations par les brevets joue un rôle plus important dans l'industrie pharmaceutique que dans d'autres secteurs. Le processus de recherche et de développement de nouveaux médicaments est coûteux et comporte des risques. Relativement peu de nouveaux composés chimiques obtiennent l'autorisation de mise sur le marché. Pour ceux qui l'obtiennent, la rentabilité commerciale est loin d'être toujours garantie. Les fabricants de produits pharmaceutiques tirent une proportion non négligeable de leurs recettes d'un assez petit nombre de produits.*

Les entreprises pharmaceutiques se caractérisent par une dépendance exceptionnellement forte à l'égard de la protection des droits de propriété intellectuelle (et notamment des brevets), qui leur garantit les revenus nécessaires pour financer leurs activités de recherche-développement. La R-D est une activité à risque. Sur 10 000 produits brevetés, une centaine seulement parviennent au stade des essais sur l'homme et une dizaine sont commercialisés. Des études ont montré que 75 pour cent des profits des sociétés pharmaceutiques provenaient de dix pour cent seulement de l'ensemble des médicaments. Quelques grandes sociétés réalisent 70 à 80 pour cent de leur chiffre d'affaires grâce à trois produits.

Tous les pays de l'OCDE sont signataires de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC), lequel fixe la durée de vie usuelle d'un brevet à 20 ans à compter du dépôt de la demande. Toutefois, la procédure d'obtention de l'autorisation de mise sur le marché peut être longue et coûteuse et s'étaler sur plusieurs années, ce qui réduit la durée de vie effective du brevet. Aussi la plupart des pays ont-ils pris des dispositions autorisant l'allongement, pour une durée maximale de cinq ans, de la durée des brevets protégeant les médicaments (la Nouvelle-Zélande et la Hongrie font figure d'exception puisqu'elles n'autorisent aucun prolongement ; l'Italie a autorisé pendant une courte période une extension plus longue). Ces dispositions s'accompagnent souvent de mesures visant à faciliter et encourager la mise sur le marché de génériques à l'expiration des brevets.

De nombreux pays ont instauré une procédure de reconnaissance mutuelle en vertu de laquelle les médicaments agréés par les autorités d'un pays peuvent bénéficier d'une procédure d'agrément accélérée (ou automatique) dans un autre pays. L'Union européenne a également mis en place une procédure centralisée au terme de laquelle les médicaments ayant reçu l'agrément peuvent être commercialisés dans l'ensemble des pays de l'Union. Le délai d'obtention de l'autorisation de mise sur le marché semble très variable : la procédure prend plusieurs années aux États-Unis mais ne dépasse pas 300 jours en Nouvelle-Zélande (pour les médicaments à haut risque), 95 jours en Corée et 90 jours au Mexique (60 jours pour les médicaments ayant obtenu un brevet dans d'autres pays).

(3) *L'intervention de l'assurance maladie (publique ou privée) conditionne fortement la demande de médicaments. Dans bien des cas, l'assurance maladie prend en charge l'intégralité ou une partie du coût de certains médicaments (en particulier les médicaments délivrés sur ordonnance). Dans la mesure où ils ne supportent pas la totalité des coûts, les assurés ne sont guère incités à modérer leur consommation. Aussi les assureurs ont-ils été conduits à introduire divers mécanismes de régulation du volume et de la qualité des dépenses de médicaments, parmi lesquels la participation aux coûts, les formulaires et la réglementation du prix des médicaments ainsi que de l'activité des médecins prescripteurs et des pharmaciens.*

Le marché des produits pharmaceutiques est largement conditionné par les caractéristiques de la demande de médicaments, et en particulier par le comportement des organismes d'assurance maladie. Dans le cas des médicaments couverts par l'assurance maladie, le consommateur est partiellement ou complètement coupé du coût des produits qu'il consomme et n'est donc guère incité à arbitrer entre coût et qualité, à se porter vers d'autres produits ou à renoncer complètement à son traitement. On distingue généralement trois marchés pharmaceutiques : (*a*) le marché des médicaments non remboursés ou en vente libre, dont le consommateur paie l'intégralité du prix ; (*b*) celui des médicaments dits "éthiques", qui sont remboursés et vendus sur prescription, dont la demande est liée au niveau de prise en charge par l'assurance maladie ; enfin, (*c*), celui des médicaments achetés par les hôpitaux. Les hôpitaux gèrent souvent eux-mêmes leurs dépenses de médicaments, ce qui peut les inciter à contrôler les coûts et à optimiser la consommation de médicaments.

Dans le cas des médicaments délivrés sur ordonnance, puisque le consommateur final n'a guère de motif pour modérer sa consommation, c'est à l'assurance maladie (qui fonctionne souvent en liaison étroite avec les pouvoirs publics) qu'incombe la responsabilité de réguler les dépenses de médicaments et d'en améliorer la qualité. Les assureurs ont à leur disposition divers mécanismes pour garantir l'efficacité de la consommation de médicaments par rapport à son coût, notamment la participation aux coûts, les formulaires, la réglementation du prix des médicaments ou les mesures de contrôle visant les médecins prescripteurs et les pharmaciens.

De nombreux pays ont institué des agences spécialisées chargées de la gestion des dépenses pharmaceutiques -- gestion des formulaires nationaux, définition des politiques de participation aux coûts et instauration des mesures de contrôle réglementaire et financier visant les médecins et les pharmaciens. Aux États-Unis, où l'essentiel du système de soins est privé, la plupart de ces fonctions sont assurées par des sociétés de gestion des soins pharmaco-thérapeutiques (les Pharmacy Benefit Managers ou PBM). L'expérience de ce pays tend à démontrer qu'il s'agit d'un domaine où la responsabilité des mesures réglementaires peut être efficacement confiée à un organisme commercial.

(a) Politiques de remboursement et de participation aux coûts

La mesure dans laquelle les patients sont incités à modérer leurs dépenses de médicaments dépend du montant du paiement marginal qu'ils doivent supporter, c'est-à-dire de leur participation aux coûts. Celle-ci peut varier en fonction du type de médicaments, de l'identité de la personne assurée ou du montant annuel des dépenses de médicaments ou de soins de santé en général encourues par l'assuré. Le montant de la participation aux coûts est généralement réduit pour les personnes démunies ou les malades chroniques. Comme la majeure partie des dépenses de santé est le fait d'une minorité de consommateurs, la limitation des remboursements jusqu'à hauteur d'un certain plafond de dépenses pharmaceutiques annuelles (système appliqué au Danemark, en Suède et en Norvège) peut être un instrument efficace de régulation des dépenses de santé.

(b) Formulaires

Presque tous les organismes d'assurance maladie ont établi des "formulaires", c'est-à-dire des listes où sont répertoriés les médicaments pris en charge par l'assurance, l'étendue et les conditions de cette prise en charge, ainsi que les conditions d'utilisation ou de prescription des médicaments. Des mesures simples, comme le fait d'exclure du formulaire les médicaments dont le rapport coût/efficacité est inférieur à un certain seuil, peuvent avoir des effets sensibles sur la consommation de médicaments.

(c) Contrôles des prix

La plupart des assureurs exercent également un contrôle sur les prix auxquels les médicaments sont vendus (ou limitent le taux de remboursement). Il existe différentes méthodes de fixation des prix. Lorsque des médicaments appartenant à une même classe thérapeutique sont de proches équivalents, leur prix est souvent aligné sur celui du produit le moins cher de cette classe.

La fixation du prix est plus délicate lorsque le médicament n'a pas de proche substitut. Dans ce cas, on se base fréquemment sur une comparaison internationale des prix de médicaments équivalents. Le fait que la grande majorité des pays s'appuient sur de telles comparaisons pour fixer les prix tend à amplifier l'importance des politiques de fixation des prix des pays qui n'ont pas recours à cette méthode. Quelques pays ont un système de fixation des prix en fonction des coûts (on parle également de système de contrôle des bénéfices). Ces dispositions sont parfois complétées par d'autres mesures applicables à l'ensemble du secteur, comme la limitation du taux d'augmentation des prix, le gel ou la réduction des prix.

Théoriquement, les prix des produits pharmaceutiques devraient être fixés en fonction d'analyses coût-avantage, encore appelées analyses pharmaco-économiques. Ces analyses consistent à quantifier les effets bénéfiques d'un médicament (par exemple, diminution des effets secondaires et du nombre d'hospitalisations -- ce type d'évaluation comportant inévitablement une part de subjectivité) puis à les comparer à son coût. En principe, tous les médicaments (ou autres biens médicaux) dont le ratio avantage-prix est supérieur à un certain seuil devraient être couverts. Plusieurs pays (dont le Royaume-Uni) ont recours aux analyses pharmaco-économiques pour évaluer la qualité des dépenses de produits pharmaceutiques et d'autres types de dépenses médicales.

(d) Mesures de contrôle visant les médecins prescripteurs et les pharmaciens

La plupart des assureurs exercent un contrôle sur les habitudes de prescription des médecins afin de s'assurer que les patients bénéficient des thérapies présentant le meilleur rapport coût-efficacité. Ce mode de régulation prend généralement la forme de lignes directrices en matière de prescriptions ou de contrôles sur les personnes autorisées à prescrire certains médicaments. Quelques pays attribuent aux médecins des budgets de prescription nominaux ou explicites, ou accordent des compensations à ceux qui prescrivent un certain volume de médicaments génériques (Espagne). Dans un petit nombre de cas, les prestataires de soins se voient allouer un budget fixe, ce qui les incite fortement à économiser sur les dépenses de médicaments et autres dépenses médicales. L'exemple le plus caractéristique de ce type de pratique est celui du Royaume-Uni, où les médecins gestionnaires d'un budget (fundholders) sont chargés d'acheter des services de santé pour un groupe de patients en contrepartie d'une somme forfaitaire par

patient. Dans ce type de systèmes, c'est la concurrence entre les médecins qui garantit le maintien de la qualité des prestations.

De nombreux assureurs contrôlent aussi l'activité des pharmaciens. La rémunération de ces derniers correspondant en général à un certain pourcentage du prix des produits qu'ils vendent, ceux-ci ont intérêt à augmenter le prix de leurs produits s'il n'existe aucun contrôle formel. De nombreux pays autorisent, encouragent ou imposent la substitution, c'est-à-dire la délivrance de produits bio-équivalents moins onéreux à la place des produits prescrits. Dans certains cas, les pharmaciens sont autorisés à conserver une fraction des économies engendrées par la substitution d'équivalents thérapeutiques moins coûteux. Le Japon et la Corée sont les deux seuls pays où les pharmaciens ont à la fois le droit de prescrire des médicaments et de les délivrer. En Corée, une proposition visant à séparer ces deux fonctions pour réduire l'incitation financière à la sur prescription est actuellement à l'étude.

(4) Les coûts de maintien d'un réseau de distribution au détail sont un élément important du coût total des produits pharmaceutiques. Dans le cas où les assurés bénéficient de la prise en charge de leurs dépenses pharmaceutiques, ils ne sont nullement incités à s'adresser à la pharmacie la plus économique et la concurrence entre pharmacies ne peut permettre d'assurer la fourniture efficiente et efficace de services de pharmacie. Il est donc nécessaire de réglementer la marge des pharmaciens.

L'accès aux produits pharmaceutiques et leur disponibilité en quantité suffisante est l'une des composantes de la qualité des services de santé. Dans le cas où les assurés bénéficient de la prise en charge de leurs dépenses pharmaceutiques, la concurrence entre pharmacies ne peut permettre d'assurer la fourniture efficiente de services de pharmacie. L'efficience des services de pharmacie nécessite dans ce cas la connaissance des coûts d'exploitation de chaque officine pharmaceutique (ou de chaque réseau d'officines). Or la plupart des pays fixent la marge des pharmaciens à l'échelle nationale sans tenir compte des variations de coûts d'une zone géographique à l'autre, de sorte que la rémunération des pharmaciens est excessive dans certaines zones et peut-être insuffisante dans d'autres (notamment dans les zones rurales). Une rémunération excessive conduit à des niveaux de prix anormalement élevés pour le consommateur et rend inefficiente l'entrée de nouveaux venus sur le marché. Aussi les pays réglementent-ils l'installation et l'implantation des pharmacies. En Australie, par exemple, une pharmacie peut être réimplantée sur un site situé à une distance d'au moins deux kilomètres d'une autre pharmacie, et peut être autorisée à se rapprocher d'un kilomètre tous les deux ans de pharmacies existantes. En Suède, les services pharmaceutiques sont dispensés par une entreprise d'Etat détentrice d'un monopole.

Une autre façon de procéder consisterait à adjuger par appel d'offres le droit de fournir des services pharmaceutiques dans un lieu donné ou d'approvisionner un réseau d'officines dans une région. La procédure d'appel d'offres permettrait de recueillir des informations sur les coûts des pharmacies. L'assouplissement des règles de remboursement des dépenses de médicaments est une autre solution envisageable. Les patients pourraient par exemple bénéficier du remboursement du prix de gros des médicaments mais non des frais de dispensation. En faisant payer aux consommateurs une partie de ces frais, on rétablirait la concurrence entre les pharmacies ainsi qu'avec d'autres types de détaillants comme les sociétés de vente de produits pharmaceutiques par correspondance ou par Internet. La vente de médicaments par correspondance ou par Internet est strictement interdite dans certains pays (notamment en République tchèque). Aux États-Unis et au Mexique, pays où les dépenses de

médicaments ne sont pas ou pratiquement pas remboursées par les régimes publics d'assurance, le marché des pharmacies est très peu réglementé.

De nombreux pays réglementent également les prix et l'activité des grossistes en produits pharmaceutiques. Les raisons pour lesquelles ils le font restent obscures. Beaucoup de pays font valoir que le secteur de la vente de produits pharmaceutiques en gros est relativement concentré. Certains accordent aux pharmacies le monopole de la vente des médicaments délivrés sans ordonnance, exigent que les propriétaires des pharmacies soient des pharmaciens, ou limitent la constitution de chaînes de pharmacies. L'utilité des ces restrictions n'apparaît pas non plus très évidente.

(5) *Les différences de politiques de fixation des prix se traduisent par des différences de prix de gros des produits pharmaceutiques entre les pays. Cette situation favorise le commerce international des produits pharmaceutiques. Ce type de commerce, encore limité pour le moment, risque d'entamer la capacité des fabricants de produits pharmaceutiques, des pouvoirs publics et des assureurs de mener des politiques différenciées selon les pays.*

Les différences de politiques de contrôle des prix encouragent les négociants à acheter des produits pharmaceutiques dans les pays à bas prix et à les vendre dans les pays où les prix sont élevés. Ce phénomène réduit la capacité des pays de mener des politiques indépendantes de fixation des prix des produits pharmaceutiques, ce qui risque de se traduire par des prix plus élevés dans les pays pauvres.

(6) *La législation sur la concurrence s'applique intégralement à l'industrie pharmaceutique (des dérogations étant possibles pour les "comportements réglementés"). On a coutume de fonder l'analyse du marché de produits pertinent sur des systèmes standardisés de classification des produits par "classe thérapeutique", comme le système de classification ATC. Le degré de concentration est élevé dans bon nombre de classes thérapeutiques, où une ou deux entreprises réalisent la majorité des ventes. Les autorités responsables de la concurrence dans les pays de l'OCDE sont intervenues à diverses reprises, notamment lors de fusions et d'ententes verticales et horizontales ou de cas d'abus de position dominante. L'une des situations les plus délicates à régler est celle des fusions ou des ententes qui risquent d'être nuisibles à l'innovation.*

Pour définir le marché de produits pertinent pour l'analyse de la concurrence dans l'industrie pharmaceutique, on a coutume d'utiliser des systèmes de classification standardisés comme la Classification anatomique thérapeutique (Classification ATC), reconnue par l'Organisation mondiale de la Santé. Cette classification des médicaments (en particulier le "niveau 3") sert souvent de point de départ à la définition du marché, certains médicaments étant exclus ou ajoutés selon que la classe thérapeutique ATC est trop large ou trop étroite pour les besoins de l'analyse de la concurrence. Il peut également s'avérer nécessaire d'opérer une différenciation des marchés de produits pharmaceutiques en fonction du mode d'administration des produits (un médicament injectable peut ne pas être considéré comme équivalent à un médicament administrable par voie orale) ou de son mode de distribution (un médicament exclusivement dispensé à l'hôpital peut ne pas faire concurrence à un produit équivalent vendu sur prescription et largement diffusé).

De nombreuses études du secteur pharmaceutique ont mis en évidence une assez forte concentration dans certaines classes thérapeutiques. Sur de nombreux segments du marché, une ou deux entreprises réalisent la majorité des ventes. Toutefois, la connaissance des parts de marché détenues à un moment donné ne donne pas forcément une image précise du marché car

ces parts évoluent avec le temps à mesure que des produits substituts sont mis au point et que les brevets arrivent à expiration.

La dernière décennie a été marquée par une vague de fusions horizontales entre les grandes sociétés pharmaceutiques. L'analyse de ces fusions sous l'angle de la concurrence doit prendre en compte non seulement les produits actuellement commercialisés, mais aussi ceux susceptibles d'être mis sur le marché au cours des prochaines années (c'est-à-dire ceux qui n'ont pas encore obtenu l'autorisation de mise sur le marché). En outre, il convient d'évaluer les conséquences des fusions sur l'incitation à innover. Lorsqu'il existe des obstacles à la mise en place d'un programme de recherche viable dans un domaine donné, la fusion de deux entreprises dont les activités de recherche se recoupent peut freiner ou limiter le rythme des innovations. C'est ainsi qu'aux États-Unis, la FTC a exigé la cession du programme de recherche-développement d'un nouveau médicament parvenu aux essais de la phase 3. Ce programme a été racheté par une firme concurrente, ce qui a permis de mettre au point un substitut viable au médicament proposé par l'entité issue de la fusion.

Les sociétés pharmaceutiques concluent fréquemment des ententes et des accords de co-entreprise aux différents stades du processus de fabrication - au stade de la R-D (par exemple, pour mettre en commun leurs découvertes brevetées) et/ou à celui de la commercialisation et de la promotion (notamment pour tirer parti de la complémentarité de leurs forces de vente). Il est fréquent qu'un accord de coopération en matière de recherche, s'il donne naissance à un produit rentable, se prolonge par un accord de co-marketing.

En ce qui concerne les fusions verticales, les autorités en charge de la concurrence dans les pays de l'OCDE ont été confrontées à des cas de fusions entre fabricants de produits pharmaceutiques et grossistes (notamment en Australie) ou entre fabricants et sociétés de gestion des soins pharmaco-thérapeutiques (États-Unis). Les autorités craignent notamment que ces fusions ne favorisent les produits des sociétés mères ou ne permettent le partage d'informations facilitant la collusion en amont.

Les cas d'abus de position dominante sont relativement rares mais il en existe. La France a connu un cas où une entreprise fabriquant un produit A pour lequel elle détenait une position nettement dominante, et un produit B dont le brevet arrivait à expiration, a tenté de préserver les recettes procurées par le produit B en obligeant les acheteurs du produit A à acquérir également le produit B. Les États-Unis rapportent que des groupes de pharmacies ont engagé une action collective pour s'opposer à la diminution des taux de remboursement proposés par les assureurs. En outre, plusieurs pays font état d'actions engagées contre des groupements de pharmaciens qui tentaient de coordonner leurs tarifs ou les conditions d'accès à la profession.

BACKGROUND NOTE

1. Introduction

Very few industries are as profoundly influenced by regulation as the pharmaceutical industry. The nature of demand for drugs, the identity of drugs brought to market and the nature of competition in the drug market over time are all shaped by regulation. There are three main objectives to this regulation:

- securing a reward to R&D to assure a continuous flow of innovative new medications;
- ensuring the safety of drugs; and
- controlling the quantity and enhancing the quality of drug expenditures.

The combined effect of this regulation is that competition takes a different form than in other industries. On the supply side, the vagaries of the R&D process and the substantial costs and delays of the drug authorisation process make new drug development a risky and costly business. But, successful drugs, protected from competition by intellectual property rights, can yield a substantial reward. On the demand side, the presence of ubiquitous health insurance partially insulates final consumers from the prices of the drugs they consume. In their place, public and private health insurers adopt a host of mechanisms for controlling the quantity and quality of drug consumption. The nature of competition in the drug industry is determined by the interaction of both these supply and demand side effects.

Despite the ubiquitous regulation, competition is not excluded entirely from this industry. For example, competition is a key driving force behind the development of new innovative drugs and a key factor in keeping down prices and production costs of off-patent drugs. However the appropriate role for competition is not always plain. Competition advocacy in this industry requires taking a holistic view. The simple removal of some isolated constraints on competition may not always improve welfare. For example, removal of entry barriers on pharmacies may, in the presence of guaranteed margins for pharmacists, simply lead to inefficient entry and oversupply of pharmacies, wasting scarce economic resources. Alternatively, removal of price controls on prescription drugs may simply push up drug expenditure without any improvement in health outcomes or in the level of competition among drug manufacturers.

This paper describes the key features of the pharmaceutical industry and the regulations which control and shape every aspect of the development, marketing, prescribing and consumption of drugs. The paper seeks to identify, wherever possible, the opportunities for greater reliance on competition. The paper makes the following key points:

- In most OECD countries, expenditure on pharmaceuticals is growing at a faster rate than health care expenditure overall. This has focused public policy concern on mechanisms for controlling pharmaceutical expenditure. Cross-country comparisons of pharmaceutical consumption show that although richer countries consume more pharmaceuticals per capita, some countries, such as France, USA and Japan have high pharmaceutical consumption per capita which cannot be explained on the basis of higher national incomes alone.

- The pharmaceutical industry is characterised by substantial investment in R&D and a continuous flow of new innovations. Almost all the R&D of the industry is carried out by large multinational firms. This R&D is funded primarily from the profits flowing from exclusive rights granted to a patent holder during a patent's life time. These exclusive rights can lead to substantial market power and wide margins between price and cost. Many countries have sought to extend patent life in the pharmaceutical industry, in part to offset the substantial costs and delays associated with obtaining marketing approval. At the same time, many countries have adopted policies to engage competition from rival manufacturers once a patent expires.

- Research-based pharmaceutical companies operate in a high-risk/high-reward environment. The process of obtaining marketing approval for a new drug is very long and costly, taking around eight years and with a cost of hundreds of millions of dollars. Very few new chemical compounds that are created ever receive marketing approval, and of those only a few are successful. But the profitability of a best-selling drug can be substantial. Pharmaceutical companies spend substantial amounts promoting their brand-name drugs. Despite the research-intensiveness of this sector, pharmaceutical companies spend more on marketing than on R&D. Although there are a large number of pharmaceutical manufacturers, the level of concentration in the market for drugs to treat a given medical condition (known as the "therapeutic class") can be very high.

- In the case of prescription drugs, the nature of demand depends upon the rules, institutions and incentives established by the health insurer to control and govern the actions of the manufacturer, health consumer, the prescribing physician and the pharmacist. Health insurers use a host of mechanisms to control the quantity and quality of pharmaceutical expenditures. In the US, health insurers purchase these "pharmacy benefit management" services from independent companies. In other countries, these services are often provided by a government agency. The example of the US shows that there is scope for contracting out these services to private companies, even in countries with nationalised health insurers.

- The mechanisms used to control pharmaceutical expenditures include the use of formularies, reimbursement policies, controls on doctors, incentive schemes, controls on pharmacists and price controls. Formularies are a simple list of the drugs that the insurer will cover and any conditions on coverage. With the exception of some private insurers in the US, major insurers in all OECD countries use some form of formulary. Most OECD insurers also seek to influence the prescribing behaviour of doctors, through systems of guidelines and/or prescribing rules. This is often supported by the collection and dissemination of information on the prescribing behaviour of doctors.

- Most OECD health insurers also use reimbursement policy (in the form of co-payments, fees or charges for drugs) to moderate pharmaceutical demands. Only a few countries (most notably US HMOs and the UK fund-holder scheme) have systems which seek to directly align the incentives of the doctor and the insurer. In the UK fund-holder scheme local doctors are responsible for purchasing, on behalf of their customers, a range of health services. This gives the doctor strong incentives to use pharmaceuticals efficiently and effectively.

- All insurers also adopt some form of controls on the prices of drugs. For drugs which face adequate competition from generics, a common practice is to set the price equal to the lowest-priced drug in a therapeutic class. In some cases the lowest-priced drug is selected through tendering procedures. For drugs without effective substitutes price regulation is more difficult. Many countries explicitly base prices on prices prevailing in neighbouring countries. Other countries focus on controlling the overall profits of the manufacturer. Many countries limit the

extent to which prices, once set, can evolve over time. A full analysis of the price that an insurer is willing to pay for a drug requires a pharmaco-economic analysis of the benefits of the drug against its cost.

- The costs of maintaining a retail distribution network are a substantial component of the total costs of pharmaceuticals. In countries where the consumer is fully insulated from the cost of the pharmaceuticals he or she consumes, or where the co-payment does not vary from pharmacy to pharmacy, competition between pharmacies cannot be relied upon to ensure efficient and effective delivery of pharmacy services. In these countries it is also necessary to regulate the margins of pharmacists. The cost of pharmacy services varies from pharmacy to pharmacy and in most cases the insurer does not have the information on costs necessarily to set the margins efficiently. As a result there is a risk that either low-cost/high-volume pharmacies will be overcompensated, leading to excessive entry, or high-cost/low-volume pharmacies will be closed reducing service quality in certain areas. A preferable approach is to tender for the right to provide pharmacy services, especially in high-cost/low-volume areas.

- Most countries also have explicit policies to encourage consumption of lower-cost generic medications. These policies may operate on each of the different actors in the pharmaceutical market (doctors, pharmacists, wholesalers, consumers), such as policies to limit reimbursement to the cheapest product in a therapeutic class, requirements or economic incentives on doctors to prescribe generically (i.e., to prescribe according to the active ingredient and not by the brand name) and requirements or economic incentives on pharmacists to substitute bio-equivalent products. Where pharmacists' percentage margins are fixed they have an incentive to increase (rather than decrease) the costs of drugs. In these cases promotion of generics requires reform to pharmacists' compensation.

- Price differences between countries invite traders to arbitrage – buying pharmaceuticals in low price countries and selling them in high price countries. The effect of this "parallel trade" on prices depends on the nature of price regulation. Parallel trade may cause prices to rise in low price countries (manufacturers will be less willing to offer a discount to a country if that discount threatens prices elsewhere) and may lower prices in high price countries (if there is some mechanism by which the prices of parallel imports can be taken into account in the price-control process). The European Commission views parallel trade as "an important driving force for market integration"[1] and the European Court of Justice has, on several occasions ruled in favour of supporting parallel trade. Within Europe, parallel trade in medicines has a small, but not unimportant, market share. Parallel trade remains highly controversial.

- The presence of limited competition and barriers to entry in pharmaceutical markets and some markets for pharmacy services gives rise to market power and scope for anti-competitive behaviour. Pharmaceutical firms have been prosecuted for antitrust violations, including for cartels, price-fixing, forms of tying, exclusive marketing agreements and agreements to delay the entry of generics. Pharmacists, especially in the US, have colluded to raise the rates at which their services are remunerated. Many potential mergers in the pharmaceutical industry have been opposed on the grounds that they will unacceptably reduce competition either between current products or in the rate of innovation of new products in the future. In some cases mergers have been opposed on the grounds that the merging parties have overlapping R&D efforts and are therefore the only likely sources of new products in given therapeutic classes in the future. In many cases mergers have been conditioned on the divestment of existing products or products currently under development.

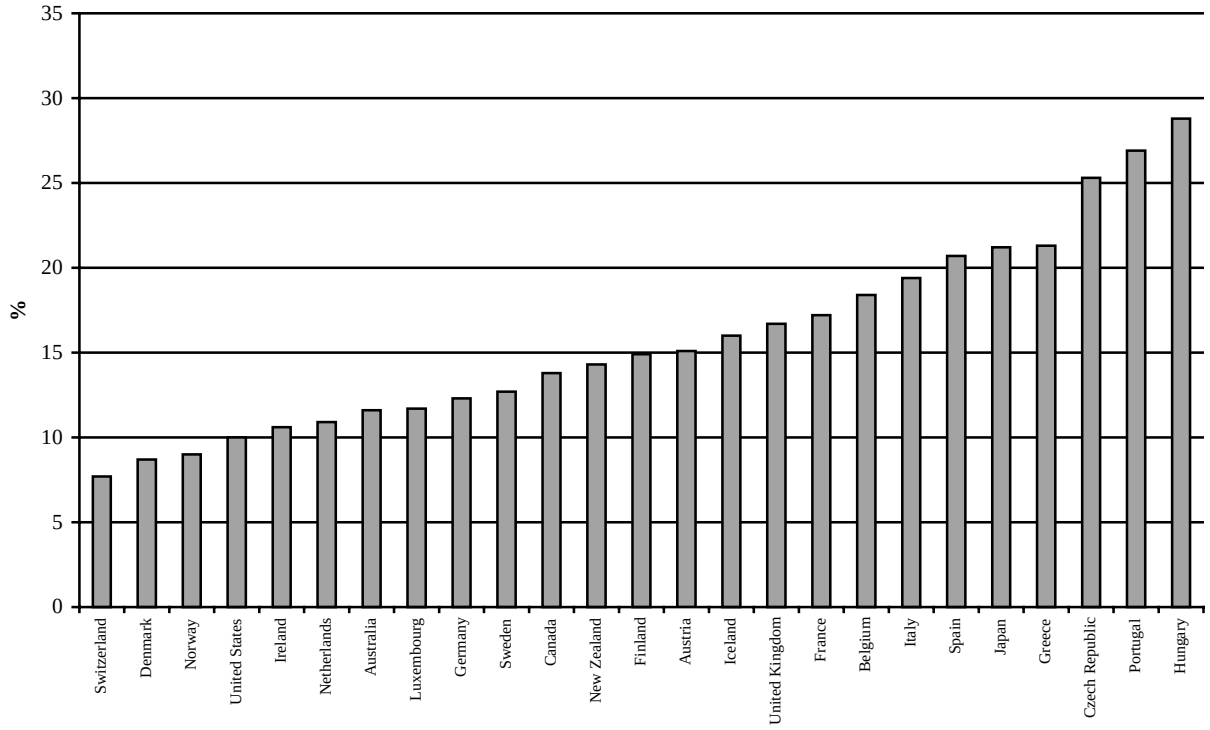
2. The Pharmaceutical Industry

This section sets out some key facts which together provide an overall picture of the nature and function of the pharmaceutical industry.[2]

2.1 The Pharmaceutical Market as Part of the Wider Health Market in OECD countries

Expenditure on pharmaceuticals accounts for a sizeable and growing share of total expenditure on health care in OECD countries. As Figure 1 shows, expenditure on pharmaceuticals accounts for between ten and 20 percent of total expenditure on health for most OECD countries. There is a clear correlation between the share of pharmaceutical expenditure in total health expenditure and GDP per capita. Richer countries spend a slightly lower proportion of total health spending on pharmaceuticals, while poorer countries spend a higher percentage.

Figure 1: Expenditure on Pharmaceuticals as a percentage of Total Expenditure on Health (1997)



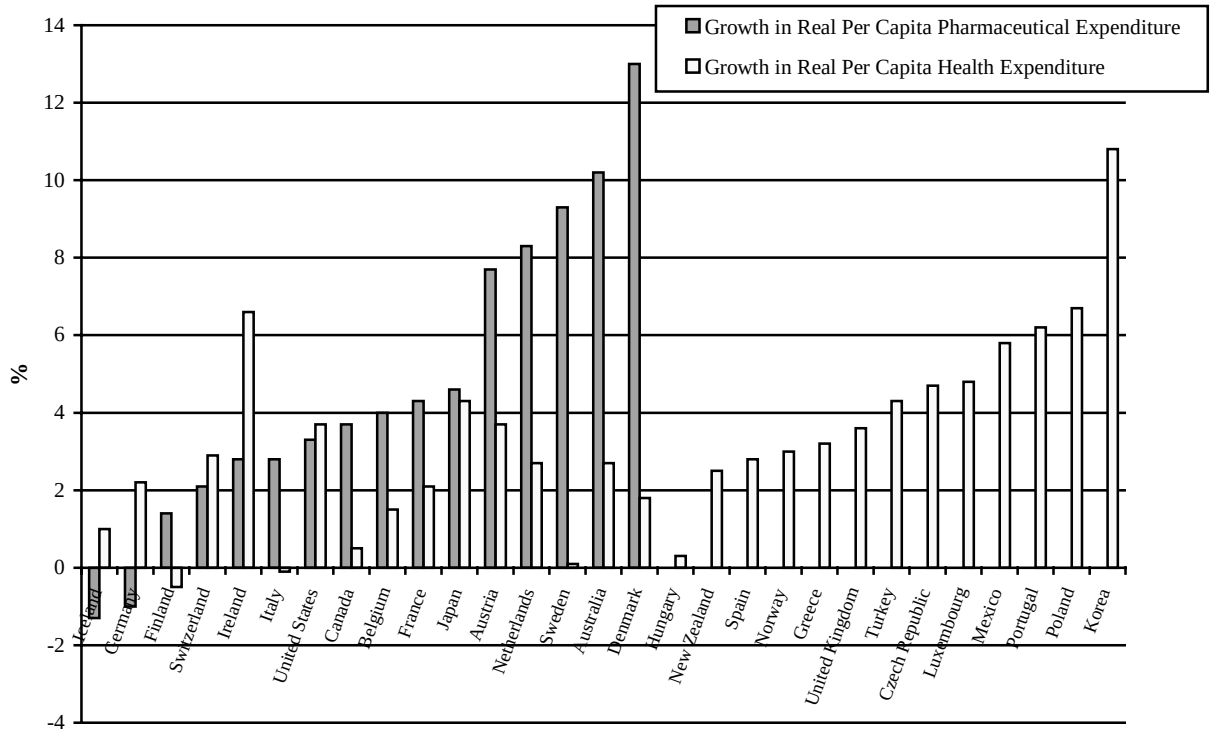
Notes: Data is for 1997, except for Norway, Ireland, Australia, Luxembourg, Japan, Greece, Hungary (1996). No data is available for Turkey, Korea, Mexico and Poland
Source: OECD Health Data 1999

During the 1990s total expenditure per capita expenditure on pharmaceuticals rose faster than the rate of inflation and faster than the rate of growth in total health care expenses in several OECD countries.[3] Of the 16 countries for which data for the 1990s is available, pharmaceutical expenditure growth exceeded total health care expenditure growth in 11 (see Figure 2).

Since, for many countries, pharmaceutical expenditures are a responsibility of the state (typically through one or more state-owned health insurers), increasing pharmaceutical expenditures has, in many countries, focused public policy attention on measures to control the quantity and quality of pharmaceutical consumption.[4] In the US, for example, in the early 1990s, President Clinton and some members of Congress proposed regulating pharmaceutical prices. In fact, during the 1993/94 session of the US Congress, three bills to control the price of prescription drugs were introduced in the US House of Representatives.[5]

High rates of growth in per-capita pharmaceutical expenditure is not necessarily a cause for concern as it may simply reflect an efficient rebalancing of total health expenditure. As new pharmaceuticals are developed which are able to treat diseases which could previously only be treated with, for example, surgery, it is appropriate that there be a rebalancing towards pharmaceutical expenditures and away from other health services.

Figure 2: Pharmaceutical Expenditure Growth 1990-1997

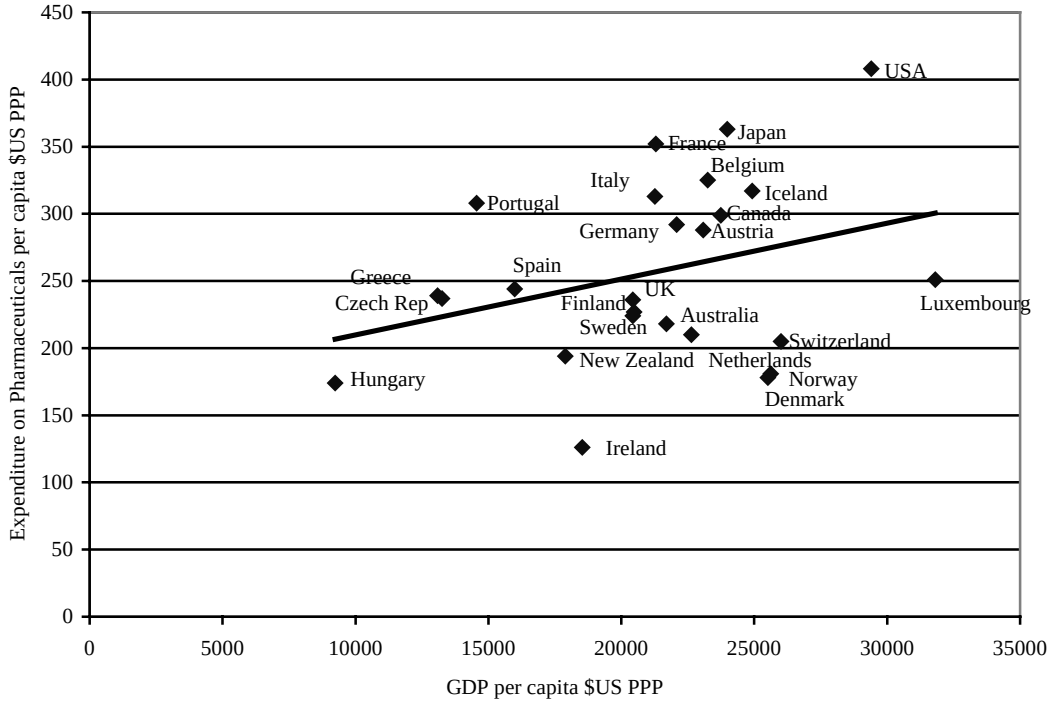


Note: Data reflects per annum growth in inflation adjusted per capita pharmaceutical expenditure and total health expenditure. Data are for 1990-1997, except pharmaceutical expenditure in Australia, Belgium, Denmark, Finland, Germany, Iceland, Ireland, Japan, Netherlands, Sweden, and US (1990-1996).
Source: OECD Health Data 1999

Pharmaceutical expenditure per capita increases with GDP per capita. An increase of $US 1000 in GDP per capita leads to an increase of about $US four per capita in pharmaceutical expenditure. Even so, there are quite large differences in per capita consumption which cannot be explained by differences in

GDP. In particular, per capita consumption of pharmaceuticals is very high in France, Japan and the USA and relatively low in Ireland, Denmark and Norway.

Figure 3: Pharmaceutical Expenditure per capita versus GDP per capita

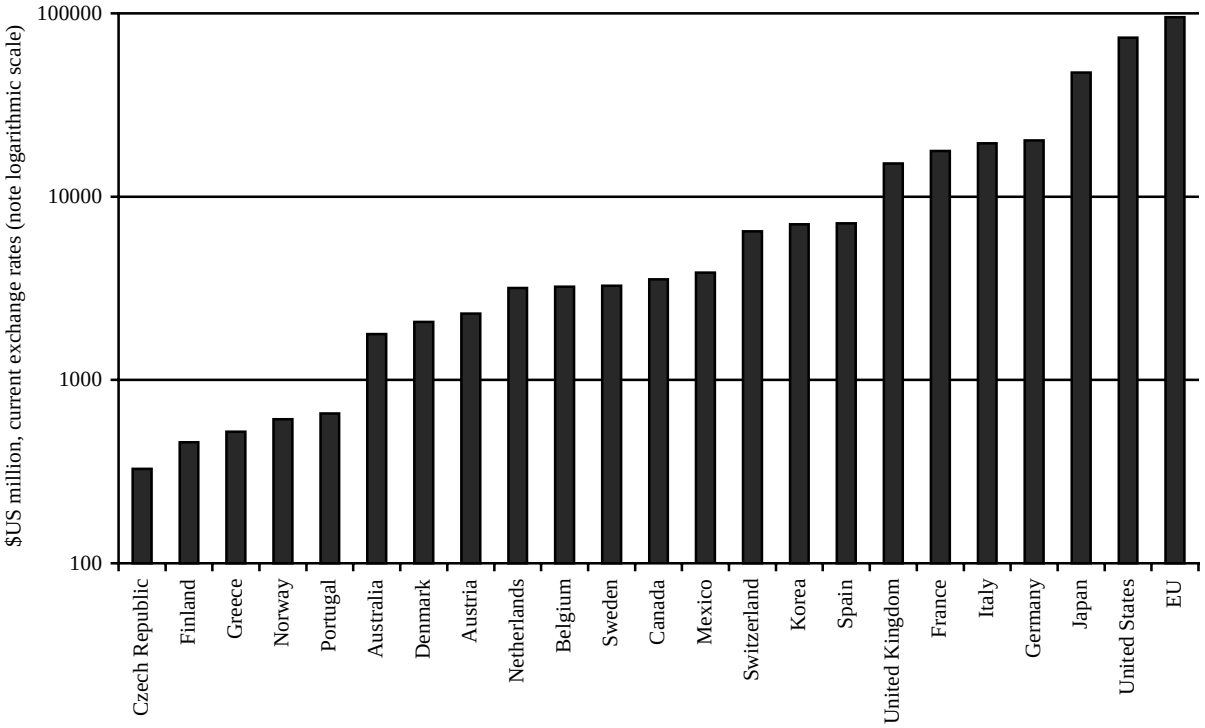


Note: Data for 1997 (1996 in some cases)
Source: OECD Health Data 1999

The demand for pharmaceuticals is likely to increase as the OECD population structure ages. Between 1990 and 2030, the population aged 65 and over as a percentage of the population aged 15-64 in the OECD area is projected to rise from 20 to 40 percent.[6] This will lead to increasing demand for health services in general, and pharmaceuticals in particular.

The bulk of all OECD production of pharmaceuticals (79 percent) is concentrated in just six countries – the US, Japan, France, Germany, Italy and the UK.[7] Taken as a whole, the EU is by far the largest producer of pharmaceutical products.

Figure 4: Pharmaceutical Production in OECD Countries (1994)



Notes: Data for 1994 (the most recent year for which reasonably complete data is available) except Netherlands and Greece (1993) and Australia, Norway and the UK (1992). Data for Italy is estimated. No data is available for Poland, Ireland, New Zealand, Luxembourg, Hungary, Turkey and Iceland.
Source: OECD Health Data 1999, Jacobzone (2000)

2.2 Pharmaceutical Producers

World-wide, a large number of firms are engaged in the production of pharmaceuticals. It is possible to divide these firms into two classes or tiers according to their level of investment in R&D. Klepper writes:

> "The size distribution of [pharmaceutical] companies shows a particular pattern which is similar throughout the industrialised countries. There is a relatively small number of global firms which dominate pharmaceutical markets and then there is a large number of small firms producing mostly for local or national markets. The roughly 100 global firms originate mostly from the US, Germany, Switzerland or the UK. They perform most of the R&D of the world's pharmaceutical industry and dominate the market for prescription drugs. … In the smaller companies very little R&D is undertaken, which to a large degree is dictated by the technology of pharmaceutical R&D and production. The world's pharmaceutical industry therefore shows a two-tier structure in which the global firms are responsible for the R&D and consequently dominate the market for patent-protected prescription drugs, whereas the smaller firms serve local needs or compete with generics against the new products".[8]

The nature of competition in this industry differs between these two sets of firms. The second tier of firms holds fewer patents, relying primarily on manufacturing off-patent "generic" medicines or patent

medicines under licence.[9] Competition between these firms takes the conventional form of competition on price, cost-efficiency and quality.

In contrast, the large research-based pharmaceutical companies, invest heavily in R&D, hold the bulk of the total patents and can often enjoy substantial market power while these patents are in force. For these companies competition is not primarily on the basis of price but rather on the basis of marketing and innovation. These companies compete to develop entirely new drugs which either treat entirely new medical conditions, improve upon existing drugs, or substitute for existing patented drugs.[10]

There are 23 pharmaceutical companies among the world's largest 500 companies (see Table 1).

Table 1: The World's Largest Pharmaceutical Companies

Company	Country	Mkt Cap $US b	Revenues $US b	Profits $US b	Profits/ Equity %	Employees	Year end
Merck	USA	152.1	26.9	5.2	34.7	57,300	12/98
Johnson and Johnson	USA	123.4	23.6	3.1	22.7	93,100	12/98
Pfizer	USA	118.8	13.5	1.9	22.5	46,400	12/98
Bristol-Myers Squibb	USA	118.0	18.2	3.1	37.0	54,700	12/98
Roche	Switz.	108.4	15.8	2.8	13.6	66,707	12/98
Novartis	Switz.	104.5	20.4	3.8	16.3	82,449	12/98
Glaxo Welcome	UK	100.7	13.1	3.0	49.8	54,350	12/98
AstraZeneca	UK	71.3	9.1	1.2	34.1	34,000	12/98
Smithkline Beecham	UK	69.6	13.2	1.1	19.9	58,300	12/98
Eli Lilly	USA	68.9	9.2	2.1	29.4	29,800	12/98
Warner-Lambert	USA	68.1	10.2	1.3	26.9	41,000	12/98
Amgen	USA	59.5	3.3	1.1	39.4	6,400	12/99
Schering-Plough	USA	55.9	9.2	2.1	52.7	26,500	12/99
American Home Products	USA	52.1	13.4	2.4	18.4	52,984	12/98
Aventis	France	44.7	13.6	0.8	12.1	65,180	12/98
Takeda Chemical Ind.	Japan	40.0	8.2	0.9	18.5	9,139	3/99
Bayer*	Germany	33.4	28.9	1.6	15.6	144,881	12/98
Genentech	USA	32.6	1.3	-1.1		3,883	12/99
BASF*	Germany	31.1	28.5	1.7	12.6	106,928	12/98
Sanofi-Synthelabo	France	28.4	6.0	0.5	11.5	-	12/98
Pharmacia & Upjohn	USA	22.6	6.9	0.7	11	30,000	12/98
Immunex	USA	14.8	0.5	0.04	17.9	1,170	12/99
Akzo Nobel*	Nether.	14.4	12.9	0.6	17.4	79,100	12/98

Source: Financial Times FT 500 (http://www.ft.com/ft500/). 4 May 2000
*Companies labelled with an asterisk are classified as in the chemicals industry by the Financial Times.

2.3 Horizontal and Vertical Consolidation in the Pharmaceutical Industry

There has been a significant wave of mergers in the pharmaceutical industry in the last few years. This merger process is continuing. Since the data in Table 1 was collected mergers have been announced between Pfizer and Warner-Lambert[11] and between Glaxo Welcome and SmithKline Beecham. A list of the major horizontal mergers that occurred between 1994 and 1999 is set out in Table 2.

Table 2: Selected Mergers and Acquisitions of Major Brand-Name Drug Companies (1994-1997)

Transaction Date	Drug Company #1	Drug Company #2	Combined Entity	Transaction Value
1994	Roche Holdings Ltd.	Syntex Corporation	Roche Holdings Ltd.	$5.3 billion
1994	Pfizer	SmithKline Beecham	Pfizer Animal Health	$1.4 billion
1994	American Home Products	American Cyanamid	American Home Products	$9.7 billion
1995	Bristol-Myers Squibb Co.	Calgon Vestal Laboratories	Bristol-Myers Squibb Co.	$261 million
1995	BASF	Boots Pharma	BASF	$1.3 billion
1995	Rhone-Poulenc Rorer	Fisons	Rhone-Poulenc Rorer	$2.9 billion
1995	Hoechst, A.G.	Marion Merrill Dow, Inc.	Hoechst Marion Rousell	$7.1 billion
1995	Pharmacia AB	UpJohn Co.	Pharmacia & Upjohn, Inc.	$13 billion
1995	Glaxo plc	Welcome plc	Glaxo-Wellcome plc	$14.1 billion
1996	Ciba-Geigy Ltd.	Sandoz Ltd.	Novartis AG	$63 billion
1997	Nycomed	Amersham	Nycomed Amersham plc	$1.06 billion
1997	Hoffmann-La Roche	Boehringer Mannheim	Hoffmann-La Roche	$11 billion
1998	Roche Holding	Corange Ltd.	Roche Holding	$11 billion
1999	Zeneca Group plc	Astra	AstraZeneca	
1999	Hoechst	Rhône-Poulenc	Aventis	
2000	Glaxo-Wellcome	SmithKline Beecham	Glaxo SmithKline	
2000	Pfizer	Warner-Lambert	Pfizer Warner-Lambert	

Source: Levy (1999), table 2.8, updated using FTC (1999) and news reports.

Over the same period several US drug companies integrated vertically into Pharmacy Benefit Managers (PBMs). PBMs are companies which, acting on behalf of insurers, negotiate with pharmaceutical manufacturers, pharmacists and prescribing physicians to control pharmaceutical expenditures. The largest of these acquisitions were the purchase by Eli Lilly of PCS Health Systems, the purchase by Merck of Medico Containment, and the purchase by SmithKline Beecham purchase of Diversified Pharmaceutical. By 1996, US drug companies had control of PBMs accounting for more than 71 percent of all prescriptions and more than 53 percent of all insured Americans. Outside the US, the functions of PBMs are performed by government agencies, virtually ruling out the possibility of similar vertical consolidation in other countries.

2.4 Research and Development Expenditures

The continuing profitability of research-based companies depends entirely on their ability to continually develop new chemical entities with superior chemical properties and to market these drugs in a profitable way. This development process is costly, lengthy and failure rates are high.

There are many stages in the process of developing a new drug. The initial phases often involve large-scale screening of many molecules in order to identify a compound with potential therapeutic benefits.[12]. This is followed by in-vivo experiments on animals. If the compound is promising a patent will be sought at this stage.[13]. Once a product is patented, the compound passes through a series of human clinical trials.[14] These clinical trials are both expensive and time consuming. It can take ten-20 years from basic research to the market with an average time from initial synthesis to final approval of nearly 12 years. According to one commentator, for every 10 000 pharmaceutical products patented about 100 will get into human trials and less than ten will actually reach the market.[15]

Even those drugs which are successfully cleared by the licensing authorities do not necessarily sell in sufficient quantities to be profitable. But the profits from one or two "best sellers" can be substantial. Grabowski and Vernon (1992b) find that only the top 20 percent of new drugs are profitable at all and 75 percent of drug companies profits come from ten percent of the total drugs.[16] For many drug companies a substantial proportion of the total income comes from a few drugs.[17].

The total cost of developing and obtaining approval for a new drug can run to many hundreds of millions of dollars. Grabowski and Vernon (1992b) estimated that the total R&D costs in the early 1980s in the United States amounted to $231 million for each new product brought to market. But the productivity of R&D in the pharmaceutical industry seems to be declining. More recent estimates have put this figure at $350 million in 1995 and $500 million in 2000.[18] Evidence from empirical research indicates that nominal pharmaceutical company R&D costs rose from an average of $231 million in 1987 to $359 million per new drug in 1990.

Overall, pharmaceutical R&D is a high-risk venture. New drugs can fail at any stage of the approval process. Most of the few drugs that are approved will face competition from rival's products. "The combination of high up-front R&D costs, potential competition on final sales, and a lengthy development period serve to make pharmaceutical R&D a higher risk business than other industries".[19].

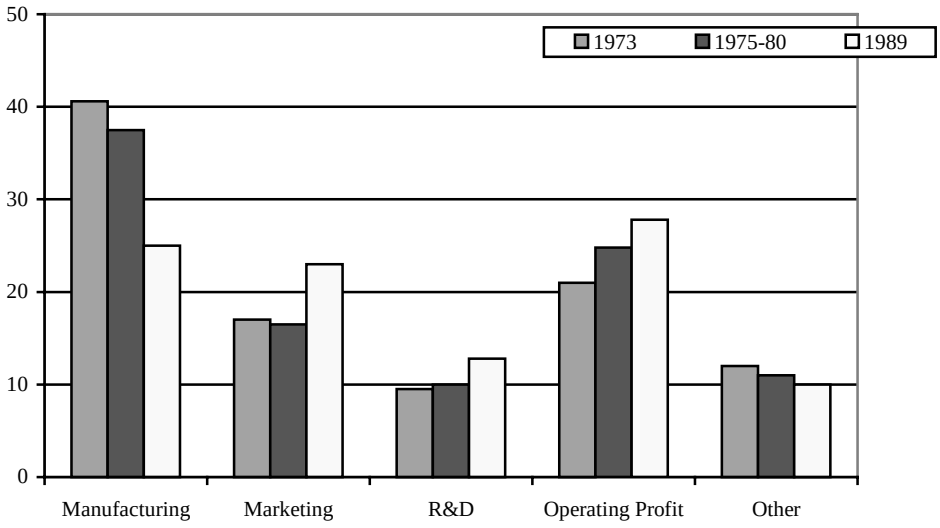
2.5 Marketing and Promotion

Once a product is brought to market, pharmaceutical companies spend heavily on marketing and promotion. The larger drug companies maintain a large sales force which makes direct regular contact with individual prescribing physicians and other pharmaceutical decision makers. The sums spent on marketing are large. "It is estimated that the [US pharmaceutical] industry spends at least $five billion annually on advertising and marketing – more than $8 000 for every physician in the United States (Rennie, 1991). In fact, the [US] drug industry spends approximately $one billion more on marketing and advertising than on research (US Senate, 1991)".[20]

Marketing expenditures show no sign of decreasing. Marketing expenditures (as a proportion of sales) rose sharply in the period 1973-1989, with profits (as a proportion of sales) rising over the same period. In the US, the number of pharmaceutical sales representatives increased by 50 percent during the 1980s, despite the growth in HMOs.[21] Pharmaceutical companies in the US have also increasingly made use of direct-to-consumer advertising in recent years.[22]. As Figure 5 shows, despite the fundamental

importance of R&D, in 1989 R&D expenditure was less than half that of marketing. Manufacturing costs accounted for only 25 percent of the revenue of pharmaceutical companies.

Figure 5: Breakdown of Costs in the Pharmaceutical Industry 1973-1989



Notes: Figures are based on data for research-oriented firms only.
Source: Jacobzone (2000), chart 10.

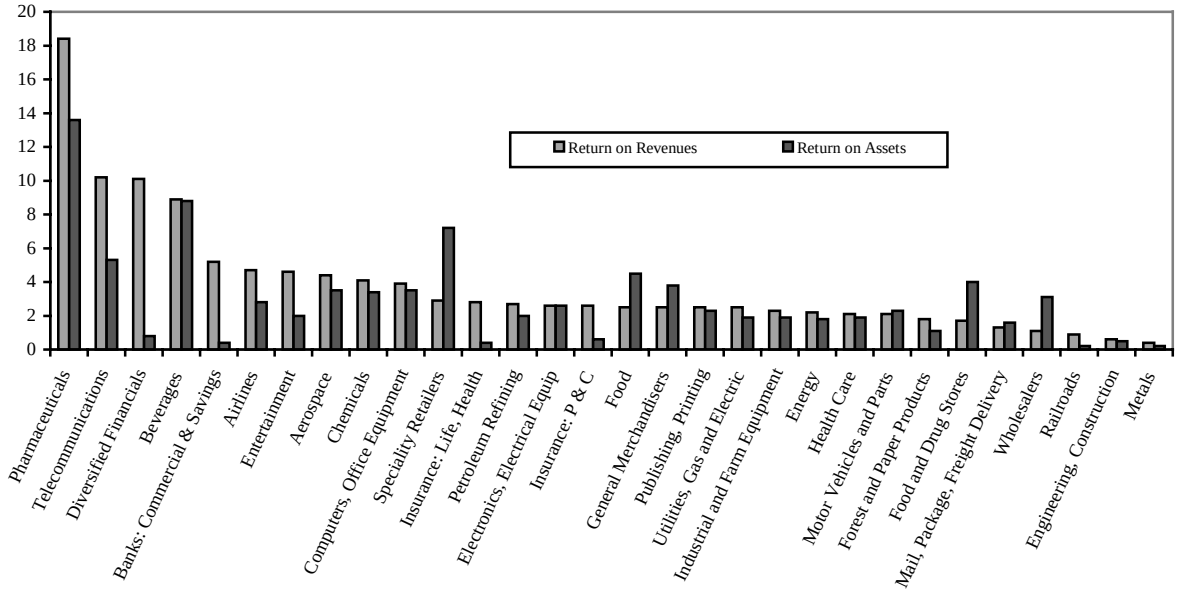
Given the huge fixed costs of maintaining a sales force, drug companies do not always seek to carry out all their marketing themselves. Instead it is common for companies to enter into arrangements in order to make use of another firm's marketing expertise. This might especially be the case for a small, research-focused firm, which cannot sustain its own sales force. Alternatively, two companies might have sales forces in different regions of the globe. These companies might choose to enter into "co-promotion" agreements where they both agree to produce and sell a drug under the same brand name or "co-marketing" agreements where they both agree to produce and market a drug, but under separate brand names.[23]

Pharmaceutical marketing efforts are not only directed at physicians and consumers. Drug companies have also sought to directly influence pharmacists, in some cases paying pharmacists to induce customers to change their drug consumption habits.[24].

2.6 Profitability of Research-Based Pharmaceutical Companies

By traditional measures, the pharmaceutical industry as a whole appears to be consistently profitable. In 24 out of the 32 years between 1960 and 1991 the pharmaceutical industry held first or second position in Fortune magazine's ranking of the most profitable sectors of the US economy.[25] Over this 32 year period the return on equity averaged 18.4 percent for pharmaceuticals and 11.9 percent for the 500 largest industrial companies.[26] This is consistent with investment reports that also point to the above-average returns earned by pharmaceutical company shareholders.[27] The 1998 Fortune ranking of industries by profitability is set out below.

Figure 6: Profitability of Different Sectors 1998



Note: Data for 1998. (www.fortune.com)

Measurement of profitability is seldom straightforward or uncontroversial. Accounting measures of profitability are likely to overstate the actual profitability of pharmaceutical companies due to a failure to properly account for the capital nature of investments in R&D and marketing. R&D and marketing investments are typically incorrectly characterised as "expenses" rather than as an increment to the asset bases. As a result the rate of return on assets "is calculated using an asset base that improperly excludes accumulated intangible R&D and marketing capital. Accounting figures tend to overstate the true rate of return under these conditions"[28].Correcting for these anomalies reduces indicated rates of return. A study by the US Office of Technology Assessment found that the corrected average returns on investment "exceeded benchmarks for control groups by two to three percentage points on average".[29] Another study of US industries found that the "adjusted" accounting rate of return for pharmaceuticals was 13.3 percent compared to 10.3 percent average across 14 industry sectors.[30]

2.7 Market Share in Individual Therapeutic Classes

In the pharmaceutical industry it is common to group drugs which are intended to treat the same condition into a "therapeutic class". The drugs in a therapeutic class are (more or less) substitutes from the perspective of health consumers. The therapeutic class is therefore often used as a proxy for the competition law concept of the relevant product market. Although there are a large number of pharmaceutical producers and a very large number of pharmaceutical products, in any one specific market one product may hold a high market share.

Information about market shares by therapeutic class is usually proprietary and difficult to obtain, however, some information on concentration in different therapeutic groups has been collected by Burstall (1985). Table 3 shows the share of the top-selling and the five top-selling products in 12 therapeutic groups in France, Germany and the UK in 1982. The level of concentration is quite high in several classes, even though the therapeutic groups shown in the table cover several distinct therapies for which the products

mentioned here may not compete. These numbers therefore probably underestimate the market power of a company in a specific therapeutic group.[31]

Table 3: Concentration in Selected Therapeutic Classes

	UK		Germany		France	
	C1	**C5**	**C1**	**C5**	**C1**	**C5**
Cardiovascular:						
Myocardial Agents	35	80	20	67	25	60
Peripheral Vasodilators			15	45	15	43
Beta-Blockers	22	85	15	50	17	40
Hypotensives	-	-	25	60	33	60
Anti-Ulcer Treatment	70	-	68	-	80	-
Psycholeptics:						
Tranquillisers	26	80	26	68	26	70
Hypnotics	24	86			21	70
Analgesics	14	36	10	36	33	75
Systemic Antirheumatics	18	65	20	50	20	60
Systemic Antibiotics	26	46	7	23	25	35
Anti-Asthmatics	35	77	21	41	-	-
Diuretics	25	69	33	70	32	79

Note: Data is for 1982. C1 = market share of the top brand, C5 = market share of the top five brands.
Source: Burstall (1985)

More up-to-date information has been collected by Levy (1999). Table 4 sets out the market share of the top four drugs in eight therapeutic classes. In four of these eight classes the share of the market held by the four most popular drugs exceeds 80 percent. In several classes two or more popular drugs are made by the same manufacturer, so the numbers presented here under-estimate the four-firm concentration ratio. These therapeutic classes do not necessarily coincide closely with the relevant antitrust markets.[32]

Table 4: Category Shares of Leading Brands by Drug Class (1992)

Drug Class	**Brand and Share**				**Sub-total**
ACE Inhibitors	Vasotec* 39.8%	Capoten 23.6%	Zestril 15.5%	Prinivil* 11.4%	90.3%
Allergy Drugs	Seldane* 29.2%	Seldane D* 14.4%	Hismanal 10.6%	Tavist 6.4%	60.6%
Analgesics	Anapr.DS* 16.0%	Toradol* 9.3%	Florinal 7.8%	Dolobid 4.7%	37.8%
Antibiotics	Ceclor 7.1%	Augmentin 4.8%	Cipro 3.8%	Biaxin 1.3%	17.0%
Anxiety Drugs	Xanax 22.5%	Valium 4.5%	BuSpar 3.7%	Ativan 3.0%	33.7%
Calcium Antagonist	Procardia 32.1%	Cardizen 26.6%	Calan 17.7%	Veralan 4.0%	80.4%
Cholesterol Drugs	Mevacor 43.5%	Lopid 27.4%	Questran* 11.1%	Pravachol* 9.4%	91.4%
Ulcer Drugs	Zantac 42.8%	Tagamet 19.2%	Pepcid 10.8%	Axid 8.3%	81.1%

Notes: * indicates brands owned by the same pharmaceutical company. The sub-total measures concentration among the top four brands in each category and not the top four drug companies. These categories do not necessarily correspond to properly defined markets.
Source: Levy (1999), table A.11.

Further information on market shares in therapeutic classes can be found in the submissions of Mexico, Norway and Italy.[33] As in other industries, information on market share needs to be interpreted with caution. A high market share in any one period does not necessarily indicate a lack of effective competition if that market share is quickly eroded with new entry (either from new patented drugs or from generics). In the pharmaceutical sector new entry requires a length testing and approval process (discussed in the next section). One of the consequences of this process is that it is possible to obtain a picture of the likely new entrants to the market over the short to medium term. Thus, a full analysis of the state of competition in a pharmaceutical market requires an analysis of both the market shares today and the likely consequence of new entry from generics and drugs currently in the approval pipeline.

2.8 Summary

In most OECD countries, expenditure on pharmaceuticals is growing at a faster rate than health care expenditure overall. This has focused public policy concern on mechanisms for controlling pharmaceutical expenditure. Cross-country comparisons of pharmaceutical consumption show that although richer countries consume more pharmaceuticals per capita, some countries, such as France, USA and Japan have high pharmaceutical consumption per capita which cannot be explained on the basis of higher national incomes alone. These countries, together with Germany, Italy and the UK are also major pharmaceutical producers.

The world's largest pharmaceutical companies are very large, profitable organisations. The pharmaceutical industry is consistently ranked as one of the world economy's most profitable sectors. Large research-based pharmaceutical companies operate in a high-risk/high-reward environment. Although the process of identifying new drugs and bringing them to market is costly, lengthy and uncertain, the profitability of a best-selling drug can be substantial. Pharmaceutical companies spend substantial amounts promoting their brand-name drugs. Despite the research-intensiveness of this sector, pharmaceutical companies spend more on marketing than on R&D.

Although there are a very large number of approved pharmaceutical products, the number of potential substitutes for the treatment of a specific condition can be limited. Many drugs face little effective competition in their therapeutic class.

3. The Regulation of Drug Supply

Having described the key features of the industry, we turn now to an examination of the regulatory factors which affect the demand and supply of pharmaceuticals in this industry.

3.1 Intellectual Property Rights

The protection of intellectual property rights lies at the foundations of R&D investment in the pharmaceutical industry. In the absence of that protection, margins on pharmaceutical products and the incentives for R&D investment would decline.[34] "Some evidence suggests that 65 percent of pharmaceutical products would not have been introduced and 60 percent would not have been developed without adequate patent protection".[35]

There is some evidence that intellectual property rights, in the form of patents and trademarks, are relatively more important in the pharmaceutical industry than in other sectors. One survey of several industries ranked the pharmaceutical industry the highest in its reliance on patent protection.[36] This may be

due to the fact that patents on prescription drugs are a more effective means of raising imitation costs than patents on other products.[37]

The value of patent protection depends upon the length of the period of exclusivity. Although patent life is fixed by international agreement at 20 years from the date on which the patent application is filed, in practice, due to the delay between patenting and obtaining marketing approval, the "effective life" of a patent is much less than 20 years. The effective life for patents in the USA, UK and Germany declined significantly from 1960-1980 as more and more onerous testing requirements were imposed. The effective patent life in the US was around 15 years in 1960, declining to less than eight in 1980.

In a response to concerns about declining effective patent lives, both the US and the EU have adopted special legislative provisions extending the life of pharmaceutical patents. In the case of the US, the Waxman-Hatch Act extended patent protection on name-brand drugs for up to five years, but also limits the total period of exclusivity following marketing approval to 14 years. Within the EU, patent life can be extended by up to five years by means of a so-called "supplementary protection certificate" ("SPC").

Patents play a critical role in stimulating and rewarding research and innovation in the pharmaceutical industry. The role of intellectual property rights in modern industrial society is so fundamental as to be largely taken for granted. However, it is useful to recall that patent protection of pharmaceuticals (like patent protection of other products) has both advantages and disadvantages. The primary disadvantages of patent protection are its bluntness as a policy instrument and the resulting market power which it generates. The primary advantages are its efficient use of information and the fact that the patent process makes new innovations public information.

A theoretically ideal R&D policy would ensure a sufficient reward to all those (and only those) innovations for which the total value to the economy exceeds the research and development cost. Patents provide that reward by granting the patent holder a period of exclusivity, allowing the patent holder to capture a portion of the value of his/her innovation to society, independent of the costs of developing the innovation. This period of exclusivity is not unlimited because the exclusivity itself creates an inefficiency – in the form of market power. The problem is that the share of the total economic value that the patent holder can capture depends on market characteristics, such as the ability to price-discriminate, pricing and reimbursement policies and the presence of rival innovations and may bear little relation to the underlying cost of the innovation. In some cases even a small, inexpensive improvement on an existing patent can warrant the same degree of exclusivity as the original. Finally, all patents last the same length, even though the harmful consequences of market power presumably varies from product to product.[38]

These problems have direct application in the pharmaceutical industry. The developer of a breakthrough pharmaceutical cannot necessarily prevent the development of all rival techniques for treating the same disease, even if those rival treatments can be developed at substantially lower cost than the original innovation. As a consequence, even an extremely valuable innovation may not be developed if the innovator anticipates that it could not prevent the development of substitutes. On the other hand, a major innovation may stimulate a host of research along similar lines, seeking improvements or substitutes to a breakthrough drug, even though the extra value of that research from the overall perspective of society is small.[39]

Furthermore, the protection offered by a patent may be disproportionate to the cost of the innovation when there is inadequate competition in R&D. For example, in the absence of effective competition in R&D, a company may be able to choose the timing of the granting of a new patent in such a way as to extend the protection over an existing drug. Recently SmithKline Beecham was granted a new US patent on its brand-name antibiotic Augmentin. Just before the end of the original patent period,

SmithKline filed an additional patent covering other elements of the drug, including an acid that stops the active ingredient in Augmentin from degrading. The new patent ensures a substantial new period of exclusivity with very little or no new research.[40]

Similarly, new techniques have allowed drug manufacturers to separate out non-active and possibly harmful components of existing drugs, increasing potency and reducing side-effects. By patenting the new forms of the drugs, the original period of exclusivity can be extended. The drugs affected by these new techniques include Prozac Jr, a version of the anti-depressant Prozac (estimated 2000 sales $2.5 billion), Desloratadine, a version of Claritin, a hay-fever medication ($2.2 billion) and Nexium, a version of Losec, an ulcer medicine ($six billion) made by Astra Zeneca.[41]

In addition, as mentioned above, patent protection enables price to be above marginal cost, introducing the conventional economic distortion due to market power. The economic effects of this distortion can be significant. For example, the situation could arise where the price of a pharmaceutical is above the cost of certain alternatives, forcing patients to incur the costs of, for example, surgery, of forego treatment altogether, even though the cost-effectiveness of the pharmaceutical (based on its marginal cost) is higher than the cost-effectiveness of these alternative treatments. In addition, the presence of market power can lead to a variety of vertical arrangements which seek to minimise the welfare losses of pricing above marginal cost. These vertical arrangements can also be anticompetitive in their own right.

The primary advantages of patent protection is that it is efficient from the perspective of information and that it makes information about the innovation public. The economic and social value of a new innovation is extremely difficult to assess in advance. Yet, it is the innovator himself or herself who is best placed to make this judgement. Patent protection places the incentive to make a judgement about the benefits of an innovation directly in the hands of the innovator. The patent process makes the innovation public information, creating a stock of knowledge on which other entrepreneurs can build and develop.

There may be some mechanisms by which policy-makers can reduce some of the drawbacks of patents without hindering the benefits. For example, attention to the purchasing contracts between manufacturers and national health insurers can reduce the negative impact of pricing above marginal cost. National health insurers might offer to pay a fixed annual fee in exchange for purchasing a brand-name drug at its marginal cost. The fee could be chosen so as to compensate the manufacturer for its market power (and therefore its R&D expenditure) while, at the same time, eliminating the distortionary effect of pricing above marginal cost. The same desire may lie behind systems of volume-discounts or other pricing strategies adopted by PBMs and government pharmaceutical purchasing agencies. This is discussed further in the following box:

Are There Alternative Mechanisms For Rewarding Pharmaceutical R&D?

As we have seen, patent protection of pharmaceuticals has certain drawbacks. It is rather a blunt instrument, subject to forms of abuse, induces a distortion in economic decisions and gives rise to the potential for various forms of anti-competitive behaviour. In addition, as we will see later in this paper, virtually all countries have a system of price controls on pharmaceuticals. These price controls may run into direct conflict with the objective of ensuring an adequate return to pharmaceutical R&D.

This raises the question of the effectiveness of alternative mechanisms for rewarding pharmaceutical R&D, such as prizes of research contracts. Many OECD countries directly fund pharmaceutical research, through systems of grants and contracts. In effect, this amounts to purchasing the R&D directly, rather than rewarding R&D indirectly by allowing the innovator to capture some of the social value via a patent. Of course, the effectiveness of this system depends on the incentives and competencies of those authorities charged with purchasing R&D. Another approach is to offer a price for a successful innovation which meets a pre-defined standard.[42]

Yet another approach would be to preserve patent rights but for a government or large insurer to negotiate with the owner of a successful patent to buy out the patent rights and then to manufacture the drug directly and distribute it at marginal cost. This approach would both eliminate the dead-weight loss arising from the price-cost margin due to market power and would also significantly reduce the marketing expenditures which, as we have seen, are themselves a sizeable component of total pharmaceutical costs. Since the patent holder would be under no obligation to sell for less than the present discounted value of the future income stream from the patent, the incentive to innovate would be fully preserved. A system of this kind operates in New Zealand.[43]

A few drawbacks with this approach should be noted. First, under this system the patent holder would have little incentive to engage in marketing effort. The role of dissemination of information about the drug would need to be taken over by the purchaser of the rights. Second, the policy may induce inefficient substitution away from drugs not in the programme to drugs in the programme. Third, it may be difficult to prevent other governments or insurers benefiting from access to the low-priced drug – buying the drug at marginal cost from sources supplied by the insurer which has acquired the patent rights and selling it to consumers elsewhere. Where it is not possible to prevent such "parallel trade", adopting such an approach would require multilateral co-ordination between insurers in different countries. This is a potential topic for future discussions.

3.2 Generics

Following the expiration of a patent, the patent-holder can no longer prevent other manufacturers from producing and distributing copies of the patented drug. Drugs which are bioequivalent to formerly patented drugs are known as "generics".

The competitive impact of generics depends upon the nature of pharmaceutical demand, which depends, in turn, on the mechanisms and institutions which regulate the demand for pharmaceuticals, discussed in the next section. Although generics can have an important competitive impact, their impact depends upon brand loyalty and the price sensitivity of pharmaceutical buyers. Often the first product in a new therapeutic class can, through reliance on trademark protection, develop a substantial loyalty to a particular brand which is not immediately eroded by competitive entry. [44] Unlike patents, trademarks do not expire, thus trademarks can be an important tool for extending market power beyond the end of the patent life. Levy, speaking in the context of the US market, notes: "Due to considerations such as first-mover advantages, product differentiation and brand loyalty, initial entrants do not face significant price competition from subsequent suppliers of alternative drug treatments".[45]

Some studies have in fact found that the price for a brand name drug can rise (rather than fall) following patent expiration, simultaneous with the entry of lower-priced generics. [46] This could be due to the existence of two separate markets, one of which is sensitive to prices, which benefits greatly from generic competition and another market which is largely insensitive to price and is loyal to the incumbent brand. This "separate markets" explanation is also consistent with the observation that many brand-name drug manufacturers have themselves chosen to enter the market for generics which are bioequivalent to their own brands.

It is clear that generics, at least in those markets where drug consumption is sensitive to prices, are a very important source of competition to brand-name drugs. Generics typically sell for 30-50 percent below the branded equivalent and, in the United States, it is not unusual for a generic to achieve a 50 percent market share (by volume) within a year of the patent expiring.[47] Several countries have adopted policies which seek to facilitate the approval process for generic drugs, by adopting an abbreviated marketing approval procedure and by allowing generic manufacturers to conduct trials to establish bioequivalence prior to the expiration of the original patent. For example, the US adopted an abbreviated process for approving generic drugs in adopting the Waxman-Hatch Act 1984.[48]

Under Canadian legislation, for example, companies can conduct development work and product testing prior to patent expiration.[49] This legislation was challenged by the EC as violating the WTO's TRIPs agreement.[50] In this case, however, a WTO panel upheld the Canadian law on the basis that the TRIPs agreement allows "limited exceptions" to the exclusive rights of patent holders, such as the ability of a generics firm to conduct development work for the purposes of obtaining marketing approval.

Incumbent manufacturers will go to substantial lengths to prevent the entry of rival manufacturers. One strategy that has been adopted in the EU, is based on the fact that under EU law generic manufacturers do not need to replicate the extensive clinical trials necessary to obtain the original marketing approval of a new drug. Instead they only need to show "bioequivalence" with the original branded "reference" product provided that the reference product "is marketed in the member state for which the application is made"[51]. Recognising this, some manufacturers have taken to removing the original product from the market shortly before patent expiration and replacing it with a "new and improved" version. The generic manufacturer runs the risk that its application will be rejected on the grounds that there is no longer a marketed reference product with which to compare the generic medicine. AstraZeneca has been accused of using this strategy to protect Losec, its valuable ulcer drug.[52] The EC is currently drafting a guideline clarifying the position of generic manufacturers in this situation.[53]

In the US, an alternative strategy is open to incumbents. Under US rules, the first generic manufacturer to the market receives a period of six months of exclusivity from the date it starts marketing its generic drug. This opens up the possibility of a strategy in which the incumbent directly pays the first generic manufacturer out of the blocks to not start marketing. The two can then share the monopoly profits without fear of further entry. The FTC has filed charges against Aventis and Abbott Laboratories, and the generic manufacturers Andrx and Geneva Pharmaceuticals alleging that the brand-name companies were following just this strategy.

3.3 The Regulation of Safety and Entry to the Market

All OECD countries control the entry of new drugs onto the market, with the primary objective of ensuring drug safety. In some cases pharmaceutical companies must also secure approval of their production processes and labelling inserts.[54] The process of obtaining marketing approval can be extremely costly and time consuming. In 1995 the process of securing drug approval consumed 55 percent of all R&D expenditure.[55] The following table sets out the stages in the approval process for new drugs in the USA, together with the average length of each stage.

Table 5: Stages of the FDA Approval Process

Regulatory Stage	Description	Average Time Lapse
Investigational New Drug Application (IND)	Application for Approval of Human Testing	30 days
Phase I	Safety Tests	1 year
Phase II	Efficacy Tests	2 years
Phase III	Efficacy and Long Term Reactions	3 years
New Drug Application	Application for New Drug Approval	2.5 years
Phase IV	Post-Market Testing	-

Notes: The NDA review elapsed time is the average for new drug approvals over the 1990-1994 period.
Source: Levy (1999) citing Beary (1996).

Over the past several decades the average time taken to develop new drugs has lengthened considerably, primarily due to lengthier pre-clinical and clinical stages. "The increase in clinical development time partly stems from satisfying the regulatory requirements for more and larger clinical trials. For example, the number of clinical trials per drug application rose from 30 in the late 1970s to 60 in the early 1990s, and the number of patients in those trials more than doubled over the same time period".[56]

Table 6: Stages of the FDA Approval Process

Time Period	Pre-Clinical Stages	Clinical Stages	NDA Review Stage	Total
1960s	3.2 years	2.5 years	2.4 years	8.1 years
1970s	5.1 years	4.4 years	2.1 years	11.6 years
1980s	5.9 years	5.5 years	2.8 years	14.2 years
1990-1994	6.1 years	6.1 years	2.6 years	14.8 years

Source: Levy (1999), table A.6.

The increase in the cost and the length of the approval process has a direct effect on the nature of pharmaceutical R&D and the resulting level of competition within each therapeutic class. An increase in the cost of obtaining approvals discourages competitors from investing in R&D which is aimed at developing a substitute or "me too" drug, for which the returns are lower, and, instead, diverts research effort towards innovative or "breakthrough" drugs, with higher development costs and also higher potential returns.[57] This has the effect of limiting the number of substitutes in each therapeutic class.

3.4 Summary

This section has sought to describe the key forms of regulation affecting the supply of pharmaceuticals. The primary regulatory interventions are those imposed by intellectual property rights and the drug approval process. Although ensuring a reward to R&D activity and ensuring the safety of drugs brought to market are fundamental public policy objectives, both of these regulatory interventions have their drawbacks. Patent protection directly creates market power, distorting economic outcomes and creating opportunities for anti-competitive behaviour. The drug approval process is long and costly, which may have the effect of diverting R&D effort towards breakthrough drugs, reducing the level of competition in each therapeutic class.

4. The Regulation of Drug Demand

Having looked at forms of regulation which affect entry to the drug market (intellectual property rights and the drug approval process), we turn now to look at how regulation affects the demand for drugs.

At the outset it is important to distinguish between prescription and non-prescription drugs. The consumption of non-prescription drugs is (usually) not reimbursed or subsidised by health insurance – the consumer faces the full cost of his/her choices. This market operates in a similar manner to the markets for many other branded consumer goods. According to data collected by the OECD[58], the share of non-prescription drugs in the total drugs market ranges from eight percent in Spain to 50 percent in Australia (See Table A. 1 in the appendix).

The market for prescription drugs, on the other hand, is quite different. As in the markets for many other health services, the choice over the product to consume is not (usually) made by the final consumer, but is delegated to knowledgeable expert – usually the attending physician. Furthermore, in

most cases a substantial part of the price of the drug is paid neither by the consumer, nor by the prescribing physician but by a third-party health insurer. This separation of roles – the roles of consumer, decision-maker and payer – fundamentally influences demand for pharmaceuticals and lies behind the extensive regulatory, contractual and financial mechanisms which have been erected to control demand in the pharmaceutical sector (and in the health sector more generally).

4.1 The Effect of Insurance on Pharmaceutical Demand

The effect of health insurance on the demand for pharmaceuticals (and other health services) is clearest in the extreme case in which consumers are fully insured. A fully-insured health consumer enjoys the therapeutic benefits of a drug but does not (directly) face the cost. If all consumers were fully insured only the best drugs in each therapeutic class would be consumed, irrespective of its price and irrespective of the price of alternatives. No trade-offs would be made with other drugs, even if only slightly less effective or with only slightly higher side effects, no matter what the price difference. In this world, drug companies would have very strong incentives to make huge investments to obtain even very small improvements on existing drugs. Successful drug companies could expect large margins and substantial, inelastic demand.

Consumers would have no reason to substitute for lesser known drugs or generics. The market for generic drugs would be small or non-existent, allowing the patent-holder to earn sizeable rents long after the original patent had expired. Given the key role of the prescribing physician in influencing the consumption of pharmaceuticals, drug companies would spend huge amounts to obtain the loyalty of physicians and to influence their prescribing behaviour. Although pharmacists have a more limited role, they too would be targeted by drug companies. Consumers would have little incentive to shop around for the most efficient pharmaceutical distributors allowing pharmacists and other members of the pharmaceutical supply chain to earn inflated rents.

Finally, in the absence of incentives for restraint, the consumer would consume an inefficiently high level of drugs, continuing to consume drugs to the point where the marginal benefit of the last drugs consumed is lower than the marginal cost.

We can contrast this market outcome with the hypothetical case in which consumers are perfectly knowledgeable (or perfectly well informed) about the prices and therapeutic characteristics of drugs and behave as though they are paying for the drugs themselves. In this case a consumer would have an incentive to carefully trade-off a drug's health benefits against its cost, both with respect to other competing drugs and other competing health therapies. In such a market many drugs may co-exist in the same therapeutic class, differentiated according to effectiveness and price.

Consumers would quickly substitute for cheaper bio-equivalent generics. Off-patent brand-name drugs could not be priced higher than their marginal cost of production. Prescribing physicians, to the extent that they are involved in the process, would be acutely sensitive to cost differences between competing pharmaceutical treatments. Pharmacists and other members of the pharmaceutical supply chain would face strong pressures to minimise their costs and provide the bundle of services that consumers demand. Drug consumption would be limited to the point where the marginal benefit of the last drugs consumed was equal to the marginal cost.

4.2 The Response of Health Insurance to its Effect on Demand

It is clear from these hypothetical cases that health insurance can have a sizeable distortionary effect on the pharmaceutical market.[59] In the effort to offset these distortionary effects, health insurers erect elaborate regulatory, contractual and financial mechanisms to lower the quantity and price and improve the effectiveness of the mix of drugs consumed.

In some cases the health insurer, itself, applies these policies in the pharmaceutical marketplace, but this is not always the case. Insurers often purchase the provision of such services from independent agencies. In the US, these third-party agencies are known as "Pharmacy Benefit Managers" or PBMs. PBMs seek to control drug expenditure (without compromising health outcomes) by maintaining a formulary, establishing prescription guidelines, negotiating with drug suppliers over drug prices, and (often) maintaining a network of pharmacies. Through the use of information technology PBMs are able to monitor the purchases of pharmaceuticals, to ensure that the opportunities for generic substitution are exploited and to ensure compliance with prescribing guidelines.

Outside the US, many governments have chosen to establish specialist pharmacy management agencies which take on one or more of the functions of PBMs in the US, such as responsibility for maintaining the national formulary, negotiating prices controls, or evaluating the cost-effectiveness of new drugs. Examples include the Patented Medicine Prices Review Board in Canada and Pharmac in New Zealand.

For many OECD countries, competition in the provision of pharmacy benefit management services could be enhanced by the contracting out of pharmacy benefit management services, essentially relying on private rather than public agencies to implement and operate the various demand management techniques discussed below. The tendering process would ensure that the selected company had the incentive to keep pharmaceutical costs down to a minimum and to innovate in techniques for monitoring and controlling pharmaceutical expenditure. The contractual specifications would be complex, requiring specification of the required density of pharmacies, the level of co-payments tolerated, the health care standards desired and the means by which pharmaceutical services would be integrated with the provision of other health services. Nevertheless, the practice in the US among private insurers shows that such tendering is possible. This is one of the rare cases in which responsibility for "regulatory" policies can be delegated to a private profit-maximising agency. There seems to be merit in exploring this possibility as a tool for both controlling health care expenditures and introducing competition into the pharmaceutical market. As a first step, OECD insurers could separate out pharmacy benefit management services into a separate agency, at arms-length from the insurer itself, as a precursor to full competitive tendering.

4.3 The Control of the Quantity and Quality of Pharmaceutical Expenditure

It is possible to distinguish two broad approaches to reducing the quantity and increasing the quality of drug expenditure. The first approach focuses on changing the incentives on the prescribing physicians and consumers so as to induce them to moderate their consumption and focus it on the most effective products by altering their drug prescribing/consumption practices. The second approach focuses on implementing a set of rules and regulations which directly control the prescribing/consumption practices in the manner desired. These approaches are not mutually exclusive. Most countries use a combination of both. In addition, many OECD countries seek to directly control the prices at which pharmaceuticals are sold. This gives rise, in turn, to the need to regulate pharmacists' margins.

We will examine the following policies for controlling the quantity and quality of pharmaceutical consumption.

(a) formularies – lists which set out the drugs that are covered and the conditions of coverage;

(b) reimbursement policies – policies related to the extent of health insurance coverage of pharmaceuticals (through co-payments, or ceilings on reimbursement);

(c) controls on prescribing doctors and pharmacists – either in the form of direct controls or in the form of financial incentives;

(d) controls on pharmacists' margins and entry and exit decisions; and

(e) controls on drug prices.

As mentioned earlier, these policies need only apply to reimbursed or prescription medications. The market for non-reimbursed over-the-counter pharmaceuticals operates in a similar fashion as many other economic markets, without the distortions due to health insurance.[60] One simple technique, therefore, for controlling pharmaceutical expenditures is simply to reclassify drugs from prescription-only to over-the-counter.[61]

4.4 Formularies

A key tool in achieving many of these policies is the so-called list or "formulary" of approved drugs. In the case of a "positive" formulary, a drug will not be reimbursed by the health insurer unless it is included on the list and meets the stated conditions on prescription and reimbursement. By attaching certain conditions (including conditions on prices) to the coverage of each drug, formularies become an important tool in controlling drug consumption.

The mere introduction of formulary which excludes from coverage certain drugs can have an important impact on prescribing policies. For example, in 1985 a list was introduced to the UK's National Health Service ("NHS") which excluded from NHS reimbursement all but the generic forms of a number of widely used medicines in eight therapeutic categories. The result was a 53 percent increase in the number of prescriptions written generically in a single year and a savings of about six percent in the General Practitioner ("GP") drug bill.[62]

As Table A. 1, from Jacobzone (2000), in the appendix shows, virtually all OECD countries use some form of formulary as part of their pharmaceutical policies.

What principles should guide the decision to include a drug on a formulary? As discussed further below, the decision to include a drug requires consideration of both its therapeutic benefits and its price. In principle, a drug should be included on a formulary if it is both (*a*) cheaper than bio-equivalent substitutes and (*b*) has a benefit-to-price ratio above some threshold for at least some class of patients. Since pharmaceutical therapies compete with other therapies it is clear that in drawing up a formulary it is necessary to maintain the same benefit/cost threshold across the range of possible health services. Otherwise restrictive formularies will lead to substitution away from pharmaceuticals in favour of other health services such as hospital visits and physician services, possibly raising the total cost of health care.

4.5 Reimbursement Policies

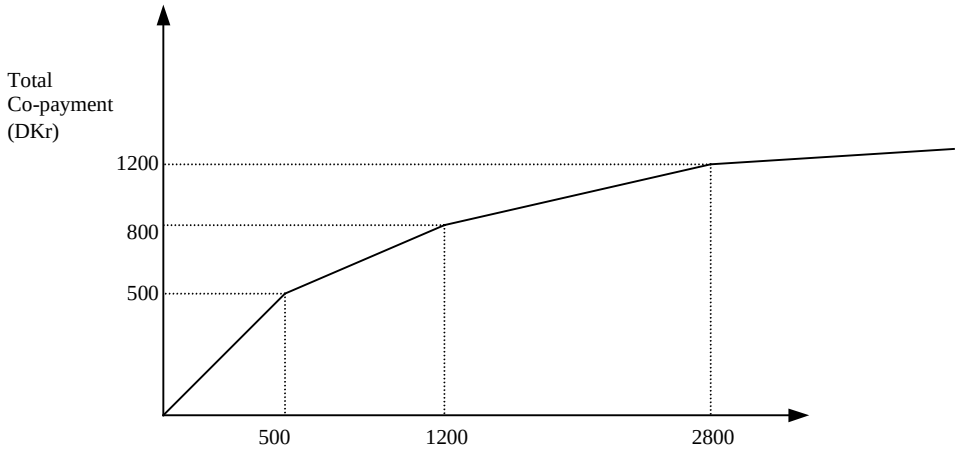
It is very common for health insurers to partially or completely exclude certain pharmaceuticals from insurance coverage. This is common practice in OECD countries. "No public health system has ever

provided all medicines free of charge. Some drugs have always been excluded from reimbursement and patient co-payments have been the norm".[63] The current practice with respect to reimbursement policies in OECD countries is set out in Table A. 3, from Jacobzone (2000), in the appendix.

Rather than focus on the level of reimbursement, it is more common to focus on the amount paid by the insured individual. The amount paid by insured individuals towards the cost of pharmaceuticals is called a "co-payment". The size of the co-payment may depend on the drug being purchased, the expenditure on this episode (i.e., for this prescription), on the total expenditure of an individual over a period (such as a year), on the identity of the individual herself, or some combination of all three. Furthermore, the co-payment can vary in various ways with the underlying expenditure. It could take the form of a minimum payment, a share of the drug costs, a maximum payment, or some combination of all three.[64]

For example, the insurer may require that an individual pays a minimum fee per drug, per prescription or per year (also called an "excess"). Alternatively, the insurer may require that the consumer pay a proportion (or all) of drug costs up to some limit per drug, per prescription or per year. For example, in the new Danish scheme, introduced in March 2000, the co-payment is based on the total annual expenditure on pharmaceuticals. Danish consumers pay 100 percent of the costs of prescriptions, up to an expenditure of DKr 500 ($66) per year. For expenditure between DKr 500 and DKr 1200 ($160), consumers pay 50 percent of the costs. Between DKr 1200 and DKr 2800 ($370), the consumer only pays 25 percent of the drug costs. Above DKr 2800, consumers only pay 15 percent of the costs. The range of possible forms of co-payments is large.[65]

Figure 7: Co-Payments under the Danish Reimbursement Scheme



The co-payment can also vary according to the identity of the individual. Certain classes of individuals make lower co-payments or no co-payments at all. In the UK, for example:

> "At present women aged 60 and over and men aged 65 and over are excluded [from co-payments], as are children under 16, expectant mothers, those suffering from certain named conditions, people receiving supplementary benefit or family income supplement and certain other minor categories. In consequence more than half the population is exempt and only 12 percent of prescriptions are chargeable".[66]

The economic consequences of co-payments depends on the manner in which the co-payment is calculated (per drug, per prescription or per year), the magnitude of the total payment and the level of the marginal payment. The higher the total payment per drug or per prescription, the greater the incentive on the consumer to reduce his/her demand for prescriptions. The higher the marginal payment the greater the incentive on the consumer to substitute cheaper forms of the same drug, or to purchase from more efficient pharmacy outlets, such as mail-order suppliers.

The primary drawback of co-payments is that they expose health consumers to the risk of larger payments, reducing the risk-spreading benefits of health insurance. Some countries attempt to combine the economic incentive effects of co-payments with the desire to limit health costs by placing an annual ceiling on the total possible co-payment of an individual. Since the bulk of pharmaceutical expenditure is accounted for by a minority of consumers, such a plan protects the minority against very large expenditures while still providing some degree of incentives on the majority to control the quantity and quality of their pharmaceutical consumption.

Co-payments for pharmaceuticals must be calibrated with co-payments for other health inputs. A higher co-payment for pharmaceuticals relative to other health inputs (such as hospital services) may reduce pharmaceutical consumption at the expense of greater reliance on other health services (such as emergency rooms), lowering the quality of health expenditures overall. Studies of coverage limits on pharmaceuticals for Medicaid patients in the US found that coverage limits reduced the consumption of drugs, but increased the consumption of other health services, increasing overall health expenditures.[67]

In some, but not all, OECD countries the beneficial incentive effects of co-payments can be neutralised by the purchase of third-party insurance. As Table A. 3 in the appendix shows, in some countries this is prohibited.

4.6 Controls on Prescribing Doctors

For most pharmaceuticals, it is not the health consumer herself who decides which pharmaceuticals to consume – this choice is typically made by a prescribing physician. The interests of the physician are not necessarily aligned with the health insurer or the health consumer. In the absence of specific controls, the typical physician has little incentive to limit the consumer's consumption or to direct the consumer towards more cost-effective medications. To make matters worse, pharmaceutical companies spend large sums in an attempt to influence the prescribing practices of physicians. As a result, virtually all OECD health insurers seek to influence the prescribing behaviour of physicians in some way. The practices of OECD countries are set out in Table A. 4, Table A. 5 and Table A. 6, from Jacobzone (2000), in the appendix.

As mentioned earlier, there are two broad approaches to controlling physician prescriptions - through direct "command and control" - type restrictions on prescribing behaviour; or through the use of financial incentives which seek to align the incentives of the physician with the insurer.

Of these two approaches, the "command and control" approach is by far the most common. The most common forms of controls on physicians are guidelines on prescribing practices and some type of limits on the quantity of drugs that can be prescribed per day or per episode. For example, physicians may be required to substitute among drugs within a particular therapeutic class, to try low-cost therapies first, or to seek advance approval before prescribing certain drugs. Some countries also assign a fixed drug budget on a national, regional or physician level.[68]

Almost all national health insurers have implemented some form of prescription guidelines to guide prescribing behaviour. In a few cases these guidelines are mandatory, and violations of the guidelines can be punished. In other cases compliance with the guidelines is voluntary, although other forms of pressure are sometimes brought to bear – such as publishing "league tables" comparing the prescribing behaviour of various doctors. As an example, in the UK, each non-fundholding[69] GP practice is assigned a nominal "drug budget" (known as an IPA for Indicative Prescribing Amounts) based on the profile of the patients served by the practice. Each practice receives a monthly breakdown of its prescribing behaviour through the Prescription Analysis and Cost (PACT) service. "Drug budgets are no more than an indication of the maximum that should be spent, although peer pressure and ultimately sanctions may be brought to bear on persistent overspenders".[70]

The primary problem with "command and control" type restrictions is that they are necessarily a blunt and inflexible instrument. Although guidelines may prevent the worst excesses or most inappropriate forms of prescribing, they do not provide incentives for doctors to finely balance the costs and benefits for each patient when choosing between a range of alternative treatments.

To address this, a few countries have sought to create financial incentives on doctors to maintain a high level of cost-effectiveness in their prescribing behaviour.[71] There are three leading examples of such financial incentives. The first is the "GP fundholder" programmes in the UK; the second is the HMO form of integration between health insurer and health provider which is common in the USA; the third is the "prospective payment" system under which hospitals (or other health service providers) receive a payment from the insurer which is independent of the actual costs incurred by the hospital. Under all of these schemes, the health provider receives a fixed payment per year and is able to exercise discretion over how these funds are used in the purchase of health outcomes. In each of these schemes competition between suppliers is an essential element. In the absence of competition, the health care supplier would have a strong incentive to restrict access to health services and would have little incentive to maintain a high level of care.[72]

In the GP fundholder scheme, the local doctor (the GP or "General Practitioner") receives a fixed sum each year according to the number of people in his/her care. The GP fundholder is responsible for allocating these funds in such a way as to purchase the maximum amount of health care possible and is able to retain any savings resulting from more efficient use of pharmaceuticals. Under this programme GPs have quite strong incentives to choose the best mix of pharmaceutical inputs (and of all health inputs in general). By 1994 about one-third of all UK GPs were involved in a fundholder scheme.[73]

The UK, which combines the fundholding scheme with conventional controls on physician prescribing behaviour provides an excellent laboratory for comparing "incentive" to "command-and-control" approaches to controlling pharmaceutical spending. Several UK studies[74] have found that fundholding practices spend relatively less on patients than practices operating under traditional controls. Baines, Whynes and Tolley (1997) find that this difference is due to five differences: (*i*) reduced overprescribing; (*ii*) using fewer drugs that have limited clinical value; (*iii*) substituting similar, but less expensive drugs; (*iv*) more generic prescribing; and (*v*) appropriate use of expensive preparations.

The "prospective payment" system is very similar in operation to the GP fundholding scheme but operates at the level of hospitals, principally in the national Medicare scheme in the US. Following the introduction of the prospective payment scheme in 1983 "hospitals sought to minimise the costs of providing health care services by aggressively negotiating discounts with their suppliers, including pharmaceutical companies" [75]. Medicare hospitals also put in place a variety of cost-containment measures including formularies and drug utilisation review (DUR) programs.

4.7 Controls on Pharmacists

Most countries have separated the roles of physician and pharmacist to ensure that physicians do not have a financial interest in the pharmaceuticals they prescribe.[76] Japan and Korea are exceptions. As we noted earlier Japan has a high rate of pharmaceutical consumption per capita, even taking into account its higher average income. Korea is currently in the process of separating the roles of physician and pharmacist. Under current Korean government proposals, from July 2000, doctors will be banned from dispensing drugs to outpatients and pharmacists will be prohibited from writing prescriptions.[77] Most countries also control the marketing efforts of pharmaceutical manufacturers by controlling the extent to which physicians can be given a financial incentive by the manufacturer to prescribe certain medications.

In some countries the pharmacist also has some degree of control over the drugs actually consumed. For example, one US study found that 77 percent of physicians asked by a pharmacist to switch prescriptions consented to do so.[78] Recognising this influence, many health insurers (and pharmaceutical companies) adopt strategies intended to control the activities of pharmacists in their interests. These controls might include giving the pharmacist the legal right and economic incentives for substituting generic equivalents of prescribed drugs, or (in some cases), suggesting cheaper, alternative, therapeutically-equivalent drugs.

For example, by 1984 every state in the US had adopted laws (reversing earlier anti-substitution laws) which permitted pharmacists to substitute lower-priced generics for brand-name drugs on a prescription. A 1994 survey found that between 18 and 25 percent of HMOs offered incentive programs to retail pharmacies and between eight and 12 percent paid extra fees to pharmacists for dispensing generic drugs.[79] The average 1994 retail pharmacy dispensing fee was $2.62 for brand-name prescriptions and $2.67 for generic drugs.[80] The issue of the structure of compensation for pharmacists is discussed further below.

4.8 Controls on Prices

One of the primary mechanisms by which health insurers can control drug expenditures is by directly controlling the price at which the drug will be sold. This can be carried out, for example, by simply fixing the level of reimbursement for a certain drug. Since, for many drugs, demand is highly elastic above its reimbursed price, a ceiling on reimbursement has a very similar effect to a direct regulatory control on the drug's price.

Table A. 7, Table A. 8, and Table A. 9, from Jacobzone (2000), in the appendix summarise the policies of OECD countries with respect to price controls on pharmaceuticals.

The key question to be addressed by health insurers is how to fix the price for each drug on its list. Allowing a price which is too high will inflate pharmaceutical expenditures and will over-compensate manufacturers. Insisting on a price which is too low may lead to the withholding of certain beneficial pharmaceutical products from the market.

The question of the efficient price is relatively straightforward in those therapeutic classes where there are many competing manufacturers producing products which are close substitutes, such as is often the case in markets for off-patent medicines. In this case, a simple approach is simply to select one product by way of a tender. The winner of the tender receives the right to be placed on the formulary. Competition between bidders in the tendering process ensures that the insurer pays the lowest possible price. An alternative approach is to set the price for all equivalent forms equal to the lowest price drug in a

therapeutic class or to simply exclude from coverage all except the lowest price drug. This is known as "reference pricing".[81]

The question of setting the efficient price is significantly more difficult in therapeutic classes dominated by a single manufacturer or in which there are two or more manufacturers producing imperfect substitutes (all of which are protected by patents). How should a country, acting alone, choose to set prices for brand-name drugs?

The decision of whether or not to include coverage of a given pharmaceutical at a given price, or equivalently the decision as to the maximum price to be paid for a given pharmaceutical, depends upon a study of the cost effectiveness of this form treatment in comparison with other potentially alternative forms of treatment. This decision is identical to that which a health insurer must make in its decision whether or not to use various other forms of treatment (whether surgical, pharmaceutical, psychological, etc.). In each case a comparison must be made of the effectiveness of the treatment against its costs. In principle, all those treatments which have a benefit-to-price ratio above a certain cut-off should be covered while those which fall below the cut-off should not.

The cut-off threshold need not be the same from insurer to insurer. Insurers in richer countries are more likely to accept a lower threshold than in poor countries. Or, in other words, to be more willing to pay the costs of more marginal treatments and more likely to be willing to pay more for the right to prescribe a given pharmaceutical.

The assessment of the benefit-price ratio of a drug is known as pharmaco-economic analysis. Such analysis, which involves assigning quantitative monetary values to various "health outcomes"(i.e., various levels of disease, disability and death) inevitably involve a degree of subjectivity. But some form of analysis of this kind is essential to ensure that only the most cost-effective treatments are covered. Otherwise, a health insurer could obtain better health outcomes at the same level of expenditure by reorganising its coverage policies, eliminating coverage of therapies with low benefit-to-price and using the money saved on therapies with a high benefit-to-price.

The UK's NHS has recently instituted a new agency to review this kind of cost-benefit analysis, not just on pharmaceuticals, but on all health procedures and services.[82] The new agency is known as the National Institute for Clinical Excellence, or "NICE". In one of its first decisions, NICE turned down NHS coverage of Relenza, an anti-flu drug made by Glaxo. However, it is rumoured that NICE will recommend far greater use of beta-interferons for treatment of multiple sclerosis and taxanes in the treatment of cancer, even though these drugs are expensive, because the alternative treatments for these conditions are even more costly. Some form of cost-effectiveness analysis is carried out by Australia[83], parts of Canada and France. Finland introduced a similar program in June 1999. A program in Norway will come into effect in January 2002. The Netherlands and Italy are also reported to be considering the use of pharmaco-economic data.[84]

4.8.1 Alternative Price-Control Mechanisms

In addition to pharmaco-economic studies OECD countries also use several other mechanisms for controlling the price of drugs. These include:

(a) international benchmarking (i.e., establishing the price for a pharmaceutical according to the prices in other reference countries);

(b) controls on the evolution of prices over time; and

(c) controls on prices relative to costs.

International benchmarking sets the price of a pharmaceutical according to the prices prevailing in several other reference countries.[85] This approach has the advantage of avoiding the need for costly evaluation and ensures that domestic prices are not out-of-line with international levels. However, this approach amounts to free-riding on the efforts of others in establishing price levels. It is not possible for all the countries in a group to use the same approach, basing domestic prices on those prices prevailing in the other countries in the group, as the resulting price would be indeterminate. Where just one of the countries in a group uses an alternative approach to fixing prices, international benchmarking amounts to a decision by all the countries in the group to "import" the same price control approach.

Another common approach is to control the evolution of prices over time. Although this approach does not eliminate the need to set the original price by some mechanism, it does eliminate the requirement to redo a costly analysis in response to either requests by the manufacturer for changes in the price over time or changes in the underlying threshold for cost-effective analysis. Many countries have imposed periods of price-freeze or price reductions on pharmaceuticals for a period (see Table A. 9 in the appendix).

A few countries (including the UK) choose to fix pharmaceutical prices with reference to the costs of the manufacturer.[86] In principle, this approach limits the market power of the manufacturer of a pharmaceutical by granting the manufacturer a fixed profit margin over its costs. The profit-margin is larger than the firm's cost of capital in order to sustain the firm's reward for innovation. The costs to be taken into account are the firm's direct costs of producing and marketing the pharmaceutical in question. The profit margin allowed in the UK is typically in the region of 17-22 percent.

Profit controls have several drawbacks. If the allowed profit margin is set too high, the firm has little incentive to control its costs. Within certain bounds any increase in, research, marketing or production expenses, is more than matched by an increase in price. The firm has strong incentives to develop lavish "gold-plated" laboratories to attract and retain, high quality staff, knowing that the resulting expenses can be passed on in higher prices. The drawbacks of profit controls are not limited to wasteful expenditure, but can also be anti-competitive. In effect, the firm's opportunity cost of increasing its marketing expenses is zero. This can raise barriers to entry, as the firm has a credible threat to increase its marketing substantially in response to the threat of new entry. On the other hand, if the allowed profit margin is set too low, the firm will have little incentive to innovate.

4.8.2 Introducing Competition into Pharmaceutical Price Controls

Experience in other industries has shown the benefits of introducing competition into competitive segments of an industry wherever possible. In the pharmaceutical industry, the production of drugs is potentially competitive – there are no barriers to entry or economies of scale which prohibit production of the same drug by many different firms.

Competition in drug production could be introduced, consistent with ensuring a return to the patent holder and consistent with a system of price controls through a system of compulsory licensing. Under a system of compulsory licensing a patent holder would be required to sub-license the right to manufacture and market a drug to any requesting firm. The requesting firm would pay the patent holder a royalty fee determined by regulation. The level of that fee would be chosen in such a way that the royalty plus direct production costs is equal to the desired (regulated) market price, ensuring the patent holder enjoys the same profit before and after compulsory licensing. This point is worth emphasising. Compulsory licensing, as it is proposed here, does not constrain the profits of the patent holder to a greater

or lesser extent than the price controls which it replaces. The requirement to pay a royalty would terminate on the date that patent terminates.

Introducing competition in this way would have certain advantages. At the least, this process would ensure productive efficiency in production. One of the charges often levelled at monopolies is a tendency towards x-inefficiency – that is, a tendency to relax pressure on costs, allowing costs to rise above the level of pure productive efficiency. This tendency is reinforced in the presence of profit controls. Introducing competition in production would offset this tendency.

In addition to introducing productive efficiency a system of compulsory licensing might also other advantages, including eliminating the opportunity for certain forms of anticompetitive behaviour. For example, the presence of multiple independent sources would prevent the patent holder engaging in tying, insisting that access to one drug be conditional on also taking others from the same manufacturer. It would also prevent the anticompetitive use of exclusive contracts between manufacturers and members of the pharmaceutical distribution chain.

Compulsory licensing may also have an impact on price-discrimination and parallel trade. A firm which is forced to license its products in a low-price country may find it more difficult to prevent the resale of those products into high price countries, undermining the ability to set different prices in different countries.

4.8.3 Price-Control, Buyer Power and the Need for Multilateral Co-ordination

Some commentators have raised the possibility that large national health insurers would have some countervailing power in negotiations with manufacturers and would be able to negotiate a price lower than the maximum that the insurer is prepared to pay. This situation might arise, for example, if the drug manufacturer is not in a position to refuse to sell to the insurer, if it perceives that the public relations cost of "withholding" a potentially valuable medication is too high.

It is possible that some national health insurers are sufficiently large as to have sizeable "bargaining power" with respect to certain manufacturers, especially for drugs which it is difficult for the manufacturer to "withhold" (such as a novel treatment for AIDS). The national health insurer might be able to use this bargaining power to force the manufacturer to accept a lower price, lowering the returns to the manufacturer and implicitly, lowering the returns to the investment in R&D. Although it is unlikely that smaller countries, such as New Zealand, which accounts for less than one fifth of one percent of OECD pharmaceutical demand has significant buying power, larger countries, like France and Germany, which account for 8-9% of OECD demand each may be able to have some influence over the prices they pay, especially if they act in concert.[87]

Some commentators have raised the concern that if several large health insurers could each individually exercise bargaining power, the combined outcome could be a reduced flow of innovative new drugs. The argument runs as follows: A national health insurer with substantial bargaining power will balance the effect that low drug prices have on incentives for R&D against the benefits of low drug prices for its domestic health consumers. Unfortunately there is a public good problem. While each health insurer benefits directly from low drug prices, it shares with foreign consumers the benefits of a flow of new drug innovations. Thus, in considering whether to raise prices a little to induce more innovation, the insurer will suffer all the cost, but will receive only part of the benefit. As a result, each insurer with bargaining power will have an incentive to reduce drug prices to a level lower than is collectively efficient for all. In the equilibrium drug prices will be too low and there will be too little innovation.

It is possible that this is only a theoretical concern. US drug prices appear high by world standards, suggesting that US consumers are contributing more than consumers in other countries to the continuing R&D of pharmaceutical firms. The UK, another large market, has not chosen to exercise any bargaining power that it might have but has deliberately chosen to directly reward pharmaceutical companies for their innovative activity. In addition, several other large countries, have chosen a system of international benchmarking, with the effect of partially or fully importing US and UK prices. Nevertheless, it is difficult to rule out the possibility that a situation of buying power might arise, especially if several national insurers decided to co-ordinate their pharmaceutical buying practices.

In the event that several insurers each exercised buying power in the market for pharmaceuticals, there might arise a need for multilateral co-operation. The arguments are analogous to the arguments for multilateral agreement on standards for intellectual property rights. In the absence of international standards, patent importing countries have an incentive to establish low or no levels of patent protection, in order to benefit from the patent without paying the cost. The same arguments apply to price controls on pharmaceuticals. Price controls are essentially a limitation on the right of the patent holder to exploit the patent. In the absence of multilateral agreement, each country has an incentive to set the price too low (limiting the rights of the patent holder) to receive the benefits of the patent without paying for the costs of its development.

Rather than pursue a multilateral agreement, it seems preferable to prevent the formation of buyer power by preventing large health buyers from colluding in their purchasing of pharmaceuticals.[88] In the case of larger countries, such as France, Germany, the UK and Japan, the buyer power of pharmaceutical purchasers could be reduced further by delegating pharmaceutical purchasing from the national to the regional or sub-national insurer level.

4.9 The Pharmaceutical Distribution Chain

4.9.1 Price Controls and the Pharmaceuticals Distribution Chain

Price controls on pharmaceuticals have important implications for the pharmaceutical distribution chain. Consumers do not purchase pharmaceuticals alone. Rather, they purchase the combination of pharmaceutical services (provided by the pharmaceutical manufacturer) and pharmacy services (provided by the pharmacist). The quality of service offered by the insurer depends, therefore, not just on the drugs that are available but also on the density of the network of pharmacies. The costs of the distribution chain are not an insignificant portion of total costs. In France, the total costs of distribution amount to 44 percent of the total sales.[89]

Suppose there is a system of price controls on the wholesale price of pharmaceuticals. If the insurer's reimbursement policy is to reimburse drug expenses 100 percent, consumers face no incentive to shop for the lowest cost pharmacy. Faced with no price competition between pharmacies, it is essential for insurers to also regulate the retail price.[90]

The question then arises as to the appropriate margin between the wholesale and retail price. This margin should correspond to the costs incurred in providing pharmacy services and will differ from pharmacy to pharmacy. This is, in effect, a classic price regulation problem. As in other price regulation problems, the principal theoretical issue is that the pharmacy has better information than the insurer about its own level of costs. If the margin is set too low, the pharmacy will close down, reducing the availability of pharmacy services. If the margin is set too high, entry of new pharmacies will be attracted which, in the absence of entry controls, will dissipate some of the extra margin in the form of higher costs.

Given the costs and difficulty associated with assessing the costs of each pharmacy, many countries have adopted the practice of simply setting a fixed nation-wide margin, independent of the costs of an individual pharmacy. This approach has many drawbacks, the most important of which is that the margin must be set high enough to sustain even the most marginal pharmacies – i.e., those in the highest cost or lowest volume areas. As a result, almost all pharmacies will be over-compensated, raising the cost of pharmaceuticals and increasing the national pharmaceutical bill. The over-compensation will attract new entry which, if permitted, would dissipate the extra profits in the form of higher costs. In order to offset this, most countries regulate entry into the pharmacy business, by limiting the number of pharmacies based on population and setting minimum distances between shops.

For example, in Hungary, there may be no more than one pharmacy per 5 000 persons, located no closer than 300 metres from each other (250 metres in cities). Pharmacies must be controlled only by pharmacists (preventing, for example, pharmacy services being offered by a chain store).[91] Denmark, in an attempt to offset the over-compensation problem, imposes a profit-pooling requirement on pharmacists, essentially requiring the most profitable to subsidise the least.[92] The situation in France is described in the following box.[93]

Reform of Pharmacy Compensation in France

In a study published in September 1999 the French Cour des Comptes is highly critical of the system of compensation of pharmacies in France. Some of the highlights of this study are as follows:

- The pharmacy sector is highly regulated in France. "There is hardly any aspect of this activity (licensing, installations, cleanliness, compensation, commercial practices…) which is not subject to regulation".[94] Despite strict limitations on new entry, new pharmacies are created at the rate of 50-60 per year, down from 250 per year between 1962 and 1991.

- In 1996, although pharmacies represented 5.9 percent of the number of retail outlets, they accounted for 7.8 percent of the turnover and 8.5 percent of the profits of the retail sector. The average profit per store was 413 000 francs for optical/photography stores, 429 000 francs for perfume stores and 761 000 for pharmacies.

- In France, there are 22 600 pharmacies, i.e., around one per 2500 inhabitants, compared with one per 3 800 inhabitants in Germany, one per 4400 in the UK and one per 3500 in Italy. The density of pharmacies varies greatly by region, from fewer than one per 3300 inhabitants in the departments of Moselle, Haut-Rhin and Bas-Rhin, to more than one per 2000 inhabitants in Creuse, Corse, Lozère, Paris and Allier.

- Until 1999 the compensation for pharmacists was based on a common nation-wide percentage margin of the selling price. This percentage margin was lower the higher the selling price of the drug. The average margin was 25.3 percent in 1998. The Cour des Comptes noted that "The question is raised whether the single nation-wide compensation system, which applies equally to all pharmacies, has the effect of sustaining the marginal pharmacies (those that, for whatever reason, are in the least satisfactory situation) and, as a consequence, assures a higher level of remuneration to those outlets in the most favourable situations".[95]

- Under an agreement between the government and the pharmacy sector in 1999, the compensation for pharmacists will consist of a fee of 3.5 francs per box and a margin of 26.1 percent up to 150 francs and ten percent thereafter.[96]

- The study notes that in the last 20 years, all policies to stimulate the market for generic medicines in France have failed. This is due to the fact that "None of the industry players in the process of manufacturing or distribution of this product have any interest seeing the generic market develop".[97] In the latest developments France has introduced a law permitting substitution of generics by the pharmacist unless the prescribing doctor specifically states that no substitution can occur. In addition, the new law allows pharmacists a much larger discount on generic products than brand-name products (10.74 percent instead of 2.5 percent) and states that compensation for generic products is to be based on the price of the brand-name product and not the generic. The object of these measures is to increase the market share of generics from five percent to 35 percent over three years.

The restrictions on prices and entry relating to pharmacies have been the target of competition advocacy by many OECD competition authorities[98], and by the OECD itself[99]. In particular, competition authorities have often argued for removal of the entry restrictions on pharmacies. However, liberalisation of entry will not necessarily lead to an efficient outcome. As long as pharmacy margins are regulated to remain above cost, liberalisation of entry will lead to inefficient entry in this sector, converting a simple economic transfer into a waste of real economic resources. A full solution to this problem requires careful attention to the manner in which pharmacies are compensated.

There are alternative regulatory approaches which limit the extent of over-compensation of pharmacists, while retaining 100 percent reimbursement and availability of pharmacies. All such approaches must, by some means, improve the availability of information about the level of costs of each individual pharmacy. One mechanism is to hold a tender for the right to provide pharmacy services in certain locations (perhaps on a local or regional basis). The tender process would ensure both that the insurer paid the lowest possible margins for tendering services and that the most efficient provider of pharmacy services would be selected.

Such an approach relies on competition for-the-market. Many competition authorities have also advocated for the promotion of some form of traditional competition in the market for pharmacies. Such competition is not possible without some relaxation of the policy of 100 percent reimbursement. For competition in the market for pharmacy services to be established it is essential that consumers have an incentive, at the margin, to seek out lower-cost pharmacies.

However the relaxation of this requirement does not mean its abandonment. One approach, for example, could be to tender for pharmacy services at individual, scattered points throughout the territory, and base reimbursement rates in that territory on the rates at the nearest tendered pharmacies. All other pharmacies would be allowed to set their own prices and freely enter and exit the market. The tendering process would reveal information about local cost conditions. This process would ensure both competition, a high-level of cost reimbursement for individual consumers and would guarantee a minimum level of service. Consumers would also be free to seek out alternative sources of pharmaceutical supplies, such as mail-order or Internet pharmacies. A related approach would involve only tendering for pharmacies in remote or rural areas, relying on competition to restrain prices in other areas of the country.

Where pharmacy compensation is based on a fixed percentage margin of the wholesale or retail price, the wholesaler or retailer has an incentive to increase, rather than reduce the prices of drugs which it distributes. This has the effect of impeding the entry of generic drugs or parallel imports. In Italy, for example, the Italian Antitrust Authority has criticised the fixed margin system in Italy as hampering the growth of the generic market.[100] In Germany, the Bundeskartellamt required wholesalers to accept lower-priced imports despite their reluctance to do so, due to the fixed margin system. [101] In France, as noted in the box, the generic market has long remained under-developed, in part due to the opposing incentives of pharmacists.

Many countries impose ownership restrictions on pharmacies, for example, requiring that pharmacies be majority-owned by an individual pharmacist, preventing a pharmacist from owning more than one pharmacy and preventing combination of pharmacies with other businesses. Provided that safety standards can be met, such restrictions are harmful to competition and economic efficiency.[102]

4.9.2 Parallel Trade in Medicines

As we noted above, when a pharmacist's percentage margins are fixed, the pharmacist has an incentive to increase, rather than decrease, the prices of the drugs it sells. On the other hand, as long as the pharmacist's retail price is fixed, the pharmacist faces a very strong incentive to reduce his/her wholesale purchasing price. Since wholesale pharmaceutical prices vary from country to country, an obvious alternative is to purchase pharmaceuticals from wholesalers in a low-price country and import them for sale in a high-price country. This is known as parallel trade.

The primary effect of parallel trade is that it increases the profitability of pharmaceutical wholesalers and retailers. Parallel trade may or may not lower the prices for pharmaceuticals in the high-price country. If the insurer is able to observe the prices paid by the pharmacist for the imported pharmaceuticals, it may be able to adjust the regulated retail price accordingly. However, this is not always possible. In the UK, a high-price country which is a popular destination for parallel imports, the NHS simply takes the approach of reducing pharmacists remuneration across the board by 0.92 percent on the basis that all pharmacies are dealing in parallel imports, whether they do so or not.[103]

Overall, the welfare implications of parallel trade are unclear. On one hand, as already noted, the effect of parallel trade in lowering prices in high-price countries is muted. The primary beneficiaries, in the first instance, are the traders. Even if parallel trade has a direct effect on prices, its beneficial effects are uncertain. Parallel trade limits the ability of drug manufacturers to discriminate in their prices across different countries.[104] This raises prices in poorer countries, limiting their access to medicines, but can increase welfare overall (in particular, if allowing parallel trade increases the total quantity of the pharmaceutical sold). To date, the European Court of Justice, in a series of decisions, has consistently ruled in favour of allowing parallel trade within Europe.[105] The European Commission notes:

> "Unless parallel trade can operate dynamically on prices, it creates inefficiencies because most, but not all, of the financial benefit accrues to the parallel trader rather than to the health care system or patient. However, parallel trade must equally be seen as an important driving force for market integration and, consequently, for achieving the Single Market. In as far as the market structure does not provide for the financial benefits of parallel trade to be passed on to consumers and taxpayers, this can normally be ensured through adequate national measures."[106]

Estimates of the market share of parallel traded pharmaceuticals are difficult to obtain. A 1990 study found that parallel imports amounted to about one percent of total sales in Germany, eight percent in the UK and five-ten percent in the Netherlands.[107]

4.10 Summary

This section has sought to present the key forms of regulation which have a direct impact on the demand for pharmaceuticals. The effect of health insurance is to blunt the sensitivity of drug consumers to price. In their place, health insurers implement a wide variety of mechanisms for controlling the quality and quantity of drug expenditures. These mechanisms include the use of formularies, controls on prescribing behaviour, controls on pharmacists and price controls. Competition could be introduced into

the implementation and operation of these mechanisms by tendering for the services of a Pharmacy Benefit Manager, as occurs in the health market in the US.

Virtually all countries adopt some system of price controls of pharmaceutical prices as a tool for controlling pharmaceutical expenditure. The possibility arises that larger health insurers may have some "buying power", giving them the ability to extract a lower price from pharmaceutical manufacturers. This may reduce the profitability of manufacturers, lowering the returns to R&D.

Health insurance also blunts the incentives of consumers to shop for lower cost pharmaceutical distributors, so many health insurers also need to regulate the margins of pharmacies. These margins are sometimes set independent of pharmacists' costs, over-compensating some pharmacists and putting pharmacists in high-cost/low-volume areas at risk. Where margins are set too high, many countries prevent excessive entry in the pharmaceutical business by explicitly limiting new entry. Reforms to pharmacy compensation, such as tendering for pharmacy services, could remove the problem of under/over compensation, would eliminate the need for entry controls and could enhance the market for generic medicines.

5. Competition Issues in the Pharmaceutical Industry

The picture of competition in the pharmaceutical industry which emerges from the following sections can be summarised as follows.

The level and nature of competition in each therapeutic class depends on two factors – the number of independent producers and the nature of demand for pharmaceuticals. In some therapeutic classes there are very few independent manufacturers. Under some insurance schemes pharmaceutical spending is fully or almost fully reimbursed, with relatively few controls on quality or quantity of that spending. In those therapeutic classes where there are a large number of rival producers and where the demand for pharmaceuticals is sensitive to price there can be a high degree of effective competition. In those therapeutic classes with few rival producers, or where demand for pharmaceuticals is insensitive to price, competition is not focused primarily on price, but on non-price dimensions, such as R&D or marketing.

For many products which face few rivals in their therapeutic class, the primary competitive threat is the threat that rival firms will develop substitutes. However, barriers to entry are substantial. The significant risks and costs associated with the R&D process limit the number of potential entrants. Rapid entry is not possible. Because of the substantial delays associated with the process of obtaining marketing approval, incumbent firms benefit from a long period of advance notice before the entry of a rival product onto the market.

In almost all OECD countries the pharmaceutical sector is subject to the competition law although the ubiquitous impact of regulation may, in practice, limit the application of the competition law in this sector. The following is a summary of some of the issues that have arisen and the problems that have been addressed in competition law enforcement.

5.1 Market Definition

As we have noted several times, the relevant product market for competition analysis in the pharmaceutical industry is, for any given condition, the set of drugs which are substitutes in the treatment of that condition. There is often a relatively close correspondence between the relevant product market and what is known in the industry the therapeutic class. The European Commission's Competition Directorate

has adopted the practice of defining the relevant product market according to the therapeutic classes set out in the Anatomical Therapeutic Classification ("ATC") system which is recognised and used by the World Health Organisation. This system is understood and accepted by those in the pharmaceutical business and has the added advantage that very detailed statistical information is collected based on this system.[108]

The relevant product market is also affected by the nature and extent of insurance reimbursement. Even though two high-priced drugs are medically substitutable, the extent of competition between them may be small if one is reimbursed by the health insurer and the other is not. On the other hand, in the presence of co-payments, a low-priced over-the-counter drug could act as a competitive constraint on a prescription medicine.

Although pharmaceuticals are easily transported and are marketed on a global basis, the need to take into account drug purchasing and reimbursement policies means the relevant geographic market for competition analysis is usually much smaller and is typically national in scope. Differing reimbursement and drug purchasing policies in different countries means that pharmaceutical prices and individual products' market shares can differ widely from one country to the next. In addition, drug manufacturers often adopt differing branding, sizing and distribution strategies in different countries either in response to differences in national markets or as a tool to further separate those markets.[109]

5.2 Agreements

Pharmaceutical companies have on occasion been found to be colluding.

In one recent case, a number of pharmaceutical manufactures have been found guilty of maintaining a global cartel to fix prices and allocate market shares for the sale of certain vitamins over a ten year period. The penalties imposed in this case have been substantial. Hoffmann-LaRoche and BASF have paid a total of $US 750 million in fines, with other firms paying close to $US 350 million. Two Hoffman-La Roche executives agreed to go to the US, plead guilty, serve four and five months jail terms, and pay substantial fines. Rhone-Poulenc, which was also directly involved with the cartel, was not fined because of its co-operation with the US authorities.[110]

In another example, the Italian Antitrust Authority prosecuted five drug companies, including Merck, Sharp and Dohme Italy for the price-fixing of certain "category C" (non-reimbursed) drugs used in the treatment of hypercholesterolaemia. These firms had 67 percent of the market for this category segment of drugs. The authority found that Merck gave the other companies advance notice of its intention to raise prices and invited them to follow, which they did. The agreement had the practice of raising prices by 47 percent in ten months. Surprisingly, the resulting fine was derisory, amounting to only three percent of the sales revenue for the products in question.[111] In December 1999 the Italian Antitrust Authority fined Farmindustria, the National Association of the Pharmaceuticals Industry, for a host of anti-competitive actions in which Farmindustria issued instructions to members restricting competition. [112]

In the pharmacy sector a few cases have also arisen. For example, in the Netherlands, the pharmacy federation foundation "Pharmacon" sought dispensation for price-fixing by pharmacists on sales of non-prescription drugs. This was turned down by the Netherlands competition authority and a subsequent appeal was withdrawn.[113] In the Czech Republic a private association of pharmacists known as the Czech Pharmaceutical Chamber raised the requirements for obtaining a certificate required to establish a pharmacy to non-members of the chamber, significantly restricting opportunities for non-pharmacists to enter this business.[114]

In an interesting case in Germany, price controls for pharmaceutical products were previously determined by the country's insurance funds acting together. In 1999 a German court ruled that the insurance funds were colluding in breach of competition law. In response, the German health Minister has announced plans to establish a state agency to determine pharmaceutical prices.[115]

5.3 Mergers

Like any other merger, a horizontal merger of two pharmaceutical manufacturers may reduce competition in those markets in which both firms are currently competing. In addition, since in many drug markets, the primary competitive threat comes from products currently under development, a merger may also reduce competition in the future by eliminating the threat of entry of rival products. It is for this reason that many OECD competition authorities pay attention not only to current products but also to drugs currently under development when assessing the implications of mergers of pharmaceutical companies.

For example in the case of the Glaxo acquisition of Wellcome plc, both companies had development programs for non-injectable migraine drugs. Glaxo was already marketing a non-injectable drug and was developing an improved product called Naramig. Wellcome did not have a migraine product on the market but had a drug in Phase III trials known as Zomig. Zomig was expected to be introduced in 1997 (two years after the merger). The FTC required the merged firm to divest, within a specified time limit, Welcome's Zomig to an FTC-approved third-party. The divestiture of Zomig to Zeneca was approved a year later. In this case, the FTC's intervention seems to have been a particular success. Glaxo Wellcome's Naramig received regulatory approval in March 1997, just eight months ahead of Zeneca's Zomig. "It seems that the FTC intervention in the Glaxo case preserved, if not boosted, competition in the migraine market for the benefit of America's millions of migraine sufferers".[116]

The effect of mergers in reducing R&D competition was also directly observed in the case of the Hoechst acquisition of Marion Merrill Dow. In this case the FTC alleged that potential competition would be harmed in four separate markets, of which the largest was the $one billion per day market for diltaizem in which Marion Merrill Dow's product Cardizem CD had a dominant market share. Hoechst had a rival product, Tiazac under development. The Commission alleged that the "pendency of the merger negotiations affected Hoechst's incentives with respect to the development of Tiazac" resulting in delayed FDA approval.[117]

A difficulty with respect to reliance on competition from products currently under development (so-called "pipeline" products) is that the approval process is inherently uncertain. At each stage of the process a significant number of compounds are eliminated. The existence of a product under development may not inevitably lead to actual competition in the future. For this reason the European Commission has adopted the policy of only considering products in the final stages (Phase III) of clinical trials. The focus on products under development has also been criticised on the grounds that while a lack of competition in conventional markets leads directly to welfare loss, it is not as clear that a lack of competition on R&D leads directly to a welfare loss. It is not clear that less R&D competition leads to less R&D or that less R&D leads to a welfare loss.[118]

Concerns have also been expressed that drug company mergers may facilitate collusion in the industry. In particular, the susceptibility of the pharmaceutical industry to collusive behaviour might be further enhanced if drug companies could increase the potential to enter each others' market. If there are economies of scope in R&D, firms with larger R&D programmes are more likely to enter any given market. The greater competitive threat may facilitate forms of collusion, such as an implicit agreement to divide R&D efforts in therapeutic classes between the colluding firms.

Where a merger raises competition concerns, what remedies can be imposed? In the case of products which are currently being marketed, the potential remedies take their conventional forms – divestiture of licences and/or manufacturing assets. In the case of competition from R&D programmes it remains possible to impose divestiture as a remedy, although, as always, it remains essential to give careful consideration to the question of whether the divested assets will be an effective source of competition. Levy notes:

> "The costly, risky, and time-consuming characteristics of the prescription drug R&D process may make it hard to restore innovation to pre-acquisition levels using [conventional divestiture remedies]. An initial difficulty is that any acquirer of the divested assets may otherwise lack the capability to compete with the merging parties in the innovation market at issue. Further, these divestitures may threaten any efficiencies that flow from a combination of complementary R&D assets that could characterise some mergers involving innovation markets. But, when the assets required for R&D are readily identified, when the foregone scope economies in research are small relative to the benefit to consumers from protecting R&D competition, and when a strong buyer can be identified, divestitures of overlapping innovation assets can reasonably be employed to remedy potentially anticompetitive drug mergers".[119]

The US FTC, alone amongst OECD antitrust authorities, has raised concerns regarding a number of vertical mergers in the US pharmaceutical industry – between drug manufacturers and Pharmacy Benefit Managers. As discussed earlier, PBMs provide services to health insurers, including the maintenance of a drug formularies, claims processing, drug utilisation reviews and pharmacy network administration. The FTC's concerns regarding these mergers included concerns that the PBM would favour its affiliate's drugs over those of other manufacturers, and the concern that ownership of the PBM would facilitate collusion amongst drug manufacturers by giving the drug manufacturer detailed information regarding its rival's rebates, discounts and product prices. In one of the largest cases (the purchase by Eli Lilly of PCS), the FTC cleared the merger but cautioned that it might take future action, including post-acquisition divestiture if it concluded there were signs of anticompetitive conduct in the industry.[120]

Mergers have also been challenged in pharmaceutical distribution. In the UK, for example, Unichem and Gehe AG, two major wholesalers in the UK, were bidding for acquiring Lloyds Chemists. The Director-General for Fair Trading was concerned that the divestiture of wholesaling depots in certain areas of the country would not be sufficient to ensure effective competition in pharmaceutical wholesaling. Ultimately the Secretary of State was satisfied that satisfactory divestiture undertakings were obtained and the merger went ahead.[121] In the US, the FTC successfully opposed the mergers of the four largest pharmaceutical wholesalers into two companies. This would have given the two survivors control over 80 percent of the prescription drug wholesaling market, significantly reducing competition on prices and services.[122]

5.4 Abuse of Dominance

Given the dominant position held by some drugs in some therapeutic classes, it is not surprising that drug companies have on occasion sought to use this dominant position to restrict competition.

For example, in France, Lilly-France adopted the practice of offering discounts to hospitals who purchased its generic drugs along with the brand-name drugs for which it held a dominant position. The French Competition Council and Court of Appeal held that the purpose of this discount was to illegally restrict access by rivals to hospitals in the market for generic drugs.[123]

In 1992 the US FTC, settled charges against Sandoz that alleged that Sandoz unlawfully required those who purchased its schizophrenia drug, clozapine, to also purchase distribution and patient monitoring services from Sandoz. The consent order "guards against the possibility that Sandoz might restrict other firms that want to market generic clozapine in the US after Sandoz's exclusive selling right expires in 1994, by requiring Sandoz to provide information on reasonable terms if any company is in need of information about patients who have had adverse reactions to the drug".[124]

On numerous occasions in the US groups of pharmacies with a dominant position in a given geographic area have sought to use that dominant position in an anti-competitive fashion. FTC cases against the Pharmaceutical Society of the State of New York, the Southeast Colorado Pharmacal Association, the Baltimore Metropolitan Pharmaceutical Association and the Maryland Pharmacists Association, all involved the attempt by an association of pharmacists with a dominant position in the market for pharmacy services, to engage in a collective boycott in an attempt to raise reimbursement rates from health insurers.[125] The FTC settled these cases with consent orders which prohibit the associations from refuse to enter into, or to withdraw from, any participation agreement offered by a third-party payer.

6. Conclusion

The pharmaceutical industry has a key role in OECD countries. It is a major source of R&D investment, of high-paying jobs, and through the continual flow of new and innovative drugs for the treatment of all kinds of human illnesses, has made a highly significant contribution to overall health and well-being.

Yet, few sectors of OECD economies are more heavily regulated that the pharmaceutical sector. Every step in the life-cycle of a pharmaceutical product – from initial conception, to marketing approval, commercialisation, patent expiration and generic competition – is influenced by regulation. Each actor in the pharmaceutical industry – the manufacturer, the wholesaler and retailer, the prescribing doctor, the health insurer and the health consumer – is profoundly influenced by the rules and incentives established by regulation.

In particular, the nature of competition in the pharmaceutical marketplace is fundamentally influenced by the effect of health insurance and the mechanisms established by health insurers to control pharmaceutical demand. These mechanisms include the use of formularies, drug utilisation review procedures, prescribing guidelines and price controls. Their effectiveness varies from insurer to insurer. The quality of these mechanisms and the effectiveness of overall drug spending could be enhanced by contracting out for these pharmacy benefit management services, even in those countries where the primary national health insurer is state-owned. The periodic tendering process would provide continual incentives for innovations in contracting, processes and the use of technology in the control of pharmaceutical expenditures. This is one of the rare occasions where responsibility for "regulatory" policies can be delegated to a private profit-maximising organisation.

Such contracting out for pharmacy benefit management services would also ensure that attention is given to a host of other minor improvements in the pharmaceutical marketplace, including the use of two-part pricing schemes in contracts with brand-name drug manufacturers, and attention to the manner in which pharmacists are compensated. The use of two-part pricing schemes could reduce the incentive to inefficiently switch consumption away from high-margin brand-name drugs, without sacrificing the manufacturer's incentive to invest in R&D. Where pharmacists' compensation is not related to their underlying costs, there are strong incentives for excessive and wasteful new entry in profitable areas, leading to significant restrictions on new entry. The careful use of tendering for pharmacy services would ensure that pharmacists are neither over- nor under-compensated.

NOTES

1. Commission Communication on the Single Market in Pharmaceuticals, COM (98) 588, page 4

2.. See also Jacobzone (2000), pp. 11-14.

3. In the long run, however, there is little evidence that pharmaceutical expenditures have been rising faster than health expenditures more generally.

4. For example, the UK Government expressed concern over prescribing-cost inflation in its 1989 White Paper, noting "Expenditure on medicines has grown on average by four percent a year above the rate of inflation over the last five years" and the cost of drugs was "more than the cost of the doctors who wrote the prescriptions". UK Department of Health (1989), p57. In a review of pharmaceutical price regulation in Canada, Anis and Wen (1998) note that "The bill for pharmaceutical products is the fastest growing component of total health care expenditures in Canada. Since 1993, drug costs have become the second largest category of health care spending after institutional expenses, and exceeded payments to physicians". Anis and Wen (1998), p21.

5. These bills followed a report by the US Senate that claimed that despite drug company promises to voluntarily limit price increases during 1992 to the rate of inflation, drug prices had increased by four times the rate of inflation during that year. Abbott (1995), p551-552.

6. OECD (1997), p9.

7. Jacobzone (2000), chart 11.

8. Klepper (1995), p330.

9. "These non-research firms will either produce drugs under licence for a local market which the licence holder does not want to serve or they produce out-of-patent drugs which do not require any large research facilities. Since the bulk of production as well as conversion into dosage forms involves little economies of scale these firms could be rather mobile and entry and exit from the industry relatively easy". Klepper (1995), 338. In addition, the second-tier contains a group of small firms which enjoy the benefits of intellectual property-rights acquired historically but which carry out little new R&D of their own.

10. "Suppliers are not so much in competition with one another with a given product. Rather they attempt to safeguard their economic survival through *innovation*". Zweifel and Breyer (1997), p301.

11. "US drugs giants poised to announce $84bn merger", *Financial Times*, 7 February 2000

12. Over the last decade advances in information technology and biotechnology have allowed drug companies to select promising compounds without the need for large-scale screening.

13. The process of patenting makes the compound public information, so a patent is usually sought at the last possible moment consistent with competitors research efforts and the need to commence clinical trials.

14. Ben-Asher (1999), p18.

15. Ben-Asher (1999), p16. Levy (1999), p178 suggests slightly different figures: From the screening of 5 000 to 10 000 compounds, only five ever reach the clinical phase of the FDA approval process and only one of these five receive FDA approval.

16. Grabowski and Vernon (1992b), p356, figure 3. As a result of this dependence on relative few drugs, company revenues can vary from year to year as new products are developed and old products go off-patent. "The stochastic nature of this process is illuminated first of all by the frequent changes in the ranking of the largest pharmaceutical producers by turnover. A successful new product (such as Glaxo's Zantac) can push a company way up. The same company can fall in the rankings when the patent for such a product expires. The world's top-ranking global firms therefore constantly change positions but rarely does a new one enter or an established producer disappear". Klepper (1995), p340.

17. "The extent to which major pharmaceutical companies rely on the revenues generated by a small number of products is striking. For some major firms, three products alone account for 70-80 percent of total pharmaceutical sales, and for most firms, these percentages are substantial". Comanor (1986), p1182.

18. Ben-Asher (1999), p12. Testimony collected during FTC hearings on global competition indicated that the average cost of launching a successful prescription drug was about $359 million in the 1980s. Levy (1999), p175. From the mid 1980s to the mid 1990s, US expenditure on pharmaceutical R&D rose without a corresponding increase in the rate of introduction of new drugs.

19. Levy (1999), p179.

20. Schweitzer (1997), p46.

21. HMOs, or Health Maintenance Organisations, are health care providers which, by integrating the roles of health insurers and providers can maintain tighter controls on the quantity and quality of health spending than traditional forms of health insurance.

22. Levy (1999), p187.

23. See Collins (2000).

24. For example, Miles, Inc., "paid pharmacists $35 for each patient switched from a competing antihypertension drug to its Adalat CC. Upjohn Co. offered financial incentives to pharmacists who provided information about its diabetes drug to consumers of competing brand names. Merck & Co. established several incentive programs encouraging substitution of its brand names for those of competing drug companies, including rebate programs for the brand-name antihypertensive drugs, Prinivil and Prinzide". Levy (1999), p19.

25. Scherer (1996).

26. Scherer (1993), p98.

27. Levy (1999), p 209.

28. Scherer (1993), p104.

29. Scherer (1993), p105. See OTA (1993) and CBO (1994). cited by Levy (1999), p210.

30. Clarkson, Kenneth W., "The Effects of Research and Promotion on Rates of Return"in Robert B. Helms, ed., *Competitive Strategies in the Pharmaceutical Industry*, Washington D.C.: The AEI Press, 1996. One potential explanation for higher average return in the pharmaceutical industry is a higher cost of capital due to the risks inherent in the pharmaceutical business. The persistently high average industry return could mask substantial variation in the profitability of individual companies over time. See Meyers and Shyam-Sunder (1996).

31. Klepper (1995), p341.

32. Levy (1999) notes: "A comparison of share data for antibiotics and ACE inhibitors might not accurately represent any differences in sales concentration across appropriately-defined drug classes. Arguably, the fact that there are distinct subclasses of antibiotics suggests that antibiotics is a broader drug category than ACE inhibitors which also compete with other antihypertensive drugs. If so, then the sales concentration data in [this table] for these two therapeutic classes are not necessarily comparable. Instead, it might be more appropriate to compare sales concentration data for antibiotics and all antihypertensive drugs, including ACE inhibitors". Levy (1999), p196.

33. Based on the ATC level 4, the Italian submission identifies 321 product markets for medicines in Italy. Of these, around 78 percent in 1997 were characterised by a CR4 above 80 percent.

34. "Without patent protection there would be no marketing exclusivity and competitors would immediately enter any market with a successful product, driving price down eventually to the marginal production costs. Future R&D would never take place because there would be no way for firms to earn a yield on those investments in developing intellectual property. Patent laws, however, entail societal cost, for protection of intellectual property raises the cost of diffusion of knowledge and makes innovations prohibitively expensive for some who would benefit from its use. Patent protection can be seen as a trade-off between present and future gains. At any point in time uninhibited diffusion of knowledge will confer short-term benefits to some. But their gain, if realised will deprive those who originated the knowledge of the return on their intellectual investment and destroy any incentive for future such investments. Striking the right balance is a critical societal goal". Schweitzer (1997), p196.

35. Levy (1999), citing Mansfield (1986).

36. Mansfield (1986).

37. See Levy (1999), p180.

38. For a theoretical discussion of optimal patent life see, for example, Cornelli and Schankerman (1999).

39. "Out of 14 active substances newly introduced in the German market in 1988, only three were classified by the federal association of sick funds as new and therapeutically significant. In other words, almost 80 percent of the preparations newly introduced a considered to be marginal advances to existing preparations commonly called 'me too' drugs". Zweifel and Breyer (1997), p301.

40. See "Drug Abuses", Financial Times, 20 April 2000, p12.

41. "Drug Abuses", Financial Times, 20 April 2000, p12. See also Scotchmer, Suzanne, "Protecting Early Innovators: Should Second-Generation Products Be Patentable?", *Rand Journal of Economics*, 27(2), Summer 1996, 322-321 and O'Donoghue, Ted, "A Patentability Requirement for Sequential Innovation", *Rand Journal of Economics*, 29(4), Winter 1998, 654-679.

42. See for example Wright, Brian, "The Economics of Incentives: Patents, Prizes and Research Contracts", *American Economic Review*, 74(4), 1983, 691-707.

43. See the New Zealand submission.

44. This is discussed further in Grabowski and Vernon (1992a).

45. Levy (1999), p205.

46. Levy (1999), p206 notes: "Frank and Salkever (1997), in a study of 32 drugs that lost patent protection during the 1980s found that brand-name drug prices increase after generic entry and generic drug prices decline significantly as generic companies enter these product categories. … In a study of name-brand drugs exposed to generic competition from 1983 to 1987, Grabowski and Vernon (1992a) found that name-brand prices rose slightly after generic entry, and that average prices declined by approximately 20% two years after the entry of generic competitors".

47. See Griliches and Cockburn (1995).

48. The US FDA received some 800 applications for approval under the abbreviated process within seven months of the passing of the Act. This legislation has likely contributed to a rise in the volume share of generic drugs in the US, from 18.3 percent in 1984 to 44.3 percent in 1997. Levy (1999), table 2.1.

49. This is known as a "Roche-Bolar" provision.

50. See "EC loses fight at WTO", European Regulatory Affairs News, April 2000.

51. EC Directive 65/65, article 4.8(a)(iii).

52. "Drug Abuses", Financial Times, 20 April 2000, p12.

53. See "EC Paper on Generic Applications", European Regulatory Affairs News, April 2000.

54. See Levy (1999), p182.

55. Levy (1999), p182.

56. Levy (1999), p184.

57. "In consequence, while the research and development process does lead to competing drugs, some drugs on the market have few close rivals, limiting price competition in existing products, and competition is often directed into innovation aimed at developing new pharmaceuticals that leapfrog existing technologies". Levy (1999), p8.

58. Cross-country comparisons using this data may not be reliable due to differences in the definition of non-prescription medicines.

59. And the market for health services in general.

60. Price controls on non-reimbursed medicines serve only to limit the profitability of the patent-holder, potentially conflicting with other public policy objectives. In any case, the profitability of holders of patents of OTC medicines could be reduced, with less harm to competition, by limiting the life of the patent. The EC has, for example, called for the lifting of price controls on over-the-counter medicines. "EU weighs lifting of price controls", *International Herald Tribune*, 18 November 1998, p20.

61. For a further discussion of different techniques for controlling pharmaceutical expenditure see Gross et al (1994), Hutton et al (1994) and Jacobzone (2000).

62. This policy was considered to be an outstanding success. Burstall (1997), p. S36 and S38. In 1992 this policy was extended to ten more therapeutic areas. In the more recent case, no attempt was made to confine reimbursement to generic equivalents alone.

63. Burstall (1997), p. S38.

64. For example, in Italy, following a reform in 1994, all drugs on the formulary were grouped into three classes. Class A for essential and chronic-disease drugs, class B for drugs not in class A but meeting primary therapeutic requirements, and class C for all other drugs. Class C drugs are not reimbursed. Class B drugs are subject to a 50 percent co-payment. Class A drugs have a flat per-prescription charge of 3000 or 6000 lira according to whether the prescription contains one or more items. Fattore and Jommi (1998), p27.

65. The Swedish reimbursement system is described in Jönsson (1996) and the Belgium scheme in Annemans et al (1997). See also the Norwegian and Swedish submissions.

66. Burstall (1997), p. S38.

67. Levy (1999), p23.

68. See for example the Czech Republic submission.

69. The concept of GP fundholding is described below.

70. Burstall (1997), p. S37.

71. It is clear that any such financial incentives on doctors have to cover not just pharmaceuticals but the whole range of possible medical treatments (otherwise doctors would economise on pharmaceuticals at the expense of higher reliance on other health inputs and higher costs overall).

72. In some cases, especially the US, the legal liability system also creates incentives to maintain high levels of health service.

73. Burstall (1997), p. S29.

74. Cited in Baines, Whynes and Tolley (1997).

75. Levy (1999), p200.

76. Another possible reason for separation relates to safety – separation ensures a second pair of expert eyes oversee the drug consumption habits of health consumers.

77. This change has been opposed by doctors in Korea who supplement low medical fees with income from pharmaceutical sales. "South Korea Industry – A different kind of drugs war", 9 March 2000, Economist Intelligence Unit.

78. See Weinstein and Culbertson (1997), p262.

79. Levy (1999), table 2.2.

80. Levy (1999), p32.

81. For example, in 1996 Italy introduced a policy called "same prices for same drugs" under which "drugs with the same active ingredient, the same or therapeutically comparable pharmaceutical form, but possibly different dosages, must have the same price per unit of compound, if not all drugs but the cheapest are … excluded by NHS coverage". Fattore and Jommi (1998), p29.

82. See "Profile: NICE: The fourth hurdle – boon and bane", FT, 6 April 2000.

83. See Harris (1994).

84. "Norway introduces pharmacoeconomics", European Regulatory Affairs News, April 2000, p12.

85. For example, in Italy, price of pharmaceuticals are not allowed to exceed a level known as the "Average European Price", corresponding to the prices in France, Germany, UK and Spain, converted using OECD GDP PPP figures. Fattore and Jommi (1998), p28.

86. For a detailed discussion of the Pharmaceutical Price Regulation Scheme in the UK and possible alternatives, see Bloom and Van Reenen (1998).

87. The Australian submission implies that the Australian government considers it has monopsony power.

88. In one case along these lines, the German insurance funds were found to be illegally colluding by co-operating in their establishment of pharmaceutical prices. "Germans pursue price regulation plan", European Regulatory Affairs News, April 2000.

89. Cour des Comptes (1998), p223.

90. Mexico, which has very little insurance coverage of pharmaceuticals, has no regulation of pharmacies.

91. There have been 70-80 court cases in Hungary, challenging, on constitutional grounds, the numerical and location limits applied to pharmacies. DAFFE/CLP(99)32, "Regulatory Reform: The Hungary Country Review", p31-32. In contrast, the Finnish Office of Free Competition proposed abolishing needs testing with respect to operating permits of pharmacies and the medical tariff guiding the retail pricing of pharmaceuticals. DAFFE/CLP(99)23, "Competition Policy in OECD Countries 1996-1997".

92. DAFFE/CLP(99)12, "Regulatory Reform: The Denmark Country Review", p5.

93. See also the Australian submission to this roundtable.

94. Cour des Comptes (1999), p228.

95. Cour des Comptes (1999), p230.

96. Hungary also has an elaborate sliding scale system for pharmacy margins. See the Hungarian submission.

97. Cour des Comptes (1999), p232.

98. For example, the Norwegian Competition Authority notes that "The NCA is of the opinion that a system of free entry combined with a qualification based approval system will lead to more efficient retail distribution than today". DAFFE/CLP(98)17/14, "Annual Report on Competition Policy Developments in Norway", p10.

99. OCDE/GD(97)145, "Regulation and Performance in the Distribution Sector", p44.

100. DAFFE/CLP(98)2, "Competition Policy in OECD Countries", p194.

101. In Germany, the Bundeskartellamt held that pharmaceutical wholesalers could not refuse to supply re-imports and parallel imports of drugs. This was designed to offset the incentive of pharmacists to refuse to supply lower-priced drugs because of the lower income they would receive in Germany's system of fixed percentage margins. However, in 1996 the German government revoked the legal obligation under section 129(1) no. 2 of the Code of Social Law V to sell imported drugs. DAFFE/CLP(99)23, "Competition Policy in OECD Countries 1996-1997", p125.

102. See for example the comments of the Czech competition authority in DAFFE/CLP(98)2, "Competition Policy in OECD Countries"

103. Burstall (1997), p. S36.

104. Within the EU, price discrimination might constitute an abuse in the sense of Article 82 of the EC Treaty.

105. See Darba and Rovira (1998).

106. Commission Communication on the Single Market in Pharmaceuticals, COM (98) 588, page 4-5.

107. EC (1992).

108. See the submission of the European Commission and Gatti (1996).

109. See Gatti (1996).

110. This case concerned non-patented and (usually) non-reimbursed pharmaceutical products and therefore can be distinguished from the markets for pharmaceutical products which are the primary focus of this paper.

111. DAFFE/CLP(99)24/12, "Annual Report on Competition Policy Developments in Italy", p6. The Italian antitrust authority has also prosecuted a case of price fixing between Byk Gulden Italia Spa and Istituto Gentili Spa in relation to price fixing in the markets for drugs for the treatment of throat infections. In another case, the Danish Competition Council has acted against tacit collusion between parallel importers. See DAFFE/CLP(99)23, "Competition Policy in OECD Countries 1996-1997".

112. AGCM Press Release of 28 December 1999. It should also be mentioned that pharmaceutical companies often seek to enter into co-operative joint venture arrangements, which have been subject to scrutiny by competition authorities. See the discussion in Gatti (1996).

113. DAFFE/CLP(99)23, "Competition Policy in OECD Countries 1996-1997", p239.

114. DAFFE/CLP(98)2, "Competition Policy in OECD Countries", p77.

115. "Germans pursue price regulation plan", European Regulatory Affairs News, April 2000, p10.

116. Ben-Asher (1999), p29. See also Levy (1999), p131. The Glaxo/Wellcome merger from the perspective of the EU is discussed in Gatti (1996).

117. See FTC (1999), p11.

118. This is discussed further in Ben-Asher (1999).

119. Levy (1999), p132.

120. DAFFE/CLP(98)2, "Competition Policy in OECD Countries", p398.

121. DAFFE/CLP(99)23, "Competition Policy in OECD Countries 1996-1997", p379.

122. FTC (1999), p8.

123. For a fuller summary of this case see the French submission.

124. FTC (1999), p8.

125. See FTC (1999), p5

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APPENDIX

(The following tables are taken from Jacobzone (2000))

Table A. 1: Non-prescription drugs, and over the counter drugs (OTC), 1996

	Consumption 1996 US$PPP per capita		Share of non prescription drugs in total drug consumption in %	
Australia	131	**	50	*1
Austria	31		12	
Belgium	57		19	
Canada	n.a.		29	***
Czech Republic	40		17	
Finland	27		13	
France	105		31	
Germany	103		35	
Hungary	29		17	
Ireland	22		17	
Italy	32		11	
Japan	n.a.		23	***
Netherlands	30		15	
Norway	13		7	
Portugal	33		12	
Spain	33		15	
Sweden	17		8	
Switzerland	84		44	
United Kingdom	44		20	
United States	110		32	
OECD average	**52**		**21**	

Notes: For most countries, the definition corresponds to non prescription drugs. For the United States, the definition may be a little different (OTC) due to specific market characteristics (see figure 2 and box 1 for definition of the pharmaceutical market).

(1) Denmark, Greece, Iceland, Korea, Luxembourg, Mexico, New Zealand, Poland and Turkey are not included due to lack of data.

(2) The unweighted OECD average does not include ...

n.a.: not available, *Data was interpolated, **data from 1995, ***data from 1994, ****data from 1993.

*1 The Australian data for the share of prescription in total drug consumption results from a slightly different definition (OTC) and should be treated with caution

Source of data: OECD Health data 1998.

Table A. 2: Listing of Drugs Eligible for Public Insurance Reimbursement

Country	Listing of drugs	Comments
Australia	Yes	Listing according to medical needs and cost-effectiveness, updated every 3 months.
Austria	Yes	Listing according to medical and economic criteria. List updated every 3 months to reflect medical and market changes. There is a list of drugs reimbursable without prior approval by sickness funds
Belgium	Yes	List updated every month.
Canada	Yes(1)	Lists and formularies are part of the reimbursement system of provincial insurance plans. The criteria often include pharmaco-economic considerations.
Czech Republic	Yes	The general list of medicines available under prescription is issued by the Ministry of Health
Denmark	Yes	List constantly updated.
Finland	Yes	Listing according to effectiveness of drugs. Constantly adapted.
France	Yes	Listing according to the marginal improvement of health service allowed by the drug and the reduction in costs of medical treatments. Difficulties for proper update.
Germany	Yes(2)	Listing according to pharmacological criteria
Greece	Yes	The list was adapted and implemented in 1989/90, but physicians continue prescribing out of the list, justifying exemptions. Since 1995, a National Committee has the responsibility to adapt the list for all the insurance funds and the NHS. In 1997 a positive list was introduced by IKA and generalised to other insurance funds in 1998.
Hungary	Yes	Listing according to the indication and frequency of the illness.
Italy	Yes	Positive listing introduced in 1978 (Prontuario Terapeutico Nazionale). Important revision and de-listing in 1994 and 1995. Some products readmitted under conditions in 1998. .
Japan	Yes	Listing according to the effectiveness of drugs.
Korea	Yes	Listing according to criteria such as the therapeutic value of drugs, the cost of comparable treatments, and prices observed in foreign countries.
Luxembourg	Yes	List updated monthly.
Mexico	Yes	The list has to cover the existing pathologies at the lowest possible cost. It is adapted based upon medical progress and population health needs
Netherlands	Yes	Listing according to effectiveness. The list is updated regularly.
New Zealand	Yes(3)	
Norway	Yes	Listing according to type and seriousness of disease. Constantly adapted.
Spain	Yes(2)	Listing according to medical criteria, severity and time of the pathology, therapeutic and social use of the drugs; Socio-economic criteria include use of alternative drugs at lower prices, public expenditure fiscal constraints.
Sweden	Lists of recommended drugs set by country councils.	
Switzerland	Yes	Drugs listed must be effective, economically efficient and appropriate. Positive list updated twice a year.
UK	Yes	N/A
USA	Yes (HMOs, PBMs)	N/R.

(1) Most of the provinces and territories have established their own formulary for the provincial schemes. (2) Negative list. (3) List of subsidised items only, for reference pricing.

Source: OECD Questionnaire on pharmaceutical management and regulation, and various sources.

Table A. 3: Co-payments and Patient Cost-Sharing Policies in OECD Countries

Country	Differentiation	Method	Modifications	Reinsurance of second-tier co-payment allowed?	Does reinsurance offset co-payment?
Australia	By type of beneficiary	Fixed amount depending on beneficiary type Max 11 $ per prescription. Waiver for concessional cardholders, low income, chronically sick.	Changes regularly in line with Federal Budget decision.	Private insurance but mainly for hospital care.	Not usually
Austria	By type of beneficiary	Fixed amount per package 5$. 43 ATS in 1998	Yearly adjustment according to inflation	No	NR
Belgium	By type of drug and of beneficiary	Percentages depending on the category of the active person and of his dependants. (100/80/60/50 0%)	News categories defined in 1980	In hospital only by non-profit insurance, profit insurance is allowed.	N/A
Canada	By type of drug and beneficiary	Most provinces use a combination of co-payments and deductibles as part of cost sharing with beneficiaries. Overall 88% of Canadian have coverage, 62 % private plans, 19 % provincial plans, 7% under both, Universal coverage in Alberta, British Columbia, Quebec and Saskatchewan.		Yes	NR
Czech Republic	By type of drug	N/A	Changes almost every year to reflect change in drug prices and structure of drug consumption	Yes	N/A
Denmark	By type of drug and partly by beneficiary	50.2% for drugs with definite and valuable therapeutic effects, 25.3% for drugs used for the treatment of well-defined and often life-threatening diseases. 0% for insulin preparation.	Yes, in January 1996, 50% and 25% were changed in order to finance the compensation of iatrogenic diseases. The rule of 0% co-payment for insulin came into force in January 1990.	Yes	In some cases
Finland	By type of drug and beneficiary	A fixed deductible different for each of the three categories of reimbursement. Co-payment 60% in excess of 8$. Level of co-payment also influenced by the categories.	Fixed deductible was changed several times, and the categories were changed in 1986, 1992 and 1994.	Yes	Yes
France	By type of drug and beneficiary	A percentage of the price of the drug, according to the type of drug. Waivers for certain beneficiaries 0/35/65% co-payment.	The reimbursement level was decreased several times. Last 5 % decrease was in 1993.	Yes	Yes, almost fully, this is usually the case.

N/A: not available, NR: not relevant. Amounts in USD or national currency. **Source:** OECD Questionnaire on pharmaceutical management and regulation, OECD (1998) Social and Health Policies, Health Policy Studies n° 7, WHO (1997) European Series n° 72.

Table A. 3: Co-payments and Patient Cost-Sharing Policies in OECD Countries (follows)

Country	Differentiation	Method	Modifications	Reinsurance of second-tier copayment allowed?	Does reinsurance offset co-payment?
Germany	By size of the prescription and beneficiary	By law in 1992. Since July 1997 copayment of 9/11/13 DM (5 to 7$) in relation to package-volume (DM 8/9/10 since January 1999); exemptions, e.g. chronic diseases. (For drugs under the reference pricing scheme, patients also pay the difference between the reference and the actual price).	Yes, increase of 1 DM from 1 January 1997	No	NR
Greece	Very partial	Fixed contribution of 25% of the total drug value, but only 10% for pregnant women, 0% for chronic diseases	Before 1992, level was 10-15%. No change since then.	Yes	No
Hungary	By type of drug and beneficiary	A percentage of the price of the drug from 0% to 100% depending on the type of drugs.	Yes, year by year, depending on the deficit.	Yes, for non-profit insurance company	N/A
Ireland	By type of beneficiary	GMS patients are exempted, mx 90 £(Irl) per quarter for category II patients		NA	NA
Italy	By type of drug and beneficiary	Prescription charge of 3 $ plus percentage of the price. Three main drug categories (0, 50, 100 %). Moving towards more prescription charge and reduction of the share of drugs with patient charge (more or nothing). Exemption according to income, age and health status.	First introduced in 1978. Revised in 1983,	NA	NA
Japan	By type of beneficiary	Fixed amount. From 0 to around 1$ for three internal or six external drugs. Special rules for the elderly and certain diseases. Waivers for elderly, children and low income.	1984. Additional patient participation added in 1997, but with some wavers.	No	N/R
Korea	Not by type of beneficiary or size.	Differentiated percentage of co-payment by type of medical facility: in-patient: 20%; outpatient: pharmacies: 40%, Local clinic: 30%, Hospital: 40%, General Hospital: 55%.	No	Yes	Yes
Luxembourg	By type of drug and beneficiary	According the type of drugs (0, 20, 60 and 100%). 20% is the normal level of co-payment applied for majority of drugs. Pharmaceutical products are totally reimbursed for in-patient care.	Yes, in 1994 for cost containment/ budgetary reasons.	Yes	N/A
Mexico	By size of the prescription and beneficiary	Public insurance: co-payments according to income and geographical/rural area. Private health insurance plans have their own co-payments.	No	Yes	Yes

N/A: not available, NR: not relevant. Amounts in USD or national currency.

Source: OECD Questionnaire on pharmaceutical management and regulation, OECD (1998) Social and Health Policies, Health Policy Studies n° 7, WHO (1997) European Series n° 72.

Table A. 3: Co-payments and Patient Cost-Sharing Policies in OECD Countries (follows)

Country	Differentiation	Method	Modifications	Reinsurance of second-tier copayment allowed?	Does reinsurance offset co-payment?
Netherlands	No	20% co-payment, with a ceiling on the total annual co-payment (67$). Income-adjusted stop-loss annual ceiling.	No. The policy is very recent.	Yes	N/A
New Zealand	By type of beneficiary	Partial insurance for the most needy persons means tested. Difference between actual price and reference price, and co-payment. 2 to 8$ co-payment	Waivers for children have been added	Yes	No
Norway	By type of beneficiary	50% co-payment. Waiver for children and elderly. Maximum 43 $ per prescription.	No	Yes	N/A
Portugal	By type of beneficiary	0/30/60% of price, reduced for low income			
Spain	By type of drug and beneficiary	Based on the price of the drug. 0 or 40%. Exemptions for pensioners and chronically ill.	Changed 6 times.	No	Yes
Sweden	By prescription size and beneficiary	Fixed amount, SEK 160 for first item and SEK 60 for further items. Percentage of the cost. , Stop loss 1800 Skr per 12 months, amount per prescription item.	Yes, since 1968, the co-payment has been changed about 15 times. last changed in 1995.	Yes	Yes
Switzerland	Partly by beneficiary	Franchise 230 SFr, plus 10 per cent of the costs, with annual stop loss ceiling 600 NCU SFr per year. Exemption for children.	Sickness Law 1994. Franchise and co-payment rates were raised in 1995.	No	NR
Turkey	By type of beneficiary	10% retired 20% active.		Unknown	N/A
UK	By type of beneficiary	Fixed amount charge, currently £ 5.5 per prescription. Many waivers(1)	Fixed amount re-valued on an annual basis. Increased in real terms over the 1980s.	Unknown	N/A
USA	NR	Drugs not included in Medicare but may be covered if HMO. Most private insurance plans have co-payment requirements. 60% of retail sales paid by third parties to some exempt. Fixed prescription charges in HMOs, against co-payments plus a deductible in Fee For Service Planes, Medicaid Covers Some Drugs.		Yes	N/A

(1) In 1995, 16% of the total number of the prescriptions carried a prescription charge, and 22% of the value of total prescriptions carried a charge.
N/A: not available, NR: not relevant. Amounts in USD or national currency.
Source: OECD Questionnaire on pharmaceutical management and regulation, OECD (1998) Social and Health Policies, Health Policy Studies n° 7, WHO (1997) European Series n° 72.

Table A. 4: Guidelines for Prescription

Country	Guidelines	Comments	Possible Sanctions
Australia	Yes	Advisory guidelines, including newsletter to prescribers, and feedback to prescribers on their performance against the average. State guidelines also.	No
Austria	Yes	The guidelines apply to the whole range of medical treatment options.	Yes, contractual obligations include refunds or termination of contracts.
Canada	Not at federal level but in most provinces have	Most provinces have a clinical practice guideline activity underway, including prescribing guidelines.	N/A/
France	Yes	Negative Reference Mandatory Guidelines for certain drugs.	Yes, in theory, there are financial and contractual sanctions.
Germany	Yes	In fact, physician prescription is reviewed ex post at the level of sickness funds.	Yes, prescriptions are examined by sickness funds.
Greece	Yes	IKA doctors have to follow the list of drugs and they are reviewed ex-post to detect over-prescribing physicians.	Yes, IKA Board of Directors and the Governor of IKA normally give fines to doctors who over-prescribe and in very few cases fire them.
Hungary	Yes	Therapeutic protocols exist for the treatment of the most frequent pathologies. These protocols suggest effective and cheap medicines.	Yes, financial sanctions from the Insurance Fund Administration.
Japan	Yes	There are guidelines for the treatment of the elderly high blood pressure.	No
Korea	Yes	Guidelines from medical insurance to restrict use of treatments with limited efficacy.	No
Luxembourg	Yes	"Transparency list" and negative mandatory medical guidelines, following the French model.	Yes in theory. R.M.O. guidelines regulation in preparation. Close to the French model.
Mexico	Yes	Therapeutic-Diagnostic guides are distributed to physicians.	No
Netherlands	Yes	Guidelines are set both for general practitioners and specialists. National network of 650 local groups participating in pharmaco-therapeutic consultation.	No, used by the insurers mostly for feedback
New Zealand	Yes	Information is distributed by the pharmaceutical agency to physicians.	No
Norway	Yes	There are broad guidelines	No
Sweden	Yes	Information is distributed to prescribing physicians. (guidelines for 11 common diseases).	No
UK	Yes	Advice issued across a wide range of practices in line with policy towards clinical and cost effectiveness. Relevant professional body also issue advice to their members. Computer aided prescribing system under trial within the NHS should provide detailed information on cost-effectiveness.	No
USA	Yes	There are various publications available for use by physicians. Guidelines are set by managed care organisations.	Yes, according to the type of managed care setting.

At the time of this questionnaire, No data is available for Spain. No guidelines were reported in Belgium, the Czech Republic, Denmark, Finland, Spain, Switzerland, and Turkey. There may however exist in these countries other types of incentives to prescribe cheaper drugs.
Source: OECD Questionnaire on pharmaceutical management and regulation, and various sources

Table A. 5: Fixed Budgets, Direct Limitations of Volume and Expenditure

Country	Fixed budgets Global volume targets	Some type of individual control per physician, episode or per day	Comments
Austria	No	Yes, per episode	Limitations on volume per individual drug and per episode of care.
Belgium	Yes, global indicative target	Yes, various limitations, per episode, per physician, or per day, but only for expensive specialities	Limitations for expensive specialities are applied per day and per episode, with reference to the period of treatment and the posology. These specialities represent 30% of the annual expenditure and are under the control of medical advisors of the mutual sickness fund.
Canada	No	Yes, supply days per script	Some provinces limit the supply days per scrip. In many cases the limit is set to around 30 days for episodic medicines, and 100 days for maintenance medicines. However physicians are able to provide automatic repeats on scrip enabling a patient to refill the order without a new prescription.
France	Yes, since 1996	Yes, guidelines for specific drugs	The National Target of health care expenditure (ONDAM) includes a target for reimbursement of pharmaceutical prescriptions. In addition, three-year agreements are signed with pharmaceutical companies, with expenditure targets. Higher taxes on pharmaceutical companies when targets were not respected. Rather limited control is exerted on individual prescriptions except for specific drugs included in guidelines.
Germany	Yes	N/A	Global budgets at the national level, which are translated into prescription targets for physicians in a defined region. "Contracts" between sickness funds and physicians' organisations.
Greece	Yes, but only for the main social insurance fund	Yes, per day, per physician	For IKA social insurance fund, 50% of the insured people) The mean average of all the doctors' prescriptions.
Hungary	No	Yes	Volume prescribed at the time. Physicians are allowed to prescribe pharmaceuticals for 30 days period only.
Italy	Yes, set up in 1994, effective in 1996	Yes, for exempted patients.	Delisting occurred in 1996 to prevent budget overrun. For exempted patients, maximum 16 prescriptions, introduced by law in 1992, abolished in 1993 and reintroduced in 1994. Payback decided in 1998 : in case of global budget overruns, 60% of the deficit borne by industry and distribution. Expenditure targets for GPs since the reform.
Mexico	Yes	N/A	Through pharmaceutical budget ceilings, which are set for every medical unit on an annual basis. Once the annual health global budget is determined, a certain proportion is destined to pharmaceutical expenditures, based on medical experience and expected price increases.
Netherlands	No	Yes, some limitation per episode	The volume of prescription should not last more than 3 months (except for some classes of medicines).
New Zealand	No	Yes, Some limitation per episode	1. Volume per month (dispensing limits), the maximum prescription is for 3 months. 2. Dosage strength and period of dosage for some pharmaceuticals. The pharmaceutical agency, PHARMAC, negotiates with drug companies according to decision criteria set by government.
Switzerland	No	Yes, some volume controls per episode for specific therapeutic groups of drugs of the specialist list. Some expenditure control, per day and per episode	By number of packages or number of points within three months.
UK	Yes, at a decentralised level per physician, (1991)		General Practitioners can become fund-holders, and receive a budget covering some elective care and also prescription. Non-fundholding GPs (a minority) were set indicating prescribing budgets. All physicians have now to participate in some form of fundholding, within primary care groups.

The following countries did not mention official control of the volume of prescription or specific limitations on expenditure per day, per episode or per physician. This does not necessarily mean that strong influences may not be used to invite physicians to prescribe in a rigorous way. These countries are Australia, Czech Republic, Denmark, and Finland, Japan, except for some expenditure targets, Korea, Luxembourg (except for exceptional drugs such as Sumatriptan), Norway, Spain, Sweden, Turkey, United States (except for some State Individual Medicaid Agencies). Information was not available for Ireland, but drug budgets for doctors have been reported in this country.

Source: OECD Questionnaire on pharmaceutical management and regulation and various sources.

Table A. 6: Prescription of Generics

Country	Explicit policy	Type of incentives	Comment
Australia	Yes	Consumer education and financial incentive	Patient payment if drug chosen at any higher price than generic base. (Close to reference pricing system).
Austria	Yes	Guideline for prescription by physicians	Doctors are regularly informed with lists of low cost generic drugs.
Canada	Yes except in one province		Lowest cost alternative: stipulating that for drugs where generics exists, reimbursement rates will be set at the cost of the least expensive bio-equivalent. In some provinces, pharmacists are able to substitute with a generic alternative, provided there aren't any explicit instructions from the physician.
Czech Republic	Yes	Information	Generics are included in the general list of drugs available under prescription, however there is a lack of incentives for physicians to prescribe them.
Denmark	Yes	N/A	The prescription scheme of generics, called "G" scheme, was introduced in November 1991 and includes most of the pharmaceuticals for which synonymous drugs exist. When a physician prescribes a drug covered by the G scheme, he may write a "G" on his prescription to indicate to the pharmacists that this should be filled with generics, unless the consumer refuses.
Finland	Yes	No explicit incentives	From March 1996, prescribers are able to write their prescription in generically written form. Pharmacists have then to dispense the cheapest product.
France	Yes	Global budgets on physician prescription, information for physicians	Implementation of stronger incentives for generic prescription is underway in the main action plans presented by the Ministry of Social Affairs.
Germany	Yes	Global budgets for physicians and guideline on prescription for physicians	
Greece	Yes	N/A	The policy included 14% price reduction of all the generic related to the similar branded drugs.
Hungary	Yes	Budget constraints, guidelines for prescriptions and consumer education	
Italy	Yes		Introduced in Italian law in 1996. Negligible market.
Mexico	Yes	Budget constraints, guidelines for prescription, consumer education, and manufacturing side	
Netherlands	Yes	Some budget constraints, guidelines for prescription and consumer education	In order to encourage generic delivery, pharmacists can share some of the savings they generate and they receive a fraction (currently 33.3%) of the price difference, if the product delivered is cheaper than the "reference price" for that group of medicines.
New Zealand	Yes	Guidelines for prescription, consumer education and economic incentives	Consumer has to pay the difference between generic product and branded product if the latter is chosen.
Norway	Yes	Budget constraints and guidelines for physicians	Physicians have to take economic considerations when prescribing, and prescribe the cheapest alternative.
Sweden	Yes	Guidelines for prescription	
Switzerland	Yes	Guidelines for prescription and consumer education	There are legal incentives to prescribe generics (art. 52, al.1 of the Sickness Law) which have to be 25% cheaper but there is a lack of effective economic incentives for doctors and pharmacists to deliver them. Substitution right for pharmacists to be introduced in 2000.
UK	Yes	Incentives for GP fundholders and prescription guidelines. From 1985, all but the generic forms of a number of widely used medicines were excluded from NHS reimbursement.	Possibility to write prescriptions in generic format.
USA	Yes	Prescription guidelines and consumer education	In private sector, most insurance plans require generics rather than brand name drugs

Generics are only virtually present in Belgium, with only 36 generic specialities available. Japan, Korea, Luxembourg and Turkey had no explicit policy for generics at the time of the survey. There was no explicit policy in Spain also, but recent changes in the legislation were about to consider it.

Source: OECD Questionnaire on pharmaceutical management and regulation, and various sources

Table A. 7: Price controls

Country	Control	Since	Characteristics taken into account to fix the price				Comments
			Therapeutic value of the drug	Cost of comparable treatments	Pharmaceutical contribution to the economy	Price in other countries	
Australia	Yes	1951/1986	YES	YES	YES	YES	Various references used to set reimbursement and price level: this applies to 48 % of the market. Price according to volume and cost-effectiveness. Price level linked to market approval, with economic guidelines..
Austria	Yes	1976				YES	See Öbig 1998.
Belgium	Yes	1963/1995-	YES	YES	YES	YES	Distribution and manufacturing costs.
Canada	X[4]	1987		YES		YES	For patented drugs only (PMPRB duty). Price related to cost-effectiveness.
Czech Republic	Mixed	1992[1]/1995	YES	YES		YES	For both producers and importers. Domestic producers must submit their production-cost-formula; importers must submit their price list.
Finland	Yes	1968-1993 [2] 1994-[3]	YES	YES		YES	Trade off: cost of treatment, manufacturing and R&D costs vs. available funds for reimbursement.
France	Yes	1945	YES	YES		YES	Since 1994, joint negotiation on volumes. Innovative value
Greece	Yes	≅1978				YES	Imported drugs: cheapest price among the three lower prices of EU. Domestic drugs: individual product price setting cost-based plus an index of international prices.
Hungary	Mixed	1990	YES	YES	YES	YES	Price negotiation between manufacturers and public health insurance body. Impact of currency devaluation of currency and different duties integrated. International reference to Spain, France, Greece and the Czech Republic.
Italy	Yes/mixed	1978, 1995 ref.				YES	Before 1995, prices according to cost information, after "free prices" under Average European Price. Price negotiated since then for innovative products.
Japan	Yes	1950	YES	YES		YES	Weighted average of the prices at which a brand is transacted in all available packaging forms.
Korea	Yes	1977	YES	YES	YES	YES	
Luxembourg	Yes	1964				YES	With reference to the price existing in the respective country of origin (Belgium, France, Germany and Switzerland)
Mexico	Yes	1993				YES	Self-regulating formula taking into account the firm's operating costs. 50 % is sold in a private sector in a free basis. In the public sector, basic list of medicines with competitive bidding by firms.
Netherlands	Mixed	1996				YES	Since 1996, for 3000 products maximum authorised prices.
Norway	Mixed	always/1993	YES	YES		YES	Specific reimbursement following generic prices plus 5 % in 1993. RD and manufacturing costs
Spain	Yes	unknown	YES	YES	YES	YES	
Sweden	Mixed	1993	YES	YES		YES	Direct negotiations with central public pharmacy body (Apoteksbolaget) until 1993 and National Social Insurance Board since 1993. Partial reference pricing scheme 1993.
Switzerland	Yes	1962	YES	YES		YES	Public price integrates manufacturer's price, distribution margins and VAT. Price revisions for older products in 1995, comparisons with other countries
Turkey	Yes	1928	YES	YES	YES	YES	Real manufacturing costs

Mixed means that the control may apply only to part of the prescription market. Germany Denmark, the Netherlands and the United States have very little or no price control. In the United Kingdom price considerations are not absent from negotiations between NHS authorities and manufacturers. Apart from the general profit control target, prices in other countries and the pharmaceutical contribution to the economy are also taken into account in this country. In addition, prices were not adjusted for inflation in years of high inflation. In Germany, price cuts have also been enforced (see table 14). (1) Price control also existed in Czechoslovakia before 1992. (3) From 1994 only price negotiation with companies that want to include their products in the National Drug Reimbursement Scheme. (2) Direct price control on all medicines. (4) Pharmaceutical policy depends on the provinces. Reference pricing in British Columbia. Price controls in all provinces for patented drugs. In the UK existing drug prices cannot be raised but new products are priced subject to profit constraint.

Source: OECD Questionnaire on pharmaceutical management and regulation and various sources

Table A. 8: Profit controls

Country	Profit Control	Date	Method
Czech Republic	For domestic producers	1992	30% profit for domestic producers, 35% margin for pharmacists and distributors
Korea	Yes	1997	Determine the ceiling level or the range through consultations with the institute authorised by the government. For instance, Korean productivity centre and etc.
Mexico	Yes	1993	Each firm's operating costs. There is an self-regulated formula that considers each pharmaceutical firm's operating costs, and according to the governmental pricing policy, price increment ceilings are set.
Spain	Yes	NA	Prices based on "cost". Includes a ceiling of promotion expenditure (12 to 14 % of retail price).
Turkey	Yes	1984	15% of annual profits, based on annual net profit
UK	Yes(1).	1957(2)	The target rate of return was set at 17-21% return on capital employed with a 25% margin of tolerance and a system of allowances such as R&D allowance. Includes a ceiling on promotion expenditure

(1) The Pharmaceutical Price Regulation Scheme (PPRS) in the UK is a profit control scheme. The overall aims of the system were outlined in the 1993 agreement: 1. To secure the provision of sale and effective medicines for the NHS at reasonable prices; 2. To promote a strong and profitable industry in the UK capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines; 3. To encourage in the UK the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries

(2) Re-negotiated on a period basis since that time. Other analysts date it to 1969. Most recent: 1993 and should run for 5 years.

Source: OECD Questionnaire on pharmaceutical management and regulation and various sources.

Table A. 9: Price freezes and cut measures in selected countries

Country	Price Freeze	Date	Method/Intensity	Comments
Austria	Yes	1997	Price reduction, agreement of the social insurance and the industry to reduce the manufacturers' prices.	
Belgium	Yes	1993, 1996, 1997	Prices frozen on the level of 1 January 1993 or 1996 and 2% price cut in June 1996.	General consultation was organised with the pharmaceutical industry, medical associations, mutual funds, trade unions, etc…
Canada	No at the federal level but in two provinces	N/A	These two provinces have either cut or frozen prices on drugs for their insurance programs, which is reimbursement levels and not actual price control.	
Czech Republic	Yes, but not applied	N/A	The Ministry of Finance sets up the maximum prices.	Maximum prices are re-valued each year and may be slightly under-re-valued. If the general effect may be rather limited, individual changes may be more pronounced.
Denmark	Yes	From 1994 to 1997	Price freezes from January 1994 to 1st April 1995. Cut prices in April 1995 and frozen prices until April 1997.	From April 1995 to April 1997, agreement with the pharmaceutical industry. Target for reduction in public pharmaceutical expenditure in the State Budget. According to this agreement, general price reduction of 5% on prescription drug covered by the reimbursement scheme. Prices of prescription drugs not covered by the scheme and OTC products were lowered by 2%.
France	Implicit		Prices may be under-re-valued with the annual changes.	This had a stronger effect in years of accelerating inflation, at the beginning of the 1980s
Germany	Yes	1993 for 2 years	For prescription drugs by 5% and for over the counter drug (OTC) by 2%.	Consultation process.
Greece	Yes	Several times	Price freeze	Consultation process.
Italy	Yes	1995, 1996	Price cut of 2.5% in 1995, price freezes in 1996.	
Korea	Yes	1977		Consultation process.
Luxembourg	Yes	N/A	Price cuts from neighbouring country, applied in Luxembourg.	
Netherlands	Yes	1994		Negotiations with pharmaceutical industry.
Spain	Yes	1993	Price cut of 3% for 3 years.	Consultation with pharmaceutical industry.
Switzerland	Yes	1992-96, 1997	1992-96, price freeze for specialist list products. From 1997, new Sickness Law.	
UK	Yes	Oct-93	2.5% price cut was determined at the time of the re-negotiation of the Pharmaceutical Price Regulation Scheme in 1993.	Consultation with pharmaceutical industry, companies could choose the method to obtain an average 2.5% price cut. (They could also choose to return their profit).

Price cuts or price freeze were not reported in Australia, Austria, Finland, Hungary, Japan, Mexico, New Zealand except for incidental effects of reference pricing, Norway, Sweden, Turkey and the United States. N/A not available. **Source:** OECD Questionnaire on pharmaceutical management and regulation and various sources.

NOTE DE RÉFÉRENCE

1. Introduction

Très peu d'industries sont aussi profondément influencées par la réglementation que l'industrie pharmaceutique. La nature de la demande de médicaments, le type de médicaments introduits sur le marché et la nature de la concurrence sont tous au fil des ans marqués par la réglementation. Celle-ci vise trois grands objectifs :

- rentabiliser la R-D afin d'assurer d'un flux continu de nouveaux médicaments ;
- veiller à l'innocuité des médicaments ;
- contrôler le volume et améliorer la qualité des dépenses en médicaments.

En raison des effets conjugués des objectifs de la réglementation, la nature de la concurrence n'est pas la même que dans d'autres industries. Du côté de l'offre, les aléas de la R-D et les coûts et délais des procédures d'autorisation font de la mise au point de nouveaux médicaments une activité risquée et coûteuse. Par contre, une fois introduits sur le marché, les nouveaux médicaments peuvent procurer des gains importants parce que les droits de propriété intellectuelle les mettent à l'abri de la concurrence. Du côté de la demande, l'omniprésence du régime d'assurance maladie coupe les consommateurs de la réalité du coût des médicaments qu'ils consomment. Ce sont les assureurs publics et privés qui, se substituant à eux, mettent en place toute une série de mécanismes pour contrôler le volume et la qualité de la consommation de médicaments. La nature de la concurrence dans l'industrie pharmaceutique dépend de l'interaction de ces effets du jeu de l'offre et de la demande.

Malgré une réglementation omniprésente, la concurrence n'est pas tout à fait absente de cette industrie. Elle est, par exemple, l'un des grands déterminants du développement de nouveaux médicaments et l'un des facteurs clés permettant de freiner la hausse des prix et des coûts de production des médicaments non brevetés. Mais le rôle que doit jouer la concurrence n'est pas toujours clair. Promouvoir la concurrence exige une approche globale. Il ne suffit pas toujours d'éliminer certaines contraintes ponctuelles pour améliorer le bien-être. Par exemple, en ce qui concerne les officines, l'élimination des obstacles à l'entrée de nouveaux venus sur un marché où les marges bénéficiaires des pharmacies sont garanties pourrait se traduire par une offre excédentaire de pharmaciens et entraîner le gaspillage de ressources économiques rares. Quant à l'abolition du contrôle des prix des médicaments vendus sur ordonnance, elle pourrait tout simplement faire augmenter les dépenses de médicaments sans se traduire par une amélioration de la santé ou de la concurrence entre les fabricants.

Le présent document brosse un tableau des principales caractéristiques de l'industrie pharmaceutique et de la réglementation qui contrôle et détermine le développement, la commercialisation, la prescription et la consommation de médicaments. Il cherche dans toute la mesure du possible à définir les secteurs où il serait possible d'introduire plus de concurrence. Plusieurs grandes questions y sont traitées, à savoir :

- Dans la plupart des pays de l'OCDE, la progression des dépenses pharmaceutiques est plus apide que celle des dépenses de santé en général. C'est pourquoi la mise en place de mécanismes de maîtrise des dépenses pharmaceutiques est au cœur de l'action des pouvoirs publics. Les analyses comparatives montrent que les pays riches consomment plus de médicaments par habitant, mais que dans certains pays, comme la France, les États-Unis et le Japon, le niveau élevé du revenu national ne peut à lui seul expliquer que la consommation de produits pharmaceutiques y soit aussi forte.

- L'industrie pharmaceutique est caractérisée par des investissements élevés en R-D et un flux constant d'innovations. La quasi-totalité de la R-D dans ce secteur est le fait de grandes entreprises multinationales. Elle est essentiellement financée sur les bénéfices découlant de l'exploitation des droits exclusifs accordés au titulaire d'un brevet pendant la durée de vie de celui-ci. Ces droits peuvent donner lieu à une position de force sur le marché et à de fortes marges. Nombreux ont été les pays qui ont cherché à prolonger la durée de vie des brevets dans l'industrie pharmaceutique, en partie à cause des coûts et des délais qu'occasionne l'obtention de l'autorisation de mise sur le marché. Beaucoup de pays ont en même temps mis en œuvre des politiques qui visaient à soutenir la concurrence de fabricants rivaux une fois le brevet arrivé à expiration.

- Les sociétés pharmaceutiques axées sur la recherche opèrent dans un environnement caractérisé par des risques élevés, mais aussi par des possibilités de gains importantes. L'obtention de l'autorisation de mise sur le marché est un processus très long et très coûteux, qui prend environ huit ans et peut coûter des centaines de millions de dollars. Très rares sont les nouveaux composés chimiques qui sont autorisés à être mis sur le marché, et ceux qui obtiennent cette autorisation ne sont pas nombreux à percer. Par contre, lorsqu'il se vend bien, un médicament peut s'avérer très rentable.. Les entreprises pharmaceutiques consacrent des sommes énormes à la promotion de leurs médicaments de marque déposée. Même si elles opèrent dans une industrie à forte intensité de recherche, elles dépensent plus en commercialisation qu'en R-D. Il existe un grand nombre de fabricants dans le secteur, mais le taux de concentration des entreprises sur le marché des médicaments destinés à traiter un certain état pathologique (les médicaments dits de "classe thérapeutique") peut être très élevé.

- En ce qui concerne les médicaments vendus sur ordonnance, la nature de la demande varie selon les règles, les institutions et les incitations mises en place par l'assureur pour contrôler et régir les décisions du fabricant, du consommateur, du médecin prescripteur et du pharmacien. Dans le domaine de la santé, les assureurs recourent à une série de mécanismes pour contrôler le volume et la qualité des dépenses pharmaceutiques. Aux États-Unis, ils achètent ces services de "gestion de soins pharmacothérapeutiques" auprès de sociétés indépendantes. Dans d'autres pays, ce sont souvent des organismes publics qui fournissent ces services. Le cas des États-Unis montre qu'il y a moyen de sous-traiter la fourniture de ces services dans le secteur privé, même dans les pays où l'assurance maladie relève de l'État.

- Les mécanismes utilisés pour maîtriser les dépenses pharmaceutiques prennent notamment la forme de nomenclatures, de règles de remboursement, de mesures de contrôle visant les médecins et les pharmaciens, de programmes d'incitation et de contrôles des prix. Les nomenclatures sont simplement des listes de médicaments pris en charge par l'assureur qui précisent aussi les conditions auxquelles les frais sont remboursés. À l'exception de quelques compagnies d'assurance privées aux États-Unis, dans tous les pays de l'OCDE, les principaux assureurs se servent d'une forme ou d'une autre de nomenclature. La plupart des compagnies d'assurance dans les pays de l'OCDE cherchent aussi à influencer le comportement des médecins prescripteurs au moyen de lignes directrices et/ou de règles concernant la prescription de

médicaments. Celles-ci reposent souvent sur la collecte et la diffusion d'informations sur le comportement de prescription des médecins.

- La plupart des organismes d'assurance maladie dans les pays de l'OCDE mettent en œuvre également une politique de remboursement (sous forme de participation aux coûts, de droits ou de frais pour les médicaments) afin de freiner la demande de produits pharmaceutiques. Quelques pays seulement (surtout les organisations de soins de santé coordonnés (HMO) aux États-Unis et les systèmes de gestion de budgets au Royaume-Uni) ont mis sur pied des dispositifs qui visent directement à faire coïncider les incitations du médecin et de l'assureur. Dans le système britannique de gestion de budgets, les médecins locaux sont responsables de l'achat d'une série de services de santé pour le compte de leur clientèle. Le médecin est ainsi fortement encouragé à prescrire des produits pharmaceutiques de façon efficiente et efficace.

- Tous les assureurs exercent une certaine forme de contrôle des prix des médicaments. Dans le cas des médicaments auxquels les produits génériques livrent une concurrence suffisante, il est courant que leur prix corresponde à celui du médicament d'une classe thérapeutique le moins coûteux. Parfois, celui-ci est choisi par appel d'offres. Dans le cas des médicaments pour lesquels il n'existe pas vraiment de substituts, il est plus difficile de réglementer les prix. Bon nombre de pays fondent directement les prix sur ceux en vigueur dans des pays voisins. D'autres pays s'efforcent de contrôler le bénéfice total du fabricant. De nombreux pays définissent les fourchettes à l'intérieur desquelles les prix une fois fixés peuvent varier dans le temps. Pour analyser dans le détail le prix qu'un assureur est disposé à payer pour un médicament, il faut effectuer une analyse pharmaco-économique des coûts et avantages du médicament en question.

- Les coûts de maintien d'un réseau de distribution au détail sont un élément important du coût total des produits pharmaceutiques. Dans le cas des pays où le consommateur est complètement coupé de la réalité du coût des produits pharmaceutiques qu'il consomme, ou la participation aux coûts ne diffère pas d'une officine à l'autre, la concurrence entre pharmacies ne peut permettre d'assurer la fourniture efficiente et efficace de services de pharmacie. Il faut aussi dans ces pays réglementer les marges bénéficiaires des pharmaciens. Le coût des services de pharmacie varie d'une officine à l'autre et dans bon nombre de cas l'assureur ne possède pas nécessairement les données sur les coûts qui lui permettent de contrôler les marges bénéficiaires de façon efficiente. Il est donc possible que les pharmacies à faibles coûts ou à volume de ventes élevé perçoivent une rémunération excessive, ce qui incite les nouveaux venus à entrer en masse sur le marché, ou que les pharmacies à coûts élevés ou à volume de ventes faible ferment leurs portes, ce qui diminue la qualité des services dans certaines zones. Aussi est-il préférable d'adjuger par appel d'offres le droit de fournir des services de pharmacie, en particulier dans les zones où les coûts sont élevés ou les volumes de ventes faibles.

- La plupart des pays ont mis en place des mesures qui encouragent directement la consommation de médicaments génériques moins coûteux. Ces mesures peuvent agir sur chacun des différents agents du marché pharmaceutique (médecins, pharmaciens, grossistes, consommateurs), comme celles visant à limiter le remboursement au produit d'une classe thérapeutique le plus économique, à exiger des médecins qu'ils prescrivent des médicaments génériques (c'est-à-dire en tenant compte de la substance active et non de la marque déposée du produit) ou à leur offrir des incitations économiques pour le faire, et à obliger les pharmaciens à offrir des médicaments bio-équivalents ou à leur accorder des stimulants économiques à cet effet. Lorsque le pourcentage de leurs marges bénéficiaires est réglementé, les pharmaciens sont incités à augmenter (et non à diminuer) le coût des médicaments. Dans ce cas, il faut modifier la méthode de calcul de la rémunération des pharmaciens si l'on veut promouvoir la consommation de médicaments génériques.

- Les différences de prix entre les pays incitent les grossistes à effectuer des opérations d'arbitrage, c'est-à-dire à acheter des produits pharmaceutiques dans des pays à bas prix et à les vendre dans des pays à prix élevés. L'effet de ce "commerce parallèle" sur les prix dépend du type de réglementation des prix. Le commerce parallèle peut faire monter les prix dans les pays à bas prix (les fabricants seront moins disposés à accorder un rabais à un pays si un tel rabais compromet leurs prix de vente dans un autre pays) et les faire baisser dans les pays à prix élevés (s'il existe un mécanisme tenant compte des prix des importations parallèles dans le processus de réglementation des prix).. La Commission européenne estime que le commerce parallèle est une force motrice de l'intégration des marchés[1] et, à plusieurs reprises, la Cour européenne de justice a statué en faveur du commerce parallèle. En Europe, le commerce parallèle des médicaments occupe une part de marché qui est petite, mais non négligeable. Ce type de commerce demeure très controversé.

- L'existence d'une concurrence limitée et d'obstacles à l'entrée dans les marchés des produits pharmaceutiques et certains marchés de services de pharmacie donne lieu à l'exercice d'un pouvoir de marché et ouvre la voie à des comportements anticoncurrentiels. Les entreprises pharmaceutiques ont souvent fait l'objet de poursuites pour violation des législations antitrust, notamment pour formation de cartels, ententes sur les prix, certaines formes d'accords de ventes ou d'achats liés, arrangements d'exclusivité en matière de commercialisation et accords visant à retarder l'introduction de produits génériques sur le marché. Les pharmaciens, en particulier aux États-Unis, ont conclu des ententes collusoires pour majorer la tarification de leurs services. Il a été fait obstacle à de nombreux projets de fusion dans l'industrie pharmaceutique au motif qu'ils auraient eu pour résultat de réduire la concurrence entre les produits existants ou de freiner par la suite le rythme des innovations. Pour certains projets, on a fait valoir que les activités de R-D des parties envisageant une fusion se recoupaient et que les sociétés en cause étaient donc les seules susceptibles de mettre au point de nouveaux produits de certaines classes thérapeutiques. Souvent, les fusions ont été subordonnées à l'abandon de produits existants ou de produits en cours de développement.

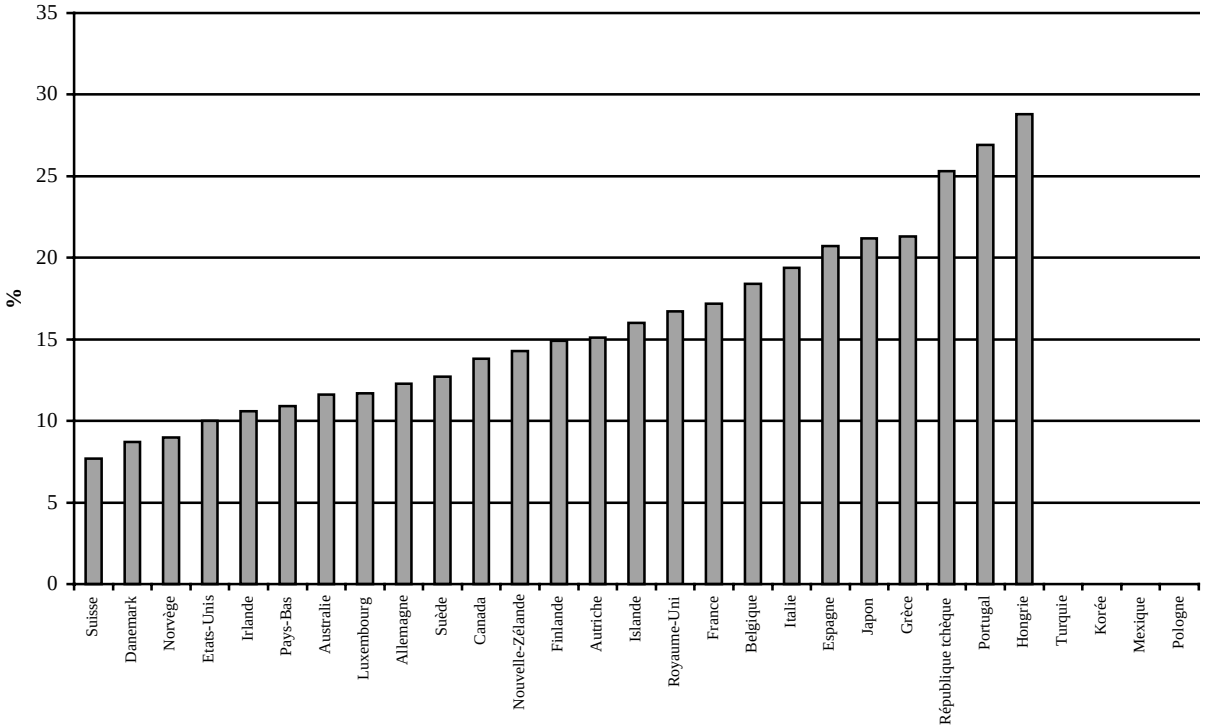
2. L'industrie pharmaceutique

Dans cette section, nous exposerons les faits essentiels permettant de brosser un tableau général de la nature et du rôle de l'industrie pharmaceutique.[2]

2.1 Le marché des produits pharmaceutiques fait partie du marché plus large de la santé dans les pays de l'OCDE

Les dépenses de produits pharmaceutiques représentent une part appréciable et croissante des dépenses totales de santé dans les pays de l'OCDE. Comme l'indique le Figure 1, dans la plupart des pays de l'OCDE, les dépenses pharmaceutiques comptent pour dix à 20 pour cent des dépenses totales de santé. Il existe par ailleurs une corrélation évidente entre la part des dépenses pharmaceutiques dans les dépenses totales de santé et le PIB par habitant. Dans les pays riches, la part des dépenses totales de santé allouée aux produits pharmaceutiques est légèrement plus faible, alors que dans les pays pauvres, elle est plus élevée.

Graphique 1 : Dépenses pharmaceutiques en pourcentage des dépenses totales de santé (1997)



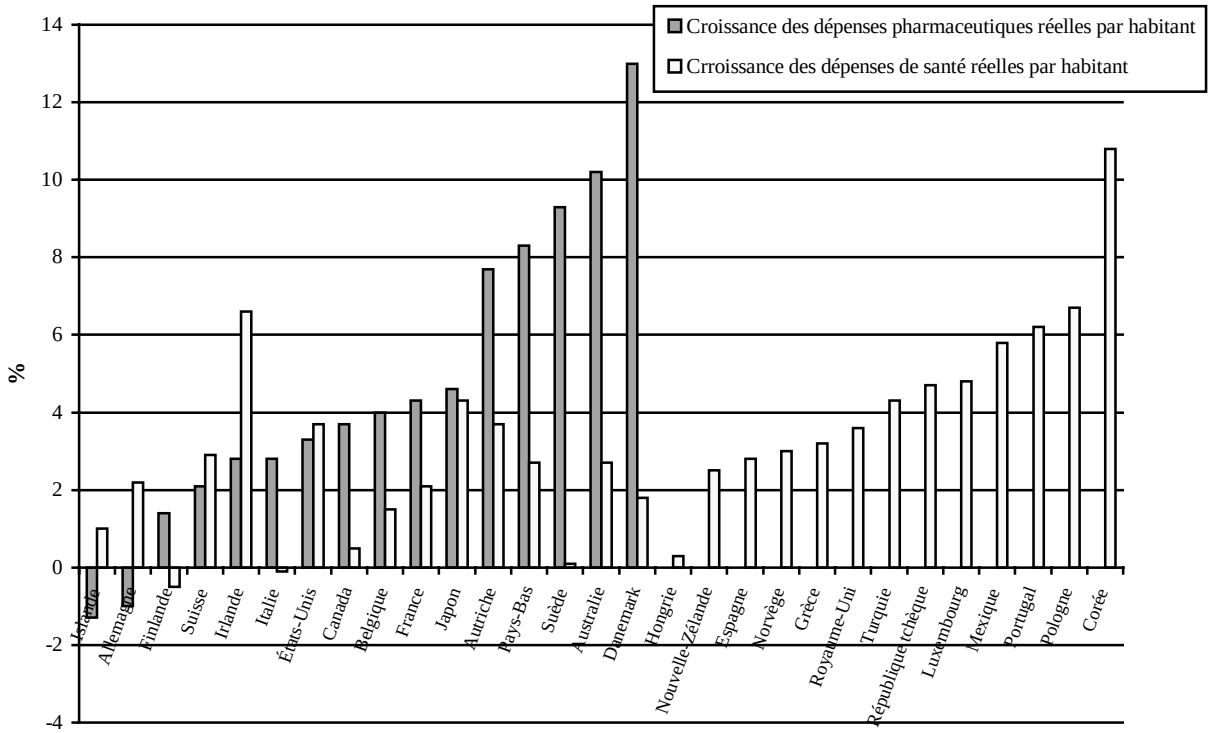
Notes : Données de 1997, sauf pour la Norvège, l'Irlande, l'Australie, le Luxembourg, le Japon, la Grèce et la Hongrie (1996). Aucune donnée n'est disponible pour la Turquie, la Corée, le Mexique et la Pologne
Source : Eco-Santé OCDE, 1999

Pendant les années 90, la croissance des dépenses totales de produits pharmaceutiques par habitant a été supérieure au taux d'inflation et elle a été plus rapide que la progression des dépenses totales de santé dans plusieurs pays de l'OCDE.[3] Dans 11 des 16 pays pour lesquels des données sont disponibles pour les années 90, la croissance des dépenses pharmaceutiques a dépassé celle des dépenses totales de santé (voir le Figure 2).

Comme, dans de nombreux pays, les dépenses pharmaceutiques relèvent de l'État (habituellement par l'intermédiaire d'un ou de plusieurs assureurs publics), leur croissance a souvent amené les responsables à mettre en place des mesures de maîtrise du volume et de la qualité de la consommation de produits pharmaceutiques.[4] Aux États-Unis, par exemple, au début des années 90, le Président Clinton et plusieurs membres du Congrès ont proposé de réglementer les prix des produits pharmaceutiques. En fait, durant la session 1993-1994 du Congrès américain, trois projets de loi visant à contrôler les prix des médicaments vendus sur ordonnance ont été soumis à la Chambre des représentants.[5]

Le fait que les taux de croissance des dépenses pharmaceutiques par habitant soient élevés n'est pas nécessairement inquiétant, car cela peut simplement témoigner d'un rééquilibrage efficient des dépenses totales de santé. A mesure que sont mis au point de nouveaux médicaments susceptibles de soigner des maladies que seules des interventions chirurgicales, par exemple, pouvaient auparavant traiter, il est en effet logique que se produise un tel rééquilibrage, les dépenses pharmaceutiques augmentant par rapport à celles affectées aux autres services de santé.

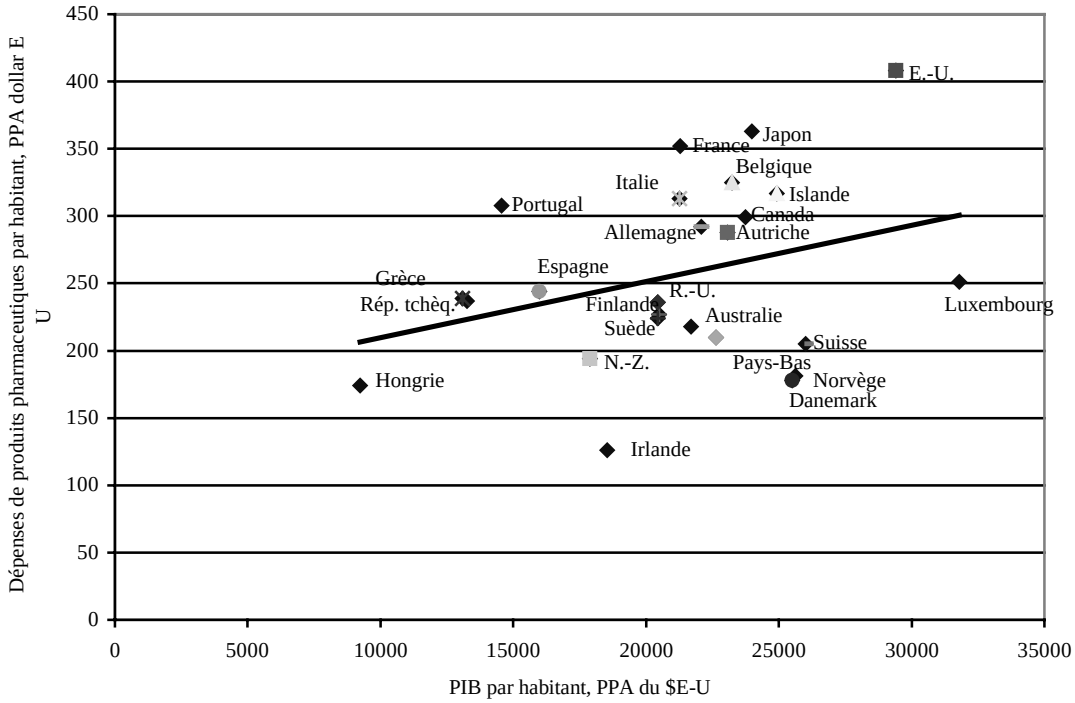
Graphique 2 : Croissance des dépenses pharmaceutiques, 1990-1997



Note : Les données représentent la croissance annuelle des dépenses pharmaceutiques et des dépenses totales de santé par habitant corrigées de l'inflation. Données de 1990-1997, sauf pour les dépenses pharmaceutiques en Australie, en Belgique, au Danemark, en Finlande, en Allemagne, en Islande, en Irlande, au Japon, aux Pays-Bas, en Suède et aux États-Unis (1990-1996).
Source : Eco-santé OCDE, 1999

La croissance des dépenses pharmaceutiques par habitant suit celle du PIB par habitant. Lorsque le PIB par habitant augmente de 1 000 dollars des Etas-Unis, les dépenses pharmaceutiques par habitant s'accroissent de quatre dollars environ. Il existe quand même des différences assez marquées dans la consommation par habitant que ne peuvent expliquer les écarts de PIB. En particulier, la consommation de produits pharmaceutiques par habitant est très élevée en France, au Japon et aux Etats-Unis, alors qu'elle est relativement faible en Irlande, au Danemark et en Norvège.

Graphique 3 : Dépenses pharmaceutiques par habitant et PIB par habitant

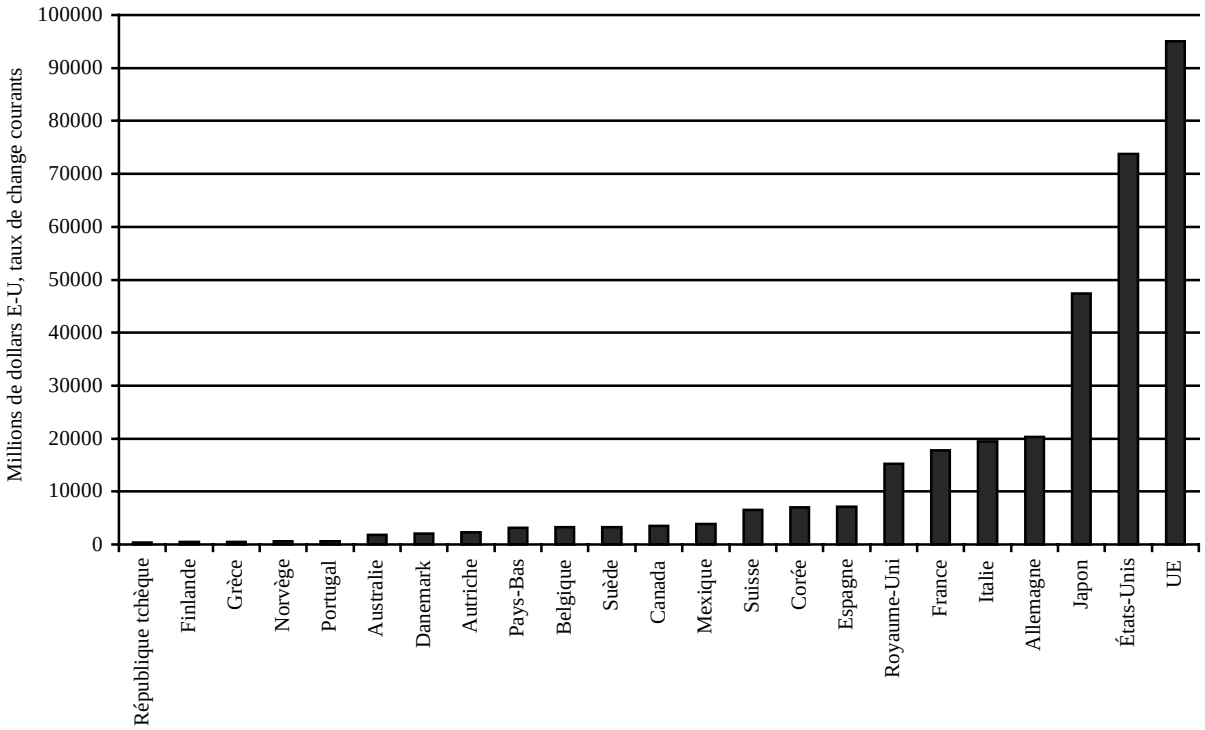


Note : Données de 1997 (1996 dans certains cas)
Source : Eco-Santé OCDE, 1999

La demande de produits pharmaceutiques est susceptible d'augmenter avec le vieillissement de la population de l'OCDE. On prévoit qu'entre 1990 et 2030, la population de 65 ans et plus devrait, en proportion de la population des 15 à 64 ans, passer de 20 à 40 pour cent dans la zone de l'OCDE.[6] Il en résultera une augmentation de la demande de services de santé en général, et de produits pharmaceutiques en particulier.

La majeure partie de la production totale de produits pharmaceutiques dans l'OCDE (79 pour cent) est le fait de six pays seulement – les États-Unis, le Japon, la France, l'Allemagne, l'Italie et le Royaume-Uni.[7] Dans son ensemble, l'UE est de loin le principal fabricant de produits pharmaceutiques.

Graphique 4 : Production pharmaceutique dans les pays de l'OCDE (1994)



Notes : Données de 1994 (soit la dernière année pour laquelle des données suffisamment complètes sont disponibles), sauf pour les Pays-Bas et la Grèce (1993), et l'Australie, la Norvège et le R-U (1992). Dans le cas de l'Italie, il s'agit d'estimations. Aucune donnée n'est disponible pour la Pologne, l'Irlande, la Nouvelle-Zélande, le Luxembourg, la Hongrie, la Turquie et l'Islande.
Source : Eco-Santé OCDE, 1999 ; Jacobzone (2000)

2.2 Fabricants de produits pharmaceutiques

Au niveau international, un grand nombre d'entreprises fabriquent des produits pharmaceutiques. Il est possible de les répartir en deux catégories ou niveaux, selon le niveau de leurs investissements en R-D. D'après Klepper :

> "La répartition des sociétés [pharmaceutiques] selon leur taille révèle un profil particulier que l'on retrouve dans tous les pays industrialisés. On constate d'abord la présence d'un nombre relativement faible d'entreprises internationales qui dominent les marchés des produits pharmaceutiques, puis de nombreuses petites sociétés qui approvisionnent surtout les marchés locaux ou nationaux. La centaine d'entreprises internationales provient principalement des États-Unis, d'Allemagne, de Suisse ou du Royaume-Uni. Ce sont elles qui effectuent l'essentiel de la R-D dans l'industrie pharmaceutique mondiale et qui dominent le marché des médicaments vendus sur ordonnance. … Les petites sociétés font très peu de R-D, ce qui s'explique dans une large mesure par la technologie de la R-D et de la fabrication des produits pharmaceutiques. L'industrie pharmaceutique mondiale se caractérise donc par une structure à deux niveaux, où ce sont les entreprises internationales qui assument la R-D et qui, par conséquent, dominent le marché des médicaments vendus sur ordonnance et protégés par des brevets, tandis que les petites sociétés répondent aux besoins locaux ou concurrencent les nouveaux produits avec des médicaments génériques."[8]

La nature de la concurrence dans cette industrie n'est pas la même pour les deux catégories d'entreprises. Les sociétés du second niveau détiennent moins de brevets et elles se consacrent principalement à la fabrication de médicaments "génériques" non brevetés ou de médicaments brevetés pour lesquels des licences leur ont été accordées.[9] La concurrence que se livrent ces entreprises est de type classique et s'exerce sur les prix, le rapport coût-efficacité et la qualité.

Par contre, les grandes sociétés pharmaceutiques axées sur la recherche investissent énormément en R-D, détiennent la majeure partie des brevets et peuvent souvent occuper une position de force sur le marché pendant la durée de vie de ces brevets. Pour ces entreprises, ce n'est pas sur les prix, mais plutôt sur la commercialisation et l'innovation que s'exerce surtout la concurrence. Celle-ci se fait sentir au niveau du développement de médicaments entièrement nouveaux qui permettent de traiter des pathologies tout à fait nouvelles, constituent une amélioration par rapport à des médicaments existants ou remplacement des médicaments brevetés déjà commercialisés.[10]

On compte 23 sociétés pharmaceutiques parmi les 500 plus grandes entreprises mondiales (voir le tableau 1).

Tableau 1 : Les plus grandes sociétés pharmaceutiques du monde

Société	Pays	Capitalisation boursière Milliards $EU	Chiffre d'affaires Milliards $EU	Bénéfices Milliards $EU	Bénéfices/ fonds propres %	Nb. Salariés	Fin exercice
Merck	E-U	152.1	26.9	5.2	34.7	57 300	12/98
Johnson and Johnson	E-U	123.4	23.6	3.1	22.7	93 100	12/98
Pfizer	E-U	118.8	13.5	1.9	22.5	46 400	12/98
Bristol-Myers Squibb	E-U	118.0	18.2	3.1	37.0	54 700	12/98
Roche	Suisse	108.4	15.8	2.8	13.6	66 707	12/98
Novartis	Suisse	104.5	20.4	3.8	16.3	82 449	12/98
Glaxo Wellcome	R-U	100.7	13.1	3.0	49.8	54 350	12/98
AstraZeneca	R-U	71.3	9.1	1.2	34.1	34 000	12/98
Smithkline Beecham	R-U	69.6	13.2	1.1	19.9	58 300	12/98
Eli Lilly	E-U	68.9	9.2	2.1	29.4	29 800	12/98
Warner-Lambert	E-U	68.1	10.2	1.3	26.9	41 000	12/98
Amgen	E-U	59.5	3.3	1.1	39.4	6 400	12/99
Schering-Plough	E-U	55.9	9.2	2.1	52.7	26 500	12/99
American Home Products	E-U	52.1	13.4	2.4	18.4	52 984	12/98
Aventis	France	44.7	13.6	0.8	12.1	65 180	12/98
Takeda Chemical Ind.	Japon	40.0	8.2	0.9	18.5	9 139	3/99
Bayer*	Allemagne	33.4	28.9	1.6	15.6	144 881	12/98
Genentech	E-U	32.6	1.3	-1.1		3 883	12/99
BASF*	Allemagne	31.1	28.5	1.7	12.6	106 928	12/98
Sanofi-Synthelabo	France	28.4	6.0	0.5	11.5	-	12/98
Pharmacia & Upjohn	E-U	22.6	6.9	0.7	11	30 000	12/98
Immunex	E-U	14.8	0.5	0.04	17.9	1 170	12/99
Akzo Nobel*	Pays-Bas	14.4	12.9	0.6	17.4	79 100	12/98

Source: Financial Times FT 500 (http://www.ft.com/ft500/). 4 mai 2000
*L'astérisque désigne des sociétés que le Financial Times inclut dans l'industrie chimique.

2.3 Concentration horizontale et verticale dans l'industrie pharmaceutique

Ces dernières années, l'industrie pharmaceutique a été marquée une importante vague de fusions. Le mouvement de consolidation n'est d'ailleurs pas terminé. Depuis la compilation des données du Table 1, Pfizer et Warner-Lambert[11], et Glaxo Wellcome et SmithKline Beecham ont annoncé leur fusion. Le Table 2 énumère les grandes fusions horizontales qui ont eu lieu entre 1994 et 1999.

Tableau 2: Fusions et acquisitions de grands fabricants de médicaments de marque déposée (1994-1997)

Date de la transaction	Société pharmaceutique n^0 1	Société pharmaceutique n^0 2	Nouvelle entité	Valeur de la transaction (en dollars)
1994	Roche Holdings Ltd.	Syntex Corporation	Roche Holdings Ltd.	5.3 milliards
1994	Pfizer	SmithKline Beecham	Pfizer Animal Health	1.4 milliards
1994	American Home Products	American Cyanamid	American Home Products	9.7 milliards
1995	Bristol-Myers Squibb Co.	Calgon Vestal Laboratories	Bristol-Myers Squibb Co.	261 millions
1995	BASF	Boots Pharma	BASF	1.3 milliards
1995	Rhone-Poulenc Rorer	Fisons	Rhone-Poulenc Rorer	2.9 milliards
1995	Hoechst, A.G.	Marion Merrill Dow, Inc.	Hoechst Marion Rousell	7.1 milliards
1995	Pharmacia AB	UpJohn Co.	Pharmacia & Upjohn, Inc.	13 milliards
1995	Glaxo plc	Wellcome plc	Glaxo-Wellcome plc	14.1milliars
1996	Ciba-Geigy Ltd.	Sandoz Ltd.	Novartis AG	63 milliards
1997	Nycomed	Amersham	Nycomed Amersham plc	$1.06 billion
1997	Hoffmann-La Roche	Boehringer Mannheim	Hoffmann-La Roche	11 milliards
1998	Roche Holding	Corange Ltd.	Roche Holding	11 milliards
1999	Zeneca Group plc	Astra	AstraZeneca	
1999	Hoechst	Rhône-Poulenc	Aventis	
2000	Glaxo-Wellcome	SmithKline Beecham	Glaxo SmithKline	
2000	Pfizer	Warner-Lambert	Pfizer Warner-Lambert	

Source: Levy (1999), tableau 2.8, données mises à jour à l'aide des données de la Commission fédérale du commerce (FTC) (1999) et d'informations journalistiques.

Au cours de la même période, plusieurs sociétés pharmaceutiques américaines se sont intégrées verticalement en sociétés de gestion de soins pharmacothérapeutiques (Pharmacy Benefit Managers ou PBM). Les PBM sont des entreprises qui négocient pour le compte des assureurs avec les fabricants de produits pharmaceutiques, les pharmaciens et les médecins prescripteurs afin de maîtriser les dépenses pharmaceutiques Les principales acquisitions de ce type ont été l'achat par Eli Lilly de PCS Health Systems, l'achat par Merck de Medco Containment, et l'achat par SmithKline Beecham de Diversified Pharmaceutical. En 1996, les sociétés pharmaceutiques américaines contrôlaient des entreprises PBM qui représentaient 71 pour cent de l'ensemble des ordonnances et plus de 53 pour cent des Américains couverts par un régime d'assurance. A l'extérieur des États-Unis, les fonctions des PBM sont assurées par des organismes publics, ce qui écarte pratiquement toute possibilité de consolidation verticale du même type dans les autres pays.

2.3 Dépenses de recherche et développement

La rentabilité des sociétés axées sur la recherche dépend entièrement de leur capacité de mettre sans cesse au point des entités chimiques ayant des propriétés chimiques supérieures et de commercialiser

ces médicaments de manière profitable. Le processus de développement est coûteux et long, et les taux d'échec sont élevés.

Le processus de mise au point d'un nouveau médicament comprend plusieurs étapes. Les premières étapes consistent souvent à procéder au criblage à grande échelle de nombreuses molécules pour pouvoir sélectionner un composé ayant un potentiel thérapeutique.[12] Par la suite, des expériences sont effectuées sur des animaux vivants. Si le composé est prometteur, c'est à cette étape que la société déposera un brevet.[13] Une fois le produit breveté, le composé subit une série d'essais cliniques (sur l'être humain).[14] Ces essais cliniques sont non seulement coûteux mais longs. Il peut s'écouler dix à 20 ans entre le début des travaux de recherche et la mise sur le marché, le délai moyen entre la synthèse initiale et l'autorisation finale étant d'une douzaine d'années. Selon un spécialiste de l'industrie, pour 10 000 produits pharmaceutiques brevetés, il n'y en a qu'une centaine environ qui subiront des essais cliniques et moins d'une dizaine qui atteindront en fait l'étape de la mise sur le marché.[15]

Même les médicaments qui ont été autorisés ne se vendent pas nécessairement en quantités suffisantes sur le marché pour pouvoir être rentables. Mais les bénéfices que rapportent un ou deux médicaments qui connaissent un grand succès commercial peuvent être substantiels. Grabowski et Vernon (1992b) estiment que seuls 20 pour cent des nouveaux médicaments sont rentables et que 75 pour cent des bénéfices des sociétés pharmaceutiques proviennent de la vente de dix pour cent de tous les médicaments existant sur le marché.[16] Une forte proportion du revenu total de nombreuses sociétés pharmaceutiques provient de la vente de quelques médicaments.[17]

Le coût total de la mise au point et de l'approbation d'un nouveau médicament est de l'ordre de plusieurs centaines de millions de dollars. Grabowski et Vernon (1992b) estiment qu'aux début des années 80 le coût total de la R-D effectuée aux États-Unis atteignait 231 millions de dollars pour chaque nouveau produit introduit sur le marché. Mais il semble que la productivité de la R-D dans l'industrie pharmaceutique soit en baisse. Selon de plus récentes estimations, le chiffre correspondant serait de 350 millions de dollars en 1995 et de 500 millions en 2000.[18]. Des recherches empiriques indiquent que pour chaque nouveau médicament, les coûts nominaux de la R-D dans les sociétés pharmaceutiques sont passés en moyenne de 231 millions de dollars en 1987 à 359 millions en 1990.

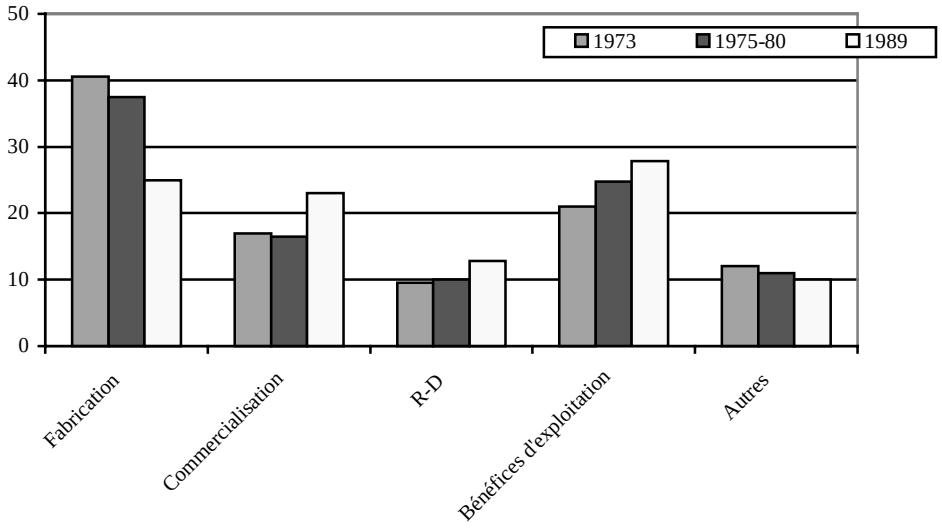
Dans l'ensemble, la R-D dans l'industrie pharmaceutique représente un investissement très risqué. Un nouveau médicament peut échouer à n'importe quelle étape de la procédure d'autorisation. La plupart des quelques médicaments autorisés devront faire face à la concurrence de produits rivaux. "En raison de l'importance des coûts initiaux de la R-D, de la concurrence qui peut s'exercer au niveau des ventes finales, et de la durée de la période de développement, la R-D est plus risquée dans l'industrie pharmaceutique que dans d'autres secteurs."[19]

2.4 Commercialisation et promotion

Une fois qu'un produit est mis sur le marché, les sociétés pharmaceutiques consacrent des sommes considérables à sa commercialisation et à sa promotion. Les grandes sociétés utilisent une force de vente importante qui a régulièrement des contacts directs avec les médecins prescripteurs et d'autres responsables du marché des produits pharmaceutiques. Les sommes affectées à la commercialisation sont élevées. "On estime que l'industrie [pharmaceutique américaine] dépense au moins cinq milliards de dollars par an en publicité et commercialisation – soit plus de 8 000 dollars par médecin aux États-Unis (Rennie, 1991). En fait, l'industrie pharmaceutique [américaine] dépense environ un milliard de dollars de plus en commercialisation et publicité qu'en recherche (Sénat des États-Unis, 1991)."[20]

Les dépenses de commercialisation ne semblent pas vouloir diminuer. Au cours de la période 1973-1989, elles ont (en proportion du chiffre d'affaires) fortement progressé, les bénéfices (en proportion du chiffre d'affaires) augmentant eux aussi pendant la même période. Aux États-Unis, le nombre de représentants de commerce en produits pharmaceutiques s'est accru de 50 pour cent dans les années 80, malgré la croissance du nombre de HMO.[21] Ces dernières années, les sociétés pharmaceutiques aux États-Unis mènent de plus en plus de campagnes publicitaires directement auprès des consommateurs.[22] Comme l'indique le Figure 5, malgré l'importance fondamentale que revêt la R-D, en 1989, les dépenses de R-D étaient de moitié inférieures à celles de commercialisation. La fabrication ne représentait que 25 pour cent des coûts des sociétés pharmaceutiques.

Graphique 5: Ventilation des coûts dans l'industrie pharmaceutique, 1973-1989



Notes: Les chiffres ne tiennent compte que des données concernant les entreprises axées sur la recherche.
Source: Jacobzone (2000), graphique 10.

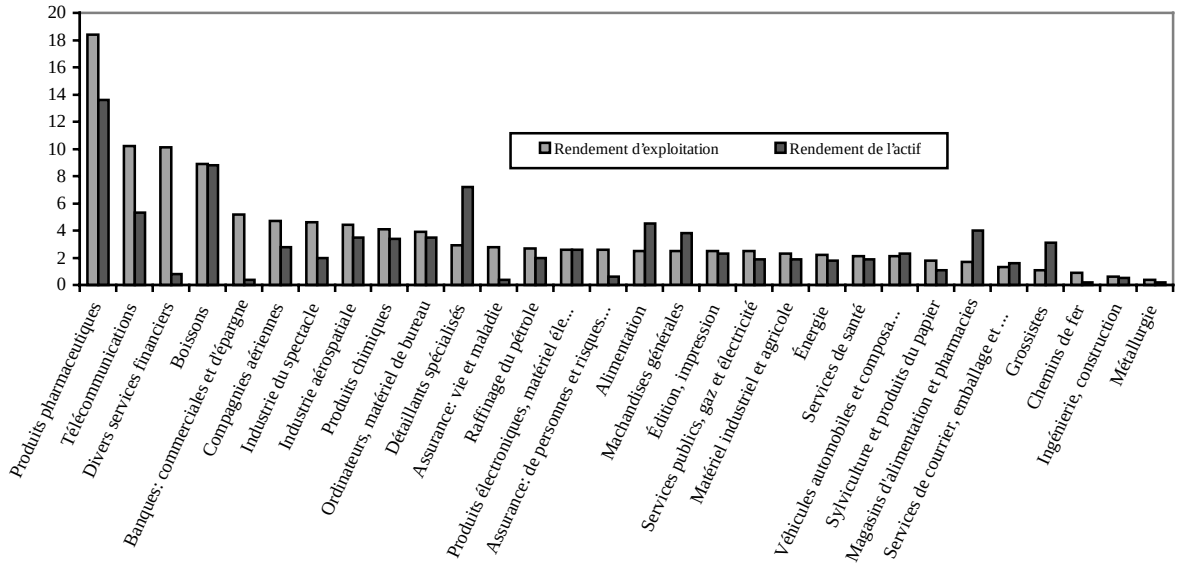
Étant donné les coûts fixes considérables que représente la force de vente, les sociétés pharmaceutiques ne cherchent pas toujours à effectuer leur commercialisation elles-mêmes. Il est courant qu'elles fassent appel à l'expertise d'une autre entreprise dans ce domaine. Ce sera le cas en particulier des petites sociétés axées sur la recherche qui n'ont pas les moyens de posséder leur propre force de vente. Il est possible également que deux sociétés aient des forces de vente dans des régions différentes du globe. Elles pourront alors conclure des accords de "co-promotion", aux termes desquels elles conviendront toutes deux de produire et de vendre un médicament sous la même marque déposée, ou des accords de "co-commercialisation" en vertu desquels elles conviendront de produire et de commercialiser un médicament, mais sous des marques déposées différentes.[23]

Les efforts de commercialisation ne ciblent pas uniquement les médecins et les consommateurs. Les sociétés pharmaceutiques ont également cherché à influencer les pharmaciens, allant dans certains jusqu'à les rémunérer pour qu'ils incitent les consommateurs à changer leurs habitudes de consommation de médicaments.[24]

2.5 Rentabilité des sociétés pharmaceutiques axées sur la recherche

A en juger par les indicateurs traditionnels, l'industrie pharmaceutique dans son ensemble semble être systématiquement rentable. Pour 24 des 32 années qui se sont écoulées entre 1960 et 1991, elle s'est classée au premier ou au second rang des secteurs les plus rentables de l'économie américaine, selon le classement du magazine Fortune.[25] Au cours de cette période de 32 ans, le rendement des fonds propres a atteint en moyenne 18.4 pour cent dans l'industrie pharmaceutique comparativement à 11.9 pour cent pour les 500 premières sociétés industrielles.[26] Ces données concordent avec celles des analystes financiers, qui indiquent que les sociétés pharmaceutiques procurent à leurs actionnaires des rendements supérieurs à la moyenne.[27] On trouvera ci-dessous le classement des industries en 1998 selon le magazine Fortune.

Graphique 6: Rentabilité de divers secteurs, 1998



Note: Données de 1998. (www.fortune.com)

Il est rare que la mesure de la rentabilité soit simple ou qu'elle ne suscite pas de controverses. Les mesures comptables sont susceptibles à surestimer la rentabilité réelle des sociétés pharmaceutiques car elles ne tiennent pas dûment compte de la nature des investissements en R-D et commercialisation qui constituent du capital. La R & D et les investissements commerciaux sont définis de manière incorrecte comme des "dépenses" plutôt que comme des éléments d'actif. De ce fait, le taux de rentabilité de l'actif est calculé en utilisant une base d'actif qui exclut de manière inappropriée le capital commercial et la R & D accumulée, qui sont intangibles. Les éléments comptables tendent à surévaluer le véritable taux de retour[28]. Corriger ces anomalies réduit les taux de retour affichés. Selon une étude du US Office of Technology Assessment, les taux de retour moyens sur investissement dépassaient les références de 2 ou 3 points de pourcentage en moyenne[29]. Selon une autre étude portant sur les industries américaines, le taux de retour comptable "ajusté" était de 13.3 pour cent pour les produits pharmaceutiques (contre 10.3 pour cent en moyenne pour 14 secteurs industriels).[30]

2.6 Part de marché selon la classe thérapeutique

Dans l'industrie pharmaceutique, il est courant de regrouper les médicaments qui sont destinés à traiter le même état pathologique dans des "classes thérapeutiques". Pour les consommateurs, les médicaments appartenant à une même classe thérapeutique sont (plus ou moins) des substituts. La classe thérapeutique est donc souvent utilisée comme indicateur du concept de marché de produits pertinent qu'on utilise dans le droit de la concurrence. Bien qu'il y ait un grand nombre de fabricants de produits pharmaceutiques et une profusion de produits pharmaceutiques, un produit peut représenter une forte part de marché sur un marché spécifique.

Les données sur les parts de marché par classe thérapeutique sont habituellement de nature exclusive et difficile à obtenir, mais Burstall (1985) a pu recueillir certains renseignements sur la concentration dans différentes classes thérapeutiques. Le tableau 3 illustre la part du produit le plus vendu et des cinq produits les plus vendus dans 12 classes thérapeutiques en France, en Allemagne et au Royaume Uni, en 1982. Le taux de concentration est assez élevé dans plusieurs classes, quoique les groupes thérapeutiques indiqués dans le tableau portent sur plusieurs thérapies distinctes pour lesquelles les produits mentionnés ne se livrent peut-être pas concurrence. Il est donc probable que ces chiffres sous-estiment le pouvoir de marché d'une société pour une classe thérapeutique donnée.[31]

Tableau 3: Concentration dans certaines classes thérapeutiques

	R-U		**Allemagne**		**France**	
	C1	**C5**	**C1**	**C5**	**C1**	**C5**
Traitement cardiovasculaire :						
Agents myocardiques	35	80	20	67	25	60
Vasodilateurs périphériques			15	45	15	43
Agents bêta-bloquants	22	85	15	50	17	40
Hypotenseurs	-	-	25	60	33	60
Traitement antiulcéreux	70	-	68	-	80	-
Psycholeptiques :						
Tranquillisants	26	80	26	68	26	70
Somnifères	24	86			21	70
Analgésiques	14	36	10	36	33	75
Antirhumatismaux à action systémique	18	65	20	50	20	60
Antibiotiques à action systémique	26	46	7	23	25	35
Antiasthmatiques	35	77	21	41	-	-
Diurétiques	25	69	33	70	32	79

Note : Données de 1982. C1 = part de marché de la marque la plus vendue, C5 = part de marché des cinq marques les plus vendues.
Source : Burstall (1985)

Levy (1999) a recueilli des données plus récentes. La part des quatre médicaments les plus vendus appartenant à huit classes thérapeutiques est indiquée au Table 4. Dans ces huit classes, la part de marché des quatre médicaments qui se vendent le mieux est supérieure à 80 pour cent. Dans plusieurs classes, deux médicaments ou plus sont fabriqués par la même société, de sorte que les chiffres indiqués sous-estiment le taux de concentration à quatre entreprises. Ces classes thérapeutiques ne coïncident pas nécessairement de près avec les marchés du point de vue de la concurrence.[32]

Tableau 4 : Parts des marques les plus vendues selon la classe de médicaments (1992)

Classe de médicaments	Marque et part				Sous-total
Inhibiteurs de l'enzyme de conversion	Vasotec* 39.8%	Capoten 23.6%	Zestril 15.5%	Prinivil* 11.4%	90.3%
Médicaments allergologiques	Seldane* 29.2%	Seldane D* 14.4%	Hismanal 10.6%	Tavist 6.4%	60.6%
Analgésiques	Anapr.DS* 16.0%	Toradol* 9.3%	Florinal 7.8%	Dolobid 4.7%	37.8%
Antibiotiques	Ceclor 7.1%	Augmentin 4.8%	Cipro 3.8%	Biaxin 1.3%	17.0%
Antianxiogènes	Xanax 22.5%	Valium 4.5%	BuSpar 3.7%	Ativan 3.0%	33.7%
Inhibiteurs calciques	Procardia 32.1%	Cardizen 26.6%	Calan 17.7%	Veralan 4.0%	80.4%
Hypocholestérol émiants	Mevacor 43.5%	Lopid 27.4%	Questran* 11.1%	Pravachol* 9.4%	91.4%
Antiulcéreux	Zantac 42.8%	Tagamet 19.2%	Pepcid 10.8%	Axid 8.3%	81.1%

Notes : * *L'astérisque désigne des marques appartenant à la même société pharmaceutique. Les sous-totaux mesurent la concentration parmi les quatre marques les plus vendues de chaque catégorie et non pour les quatre premières sociétés pharmaceutiques. Ces catégories ne correspondent pas n
écessairement à des marchés bien définis.
Source : Levy (1999), tableau A.11.

On peut trouver davantage d'informations dans les contributions du Mexique de la Norvège et de l'Italie[33] sur les parts de marché dans des classes de médicaments. Comme dans d'autres industries, l'information sur les parts de marché doit être interprétée avec prudence. Une part de marché élevée à un moment donné ne signifie pas nécessairement un manque réel de concurrence si cette part de marché est rapidement érodée par de nouvelles entrées (qu'il s'agisse de nouveaux médicaments brevetés ou de médicaments génériques). Dans le secteur pharmaceutique, toute nouvelle entrée nécessite des tests sur une certaine période et une procédure d'autorisation (voir section ci-dessous). Il en résulte qu'il est possible d'avoir un aperçu des nouveaux entrants potentiels sur le court et le moyen terme. Dans ces conditions, une analyse complète de l'état de la concurrence sur le marché pharmaceutique nécessite à la fois une analyse des parts de marché existantes et des conséquences probables qu'aura l'arrivée de nouveaux produits actuellement en cours d'autorisation.

2.7 Résumé

Dans la plupart des pays de l'OCDE, la progression des dépenses pharmaceutiques est plus rapide que celle des dépenses de santé en général. C'est pourquoi la mise en place de mécanismes de maîtrise des dépenses pharmaceutiques est au cœur des objectifs des pouvoirs publics. Les analyses comparatives entre pays montrent que les pays riches consomment plus de médicaments par habitant, mais que dans certains pays, comme la France, les États-Unis et le Japon, le niveau élevé du revenu national ne peut à lui seul expliquer que la consommation de produits pharmaceutiques y soit aussi forte. Avec l'Allemagne, l'Italie et le R-U, ces pays sont aussi de grands producteurs de médicaments.

Les premières sociétés pharmaceutiques du monde sont des entreprises de grande envergure et très rentables. L'industrie pharmaceutique se classe régulièrement parmi les secteurs les plus rentables de l'économie mondiale. Les grandes sociétés pharmaceutiques axées sur la recherche exercent leurs activités dans un environnement très risqué, mais aussi caractérisé par des possibilités de gains importantes. Bien

que le processus de sélection et de mise sur le marché des nouveaux médicaments soit coûteux, long et incertain, la rentabilité d'un médicament qui connaît un grand succès commercial peut être élevée. Les sociétés pharmaceutiques dépensent des sommes considérables pour promouvoir leurs médicaments de marque déposée. Même si elles opèrent dans une industrie à fort coefficient de recherche, elles dépensent plus en commercialisation qu'en R-D.

Le nombre de produits pharmaceutiques dont la mise sur le marché est autorisée est certes très élevé, mais le nombre de produits qui peuvent s'y substituer pour le traitement d'un état pathologique spécifique peut s'avérer limité. La concurrence à laquelle font effectivement face de nombreux médicaments dans leur classe thérapeutique est faible.

3. La réglementation de l'offre de médicaments

Après avoir présenté les principales caractéristiques de l'industrie pharmaceutique, nous examinerons maintenant les facteurs réglementaires qui agissent sur l'offre et la demande de produits pharmaceutiques.

3.1 Droits de propriété intellectuelle

Dans l'industrie pharmaceutique, la protection des droits de propriété intellectuelle est au cœur des investissements en R-D. En l'absence d'une telle protection, les marges bénéficiaires et les incitations à investir en R-D diminueraient.[34] "Il semblerait que 65 pour cent des produits pharmaceutiques n'auraient pu être lancés et 60 pour cent des médicaments n'auraient pas été mis au point sans protection adéquate via un brevet".[35]

Il apparaît que les droits de propriété intellectuelle, sous forme de brevets et de marques de commerce, jouent un rôle relativement plus important dans l'industrie pharmaceutique que dans d'autres secteurs. Dans une étude portant sur plusieurs industries, le secteur pharmaceutique est classé au premier rang pour ce qui est de la dépendance à l'égard de la protection conférée par les brevets.[36] Il est possible que cela soit dû au fait que les brevets attachés aux médicaments vendus sur ordonnance renchérissent plus efficacement les coûts d'imitation que les brevets associés à d'autres produits.[37]

L'utilité de la protection conférée par un brevet dépend de la durée de la période d'exclusivité. Bien que la durée de vie du brevet soit fixée en vertu des conventions internationales, à 20 ans à compter de la date à laquelle est déposée la demande de brevet, en pratique, à cause du délai qui s'écoule entre le brevetage et l'obtention de l'autorisation de commercialiser le produit, la "durée de vie effective" d'un brevet est bien inférieure à 20 ans. La durée de vie effective des brevets aux États-Unis, au R-U et en Allemagne a considérablement diminué entre 1960 et 1980 parce que des tests de plus en plus nombreux et de plus en plus coûteux ont été exigés. Aux États-Unis, elle se situait aux alentours de 15 ans en 1960, mais elle était tombée à moins de huit ans en 1980.

Face aux préoccupations suscitées par la diminution de la durée de vie utile des brevets, les États-Unis et l'UE ont adopté des mesures législatives spéciales pour prolonger la durée de vie des brevets pharmaceutiques. Aux États-Unis, la loi Waxman-Hatch a allongé de cinq ans au maximum la durée de la protection des médicaments par un brevet, mais elle a ramené aussi à 14 ans la période totale d'exclusivité à compter de l'autorisation de mise sur le marché. Dans l'UE, la durée de vie d'un brevet peut être prolongée de cinq ans au plus grâce à l'obtention d'un "certificat complémentaire de protection".

Les brevets jouent un rôle clé dans la stimulation et la rétribution de la recherche et de l'innovation dans l'industrie pharmaceutique. Le rôle des droits de propriété intellectuelle dans la société

industrielle moderne est tellement important qu'il est tenu pour acquis. Il est cependant utile de rappeler que la protection des produits pharmaceutiques par un brevet (tout comme la protection d'autres produits par des brevets) comporte à la fois des avantages et des inconvénients. Les principaux inconvénients sont son manque de souplesse en tant qu'instrument d'action des pouvoirs publics et le pouvoir de marché qu'elle confère. Ses principaux avantages sont son efficacité pour ce qui est de l'utilisation de l'information et le fait que la procédure de délivrance des brevets permet de faire connaître les innovations au public.

Sur le plan théorique, une politique de R-D qui serait idéale permettrait de procurer des gains suffisants pour toutes les innovations (et uniquement pour celles-là) dont la valeur totale pour l'économie serait supérieure au coût de la recherche et développement. Les brevets procurent de tels gains parce qu'ils accordent au titulaire de brevet une période d'exclusivité et lui permettent de s'attribuer une partie de la valeur que son innovation apporte à la société, quels que soient les coûts de développement de l'innovation. Cette période d'exclusivité n'est pas illimitée, parce que l'exclusivité crée en soi une inefficience – sous la forme d'un pouvoir de marché. Le problème est que la part de la valeur économique totale que peut obtenir le titulaire de brevet dépend des caractéristiques du marché, notamment de la capacité d'établir une discrimination par les prix, des politiques de fixation des prix et de remboursement de et la présence d'innovations concurrentes, et qu'elle n'a peut-être pas grand chose à voir avec le coût même de l'innovation. Dans certains cas, une légère amélioration peu coûteuse d'un brevet existant peut même conférer la même exclusivité que l'original. Enfin, tous les brevets ont la même durée, alors que les conséquences dommageables du pouvoir de marché varient, semble-t-il, d'un produit à l'autre[38].

Ce sont ces mêmes problèmes que l'on retrouve dans l'industrie pharmaceutique. L'entreprise qui met au point un produit pharmaceutique révolutionnaire ne peut pas nécessairement empêcher des concurrents de développer d'autres techniques pour traiter la même maladie, même si celles-ci peuvent être mises au point à un coût considérablement inférieur à celui de l'innovation originale. Par conséquent, aussi utile soit-elle, une innovation risque de ne pas voir le jour si l'innovateur estime qu'il ne pourra pas s'opposer à la mise au point de substituts. En revanche, une innovation majeure peut inciter la concurrence à entreprendre toute une série de recherches du même genre, pour trouver des améliorations ou des substituts à un médicament révolutionnaire, alors que du point de vue de la société dans son ensemble la valeur de ces recherches est négligeable. [39]

En outre, la protection offerte par un brevet peut être démesurée par rapport au coût de l'innovation lorsque la concurrence pour la R-D est insuffisante. Par exemple, si cette concurrence n'est pas efficace, une entreprise peut être en mesure de décider de se faire délivrer un nouveau brevet au moment qu'elle juge approprié pour pouvoir étendre la protection accordée à un médicament existant. Récemment, un nouveau brevet américain a été accordé à SmithKline Beecham pour son antibiotique de marque déposée Augmentin. Juste avant l'expiration de la protection conférée par le brevet originel, SmithKline a présenté une autre demande de brevet portant sur d'autres éléments du médicament, dont un élément acide qui prévient la dégradation de la substance active que contient l'Augmentin. Le nouveau brevet accorde à la société une nouvelle période substantielle d'exclusivité sans d'importants travaux de recherche, voire aucun.[40]

De la même manière, de nouvelles techniques ont permis aux fabricants de médicaments d'éliminer les substances non actives, et peut-être nocives, des médicaments existants, de manière à accroître ainsi l'efficacité des médicaments et à atténuer leurs effets secondaires. Il est possible de prolonger la période initiale d'exclusivité grâce au brevetage de nouvelles formes de médicaments. Les médicaments qui ont bénéficié de ces nouvelles techniques comprennent le Prozac Jr, une version de l'antidépresseur Prozac (dont les ventes pour 2000 sont estimées à 2.5 milliards de dollars), la Desloratadine, une version du Claritin, médicament anti-allergique (2.2 milliards de dollars), et le Nexium, une version du Losec, médicament contre les ulcères (6 milliards de dollars), fabriqué par Astra Zeneca.[41]

En outre, comme on l'a indiqué, la protection que confère un brevet permet de fixer les prix à un niveau supérieur au coût marginal, introduisant de ce fait la distorsion économique classique due à l'exercice d'un pouvoir de marché. Les effets économiques de cette distorsion peuvent être importants. Ainsi, il pourrait arriver que le prix d'un produit pharmaceutique soit supérieur au coût de certains traitements de remplacement, ce qui obligerait les patients à supporter le coût, par exemple, d'une intervention chirurgicale ou à renoncer carrément à un traitement, alors que le rapport coût-efficacité du produit pharmaceutique (compte tenu de son coût marginal) dépasse celui de ces traitements de remplacement. De plus, l'existence d'un pouvoir de marché peut donner lieu à la mise en place de divers dispositifs verticaux en vue de réduire le plus possible les pertes de bien-être occasionnées par la fixation des prix à un niveau supérieur au coût marginal. Ces dispositifs peuvent aussi s'avérer en soi anticoncurrentiels.

La protection conférée par un brevet a pour principaux avantages d'être efficace du point de vue de l'information et de rendre publique l'information concernant l'innovation. Il est extrêmement difficile d'évaluer à l'avance la valeur économique et sociale de l'innovation. Pourtant, c'est l'innovateur lui-même qui est le mieux placé pour porter un tel jugement. La protection par un brevet conduit directement l'innovateur à se prononcer sur les avantages de son innovation. Le brevetage rend publics les informations concernant l'innovation, ce qui crée un fonds de connaissances sur lequel peuvent s'appuyer les autres entrepreneurs et qu'ils peuvent développer.

Les pouvoirs publics peuvent recourir à plusieurs mécanismes pour réduire certains inconvénients des brevets sans compromettre leurs avantages. Par exemple, en s'intéressant aux contrats d'achat entre les fabricants et les assureurs maladie nationaux, ils peuvent atténuer l'incidence négative de la fixation de prix au-dessus du coût marginal. Les assureurs nationaux peuvent proposer de verser un droit annuel fixe pour acheter un médicament de marque déposée à son coût marginal. Un tel droit permettrait de dédommager le fabricant pour son pouvoir de marché (et à le dédommager par conséquent de ses dépenses de R-D) tout en éliminant les effets de distorsion dus à la fixation des prix à un niveau supérieur au coût marginal. C'est le même objectif que peuvent viser les rabais sur volume ou les autres stratégies de fixation des prix adoptées par les PBM et les organismes publics d'achat de produits pharmaceutiques. Cet aspect est examiné plus en détail dans l'encadré ci-dessous.

Existe-t-il d'autres mécanismes pour rentabiliser la R-D dans l'industrie pharmaceutique?

Comme nous l'avons vu, la protection des produits pharmaceutiques par un brevet comporte certains inconvénients. Il s'agit d'un instrument plutôt rigide, pouvant entraîner certaines formes d'abus, qui introduit une distorsion dans les décisions économiques et qui est susceptible de donner lieu à diverses formes de comportement anticoncurrentiel. En outre, comme nous l'indiquerons plus loin, la quasi-totalité des pays ont mis en place des systèmes de contrôle des prix des produits pharmaceutiques. Ces contrôles peuvent nuire directement à l'objectif de rentabilisation satisfaisante de la R-D dans l'industrie pharmaceutique.

D'où la question de savoir s'il n'existe pas d'autres moyens efficaces de rentabiliser la R-D dans l'industrie pharmaceutique, par exemple en décernant des prix pour des contrats de recherche..

De nombreux pays de l'OCDE financent directement la recherche dans l'industrie pharmaceutique grâce à des subventions et à des contrats. Cela revient en fait à acheter directement la R-D, au lieu de la rétribuer indirectement en permettant à l'innovateur d'acquérir une partie de la valeur sociale qui en découle grâce au brevet qui lui est délivré. Bien sûr, l'efficacité de ce système dépend des incitations et des compétences des autorités chargées d'acheter la R&D. Une autre approche consiste à décerner un prix pour une innovation réussie répondant à des normes préétablies[42]

Une autre possibilité encore serait de préserver les droits conférés par un brevet, mais les pouvoirs publics ou un important assureur négocieraient avec le titulaire d'un brevet pour l'achat des droits attachés à celui-ci et la fabrication directe du médicament et sa distribution à son coût marginal. Cette façon de procéder permet à la fois d'éliminer la perte économique résultant de l'écart entre les prix et les coûts imputables à l'exercice du pouvoir de marché, et de réduire sensiblement les dépenses de commercialisation qui, ainsi que nous l'avons vu, sont elles-mêmes un élément appréciable du coût total des produits pharmaceutiques. Dans la mesure où le titulaire du brevet n'aurait pas l'obligation de vendre en dessous de la valeur actualisée du revenu futur retiré du brevet, l'incitation à innover serait pleinement préservée.. Un système de ce type existe en Nouvelle Zélande[43]

Par contre, il convient de relever quelques uns des inconvénients d'une telle approche. Premièrement, le titulaire du brevet aurait dans ce système peut d'incitation à se lancer dans des efforts de marketing. Le rôle de diffusion de l'information sur le médicament devrait être assumé par l'acquéreur des droits. Deuxièmement, cette politique peut aboutir à un remplacement inefficient de médicaments ne bénéficiant pas de ces mesures par des médicaments en bénéficiant. Troisièmement, il peut être difficile d'empêcher d'autres autorités publiques ou assureurs de tirer avantage de l'accès au médicament à bas prix en l'achetant au coût marginal auprès de sources approvisionnées par l'assureur qui a acquis les droits du brevet et en le vendant à des consommateurs à l'étranger. S'il n'est pas possible de faire obstacle à un tel "commerce parallèle", il faudrait que les assureurs des différents pays coordonnent leurs initiatives au niveau multilatéral. Il s'agit d'une question qui pourrait faire l'objet d'examens futurs.

3.2 Produits génériques

Une fois le brevet arrivé à expiration, son titulaire ne peut plus empêcher d'autres fabricants de produire et de distribuer des copies du médicament breveté. Les médicaments qui sont bio-équivalents à d'anciens médicaments brevetés portent le nom de "produits génériques".

L'incidence des produits génériques sur la concurrence dépend de la nature de la demande de produits pharmaceutiques, laquelle dépend à son tour des mécanismes et des institutions qui réglementent cette demande (voir la section suivante). Les produits génériques peuvent avoir une forte incidence sur la concurrence, mais cette incidence dépend de la fidélité à la marque et de la sensibilité aux prix des consommateurs de produits pharmaceutiques. Le premier produit d'une nouvelle classe thérapeutique peut souvent, en raison de la protection de la marque de fabrique ou de commerce, susciter à l'égard d'une marque une grande fidélité que l'entrée de concurrents sur le marché n'affaiblit pas directement. [44] Contrairement aux brevets, les marques de fabrique ou de commerce n'ont pas de date d'expiration, de sorte qu'elles peuvent s'avérer très utiles pour maintenir un pouvoir de marché après l'expiration du brevet. À propos du marché américain, Levy fait observer : "En raison de considérations telles que les avantages d'antériorité, la différenciation des produits et la fidélité à la marque, les premiers arrivants sur le marché ne sont pas confrontés à une forte concurrence sur les prix de la part de fournisseurs qui offrent par la suite d'autres traitements pharmaceutiques."[45]

Certaines études ont en fait permis de constater que le prix d'un médicament de marque déposée peut augmenter (au lieu de baisser) après l'expiration d'un brevet, au moment où des produits génériques moins coûteux sont introduits sur le marché. [46] Il est possible que cela soit dû à l'existence de deux marchés distincts, l'un qui est sensible aux prix et avantage donc grandement les produits génériques concurrents, et l'autre qui est en grande partie insensible aux prix et se caractérise par la fidélité à la marque déjà implantée sur le marché. Une telle explication va aussi dans le même sens que le constat suivant : de nombreux fabricants de médicaments de marque déposée ont eux-mêmes décidé d'entrer dans le marché des produits génériques qui sont bio-équivalents à leurs propres marques.

Il est clair que les produits génériques, du moins dans les marchés où la consommation de médicaments est sensible aux prix, sont une source de concurrence très importante pour les médicaments

de marque déposée. Les produits génériques se vendent habituellement 30 à 50 pour cent au-dessous du prix de leurs équivalents de marque et, aux États-Unis, il n'est pas rare qu'un produit générique occupe (en volume) une part de marché de 50 pour cent dans les douze mois suivant l'expiration d'un brevet.[47] Plusieurs pays ont pris des mesures pour faciliter la procédure d'autorisation des médicaments génériques ; elles consistent à adopter une procédure abrégée d'autorisation de mise sur le marché et à permettre aux fabricants de produits génériques de réaliser les essais destinés à établir la bio-équivalence de leurs produits avant l'expiration du brevet originel. Par exemple, les États-Unis ont mis en place une procédure abrégée d'autorisation des médicaments génériques avec l'adoption de la loi Waxman-Hatch de 1984.[48]

Par exemple, en vertu de la loi canadienne, les travaux de mise au point et d'essai des produits peuvent être effectués avant l'expiration du brevet.[49] Cette loi a été mise en cause par l'UE, qui la jugeait contraire aux dispositions de l'Accord de l'Organisation mondiale du commerce (OMC) sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC).[50] Dans cette affaire toutefois, un groupe spécial de l'OMC a confirmé la légitimité de la loi canadienne du fait que l'Accord sur les ADPIC prévoit des "exceptions limitées" aux droits exclusifs des titulaires de brevets, telles que la possibilité, pour une entreprise fabriquant des produits génériques d'effectuer des travaux de mise au point dans le but d'obtenir l'autorisation de mise sur le marché.

Les fabricants déjà positionnés sur le marché se donnent énormément de mal pour faire obstacle à l'entrée de nouveaux concurrents. L'une des stratégies mises en œuvre dans l'UE repose sur le fait qu'aux termes de la législation communautaire, les fabricants de produits génériques ne sont pas tenus de reprendre les nombreux essais cliniques nécessaires à l'obtention de l'autorisation initiale de mise sur le marché d'un nouveau médicament. Ils sont seulement obligés de démontrer la "bio-équivalence" de leurs produits avec le médicament de marque originel "de référence", dès lors que celui-ci est "commercialisé dans l'État membre concerné par la demande"[51]. De ce fait, certains fabricants ont décidé de retirer le princeps du marché peu avant l'expiration du brevet et de le remplacer par une version "nouvelle et améliorée". Le fabricant de produits génériques risque alors de voir sa demande refusée au motif qu'il n'existe plus de produit de référence commercialisé avec lequel comparer le médicament générique. La société AstraZeneca a été accusée d'utiliser une telle stratégie pour protéger le précieux médicament qu'elle avait mis au point pour lutter contre les ulcères, le Losec.[52] L'UE prépare actuellement une ligne directrice pour clarifier la position des fabricants de produits génériques qui se trouvent dans cette situation.[53]

Aux États-Unis, les sociétés établies sur le marché peuvent recourir à une autre stratégie. Aux termes de la réglementation américaine, le premier fabricant qui commercialise son produit générique bénéficie d'une période d'exclusivité de six mois à compter de la date de lancement du médicament générique sur le marché. Cela offre la possibilité au fabricant déjà établi sur le marché de rétribuer directement le premier fabricant à se lancer dans la production d'un générique pour qu'il ne commercialise pas son produit. Les deux fabricants peuvent alors se partager les fruits de leur monopole sans craindre l'arrivée de nouveaux concurrents. La FTC a récemment engagé des poursuites contre Aventis et Abbott Laboratories, et contre les fabricants de produits génériques Andrx and Geneva Pharmaceuticals, en alléguant que les fabricants de médicaments de marque utilisaient justement cette stratégie.

3.3 La réglementation de la sécurité et de l'entrée sur le marché

Tous les pays de l'OCDE contrôlent l'introduction de nouveaux médicaments sur le marché, avec pour objectif premier d'assurer l'innocuité des médicaments. Dans certains cas, les sociétés pharmaceutiques doivent également faire approuver leurs procédés de fabrication et leur étiquetage.[54] La procédure d'autorisation de mise sur le marché peut-être extrêmement longue et coûteuse. En 1995, l'obtention de cette autorisation a représenté 55 pour cent des dépenses de R-D.[55] Le tableau ci-après

indique les diverses étapes de la procédure d'autorisation des nouveaux médicaments aux États-Unis, ainsi que la durée moyenne de chacune d'elles.

Tableau 5 : Étapes du processus d'approbation de la FDA

Étape réglementaire	Description	Durée moyenne
Demande d'expérimentation d'un nouveau médicament (IND)	Demande d'autorisation d'essais sur l'être humain	30 jours
Phase I	Tests de sécurité	1 an
Phase II	Tests d'efficacité	2 ans
Phase III	Efficacité et réactions à long terme	3 ans
Demande d'autorisation d'un nouveau médicament	Demande d'autorisation de mise sur le marché du nouveau médicament	2,5 ans
Phase IV	Essais après commercialisation	-

Notes : La durée de l'évaluation de la demande de mise sur le marché d'un nouveau médicament équivaut au délai moyen d'autorisation des nouveaux médicaments au cours de la période 1990-1994.
Source : Levy (1999) citant Beary (1996).

Au cours des dernières décennies, le délai moyen de mise au point de nouveaux médicaments s'est considérablement allongé, en raison principalement de l'allongement des étapes des essais précliniques et cliniques. "L'accroissement des délais de mise au point clinique est en partie dû aux exigences réglementaires qui imposent des essais cliniques plus nombreux et plus étendus. Par exemple, pour chaque demande d'autorisation, le nombre d'essais cliniques est passé de 30 à la fin des années 70 à 60 au début des années 90, et le nombre de patients participant aux essais a plus que doublé au cours de la même période".[56]

Tableau 6 : Étapes de la procédure d'autorisation de la FDA

Période	Essais précliniques	Essais cliniques	Évaluation des demandes de mise sur le marché	Total
Années 60	3,2 ans	2,5 ans	2,4 ans	8,1 ans
Années 70	5,1 ans	4,4 ans	2,1 ans	11,6 ans
Années 80	5,9 ans	5,5 ans	2,8 ans	14,2 ans
1990-1994	6,1 ans	6,1 ans	2,6 ans	14.8 ans

Source : Levy (1999), tableau A.6.

L'augmentation du coût et de la durée de la procédure d'autorisation a des conséquences directes sur la nature de la R-D dans l'industrie pharmaceutique et sur l'intensité de la concurrence qui en découle au sein de chaque classe thérapeutique. Lorsque le coût de l'obtention des autorisations augmente, les concurrents ne sont pas incités à investir dans la R-D pour mettre au point un produit de substitution ou un succédané dont le rendement est moins intéressant et ils font plutôt porter leurs efforts de recherche sur la

mise au point de médicaments novateurs ou considérés comme une découverte, dont la mise au point est plus coûteuse mais dont le rendement peut aussi être plus élevé.[57] D'où une limitation du nombre de produits de substitution dans chaque classe thérapeutique.

3.4 Résumé

Dans la présente section, nous avons cherché à décrire les principaux types de mesures réglementaires qui agissent sur l'offre de produits pharmaceutiques. Il s'agit essentiellement des droits de propriété intellectuelle et de la procédure d'autorisation de mises sur le marché. Bien que l'action des pouvoirs publics ait pour objectif fondamental de veiller à la rétribution de la R-D et à l'innocuité des médicaments mis sur le marché, ces deux types d'intervention réglementaire ont leurs inconvénients. La protection conférée par un brevet donne directement lieu à un pouvoir de marché, ce qui fausse les résultats économiques et peut susciter un comportement anticoncurrentiel. La procédure d'autorisation des médicaments est longue et coûteuse, ce qui peut orienter les efforts de R-D vers la mise au point de médicaments considérés comme une découverte et réduire ainsi l'intensité de la concurrence au sein de chaque classe thérapeutique.

4. La réglementation de la demande de médicaments

Après avoir considéré les types de mesures réglementaires qui influent sur l'entrée dans le marché des médicaments (les droits de propriété intellectuelle et la procédure d'autorisation de mise sur le marché), nous examinerons maintenant de quelle manière les mesures réglementaires agissent sur la demande de médicaments.

Il importe d'emblée d'établir une distinction entre les médicaments vendus sur ordonnance et les médicaments en vente libre. Les médicaments en vente libre ne sont (généralement) pas remboursés ou subventionnés par les régimes d'assurance maladie – le consommateur doit assumer le coût total de ses choix. Le marché des médicaments en vente libre fonctionne de manière similaire aux marchés des nombreux autres biens de consommation de marque. D'après les données rassemblées par l'OCDE[58], la part des médicaments en vente libre sur le marché des médicaments varie entre huit pour cent en Espagne et 50 pour cent en Australie (voir le Table A. 1 de l'annexe).

Le marché des médicaments sur ordonnance est très différent. Comme c'est le cas pour de nombreux autres services de santé, le choix du produit à consommer n'est (généralement) pas fait par le consommateur final ; la décision est prise par un expert bien informé – habituellement le médecin traitant. En outre, dans la plupart des cas, une fraction substantielle du prix du médicament n'est payée ni par le consommateur ni par le médecin prescripteur, mais par un organisme d'assurance maladie. Cette séparation des rôles - ceux du consommateur, du décideur et du payeur – influe de façon radicale sur la demande de produits pharmaceutiques et elle est à l'origine des mécanismes réglementaires, contractuels et financiers très développés qui ont été mis en place pour maîtriser la demande dans le secteur pharmaceutique (et dans le secteur de la santé de façon plus générale).

4.1 Effet de l'assurance sur la demande de produits pharmaceutiques

L'effet de l'assurance maladie sur la demande de produits pharmaceutiques (et d'autres services de santé) ressort le plus clairement dans le cas extrême où les consommateurs sont couverts à 100 pour cent. Dans ce cas, le consommateur jouit des bienfaits thérapeutiques du médicament sans avoir à en assumer (directement) le coût. Si tous les consommateurs étaient couverts à 100 pour cent, ce seraient seulement les meilleurs médicaments de chaque classe thérapeutique qui seraient consommés, quels que

soient leur prix et celui des produits de remplacement. Les autres médicaments, même s'ils n'étaient que légèrement moins efficaces ou s'ils avaient des effets secondaires légèrement plus prononcés, ne seraient pas une option et ce, quelle que soit la différence de prix. Les sociétés pharmaceutiques seraient très fortement incitées à effectuer des investissements considérables pour obtenir ne serait-ce que de très faibles améliorations par rapport à des médicaments existants. Celles qui perceraient sur le marché pourraient s'attendre à avoir des marges substantielles et à faire face à une demande importante et inélastique.

Les consommateurs n'auraient aucune raison d'opter pour des médicaments moins connus ou des produits génériques. Le marché des médicaments génériques serait petit, voire inexistant, ce qui permettrait aux titulaires de brevets de tirer des rentes appréciables longtemps après l'expiration du brevet original. Compte tenu du rôle capital joué par le médecin traitant dans la consommation de produits pharmaceutiques, les sociétés pharmaceutiques dépenseraient des sommes énormes pour s'attirer leur fidélité et pour agir sur leurs habitudes de prescription. Même s'ils jouent un rôle plus limité, les pharmaciens seraient également ciblés par les sociétés pharmaceutiques. Les consommateurs serait peu tentés de rechercher les distributeurs de produits pharmaceutiques les plus efficaces, ce qui permettrait aux pharmaciens et aux autres intervenants de la filière pharmaceutique de générer des rentes excessives.

Enfin, s'il n'a aucune incitation à se restreindre, l'utilisateur consommerait une quantité élevée et inefficiente de médicaments et serait ainsi amené à continuer d'en consommer jusqu'à ce que l'avantage marginal des derniers médicaments consommés tombe en deçà de leur coût marginal.

Nous pouvons opposer cette situation à celle, hypothétique, où les consommateurs sont parfaitement informés des prix et des caractéristiques thérapeutiques des médicaments et se comportent comme si c'était eux qui payaient les médicaments. Dans ce cas, le consommateur serait incité à prendre soigneusement en compte les bienfaits d'un médicament par rapport à son coût, tant en les comparant à d'autres médicaments concurrents qu'à d'autres thérapies concurrentes. Dans un tel marché, il peut exister de nombreux médicaments au sein d'une même classe thérapeutique, leurs critères de différenciation étant leur efficacité et leur prix.

Les consommateurs ne tarderaient pas à se tourner vers des produits génériques bio-équivalents. Le prix des médicaments de marque déposée non brevetés ne pourrait être supérieur à leur coût marginal de production. Pour autant qu'ils participent au processus, les médecins prescripteurs seraient extrêmement sensibles aux différences de coûts entre des traitements pharmaceutiques concurrents. De fortes pressions seraient exercées sur les pharmaciens et les autres intervenants de la filière pharmaceutique pour qu'ils réduisent le plus possible leurs coûts et offrent toute la gamme de services que demandent les consommateurs. La consommation de médicaments serait limitée jusqu'à ce que l'avantage marginal des derniers médicaments achetés soit égal à leur coût marginal.

4.2 Adaptation de l'assurance maladie aux effets qu'elle a sur la demande

Il ressort clairement de ces situations hypothétiques que l'assurance maladie peut avoir un effet marqué de distorsion sur le marché des produits pharmaceutiques.[59] Pour neutraliser cet effet, les assureurs mettent en place des mécanismes réglementaires, contractuels et financiers qui réduisent la quantité et les prix des médicaments et qui améliorent l'efficacité des divers médicaments consommés.

Dans certains cas, l'assureur lui-même applique de telles mesures au marché des produits pharmaceutiques, mais pas toujours. Les assureurs se procurent souvent ces services auprès d'organismes indépendants. Aux États-Unis, il s'agit des sociétés de gestion de soins pharmacothérapeutiques (Pharmacy Benefit Managers ou PBM). Celles-ci s'efforcent de contrôler les dépenses de médicaments (sans compromettre leurs effets sur la santé) par des nomenclatures, des lignes directrices concernant la

prescription de médicaments, la négociation des prix des médicaments avec les fournisseurs et (souvent) la création d'un réseau de pharmacies. Grâce aux technologies de l'information, les PBM sont en mesure de contrôler les achats de produits pharmaceutiques, de veiller au remplacement par des produits génériques et de s'assurer du respect des lignes directrices concernant la prescription de médicaments.

En dehors des États-Unis, bon nombre d'Etats ont choisi de créer des organismes spécialisés de gestion des médicaments qui assument une ou plusieurs des fonctions des PBM américains, telles que l'établissement de la nomenclature nationale, la négociation de dispositifs de contrôle des prix ou l'évaluation du rapport coût-efficacité des nouveaux médicaments. A titre d'exemple, mentionnons le Conseil d'examen du prix des médicaments brevetés au Canada et Pharmac en Nouvelle-Zélande.

Dans de nombreux pays de l'OCDE, il serait possible d'améliorer la concurrence dans la prestation des services de gestion de soins pharmacothérapeutiques si la fourniture de ceux-ci était sous-traitée, c'est-à-dire si des organismes privés et non publics étaient responsables de l'exécution et du fonctionnement des diverses techniques de gestion de la demande dont il sera question ci-après. La procédure d'appel d'offres permettrait de s'assurer que la société retenue est déterminée à maintenir les coûts le plus bas possible et à rechercher de nouvelles techniques de surveillance et de maîtrise des dépenses pharmaceutiques. Les clauses du contrat seraient complexes et devraient spécifier la densité requise du réseau de pharmacies, le niveau acceptable de la participation aux coûts, les normes de santé souhaitées et les moyens d'intégration des services pharmaceutiques à la prestation des autres services de santé. Il n'en reste pas moins qu'à en juger par la pratique que suivent les assureurs privés aux États-Unis, il est possible de procéder ainsi par appel d'offres. Il s'agit en effet de l'une des rares situations où il y aurait moyen de confier à des organismes privés recherchant la maximisation de leurs bénéfices la responsabilité des politiques "de réglementation". Il y aurait avantage, semble-t-il, à étudier cette possibilité pour pouvoir à la fois maîtriser les dépenses de santé et introduire la concurrence sur le marché des produits pharmaceutiques. Dans un premier temps, les assureurs dans les pays de l'OCDE pourraient confier les services de gestion des soins pharmacothérapeutiques à un organisme distinct n'ayant aucun lien de dépendance avec l'assureur, en attendant de passer à un régime reposant uniquement sur des appels d'offres.

4.3 Contrôle du volume et de la qualité des dépenses pharmaceutiques

On peut distinguer deux grandes approches pour réduire le volume des dépenses de médicaments et en améliorer la qualité. La première consiste à agir sur les motivations des médecins prescripteurs et des consommateurs de manière à les inciter à réduire leur consommation et à privilégier les produits le plus efficaces en modifiant leurs habitudes de prescription/consommation. La seconde approche consiste à mettre en œuvre un ensemble de réglementations pour donner directement aux habitudes de prescription/consommation l'orientation souhaitée. Ces deux approches ne sont pas incompatibles. La plupart des pays les combinent. En outre, de nombreux pays de l'OCDE cherchent à contrôler directement les prix de vente des produits pharmaceutiques. D'où la nécessité de réglementer les marges des pharmaciens.

Nous examinerons maintenant les mesures destinées à contrôler le volume et la qualité de la consommation de produits pharmaceutiques :

- nomenclatures – il s'agit de listes répertoriant les médicaments pris en charge et précisant les conditions de prise en charge ;

- politiques de remboursement – ce sont les mesures relatives à l'étendue de la prise en charge des produits pharmaceutiques par l'assurance maladie (au moyen d'une participation aux coûts ou du plafonnement des remboursements) ;

- mesures de contrôle visant les médecins prescripteurs et les pharmaciens – sous forme soit de contrôles directs, soit de mesures d'incitation financière ;

- contrôle des marges des pharmaciens et des décisions d'entrer dans le marché ou d'en sortir ;

- contrôle des prix des médicaments.

Comme on l'a indiqué précédemment, ces mesures n'ont à s'appliquer qu'aux médicaments qui sont remboursés ou qui sont vendus sur ordonnance. Le marché des produits pharmaceutiques non remboursés en vente libre fonctionne de manière similaire à de nombreux autres marchés, sans souffrir des distorsions causées par l'assurance maladie.[60] Une technique simple de maîtrise des dépenses pharmaceutiques consiste donc à faire passer les médicaments de la catégorie des produits vendus uniquement sur ordonnance à celle des produits en vente libre. [61]

4.4 Nomenclatures

L'un des principaux instruments d'exécution de bon nombre de ces politiques est la nomenclature des médicaments autorisés. Dans le cas d'une nomenclature "positive", le médicament ne sera pas remboursé par l'assureur sauf s'il figure sur la liste et satisfait aux conditions énoncées concernant la prescription et le remboursement. La prise en charge de chaque médicament étant assortie de conditions (notamment de conditions concernant les prix), les nomenclatures deviennent un important mécanisme de maîtrise de la consommation de médicaments.

Le simple fait d'établir une nomenclature qui exclut certains médicaments de la prise en charge peut avoir une incidence importante sur les politiques de prescription. Par exemple, en 1985, au Royaume-Uni, une liste a été établie au National Health Service afin de ne rembourser que versions génériques de plusieurs médicaments d'usage répandu appartenant à huit catégories thérapeutiques. En un an, il en a résulté une hausse de 53 pour cent du nombre d'ordonnances prescrivant des médicaments génériques et une économie de six pour cent environ sur le coût des médicaments prescrits par les généralistes.[62]

Comme le montre le Table A. 1, provenant de Jacobzone (2000) et reproduit à l'annexe, la quasi-totalité des pays de l'OCDE recourent à une forme quelconque de nomenclature dans leurs mesures applicables aux produits pharmaceutiques.

Quels sont les principes sur lesquels devrait se fonder la décision d'inscrire un médicament dans une nomenclature ? Comme on le verra ci-dessous, pour prendre cette décision, il faut considérer à la fois les bienfaits thérapeutiques du médicament et son prix. En principe, un médicament devrait figurer à la nomenclature à condition *a*) qu'il soit plus économique que ses substituts bio-équivalents et *b*) que son ratio avantages-prix dépasse un seuil donné pour une certaine catégorie de patients au moins. Puisque les thérapies pharmaceutiques concurrencent d'autres thérapies, il est évident que pour établir une nomenclature il faut que le ratio coût/avantage minimal soit le même pour toute la gamme de services de santé envisageables. Sinon, les nomenclatures restrictives inciteront à délaisser les produits pharmaceutiques au profit d'autres services de santé, tels que les consultations à l'hôpital et les services des médecins, ce qui risque de faire augmenter le coût total des soins de santé.

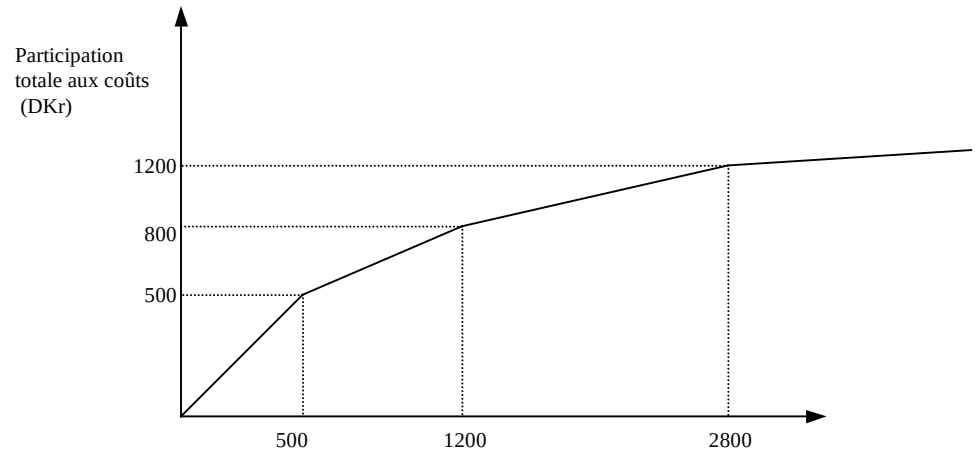
4.5 Politiques de remboursement

Il est très fréquent que les assureurs ne prennent pas en charge en partie ou en totalité certains produits pharmaceutiques. C'est une pratique courante dans les pays de l'OCDE. "Aucun service public de santé n'a jamais fourni gratuitement tous les médicaments. Certains produits ont toujours été exclus du remboursement et la participation des patients aux coûts est la norme".[63] Les pratiques en vigueur dans les pays de l'OCDE pour ce qui est du remboursement des médicaments sont présentées au tableau A4 provenant de Jacobzone (2000) et reproduit à l'annexe.

Il est plus courant de considérer le montant payé par la personne assurée que le niveau de remboursement. La partie du coût des produits pharmaceutiques à la charge de la personne assurée représente la participation au coût. Le niveau de celle-ci peut dépendre du médicament acheté, à savoir des dépenses associées à l'état pathologique (c'est-à-dire à une ordonnance spécifique), des dépenses totales d'une personne pendant une certaine période (par exemple, pendant une année), de l'identité de la personne elle-même, ou d'une quelconque combinaison de ces trois facteurs. En outre, la participation aux coûts peut varier de diverses manières en fonction de la dépense considérée. Elle peut se présenter sous forme d'un paiement minimal, d'une fraction du coût du médicament, d'un paiement maximum ou d'une quelconque combinaison de ces trois éléments.[64]

Par exemple, l'assureur peut exiger du bénéficiaire qu'il acquitte des frais minimums par médicament, par ordonnance ou par année. Autre solution, l'assureur peut obliger le consommateur à payer une fraction (ou la totalité) du coût des médicaments à hauteur d'une certaine limite par médicament, par ordonnance ou par année. Par exemple, dans le nouveau régime danois, entré en vigueur en mars 2000, la participation aux coûts est fonction des dépenses annuelles totales de produits pharmaceutiques. Les consommateurs danois supportent 100 pour cent du coût des ordonnances jusqu'à hauteur d'un montant annuel total de 500 DKr (66 dollars). Ils acquittent 50 pour cent du coût pour les dépenses comprises entre 500 et 1 200 DKr (160 dollars) et 25 pour cent seulement des coûts lorsque les dépenses se situent entre 1 200 et 2 800 DKr (370 dollars). Pour les dépenses supérieures à 2 800 DKr, ils assument seulement 15 pour cent des coûts. L'éventail des diverses formules possibles de participation aux coûts est très large.[65]

Graphique 7 : La participation aux coûts dans le dispositif de remboursement danois



La participation aux coûts peut également varier en fonction de l'identité de la personne assurée. Certaines catégories de personnes participent moins aux coûts ou n'y participent pas du tout. Par exemple, au Royaume-Uni :

> "Actuellement, les femmes de 60 ans et plus et les hommes de 65 ans et plus sont exclus [de la participation aux coûts], tout comme les enfants de moins de 16 ans, les femmes enceintes, les personnes souffrant de certaines pathologies spécifiques et celles qui perçoivent les allocations supplémentaires ou les suppléments au revenu familial, ainsi que certaines autres catégories mineures. Par conséquent, plus de la moitié de la population en est exclue et 12 pour cent seulement des ordonnances sont facturables".[66]

Les conséquences économiques de la participation aux coûts dépendent de la façon dont est calculée cette participation (par médicament, par ordonnance ou par année), de l'importance du paiement total et du niveau du paiement marginal. Plus le paiement total par médicament ou par ordonnance est élevé, plus le consommateur est incité à réduire sa demande de prescription de médicaments. Et plus le paiement marginal est élevé, plus le consommateur est incité à se tourner vers des variantes moins coûteuses du même médicament ou vers des points d'approvisionnement pharmaceutiques plus efficaces tels que les entreprises de vente par correspondance.

Le principal inconvénient de la participation aux coûts est que les consommateurs de services de santé courent le risque d'assumer des paiements plus élevés, ce qui rend moins avantageuse la répartition des risques de l'assurance maladie. Certains pays essaient de concilier les effets d'incitation économique de la participation aux coûts avec la volonté de limiter les coûts de santé en plafonnant le montant annuel de la participation totale de l'assuré aux coûts. Comme la majeure partie des dépenses de santé est le fait d'une minorité de consommateurs, un tel plafonnement évite à celle-ci d'assumer des dépenses très élevées tout en incitant dans une certaine mesure la majorité des consommateurs à contrôler le volume et la qualité de leur consommation de produits pharmaceutiques.

La participation aux coûts des produits pharmaceutiques doit être alignée sur celle des autres services de santé. Si elle est supérieure à celle d'autres services de santé (tels les services hospitaliers), le consommateur peut être incité à délaisser les produits pharmaceutiques au profit d'autres services (comme les services d'urgence), ce qui amoindrit la qualité des dépenses de santé dans leur ensemble. Des études du plafonnement de la couverture des produits pharmaceutiques assurés par Medicaid aux États-Unis ont permis de constater qu'un tel plafonnement faisait baisser la consommation de produits pharmaceutiques, mais augmentait la consommation d'autres services de santé, entraînant ainsi vers le haut les dépenses totales de santé.[67]

Dans quelques pays de l'OCDE, la souscription d'une assurance complémentaire risque de neutraliser les effets incitatifs positifs de la participation aux coûts. Ainsi que l'indique le tableau A.3 de l'annexe, cette pratique est interdite dans certains pays.

4.6 Mesures de contrôle visant les médecins prescripteurs

Pour la plupart des produits pharmaceutiques, ce n'est pas le consommateur lui-même qui choisit ses médicaments – c'est une décision qui revient habituellement au médecin prescripteur. Les intérêts du médecin ne sont pas nécessairement compatibles avec ceux de l'assureur ou du consommateur. En l'absence de mesures de contrôle, le médecin type est peu incité à restreindre la consommation de médicaments du consommateur ou à prescrire des médicaments ayant un meilleur rapport coût-efficacité. Pire encore, les sociétés pharmaceutiques dépensent de très fortes sommes importantes pour chercher à influencer les pratiques de prescription des médecins. Par conséquent, pratiquement tous les assureurs des

pays de l'OCDE s'efforcent d'une certaine façon à influer sur les habitudes de prescription des médecins. Les tableaux A.6, A.8 et A.10 provenant de Jacobzone (2000) et reproduits à l'annexe décrivent les pratiques des pays de l'OCDE en la matière.

Comme on l'a indiqué précédemment, deux grandes approches sont utilisées pour contrôler les habitudes de prescription des médecins – l'imposition directe par les autorités de restrictions au comportement de prescription ou le recours à des incitations financières pour amener le médecin à avoir les mêmes motivations que l'assureur.

Des deux approches, c'est la première qui est de loin la plus répandue. Les mesures de contrôle les plus courantes sont les lignes directrices concernant les pratiques de prescription et certaines formes de limitation de la quantité de médicaments qui peuvent être prescrits par jour ou par affection. Par exemple, il peut être demandé aux médecins de substituer les uns aux autres des médicaments appartenant à une classe thérapeutique donnée, de faire dans un premier temps l'essai des thérapies les moins coûteuses, ou d'obtenir une autorisation préalable pour la prescription de certains médicaments. Certains pays allouent également aux niveaux national ou régional ou à chaque médecin un budget fixe pour les médicaments.[68]

Presque tous les assureurs nationaux ont établi une forme quelconque de lignes directrices pour orienter le comportement en matière de prescription. Dans quelques cas, le respect de ces lignes directrices est obligatoire, et leur inobservation est passible de sanctions. Dans d'autres cas, elle est facultative, quoique certains formes de pression soient parfois exercées – telles que la publication de "palmarès" qui permettent de comparer le comportement de prescription des médecins. Par exemple, au Royaume-Uni, chaque médecin généraliste qui n'est pas responsable de la gestion d'un budget[69] se voit allouer un budget fictif pour les médicaments (connu sous le nom d'IPA ou Indicative Prescribing Amounts (montants indicatifs des prescriptions)), qui tient compte du profil des patients du cabinet médical. Chaque cabinet reçoit tous les mois un relevé indiquant les tendances de son comportement en matière de prescription, que lui fait parvenir le service de l'analyse et du coût des prescriptions (PACT). "Les budgets de médicaments indiquent seulement le montant maximal à dépenser, mais les pressions des pairs et, en dernier ressort, des sanctions peuvent s'exercer à l'encontre des généralistes qui persistent à dépasser les limites fixées".[70]

La principale difficulté que posent les restrictions imposées par les autorités est qu'il s'agit nécessairement d'un instrument rigide qui manque de finesse. Les lignes directrices peuvent certes faire obstacle aux pires excès ou aux formes de prescription les plus inadaptées, mais elles ne peuvent inciter les médecins à mettre soigneusement en balance les coûts et les bienfaits des divers traitements pour chaque patient.

C'est pourquoi quelques pays ont cherché à mettre en place des incitations financières pour que les médecins soient très sensibilisés au rapport coût-efficacité lors de la prescription.[71] Il y a trois grands exemples de ces incitations financières. Tout d'abord, au Royaume-Uni, les programmes visant les médecins généralistes qui sont responsables de la gestion d'un budget ; puis l'intégration, par le biais des HMO de l'assurance et de la fourniture des services de santé, fréquente aux Etats-Unis ; enfin, le système de "dotation prospective" en vertu duquel les hôpitaux (ou d'autres fournisseurs de services de santé) reçoivent de l'assureur un paiement qui n'est pas fonction des coûts réels assumés par l'hôpital. Dans les trois systèmes, le fournisseur de services de santé perçoit un montant annuel fixe et il est en mesure de décider de l'affectation de ces fonds aux divers traitements. La concurrence entre les fournisseurs est une caractéristique essentielle de chacun de ces systèmes. S'il n'y avait pas de concurrence, le fournisseur de services de santé serait fortement tenté de restreindre l'accès à ces services et ne serait guère incité à maintenir des soins d'un niveau élevé.[72]

Avec le système du généraliste responsable de la gestion d'un budget, le médecin local (le médecin généraliste) perçoit chaque année une somme fixe dont le montant dépend du nombre de

personnes qu'il soigne. Il lui incombe d'affecter ces fonds de manière à acquérir le plus de services de santé possible et il peut conserver toutes les sommes économisées grâce à une utilisation plus efficace des produits pharmaceutiques. Dans le cadre de ce programme, les généralistes sont fortement incités à choisir la meilleure combinaison de produits pharmaceutiques (et de tous les services de santé en général). En 1994, le tiers environ de tous les généralistes du Royaume-Uni participaient à un système de gestion de budgets.[73]

Le Royaume-Uni, qui applique à la fois le système de gestion de budgets et des mesures de contrôle traditionnelles du comportement de prescription, se prête tout particulièrement à des comparaisons entre l'approche "incitative" et l'approche "autoritaire" pour la maîtrise des dépenses pharmaceutiques. Plusieurs études réalisées au Royaume-Uni[74] ont constaté que les sommes consacrées aux patients sont relativement moins élevées dans le système de gestion de budgets qu'avec les mesures de contrôle traditionnelles. Selon Baines, Whynes et Tolley (1997), cela est attribuable à cinq facteurs : *i*) la "surprescription" est moins importante ; *ii*) les médicaments ayant une moindre valeur clinique sont moins utilisés ; *iii*) les médicaments similaires sont remplacés par des produits moins coûteux ; *iv*) la prescription de médicaments génériques est plus fréquente ; et *v*) le recours à des préparations coûteuses est judicieux.

Le système de "dotation prospective" fonctionne de manière très analogue au système de gestion de budgets, mais au niveau des hôpitaux, et on le retrouve principalement dans le régime Medicare aux États-Unis. Après le lancement de ce système en 1983, "les hôpitaux ont cherché a réduire le plus possible les coûts de la fourniture de services de santé en négociant très activement des rabais avec leurs fournisseurs, notamment les sociétés pharmaceutiques" [75]. Les hôpitaux affiliés à Medicare ont également mis en place des mesures de compression des coûts, notamment par le biais de nomenclatures et de dispositifs d'examen de l'utilisation des médicaments (DUR).

4.7 Mesures de contrôle visant les pharmaciens

Dans la plupart des pays, les rôles des médecins et des pharmaciens sont bien dissociés afin que les médecins n'aient aucun intérêt financier à l'égard des produits pharmaceutiques qu'ils prescrivent.[76] Le Japon et la Corée font cependant exception. Comme nous l'avons indiqué précédemment, la consommation de produits pharmaceutiques par habitant est élevée au Japon, même si l'on prend en compte le niveau supérieur du revenu moyen. La Corée entreprend actuellement de dissocier les rôles du médecin et du pharmacien. Aux termes des propositions actuelles du gouvernement coréen, à compter de juillet 2000, il sera interdit aux médecins de distribuer des médicaments aux malades externes et les pharmaciens ne pourront pas établir d'ordonnances.[77] La plupart des pays contrôlent aussi l'effort de commercialisation des fabricants de produits pharmaceutiques en cherchant à limiter les incitations financières que ces derniers peuvent offrir aux médecins pour qu'ils prescrivent certains médicaments.

Dans plusieurs pays, le pharmacien exerce aussi un certain contrôle sur les médicaments effectivement consommés. Ainsi, selon une étude américaine, 77 pour cent des médecins auxquels un pharmacien avait demandé de modifier leur prescription ont accepté de le faire.[78] Conscients de l'influence des pharmaciens, de nombreux assureurs (et sociétés pharmaceutiques) ont adopté des stratégies pour influencer les activités des pharmaciens dans le sens de leurs intérêts. Il peut s'agir de donner au pharmacien le droit et les incitations économiques voulues pour qu'il substitue des équivalents génériques aux médicaments prescrits, ou (dans certains cas) qu'il propose d'autres médicaments moins coûteux équivalents d'un point de vue thérapeutique.

Par exemple, en 1984, chaque État américain avait adopté des lois (abrogeant des lois antérieures qui rendaient illégale la substitution des médicaments) pour permettre aux pharmaciens de remplacer les médicaments de marque déposée prescrits par des produits génériques moins coûteux. Selon une étude

réalisée en 1994, 18 à 25 pour cent des HMO offraient des programmes d'encouragement aux pharmacies, et huit à 12 pour cent des HMO accordaient une rétribution supplémentaire aux pharmaciens qui délivraient des médicaments génériques.[79] En 1994, la moyenne des honoraires du pharmacien était de 2.62 dollars pour chaque ordonnance prescrivant des médicaments de marque déposée, mais de 2.67 dollars pour les produits génériques.[80] La question du système de rémunération des pharmaciens est examinée en détail dans la suite de ce texte.

4.8 Contrôles des prix

L'un des principaux mécanismes qui permettent aux assureurs de maîtriser les dépenses de médicaments consiste à exercer un contrôle direct sur les prix auxquels seront vendus les médicaments. Pour ce faire, il suffit, par exemple, de fixer le taux de remboursement du médicament. Puisque, pour de nombreux médicaments, la demande est très élastique lorsque le prix est supérieur au prix de remboursement, le plafonnement de celui-ci a un effet très similaire à celui de la réglementation directe du prix du médicament.

Les Table A. 7, A.14 et A.16 provenant de Jacobzone (2000) et reproduits à l'annexe présentent une synthèse de politiques en vigueur dans les pays de l'OCDE pour ce qui est du contrôle des prix des produits pharmaceutiques.

La grande question que doivent résoudre les assureurs est de savoir à quel niveau fixer le prix de chaque médicament inscrit sur leurs listes. Si le prix est trop élevé, il gonflera les dépenses pharmaceutiques et la rémunération des fabricants sera excessif. Par contre, s'il est trop faible, certains produits pharmaceutiques intéressants risquent d'être retirés du marché.

La question du prix judicieux est relativement claire lorsqu'il s'agit de classes thérapeutiques pour lesquelles de nombreux fabricants se livrent concurrence et fabriquent des produits qui sont de proches substituts, comme c'est souvent le cas dans les marchés des médicaments non brevetés. Il suffit simplement en l'occurrence de choisir un seul produit au moyen d'un appel d'offres. Le soumissionnaire retenu obtient alors l'inscription du produit à la nomenclature. La concurrence entre soumissionnaires garantit à l'assureur qu'il paiera le plus bas prix possible. Une autre méthode consiste à fixer le prix de tous les types de médicaments équivalents au même niveau que celui du médicament le moins cher d'une classe thérapeutique ou tout simplement à exclure de la prise en charge tous les médicaments sauf le moins cher. C'est la méthode dite de fixation d'un prix de référence.[81]

La question de la fixation du prix efficient est bien plus difficile dans les classes thérapeutiques dominées par un seul fabricant ou dans celles où l'on retrouve deux fabricants ou plus qui produisent des substituts imparfaits (qui sont tous protégés par des brevets). Comment un pays agissant seul procédera-t-il pour fixer les prix des médicaments de marque déposée ?

La décision de prendre en charge ou non un certain produit pharmaceutique à un prix donné, ou de la même manière, la décision concernant le prix maximum à payer pour un certain produit pharmaceutique, dépend de l'étude du rapport coût-efficacité de ce type de traitement comparativement à d'autres formes de traitement possibles. Elle est identique à celle que doit prendre un assureur lorsqu'il s'agit de savoir s'il faut ou non utiliser diverses autres formes de traitement (intervention chirurgicale, traitement pharmaceutique, psychologique, etc.). Dans chaque cas, il faut comparer l'efficacité du traitement et son coût. En principe, tous les traitements dont le rapport avantages-coûts est supérieur à un certain seuil doivent être pris en charge, et les autres non.

Ce seuil ne sera pas nécessairement le même d'un assureur à l'autre. Dans les pays riches, les assureurs sont plus susceptibles d'accepter un seuil plus bas que dans les pays pauvres. Autrement dit, les pays riches sont plus disposés à assumer les coûts de traitements plus marginaux et ils sont plus susceptibles d'être disposés à payer davantage pour conférer le droit de prescrire un certain produit pharmaceutique.

L'évaluation du ratio avantages-prix d'un médicament porte le nom d'analyse pharmacoéconomique. Cette analyse, qui consiste à affecter des valeurs monétaires à divers états de santé (c'est-à-dire les divers niveaux de maladie et d'invalidité, et le décès), comporte inévitablement un certain degré de subjectivité. Mais il est essentiel d'effectuer certaines analyses de ce genre pour veiller à ce que seuls les traitements les plus efficaces en termes de coût soient pris en charge. Sinon, à dépenses égales, l'assureur pourrait obtenir de meilleurs résultats en termes de santé s'il réorganisait son dispositif de prise en charge, en ne prenant pas en charge les thérapies dont le ratio avantages-coûts est faible et en affectant les sommes ainsi économisées à la prise en charge de thérapies dont le ratio avantages-coûts est élevé.

Au Royaume-Uni, le NHS a récemment créé un organisme chargé d'examiner ce type d'analyse coûts-avantages, non seulement des produits pharmaceutiques, mais également de tous les soins et services de santé.[82] Ce nouvel organisme porte le nom de National Institute for Clinical Excellence (Institut national de l'excellence clinique) ou "NICE". Dans l'une de ses premières décisions, il a refusé qu'un médicament antigrippal, le Relenza fabriqué par Glaxo, soit pris en charge par le NHS. Selon une rumeur, le NICE recommandera toutefois un usage accru des interférons bêta pour traiter la sclérose en plaques et des taxanes pour le traitement du cancer, même si ces médicaments sont coûteux, parce que les autres méthodes de traitement de ces maladies coûtent encore plus cher. L'Australie[83], certaines provinces du Canada et la France effectuent des analyses coût-efficacité. La Finlande a lancé un programme similaire en juin 1999. La Norvège le fera en janvier 2002. Les Pays-Bas et l'Italie envisageraient aussi d'utiliser des données pharmaco-économiques.[84]

4.8.1 Autres mécanismes de contrôle des prix

Outre les études pharmaco-économiques, les pays de l'OCDE recourent aussi à plusieurs autres mécanismes pour contrôler les prix des médicaments. Il s'agit notamment :

- de l'alignement sur les prix internationaux (c'est-à-dire la fixation des prix des produits pharmaceutiques en se fondant sur les prix en vigueur dans d'autres pays de référence) ;
- du contrôle de l'évolution des prix dans le temps ;
- du contrôle des prix par rapport aux coûts.

L'alignement sur les prix internationaux consiste à fixer le prix d'un produit pharmaceutique en se fondant sur les prix en vigueur dans plusieurs autres pays de référence.[85] Cette méthode a l'avantage d'éviter une évaluation coûteuse et permet de faire en sorte que les prix intérieurs ne soient pas trop décalés par rapport aux prix internationaux. Mais elle revient en fait à profiter sans frais des efforts d'autrui. Il est impossible que tous les pays d'un même groupe utilisent la même méthode, en basant leurs prix intérieurs sur ceux en vigueur dans les autres pays du groupe, car le prix en résultant serait alors indéterminé. Lorsqu'un seul des pays d'un même groupe recourt à une autre méthode de fixation des prix, l'alignement sur les prix internationaux revient en fait à ce que tous les autres pays décident d'"importer" la même méthode de contrôle des prix.

Une autre approche courante consiste à contrôler l'évolution des prix dans le temps. Bien qu'elle n'élimine pas la nécessité de recourir à un autre mécanisme pour fixer le prix initial, elle évite d'avoir à refaire d'autres analyses coûteuses lorsque le fabricant demande des changements de prix ou lorsque le prix de seuil sous-tendant l'étude coût-efficacité varie. Bon nombre de pays ont imposé des gels ou des réductions de prix des produits pharmaceutiques pendant un certain temps (voir le tableau A9 de l'annexe).

Quelques pays (dont le Royaume-Uni) ont décidé de fixer les prix des produits pharmaceutiques sur la base des coûts du fabricant.[86] En principe, cette méthode limite le pouvoir de marché du fabricant d'un produit pharmaceutique, du fait qu'il se voit fixer une marge bénéficiaire fixe. Cette marge est supérieure au coût du capital afin que l'entreprise puisse rentabiliser son innovation. Les coûts à prendre en compte sont les coûts directs de production et de commercialisation du produit pharmaceutique considéré. La marge bénéficiaire autorisée au Royaume-Uni est habituellement de l'ordre de 17 à 22 pour cent.

Les mécanismes de contrôle des bénéfices comportent plusieurs inconvénients. Si la marge bénéficiaire admissible est trop élevée, l'entreprise n'est guère incitée à maîtriser ses coûts. Dans certaines limites, toute hausse des dépenses de recherche, de commercialisation ou de production est plus que compensée par l'augmentation du prix. L'entreprise est fortement incitée à construire de somptueux laboratoires pour attirer et conserver un personnel de haut calibre, tout en sachant que les dépenses qui en résultent peuvent être récupérées par majoration des prix. Les inconvénients des mécanismes de contrôle des bénéfices ne se limitent pas à des dépenses inutiles, mais peuvent aussi être de nature anticoncurrentielle. En fait, le coût d'opportunité de l'entreprise qui accroît ses dépenses de commercialisation est nul. Il peut en découler des obstacles à l'entrée, car l'entreprise est fortement tentée de réagir à l'entrée éventuelle d'un nouveau concurrent en augmentant sensiblement ses dépenses de commercialisation. En revanche, si la marge bénéficiaire autorisée est trop faible, l'entreprise ne sera guère incitée à innover.

4.8.2 Introduction de la concurrence dans le contrôle des prix des produits pharmaceutiques

Le cas d'autres secteurs montre qu'il est avantageux d'introduire le plus possible la concurrence dans les segments concurrentiels d'une industrie. Dans l'industrie pharmaceutique, la production de médicaments est susceptible d'être concurrentielle– il n'y a aucun obstacle à l'entrée ni d'économies d'échelle pouvant empêcher de nombreuses entreprises de fabriquer le même médicament.

Il serait possible d'introduire la concurrence dans la production de médicaments au moyen d'un régime de licences obligatoires, tout en assurant une exploitation rentable au titulaire du brevet et en appliquant un système de contrôle des prix. Dans le cadre d'un tel régime, le titulaire d'un brevet serait tenu de concéder à toute entreprise qui le demande le droit de fabriquer et de commercialiser un médicament au moyen d'une sous-licence. L'entreprise requérante verserait au titulaire du brevet une redevance dont le montant serait déterminé par voie de réglementation. Le montant de la redevance serait fixé de telle manière que le total de la redevance et des coûts de production directs soit égal au prix du marché souhaité (réglementé), de sorte que le titulaire du brevet obtiendrait le même bénéfice avant et après la mise en place du régime de licences obligatoires. Il faut bien souligner ce point. Le régime de licences obligatoires, tel que proposé ici, ne limite ni plus ni moins les bénéfices du titulaire du brevet que les mesures de contrôle des prix qu'il remplace. L'obligation de verser une redevance prendrait fin à la date d'expiration du brevet.

Cette façon d'introduire la concurrence comporterait certains avantages. Elle garantirait à tout le moins l'efficience productive. On reproche souvent aux monopoles leur tendance à l'inefficience X – à savoir leur tendance à laisser filer les coûts, ce qui les fait monter au-dessus du niveau d'efficience

productive. L'existence de mécanismes de contrôle des bénéfices vient renforcer cette tendance. Le fait d'introduire la concurrence au niveau de la production y ferait contrepoids.

En plus de favoriser l'efficience productive, un régime de licences obligatoires pourrait comporter d'autres avantages, notamment l'élimination des risques d'apparition de certaines formes de comportement anticoncurrentiel. Par exemple, la présence de multiples sources indépendantes d'approvisionnement empêcherait le titulaire d'un brevet de conclure des accords de vente liée aux termes desquels la vente d'un médicament est subordonnée à celle d'autres médicaments. Le régime de licences obligatoires ferait aussi obstacle à la pratique anticoncurrentielle que constitue la conclusion d'accords d'exclusivité entre le fabricant et les membres du circuit de distribution des produits pharmaceutiques.

Un régime de licences obligatoires pourrait aussi avoir des effets sur la discrimination par les prix et sur le commerce parallèle. Une entreprise obligée de concéder une licence pour ses produits dans un pays à bas prix pourra éprouver plus de difficultés à empêcher la revente de ces produits dans des pays à prix élevés, de sorte qu'elle sera moins à même de fixer des prix différents dans les différents pays.

4.8.3 Contrôle des prix, capacité d'achat et nécessité d'une coordination multilatérale

Certains observateurs ont évoqué la possibilité que les grands assureurs nationaux disposent d'un certain pouvoir pour faire contrepoids aux fabricants dans leurs négociations et soient à même de négocier un prix inférieur au prix maximal que l'assureur serait disposé à payer. Ce pourrait, par exemple, être le cas si le fabricant du médicament n'est pas en mesure de refuser de vendre son produit à l'assureur, ou s'il juge qu'en termes de relations publiques il serait trop onéreux de ne pas mettre sur le marché un médicament très prometteur.

Il est possible que certains assureurs nationaux aient un poids suffisant pour avoir un "pouvoir de négociation" appréciable auprès de certains fabricants, en particulier dans le cas des médicaments que le fabricant aurait des difficultés à refuser de mettre sur le marché (tel qu'un nouveau traitement pour le SIDA). L'assureur national pourrait se servir de son pouvoir de négociation pour obliger le fabricant à accepter un prix plus bas, réduisant ainsi la rentabilité du fabricant et, indirectement celle de l'investissement en R-D. Il est peu probable que de petits pays, comme la Nouvelle-Zélande, qui compte pour moins d'un cinquième de un pour cent de la demande de produits pharmaceutiques dans l'OCDE, aient un pouvoir de négociation important, mais de grands pays, tels la France et l'Allemagne, qui représentent chacun pour 8 à 9 pour cent de la demande dans l'OCDE, peuvent avoir une certaine influence sur les prix, en particulier s'ils coordonnent leur action.[87]

Certains observateurs ont fait part de leur crainte que le flux de nouvelles innovations pharmaceutiques ne s'appauvrisse si plusieurs grands assureurs pouvaient chacun de leur côté exercer leur pouvoir de négociation. Leur argumentation est la suivante : l'assureur national qui jouit d'un important pouvoir de négociation comparera les effets de la baisse des prix des médicaments sur les incitations à la R-D avec les avantages que comportent le bas niveau des prix des médicaments pour les consommateurs. Il se pose malheureusement un problème de bien collectif. Alors que chaque assureur bénéficie directement du bas prix des médicaments, il partage avec les consommateurs étrangers les avantages du flux des nouvelles innovations pharmaceutiques. Ainsi, s'il envisage de relever légèrement les prix des médicaments pour encourager l'innovation, il devra assumer tous les coûts, mais il n'obtiendra qu'une partie des avantages. Par conséquent, chaque assureur ayant un pouvoir de négociation sera incité à faire baisser les prix des médicaments à un niveau inférieur à celui qui est efficient pour la collectivité. A l'équilibre, les prix des médicaments seront trop faibles et les innovations insuffisantes.

Il est possible qu'il ne s'agisse que d'une préoccupation théorique. Aux États-Unis, il semble que les prix des médicaments soient élevés par rapport aux autres pays, ce qui donne à penser que les consommateurs américains contribuent davantage que les consommateurs des autres pays à la R-D des entreprises pharmaceutiques. Le Royaume-Uni, autre marché important, n'a pas choisi d'exercer le pouvoir de négociation qu'il pourrait avoir, mais il a délibérément choisi de rétribuer directement les sociétés pharmaceutiques pour leurs innovations. En outre, plusieurs autres grands pays ont opté pour l'alignement sur les prix internationaux, de sorte qu'ils importent en partie ou en totalité les prix américains et britanniques. En tout état de cause, il est difficile d'exclure la possibilité que l'acheteur use de son pouvoir, en particulier si plusieurs assureurs nationaux décidaient de coordonner leurs pratiques d'achat de produits pharmaceutiques.

Si plusieurs assureurs exerçaient chacun le pouvoir que leur confère leur capacité d'achat sur le marché des produits pharmaceutiques, une coopération multilatérale pourrait s'avérer nécessaire. Les arguments sont semblables à ceux invoqués en faveur d'accords multilatéraux sur les normes relatives aux droits de propriété intellectuelle. En l'absence de normes internationales, les pays qui importent des brevets sont incités à accorder une faible protection aux brevets, voire aucune, afin de pouvoir bénéficier des brevets sans avoir à en assumer les coûts. Le même raisonnement vaut pour le contrôle des prix des produits pharmaceutiques. Ce contrôle consiste essentiellement à restreindre le droit du titulaire d'un brevet d'exploiter son brevet. En l'absence d'accord international, chaque pays est incité à fixer le prix à un niveau trop bas (restreignant ainsi les droits du titulaire du brevet) pour obtenir les avantages du brevet sans en assumer les coûts.

Au lieu de rechercher un accord multilatéral, il semble préférable de faire obstacle à la création d'un pouvoir des acheteurs en empêchant les grands acheteurs de services de santé de s'unir pour effectuer leurs achats de produits pharmaceutiques.[88] Dans les grands pays comme la France l'Allemagne, le Royaume-Uni et le Japon, il serait possible de réduire encore plus ce pouvoir des acheteurs si les achats de produits pharmaceutiques relevaient du niveau régional ou infranational et non du niveau national.

4.9 Le circuit de distribution des produits pharmaceutiques

4.9.1 Contrôle des prix et circuit de distribution des produits pharmaceutiques

Le contrôle des prix des produits pharmaceutiques a d'importantes conséquences pour le circuit de distribution. Les consommateurs n'achètent pas uniquement des produits pharmaceutiques. Ils se procurent plutôt une combinaison de services pharmaceutiques (fournis par le fabricant de produits pharmaceutiques) et de services de pharmacie (fournis par le pharmacien). La qualité du service offert par l'assureur dépend donc non seulement des médicaments qui sont disponibles, mais également de la densité du réseau de pharmacies. Les coûts du circuit de distribution représentent une partie non négligeable des coûts totaux. Ainsi, en France, les coûts totaux de distribution atteignent 44 pour cent des ventes totales.[89]

Posons l'hypothèse qu'il existe un système de contrôle des prix de gros des produits pharmaceutiques. Si l'assureur a pour politique de rembourser 100 pour cent des dépenses de médicaments, les consommateurs ne sont nullement incités à s'adresser à la pharmacie pratiquant les prix les plus bas. S'il n'y a aucune concurrence sur les prix entre les pharmacies, il est indispensable que les assureurs réglementent aussi le prix de détail.[90]

La difficulté qui se présente alors est celle de la marge appropriée entre les prix de gros et de détail. Elle devrait correspondre aux coûts supportés pour fournir des services de pharmacie et elle variera d'une officine à l'autre. Il s'agit en fait d'un problème classique de réglementation des prix. Comme c'est le cas pour les autres problèmes de ce genre, sur le plan théorique, la principale difficulté est que la

pharmacie connaît mieux ses propres coûts que l'assureur. Si la marge est trop faible, la pharmacie cessera ses activités, ce qui réduira le nombre de services de pharmacie disponibles. Si la marge est trop élevée, de nouveaux venus seront attirés dans le marché, ce qui, en l'absence de mesures de contrôle de l'entrée, éliminera une partie de la marge excédentaire en raison de l'augmentation des coûts.

Compte tenu du coût et des difficultés associés à l'évaluation des coûts de chaque pharmacie, de nombreux pays ont décidé d'établir simplement une marge nationale fixe sans tenir compte des coûts de chaque pharmacie. Cette façon de procéder comporte de nombreux inconvénients, le principal étant que la marge doit être suffisamment élevée pour assurer la survie des pharmacies les plus marginales – c'est-à-dire celles dont les coûts sont les plus élevés ou dont le chiffre d'affaires est le plus faible. Par conséquent, presque toutes les pharmacies obtiendront une rémunération excessive, ce qui fera monter le prix des produits pharmaceutiques ainsi que la facture pharmaceutique nationale. La surrémunération attirera de nouveaux venus qui, s'ils sont admis, feront disparaître les bénéfices excédentaires en raison de l'augmentation des coûts. Pour neutraliser ces effets, la plupart des pays réglementent l'entrée, en limitant le nombre de pharmacies en fonction de la population et en fixant des distances minimales entre les pharmacies.

Par exemple, en Hongrie, il ne peut y avoir plus d'une pharmacie pour 5 000 habitants et les pharmacies ne doivent pas se trouver à moins de 300 mètres les unes des autres (250 mètres en milieu urbain). Les pharmacies ne doivent appartenir qu'à des pharmaciens (pour empêcher, par exemple, que des services de pharmacie ne soient offerts par un magasin à succursales multiples).[91] Dans le but de résoudre le problème de la surrémunération, le Danemark oblige les pharmaciens à faire masse de leurs bénéfices, de sorte que ce sont essentiellement les plus rentables qui subventionnent les moins rentables.[92] La situation en France est décrite dans l'encadré ci-dessous.[93]

La réforme de la rémunération des pharmacies en France

Dans une étude publiée en septembre 1999, la Cour des Comptes émet de sérieuses critiques à l'endroit du système de rémunération des pharmacies en France. On trouvera ci-après certains des faits saillants de cette étude.

- Le secteur des pharmacies est très réglementé en France. "Il n'est guère d'aspects de cette activité (diplôme, installation, propriété, rémunération, pratiques commerciales …) qui ne soient réglementés.".[94] Malgré les strictes restrictions à l'entrée, de nouvelles officines voient le jour au rythme annuel de 50 à 60, comparativement à 250 par an entre 1962 et 1991.

- En 1996, alors que les pharmacies représentaient 5.9 pour cent du nombre des entreprises de commerce de détail, elles ont réalisé 7.8 pour cent du chiffre d'affaires et 8.5 pour cent de la marge brute de cette activité. L'excédent brut d'exploitation par point de vente s'est élevé à 413 000 francs dans le secteur de l'optique-photographie, à 429 000 francs dans celui de la parfumerie et à 761 000 francs pour les pharmacies.

- En France, on dénombre 22 600 officines, c'est-à-dire une officine environ pour 2 500 habitants, comparativement à une pour 3 800 habitants en Allemagne, pour 4 400 habitants au Royaume-Uni et pour 3 500 habitants en Italie. La densité des pharmacies varie grandement d'une région à l'autre ; on en recense moins d'une pour 3 300 habitants dans les départements de la Moselle, du Haut-Rhin et du Bas-Rhin, mais plus d'une pour 2 000 habitants dans les départements de la Creuse, de la Corse, de la Lozère, de Paris et de l'Allier.

- Jusqu'en 1999, la rémunération des pharmaciens était fonction d'un taux de marge national commun sur le prix de ventes de médicaments. Il s'agissait d'un taux de marge dégressive, puisqu'il diminuait à mesure qu'augmentait le prix de vente. La marge moyenne s'établissait à 2.8 pour cent en 1998. La Cour des Comptes a relevé que : "la question se pose de savoir si le système de rémunération – qui est unique et s'applique de manière identique à toutes les officines – ne garantit pas en fait la pérennité de la pharmacie marginale (celle qui, quelles qu'en soient les raisons, est dans la moins bonne situation), assurant, en conséquence, une rémunération plus élevée aux points de vente placés dans des conditions plus favorables".[95]

- Aux termes d'un accord conclu entre le gouvernement et la profession en 1999, la rémunération des pharmaciens consistera en un forfait de 3.5 francs par boîte, auquel s'ajoute une marge à deux tranches : 26.1 pour cent du prix compris entre zéro et 150 francs et dix pour cent pour la partie du prix excédant 150 francs.[96]

- L'étude constate qu'au cours des 20 dernières années, toutes les actions engagées pour développer le marché des médicaments génériques ont échoué. Cela est dû au fait qu'"aucun des intervenants dans le processus de fabrication et de diffusion de ce type de produit n'avait intérêt à ce que ce marché se développe".[97] Récemment, la France a adopté une loi autorisant le pharmacien à substituer des produits génériques aux médicaments prescrits, sauf si le médecin indique expressément qu'il ne peut y avoir substitution. En outre, la nouvelle loi accorde aux pharmaciens une remise bien plus élevée sur les produits génériques que sur les médicaments de marque déposée (10.74 pour cent au lieu de 2.5 pour cent) et elle précise que, pour les produits génériques, la marge est calculée sur le prix de vente du médicament de marque déposée et non sur celui du générique. Ces mesures ont pour objectif de faire passer la part de marché des produits génériques de 5 à 35 pour cent en trois ans.

Les restrictions imposées sur les prix et à l'entrée dans le secteur des pharmacies ont été dénoncées par de nombreuses autorités responsables de la concurrence dans les pays de l'OCDE[98], et par l'OCDE elle-même[99]. En particulier, les autorités de la concurrence ont souvent préconisé l'élimination des restrictions à l'entrée sur le marché des pharmacies. Mais la libéralisation de l'accès n'aura pas nécessairement un résultat efficient. Tant que les marges des pharmacies sont réglementées de façon à être maintenues au-dessus des coûts, la libéralisation de l'accès rendra inefficiente l'entrée des nouveaux venus et transformera un simple transfert économique en un gaspillage de ressources économiques réelles. Pour pouvoir résoudre efficacement ce problème, il faut examiner de près le mode de rémunération des pharmacies.

Il existe d'autres approches réglementaires qui limitent la surrémunération des pharmaciens tout en maintenant le remboursement à 100 pour cent et un nombre suffisant d'officines. Toutes ces approches doivent trouver le moyen de rendre plus accessibles les renseignements concernant le niveau des coûts de chaque pharmacie. L'une des façons de procéder consisterait à lancer un appel d'offres pour obtenir le droit d'offrir des services de pharmacie à certains endroits (peut-être au niveau local ou régional). Une procédure d'appel d'offres permettrait à la fois de veiller à ce que l'assureur paye la plus faible marge possible et que le soumissionnaire retenu soit le fournisseur le plus efficient.

Une telle approche repose sur la concurrence "pour le marché". Bon nombre d'autorités responsables de la concurrence ont également recommandé d'encourager une certaine forme de concurrence dans le marché des pharmacies. Une telle concurrence ne pourrait voir le jour sans un assouplissement de la politique de remboursement à 100 pour cent. Pour qu'il y ait concurrence pour la fourniture de services de pharmacie, il est indispensable que les consommateurs soient incités à la marge à rechercher les pharmacies les moins chères.

L'assouplissement de cette exigence n'entraîne toutefois pas son abandon. Par exemple, une solution pourrait consister à lancer des appels d'offres pour la fourniture de services de pharmacie à des endroits répartis sur l'ensemble du territoire, et à fonder les taux de remboursement sur les taux en vigueur dans les plus proches pharmacies dont les services ont fait l'objet d'un appel d'offres. Toutes les autres pharmacies seraient autorisées à fixer leurs propres prix et à entrer dans le marché et en sortir librement. La procédure d'appel d'offres permettrait de connaître les coûts locaux. Il y aurait ainsi concurrence, les consommateurs bénéficieraient d'un taux de remboursement élevé et un niveau de service minimal serait garanti. Les consommateurs seraient également libres de s'adresser à d'autres sources d'approvisionnement, comme la vente par correspondance ou sur Internet. Une autre méthode similaire consisterait à ne lancer des appels d'offres que pour les services de pharmacie offerts en région excentrée ou rurale, et à se fier à la concurrence pour maintenir les prix à un bas niveau dans les autres régions du pays.

Lorsque la rémunération des pharmacies est fonction d'un taux de marge fixe sur le prix de gros ou de détail, le grossiste ou le détaillant est incité à majorer, et non à réduire, le prix des médicaments qu'il distribue. Il est ainsi fait obstacle à l'entrée de médicaments génériques ou aux importations parallèles. En Italie, par exemple, l'autorité de la concurrence a reproché au système de marge fixe de nuire à la croissance du marché des génériques.[100] En Allemagne, le Bundeskartellamt a imposé aux grossistes d'accepter les importations à plus bas prix malgré leurs réticences du fait du système de marge fixe. [101] En France, ainsi qu'il est mentionné dans l'encadré, le marché des génériques n'est plus sous-développé, en partie grâce aux incitations en sens contraire des pharmaciens.

De nombreux pays imposent des restrictions concernant la propriété des pharmacies, en exigeant, par exemple, qu'un pharmacien y ait une participation majoritaire, en interdisant à un pharmacien de posséder plus d'une pharmacie et en ne permettant pas à des entreprises d'autres secteurs de détenir des pharmacies. Pour autant que les normes de sécurité puissent être respectées, de telles restrictions nuisent à la concurrence et à l'efficience économique.[102]

4.9.2 Commerce parallèle des médicaments

Comme on l'a vu ci-dessus, lorsque les taux de marge du pharmacien sont fixes, celui-ci est incité à majorer, plutôt qu'à réduire, les prix des médicaments qu'il vend. En revanche, tant que son prix de détail est fixe, le pharmacien est très fortement incité à réduire son prix de gros. Comme les prix de gros des produits pharmaceutiques varient d'un pays à l'autre, il est évident que l'une des solutions qui s'offrent

à lui est de se procurer ces produits auprès de grossistes de pays à bas prix et de les importer pour les vendre dans un pays où les prix sont élevés. Cette pratique porte le nom de commerce parallèle.

Le principal effet du commerce parallèle est d'accroître la rentabilité des grossistes et des détaillants en produits pharmaceutiques. Le commerce parallèle peut ou non faire baisser les prix des produits pharmaceutiques dans le pays à prix élevé. Si l'assureur est en mesure de connaître les prix des produits pharmaceutiques importés payés par le pharmacien, il peut ajuster le prix de détail réglementé en conséquence. Mais cela n'est pas toujours possible. Au Royaume-Uni, pays à prix élevé et destination privilégiée des importations parallèles, le NHS se contente simplement de réduire globalement de 0.92 pour cent la rémunération des pharmaciens en faisant valoir que toutes les officines effectuent des importations parallèles, que ce soit ou non vraiment le cas.[103]

Au total, les conséquences du commerce parallèle en termes de bien-être sont ambiguës. Comme il a été indiqué précédemment, l'effet du commerce parallèle du point de vue de la baise des prix dans les pays à prix élevé se trouve atténué. Les principaux bénéficiaires en sont en premier lieu les grossistes. Même si le commerce parallèle a un impact direct sur les prix, ses effets positifs sont incertains. Il restreint la capacité des fabricants de médicaments d'établir une discrimination par les prix entre différents pays.[104] Par conséquent, les prix augmentent dans les pays pauvres, ce qui limite leur accès aux médicaments, mais il peut y avoir globalement gain de bien-être (en particulier si en autorisant le commerce parallèle on augmente le volume total des ventes de médicaments). Jusqu'à présent, la Cour de justice européenne s'est systématiquement prononcé dans une série d'arrêts en faveur du commerce parallèle en Europe.[105] La Commisison européenne relève à cet égard :

> "A moins que le commerce parallèle ne puisse exercer un effet dynamique sur les prix, il entraîne des inefficacités puisque la plus grande partie, quoique pas la totalité du gain financier, revient à celui qui pratique le commerce parallèle plutôt qu'au système de soins de santé ou au patient. Cependant, le commerce parallèle doit également être considéré comme une importante force motrice pour l'intégration du marché et, par conséquent, pour l'achèvement du marché unique. Pour autant que la structure du marché ne permette pas aux consommateurs et aux contribuables de profiter des avantages financiers du commerce parallèle, des mesures nationales appropriés peuvent normalement fournir la solution.[106]

Il est difficile d'obtenir des estimations de la part de marché des importations parallèles de produits pharmaceutiques. Selon une étude réalisée en 1990, ces importations représentaient un pour cent environ des ventes totales en Allemagne, 8 pour cent au Royaume-Uni et cinq à dix pour cent aux Pays-Bas.[107]

4.10 Résumé

Dans la présente section nous avons essayé de présenter les principales formes de réglementation qui ont une incidence directe sur la demande de produits pharmaceutiques. L'assurance maladie rend les consommateurs de médicaments moins sensibles aux prix. Les assureurs mettent en place un grand nombre de mécanismes pour contrôler le volume et la qualité des dépenses de médicaments. Il s'agit notamment du recours à des nomenclatures, du contrôle du comportement de prescription, des mesures de contrôle visant les pharmaciens et du contrôle des prix. Il serait possible de rendre concurrentiels la mise en œuvre et le fonctionnement de ces mécanismes en procédant à des appels d'offres pour la fourniture des services de gestionnaires de soins pharmacothérapeutiques, comme c'est le cas sur le marché américain de la santé.

Presque tous les pays ont mis en place un système de réglementation des prix des produits pharmaceutiques afin de maîtriser les dépenses pharmaceutiques. Il est possible que les grands assureurs disposent d'un certain "pouvoir d'acheteur" qui leur donne la possibilité d'obtenir un meilleur prix des fabricants, ce qui pourrait avoir pour effet de réduire la rentabilité de ces derniers et de faire baisser le rendement de la R-D.

1. L'assurance maladie n'incite guère les consommateurs à rechercher les distributeurs de produits pharmaceutiques à faibles coûts, de sorte que bon nombre d'assureurs doivent également réglementer les marges des pharmacies. Le taux de ces marges ne tient parfois pas compte des coûts des pharmaciens, ce qui procure une rémunération excessive à certains pharmaciens tout en mettant en péril la survie des pharmaciens dont les coûts sont élevés ou les ventes faibles. Lorsque les marges sont trop élevées, de nombreux pays font obstacle à l'entrée d'un nombre excessif de pharmaciens en limitant directement le nombre de nouveaux venus. La réforme de la rémunération des pharmacies, grâce par exemple à des appels d'offres pour la fourniture de services de pharmacie, pourrait éliminer le problème de la rémunération excessive ou insuffisante, ce qui rendrait inutile l'imposition de contrôles à l'entrée et pourrait assurer le développement du marché des génériques.

5. Questions de concurrence dans l'industrie pharmaceutique

On peut résumer comme suit l'état de la concurrence dans l'industrie pharmaceutique tel qu'il est présenté dans les sections ci-après.

Le niveau et la nature de la concurrence dans chaque classe thérapeutique dépendent de deux facteurs – le nombre de producteurs indépendants et la nature de la demande de produits pharmaceutiques. On trouve très peu de fabricants indépendants dans certaines classes thérapeutiques. Certains régimes d'assurance remboursent intégralement ou presque intégralement les dépenses pharmaceutiques, et il existe relativement peu de contrôles de la qualité ou du volume de ces dépenses. Dans les classes thérapeutiques comportant un grand nombre de producteurs concurrents et où la demande de produits pharmaceutiques est sensible aux prix, la concurrence effective peut être forte. Mais dans les classes thérapeutiques où il y a peu de producteurs rivaux, ou dans celles où la demande de produits pharmaceutiques n'est pas sensible aux prix, la concurrence ne porte pas principalement sur le prix, mais sur d'autres aspects, tels que la R-D ou la commercialisation.

Pour de nombreux produits qui font face à une faible concurrence dans leur classe thérapeutique, la principale menace est la mise au point de substituts par les concurrents. Les obstacles à l'entrée sont toutefois importants. Les risques et les coûts élevés associés à la R-D limitent le nombre de nouveaux entrants potentiels. Il n'est pas possible d'entrer rapidement dans le marché. En raison de la durée de la procédure d'autorisation de mise sur le marché, les entreprises établies bénéficient d'un long préavis avant qu'un produit concurrent ne soit lancé sur le marché.

Dans presque tous les pays de l'OCDE, le secteur pharmaceutique est soumis à la législation sur la concurrence, quoique les effets généralisés de la réglementation puissent en pratique restreindre l'application de cette législation dans le secteur. On trouvera ci-après un résumé des questions et des problèmes soulevés par l'application de la législation sur la concurrence.

5.1 Définition du marché

Ainsi que nous l'avons mentionné à plusieurs reprises, le marché de produits pertinent pour l'analyse de la concurrence dans l'industrie pharmaceutique est, pour une pathologie donnée, la série de

médicaments qui constituent des substituts pour son traitement. Il existe souvent une correspondance relativement étroite entre le marché de produits pertinent et ce qui, dans l'industrie, porte le nom de classe thérapeutique. La Direction générale de la concurrence de la Commission européenne a pour pratique de définir le marché de produits pertinent en fonction des classes thérapeutiques retenues dans le système de classification anatomique thérapeutique (ATC) qui est reconnu et utilisé par l'Organisation mondiale de la santé. Ce système est compris et accepté par les intervenants de l'industrie pharmaceutique et il a en outre pour avantage de permettre la collecte de données statistiques très détaillées.[108]

La nature et les taux de remboursement du régime d'assurance influent aussi sur le marché de produits pertinent. Même si deux médicaments chers peuvent, d'un point de vue médical, être substitués l'un à l'autre, il est possible qu'ils se concurrencent peu si l'un d'eux est remboursé par l'assureur et l'autre ne l'est pas. En revanche, lorsqu'il y a participation aux coûts, un médicament en vente libre et à bas prix pourrait faire concurrence à un médicament vendu sur ordonnance.

Bien que les produits pharmaceutiques soient facilement transportables et qu'ils soient commercialisés à l'échelle mondiale, la nécessité de prendre en compte, aux fins de l'analyse de la concurrence, les politiques d'achat et de remboursement des médicaments fait que le marché géographique pertinent est généralement de dimension bien plus faible et d'envergure habituellement nationale. Comme les politiques d'achat et de remboursement des médicaments diffèrent d'un pays à l'autre, les prix des produits pharmaceutiques et les parts de marché de chaque produit peuvent aussi varier grandement entre les pays. En outre, souvent, les fabricants de médicaments adoptent selon le pays des stratégies variables pour ce qui est des marques, du volume et de la distribution, soit à cause de différences au niveau des marchés nationaux, soit pour établir une plus grande distinction entre ces marchés.[109]

5.2 Ententes

Il y a eu à plusieurs reprises collusion entre des sociétés pharmaceutiques.

Dans une affaire récente, plusieurs fabricants de produits pharmaceutiques ont été jugés coupables d'avoir mis en œuvre pendant dix ans un cartel international en vue de la fixation des prix et de répartition des marchés pour la vente de vitamines. De fortes amendes ont été infligées en l'occurrence. Les sociétés Hoffmann-LaRoche et BASF ont versé des amendes totalisant 750 millions de dollars américains et les autres entreprises en ont payé près de 350 millions. Deux dirigeants de la société Hoffman-La Roche ont accepté de se rendre aux États-Unis pour y plaider coupables, y purger quatre et cinq mois d'emprisonnement et y acquitter de fortes amendes. La société Rhone-Poulenc, qui avait aussi participé directement au cartel, n'a pas eu à payer d'amendes parce qu'elle avait coopéré avec les autorités américaines.[110]

Il convient de mentionner aussi les poursuites intentées en Italie par l'Autorité de la concurrence contre cinq sociétés pharmaceutiques, dont Merck, Sharp et Dohme Italia, accusées d'avoir imposé le prix de certains médicaments de "catégorie C" (non remboursés) qui sont utilisés pour le traitement de l'hypercholestérolémie. Ces sociétés occupaient une part de marché de 67 pour cent pour le segment correspondant à cette catégorie. L'Autorité a constaté que la société Merck notifiait au préalable aux autres entreprises son intention de relever ses prix en les invitant à s'y conformer, ce qu'elles ont fait. L'entente a eu pour effet de majorer les prix de 47 pour cent en dix mois. Curieusement, l'amende imposée aux sociétés mises en cause a été dérisoire, puisqu'elle équivalait à trois pour cent seulement du chiffre d'affaires généré par les produits considérés.[111] En décembre 1999, L'Autorité italienne de la concurrence a infligé une amende à l'Association nationale de l'industrie pharmaceutique, Farmindustria, pour une série de mesures anticoncurrentielles par lesquelles Farmindustria donnait instruction à ses membres de restreindre la concurrence.[112]

Quelques affaires ont également eu lieu dans le secteur des pharmacies. Par exemple, aux Pays-Bas, la fondation de la fédération des pharmacies, “Pharmacon”, a demandé que les pharmaciens ne soient pas soumis à l’interdiction des ententes sur le prix pour les médicaments non vendus sur ordonnance. L’autorité hollandaise de la concurrence a rejeté la demande et Pharmacom s’est par la suite désistée.[113] En République tchèque, une association privée de pharmaciens, la Chambre tchèque des pharmaciens, a demandé que les non-membres de la Chambre soient tenus d’obtenir un certificat pour ouvrir une pharmacie, ce qui réduit sérieusement la possibilité pour les non-pharmaciens de s’installer dans ce secteur.[114]

Dans une autre affaire intéressante, en Allemagne cette fois, les mesures de contrôle des prix des produits pharmaceutiques étaient conjointement déterminées par les caisses d’assurance maladie du pays. En 1999, un tribunal allemand a estimé que les caisses d’assurance étaient coupables de collusion, contrevenant ainsi à la loi sur la concurrence. Le ministre allemand de la santé a réagi en annonçant qu’un organisme d’État serait créé pour déterminer les prix des produits pharmaceutiques.[115]

5.3 Fusions

Comme toute autre fusion, la fusion horizontale de deux fabricants de produits pharmaceutiques peut affaiblir la concurrence dans les marchés où les deux entreprises se font déjà concurrence. En outre, comme dans de nombreux marchés des médicaments la principale menace provient de produits en cours de développement, une fusion peut aussi réduire la concurrence future car elle écarte le risque que soient lancés des produits rivaux. C’est pourquoi de nombreuses autorités responsables de la concurrence dans les pays de l’OCDE s’intéressent non seulement au produits existants mais aussi aux médicaments en cours de développement lorsqu’elles évaluent les conséquences des fusions de sociétés pharmaceutiques.

Par exemple, dans le cas de l’acquisition de Wellcome plc par Glaxo, les deux sociétés disposaient de programmes de développement de médicaments non injectables contre la migraine. Glaxo commercialisait déjà un médicament non injectable et elle développait un produit amélioré, le Naramig. Wellcome n’avait pas lancé de produit contre la migraine sur le marché, mais elle avait développé un médicament, le Zomig, qui en était aux essais de la phase III. Le Zomig devait être commercialisé en 1997 (deux ans après la fusion). La FTC a demandé à la société résultant de la fusion de céder dans un certain délai le Zomig mis au point par Wellcome à une tierce partie qu’elle devait agréer. Un an plus tard, la cession du Zomig à Zeneca était approuvée. Dans cette affaire, il semble que l’intervention de la FTC ait été particulièrement positive. Le Naramig de la société Glaxo Wellcome a obtenu l’approbation réglementaire en mars 1998, à peine huit mois avant la cession du Zomig à Zeneca. “Il semble que l’intervention de la FTC dans l’affaire Glaxo ait protégé, voire encouragé, la concurrence dans le marché des médicaments contre la migraine, pour le bien des millions d’Américains qui souffrent de ce mal.”.[116]

L’acquisition de Marion Merrill Dow par Hoechst a aussi permis d’observer directement l’effet des fusions du point de vue de l’affaiblissement de la concurrence dans la R-D. La FTC faisait valoir en l’occurrence que la concurrence future s’en ressentirait dans quatre marchés distincts, dont le plus important était celui du diltiazem, qui génère un milliard de dollars par jour et pour lequel le Cardizem CD commercialisé par Marion Merrill Dow occupe une part dominante. Hoechst développait un produit concurrent, le Tiazac. La Commission a allégué que “les négociations entourant la fusion n’incitaient pas Hoechst à poursuivre le développement du Tiazac”, ce qui aboutissait à retarder l’approbation par la FDA.[117]

L’une des difficultés que soulève le fait de compter sur la concurrence à venir des produits en cours de développement (le "pipeline" de médicaments) réside en ce que la procédure d’autorisation est par définition incertaine. A chaque étape, un nombre élevé de composés sont éliminés. L’existence d’un

produit en cours de développement ne signifie pas nécessairement qu'il sera lancé sur le marché. C'est pourquoi la Commission européenne a adopté pour politique de ne considérer que les produits atteignant les étapes finales (phase III) des essais cliniques. On a également fait valoir, à l'encontre de ceux qui mettent l'accent sur la concurrence des produits en cours de développement, que si l'insuffisance de la concurrence dans les marchés classiques cause directement une perte de bien-être, il n'est pas clair que ce soit le cas de l'insuffisance de concurrence pour la R-D. Rien ne prouve qu'une diminution de la concurrence dans la R-D se traduit par un baisse de la R-D ni qu'une réduction de la R-D cause une perte de bien-être.[118]

On peut craindre aussi que les fusions de sociétés pharmaceutiques ne facilitent la collusion dans l'industrie. En particulier, la prédisposition de l'industrie pharmaceutique à avoir un comportement collusoire risque de s'accentuer si les sociétés pharmaceutiques peuvent davantage pénétrer dans leurs marchés respectifs. Si la R-D permet de réaliser des économies de diversification, les entreprises qui disposent d'importants programmes de R-D sont plus susceptibles d'entrer dans n'importe quel marché donné. L'accroissement des risques de concurrence peut faciliter l'apparition de certaines formes de collusion, telles que la conclusion d'une entente implicite pour se répartir les activités de R-D dans des classes thérapeutiques.

Quels sont les mesures correctrices à prendre si une fusion suscite des préoccupations sur le plan de la concurrence? En ce qui concerne les produits actuellement commercialisés, il peut s'agir de mesures de type conventionnel – cession de licences et/ou de biens de production. Pour ce qui est de la concurrence dans les programmes de R-D, il demeure possible de recourir à des cessions d'actifs, quoiqu'il reste essentiel, comme c'est toujours le cas, de déterminer si les actifs cédés seront une source efficace de concurrence. Lévy relève ce qui suit :

> "En raison des coûts, des risques et de la durée du processus de R-D pour les médicaments vendus sur ordonnance, il peut s'avérer difficile de rétablir un niveau d'innovation égal à celui qui prévalait avant l'acquisition en recourant à [des mesures conventionnelles de cession]. L'une des premières difficultés est que l'acquéreur des actifs risque par ailleurs de ne pas être en mesure de soutenir la concurrence des entreprises qui fusionnent dans le marché de l'innovation considéré. En outre, ces cessions d'actifs peuvent nuire aux efficiences résultant d'une combinaison d'actifs de R-D complémentaires qui pourraient caractériser certaines fusions mettant en cause des marchés d'innovation. Mais lorsque les actifs nécessaires à la R-D sont aisément identifiables, lorsque les pertes d'économies de diversification dans la recherche sont faibles par rapport à l'avantage que retirent les consommateurs de la protection de la concurrence dans la R-D, et lorsqu'un acheteur solide peut être trouvé, la cession des actifs d'innovation qui font double emploi peut raisonnablement servir à remédier aux fusions susceptibles de nuire à la concurrence".[119]

La FTC aux États-Unis a été la seule parmi les autorités de la concurrence des pays de l'OCDE à faire part de son inquiétude face au nombre de fusions verticales dans l'industrie pharmaceutique américaine – entre les fabricants de médicaments et les gestionnaires de soins pharmacothérapeutiques (PBM). Ainsi que nous l'avons vu précédemment, les PBM fournissent des services aux assureurs, dont l'établissement d'une nomenclature, le traitement des demandes, l'examen de l'utilisation des médicaments et l'administration du réseau de pharmacies. Ces fusions inquiètent la FTC, qui redoute que les PBM privilégient les médicaments des sociétés qui leur sont affiliées par rapport à ceux des autres fabricants, et que le fait qu'ils soient propriétaires de PBM ne facilite la collusion des fabricants de médicaments, à même d'obtenir des renseignements détaillés sur les remises, les rabais et les prix de leurs concurrents. Dans l'une des fusions les plus importantes (l'acquisition de PCS par Eli Lilly), la FTC a donné son autorisation, mais elle a fait savoir qu'elle pourrait prendre d'autres mesures, dont la cession

d'actifs après l'acquisition, si elle parvenait à la conclusion qu'il y avait des signes de comportement anticoncurrentiel dans l'industrie.[120]

Certaines fusions qui ont eu lieu dans le secteur de la distribution de produits pharmaceutiques ont aussi été contestées. Au Royaume-Uni, par exemple, Unichem et Gehe AG, deux importants grossistes britanniques, avaient fait une offre d'acquisition à Lloyds Chemists. Le Directeur général pour la loyauté dans le commerce craignait que la cession d'entrepôts dans certaines régions du pays ne suffise pas à assurer une véritable concurrence dans le secteur du commerce de gros des produits pharmaceutiques. En fin de compte, le Secrétaire d'État s'est déclaré satisfait des engagements obtenus en matière de cession et la fusion a pu aller de l'avant.[121] Aux États-Unis, la FTC s'est opposée au regroupement des quatre principaux grossistes en produits pharmaceutiques en deux sociétés. Si elles avaient vu le jour, les fusions auraient permis aux deux nouvelles sociétés de contrôler plus de 80 pour cent du marché de gros des médicaments vendus sur ordonnance, ce qui aurait grandement nui à la concurrence sur les prix et les services.[122]

5.4 Abus de position dominante

Étant donné la position dominante de quelques médicaments dans certaines classes thérapeutiques, il n'est pas étonnant que les sociétés pharmaceutiques aient parfois cherché à se servir de cette position pour restreindre la concurrence.

Par exemple, en France, Lilly-France appliquait des remises aux hôpitaux qui achetaient ses produits génériques ainsi que des médicaments de marque déposée pour lesquels elle détenait une position dominante. Le Conseil de la concurrence et la Cour d'appel ont jugé que la remise avait pour objet de restreindre illégalement l'accès des concurrents aux hôpitaux dans le marché des médicaments génériques.[123]

En 1992, la FTC américaine a poursuivi Sandoz au motif que cette société obligeait illégalement ceux qui achetaient son médicament contre la schizophrénie, la clozapine, à acquérir également ses services de distribution et de surveillance des patients. Le jugement transactionnel "prend des mesures pour empêcher Sandoz de restreindre l'accès d'autres entreprises qui voudraient commercialiser des génériques de la clozapine aux États-Unis lorsque son droit exclusif de vente arrivera à expiration en 1994, et oblige donc Sandoz à fournir à des conditions raisonnables des informations à toute société qui aurait besoin de savoir si des patients auraient eu des réactions négatives au médicament".[124]

Aux États-Unis, des groupements de pharmacies occupant une position dominante dans une région géographique donnée ont à maintes reprises cherché à se servir de cette position de manière anticoncurrentielle. Les poursuites engagées par la FTC contre la Pharmaceutical Society of the State of New York, la Southeast Colorado Pharmacal Association, la Baltimore Metropolitan Pharmaceutical Association et la Maryland Pharmacists Association, concernaient toutes les tentatives faites par une association de pharmaciens occupant une position dominante dans le marché des services de pharmacie pour se livrer à un boycott collectif dans le but d'obliger les assureurs à majorer les taux des remboursements.[125] La FTC a réglé ces affaires au moyen de jugements transactionnels qui interdisaient aux associations de refuser de conclure un accord de participation proposé par un tiers payeur ou de s'en retirer.

6. Conclusion

L'industrie pharmaceutique joue un rôle clé dans les pays de l'OCDE. C'est une source importante d'investissement dans la R-D et d'emplois bien rémunérés, et grâce au flux continu de

médicaments novateurs et révolutionnaires destinés à traiter toutes sortes de maladies chez l'être humain, elle a contribué très largement à l'amélioration de la santé et du bien-être de la collectivité.

Pourtant, dans les pays de l'OCDE, peu de secteurs économiques sont aussi réglementés que l'industrie pharmaceutique. Chaque étape du cycle de vie d'un produit pharmaceutique – conception, autorisation de mise sur le marché, commercialisation, expiration du brevet et concurrence des génériques – est étroitement réglementée. Chaque acteur de l'industrie pharmaceutique – le fabricant, le grossiste et le détaillant, le médecin prescripteur, l'assureur et le consommateur – est fortement influencé par les règles et les incitations établies par voie de réglementation.

En particulier, la nature de la concurrence dans le marché des produits pharmaceutiques dépend fondamentalement des effets de l'assurance maladie et des mécanismes mis en place par les assureurs pour maîtriser la demande. Ces mécanismes comprennent notamment le recours à des nomenclatures, les procédures d'examen de la consommation de médicaments, les lignes directrices en matière de prescription et le contrôle des prix. Leur efficacité varie d'un assureur à l'autre. Il serait possible d'améliorer la qualité de ces mécanismes et l'efficacité des dépenses totales de médicaments si la fourniture des services de gestion de soins pharmacothérapeutiques était externalisée, même dans les pays où le principal assureur national relève de l'État. Des appels d'offres périodiques permettrait de stimuler continuellement l'innovation dans les modalités contractuelles, procédures et moyens technologiques de maîtrise des dépenses pharmaceutiques. C'est l'un des rares cas où l'on pourrait confier à des organismes privés recherchant la maximisation de leurs bénéfices la responsabilité des politiques "de réglementation".

L'externalisation des services de gestion de soins pharmacothérapeutiques permettrait aussi de prendre en compte une foule d'autres améliorations mineures dans le marché des produits pharmaceutiques, notamment le recours à des mécanismes de fixation des prix de type binôme pour les contrats conclus avec les fabricants de médicaments de marque déposée, ainsi que la manière dont sont rémunérés les pharmaciens. Les tarifs binômes pourraient rendre moins intéressant l'abandon inefficient de la consommation de médicaments de marque déposée générant des marges élevées, sans dissuader le fabricant d'investir dans la R-D. Lorsque la rémunération des pharmaciens ne dépend par de leurs coûts sous-jacents, elle encourage fortement l'entrée inutile et en grand nombre de nouveaux venus dans les zones rentables ; d'où les amples restrictions qui sont imposées à l'entrée sur le marché. Le recours judicieux à des appels d'offres pour la fourniture de services de pharmacie permettrait de s'assurer que la rémunération des pharmaciens n'est ni excessive ni insuffisante.

NOTES

1. Communication de la Commission sur le marché unique des produits pharmaceutiques COM(98)588, p.4.

2. Voir également Jacobzone (2000), pages 11 à 14.

3. Mais à long terme il existe peu d'éléments montrant que les dépenses pharmaceutiques ont progressé plus vite que les dépenses de santé de façon plus générale.

4. Par exemple, dans son livre blanc de 1989, le gouvernement britannique s'est déclaré préoccupé par l'inflation des coûts des médicaments prescrits, faisant remarquer que "en moyenne, les dépenses de médicaments ont au cours de chacune des cinq dernières années dépassé de 4 pour cent le taux d'inflation" et que le coût des médicaments était "supérieur à la rémunération des médecins qui avaient établi les prescriptions". Ministère de la santé du Royaume-Uni (1989), page 57. Analysant la réglementation des prix des produits pharmaceutiques au Canada, Anis et Wen (1998) font observer que "le coût des produits pharmaceutiques est la composante des dépenses totales de santé qui croît le plus au Canada. Depuis 1993, les coûts des médicaments sont par ordre d'importance la deuxième catégorie de dépenses de santé, après les dépenses institutionnelles, et ils sont supérieurs aux sommes versées aux médecins". Anis et Wen (1998), page 21.

5. Ces projets de loi faisaient suite à un rapport du Sénat américain qui faisait valoir que même si les sociétés pharmaceutiques s'étaient engagées à ramener volontairement les hausses de prix des médicaments au niveau du taux d'inflation en 1992, les prix des médicaments avaient augmenté quatre fois plus vite que le taux d'inflation au cours de cette même année. Abbott (1995), pages 551 et 552.

6. OCDE (1997), page 9.

7. Jacobzone (2000), graphique 11.

8. Klepper (1995), page 330.

9. "Ces entreprises qui ne font pas de recherche fabriquent sous licence des médicaments destinés à un marché local que le détenteur de la licence ne veut pas approvisionner ou elles produisent des médicaments non brevetés ne nécessitant pas de grands équipements de recherche. Comme les économies d'échelle sont peu nombreuses pour la majorité des activités de production et la préparation des médicaments sous forme posologique, ces entreprises peuvent avoir une assez grande mobilité et entrer dans l'industrie ou en sortir sans trop de difficulté". Klepper (1995), page 338. En outre, les entreprises du second niveau comptent un petit nombre de sociétés qui bénéficient des avantages des droits de propriété intellectuelle acquis par le passé, mais qui effectuent elles-mêmes peu de nouveaux travaux de R-D.

10. "Les fournisseurs ne se livrent pas tant concurrence avec un produit particulier. Ils cherchent plutôt à assurer leur survie économique grâce à l'*innovation*". Zweifel et Breyer (1997), page 301.

11. " US drugs giants poised to announce $84bn merger" (Les géants américains de l'industrie pharmaceutique doivent annoncer un projet de fusion de 84 milliards de dollars), *Financial Times*, 7 février 2000.

12. Au cours de la dernière décennie, les progrès des technologies de l'information et de la biotechnologie ont permis aux sociétés pharmaceutiques de sélectionner des composés prometteurs sans avoir à effectuer de criblage à grande échelle.

13. Le brevetage rend publique l'information sur le composé et c'est pourquoi le brevet est habituellement demandé le plus tard possible compte tenu des travaux de recherche effectués par les concurrents et de la nécessité de débuter les essais cliniques.

14. Ben-Asher (1999), page 18.

15. Ben-Asher (1999), page 16. Levy (1999), page 178, avance des chiffres légèrement différents. Suite au criblage de 5 000 à 10 000 composés, il n'y en a que cinq à atteindre l'étape des essais cliniques de la procédure d'autorisation de l'Office de contrôle des médicaments et des produits alimentaires (Food and Drug Administration, FDA) et un seul de ceux-ci sera autorisé par la FDA.

16. Grabowski et Vernon (1992b), page 356, graphique 3. Du fait qu'ils dépendent d'un nombre relativement restreint de médicaments, les revenus des sociétés peuvent varier d'une année à l'autre alors que de nouveaux produits sont mis au point et que d'anciens produits ne sont plus protégés par un brevet. "Le caractère aléatoire de ce processus est d'abord illustré par les fréquents changements de classement des grandes sociétés pharmaceutiques selon leur chiffre d'affaires. Un nouveau produit qui connaît un grand succès commercial (comme le Zantac de Glaxo) peut propulser une société aux premiers rangs de l'industrie. Cette même société peut perdre du terrain dès lors que le brevet d'un tel médicament arrive à expiration. Les entreprises internationales qui se situent aux premiers rangs de l'industrie changent donc constamment de position, mais il est rare qu'un nouveau fabricant entre sur le marché ou qu'un producteur établi s'en retire." Klepper (1995), page 340.

17. "Il est étonnant de constater à quel point les grandes sociétés pharmaceutiques sont tributaires des revenus que leur rapportent un petit nombre de produits. Pour certaines grandes entreprises, ces produits représentent à eux seuls 70 à 80 pour cent des ventes totales de produits pharmaceutiques, et pour la plupart des sociétés, ces proportions sont élevées." Comanor (1986), page 1182.

18. Ben-Asher (1999), page 12. Selon les témoignages qui ont eu lieu lors des auditions de la FTC sur la concurrence internationale, le coût moyen du lancement réussi d'un médicament vendu sur ordonnance était de l'ordre de 359 millions de dollars dans les années 80. Levy (1999), page 175. Entre le milieu des années 80 et le milieu des années 90, les dépenses de R-D de l'industrie pharmaceutique américaine ont augmenté sans qu'il n'y ait une hausse correspondante du nombre de nouveaux médicaments introduits sur le marché.

19. Levy (1999), page 179.

20. Schweitzer (1997), page 46.

21. Les HMO, ou Health Maintenance Organisations (organisations de soins de santé coordonnés), sont des fournisseurs de services de santé qui, du fait qu'ils cumulent les fonctions d'assureur et de fournisseur, peuvent exercer des contrôles plus serrés que les autres assureurs traditionnels sur le volume et la qualité des dépenses de santé.

22. Levy (1999), page 187.

23. Voir Collins (2000).

24. Par exemple, Miles, Inc., “a versé aux pharmaciens 35 dollars pour chaque client qui délaissait un médicament hypertenseur concurrent et adoptait son Adalat CC. La société Upjohn Co. a offert des incitations financières aux pharmaciens qui fournissaient des renseignements sur son médicament contre le diabète aux clients de marques concurrentes. Merck & Co. a mis sur pied plusieurs programmes pour encourager la substitution de ses médicaments de marque à ceux de sociétés concurrentes, dont des programmes de remises pour les médicaments hypertenseurs de marque déposée, Prinivil et Prinzide”. Levy (1999), page 19.

25. Scherer (1996).

26. Levy (1999), page 209, citant Scherer (1993), et Scherer (1996).

27. Levy (1999), page 209.

28 . Scherer (1993), p. 104

29 . Scherer (1993), p. 105, voir OTA (1993) et CBO (1994) cités par Levy (1999), P. 210.

30 . Clarkson, Kenneth W., “The Effects of Research and Promotion on Rates of Return” in Robert B. Helms, ed. *Competitive Strategies in the Pharmaceutical Industry*, Washington D.C.: The AEI Press, 1996. On peut expliquer le taux de rendement moyen plus élevé dans l’industrie pharmaceutique par le coût plus élevé du capital du fait des risques liés aux activités pharmaceutiques. Le niveau moyen de rendement élevé dans cette industrie pourrait dissimuler de fortes variations de la rentabilité des différentes entreprises dans le temps. Voir Meyers et Shyam-Sunder (1996).

31. Klepper (1995), page 341.

32. Levy (1999) relève ce qui suit: “Dans le cas des antibiotiques et des inhibiteurs de l’enzyme de conversion, il est possible que les données concernant les parts de marché ne fassent pas ressortir avec précision les différences existant au niveau de la concentration des ventes de classes bien définies de médicaments. On pourrait soutenir que le fait qu’il existe des sous-classes distinctes d’antibiotiques donne à entendre que les antibiotiques constituent une catégorie plus étendue que celle des inhibiteurs de l’enzyme de conversion qui font aussi concurrence à d’autres médicaments antihypertenseurs. Si c’est le cas, les données concernant la concentration des ventes présentées [dans ce tableau] pour les deux classes thérapeutiques ne sont pas nécessairement comparables. Il conviendrait plutôt de comparer les données concernant la concentration des ventes des antibiotiques et de tous les médicaments hypertenseurs, y compris les inhibiteurs de l’enzyme de conversion”. Levy (1999), page 196.

33 . Sur la base du niveau 4 de l'ATC, la contribution italienne distingue 321 marchés pour les médicaments en Italie, sur lesquels environ 78%, en 1997, avaient un taux de concentration à 4 supérieur à 80%.

34. “Sans la protection conférée par les brevets, il n’y aurait pas d’exclusivité en matière de commercialisation et les concurrents entreraient immédiatement dans n’importe quel marché avec un produit efficace, ce qui à la longue pourrait faire tomber les prix au niveaux des coûts marginaux de production. Les entreprises n’investiraient plus en R-D parce qu’il ne leur serait plus possible de rentabiliser leurs investissements en mettant au point des produits bénéficiant de

droits de propriété intellectuelle. La législation sur les brevets comporte toutefois des coûts pour la collectivité, car la protection des droits de propriété intellectuelle augmente le coût de diffusion des connaissances et rend l'innovation prohibitive pour certains de ceux qui bénéficieraient de son exploitation. On pourrait dire que la protection conférée par les brevets représente un arbitrage entre les gains actuels et futurs. La diffusion sans restriction des connaissances confère à tout moment des avantages à court terme à certains. Mais, s'ils se matérialisent, leurs gains empêcheront ceux qui sont à l'origine des nouvelles connaissances de rentabiliser leur investissement en propriété intellectuelle et dissuaderont quiconque d'effectuer d'autres investissements similaires à l'avenir. Trouver le juste milieu est un objectif de société qui est délicat à atteindre". Schweitzer (1997), page 196.

35. Levy (1999), citant Mansfield (1986).

36. Mansfield (1986).

37. Voir Levy (1999), page 180.

38 . Pour une discussion théorique de l'espérance de vie optimale, voir par exemple Cornelli et Schankerman (1999).

39. "L'association fédérale des caisses d'assurance maladie a considéré que seulement trois des 14 substances actives lancées sur le marché allemand en 1988 étaient nouvelles et avaient une valeur thérapeutique, significative. Autrement dit, près de 80 pour cent des … préparations nouvellement introduites communément appelées des succédanés sont considérées comme des progrès marginaux par rapport aux préparations existantes ". Zweifel et Breyer (1997), page 301.

40. "Drug Abuses" (Les excès de l'industrie pharmaceutique), Financial Times, 20 avril 2000, page 12.

41. "Drug Abuses", Financial Times, 20 avril 2000, page 12. Voir aussi Soechmer, Suzanne "Protecting Early Innovators: Should second generation products be patentable?" Rand Journal of Economics 27(2). Summer 1996 322-321 and O' Donoghoe , Ted "A patentability Requirement for Sequential Innovation", Rand Journal of Economics 29(4). Winter 1998, 654-679.

42 . Voir par exemple Wrigth, Brian "The Economics of Incentives: Patents, Prizes and Research Contracts" *American Economic Review 74(4) 1983, 691-707.*

43 . Voir la contibution de la Nouvelle-Zélande.

44. Cet aspect est examiné en détail dans Grabowski et Vernon (1992a).

45. Levy (1999), page 205.

46. Levy (1999), page 206 relève: "Dans une étude portant sur 32 médicaments qui n'étaient plus protégés par un brevet pendant les années 80, Frank et Salkever (1997) ont constaté que les prix des médicaments de marque déposée augmentaient après l'introduction sur le marché de produits génériques et que les prix de ces derniers baissaient considérablement au moment où les sociétés les fabriquant se lançaient à l'attaque de ces catégories de produits. … Dans une étude des médicaments de marque déposée soumis à la concurrence de produits génériques entre 1983 et

1987, Grabowski et Vernon (1992a) ont constaté que les prix des médicaments de marque déposée augmentaient légèrement après l'introduction de produits génériques sur le marché, et que les prix moyens diminuaient de 20 pour cent environ deux ans après l'entrée sur le marché de produits génériques concurrents ".

47. Voir Griliches et Cockburn (1995).

48. La FDA des États-Unis a reçu quelque 800 demandes d'approbation dans le cadre de la procédure abrégée dans les sept mois ayant suivi l'adoption de la loi. Il est probable que celle-ci a contribué à l'augmentation de la part en volume des médicaments génériques aux États-Unis, qui est passée de 18,3 pour cent en 1984 à 44,3 pour cent en 1997. Levy (1999), tableau 2.1.

49. Il s'agit de la clause "Roche-Bolar".

50. Voir "EC loses fight at WTO" (Les CE perdent la bataille à l'OMC), European Regulatory Affairs News.

51. Directive 65/65 CEE, article 4.8 a) iii).

52. "Drug Abuses", Financial Times, 20 avril 2000, page 12.

53. Voir "EC Paper on Generic Applications", European Regulatory Affairs News, avril 2000.

54. Voir Levy (1999), page 182.

55. Levy (1999), page 182.

56. Levy (1999), page 184.

57. "Par conséquent, s'il est vrai que le processus de recherche et développement donne effectivement naissance à des médicaments concurrents, certains médicaments mis sur le marché connaissent peu de concurrents directs, ce qui restreint la concurrence sur les prix entre les produits existants, et la concurrence joue souvent au niveau de l'innovation et du développement de nouveaux produits pharmaceutiques qui représentent un saut technologique". Levy (1999), page 8.

58. Les comparaisons internationales de ces données ne sont peut-être pas fiables en raison des différences dans les définitions des médicaments en vente libre.

59. Et le marché de services de santé en général.

60. Le contrôle des prix des médicaments non remboursés ne vise qu'à limiter la rentabilité du titulaire de brevet, et est susceptible d'entrer en conflit avec d'autres objectifs des pouvoirs publics. Quoi qu'il en soit, il serait possible de réduire le rendement des titulaires de brevets portant sur des médicaments en vente libre, tout en nuisant moins à la concurrence, si la durée de vie des brevets était limitée. Par exemple, la CE a demandé que soit levé le contrôle des prix des médicaments en vente libre. "EU weighs lifting of price controls" (L'UE envisage de lever le contrôle des prix), *International Herald Tribune*, 18 novembre 1998, page 20.

61. Pour une étude détaillée des différentes techniques de maîtrise des dépenses pharmaceutiques, voir Gross et al. (1994), Hutton et al. (1994) et Jacobzone (2000).

62. On estime que cette politique a connu un succès exceptionnel. Burstall (1997), pages S36 et S38. En 1992, elle a été étendue à dix autres classes thérapeutiques. Lors de la dernière modification, rien n'a été fait pour limiter le remboursement aux seuls équivalents génériques.

63. Burstall (1997), page S38.

64. Par exemple, en Italie, après la réforme de 1984, tous les médicaments figurant à la nomenclature ont été regroupés en trois classes. La classe A comprend les médicaments essentiels et ceux destinés à traiter les maladies chroniques, la classe B, les médicaments non inclus dans la classe A mais répondant à des besoins thérapeutiques primaires, et la classe C tous les autres médicaments. Pour les médicaments de la classe B la participation aux coûts est de 50 pour cent. Les médicaments de la classe A sont assujettis à un forfait de 3 000 ou 6 000 lires par ordonnance, selon que celle-ci prescrit un ou plusieurs produits. Fattore et Jommi (1998), page 27.

65. Le dispositif de remboursement suédois est décrit dans Jönsson (1996) et le régime belge dans Annemans et al. (1997). Voir également les contributions norvégienne et suédoise.

66. Burstall (1997), page S38.

67. Levy (1999), page 23.

68 . Voir, par exemple, la contribution tchèque.

69. Le concept de généraliste responsable de la gestion d'un budget est commenté plus loin.

70. Burstall (1997), page S37.

71. Il est clair que de telles incitations financières ne concernent pas uniquement les produits pharmaceutiques, mais toute la gamme de traitements médicaux possibles (sinon, les médecins économiseraient sur les produits pharmaceutiques et négligeraient de prendre davantage en compte d'autres services de santé, ce qui ferait augmenter les coûts dans leur ensemble).

72. Parfois, en particulier aux États-Unis, le régime juridique de responsabilité incite aussi à maintenir un niveau élevé de services de santé.

73. Burstall (1997), page S29.

74. Citées dans Baines, Whynes et Tolley (1997).

75. Levy (1999), page 200.

76. La séparation des rôles est peut-être aussi dû à des considérations liées à la sécurité – elle permet de faire en sorte qu'un second expert supervise les habitudes de consommation de médicaments des patients.

77. Les médecins coréens se sont opposés à ce projet parce qu'ils complètent leurs faibles honoraires par les revenus que leur procure la vente de produits pharmaceutiques. "South Korea Industry – A different kind of drugs war" (L'industrie sud-coréenne – Un autre type de guerre des médicaments), 9 mars 2000, Economist Intelligence Unit.

78. Voir Weinstein et Culbertson (1997), page 262.

79. Levy (1999), tableau 2.2.

80. Levy (1999), page 32.

81. Par exemple, en 1996, l'Italie a lancé une politique intitulée "le même prix pour les mêmes médicaments" en vertu de laquelle "les prix des médicaments contenant la même substance active, et ayant le même type pharmaceutique ou un type pharmaceutique comparable d'un point de vue thérapeutique, mais dont les dosages peuvent être différents, doivent être les mêmes par unité de composé, sinon tous les médicaments, à l'exception des moins coûteux sont … exclus de la prise en charge par l'assurance maladie nationale". Fattore et Jommi (1998), page 29.

82. Voir "Profile: NICE: The fourth hurdle – boon and bane" (Profil: NICE: le quatrième obstacle – bénédiction et fléau), Financial Times, 6 avril 2000.

83. Voir Harris (1994).

84. "Norway introduces pharmacoeconomics" (La Norvège se lance dans la pharmacoéconomie), European Regulatory Affairs News, avril 2000, page 12.

85. Par exemple, en Italie, les prix des produits pharmaceutiques ne peuvent dépasser un certain niveau, à savoir le "prix européen moyen", qui correspond aux prix en vigueur en France, en Allemagne, au Royaume-Uni et en Espagne, lesquels sont convertis au moyen des données de l'OCDE en termes de PPA du PIB. Fattore et Jommi (1998), page 28.

86. Pour une étude détaillée du régime de réglementation des prix des produits pharmaceutiques au Royaume–Uni et des autres solutions possibles, voir Bloom et Van Reenen (1998).

87 . Selon la contribution australienne, le gouvernement australien considère qu'il dispose d'un pouvoir de monopsome.

88. Par exemple, dans le même ordre d'idées, les caisses d'assurance allemandes ont été condamnées pour collusion en ayant coopéré pour la fixation des prix des produits pharmaceutiques.. "Germans pursue price regulation plan" (Les Allemands mettent en œuvre un programme de réglementation des prix), European Regulatory Affairs News, avril 2000.

89. Cour des Comptes (1998), page 223.

90 . Le Mexique, où les médicaments sont très peu pris en charge, n'a pas de réglementation concernant les pharmacies.

91. En Hongrie, 70 à 80 actions en justice ont été intentées pour contester, pour des raisons constitutionnelles, les restrictions concernant le nombre et l'emplacement des pharmacies. DAFFE/CLP(99)32, "Réforme de la réglementation: Examen de la Hongrie". Comparativement, l'Office finlandais de la concurrence a proposé d'éliminer le critère des besoins utilisé pour délivrer les autorisations d'exercice aux pharmacies ainsi que le barème des tarifs médicaux à partir duquel sont déterminés les prix au détail des produits pharmaceutiques. DAFFE/CLP(99)23, "La politique de la concurrence dans les pays de l'OCDE en 1996-1997".

92. DAFFE/CLP(99)12, "Réforme de la réglementation: Examen du Danemark", page 5.

93 . Voir également la contribution australienne à cette table ronde.

94. Cour des Comptes (1999), page 228.

95. Cour des Comptes (1999), page 230.

96 . La Hongrie applique également un système de marge mobile. Voir la contribution hongroise.

97. Cour des Comptes (1999), page 232.

98. Par exemple, l'Autorité norvégienne de la concurrence "est d'avis que la combinaison d'un système de libre accès au marché et d'un système d'agrément fondé sur les qualifications rendra la distribution au détail plus efficace qu'elle ne l'est aujourd'hui". DAFFE/CLP(98)17/14, "Rapport annuel sur les développements en matière de politique de la concurrence en Norvège".

99. OCDE/GD(97)145, "Regulation and performance in the Distribution Sector", page 44.

100. DAFFE/CLP(98)2, " La politique de la concurrence dans les pays de l'OCDE".

101. En Allemagne, le Bundeskartellamt a considéré que les grossistes en produits pharmaceutiques ne pouvaient refuser de vendre en cas de réimportation et d'importation parallèle de médicaments. Le but était de dissuader les pharmaciens de refuser de distribuer des médicaments à plus bas prix parce que le système des taux de marge fixes en vigueur en Allemagne ferait baisser leurs revenus. Mais en 1996, le gouvernement allemand a abrogé l'obligation légale au titre de l'article 129, paragraphe 1, no 2 du Code social, volume V, de vendre des médicaments importés. DAFFE/CLP(99)23, " La politique de la concurrence dans les pays de l'OCDE en 1996-1997".

102. Voir, par exemple, les observations formulées par l'autorité tchèque de la concurrence dans DAFFE/CLP(98)2, " La politique de la concurrence dans les pays de l'OCDE"

103. Burstall (1997), page S36.

104 . Dans l'UE, la discrimination par les prix peut être abusive au sens de l'article 82 du Traité CE.

105. Voir Darba et Rovira (1998).

106 . Communication de la Commission concernant le marché unique des produits pharmaceutiques, COM(98)588, p.6.

107. CE (1992).

108. Voir la contribution de la Commission européenne et Gatti (1996).

109. Voir Gatti (1996).

110 . Cette affaire concernait des produits pharmaceutiques non brevetés et généralement non remboursés, qu'on peut donc distinguer des produits pharmaceutiques proprement dits, sur lesquels est axée la présente étude.

111. DAFFE/CLP(99)24/12, “Rapport annuel sur les développements en matière de politique de la concurrence en Italie”, page 6. L’Autorité de la concurrence a également engagé des poursuites contre Byk Gulden Italia Spa et Istituto Gentili Spa, qui s’étaient entendus pour fixer les prix sur les marchés des médicaments destinés au traitement des infections de la gorge. Au Danemark, le Conseil de la concurrence s’est opposé à une collusion tacite entre des entreprises effectuant des importations parallèles. Voir DAFFE/CLP(99)23, “La politique de la concurrence dans les pays de l’OCDE en 1996-1997”.

112. Communiqué de presse de l’AGCM du 28 décembre 1999. Il convient également de mentionner que les sociétés pharmaceutiques cherchent souvent à conclure des accords de coentreprise, qui ont été passées au crible par les autorités responsables de la concurrence. Voir l’examen qu’en fait Gatti (1996).

113. DAFFE/CLP(99)23, “, “La politique de la concurrence dans les pays de l’OCDE en 1996-1997”.

114. DAFFE/CLP(98)2, “, “La politique de la concurrence dans les pays de l’OCDE”.

115. “Germans pursue price regulation plan” (Les Allemands mettent en œuvre un programme de réglementation des prix), European Regulatory Affairs News, avril 2000, page 10.

116. Ben-Asher (1999), page 29. Voir aussi Levy (1999), page 131. La question de la fusion Glaxo/Wellcome du point de vue de l’UE est traitée dans Gatti (1996).

117. Voir FTC (1999), page 11.

118. Cette question est examinée en détail dans Ben-Asher (1999).

119. Levy (1999), page 132.

120. DAFFE/CLP(98)2, “La politique de la concurrence dans les pays de l’OCDE”.

121. DAFFE/CLP(99)23, “ La politique de la concurrence dans les pays de l’OCDE en 1996-1997”.

122. FTC (1999), page 8.

123 . Pour plus de détails, voir la contribution de la France.

124. FTC (1999), page 8.

125. Voir FTC (1999), page 5

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ANNEXE

(Les tableaux reproduits ci-après proviennent de Jacobzone (2000))

Tableau A.1 : Médicaments non vendus sur ordonnance et médicaments en vente libre, 1996

	Consommation En $ US PPA 1996 par habitant		Part en pourcentage des médicaments non vendus sur ordonnance dans la consommation totale de médicaments	
Australie	131	**	50	*1
Autriche	31		12	
Belgique	57		19	
Canada	n.a.		29	***
République tchèque	40		17	
Finlande	27		13	
France	105		31	
Allemagne	103		35	
Hongrie	29		17	
Irlande	22		17	
Italie	32		11	
Japon	n.a.		23	***
Pays-Bas	30		15	
Norvège	13		7	
Portugal	33		12	
Espagne	33		15	
Suède	17		8	
Suisse	84		44	
Royaume-Uni	44		20	
États-Unis	110		32	
Moyenne OCDE	**52**		**21**	

Notes: Pour la plupart des pays, la définition correspond aux médicaments non vendus sur ordonnance. Pour les États-Unis, elle peut être un peu différente (médicaments en vente libre) en raison des caractéristiques spécifiques du marché (voir le graphique 2 et l'encadré 1 pour la définition du marché des produits pharmaceutiques).

(1) Le Danemark, la Grèce, l'Islande, la Corée, le Luxembourg, le Mexique, la Nouvelle-Zélande, la Pologne et la Turquie ne sont pas inclus car les données les concernant sont incomplètes.

(2) La moyenne non pondérée pour l'OCDE ne comprend pas ...

n.d.: non disponible, *Données interpolées, **données de 1995, ***données de 1994, ****données de 1993.

*1 Pour l'Australie, les données concernant la part de marché des médicaments vendus sur ordonnance a été calculée à partir d'une définition légèrement différente (médicaments en vente libre) et elles doivent donc être interprétées avec prudence.

Source des données: Eco-Santé OCDE, 1998.

Tableau A.2 : Listes des médicaments remboursables par les régimes d'assurance publics

Pays	Listes des médicaments	Observations
Australie	Oui	La liste est établie en fonction des besoins médicaux et du rapport coût-efficacité ; elle est mise à jour tous les trois mois.
Autriche	Oui	La liste est établie à partir de critères médicaux et économiques. Elle est mise à jour tous les trois mois pour tenir compte des changements d'ordre médical et de l'évolution du marché. Il existe une liste des médicaments remboursables sans autorisation préalable des caisses d'assurance maladie.
Belgique	Oui	La liste est mise à jour tous les mois.
Canada	Oui(1)	Les listes et les nomenclatures font partie des régimes d'assurance provinciaux. Les critères tiennent souvent compte de facteurs pharmacoéconomiques.
République tchèque	Oui	La liste générale des médicaments délivrés sur ordonnance est publiée par le ministère de la Santé.
Danemark	Oui	La liste est continuellement mise à jour.
Finlande	Oui	La liste est établie selon l'efficacité des médicaments. Elle est continuellement mise à jour.
France	Oui	La liste est établie en fonction de l'amélioration marginale du service de santé permise par le médicament et de la réduction des coûts des traitements médicaux. Sa mise à jour régulière pose des difficultés.
Allemagne	Oui(2)	La liste est établie selon des critères pharmacologiques.
Grèce	Oui	La liste a été adaptée et est entrée en vigueur en 1989-1990, mais les médecins continuent de prescrire des médicaments ne figurant pas sur la liste, en invoquant des dérogations. Depuis 1995, un comité national est responsable de l'adaptation de la liste pour toutes les caisses d'assurance et le régime national d'assurance maladie. En 1997, une liste positive a été introduite par l'IKA et étendue aux autres caisses d'assurance en 1998.
Hongrie	Oui	La liste est établie selon les symptômes et la fréquence de la maladie.
Italie	Oui	Une liste positive a été introduite en 1978 (Prontuario Terapeutico Nazionale). Des révisions importantes y ont été apportées et des médicaments en ont été retirés en 1994 et 1995. Certains produits ont été remis sur la liste en 1998 avec certaines conditions.
Japon	Oui	La liste est établie selon l'efficacité des médicaments.
Corée	Oui	La liste est établie en fonction de critères tels que la valeur thérapeutique des médicaments, le coût des traitements comparables et les prix en vigueur à l'étranger.
Luxembourg	Oui	La liste est mise à jour tous les mois.
Mexique	Oui	La liste est établie en fonction du traitement au moindre coût des maladies existantes. Elle est adaptée en fonction des progrès médicaux et des besoins de la population.
Pays-Bas	Oui	La liste est établie en fonction de l'efficacité. Elle est régulièrement mise à jour.
Nouvelle-Zélande	Oui(3)	
Norvège	Oui	La liste est établie selon le type de maladie et sa gravité. Elle est continuellement adaptée.

Tableau A.2 : Listes des médicaments remboursables par les régimes d'assurance publics (suite)

Pays	Listes des médicaments	Observations
Espagne	Oui[2]	La liste est établie selon des critères médicaux, la gravité et la durée de la maladie, l'utilisation thérapeutique et sociale des médicaments. Les critères socio-économiques comprennent l'emploi d'autres médicaments à plus bas prix et les contraintes financières des pouvoirs publics.
Suède	Les listes des médicaments recommandés sont établies par des conseils nationaux.	
Suisse	Oui	Les médicaments figurant sur la liste doivent être efficaces, efficients d'un point de vue économique et appropriés. La liste positive est mise à jour deux fois par an.
R.-U.	Oui	N/D
E.-U.	Oui (HMO, PBM)	N/A

(1) La plupart des provinces et territoires ont établi leur propre formulaire aux fins des régimes provinciaux. (2) Liste négative. (3) Liste des produits subventionnés uniquement, pour la fixation de prix de référence.
Source: Questionnaire de l'OCDE sur la gestion et la réglementation dans le secteur pharmaceutique, et diverses sources.

Tableau A.3. Participation aux coûts et politiques en matière de partage des frais par les patients dans les pays de l'OCDE

Pays	Différenciation	Méthode	Modifications	La réassurance aux fins de la participation d'un tiers aux coûts est-elle permise?	La réassurance compense-t-elle la participation aux coûts?
Australie	Selon le type de bénéficiaire	Montant fixe selon le type de bénéficiaire. Maximum de 11 dollars par ordonnance. Exemption pour les titulaires de cartes de privilèges, les personnes à faible revenu et les malades chroniques.	Modifications régulières conformément au budget fédéral.	Assurance privée, mais surtout pour les soins hospitaliers.	Généralement pas.
Autriche	Selon le type de bénéficiaire	Montant fixe de 5,43 schillings par traitement en 1998.	Ajustement en fonction de l'inflation	Non.	N/A
Belgique	Selon le type de médicament et de bénéficiaire	Les pourcentages dépendent de la tranche de revenu de la personne couverte et des personnes à sa charge (100/80/60/50 0 pour cent)	De nouvelles catégories ont été définies en 1980	Soins hospitaliers seulement pour les compagnies d'assurance à but non lucratif, l'assurance à but lucratif est autorisée.	N/D
Canada	Selon le type de médicament et de bénéficiaire	La plupart des provinces recourent à la fois à la participation aux coûts et à des franchises dans le cadre du système de partage des frais avec les bénéficiaires. Au total, 88 pour cent des Canadiens sont couverts, 62 pour cent par des régimes privés, 19 pour cent par des régimes provinciaux, et 7 pour cent par les deux types de régimes à la fois. La couverture est universelle en Alberta, en Colombie-Britannique, au Québec et en Saskatchewan.		Oui	N/A
République tchèque	Selon le type de médicament	N/D	Des modifications sont apportées presque chaque année pour tenir compte de l'évolution des prix des médicaments et du profil de consommation des médicaments.	Oui	N/D
Danemark	Selon le type de médicament et en partie selon le type de bénéficiaire	50,2 pour cent pour les médicaments ayant des effets thérapeutiques certains et utiles, 25,3 pour cent pour les médicaments servant au traitement de maladies bien définies et souvent dangereuses. Zéro pour cent pour les préparations d'insuline.	Oui, en janvier 1996, les taux de 50 et 25 pour cent ont été modifiés pour pouvoir financer le remboursement du traitement des maladies iatrogéniques. La règle relative à la participation de zéro pour cent aux frais des traitements à l'insuline est entrée en vigueur en janvier 1990.	Oui	Dans certains cas

Tableau A.3. : Participation aux coûts et politiques en matière de partage des frais par les patients dans les pays de l'OCDE (suite)

Pays	Différenciation	Méthode	Modifications	La réassurance aux fins de la participation d'un tiers aux coûts est-elle permise?	La réassurance compense-t-elle la participation aux coûts?
Finlande	Selon le type de médicament et de bénéficiaire	Franchise d'un montant fixe, mais différente pour chacune des trois catégories de remboursement. Participation aux coûts de 60 pour cent pour les frais supérieurs à 8 dollars. Le taux de participation aux coûts dépend aussi des catégories.	Le montant fixe de la franchise a été modifié à plusieurs reprises, et les catégories ont été redéfinies en 1986, 1992 et 1994.	Oui	Oui
France	Selon le type de médicament et de bénéficiaire	Pourcentage du prix du médicament, selon le type de médicament. Exemptions pour certains bénéficiaires. Ticket modérateur de 0/35/65 pour cent.	Le taux de remboursement a baissé plusieurs fois. La dernière diminution de 5 pour cent a eu lieu en 1993.	Oui	Oui, presque intégralement, cela est généralement le cas.
Allemagne	Selon le volume de l'ordonnance et selon le bénéficiaire	Loi de 1992. Depuis juillet 1997, la participation aux coûts est de 9/11/13 DM (5 à 7 dollars) en fonction de la taille et du dosage de la présentation (8/9/10 DM depuis janvier 1999); exemptions, par exemple, maladies chroniques. (Pour les médicaments dont le prix est fondé sur un prix de référence, les patients doivent aussi payer la différence entre le prix de référence et le prix réel effectif).	Oui, augmentation d'un DM à compter du 1er janvier 1997	Non	N/A
Grèce	Très partielle	Forfait de 25 pour cent de la valeur totale du médicament, mais de 10 pour cent seulement pour les femmes enceintes et de zéro pour cent pour les malades chroniques.	Avant 1992, le taux était de 10 à 15 pour cent. Il n'y a pas eu de changement depuis.	Oui	Non
Hongrie	Selon le type de médicament et de bénéficiaire	Un pourcentage du prix du médicament allant de zéro à 100 pour cent selon le type de médicament.	Oui, chaque année, selon le déficit.	Oui, pour les compagnies d'assurance à but non lucratif	N/D
Irlande	Selon le type de bénéficiaire	Les patients prenant de la monostéarine sont exemptés, maximum de 90 livres irlandaises par trimestre pour les patients de la catégorie II.		N/D	N/D

N/D: non disponible, N/A: non applicable. Les montants sont en dollars américains ou en monnaie nationale.
Source: Questionnaire de l'OCDE sur la gestion et la réglementation dans le secteur pharmaceutique, OCDE (1998) Politiques sociales et politiques de la santé, Études de la politique de la santé n°7, OMS (1997), European Series n° 72.

Tableau A. 3: Participation aux coûts et politiques en matière de partage des frais par les patients dans les pays de l'OCDE (suite)

Pays	Différenciation	Méthode	Modifications	La réassurance aux fins de la participation d'un tiers aux coûts est-elle permise?	La réassurance compense-t-elle la participation aux coûts?
Italie	Selon le type de médicament et de bénéficiaire	Frais d'ordonnance de 3 dollars plus un pourcentage du prix. Trois grandes catégories de médicaments (0, 50, 100 pour cent). Tendance à augmenter les frais d'ordonnance et à réduire la proportion des médicaments avec ticket modérateur (plus ou rien). Exemption en fonction du revenu, de l'âge et de l'état de santé.	Lancé en 1978. Révisé en 1983	N/D	N/D
Japon	Selon le type de bénéficiaire	Montant fixe. De zéro à près d'un dollar pour trois médicaments d'usage interne ou six médicaments d'usage externe. Règles spéciales pour les personnes âgées et certaines maladies. Exemptions pour les personnes âgées, les enfants et les personnes à faible revenu.	1984. Participation additionnelle du patient en 1997, mais avec certaines exemptions.	Non	N/A
Corée	Ni selon le type de bénéficiaire ni selon le volume de l'ordonnance	Pourcentage différent de la participation aux coûts selon le type de traitement médical : patients internes : 20 pour cent; patients externes : pharmacies: 40 pour cent, cliniques locales: 30 pour cent, hôpitaux: 40 pour cent, hôpital général: 55 pour cent.	Non	Oui	Oui
Luxembourg	Selon le type de médicament et de bénéficiaire	Selon trois types de médicaments (0, 20, 60 et 100 pour cent). Le taux normal de participation aux coûts est de 20 pour cent pour la majorité des médicaments. Les produits pharmaceutiques sont intégralement remboursés pour les patients internes.	Oui, en 1994 pour des raisons de compression des coûts/budgétaires.	Oui	N/D
Mexique	Selon le volume de l'ordonnance et le bénéficiaire	Assurance publique: la participation aux coûts dépend du revenu et de la région géorgraphique/rurale. Les régimes d'assurance privés possèdent leurs propres systèmes de participation aux coûts.	Non	Oui	Oui

N/D: non disponible, N/A: non applicable. Les montants sont en dollars américains ou en monnaie nationale.
Source: Questionnaire de l'OCDE sur la gestion et la réglementation dans le secteur pharmaceutique, OCDE (1998) Politiques sociales et politiques de la santé, Études de la politique de santé n°7, OMS (1997), European Series n° 72.

Tableau A. 3: Participation aux coûts et politiques en matière de partage des frais par les patients dans les pays de l'OCDE (suite)

Pays	Différenciation	Méthode	Modification	La réassurance aux fins de la participation d'un tiers aux coûts est-elle permise?	La réassurance compense-t-elle la participation aux coûts?
Pays-Bas	Non	Taux de participation aux coûts de 20 pour cent et plafonnement du montant annuel total de la participation (67 dollars). Plafond annuel de l'excédent de pertes indexé sur le revenu.	Non. Cette politique est très récente	Oui	N/D
Nouvelle-Zélande	Selon le type de bénéficiaire	Assurance partielle pour les personnes les plus démunies après évaluation des besoins. Différence entre le prix réel et le prix de référence, et participation aux coûts de 2 à 8 dollars	Des exemptions pour les enfants ont été ajoutées.	Oui	Non
Norvège	Selon le type de bénéficiaire	Participation aux coûts de 50 pour cent. Exemption pour les enfants et les personnes âgées. Maximum de 43 dollars par ordonnance.	Non	Oui	N/D
Portugal	Selon le type de bénéficiaire	0/30/60% du prix, taux réduits pour les personnes à faible revenu.			
Espagne	Selon le type de médicament et de type de bénéficiaire	Selon le prix du médicament, Zéro ou 40 pour cent. Exemptions pour les retraités et les malades chroniques.	Modifié à six reprises	Non	Oui
Suède	Selon le volume de l'ordonnance et le bénéficiaire	Montant fixe, 160 couronnes pour le premier produit et 60 couronnes pour les produits suivants. Pourcentage du coût. Plafond de 1 800 couronnes sur 12 mois, montant par produits prescrit.	Oui, depuis 1968, la participation aux coûts a changé 15 fois. Le dernier changement a eu lieu en 1995.	Oui	Oui
Suisse	En partie selon le bénéficiaire	Franchise de 230 francs suisses, plus 10 pour cent des coûts avec un plafond annuel de 600 francs suisses pour l'excédent de pertes. Exemption pour les enfants.	Loi de 1994 sur l'assurance maladie. Les taux de la franchises et de la participations aux coûts ont été relevés en 1995.	Non	N/A
Turquie	Selon le type de bénéficiaire	10% pour les retraités, 20% pour les personnes actives		Non connu	N/D
R.-U.	Selon le type de bénéficiaire	Forfait fixe, actuellement de 5.5 livres par ordonnance. Nombreuses exemptions(1)	Le forfait fixe est réévalué chaque année. Il a été majoré en termes réels au cours des années 80.	Non connu	N/D
E.-U.	N/A	Les médicaments ne sont par pris en charge par Medicare mais ils peuvent l'être par les HMO. La plupart des régimes d'assurance privés prévoient une participation aux coûts. 60% du prix de vente au détail payé par des tiers pour certaines personnes exemptées. Frais fixes par ordonnance dans les HMO, participations aux coûts et franchise dans les régimes Fee For Service Plans, Medicaid prend en charge certains médicaments.			

(1) En 1995, des frais d'ordonnance étaient exigés pour 16 pour cent du nombre total d'ordonnances, et pour 22 pour cent de la valeur du nombre total d'ordonnances.
N/D: non disponible, N/A: non applicable. Les montants sont en dollars américains ou en monnaie nationale.
Source: Questionnaire de l'OCDE sur la gestion et la réglementation dans le secteur pharmaceutique, OCDE (1998) Politiques sociales et politiques de la santé, Études de la politique de santé n°7, OMS (1997), European Series n° 72.

Tableau A.4: Lignes directrices concernant la prescription

Pays	Lignes directrices	Observations	Pénalités possibles
Australie	Oui	Lignes directrices indicatives, dont un bulletin adressé aux prescripteurs, et rapport aux prescripteurs sur leur situation par rapport à la moyenne. Lignes directrices des Etats également.	Non
Autriche	Oui	Les lignes directrices s'appliquent à l'ensemble des traitements médicaux possibles.	Oui, les obligations contractuelles prévoient des remboursements ou la résiliation des contrats.
Canada	Pas au niveau fédéral, mais dans la plupart des provinces	La plupart des provinces ont adopté des lignes directrices pour la pratique clinique, notamment pour la prescription.	N/D
France	Oui	Il existe des lignes directrices de référence négatives d'application obligatoire pour certains médicaments.	Oui, en principe, il existe des sanctions pécuniaires et contractuelles.
Allemagne	Oui	En fait, l'ordonnance du médecin est examiné ex post par les caisses d'assurance maladie.	Oui, les ordonnances sont examinées par les caisses d'assurance maladie.
Grèce	Oui	Les médecins de l'IKA doivent s'en tenir à la liste des médicaments et ils font l'objet d'un examen ex post pour repérer les médecins qui prescrivent trop de médicaments.	Oui, le conseil d'administration et le gouverneur de l'IKA imposent chaque année des amendes aux médecins qui prescrivent trop de médicaments et il arrive à l'occasion qu'ils en congédient.
Hongrie	Oui	Il existe des protocoles thérapeutiques pour le traitement des maladies les plus courantes. Ces protocoles recommandent des médicaments efficaces et peu onéreux.	Oui, des sanctions pécuniaires sont imposées par l'administration de la caisse d'assurance.
Japon	Oui	Il existe des lignes directrices pour le traitement de l'hypertension chez les personnes âgées.	Non
Corée	Oui	L'assurance médicale publie des lignes directrices pour restreindre le recours à des traitements ayant une efficacité limitée.	Non
Luxembourg	Oui	Une "liste de transparence" et des lignes directrices médicales négatives d'application obligatoire, inspirées du modèle français.	Oui, en principe. Des dignes directrices et des règlements R.M.O. sont en cours d'élaboration. Inspirés du modèle français.
Mexique	Oui	Des guides diagnostiques thérapeutiques sont distribués aux médecins.	Non
Pays-Bas	Oui	Des lignes directrices s'adressent tant aux généralistes qu'aux spécialistes. Un réseau national de 650 groupes locaux participe à la consultation pharmacothérapeutique.	Non, utilisées surtout par les assureurs à titre de rétroaction.
Nouvelle-Zélande	Oui	Des informations sont diffusées aux médecins par l'agence du médicament.	Non

Tableau A.4: Lignes directrices concernant la prescription (suite)

Pays	Lignes directrices	Observations	Pénalités possibles
Norvège	Oui	Il existe des lignes directrices générales.	Non
Suède	Oui	Des informations sont diffusées aux médecins prescripteurs (lignes directrices pour onze maladies courantes).	Non
R.-U.	Oui	Des conseils sont donnés à un grand nombre de praticiens conformément à la politique visant l'efficacité clinique et l'efficacité des coûts. L'ordre professionnel concerné publie aussi des avis à l'intention de ses membres. Un système de prescription assistée par ordinateur actuellement à l'essai au NHS devrait fournir des renseignements détaillés en matière de coût-efficacité.	Non
E.-U,	Oui	Diverses publications s'adressent aux médecins Des lignes directrices sont établies par des organismes de soins coordonnés.	Oui, selon le type de système de gestion des soins en place.

Au moment où le questionnaire a été établi, aucune donnée n'était disponible pour l'Espagne. La Belgique, la République tchèque, le Danemark, la Finlande, l'Espagne, la Suisse et la Turquie n'ont pas rapporté l'existence de lignes directrices. Il existe toutefois dans ces pays d'autres types d'incitations pour prescrire des médicaments moins onéreux.
Source: Questionnaire de l'OCDE sur la gestion et la réglementation dans le secteur pharmaceutique, et diverses sources.

Tableau A.5 : Budgets fixes, limitation directe du volume et des dépenses

Pays	Budgets fixes Objectifs globaux en matière de volume	Certains types de contrôle individuel, par médecin, par affection ou par jour	Observations
Autriche	Non	Oui, par affection	Limitation du volume pour chaque médicament et par affection
Belgique	Oui, Objectif indicatif global	Oui, diverses limitations, par affection, par médecin, ou par jour, mais uniquement pour les spécialités coûteuses.	Des limitations pour les spécialités coûteuses s'appliquent par jour et par affection, pour ce qui est de la durée du traitement et de la posologie. Ces spécialités représentent 30 pour cent des dépenses annuelles et elles sont contrôlées par les conseillers médicaux de la mutuelle d'assurance maladie.
Canada	Non	Oui, jours-médicaments par ordonnance	Certaines provinces limitent les jours-médicaments par ordonnance. Souvent, la limite est de l'ordre de 30 jours pour les médicaments épisodiques et de 100 jours pour les médicaments d'entretien. Les médecins sont toutefois en mesure d'accorder des renouvellements automatiques par écrit, ce qui permet au patient de renouveler ses médicaments sans avoir besoin d'une nouvelle ordonnance.
France	Oui, depuis 1996	Oui, il existe des lignes directrices pour des médicaments spécifiques	L'objectif national pour les dépenses d'assurance maladie (ONDAM) comprend un objectif de remboursement des prescriptions de produits pharmaceutiques. En outre, des accords triennaux sont signés avec les sociétés pharmaceutiques et prévoient des objectifs de dépenses. Les sociétés pharmaceutiques sont plus lourdement taxées en cas de dépassement des objectifs. Un contrôle assez limité s'applique aux prescriptions, sauf pour les médicaments spécifiques visés par les lignes directrices.
Allemagne	Oui	N/D	Il existe au niveau national des budgets globaux, qui sont traduits en objectifs par prescription pour les médecins dans chaque région. Il existe des "contrats" entre les caisses d'assurance maladie et les associations de médecins.
Grèce	Oui, mais seulement pour la principale caisse d'assurance sociale.	Oui, par jour, par médecin	Pour la caisse d'assurance sociale de l'IKA, qui représente 50 pour cent des personnes assurées. La moyenne arithmétique de toutes les ordonnances.
Hongrie	Non	Oui	Volume prescrit dans le temps. Les médecins peuvent prescrire des produits pharmaceutiques pour une période de 30 jours seulement.
Italie	Oui, créé en 1994, entré en vigueur en 1996	Oui, pour les patients exemptés.	Des médicaments ont été retirés de la liste en 1996 pour éviter des dépassements de budget. Pour les patients exemptés, limite de 16 ordonnances au plus, introduite par voie de législation en 1992, abolie en 1993 et réintroduite en 1994. Remboursement adopté en 1998 : en cas de dépassement du budget global, 60 pour cent du déficit est à la charge de l'industrie et des distributeurs. Depuis la réforme, il existe des plafonds de dépenses pour les généralistes.
Mexique	Oui	N/D	Des plafonds des dépenses pharmaceutiques sont fixés chaque année pour chaque unité médicale. Une fois le budget annuel global de la santé arrêté, une certaine proportion est affectée aux dépenses pharmaceutiques en fonction de l'historique des dépenses et des hausses de prix attendues.
Pays-Bas	Non	Oui, certaines limites par affection	L'ordonnance ne doit pas porter sur plus de 3 mois (sauf pour certaines classes de médicaments).

Tableau A.5 : Budgets fixes, limitation directe du volume et des dépenses (suite)

Pays	Budgets fixes Objectifs globaux en matière de volume	Certains types de contrôle individuel, par médecin, par affection ou par jour	Observations
Nouvelle-Zélande	Non	Oui, certaines limites par affection	1. Volume mensuel (limites de dispensiation), L'ordonnance porte sur 3 mois au plus. 2. Dosage et durée de l'administration pour certains produits pharmaceutiques. L'Agence du médicament, PHARMAC, négocie avec les sociétés pharmaceutiques selon les critères établis par le gouvernement.
Suisse	Non	Oui, certains contrôles du volume par affection pour des classes thérapeutiques spécifiques de la liste des spécialités. Certains contrôles des dépenses par jour et par affection.	Selon le nombre de conditionnements ou de points sur trois mois.
R.-U.	Oui, à un niveau décentralisé par médecin (1991)		Les généralistes peuvent devenir des gestionnaires de budgets et obtiennent un budget portant sur certains soins non urgents et sur les prescriptions également. Les généralistes non responsables de la gestion d'un budget (la minorité) ont obtenu des budgets indicatifs pour les prescriptions. Tous les médecins doivent dorénavant participer à une forme quelconque de gestion de budgets à l'intérieur des groupes de soins primaires.

Les pays mentionnés ci-après n'ont pas rapporté de contrôle officiel du volume des ordonnances ni de limitation spécifique des dépenses par jour, par affection ou par médecin. Cela ne veut pas nécessairement dire que de fortes pressions ne soient pas exercées pour encourager les médecins à faire preuve de rigueur dans la prescription. Ces pays sont l'Australie, la République tchèque, le Danemark et la Finlande, le Japon (sauf pour certains objectifs de dépenses), la Corée, le Luxembourg (sauf pour des médicaments exceptionnels comme le Sumatriptan), la Norvège, l'Espagne, la Suède, la Turquie, les États-Unis (sauf pour des agences relevant de Medicaid dans certains États). Aucune donnée n'était disponible pour l'Irlande, mais des budgets de médicaments affectés à des médecins sont signalés dans ce pays.

Source: Questionnaire de l'OCDE sur la gestion et la réglementation dans le secteur pharmaceutique, et diverses sources.

Tableau A.6: Prescription de génériques

Pays	Politique officielle	Type d'incitations	Observations
Australie	Oui	Sensibilisation du consommateur et incitations financières	Coût à la charge du patient si le prix est supérieur à celui des génériques. (Proche du système de fixation de prix de référence.)
Autriche	Oui	Lignes directrices concernant la prescription à l'intention des médecins	Les médecins sont régulièrement informés de la liste des médicaments génériques à bas prix.
Canada	Oui, sauf dans une province		La solution la moins coûteuse : dans le cas des médicaments pour lesquels il existe des génériques, les taux de remboursement sont fondés sur le coût du bio-équivalent le moins coûteux. Dans certaines provinces, les pharmaciens peuvent substituer des génériques à condition que le médecin n'ait pas donné d'instruction spécifique à l'effet contraire.
République tchèque	Oui	Information	Les génériques sont inclus dans la liste générale des médicaments pouvant être prescrits, mais les médecins ne sont pas suffisamment encouragés à les prescrire.
Danemark	Oui	N/D	Le système de prescription de génériques, ou système "G", a été lancé en novembre 1991 et inclut la plupart des produits pharmaceutiques pour lesquels il existe des médicaments similaires. Lorsqu'un médecin prescrit un médicament visé par le système G, il peut écrire un "G" sur l'ordonnance pour indiquer au pharmacien que l'ordonnance devrait être exécutée au moyen d'un générique, sauf si le consommateur s'y oppose.
Finlande	Oui	Aucune incitation explicite	Depuis mars 1996, les prescripteurs peuvent prescrire des génériques. Les pharmaciens doivent alors fournir le produit le moins cher.
France	Oui	Budgets globaux pour les prescriptions des médecins, informations destinées aux médecins	La mise en place d'incitations plus efficaces pour la prescription de génériques est envisagée dans les grands plans d'action présentés par le Ministère des affaires sociales.
Allemagne	Oui	Budgets globaux pour les médecins et lignes directrices concernant la prescription à l'intention des médecins.	
Grèce	Oui	N/D	La politique mise en œuvre comportait une réduction de prix de 14 pour cent pour tous les génériques pouvant être substitués à des médicaments de marque déposée similaires.
Hongrie	Oui	Contraintes budgétaires, lignes directrices concernant la prescription et sensibilisation des consommateurs	
Italie	Oui		Introduite dans la législation italienne en 1996. Marché négligeable.
Mexique	Oui	Contraintes budgétaires, lignes directrices concernant la prescription, sensibilisation des consommateurs et initiatives du côté des fabricants	
Pays-Bas	Oui	Certaines contraintes budgétaires, lignes directrices concernant la prescription et sensibilisation des consommateurs	Pour encourager la délivrance de génériques, les pharmaciens peuvent partager une partie des économies qu'elle génère et ils reçoivent une fraction (actuellement 33,3 pour cent) de la différence de prix, si le prix du produit vendu est moins élevé que le "prix de référence" du groupe de médicaments considéré.
Nouvelle-Zélande	Oui	Lignes directrices concernant la prescription, sensibilisation des consommateurs et incitations économiques	Le consommateur doit payer la différence de prix entre le produit générique et le produit de marque déposée si ce dernier est choisi

Tableau A.6: Prescription de génériques (suite)

Pays	Politique officielle	Type d'incitations	Observations
Norvège	Oui	Contraintes budgétaires et lignes directrices à l'intention des médecins	Les médecins doivent tenir compte des considérations économiques lorsqu'ils prescrivent des médicaments et prescrire le produit le moins cher.
Suède	Oui	Lignes directrices concernant la prescription	
Suisse	Oui	Lignes directrices concernant la prescription et sensibilisation du consommateur	Il existe des incitations juridiques pour prescrire des génériques (article 52, alinéa 1 de la loi sur l'assurance maladie), qui doivent coûter 25 pour cent de moins, mais les incitations économiques offertes aux médecins et aux pharmaciens ne sont pas suffisantes. Les pharmaciens auront le droit de substituer des génériques à compter de 2000.
R.-U.	Oui	Incitations pour les généralistes responsables de la gestion d'un budget et lignes directrices concernant la prescription. Depuis 1985, un certain nombre de médicaments d'usage courant ont été exclus du remboursement par le NHS (sauf sous leur forme générique).	Possibilité de prescriiption de génériques.
E.-U.	Oui	Lignes directrices concernant la prescription et sensibilisation du consommateur	Dans le secteur privé, la plupart des régimes d'assurance stipulent l'emploi de génériques plutôt que de médicaments de marque déposée.

Les génériques sont pratiquement absents en Belgique, 36 spécialités génériques seulement étant disponibles. Le Japon, la Corée, le Luxembourg et la Turquie n'avaient pas de politique clairement établie pour les génériques au moment de l'étude. Il n'y avait pas non plus de politique clairement établie en Espagne, mis des modifications de la législation étaient envisagées.
Source: Questionnaire de l'OCDE sur la gestion et la réglementation dans le secteur pharmaceutique, et diverses sources.

Tableau A.7: Contrôle des prix

Pays	Mesure de contrôle	Entrée en vigueur	Facteurs pris en considérations pour fixer le prix				Observations
			Valeur thérapeutique du médicament	Coût des traitements comparables	Contribution de l'industrie pharmaceutique à l'économie	Prix dans les autres pays	
Australie	Oui	1951/1986	OUI	OUI	OUI	OUI	Divers critères de référence sont utilisés pour fixer les taux de remboursement et les prix : 48 pour cent du marché sont concernés. Les prix sont fixés en fonction du volume et du rapport coût-efficacité. Le niveau des prix dépend de l'autorisation de mise sur le marché, et il existe des lignes directrices économiques.
Autriche	Oui	1976				OUI	Voir Öbig 1998.
Belgique	Oui	1963/1995-	OUI	OUI	OUI	OUI	Coûts de distribution et de fabrication.
Canada	X[4]	1987		OUI		OUI	Pour les médicaments brevetés uniquement (prélèvement du CEPMB). Les prix dépendent du rapport coût-efficacité.
République tchèque	Mixte	1992[1]/1995	OUI	OUI		OUI	Pour les producteurs et pour les importateurs. Les producteurs nationaux doivent présenter leur formule de coûts de production; et les importateurs leur liste de prix..
Finlande	Oui	1968-1993 [2] 1994-[3]	OUI	OUI		OUI	Arbitrage entre coût des traitements, coûts de fabrication et coûts de la R-D par rapport aux fonds disponibles pour les remboursements..
France	Oui	1945	OUI	OUI		OUI	Depuis 1994, négociation conjointe sur les volumes. Valeur de l'innovation.
Grèce	Oui	≅1978				OUI	Médicaments importés : le moins élevé des trois plus bas prix de l'UE. Médicaments nationaux : le prix de chaque produit est fondé sur les coûts et pondéré par un indice des prix internationaux..
Hongrie	Mixte	1990	OUI	OUI	OUI	OUI	Négociation des prix entre les fabricants et l'organe responsable de l'assurance santé publique. Incidence de la dévaluation de la monnaie et de divers prélèvements prise en compte. Alignement sur les prix en vigueur en Espagne, en France, en Grèce et en République tchèque.
Italie	Oui/mixte	1978, 1995 ref.				OUI	Avant 1995, les prix étaient fondés sur les coûts, par la suite "prix libres" fondés sur la moyenne des prix européens. Prix négociés depuis pour les produits novateurs.
Japon	Oui	1950	OUI	OUI		OUI	Moyenne pondérée des prix auxquels sont commercialisés les produits de marque déposée sous toutes les formes de présentation existantes.
Corée	Oui	1977	OUI	OUI	OUI	OUI	
Luxembourg	Oui	1964				OUI	Alignement sur le prix en vigueur dans le pays d'origine (Belgique, France, Allemagne et Suisse)
Mexique	Oui	1993				OUI	Formule automatique prenant en compte les coûts d'exploitation de l'entreprise. 50 pour cent des produits sont vendus librement dans le secteur privé. Dans le secteur public, liste de base des médicaments et soumissions concurrentielles des entreprises..
Pays-Bas	Mixte	1996				Oui	Depuis 1996, il existe des prix maximums autorisés.
Norvège	Mixte	toujours/1993	OUI	OUI		OUI	Remboursement à un taux spécifique fondé sur le prix des génériques, et majoration de 5 pour cent en 1993. Coûts de la R-D et coûts de fabrication.

Tableau A.7: Contrôle des prix (suite)

Espagne	Oui	Inconnu	OUI	OUI	OUI	OUI	
Suède	Mixte	1993	OUI	OUI		OUI	Négociations directes avec l'organe pharmaceutique public central (Apoteksbolaget) jusqu'en1993 et avec l'Office national d'assurance sociale depuis 1993. Système partiel de prix de référence en 1993.
Suisse	Oui	1962	OUI	OUI		OUI	Le prix public englobe le prix du fabricant, les marges de distribution et la TVA. Révision des prix en 1995 pour les produits anciens, comparaisons avec d'autres pays.
Turquie	Oui	1928	OUI	OUI	OUI	OUI	Coûts réels de fabrication.

Par "mixte", il faut entendre que la mesure de contrôle peut s'appliquer en partie seulement au marché des médicaments vendus sur ordonnance. L'Allemagne, le Danemark, les Pays-Bas et les États-Unis ont très peu, voire aucune mesure de contrôle. Au Royaume-Uni, il est tenu compte des prix dans les négociations entre les autorités responsables du NHS et les fabricants. Outre l'objectif général de contrôle des bénéfices, il est également tenu compte dans ce pays des prix à l'étranger et de la contribution de l'industrie pharmaceutique à l'économie. De plus, les prix n'ont pas été rajustés en fonction de l'inflation pendant les années de forte inflation. En Allemagne, des réductions de prix ont aussi été appliquées (voir le tableau 14). (1) Il existait aussi des mesures de contrôle des prix en Tchécoslovaquie avant 1992. (3) Depuis 1994, les prix n'étaient négociés qu'avec les sociétés qui voulaient que leurs produits soient inclus dans le programme national de remboursement des médicaments. (2) Contrôle direct des prix de tous les médicaments. (4) La politique relative à l'industrie pharmaceutique relève de la compétence des provinces. Un système de fixation de prix de référence est en vigueur en Colombie-Britannique. Il existe des contrôles des prix des médicaments brevetés dans toutes les provinces. Au Royaume-Uni, les prix des médicaments existants ne peuvent être majorés, mais le prix des nouveaux produits est fixé en tenant compte des contraintes en matière de bénéfices.

Source: Questionnaire de l'OCDE sur la gestion et la réglementation dans le secteur pharmaceutique, et diverses sources.

Tableau A. 8 : Contrôle des bénéfices

Pays	Contrôle des bénéfices	Date	Méthode
République tchèque	Des producteurs nationaux	1992	30 pour cent de bénéfices pour les producteurs nationaux, marge de 35 pour cent pour les pharmaciens et les distributeurs.
Corée	Oui	1997	Détermination du plafond ou de la fourchette dans le cadre des négociations tenues avec l'institut agréé par les pouvoirs publics. Par exemple, centre coréen de productivité, etc.
Mexique	Oui	1993	Coûts d'exploitation de chaque entreprise. Il existe une formule automatique qui prend en compte les coûts d'exploitation de chaque entreprise et, conformément à la politique publique en matière de fixation des prix, les hausses de prix sont plafonnées.
Espagne	Oui	N/D	Les prix sont fondés sur le "coût". Inclut un plafond pour les dépenses promotionnelles (12 à 14 pour cent du prix de détail).
Turquie	Oui	1984	15% de bénéfices annuels, compte tenu du bénéfice annuel net
R.-U.	Oui(1).	1957(2)	L'objectif pour le taux de rendement a été fixé à 17-21 pour cent du capital utilisé, sous réserve d'une marge de tolérance de 25 pour cent et d'un système d'allocations telles que l'allocation pour la R-D. Inclut un plafond pour les dépenses promotionnelles.

(1) Le Pharmaceutical Price Regulation Scheme (PPRS) au Royaume-Uni est un programme de contrôle des bénéfices. Les objectifs généraux du système ont été énoncés dans l'accord de 1993 : 1. faire en sorte que des médicaments efficaces soient vendus au NHS à des prix raisonnables; 2. promouvoir au Royaume-Uni une industrie solide et rentable en mesure d'effectuer des dépenses de recherche et développement qui devraient lui permettre à l'avenir de mettre au point des médicaments nouveaux et améliorés; 3. encourager au Royaume-Uni le développement et l'offre de médicaments efficients et concurrentiels pour approvisionner les marchés des produits pharmaceutiques national et étrangers.

(2) Le programme a été renégocié périodiquement depuis. D'autres analystes estiment qu'il remonte à 1969. Négocié la dernière fois en 1993 pour une période de 5 ans.

Source: Questionnaire de l'OCDE sur la gestion et la réglementation dans le secteur pharmaceutique, et diverses sources.

Tableau A.9 : Gels et mesures de réduction des prix dans certains pays

Pays	Gel des prix	Date	Méthode/Ampleur	Observations
Autriche	Oui	1997	Réduction des prix, accord entre la caisse d'assurance sociale et l'industrie pour réduire les prix des fabricants.	
Belgique	Oui	1993, 1996, 1997	Gel des prix à leur niveau du 1er janvier 1993 ou 1996 et réduction de prix de 2 pour cent en juin 1996.	Une consultation générale a eu lieu avec l'industrie pharmaceutique, les associations médicales, les mutuelles d'assurance, les syndicats, etc…
Canada	Pas au niveau fédéral, mais dans deux provinces	N/D	Ces deux provinces ont soit réduit ou gelé les prix des médicaments pour leurs programmes d'assurance, ce qui revient à contrôler les taux de remboursement et pas les prix réels.	
République tchèque	Oui, mais n'a pas été appliqué	N/D	Le Ministre des finances fixe les prix maximums.	Les prix maximums sont réévalués chaque année et peuvent être légèrement sous-réévalués. Si dans l'ensemble l'effet risque d'être plutôt limité, au niveau individuel, les variations peuvent être plus prononcées.
Danemark	Oui	De 1994 à 1997	Gel des prix de janvier 1994 au 1er avril 1995. Réductions de prix en avril 1995 et gel des prix jusqu'en avril 1997.	Entre avril 1995 et avril 1997, accord avec l'industrie pharmaceutique. Établissement d'un objectif de réduction des dépenses pharmaceutiques publiques dans le budget de l'État. Selon l'accord, réduction générale des prix de 5 pour cent pour les médicaments vendus sur ordonnance et pris en charge. Les prix des médicaments vendus sur ordonnance et non pris en charge et des médicaments en vente libre ont été abaissés de 2 pour cent.
France	Implicite		Les prix peuvent être sous-réévalués lors des changements effectués chaque année.	L'effet s'est davantage fait sentir les années de forte inflation, au début des années 80.
Allemagne	Oui	En 1993 pour 2 ans	Réduction de 5 pour cent pour les médicaments vendus sur ordonnance et de 2 pour cent pour les médicaments en vente libre.	Processus de consultation.
Grèce	Oui	Plusieurs fois	Gel des prix	Processus de consultation.
Italie	Oui	1995, 1996	Réduction des prix de 2,5 pour cent en 1995, gel des prix en 1996.	
Corée	Oui	1977		Processus de consultation.

Tableau A.9 : Gels et mesures de réduction des prix dans certains pays (suite)

Pays	Gel des prix	Date	Méthode/Ampleur	Observations
Luxembourg	Oui	N/D	Réduction des prix appliquées dans les pays voisins mises en œuvre au Luxembourg.	
Pays-Bas	Oui	1994		Négociations avec l'industrie pharmaceutique.
Espagne	Oui	1993	Réduction de prix de 3 pour cent pour 3 ans.	Consultation de l'industrie pharmaceutique.
Suisse	Oui	1992-96, 1997	1992-96, gel des prix des produits figurant sur la liste des spécialités. À compter de 1997, nouvelle loi sur l'assurance maladie.	
R.-U.	Oui	Oct. 93	Réduction de prix de 2,5 pour cent au moment de la renégociation du Pharmaceutical Price Regulation Scheme en 1993.	Consultation de l'industrie pharmaceutique, les sociétés pouvaient appliquer la méthode de leur choix pour que la réduction de prix soit en moyenne de 2,5 pour cent. (Elles pouvaient aussi décider de restituer leurs bénéfices.)

L'Australie, l'Autriche, la Finlande, la Hongrie, le Japon, le Mexique, la Nouvelle-Zélande (sauf pour ce qui est des effets connexes de la fixation de prix de référence), la Norvège, la Suède, la Turquie et les États-Unis n'ont pas rapporté de réductions ou de gel des prix. N/D : non disponible. **Source:** Questionnaire de l'OCDE sur la gestion et la réglementation dans le secteur pharmaceutique, et diverses sources.

AUSTRALIA

1. Introduction

Australia operates a national Pharmaceutical Benefits Scheme (PBS) to provide timely, reliable and affordable access for the community to necessary and cost effective pharmaceuticals. Considerable subsidies are paid for pharmaceuticals covered by the PBS[1].

Approximately 90 percent of prescriptions in the Australian pharmaceutical market are prescribed for PBS items. For the twelve months ended 30 June 1999, the total cost of the PBS was $A3.7 billion of which $A3.1 billion was covered by the Government.

- Australian consumers pay a maximum of $A20.60 ($A3.30 for concession holders) for each item listed on the PBS[2]. Safety Net limits benefit chronically ill or those less able to afford medications[3].

- This scheme has been in operation in Australia for more than 50 years and currently covers about 560 drug substances available in about 1 350 forms and strengths and marketed as about 2 000 different brands.

- The terms for remunerating pharmacists dispensing benefits under the PBS are set out in an agreement between the Government and the pharmacy trade association, the main elements being a dispensing fee[4] and product mark-up[5].

Demand for pharmaceutical products in Australia is heavily influenced by the PBS subsidy and pharmaceutical sponsors therefore are keen for their products to be listed on the PBS to generate sales.

Pharmaceuticals listed under the PBS fall into three broad categories:

- unrestricted – These medications have no restrictions on their therapeutic uses;

- restricted Benefit – The listing in the PBS Schedule details the specific therapeutic uses for which these medications can be prescribed; and

- authority Required Benefit – As with the Restricted Benefit, the Schedule lists the specific uses for which these medications can be prescribed. In addition, for items listed under this category, the prescribe is required to obtain prior approval from the Government's Health Insurance Commission.

Regulatory procedures aim to ensure that the quality, safety and efficacy of therapeutic goods available in Australia are of acceptable standard, equal to that of comparable countries. Overall control of the supply of medicinal drugs in Australia is exerted through three main processes:

- the pre-market evaluation and approval of products intended for supply in Australia;
- the licensing of manufacturers; and
- post market surveillance.

2. The pharmaceutical industry: market structure

The Australian pharmaceutical sector is a high technology and knowledge-intensive industry with significant investment in plant. It sits beside the telecommunications industry as the fastest growing and most research-intensive sector of Australian manufacturing.

The Australian industry comprises 120 firms employing over 11 500 people. It spent $A254 million on research and development (R&D) in 1998. Industry statistics[6] indicate a $A6.04 billion turnover in 1998–99, with exports valued at $A1.2 billion and an exports to imports ratio of 41.9 percent.

In 1998 the top 20 firms accounted for 74 percent of sales in the $A3.4 billion prescription and pharmacist-only medicine market[7]. No firm has a market share in excess of nine percent. Details of those firms and of the top 20 products sold are provided in Annex 1.

2.1 Co-operation for R&D or marketing

A 1996 survey of 14 firms revealed a well-developed network of R&D collaborations. In these firms alone, 571 relationships were identified involving 261 different organisations[8].

2.2 Associations and political importance

There are a number of industry associations, which are listed in Annex 2. These associations and the Australian Government enter into effective Government/Industry dialogue on pharmaceutical industry matters.

3. Regulation of supply

3.1 Protection of intellectual property rights

Australia is a signatory to TRIPS and Australia's patents law provides for 20 year patents. In addition, the *Intellectual Property Laws Amendment Act 1998*[9] provides for extensions of up to five years for standard twenty year pharmaceutical patents in Australia[10]. The Act also provides for 'spring boarding'[11] activities, to allow manufacturers of generic drugs to undertake approved activities to meet pre-marketing regulatory approval requirements once an extension on a patent has been granted. An extended patent is not infringed by a person obtaining regulatory approval to have goods registered for therapeutic use under a law of a foreign country.

3.2 New drug approvals

A flow chart of the approval process for registration of prescription pharmaceuticals in the *Australian Register of Therapeutic Goods* is set out as Annex 3.

3.3 Trade regulation

There are no specific barriers to the importation of pharmaceuticals which meet regulatory requirements. Likewise overseas firms which wish to manufacture in Australia are generally free to do so, as evidenced by the number of overseas-controlled firms operating.

There are also no restrictions on the international trade in drugs by third parties.

At least two Internet sites operate in Australia for dispensing of Australian prescriptions domestically to consumers. Under the personal import scheme, individuals can legally import most medicines for personal use[12].

There is no substantive difference in regulatory treatment between domestic and foreign firms submitting pharmaceuticals for approval or inclusion on the PBS (where the criterion is value for money).

3.4 Industrial policy

The Pharmaceutical Industry Investment Program (PIIP) commenced on 1 July 1999 and will run for five years. This $A300 million program compensates, in part, for the impact on activity from the Government exercising its monopsony purchasing power under the PBS and aims to stimulate investment in pharmaceutical activity by both domestic and multinational companies.

Nine companies are currently participating in the PIIP and each will earn price increases for nominated products listed on the PBS by meeting commitments to increase production value added, R&D and other internationally competitive activities. Entry to the program was competitive with companies selected on the basis of merit.

General programs which pharmaceutical companies can access include, the R&D Start Program, the 125 percent tax concession and the Co-operative Research Centres program.

4. Regulation of demand: Controls on pharmaceutical prices, quantities and consumption

As noted in the introduction, demand for prescription pharmaceuticals is significantly influenced by the operation of the taxpayer-funded PBS. Accordingly, pharmaceutical firms are keen for their products to be listed on the PBS to generate sales.

4.1 Health insurance coverage

The operation of the PBS, including its safety net limits, largely makes the need for private health insurance for pharmaceuticals redundant. While there are limited circumstances where private health insurance cover is possible, these generally do not cover the cost of pharmaceuticals not included in the PBS.

4.2 Formularies

For the purposes of this paper, the positive formularies in Australia are taken to be the pharmaceuticals covered by the PBS.

Products will be considered for listing after receiving marketing approval from the Therapeutic Goods Administration (TGA), which considers safety and efficacy issues. Applications for listing on the PBS are considered by the independent Pharmaceutical Benefits Advisory Committee. The Committee consists of medical specialists, general practitioners, a pharmacist and a consumer representative. When recommending which drugs and medicinal preparations should be subsidised through the PBS, the Committee must be assured that the drug is effective, safe and cost-effective in comparison with other available treatments[13].

Prior to consideration by the Committee, its Economics Sub-Committee considers the economic aspects of the submission and provides advice to the PBAC on the strength of the evidence and the economic aspects, including modelling. The Sub-Committee consists of clinicians and health economists.

4.3 Price Control Policies

The majority of prescriptions in Australia are written for medications that are subsidised under the PBS. The price of all products listed on the PBS are reviewed annually by the Pharmaceutical Benefits Pricing Authority. The Authority:

- is an independent non-statutory body with the objective to secure a reliable supply of pharmaceutical products at the most reasonable cost to the Australian taxpayers and consumers;
- comprises an independent chairperson, an industry and consumer nominee and representatives of the industry and health departments;
- recommends prices for new products that have been recommended for listing on the PBS[14].

In reviewing the price of listed items and in considering the price of items recommended for listing, the Authority takes into account the following factors:

- pharmaceutical Benefits Advisory Committee comments on clinical and cost effectiveness aspects of items;
- the price of alternative brands of a drug;
- comparative prices of drugs in the same therapeutic group;
- cost information provided by the supplier;
- prescription volumes, economies of scale and other factors such as expiry dating, storage requirements, product stability and special manufacturing requirements;
- the level of activity being undertaken by a company in Australia, including new investment, production, research and development (the funding for this in provided by the Industry portfolio rather than the Health portfolio - it provides financial incentives to companies who

undertake additional activity in Australia - payment is based on additional value added achieved);

- prices of the drug in reasonably comparable countries;
- other relevant factors which the applicant company may wish the Authority to consider; and
- any directions of the Minister.

An explanation of the pricing methods employed by the Authority is set out in Annex 4.

4.4 Control on physician prescribing practices

In Australia, there are no physical controls, such as rationing, placed on prescribes. However, there are indirect controls through restricting use of medications to particular indications; requiring value for money to be demonstrated for new products; and promoting quality use of medicines.

Another system in place to encourage high quality cost-effective physician prescribing practices is the active promotion of the Quality Use of Medicines (QUM) policy and the linkages made between current QUM initiatives and high quality cost effective physician prescribing practices. The QUM policy aims to improve the way medicines are prescribed by doctors, dispensed by pharmacists, and used by consumers – therefore ensuring better health for the Australian community. The specific objectives of QUM are to promote:

- judicious use of medicines: ensuring the best possible treatment plan is chosen;
- appropriate use of medicines: ensuring that when medicines are needed they are carefully selected, managed; monitored and reviewed;
- safe use of medicines: minimising misuse, overuse, and under-use of medicine;
- efficacious use of medicines: ensuring that medicines achieve the goals of therapy by delivering beneficial changes in actual health outcomes.

The QUM policy promotes the concept that members of the 'medication team', comprising doctors, pharmacists, nurses, and consumers, each have a role to play in ensuring that medicines are used wisely[15]. The development and implementation of the QUM policy is being achieved by the Pharmaceutical Health and Rational use of Medicines Committee through a partnership approach with QUM stakeholders, including health professionals, consumers, industry, and government.

4.5 Regulation of retail pharmacies

Entry to the retail pharmacy sector and ownership structures are highly regulated. Generally, under State and Territory laws ownership and control of community pharmacies is confined to registered pharmacists and in each State and Territory there is a limit on the number of pharmacies an individual pharmacist may own.

The Government exercises significant national control on pharmacy numbers and their location – although not directly. It achieves control by issuing approvals to dispense pharmaceutical benefits under section 90 of the *National Health Act 1953*[16]. In practical terms:

- a new pharmacy cannot be approved to dispense PBS-subsidised medicines unless it can satisfy a set of definite community need criteria;

- apart from special provisions for shopping centres and private hospitals, pharmacies can be relocated to a site no closer than two kilometres from another pharmacy and can move closer to existing pharmacies in steps of one kilometre each two years.

The aim of these controls is to encourage relocation of existing pharmacies rather than the establishment of new pharmacies.

Applications are assessed by the Australian Community Pharmacy Authority. This body is required to consider all applications against the range of criteria set out in the Determination and then make recommendations to the Secretary of the Commonwealth Department of Health and Aged Care.

4.6 Policy towards generics

Use of generics has been encouraged since December 1994 under the PBS arrangements for brand substitution by pharmacists. The Schedule of Pharmaceutical Benefits shows differences in price between some alternative brands of the same drug product and manufacturers can develop generic equivalents and apply to have them listed on the PBS[17].

Under the PBS, the Government subsidises up to the price of the lowest priced brand (except in those instances where the lowest priced brand has, as part of its price, a therapeutic group premium). This means that consumers may have to pay extra for more expensive brands (those with a brand premium). Brand substitution by pharmacists without reference to the prescribe is permitted for PBS prescriptions under certain conditions[18].

The market share held by generics supplied through the PBS has increased over the past ten years. In cost terms, generics increased from 4.5 percent in 1990/91 to 10.2 percent in 1998/99, whilst prescription volumes rose from five percent in to 15.5 percent. No data is held on non-prescription market shares held by generics[19].

The policy for alternative brands has the effect of making it possible for prescribes and patients to be more aware of the price of drugs. The policy also allows companies to establish prices taking into account competition and the heightened consumer awareness of price differentials.

The Brand Pricing Policy was introduced in December 1990 to reduce price control by allowing suppliers to set their own prices on multi-branded and therapeutically interchangeable brands listed on the PBS, provided one brand was available at the subsidised price. This also encourages the development of the generic pharmaceutical industry in Australia. The policy operates where there is more than one brand of a particular drug available through the PBS and where the brands are therapeutically interchangeable.

Under the policy, suppliers of multi-branded items are able to set their own prices at a level they think the market will bear. At the same time, prescribes, pharmacists and patients can decide whether it is necessary to pay more for a particular brand when a cheaper equivalent and therapeutically interchangeable brand is available.

Essentially, the policy operates by:

- the Commonwealth subsidising a drug to the level of the lowest priced brand;
- suppliers of other brands of that drug being able to set a price above the price charged by the supplier of the lowest priced brand, where the brands are bio-equivalent; and
- the patient paying the brand premium which is the price difference between the lowest priced brand and the brand prescribed.

As the brand premium is not a Government charge, it does not count towards a patient's safety net. The premium arises from the supplier's price setting and the majority of it goes to the supplier, with wholesalers and pharmacists receiving a percentage.

The brand premium policy is supplemented by the Government's policy on brand substitution. This allows pharmacists to substitute between brands with the agreement of the patient and provided it is not vetoed by the prescribe.

As at 30 June 1999 there were 226 benefit items with a brand premium that could be therapeutically interchanged. The average brand premium was $A1.80 and premiums ranged from $A0.23 cents to $A7.28. The majority of brand premiums were in the range of $A1.00 to $A1.50. There were 397 brands at the benchmark price.

Out of a total of 129 million PBS prescriptions, 51 million were subject to the brand premium policy. Of these 46 percent were for the benchmark brand.

5. Competition issues in the pharmaceutical sector

The provisions in the national competition statute, the *Trade Practices Act 1974*, apply generally to all business activity carried on in Australia, including that conducted by governments or their authorities. This national statute contains prohibitions against anti-competitive agreements and mergers[20] and the misuse of market power and operates subject to the regulatory regimes addressed above. The Australian Competition and Consumer Commission is responsible for enforcing the competition law universally, including in the pharmaceutical sector.

5.1 Market definition issues and barriers to entry and exit

The Commission has had the opportunity to consider the issue of market definition in the pharmaceutical sector on a number of occasions in the context of mergers and acquisitions. Its approach to the issue of the relevant product market has varied depending on which functional segment of the industry has been under consideration.

In the manufacturing segment, two possible definitions of the relevant product market have been identified:

- a broad definition, being one market for prescription pharmaceuticals and another market for over-the-counter (OTC) pharmaceuticals; or

- a narrow definition, being a separate market for each particular therapeutic group of pharmaceuticals (e.g. one market for antihistamines, another for antibiotics, another for anti-ulcerates, etc.)

In construing the relevant market, the Commission has recognised that pharmaceutical companies operating in Australia typically produce a range of pharmaceutical products within some or all of the major pharmaceutical product categories including:

- ethical (prescription only pharmaceuticals that are listed on the PBS);

- non – PBS (prescription only);

- over-the-counter (OTC) (pharmaceuticals not requiring a prescription and related consumer products); and

- pharmacy-only (non-prescription pharmaceuticals available from pharmacies exclusively).

Each of these major product categories are then able to be broken down further into respective therapeutic groups designated according to the end use of all products contained within each separate category.

On the demand side, it has been found that there is little substitution between products in each different therapeutic group (but that substitution between products within groups is possible) on the basis that each group relates to a particular class of treatment and all products within that group serve a particular therapeutic purpose.

On the supply side, it has been found that there is a degree of substitution (subject to patent laws) over a range of prescription pharmaceutical products. However, due to strict regulations controlling the supply of prescription pharmaceuticals, it has been found that there is little supply side substitution between the manufacturers of OTCs and the manufacturers of prescription products.

It has not been necessary for the Commission to come to a decisive conclusion on the issue of relevant product market in the cases it has considered in this segment of the market as its decisions have not hinged on the issue of market definition. However, there has been a tendency for the Commission to favour the narrow approach which, as outlined above, approximates the relevant product market by commonly accepted therapeutic groups.

Conversely, in the wholesaling *sector*, the Commission has tended to favour a broad definition of the relevant product market and has defined the market as that for the wholesaling of ethical and over-the-counter pharmaceuticals.

The Commission has favoured this approach on the basis that suppliers are generally unwilling to operate other than through wholesalers and there appear to be economies of scale and scope in the wholesale distribution of pharmaceutical products to retailers. Further, it appears to be generally accepted that retailers must obtain products from a supplier which can supply a complete range of pharmaceuticals and other support services (including bank guarantees, merchandising and marketing services and computer advisory, ordering and invoicing systems) to have a commercially viable business.

5.2 Geographic market

In the *manufacturing* segment of the industry the Commission has favoured defining the market as a national market on the basis that pharmaceuticals are able to be supplied and are supplied by manufacturers on a nation wide basis.

In the wholesaling segment, the Commission has favoured a more narrow market definition and has defined the market as state-based. The market has been defined as such on the basis that retail pharmacies have limited storage capacity and generally demand daily or twice daily deliveries. Therefore, while it may be possible for an individual pharmacist (or group of pharmacists) to obtain large quantities of high-turnover ethical and OTC pharmaceuticals from an interstate supplier, it appears pharmacists still need to access local suppliers for urgent deliveries and low-turnover products. Further, with the increasing range of associated services such as training and continuous stock monitoring and replenishment demanded by pharmacists, wholesalers seem to require staff based in the same state as the pharmacists to whom they distribute to compete effectively.

5.3 Retail segment

The ownership of retail pharmacies in Australia is highly regulated. As noted above, under the present legislative scheme, the ownership of pharmacies is limited to qualified pharmacists and there are limits on the number of pharmacies in which any individual pharmacist may have a pecuniary interest.

Given this regulatory environment, the Commission has not been required to consider market definition issues related to consolidation at the retail level directly. However, the Commission has considered a number of mergers involving the acquisition of retail marketing or 'banner' groups by upstream market participants.

In these matters, the Commission has generally considered the competitive effect of the acquisition in terms of the extent to which it is likely to affect the market share of participants operating at the wholesale level by increasing their ability to control or further influence sales to retail pharmacies that are part of the newly acquired banner group. Given that approximately 60 percent of pharmacists still operate independently and pharmacists that are part of banner groups are usually not tied exclusively to the banner group wholesaler, acquisitions of this nature have generally not been found to be anti-competitive. However, in some cases, the Commission has thought it necessary to seek enforceable undertakings from the parties to the acquisition to ensure pharmacists that are part of the banner group are not required to acquire goods exclusively from the banner group affiliated wholesaler.

5.4 Barriers to entry and exit

In the cases it has considered to date, the Commission has found the pharmaceutical industry to be characterised by relatively high barriers to entry.

In the manufacturing sector, barriers that have been identified include:

- capital (up to $A50 million to set up appropriate production facilities);
- patent protection of products;
- management skill;

- low margins imposed by legislation (for prescription pharmaceuticals); and

- critical mass at start-up.

In the wholesaling sector, barriers that have been identified include:

- industry knowledge;

- high cost of establishing an adequate distribution system (due to scale economies);

- existing supplier arrangements with retailers (financial guarantees and electronic links) including the operation of major retail banner groups (buying/marketing groups) and in some cases ownership of retail chains; and

- low margins imposed by legislation (for listed prescription pharmaceuticals).

5.5 Anti-competitive agreements

The Commission has not as yet had the occasion to address issues of explicit or implicit collusion in the pharmaceutical sector. Similarly, it has not had the opportunity to examine the competitive effects of co-operative or collaborative ventures such as co-marketing, co-promotion or joint research and development agreements.

5.6 Mergers and acquisitions

Key non-confidential mergers or acquisitions the Commission has addressed in the pharmaceutical sector are summarised briefly in Annex 5.

In the cases the Commission has considered to date, concerns over market power have been most focused on mergers involving consolidation in the wholesaling segment of the industry. This has been primarily due to currently high levels of concentration in that part of the industry in Australia.

The primary anti-competitive effect of mergers in the pharmaceutical industry in Australia appears to be the potential effect increased vertical integration may have on raising barriers to entry in the industry, particularly at the wholesaling level. The Commission has expressed concern in a number of cases that vertical integration into the retailing segment of the industry (by the acquisition of interests in retail banner groups) may have the effect of tying pharmacists into exclusive supply arrangements with particular suppliers and thereby adversely affect competition in the market.

At present, there appears to be a growing trend for increased vertical integration in the pharmaceutical industry in Australia. As noted above and detailed in Annex 5, the Commission has considered a number of merger cases involving acquisition of a downstream player by an upstream player in the industry and as such, a situation when the parties to the merger were not directly competing at the time of the acquisition. The Commission has indicated the importance of considering the potential flow on effects of further vertical integration in the market but has not opposed a merger simply on the basis that the merger parties might be competitors in the future.

However, in its consideration of all merger proposals, the Commission is cognisant of the importance of considering such proposals in the context of the changing dynamics of the market. As such,

the Commission takes all issues relevant to market dynamics into account when assessing an acquisition's likely impact on competition in the market both at the time of the acquisition and into the future.

Remedies that have been imposed as a condition on merger approval include structural and behavioural undertakings.

Sigma (Pharmaceuticals) Limited QDL Limited is an example of an occasion when the Commission's concerns as to the anti-competitive effect of the proposed acquisition were able to be resolved by means of a divestiture undertaking submitted to the Commission by the acquiring party. In that case the Commission decided not to oppose the acquisition following its acceptance of a court enforceable undertaking from Sigma to divest QDL's Victorian pharmaceutical wholesaling assets.

Further, in its consideration of the Sigma Company Limited/AMCAL matter the Commission's competition concerns were able to be resolved by means of a behavioural undertaking. In that case, the Commission decided not to oppose the acquisition following its acceptance of an enforceable assurance from the acquiring company that it would not, in future, prevent members of the AMCAL banner group from acquiring goods or services from alternative sources, either wholesalers or directly from manufacturers for a period of three years. The undertaking was accepted on the basis that it would ensure there was no attempt to tie banner members to exclusive distribution agreements with a particular wholesaler.

More recently, the Commission resolved its competition concerns in relation to the Australian Pharmaceutical Industries Limited/Washington H Soul Pattinson and Company Limited acquisition by undertakings similar to those accepted in the Sigma/AMCAL matter.

5.7 Abuse of dominance

The Commission has not yet had the opportunity directly to address the issue of abuse of dominance in the pharmaceutical sector. A small number of allegations of misuse of market power have been received but such allegations have not been able to be substantiated.

5.8 Other anti-competitive conduct

The Commission has also considered a small number of cases of alleged resale price maintenance in the retail sector of the industry. The alleged conduct investigated in those cases has concerned the supply of over-the-counter pharmaceuticals through pharmacies. Again, none of the allegations investigated have as yet been able to be substantiated.

NOTES

1. . Pharmaceuticals not covered by the PBS may be purchased at full market price.

2. . A consumer may be charged a premium for a particular brand, if the patient agrees and the prescriber indicates on the prescription form that no substitution is to occur.

3. . Concessional patients pay a maximum of $A171.60 per year for their PBS items. Once this limit is reached they receive their PBS items free of charge for the remainder of that year. General patients pay a maximum of $A631.20 for their PBS items. Once this level is reached they pay $A3.30 for each PBS item for the remainder of that year. This patient contribution is indexed annually. In addition, eligible pensioners such as veterans, people on sickness allowance and other recipients of income support, receive a pharmaceutical allowance to help defray their out-of-pocket pharmaceutical expenses.

4. The current dispensing fee is $A4.39 per prescription for ready prepared (RP) items and $A6.27 for extemporaneously prepared (EP) items. The dispensing fee is updated annually in accordance with the movement in the Consumer Price Index. A discount to the increase applies if volume growth exceeds 2.5 percent.

5. The mark-up arrangements provide rates on the price to pharmacist of PBS prescriptions of 10per cent on drugs up to $A180; $A18 flat for drugs up to $A360 and a rate of five percent beyond $A360. In addition, an Isolated Pharmacy Allowance and Remote Pharmacy Allowance is also payable to eligible approved pharmacists in an endeavour to maintain a pharmaceutical service in isolated and rural areas.

6. Provided by the Australian Pharmaceutical Manufacturers Association

7. Based on sales ex-manufacturer.

8. Principally hospitals (107), although 17 other firms were involved, together with 69 medical research funding bodies, 37 research institutes, 17 universities and four co-operative research centres. Highlights during 1998-99 included:

   - regulatory clearance for Relenza, an orally inhaled influenza treatment developed by Biota Holdings with Glaxo Wellcome. Biota also received US FDA clearance for its related flu diagnostic test;
   - CSL Ltd announced a joint venture with the American Red Cross to develop a new fibrin bandage to stop major haemorrhaging almost immediately and will have important applications in trauma situations; and
   - biodiscovery Ltd and CSIRO Entomology entered into collaboration with Aventis to screen Australian insects for agrochemical and pharmaceutical lead compounds.

9. In force from 27 January 1999

10. The Act extends the maximum effective patent term for pharmaceuticals by up to fifteen years (as measured by the period from the registration of the product to the expiry of the patent term). Patentees of new or standard twenty year pharmaceutical patents in force in Australia on or after 1 July 1999 are eligible to apply for an extension.

11. Spring boarding' is the legitimate carrying out of activities that would normally infringe a patent if undertaken without the patentee's authority and allows the development and manufacture of a drug whilst still under patent to secure regulatory approval for entry onto the market once the patent has expired

12. The scheme does not allow importation of drugs prohibited by Customs legislation or of certain injectible drugs and an Australian prescription may be required.

13. The requirement that drugs must be cost-effective before listing on the PBS has been in place since 1991. Since then, pharmaceutical manufacturers have been required to provide both clinical and economic evidence in their submissions to support the listing of a drug on the PBS. These submissions are subject to rigorous evaluation.

14. The Department of Health and Aged Care, on behalf of the Minister, negotiates with the relevant pharmaceutical suppliers.

15. The Government has further strengthened its support for quality prescribing and promotion of QUM through the establishment of the National Prescribing Service (NPS) in March 1998. The Federal Government provided $A3 million to establish the NPS and $A6 million per annum over three years for its operation. The NPS is an independent public company, operating within the framework of the National Medicinal Drug Policy. The goal of the NPS is to improve the health outcomes of the community through quality (judicious, appropriate, safe and cost-effective) use of medicines. Members include peak medical, pharmacy, nursing, pharmaceutical industry, consumer and hospital organisations.

16. Very few pharmacies that would be viable if they were not able to dispense pharmaceutical benefits.

17. In doing this manufacturers need to ensure that they comply with the relevant legislation applicable to patents. These brands are clinically equivalent and must undergo the same strict quality controls. Although these brands are designed to act on the body in exactly the same way, they are usually cheaper than the originator brands.

18. Where:

- the patient agrees to the substitution;
- the brands are identified in the Schedule of Pharmaceutical benefits as being interchangeable;
- the prescriber has not indicated on the prescription form that substitution is not to occur; and
- substitution is permitted under the relevant State or Territory legislation.

19. For hospital markets, it is expected that the generic share would be reasonably high as most drug purchases would be through tender arrangements.

20. Anti-competitive agreements and mergers which result in a net public benefit may be authorised under administrative procedures.

ANNEX 1

TOP 20 FIRMS* AND PRODUCTS

	Firm	$A m	%	Product	$A m
1	Astra	302.2	8.9	Losec (omeprazole)	173.5
2	Merck Sharp & Dohme	269.3	7.9	Zocor (simvastatin)	111.7
3	Glaxo Wellcome	238.7	7.0	Lipitor (atorvastatin)	72.9
4	Alphapharm	149.6	4.4	Lipex (simvastatin)	71.9
5	SmithKline Beecham	134.6	4.0	Renitec (enalapril)	59.4
6	Bristol-Myers Squibb	128.6	3.8	Zantac (ranitidine)	51.6
7	Pfizer	128.4	3.8	Atrovent (ipratropium)	49.8
8	Hoechst Marion Roussel	122.2	3.6	Norvasc (amlodipine)	49.6
9	Roche	116.0	3.4	Zoloft (sertraline)	47.8
10	AMRAD	109.7	3.2	Pravachol (pravastatin)	46.4
11	Parke Davis	107.8	3.2	Ventolin (salbutamol)	44.7
12	Pharmacia & Upjohn	107.0	3.1	Zyprexa (olanzapine)	35.2
13	Eli Lilly	105.4	3.1	Pulmicort (budesonide)	34.9
14	Wyeth	103.0	3.0	Aropax (paroxetine)	34.9
15	Zeneca Pharmaceuticals	83.4	2.5	Zoladex Depot (goserelin)	34.4
16	Novartis	82.7	2.4	Zoton (lansoprazole)	33.1
17	Rhone-Poulenc Rorer	63.1	1.9	Coversyl (perindopril)	31.9
18	Boehringer Ingelheim	59.4	1.7	Cardizem (diltiazem)	30.6
19	Sigma Pharmaceuticals	57.9	1.7	Aurorix (moclobemide)	27.6
20	Schering Plough	57.1	1.7	Flixotide (fluticasone)	27.6
	Totals	2,526.1	74.3%		1,069.5

* Top 20 suppliers by market share of prescription and pharmacist-only medicine sales ex-manufacturer, 1998

Source: Australian Pharmaceutical Manufacturers Association, Pharmaceutical Fact Book, Sydney, 2000

ANNEX 2

PHARMACEUTICAL SECTOR TRADE ASSOCIATIONS

Australian Pharmaceutical Manufacturers Association

Active Pharmaceutical Ingredients Manufacturers Association of Australia

Australian Biotechnology Association

Australian Chemical Specialities Manufacturers Association

Australian Diagnostic Manufacturers Association

Complementary Healthcare Council of Australia

Cosmetic, Toiletry and Fragrance Association of Australia

Medical Industry Association of Australia

National Association for Crop Production and Animal Health

National Pharmaceutical Services Association

Plastics and Chemicals Industries Association

Proprietary Medicines Association of Australia

Source: Australian Pharmaceutical Manufacturers Association, Directory, Sydney, 2000

ANNEX 3

NEW DRUG APPROVALS- PROCEDURE

(See Next Page)

Notes to the Chart

1. For a detailed guide to the process of registering prescription medicines see the TGA publication, *Australian Guidelines for the Registration of Drugs* (AGRD), Volume 1. This publication is essential reading before undertaking a complex registration process.

   Although, the Drug Safety Evaluation Branch (DSEB) generally evaluates all high risk registered medicines, sponsors can apply for the Chemicals and Non-prescription Medicines Branch to evaluate their medicine, provided certain criteria are met. See the *Justification for a Particular Route of Evaluation* guidelines, which are available from the TGA.

   Contact the Orphan Drug Unit of DSEB on (02) 6232 8101 if you believe that your product may meet the criteria for orphan drug status (for further details, see the *Frequently Asked Questions* booklet, page 10).

2. For Category 1 and 2 applications, 75% of the fee is payable at the time of lodgement of a submission, unless the fee is over $100,000 (in which case, an invoice will be sent). For Category 3 applications, 100% of the fee is payable on lodgement.

   Evaluation targets are 255 working days (category 1) and 175 days (category 2) from the date of acceptance of the evaluation. Unless these evaluation targets are met the outstanding 25% of the fee is not payable.

   Documents should be prepared as a four-part dossier:

Part I	5 copies	Summary of the dossier;
Part II	2 copies	Chemical, pharmaceutical and biological documentation (include bioavailability and bioequivalence studies);
Part III	1 copy	Pharmaco-toxicological (pre-clinical) documentation;
Part IV	1 copy	Clinical documentation (include bioavailability and bioequivalence studies).

   Note that time taken for sponsors to respond to requests for further information is excluded from processing times.

3. Category 3 applications are those variations which do not need to include clinical, preclinical, or bioequivalence data. Category 3 applications/changes to product information do not require a Part 1 Summary.

   Note that the time taken for sponsors to respond to requests for further information is excluded from the processing times. Application target is 45 working days from receipt of submission or payment of fee (whichever is later date), after which it is deemed that the application has been approved (provided that no objections have been raised).

4. Not all applications are referred to ADEC. (For more information on the operation and role of ADEC and the other advisory committees, see the *Where Do You Get It?* booklet.)

5. Priority status may be granted in order to speed up applications, where:—
   - active ingredients are new chemical entities; and
   - product is for treatment or diagnosis of a serious, life threatening, or severely debilitating disease or condition; and
   - clinical evidence indicates that the medicine may provide an important therapeutic gain.

6. If an application is unsuccessful, appeal provisions apply. Sponsors will receive notification of the decision, the reasons for non-approval, and the appeal mechanisms available to them. Information on appeal provisions can be found in section 60 of the *Therapeutic Goods Act 1989* and section 48 of the *Therapeutic Goods Regulations*. Also see the *Where Do You Get It?* booklet.

7. The date on the Certificate of Registration is the date from which supply of the medicine may commence. It is illegal to supply most medicines in Australia that are not entered in the ARTG.

Disclaimer

Information in this roadmap may be affected by subsequent amendments to legislation. Check the TGA website **http://www.health.gov.au/tga** for updates to regulatory requirements and process. THE DISCLAIMER AT THE COMMENCEMENT OF THE *OVERVIEW* BOOKLET (IN THIS INFORMATION KIT) ALSO APPLIES IN FULL TO THIS ROADMAP.

TGA
THERAPEUTIC GOODS ADMINISTRATION

Health and Aged Care

AUSTRALIA

Prescription (High Risk) Registered Medicines

Prescription (High Risk) Registered Medicines

A roadmap to registering prescription (high risk) medicines in the Australian Register of Therapeutic Goods

ROADMAP

TGA
THERAPEUTIC GOODS ADMINISTRATION

Health and Aged Care

AUSTRALIA

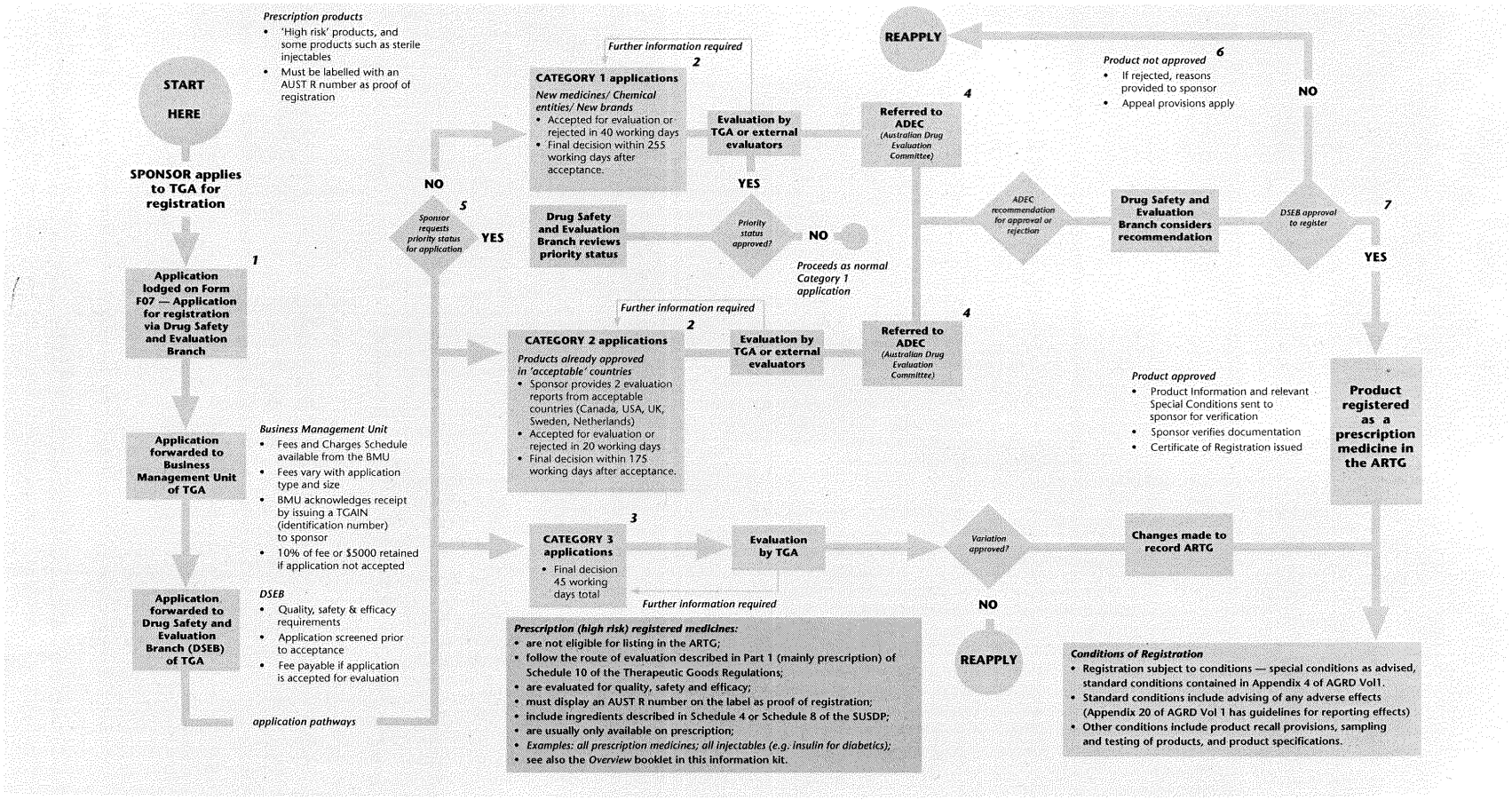
Prescription (High Risk) Registered Medicines

A roadmap to registering prescription (high risk) medicines in the *Australian Register of Therapeutic Goods*

This roadmap outlines the process for registering a prescription (high risk) medicine in the *Australian Register of Therapeutic Goods* (ARTG). It is a requirement that any medicines for general supply in Australia (or export from Australia) must be included in the ARTG. This roadmap applies ONLY to medicines which are for supply in Australia. (For medicines which are solely for export, see the *Export* booklet.)

Registered medicines are divided into two groups: ***high-risk*** (mostly prescription medicines available under the Pharmaceutical Benefits Scheme) and ***low-risk*** (medicines which are mostly available as 'over-the-counter' (OTC) medicines for self-treatment by consumers). See the *Overview* booklet for more detail.

Notes relating to the boxes on this chart can be found on the back of this roadmap. It is important to read these.



ANNEX 4

PHARMACEUTICAL BENEFITS PRICING AUTHORITY - PRICING METHODS

1. Benchmark pricing

When reviewing prices, the Pharmaceutical Benefits Pricing Authority (PBPA) considers drugs in their therapeutic sub groups - that is like products are grouped together. A benchmark product is chosen on the basis of the lowest costs - either the price the manufacturer is prepared to supply for or the lowest cost of production (cost submitted by the manufacturer). Other products are priced in line with the benchmark product.

A premium above the benchmark price is allowed where the supplier of the product is able to demonstrate an advantage in clinical and cost effectiveness terms. More detail of the pricing structure and price comparisons within a therapeutic group are contained in the relativity sheets retained by the PBPA and issued to drug sponsors.

Most products listed on the PBS are priced under this method. It is often the case that no price increases can be justified as one or more products in the therapeutic group have not sought any increase or prices are considered reasonable by the PBPA.

When recommending the listing of a new product, the PBAC advises on specific relativity's between drugs. This relativity is maintained by the PBPA through price adjustments - for example sponsors at times list new drugs at lower prices than currently listed comparators. When this occurs, the PBPA will approach the existing suppliers to reduce their price or demonstrate that their product is cost effective at the higher price.

These arrangements have existed with the PBPA since its inception in 1988 but has been more enhanced since the PBAC adopted cost effectiveness from January 1993.

2. Cost plus method

Under this approach, the price recommended by the PBPA is based on the cost of manufacture plus a margin. Costs allowed under this method do not include distribution costs, promotional or marketing activity or general administration.

This method is used for stand alone items and for benchmark products. It relies on pharmaceutical suppliers providing the PBPA with accurate cost data.

The margin provided under this approach can vary from 15 percent to 40 percent (equivalent to a mark-up of between 18 percent and 67 percent) depending on a number of factors including the price sought by supplier, the estimated usage, the unit price and overseas prices.

3. Average monthly treatment cost

This is a variation of the reference price method which can be applied within a therapeutic sub group usually where a medicine used to treat chronic conditions is supplied in a number of strengths. The method takes into account actual clinical usage and requires detailed utilisation data.

Under this approach, the weighted average monthly treatment cost is calculated for each of the drugs in the sub group and these costs are compared. Prices can be adjusted up or down to bring products into line with the alternatives. A paper showing the calculations involved is attached.

4. Prices for new items

The main mechanism to determine initial prices is the advice from the Pharmaceutical Benefits Advisory Committee (PBAC) which is an independent body of medical experts established to advise the Minister for Health about which products and for what indications products should be subsidised by the Government. PBAC provides advice on clinical effectiveness and cost effectiveness (value for money). It has been a requirement for drugs sponsors to submit cost effectiveness data on new items since the start of 1993.

In recent years, the PBPA has increasingly recommended the use of price/volume arrangements (unit prices decrease as volume increases), particularly where unit prices are reasonably high and there is the potential for significant volumes or where there is uncertainty about future volumes.

5. Special cases for pricing

Brand premiums – The benchmark price of a drug is determined by the PBPA reviewing its established criteria. Sponsors of alternative brands are allowed to charge a premium if they so desire provided their brand is proven to be bio-equivalent or interchangeable with the benchmark brand. The level of the premium is a matter for the sponsor of that brand. The amount of the premium, plus the pharmacists mark-up is payable by the patient.

Therapeutic Group Premium Arrangements - This relates to four particular groups of drugs, the H2 antagonists, calcium channel blockers, ACE inhibitors and the HMG CoA reductase inhibitors. The products in these groups have their prices reviewed on a weighted average monthly treatment cost and at least one product from the group will set the therapeutic benchmark price. Sponsors of the alternate drugs are free to apply a therapeutic premium.

The premium charge is a sponsor charge paid by patients over and above the normal patient contributions. There are provisions for exemption to be sought from the HIC for patients having to pay the premium, these exemption provisions are:

- adverse effects and/or drug reactions occurring, or expected to occur, with all of the base-priced drugs; or

- the transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.

Special Patient Contribution Arrangements – This is rarely used. Special pharmaceutical benefits arrangements apply where the sponsor and Government cannot agree on price for special unique items that have been recommended for listing on the PBS. The sponsor requests a higher price than the Government is willing to accept. The Government will subsidise up to a certain level. The patient will have to pay extra special patient contribution between the Government dispensed price and the sponsors requested dispensed price.

ANNEX 5

NON-CONFIDENTIAL MERGERS OR ACQUISITIONS ASSESSED BY THE AUSTRALIAN COMPETITON AND CONSUMER COMMISSION

ACCC Decision	Parties	Nature of transaction	Market definition	Outcome
2 Feb 1994	FH Faulding Wholesale Pty Ltd/QDL Limited	Faulding, a wholesaler of pharmaceutical products in South Australia, Victoria and New South Wales proposed a take-over of QDL, a pharmaceutical wholesaler operating in Queensland, New South Wales and Victoria.	Pharmaceutical wholesaler services market in Queensland and New South Wales.	Opposed on the basis that the acquisition would be likely to result in a substantial lessening of competition in the relevant markets.
2 Feb 1995	QDL Limited/LKJ Newman & Co Pty Ltd	QDL proposed to acquire the business of Newman, a Victorian pharmaceutical wholesaler.	Market for the supply of pharmaceutical wholesale services in Victoria.	Not opposed.
11 Oct 1995	Sigma (Pharmaceuticals) Limited/QDL Limited	Involved the acquisition by Sigma of QDL, a pharmaceutical wholesaler.	Market for the supply of pharmaceutical wholesale services in Victoria.	Originally opposed but competition concerns resolved by divestiture undertakings.
26 Jun 1996	Glaxo PLC/Wellcome PLC	Involved the acquisition by Glaxo of 87 percent of shares in Welcome.	Market for the supply of anti-migraine pharmaceuticals in Australia.	Not opposed – concentration thresholds not crossed.
27 Aug 1996	Parke Davis Pty Ltd & Wellcome PLC joint venture	Joint venture in manufacture of certain pharmaceutical products.	Market for the supply of respiratory OTC products in Australia.	Not opposed – concentration thresholds not crossed.
21 May 1997	Sigma (Pharmaceuticals) Limited/Andrews Laboratories P/L;	Sigma proposed to acquire Andrews regionally based pharmaceutical wholesaling operations.	Market for the wholesale supply of pharmaceuticals in NSW.	Not opposed – concentration thresholds not crossed.
7 Oct 1998	Sigma Company Limited/Allied Master Chemists of Australia Limited (AMCAL)	Sigma proposed to acquire AMCAL which is a national pharmaceutical marketing and distribution group acting as an umbrella organisation which offers assistance, guidance and support on marketing, product and retailing to retail pharmacies.	Market for the wholesale supply and distribution of ethical and over-the-counter pharmaceuticals in either Victoria or Australia.	Originally opposed but competition concerns resolved by behavioural undertakings.

ACCC Decision	Parties	Nature of transaction	Market definition	Outcome
1 Sep 1999	Sigma Company Limited/Glaxo Wellcome Australia Pty Ltd	Involved the sale by Glaxo to Sigma of 11 prescription pharmaceutical products and an agreement for Glaxo to grant Sigma a licence to relevant 'know how' for the manufacturing, sale and distribution of the 11 products within Australia.	Either: The market for the supply of prescription pharmaceutical products in Australia; or Separate markets for the supply of each different therapeutic category of products in Australia (eg analgesics)	Not opposed – concentration thresholds not crossed.
20 Oct 1999	Hoechst AG/Rhone – Poulenc SA	Involved the merger of Hoechst and Rhone Poulenc's pharmaceutical manufacturing and supply divisions.	Either: The market for the supply of prescription pharmaceutical products in Australia and another market for the supply of OTC pharmaceuticals in Australia or Separate markets for the supply of each different therapeutic category of products in Australia (e.g. analgesics)	Not opposed – concentration thresholds not crossed.
21 Dec 1999	Australian Pharmaceutical Industries Limited ('API')/ Washington H Soul Pattinson and Company Limited ('Soul Pattinson')	API proposed to acquire the pharmaceutical manufacturing and wholesaling operations of Soul Pattinson.	Market for the wholesale supply of pharmaceutical products and services in New South Wales.	Originally opposed but competition concerns resolved by behavioural undertakings.

CZECH REPUBLIC

1. The pharmaceutical industry: market structure

1.1 Market structure

(1.1) Please describe the market structure of pharmaceutical firms in your country- which firms are active, with what market share, in which therapeutic classes and with what level of R&D (including generic producers). Which firms co-operate to jointly undertake R&D or to jointly market certain products? Is there one or more associations of pharmaceutical manufacturers in your country? Is this association politically important?

There are a lot of competitors in the pharmaceutical market in the Czech Republic, the total number of licensed suppliers of pharmaceuticals exceeds four hundred. There are both domestic and foreign manufacturers. The Czech company Léčiva is the principal pharmaceutical supplier to the domestic market. It is the only company with a market share greater than ten percent of the total turnover of the market. The market share of other competitors supplying the domestic market with pharmaceuticals is below six percent.

The list of ten major suppliers of pharmaceuticals in the Czech Republic:

1. LÉCIVA (CZ)
2. SLOVAKOFARMA (SK)
3. NOVARTIS (CH)
4. AVENTIS (CH)
5. SCHERING (D)
6. KRKA (SLO)
7. BRISTOL-MYERS (GB)
8. MERCK (USA)
9. GALENA (CZ)
10. KNOLL (D)

There is effective competition in the pharmaceutical market in the Czech Republic.

In the Czech Republic there is no association of pharmaceutical manufacturers.

2. Regulation of supply

2.1 Protection of intellectual property rights

(2.1) Please describe the regulatory framework established for the protection of intellectual property rights in the pharmaceutical industry.

The Industrial Property Office is responsible for overseeing the implementation of legislation dealing with intellectual property rights. The primary legal framework is set out in Act No. 527/1990 Coll. on inventions, industrial designs and innovative proposals, determining a twenty-year protection period for active ingredients protected by a patent. If the patented active substances are components of pharmaceuticals, which prior to launch are subject to registration at the government body (State Institute for Drug Control), then upon request the Industrial Property Office can grant an additional protective certificate for those substances to prolong the patent protection of those pharmaceuticals. The certificate is valid five years at most, with the resulting rights and obligations equivalent to those resulting from the basic patent.

The obligation of the patent owner to provide a so-called compulsory licence corresponds to that dictated by TRIPS.

2.2 New drug approvals

(2.2) Please provide an overview of the drug approval process.

The new drug approval process is described in Appendix No. 1 (Source: State Institute for Drug Control, Annual Report 1999).

2.3 Trade regulation

(2.3) Please describe any barriers to international trade or investment in pharmaceuticals. Are there restrictions on international trade in drugs by third-parties (such as parallel trade or re-imports)? Are there restrictions on mail-order or Internet supply of drugs? Does the regulatory regime distinguish between domestic and foreign firms in any way?

A subject intending to import pharmaceuticals into the Czech Republic has to meet the following requirements:

- to choose the authorised representative or distributor, respectively;
- to pay the administration fee for the registration;
- pharmaceuticals are commodities with a regulated price, i.e. the manufacturer or its representative registers the maximum price (in this case with the Ministry of Finance);
- to register the drug for categorisation.

Therefore, every drug import not complying with the above mentioned requirements is illegal.

Compliance with the legal requirements for drug import is secured through following measures:

- customs checks;
- application for registration (only notary-verified documents to represent the manufacturer are accepted);
- approved packaging of drugs, distribution only in the local language;
- published list of registered drugs and their registration numbers;

Mail-order or Internet supply of drugs is illegal and carries penalties. To prevent such supplies, strict inspections are carried out at all the points of the drug distribution chain (manufacturer, distributor, pharmacy or shop).

The regulatory regime in the Czech Republic does not distinguish between domestic and foreign producers of pharmaceuticals.

2.4 Industrial policy

(2.4) Please describe any industrial policy objectives in this sector. Describe the objectives and effects of any tax concessions or subsidies that exist.

N/a

3. Regulation of demand: controls on pharmaceutical prices, quantities and consumption

3.1 Health insurance coverage of pharmaceuticals

The vast majority of health consumers in OECD countries benefit from health insurance which at least partially reimburses the costs of pharmaceuticals. As a result, demand at the point of final consumption may be very inelastic to price. It therefore falls to the insurer to ensure that the quantity consumed and the price paid for the pharmaceuticals is reasonable and that the right mix of pharmaceuticals is consumed (i.e., those pharmaceuticals which have the highest benefit/cost ratio).

(3.1) We invite you to discuss how the predominant forms of health insurance in your country (whether public or private) affect the demand of health consumers for pharmaceuticals.

Health insurance in the Czech Republic is public and compulsory for all citizens. Given the fact that the state guarantees quality and well-balanced health care reimbursed from that insurance, the system of drug reimbursement is part of the system of financial expenditure from health insurance funds and is both directly and indirectly affected by the health care consumers' and suppliers' behaviour.

3.2 Formularies

Most health insurance schemes (public or private) maintain a list of drugs that either are either specifically covered by the insurance scheme or specifically not covered. A list of covered drugs

is known as a "positive list" or "positive formulary". A list of drugs not covered id known as a "negative list" or "negative formulary".

(3.2) Please describe the main features of the formulary system in your country.

In the Czech Republic, there is no system of "negative" and "positive" formularies corresponding to the drugs covered or not covered by health insurance. There is a list of pharmaceuticals and the extent to which they are funded (irrespective of the current level of funding, zero funding is also possible). This list does not include OTC drugs, paramedicinal drugs and homeopathic drugs. The latter are not covered by public health insurance and are not included in a separate list.

3.3 Price control policies

Many OECD countries, often through reimbursement policies, have some form of controls on the prices of the drugs they purchase.

(3.3) Please describe the operation of the controls on pharmaceutical prices in your country.

All the pharmaceuticals manufactured or imported are commodities subject to maximum price regulation, or – for a small percentage – a materially regulated price.

- maximum price – the highest price in fixed period (usually one year), for which the product can be sold to the end user – is determined based on a calculation from the importer's quotation price, the average rate of the Czech National Bank and a coefficient for the maximum trade surcharge;

- the list of drugs and their maximum prices for the period given (usually one year) is published in the Bulletin of the Ministry of Finance; these prices are valid from the date of release, unless otherwise specified.

3.4 Control of physician prescribing practices

Nearly all countries impose some forms of controls on physicians to control the quantity and quality of the drugs prescribed.

(3.4) Please describe the system in place to encourage high-quality cost-effective physician prescribing practices.

Prescribing physicians are restricted as to the spending of the funds from public health insurance by means of a "budget" for a three-month period, which is determined by retrospective analysis of their prescription of covered/partially covered drugs over the comparable time period of the previous year and by comparison with the average financial expenditure of physicians of the same professional branch in the same area and in the comparable time period. Should the budget for the period be exceeded without relevant explanation, (e.g. an epidemic), the physician is sanctioned by not disbursing of the full expenses remitted, or a penalty is imposed on him. Those "budgets" are determined, monitored and assessed by individual health insurance companies. The manufacturers or their representatives shall communicate price changes (only prices below the maximum price), which are subsequently published in the 'code-books' of the health insurance companies.

3.5 Regulation of pharmacies and pharmaceutical distribution

In those countries in which pharmaceutical prices are controlled, it is essential to also control the margins of the pharmaceutical distribution chain and in particular the retail outlets – pharmacies.

(3.5) Please describe the nature of any controls on pharmacy margins, entry and/or ownership structure. Please describe also the nature of any rules governing the discretion of pharmacists in substituting other products.

- The control of the pharmacy margins – in terms of not exceeding the maximum fixed margin for distributors and pharmacists and at the same time not exceeding the maximum price of the drug – is the responsibility of the Ministry of Finance.

- Apart from pharmaceuticals, other products can be sold in pharmacies (usually cosmetics, health care products and nutritional supplements); the internal regulations of the Czech Pharmacy Chamber does not tolerate actions incompatible with pharmacy profession and good practice.

- Medicines can be given out only in the places the character and conditions of which are given by law; these conditions are not met by combined places of sale such as supermarkets, etc.

- Substitution of the prescribed drug by the pharmacist can be done only upon approval of the prescribing physician – if the alternative product contains an identical active ingredient; should the substitution involve another substance, written permission of the prescribing physician is necessary.

3.6 Policy towards generics

Nearly all countries have some form of explicit policy to encourage consumption of generic as opposed to brand-name drugs.

(3.6) What share of the non-prescription/over-the-counter, prescription and hospital markets are held by generics? Please describe the programs you have adopted to promote the consumption of generics.

There are no programs directly supporting generics consumption in the Czech Republic. These pharmaceuticals - as opposed to brand-name drugs - can be registered in simplified and thus shortened registration process (provided there is approval from the original manufacturer and the licence available). Generics are automatically included in the 'code-books' of the insurance companies, i.e. they do not depend on the categorisation process. As a consequence of their lower prices, generics are actively sought by the prescribing physician.

4. Competition issues in the pharmaceuticals sector

(4.1) Does the competition law apply to the different components of this sector (manufacturing, health insurance, health services, distribution and pharmacies) without exemption or exception? Which agency is responsible for enforcing the competition law in this sector?

The Czech Act on the Protection of Economic Competition is generally applicable and applies to all components of this sector (manufacturers, health insurance companies, health institutions, drug distributors, etc.).

The Office for the Protection of Economic Competition ("the Office") bears responsibility for enforcing competition rules in the Czech Republic.

4.1 Market definition issues and barriers to entry and exit

(4.1) Have you had the occasion to address the definition of the relevant market in the pharmaceuticals sector? Did you find that the relevant product market could be approximated by commonly-accepted therapeutic groups? What techniques did you use to determine whether certain products were effective substitutes? Did you find it necessary to distinguish the market for drugs consumed in hospitals from the market for drugs prescribed by physicians and/or the market for over-the-counter (non-prescription) drugs? Was the relevant geographic extend of the market national or international?

The Office has defined the relevant market in the pharmaceutical sector several times. The appraisal of the competitor's position in the pharmaceutical market is based on segmentation according to the anatomical-therapeutical-chemical classification (ATC) recommended by the WHO. From the point of view of their application, the individual ATC groups (and the products included) are not generally interchangeable, thus the Office considers them to be separate markets for pharmaceuticals. In the framework of each market there is the whole group of products used for a particular purpose.

Defining the relevant market, the Office also takes into account the opinions of researchers, physicians, manufacturers and drug distributors. Data needed for defining the relevant markets is also provided by the State Institute for Drug Control.

The Office has also defined the relevant market of veterinary drugs. Veterinary drugs are segmented according to pharmacological and indicative groups, i.e. according to the effect of the active substance on the organism and according to the therapeutic usage. Veterinary drugs placed into one particular group are not interchangeable with veterinary drugs from another group.

So far, the Office has not had to distinguish between the pharmaceutical markets, hospital markets and over the counter markets.

From the point of view of the Czech Act on the Protection of Economic Competition, the maximum geographical extent of the market is the whole area of the Czech Republic.

(4.2) Did you consider that the pharmaceutical industry is characterised by barriers to entry/exit? What barriers did you identify?

Assessing the impact on the competitive environment, the Office always judges the barriers to entry. Especially the cost for research and development, innovative market dynamics related to patent utilisation, know-how and other intellectual property rights, financial and time demands in establishing and implementing new production plant, state and government regulatory barriers to market entry (licence, approval or certificate granting, assessment of the import/export quotas, and customs duties) are dealt with.

4.2 Anti-competitive agreements

(4.3) Have you had the opportunity to address questions of explicit or implicit collusion in the pharmaceuticals sector? What forms of collusion have you found? Have you found that pharmaceutical manufacturers deliberately choose to target different therapeutic classes or geographic markets, in order to avoid competition? Does the fact that the large pharmaceutical manufacturers compete in many different product and geographic markets have a tendency to lessen competition? Have pharmaceutical manufacturers or pharmacies acted in combination to attempt to increase (or resist decreases in) pharmaceutical reimbursement rates in health insurance plans?

The Office has not yet encountered prohibited agreements between pharmaceutical manufacturers, such as agreements covering the geographical division or agreements concerning allotment of various therapeutic groups to various manufacturers. Further to the investigation of the world-wide cartel of vitamin manufacturers (Roche, Rhône-Poulenc, BASF) performed by the pertinent agencies in the USA and EU, the Office has also dealt with this issue; however no effects of the foreign cartel agreement were found in the domestic market.

In 1996 the Office conducted two administrative proceedings against the Czech Pharmacy Chamber (CPC). The CPC was appointed by law as a non-political autonomous professional organisation with compulsory membership for all pharmacists.

In the first case, in order to prevent not fully qualified subjects entering the market, the CPC has prescribed the obligation to pay for the license to run the pharmacy different fees for various groups of pharmacy operators (1 000 CZK or 1 000 000 CZK); without that license the pharmacy cannot be run. This behaviour was considered to be a decision of trade association and was forbidden.

In the second case, the CPC has assigned different requirements for individual applicants for the licence to perform private pharmacy practice. This behaviour was considered to be a decision of trade association and was forbidden, and the CPC was penalised.

So far, the Office has not observed a tendency to restrict competition as a result of the operation of major manufacturers in various product and geographical markets.

(4.4) Co-operative or collaborative ventures (such as co-marketing and co-promotion agreements) seem to be an important component of the pharmaceutical industry. Have you had the opportunity to examine the competitive effects of such agreements? What features of these agreements give rise to competition concerns? Have you opposed joint research and development and/or joint marketing arrangements?

Co-operative ventures (such as co-marketing and co-promotion agreements) in the pharmaceutical industry have not been assessed by the Office.

4.3 Mergers and acquisitions

(4.5) What cases of mergers or concentrations have you addressed in the pharmaceutical industry? In what markets were concerns over market power most focused? In the pharmaceuticals industry where competition is primarily by way of new innovation (as opposed to competition on prices), what are the primary anti-competitive effects of a merger? Have mergers been opposed on the grounds that the merging companies might be competitors in the future (although they were not actually competing at the time of the merger)?

In the pharmaceutical area, the Office has dealt with the following mergers:

The merger of Léciva a.s. and VÚFB a.s. (Research Institute for Pharmacy and Biochemistry)

Léciva a.s. acquired control over VÚFB a.s. During this merger, the vertical merger of two competitors occurred, one of them operating in pharmaceutical research and development (VÚFB), the other in the field of pharmaceutical production. Both activities were compatible. Resulting from the merger of both companies, the number of independent competitors dealing with research decreased. Having assessed the case, the Office concluded that the damage which possibly could occur by the disruption of competition would be outweighed by the economic advantages arising from this merger (particularly the investments into the research and development of innovative and original pharmaceuticals); the merger was approved without any conditions attached.

The merger of ICN International, Inc. and Nystepharm a.s.

ICN is an American company operating world-wide in the field of pharmaceuticals and biomedical products. It has acquired control over the Czech pharmaceutical manufacturer Nystepharm, producing especially Ephedrine and Nystatin. Only Nystepharm operated in both defined relevant markets of Ephedrine and Nystatin, respectively, while ICN does not participate in those relevant markets. Thus the merger of both companies did not further strengthen the position of both subjects and the competitive environment in the relevant markets did not deteriorate.

The merger of Rhône-Poulenc and Hoechst

This merger of two foreign companies also affected the domestic market, since resulting from the merger, the share of the products in the defined markets (products for plant protection, chemicals, human pharmaceuticals) exceeded the 30 percent threshold stated by law for the necessity of merger approval. The Office approved the merger, because the economic advantages, consisting mainly in the support of research and development, providing capital for entry into genetic engineering and providing a full range of products for consumers outweighed the damage to competition resulting from the concentration.

The merger of Akzo Nobel and Hoechst Roussel Vet

In the approval of the merger of Rhône-Poulenc and Hoechst, the European Committee imposed the structural obligation on Hoechst to transfer the production in the field of veterinary health care to a third party. This field was acquired by the Akzo Nobel group. Considering the fact that Akzo Nobel and Hoechst operate in the Czech Republic via several affiliates, the Office investigated whether this transfer of production activities abroad would effect the domestic market. Based on the investigations and analyses carried out, the Office concluded that despite the increase in the dominant share in the defined relevant markets, effective competition will be preserved: therefore the merger was approved.

The merger of Pliva and Lachema a.s.

The Croatian company Pliva acquired the domestic manufacturer of pharmaceuticals, diagnostics and special chemicals. The merger was approved given that the merging companies do not compete in individual product markets.

(4.5) What sorts of remedies have been imposed as a condition on merger approval? Have the merging companies been required to divest or license certain products to third parties?

Considering the fact that no significant damage to the competition occurred, no conditions and/or restrictions necessary for the protection of economic competition were imposed by the Office in the merger approval.

(4.6) Have pharmaceutical manufacturers sought to integrate into downstream components of the health industry, such as hospitals, insurers, pharmacies or so-called pharmacy benefits managers ("PBM"s)? Have you found such actions to be anti-competitive? What remedies have you imposed?

Observing the trends of development in the pharmaceuticals market, the Office did not notice any efforts from the pharmaceutical manufacturers to integrate themselves into the downstream components of the health industry. Yet following the complaint of some pharmacists, the Office investigated the case of merging of major distributing companies with pharmacies. Considering the fact that the share of merging subjects did not exceed the limit given by the Act on the Protection of Economic Competition for the control competence of the Office, administrative proceedings have not been launched.

4.4 Abuse of dominance

(4.7) What cases of abuse of dominance have you addressed? Have you addressed cases of ting or predatory pricing? In what ways can a pharmaceutical firm with a dominant position reduce competition form rivals?

The Office has issued one decision on the abuse of a dominant position in the pharmaceuticals field. In 1992, Galena, which occupied a monopsony position in the ergot market, forced ergot suppliers to accept changes in the payment terms in already concluded contracts, threatening to terminate the contractual liaison. A penalty was imposed upon Galena.

FRANCE

Le Conseil de la concurrence a eu à connaître de pratiques anticoncurrentielles ayant affecté la concurrence dans le secteur des produits pharmaceutiques notamment à l'occasion de deux affaires récentes.

Dans les deux cas, ces affaires ont posé de nombreux problèmes de procédure et de fond. La Cour d'Appel de Paris et de la Cour de Cassation ont entériné les analyses du Conseil de la concurrence sur le fond.

1. Description des affaires

Les deux affaires en cause ont concerné, d'une part, les conditions de commercialisation par la société Lilly France de médicaments destinés aux hôpitaux dont le brevet était venu à échéance,[1] et, d'autre part, des pratiques relevées dans le secteur du portage des médicaments à domicile.[2]

1.1 Rappel de l'affaire des pratiques de la société Lilly-France dans le secteur des spécialités pharmaceutiques

A partir de 1988, la société Lilly France, filiale du groupe pharmaceutique nord-américain Lilly, a cherché à préserver sa position sur le marché d'une manière anticoncurrentielle lors de l'expiration du brevet d'un médicament antibiotique pour le traitement des maladies à staphylocoques : la Vancomycine. Cette action anticoncurrentielle s'est développée dès l'apparition d'une mise en concurrence organisée par les établissements hospitaliers français pour la fourniture de leurs pharmacies. Deux types d'entreprises étaient alors présentes sur le marché pour la fourniture de ce médicament :

- d'une part, Lilly France le producteur originel de cette spécialité développée à partir de la recherche effectuée dans ses propres laboratoires et qui disposait jusqu'alors du monopole de la production et de la commercialisation de ce produit. Le pourcentage des ventes réalisé sur la Vancomycine en 1991 par Lilly France était encore de 67.30 pour cent, avec un C.A. global de près de deux milliards de francs en France ;

- d'autre part, deux entreprises qui, après l'expiration du brevet, ont développé la production d'équivalents génériques : Le Laboratoire Lederlé, filiale française du groupe nord-américain American Cyanamid (9.4 pour cent de parts de marché de la Vancomycine en 1991, réalisant un C.A. global de l'ordre de 600 millions de francs en France) a Dakota-Pharm, filiale du groupe suisse Siegfried A.G. (25, 56 pour cent des ventes de Vancomycine en 1991, avec un C.A. total de 25.1 millions de francs en France).

Par ailleurs, la société Lilly disposait du monopole de production et de commercialisation d'un autre médicament (pour le soin des maladies cardiaques), le Dobutrex, que tous les responsables d'hôpitaux se procurent puisqu'il est jugé indispensable pour de nombreux traitements. A partir de la fin

1988, la société Lilly a proposé aux établissements hospitaliers l'octroi de remises tarifaires importantes sur des spécialités dont elle détient le monopole, notamment le Dobutrex, à condition que ces établissements se procurent également auprès d'elle de la Vancomycine sous un nouveau nom - la Vancocine - ; parallèlement, les tarifs de base sur le Dobutrex ont été augmentés.

Le Conseil a considéré que ces pratiques étaient caractéristiques d'un abus de position dominante, visant à empêcher les clients de Lilly France de se fournir en Vancomycine auprès de fournisseurs plus compétitifs et à limiter l'accès au marché de la Vancomycine pour les sociétés Lederlé et Dakota-Pharm, au préjudice des consommateurs de soins hospitaliers nationaux. La société Lilly a été condamnée à une amende de 30 millions de francs. Comme il a été déjà indiqué, cette décision du Conseil de la concurrence a été confirmée en appel par la Cour d'Appel de Paris, celle-ci ayant reprécisé les conditions de la définition du marché pertinent. De même, la décision du Conseil de la concurrence et de la Cour d'Appel de Paris ont été confirmées par la Cour de Cassation. Enfin, les arrêts de ces deux juridictions ont été publiés.[3]

1.2 Rappel de l'affaire des pratiques relevées dans le secteur du portage de médicaments à domicile

La seconde affaire concerne une nouvelle activité de service, la livraison à domicile de médicaments, qui s'est développée au plan local : deux opérateurs susceptibles d'assurer cette livraison couvrent l'ensemble du territoire français. Ces entreprises se font remettre les ordonnances médicales par les malades, les présentent au pharmacien auquel elles achètent le médicament pour le compte du malade puis livrent le médicament au domicile du malade.

En février 1993, le président du conseil central de la section A de l'Ordre des pharmaciens, qui regroupe l'ensemble des pharmaciens titulaires d'officines de préparation et de distribution, a diffusé un communiqué auprès de ses adhérents. Dans ce document, il a indiqué que cette instance de l'Ordre des pharmaciens était opposée au portage à domicile "organisé" par des sociétés diverses, parce que cette modalité de distribution dépersonnalisait la dispensation au détail des médicaments et était contraire au bon déroulement de l'acte pharmaceutique. Cette mise en garde a été répercutée par divers conseils régionaux à leurs membres et certaines entreprises de portage de médicaments à domicile ont été destinataires de courriers leur rappelant les dispositions du code de la santé publique en matière de dispensation du médicament. Par ailleurs, certaines de ces entreprises se sont vues refuser la vente de médicaments par des pharmaciens d'officine.

Le Conseil a considéré qu'en diffusant ce communiqué, le conseil central de la section A de l'Ordre avait incité les pharmaciens à ne pas délivrer les ordonnances qui leur seraient présentées par une entreprise de portage de médicaments à domicile, l'empêchant de poursuivre son activité. Par cette action le conseil central de la section A de l'ordre des pharmaciens a donc mis en œuvre une pratique concertée de boycott, contraire aux dispositions du droit français de la concurrence. Le même raisonnement a été tenu à l'égard de recommandations comparables diffusées par les conseils régionaux. Le Conseil de la concurrence a également sanctionné les refus de vente opposés par certains pharmaciens, en considérant que ceux-ci s'étaient associés à la pratique de boycott.

Le Conseil de la concurrence a écarté les moyens invoqués par les instances ordinales en cause, qui soutenaient que ces recommandations ne procédaient pas d'une entente entre le conseil central de la section A et des conseils régionaux et qu'elles n'avaient eu aucun effet, faute d'avoir un caractère contraignant. Sur le premier point, le Conseil a relevé, d'une part, que les mises en garde effectuées par les instances ordinales étaient l'expression de la concertation menée en leur sein et que, d'autre part, toutes les mises en garde diffusées par les conseils régionaux l'avaient été dans la période immédiatement postérieure

au communiqué diffusé par le conseil central et qu'elles s'y référaient dans certains cas expressément. Sur le second point, le Conseil de la concurrence a relevé que les mises en garde des instances ordinales avaient été largement diffusées aux pharmaciens d'officine, avaient pour objet de les mettre en garde contre les entreprises de portage de médicaments à domicile et pouvaient avoir pour effet d'empêcher l'accès au marché des entreprises proposant ce type de services. La Cour d'appel de Paris, dans un arrêt publié en 1998, a entièrement confirmé l'analyse du Conseil[4].

En outre, la Cour de Cassation a également confirmé cette analyse dans un arrêt qui vient d'être rendu le 16 mai 2000[5].

2. Points intéressant la discussion au cours de la table-ronde

Du point de vue de la mise en œuvre du droit de la concurrence dans le secteur des produits pharmaceutiques, les points qui ont été soulevés par les parties au cours des deux affaires qui viennent d'être rappelées permettent de dégager au moins trois thèmes :

2.1 La définition du marché pertinent

La première affaire a permis de procéder à une réflexion sur la définition du marché applicable au secteur des produits pharmaceutiques et de préciser que la commercialisation d'un médicament dont la formule chimique est originale détermine un marché sur lequel s'apprécie une éventuelle domination d'un opérateur. En particulier, le Conseil de la concurrence a précisé qu'un médicament sous brevet est insubstituable, et présente de telles particularités que les spécialités pharmaceutiques ne peuvent faire l'objet des mêmes études que les biens de consommation courante, notamment en raison des restrictions aux possibilités de substitution des médicaments telles que notamment :

- les propriétés thérapeutiques et pharmacologiques des médicaments en cause,
- les particularités de la demande qui font que la vente de médicament est liée à une prescription médicale préalable.

Toutefois, le Conseil de la concurrence n'a pas retenu la nomenclature de division des classes thérapeutiques préconisée par l'Organisation mondiale de la santé (dite nomenclature ATC), ce qu'avait souhaité le défendeur. Faisant droit à ce dernier, la Cour d'Appel de Paris a retenu la nomenclature en question, tout en confirmant la décision du Conseil sur le fond, et notamment sur le fait que le Dobutrex produit par Lilly France «constitue un marché de produit de référence sur lequel Lilly France, qui en détient le monopole de production et de commercialisation, occupe une position dominante".

2.2 Des précisions intéressantes sur la notion d'abus de position dominante

Toujours dans l'affaire mettant en cause les pratiques de la société Lilly France, le Conseil s'est prononcé, en se référant à la jurisprudence communautaire, sur la mise en œuvre de pratiques d'une entreprise en position dominante, qui, en elles-mêmes, ne sont pas interdites, telles qu'une clause d'exclusivité. A cette occasion, le Conseil a notamment indiqué : "une entreprise en position dominante et confrontée à l'arrivée d'un concurrent est en droit de se défendre ou de développer sa part de marché pourvu quelle demeure dans les limites d'un comportement compétitif normal et d'une concurrence légitime ; en revanche, le fait pour l'entreprise détenant une telle position de tenter de limiter l'accès au marché sur lequel elle est en position dominante, ou sur un autre marché, en recourant par des moyens autres que la concurrence par les mérites revêt un caractère abusif. En particulier, la remise de couplage

des ventes de Dobutrex et de Vancomycine avait nécessairement pour objet et a eu pour effet de "dissuader les pharmacies d'établissements hospitaliers de s'adresser à des entreprises concurrentes pour obtenir séparément de la vancomycine". De surcroît, la stratégie de couplage s'est poursuivie pendant la durée de l'instruction de l'affaire.

2.3 L'application du droit de la concurrence en relation avec l'exercice de droits de propriété intellectuelle

La même affaire a permis de voir appliquer le droit de la concurrence dans un secteur, celui des produits pharmaceutiques, dans lequel les brevets et droits de propriété intellectuelle revêtent une importance particulière. A cette occasion, les débats de la table-ronde du 7 juin 2000 permettent de revenir sur le thème qui avait été traité au cours de la table-ronde du 23 octobre 1997 sur le thème "droit de la concurrence, droits de propriété intellectuelle et marchés d'innovation".

En particulier, trois options avaient été dégagées pour déterminer les axes généraux de mise en œuvre du droit de la concurrence par rapport à un problème posé par l'usage des droits de propriété intellectuelle :

- dans une approche jugée dans l'ensemble assez négativement par l'analyse économique, en raison de son interventionnisme excessif dans la vie économique, la correction par les autorités de concurrence, d'une manière extensive et assez systématique, des excès ou des insuffisances liées à la protection des droits de propriété intellectuelle (par exemple, en ce qui concerne les prix de cession d'un procédé ou d'une formule) ;

- toujours dans une approche jugée assez négativement par l'analyse économique, parce qu'elle limite abusivement les droits de l'innovateur au profit des imitateurs, l'appréciation par l'autorité de concurrence de l'usage d'un droit de propriété intellectuelle en relation avec les processus d'innovation en vue d'assurer la diffusion la plus rapide de l'émergence du produit ou du marché ;

- dans le cadre d'une approche qui est préférée par l'analyse économique, la mesure par l'autorité de concurrence de la réduction de concurrence existante induite par l'usage d'un droit de propriété intellectuelle sur les marchés de produits ou services existants et/ou innovants. Dans le cas d'un usage abusif de ce droit, il appartient à l'autorité de concurrence de limiter les abus éventuels de détenteurs de droits.

Dans l'affaire Lilly France, jugée antérieurement à cette table-ronde d'octobre 1997, le Conseil de la concurrence a appliqué le droit de la concurrence conformément à la troisième approche en traitant le détenteur d'un droit de propriété intellectuelle en cause comme celui "d'une entreprise en monopole qui a cherché à entraver la concurrence sur un marché" connexe, un marché "où la clientèle est d'autant plus captive qu'en matière pharmaceutique les acheteurs sont liés par les prescriptions médicales". Au surplus le conseil a rajouté que «la pratique relevée, sans préjudice de sa qualification au regard du code des marchés publics, était de nature à limiter le développement des médicaments génériques susceptibles de réduire les coûts de la santé".

2.4 L'application du droit de la concurrence dans un secteur réglementé

La décision relative au portage à domicile révèle également dans quelles conditions le Conseil de la concurrence peut être amené à appliquer le droit de la concurrence à des opérateurs qui disposent par

ailleurs de prérogatives réglementaires qui peuvent partiellement les faire échapper au droit de la concurrence.

En France, les articles L. 520 à L 548 du code de la santé publique instituent un Ordre national des pharmaciens qui a "pour objet d'assurer le respect des devoirs professionnels et la défense de l'honneur et de l'indépendance de la profession". La profession de pharmaciens est donc réglementée d'une manière analogue à celle de nombreux pays membres de l'OCDE, comme l'ont montré différentes études de l'OCDE menées sur les professions réglementées au cours des deux dernières années.

Au cas considéré, si le Conseil de la concurrence souligne l'importance des compétences réglementaires confiées à l'ordre des pharmaciens pour garantir le bon fonctionnement des missions de santé publique de cette profession libérale réglementée, il n'en a pas moins considéré que "s'il est qualifié pour représenter son domaine d'activité, la profession pharmaceutique, auprès des autorités publiques et auprès des organismes d'assistance et participe à l'élaboration du code de déontologie" et que "si l'Ordre national des pharmaciens peut donner son avis aux pouvoirs publics sur les questions relevant de sa compétence, il sort de sa mission en diffusant des mises en garde constituant un appel à un boycott collectif du portage des médicaments à domicile, portage dont les conditions sont précisées par les dispositions de l'article L 589 du Code de la santé publique". De ce fait, précise encore le Conseil de la concurrence, "les pratiques du conseil central de l'Ordre national des pharmaciens" et celles "des conseil régionaux" qui leur ont été associées, "ont eu pour objet et pu avoir pour effet d'empêcher l'accès au marché des entreprises de portage de médicaments à domicile" et de telles pratiques "sont prohibées par les dispositions de l'article 7" du texte français définissant le droit de la concurrence, "sans que le conseil central de la section A de l'Ordre national des pharmaciens, ni les conseil régionaux puissent utilement invoquer les dispositions du code de la santé publique" pour bénéficier d'une exonération de l'application du droit de la concurrence.

Dans ce cas encore, les considérations développées et les condamnations prononcées par le Conseil de la concurrence ont été validées par la Cour d'appel de Paris et la Cour de Cassation. Cette dernière a même précisé dans son arrêt du 16 mai 2000 précité "qu'en l'état de ces constations et énonciations, la cour d'appel a pu décider que la diffusion" du communiqué en cause "dans lequel le Conseil central diffusait une interprétation inexacte du code de la santé publique sur laquelle il se fondait pour manifester son opposition à l'activité de portage de médicaments à domicile, ne manifestait pas l'exercice d'une prérogative de puissance publique, sortait de la mission de service public qui lui est conférée en tant qu'ordre professionnel, et constituait une intervention sur le marché du portage de médicaments à domicile dont le Conseil de la concurrence pouvait connaître".

NOTES

1. Décision n° 96-D-12 du Conseil de la concurrence en date du 5 mars 1996 relative aux pratiques mise en œuvre par la société Lilly France dans le secteur des spécialités pharmaceutiques destinées aux hôpitaux, *Dixième Rapport Annuel d'Activité du Conseil de la concurrence*, p. 232-241. Voir aussi l'arrêt de la Cour d'Appel de Paris (chambre économique et financière) en date du 6 mai 1997 relatif au recours formé par la société Lilly France SA contre la décision susnommée, publiée au *Bulletin Officiel de la concurrence de la consommation et de la répression des fraudes (BOCCRF)* du 11 juin 1997. Voir enfin l'Arrêt de la Cour de Cassation (chambre commerciale, financière et économique) en date du 15 juin 1999 relatif au pourvoi formé par la société Lilly France SA contre la même décision du Conseil de la concurrence, publiée au *BOCCRF* du 27 juillet 1999.

2. Décision n° 97-D-18 du Conseil de la concurrence en date du 18 mars 1997 relative à des pratiques relevées dans le secteur du portage des médicaments à domicile, *Neuvième Rapport Annuel d'Activité du Conseil de la concurrence*, p. 286-299. Voir aussi l'arrêt de la Cour d'Appel de Paris (1ère chambre, concurrence, section H) du 10 février 1998, publiée au *BOCCRF* du 28 février 1998 et l'arrêt de la Cour de Cassation (chambre commerciale et financière) en date du 16 mai 2000 contre la décision n° 97-D-18 du Conseil de la concurrence susmentionnée (non encore) publiée).

3. Voir plus haut note 1.

4. Voir ci-dessus note 2.

5. Non encore publié.

HUNGARY

1. Market Structure

By the mid '90s there became many market players in the Hungarian pharmaceutical industry. Besides some big undertakings small and medium-sized entrepreneurs have also appeared. The first twenty undertakings - ranked according to their turnovers - cover around 80 percent of the market.

In 1998 the number of producers was 199[1] in the Hungarian pharmaceutical industry.

The market shares of the leading producers
(on the basis of turnovers)

		1998	1999
1.	GEDEON RICHTER	10,22%	9,57%
2.	EGIS	9,18%	8,46%
3.	NOVARTIS	7,02%	6,76%
4.	CHINOIN SAN.WINTHR	6,45%	5,92%
5.	BIOGAL	5,82%	5,25%
6.	PFIZER	3,01%	3,69%
7.	MERCK SHARP DOHME	3,08%	3,61%
8.	ROCHE HUNGARY	3,18%	3,56%
9.	ELI LILLY	3,50%	3,55%
10.	GLAXO WELLCOME	2,68%	2,80%
11.	SCHERING PLOUGH	2,63%	2,79%
12.	BRISTOL MYERS SQUI	2,87%	2,79%
13.	PHARMACIA UPJOHN	2,68%	2,65%
14.	JOHNSON/JOHNSON CO	2,17%	2,08%
15.	ASTRA	1,87%	2,05%
16.	AVENTIS PHARMA	1,76%	2,02%
17.	SMITHKLINE BEECHAM	2,02%	1,99%
18.	HUMAN	2,07%	1,79%
19.	ICN HUNGARY	2,02%	1,71%
20.	ZENECA	1,40%	1,67%
21.	NOVO NORDISK	1,53%	1,56%

Six Hungarian pharmaceutical producers are owned by foreign professional investors. However Richter Gedeon Plc. refused its majority acquisition by a foreign pharmaceutical producer[2]. (A stake representing 25.2 percent of the shares owned by the State Privatisation and Asset Management Plc. (SPAM Plc.) and the pension fund cannot be sold until 31 December 2000.)

By the end of 1996 transformation was performed in every Hungarian pharmaceutical producing undertakings and the majority state ownership was terminated. Foreigners acquiring ownership in the

Hungarian pharmaceutical industry are medium-sized enterprises, which perform their expansion through acquiring control this way.

The Ownership Structure of 7 Pharmaceutical Producers (State of 31 December 1998)[3]

	Producers (Original old Hungarian names)	Main Owners	Percent of Ownership of the Main Owners	Other Owners
1.	Biogal	Orvet GmbH/Teva (Izrael)	97,8	2,2
2.	Chinoin	Sanofi-Synthelabo (France)	99	1
3.	Egis	Servier(France)	51	49
4.	Human	Novopharma (Canada) Pension Fund	55,5 25,3	19,2
5.	Alkaloida	ICN Pharmaceuticals (USA) SPAM Plc.	67,1 25,7	7,2
6.	Pharmavit	Bristol Myers-Squibb (USA) Foreign financial investors	99,9 56,9	0,1
7.	Richter Gedeon	SPAM Plc. Pension Fund	15,7 9,5	17,9

The market positions of some of the producers above is as follows:

Richter Gedeon (RG) Plc.

The Richter Gedeon Chemical Plc. is an undertaking registered in the Hungarian Republic with Budapest location. It was established in 1923. In 1990 the "Kõbánya Pharmaceutical" became a public limited company and it was acquired by RG. In 1994 the firm raised its capital, consequently the proportion of state property decreased. The shares of the Plc. were introduced on the Budapest Stock Exchange. In 1998 the turnover of the Plc. reached HUF 55 billion (around Euro/USD 220 million) closely one-third of which was realised on the Hungarian market.

The Plc. which has a leading role on the domestic market (with its 10,2 percent market share) makes also great efforts to regain the ex-CMEA markets. States belonging to this category occupies the first three places on its export markets. The export of the RG Plc. goes to the next countries (in decreasing order): Russia, Poland, Ukraine, United States, Baltic States, Czech Republic, Vietnam, Slovak Republic, Romania, China[4].

Products

During the last few years the Plc. renewed its product portfolio to a great extent. New products which have been introduced since 1990 to the domestic market represents 42 percent of the whole domestic turnover[5].

The structure of the product portfolio by origin is as follows: 62 percent stems from reproduced and generic products, 15 percent is the rate of licensed products and original products have 23 percent.

Business policy

In the field of export the Plc. reckons to a great extent upon the products which patent protection expire from 2000, since in the US and also in Western Europe patent protection of many products having great turnover will be terminated. The firm has prepared itself to produce these generic products, moreover, this production would be based on its own ingredients, so it could be competitive compared to its competitors producing generic products and active in developed countries.

In addition to acquisitions the RG Plc. tries to expand its markets through establishing firms abroad as well. The Plc has acquired decisive control over a Romanian pharmaceutical producer and it has closely 60 percent ownership also in a Russian firm. The Plc. spend around seven-nine percent of its turnover to R&D.

Egis Plc.

In 1995 the French Servier holding company acquired 51 percent of the Egis shares. According to professional opinions the Egis Plc. is one of the most reliable Hungarian undertakings. The market share of the Plc. was 9.2 percent on the Hungarian market in 1998. 47 percent of the turnover was realised on the domestic market.

The main markets of the Egis Plc. are as follows: domestic market (47.7 percent), Central- and Eastern-Europe (3.8 percent), Russia and CIS countries (12.9 percent), Western-Europe (9.3 percent), North-America and Japan (6.8 percent).

Products

The major part of the Plc's turnover stems from selling human drugs and pharmaceutical ingredients form a smaller part. As for the origin of the products sold, the generic products have a decisive role, in 1998 these products gave 73 percent of the turnover. One-fourth of the Egis products originates from licensed products (licences with rights for production and distribution) and the original Egis products give remaining two percent of the turnover.

From 15 July 1999 the Plc. introduced 24 new products of 12 product group to the Hungarian market three out of which are licensed products and all of them are reimbursed products at the same time. The Plc. focuses its activities to heart-, circulation-, central nervous system and respiratory system pharmaceutical products.

Business policy

Egis Plc. has trading undertakings registered abroad (Egis Polska, Egis Praha, Egis Slovakia, Aegis), due to the consolidated balance sheets performances of which can be found in the balance of the Egis Plc. Egis has 100 percent ownership in Medimpex Trading Plc., which pursues export services for Egis and to some extent it pursues its own export/import business.

In abroad Egis submitted 179 registrations (for products which has been marketed in Hungary). As a result of its co-operation with Servier 14 products of six Egis product groups have been registered in France.

Chinoin Rt. (Sanofi-Synthelabo)

When Sanofi acquired majority ownership over Chinoin the restructuring of activity- and product portfolio began immediately. The Hungarian toxicological plant of the firm was closed (in Vác). Recently the firm having 6.5 percent market share on the Hungarian market and stands on the fourth place.

Products

In the past the firm developed many products from its own resources, the patent protection of the majority of which has expired. The generic products represent the highest proportion in the turnover of the firm, but during the last few years more and more Sanofi products which were marketed world-wide were introduced also to the Hungarian market.

Business policy

Prior to its acquisition by Sanofi, the Chinoin had a wide-range R&D capacity. As part of its rationalisation project, Sanofi decreased the 12 research programmes into two, in addition to this, the R&D budget was increased from six percent into eight percent (percentage related to the turnover) which means around HUF 1.5 billion (Euro/USD six million).

The Eastern markets represent important role in the export turnovers of human products, in spite of the fact, that the collapse of the Russian market in 1999 resulted in substantial market loss.

Expansion forms Sanofi's world-wide policy and acquisitions have important role in this policy. Sanofi was one of the parties to the last merger in the pharmaceutical industry (Sanofi/Synthelaboval).

2. Regulation of supply

2.1 Protection of Intellectual property rights and Patent protection

Prior to the 1990's, patents were not issued for products as such, but the manufacturing process was patented. Therefore, it was totally legal for a copy of an existing product to be manufactured and sold if a different manufacturing process was used.

Product patents were introduced in 1994 in order to abide by international patent standards. Pharmaceuticals, chemicals and foodstuffs can now be patented, but products which were filed for registration between July 1994 and July 1995 benefit from a transitional period. The law allows to continue to manufacture all products that were patented before 1988 provided they existed on the Hungarian market before the 1994 legislation.

According to the law the patent protection period is granted by 20 years. Currently there is not such provision in the Hungarian regulation which would allow to extend the patent protection period up to 25 years. The Hungarian government asked for derogation in the EU accession negotiation in this regard.

In Hungary the clinical data for registration is protected by the civic law and by the competition law. There is no specific restriction associated with submitting file for registration of generic product. No specific period for data exclusivity exist. Roche-Bolar type exemption is applied.

2.2 Drug registration

A pharmaceutical product can only be sold if it is registered and has obtained a marketing authorisation. Registration is the responsibility of the National Institute of Pharmacy. The National Institute of Pharmacy both registers and grants the marketing authorisation.

2.3 The national institute of pharmacy

The National Institute of Pharmacy *(OGYI - Országos Gyógyszerészeti Intézet*), an independent agency created in 1962, is responsible for the registration and the marketing authorisation of all pharmaceutical products. It is also in charge of conducting post-marketing surveys on quality defects and drug utilisation. The Institute produces guidelines for drug utilisation which are in line with the European Union guidelines and with the International Conference on Harmonisation (ICH*),* but it does not have the means to assure that these standard treatment guidelines are enforced. Finally, the NIP also carries out GMP (Good Manufacturing Practice) and GLP (Good Laboratory Practice) inspections, which are mandatory every two years, and marketing surveillance (i.e., to monitor adverse drug reactions). For international manufacturing certification the NIP usually relies on Pharmaceutical Inspection Agreements under which they acknowledge tests conducted by their counterparts in foreign manufacturers' countries. If there is no agreement with foreign countries, the Institute sends inspectors abroad, to inspect manufacturing processes. There is no mutual recognition agreement with the US, but the NIP accepts the United States' Food and Drug Administration (US-FDA) approvals.

The NIP raises the majority of its resources from fees paid by manufacturers at registration (90 percent of its budget). The remaining resources are from the central government via the Ministry of Welfare budget. Registration fees are determined by the Ministry of Welfare. They depend on the category of the product to be registered (US 800 for generic products, USD 3 200 for a new product -first registration). The fees are set to cover all testing activities undertaken by the Institute.

The NIP was reorganised in 1990 to cope with the expected increase in the number of registered products. A crucial problem remains, however, the shortage of staff, which has been imposed on the Institute due to public sector restrictions. In 1996, the staff was reduced from 170 to less than 150 due to a reduction across the civil service recommended by the International Monetary Fund (IMF). The quantity of work which must be accomplished by the NIP could justify higher staff levels, according to its director.

2.4 The registration process

The formal registration process consists of two steps: registration and marketing authorisation. The latter is a carryover from the pre-market economy era and is automatically granted once the product is registered.

The objectives of the registration process are to ensure that the new drug complies with the following principles: safety, efficacy, and quality. The National Institute of Pharmacy has testing facilities and conducts tests itself, but it would rarely re-conduct all the tests which have been done by the company. The NIP does not conduct pharmaco-economics studies, as they are not part of the registration process.

Around 600 products are registered every year (plus 200 homeopathic monocomponent drugs). There were approximately 2 000 pending applications at the end of 1997. The following registration processes are used by the NIP:

- normal process (applies to most products): It used to take more than three years from the initial application to the marketing authorisation,[6] but this period has recently gone down to between two to 2.5 years. In some difficult cases, however, the process can take up to four years. According to the new law on pharmaceuticals, the registration period should be brought down to no more than two years.

- European centralised procedure: The National Institute of Pharmacy has accepted the common European procedure. This should considerably speed up the registration process for eligible medications. This procedure has been used to register seven to eight products and the registration period was cut down to 15 to 20 months.

There are no separate queues within each category and the first product which has entered the queue is the first to be considered and generally the first to obtain marketing authorisation. There is no separate OTC product queue, except for homeopathic products. New products which must be considered are those with different active principles, dosage forms and strength; not those with identical elements but different packing sizes.

At the time of registration, the National Institute of Pharmacy also assigns medicines to the prescription and non-prescription categories (this used to be the legal responsibility of the Ministry of Welfare until last year). The definition is mostly based on European guidelines but social objectives are sometimes introduced in the definition.

2.5 Trade regulation

There are no barriers to international trade and investment. There is no restriction on the import of medicinal products. The multinational companies are allowed to market their products without quantitative limitation.

Parallel trade is not prohibited. However the Hungarian authority is not aware of this kind of ongoing activities of wholesalers since the Hungarian prices are lower compared to prices in EU member states and other western European countries. The mail order pharmacy and using Internet for ordering medicinal products are prohibited. There is not such type of trade related regulation put in place which distinguish between domestic and foreign firms.

2.6 Industrial policy

Although the intention of Hungarian government is to promote the manufacturing of medicinal products in the territory of Hungary, there is no specific allowance for pharmaceutical companies related to taxation. The law about company taxation is applied to all pharmaceutical companies. The maximum company tax is 18 percent. In case of significant investment the company can be tax waived for five years. After five years, the tax to be paid is gradually increased on a annual basis up to 18 percent.

By 1996, all the six formerly Hungarian based companies were privatized and bought by multinational pharmaceutical companies. The foreign companies benefit from tax concession and the generally low company tax in Hungary.

3. Regulation of demand: controls on pharmaceutical prices. Quantities and consumption

3.1 Health insurance coverage of pharmaceuticals

The drug reimbursement system is applied to all Hungarian citizens. The current policies of the Hungarian drug reimbursement system came into force in February 1995. Since this date no major changes of the drug regulation were introduced. In line with the Transparency Directive (89/105/ECC) concerning the transparency requirements of drug pricing and reimbursement policies, the principles of drug reimbursement were published in 1996. Welfare Gazette Number 25, as ministerial statement.

According to these principles the drugs can be reimbursed at 0/50/70/90/100 percent. The bio-equivalent generic drug products are subsidised with a fixed amount, which is based on the price of the least expensive alternative product included in the given group of products. For 75 INN groups fixed reimbursement was introduced. In cases of choosing the higher priced brand-name drugs, the difference between the fixed reimbursement and the price has to be paid by the patients.

There are two groups of patients who are considered to be exempted. Individuals, who suffer severe chronic disease can receive their medicines for free of charge or reimbursed at 90 percent. Individuals who are eligible for some kind of public assistance, can also receive their medicines free of charge. Medicines that can be prescribed to the exempted population free of charge are specified and published in the official Gazette of Ministry of Health. Clinical effectiveness and price are considered in the selection of the these medicines. Country of origin is not taken into account.

Since pharmaceutical products manufactured in Hungary are generally lower priced than foreign companies' products, medicines on the social list are mostly products that are manufactured in Hungary. Approximately 500 thousand Hungarian citizens are eligible for public assistance and medicines free of charge. The local governments decide about who can be entitled for public assistance, and the central government provides the necessary funds for covering the co-payment on the behalf of this population.

3.2 Formularies

The reimbursement categories:

- maximum reimbursement for special diseases (90 to 100 percent);
- maximum reimbursement for "socially handicapped" (100 percent);
- other reimbursement categories: 90, 70, 50 and fixed; and
- no reimbursement (zero percent).

Some drugs must be prescribed by a specialist doctors in order to be reimbursed. The most important reimbursement category is the "100 percent" category, with 32 percent of the budget, followed by the "90 percent" category, with 28 percent.

3.2.1 Maximum reimbursement for special diseases (90-100 percent)

Prescriptions for specified, very serious, diagnoses are reimbursed at 90 or 100 percent for (nearly) all the drugs they consume to treat this special disease when the medication is prescribed by a

specialist doctor. In addition, there is a special list of very expensive drugs, which can only be fully reimbursed if they are prescribed in tertiary care institutions outpatient services, usually the National Institutes.

The list of these special diseases is defined in a governmental decree. There are 23 conditions which warrant 100 percent reimbursement (such diabetes, cancer, or multiple sclerosis) and another 37 conditions make patients eligible to a 90 percent reimbursement (such as asthma, epilepsy, Parkinson's disease and rheumatoid arthritis). Patients who suffer from cancer would get nearly all drugs reimbursed at the highest level, from weak pain-killers to the most expensive- special cancer drugs. If a general practitioner prescribes the same drug for the same diagnosis, the drug may only be reimbursed at a lower level. In some cases, however, the specialist can delegate the right to prescribe for the highest reimbursement level to a GP, especially for chronic diseases. The treatment period may be limited for certain diseases: for instance, treatment for psychiatric diseases are covered for this special reimbursement category for only six months.

3.2.2 Maximum reimbursement for "socially handicapped" (100 percent)

In 1995, a drug subsidy system based on a drug formulary, the "közgyógyellátás" system, was introduced. Products used in the treatment of the most common chronic conditions were put on this list of essential drugs, which can be dispensed with a social insurance subsidy of between 90 and 100 percent. Beneficiaries of the scheme are the "socially disabled," (i.e. those who have a minimal monthly income). They must also be particularly ill (i.e., to have a monthly drug consumption above a certain level). These patients need to obtain an identification card. They can only benefit from the subsidy when the drug has been prescribed by their family doctor, and when it has been dispensed by the pharmacy they have registered with for this purpose. These measures are to improve control over a subsidy system which has been prone to fraud, as mentioned below.

The "socially handicapped" list presently contains 600 products. The list is revised every year over by a committee presided over by the Ministry of Health, with experts from the OEP, general practitioners, pharmacists and representatives of the Ministry of Health. The OEP is liable for its normal reimbursement price. The difference is covered by a central government budget.

3.2.3 Other reimbursement categories: 90, 70, 50 and fixed

Most diseases warrant drug subsidies of 70 and 50 percent of the drug's retail selling price. These two categories only account for 25 percent of OEP's drug reimbursement budget.

"Fixed reimbursement" is a system similar to the reference price system used in Germany. The reimbursement price for drugs containing the same chemical compound is the reimbursement price which applies to the least expensive drug containing this compound. As a result, if the least expensive drug is reimbursed at 50 percent, the fixed reference price amount can represent much less than 50 percent of the price. The existence of copy products in the market means that copy product prices are often the reference to price licensed products, under the fixed reimbursement system. If the dosage is different, a ratio is applied to take account of this variation.

This system does not currently apply to drugs within the same ATC group, but it can be introduced in certain clinically well established categories- when an ATC group-based fixed system is to be introduced because of budgetary restrictions. This system will probably increase the proportion of co-payments to be paid by patients but it is likely to arouse doctors' opposition, who usually "do not like to say that drugs are equivalent" and usually prefer to use more expensive brand names rather than generics.

3.2.4 No reimbursement (zero percent)

Non-prescription drugs are not reimbursed. In addition, a few prescription drugs, such as analgesics or sleeping pills, are not reimbursed either. Around 26 percent of drugs are in the category of 0% reimbursement with a lot of new drugs. Note that many of these medications are usually only used in in-patient settings.

From January 1998, a system equivalent to a "negative list" has been introduced. This means that products which are not likely to obtain reimbursement can be submitted by manufacturers directly to the Ministry of Health, without the need to obtain the expert committee's agreement. These products can be marketed without having to go through price and reimbursement negotiations with the committee.

3.3 Price control policies

3.3.1 Price-setting negotiations for reimbursed products

Following the LXXXVII Act (1990) which provided for drug prices to be freely determined, in case of reimbursed products prices are determined on the basis of negotiations between drug manufacturers and an expert committee composed of the representatives of Ministry of Health, Ministry of Finance and Health Insurance Fund. These are closely linked to reimbursement levels negotiations. Functionally there are two kinds of price negotiations:

- case-by-case negotiations to set the price of new products;
- industry wide negotiations to agree on annual price increases.

3.3.2 New products

Manufacturers, both domestic and international, have to agree on a price for newly launched products with the above mentioned expert committee. On the basis of the price proposal, the committee would consider reference prices abroad (for example in Spain and in France) or within Hungary for a drug with the same active compound as an existing drug. If the committee finds the proposed price too high, it may ask the company to formulate a new proposal. This process can be repeated on an iterative basis.

3.3.3 Annual price negotiations

Each year negotiations take place between the expert committee and each manufacturer to determine price increases for the following year. In advance of the negotiation period, the government targets price changes for the new year. They send a formal letter to manufacturers asking for relevant information to be returned on a floppy disk.

Price setting negotiations are in two, simultaneous parts. The first part sets the manufacturers and therefore the retail prices that the expert committee will recognise. The second part assigns the medicines to a reimbursement category.

In the first phase, manufacturers propose a price to the National Health Insurance Fund, but do not provide "cost" information as there is no rate of return regulation. The price negotiation goes hand in hand with the negotiation for the reimbursement classification, which can be more important to

manufacturers. If the expert committee deems that the proposed price is too high and therapeutic criteria allow it, expert committee can put the product in a lower reimbursement category or grant reimbursement only if a particular specialist prescribes the drug. A registered drug does not necessarily obtain price reimbursement as the criteria of quality and efficacy may conflict with cost-containment. The committee can refuse to grant any reimbursement, especially if similar drugs are already on the market.

The outcome of the negotiation was then be ratified by the Ministry of Health until 1999. By the year of 2000 it will be ratified by the Government based on the proposal of Finance minister and Health minister. Details of the new product, its price and reimbursement level are then published in the official journal.

3.3.4 Price–setting for non-reimbursed medicinal products

From January 1998, manufacturers do not have to negotiate the price of those products which are not reimbursed by the OEP. The list of those medicines which are not reimbursed is published by the Ministry every year. The same system to fix wholesale and retail margins applies to these products.

3.4 Control of physicians prescribing practice

The pharmacies are all computerised in Hungary. The use of the highly subsidised exempted medicines is monitored through the computerised prescription recording system. High priced prescriptions, patient generating the highest monthly drug expenses for the health insurance fund and physicians with extremely high drug spending are selected for more scrutinised control.

In 1999 it was discussed several times between professional organisation and government officers that rational prescription and use of medicines can be encouraged by providing financial incentive to physicians as one part of the saving that they make would be put at their disposal. This saving could be used for improving their practice. However the final decision on the introduction date has not been made so far.

3.5 Regulation of pharmacies and pharmaceutical distribution

After 1990, the distribution system of pharmaceuticals underwent major changes in Hungary. The government owned wholesalers and pharmacies were privatized and many new pharmacies were established. The non-price-competitive feature of the socialist chain pharmacy system was continued in the new private system. The drug prices in retail pharmacies are regulated and uniform. In 1999, there were 24 large wholesalers, 2 015 retail pharmacies and 531 branches in Hungary.

Wholesaler margins

Wholesale margins are set in a governmental decree. The margins were modified by 15th of July, 1999. They depend on the manufacturing selling price of the product: the higher the product price, the lower the wholesaler margin, as shown below.

Wholesaler margins

Ex-Manufacturer price	Wholesale margin (%)	Flat rate (Ft.)
0-150.00	12.0	-
150.01-180.00	-	18.00
180.01-300.00	10.0	-
300.01-333.00	-	30.00
333.01-500.00	9.0	-
500.01-600.00	-	45.00
600.01-1,000.00	7,5	-
1,000.01-1,154.00	-	75.00
1,154.01-2,000.00	6,5	-
2,000.01-2,600.00	-	130.00
2,600.01-	5.0	-

Pharmacy margins

All pharmacies must charge the same retail price. They are not allowed to discount the retail price except to inpatient units which do no have a pharmacy on their premises.

Pharmacy margins are regulated by government decree. Regulated margins are between 16 and 30 percent. The highest margins apply to the cheapest products, as shown in below. Some retail pharmacies have started forming co-operatives to purchase pharmaceuticals and obtain better deals from wholesalers (they can get an additional margin of one to two percent in certain cases).

Retail pharmacy margins

Wholesale price (Ft.)	Retail Margin (%)	Retail price (Ft.)
0-200	30	0-260
201-500	26	261-630
501-1,500	20	631-1,800
1,501-3,500	18	1,801-4130
3,501-	16	4,131-

Source: Ministry of Welfare

Retail margins were raised in 1997 to adjust for inflation. Previously it appears that retail margins had remained unchanged for six to seven years as there is no automatic mechanism for adjusting prices to inflation.

The pharmacists are not obliged to substitute the brand names prescriptions for generics. They have the right to do so in case the physician does not prohibit it by marking it on the prescription.

3.6 Policy towards generics

In general, the generic drug products are priced at lower level than brand-name pharmaceuticals. Starting in 1999, only those generic products were put on the reimbursement list which were priced 20 percent less than the original product. In those cases when the price difference between the generic and original product is significant and fix reimbursement is applied based on the price of the generic product, the generic product can obtain bigger market share compared to those cases when the fixed reimbursement is not used. Until now there were no such provisions in Hungary that would give incentives to physicians

and pharmacists for prescribing or substituting generic products. The estimated market share of generic products (in value) was about 30 percent in 1999.

4. Competition issues in the pharmaceuticals sector

Competition law is applicable to the whole economy and each industry. There are no activities that would in their entirety constitute an ab ovo exception or would also be exempted from the scope of the Act. (In theory this would be possible because the scope of the Act covers the market practices carried out on the territory of the Republic of Hungary by natural or legal persons and companies with no legal personality, except where differently regulated by Acts of Parliament. Such separate rules could in theory be applicable to whole sectors. This, however, would only be possible if another Act were to provide for this separately, because the Competition Act itself contains no sectoral exceptions, while rules different from those in the Competition Act can be stipulated only in Acts of Parliament.)

There are exception rules pertaining to individual sectors, but these are always partial, that is, they cover only certain market segments rather than whole sectors, or they set additional rules for restrictive agreements or merger control that take into consideration the special conditions of the industry and must be applied in addition to the competition law rules; compliance with such additional rules is enforced and controlled by the professional regulator of the industry concerned.

Furthermore, for various sectors there are specific exceptions or authorisations pertaining to specific conducts rather than the whole of the sector.

In the health sector there are some features in respect of the scope of competition law:

- Health insurance of social insurance character and providing of publicly financed health service can be qualified as regulated areas, where competition supervision is supplemented by regulation. From this point of view, this area can be regarded as exception from the application of competition law.

- In contrary to this, providing of health service financed privately can be regarded as falling fully under the general scope of competition law.

- In the fields of production of pharmaceutical products, drug wholesale and retail competition law applies on areas which are not regulated (e.g.: regulation of margins by the Act No LXXXVII of 1990 on Price-setting, or retail sales prices regulated by the Act on Operation of Pharmacies and special co-ordinating system on drug reimbursements). Rules based on these special Acts creates exceptions from the general application of rules on restriction of competition and abuse of dominant position, nevertheless this system does not except the whole sector from the application of competition rules. For example, the whole set of rules on concentration control applies, but also in the field of drugs the competition authority can proceed against a prohibited price agreement of independent producers and importers, in so far as they co-ordinate their prices or price increases.

The OEC is the only agency with competition supervision powers in the sense that the examination and evaluation of conducts in violation of the prohibition of abuse of dominance or of restrictive agreements as well as the control of concentration in line with the rules of the Competition Act is its exclusive competence. The OEC decides on case-by-case basis, whether the practice under investigation belongs to the regulated area or not. If it is established that it does not fall under a special

rule, the OEC declares its competence and proceeds according to the standard procedural rules of the competition law.

4.1 Market definition issues and barriers to entry and exit

In the practice of the OEC very few proceedings have been made only so far in connection with restrictive agreements or abusive practices as far as the pharmaceutical sector is concerned.

> In a particular case the necessity of market definition arose in connection with a product which is necessary for abdominal dialysis prescribed by the physician. In order to determine the market the competition authority relied on the professional knowledge of experts and witnesses.
>
> "The variety of the respondents' tinctures is similar in itself as far as the composition is concerned, since the tinctures serve the same purpose, nevertheless the bags containing the tincture and the necessary requisites which are connected to the drainage-hole of the abdominal catheter are individually characteristic for the particular firms and also for the respondents in this case."

In general it can be stated that there is close co-operation between the competition authority and different ministries. The Ministry of Welfare (responsible for health issues) issued a decree on the substitutability of drugs, which is the starting point in defining rational substitutability and market definition. The substitutability as defined in the decree is almost the same than the international therapeutics grouping by the WHO.

The products and consequently also their markets determine whether those belong to hospital-, prescribed- or OTC groups. Of course, in a particular case the competition authority decides taking into consideration all the circumstances of the particular case and the general rules relating to market definition.

In the pharmaceutical industry there is strong competition in both production and distribution. In addition to this characteristic, there are mainly legal, authorisation-type and financial conditions of market entry/exit, which conditions are reflected by several recent regulations and Acts[7]. As a consequence, in a particular case, defining the relevant market, market entry barriers like capital-intensity and time-consuming nature of R&D, authorisation process of drugs, exclusive rights generated by patents, introduction of a given product to the market, prohibitions on advertisement, grant for social insurance reimbursement, etc. have to be taken into consideration.

4.2 Anti-competitive agreements

There were not too many possibilities to gain information about this issue in the pharmaceutical sector.

> Actually there was one particular case where the suspicion of concerted practice has emerged, but the investigation proved that the abdominal dialysis tinctures of the four competitors - serving drug for the same illness (unsatisfactory operation of kidney) - do not substitute each other, since switch over one of the drugs to another requires physician's contribution. Consequently, the price agreements between the competitors on the one hand and the National Health Insurance Fund on the other hand were not interpreted as anti-competitive restrictions.

There is no information that the producers would share the market from geographic point of view.

Of course, the producers and importers try to make some pressure on the Ministry of Welfare (responsible also for health care issues) and the National Health Insurance Fund when they negotiate with these institutions, since they intend to acquire the best positions. On the one hand, they unify their power on the price-negotiations according to their interest, on the other hand they try to exercise some kind of lobby activity on the health insurance institution through the National Association of Pharmaceutical Producers and Importers.

There were not any examples of agreements concluded between Hungarian pharmaceutical distributors, so the competition authority has not have the possibility so far to investigate this kind of agreements.

5. Mergers and acquisitions

The world-wide merger wave has made some influence also on the Hungarian markets and in the proceedings of the OEC, since the mergers of international parent companies had relevance also in Hungary in great numbers. If the subsidiaries pursue economic activity in Hungary and their turnovers meet the notification thresholds stipulated by the Hungarian Competition Act (Act No. LVII of 1996 on the Prohibition of Unfair and Restrictive Market Practices) prior authorisation of the competition authority has to be applied for. (E.g.: Hoechst Aktiengesellschaft/Rhone-Poulenc S.A. merger, or acquisition of Novopharm Limited by Teva Pharmacentical Industries Ltd.)

No conditions of this kind have been requested by the Competition Council in the practice of the competition law enforcement.

According to the present regulation neither pharmaceutical producers nor wholesalers may have pharmacies in Hungary. Consequently, integration intentions of pharmaceutical manufacturers have not been experienced. From the practice of the last years just a disintegration example can be mentioned. Early in 2000 - through a multi-step acquisition process - a foreign undertaking (UTA Pharma Beteiligungs Gmbh.) acquired control over a chain of numerous pharmacies in the territory of five Hungarian counties from a financial investor which, on the one hand, had controlling rights over pharmacies and on the other hand, it was the third largest pharmaceutical wholesaler. At the same time the second largest wholesaler (Phoenixpharma Plc.) applied for the authorisation of the OEC since it intended to acquire control over the rest of the wholesaler branch of this third largest pharmaceutical wholesaler. As a result of these transactions, the vertical integration became separated.

Concerns have arisen in respect of connections of pharmaceutical producers, hospitals, physicians and pharmacists (sponsorship, commissions and other benefits), however stronger regulatory steps have not been taken so far. There is an increased social expectation to control the physicians as far as their prescription practice is concerned and certain prohibitions have been worded in professional ethic codes for business connections of physicians and pharmacists with pharmaceutical producers.

5.1 Abuse of dominance

There has not accumulated any law enforcement practice so far at the competition authority.

NOTES

1. According to the data of pharmaFELAX

2. Figyelő XLIII. évfolyam 7. számában 13.old. megjelent Magyar Pirula c. cikk alapján

3. Source: MAGYOSZ (National Association of Hungarian Pharmaceutical Producers)

4. Source: Richter Gedeon Plc. Annual Report 1998

5. Annual Report 1998

7. E.g.: Act No. XXV of 1998 on Drugs for Human Consumption or Ministerial Decree No 60/99 (XII. 1.) on Wholesale Activity for Drugs

ITALY

1. The Pharmaceutical Industry: Market Structure

1.1 Market structure

1.1.1 Please describe the market structure of pharmaceutical firms in your country - which firms are active, with what market share, in which therapeutic classes and with what level of R&D (including generic producers). Which firms co-operate to jointly undertake R&D or to jointly market certain products? Is there one or more associations of pharmaceutical manufacturers in your country? Is this association politically important?

In Italy, the market structure of pharmaceutical products is characterised by a very high level of concentration. According to the market definition followed by the Competition Authority, which is referred to the fourth level of the ATC (Anatomical Therapeutic Classification[1]) classification (see section 4 below), it is possible to identify 321 product markets for medicines in Italy. Of these, around 78 percent, in 1997, were characterised by a CR4 above 80 percent (see table 1).

In November 1997 the Competition Authority completed a general fact-finding survey into the Italian pharmaceuticals industry, which analysed the competitive structure of the first 27 markets in terms of total turnover (above 50 billion ITL), characterised by a CR4 above 80 percent (see table 2). Comparing the competitive structure of these markets over a five years period, the Authority concluded that in only seven markets has there been registered the entry of a new operator among the first four companies in terms of market share. In the remaining 20 markets the first four companies were, after five years, the same operators as in 1992. However, in 12 markets there was a remarkable variation among leaders' market shares. The Competition Authority concluded that notwithstanding the high levels of concentration of these 27 markets, those characterised by a high level of innovation and concerned with the launch of new products, presented competitive dynamics. The available data, for pharmacy sales, on market shares for the 27 markets considered are reported in table 2.

Italian pharmaceutical companies mainly operate through licence and co-marketing agreements with multinationals. In 1997 around 71 percent of total pharmaceutical selling was performed by operators controlled by foreign companies. In particular, around 23 percent by US owned companies and around 12 percent by German companies.This could be a measure of the underinvestment in R&D which characterises the Italian pharmaceutical industry. In 1998, the Italian pharmaceutical industry invested only 1.4 billion (ITL) in R&D. At the end of 1998, there were 285 companies producing pharmaceutical products for human use in Italy, 71 companies producing or commercialising pharmaceutical active ingredients, 33 of which have production sites in Italy, and 50 companies producing medicines for veterinary use, of which 20 also produce medicines for human use.

According to Farmindustria, the value of total production in the Italian pharmaceutical Industry in 1998 was around 24 000 billion (ITL). Of the total, around 65 percent were realised by pharmacy sales, while 12 percent represented hospital purchases[2].

In the industry there are three main associations: Farmindustria (Associazione Nazionale dell'Industria Farmaceutica) which is the Italian Pharmaceutical Manufacturers' Association; Assosalute which represents manufacturers of OTC products; and Assogenerici, which represents generics manufacturers. Farmindustria is the most important association. It currently represents 215 companies (see also section 4).

2. Regulation of supply

2.1 Protection of intellectual property rights

2.1.1 Please describe the regulatory framework established for the protection of intellectual property rights in the pharmaceutical industry

Until EEC Regulation 1768/92 became operative in Italy, law no. 349/1991 had provided a considerably longer period of patent protection for certain specialist drugs than was the case in other European countries. According to the provision of art.1 of Law 349/91, in addition to the statutory patent protection term of 20 years after filing, a supplementary protection certificate can be obtained once a pharmaceutical product has been registered. Supplementary terms of protection are calculated as the difference between 20 years and number of years that have elapsed from the filing date and the date of the initial marketing authorisation. The term of a supplementary protection certificate must in no case be more than 18 years. Supplementary protection certificates shall be covered by the same legal arrangements governing patents, with the same exclusive rights and obligations.

In 1993, was introduced in Italy the Regulation no. 1768/92 which has reduced (art.13) to a maximum of five years the period of the extension of patent protection allowed by the supplementary protection certificate. However, according to the provisions of art. 20 of the regulation no. 1768/92, the regulation is not applicable to protection certificates filed or assigned according to national laws before the adoption of the said regulation. As a consequence, about 400 active ingredient, which were registered according to the provisions of Law 349/91 have a longer period of patent protection in Italy than in other European countries.

2.2 New drug approvals

2.2.1 Please provide an overview of the drug approval process.

The regulatory authority in Italy is the Ministry of Health. Pharmaceutical products registration and marketing authorisation are undertaken by the Ministry's pharmaceutical committee, the CUF (Commissione Unica Farmaco). The Committee has the following responsibilities: Pharmacovigilance, pharmaceutical usage and pack size optimisation; Marketing authorisation renewals and regular reviews of medicines; Reimbursement; Clinical trials and provisions for special use; Monitoring pharmaceutical information and promotion; European and non-European regulatory procedures; Generic and homeopathic medicines.

In 1998, the clinical trial authorisation process was simplified. Previously, all trial applications had to be submitted to the Ministry of Health and the national ethics committee for approval. According to the new system, pharmaceutical companies need only obtain approval from a local ethics committee. There were around 80 such committees in mid-1998, with plans to increase the number to around 300 over the

following months. The ethics committees are also responsible for monitoring clinical trials, ensuring protocols are honoured and informed consent is obtained.

Recent years have been characterised by a strengthening of the process of harmonisation within EU countries, which is based on a complex registration procedure which may act at a centralised or a decentralised level[3].

2.3 Trade regulation

2.3.1 Please describe any barriers to international trade or investment in pharmaceuticals. Are there restrictions on international trade in drugs by third-parties (such as parallel trade or re-imports)? Are there restrictions on mail-order or Internet supply of drugs? Does the regulatory regime distinguish between domestic and foreign firms in any way?

The low level of foreign direct investments in pharmaceuticals in Italy may be largely attributed to the low level of prices registered by pharmaceutical products in Italy with respect to other European countries, and to the country's very cumbersome regulatory environment.

With reference to the level of prices in Italy, until the revised pricing formula has been introduced in 1998, the system introduced in 1994 (see section 3 below) led to prices in Italy being on average 30 percent lower than the EU. As a consequence, particularly with regard to innovative products, it was not profitable for manufacturers to market their products in Italy since prices were fixed at such a low level that imported products could only be sold at a loss.

With reference to the regulatory environment, the clinical trial authorisation process was simplified in 1998, following criticism that the length of time needed to receive an authorisation was so high as to discourage investment and research.

2.4 Industrial policy

2.4.1 Please describe any industrial policy objectives in this sector. Describe the objectives and effects of any tax concessions or subsidies that exist

Na

3. Regulation of demand: Controls on pharmaceutical prices, quantities and consumption

3.1 Health insurance coverage of pharmaceuticals - formularies

In 1994, pharmaceuticals have been classified for reimbursement purposes as follows[4]:

- Class A: Pharmaceuticals which are considered essential or life-saving. They are fully reimbursable and only available on prescription. To control the prescribing of this kind of drug, the prescription needs to be noted down in the local authority's public register with a specific indication of the diagnosis.

- Class B: Non-essential pharmaceuticals which meet primary therapeutic requirements. They are restricted to prescription-only and are partially reimbursable at 50 percent.

- Class C: This category contains pharmaceuticals used for minor ailments which are not reimbursable. This class includes prescription and non-prescription medicines and the price is unrestricted.

- Class H - hospital use only, generally drugs as in Class A.

Innovative products are initially given non-reimbursement status (Class C) or hospital-use only status (Class H), before their final classification is decided.

Art. 1 of D.L. n. 323/96 established that a pharmaceutical products characterised by the same therapeutic use and active principle (even if with different concentration of the same) are reimbursed by National healthcare system (SSN) only when their price is equal to the lowest price of substitute products, otherwise the product will be shifted in class C.

3.2 Price control policies

3.2.1 Please describe the operation of the controls on pharmaceutical prices in your country

Under the pricing method introduce in 1994, prices are based on the average European price formula. According to the CIPE (the Interministerial Economic Planning Committee responsible for setting up the criteria for price controls) the criteria to be taken into account in order to determine the average European prices of drugs should include the comparison of prices in four member states France and Spain, where prices are fixed, and the United Kingdom and Germany, where they are unrestricted. Moreover, for each active principle, the five most widely sold pharmaceuticals were taken into account on the basis of turnover. The legislation ruled that all drugs priced above the reference price had to be reduced immediately to that level, while those products with lower prices could raise their prices over a five year period, at the rate of one increment per year.

The revised pricing system was eventually finalised in 1998, providing for the use of up 12 EU countries for pricing comparisons. Products must be marketed in at least four countries, however, two of which must have direct pricing controls. The new system also uses actual exchange rates rather than PPPs.

Under the 1999 finance bill, some further reform has been introduced: products which were initially allocated non-reimbursement status and have since been admitted to the reimbursement list, and products which received market authorisation through the national system, were subject to automatic price cuts of 15 percent. Subsequently, the prices of the affected products will be increased to the 'average European price' level in six annual stages.

The prices of innovative products approved through the EU centralised and mutual recognition procedures were negotiated between manufacturers and the government under an Interministerial Economic Planning Committee (CIPE) regulation, using pharmacoeconomic criteria.

It is worth stressing that the pricing system introduced in Italy is not originated by efficiency reasons. Given the diversity of European pricing systems, the European average price might also reflect the inefficiencies of national systems.

With reference to the pharmaceutical product purchased by hospitals, Law no. 264/74 has introduced a minimum discount for pharmaceutical products sold to hospitals, equal to 50 percent over the fixed price.

Class C drugs, which include OTC products, are not subject to government price controls.

3.3 Control of physicians prescribing practices

3.3.1 Please describe the system in place to encourage high-quality cost-effective physician prescribing practices

In Italy there is not a system aimed at encouraging high-quality cost-effective physician prescribing practices. The recent reform in national healthcare system (SSN) introduced by Dlgs 299/99, has established the principle of imposing, by further legislation, some form of control over the physicians in order to encourage high-quality cost-effective physician prescribing practices, such as 'virtual budget constraints' over the prescriptions made. Such measures have not been implemented yet.

3.4 Regulation of pharmacies and pharmaceutical distribution

3.4.1 Please describe the nature of any controls on pharmacy margins, entry and/or ownership structure. Please describe also the nature of any rules governing the discretion of pharmacists in substituting other products

In Italy pharmaceutical distribution is provided by wholesalers (D.Lgs 538/92) and by pharmacies (EU Directive 25/92). For pharmaceutical products in class A and B, Law 662/96 has established wholesalers and pharmacies margins over medicines' fixed price, equal to 6.65 percent and 26.7 percent, respectively. The distribution of pharmacies in Italy is regulated by law. In particular, the number of pharmacies that can be licensed in each municipality is based on demographic and geographic criteria and a minimum distance rule is in force. In 1998, there were 291 wholesalers and 16 317 pharmacies in Italy, each pharmacy serving an average of 3 000 citizens. Under the Italian legislation, pharmacists have the statutory obligation to charge the same prices on medicines not eligible for refunds nation-wide, whereas wholesalers have to stock at least 90 percent of all the authorised medicinal specialities.

Finally, pharmacists have no discretion in substituting pharmaceutical products. According to art. 6 of DPR 371/98, pharmacists may substitute a pharmaceutical product with a product which presents the same active ingredient only when the product required is not available.

3.5 Policy towards generics

3.5.1 What share of non-prescription/over-the-counter, prescription and hospital markets are held by generics? Please describe the programs you have adopted to promote the consumption of generics

The generics market in Italy is comparatively small, with respect to other European countries.

Generics manufacturers have to contend with the longer exclusivity period afforded to certain products, through the Italian supplementary protection certificate system.

There are at least three main characteristics which inhibit the growth of generics in Italy.

As already stated until EEC Regulation 1768/92 became operative in Italy, law no. 349/1991 had provided a considerably longer period of patent protection for certain specialist drugs than was the case in other European countries.

Furthermore, the average time required to register a drug in Italy is extremely long, and far exceeds the period laid down in the law (120 days). These delays hamper both the registration of new speciality drugs and generic drugs, or drugs whose active ingredient is already being marketed on the European or domestic market.

Lastly, before less costly drugs with the same therapeutic effects can be widely prescribed, the doctors and pharmacists must be given adequate incentive to recall the need to reduce public and private expenditure on drugs and medicines when prescribing them. At the present time, the fact that wholesalers and pharmacists earn a proportional margin on the final selling price makes it less attractive for them to sell a low-cost drug when an equivalent more expensive drug is also available.

4. Competition issues in the pharmaceutical sector

4.1 Exemptions or exceptions

According to Law 287/90, the Competition Act has full validity to all sectors and to all enterprises (section 8.1). There is no exception to the application of the antitrust law in pharmaceutical industry, and in fact the Authority has intervened a number of times in this sectors in applying the antitrust law.

In 1995 the Authority submitted a report regarding measures to be adopted to encourage the dissemination throughout Italy of generics. The Authority stressed that in order to be able to substitute speciality drugs having the same therapeutic effects as a generic product, it is essential to have an appropriate legal framework guaranteeing that the generic drug is fully interchangeable with the corresponding speciality drug which no longer enjoys patent protection. Without this statutory guarantee, it is difficult and risky for a physician to prescribe a generic drug and for the National Health Service to include it in the national pharmacopoeia. In this connection the Authority noted that the lack of any specific definition of a "generic drug" in Italian legislation created a major problem. It also emphasised that any generic drugs in a given class of treatment or products should be publicised so that they could be more easily marketed. Furthermore, the Authority considered the average time required to register a drug in Italy is extremely long, and far exceeding the period laid down in the law (120 days), hampering by consequence both the registration of new speciality drugs and generic drugs, or drugs whose active ingredient is already being marketed on the European or domestic market. Considering all these factors, the Authority stated in its advisory report that when the regulation of the pharmaceuticals industry is overhauled, statutory provisions should be enacted to permit the generic drugs sector to develop more widely.

In 1997, the Competition Authority in its general fact-finding survey into the Italian pharmaceutical industry, suggesting the removal of the statutory obligation on pharmacies, to charge the same prices on medicines not eligible for refunds nation-wide, as the removal of the wholesalers' obligations to stock at least 90 percent of all the authorised medicinal specialities. According to the

Authority, both the obligations had the effect of discouraging competition between the manufacturers of different drugs with similar therapeutic features, as well as between pharmacies and between wholesalers.

In its advisory report of 1998, the Authority stressed that the extent of the reserve granted to pharmacists appeared excessive with respect to the indispensable objective of protecting citizens' health. According to the Authority, the objective of guaranteeing a minimum level of service throughout the country could be attained more effectively by identifying indicators of service adequacy, such as the minimum number of pharmacies that should be present in each locality, and by providing for municipal pharmacies only where it was found that not enough privately owned pharmacies had entered the market to provide an adequate service.

4.2 Market definition issues and barriers to entry and exit

According to the market definition followed by the European Commission, the Competition Authority has recurred to the ATC classification of medicines in order to define the relevant product market in pharmaceutical industry[5]. The third level classes of the ATC classification provide a grouping of medicines according to their therapeutic properties, that is, their intended use, and therefore may be accepted as an operational market definition. It may be necessary, however, to carry out analysis at other levels of ATC classification where it is appropriate to group particular 3rd level categories together or to descend to narrower classes at the 4th level as the Italian Competition Authority is used to do.

Because the pharmaceutical industry operates within a very tight legal framework, pharmaceutical markets remain essentially national. No drug may yet be marketed in any other EU Member State without the previous approval of the respective national administration, although procedures for mutual recognition of marketing authorisations exist. Notwithstanding the considerable harmonisation achieved so far in the Community with regard to pharmaceutical registration procedures, the evaluation of a drug and the decision to authorise its marketing remains at present with the competent authorities of the Member States. In addition, prices of ethical drugs are directly or indirectly regulated by national laws. The differences in the pricing and reimbursement mechanisms result in wide disparities in drug price levels among different Member States.

Prices of OTC drugs are normally excluded from price or reimbursement regulation. However, the markets also remain national for these products because of the following factors: retail distribution is legally confined to pharmacies in certain Member States, whereas in others they are available in other consumer outlets (groceries or supermarkets); the decision to confer OTC status upon a medicine is a national one; the consumer's attitude to self-medication is to a large extent determined by cultural traditions and because of the importance of branding for these products. The existence of national markets is confirmed by the absence of Europe-wide brand names and the fact that there is little or no parallel trade in OTC products, the price of which may vary from country to country.

4.3 Anticompetitive agreements

The Italian Competition Authority has recently analysed a number of anticompetitive agreements in the pharmaceutical industry, as it is listed below. One of these has also regarded the role played by the most important national association of pharmaceutical companies, Farmindustria.

4.3.1 Istituto Gentili-Merck Sharp & Dohme-Neopharmed/Sigma Tau Industrie Farmaceutiche Riunite-Mediolanum Farmaceutici

In February 1999 the Authority completed its investigation into Merck Sharp & Dohme Italia Spa, Neopharmed Spa, Istituto Gentili Spa, Sigma Tau Industrie Farmaceutiche Riunite Spa and Mediolanum Farmaceutici S.p.A. for possible violations of the prohibition on anti-competitive agreements in relation to parallel movements in the prices of certain category C drugs produced by these companies. Category C drugs are paid for entirely by patients and their prices are completely unregulated. The investigation focused, in particular, on drugs based on the active principle known as "simvastatin", which are used for the treatment of hypercholesterolaemia.

In addition to the parallel movements in the prices of the drugs in question, additional evidence of collusion was found in correspondence in which Merck Sharp & Dohme Italia gave the other companies advance notice of its intention to raise the price of its product and invited them to follow suit, which they did, and the impossibility of adducing parallel movements in costs to explain the parallel movements in prices.

Having established that the behaviour of the companies under investigation needed to be analyzed as a horizontal agreement, the Authority concluded that the practice of jointly fixing the prices of class C drugs was anti-competitive within the meaning of Article 2 of Law no. 287/1990. The agreement had the effect of increasing prices by 47 percent in just ten months and it was substantial in scope since the parties had a market share of 67 percent for the category C segment and of 63 percent for stations in category C. In view of the seriousness of the limits to competition identified, the Authority fined the companies a total of 115 million lire, equivalent to three percent of the sales revenues for the products in question.

4.3.2 Byk Gulden Italia-Istituto Gentili

Servier Italia-Istituto farmaco biologico Stroder

In February 1999 and in July 1999 the Authority completed two investigations relative to parallel movements in the prices of certain category C drugs for the treatment of throat infections: (*a*) the first investigation regarded Byk Gulden Italia Spa and Istituto Gentili Spa; (*b*) the second, regarded Servier Italia Spa and Istituto Farmaco Biologico Stroder Srl.

In both cases, the two companies involved distributed drugs based on the same active principle but with different trademarks. The Authority concluded that, in each case, the behaviour of the two companies involved was the result of a price fixing concerted practice. The grounds for this conclusion were: the parallel movements in the prices of the products in question; contacts, correspondence and discussions having as their object the pricing policies of the two companies; and the impossibility of adducing parallel movements in costs to explain the parallel movements in prices. In the second case, co-markeing agreements had also the effect of deterring potential entry in generics market. In both cases, the practices were deemed to constitute an anti-competitive agreement within the meaning of Article 2 of Law no. 287/1990. The effect of the agreement was substantial in scope in both cases since it regarded two leading companies in the specific product market analysed. In view of the seriousness of the limits to competition identified, the Authority in one case fined Byk Gulden Italia and Istituto Gentili a total of 705.57 million lire; in the other case the Authority fined Servier Italia Spa and Istituto Farmaco Biologico Stroder Srl a total of 3 000 million lire.

4.3.3 Assosalute/Self-regulatory code of conduct

In March 1998 Assosalute, the trade association of the producers of non-prescription drugs, asked the Competition Authority to exempt , under Article 4 of Law no. 287/1990, a self-regulatory code of conduct on changes in the prices of non-prescription drugs from the prohibition on anti-competitive agreements.

The Authority found that the mechanism specified in the code, based on parameters that it would be easy for the firms involved to know, would have allowed each of them to foresee the pricing policies of the others. The distortion of the price formation mechanism produced by the code would have been accentuated, moreover, by the monitoring Assosalute was to perform to ensure compliance by the members of the association, which would have further reduced the free play of price competition. The Authority concluded that the self-regulatory code proposed by Assosalute for the determination of drug prices amounted to an anti-competitive agreement within the meaning of Article 2 of Law no. 287/1990.The Authority was not satisfied that the conditions necessary for an exemption to be granted under Article 4 existed and therefore rejected the application.

4.3.4 Farmindustria/code of conduct

On 7th December 1999 the Competition Authority completed an investigation on Farmindustria, the Italian Association of Pharmaceutical Companies. The Authority has underlined that in some cases the actions followed by Farmindustria constituted anti-competitive agreements and, thus, infringements of article 2, paragraph 2 of the Law n. 287/90. In particular, Framindustria introduced in the code of conduct of associated pharmaceutical producers a provision by which the minimum discount provided by the law for the selling of products for hospitals, equal to the 50 percent over the list price, represented the maximum discount level that the associated undertakings must apply in participating to the bids. Pharmaceutical companies which did not respected this provision could be fined. The Authority showed that in several bidding processes the undertakings have effectively respected such provisions. Furthermore Farmindustria tried to block the development of generics by favouring the transfer of licences to small and medium sized companies close to the end of the patent protection period and reducing their willingness to compete aggressively.

In 1998 Farmindustria had also drafted a self regulated code of conduct Under the code, companies agreed to increase prices only once per year and by a limited amount. The Competition Authority investigated the code and concluded that it eliminated competition in a significant proportion of the market, thus inhibiting price competition for the products of class C.

4.4 Mergers and acquisitions

4.4.1 Baxter-Clark

In December 1997 the Authority completed its investigation into the acquisition by the United States Baxter International Inc. group of the controlling interest in the Clark Srl company. Both companies operate in the pharmaceuticals and health and medical products industry. On the Italian market this operation would have given Baxter almost three times the market share of its main competitor for solutions for peritoneal dialysis, and three-and-a-half times that of the market for lines and machinery used for this treatment.

After analysing the state of competition in the industry the Authority found that between 1990 and 1997, Baxter's market shares in Italy for peritoneal dialysis treatments had declined significantly as a result of the action of its main competitors. It therefore ruled that the operation did not enable the company to act significantly independently of its competitors and customers, and therefore closed the investigation.

4.5 Abuse of dominant position

Na

ANNEX 1

Tables

Table 1 - Pharmaceutical markets in Italy (by turnover and CR4) 1997.

Turnover	CR4						
(billion ITL)	<50%	50%-70%	70%-80%	80%-90%	90%-100%	100%	Total
<10	0	0	2	4	40	93	139
10-20	0	2	6	4	28	13	53
20-30	0	2	7	6	8	5	28
30-50	0	4	7	10	7	6	34
50-100	1	11	6	6	6	4	34
100-200	0	8	2	5	1	3	19
>200	1	9	1	3	0	0	14
Total	**2**	**36**	**31**	**38**	**90**	**124**	**321**

Source: Italian Competition Authority (1997) - Indagine conoscitiva settore farmaceutico

Table 2 - Pharmaceutical markets with CR4>80 % and turnover over 50 Billion Lire (Source: Italian Competition Authority (1997) - Indagine conoscitiva settore farmaceutico).

Product Markets	**Turnover**	**CR4 (1996)**	**CR4 (1992)**	**Mkt share main companies 1996**	**Mkt share main companies 1992**
Immunosuppressive agents	102,3	100	97,4	Sandoz 97,2 Segix 2,8	Sandoz 97 Segix 0,4
Gonadotrophins	63,1	100	98,2	Serono 97,8 Bruno 0,9 Amsa 0,9 Poli 0,3	Serono 94 Amsa 1,8 Bruno 1,6 Poli 0,8
Antihyperthensives	86,3	97,5	84,6	Pfizer 80,9 Lifeph. 9,1 Abbott 6,1 Fisons 1,4	Pfizer 56,1 Janssen 15,1 Abbott 7,8 Lifeph. 5,6
Other Antihyperthensives	50,9	100	99,5	Boeh. I. 63,1 **Pharm. 31,8** Merck 5,1	Merck 55,3 Boeh. I. 44,2
Grh citostatics	173,2	100	100	Takeda 45,5 Ipsen 34,6 Zeneca 16,4 Hoechst 3,5	Takeda 40,6 Zeneca 28,6 Ipsen 28,3 Hoechst 2,5
Insulins and analogues	104,2	100	100	Novo 53,2 Eli Lilly 40,4 Guidotti 6,4	Novo 54,4 Eli Lilly 40,3 Guidotti 5,3
Penicillins with extended spectrum	192,8	86,2	81	Smithk. 43,3 Pharm. 25,7 Fournier 9,7 Rottaph. 7,5	Smithk. 36,7 Pharm. 24,8 Rottaph. 10,5 Pfizer 9

Product Markets	**Turnover**	**CR4 (1996)**	**CR4 (1992)**	**Mkt share main companies 1996**	**Mkt share main companies 1992**
Antifungals for systemic use	121,1	86	93,7	Pfizer 40 Janssen 31,7 Bioind. 7,7 Lifeph. 6,6	Pfizer 57,6 Janssen 16,2 Sigmat. 10,1 Bioind. 9,8
Antiflu	59,7	85	85,5	Menar. 47,2 Boeh. I. 21,6 Smithk. 8,3 Warner 7,9	Menar. 52,1 Boeh. I. 15,9 Smithk. 9,2 Angelini 8,3
H2 antagonists	368,4	83,7	77,7	Menar. 40,2 Glaxo 36,8 Merck 3,4 Guidotti 3,3	Menar. 36,4 Glaxo 32 Sigmat. 4,8 Merck 4,5
Calcium regulators	69,9	80,8	100	Gentili 24,7 **Merck 23,8** **Neoph. 22,5** **Spa 9,8**	Chiesi 59,5 Takeda 31,4 Gentili 7,4 Boeh. M. 1,7
Contraceptives	85	100	100	Organon 32,7 Menar. 25,8 Schering 21,5 Wyeth 20	Schering 28,6 Wyeth 26,1 Organon 24,8 Menarini 20,5
Growth Hormones	110,6	99,8	100	Pharm. 35 Serono 31,4 Eli Lilly 21,8 **Novo 11,6**	Pharm. 50,4 Serono 35,4 Eli Lilly 14,1
Test for ematic glucosis	85,8	94,3	97,8	Boer. M. 37,1 Ortho 27 Bayer 22,9 Menar. 11,3	Boer. M. 49,2 Bayer 38,3 Ortho 7,3 Menar. 3
Antivirals	97,9	92,7	98,5	Glaxo 68,6 Sigmat. 11,8 **B.-Myer 10,6** **Foletto 1,7**	Glaxo 75,5 Sigmat. 20,9 Spa 1,6 Pulitzer 0,5
Calcium antagonistsi	70,9	91,8	91,7	Bayer 60,6 Italfarm. 17 Janssen 7,3 Smithk. 6,9	Bayer 58,8 Italfarm. 20 Smithk. 9,2 Janssen 3,7
Heparins	82,6	91,4	99,6	Italfar. 66,5 Ucb 10,9 Crinos 7,2 Schwarz 6,8	Italfar. 87,6 Ucb 6,8 Schwarz 4,1 Rhone P. 1,1
Antiarrhytmics	59,9	90,4	88,1	Knoll 47,5 Sigmat. 18,6 Synthel. 17,1 Boeh. I. 7,2	Knoll 38,9 Synthel. 20,9 Sigmat. 17,2 Boeh. I. 11,1
Antidiarrheal microorganisms	90,4	89,4	89,8	Sanofi 65 Bracco 10,5 Berna 8,8 Hoechst 5,1	Sanofi 58,3 Bracco 13,7 Hoechst 9,7 Berna 8,1

Product Markets	**Turnover**	**CR4 (1996)**	**CR4 (1992)**	**Mkt share main companies 1996**	**Mkt share main companies 1992**
Corticosteroids	100,3	87,8	99,9	Chiesi 51,1	Chiesi 84,7
				Glaxo 18,4	Valeas 11,7
				Valeas 10	Glaxo 2,9
				Astra 8,3	Record. 0,6
Intestinal antiinflammatory agents	52,6	86,3	83,3	Giuliani 62,5	Giuliani 51,6
				Yaman. 9,1	Parke D. 12
				Parke D. 8,9	Searle 11,3
				Pharm. 5,8	Fisons 8,4
Gastroprocinetics	165,3	85,6	86,3	Janssen 50,2	Janssen 50,9
				Fisons 19,4	Fisons 21,5
				Ravizza 9,8	Ravizza 7,8
				Sigmat. 6,2	Sigmat. 6,1
Beta-2 stimulants	117,5	83,7	93,4	Glaxo 30	Glaxo 43,8
				Sigmat. 21,1	Menar. 29,7
				Ciba G. 19,2	Dompe 15,5
				Menar. 13,4	Boeh. I. 4,4
Proton pump inhibitors	282,8	82,7	100	Bracco 24,2	Bracco 37,8
				Malesci 22,5	Malesci 33,4
				Astra 20	Schering 28,7
				Schering 16	
Antacids	69,6	82,2	86,8	Rhone 36,4	Rhone 33,7
				Roche 23,1	Roche 29,5
				Whiteh. 13,6	Whiteh. 14
				Boeh. M. 9,1	Boeh. M. 9,6
Interferon-alfa	202,5	80,2	90,9	Schering 29,3	Schering 35,6
				Roche 21,7	Glaxo 23,8
				Glaxo 14,8	Roche 22
				Alfa W. 14,4	Sigmat. 9,5
Antifungals for topical use	51,8	80,1	84,8	Janssen 44,8	Janssen 47
				Bayer 18,9	Pfizer 16,8
				Pfizer 11,7	Bayer 14,2
				Sandoz 4,7	Menar. 6,8

Source: Italian Competition Authority (1997) - Indagine conoscitiva settore farmaceutico. New entry in the relevant market are in bold charcter.

NOTES

1. The classification is made by the Nordic Council on Medicines of Uppsala.

2. Source: Farmindustria, 1999; Profound, 1999.

3. The centralised registration procedure is handled directly by the EMEA (European Medicines Evaluation Agency) which has overall responsibility for ensuring quality, safety and efficacy of medicinal products, and is required to forward a scientific opinion. The decentralised procedure relies on the principle of mutual recognition. According to the regulations, applications can be made under national procedures for products to be marketed in that particular country. After registration has been obtained in this way, application may be made for registration in one or more other member states via the decentralised procedure.

4. The EU directive 89/105/EEC, relating to the transparency of pricing mechanisms in member states, came into force on 31st December 1989. The legislation requires member states which impose price or profit controls to publish their pricing policy, but does not require national authorities to operate any particular system. Compliance with the legislation does not, therefore, lead to harmonisation of pricing policies or reimbursement schemes. The directive sets a time limit of 90 days for national authorities to agree or set a price for a new product, and requires them to state their reasons for fixing a price at a different rate to that sought by the manufacturer. If 'price freezes' are introduced, there are principles to follow which require such action not to be prolonged unnecessarily. The European Commission must be informed of national authorities' criteria for evaluating transfer prices and the classification of products by therapeutic categories. A Consultative Committee is responsible for examining matters relating to the application of the directive. The European Union's pharmaceutical registration system has been in effect for all member countries since 1st January 1995. Based on directives 65/65/EEC, 75/318/EEC and 75/319/EEC, which set out the general framework for regulation, and subsequent additions and amendments, the aim is to harmonise pharmaceutical regulations throughout the EU. The regulations deal with the mechanism for granting marketing authorisation within the EU, requirements for labelling and the provision of information for health professionals, and the criteria, norms and protocols for the assessment of safety, quality and efficacy.

5. This classification is recommended by the World Health Organisation, and most of the national administrations in the Community use it for the purposes of comparing different medicines. It is also the classification used by IMS to establish its drugs sales statistics, which are generally used by pharmaceutical firms for their market analysis.

JAPAN

1. Situation concerning pharmaceutical industry

1.1 Market structure

The Japanese pharmaceutical market accounts for approximately 15.4 percent of the world market and ranks second on the market scale after the United States.

The total amount shipped is approximately $49.5 billion, approximately 86 percent of which is pharmaceuticals for medical services and 14 percent is pharmaceuticals for general use (over-the-counter (OTC) drugs).

On a company scale, sales by the largest companies in Japan were approximately $4.905 billion on a single base and $6.452 billion on a consolidated base in FY 1998. The averages of the top ten companies are approximately $2.275 billion and $2.987 respectively. Furthermore, there are about 1 500 pharmaceutical manufacturers and importers of pharmaceuticals including OTC drugs, of which small and medium-sized enterprises account for more than 70 percent.

The average expenditure for research and development of the ten leading companies is approximately $295 million, or 14.3 percent of total sales.

Incidentally, 6 of the 30 highest ranking products in the world are said to be involved in research and development conducted by Japanese pharmaceutical companies (Note 1$ = Yen 130.91)

1.2 Industrial Policy

The policy of the pharmaceutical industry is R&D support primarily in fundamental research.

In concrete terms, the policy includes a project for fundamental technological research (including a program to create drugs through gene analysis), subsidies for R&D in orphan drugs, a loan system for R&D for pharmaceuticals and preferential tax measures for pilot research expenses.

1.3 Policy towards Generic Drugs

Generic drugs account for approximately seven percent of all pharmaceuticals used by medical services.

The promotion of generic drug use is believed to contribute to the rationalisation of medical expenses.

However, one might say that, at the present time, the environment for dissemination of generic drugs has not been sufficiently improved. Accordingly, the Ministry of Health and Welfare has endeavoured to promote improvements in the liability toward quality, through compliance reviews. In addition, we feel that information should continue to be provided and a stable supply ensured for the dissemination of generic drugs.

1.4 Price standards for medicine

Pharmaceuticals can be divided into pharmaceuticals for general use (over-the-counter drugs) and pharmaceuticals for medical service. An overwhelming majority of pharmaceuticals for medical service are used for medical treatment covered by the medical insurance program. Under Japan's health insurance program, doctors administer (drugs) to patients that they deem to be necessary, and most of the costs are paid by the insurer as medical fees.

The standard prices for pharmaceuticals that the Minister for Health and Welfare determines under the Health Insurance Law provide for the types of pharmaceuticals that can be used for medical treatment covered by the health insurance program, and they set the prices that medical institutions can charge patients for such pharmaceuticals.

2. Enforcement activities of the competition law in the pharmaceutical industry

2.1 Violation cases against the Antimonopoly Act (AMA)

The Japan Fair Trade Commission (hereinafter mentioned as "JFTC") has taken legal action against the following cases for violation of the AMA:

(1) Cartel by the industry association of pharmaceutical companies (1999 Japan Pharmaceutical Manufacturers *Association hereinafter referred to as "JPMA".) (1983).*

The standard prices for pharmaceuticals have been regularly revised according to the market prices. However, as the standard prices are prices that medical institutions charge insurers for pharmaceuticals used for treatments covered by the health insurance program, medical institutions earn the difference between standard prices and the prices at which the institutions buy pharmaceuticals as their income. Therefore, medical institutions tended to demand that pharmaceuticals suppliers lower the wholesale prices when the standard prices for pharmaceuticals were lowered. In other words, whenever the standard prices of pharmaceuticals were lowered, the wholesale prices were also lowered, which in turn caused the standard prices to decline.

In 1981, in anticipation that the standard prices of pharmaceuticals would be lowered, JPMA, which was involved in this case, decided to:

- refuse the claim of medical institutions to lower wholesale prices when the standard prices for medicines were lowered;
- lower the difference between the standard prices and wholesale prices to an appropriate level and prevent the standard prices from being lowered; and
- reduce the differences in wholesale prices between medical institutions;

- and notified its member companies of the decisions.

Furthermore, in response to the revised standard prices for pharmaceuticals, the JPMA held a meeting with the Japan Pharmaceutical Wholesalers Association (the industry organisation comprising medicine wholesalers; hereinafter referred to as "JPWA") and agreed to:

- refuse the claim of medical institutions to lower wholesale prices when the standards prices of medicines were lowered;
- lower the difference between the standard prices and wholesale prices to an appropriate level and prevent the standard prices from being lowered;
- reduce the differences in wholesale prices between medical institutions;
- prevent from selling pharmaceuticals for medical service at prices that pharmaceutical companies do not approve; and
- have joint meetings at their respective branches to implement the above-mentioned decisions.

Through the above-mentioned practices, JPMA prevented its member companies from freely determining their prices and thereby unjustly restricted the activities and functions of its member companies. In June 1983, the JFTC issued a decision to JPMA for violation of Section 8-(1)-(iv) of the AMA.

(2) Bid-rigging for vaccine and other products in Miyagi Prefecture (1992)

Municipalities in Miyagi Prefecture registered companies that met certain conditions and which sell vaccines and other products, and allowed the companies to participate in public bidding and comparison of estimates.

Twelve companies involved -- that were selling vaccines and other products in Miyagi Prefecture - supplied most of the vaccines and other products that the municipalities procured through tenders by designated bidders.

Of the 12 companies, those allowed to participate in tenders held prior consultations to predetermine the winner and the bidding prices.

In doing so, the 12 companies, contrary to the public interest, substantially restrained competition in the field of trade concerning vaccines and other products procured by the municipalities in Miyagi prefecture through the bidding competed by designated firms.

In March 1992, the JFTC issued a decision to the 12 companies for the violation of Section 3 of the AMA (Unreasonable restraint of trade)

(3) Bid-rigging by manufactures of nitrogen suboxide for medical service (1997)

Nitrogen suboxide for medical service is used as a general anesthetic when a surgical operation is performed, and is sold in a pressure-resistant container. The standard price of nitrogen suboxide is set by the Minister for Health and Welfare under the Health Insurance Law.

National universities and the National Defence Medical College selected the suppliers of nitrogen suboxide through general competitive bidding or by comparison of the estimates.

Six companies involved -- that were manufacturing or selling nitrogen suboxide for medical service -- participated in the above-mentioned tenders for nitrogen suboxide for medical service either directly or through their sales agents and thereby supplied most of the nitrogen suboxide for medical service that the universities were purchasing.

The six companies concerned:

1) held a meeting in March 1994, and decided to set the bidding price of nitrogen suboxide for medical service at 262 000 yen per 30-kilogram container as its standard price was to be raised from nine yen to 10.10 yen per gram in April 1994;

2) and decided to keep the bidding price of nitrogen suboxide for medical service to 262 000 yen per 30-kilogram container in order to prevent the standard price of the pharmaceuticals from being reduced when the Ministry of Health and Welfare reviewed the market prices and revised the standards prices of pharmaceutical in 1995.

The six companies, contrary to the public interest, substantially restrained competition in the field of trade concerning nitrogen suboxide for medical service by colluding to fix the bidding price of nitrogen suboxide per 30-kilogram container ordered by national universities and others based on the above mentioned decisions. In February 1997, the JFTC issued a decision to the six companies for the violation of Section 3 of the AMA (Unreasonable restraint of trade)

2.2 Mergers and acquisitions

Although some mergers and acquisitions of medium-standing companies have recently been observed in Japan, we have yet to witness any merger of leading pharmaceutical companies.

2.3 Abolition of the exemption system for resale price maintenance

Resale price maintenance contracts are contracts under which suppliers of commodities set the prices at which other companies resell them and have the latter companies observe the prices (hereinafter referred to as "resale price maintenance").

In principle, resale price maintenance constitutes an unfair trade practice (resale price restriction; Clause 12 of the general designation) prohibited under Section 19 of the AMA. However, the AMA does not apply to the resale price maintenance of certain commodities designated by the JFTC under Section 24-2 and publications. As of 1997, 14 cosmetic products and 14 pharmaceuticals for general use were designated by the JFTC under Section 24-2.

The government has decided at successive Cabinet decisions to review the exemption system including Section 24-2. Based on the decisions, the JFTC has reviewed the exemption system. In March 1996, the government adopted "Revised Programme for Promoting Deregulation", which stated that all the decisions under which the JFTC designated products under Section 24-2 should be abolished. Following the decision, the JFTC abolished the designation of all products, including pharmaceutical products, under Section 24-2 by April 1, 1997. Since then, the resale price maintenance of pharmaceuticals has not been excluded from the AMA.

* Sec.24-2 [Resale price maintenance contracts]

(1) The provision of this Act shall not apply to legitimate acts performed by an entrepreneur who produces or sells a commodity, the uniform quality of which is easily identifiable and which is designated by the Fair Trade Commission, with another entrepreneur who buys such commodity, in order to fix and maintain the resale price thereof (this term means hereinafter the price at which the latter entrepreneur or a third entrepreneur who purchases from him sells such commodity): Provided, That the foregoing shall not apply if the said act tends to be grossly injurious to the interest of consumers in general, or if it is done against the will of the entrepreneur who produces the said commodity by an entrepreneur whose business is to sell the said commodity.

(2) The Fair Trade Commission shall not designate a commodity under the provisions of the preceding subsection unless it comes under each of the following paragraphs:

(*i*) The commodity shall be for the daily use by the consumers in general; and
(*ii*) Free competition shall exist with respect to the commodity.

KOREA

1. The Korean pharmaceutical industry: Market Structure

1.1 Market Structure

Of about 200 Pharmaceutical firms in Korea, Dong-A topped the 1999 production list with its share of 4.99 percent, thus maintaining the competitive edge.

There was no pharmaceutical manufacturer designated by the Korea Fair Trade Commission as a Market-Dominant Enterprises under the prior regulation[1].

However, based on the calculation of market share in terms of therapeutic category, there are firms, in each category, whose market share exceeds 30 percent For example, Popol inj. of Dongkook Pharm. occupied 43.3 percent in the general anesthetic market in 1999 by sales volume.

The R&D outlays of five leading pharmaceutical firms in 1999 to their gross sales accounted for 2.6-5.7 percent.

Some Korean pharmaceutical firms are actively promoting R&D collaboration with domestic/foreign firms in an effort to conduct the preclinical tests and clinical trials involved in obtaining approval for new chemical entities. Further, some Korean companies are also implementing the co-marketing with foreign firms so as to acquire the local marketing rights of specific drugs not developed by the former, including new drug R&D projects.

1.2 Joint R&D case

Choong-wae Pharm. has agreed with Molycumetics of U.S.A. on February 2000 in order to jointly develop a next generation antirheumatoid drug. According to this agreement, the former would invest their manpower and capital, while the latter would provide their technologies and intellectual know-how.

1.3 Co-marketing Case

Through the strategic marketing partnership with Glaxo Wellcome in April 2000, Dong-A would market an anti-emetic 'Zofran', one of Glaxo Wellcome's products, to national and public hospitals, while the former would promote Zofran to private hospitals. Based on this collaboration, Dong-A would be able to acquire the local marketing right of 'Valtrex', a new antiviral agent of Glaxo Wellcome.

The three current associations of pharmaceutical manufacturers, according to the Korea Pharmaceutical Affairs Law, are the Korea Pharmaceutical Manufacturers Association, the Korea Pharmaceutical Traders Association and the Korea Pharmaceutical Industry Co-operative. Established in

October 1945, the Korea Pharmaceutical Manufacturers Association has about 200 members and has been affiliated with IFPMA (joined on November 1978) and WSMI (joined on July 1980).

2. Regulation of Supply

2.1 Protection of Intellectual Property Rights

The current Patent Law enforced by the Korean Industrial Property Office (hereinafter 'KIPO', provides for the patent rights pertaining to the substance, usage, preparation method and dosage form of drugs. The term of a patent right shall be 20 years from the date of filing the patent application. The patentee shall have an exclusive right to work the patented invention in terms of production, use, assignment and lending (Articles 2, 88 and 94 of the Korea Patent Law).

In the event that a patented invention takes an extended period of time to go through the procedure in accordance with Pharmaceutical Affairs Law and Agrochemical Control Act, patent term restoration can be applied up to five years (Article 89 of the Korea Patent Law).

Where consultations with the patentee or exclusive licensee is not possible or no agreement is reached at the consultation, a person who intends to work the patented invention may request the Commissioner of the KIPO to rule on the authorisation of a nonexclusive license thereon. The Commissioner may force the authorisation of license through such ruling.

Conditions for authorisation of nonexclusive license (Article 107 of the Korea Patent Law): (*1*) where the patent invention has not been continuously worked during a period of three years or more without the justifiable reasons, *(2)* where the working of the patented invention is necessary for public non-commercial use, etc.

2.2 New Drug Approvals

New drugs[2] shall be approved by the Commissioner of the Korea Food and Drug Administration after proper review of the specification and test methods for quality control and on the screening of safety and efficacy based on the "Regulation on the evaluation of Safety and Efficacy of drug, etc.". A person who intends to obtain an approval of new drugs shall submit to the Commissioner of the Korea Food and Drug Administration the following data: basic screening research data, efficacy data, preclinical data and clinical data.

The approval period for new drugs will require a total of 95 days for the screening of their safety and efficacy (70 days) and for license review (25 days).

The submitted data for the approval of new drugs shall not in principle be disclosed, except to the extent that it is deemed necessary for public interest. Further, a person who intends to manufacture generic products shall be discouraged not to utilise the initial data submitted by an original developer. In the case where an application for the approval of generic products shall be made by submitting the same data as those of the original developer during the first approval, such application shall be recognised by the distinct consent on the part of an original developer.

In the case where any imported drugs contain the same ingredients as local drugs that were already approved and are classified into OTC products, their product license shall be granted without any separate review of safety and efficacy. Where any drugs, which were already approved in foreign

countries, contain ingredients which are introduced for the first time in Korea, they shall be regarded as new drugs and subject to the review of safety and efficacy through the submission of clinical data, etc.

2.3 Trade regulation

The Korean pharmaceutical market is fully opened to foreign competition and there is no restriction on the local investment on the part of foreign firms.

However, a person who intends to manufacture or import a drug shall obtain its approval or notification from the Commissioner of the Korea Food and Drug Administration through the screening of safety and efficacy, irrespective of parallel imports or re-imports.

The Korean Pharmaceutical Affairs Law has prohibited any transactions of drugs elsewhere including Internet, except for pharmacy. However, when the separation of prescribing and dispensing is to be implemented on July 1, 2000, the detailed methods on the Internet marketing of non-prescription drugs will be made available.

There is no discriminatory system against foreign firms which intend to join the Korean pharmaceutical market.

2.4 Industrial Policy

Government's industrial policy in this sector aims to extend supports necessary to ensure that quality medicines are available for medical services and public health promotion but any tax privilege and subsidy has not been offered to any pharmaceutical manufacturers. However, to activate the local unstable R&D basis as part of new drug R&D projects, the government has supported since 1991 the R&D outlays.

To foster the preferred R&D atmosphere, the government has since 1995 supported the investment for facility and equipment necessary for experimental animal breeding centers and clinical trial centers on a long-term lending basis.

3. Regulation on Drug Demand: Control on the Prices, Quantities and Consumption

3.1 Health Insurance Coverage of Pharmaceuticals

In Korea, the medical insurance scheme is applied to the drugs prescribed by doctors including OTC products, which are listed into Pharmaceutical Reimbursement Schedule but the drugs used for non-therapeutic purpose or diseases inducing little convenience in the daily life or business shall be excluded from the medical insurance coverage (for example, tonics, preventive vaccines and acne drugs).

The dispensing charges of medical insurance drugs are applied on the predetermined rates on the part of the insurer or the insured. The drug charges imposed on the insured vary depending on the medical institutions. 20 percent of the total drug charges is paid by inpatients.

Medical Inst.	Pharmacy	Clinic	Hosp.	General Hosp.	Tertiary Hosp.
Burden of the insured(outpatient)	30%	30%	40%	55%	55%

The patients suffering from some chronic diseases pay only 20 percent of the drug charges (for example, hemophilia drugs, kidney rejection inhibitors, Gosher's drugs, etc.). Apart from the medical insurance, the government supports the medical expenses including drug charges for the low-income bracket by 80-100 percent.

Since November 15, 1999, the system for reimbursing the amount of actual transaction prices of drugs has been implemented. Through the above system, the National Health Insurance Corporation and Medical Insurance Society for Industry Workers have reimbursed the amount of actual transaction prices to medical institutions, when the medical reimbursement claims for drugs are requested. The amount of reimbursement shall not exceed the ceiling prices notified by the Minister of Health and Welfare.

3.2 Formularies

After acquisition of a product license from the Commissioner of Korea Food and Drug Administration, a pharmaceutical manufacturer (or importer) may request its listing into the Pharmaceutical Reimbursement Schedule to the Minister of Health and Welfare. After consultation with the Medical Insurance Reimbursement Prices Review Committee, the Minister of Health and Welfare shall determine the ceiling prices(standard prices) of each item which can be reimbursed and then, the determined prices will be listed into the Pharmaceutical Reimbursement Schedule (hereinafter."PRS")

If an item, which is necessarily required for proper treatment, is not listed into the PRS, the Minister of Health and Welfare may list it into the PRS at his own discretion.

When a specific item is not manufactured or its product license is cancelled, a pharmaceutical manufacturer (or importer) may request the Minister of Health and Welfare to delete it from the PRS. When any false data are submitted by a pharmaceutical manufacturer (or importer) during a new listing of a drug into the PRS or ex facto management, the Minister of Health and Welfare may delete it at his own discretion.

There is no regulation available on the use of specific drugs in the drug formularies in Korea.

3.3 Price control policies

The pricing control applies to medical insurance drugs only. The medical insurance prices of drugs are controlled based on the method of determining the ceiling prices which can be reimbursed, when requested (Paragraph 3, Article 29 of Medical Insurance Act).

The government has reviewed the appropriateness and economical effectiveness of the reported prices of drugs which are newly listed into the Pharmaceutical Reimbursement Schedule. As for the already listed items, the government has investigated the actual transaction prices of medical insurance drugs at each medical institution two times every year so as to readjust the ceiling prices as the actual transaction prices of medical institutions.

Among the drugs subject to medical insurance coverage, there is no difference of pricing control regulations between OTC products and Ethical products.

To promote the voluntary competition among pharmacies since January 20, 1999, the government abrogated the Standard Retail Price System[3] which had been enforced since 1984 and instead, has implemented a seller's price labeling system (open price system) so as to allow a pharmacy proprietor to freely sell the drugs. In this regard, there is no pricing control on non-reimbursement drugs on the part of the government.

In determining the medical insurance prices (ceiling prices), Korea makes distinction between the innovative new drugs and other new ones.

The medical insurance prices of the innovative new drugs shall be the average factory prices of the same items in seven countries plus their VATs and wholesale margin rates. On the other hand, in case of the prices of other new drugs, the domestic prices of five items with identical or similar efficacy and their average prices in seven countries shall be compared, and the calculated average rates shall be applied to the average prices of the other new drugs in the seven countries.

3.4 Control of Physician Prescribing Practices

To promote the qualified, cost-effective prescription of doctors, the Minister of Health and Welfare has stipulated the scopes, methods, criteria and cost calculation of reimbursement through the notification of "Criteria for Medical Insurance Benefit Level" and "Guideline on the Determination of Criteria for Medical Insurance Reimbursement Price and its Management".

The National Federation of Medical Insurance (hereinafter 'NFMI'), which is engaged in screening the medical expenses, consults with related specialists to establish the screening criteria designed to determine the feasibility of doctor's prescription. Based on the above criteria, the NFMI takes necessary measures to reduce the drug charges on in appropriate prescription or to investigate the overall matters on medical insurance.

When the NFMI designates a new screening standard, the NFMI carries this information on Internet once a month and a monthly journal (a newsletter for medical security) to notify this information to related organisation as a reference for doctor's prescription.

3.5 Regulation of Pharmacies and Pharmaceutical Distribution

There is no legal restriction on the number of pharmacies. A pharmacist who manages his/her pharmacy shall not be engaged in business other than management of pharmacy. However, other engagements not impeding the management of pharmacy within the same place shall be permitted (Article 19 of the Korea Pharmaceutical Affairs Law).

A pharmacist may dispense drugs prescribed by a doctor by substituting into other drugs whose bioequivalence is already recognised. However, such obligation is not necessarily made using other less expensive drugs (Article 23-2 of the Korea Pharmaceutical Affairs Law).

3.6 Policy toward Generics

Among the total pharmaceutical market in Korea, the ratio of OTCs (doctor's prescription is unnecessary) and Ethicals (doctor's prescription is necessary) was 53.2; 46.8 as of the end of 1999. The weight ratio of generics in the pharmaceutical market is not separately calculated.

In line with the purchase of drugs, no policy has been separately promoted to facilitate the consumption of generics. In the case of the specially managed drugs such as essential drugs or the drugs substituting the high-priced drugs in terms of cost-effectiveness, however, the government has implemented a policy to promote the use of such drugs by selecting these items so as not to be withdrawn from the market.

- This means that any medical institutions using the above items will be provided with an incentive.

- If there is a possibility that a drug whose medical insurance price is lower than their production cost are sold out due to manufacturer's avoidance or that a drug gives no proper medical treatment due to production setback, the government can compensate the production cost.

- When the insurance prices are lowered, exception may be allowed on the drugs whose withdrawal is not permitted, if deemed necessary.

4. Competition Issues in the Pharmaceuticals Sector

Pharmaceutical manufacturers, distributors and pharmacies are included in the category of enterprises subject to the application of the Monopoly Regulation and Fair Trade Act (hereinafter 'MRFTA'), Korea's general competition law enforced by the Korea Fair Trade Commission (hereinafter 'KFTC'). Therefore, the MRFTA applies, without exceptions, to any transaction involving these enterprises that infringe upon the competition law.

4.1 Market Definition Issues and Barriers to Entry and Exit

In Korea, the relevant market is defined as an area of trade where competing relations can be created (KFTC's Notification on the M&A Review Guidelines). In this case, product market is identified as a group of products to which representative consumer of a certain product can shift in response to the price increase of such product. The Guidelines also specify the criteria for determining whether a product belongs to the product market concerned, such as the similarity of function and usage of products, buyers and sellers' perception of product substitutability, and their related patterns. Therefore, in the pharmaceutical industry, relevant product market can be defined, including imported drugs, giving weight to the similarity of socially accepted effectiveness of medication, buyers and sellers' perception of substitutability, and their related behaviours.

The Korea Food and Drug Administration classifies drugs in terms of (*1*) route of administration (oral, topical and injectable form) and (*2*) therapeutic category. Since the therapeutic category is classified based on the similar efficacy (for example, drugs acting on digestive system, antipyretics, analgesic & anti-inflammatory agents), this can serve as a reference in defining relevant product market.

The KFTC also defines the relevant market based on a specific purchase group, if specific characteristics of buyer or product create such group by product, region, or stage of transaction (The Notification on M&A Review Guidelines). The pharmaceutical sector could be separated into the market for prescription drugs and for OTC drugs. However, many pharmaceutical firms that produce hundreds of drugs manufacture both prescription and non-prescription medicines. In addition, since most drugs consumed in hospitals are covered by medical insurance, the market for insurance-covered drugs is almost identical to the market for drugs used in hospitals. Thus, it is meaningless to separate the markets.

The relevant geographic market is national, since there exist no institutional or actual limitations in the operation of pharmaceutical companies. The fact that Korea's pharmaceutical firms can serve throughout the nation under relevant statutes and that distribution networks including wholesalers and pharmacies are located around the country is taken into account. No Korean pharmaceutical company is large enough to define the market as international.

Though there exist institutional regulations in market entry that are inevitable to ensure safety of pharmaceuticals, they are enforced in a way that does not serve as an entry barrier.

4.2 Details of legal/institutional regulations

The head of the KFDA, in granting license for manufacturing business, grants approval for individual item of medicine in order to guarantee the safety of medicines. With regard to the license for manufacturing business, items to be produced, compliance of facility standard with Korea Good Manufacturing Practice (KGMP), qualification of manufacturer, etc. is reviewed. Items of medicines to be manufactured are also subject to separate approvals through the pertinent test on safety and effectiveness, etc. In importing pharmaceuticals, conditions similar to those of the license for manufacturing business must be met.

In order to enter the market for a drug protected as an intellectual property right or the market of end product using an IPR protected drug, it is necessary to acquire license to use the IPR concerned. In this case, the cost of license acquisition could act as an entry barrier.

4.3 Entry Barrier arising from Characteristics of Pharmaceutical Industry

R&D capacity lies at the heart of competitiveness in the pharmaceutical sector. Therefore, the expertise, sophisticatedness, large costs and length of period involved in developing new drugs could pose as barriers to entry.

The KFTC has taken corrective measures against undue collusive acts such as price-fixing, quantity control and restrictions of transaction territories and transaction partners.

<Case> Green Cross Co. and Dongshin Pharmaceutical Co., duopolist firms which produce and sell albumin, having 62.6 percent and 37.4 percent of market share respectively, conspired to maintain or increase shipment price and also colluded to fix supply quantity. In addition, recognising the vested interest of each firm in transaction partners, they refrained from engaging in transactions with primary customers of the other firm. As such, under implicit agreement, the two firms customarily divided most of the general hospital-level market.

The KFTC found that such actions constituted undue concerted act and judged that they substantially restrained competition in the albumin manufacturing and sales market. As a result, it issued a cease and desist order.(Dec. 1995)

In Korea, pharmaceutical firms create various drugs and compete in many markets at the same time. As such, they can be deemed to be in multi-market contact. Under the M&A Review Guidelines, the KFTC shall review the possibility of concerted act among competing enterprises based on high homogeneity of products supplied by companies in competing relations and the similar terms of production and sale faced by competing firms. However, there has been no review conducted by the KFTC as to whether multi-market contact lessen competition or not.

There does exist an incentive to collude, even though there have been no concerted actions, to date, by pharmaceutical manufacturers or pharmacies to increase (or resist decrease) in ceiling prices in medical insurance plans.

The Ministry of Health and Welfare conducts semi-annual investigations to find out the actual transaction prices of medical insurance at medical institutions to adjust the ceiling prices to the level of actual transaction price, to be listed into the Pharmaceutical Reimbursement Schedule. Under the circumstances, there exist incentives for collusion between pharmaceutical manufacturers and distributors and among distributors in order to keep actual transaction prices high not to lower the ceiling prices.

Strategic alliances among domestic and foreign pharmaceutical firms in the area of marketing and R&D are on the rise. However, to date, the KFTC has never taken a corrective measure against joint venture in the pharmaceutical industry for the undue restraint of competition in violation of Article 19 (Undue Concerted Acts) of the MRFTA.

Also, undue concerted actions, conducted for the purpose of R&D, that meet certain criteria and acquire the KFTC's approval are exempted from the application of the MRFTA (Paragraph 2 of the above Article). Still, there has been no case of undue joint R&D project that applied for the approval of the KFTC.

4.4 Mergers and Acquisitions

So far, no business combination in Korea's pharmaceutical industry has been determined as anti-competitive. This finding was grounded on the judgement that a pharmaceutical firm with high market share in certain product markets is not likely to have and abuse market dominance in Korea's entire pharmaceutical industry. That is because each product market is pro-competitive with many market players and even new drug market is abundant with substitutable products.

Market dominance would be a cause for concern in the case of new potent drugs that can treat previously incurable diseases such as AIDS and cancer. However, a drug that treats cold, even if it obtained patent, would be in a substitutable relation with other existing medications.

In Korea, there have been no cases of conditional approvals granted to mergers in the pharmaceutical sector.

To date, the KFTC has dealt with no cases where pharmaceutical companies sought to vertically integrate hospitals, insurers, pharmacies, etc.

4.5 Abuse of Dominance

The KFTC has taken corrective measures against vertical restraint and refusal to deal between a pharmaceutical firm and a distributor.

<Case> Ildong Pharmaceutical Co. entered into an agency contract that included clauses on resale price maintenance, determination and coercion of sales target, unilateral termination of contract, arbitrary construction of provisions, etc. The KFTC found such contract constituted abuse of superior position (in violation of Article 29, paragraph 1 and Article 23, paragraph 4 of the MRFTA). As a result, it issued a recommendation for correction to the company to amend or delete relevant contract provisions and to notify the receipt of such recommendation to its all agencies (July, 1994).

To date, there have been no cases of tie-in sales or predatory pricing in the pharmaceutical industry against which remedies were imposed by the KFTC.

NOTES

1. The revision of the Monopoly Regulation and Fair Trade Act (MRFTA) in April 1999 abolished the annual listing of market dominant firms, introducing instead an ex-post facto determination of dominant enterprises. The Act only stipulates the criteria for presuming market dominance and determine dominance based on the actual marker power of the corporation concerned in individual investigation.

   – According to Article 4 of the Act, any enterprises whose market share in a relevant area of trade is 50 percent or more or combined market share of less than three enterprises is above 75 percent shall be presumed as a Market-Dominant Enterprise. However, in such case, any enterprise with market share of less than ten percent shall not be counted in.

2. The term "new drug" in the Korean Pharmaceutical Affairs Law (Para. 12 of Article 2) refers to the items, as designated by the Commissioner of the Korea Food and Drug Administration, which are combined preparations containing new substances as active ingredient(s) or drug containing new substances with entirely different chemical structure and Chemical entity.

3. Standard retail price system: This system was implemented in such a manner that after the Korea Pharmaceutical manufacturers Association determined the standard retail price of drug based on the factory price reported by a drug manufacturer, a pharmacy proprietor finally determined the selling price under ten percentage of the standard retail price beyond the factory price. Many consumer organisations criticised the standard retail price system on the ground that it was institutionally abused as an instrument for the resale price maintenance and the Korea Fair Trade Commission maintained the abrogation of this system for regulation reform, since this system induced the price-fixing among pharmacies. Thus, the standard retail price system was abolished through the revisions of the Korea Pharmaceutical Affairs Law in 1997.

4. Innovative new drugs: New drugs whose costs or efficacy can be significantly improved compared with existing drugs.

MEXICO

1. The Pharmaceutical Industry: Market Structure

1.1 Market Structure

(1.1) Please describe the market structure of pharmaceutical firms in your country – which firms are active, with what market share, in which therapeutic classes and with what level of R&D (including generic producers).

1.1.1 Manufacturing

As in many other countries, for a pharmaceutical company to be allowed to sell medicines and other medical products in Mexico a certain physical presence is required. For medicines that physical presence includes production and testing facilities, for medical devices storage facilities are sufficient. This is one of the reasons why most multinational pharmaceutical companies have a subsidiary in Mexico. Apart from that, there are many national pharmaceutical laboratories. These national laboratories are usually smaller and specialised in the manufacture of generics and other medicines whose patents have expired. Altogether, there are approximately 400 pharmaceutical manufacturers in Mexico.

The following table presents a list of the most important pharmaceutical firms that were active in Mexico in 1998. For each firm its share in total sales of medicines from April 1998 to March 1999 is indicated. The value of those sales amounted to approximately US$ 3 840 and covered both sales to the private and the public sector.

Table 1: Market Shares of the Main Pharmaceutical Firms
April 1998 – March 1999

Firm	Share in sales
Abbot	3.0%
Bayer	3.0%
Boehringer	4.8%
Bristol	2.5%
Glaxo Wellcome	3.6%
Hoechst	4.2%
Jansssen	2.7%
Lakeside	2.0%
Lilly	2.1%
Mead Johnson	2.7%

Table 1 (cont'd)

Firm	Share in sales
Merck	3.7%
Novartis	4.0%
Pfizer	2.7%
Pharmacia – UpJohn	2.6%
Rhône-Poulenc	2.0%
Roche	3.7%
Sanfer	2.1%
Senosian	2.6%
Syntex	3.3%
Wyeth	3.2%
Others	39.5%
Total	100.0%

Source: Anatomical Therapeutic Chemicals, International Medical Statistics, March 1999.

Evidently, relevant markets for antitrust analysis are much narrower than the market of all medicines. As a general rule, the degree of market concentration for antitrust purposes is much higher than what one would expect from the shares listed in table 1. In table 2 the sales of all medicines are split up according to therapeutic classes (level 1), which are still too broad for antitrust analysis.

Table 2: Sales of Medicines according to Therapeutic Classes (level 1)
April 1998 – March 1999

Therapeutic Class	Share
A. Alimentary Tract and Metabolism	19.0
B. Blood and Forming Organs	1.2
C. Cardiovascular System	7.7
D. Dermatologicals	6.1
G. Genito Urinary System Sex Hormones	6.5
H. System Hormonal Preparations (Excluding Sex Hormones)	1.8
J. General Anti-Infectives Systemic	19.3
K. Hospital Solutions	0.4
L. Cytostatics	0.5
M. Musculo-Skeletal System	6.6
N. Central Nervous System	11.9
P. Parasitology	1.0
R. Respiratory System	11.2
S. Sensory Organs	2.1
T. Diagnostic Agents	0.2
V. Various	4.5
Total	100.0

Source: Anatomical Therapeutic Chemicals, International Medical Statistics, March 1999.

In table 3 some of the therapeutic classes (level 1) are split up further and for several therapeutic classes (level 3) the main supplying manufacturers are listed together with their share in the sales of that class of medicines. For each class of medicines market concentration is calculated in terms of the Herfindahl and dominance indexes which are used by the Federal Competition Commission (FCC) in its merger analysis.

Table 3: Market Shares for Some Therapeutic Classes (Level 3)

Code	Therapeutic Class	Herfindahl Index	Dominance Index	Market Share
A3 Antispasmodics, anticholinergics and gastroprokinetics				
A3A	Plain antispasmodics and anticholinergics	2,318	3,933	BG: 32%, Boehringer: 31%, Senosian: 11%, Atlantis: 9%, Hoechst: 7%
A8 Antiobesity preparations, excluding diabetics				
A8A	Antiobesity preparations, excluding diabetics	3,354	5,250	Hoechst: 55%, Medix Corp.: 14%, Roche: 11%, Knoll: 9%, Searle: 5%
A11 Vitamins				
A11C	Vitamin A and D, including combinations of the two	3,737	6,849	Hoescht: 51%, Roche: 30%, RP: 14%, Sanofi: 1.5%, BG: 1.2%
C2 Antihypertensives				
C2A	Antihypertensives	1,452	2,967	AstraZeneca: 25%, Merck: 22%, BM: 13%, Bayer: 9%, Pfizer: 8%.
C3 Diuretics				
C3A	Diuretics	2,245	4,696	Hoechst: 43%, Searle: 19%, Novartis: 14%, Senosiain: 7%, Roche: 6%.
C10 Hypolipidaemics/Anti-Atheroma preparations				
C10A	Cholesterol and Triglyceride reduction preparations	1,957	3,411	Merck: 31%, BM: 23%, WL: 12%
D1 Antifungals, dermatological				
D1A	Antifungals, dermatological	1,132	2,390	Janssen: 20%, Bayer: 17%, RP: 12%, Plough: 11%; PG: 6%
D6 Topical antibiotics, sulphonamides and antivirals				
D6A	Plain topical antibiotics and /or sulphanomides	1,344	2,521	SB: 23%, Senosiain: 15%, CIC: 10%, Hoescht: 9%, Pfizer: 9%.
H2 Systemic corticosteroids				
H2A	Systemic corticosteroids, plain	2,162	5,910	Key Farma: 41%, Essex: 11%, PU: 9%, Chinoin: 9%, Cilag: 9%
J1 Systemic antibiotic				
J1C	Broad Spectrum Penicillins	1,809	3,856	BM: 31%, Sanfer: 22%, SB: 12%, Bayer: 11%, Wyeth:5%
J1F	Macrolides and similar types	2,492	4,103	PU: 38%, Abbot: 21%, Pfizer: 18%, EL: 14%, Hoechst: 5%
J1G	Fluoroquinolones	1,777	4,196	Bayer: 33%, Senosiain: 20%, Cilag: 12%, Janssen: 9%, Merck: 6%
J1H	Medium and narrow spectrum Penicillin V Penicillin G	3,395 3,366	6,303 6,966	Sanfer: 51%, Bristol: 24%, Wyeth: 12%, SB: 5%, Bayer: 3%, FL: 55%, Wyeth: 20%, Grossman: 15%, Grunenthal: 3%, Rimsa: 2%
M1 Anti-inflammatory and anti-rehumatic products				
M1A	Anti-rehumatic non-steroidal	1,113	1,276	Novartis: 20%, Syntex: 20%, Roche: 8%, SB: 5%, Boehringer: 5%
	Anti-inflammatory non-steroidal	1,891	1,031	Syntex: 26%, CG: 20%, PU: 5%, FL: 5%, SB: 4%
N2 Analgesics				
N2B	Non narcotics and anti-pyretics	1,320	2,493	Roche: 23%, Hoechst: 14%, BM: 12%, Merck: 11%, Bayer: 8%.
N5 Psycholeptics				
N5A	Antypsychotics	2,225	4,571	JJ: 38%, RP: 16%, Novartis: 14%, Armstrong: 13%, EL: 5%
R6 Systemic antihistamines				
R6A	Systemic antihistamines	1,317	2,953	Essex: 26%, GW: 14%, Plough: 12%, Jenssen: 11%, Hoechst: 6%

Source: Merger files of pharmaceutical firms, Federal Competition Commission.

Abbreviations.
BG: Byk Gulden; RP: Rhône-Poulenc; PG: Procter and Gamble;
PU: Pharmacia Upjohn; THE: Eli Lilly; SB: Smithkline Beecham; GW: Glaxo Wellcome;
BM: Bristol-Myers; CIC: Compañía Inter-Comercio México; JJ: Johnsons & Johnsons;
CG: Ciba Geigy Mexicana; FL: Pharmaceutical Lakeside; WL: Warner Lambert.

Although level 3 therapeutic classes may still be too broad for proper market definition (and occasionally too narrow if there is cross-substitutability among different classes), table 3 gives a much better picture of market concentration in the Mexican pharmaceutical industry than does table 1.

1.1.2 Wholesale Distribution

Wholesale distribution of medicines and medical devices is fairly concentrated in Mexico. The six main wholesalers account for approximately 90 percent of the market. First is Casa Autrey (three percent), second Nadro (27 percent) and third is Marzam (twelve percent).

However, it should be recognised that many medicines reach the final consumers without passing through wholesale. In the first place, the public sector (social security system, Ministry of Health) buys most of its requirements through public tendering directly from the manufacturers. In the second, large chains of pharmacies at the retail level also buy directly from manufacturers. In much the same way, an increasing number of supermarkets with a pharmacy department jumps the wholesale link by buying directly from laboratories. Evidently, this circumvention of wholesale trade limits the abuse of market power by wholesalers considerably.

1.1.3 Retail Distribution

Unlike in many other countries, pharmacies in Mexico only sell the medicines, they do not mix them, dosify them or prepare them in any other way. That is, medicines leave the pharmacies in exactly the same presentation as they entered. In view of that, entry barriers into retailing are kept very low. Any person can run a pharmacy. He does not need to possess an academic title or similar professional degree.

As a consequence, there are many pharmacies and competition is very intense; too intense according to a great number of small traditional pharmacists that claim protection against upcoming chains of pharmacies that are in a better position to take advantage of economies of scale (jumping wholesale, volume discounts) and economies of scope (running broad assortments). Still, in far-away rural areas there is a lack of pharmacies. This may be partly due to traditional price control policies which did not allow for mark-ups necessary to run a pharmacy in a thin market profitably.

1.1.4 Which firms co-operate to jointly undertake R&D or to jointly market certain products?

There is little information about R&D in pharmaceutical firms in Mexico. The development of new medicines is usually done in the laboratories of multinational companies abroad. Part of the testing of new medicines may take place in Mexico, however. No joint ventures for R&D or for joint marketing agreements have been notified to the FCC, so far.

1.1.5 Is there one or more associations of pharmaceutical manufacturers in your country?

Is association politically important?

The main producers association is the National Chamber for the Pharmaceutical Industry (CANIFARMA). Although membership is no longer compulsory since 1997, most manufacturers belong to this association and it is the CANIFARMA that acts on behalf of the industry in the dialogue with regulatory bodies.

2. Regulation of Supply

2.1 Protection of Intellectual Property Rights

(2.1) Please describe the regulatory framework established for the protection of intellectual property rights in the pharmaceutical industry.

In Mexico there are no special provisions for pharmaceutical products and processes in the legislation on industrial property; i.e. pharmaceutical products are subject to the same regulations as any other product. In the Law of Industrial Protection patents for products expire twenty years after the filing of the request. In most cases the date of registration is the priority date, i.e. the date of registration in the first country where it was registered.

If a patent is not commercially exploited during three years following its registration, the Mexican Institute of Industrial Property (MIIP) has the power to oblige the patent holder to grant a license. In principle, any person can apply to the MIIP for such a license. Commercial exploitation does not require that the product be produced in the country. Importation of the product is sufficient to shield the patent holder from the obligation to license.

2.2 New Drug Approvals

(2.2) Please provide an overview of the drug approval process

Both the private and the public sector can apply for the approval of a new drug or pharmaceutical input. Upon approval it is included in the Pharmacopoeia of the United States of Mexico or in the corresponding standards. The pharmacopoeia is a legal document in which general methods of analysis are established and the requirements to guarantee the identity, purity and quality of medicines and pharmaceutical inputs.

Applications for approval must be filed with the Ministry of Health (MH). For well-known drugs not protected by patents the resolution must be issued within 40 days. For drugs patented in other countries the approval period is 60 days. For new drugs without patents in other countries the deadline is of 90 days. These approval periods compare favourably with those of many other countries. Sanitary registration is issued for indeterminate periods.

2.3 Trade Regulation

(2.3) Please describe any barriers to international trade or investment in pharmaceuticals. Are there restrictions on international trade in drugs by third-parties (such as parallel trade or re-imports)? Are there restrictions on mail-order or Internet supply of drugs? Does the regulatory regime distinguish between domestic and foreign firms in any way?

2.3.1 Regulation of Imports

The importation of many medicines is subject to a sanitary permit by the Ministry of Health (MH). Such permits are only granted to importers who have production and testing facilities in Mexico. It is not necessary that the production facilities refer to exactly the same product as the imported one, but the testing facilities must be adaptable to the product under consideration. In practice, this makes reimportation

or parallel trade by third parties very difficult for those products. The regulation of imports does not distinguish between foreign and domestic firms.

Medicines and pharmaceutical prime materials that are not subject to sanitary permits by the MH must carry sanitary certification from the country of origin in accordance with international agreements to which Mexico has subscribed or certification by laboratories, Mexican or foreign, accredited by the MH and the Ministry of Commerce and Industrial Development (MCID). The MH has the right to take samples of imports in order to verify the content of the merchandise and its compliance with Official Mexican Standards. The importation of narcotics, psychotropics and products containing them, is subject to stricter regulations. They can be realised through certain specially designated airports and never by mail. Also some biological products and blood derivatives need a permit from the MH for their importation.

2.3.2 Regulation of Exports

For the export of medicines and prime materials the exporter does not need a sanitary license, but only an export certificate from the MH. If the acceptance by the importer in the country of destination can be accredited no sanitary registration is necessary. The MH does not grant export certificates for narcotics, psychotropics or blood derivatives. For the exportation of narcotics, psychotropics and blood derivatives an permit by the MH is required. Such exportation can only be realised from the airports referred to earlier.

2.3.3 Foreign Investment

There are no restrictions on foreign investments in the pharmaceutical industry. I.e. foreign firms can fully participate in the social capital of Mexican firms in the industry and can establish their own subsidiaries. In the regulation applicable to the pharmaceutical industry there are no discriminatory provisions favouring national companies over foreign firms.

2.4 Industrial Policy

(2.5) Please describe any industrial policy objectives in this sector. Describe the objectives and effects of any tax concessions or subsidies that exist.

No sector-specific policies are applied to promote the pharmaceutical industry in Mexico. There have only been systematic attempts to deregulate (i.e. regulate only where strictly necessary) and eliminate red tape in the registration and authorisation of new establishments and in foreign trade transactions. No subsidies are given to the industry. There is only a general exemption from the value added tax for medicines.

3. Regulation of Demand: Controls on Pharmaceutical Prices, Quantities and Consumption

3.1 Health Insurance Coverage of Pharmaceuticals

(3.1) We invite you to discuss how the predominant forms of health insurance in your country (whether public of private) affect the demand of health consumers for pharmaceuticals.

3.1.1 Public Insurance

Public health institutions in Mexico, include those of the social security system and those run by the Ministry of Health.

The social security system covers both public and private sector employees. It is financed by compulsory contributions by employees, employers and the government. It covers the costs of all services provided, related to illness, accidents, childcare and maternity. Prescribed medications are also included.

Institutions of the Ministry of Health attend everyone; i.e. not only employees. It is financed out of the government budget. Prescribed medications are not given free but sold at subsidised prices.

Although the public heath institutions cover in principle the whole population, only a part of the pharmaceutical demand is supplied by them. Medication purchases by public institutions account approximately for 16 percent (measured in value terms) of the total pharmaceutical market. Thus, there is a significant demand for pharmaceuticals not supplied by public institutions.

There are several reasons for this. First, self-employed people are not covered by the social security system. Second, there is not much coverage of public clinics and hospitals in rural zones. Third, some people of the middle class and most people of the upper classes of the population don't take advantage of public health institutions, even if they are affiliated. This is due to long waiting times and sometimes low quality of service. These people prefer to consult private physicians and buy the prescribed medicines themselves.

3.1.2 Private Insurance

In Mexico private insurance companies have comparatively little influence upon direct consumer demand for medicines although they do effectively attempt to influence consumer demand. Most companies have negative lists of excluded medicines and services and positive lists of hospitals and physicians, but the penetration of private health insurance in Mexico is low. Moreover, most insurance contracts are for "major medical expenses" not covering expenditures in medicines as a rule.

No information is available to the FCC about whether and, if so, the way in which private insurance companies attempt to influence prescription practices by positively listed doctors and hospitals.

In the few occasions where privately consumed medicines are covered by insurance contracts the consumer pays first and is reimbursed by the insurance company afterwards. To our knowledge private insurance companies do not pay pharmacies directly as is the case in some other countries. This also limits the control insurance companies can exercise over pharmacies.

3.2 Formularies

(3.2) Please describe the main features of the formulary system in your country"

The social security system has positive lists of medicines that can be provided in the social security institutions. There are three lists: one for clinics, another for second level hospitals, and still another for third level hospitals. Second and third level hospitals are classified by the level of speciality they have. The list of medications of clinics and hospitals is named the Basic List for the Public Sector, and includes 500 generic medications, in 726 presentations. See also the answer to question 3.4.

3.3 Price Control Policies

(3.3) Please describe the operation of the controls on pharmaceutical prices in your country.

Since 1996 a mechanism of self-regulation of prices is in force, that was agreed between the Ministry of Commerce and Industrial Development (MCID) and the CANIFARMA. This mechanism is more flexible than previous mechanisms of price controls which were partly based on costs of production. In the new mechanism each manufacturer may increase the prices of its products freely but subject to a basket restriction. That is, the sales-weighted average of the price increase may not be larger than some inflation indicator. The inflation indicator may be a consumer price index, a producer price index, an exchange rate, labour costs or the like, provided it be published officially, or a weighted average of them. The manufacturer may himself select which indicators apply to its company and which weights. If at a certain moment he wishes to change indicators or weights, he is free to do so, but not retroactively. To monitor the system the pharmaceutical firms that participate in the mechanism must report sales (prices and volumes) to the MCID on a regular basis.

A special feature of the self-regulation mechanism is that it is not producer prices but maximum consume*r* prices that is restricted. Such maximum consumer prices are printed on the parcel and retailers are not allowed to sell at higher prices. They may sell at lower prices if they wish. Producer and wholesale prices may freely be negotiated among the parties involved. In other words, maximum retail prices are set by manufacturers under the self-regulation scheme but then they negotiate the price they receive with wholesalers or directly with retail chains.

It is interesting to mention that there are many retail chains selling at considerable discounts. This may be considered as an indication that the price control system is not overly restrictive.

Another feature of the self regulation scheme is that it includes some incentives for investments, training of personnel, research and development, etc. Such expenditures, when appropriately proven, may lead to special allowances in the inflation indicator adopted by the manufacturers.

It is also interesting to mention that medicines are comparatively cheap in Mexico. In a not so recent study[1] it was found that in Mexico medicines are five times cheaper than in the US and three times cheaper than in Europe on the average. Evidently, such comparisons depend critically on the medicines included in the compared basket. However, the fact that many US residents in the frontier with Mexico cross the border to buy medicines in Mexico seems to confirm this finding.

3.4 Control of Physician Prescribing Practices

(3.4) Please describe the systems in place to encourage high-quality cost-effective physician prescribing practices

Only professionals (specialists, physicians, nurses, etc.) are allowed to prescribe medicines. There is a Catalogue of Substitutable Generic Medicines (CSGM). If the involved medicine is in the CSGM, the prescription must necessarily include the generic name of the medicine and can optionally include, along with the generic denomination, a pharmaceutical brand name.

This form to promote the substitution of generics for branded products is fairly recent and has not changed traditional prescribing practices very much. In practice, there are few doctors that follow these rules. I.e. many of them only put a brandname in the prescription.

Only certain specialised physicians can prescribe medicines that contain narcotics, psychotropics or similar substances. Physicians working in public and social security clinics or hospitals can only prescribe generic denominations of medicines included in the Basic List for the Public Sector. Due exemptions are allowed. These generic medicines have different presentation from those of the private market.

3.5 Regulation of Pharmacies and Pharmaceutical Distribution

(3.5) Please describe the nature of any controls on pharmacy margins, entry and/or ownership structure. Please describe also the nature of any rules governing the discretion of pharmacists in substituting other products.

There is no control on pharmacy margins. As explained under question 3.3 it is the consumer price that is controlled to a certain extent. Retail margins result ex-post from the price at which the retailers acquire the products from manufacturers and wholesalers, and from eventual discounts applied by the retailers.

There are no restrictions on ownership in pharmaceutical distribution. Entry barriers are very low. See answer to question 1.

As regards the discretion of pharmacists to substitute other products for prescribed medicines, it is useful to distinguish between six classes of medications:

a. those that can only be sold with a special prescription or permit by the MH (narcotics, psychotropics, blood derivatives);

b. those that can be sold with a prescription one single time; the prescription is held back and the sale is registered in the control books of the pharmacy;

c. those that can be sold with a prescription up to three times; the prescription is stamped each time and held back after three times;

d. those that can be sold with prescription as many times as the patient wishes;

e. those that do not require prescription but can only be sold by pharmacies;

f. those that do not require prescription and can be sold by establishments other than pharmacies.

Although the system in itself seems to be well-designed, in practice the control over pharmacies is not very tight, so that it is fairly easy to obtain medicines of group c and d even without a prescription at all.

In the first two classes of medicines, which are under severe control, there is practically no discretion for pharmacist to substitute medicines. In the last two classes there is only a small role for the pharmacist because the patient is free to choose. The pharmacist can only suggest substitution. For medicines of classes c and d, as explained before, if the medicine is contained in the CSGM the prescription includes at least the generic name and the pharmacist is allowed to provide the generic instead of the branded product. If the medicine is not contained in the CSGM, there is no generic equivalent and the pharmacist is obliged to sell the prescribed (branded) product.

3.6 Policy towards Generics

(3.6) What share of the non-prescription/over-the counter, prescription and hospital markets are held by generics? Please describe the programs you have adopted to promote the consumption of generics.

There is no information available about the relative importance of generics in the markets mentioned. Very rough proxies and trends might be derived from the fact that most national laboratories specialise in generics or branded products whose patents have expired, but even then a precise definition should be given of the concept of “generics”.

The main steps that have been taken to promote the consumption of generics versus branded medicines are three: (*i*) publication of the equivalencies, (*ii*) the obligation to mention generic equivalents in prescriptions and (*iii*) the ban on non-generic medicines in public and social security hospitals.

4. Competition Issues in the Pharmaceuticals Sector

(4.1) Does the competition law apply to the different components of this sector (manufacturing, health insurance, health services, distribution and pharmacies) without exemption or exception? Which agency is responsible for enforcing the competition law in this sector?

The Federal Law of Economic Competition (FLEC) fully applies to the different stages of the pharmaceutical industry (manufacturing, wholesale and retail distribution) and to related fields (health care and health insurance). No exemptions are applicable. The FLEC prohibits monopolies, monopolistic practices and anticompetitive mergers. Mergers and acquisitions exceeding certain thresholds must be notified. The Federal Competition Commission (FCC) is the public entity in charge of the administrative application of the FLEC. It is technically and operatively autonomous.

4.1 Market Definition Issues and Barriers to Entry and Exit

(4.2) Have you had the occasion to address the definition of the relevant market in the pharmaceuticals sector? Did you find that the relevant product market could be approximated by commonly-accepted therapeutic groups? What techniques did you use to determine whether certain products were effective substitutes? Did you find it necessary to distinguish the market for drugs consumed in hospitals from the market for drugs prescribed by physicians and/or the market for over-the-counter (non-prescription) drugs? Was the relevant geographic extent of the market national or international?

The FCC has considered the anatomical therapeutical classes at level 3 a useful approximation of relevant product markets in the pharmaceutical industry. According to that classification products in one class are clinical substitutes and only differentiated by brand, presentation and dosification. Occasionally the market had to be refined further. This was the case in the analysis of the merger between Rhône-Poulenc and Hoechst which is discussed below.

Sales to the private sector and sales to the public sector are considered to belong to different relevant markets. Sales to the private sector comprise sales to private hospitals and clinics and sales to pharmacies. Sales to the public sector comprise sales to public health institutions. In the private sector wholesale traders play an important role, whereas the public sector institutions buy directly from the manufacturers often through public bidding. The geographic dimension of markets has been taken national.

For wholesale distribution the FCC has defined the relevant market as the distribution and commercialisation of pharmaceutical products, cosmetics, and personal care products. I.e. the products that are usually sold by pharmacies. Its geographic extension has been assumed national. For retail distribution the markets are considered local (municipal) arguing that consumers are not willing to travel long distances to acquire their medicines.

(4.3) Did you consider that the pharmaceutical industry is characterised by barriers to entry/exit? What barriers did you identify?

The FCC has considered that the most important economic barriers to entry in the pharmaceutical industry are investments in R&D, patents and publicity. Research and development is not very important in Mexico. The development of new medicines is mostly undertaken in laboratories of multinational companies abroad. Only the later stages of clinical testing is sometimes done in Mexican hospitals. Patents are usually registered first in other countries.

As regards publicity, on one hand there is massive advertising of popular medications in the media. On the other hand, there is a more targeted promotion directed to physicians aimed at influencing their prescription habits. The first type of promotion is mostly limited to non-prescription drugs. The latter kind of promotion is done by advertising in specialised magazines, personal visits to physicians, inviting them to medical congresses and free samples, and concentrates upon patented medicines. There is little difference between Mexico and other countries in this respect.

Normative barriers include, apart from a number of non sector-specific requirements, sanitary licenses to operate a plant for the manufacturing of medications or biological products, and the sanitary registration of the medicines.

As mentioned earlier, there are no significant normative entry barriers in retail distribution. However, there are some economies of scale and scope in retailing which constitute economic barriers to entry. Economies of scope imply that every pharmacy must have a broad assortment of medicines to avoid

frustrated visits by customers. Thus, pharmacies must have a minimum size. Economies of scale imply sufficient turnover to negotiate favourable terms in the acquisition of medicines from wholesalers and manufacturers.

4.2 Anti-competitive Agreements

(4.4) Have you had the opportunity to address questions of explicit or implicit collusion in the pharmaceuticals sector? What forms of collusion have you found? Have you found that pharmaceutical manufacturers deliberately choose to target different therapeutic classes or geographic markets, in order to avoid competition? Does the fact that the large pharmaceutical manufacturers compete in many different product and geographic markets have a tendency to lessen competition? Have pharmaceutical manufacturers or pharmacies acted in combination to attempt to increase (or resist decreases in) pharmaceutical reimbursement rates in health insurance plans?

In June 1999 the FCC started an ex-officio investigation against the multinational companies Roche, Basf and Rhône-Poulenc for collusion in the markets of some vitamins which are used as inputs in the pharmaceutical industry. The investigations followed similar antitrust actions against those companies in other countries. The investigation has not yet been concluded.

In February 2000 the FCC started an investigation upon a complaint about collusion by pharmaceutical companies in public bidding for the acquisition of surgical sutures by the Public Health Sector. The investigation is still under way.

There is no information about whether pharmaceutical manufacturers have deliberately targeted different therapeutic classes or geographic areas in order to avoid competition or whether the fact that they were competing in many markets has lessened their competition in each of them. However, such avoidance and lessening of competition may be perfectly compatible with the market mechanism and Mexican competition law would not prohibit it. It only prohibits *agreements* between competitors aimed at avoiding or lessening competition. If a manufacturer decides on his own not to enter a market or to withdraw from it considering that competition is already very strong in that market while in others it is not, that is part of normal business behaviour and does not violate competition principles.

The FCC has not investigated any collusive behaviour between pharmaceutical manufacturers or pharmacies to improve their terms of reimbursement of medicines in health insurance plans.

(4.5) Co-operative or collaborative ventures (such as co-marketing and co-promotion agreements) seem to be an important component of the pharmaceutical industry. Have you had the opportunity to examine the competitive effects of such agreements? What features of these agreements give rise to competition concerns? Have you opposed joint research and development and/or joint marketing arrangements?

The FCC has not investigated such co-operative or collaborative ventures; neither has the FCC opposed any joint ventures in R&D or in marketing arrangements in the pharmaceutical industry.

4.3 Mergers and Acquisitions

(4.6) What cases of mergers or concentrations have you addressed in the pharmaceutical industry? In what markets were concerns over market power most focused? In the pharmaceuticals industry where competition is primarily by way of new innovation (as opposed to competition on prices), what are the primary anti-competitive effects of a merger? Have mergers been opposed on the grounds that the merging companies might be competitors in the future (although they were not actually competing at the time of the merger)?

2. Most mergers in the Mexican pharmaceutical sector have been a consequence of mergers of multinational pharmaceutical companies which affected their subsidiaries installed in Mexico. All mergers analysed have been of horizontal nature; the FCC has not evaluated vertical mergers. A list of the main mergers in the pharmaceutical sector resolved by the FCC is presented in the following table.

Main mergers of pharmaceutical firms resolved by the FCC

Firms	Year*
1. Rhône Poulenc and Hoechst A.G.	1999
2. Zeneca Group PLC and Astra A.B.	1999
3. Upjohn and Pharmacia de Mexico	1996
4. Novartis Farmacéutica and Wyeth	1999
5. Roche Mexicana de Fármacos, Syntex and Syntex Química.	1996
6. Latin America Pharmaceuticals Inc. and Roussel Uclaf	1995
7. Sandoz de México and Ciba-Geigy Mexicana	1996

*Refers to the year in which they were notified to the FCC.

The analysis of some pharmaceutical mergers in Mexico is briefly described in the following.

The FCC did not find probable anti-competitive effects in the merger of Upjohn and Pharmacia de Mexico, notified in 1996. These firms participated in 12 therapeutic classes, but they only competed in the markets of products classified in the anti-inflammatory non-steroidal class. However, the post-merger market share in this therapeutic class was low, so that there were no competition concerns. On the contrary, the merger of these two firms with small market shares would allow them to compete more vigorously with stronger competitors, and in this way, strengthen competition in the relevant market.

The international merger among Zeneca Group PLC and Astra A.B. had effects in Mexico because both firms have subsidiaries in the country. The merger was notified in 1999, it was considered to affect 12 therapeutic classes. However, the firms involved competed directly only in four of them: antihypertensive, cholesterol and triglyceride, and systemic antibiotics. The market share of the merged firm would be 25 percent in products of the antihypertensive class, and in the other classes the market share would not be significant. The FCC found no anti-competitive effects in any of the markets of the four therapeutic classes in which they compete, so the merger was approved.

In the wholesale distribution market, the FCC analysed the merger among two Mexican firms: the acquisition of Distribuidora Drogueros by Casa Autrey Group, notified in 1997. The merged firm would increase its market share up to 30 percent of the wholesale distribution market. The FCC determined that this merger would not bring anti-competitive effects. The wholesale distributors generally supply to the pharmaceutical private sector, that includes hospitals, clinics and pharmacies. Increasingly however, pharmacy chains and supermarket chains with pharmacy departments purchase directly to manufacturers.

Small pharmacies do not generally buy from manufacturers, but they can join together to purchase directly to laboratories. They can also purchase to pharmacy chains. These possibilities limit the exercise of market power by dominant firms in the wholesale distribution sector. The FCC approved this merger.

4.4 Anti-competitive effects

The only merger that has raised competition concerns was that among Rhône-Poulenc and Hoechst AG which had effects in Mexico through the implied merger of their Mexican subsidiaries. This operation involved several therapeutic classes but the merging firms only competed directly in 13 of them. The competition analysis showed that concentration would increase significantly in products elaborated with vitamins A and D, which was the relevant market upon which the analysis was focused. The possibility of including products containing vitamin C was also considered, but it was determined that they were imperfect substitutes of the vitamin A and D products to cure illnesses like rickets and vitamins A and D deficiencies.

(4.7) What sorts of remedies have been imposed as a condition on merger approval? Have the merging companies been required to divest or license certain products to third parties?

As a remedy, the FCC conditioned the transaction of Rhône-Poulenc and Hoechst to the divestiture of either the brand Aderogil 15 owned by Rhône-Poulenc or the brand Adekon owned by Hoechst, both classified in the therapeutic class of vitamins A and D. Aderogil 15 is a medication that does not require prescription for its purchase and its massive advertising is not restricted. On the other hand, Adekon is subject to prescription and its massive advertising is restricted. Nevertheless, both products were considered to be in the same relevant market, because of their similar active substances and because both can be acquired easily by the consumers in pharmacies.

(4.8) Have pharmaceutical manufacturers sought to integrate into downstream components of the health industry, such as hospitals, insurers, pharmacies or so-called pharmacy benefits managers ("PBM's")? Have you found such actions to be anti-competitive? What remedies have you imposed?

No such attempts are known to the FCC

4.5 Abuse of Dominance

(4.9) What cases of abuse of dominance have you addressed? Have you addressed cases of tying or predatory pricing? In what ways can a pharmaceutical firm with a dominant position reduce competition from rivals?

The FCC has analysed two cases regarding presumable predatory pricing in retail distribution. The complaints were filed in 1997 by small pharmacy associations against pharmacy chains and supermarket chains with pharmacy departments, both offering discounts up to 50 percent of maximum consumer prices. These associations claimed that the chains sold pharmaceutical products at a prices below the costs of acquisition.

The FCC conducted investigations concerning those complaints. It found that chains buy big amounts of medications and operate with higher inventory turnover than small pharmacies. For these reasons, they can obtain considerable volume and prepayment discounts. Small pharmacies generally

cannot obtain such discounts or to the same extent. Thus, the FCC did not find elements that proved the predatory pricing practice. Besides, there was a strong competition among the chains, and none of them had market power.

The FCC has not analysed other cases regarding abuse of dominance in the pharmaceutical sector.

NETHERLANDS

Summary

On the whole, pharmaceuticals are collectively financed in the Netherlands. The development in expenditure is therefore a matter for central government. To date, it has responded to a rise in expenditure via stricter regulations and a reduction in prices and reimbursements to pharmacists. Such interventions always had only a temporary cost-reducing effect, however. The causes underlying the development of expenditure, in particular undesirable practices by the parties involved, were not dealt with. The proposal that recently has been made by the government to regulate competition in the pharmaceuticals sector signifies a turnabout.

The crux of the proposal is as follows: the government controls the quality and accessibility of care at a distance, while the directing role is assigned to the health insurers. To this end, the health insurers need to develop a countervailing power in relation to physicians and pharmacists. It is considered that the proposal can serve as a pilot for potential regulated competition in other areas of the health care sector.

1. Introduction

In the opinion of the OECD, the quality of care in the Netherlands is relatively good. Nevertheless, the system is threatening to become bogged down due to inhibiting regulations and the control of supply. The most obvious developments concern the existence of waiting lists and markedly rising costs. In addition, the limitations of the Dutch health care system will become even more apparent as a result of increasing demand due to technological developments, demographic developments (increased proportion of elderly in the community, immigration) and growing prosperity (individuals are able and willing to pay for more expensive care). Finally, there are indications of conflict between the current regulation of supply on the one hand, and the provisions stipulated by the European Treaty (free traffic of goods and services) on the other.[2]

With a view to future developments, and taking into account the current deficiencies of the healthcare system, a discussion is currently in progress in the Netherlands to consider whether some form of regulated competition can lead to improved health care in the Netherlands, without waiting times and with more freedom of choice for the consumer. The Dutch cabinet forwarded a proposal to parliament in mid-April to bring about regulated competition in the pharmaceuticals dossier. Essential in the proposal is a government which controls the quality and accessibility of care at a distance, while the health insurers fulfil the directing role. The proposal could perhaps serve as a pilot for potential regulated competition in other parts of the health care sector. This policy proposal can be regarded as part of the deregulation reforms of the Dutch government and is intended to bring about a change in current practices.

This paper will only consider the distribution of pharmaceuticals. The production of pharmaceuticals and research & development activities will not be dealt with.

2. The stumbling block of the pharmaceuticals dossier: markedly increasing expenditure

As is the case for virtually all industrialised countries, the Netherlands is confronted by a steadily rising increase in the cost of pharmaceutical care. On the one hand, the current level of expenditure is still relatively low[3]; on the other, there is question of an absolute acceleration in growth, which is mainly determined by the volume consumed.

Pharmaceuticals are largely financed on a collective basis, comparable to other forms of care[4]. The associated financial burden therefore forms part of the collective burden. Hence, the development of expenditures is a matter for central government. To date, it has responded to a rise in expenditure by imposing more stringent regulations and cutting down on prices and reimbursements. The proposals that have been made by the government signify a turnabout in this approach.

2.1 Current regulations

The Dutch regulations as applicable to the pharmaceuticals sector are organised through price regulation, implemented via two Acts, and a reimbursement system. The price of a medicine issued on prescription by the pharmacist comprises two parts. The pharmacist receives a maximum reimbursement for the purchase price of the medicine itself and a maximum reimbursement for his care task. Both parts of the tariff are set by an independent board (CTG).

This methodology is laid down by law (Health Care Charges Act: WTG).

The WTG therefore relates to the phase where medicine is supplied by pharmacies or dispensing physicians to the patient.

The extent to which the cost of pharmaceuticals is reimbursed within the context of the social system is limited via the Drugs Reimbursement System (GVS). The GVS classifies medicines into clusters of therapeutically equivalent drugs, for which a reimbursement limit is specified. If the pharmacy supplies a more expensive prescribed medicine, the patient must make up the difference in cost. In practice, pharmaceutical manufactures tend to fix their prices at or just below the reimbursement limits.

With the application the Pharmaceuticals Prices Act (WGP), the maximum pharmacy purchase prices are fixed on the basis of the average price for comparable pharmaceuticals in Belgium, Germany, France and the United Kingdom. The WGP is applicable to the trading phase, up to and including the sale to pharmacies and dispensing physicians.

2.2 Policy response to rises in expenditure

As previously mentioned, the traditional Dutch response to a rise in expenditure consists of lowering prices and reimbursements, among other things. However, this response only has a temporary effect. The structural development of expenditures is not affected. The standard regulation therefore seems to have reached the limits of its influence, so that a fundamental turnabout in policy has become necessary. Policy should aim at the *causes* of the rise in expenditure, instead of dealing with the rise in expenditure itself.

The causes of a rise in expenditure can be traced back to autonomous factors, such as the growth in population with an increased proportion of elderly, to desirable and compliant developments such as the extramuralisation of care and the introduction of new innovative medicines, to a further increase in the chronic use of medicines and to the undesirable practices adopted by the various parties involved.

Developments such as the extramuralisation of care and the introduction of new innovative medicines are required, because they enhance the quality of health care and/or reduce the costs of care.

With regard to undesirable behaviour, one should consider for example the inefficient prescribing practices of physicians, the commercial practices of pharmacists[5], the limited application of the director's role by insurers, insufficiently critical and effective use of pharmaceuticals by patients and the market practices of producers and the wholesale industry. It is precisely the undesirable practices of the various parties that should be the focus of policy, since the autonomous developments are difficult to influence. The undesirable practices of the market parties are described below.

2.2.1 Prescribing practices of physicians

Physicians are still able to choose whether they prescribe pharmaceuticals based on the active ingredient or on the brand name. If the physician has written a prescription stipulating the brand name, the pharmacist must provide this specifically prescribed medicine to the patient. In principle, this enables the prescribing physician to specify those pharmaceuticals from the GVS cluster that hold the greatest attraction, due to the physician's relationship with the manufacturers/ wholesalers.

The government has stimulated the practice of prescribing on the basis of the active ingredient since 1995. In addition, the government is trying to influence the prescribing practices of physicians by introducing an electronic prescription system (EVS) to general practitioners (G.P.s). This instrument links the medical indication to the medication (based on active ingredient) and is therefore designed to improve quality and consistency. In consultation with the National Association of G.P.s (to which almost all G.P.s are affiliated), it was decided that in principle, the system should be installed at all G.P. practices by 2002. The EVS must be supported by formulations and protocols drawn up by the branch itself.

2.2.2 The commercial practices of pharmacists

If the physician has prescribed a medicine based on the substance name, a pharmacist may supply any product with the same active ingredient that belongs to the relevant GVS cluster. As a result, the pharmacist will issue the product with the largest profit margin.

The government tries to influence the supply practices of the pharmacist through an incentive scheme. This scheme, based on the WTG, specifies that if a pharmacist supplies a medicine that is cheaper than the set GVS reimbursement limit (for the relevant cluster), he may keep one third of the price difference.

However, the strategy as described above is negatively influenced by the claw back system. In this system an independent board (CTG) has imposed a fixed deduction of 6.82 percent with a maximum of NLG 15.00 (about $ six) per prescription line with the on-charged purchase costs of the medication. The underlying objective of the claw back system is to ensure that discounts and bonuses are credited to the care system (i.e. patient/insured party). The consequence, however, is that the claw back forces pharmacists to ensure they get discounts.

2.2.3 Insurers' limited acceptance of the directing role

In the past, public health insurers were expected to behave like administration organisations. In their role of public organisation, they only needed to reimburse the claimed health care costs. From the mid-1990s, they were given greater financial responsibility, and since early 1999, their role has been

redefined as ‘care director’. It is the intention of the government that the insurers will further expand their directing role within the field of pharmaceutical care. To do so, health insurers must develop a countervailing power by reducing their information disadvantage with respect to the care providers. Currently, health insurers have given themselves little, if any room to actually fulfil their new role.

On the one hand, health insurers make insufficient use of instruments available to them to influence the volume and price of pharmaceuticals and care. For example, they are conservative with respect to contracting new suppliers in response to the practices of the established pharmacy branch and the wholesale industry. Furthermore, health insurers do not use the options available to them[6] to purchase pharmaceuticals from wholesalers or manufacturers themselves.

On the other hand, the central agreements between the various representative organisations still limit health insurers in their directing role with respect to their contact negotiations with individual care providers. These agreements include directives with which an individual contract between an insurer and a care provider must comply. In addition, health insurers have had little time to familiarise themselves with their new role of care director.

Finally, because the majority of premiums levied are means-tested, rather than nominal premiums, the gains in efficiency achieved through effective purchasing policy can hardly lead to a reduction in premiums. Strengthening the competitive position via lower premiums therefore has a limited effect only. Hence, health insurers are not offered much financial incentive to ensure an efficient purchase of pharmaceuticals.

2.2.4 Insufficient critical and efficient use of medicines by patients

Much can also be gained by educating the end user in the medicine supply chain. A large proportion of patients use medication for a period that is either too long or too short and/or incorrectly. There is a clear task set aside here for the prescribing physicians, pharmacists and health insurers. The physicians can be supported in this respect by the electronic prescription system (EVS). However, the financial incentives provided to physicians and pharmacists have been misdirected to date.

2.2.5 Market practices of manufacturers and wholesalers

Based on their profit-oriented behaviour and thanks to the freedom the government seems to allow them within the regulated system, manufacturers and wholesalers try to influence the practices of prescribing physicians and pharmacists. This is also expressed through the financial incentives offered to prescribers in the form of discounts and bonuses to pharmacists. The challenge that now faces us is to influence the profit margin competition and the other methods applied to influence the behaviour of physicians and pharmacists through price competition.

2.3 The new policy: deregulation and instrumentation

As already noted, the government will administer the regulation policy carefully, in order to arrive at a system of regulated market forces in a gradual fashion. Once it is clear that health insurers are able to fulfil their directing role, the path of supply budgeting will no longer be taken by the government, with the exception of the WGP (which serves as safety net).

The essential prerequisite for regulated competition is that the demand side can offer a countervailing power when negotiating with care suppliers. It is important in this regard that the

information disadvantage suffered by health insurers is compensated; as representatives of the ultimate demand group, i.e. the consumers/patients, they should be given sufficient freedom and instruments to allow them to operate as fully fledged market parties on a market with many suppliers. The freedom to negotiate is also enhanced, because the system of national agreements with respect to medicine supply will be abolished. Furthermore, the financial stimuli must be designed such that care providers will benefit from maximum efficiency and quality in medicine supply.

The information lag amongst health insurers has both a medical and a financial dimension. The financial dimension, which is expressed through the numerous uncertainties surrounding the financial flows amongst prescribing physicians and pharmacists, has now been reduced via a government regulation, i.e. Administration Regulations pharmaceutical care. Via this instrument, health insurers are offered an insight into the benefits and costs associated with the supply of pharmaceuticals and the prescribing practices and expenditures of outpatient prescriptions issued by medical specialists.

Insurers can catch up their lag with respect to medical information by employing pharmacists and/or administrative and financial participations in pharmacy and wholesale organisations, for example. In addition, the Electronic Prescription System offers an insight into the prescribing practices of physicians.

Furthermore, it is of the utmost importance to enhance the competition on the supply side. To do so, barriers to entry by new pharmacists will be removed. In this way, superfluous requirements pertaining to the quality and organisation of pharmacies will be abolished, differentiation in the product range will be permitted and pharmacists will be allowed to work in more than one pharmacy. In addition, health insurers may themselves run a pharmacy and hospital pharmacists may also trade in extramural pharmaceuticals.

Following completion of the deregulation and instrumentation programme, the health insurers will be adequately equipped to offer flexibility with their insurance claims and to fulfil their directing role. The insurance claims can be defined for each health insurer on an individual basis. Furthermore, there will be an improved exchange of knowledge for the market parties, countervailing power between health insurers and care providers, greater expertise and professionalism amongst insurers and finally, the practices of the parties involved will be guided in the desired direction.

The entire programme as envisaged will depend entirely on the consistency of government policy and on the clarity of the perspectives offered to health insurers. Only then will health insurers assume their directing role, so that regulated competition with respect to the distribution of pharmaceuticals in the Netherlands is given a true chance of success.

APPENDIX

Additional answers to the questions raised in the guide for submissions

1. The pharmaceutical Industry: Market Structure

1.1 Market Structure

1.1

Most international companies have sales centres. 6 larger R&D-driven companies have European production or distribution centres, as do two larger generic producers. Several smaller companies (approx. 20) are at the R&D stage or early production stage.

Total R&D expenditure is NLG 800 M. There is no joint R&D. Specific joint market operations are not known.

Manufacturers' associations: 2 (one for R&D-driven industry, one for generics). The R&D-driven pharmaceutical association is politically the most active organisation.

2. Regulation of Supply

2.1 Protection of Intellectual Property Rights

2.1

Protection of IPR is based on European regulations, including the extension period, the Special Protection Certificate.

2.2 New Drug Approvals

2.2

The drug approval process is based on European regulations. (Registration process for approval to the market).

2.3 Trade regulation

2.3

The Netherlands does not impose any specific restrictions on international trade. Parallel import/export is not restricted. Mail order is in principle allowed, but for prescription drugs only, if a prescription is provided. In practice, mail order does not exist. There is no specific ruling for Internet supply and no distinction between domestic or foreign firms.

2.4 Industrial Policy

2.5

The Netherlands does not have any specific industrial policy for the pharmaceutical industry.

3. Regulation of Demand: Controls on Pharmaceutical Prices, Quantities and Consumption

3.1 Health Insurance Coverage of Pharmaceuticals

3.1

Patients/consumers only pay a premium (and perhaps an excess) with no personal contribution, so that there is no link between benefit and payment. This leads to over-consumption due to moral hazard behaviour by consumers. The volume is restricted by supply regulations (health insurance budget).

3.2

Insured parties are entitled to the provision of services in kind, in accordance with the Health Insurance Act.

The entitlement to extramural pharmaceutical assistance has been made more concrete through the 1996 pharmaceutical assistance scheme (the drugs reimbursement system: GVS). Registered pharmaceuticals to which patients are entitled are included in appendix 1 of the scheme. The medicines included in appendix 2 are reimbursed subject to specific conditions.

Appendix 1 is subdivided into part 1 A and part 1 B. Pharmaceuticals that are therapeutically interchangeable in accordance with the criteria as described by the scheme, and that are not subject to any clinically relevant differences, are designated to clusters as shown in appendix 1 A. They are subject to a reimbursement limit. Appendix 1 B includes medicines that cannot be clustered in the group of interchangeable pharmaceuticals and are fully reimbursed.

The inclusion of non-clusterable medicines in the reimbursement system (appendix 1 B) is only granted following assessment by the Minister of Public Health, Welfare and Sport (VWS) to ensure that they meet the criteria for therapeutic relevance and efficacy. This also considers the price level of the medicine in question (and hence the reimbursement calculated).

Non-registered medicines such as prepared by the pharmacist himself as well as sera and vaccines are also reimbursed.

The GVS system does not formally apply to privately insured parties. However, the majority of private health insurers do apply the GVS as a principle for their health insurance policies.

3.3

The price regulation of pharmaceuticals is effected in the Netherlands via two acts and a reimbursement system.

The price of a prescribed medicine supplied by the retail industry consists of two parts. The retailer receives a reimbursement for the medicine itself and a maximum reimbursement for his care task. The reimbursement level of the care task is set by an independent board (CTG). This method is laid down by law (Health Care Charges Act: WTG). The WTG therefore concerns the phase where the medicine is supplied to the patient by the pharmacy or the dispensing physician.

The level of reimbursement for the medicine within the context of the social system is limited via the Drugs Reimbursement System (GVS). The GVS divides therapeutically equivalent medicines into clusters, for which a reimbursement limit is specified. If the pharmacist/dispensing physician provides a more expensive prescribed medicine, the patient must make up the difference in cost. In practice, pharmaceutical manufacturers tend to fix their prices at or just below the reimbursement limits.

The application of the Pharmaceuticals Prices Act (WGP) specifies maximum pharmacy purchase prices, based on the average price for comparable pharmaceuticals in Belgium, Germany, France and the United Kingdom. The WGP relates to the trading phase up to and including the sale to pharmacies and dispensing physicians.

3.4 Control of Physician Prescribing Practices

3.4

Physicians are still able to choose whether they prescribe on the basis of brand or active ingredient. If the physician has written a prescription stipulating on the brand name, the pharmacist/ retailer must provide this specifically prescribed medicine to the patient. The government has stimulated the practice of prescribing on the basis of the active ingredient since 1995 and is also trying to influence the prescribing practices of physicians by introducing an electronic prescription system (EVS) to G.P.s. This instrument links the indication to the medication (based on active ingredient) and is therefore intended to improve the quality and consistency of prescription writing. In consultation with the National Association of G.P.s (to which almost all G.P.s are affiliated), it was decided that the system must be installed at all G.P. practices by 2002, in principle.

3.5 Regulation of Pharmacies and Pharmaceutical Distribution

3.5

If the physician has prescribed a medicine based on substance name, a pharmacist may supply any product with the same active ingredient that is listed in the relevant GVS cluster. As a result, the pharmacist will issue the product with the largest profit margin.

The government is trying to influence the supply practices of pharmacists through an incentive scheme. This scheme, based on the WTG, stipulates that if a pharmacist supplies a medicine that is cheaper than the GVS reimbursement limit (for the cluster in question), he may keep one third of the difference in price.

However, the strategy as described above is negatively influenced by the claw back system, where the government (through an independent board) has imposed a fixed discount of 6.82 percent with a maximum of NLG 15.- per prescription line with the on-charged purchase costs of the medication. The underlying thought of the claw back system is to ensure that discounts and bonuses are credited to the care system (i.e. patient/ insured party). However, the consequence is that the claw back forces pharmacists to ensure they get discounts.

3.6 Policy towards Generics

3.6

The volume share of generic prescriptions in 1998 was 41 percent. The cost share was 15 percent.

The brand name pharmaceuticals had a volume share of 59 percent with an associated share in costs of 85 percent, of which nine percentage points were realised via parallel import, which is equivalent to 14 percentage points of the costs.

4. Competition Issues in the Pharmaceutical Industry

4.1

The competition act applies to various parts of the industry. One exception has been made, which applies up until 2003. This exception is only valid if a decision has been issued by an administrative authority. The Dutch Competition Authority (NMa) is responsible for enforcing the competition act within the pharmaceutical industry.

4.1 Market Definition Issues and Barriers to Entry

4.3

A major barrier to entry is the inclusion of a drug in the reimbursement system and in reimbursement price setting. Registered products are not automatically admissible for reimbursement. For example, substantially new pharmaceuticals must fulfil pharmaco-economic criteria.

4.2 Anti-competitive Agreements, Mergers and Acquisitions and Abuse of Dominance

4.4, 4.5, 4.6, 4.7 and 4.9

In its two years ' existence the Dutch Competition Authority (NMa) has taken 26 decisions in the health care sector. These decisions deal with mergers between hospitals, mergers between health care insurance companies, joint purchase agreements, horizontal agreements between suppliers of health care, etc. Non of these deal with the pharmaceutical industry/trade specifically.

4.8

There is no move towards downstream integration.

NOTES

1. See World Review, the Pharmaceutical Market, 1995. The figures refer to 1994.

2. As health insurers and other parties are given more freedom with respect to their economic activities, national and European legal competition provisions are more likely to become applicable.

3. The total expenditure on pharmaceuticals per capita in 1996 in the Netherlands amounted to US $ 193.00, compared to US $ 239.70 in the OECD, on average.

4. Exceptions are confined to the excess paid by those who are privately insured and OTC medicines.

5. In the current situation, the commercial practices of pharmacists are undesirable. In a future where regulated market forces operate, commercial practices by the pharmacist in his role as entrepreneur in fact become a prerequisite.

6. The legislation relevant to the purchase of pharmaceuticals by health insurers does not offer any explicit impediments.

NEW ZEALAND

1. Introduction

The Pharmaceutical industry is a complex sector, with many institutions, players, and interests. It is characterised by high technological innovation and products that increase both longevity and quality of life of society. Yet its competitive nature is undergoing much change today. The entry of new firms and products increase competition at the same time as mergers reduce it. Moreover, society frequently makes competing demands: consumer safety and access, or low prices and corporate incentives to invest. This presents a regulatory challenge for governments.

Few industries in industrialised countries are subject to as much direct regulatory control as the pharmaceutical industry. New Zealand is no exception. Unique to the pharmaceutical market is that manufacturers can often exercise market power from intellectual property protection, rather than natural monopoly characteristics. Moreover, final consumers are often insensitive to the price of pharmaceuticals as they usually do not pay the full price.

This paper describes the market structure, regulatory institutions, and the various forms of regulation affecting the pharmaceutical sector in New Zealand. Specifically, we focus on those regulations which give rise to market power, influence prices, quantities, innovation, and exit and entry. This is presented in a demand-supply framework. We do not canvass issues of consumer protection, only to the extent that this can hinder competition.

2. Pharmaceutical Industry in New Zealand: Market Structure

The supply side of the New Zealand pharmaceutical market is characterised by an oligopolistic structure. That is, primarily composed of a small number of very large multi-national companies; with the exception of some New Zealand/Australian based 'generic' manufacturers.

Most pharmaceuticals are imported from around 150 European, Australian and North American manufacturers. The local New Zealand manufacturing base is small (approximately 20 licensed manufacturers). There are no longer any multi-national companies manufacturing pharmaceuticals in New Zealand, and only two significant manufacturers of generic medicines.

There are approximately 78 local distributors of pharmaceuticals (prescription and non-prescription medicines) in New Zealand, supplying goods valued at around NZ$810 million annually.[1] Annual sales of over-the-counter medicines comprise about $210-215 million of this total.

Drug companies in New Zealand conduct little R&D. Most research is undertaken in the form of clinical trials, which are developed for marketing purposes, although this is declining.

2.1 Pharmaceutical Industry Associations

There is an industry association representing each of the following pharmaceutical sectors in New Zealand:

- innovator medicines manufacturers;
- generic medicine manufacturers; and
- non-prescriptive medicine distributors.
- researched Medicines Industry Association of New Zealand. [2]

Each association represents the interests of their members to central Government and provides a central point for consultation. That said, however, there has been a significant increase in the number of small traders operating in the market who have been attracted by PHARMAC's tendering process for selecting sole or preferred suppliers for specified medicines.

3. Regulation of Supply

3.1 Protection of Intellectual Property Rights

An important intervention in the pharmaceutical sector is the granting of patent protection. Patent protection sacrifices some short term competition in the expectation that outweighing gains will be achieved through greater levels of innovation. There is, however, an important trade-off. On the one hand, patent protection is essential if the pharmaceutical industry is to appropriate its enormous investment in R&D. On the other hand, patent protection restricts access to markets by less expensive generic products,[3] often depriving patients of cheaper products which are essentially the same.

New Zealand law provides patent, trade mark, and copyright protection for drugs (Patents Act 1953, Trade Mark Act 1953, Copyright Act 1994). This legislation is administered by the Ministry of Economic Development. There are also data protection provisions contained in the Medicines Act 1994 which provide a period of protection for confidential supporting information (for example, trade secrets) supplied with an application for consent to distribute an innovative medicine containing a new active substance. This is usually for a period of five years from accepting application for consent.[4]

With regard to patent protection, New Zealand has a flat 20 year patent term, with no extension. It is considered that the 20 year term, together with the protection that has also been given to registration data, provides an appropriate period of protection for pharmaceuticals, recognising drug companies' investment in R&D. Systems of extensions were considered more appropriate for countries which are exporters of pharmaceuticals, which New Zealand is not.

3.2 Drug Approval Process

Entry to the New Zealand pharmaceuticals market is not controlled. Any product that meets the safety standards (established by the Medicines Act 1981) and which achieves registration by the Ministry of Health can freely be sold within New Zealand. The speed of approval of new drug products is a key issue in pharmaceutical regulation.[5]

The actual timing of a drug's approval depends on when the approval application is submitted, as well as the length of the review process, itself. It also depends on the responsiveness of drug companies to questions raised by the reviewing authority (which has been anywhere up to towers in the New Zealand case). Ambitious approval performance targets are set by New Zealand's approval agency, Medsafe. (These performance targets are set out in Annex 1).

"Medsafe" is the New Zealand Medicines and Medical Devices Safety Authority and determines which pharmaceuticals can be marketed and sold within New Zealand. It is responsible for applying a framework of controls designed to ensure that the therapeutic products available in New Zealand are those that can be expected to have greater benefits than risks if used appropriately.[6] This is achieved through:

- *pre-marketing approval*: This must be obtained for new medicine, and changes to existing medicines. New medicines can not be marketed in New Zealand without the consent of the Minister of Health (or their delegate). Medicines to which changes have been made can not be marketed without the consent of the Director-General of Health (or their delegate). Data that satisfactorily establish the quality, safety, and efficiency of the product, for the purposes for which it is used, must be submitted for evaluation before consent can be granted.

- *Post-marketing surveillance*: Monitors the safety of medicines (and medical devices) in use. Products shown to be unsafe are removed from use. Ensures prescribes are advised about new safety information for products.

3.3 Trade Regulation

In general, New Zealand imposes no barriers to international trade or investment in pharmaceuticals, beyond standard restrictions such as requiring regulatory approval before a product can be marketed. Changes to the Copyright Act in 1998 enabled parallel importing of other goods, but legislative restrictions in the Medicines Act, through a number of technical requirements, effectively prohibit it for medicines.

The distribution of medicines via mail-order or the Internet is subject to the same regulatory requirements as medicines otherwise distributed. An area of concern for New Zealand regulators is Internet sales of prescription medicines to overseas buyers when the buyer has no valid prescription. A legislation change is in train to prohibit such sales.

4. Regulation of Demand: Control on Pharmaceutical Prices, Quantities, and Consumption

It is worthwhile to briefly focus on a few key statistics which point to a general growth in the demand for pharmaceuticals in New Zealand. First, the number of GP consultations in New Zealand is rising, increasing from 13.8 million in 1993 to 15.4 million in 1997.[7] This represents an increase of 11.6 percent over this period. Second, the total government spending on pharmaceuticals in New Zealand has increased in the last decade or so (around 10 percent in real terms over the period 1987 to 1997).[8]

Likewise, total government and per capita spending on pharmaceuticals, via the national Pharmaceutical Schedule, has also increased during this period. In particular, per capita expenditure on pharmaceuticals subsidised by the government rose from $134 in 1987 to $200 in 1997. This also corresponds to an increase in the number of subsidised pharmaceutical items per capita, rising from 5.1 in 1993 to 8.4 in 1997.

4.1 Health Insurance Coverage of Pharmaceuticals

The health system in New Zealand is not an insurance based one. It is mainly financed out of taxation. Private health insurance is available, but in 1997/98 accounted for only 6.2 percent of all expenditure on health. The proportion of the population covered by health insurance has fallen since the mid-1990s.

In terms of pharmaceuticals, in 1997/98, 71 percent of expenditure was publicly funded, 26 percent came from patient charges with only three percent being covered by health insurance. The position with pharmaceuticals is further complicated with the existence of subsidies for certain drugs which differ amongst different age groups and socio-economic categories.

Given the relatively small importance of health insurance in reimbursing pharmaceutical expenditure it is unlikely that it has a great impact upon demand. Of greater importance within New Zealand are the subsidy arrangements administered by the Pharmaceutical Management Agency Ltd (PHARMAC), as described.

4.2 Level of Patient Subsidies

Government subsidies met a proportion of the patients costs of prescription pharmaceuticals, with patients making contributions in three areas:

- Patients pay a co-payment for each prescription. This varies from $0 to $15 depending on age, income level, and health status.
- If the price of the pharmaceutical exceeds the subsidy, the patient pays the difference.
- If the pharmaceutical is not subsidised by the Government, the patient pays the full price.

4.3 Pharmaceutical Management Agency Ltd (PHARMAC).

As noted above, the supply side of New Zealand's pharmaceutical market is characterised by an oligopolistic structure. It was considered that in dealing with these suppliers, a single purchasing organisation could best protect the interests of consumers in New Zealand. Of importance here is the relatively small population and purchasing power of New Zealand. Accordingly, PHARMAC was established as a single purchasing entity responsible for managing the government's spending on pharmaceutical subsidies within community healthcare. Its responsibilities are separate from the purchase and use of pharmaceuticals within hospitals.

The rationale for a centralised purchasing body is the view that it effectively prevents the possibility of pharmaceutical manufactures fragmenting the New Zealand market, to the detriment of the New Zealand consumer. It was considered that a centralised purchasing agent would increase economies of scale and reduce the transaction costs that would otherwise be passed on to the New Zealand consumer.

PHARMAC is a non-profit company owned by the government Health Funding Authority (HFA). The task of PHARMAC is to mange the Pharmaceutical Schedule. That is, the list of drugs subsided in New Zealand, the prices and subsidies of those drugs, and any restrictions on access to the subsidy. There are approximately 3 000 items listed on the Pharmaceutical Schedule.[9] Specifically, PHARMAC's primary role is to ensure that limited funds available to purchase pharmaceuticals are spent in a way that maximises the benefits to all New Zealanders. This means getting the best value (in terms of

health gains) from the Government's expenditure on pharmaceuticals when deciding which drugs should be subsidised, and at what levels.

In this context, a number of criteria are used including efficacy and cost-effectiveness.[10] PHARMAC carries out competitive tendering and negotiations with companies to ensure the best deals are obtained on behalf of New Zealand taxpayers. In this way, price is established by negotiation; a process which parallels standard commercial negotiations. Savings are derived from the stimulation of price competition by listing new product and by reviewing the terms and conditions of products already listed on the Pharmaceutical Schedule.

4.4 The Operating Framework[11]

PHARMAC's mission is clear: "to optimise the contribution of pharmaceuticals to the healthcare of New Zealanders". This means obtaining the best value from the Government's expenditure on pharmaceuticals. Part of this goes to providing patients with the widest possible access to drugs, best suited to their conditions, while, at the same time, keeping costs low. Cost-quality analysis is a key tool used in making judgements of healthcare gains. This types of analysis considers both gains to the patient as well as savings in other parts of the health system, such as avoiding hospitalisations.[12]

There are three pre-defined and publicised steps in any typical subsidy decision made by the PHARMAC Board:

- independent medical advice as appropriate, provided by the Pharmacology and Therapeutic Advisory Committee;
- feedback from consultation, as appropriate, with pharmaceutical companies, medical groups, and other interested parties; and
- consideration of a specific set of principles (the decision criteria).

The decision criteria include the health needs of the population, the ability of pharmaceuticals to meet these needs, the clinical benefits, risks and cost of pharmaceuticals, the financial costs to the government and the patient, and the cost-effectiveness of the pharmaceutical.[13] As part of the decision-making process, PHARMAC assess the value of price-subsidy interventions through the use of cost-utility analysis.

4.5 Price Competition

Price competition among suppliers is a significant objective for PHARMAC as a means of managing pharmaceutical subsidies. Companies have always competed, but primarily on R&D and marketing. Price competition has not historically been a feature of the New Zealand market because government subsidies meant that doctors and patients – who jointly make the purchase decision – do not face the true cost of prescriptions. PHARMAC has introduced a measure of cost sensitivity and price competition to New Zealand that is taken for granted in other markets in New Zealand but, until recently, was absent from pharmaceuticals.

PHARMAC's strategies for efficient subsidies and prices include:

- *Reference pricing*. The primary way PHARMAC stimulates price competition among suppliers is through reference pricing. Approximately 60 percent of the drugs on the

Pharmaceutical Schedule, measured by their value, are covered by some form of reference pricing. Reference pricing establishes a common subsidy for drugs that have the same or similar therapeutic effect.[14] The subsidy is set at the level of the lowest-priced drug within the same sub-group, and in this way acts to encourage price competition. If a drug company lowers the price of its drug, and other companies do not follow, then the manufacturer's surcharge is a disincentive for doctors to prescribe those products. Therefore, the lower priced product gains market share.

- *Market caps*. This establishes limits for expenditure on a particular drug. These capped maximum annual contracts involve PHARMAC paying a fixed annual maximum amount to a supplier, regardless of the amount prescribed, dispensed or consumed. Therefore, if annual subsidy expenditure exceeds the agreed cap, the balance is refunded by the drug company to government. This means that the companies share a degree of the commercial risk. Companies gain the listing or de-restriction of their product, which boost sales, and PHARMAC is protected against uncontrolled expansion in expenditure. A price cap may also complement targeting as it encourages drug companies to be selective in their marketing.[15].
- *Tendering*. A tendering process has been used to enhance the level of price competition in generic markets. This involves selecting one brand of an off-patent drug to be the sole listed brand on the Schedule. This technique enables generic suppliers to achieve greater market share and overcomes the tendency of New Zealand doctors to prescribe by brand name. Tendering has produced significant price and subsidy reductions. Moreover, companies have sometimes provided price reductions on their products in order to avoid tendering. Tendering for drugs has led to average price reductions of 39 percent.
- *Targeting*. There are restrictions on the access to a subsidy for a limited amount of drugs on the *Pharmaceutical* Schedule. The primary purpose of the restriction is to: target the subsidy for the drug to those patients for whom it will provide the best value (primarily for the more expensive drugs); take account of specific features of the drug (for example, a need to be prescribed by a specialist with the appropriate expertise); help manage expenditure; and provide a bargaining tool with drug companies.

4.6 Formularies

PHARMAC publishes the Pharmaceutical Schedule, a list of those drugs that are subsidised by the government, the prices at which they are subsidised, and any criteria that need to be met for patients to access subsidy for those drugs. The Pharmaceutical Schedule is effectively a "positive closed formulary". The PHARMAC board controls the listing of products on the Schedule and applies their decision criteria in considering application from drug pharmaceutical suppliers to have their products listed.

The Schedule is extensive with approximately 3 000 products listed. The Schedule records the price of each drug, the subsidy it receives from public funds and the guidelines, or conditions, under which it may be funded. It is updated monthly and reprinted three times annually. In addition, the Health Funding Authority operates an Exceptional Circumstances scheme whereby patients may gain access to subsidy for non-listed items.

Pharmaceutical suppliers submitting applications to have new products listed on the Pharmaceutical Schedule must provide pharmacological information (dosages, and side effects), therapeutic information (how the product compares with existing therapies), price information (selling price, the selling price in other countries, and any alternative pricing proposals the manufacturer may have contemplated), epidemiological information (how suitable the drug is for New Zealand population and the numbers of people who would benefit from the treatment), market information (cost to PHARMAC given

NZ demand), information on the cost and benefits to health authorities of listing the drug, and other supporting information.

4.7 Control of Physician Prescribing Practices

Consumption decisions for individual pharmaceuticals are made by prescribers, and to a lesser extent patients, via prescriptions written by doctors for their patients. However, because of the subsidy regime, neither of these parties bear the full cost of the consumption decision. The HFA and PHARMAC, through their contacts with general practitioners and specialists, attempt to influence prescribing behaviour (demand) for pharmaceuticals to ensure that treatments/medicines are cost-effective and are directed at those who benefit most. Strategies include:

- *Budget-holding*. Most GPs have entered into budget-holding arrangements to encourage cost-effective use of medicines.

- *Treatment restrictions.* For some drugs there is restricted access to the subsidy. For instance, a patient must meet specified criteria in order to be eligible for subsidy.

- *Prescriber guidelines*. These aim to help physicians more appropriately target pharmaceutical use and are based on the recommendations from user groups and relevant specialists and professional organisations, societies, and colleges. The influence of such guidelines to prescribing practices is unclear.

- *Restricted prescribing rights*. In some cases, the restriction may also extend to the type of prescriber. For example, PHARMAC's Pharmaceutical Schedule provides for six categories of listing which aim to improve targeting.

  - *Listed*. Most drugs are in this category, and may be prescribed by any quantified medical practitioner and in some cases by dentists or midwives.

  - *Retail Pharmacy-Specialist Prescription*. May be written by a medical practitioner in the specialist category defined in the Schedule, but may be dispensed by any pharmacy.

  - *Retail Pharmacy-Specialist*. Prescriptions may be written by a general practitioner on the recommendation of a specialist, and any retail pharmacy may dispense.

  - *Hospital Pharmacy-Specialist Prescription*. Prescriptions may only be written by a medical practitioner in the specialist category defined by the Schedule, and only hospital pharmacies may dispense.

  - *Hospital Pharmacy-Specialist.* Prescriptions for these drugs may be written by a general practitioner on the recommendation of a specialist, but must be dispensed by a hospital pharmacy.

  - *Specialist Authority*. These prescriptions are only subsidised after approval is obtained from Health Benefits Limited (patient must meet the specific criteria).

4.8 Regulation of Pharmacies and Pharmaceutical Distribution

Pharmacy margins are controlled contractually. There is a fixed sum of money, the "pool", limiting the amount of money paid to pharmacists for distribution and dispensing services. Each pharmacist receives a payment from the pool, based on the number of prescriptions that the pharmacist dispenses. Pharmacy ownership is controlled by the Pharmacy Act 1970. The Act restricts ownership of pharmacies to registered pharmacists. There is also a prohibition on any one pharmacist owning more than one pharmacy.

4.9 Policy towards Generics

Generic drugs are essentially identical products to other drugs but are much cheaper. They are typically manufactured by firms that have not engaged in original R&D work and therefore have only modest fixed costs. New Zealand does not have any policies specifically favouring generics. For instance, there is no universal sanctioning of generic substitution.

Instead, PHARMAC's policies are aimed at ensuring there are no impediments to generics competing against branded companies. For some generic products, a tender is held to select one supplier that will be the sole subsidised brand of that product. In these circumstances, generic suppliers can compete on tangible factors such as price and reliability of supply, and are not hampered by having lesser brand recognition amongst doctors compared with research based company products.

Price competition is encouraged in generics in order to more closely align New Zealand off-patent drug prices with international levels. In the past, New Zealand prices have been higher than overseas generics. Evidence in New Zealand suggests that once drugs go off-patent, prices drop dramatically. For example, a cyclovir (Zovirax) dropped by 70 percent during the year following patent expiry.

5. Competition Issues in the Pharmaceutical Sector

The purpose of the Commerce Act is to "promote competition in markets within New Zealand." This recognises that the competitive process leads to economic efficiency and thus economic growth. The Commerce Commission is the agency responsible for enforcing the Commerce Act.

Competition law applies to most of the different components of the pharmaceutical sector (manufacturing, health insurance, distribution, and pharmacies), with the partial exception of PHARMAC; the centralised purchasing body responsible for negotiating the government subsidy.

The partial exemption to the Commerce Acts is considered necessary for PHARMAC to carry out its role. Specifically PHARMAC is exempted from the trade practices provisions of the Commerce Act (contained in Part II of the Act) for the purposes of entering contracts for the purchase of pharmaceuticals. The exemption provides legal certainty for PHARMAC's purchasing activities and prevents costly litigation.

Competition therefore exists within the New Zealand pharmaceutical market at two levels:

- Competition for access to subsidies. That is, pharmaceutical companies compete with each other to have their products subsidised. It is considered that competition for access to subsidies improves the value that the Government receives from its expenditure on pharmaceutical subsidies.

- Competition for pharmaceuticals that are not subsidised. Here, pharmaceutical companies are free to price their products in New Zealand at whatever they consider attractive to the consumer and what they determine their profit maximising level to be.

5.1 Market Definition Issues

In New Zealand there have been no legal cases that have involved defining relevant pharmaceutical markets. Actions that have been initiated have been settled or withdrawn before reaching resolution. When PHARMAC applies reference pricing, it groups drugs into therapeutic sub-groups. A sub-group is defined as drugs that have the same or similar therapeutic effect for the same or similar condition. PHARMAC makes judgements about sub-grouping following advice from a committee of independent medical advisors.

5.2 Barriers to Entry and Exit

Access to the New Zealand market is straightforward. Any pharmaceutical supplier can market its products if it can demonstrate to the Ministry of Health that the products are safe and have a positive clinical effect. The Ministry's testing is similar to that found in other OECD countries. Specifically, pharmaceutical products are subject to scrutiny as to the benefits and safety. Medsafe (the New Zealand Medicines and Medical Devices Safety Authority) is the authority responsible for the regulation and evaluation of therapeutic products in New Zealand.

Once a product is registered with Medsafe it is able to be sold. There are no restrictions on the price a supplier may charge for it. Companies also have reasonable freedom over product promotion and, unlike some other countries, are able to advertise direct to the consumer.

PHARMAC's role and practices relate primarily to access to government subsidy. PHARMAC selects the drugs that are to be subsidised and declines to subsidise others. If a pharmaceutical company wants the product to be placed on the Pharmaceutical Schedule, it is required to meet PHARMAC's criteria.

6. Conclusion

The supply side of the New Zealand market is characterised by an oligopolistic structure, primarily composed of a small number of very large muti-national companies. The local New Zealand manufacturing base is small (approximately 20 licensed manufacturers) and there are no multi-national companies manufacturing pharmaceuticals in New Zealand. Most pharmaceuticals are imported. There is also minimal R&D carried out in New Zealand with most research undertaken in the form of clinical trials for marketing purposes.

As in other countries, the demand for pharmaceuticals in New Zealand is growing, along with government spending in this area. Optimising the contribution of pharmaceuticals to the healthcare of New Zealanders is a key objective of New Zealand's regulatory regime. This means providing the patients with the widest possible access to drugs, best suited to their conditions, while at the same time, keeping costs low.

With a relatively small population, and weak purchasing power, a single purchasing organisation is considered best able to protect the interests of New Zealand consumers in regard to community healthcare. Here, price competition is a key objective. This paper has highlighted a number strategies aimed at promoting price competition and efficiently managing the pharmaceutical subsidies.

ANNEX 1

NEW DRUG APPROVAL PROCESS: PERFORMANCE TARGETS

Performance targets (**in working days**) are shown in the following table:

Phase	**New higher-risk medicine applications**	**Intermediate-risk New Medicine Applications**	**Lower-risk New Medicine & Related Product Applications**	**Changed Medicine & Related Product Notifications**
Receipt and acknowledgement of application	Application acknowledged within **5 days** of receipt	Application acknowledged within **5 days** of receipt	Application acknowledged within **5 days** of receipt	Application acknowledged within **5 days** of receipt
Initial evaluation	**295 days**	Initial evaluation completed within **30 days** of acknowledgement of application	Initial evaluation completed within **20 days** of acknowledgement of application	Initial evaluation completed within **20 days** of acknowledgement of application
Evaluation of additional data		Applicant's first response evaluated within **20 days** of receipt	Applicant's first response evaluated within **15 days** of receipt	Applicant's first response evaluated within **15 days** of receipt
Ongoing requests for additional information and evaluation of responses - No performance target				
Consent process	Consent notice submitted for publication in *Gazette* within **5 days** of decision to recommend approval	Consent notice submitted for publication in *Gazette* within **5 days** of decision to recommend approval	Consent notice submitted for publication in *Gazette* within **5 days** of decision to recommend approval	N/A
Evaluation and the finalising of data sheet - No performance target				
Total time application under Medsafe action	**300 days**	**60 days**	**45 days**	**40 days**

Source: New Zealand Regulatory Guidelines for Medicines: Volume 1.

NOTES

1. NZ$1=US$0.46

2. This is the principal organisation representing pharmaceutical companies.

3. Generic drugs are essentially identical products to other drugs but are much cheaper. They are typically manufactured by firms that have not engaged in original R&D work and therefore have only modest fixed costs.

4. See guidelines in "New Zealand Regulatory Guidelines for Medicines:" Vol. 1- section 3.8: *www.medsafe.govt.nz*.

5. Indeed, a slow drug approval process can create a harmful 'drug lag".

6. Medsafe is responsible for administering the Medicines Act 1981 and the Regulations 1984, and parts of the Misuse of Drugs Act 1975 and Regulations 1977.

7. Ministry of Health, *Health Expenditure Trends in New Zealand, 1980-1997*.

8. Ministry of Health, *Health Expenditure Trends in New Zealand, 1980-1997*.

9. PHARMAC. The Pharmaceutical Schedule. Available from: URL: http//www.pharmac.govt.nz

10. PHARMAC employs a range of strategies in an effort to achieve greater cost efficiencies in pharmaceutical purchase and utilisation (including reference pricing).

11. For detailed description of operating framework, assessing value for money, and strategies and tools for managing pharmaceutical expenditure, see Braae, R, McNee W, and D. Moore (1999) "Managing Pharmaceutical Expenditure while Increasing Access: The PHARMAC Experience", *Pharacoeconomics*, 16(6), December.

12. See *http://www.pharmac.govt.nz*

13. See for more detail *http://www.pharmac.govt.nz*

14. PTAC makes recommendations on the therapeutic sub-grouping of drugs.

15. Significant expenditure caps have been negotiated for: fluoxetine, aciclovir, paroxetine, atorvastatin and sumatriptan, and in aggregate across pump inhibitors and H^2- receptor antagonists.

NORWAY

1. The pharmaceutical industry in Norway: Market structure

Sales of pharmaceutical products in Norway amounted to NOK 6.8 billion in 1999 at the pharmacy purchase level and 10.7 billion at the pharmacy retail level. This represents an increase of 13 percent from 1998 to 1999, and is mainly due to the introduction of more expensive pharmaceuticals for certain diseases.

As a result of the EEA agreement parallel import of pharmaceuticals is allowed in Norway, but only within the EEA market. From 1 January 1995 it is also legal to parallel import patented pharmaceuticals. Parallel importers can only bring pharmaceuticals to Norway, which are already marketed by a direct importer. In 1999 the parallel importers represented 7.4 percent of the market but for certain pharmaceuticals they have a market share far above this.

1.1 Pharmaceutical companies

There are approximately190 pharmaceutical companies on the Norwegian market.[1] The majority of the pharmaceutical companies established in Norway are foreign- owned companies, which import and distribute their drugs in Norway. Generic producers dominate the pharmaceutical industry in Norway. There are 12 importers of parallel drugs in Norway.

The top 25 companies had total sales of 5 820 million NOK in 1999, corresponding to approximately 84 percent of the total sales at the pharmacy purchase level.

The Herfindahl-Hirschman index for the pharmaceutical sector is approximately 450.

Table 1: The 10 largest pharmaceutical companies on the Norwegian market in 1999

Company	Total sales, mill NOK*	% of the Norwegian market
1. ASTRAZENICA AS	749	11 %
2. MSD (Norge) AS	659	9.7 %
3. GLAXO WELLCOME AS	560	8.2 %
4. PFIZER AS	476	7 %
5. PHARMACIA & UPJOHN AS	352	5.2 %
6. NYCOMED PHARMA AS	309	4.5 %
7. NOVO NORDISK PHARMA AS	229	3.4 %
8. PARANOVA AS	216	3.2 %
9. AVENTIS AS	203	3 %
10. NORVATIS NORGE AS	194	2.9 %
Total	3947	58,1 %

* pharmacy purchase price.
Source: FARMASTAT/LMI

The following companies produce pharmaceuticals in Norway: Alpharma AS, Fresenius AS, Nycomed Pharma AS, Nycomed Imaging AS, Pronova AS and Weifa AS. Alpharma, Nycomed and Weifa had approximately a ten percent market share of the total sales in Norway in 1999. Of the number of marketed drugs[2], 12 percent are manufactured in Norway and 88 percent are manufactured abroad. The total import of pharmaceutical products amounted to NOK 5 267 million, and the total export to NOK 1691 million in 1998.

The number of employees in 1999 in the pharmaceutical industry in Norway was 4 152, and 2 674 were employed in the pharmaceutical production plants.

Table 2: Employees in the pharmaceutical production plants in 1999

Company	Number of employees in Norway
ALPHARMA AS	555
NYCOMED AS*	1495
WEIFA AS	171
PRONOVA AS	115
FRESENIUS AS	338
TOTAL	2674

* Nycomed Pharma and Nycomed Imaging
Source: LMI

Table 3: Drug sales by therapeutic group (ATC) in 1999 in mill NOK, pharmacy purchase level

ATC groups	Sales in 1999	Share % in 1999
C cardiovascular system	1 579	23,1
N central nervous system	1 235	18,1
A alimentary and metabolism	858	12,6
R respiratory system	859	12,6
L antineoplastic and immunomodulating agents	396	5,8
J systematic antiinfectives	364	5,3
G urogenital and sex hormones	357	5,2
M musculo-skeletal system	266	3,9
B blood and bloodforming organs	304	4,4
D dermatologicals	184	2,7
H systemic hormones excl. sex hormones	174	2,5
S sensory organs	149	2,2
P antiparasitic products	14	0,2
V various	91	1,3
Total	6 831	100

Source: FARMASTAT

Table 4: The 10 largest firm's in the pharmaceutical sector, their market share within each therapeutic class in 1999 in percentage

Firms	C	N	A	R	L	J	G	M	B	D	H	S	P	V
Astrazenica AS	11.4	5.5	28.4	14.8	24	9	-	-	-	3.8	-	-	9.3	-
MSD AS	32.7	-	-	-	-	-	3	15.3	-	-	2.9	25	-	-
Glaxo Wellcome AS	-	11.2	5.9	35.8	-	12	-	-	-	8.4	-	-	0.1	-
Pfizer AS	21.7	5.9	-	-	-	6	9.5	-	-	-	-	2.3	-	-
Pharmacia & Upjohn AS	4.2	6.2	7.3	-	-	-	12.4	3.5	12.3	-	27.5	15	-	0.4
Nycomed Pharma AS	0.5	2.3	5.8	4.4	1.8	0	0.1	11	15.5	10.6	15	2	0.3	4.8
Novo Nordisk Pharma AS	-	-	-	-	-	-	18.4	-	-	-	8	-	-	-
Paranova AS	6.6	-	2.8	2.3	4.9	-	-	4	-	-	-	-	-	-
Aventis AS	1.4	-	2.9	2.5	-	3.9	-	6.7	-	-	-	-	0.3	-
Norvatis Norge AS	1.3	-	-	4.2	4	-	-	9	-	9	13	9.4	-	1.6

Not available: - (also means that the company is not among the 10 largest companies within the therapeutic group)
Source: FARMASTAT/LMI

Table 5: The total market share of the 4 largest pharmaceutical companies within each therapeutic group in 1999 in percentage

Therapeutic group	Market share for the 4 largest firms
C	72,5 %
N	41 %
A	58,5 %
R	63 %
L	48,3 %
J	37,4 %
G	55 %
M	41,5 %
B	43,4 %
D	38 %
H	68,6 %
S	61,5 %
P	50,7 %
V	8,6 %

Source: LMI

1.2 Research and development

Approximately 11 percent of the pharmaceutical sales are reinvested in research and development of new pharmaceuticals. In 1998 the Norwegian pharmaceutical industry spent approximately NOK 663 million on clinical and preclinical trials in Norway. Research is carried out within vaccine development and in most therapeutic areas.

The pharmaceutical companies' individual level of research and development is a professional secrecy and is therefore not available.

1.3 Associations of pharmaceutical firms

The Norwegian Association of Pharmaceutical Manufacturers (LMI) has 46 members, which represents approximately 90 percent of the total sales in Norway.

The Norwegian Association of Euro Pharmaceutical Companies (NAEPC) has three members.

2. Regulation of supply

The pharmaceutical industry is regulated by several Norwegian and international regulations. There are mainly two types of regulations; regulation of price and availability as well as regulations of the products' physical qualities (side effects, documentation, compliance etc.).

In a public report[3] it was emphasised that because of the substantial regulation of the pharmaceutical industry, there is a strong dependence on the regulators. This results in an extensive communication with the regulating authorities and the opportunity for the industry to seek to influence the regulators to obtain the best conditions for the pharmaceutical industry.

2.1 Regulation on production and import

The regulation on production and import of pharmaceuticals is fully harmonised with EC-legislation. Production of pharmaceuticals is not allowed without permission from the Norwegian Board of Health. The same applies for import of pharmaceuticals. Import of pharmaceuticals from third countries is more strongly regulated than from EEA-countries, for example there is a need for a production permit in addition to the import permit for import from third countries.

2.2 Regulation on marketing

Marketing of pharmaceutical is more restricted than for other products. The regulation on marketing of pharmaceuticals is harmonised in accordance with EC legislation. Under certain conditions its is allowed to advertise non-prescription drugs to the general public. Advertising on television is however not allowed. Advertising of prescription drugs can only be directed to pharmacists, physicians, pharmacists, dentists, nurses etc. The prohibition on advertisement of prescription drugs to the general public applies to the whole pharmaceutical chain.

2.3 Protection of intellectual property rights

The Norwegian Patent Act[4] regulates the protection of intellectual property rights including the pharmaceutical industry. As a result of the EEA Agreement, Norway in 1994 implemented the Council Regulation (EEC) No.1768/92 on the creation of a supplementary protection certificate for medicinal products. This signifies that life of a patent on pharmaceuticals can be extended up to five years when the marketing approval has been delayed.

The Norwegian Patent Office (Patentstyret) handles and determines the patent applications and ensures the registration of designs and trademarks.

Norway is affiliated to the *Paris Convention* (since 1886), the *Patent Co-operation Treaty* (since 1980) and the WTO agreement on *TRIPS*.

2.4 New drug approval

All drugs introduced to the Norwegian market must be approved and have a marketing licence. The regulation on approval of pharmaceuticals is fully harmonised in accordance with EC legislation. As a result Norway has the same requirements for documentation on the pharmaceuticals quality, safety and efficacy. The drug approval procedure is largely the same as in the EU. Since 1. January 2000 Norway has been fully associated to the EU drug approval system. All EU directives concerning pharmaceuticals are implemented in Norwegian legislation. There are now three different ways for drug approval in Norway; the national procedure, the centralised procedure through EMEA (The European Agency for the Evaluation of Medicinal Products) and the mutual recognition approval procedure within EEA.

The average time of application process in 1999 was ten months. The required time of process is now seven months.

The Norwegian Medicines Control Authority must also approve parallel imported drugs but the approval process is simplified. The authority's most important task in its approval of parallel imported drugs is to control that there are no therapeutic differences of significance between the parallel imported drug and the direct imported drug and to ensure that the owner of the marketing licence is the same.

The information submitted by the pharmaceutical firms during the process of market approval is protected by the Act on Pharmaceuticals § 30. The Norwegian Medicines Control Authority is bound to professional secrecy for information concerning management and business secrecy. This regulation fulfils Norway's engagement in accordance with the WTO agreement on TRIPS article 39.3.

2.5 Trade regulation

With the exception of the drug approval system there are no barriers to trade for pharmaceuticals in the EEA market. As already mentioned parallel import only applies for the EEA market and import from third countries is more strongly regulated.

There are 2 843 pharmaceuticals on the Norwegian market.

The pharmacies have the exclusive rights of retail trade of drugs in Norway [5] (the Pharmacy Act). The new Pharmacy Act specifies that as a principal rule the drug should be sold over the counter to ensure compliance. The pharmacy distribution of drugs by mail must therefore be restricted to a minimum and only to customers with bad accessibility to the pharmacy.

There are several restrictions on trade on pharmaceuticals in Norway; importers of pharmaceuticals can only sell to wholesalers. There are requirements on product assortment and 24 hours delivery for wholesalers and wholesalers can as a principal rule only sell to pharmacies. There is a need for ownership license and a management license for pharmacies. Pharmacies have exclusive rights to retail trade of all pharmaceuticals. These regulations will be discussed in part IV of this note.

2.6 Industrial policy

The overall governmental goals for the pharmaceutical industry are to secure the pharmaceuticals quality, safety and efficacy and to secure that the access to pharmaceuticals, as far as possible, shall be independent of the consumers financial capacity and their place of residence.

3. Regulation of demand: controls on pharmaceutical prices, quantities and consumption

3.1 Health insurance coverage of pharmaceuticals

3.1.1 The National Insurance Scheme

The major cost of the consumption of pharmaceuticals is financed through the national reimbursement of prescribed pharmaceuticals. The government covered 68.3 percent of the total cost in 1998.

The National Insurance Act [6] covers among other things partly reimbursement of treatment and of important pharmaceuticals. The regulation of the act specifies diseases and groups of pharmaceuticals that are covered by the reimbursement scheme.

The patient has to pay a share of the cost of treatment, for prescriptions of important drugs and for transportation costs in connection with examination or treatment. The municipality and/or the National Insurance cover the main part of the expenses. The cost-sharing for an adult is NOK 108 for each consultation, and 36 percent of the expenses of important pharmaceuticals (maximum NOK 340 per prescription).

There are certain exemptions from the cost-sharing provisions for special diseases and groups of people.

A ceiling for cost sharing has been introduced. The ceiling is fixed by the Parliament for one year at a time. For 2000 it is fixed to NOK 1 370 for consultations and pharmaceuticals. After the ceiling has been reached, a card is issued giving entitlement to free treatment and benefits as mentioned for the rest of the calendar year.

All insured persons are granted free accommodation and treatment, including pharmaceuticals, in hospitals.

3.1.2 Private health insurance scheme

Private health insurance scheme is not very common in Norway. There are 15 700 private health insurance scheme per May 2000. The private insurance schemes have different conditions, but the majority of them covers reimbursement of hospitalisation, specialist treatment and pharmaceuticals.

3.1.3 Generics and the reference pricing system

Since 1991, physicians have been obliged to prescribe the cheapest generic pharmaceuticals. Furthermore since 1995 the pharmacies have the opportunity to substitute a prescribed drug with a parallel imported drug. The new Pharmacy Act will also give the pharmacies the possibility to substitute a prescribed drug with a generic drug. However the physicians may specify that no substitution shall take place.

There is also a reference pricing system for generic pharmaceuticals, under which patients must pay extra should they require a brand of drug that is more expensive than the cheapest available therapeutic

drug.[7] In 1998 patented drugs were included in the reference pricing system. The reference-pricing list is distributed to physicians, pharmacies, health insurance offices etc.

3.2 Formularies

There are 42 groups of chronic diseases that are covered by the national reimbursement scheme. The pharmaceuticals eligible for reimbursement are registered on a list. The positive list is constantly updated and published at least once a year with the criteria to be put on the list. The list of pharmaceuticals is administrated by the National Insurance Administration (Rikstrygdeverket) and is distributed to the pharmacies and the health insurance offices around the country.

3.3 Price control policies

Since 1994 the prices of non-prescription drugs have not been regulated, consequently the market has determined the prices for these drugs.[8] However the prices of all prescription drugs are regulated. The Norwegian Medicines Control Authority determines the maximum pharmacy purchase price (AIP). The Ministry of Health and Social Affairs (delegated to the Norwegian Board of Health) sets the maximum pharmacy gross profit for prescription drug sales. On that basis the Norwegian Medicines Control Authority calculates the maximum pharmacy retail price (AUP) on all prescription drugs.

The Norwegian Medicines Control Authority determines the maximum pharmacy purchase price on prescription drugs primarily on the basis of price comparisons with the EU-countries. This is also done when producers require a price increase on their medicinal products.

The price to wholesalers is not regulated and is determined by negotiations between the producer or importer and the wholesaler.[9]

3.4 Control of physician prescribing practices

The physicians, as mentioned, are obligated to prescribe the cheapest generic pharmaceuticals, but there are no sanctions for breaching the guidelines and no real incentives for physicians to do that.

The Norwegian Board of Health (Statens helsetilsyn) is responsible for the overall supervision of all health services and health personnel (internal control systems are major instruments).

3.5 Regulation of pharmacies and pharmaceutical distribution

The pharmacy sector is strongly regulated. The most important regulations from the competition point of view are the exclusive retail rights, price regulations, duty to provide, ownership requirements and the need for license which have made it very difficult to establish new pharmacies or even to move existing pharmacies.

A new Pharmacy Act was adopted by the Parliament in spring 2000. The most important change, from a competition viewpoint, is that it now will be possible for other than pharmacists to own a pharmacy and somewhat easier to establish new pharmacies. It is no longer a legal requirement that owners of pharmacies are pharmacists.[10] Producers of pharmaceuticals and persons with the right to prescribe pharmaceuticals are however not allowed to own pharmacies. Furthermore, the Act requires that a pharmacist (head dispenser) must run the pharmacies. Establishment of a pharmacy requires an ownership

concession and a concession to operate a pharmacy. In order to cope with the scarcity of pharmacist in the districts, the Ministry of Health and Social Affairs can put a ceiling on the pharmacy concessions in the major cities.

With some exceptions for direct delivery to hospitals and other health institutions, the pharmacies have the exclusive rights to retail trade of all pharmaceuticals.[11] All pharmacies have a duty to distribute all marketed pharmaceuticals and regular medical appliances. The sale of other products through pharmacies is also regulated. In the new Pharmacy Act the principal rule is that the pharmacy can sell goods and services that have a natural link to the pharmaceuticals and the medical appliances.

The new Pharmacy Act provides the pharmacies the opportunity to substitute a prescribed drug with a parallel or generic drug.

The Act gives the Ministry of Health and Social Affairs the opportunity to regulate competition locally in the pharmacy market.

Both the maximum prices to the pharmacy and the pharmacy maximum gross profit for prescription drugs is regulated. Hence the maximum price to the consumer is determined. A percentage rate and a fixed rate compose the pharmacies maximum margin.

3.6 Policy towards generics

The market share for generics is not available. The pharmaceuticals are not yet coded in a way that makes it possible to differentiate generics from original pharmaceuticals. However the sales of pharmaceuticals are divided into two groups; innovative and non-innovative pharmaceuticals, and as a rough estimate one can assume that generics constitute a large part of the non-innovative pharmaceuticals. The non-innovative pharmaceuticals represent approximately 30 percent of the total sales in 1999, and thus the innovative pharmaceuticals represent approximately 70 percent Norwegian production of pharmaceuticals is mainly generics.

The physician's duty to prescribe the cheapest generic pharmaceuticals and the pharmacies opportunity to substitute a prescribed drug with a parallel or generic drug promotes the use of generics.

The reference pricing system for generic pharmaceuticals, under which patients must pay extra should they require a brand of drug that is more expensive than the cheapest available generic drug, promotes competition between generic drugs and between generic and original drugs.

4. Competition issues in the pharmaceutical sector

4.1 The Norwegian Competition Act[12]

The purpose of the Act is to achieve efficient utilisation of society's resources by providing the necessary conditions for effective competition.

The Competition Act applies to any kind of commercial activity, regardless of the kind of goods or services the activity concerns, and irrespective of whether it is private or carried out by central or local government authorities.

Provisions of this Act must not conflict with decisions passed by the Parliament. Where a matter that comes under this Act also comes under provisions concerning regulation and supervision in other Acts, the King may issue specific provisions for the mutual limitation of jurisdiction of the authorities involved.

The Norwegian Competition Authority (NCA) enforces the competition law in all sectors.

4.2 The NCA's activities in the pharmaceutical sector

The authority has not dealt with any cases concerning mergers or abuse of dominance in the pharmaceutical industry. The authority is however currently dealing with two cases concerning distribution of pharmaceuticals.

The NCA's activities concerning the pharmaceutical sector have been focused on influencing sector specific regulation, which restricts competition. The Competition Act § 2-2 d states that the NCA shall call attention to restraining effects on competition of public measures, where appropriate by submitting proposals aimed at increasing competition and facilitating entry for new competitors. Based on this, the NCA has given several statements in public hearings and has participated in committees. The NCA's work has mainly been concentrated on regulation issues regarding wholesale and retail trade.

The principal remaining competition concerns in the pharmaceutical sector in Norway are as follows;

- The regulation on wholesalers

  The Regulation of Wholesalers obligates the wholesalers to deliver all drugs that are in demand within 24 hours (48 hours in sparsely populated areas). This can substantially weaken the wholesaler position when negotiating with the producers or importers of pharmaceuticals, because the wholesalers must stock every pharmaceutical that is in demand. The wholesaler's possibility to negotiate lower purchase prices is therefore limited. The requirements can further result in higher barriers to entry at the wholesaler level because of higher costs for new wholesalers, which have to build up a distribution system and a stock that satisfies the requirements.

  It is the NCA's opinion that the above mentioned requirements are not necessary and that the objectives for the requirements could be reached more efficiently. To secure delivery of important pharmaceuticals the NCA has suggested use of tenders or a more restricted assortment obligation.

- Increase the possibilities for direct delivery to hospitals and other health institutions

  For certain pharmaceuticals that hospitals consume in large quantities, there are today some possibilities for direct delivery to hospitals. It is the NCA's assessment that increased possibilities for direct delivery to hospitals and other health institutions, for instance for importers, can generate efficiency gains for hospitals and suppliers and will lead to increased competition at the supplier level.

- The pharmacy licences

  In order to cope with the scarcity of pharmacist in the districts the Ministry of Health and Social Affairs can set an upper limit for the pharmacy licenses in the major cities. Norway has among the lowest number of pharmacies per capita in Europe. In an assessment to the ministry the NCA stated that to prohibit establishment of new pharmacies in some cities, will reduce the competition in the cities concerned and is an inadequate method to secure pharmaceutical labour in the districts. Therefore other means should be taken into consideration, for instance obligatory work for pharmacists, tax reductions etc.

- The pharmacies' exclusive rights on retail sale of non-prescription pharmaceuticals

  It is the NCA's assessment that there should be possible to sell certain non-prescription pharmaceuticals by other outlets than pharmacies. This should apply for pharmaceuticals where the possibility for abuse or dangerous side effects is low. It is the authority's assessment that the existence of some dangerous pharmaceuticals should not obstruct a free retail sale of other non-prescription pharmaceuticals. A free retail sale of such pharmaceuticals will increase the competition at the retail level, and give the consumers improved availability to such pharmaceuticals.

- The profit-sharing model does no longer apply for the reference pricing system.

  The profit-sharing model for pharmacies implies that at least half of the difference between the maximum price and the actual pharmacy purchase price must be assigned to the consumers. The rule was established due to weak competition among pharmacies. The profit-sharing model is now suspended for pharmaceuticals within the reference pricing system. Due to the proportional pharmacy profit, this means that lower purchase prices in its entirety must be assigned to the consumers. This gives no incentives (in fact negative incentives) to the pharmacies or chain of pharmacies to negotiate lower purchase prices.

- The enforcement of the new Pharmacy Act

  The Ministry of Health and Social Affairs has still not decided when the new Pharmacy Act will come into force. This creates an uncertainty in the market, especially for those who want to buy or establish pharmacies.

- Pending cases

  The NCA is currently working on an acquisition case. A chain of pharmacies –Apokjeden – that represents between 70 and 80 percent pharmacies in Norway, has acquired 49 percent wholesaler Tamro Norge AS, which has a ten percent at the wholesale level. At the same time the 51 percent f Tamro Norge AS has acquired 23 percent stocks in Apokjeden. In addition the parties has agreed that Apokjeden will purchase most of its goods from Tamro Norge AS. The main competition concerns in this case is the cross ownership and the exclusive purchase agreement between the parties. The acquisition will enhance the wholesaler's market share mainly because of the purchase agreement. Tamro's dominant position creates competitive concerns at the wholesaler level. The pharmacy chain's dominant position could also create some competition concerns. However it is expected that when the new Pharmacy Act enters into force their dominant position will decline notably.

In addition the pharmacy chain has entered into an agreement with NAF-gårdene, which is the Daughter Company of the Norwegian Pharmacy Association. The agreement gives the pharmacy chain first priority to premises that are suitable for pharmacies. This agreement could be a barrier for entry in the Norwegian pharmacy market. The NCA considers this case independently from the acquisition above.

NOTES

1. This includes agencies that sell only one drug and some pharmacies that produce some pharmaceuticals. The Norwegian Association of Pharmaceutical Manufacturers estimates that there are 50 pharmaceutical companies of significance in Norway.

2. Product names, excluding strengths and dosage forms.

3. NOU1997:8 ”Rammevilkår for omsetning av legemidler”. The NCA was represented in this commitee.

4. Lov om 15. desember 1967 nr. 9 om patenter.

5. With some exceptions for direct deliverance to hospitals and other health institutions.

6. Compulsorily insured under the National Insurance Scheme are all persons residing or working in Norway.

7. This was mostly in accordance with the NCA’s recommendations in a public hearing.

8. In a statement to the Ministry of Health and Social Affairs, the Norwegian Competition Authority warned against the deregulation of prices of non-description drugs without simultaneously modifying the ways of distribution at the retail level

9. However the Regulation of Wholesalers obligates the wholesalers to deliver all drugs that are in demand within 24 hours (48 hours in sparsely populated area). This can substantially weaken the wholesaler position when negotiating with the producers or importers of drugs and is a barrier to entry in the wholesale market.

10. Persons with the pharmaceutical university degree cand. pharm or similar.

11. NCA is of the opinion that there should be some possibilities for certain non prescription pharmaceuticals to be sold by other outlets than pharmacies.

12. Lov av 11. juni 1993 nr. 65 om konkurranse i ervervsvirksomhet.

SPAIN

1. The pharmaceutical industry

1.1 Market Structure

In 1998, the number of pharmaceutical firms with producing activity in Spain was 266 and the number of register holders was 374. The number of employees in this industry reached 38 400 people, which represents 2.9 percent of the employed labour force In Spain. As regards the size of these firms, the sales of the 20 largest suppliers account for 50.9 percent of the value of prescriptions and OTC total sales. The sales of the five largest suppliers account for the 21 percent of the total sales.

In 1998, the value of pharmaceuticals sales in pharmacies was of 1 274 110 million pesetas, 94 percent of which were prescriptions and six percent OTC. The value of pharmaceuticals sales in pharmacies paid by the Social Secutrity in 1998 was 926.262 million pesetas.

Due to the innovative and research features of this sector, the Ministry of Industry and Energy has supported several plans, from 1987 in order to increase R&D expenditure in this sector. As a consequence of these plans, and having into account only the companies included in them, R&D expenditure reached in 1997 a 7.8 percentage of pharmaceutical sales for human use in the national market, a percentage still quite far from the EU average, 20.1 percent but much higher than the spanish ratio for R&D expenditure in all sectors 0.89 percent (as a percentage of GDP).

The major pharmaceutical manufacturers association in Spain is Farmaindustria. Farmaindustria acts as speaker, on behalf of pharmaceuticals undertakings, to reach agreements with the Ministry of Health on prices negotiations.

2. Regulation of supply

2.1 Protection of intellectual property rights

The law that rules, at present, intellectual property rights in Spain is the Patent Act 11/1986. Spain didn't sign the Munich Convention till October 1986. According to law 11/1986, chemicals and pharmaceuticals have been protected as products since october, 1992. Prior to that date, it was only allowed to patent chemical or pharmaceutical methods or processes but not products. That is the reason why in the spanish market there have been a large number of pharmaceuticals with the same compound as the "original" product but obtained through different process.

According to law 11/1986, protection is provided for a period of 20 years, which runs from the date the patent application is submitted. Generally , the patent application is filed some years before the product is ready to ask the Health Ministry for the marketing authorisation. In 1993, the UE introduced

Supplementary Protection Certificates (SPC) which grants up to a maximum of five years of patent-like protection after the expiring date of the pharmacutical patent. Nevertheless, the length of the five years SPC is limited by the need of no more than 15 years of combined patent and SPC protection from the date of first marketing authorisation for the product.

Once patent and SPC protection has expired, competitors can produce generic forms of the same pharmaceutical products.

2.2 New drug approvals

From January 1998, there are two approval procedures in the EU. On the one hand, a centralised procedure, in charge of which is the European Medicines Evaluation Agency (EMEA), compulsory for new biotechnology products and optional for very important new chemical entities. Through this procedure, a single authorisation is valid in all 15 Member States. On the other hand, a decentralised procedure, which affects a group of national licences. Nevertheless, once a pharmaceutical has been authorised by a Member State, the principle of mutual recognition has been approved by the Commission and has come into force at the beginning of 1998.

In Spain, the institution in charge of the approval procedure is the Spanish Medicines Agency. Both EU processes have been adopted by the spanish Government. As regards the decentralised procedure, the authorisation must be given in a period of 120 days since the application form has been submitted. In the case of a pharmaceutical authorised by another Member State, the period will be reduced to 90 days. The information submitted by firms during the process is confidential.

2.3 Trade regulation

From october, 1995 there is freedom to trade with pharmaceuticals. The reason of that date can be found in article 47 of Spain EEC Membership Treaty which gave Spain a three year period after the patent protection for pharmaceuticals came into force (as it was mentioned before, pharmaceuticals have been protected as products since October, 1992). According to this article, firms with patents in other EU countries were not allowed to import their own products produced and marketed in Spain till October 1995.

In Spain pharmaceutical prices are set by Central Government and are believed to be lower than in other european countries. This fact has been the origin of a flow of exports from Spain to other countries such as Denmark, Germany and the United Kingdom, among others. Distributors benefit from the differences in prices between low prices countries (Spain, for example) and high prices countries, buying pharmaceuticals in the former and selling them in the high price area.

In order to avoid these practices, a spanish pharmaceutical firm, decided in March 1998, to set a different price for products to be exported, higher than prices fix by Government. At the same time, the same pharmaceutical firm notified the Commission its new conditions of sale requesting negative clearance or confirmation that these conditions could benefit from an individual exemption. Several spanish associations of exporters and wholesalers submitted complaints to the Spanish Service for the Defense of Competition and to the Commission alleging that, by implementing a dual price system, the new conditions of sale infringe spanish and EC compettition law. Both authorities have been coordinating their procedures but still there is no decision.

Up to now, the only measure adopted by the spanish competition authorities in this case was taken in October, 1998 by the Tribunal for the Defence of Competition, who forbade the new conditions of sale during six months (renewed six months more in July, 1999) until there was a formal decision.

Nevertheless, since January 2000, Government has introduced an amendment on Pharmaceuticals Act in order to allow the pharmaceutical industry to set two different prices for pharmaceuticals. One, controlled by public authorities, for sales in Spain and the other, free, for sales abroad. Once more, several spanish associations of exporters and wholesalers have submitted complaints to the Commission alleging that this dual system infringe EC compettition law.

3. Regulation of demand: controls on pharmaceutical prices, quantities and consumption

3.1 Formularies

When a pharmaceutical firm asks the marketing authorization for a drug to the Health Ministry it negotiates if the drug will be covered by the public insurance scheme. In 1993 the Government for the first time published a negative formulary of 660 presentations, and in 1998,. 1 121 additions were made to this negative formulary. At present, 6 863 presentations are reimbursable by the National Health System.

3.2 Price control policies

As it is stated on the Pharmaceuticals Act 25/1990, pharmaceuticals prices are subject to Government control. That means that industrial prices as well as prices of distribution (wholesalers and pharmacies) are fix by Government. As regards industrial prices, they are maximum prices and are fixed according to costs supplied by the pharmaceuticals firms plus a certain profit related to the economic situation of the pharmaceutical industry. As regards commercial margins, the Health Ministry also fix them for wholesalers and pharmacies, in the case of wholesalers as a fixed percentage of wholesaler prices (9.6 percent), and in the case of pharmacies.as a percentage of consumer prices (27.9 percent) without taxes.

Legislation applies to all pharmaceuticals except to over the counter products, whose price is free. Consumer prices are the same all over the country.

In the last four years there has been three industrial pharmaceutical price revisions; one in 1996 (+ 0.8percent), another in 1997 (+ 0.8 percent) and the last one in 1999, when the modification of prices was calculated applying an equation, as a result industrial pharmaceuticals prices as a whole underwent an average decrease of six percent.

3.3 Control of physician prescribing practices

There is a recent proposal to give physicians an extrordinary wage twice a year if generics prescribed represent more than a certain percentage of all the drugs prescribed. The measure has not come into force yet.

3.4 Regulation of pharmacies and pharmaceutical distribution

Although pharmacies regulationconcerns regional governments (“Comunidades Autónomas”), Central Government can establish basic legislation. A law regulating services of pharmacies was passed in 1997. The law defines pharmacies as health establishments among whose duties are the sale of pharmaceuticals. A pharmacist should be always in charge of a pharmacy. One pharmacist can have the ownership of only one pharmacy and if he has a pharmacy he cannot work as pharmacist in any firm.The

law introduced freedom of business hours but regional governments are able to set certain rules (minimum) which guarantee a proper performance of this basic service. The law, finally, introduced certain minimum requirements as regards population and distances.

3.5 Policy towards generics

At the end of 1996, Government introduced the regulation of generics and the establishment of a reference pricing system on certain pharmaceuticals. Royal Decree 1035/1999 fixes the reference pricing system applied to pharmaceuticals which benefit from health insurance coverage. The reference price is set according to all pharmaceuticals included in an specific and homogeneous group in which, at least, one generic should be present. The reference price shows the maximum price covered by the insurance scheme. This system has not yet come into force because at present there are not many generics in the market. As far as we know, about 350 generics have been authorised. Their market share at the end of november 1999 is estimated at 2.02 percent of pharmaceutical consumption.

4. Competition issues in the pharmaceuticals sector

4.1 Market definition issues and barriers to entry and exit

There are a good number of barriers to entry in the pharmaceutical sector. In order to identify them, it should be taken into account, first of all, that in this sector there are a lot of groups involved: industry, wholesalers, pharmacies, traders, authorities, demand/physicians and consumers (who generally do not pay for what they buy). Some of the barriers are strictly related to safety issues (sanitary conditions, for example) and are not going to be considered. Among the others,the most relevant for competition issues, are:

- intellectual property rights which grant a monopoly to the holder (the firm that did the research);
- authorisation required to open a pharmacy;
- pharmacy openings requirements: distance and population;
- only pharmacists can own a pharmacy; each pharmacist can own only one pharmacy;
- only pharmacies can sale pharmaceuticals;
- pharmacies can not deliver pharmaceuticals at home.

4.2 Mergers and acquisitions

Most of the cases analysed in Spain relate to cases notified to the Commission according to EU legislation. A spanish case studied about five years ago, the ATC was used to define the relevant product market. The geographic extent of the market was considered to be national in scope given the diferences in pharmaceuticals pricing, the influence of purchasing policies by national health services and the different national authorisation procedures.

4.3 Abuse of dominance

Related to paralel trade,In the same case refered to above, a spanish wholesaler submitted complaints to the Service for the Defense of Competition alleging that the pharmaceutical firm had denied to supply several pharmaceuticals because it had not accepted the new established. conditions of sale .No decision has been taken yet. It must be reminded that the pharmaceutical firm is very important and has a dominant position in certain medicines.

SUISSE

1. Caractéristiques de base des secteurs considérés

1.1 Electricité

1.1.1 Généralités

De facto, les marchés sont actuellement fermés. Le domaine de la fourniture d'électricité est caractérisé par la coexistence d'une pluralité de monopoles régionaux et locaux (il existe en Suisse plus de 1 000 entreprises électriques). Les entreprises électriques sont généralement verticalement intégrées et majoritairement détenues par les communes et les cantons. La réglementation des marchés est encore essentiellement du ressort des cantons.

Une loi fédérale de 1930 a introduit la possibilité pour les fournisseurs d'obtenir un droit d'expropriation pour le transport d'énergie électrique sur les réseaux existants d'opérateurs tiers[1]. Cette disposition, qui visait essentiellement à éviter la construction de réseaux parallèles, est cependant restée lettre morte ; elle n'a donc pas contribué à l'ouverture des marchés en Suisse.

Un projet de loi fédérale visant l'ouverture des marchés (Loi sur le marché de l'électricité, LME) est actuellement en discussion devant le Parlement[2]. Ce projet s'inspire de la Directive européenne 96/92/CE. Il prévoit une ouverture des marchés échelonnée sur six ans sur la base d'un "Regulated Third Party Access".

Plusieurs plaintes fondées sur l'art. 7 LCart (abus de position dominante) ont été déposées devant la Commission de la concurrence par des fournisseurs ainsi que des consommateurs d'électricité du secteur industriel afin d'obtenir l'accès aux réseaux d'opérateurs tiers. Dans une de ces procédures, la Commission a confirmé dans un *obiter dictum* que le refus d'accorder l'accès au réseau pouvait tomber sous le coup de l'art. 7 LCart[3]. A ce jour, la Commission de la concurrence a ouvert deux enquêtes ainsi que deux enquêtes préalables à l'encontre d'entreprises refusant l'accès à leur réseau.

1.1.2 Réglementation en matière de prix

Il n'existe pas au niveau fédéral de réglementation spéciale relative au prix du transit et de la vente de courant électrique.

Au niveau fédéral, seule des lois de portée générale, LCart et loi sur la surveillance des prix (RS 942.20), entrent en ligne de compte.

Dans certains cantons, les prix de l'électricité font en revanche l'objet d'une réglementation spéciale.

Le projet de LME prévoit que le prix facturé par les opérateurs de réseau pour le transit d'électricité doit être aligné sur les coûts indispensables à une exploitation efficace du réseau (art. 6 al. 1). Ce principe doit encore être concrétisé dans le droit dérivé.

1.2 Gaz naturel

Tout comme dans le secteur de l'électricité, les marchés relevant du secteur du gaz naturel sont actuellement fermés. Le secteur est par ailleurs également constitué d'une série de monopoles régionaux et locaux. L'organisation des marchés dépend actuellement essentiellement du droit cantonal.

Une Loi fédérale de 1963 sur les installations de transport par conduites (SR 746.1, art. 13) oblige les exploitants de pipelines à transporter le gaz naturel de tiers. Cette disposition est cependant restée lettre morte ; elle n'a donc pas contribué à l'ouverture des marchés.

Tout comme dans le secteur de l'électricité, il est actuellement question d'ouvrir les marchés par le biais d'une loi fédérale sur le modèle européen (Directive 98/30/CE). Les travaux relatifs à cette loi sont nettement moins avancés que ceux qui concernent l'électricité. Un avant-projet a été mis en consultation interne à l'administration fédérale par l'Office fédéral de l'énergie en mai 2000.

1.3 Télécommunications

1.3.1 Généralités

Le domaine des télécommunications est régi par la loi sur les télécommunications du 30 avril 1997 (RS 784.10 ; LTC) et l'ordonnance sur les services de télécommunication (RS 784.101.1 ; OST), toutes deux entrées en vigueur le 1er janvier 1998. Cette date marque également la fin du monopole de l'opérateur historique Swisscom ainsi que l'ouverture à la concurrence des marchés des services de télécommunications.

L'opérateur historique Swisscom est une société anonyme dans laquelle la Confédération détient obligatoirement la majorité du capital et des voix (loi fédérale sur l'organisation de l'entreprise fédérale des télécommunications, RS 784.11, art. 6).

Les opérateurs sur le marché des télécommunications doivent être au bénéfice d'une concession délivrée par la Commission fédérale de la communication (art. 4-5 LTC). A ce jour, toutes les demandes de concession ont été accordées.

L'art. 11 LTC prévoit que les fournisseurs de télécommunication ayant une position dominante, parmi lesquels se trouve Swisscom, sont tenus de garantir l'interconnexion à l'égard d'autres fournisseurs de manière non discriminatoire et selon les principes d'une politique de prix transparente et alignée sur les coûts.

Les différends relatifs à l'interconnexion sont du ressort d'une commission indépendante, la Commission de la communication.

Le domaine des télécommunications ne connaît aucun marché qui ne soit pas ouvert à la concurrence. Ainsi, s'agissant du Local Loop, où Swisscom jouit encore toujours d'une position dominante, l'art. 11 LTC est applicable.

1.3.2 Réglementation en matière de prix

Selon l'art. 34 OST, les prix d'interconnexion doivent être alignés sur les coûts en tenant compte des éléments suivants (depuis le 1er janvier 2000) :

- les coûts causés par le service d'interconnexion (coûts pertinents) ;
- les coûts additionnels à long terme des composants de réseau pris en considération et ceux qui découlent exclusivement de la fourniture d'un service d'interconnexion (long run incremental costs ; LRIC) ;
- un supplément constant (constant mark up), équivalent à une partie équitable des coûts joints et des frais pertinents (joint and common costs) ;
- la rémunération, conforme aux usages en vigueur dans le secteur, du capital utilisé pour les investissements.

Les prix des services de télécommunication sont quant à eux fixés librement par les opérateurs. Une exception existe cependant pour les prix des prestations relevant du service universel pour lesquels le Conseil fédéral (gouvernement) fixe des plafonds (art. 17 al. 2 LTC).

2. Cas de séparation et effets

2.1 Télécommunications

Dans le domaine des télécommunications, il n'existe aucune décision ou réglementation prévoyant une séparation structurelle. Swisscom et les autres opérateurs ont donc ainsi la possibilité d'être actifs à tous les niveaux de la filière. Une séparation comptable est par contre prévue pour le domaine de l'interconnexion.

L'art. 36 OST prévoit en effet que les fournisseurs de services de télécommunication établissent une comptabilité séparée pour les services d'interconnexion. Elle doit présenter distinctement les services internes et externes et comprendre la comptabilité interne des services d'interconnexion.

Cette séparation comptable doit permettre à la Commission de la communication de faire respecter les règles relatives à la tarification des services d'interconnexion et d'empêcher les subventions croisées entre services réglementés et non-réglementés.

2.2 Electricité

Le droit en vigueur ne prévoit aucune obligation de séparer les activités exercées par les entreprises du secteur électrique. Une entreprise électrique peut donc légitimement exercer l'ensemble des activités relevant de sa filière.

Le projet de LME prévoit une séparation structurelle au niveau du réseau de transport (réseau haute tension). Il est en effet prévu de fonder une société nationale unique chargée de son exploitation (art. 8 du projet). Cette société ne pourrait elle-même exercer aucune activité se rattachant à la production ou à la distribution de courant, ni posséder des parts dans des entreprises de ces secteurs. En revanche, le projet

n’empêche pas les producteurs ou distributeurs de détenir des parts dans la société de réseau ou même de la contrôler.

Aucune séparation structurelle n’est en revanche prévue s’agissant du réseau de distribution (réseau moyenne et basse tension).

Le projet de LME prévoit une séparation comptable ("unbundling of accounts") des activités liées à la production, au transport, à la distribution et aux autres activités (art. 7 du projet). Cette séparation a pour vocation d’éviter les discriminations, les subventions croisées et les distorsions de concurrence.

NOTES

1. . Voir art. 44 let. b de la loi fédérale sur les installations électriques (SR 734.0).

2. . Projet présenté le 7 juin 1999.

3. Décision BKW FMB Energie AG, DPC 2000/1, p. 29. Voir aussi affaire EEF, DPC 2000/2, p. 153.

SWEDEN

1. Introduction

Public and consumer spending on medicinal products in 1998, based on pharmacy retail prices (PRP), amounted to approx. SEK 21 000 million excl. VAT, or approx. SEK 2 200 per capita (approx. USD 260). Total spending on medicinal products in the in-patient or hospital care sector amounted to approx. SEK 2 500 million for the same period. The 21 county councils responsible for medical care in their respective areas finance this expenditure. Spending on pharmaceuticals elsewhere in the care sector or in outpatient care is largely financed by the state via an insurance system, known as the pharmaceutical health insurance programme. Central government costs for this system amounted to approx. SEK 13 000 million in 1998.

2. Market Structure

2.1 The pharmaceutical industry

In 1998, Sweden had some 215 pharmaceutical companies that sold at least one product during the year. Pharmaceutical sales for the 15 largest pharmaceutical groups amounted to approx. SEK 11 400 million based on the pharmacies' purchasing price (PPP). This sum corresponded to approx. 70 percent of total pharmaceutical sales as per PPP. The corresponding figures for the five largest groups – Astra, Pharmacia & Upjohn, Glaxo Wellcome, MSD and Novo Nordisk – were approx. SEK 7 000 million and around 40 percent.

In 1995, the five and 15 largest pharmaceutical groups accounted for 39 and 57 percent respectively of total pharmaceutical sales in Sweden (PPP). This means that in 1998, the total market share of the 15 'best-selling' companies had increased by approx. 13 percentage points in relation to 1995, while the five largest companies did not significantly increase their share during this period. This suggests that market concentration at manufacturing or producer level is not particularly high. Individual companies, however, may have a high market share if the figures are calculated at the level of product and turnover for various therapeutical spheres (ATC groups).

Three generics manufacturers, owned by pharmaceutical companies Pharmacia & Upjohn, Merck AB and AstraZeneca AB, dominate sales of generics in Sweden. In all, these companies accounted for approx. 90 percent of generics sales in Sweden in 1998. High market concentration in the generics field is due among other things to the fact that pharmaceutical manufacturers have bought independent generics companies. The three generics companies sell generics corresponding to original drugs no longer enjoying patent protection manufactured both by companies that are part of the proprietary group concerned and by other companies. The use of generics in in-patient care in 1998 is estimated to have been approx. 10 per cent of total pharmaceuticals sales.

The parallel *import* of medicinal products began in Sweden in 1996. A parallel importer normally buys original drugs from wholesale companies in countries where the prices of these drugs are lower than in Sweden. This trade also involves companies buying original drugs from a wholesale company in Sweden and exporting them to a country where prices are higher than in Sweden. In mid-1999, about a dozen companies in Sweden were trading in parallel imports of medicinal products. Importers use one or other of the two wholesale companies described below for warehousing and distribution to pharmacies. The largest parallel importer of medicinal products at the beginning of 1999 was Cross-Pharma AB, followed by Medartuum AB, Orifarm AB and Paranova Läkemedel AB. In 1998, these four companies accounted for around 90 percent of total sales of parallel-imported medicinal products. In that year, parallel imports in Sweden encompassed some 40 different drugs. Turnover was just over SEK 1 000 million (PPP), corresponding to six percent of pharmaceutical sales in the out-patient care sector. The in-patient care sector has yet to make us of parallel-imported drugs.

2.2 The wholesale trade

Two wholesale companies carry out nearly all distribution of medicinal products from pharmaceutical companies to pharmacies. These are Tamro Distribution (Tamro), a subsidiary of the Finnish Oy Tamro Abp group, and Kronans Droghandel (KD), owned primarily by a number of pharmaceutical companies. In 1998, Tamro accounted for approx. 57 percent of the distribution of medicinal products to the pharmacies (PPP), while the corresponding share for KD was just under 43 percent.

The pharmacies' purchasing price includes payment to wholesalers, one of whose tasks are to provide warehousing and distribution. In addition, the wholesale companies have the right of return vis-à-vis the pharmaceutical companies. The wholesale companies negotiate with the pharmaceutical companies on their return for distribution, which is approx. three-four percent of PPP. Medicinal products sales (PPP) amounted to approx. SEK 18 300 million in 1998. The added value at the wholesale stage may be estimated at SEK 600-700 million.

2.3 The retail trade – the pharmacies

In 1999, there were some 900 pharmacies in Sweden, of which approx. 90 were hospital pharmacies, as well as about a thousand pharmacy representatives at food stores and petrol stations, etc. The latter constitute issuing points for medicinal products on order and are mainly to be found in sparsely populated areas. All pharmacies are owned by the state company, Apoteket AB (AAB). Under agreements concluded with the state, the companies are required to maintain a good supply of medicinal products in Sweden and to promote the rational use of medicinal products. AAB sales of medicinal products have increased substantially in recent years, at a rate of approx. ten percent a year. As has been the case for many years, this rise was principally due to increases in volume – via increased prescription and the introduction of new and more expensive drugs – while price increases on existing medicinal products accounted for a smaller share.

2.4 Miscellaneous

There are two trade organizations in Sweden in the pharmaceutical field, i e the Swedish Association of the Pharmaceutical Industry and the Association of Parallel Importers of Pharmaceuticals.

3. Regulation of Supply

3.1 Protection of intellectual property rights

In Sweden, the principal rule is that the company developing a new (and approved) drug is given the exclusive right of disposal (patent) for twenty years from the date the patent application was submitted to the competent authority. Companies normally apply for a patent at an early stage in the development process. As a result, the effective patent period, or the period during which the finished pharmaceutical product may be sold on the market under protection by a patent, is less than twenty years. The patent period may be extended by the number of years of development of the product above five years. The extension period, however, may not be more than five years; in other words, the effective patent period may not in this case exceed 15 years.[1]

3.2 The drug approval process

The pharmaceuticals industry can primarily choose between one of two ways of obtaining approval for its drugs – either via the central procedure or via the mutual approval procedure. The establishment of a European drug approval authority, currently the European Agency for the Evaluation of Medicinal Products, EMEA, made the central procedure possible. After an application has been approved by the EMEA, the product may be sold in any of the EU countries. The national drug approval system is still available for products that are intended for sale in only one EU country.

All forms of drug manufacturing or importation in Sweden from a non-EU country require special permission from the Medicinal Products Agency. The regulatory framework is provided by the Medicinal Products Act (1992:859), where the requirements for obtaining approval are set out. The requirements cover parallel-imported drugs as well. The regulations governing mutual recognition of medicinal products in the EU also extend to generics. Applicants are required to show that the drug intended for sale in Sweden corresponds to a drug that has been approved for sale for at least ten years in one or more of the EU countries.

The Medicinal Products Act is augmented by the State Control of Medicinal Products (Fees) Ordinance (1993:595). This states the fees stipulated for the approval of parallel-imported drugs.

If the drug has already been approved for sale in another EU country, the Medicinal Products Agency only examines issues relating to approval in accordance with the mutual procedure. This procedure, which is based on EC directives, presupposes that the Medicinal Products Agency utilises another EU country's investigation of the drug in question as a basis for its own decision. If the countries concerned cannot agree, the company can withdraw its application. Alternatively, the case may be referred to central processing at Union level leading to a binding decision by the Commission.

3.3 Barriers to international trade

Of total sales of medicinal products in Sweden, imports account for approx. 40 percent.

Three factors in particular affect or impede trade in medicinal products to and from Sweden. Such cases primarily involve parallel trading in drugs.

One of the factors is the effect of the ruling by the European Court of Justice of 16 July 1998 in the Silhouette Case. The ruling concerned the interpretation of an article in Directive 89/104/EEC relating

to trade marks and determined that exhaustion of trade mark rights in the EEA zone (the EU countries plus Norway, Liechtenstein and Iceland) occurs regionally and not globally. Put simply, the implication of the ruling is that in the EEA zone parallel imports are not allowed from non-EEA countries without the permission of the trade mark owner. Thus the ruling may be taken to mean that the business sector in EEA countries is protected against certain kinds of parallel importation and the competition this entails. The aim of the Swedish Government is to modify EC regulations in this field so that the principle of global exhaustion, previously valid in Sweden, may again be applied in the future.

The second factor concerns the changes made in a trademark name by pharmaceutical manufacturers when selling the same product in different countries. Often these changes are only very slight (two letters at the most). Such changes make parallel trading in the drug harder as the parallel importer, when selling in the import country, cannot automatically use the original name, due to the regulations governing trade mark rights. Swedish courts are currently dealing with cases in this area.

The third factor is the refusal of a wholesale company on occasion to sell drugs intended for the parallel export market.

4. Regulation of Demand: Controls on Pharmaceutical Prices, Quantities and Consumption

4.1 Health Insurance Coverage of Pharmaceuticals

In Sweden, the state health insurance system extends in the pharmaceutical field to all prescription drugs and certain non-prescription drugs.

As of 1 January 1997, medicine insurance coverage takes the form of protection against high costs. Consumers do not need to pay for drugs covered by the insurance system once their expenditure on drug purchases has reached a predetermined level, which as of 1 June 1999 is SEK 1 800. In addition, a discount scale offers progressively higher discounts the more the consumer purchases until the ceiling is reached.

Under the discount system, drug purchases over a twelve-month period totalling SEK 900 are not eligible for any discount. Drug purchases totalling between SEK 900 and 1 800 are eligible for a discount on a rising scale. Thereafter, drug purchases are free of charge. Swedish pharmacies offer credit (instalment payments) for drug purchases.

4.2 Price control policies

Pricing in respect of most medicinal products is governed or affected by state regulations and official decisions connected with the health insurance system for the pharmaceutical field. The supervisory authority in this case is the National Social Insurance Board (RFV). In order for a drug to be covered by the health insurance system, it must as of 1 January 1997 be offered at a price established by the RFV.

In the case of patented original pharmaceuticals, the RFV must have established the PPP for these to be included in the health insurance system. Decisions on prices for original pharmaceuticals take into account things like anticipated medical and health-economic value, sales volumes and prices in the parent company’s home country.

In the case of original pharmaceuticals whose patents have expired, and which have subsequently acquired one or more generic equivalents, and in the case of generics, the RFV sets a maximum discount-

based price known as a reference price, i e the price to the consumer that will be eligible for a subsidy via the health insurance system. The reference price system came into force on 1 January 1993. The reference price constitutes 110 percent of the cheapest generic alternative. If the price for a non-patented original drug or a generic drug is higher than the reference price, the patient pays the difference. The reference price system is no longer used to any great extent. The system covers only 300-400 articles, which in 1996 corresponded to just over seven percent of pharmaceuticals sales as a whole.

The RFV has declared that the price of a parallel-imported original drug should be at least ten percent lower than the price of a directly imported original drug. At present, however, it is not completely clear to what extent central government is allowed to impose prices on the former category that differ from those of the latter.

In the case of medicinal products not covered by the health insurance system - i e most non-prescription drugs, some prescription drugs and drugs used only for in-patient care – free pricing applies.

4.3 Regulation of pharmacies and pharmaceutical distribution

Under the Medicinal Products (Trading) Act (1996:1152) and the Medicinal Products (Trading) Ordinance (1996:1290), governing sales to consumers, prescribers, hospitals, etc, the Swedish state has exclusive rights to retail trading in the pharmaceutical field. Further, the law defines wholesale trading as another form of selling.

As we have noted, the RFV sets the pharmacies' purchase prices for medicinal products (PPP) within the framework of the health insurance system, and, after consultation with the AAB, the prices to the consumer (PRP), including the pharmacy's trading margin. The margin is calculated in the form of a combined cash and percentage mark-up, which in 1998 amounted to an average of almost 20 percent.

Wholesale trading in pharmaceuticals may only be conducted with the permission of the Medical Products Agency, which imposes certain requirements on the company concerned. One requirement is that the company must ensure that its products are constantly available and can be delivered at short notice. In practice, the regulations mean that the wholesale companies must be able to distribute products to the pharmacies within not more than 24 hours of receiving the order.

At present, the distribution of medicinal products used in the in-patient care (hospital) sector is also carried out via AAB pharmacies. Hospital principals, however, may operate hospital pharmacies themselves. In the present circumstances, though, it is difficult for hospital principals to start such operations as an alternative to AAB pharmacies. This is mainly because of the difficulties they encounter when seeking to build up and maintain skilled staffing of their own in this field. This in turn should be viewed in the light of the current situation in Sweden whereby one market player is formally entitled to provide all distribution or retailing in this sphere. Furthermore, all hospital principals currently have agreements with the AAB giving the company's hospital pharmacies the responsibility for providing the distribution of medicinal products in the in-patient care sector.

4.4 Control of physician prescribing practices

So as to achieve cost-effective usage of medicinal products, hospital principals have established special advisory committees on medicines in each county/region as of 1 January 1997. One of the chief tasks of these committees is to ensure reliable and cost-effective usage of drugs. This is to be achieved by such means as making recommendations to prescribers (usually physicians) regarding the drugs that should primarily be favoured for use in various medical or therapeutical spheres.

In certain circumstances, pharmacies may supply another (generic) product instead of the medicine stated on the prescription form. The general rule in such cases, however, is that the pharmacy is to contact the prescriber first. Generic substitution is not allowed if the prescriber refuses consent. In some cases, however, there are agreements whereby pharmacies and the medical centres in their area may apply generic substitution without the pharmacy having to obtain the permission of the prescriber in each individual case. The consumer, however, is entitled to reject generic substitution. The AAB has informed Sweden's pharmacies that, unless the relevant advisory committee has recommended otherwise, they should provide the cheapest medicine if parallel-imported alternatives are available.

Boosting incentives for prescribers and consumers to choose cost-effective drugs is made difficult by the fact that the person who uses the drug only has to pay for a small part of the cost while the person who prescribes it pays for no part at all. Instead, it is a third party, the public, that finances or subsidises the bulk of the costs for medicinal products. This means that on the whole, both care providers and patients are less motivated to choose the form of treatment and the medicine that is the most rational or appropriate.

Generally speaking, the higher the share of the drug cost that is paid by the consumer (personal payment), the greater his/her awareness of price and cost. A large personal payment makes over-consumption of the drug less likely and motivates prescribers, consumers and others to demand a greater range of alternatives such as parallel-imported products and generics. Further, it is thought likely that a large personal payment reduces the risk of excessive prices in the pharmaceuticals trade.

On the other hand, a large personal payment may prevent individuals from purchasing the medicines they need for cost reasons, with the result that the cost of medical treatment goes up. Arriving at an optimal level for personal payments from a macro-economic perspective is difficult, not to say unrealistic, bearing in mind the varying interests to be satisfied in this context.

The latter conclusion should also be viewed in the light of the fact that subsidising the price of a product generally stimulates demand for that product. Such a situation, compared to conditions in a smoothly functioning competitive market where the price of the product normally reflects an effective use of resources, may have an unfavourable impact on efficiency and productivity in the market.

In recent years, hospital principals have prioritised measures aimed at reducing pharmaceutical costs. One such step is to increase information about cost-effective products as part of the work performed by the advisory committees. The provision of information and in-service training to prescribers in this context should help develop medical care and the achievement of a rational usage of medicinal products. From a competitive viewpoint, information and training programmes should as far as possible be objective and free from ties with any producer.

The work of the advisory committees on medicines may be considered to have facilitated the choices that prescribers and consumers have had to make between various types of medicines. It has also shown, however, that creating a situation in which prescribers generally play a more active part in achieving a more efficient usage of medicines is no easy matter. The way information about drugs is provided is also important. The pharmaceutical companies are often thought to have exploited person-to-person meetings with notable success whereas producer-independent information has largely been provided in written form.

5. Competition Issues in the Pharmaceutical Sector

The Swedish Competition Act (1993:20) is applicable in the pharmaceuticals field and no exceptions are stipulated under this law. The Act was modelled on the competition rules in the Treaty of

Rome and is based, as are its provisions, on a prohibition against agreements that manifestly restrict competition and against abuse of a dominant position. Further, the law contains provisions for assessing company acquisitions with regard to competition.

The Swedish Competition Authority is the agency responsible for implementing the Competition Act.

In Sweden, the EU competition rules also apply.

5.1 Anti-competitive agreements

Two cases in particular involving allegedly anti-competitive behaviour in the Swedish pharmaceuticals market have been examined under the Competition Act, both of which have general significance from a competition viewpoint. One of the cases concerned the wholesale companies' system for distributing to the pharmacies, known as the single-channel system. The other concerned the refusal by one of the wholesale companies to supply pharmaceuticals intended for parallel *export*.

The single-channel system means that pharmaceuticals are distributed with certain exclusive rights for the wholesale company. The system was introduced in the early 1970s with government support but no state regulations exist for this sphere. From the time the system was introduced up until the end of 1994 and the beginning of 1995, it involved the wholesalers negotiating exclusive distribution agreements with the pharmaceutical companies. Under these agreements, the pharmaceutical companies pledged to distribute their entire range of medicinal products through only one wholesale company.

The Competition Authority took the view that the single-channel system violated the prohibition contained in the Competition Act with regard to anti-competitive inter-company agreements. The Authority has, however, decided to grant exemptions from this ban on a number of occasions.

These decisions meant that the single-channel system was allowed to continue on condition that Tamro and KD agreed to certain undertakings. One of these was that pharmaceutical companies should not be required to make their entire range or all their products available for distribution by one and the same wholesale company. Instead, the distribution commitment was limited to all supplies of one particular product. Another undertaking involved limiting agreements between pharmaceutical companies and wholesalers to one year at a time. The Competition Authority's contention in motivating its ruling was that the advantages of the system, once the companies had agreed to the suggested undertakings, outweighed the disadvantages in the form of the system's anti-competitive effects. This was to be viewed in the light of the fact that a single company (AAB) currently enjoyed exclusive rights for the sale of medicinal products to the consumer.

The second case concerned a parallel trading company that lodged a complaint with the Competition Authority about a wholesaler's refusal to supply an original drug to the company. This company intended to export the drug to an EU country where it commanded a higher price than in Sweden. The Competition Authority ruled that the wholesaler's refusal of supply violated the prohibition in the Competition Act against abuse of a dominant position, and enjoined the wholesale company to supply the drug in question.

This ruling was appealed by the wholesaler to the Stockholm District Court, which in September 1996 rescinded the Competition Authority's ruling. The court declared that the company's refusal to sell a product intended for sale in another country did not come within the jurisdiction of the Competition Act. Thus it considered that a refusal of supply in this particular case did not directly affect the Swedish market and that the Competition Act was therefore not applicable.

Examination of the case by the European Commission might have resulted in a different outcome.

5.2 Mergers and acquisitions

In the 1990s, some 20 major company mergers have taken place in the Swedish pharmaceuticals market. Well-publicised mergers with international ramifications included those in 1995 and 1999 respectively between the Swedish company Pharmacia and the US company Upjohn and between the Swedish company Astra and the UK company Zeneca. The European Commission examined these mergers.

Perhaps the most common argument used to motivate pharmaceutical mergers is that development of new drugs has become increasingly costly and that creating larger pharmaceutical companies can enhance the co-ordination and financing of research and development. Structural change in the pharmaceutical sector has entailed only a limited increase in market concentration in Sweden.

UNITED STATES

1. The Pharmaceutical Industry: Market Structure

1.1 Market Structure

(1.1) Please describe the market structure of pharmaceutical firms in your country - which firms are active, with what market share, in which therapeutic classes and with what level of R&D (including generic producers). Which firms co-operate to jointly undertake R&D or to jointly market certain products? Is there one or more associations of pharmaceutical manufacturers in your country? Is this association politically important?

The US pharmaceutical industry is composed of approximately 700 companies that develop, manufacture and market ethical pharmaceutical products, including proprietary (brand name) and generic medicines.[2] The value of US shipments of pharmaceutical products in 1997 was estimated at nearly $83 billion. Sales from the US operations of the ten largest pharmaceutical companies with operations in the US were about $49 billion in 1997.[3] As noted below, there has been continuing industry consolidation but recent market share figures are not readily available.

The most useful sources of data on market share in the form requested are proprietary. Appendix 1 contains available public data on market shares for some therapeutic classes, and public information from private sources listing the firms that are engaged in manufacturing, fabricating or processing drugs in pharmaceutical preparations for human or veterinary use, their profits and their expenditures for research and development.

More important than market share is the evolution of the US market toward increased horizontal consolidation and vertical integration involving both companies producing brand -name and generic drugs. There has also been a movement toward price competition from non-price competition as a result of cost containment strategies of managed care organizations and pharmacy benefit management companies. For one discussion of the industry changes, see FTC Bureau of Economics Staff Report, "The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change," Chapter II (March 1999) (available at www.ftc.gov/ftc/economics.htm).

Given the high cost of R&D and the efficiencies of co-promotion and co-marketing, joint efforts in these areas are common among drug producers. Specific information on joint venture activity can be found in each individual firm's annual report but, to our knowledge, is not collected for publication.[4]

According to the Pharmaceutical Research and Manufacturers of America ("PhRMA'), a trade association that represents nearly all major prescription pharmaceutical firms in the US, the drug industry devotes a higher percentage of sales to R&D than any other industry in the US. PhRMA reports that industry R&D to develop prescription pharmaceuticals in 1999 accounted for 20.8 percent of total revenues, up from 16.2 percent in 1990[5] and that most leading pharmaceutical manufacturers spend between 14 percent and 18 percent of their revenues on R&D.[6]

The main industry trade associations are: Generic Pharmaceutical Industry Association (generic drug manufacturers), National Association of Pharmaceutical Manufacturers (independent generic drug manufacturers and suppliers of bulk pharmaceutical chemicals), Non-prescription Drug Manufacturers Association (over-the counter drug manufacturers) and Pharmaceutical Research and Manufacturers of America (prescription pharmaceutical firms). These associations represent their members in legislative, regulatory and related matters.

2. Regulation of Supply

2.1 Protection of Intellectual Property Rights

(2.1) Please describe the regulatory framework established for the protection of intellectual property rights in the pharmaceutical industry.

Article I, Section 8, Clause 8 of the United States Constitution grants Congress the power to create a patent system. A patent for an invention is the grant of a property right to the inventor and is issued by the US. Patent and Trademark Office. US patent grants are effective only within the US and its territories and possessions. Patents on pharmaceutical products can be issued either on a drug's chemical structure or on its method of manufacture or synthesis. The term of the patent is twenty years from the date on which the application for the patent was filed or, in special cases, from the date an earlier related application was filed, subject to the payment of maintenance fees.[7] Patents confer rights to exclude others from making, using, offering for sale or selling the invention claimed by the patent in the U.S. or importing such invention into the US.

Under the Drug Price Competition and Patent Term Restoration Act of 1984 and amendments thereto, commonly known as the Hatch-Waxman Act, a holder of a pharmaceutical patent for a new chemical entity never approved by the U.S. Food and Drug Administration ("FDA") is entitled to extend patent protection in order to compensate for delays caused by the FDA's premarket approval process. Those extensions, granted after the drug is approved, equal half of the time the drug spent in clinical testing (usually six to eight years) plus the time FDA spent reviewing its new drug application (usually two years). However, the extension cannot be longer than five years, and the FDA cannot grant a total period of patent protection that exceeds fourteen years after the drug is approved. See Appendix 3 for details. The patent term extension was given to the patent holders in exchange for a provision authorising generic producers to rely on safety and efficacy testing submitted by the original patent holder, thus expediting FDA approval of lower cost generic drugs by eliminating the need for generic producers to submit their own test data to the FDA.

The Food and Drug Administration Modernisation Act of 1997 added six months of patent exclusivity for drugs requiring further review for pediatric applications.[8]

During the FTC's 1995 Hearings on Global and Innovation-Based Competition, the pros and cons of compulsory licensing as a remedy were debated by numerous participants at the hearings. Some argued that antitrust should be more receptive to this remedy. Others asserted, however, that compulsory licensing would stifle follow-on innovation. [9] Compulsory licensing has been a remedy in antitrust actions brought by the Antitrust Division of the Department of Justice alleging unlawful provisions in patent and copyright licenses, in addition to enjoining further enforcement of the offending provisions or entering into similar agreements. See, e.g. United States v. Glaxo Group, 410 US. 52, 64 (1973). In that case, the Supreme Court stated that "[m]andatory selling on specified terms and compulsory patent licensing at reasonable charges are recognised antitrust remedies." Id. at 64. The Commission has ordered compulsory

licensing in one recent case to restore competition allegedly reduced as a result of a proposed merger. In 1997, the Commission challenged the merger of Ciba-Geigy and Sandoz, alleging that the merger would have given Ciba-Geigy a monopoly in certain patents and trade secrets for the development of gene therapies, which hold promise for the treatment of some forms of cancer and AIDS. The Commission's consent order required Ciba-Geigy to license certain patents and technologies so that R&D efforts to develop those products would not be dominated by a single firm.[10]

2.2 New Drug Approvals

(2.2) Please provide an overview of the drug approval process.

The Food and Drug Administration regulates the approval of prescription drugs in the US. To receive marketing approval companies are required to demonstrate that drugs are safe and effective. Estimates for the 1990-96 period indicate that new drug approvals have taken an average of 14.9 years with elapsed times varying across the regulatory stages.[11] The first stage of the FDA approval process involves the submission of an Investigational New Drug Application (IND). After 30 days, if the FDA does not place a hold on the IND, the applicant may begin testing the drug in humans, typically in three phases. Phase 1 involves safety tests on 20-100 volunteers (usually healthy people) to determine safe dosage levels and toxicity. This takes on average several months. Phase 2 involves efficacy and some short-term safety tests, using up to several hundred people with the disease that the drug is designed to combat. This takes on average of up to two years. Phase 3 looks at additional safety issues, efficacy and dosing. The drug is tested in up to several thousand persons, usually in two controlled clinical trials. Phase 3 studies are also used to determine whether the benefits are statistically significant and possible side effects. This phase typically last from one to four years. After the Phase 3 studies are completed, the applicant submits a New Drug Application (NDA) to the FDA. The NDA contains pre-clinical studies, clinical human studies (from Phases 1-3), manufacturing details, labeling, and additional information. The FDA's current median time for approval of an NDA is 12 months. Following approval, the agency continues to monitor the post-marketing testing and use of the drug, and makes any necessary regulatory changes (e.g., modify labeling to reflect new safety concerns).[12]

The Hatch-Waxman Act provides new procedures for abbreviated new drug applications (ANDAs) for generic versions of previously approved drugs.[13] To begin the FDA approval process, the generic application must submit information that shows that: *1*) the conditions of use for the proposed drug are the same as those for the listed drug; *2*) the active ingredient(s) for the proposed drug are the same as those for the listed drug; *3*) the route of administration, dosage form and strength of the proposed drug are the same as those for the listed drug; *4*) the proposed drug is bioequivalent to the listed drug; and *5*) the labeling for the proposed drug is the same as that for the listed drug. The application must also contain one of the following four certifications: *1*) the patent information has not been submitted to the FDA (paragraph I certification); *2*) the patent has expired (paragraph II certification); *3*) the date on which the patent will expire (paragraph III certification); or *4*) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted (paragraph IV certification).

An applicant relying on a paragraph IV certification must: *1*) certify in its ANDA that the patent in question is invalid or is not infringed by the generic product; and *2*) notify the patent holder of the filing of the ANDA. If the patent holder files an infringement suit against the generic applicant within 45 days of the ANDA notification, FDA approval to market the generic drug is automatically stayed for 30 months unless the patent expires or is judicially determined to be invalid or not infringed. This stay allows the patent holder time to assert its patent rights in court before a generic competitor is permitted to enter.

Under the ANDA process, entry with a therapeutically equivalent generic form requires: *1*) developing a generic formulation for possible clinical evaluation; *2*) meeting FDA bio-equivalence requirements for ANDA approval; *3*) meeting FDA's chemistry, manufacturing and control requirements; *4*) complying with FDA's Good Manufacturing Practice regulations; *5*) meeting FDA labeling requirements; and *6*) marketing the generic drug after FDA approval. Establishing bio-equivalence typically requires clinical studies with a group of 18 to 36 to establish that the rate and extent of absorption of the generic form does not significantly differ from that of the brand-name drug. The Hatch-Waxman Act (Bolar Amendment) permits the preliminary production and testing of generic drugs prior to the expiration of any relevant patents on corresponding brand name drugs. Thus, generic entrants can receive ANDA approval as soon as the patents expire.

2.3 Trade Regulation

(2.3) Please describe any barriers to international trade or investment in pharmaceuticals. Are there restrictions on international trade in drugs by third parties (such as parallel trade or re-imports)? Are there restrictions on mail-order or Internet supply of drugs? Does the regulatory regime distinguish between domestic and foreign firms in any way?

Parallel imports are defined as genuine goods produced or sold abroad with the consent of the owner of the applicable intellectual property right – copyright, trademark or patent – that are subsequently sought to be imported into the domestic market without the consent of the intellectual property right owner. Over the past decade, the United States has advocated the need for protection from parallel importation in the copyright and patent laws of our trading partners, a position which is consistent with US law. Appendix 2 briefly summarises US law on parallel imports.

The Food, Drug and Cosmetic Act ("FDCA"),[14] enforced by the FDA, to control parallel imports. The FDCA requires manufacturers and sellers of drugs to register with the FDA and comply with FDA rules. It applies also to firms that relabel drugs and covers imports as well as domestically made drugs. The FDCA also prohibits counterfeit drugs from being marketed in the US; this also applies to parallel imports of such products.[15] Section 801(d) of the FDCA bars the reimportation of prescription drugs made in the US by any person other than the original manufacturer or by the FDA for emergency medical care.

Additional record-keeping and registration requirements apply if the drug is a controlled substance. See 21 U.S.C. § § 822, 829, and 841. Sections 5 (prohibition of unfair or deceptive acts or practices) and 12 (prohibition of false advertising of food, drugs and cosmetics) of the Federal Trade Commission Act could furnish bases for a federal enforcement action where an online company makes false or misleading claims about the products or services it provides.

The FDA does not distinguish between foreign and domestic products; all pharmaceuticals sold in the US must meet FDA regulatory requirements. Foreign firms shipping to the US must register with the FDA. There is no requirement for domestic manufacture. The US and the EU negotiated in 1997 a pharmaceutical Mutual Recognition Agreement to eliminate regulatory barriers and promote trade between them. They agreed to recognise each other's inspections of manufacturing facilities for human drugs and biologics in their respective regions (previously, inspectors from each area had to inspect every factory in which a drug imported into that jurisdiction was manufactured).

Under federal law, prescription drugs may be dispensed only with a valid prescription under the professional supervision of a physician or other practitioner licensed to administer the drug. 21 U.S.C. § 353. A prescription drug that is dispensed without a valid prescription is "misbranded." 21 U.S.C.

§ 353(b). The introduction or distribution of misbranded drugs into interstate commerce is prohibited by section 301(a) of the FDCA.

Regarding Internet sales in particular, many government officials and health care professionals are raising concerns about the availability of prescription drugs over the Internet without a valid prescription or based solely on answers to online questionnaires. Several states have challenged online companies that dispense prescription drugs without a valid prescription based on state consumer protection laws as well as state medical and pharmacy regulations. The grounds for these state challenges include deceptive misrepresentation or omissions, and practice of medicine without a license.

2.4 Industrial Policy

(2.4) Please describe any industrial policy objectives in this sector. Describe the objectives and effects of any tax concessions or subsidies that exist.

The US relies on the market for the development of the pharmaceutical sector. Other than government subvention of academic institutional research, we are unaware of any subsidies targeted to the pharmaceutical industry.

The industry, like many others, takes advantage of generally available tax credits (e.g. the 1981 Economic Recovery Tax Act, discussed below) and participates in joint R&D activities with federal and university laboratories that promote scientific breakthroughs and product innovation that benefit society. The credit provides tax incentives for companies that increase their R&D spending over a base amount. Congress has extended the R&D tax credit for limited periods (usually one year) ten times since it was first enacted. The most recent extension expired in 1999.

The Orphan Drug Act is specifically designed to encourage R&D for drug products used to treat rare diseases or conditions with small patient populations, where there is little commercial incentive.[16] If the FDA agrees that the drug meets the statutory definition, manufacturers may receive tax credits and certain other assistance for the cost of clinical trials and, upon the date of new drug approval or biological licensure, extended periods of market exclusivity,[17] as incentives to invest in the development of potential treatments.

As more fully explained in Appendix 3, the patent term extension provisions of the Hatch-Waxman Act, discussed above, were designed to create new incentives for R&D of certain products subject to premarket government approval by a regulatory agency.

3. Regulation of Demand: Controls on Pharmaceutical Prices, Quantities and Consumption

(3.1) We invite you to discuss how the predominant forms of health insurance in your country (whether public or private) affect the demand of health consumers for pharmaceuticals.

There is abundant literature on the effect of health insurance, in particular of health maintenance organisations ("HMO"), on the demand for pharmaceuticals. The Health Insurance Association of America, which represents a cross-section of companies that finance and deliver health care and provide other health insurance products and services, released in September 1999 a white paper on "Prescription Drugs: Cost and Coverage Trends." The report cited liberal coverage policy by most health plans that insulates the consumer from the total cost of drugs as one factor driving increased pharmaceutical use. The paper does not, however, estimate the percent or dollar impact of each factor.[18] Nonetheless, the inclusion of a manufacturer's drug on a formulary in return for a manufacturer-provided discount or a formulary

practice of limiting the therapeutic class of approved drugs to a few products, may significantly influence the demand for a particular drug.

Many health insurance plans (including traditional fee-for-service plans) hold down drug costs by managing their outpatient prescription drug benefits either themselves or through organisations called pharmaceutical benefit management companies (PBMs). As described more fully in the response to question 3.3 below, these techniques, in particular the use of formularies, have put downward pressure on the prices that PBMs and health plans pay for brand-name drugs sold through pharmacies. They have also significantly increased the purchase of generic drugs.

Such cost containment techniques have a significant effect on drug usage. Use of prescription drugs may be higher in HMOs and some other managed care plans because they tend to have more extensive coverage of physicians' services and sometimes of prescription drugs. Managed care plans also may sometimes favor the use of prescription drugs over other, more expensive forms of medical treatment.[19] As a result the increasing prevalence of managed care plans may have resulted in an increase in the quantity of prescription drugs sold in the U.S.

3.2 Formularies

(3.2) Please describe the main features of the formulary system in your country.

Managed care organisations, especially HMOs, have developed a number of cost containment strategies for prescription drugs including generic substitution, drug utilisation review, formularies, and therapeutic interchange and step-care therapy.[20] The emergence of professionally managed prescription drug benefit programs - pharmacy benefit management companies or PBMs - is an important force in the managed care revolution. PBMs administer the prescription part of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and HMOs. PBMs typically select participating pharmacists, drug manufacturers and suppliers, administer point of sale claims processing systems, negotiate quantity discounts with pharmaceutical manufacturers and pharmacists, administer plan record keeping and payment systems, and maintain quality control. A common technique PBMs use to manage pharmacy care is formulary development. They attempt to control costs by negotiating discounts from manufacturers, usually in the form of rebates, in return for placing the manufacturer's drug on the PBM's formulary.

A formulary is a list of prescription drugs grouped by therapeutic category that are approved for insurance coverage. The formulary is produced by the PBM, the health plan or others. Drugs are included in the formulary on the basis of therapeutic value, side effects and cost - a formulary includes relative cost information. Formularies are made available to pharmacies, physicians, third-party payers, or other persons involved in the health care industry to guide them in the prescribing and dispensing of pharmaceuticals. PBMs and health plan sponsors typically encourage physicians to prescribe lower-cost formulary drugs over both non-formulary and higher-cost formulary drugs for health plan enrollees. The formularies encourage the substitution of brand-name drugs with generic versions, or sometimes with other, less expensive brand-name drugs. Formularies range in restrictiveness from "open" to " closed." An "open" formulary allows for the reimbursement of any drug a physician prescribes,[21] whether or not it is actually listed on the formulary, whereas a "closed" formulary limits reimbursement to the specific drugs listed. Based on industry sources, the percentage of HMOs using closed formularies was almost 50 percent in 1999.[22] A 1995 study by the US. General Accounting Office found that the vast majority of formularies managed by PBMs were open.[23] However, a 1997 private-sector report notes a strong trend towards adoption of a "selective/partially closed" formulary in which reimbursement is limited to prescribed

formulary drugs plus select non-formulary drugs, utilising such processes as prior authorisation to determine approval.[24]

Private sector health plans and PBMs use computer networks at pharmacies and electronic card systems for enrollees that allow pharmacists, before filling an enrollee's prescription, to consult a list (or formulary). Savings result not only from substitution but also discounts offered to health plans or PBMs by manufacturers of brand-name drugs in exchange for being included on their formulary. PBMs, which represent a large pool of customers, can also negotiate with networks of pharmacies to obtain discounts from the retail price per prescription for the health plan enrollees. Since the late 1980s, those techniques have put downward pressure on prices that PBMs and health plans pay for prescription drugs.

The Departments of Veterans Affairs (VA) and Defense (DoD) provide medications and medical supplies to their beneficiaries as an adjunct to their health care delivery systems. The VA utilises a formulary developed by field-based practitioners to address medication and medical supply needs for its beneficiaries.[25] The VA's formulary process includes the development, promulgation and growing use of pharmacologic treatment guidelines. The guidelines reflect best practices for a predominantly geriatric patient population. The VA does not seek discounts or rebates in exchange for formulary listing (see discussion of private health care in response to 3.3 below). The VA determines what is clinically best for veteran beneficiaries and then contracts for an individual drug or therapeutic class of drugs. DoD utilises a so-called "core formulary" of items available at its own medical treatment facilities; a larger array of drug products is available to DoD beneficiaries through a retail pharmacy network and mail order provider.

See also response to question 3.3.

3.3 Price Control Policies

(3.3) Please describe the operation of the controls on pharmaceutical prices in your country

The US has no direct price controls on pharmaceuticals. With respect to cost containment programs, The Omnibus Budget Reconciliation Act of 1990 ("OBRA") contains regulations intended to reduce Medicaid's outlay for prescription drugs. In effect, OBRA requires drug companies to treat Medicaid recipients as a "most-favoured-nation" class. It mandates that drug companies, in order to have their drugs reimbursed by the Medicaid program, pay a rebate on these products to the state Medicaid program that is based on the lowest prices available to other customers. In general the rebate on outpatient prescription drugs equals the greater of a fixed percentage of the average manufacturing price ("AMP") or the difference between the AMP and the lowest price any purchaser paid for that drug, called the "drug's best price." Rebate amounts are based on a unit amount computed by the Department of Health and Human Services to which the Medicaid utilisation information is applied by states in invoicing the manufacturer for rebates. Another Medicaid reimbursement policy is the use of formularies by certain states as criteria for reimbursement.

The 1992 Veteran Health Care Act conditioned Medicaid coverage for a manufacturer's drugs on participation in three additional discount programs: the federal ceiling price program, the public health service grantees; and federal supply schedule. The federal ceiling price program requires that manufacturers sell new (non-generic) prescription drugs to the VA, the DOD, the Public Health Service and the Coast Guard at or below federal ceiling prices that are average non-federal manufacturer's price minus 24 percent. Manufacturers are also required to sell to the Public Health Service grantees (e.g., community and migrant health centers, hemophilia centers, AIDS drug-assistance programs) at discounted prices equal to the AMP minus the Medicaid rebate. Brand-name manufacturers also must agree to list all

pharmaceutical products on the Federal Supply Schedule, a government-wide list of discounted products for federal agency procurement.

Another major government discount program is conducted by the Department of Defense. This program is voluntary and is not required for Medicaid reimbursement. The Department negotiates the prices for purchases with manufacturers through its prime vendors. These payments cannot exceed federal ceiling prices.

Under the Medicare program, health insurance provided to the elderly and the disabled, drugs furnished to a beneficiary during an in-patient hospital stay are covered as part of Medicare's payment to the hospital for that stay (i.e., payment based on the appropriate diagnosis related group or DRG). Medicare covers outpatient drugs only in the following situations:

- Drugs Furnished Incident To a Physician's Services: These are injectable or intravenous drugs that are furnished by a physician or under the physician's direct supervision and cannot be self-administered.

- Statutorily Covered Drugs: Examples include immuno-suppressive drugs, hemophilia clotting factors, erythropoietin for trained home dialysis patients, allergens under certain conditions, and certain oral anti-cancer drugs, pneumococcal, influenza and hepatitis vaccines.

- DME Drugs: A very few drugs that are used in conjunction with Medicare-covered durable medical equipment; e.g., inhalation drugs (albuterol sulfate) used with a nebulizer.

The Balanced Budget Act of 1997 set Medicare payment based on the lower of the billed charge or 95 percent of average wholesale price (AWP). In 1998, the total Medicare billed charges were approximately $seven billion for drugs that are paid by Medicare at the lesser of the actual charge or 95 percent of the AWP.

3.4 Control of Physician Prescribing Practices

(3.4) Please describe the systems in place to encourage high-quality cost-effective physician prescribing practices

In the managed care sector, high-quality, cost-effective physician prescribing practices are promoted through use of best practice guidelines, disease management programs, provider profiling and dynamic medication use committees.[26] In addition, the cost containment strategies of HMOs and other health insurance plans discussed above, in particular the monitoring of physician's prescribing practices under the drug utilisation review, are aimed at encouraging physicians to prescribe the lowest cost/highest quality prescription drugs.

3.5 Regulation of Pharmacies and Pharmaceutical Distribution

(3.5) Please describe the nature of any controls on pharmacy margins, entry/or ownership structure. Please describe also the nature of any rules governing the discretion of pharmacists to substitute other products

Entry is largely controlled by the state governments. The 1999-2000 National Association of Boards of Pharmacy's Survey of Pharmacy Law reports that 13 states impose some limitation on prescriber

ownership of a pharmacy; examples are prohibition of ownership if the prescriber is likely to benefit due to the prescriptions he/she writes and prohibition of self-referral.

Pharmacies are typically part of PBM networks (see response to question 3.3, *supra*) that administer the drugs benefits portions of health insurer plans. Computers linking network pharmacies to PBMs enable pharmacists to check which brand name or generic substitutions are required by the patient's health insurer, whether the doctor is prescribing according to health plan policy, and what co-payment amount applies. Managed care payors accounted for about 68 percent of all retails pharmacy prescriptions dispensed between June 1998 an June 1999; Medicaid represented 11 percent.[27]

There are state laws that govern the discretion of pharmacists to substitute a generic drug when a prescription specifies a brand name one. In the early 1970s, it was illegal in many states for a pharmacist to dispense a generic drug when a physician prescribed a brand name drug. By 1984, all states had drug-product substitution laws that gave pharmacists more discretion. Under these new laws, a pharmacist can dispense a generic drug even when a brand name drug is specified as long as the physician had not indicated otherwise on the prescription.

See also response to question 3.3 above.

3.6 Policy towards Generics

(3.6) What share of non-prescription/over-the-counter, prescription and hospital markets are held by generics? Please describe the programs you have adopted to promote the consumption of generics?

According to data supplied by the Generic Pharmaceutical Industry Association, in 1998 generics accounted for 41 percent of retail prescriptions and 8.6 percent of total dollars spent on pharmaceuticals.

The Hatch-Waxman Act (see response to question 2.2 *supra*) streamlined the process for approving generic drugs by requiring only that manufacturers demonstrate "bio-equivalence" to an already-approved innovator drug, making generic entry easier and less costly. As noted above, most states have passed drug-product substitution laws that allow pharmacists to dispense a generic drug even when the prescription calls for a brand-name drug.

In addition, privately managed care providers and government programs such as Medicaid and VA have actively promoted generic substitution. The VA reports that 91 percent of its drug expenditures are for branded products and the remaining nine percent on generics. Its policy is to use FDA-approved generic products unless there are specific clinical reasons not to do so.

4. Competition Issues in the Pharmaceuticals Sector

(4.1) Does the competition law apply to the different components of this sector (manufacturing, health insurance, health services, distribution and pharmacies) without exemption or exception? Which agency is responsible for enforcing the competition law in this sector?

The US antitrust laws, including the Sherman Act, the Clayton Act, and the Federal Trade Commission Act and state antitrust laws generally apply to all components of the pharmaceutical sector. These laws are enforced by the Federal Trade Commission, the Antitrust Division of the Department of Justice, the state attorneys general and private plaintiffs.

The McCarran–Ferguson Act, 15 U.S.C.§ 1011-15 (1994), which reserves to the states the power to regulate and tax the business of insurance, provides a limited antitrust exemption for conduct relating to health insurance. The Sherman, Clayton, and FTC Acts apply to the "business of insurance" to the extent that such business is not regulated by state law.[28] To qualify for the exemption the challenged activity must be (*1*) part of "the business of insurance," (*2*) "regulated by State Law," and (*3*) not constitute an a agreement to or act of boycott, coercion, or intimidation.[29]

Additionally under the judicially created "state action" doctrine, anticompetitive activities by private parties may be immune from challenge under the Federal antitrust laws if (*1*) the challenged restraint is "clearly articulated and affirmatively expressed as state policy" and (*2*) "the policy [is] 'actively supervised' by the state. [30] Many states have enacted legislation purporting to confer state action immunity upon health care "networks" that apply to the state for approval of the network's proposed structure and plans. Whether such statutes are able to confer such immunity is, however, open to question.

4.1 Market Definition Issues and Barriers to Entry

(4.2) Have you had the occasion to address the definition of the relevant market in the pharmaceuticals sector? Did you find that the relevant product market could be approximated by commonly-accepted therapeutic groups? What techniques did you use to determine whether certain products were effective substitutes? Did you find it necessary to distinguish the market for drugs consumed in hospitals from the market for drugs prescribed by physicians and/or market for over-the-counter (non-prescription) drugs? Was the relevant market national or international?

As indicated by the cases discussed below, the US antitrust agencies an courts frequently have addressed market definition issues in the pharmaceuticals sector. We define product and geographic markets on a case-by-case basis, examining demand substitution following the analytical approach set forth in Sections 1.1 and 1.2 of the FTC and DOJ Horizontal Merger Guidelines.[31] The agencies rely on evidence from customers, competitors, medical experts and market data to make this determination. Any distinctions between drugs consumed in hospitals from those prescribed by physicians or non-prescription drugs are made on a case-by-case basis using the standards set out in the Merger Guidelines.

The United States typically is the relevant geographic market for finished, prescription drugs because the FDA regulations and US patent and other intellectual property laws impose significant barriers to entry on the introduction of products that do not meet these legal requirements.

For an example of how the U.S. authorities define a product market, see the discussion below (responses to questions 4.6 and 4.7) of the FTC's successfully litigated case challenging two separate mergers of the four largest drug wholesalers in the US. For a second example, in the FTC's recent (non-merger) case against Abbott Laboratories and Geneva Pharmaceuticals, summarised in our response to question 4.4, below, the complaint identifies terazosin HCL as the relevant product market, alleging that other drugs are not effective substitutes because they have different chemical compositions, safety, efficacy, and side effects. In addition, the complaint alleges little price sensitivity between terazosin HCL and non-terazosin HCL products.

(4.3) Did you consider that the pharmaceutical industry is characterised by barriers to entry/exit? What barriers did you identify?

The FTC has alleged high entry barriers in several of its complaints involving horizontal mergers, for an example, those identified for the gene therapy market in the FTC's complaint accompanying a consent order challenging the 1996 merger of Ciba-Geigy and Sandoz to become the merged entity, Novartis:

> Entry into the gene therapy market requires lengthy clinical trials, data collection and analysis, and expenditures of significant resources over many years to qualify manufacturing facilities with the Food and Drug Administration. Entry into each gene therapy market can extend up to and beyond 10-12 years. The complaint further alleges that the most significant barriers to entry include technical, regulatory, patent, clinical, and production barriers. The FDA must approve all phases of gene therapy development, including pre-clinical and clinical work. No company may reach advanced stages of development in the relevant gene therapy markets without: (*i*) clinical gene therapy expertise; (*ii*) scientific research that requires years to complete; (*iii*) patent rights to all the necessary proprietary inputs in to the gene therapy product sufficient to provide the company with reasonable assurances of freedom to operate; and (*iv*) clinical grade product manufacturing expertise, regulatory approvals and capacity to complete clinical development. The necessary proprietary inputs include genes, vectors and vector manufacturing technology, and cytokines, proteins necessary for many gene therapy applications.

The FTC's complaint in the *Zeneca/Astra* merger, discussed below, succinctly described the barriers to entry as "the difficulty of researching and developing a new product, obtaining FDA approval and gaining customer acceptance."

4.2 Anticompetitive Agreements

(4.4) Have you had the opportunity to address questions of explicit or implicit collusion in the pharmaceutical sector? What forms of collusion have you found? Have pharmaceutical manufacturers or pharmacies acted in combinations to attempt to increase (or resist decreases in) pharmaceutical reimbursement rates in health insurance plans?

The Commission has brought two cases involving generic drug competition for brand-name drugs, alleging that agreements between producers of prescription drugs were intended to delay the introduction of lower-cost generic alternative to particular drugs. This is a tremendously important area, with high stakes to consumers and the efforts to control medical costs. Generics drugs play a vital role in bringing low-cost drugs to the market.

The FTC's complaint against Hoechst Marion Roussel (recently renamed Aventis following the merger between Hoechst and Rhone-Poulenc) and Andrx Corp., issued in March 2000,[32] involves a widely prescribed once-a-day diltiazem drug for treatment of hypertension and angina, Cardizem CD. The complaint alleges that Hoechst agreed to pay Andrx millions of dollars in return for Andrx's agreement to delay bringing to market a generic drug that would compete with Cardizem CD, which possessed 70 percent of a $700 million market. Under current federal drugs laws, Andrx, as the first generic applicant for Cardizem CD, is entitled to 180 days of marketing exclusivity before other generic competitors can enter the market. Pursuant to the agreement with Hoechst, Andrx would not market its product when it received approval from the FDA, would not give up or transfer its 180-day exclusivity right as the first to file its application for FDA approval of a generic version of Cardizem CD, and would not even market a non-infringing generic version of Cardizem CD. According to the complaint, the agreement acted as a

bottleneck preventing any other potential competitors from entering the market because: *i*) Andrx would not market its product and thus its 180 days of exclusivity would not begin to run; and *ii*) other generics were precluded from entering the market because Andrx agreed not to give up or transfer its exclusivity. The complaint charges that the agreement between Hoechst and Andrx was an unlawful restraint of trade because it prevented or discouraged lower cost generic entry; and that Hoechst attempted to preserve its monopoly and conspired with Andrx to create a monopoly in the relevant market.

Simultaneously, the Commission entered into a consent order with Abbott Laboratories and Geneva Pharmaceuticals[33] to settle similar allegations involving another drug, Hytrin, the brand name for terazosin HCL, a prescription drug widely used to treat hypertension and benign prostatic hyperplasia (enlarged prostrate). Accordingly to the complaint, Abbott paid Geneva $4.5 million per month to keep Geneva's generic version of Hytrin off the US market. This agreement allegedly also resulted in significant delay in the introduction of other generic versions of Hytrin because Geneva was the first filer with FDA and other companies could not market their generic products until 180 days after Geneva's entry. Abbott had forecast that entry of a generic version of Hytrin would eliminate over $185 million in Hytrin sales in just six months. The consent order bars Abbott and Geneva from, among other things, entering into agreements in which a generic company agrees with a manufacturer of a branded drug to delay or stop the production of a competing drug. This provision remains in effect for ten years. In connection with this consent, the Commission issued a statement placing pharmaceutical companies on notice that it would consider its entire range of remedies against such agreements in future matters, including possibly seeking disgorgement of illegally obtained profits.

The Commission has brought several enforcement actions against pharmacies and pharmaceutical associations for acting in combination to increase or resist decreases in pharmaceutical reimbursement rates in health insurance plans.[34] An example is Institutional Pharmacy Network,[35] in which the FTC alleged that five institutional pharmacies unlawfully fixed prices and restrained competition among institutional pharmacies in Oregon, leading to higher reimbursement levels for serving Medicaid patients in Oregon long-term care institutions. The five pharmacies, which provided institutional pharmacy services for 80 percent of patients in Oregon receiving such services, compete to provide prescription drugs and services to long term care institutions. According to the complaint, the pharmacies formed Institutional Pharmacy Network (IPN) to offer their services collectively and maximise their leverage in bargaining over reimbursement rates, but did not share risk or provide new or efficient services.

The order prohibits IPN and the institutional pharmacy respondents from entering into similar price fixing arrangements. The order, however, allows the respondents to engage in *1*) any "qualified clinically integrated joint arrangement" (with prior notice to the Commission), and *2*) conduct that is reasonable necessary to operate any "qualified risk-sharing joint arrangement" as set forth in the DOJ/FTC Statements of Antitrust Enforcement Policy in Health Care.[36]

In United States v. Bolar Pharmaceutical Co., Inc., the DOJ alleged the defendants – Bolar Pharmaceutical Co,, Inc. ("Bolar"), a corporation that manufactures and sells generic drug products throughout the US, Vitarine Pharmaceuticals, Inc. ("Vitarine"), a corporation that also manufactures and sells generic drug products throughout the US, two senior executives of these firms, and unnamed co-conspirators with conspiring to fix the price of generic Dyazide, a medication generally prescribed to treat high blood pressure, and to allocate certain customers that purchased generic Dyazide. The DOJ alleged that this conspiracy eliminated competition in the sale of generic Dyazide sold throughout the US. Vitarine pled *nolo contendere* and was fined $500 000; Bolar pled *nolo contendere* and was fined $ one million.

(4.5) Co-operative or collaborative ventures (such as co-marketing and co-promotion agreements) seem to be an important component of the pharmaceutical industry. Have you had the opportunity to examine the competitive effects of such agreements? What features of these

agreements give rise to competition concerns? Have you opposed joint research and development and/or joint marketing arrangements?

The recently issued FTC/DOJ Antitrust Guidelines for Collaborations among Competitors[37] provide a general statement of the agencies' analytical approach to competitor collaborations. The guidelines describe an analytical framework addressing a broad range of horizontal agreements, including joint ventures, strategic alliances and other competitor collaborations.[38] They also set forth general principles concerning potential procompetitive benefits and potential anticompetitive harms. The FTC and the DOJ have brought no cases challenging joint research and development or joint marketing arrangements in the pharmaceutical industry in recent years.[39]

(4.6) &(4.7)

What cases of mergers or concentrations have you addressed in the pharmaceutical industry? In what markets were concerns over market power most focused? In the pharmaceutical industry where competition is primarily by way of new innovation (as opposed to competition on prices), what are the primary anti-competitive effects of a merger? Have mergers been opposed on the grounds that the merging companies might be competitors in the future (although they were not actually competing at the time of the merger)? What sorts of remedies have been imposed as a condition on merger approval? Have the merging companies been required to divest or license certain products to third parties?

Acquisitions in the pharmaceutical sector may produce procompetitive as well as anticompetitive effects. Possible anticompetitive effects include not only higher prices but also slowing innovation of life-enhancing products. The Commission has addressed horizontal mergers between actual[40] and potential[41] competitors and vertical mergers (see response to 4.8 below). In 1998 the FTC successfully challenged two mergers involving the four largest wholesalers in the US – McKesson Corporation merging with AmeriSource Health Corporation and Cardinal Health with Bergen-Brunswig.[42] The $2.25 billion acquisition by McKesson of AmeriSource would have combined the largest and fourth largest full service wholesale distributors of prescription drugs in the US and Canada. The $ 2.5 billion acquisition of Bergen Brunswig Corporation by Cardinal Health, Inc. would have combined the nation's largest supplier of pharmaceuticals to the managed care market and second largest wholesale distributor of pharmaceuticals with the nation's third largest wholesale distributor of prescription drugs, over-the-counter pharmaceutical products and health and beauty aids with the country's largest supplier. The FTC filed the two actions in district court in March 1998, alleging that if the mergers had been permitted, the two surviving firms would have controlled over 80 percent of the prescription drug wholesaling market and would significantly reduce competition on price and services. The case was litigated for approximately seven weeks. The court granted the Commission's motion blocking the proposed acquisitions on July 31, 1998. Subsequently, the parties abandoned the transactions.

As in most merger cases, definition of the relevant product market was a hotly contested issue. The FTC allege that the relevant market consisted of the cluster of services provided by drug wholesalers to institutional customers (e.g., hospitals) and retail pharmacies, including warehousing, distribution, and other value-added services. The defendants argued for a broader market that would included such other means of distribution as direct purchases from manufacturers and self-warehousing. Addressing the key question of whether customers had economically viable substitutes for wholesale distribution services, the court found that hospitals and independent drugstores would not turn to purported substitutes – primarily direct delivery and self-warehousing– to defeat an anticompetitive price increase, adopting the narrower market that the FTC asserted. The court, observing that different classes of customers have varied ability to substitute the services currently provided by wholesalers, concluded that the majority of Defendants' customers cannot replicate the wholesalers' services themselves nor obtain them from any other source or supplier. The court relied not only on testimony from customers, but also on defendants' documents

reflecting that they did not view the other forms of distribution to be viable competitors or substitutes. In sum, the court relied on the practical, rather than the theoretical, boundaries of substitutability to define the relevant product market.

The court opinion also provided an detailed and thoughtful analysis of the timeliness, likelihood, and sufficiency of entry. One issue that arose during trial was whether there was some form of regulatory relief that could be imposed to ameliorate the anticompetitive effects and to permit the mergers to occur. The parties pledged not to increase prices and to pass on 50 percent of any costs savings resulting from the merger. The FTC argued that involving the court as a regulator of prices would be a "second best" solution to continued competition among the four firms, would be unsound antitrust policy, and was contrary to law. The court agreed with the FTC position, finding that resorting to a "price cap" would deprive consumers of the lower prices that would result from competition.

In several recent merger cases, the FTC considered acquisitions of patents and related technology where the merging firms were either the only two, or two of only a few, firms capable of innovating in high-tech markets. Many of the Commission's pharmaceutical merger cases involve the acquisition of intellectual property and relevant product markets defined as innovation markets. Innovation markets arise from the recognition that future competition can be harmed by a reduction in research and development.[43] In industries where the main focus of competition is the development of new technologies rather than price competition, antitrust principles will apply, and the competitive rivalry must be protected. If too much of the ability to innovate in a relevant market is accumulated in one entity, and substitutes are lacking, competition will suffer. The FTC/DOJ Merger Guidelines recognise that a transaction may lessen competition in such non-price attributes as "product quality, service or innovation."[44]

An interesting example of an innovation market merger is the FTC's 1995 enforcement action in Glaxo/Wellcome.[45] In that case, the FTC alleged harm to innovation markets where the merging parties, Glaxo and Burroughs Wellcome, were the two firms furthest along in developing an oral drug to treat migraine headaches. Current migraine drugs were available only in injectable form and were not sufficiently substitutable to be included in the relevant market. According to the complaint, both Glaxo and the acquired firm, Wellcome, competed to develop the new drugs, and the expectation was that the drugs would compete with each other after they were developed. Barriers to entry, based on the necessity of completing the FDA approval, were alleged to be high. The Commission alleged that the acquisition would eliminate actual competition between the two companies in researching and developing migraine remedies. The Commission also alleged that the acquisition would reduce the number of research and development tracks for these migraine treatments and increase Glaxo's unilateral ability to reduce research and development of these oral drugs. Glaxo allegedly would have had the incentive to do so because the remaining research and development effort would presumably produce a monopoly product until another firm could complete the FDA approval process many years later.

Glaxo and Wellcome reached a consent agreement with the FTC that allowed them to proceed with the merger. The agreement required the combined firm to divest Wellcome's assets related to the research and development of the oral drug, including patents, technology, manufacturing information, testing data, research materials and customer lists. The assets also included inventory needed to complete all trials and studies required to obtain FDA approval. The order imposed significant obligations on Glaxo to assist the acquirer of these divested assets in its efforts to continue the research and development successfully. Glaxo had to provide information, technical assistance and advice to the acquirer about the research and development efforts, including consultation with and training by Glaxo employees knowledgeable about the project. It appears that the remedy succeeded, as both Glaxo and the acquirer, Zeneca Pharmaceuticals, now have oral migraine drugs on the market. With the required assistance from Glaxo, Zeneca received complete FDA approval within 15 months after the FTC approved Glaxo's application to divest to that firm.

(4.8) Have pharmaceutical manufacturers sought to integrate into downstream components of the health industry, such as hospitals, insurers, pharmacies or so-called pharmacy benefits managers ("PBMs")? Have you found such actions to be anti-competitive? What remedies have you imposed?

When Merck and Co., Inc., acquired Medco Containment Services in 1993, it became the first pharmaceutical manufacturer to vertically integrate into the then relatively new business of pharmacy benefit management. Since then several other pharmaceutical companies have joined with PBMs. On August 27, 1998, the Commission accepted an agreement with Merck to resolve antitrust concerns regarding the 1993 Medco acquisition.[46]

Medco is the largest PBM in the US. As an intermediary between pharmaceutical companies and managed care plans, Medco negotiates with pharmaceutical manufacturers, including Merck, concerning placement of drugs on the Medco formulary - a list of drugs that it gives to pharmacies, physicians, and third-party payers to guide them in prescribing and dispensing prescriptions to health plan beneficiaries. Medco also negotiates rebates, discounts, and prices that pharmacy benefit plans managed by Medco pay for pharmaceutical products. According to the complaint, Medco thereby influences the prices of pharmaceutical products and the availability of such products under its pharmacy benefit plans. The complaint alleges that the merger tended to cause a reduction in competition for pharmaceutical products stemming from Medco's favouritism toward Merck drugs in the formularies of drugs available under the plans that it manages. In addition, there were concerns raised because the merger had made it possible for Medco to provide Merck with sensitive pricing information obtained from Merck's competitors, with the potential for fostering collusion among manufacturers. The complaint also alleges likely anticompetitive effects in eliminating Medco as an independent negotiator of pharmaceutical prices with manufacturers and a likely reduction of other manufacturers' incentives to develop innovative pharmaceuticals.

The consent order requires Merck-Medco to maintain an "open formulary" – a formulary including drugs selected and approved by an independent committee consisting of physicians and pharmacologists with no financial interest in Merck. It also requires that Merck cause Medco to accept all discounts, rebates, or other concessions offered by other manufacturers on the open formulary, and to accurately reflect the impact of these factors on price in establishing relative rankings of products on that formulary. An addition order provision prohibits Merck and Medco from sharing "non-public information" with each other, including information concerning other firm's bids, proposals, contracts, prices, rebates, discounts, and other terms of sale.

In 1995, the FTC challenged Eli Lilly and Company's acquisition of PCS, another PBM, from the McKesson Corporation,[47] and pledged to monitor the industry carefully to determine if further action against manufacturer-pharmacy benefit manager integrations was necessary. As in Merck/Medco, the complaint alleged that Lilly's ownership of PCS would allow Lilly to favor its own drugs on PCS's formularies. The consent order settling the charges requires Lilly/PCS to maintain an open formulary.

(4.9) What cases of abuse of dominance have you addressed. In what ways can a pharmaceutical firm with a dominant position reduce competition from rivals?

In a complaint seeking injunctive and other relief filed on December 23, 1998 in US. District Court for the District of Columbia, the Commission charged Mylan Laboratories and three other companies, Profarmaco S.R.L., Cambrex Corporation, and Gyma Laboratories, with restraint of trade, monopolization and conspiracy to monopolize the market for two generic anti-anxiety drugs, lorazepam and chlorazepate.[48] Thirty-four state Attorneys General filed a companion complaint.[49]

Lorazepam, the generic version of the brand-name product Ativan, is used to treat anxiety, agitation, insomnia and panic disorder, and as a preoperative sedative. Chlorazepate, the generic version of Tranxene, is used to treat anxiety, as well as hypertension, and in adjunct therapy for nicotine and opiate withdrawal. Doctors in the United States annually issue over three million chlorazepate prescriptions, and over 18 million lorazepam prescriptions.

According to the FTC's complaint, Mylan, the nation's second largest generic drug manufacturer, sought to restrain competition through exclusive licensing arrangements for the supply of the raw material necessary to produce the lorazepam and chlorazepate tablets, allowing Mylan to dramatically increase the price of lorazepam and chlorazepate tablets. The FTC's complaint alleges, *inter alia*, that Mylan sought and obtained agreements with Profarmaco and its agent and US. distributor, Gyma. The agreements provided that Profarmaco would supply exclusively to Mylan for ten years the active pharmaceutical ingredients (API) used in Mylan's manufacture of the two drugs and, in return, Mylan would share its profits from the sale of these drugs with Profarmaco. In 1997, Profarmaco supplied through Gyma over 90 percent of the lorazepam API and 100 percent of the chlorazepate API to generic manufacturers in the US market.

The FTC complaint charges that, as a result of the exclusive agreements and other acts by the defendants, Mylan effectively monopolised the markets for the two drugs (and their APIs) and, thereupon, raised the prices of lorazepam from $11.36 to approximately $377.00 per bottle of 500 tablets, and of chlorazepate from $7.30 to approximately $190.00 per bottle of 500 tablets. The complaint alleges that competitive entry to defeat these prices increases is not likely to be timely and effective because entry into these markets is subject to FDA regulation and takes an average of 18 months, but can take even longer.

After the parties received notice of the FTC's complaint, they announced that they would drop the exclusivity and profit-sharing provisions of the agreement. The parties' action does not remedy the harm already done to consumers nor does it guarantee that the parties will not continue to pursue the strategy embodied in their agreements. To remedy the harm caused to consumers by the anticompetitive conduct of the defendants, the FTC has asked the court to enjoin the parties from their allegedly unlawful conduct, to rescind the exclusive agreements, and to order the disgorgement and restitution of an amount exceeding $120 million plus interest, which represents the estimated revenues resulting from the defendants' anticompetitive agreements and conduct.

On July 7, 1999, the court denied defendants' motions to dismiss the FTC complaint, finding that § 13(b) of the FTC Act allows the Commission to seek permanent injunctive relief for violations of "any provision of law" enforced by the FTC, and allows the Commission to seek monetary remedies such as the disgorgement of profits, which the complaint in this case seeks. Trial is scheduled for early 2001.

NOTES

1. The rules governing extensions of patent periods are to be found in the Commission's ruling (EEC) 1768/92 of 18 June 1992 on the introduction of supplementary protection for medicinal products. In Sweden, new rules in this sphere came into force on 1 January 1994 under a new law (1993:1406) amending the Patents Act (1967:837). Further legislative amendments were introduced on 1 January 1995 (1994:1511).

2. U.S. International Trade Commission, Review of Global Competitiveness in the Pharmaceutical Industry ("ITC report 1999"), Publication 3172, April 1999, at 3-4. An "ethical" product is on that is available only through prescription and can be either brand name or generic.

3. Id. at 3-5

4. *See generally* www.pharma.org/facts/index/html.

5. Standard and Poor's, Industry Surveys - Healthcare: Pharmaceuticals , Dec. 16, 1999 ("Standard and Poor's Industry Survey") at 22.

6. Id. at 24.

7. 35 U.S.C. 154 (a) (2)(1994). To accommodate the transition from a 17-year to a 20-year patent term, measured from the date of filing and not issuance, the Uruguay Round Agreements Act provides that any patent that was either in force on, or resulted from an application filed prior to, June 8, 1995 (the effective date of the change in the patent term) will have a term that is 17 years from the year of issuance or 20 years from the date of filing, whichever is longer.

8. Public Law No. 105-115.

9. See Susan DeSanti, "The Intersection of Antitrust and Intellectual Property Issues: A Report from the FTC Hearings," Remarks before the Conference on Antitrust for High-Tech Companies Business Development Associates, San Francisco, February 2, 1996 (www.ftc.gov./speeches/other/desanti1.htm).

10. See *Ciba-Geigy Ltd.*, Dkt C- 3275 (consent order, March 29, 1997).

11. ITC report 1999, *supra* note 1, at 3-13. Using 14.9 years as the base, the approval process consists of an average of 6.0 years for pre-clinical testing of the drug involving laboratory and animal testing of a chemical to gauge its safety for testing in humans, 6.7 years for the FDA-required clinical trials, and 2.2 years for final FDA approval phase. During the 1990s the FDA took several steps to speed approval of new drugs with successful results. Id. at 3-13 - 3-15. According to one trade association, the FDA as able to cut drug approval times in half during 1993-1997. See Pharmaceutical Research and Manufacturs of America, 1999 Pharmaceutical Industry Profile, Ch.3, at 6.

12. The FDA's Internet site has further information under "New Drug Development and Review" at http://www.fda.gov/cder/handbook/index.htm.

13. 21 U.S.C. 355(j)(2)(A).

14. 21 U.S.C. §§ 321-393.

15. 21 U.S.C. § 352(i).

16. 21 U.S.C. 360 aa-ee.

17. The law provides a guarantee of 7 years of market exclusivity.

18. A link to the paper can be found at www.hiaa.org.

19. See, e.g., Standard and Poor's Standard and Poor's Industry Survey, *supra* note 5, at 22, stating that managed care has historically favored drug therapies because of their cost-effectiveness.

20. Therapeutic interchanges involve the dispensing of a different drug having a different chemical composition than the one prescribed within the same therapeutic class. Step-care therapy requires that physicians follow a sequence of treatments for a given condition, usually starting with the lowest-cost treatment and progressing to higher-cost treatments only if previous treatments are not effective. Drug utilization review involves retrospective monitoring of physicians' prescribing patterns to ensure that the lowest cost/highest quality prescription drugs are made available to plan enrollees. Generic substitution programs require substitution of generic for brand-name drugs.

21. Nonlisted drugs carry higher co-payments than listed drugs.

22. Standard and Poor's, *supra* note 5, at 11.

23. GAO/HEHS-96-45 Pharmacy Benefit Managers at 7.

24. Novartis Pharmacy Benefit Report: 1997 Trends and Forecasts at 13.

25. The VA's formulary and other information about VA's drug benefit is available at www.dppm.med.VA.gov.

26. Best practice guidelines are clinical practice guidelines for the treatment of disease that reflect the opinion and experience of experts in the specific field. Disease management programs are mostly aimed at chronic diseases and at efficient and effective treatment of a disease, integrating various treatment components. Provider profiling consists of ongoing review, analysis and sharing of prescribing patterns for an individual prescribers and their peers with the aim of modifying physician practice patterns to reflect those of his/her peers without compromising quality patient care. Dynamic medication use committees are intended to enhance traditional pharmacy and therapeutic committee functions, i.e., the creation and maintenance of formularies through dynamic, systematic analyses and include ongoing adverse event monitoring and trending and applied research involving therapeutic outcomes.

27. Standard and Poor's, *supra* note 9 at 11.

28. 15 U.S.C. § 1013 (b).

29. See, e.g., Group Life & Health Insurance Co. v. Royal Drug, 440 U.S. 205 (1979).

30. See, e.g., *California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.*, 445 U.S. 97 (1980).

31. U.S. Department of Justice and Federal Trade Commission, Horizontal Merger Guidelines (April 2, 1992).

32. Hoechst-Andrx, Docket No. 9293.

33. Abbot-Geneva, File No. 981-0395.

34. See www.ftc.gov/bc/rxupdate.htm for a complete listing of such cases.

35. C-3822 (consent order issued August 11, 1998).

36. Revised Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care, August 26,1996. See www. ftc.gov./bc/guidelin.htm.

37. See www. ftc.gov./antitrust.

38. In the Preamble, "competitors" are defined to include both actual and potential competitors, and a "competitor collaboration" is defined as "a set of one or more agreements, other than merger agreements, between or among competitors to engage in economic activity, and the resulting economic activity."

39. In United States v. Proctor & Gamble Co. (Civ 90-5144, 8/7/90), the DOJ filed suit to stop defendants – the Proctor & Gamble Co. ("P&G"), which produces and sells the over-the-counter ("OTC") stomach remedy Pepto Bismol, and Rhone-Poulenc Rorer, Inc. ("Rorer") which produces and sells the OTC Maalox line of stomach remedies, from consummating an agreement pursuant to which P&G would acquire the exclusive right to market and distribute, and an option to purchase the assets used to manufacture, the OTC Maalox line of stomach remedies from Rorer. The DOJ alleged that, if consummated, the transaction would eliminate competition in the U.S. between P&G and Rorer, as well as substantially lessen competition in the U.S. OTC stomach remedies market. P&G and Rorer announced on August 23, 1990, their intention to terminate their proposal that P&G acquire the rights to Rorer's Maalox line of OTC stomach remedies. On August 27, 1990, the parties agreed to, and submitted to the court, a Stipulation of Voluntary Dismissal.

40. See, e.g., Roche Holding Ltd, C-3809 (Feb. 25, 1998, consent order). The FTC charged that Roche Holding's proposed acquisition of Corange Ltd. would eliminate actual competition between the two firms in the markets for research, development, manufacture and sale of cardiac thrombolytic agents and of DAT reagents use in workplace testing. The complaint alleged that the acquisition would increase the likelihood that Roche, as the producer of the two safest and most effective agents in the U.S., would unilaterally exercise market power in the market for cardiac thrombolytic agents and the likelihood of collusion or coordinated action among the remaining firms in the highly-concentrated DAT reagents market.

41. See, e.g., Zeneca Group plc, C-3880 (March 25, 1999, consent order). The FTC alleged that Zeneca's proposed acquisition of Astra allegedly was likely to lead to anticompetitive effects by eliminating Zeneca as an actual potential competitor in the US market for long-acting local anesthetics. Astra is the leading supplier in the US and worldwide, and is one of only two companies with FDA approval for the manufacture and sale of long-acting local anesthetics in the US. While Zeneca was not then producing or selling long-acting anesthetics, it entered into an agreement with Chiroscience Group plc, to market and assist in the development of

levobupivacaine, a new long-acting local anesthetic that allegedly represents the only potential new competition in the relevant market for the foreseeable future.

42. FTC v. Cardinal Health, Inc., and FTC v. McKesson Corp., 12 F. Supp. 2d 34 (D.D.C. 1998).

43. In the FTC/DOJ 1995 Antitrust Guidelines for the Licensing of Intellectual Property, www.ftc.gov/bc/guidelin.htm, an innovation market is defined as follows:

An innovation market consists of the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development. The close substitutes are research and development efforts, technologies, and goods that significantly constrain the exercise of market power with respect to the relevant research and development, for example by limiting the ability and incentive of a hypothetical monopolist to retard the pace of research and development. The Agencies will delineate an innovation market only when the capabilities to engage in research and development can be associated with specialised assets or characteristics of specific firms.

. Id. at 11.

44. Merger Guidelines § 0.1 n.6.

45. Glaxo PLC, 119 FTC 815 (June 14, 1995).

46. C-3853 (Feb. 18, 1999, consent order).

47. C-3594 (July 28, 1995, consent order). The order was recently set aside because Lilly sold PCS to Rite Aid Corp. Eli Lilly/PCS, C-3594 (July 28,1995).

48. FTC v. Mylan Laboratories et. al., Civil Action No. 1:98CV3114 (D.D.C., filed December 22, 1998; amended complaint filed February 8, 1999).

49. Civil Action No. 1:98CV3115 (D.D.C.), filed December 22, 1998; amended complaint filed February 8, 1999.

APPENDIX 1-1

PRODUCT LINE SALES AND PROFITS FOR MAJOR PHARMACEUTICAL COMPANIES

COMPANY	PRODUCT CATEGORY	1998 SALES (MIL. $)	1998 PROFITS (MIL. $)
Abbott Labs	Pharmaceuticals	2,601	1,402
American Home Products	Pharmaceuticals	8,902	2,488
Glaxo Wellcome	Pharmaceuticals	13,230	3,043
Johnson & Johnson	Pharmaceuticals	8,562	3,016
Pfizer	Pharmaceuticals	12,230	3,351
Pharmacia & Upjohn	Pharmaceuticals	6,127	691
Schering-Plough	Pharmaceuticals	7,342	2,261
SmithKline Beecham	Pharmaceuticals	7,701	2,010
Warner-Lambert	Pharmaceuticals	5,604	1,474

Source: Standard & Poor's, Healthcare: Pharmaceuticals Industry Survey

APPENDIX 1 -2

RESEARCH & DEVELOPMENT EXPENDITURES

COMPANY	1998 MIL. $	% OF SALES
Abbott	1,222	10
American Home Products	1,655	12
Bristol-Myers Squibb	1,577	9
Eli Lily	1,739	19
Glaxo Wellcome	1,927	15
Johnson & Johnson	2,269	10
Merck	1,821	7
Pfizer	2,279	17
Pharmacia & Upjohn	1,199	18
Schering-Plough	1,007	12
SmithKline-Beecham	1,508	11
Warner-Lambert	877	9

Source: Standard & Poor's, Healthcare: Pharmaceuticals Industry Survey (December 16, 1999)

APPENDIX 1-3

STANDARD INDUSTRY SURVEYS & P00RS

Healthcare,
Pharmaceuticals

DECEMBER 16, 1999 / HEALTHCARE: PHARMACEUTICALS THIS ISSUE REPLACES THE ONE DATED JULY 29, 1999. THE NEXT UPDATE OF THIS SURVEY IS SCHEDULED FOR JUNE 2000.
Herman -Saftlas
Pharmaceuticals Analyst

(Excerpt from CURRENT ENVIRONMENT, pages 4-7)

Yet new products in the industry's R&D pipeline are relatively sparse. Part of the problem reflects more competition from biotechnology drugs that have eclipsed conventional drugs in many therapeutic categories. At the same time, FDA approvals of breakthrough products (defined as new molecular entities, or NMEs), have been in a downtrend in recent years. Pharmaceutical NMEs totaled 30 in 1998, down from 39 in 1997 and 53 in 1996.

but long-term fundamentals remain sound

Despite its problems, the domestic pharmaceutical industry is still one of the healthiest and highest-margined industries in the United States. Historically, the industry has rejuvenated itself by developing premium-priced breakthrough therapies that made older drugs obsolete and opened up entirely new markets, and we fully expect that this pattern to persist.

An estimated 50 000 scientists employed by US. pharmaceutical companies are currently researching several thousand new compounds to treat cancer, heart disease, AIDS, Alzheimer's disease, and many other diseases. More than one thousand new drugs are now in the industry's R&D pipeline to treat cancer, heart disease, AIDS, mental illness, and other ailments.

The overall drug discovery process is undergoing a transformation, thanks to major advances in biomedical science. New processes have been invented that should help scientists develop growing numbers of compounds that can be used in the battle against major diseases in the years ahead. Some of the new methods that hold much future promise include rational drug design, combinatorial chemistry, and high throughout screening. (See this issue's "How the Industry Operates" section for more details on these methods.)

Strategic alliances proliferate

Rather than engage in costly mergers and acquisitions, many pharmaceutical companies firms have chosen alternative means of maximising product sales. These include: entering into co-promotion deals with other drugmakers; expanding product offerings by manufacturing and/or distributing drugs developed by other firms (a process known in-licensing); and developing new biotech products through research collaborations with smaller firms.

The industry has witnessed a flurry of co-marketing deals as drug companies pool their sales forces to make a greater impact. Most leading drugmakers are also stepping up their joint venture and licensing activities with smaller biotechnology companies to empower their R&D programs. According to Burrill & Co., a private merchant bank, the value of drug biotech partnering deals (in up-front payments and equity investments) was nearly $3.7 billion in the first nine months of 1999.

These deals are seen as a "win-win" situation for all parties. For large companies, collaborations provide limited-risk access to cutting-edge research expertise in areas where they're weak. For the smaller firms, these arrangements provide cash to finance ongoing research, manufacturing, and marketing efforts. These collaborations are becoming relatively more important to large drug companies, whose in-house pipelines are less promising than several years ago.

Recent performance in key ethical sectors

In this section, we review this market's key therapeutic categories and examine their recent performance, principal products, and developments affecting each sector.

Central nervous system drugs

Representing the largest single ethical drug segment in the United States, central nervous system (CNS) drugs are also one of the industry's fastest-growing sectors. Accounting for about. 21 percent of the US retail pharmacy market, sales of CNS drugs rose 14 percent in the 12 months ended August 1999, based on data provided by IMS Health Inc., a Connecticut-based market research firm specialising in pharmaceuticals.

CNS drugs include various narcotic and non-narcotic analgesics, sedatives, anti-anxiety agents, antidepressants, anti-epileptics, and non-steroidal anti-inflammatory drugs (NSAIDs, which are prescribed mainly for arthritis). This sector also includes drugs for Alzheimer's disease, Parkinson's disease, and related neurological disorders.

Antipsychotics

One of the strongest CNS segments has been antipsychotics, whose overall US market is expected to expand from about $2.2 billion in 1998 to $3.5 billion in 2000. The worldwide antipsychotic market is projected to approach $six billion by 2002, up from an estimated $four billion in 1999.

The leading product is this class is Johnson & Johnson's Risperdal, with one third of the US market as of September 1999. Steadily gaining is Eli Lillys Zyprexa, with about 28 percent of the market. Recently, Zyprexa prescriptions have grown more rapidly than Risperdal, helped by the drug's ability to treat all major symptoms of schizophrenia without the often-severe side effects associated with some of the older medications. Lilly recently received what is called an "approveable" letter from an FDA advisory committee, allowing Zyprexa to be used for the treatment of bipolar (or manic-depressive) illness. The drug is also being studied for use in treating Alzheimer's disease. Other important antipsychotics include Novartis's Clozaril and AstraZeneca's Seroquel.

Selective serotonin reuptakc inhibitors (SSRIs). Total US retail prescriptions written for SSRIs in September 1999 were 9.9 percent above September 1998, based on IMS data. Greater acceptance of depression as a drug-treatable illness, several successful new products, and expanded insurance reimbursement have all contributed to more widespread use of SSRIs in recent years.

Eli Lilly's Prozac still leads this antidepressant class with about a 17 percent market share as of September 1999. However, its market position has eroded in recent years, as new rivals with enhanced benefits have nudged it from its former pre-eminent position. Prozac sales dropped 13 percent during the third quarter of 1999 and are expected to show further erosion in 2000 as well.

Other leading antidepressants that have exhibited good growth in recent years include: Pfizer's Zoloft (with a 16 percent market share), SmithKline Beecham's Paxil (14 percent), and American Home Products's Effexor (six percent).

Although it currently holds only a small portion of the total market, Forest Laboratories Inc.'s Celexa antidepressant is exhibiting vigorous growth and is rapidly moving up to the big leagues. As of September 1999, Celexa accounted for about 5.4 percent of all new SSRI prescriptions, up from less than one percent a year earlier. This drug, which is being co-marketed by Warner-Lambert, is benefiting from a number of purported advantages over conventional antidepressants. These include a lower incidence of sexual dysfunction, reduced negative interactions when taken with other prescription drugs, and more rapid onset of therapeutic action.

* **Migraine treatments**

The migraine market is on the verge of substantial growth in the years ahead. It is estimated that close to ten percent of the general population suffers from migraines, but that fewer than half of them treat their condition with prescription drugs. A substantial percentage of these individuals would benefit from treatment.

At present, the $1.5 billion world-wide market is dominated by Glaxo Wellcome's Imitrex, with roughly half of the US market as of September 1999. The overall migraine drug market is expected to triple over the next four years, augmented by direct-to-consumer (DTQ advertising campaigns that will accompany the launch of several new products. These campaigns should significantly raise the proportion of migraine sufferers receiving treatment. Four new drugs targeting this market include: AstraZeneca's-Zomig (with a nine percent market share in September 1999), Merck's Maxalt (seven percent), and Elan Corp.'s Midrin (three percent). Warner-Lambert's Relpax is being readied for this market, subject to FDA approval. Relpax is believed to have better efficacy than Imitrex.

* **Antiarthritics**

The principal drugs used to treat osteoarthritis, a painful inflammatory condition affecting close to 20 million Americans, are nonsteroidal anti-inflammatory drugs (NSAIDs). The outstanding success of a new wave of NSAIDs have breathed new life into a sector that had previously shown only modest growth. Bolstered by the new drugs called COX-2 inhibitors, total anti-arthritic prescriptions in September 1999 were about 21 percent higher than those of September 1998.

The new products are Searle's Celebrex (with a 21 percent market share) and Merck's Vioxx (eight percent). These drugs are potent treatments for arthritis and pain, without the adverse gastrointestinal side effects associated with existing NSAIDs. Merck's lower market share reflects its launch in late May 1999, about six months after Celebrex. The rest of the NSAID market is fairly crowded with older drugs, most with market shares of less than three percent.

Cardiovasculars

Cardiovascular drugs comprise the second-largest therapeutic segment, with about 18 percent of the US retail market. This broad-based group includes treatments for heart attacks, hypertension, angina, arrhythmia, and elevated cholesterol levels.

Cardiovasculars; have shown decent growth, with sales for the 12 months through August 1999 up 11 percent from the preceding 12-month period. Heart drugs represent a high priority for many leading drug companies, given the huge size of the heart-patient market and the life-saving potential of these therapies. Plus, from a purely business standpoint, these are patients that need to remain on medication for the rest of their lives.

Cholesterol drugs

The cholesterollowering market is expected to exhibit vigorous growth in the years ahead, as people become more aware of the dangers of elevated blood cholesterol. Total prescriptions written for this class in September 1999 were 20 percent above the year-earlier level.

The American Heart Association has estimated that over 50 percent of all American adults have elevated blood cholesterol counts. Persons with high cholesterol are initially advised to change their diets to low-fat foods and to lose weight through exercise. However, if these measures are unsuccessful, physicians often recommend drug therapies. Only about one-fifth of all persons who could benefit from these drugs are currently taking them.

The strongest performer in the cholesterol market has been Warner-Lambert's Lipitor. This drug has shown to be more efficacious than its rivals while maintaining an excellent side-effect profile. Sales of Lipitor are expected to rise from an indicated $3.4 billion in 1999 to more than $eight billion within the next five years. As of September 1999, Lipitor accounted for about 42 percent all new prescriptions for cholesterol reducers. Other leading cholesterol drugs include Merck's Zocor (21 percent of the market) and Bristol-Myers Squibb Co.'s Pravachol (14 percent).

* **Antihypertensives**

Affecting close to 60 million Americans, hypertension or high blood pressure is a generally symptomless condition that if left untreated can lead to stroke, aneurysm, heart attack, and kidney failure. A large number of drugs with different mechanisms of action are available to treat hypertension.

The largest-selling categories include calcium channel blockers, led by Pfizer's Norvasc, and ACE inhibitors, of which Merck's Vasotec/Vaseretic is the biggest seller. Older groups include products such as beta blockers, diuretics, vasodilators, and others.

The most recent wave of antihypertensives are angiotensin II antagonists, led by Merck's Cozaar/Hyzaar (with about a 50 percent market share of the angiotensin 11 market as of September 1999). Other leading drugs in this class include Novartis's Diovan/Diovan HCT (27percent) and Bristol-Myers's Avapro (15 percent). Bristol-Myers is expected to soon launch a new antihypertensive called Vanlev. This drug has a unique advantage in that it lowers both diastolic and systolic blood pressure (when the heart relaxes and contracts, respectively), whereas conventional antihypertensives lower only diastolic pressure. (In most cases, the diastolic number is the most significant.)

Gastrointestineffinetabolism agents

This large sector, which includes antiulcer drugs, diabetes compounds, antiobesity agents, oral contraceptives, and related drugs, accounted for 15 percent of US drug sales in the 12 months through August 1999, based on IMS data. Volume growth for most drugs in this class has been in only the single digits in recent years, reflecting the market's relative maturity and a rising proportion of inexpensive generics in the total mix. However, certain segments such as diabetes treatments are showing above-average growth.

*** Antiulcer drugs**

This $6.S billion US market comprises older H2 antagonists such as SmithKline Beecham's Tagamet and Glaxo Wellcome's Zantac, as well as newer proton pump inhibitors such as AstraZeneca's Prilosec - the largest-selling prescription drug in the world, with sales of more than $four billion in 1998.

Unlike rival H2 antagonists, Prilosec (accounting for 34 percent of all prescriptions in this class in September 1999) is a proton pump inhibitor combined with an antibiotic. It's used to eradicate helicobacter pylori, the bacterium responsible for recurrent peptic ulcers. Another popular proton pump antiulcer drug is Abbott Laboratories's Prevacid, which has a 22 percent market share.

Diabetes drugs. This $3.5 billion market is expected to quadruple over the next several years, fueled by a growing patient population and new breakthrough treatments. Most of the growth should reflect rapid expansion in sales of new drugs for Type 2, or adult-onset, non-insulin-dependent, diabetes. Typically affecting persons who are over 40 or clinically obese, this condition is characterised by the body's inability to make enough insulin or to use it properly. The number of patients suffering from Type 2 diabetes has increased significantly in recent years, to a large extent reflecting unhealthy American diets.

The industry leader in this marker is Bristol-Myers Squibb's Glucophage (with about 32 percent of the market in September 1999), followed by Pfizer's Glucotrol (15 percent). Recent entrants include SmithKline Beecham's Avandia and Eli Lilly's Actos.

Type I diabetes is a serious condition in which the body does not produce any insulin. Daily injections of the hormone are necessary for the patients survival. A number of companies are now working on newer non-injectible insulin products, including oral and inhaled formulations.

APPENDIX 2

Parallel Imports

The following paragraphs briefly summarise US law in each of the three major areas of intellectual property rights.

(1) Copyright

The Copyright Act, 17 U.S.C. 106 *et seq.*, provides protection against parallel imports manufactured abroad and imported into the United States without the consent of the right holder. The Supreme Court decision in the Quality King case clarifies that parallel import protection is not available for copyrighted works that are manufactured in the United States, then exported and re-imported.[1] The Court's opinion, however, turns on its interpretation of the first sale doctrine in section 109(a), which applies to copies "lawfully made under this title" (*i.e.*, made in the US). For this reason, works manufactured abroad, that are protected not under US copyright law but under foreign copyright law, do not fall within the purview of the ruling. Their importation is prohibited under 17 U.S.C. 602(a), which provides that "importation into the United States, without the authority of the owner of copyright under this title, of copies or phonorecords of a work that have been acquired outside the United States is an infringement of the exclusive right to distribute copies."

(2) Patent

i. Patent Act

United States patent law recognises that the rights of the patent holder include the right to prevent unauthorised importation of patented inventions. Section 271 of title 35 of the United States Code provides, in part, that "whoever without authority ¼ imports into the United States any patented invention during the term of the patent thereof, infringes the patent." The first sale doctrine applies in the patent context, but its applicability to the parallel import situation is limited by the requirement that the patent holder must have authorized the sale of such imports within the United States. In other words, the holder of a United States patent may maintain an action for patent infringement against an importer who acquired its products from a foreign licensee or distributor that was not authorised by the patentee to import the patented technology into the United States. See Boesch v. Graff, 133 U.S. 697 (1890); Sanofi, S.A. v. Med-Tech Veterinarian Prod., Inc., 220 U.S.P.Q. 416 (D.N.J. 1983).

ii. Prescription Drug Marketing Act

US law effectively prevents parallel imports (except in limited emergency medical situations). The Prescription Drug Marketing Act of 1987 prohibits the reimportation of prescription drugs except by the manufacturer. See 21 U.S.C. §§ 381(d)(1) & (2) (no prescription drug "which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug"). In passing this statute, Congress found that "[t]he existence and operation of a wholesale submarket, commonly known as the "diversion market," prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases;" that reimported drugs "are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping;" and that "the ready market for prescription drug reimports has been the catalyst for a continuing series of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs." P.L. 100-293, § 2 (1988), reprinted in

notes accompanying 21 U.S.C. § 353. The legislative history of this provision elaborates on these concerns. See Prescription Drug Marketing Act of 1987, S. Rep. 100-303, p. 58 (Mar. 18, 1988).

(3) Trademark

i. Genuine Goods Exclusion Act (19 U.S.C. § 1526(a))

This Act prohibits importation of a product "that bears a trademark owned by a citizen of the United States, and is registered in the [PTO] unless written consent of the owner of such trademark is produced." Treasury Department regulations upheld by the Supreme Court provide an exception where the foreign and domestic trademark owners are the same or subject to common control. See 19 C.F.R. 133.21(c)(1) and (2); K-Mart v. Cartier, Inc., 486 U.S. 281 (1988). Where they are not the same or subject to common control, section 1526(a) bars the parallel imports.

ii. Lanham Act (15 U.S.C. § 1124)

The Lanham Act provides a second statutory basis for protection against parallel imports that are physically or materially different from the products sold under the trademark in the United States. Lever Bros. Co. v. United States, 981 F.2d 1330 (D.C. Cir. 1993). In the context of a case under Section 337 of the Trade Act, the US. International Trade Commission has prohibited parallel imports of a trademarked product based on a finding of material differences, and the Administration allowed the order to enter into effect. Inv. No. 337-TA-380 (1997). New Treasury regulations establish a procedure by which Customs will allow importation of physically different products, provided that they are properly labeled as such. 64 Fed. Reg. 9058 (1999).

APPENDIX 3

Patent Term Extension Under 35 U.S.C. 156

The right to a patent term extension based upon regulatory review is the result of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 St. 1585 (Codified at 21 U.S.C. 355(b),(j),(l), 35 U.S.C. § 156, 271,282) (Hatch-Waxman Act). The act sought to eliminate two distortions to the normal "patent term produced by the requirement that certain products must receive premarket regulatory approval." Eli Lilly & Co. v. Medtronic Inc., 496 U.S. 661, 669, 15 USPQ2d 1121, 1126 (1990). The first distortion was that the patent owner loses patent term during the early years of the patent because the product cannot be commercially marketed without approval from a regulatory agency. The second distortion, occurred after the end of the patent term because competitors delayed entry into the market because they were not allowed to begin testing and performing other activities necessary for their own approval process until the patent had expired.

The part of the act codified as 35 U.S.C. 156 was designed to create new incentives for research and development of certain products subject to premarket government approval by a regulatory agency. The statute enables the owners of patents on certain human drugs, food or color additives, medical devices, animal drugs, and veterinary biological products to restore to the terms of those patents some of the time lost while awaiting premarket government approval from a regulatory agency.

The rights derived from extension of the patent are limited to the approved product. 35 U.S.C. 156(b). Accordingly, if the patent claims other products in addition to the approved product, the exclusive patent rights to the additional products expire with the original expiration date of the patent. In exchange for extension of the term of the patent, Congress legislatively overruled Roche Products v. Bolar Pharmaceuticals, 733 F.2d 858, 221 USPQ 937 (Fed. Cir. 1984) as to products covered by 35 U.S.C. 271(e) and provided that it shall not be an act of infringement, for example, to make and test a patented drug solely for the purpose of developing and submitting information for an Abbreviated New Drug Application (ANDA). 35 U.S.C. 271(e)(1). See Donald O. Beers, Generic and Innovator Drugs: A Guide to FDA Approval Requirements, Fourth Edition, Aspen Law & Business, 1995, 4.3[2] for a discussion of the Hatch-Waxman Act and infringement litigation. Furthermore, Congress provided that an ANDA cannot be filed until five years after the approval date of the product if the active ingredient or a salt or ester of the active ingredient had not been previously approved under section 505(b) of the Federal Food, Drug and Cosmetic Act. 21 U.S.C. 355(j)(4)(D)(ii). See also, Lourie, Patent Term Restoration: History, Summary, and Appraisal, 40 Food, Drug and Cosmetic L. J. 351, 353-60 (1985). See also Lourie, Patent Term Restoration, 66 J. Pat. Off. Soc'y 526 (1984).

On November 16, 1988, 35 U.S.C. 156 was amended by Public Law 100-670, essentially to add animal drugs and veterinary biologics to the list of products that can form the basis of patent term extension. Animal drug products which are primarily manufactured through biotechnology are excluded from the provisions of patent term extension.

On December 3, 1993, 35 U.S.C. 156 was further amended to provide for interim extension of a patent where a product claimed by the patent was expected to be approved, but not until after the original expiration date of the patent. Public Law 103-179, Section 5.

Patent term extension under 35 U.S.C. 156 restores a portion of the patent term lost as a result of regulatory agency premarketing testing and approval requirements for human drugs, food additives, color additives, medical devices, animal drugs, and veterinary biological products. Under specified

circumstances, the statute authorises the extension of the term of a patent which claims these federally regulated products or methods of using or manufacturing these federally regulated products.

An application for the extension of the term of a patent under 35 U.S.C. 156 must be submitted by the owner of record of the patent or its agent within the sixty day period beginning on the date the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. See 35 U.S.C. 156(d)(1). The Patent and Trademark Office initially determines whether the application is formally complete and whether the patent is eligible for extension. The statute requires the Commissioner of Patents and Trademarks to notify the Secretary of Agriculture or the Secretary of Health and Human Services of the submission of an application for extension of patent term which complies with the section within sixty days and to submit to the Secretary a copy of the application. Not later than thirty days after receipt of the application from the Commissioner, the Secretary will determine the length of the applicable regulatory review period and notify the Commissioner of the determination. If the Commissioner determines that the patent is eligible for extension, the Commissioner calculates the length of extension for which the patent is eligible under the appropriate statutory provision and issues an appropriate Certificate of Extension.

EUROPEAN COMMISSION

1. General remark

The questions in the "Guide for country submissions" are mainly addressed to Member States. In its written submission the European Commission's Directorate General (DG) for Competition will therefore comment only on questions which are directly related to competition issues as set out in Chapter IV of the catalogue. Only reported cases are commented upon. For reasons of confidentiality DG Competition is not in a position to comment on any pending cases.

1.1 Does the competition law apply to the different components of this sector (manufacturing, health services, distribution and pharmacies) without exemption or exception. Which agency is responsible for enforcing competition law in this sector ?

Exceptions/Exemptions: There are no sector-specific exceptions or exemptions of a regulatory nature. The EC Treaty provisions concerning competition contain, however, certain general derogations (state aids: Art. 87(3) EC-Treaty) or exemptions (agreements: Art. 81(3) EC-Treaty) which can be applied in the pharmaceutical sector as in any other sector.

Responsible Agency: The Commission's Competition DG is responsible for applying competition law in this sector. Within this DG there is a unit in charge of state aids. Mergers are handled by a separate directorate. As to the traditional anti-trust issues raised by concertation or unilateral behaviour of pharmaceutical producers and distributors, these are dealt with by the unit specifically responsible for pharmaceutical products, whereas the health insurance schemes fall within the ambit of the unit responsible for financial services.

1.2 Market Definition

1.2.1 Have you had the occasion to address the definition of relevant market in the pharmaceutical sector?

The Commission is required to define the relevant product market as well as the relevant geographic market in each case. Even if certain markets have been dealt with in previous Commission decisions, this earlier assessment can only serve as an indicator. The Commission is indeed required to make a fresh analysis of the conditions of competition which might not necessarily be based on the same considerations[2].

1.2.2 Did you find that the relevant product market could be approximated by commonly accepted therapeutic groups?

According to the Commission's Notice on the definition of relevant markets for the purpose of Community competition law[2], demand-substitutability is an important factor for assessing which products compete with each other in the same market. In the pharmaceutical area this obviously refers to the therapeutic indication for which the medicine will be applied. It would therefore be desirable if the relevant product market could be approximated by commonly accepted therapeutic groups.

This is especially important in light of the fact that without in-depth medical insight it is extremely difficult for DG Competition to inquire about substitutes and to develop the correct market definition. The DG Competition services will typically request in-depth information from the notifying parties or complainants. They will then regularly double-check that information with the market (competitors and customers). In the case of an ex-officio procedure, the Commission is left on its own. A commonly accepted therapeutic grouping could therefore serve as a means for verifying information given by the parties or for starting an investigation.

However, it needs to be clearly understood that any comprehensive listing of therapeutic groupings, although most desirable and useful, can only serve as a first screening tool for market analysis and cannot produce any binding effect whatsoever. Experience shows that therapeutic listings, if they are to serve any meaningful purpose, cannot be too broad and will focus on product groups which are normally used for the same therapeutic indication. Nevertheless, pharmaceutical medicines can have various therapeutic indications and many diseases can be treated with a variety of products which do not belong to the same therapeutic grouping. In this case, an independent market analysis will always be necessary. Results might deviate from the commonly accepted standard.

In addition, antitrust and merger decisions increasingly concern innovative markets for which a commonly-accepted standard has not yet been developed. Existing therapeutic classifications can give a first indication, but might no longer serve a suitable basis for finding competing substitutes in this new market. Any commonly accepted standard should therefore be drafted in such a way that it can be easily amended in order to take due account of new developments. This of course means that the adoption process for new therapeutic categories does not involve too complicated a procedure.

1.2.3 What techniques did you use to determine whether certain products were effective substitutes?

The Commission has established a number of principles in its practice,[3] especially in the field of mergers. Product markets in the pharmaceutical industry can be grouped into pharmaceutical specialities, active substances and future products[4].

Pharmaceutical specialities: These are used for the treatment of human illnesses and diseases. The Commission has often used the "Anatomical Therapeutic Chemical" (ATC) classification recognised by the World Health Organisation (WHO). The third level of the ATC classification which groups medicines in terms of their therapeutic indications, is very often used as an operational market definition. However, as already pointed out earlier, ATC 3rd level might not in all cases be an appropriate instrument and it might be necessary in certain cases to carry out analyses at other levels of the ATC classification. For example, it may be necessary to bring certain groups of pharmaceutics specialities together in a broader market. On the other hand, it might also be necessary to apply a narrower market definition where the pharmaceutics specialities forming part of a certain ATC 3 class have clearly differing indications.

Very often notifying parties or complainants refer to a different ATC classification, namely the one established by the European Pharmaceutical Market Research Association (EphMRA). This ATC classification is based on the market data of Intercontinental Medical Statistics (IMS). IMS is a market research company which gathers and sells market data for the pharmaceutical sector. Quite often, the IMS system is quicker to take up new developments – e.g. emergence of new drugs – and might therefore provide a clearer picture of recent market developments.

The Commission has accepted the use of IMS data and the EphMRA classification in some cases.[5] Given the fact that the WHO and the EPHRMS classifications are similar, but nevertheless have distinct differences (e.g. the number of ATC levels) it would be desirable to reach a common standard.

Active substances: The manufacturing process for pharmaceutical drugs includes two separate steps: the manufacturing of active substances, followed by the manufacturing of pharmaceutical products. The Commission considers that active substances are separate and specific markets which are upstream in relation to the markets for pharmaceutical specialities. Active substances are produced from chemical and biological products and may be either manufactured for in-house purposes or traded. There are markets for active substances to the extent that such substances are the object of transactions between a producer and a buyer of these substances.

Future products: In the pharmaceutical industry, a full assessment of the competitive situation regularly requires examination of products which are not yet on the market, but which are at an advanced stage of development. The potential for these products to enter into competition with other products which are either at the development stage or already on the market can be assessed by reference to their characteristics and intended therapeutic use. The Commission has to look at R&D potential in terms of its importance for existing, but also for future market situations. Quite naturally, the relevant product market tends to be defined in a less clear cut manner than in the case of existing markets. Market definition will very often not be based on existing ATC classes, but primarily guided by the characteristics of future products as well as by the indication to which they are to be applied.

1.2.4 Did you find it necessary to distinguish the market for drugs consumed in hospitals from the market for drugs prescribed by physicians and/or the market for over-the-counter drugs?

The Commission has recognised that a classification on ATC level 3 might be further subdivided on the basis of a variety of demand-related criteria. A possible distinction between prescription drugs and over-the-counter has been identified.[6] However, in most of the cases it was not discussed further whether these two groups constituted separate product markets because the outcome of the assessment did not depend on this.[7]

In some cases, parties identified separate markets for in-hospital and commodity products on the basis of the following criteria: mode of administration, products' presentation, different distribution methods (greater role of wholesalers for distribution to pharmacies), different kind of products used for hospital-acquired and community-acquired diseases. The Commission has dealt with this distinction between hospital markets and markets for drugs prescribed by physicians only in very few decisions. In *Rhône-Poulenc Cooper*,[8] the question was left open.

1.2.5 Was the relevant geographic extent of the market national or international?

Pharmaceutical specialities: There are Community efforts for standardisation in the pharmaceutical sector. Measures include *inter alia* the harmonisation of technical provisions within the Community and the entry into force of new registration procedures for medicines. Since the beginning of

1995, pharmaceutical companies have the option (and for biotechnology products the obligation) of submitting an application for registration of a new medicine to the European Agency for the Evaluation of Medicinal Products for a centralised authorisation procedure. [9]

The sale of medicines is, however, still influenced by the administrative procedures or purchasing policies which the national health authorities have introduced in the Member States. Some countries exercise a direct or indirect influence on prices, and there are different levels of reimbursement by the social security system for different categories of medicines. For this reason, the prices for medicinal products differ from one Member State to another. In addition, there are far-reaching differences in terms of brand and pack-size strategies and in distribution systems. These differences lead to national market characteristics.

Active substances: In some merger decisions, the Commission has established that the upstream market for active substances is at least EEA-wide. [10]

Future products: Because research and development is normally global, the said national restrictions do not create the same entry barriers as for existing pharmaceuticals. The issue of future markets is therefore considered at least in terms of territory of the Community and possibly the world-wide market.

1.3 Did you consider that the pharmaceutical industry is characterised by barriers? What barrier do you identify?

A barrier to entry refers to a cost borne by new entrants that has not been borne (or at least not the same extent) by the incumbent market players. However, the notion of a barrier to entry into the pharmaceutical industry sometimes refers to a broader concept relating to the large investment in R&D that is necessary to develop new products. This need for a large financial effort seems to be due to the length of time required to run through the different development phases of a new product, according to a process which is partially governed by regulatory provisions.

Besides, large investments are also required at the level of marketing. Regulatory provisions that define categories of drugs available only by prescription lead pharmaceutical companies to devote the bulk of promotional expenditures to visits to individual physicians (so called practice of detailing). Since the level of a company's detailing activity is closely related to its size, marketing efforts play the role of an entry barrier analogous to the set up cost involved in the development of new drugs.

The new wave of mergers in the pharmaceutical and agrochemical industry seems to be the market response to the need for such a large financial base. Size is claimed to be an increasingly important competitive factor in the pharmaceutical industry, for it allows to leverage increasing R&D costs across a broader range of products and to spread the risk inherent in every new research project over a large capital base. Strong pharmaceutical producers therefore might not face serious problems to enter a market on which they so far have not been present. Smaller pharmaceutical companies try to overcome this difficulty by teaming up with established producers who might contribute to the R&D investment and the later marketing of the product.

Potential entry barriers resulting from the need to obtain market authorisation are now mitigated by the centralised authorisation procedure referred to above. This procedure enables pharmaceutical producers to acquire a single authorisation from the European Agency for the Evaluation of Medicinal Products for the entire Community.

Patent protection in this sector (20 years plus additional five years protection according to the Supplementary Protection Certificate) has been identified as an entry barrier in the merger decision Ciba/Geigy .[11]

1.4 Collusion

The OECD's question mainly refers – by implication - to horizontal forms of concertation between pharmaceutical producers (e.g. market sharing or sales quota cartels). Until now, the Commission has not had to look into this kind of practices.

The Commission's antitrust decisions mainly concern vertical agreements between pharmaceutical producers and their wholesalers which have as their object and/or effect to exclude or impede parallel trade (see e.g. Commission's decision in Adalat, still pending before the Court of First Instance). It is also in the public domain that the Commission is currently examining Glaxo Wellcome's pricing policy in Spain in light of its negative impact on parallel trade.

1.5 Co-operative or collaborative ventures (such as co-marketing and co-promotion agreements) seem to be an important component of the pharmaceutical industry.

1.5.1 Have you had the opportunity to examine the competitive effect of such agreements?

The Commission has already examined several cases of co-marketing and co-promotion in the pharmaceutical sector. Other cases are under investigation. Each case has so far been considered on its own merits. So far, the Commission's services have informally cleared all co-marketing or co-promotion agreements that have been brought to their attention.

1.5.2 What features of these agreements give rise to competition concerns?

The main competition concerns of these agreements derive from the fact that the original producer and the partner become active on the same geographical market, under the same (co-promotion) or under different trademarks (co-marketing).

As far as co-marketing is concerned, the agreement may restrict competition if both partners already manufacture substitutable products or are likely to so in the foreseeable future. Furthermore, a network of co-marketing arrangements may foreclose access to the market for third parties, i.e. newcomers or potential entrants of long duration, especially if the co-marketing partners have subscribed to non-compete obligations.

Co-promotion agreements are in general less restrictive than co-marketing agreements, the co-promoter not being responsible for the main elements of the contract: prices, quantities, positioning, market effort, etc.

1.5.3 Have you opposed joint research and development and/or joint marketing arrangements?

No.

Research & Development: these arrangements have been cleared either as being non-restrictive or in any event exemptable when they are to some extent restrictive. These agreements may restrict competition when they limit the exploitation of the results of the R&D, when there is not sufficient competition at the level of R&D itself and finally, when, as a result of the co-operation, third parties are foreclosed from access to necessary technology or R&D.

Co-marketing and Co-promotion: The Commission has not found restrictions of competition in most cases. In other cases, it has granted an exemption in accordance with article 81.3 after the parties had appeased its concerns.

1.6 What cases of mergers have you addressed in the pharmaceutical industry?

The EU merger control applies to all concentrations which have a "Community dimension". The Community dimension is given where the combined aggregate world-wide turnover of all undertakings concerned is more than 5 000 million Euro and the aggregate Community turnover of each of at least two of the undertakings concerned is more than Euro 250 million, unless each of the undertakings concerned achieves more than two thirds of its aggregate Community-wide turnover within one and the same Member State. Recently, a number of mergers have been notified to the European Commission in the pharmaceutical sector: Glaxo Wellcome/SmithKline Beecham, Pfizer/Warner Lambert, Astra/Zeneca, Hoechst/Rhône-Poulenc, American Home Products/Monsanto etc.

1.6.1 In what markets were concerns over market power most focused?

As illustrated (see 4.2), the European Commission takes ATC classification level 3 as a starting point for its operational market definition. However, in the individual case the market might be defined in a broader or narrower way.

So far, mergers rarely caused competition concerns on the same relevant markets. The Commission assumes a dominant position in the pharmaceutical sector only where the parties achieve relatively high market shares, taking into consideration that pricing is strongly influenced by regulation or reimbursement systems. Thus, the probability that a (another) merger would create a dominant position on the same market, is fairly low (except, of course, the same company is involved).

Competition problems more frequently have occurred for markets were one of the merging parties has hold the gold standard for a particular drug whilst the other party would have added market share. A specific pattern, related to certain product groups, has not appeared yet. Competition problems are rather related to individual strengths of the merging companies or, more precisely, the market share overlap of the merger. It seems that mergers between international pharmaceutical companies are not directly targeted to create high market shares for particular markets (see below).

On the other hand, mergers have raised competition concerns in a number of markets on which only little economic interest was identified (for example shrinking markets with low and decreasing value) and only a few companies are active. New competitors are unlikely to enter the market. In these types of markets, mergers of incumbent firms may create a very strong position of the parties and not be challenged by pipeline products.

1.6.2 What are the primary anti-competitive effects of a merger? Have mergers been opposed on the grounds that the merging companies might be competitors in the future?

The increasing merger activity over the last years could be explained by the companies objective to increase their future competitiveness. Two things appear to be the most important in this context: The development of new products including the use of new methods for discovery (including biotechnology) is calling for increasing resources devoted to research and development. On the other hand a new product has to be marketed in the most effective way before the product gets off patent in order to achieve a maximum of return of investment. The combination of both, successful product development and world wide marketing, could possibly be optimised within bigger companies, bundling and targeting (more) resources to profitable activities. Thus, mergers are not anti-competitive per se: more efficient marketing and research capacities might result in new products which may enter in markets were incumbent market leaders are holding dominant positions.

In examination of the future effects of a merger within the pharmaceutical industry, the Commission assesses the parties products which are not yet on the market but which are at an advanced stage of development. Starting from the market situation at present the Commission examines the potential for pipeline products to enter into competition with other products, which are either at the development stage or already on the market. In relation to the long term strategies parties may have when agreeing on a merger, an analysis, only taking into account a snapshot of today's market situation (or when assessing pipeline products perhaps a future period of three years) may be considered as unsatisfactory. On the other hand it appears difficult if not impossible to predict the economic success of future products, especially if they are in early stages of development. Market shares may change quickly in this sector as long as enough companies have the capacity to develop new products and to bring them successfully on the market.

1.6.3 What sorts of remedies have been imposed as a condition on merger approval?

Merging parties most generally propose undertakings in the form of a divestment or licensing (including pipeline products) if competition concerns have been identified for specific markets. The undertakings should eliminate the market share overlap or (in cases where the parties have more than two products on the market) reduce the market share increment in order to remove competition concerns.

1.7 Abuse of dominance

1.7.1 What cases of abuse of dominance have you addressed?

As stated above in 4.1, Community competition law, including Article 82 of the EC Treaty and the caselaw based thereon, applies fully to the pharmaceutical sector.

There are however as yet no decisions involving abuses of dominant position by pharmaceutical companies.

1.7.2 Have you addressed cases of tying or predatory pricing?

Predatory pricing: In general terms, predatory pricing by a dominant pharmaceutical company does not appear to be a likely scenario as far as in-patent products are concerned. The pharmaceutical company holding the patent for the only product on the market will not normally seek to engage in

predatory pricing to gain market share given its temporary monopoly-like position. Quite on the contrary, the patent holder will set prices at levels that enable it to recoup its R & D investments.

Tying: No

1.8 In what ways can a pharmaceutical firm with a dominant position reduce competition from its rivals?

A classic means whereby competition from rivals can be reduced is refusal to deal, including refusal to supply certain services or products. A refusal by a pharmaceutical company to supply a wholesaler or a parallel trader could in principle be abusive if the general conditions developed by the Court were met.

A refusal to licence patents relating to pharmaceutical products could potentially be considered in terms of national and international (for example the TRIPs Agreement) rules regarding compulsory licensing.

In the context of competition between pharmaceutical companies and generic producers there would, generally speaking, appear to be scope for practices whereby a dominant firm can reduce competition from its rivals. The US authorities appear to be better placed to elaborate as to the specific nature of such practices. For example, the US experience includes instances of pharmaceutical companies paying generic producers not to launch generic versions of certain drugs.

The Commission is however currently examining a case involving possible abuses by a dominant research-based pharmaceutical company in relation to its generic competitors. The alleged abuses relate primarily to activities before national patent offices and courts as well as to the issue of withdrawal of marketing authorisations.

NOTES

1. Quality King Distributors Inc. v. L'Anza Research International Inc., 523 U.S. 135 (1998).

2. See judgement of the CFI in Coca-Cola Company v. Commission, T-125/97, 22.03.2000 (not yet published in the ECR) par. 82. See also Commission Notice on the definition of relevant market for the purposes of Community competition law, OJ C 372, 09.12.1997, p.5.

2. OJ C 372, 09.12.1997, p. 5.

3. Case Sanofi/Sterling Drug (IV/M.072) OJ C156, 14/06/1991, p.10; Procordia/Erbamont (IV/M.223) OJ C128, 08/05/1993, p. 5; Rhône-Poulenc/Cooper (IV/M.426) OJ C113, 23/04/1994, p.2; La Roche/Syntex (IV/M.457) OJ C178, 30/06/1994, p.15; AHP/Cynamid (IV/M.500) OJ C278, 5/10/1994, p.3; Glaxo/Wellcome (IV/M.555) OJ C065, 16/03/1995, p.3; Behringwerke AG/Armour Pharmaceutical Co. (IV/M.495) OJ C134, 1/6/1995, p.4; Hoechst/Marion Merell Dow (IV/M.587) OJ C193, 27/07/1995, p.5; Upjohn/Pharmacia (IV/M.631) OJ C294, 09/11/1995, p. 9; Ciba-Geigy/Sandoz (IV/M.737) OJ L201, 29/07/1997, p.1; Hoffman La Roche/Boehringer Mannheim (IV/M.950) OJ L234, 21/08/1998, p.14; American Home Products/Monsanto (IV/M.1229) OJ C109, 20/04/1999, p.4; Astra/Zeneca (IV/M.1403) OJ C335, 23/11/1999 p.3; Sanofi/Synthélabo (IV/M.1397) OJ C023, 27/01/2000, p.4.

4. See e.g. Hoechst/Rhône Poulenc, IV/M1378 of 09.08.1999.

5. See e.g. Ciba-Geigy/Sandoz, Decision IV/M737(footnote 3).

6. Decision IV/M.1403 - Astra Zeneca (footnote 3) par. 9. In earlier Commission decisions however, it has been noted that "within the pharmaceutical industry, it is generally considered that OTC and ethical products constitute two distinct markets, although this distinction might be blurred". This formula used in Case IV/M72 – Sanofi/Sterling Drug (footnote 3) was not repeated in later Commission's decisions.

7. Case IV/M464 - BMSC/UPSA of 06.09.1994, OJ L2985,at par. 11.

8. Case IV/ M426 – Rhône-Poulenc/Cooper (footnote 3), at par.16.

9. See Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, O.J. N° L214.

10. Case No. IV/M.737-Ciba Geigy/Sandoz, Case IV/M.1229 - American Home Products/Monsanto (see footnote 3).

11. See footnote 3.

BIAC

James F. Rill, Vice-Chairman

1. Introduction

I am the Vice Chair of the Competition Committee of the Business and Industry Advisory Committee (BIAC) and the Vice Chair of the Competition Committee of the US Council for International Business (USCIB). I appreciate the opportunity to speak with you today on the subject of competition and regulation in the pharmaceutical industry. The thoughts that I offer here today are my own and do not necessarily represent the views of all members of BIAC or the USCIB, but this paper has been reviewed by a number of BIAC members and is being distributed by BIAC.

There are three themes that I would like to emphasize today:

1. Intellectual property rights play a key role in rewarding investments in research and development, and therefore are critical to promoting innovation and the development of new pharmaceutical products. Diluting the intellectual property rights of pharmaceutical manufacturers (for example, by imposing compulsory licensing requirements) in an attempt to limit manufacturers' profits and to address anticompetitive conduct in the pharmaceutical industry will decrease both the quantity and quality of drugs available to consumers.

2. Pharmaceutical economics dictate that manufacturers earn prices above marginal cost on successful drugs; pricing above marginal cost, in and of itself, should not be considered anticompetitive. Genuine abuses of market dominance undertaken by patent holders in the pharmaceutical industry can be addressed through the nondiscriminatory and rational application of traditional competition law principles. Traditional antitrust enforcement, together with an FDA-type framework that regulates the introduction, production and marketing of pharmaceutical products, is the most efficient means of insuring that consumers receive the benefits of safe, effective and affordable pharmaceutical products. Price controls and other forms of regulatory intervention distort market mechanisms and threaten to lower the quantity and quality of pharmaceutical products ultimately available to consumers.

3. To the extent that the proposals in the Secretariat's Note attempt to replace the application of traditional competition law principles with other types of regulatory intervention in the pharmaceutical industry, and/or to dilute the intellectual property rights of pharmaceutical companies, those proposals should be rejected as harmful to consumer welfare.[1]

2. First principles: The proper blend of intellectual property rights and rational antitrust law enforcement is best suited to enhancing consumer welfare

A recent speech by Debra Valentine, General Counsel of the US Federal Trade Commission, illustrates well the complementary roles of strong intellectual property rights and judicious antitrust enforcement in enhancing consumer welfare.

> "On their face, [the antitrust and intellectual property law] regimes may appear to conflict: intellectual property law rewards and encourages innovation by providing limited monopoly rights, while antitrust law prohibits monopolization. But ultimately, both serve, and are interpreted by US courts and enforcers to further, 'the common purpose of promoting innovation and enhancing consumer welfare."

> "Antitrust law promotes market structures that encourage initial innovation with a competitive market 'stick' – that is, firms that fail to innovate will get left behind. Intellectual property law encourages initial innovation with the 'carrot' of limited exclusivity, and the profits that flow therefrom. Antitrust law enables follow-on innovation by protecting competitive opportunities beyond the scope of the exclusive intellectual property right. Intellectual property law enables follow-on innovation by requiring public disclosure of the initial innovation (at least in the patent context) and affording follow-on innovators rights of 'fair use' and freedom from intellectual property 'misuse.' The basic principle that mediates the tensions [between these two bodies of law] . . . is that intellectual property rights provide legal monopoly power, but only within the defined, limited scope of that right."

Debra A. Valentine, General Counsel, US Federal Trade Commission, Abuse of Dominance in Relation to Intellectual Property: US Perspectives and the Intel Cases, Before The Israel International Antitrust Conference, Tel Aviv, Israel (Nov. 15, 1999) (citations omitted).

3. Diluting or abolishing intellectual property rights in the pharmaceutical industry will decrease consumer welfare

A. The Secretariat's Note states that patent protection is "a blunt instrument"[2] that is "subject to forms of abuse" and that "induces a distortion in economic decisions and gives rise to the potential for various forms of anticompetitive behaviour." Secretariat's Note at 20. To address this potential for anticompetitive conduct, the Note offers various proposals that rely on the dilution of intellectual property rights for pharmaceutical manufacturers, including compulsory licensing.

B. It is widely acknowledged that patents play a critical role in stimulating and rewarding research and innovation in the pharmaceutical industry. A strong system of intellectual property rights that includes both patents and trademarks should be used to promote and reward research and innovation in this industry. The essence of the patentee's patent right is the right to exclude others from the use of the invention for a period of years. Requiring compulsory licensing or diluting the rights of intellectual property holders in other ways ultimately will decrease the quantity and quality of pharmaceutical products available to consumers.

C. Secretariat's Note:

1. The Secretariat's Note itself acknowledges that the "protection of intellectual property rights lies at the foundations of R&D investment in the pharmaceutical industry. In the absence of that protection, margins on pharmaceutical products and the incentives for R&D investment would decline." Secretariat's Note at 18 (emphasis added).

2. In addition, the Secretariat's Note acknowledges that "almost all the R&D effort of the pharmaceutical industry is carried out by large multinational firms" and that this R&D "is funded primarily from the profits flowing from exclusive rights granted to a patent holder during a patent's life time." Secretariat's Note at 2-3. Wholly apart from the fact that cash flow is the relevant factor in funding research, the implicit conclusion that can be drawn from this statement is that, absent the patent protection that permits patent holders to generate profits, the funding to support additional R&D could not be obtained.

D. Economic Literature:

1. A significant body of economic literature supports the proposition that intellectual property rights promote research and innovation in the pharmaceutical industry. The Secretariat's Note cites one study, for example, which found that 65 percent of pharmaceutical products would not have been introduced, and 60 percent would not have been developed, without adequate patent protection. See Secretariat's Note at 18, citing Edwin Mansfield, Patents and Innovation: An Empirical Study, Management Science, 173-181 (Feb. 1986). *See also* Richard C. Levin et al., Appropriating the Returns from Industrial R&D, Yale Cowles Foundation Discussion Paper 862, Yale University (Feb. 1988); Richard C. Levin et al., Appropriating the Returns from Industrial R&D, Brookings Papers on Economic Activity, 783-820 (1987).

2. Pricing above marginal cost on successful pharmaceutical products, by itself, should not be considered anticompetitive. Indeed, pharmaceutical economics dictate that manufacturers earn higher prices on successful medicines. The Secretariat's Note itself recognizes the high-risk nature of pharmaceutical research, which militates in favor of significant rewards.

a) The Note acknowledges that "[r]esearch-based pharmaceutical companies operate in a high-risk/high-reward environment. The process of obtaining marketing approval for a new drug is very long and costly, taking around eight years and with a cost of hundreds of millions of dollars. Very few new chemical compounds that are created ever receive marketing approval, and of those only a few are successful." Secretariat's Note at 3. In addition, the Note states that "according to one commentator, for every 10 000 pharmaceutical products patented, about 100 will get into human trials and less than ten will actually reach the market . . . Even those drugs which are successfully cleared by the licensing authorities do not necessarily sell in sufficient quantities to be profitable." *Id.* at 12.

b) "It takes an average of 12 to 15 years and more than $500 million to bring a new drug from the laboratory to the patient. Only one in every 5 000

compounds tested becomes a marketed drug, and only three out of ten approved drugs make more money than the average drug development costs." PhRMA, Prescription Medicines*:* Benefits and Costs, www.phrma.org.

3. US Federal Trade Commission: Similarly, the US FTC recently emphasized the importance of intellectual property rights in promoting R&D and innovation in the pharmaceutical industry. See Roy Levy, Bureau of Economics, US Federal Trade Commission, The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change (Mar. 1999). The Report states that:

"The supply of brand-name prescription drugs depends critically on the research and development (R&D) activities of pharmaceutical companies. R&D activities, in turn, depend on the companies' access to intellectual property rights . . ." The Pharmaceutical Industry at 173.

"Although intellectual property rights protection might not be necessary to foster innovation in all industries, pharmaceutical companies rely especially heavily on intellectual property rights in the form of patents and trademarks. In fact, empirical research indicates that new product development in the pharmaceutical industry is more dependent on patent protection than in many other industries, including semiconductors, computers, [and] automobiles. In particular, some evidence suggests that 65 percent of pharmaceutical products would not have been introduced and 60 percent would not have been developed without adequate patent protection . . . ." *Id.* at 179-180 (footnotes and citations deleted).

"[T]he Waxman-Hatch Act of 1984… encouraged additional brand-name drug development by effectively extending patent protection on brand-name pharmaceutical products." *Id.* at 139.

E. Given the widely acknowledged importance of patent protection in stimulating R&D and innovation in the pharmaceutical industry, it seems clear that any dilution of intellectual property rights in an attempt to address anticompetitive conduct in the pharmaceutical industry would result in less innovation and, ultimately, fewer and lower-quality drugs, and further would adversely affect innovation in related biotechnology and other healthcare product industries. Thus, any weakening of intellectual property rights in this industry would diminish first funding, then innovation, and then development, all to the detriment of consumer welfare.

4. Competition law principles best-suited to address anticompetitive conduct in the pharmaceutical industry

A. The Secretariat's Note asserts that the presence of limited competition and barriers to entry in pharmaceutical markets "fosters anticompetitive behaviour" in the industry. Secretariat's Note at 4. For example, the Note observes that pharmaceutical manufacturers "have often been prosecuted for antitrust violations, including for cartels, price-fixing, forms of tying, exclusive marketing agreements and agreements to delay the entry of generics." *Id*.

B. The US antitrust authorities have prosecuted various types of anticompetitive conduct in the pharmaceutical industry and related industries during recent years. See Bureau of

Competition, US Federal Trade Commission, FTC Antitrust Actions in Pharmaceutical Services and Products (Dec. 1999). Of concern, however, is the fact that the Secretariat's Note appears to overstate the presence of collusion in the pharmaceutical industry, at least with respect to the support for this assertion that can be provided by certain US precedents. Specifically, to support the assertion that pharmaceutical companies "have on many occasions been found to be colluding," (Secretariat's Note at 41), the Note references the prescription drugs antitrust litigation and the vitamins antitrust litigation. These references do not support the Secretariat's assertions.

1. To support its assertions regarding the presence of collusion in the pharmaceutical industry, the Secretariat's Note references the 1996 opinion of the district court denying summary judgment in the Brand Name Prescription Drugs Antitrust Litigation. In fact, several defendants took the federal class action case to trial in 1999, and the same judge who denied summary judgment in 1996 ultimately granted the defendants' motion for a directed verdict after hearing the plaintiffs' evidence. Announcing his decision orally in court, the judge stated that the "evidence of conspiracy is meager, and the evidence as to individual defendants is paltry or non-existent. It would be a miscarriage of justice to hold otherwise." (11/30/98 Trial Tr. at 6442). In his written opinion, the judge held that the evidence was "incompatible with the antitrust conspiracy set forth in the Class Plaintiffs' complaint" and that the plaintiffs had relied on "speculation and conjecture rather than fair or reasonable inferences for the conclusions they offer[ed]" (1/19/99 Op. at 15, 23). A few months after issuing this opinion, the judge sanctioned the class plaintiffs' lawyers for misrepresenting the record at the summary judgment stage, which misrepresentations contributed to the denial of the motions in 1996 and the issuance of the opinion now relied upon by the Secretariat's Note.

2. The Secretariat's Note also references price-fixing in the vitamins industry as evidence of the many instances of collusion in the pharmaceutical industry. It is worth noting that while some of the companies allegedly implicated in that conduct are also pharmaceutical manufacturers, that conduct involves the price-fixing of commodity products. As a commodity market, the vitamins industry lacks the unique characteristics that the Note says make the pharmaceutical industry particularly conducive to anticompetitive behavior. It seems inappropriate to base an argument for revision of patent protection on a case involving commodity products like vitamins.

C. To address anticompetitive conduct in the pharmaceutical industry, the Secretariat's Note proposes that price controls or other forms of regulatory intervention could be used. In fact, a wealth of economic theory and experience indicates that price controls and other types of regulatory intervention introduce market distortions and impede allocative efficiency.

1. "The enactment of cost-containment programs, price controls, or both, on a national level, often results in decreased levels of R&D spending in that these programs reduce revenues that can be reinvested in R&D programs. Several countries that have implemented such programs have seen their pharmaceutical industries weaken or shift outside their borders." US International Trade Commission, Report to the Senate Committee on Finance, 1991.

2. "In countries that have imposed [price regulations on pharmaceutical products], patients face delays of months and years for surgery, government bureaucrats decide treatment

options instead of doctors and patients, and innovations in medical techniques and pharmaceuticals are drastically reduced." *Open Letter from 565 Economists to President William J. Clinton*, New York Times (Jan. 13, 1995).

3. "Economists may not know much. But we know one thing very well: how to produce surpluses and shortages. Do you want a shortage? Have the government legislate a maximum price that is below the price that would otherwise prevail." Milton Friedman, Economist, quoted in Price Controls Throughout History, www.pharma.org.

Thus, reliance on price controls to correct anticompetitive conduct or market distortions in the pharmaceutical industry will further diminish, rather than enhance, efficiency and consumer welfare.

D. To the extent that it exists, anticompetitive conduct in the pharmaceutical industry is best addressed through the enforcement of traditional competition law principles. The pharmaceutical industry does have certain characteristics that distinguish it from the "smokestack industries" for which the antitrust laws were originally designed in the nineteenth century: the pharmaceutical industry is a health care industry, a high-technology industry, and heavily reliant on intellectual property rights. While these characteristics of the industry may warrant a judicious approach toward antitrust enforcement, they do not render traditional competition law principles inadequate to address abuses of market power by pharmaceutical manufacturers.

E. The US antitrust enforcement authorities have recognized that it is appropriate to apply traditional competition principles to the health care industry and to high-technology industries, including the pharmaceutical industry, just as these principles are applied to other industries.

1. The Introduction to the 1996 US Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care states that traditional competition principles are "sufficiently flexible to take into account the particular characteristics of health care markets and the rapid changes that are occurring in those markets."

2. Similarly, enforcement authorities have emphasized in several recent speeches that it is appropriate to apply traditional antitrust principles to high-technology industries, including the pharmaceutical industry. See US FTC Press Release, *Current Antitrust Laws Adequate to Address High-Tech Competition Issues* (Feb. 25, 1999) (US FTC Chairman Robert Pitofsky stated that nineteenth century antitrust laws are adequate to address competition issues presented by twenty-first century high-technology industries, including the drug industry); US FTC Commissioner Orson Swindle, *A Common Sense Approach to High Tech*, Before the Continuing Legal Education Program, San Diego, California (Nov. 4, 1999) ("There is a recurring topic of discussion as to whether or not traditional antitrust concepts apply to . . . rapidly changing [high-technology] industr[ies]. Rest assured, they do."); US FTC Commissioner Thomas B. Leary, *Antitrust Law as a Balancing Act*, Before the Tenth Annual Seattle Computer Law Conference, Seattle, Washington (Dec. 17, 1999) ("it is not necessary to develop new antitrust principles to deal with so-called 'high-tech' industries; what is required is a discriminating application of familiar principles to the special facts of a 'high-tech' environment.").

F. The US antitrust enforcement authorities routinely employ traditional antitrust enforcement to address anticompetitive conduct in the pharmaceutical industry. See, e.g., *FTC v. Mylan Laboratories, Inc.*, CV-98-03114 (complaint) (D.D.C., filed Dec. 22, 1998; amended complaint filed Feb. 8, 1999) (FTC charged Mylan Laboratories, one of the largest generic drug manufacturers in the U.S., with monopolization, attempted monopolization and conspiracy to eliminate much of Mylan's competition for two widely prescribed drugs by tying up key active ingredients); *In re Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andryx Corp.*, Docket No. 9293 (March 16, 2000) (complaint) (FTC complaint alleged that Hoechst (now Aventis) agreed to pay Andryx millions of dollars to delay bringing to market a drug that would compete with Hoechst's Cardizem product while Hoechst sued Andryx for alleged patent infringement); *In re Abbott Laboratories*, FTC File No. 981 0395 (Mar. 16, 2000) (complaint and proposed consent order) and *In re Geneva Pharmaceuticals, Inc.*, FTC File No. 981 0395 (Mar. 16, 2000) (complaint and proposed consent order) (Abbott Laboratories and Geneva Pharmaceuticals agreed to settle FTC charges that Abbott paid Geneva approximately $4.5 million per month to keep Geneva's generic version of Abbott's Hytrin product off the US market).

G. Thus, governments can use patents to stimulate R&D and reward innovation in the pharmaceutical industry while addressing anticompetitive conduct in this industry through the nondiscriminatory application of traditional competition law principles. Rather than enhancing consumer welfare, addressing anticompetitive conduct in the pharmaceutical industry through the use of price controls and other types of regulatory mechanisms further lessens consumer welfare.

5. Proposals in the secretariat's note undermine these principles

If implemented, proposals in the Secretariat's Note would upset the delicate balance between the protection of competition and pharmaceutical manufacturers' incentives to innovate, thereby harming consumers by depriving them of more and better-quality pharmaceutical products.

A. For example, the Secretariat's Note proposes that drug competition could be improved by using a system of compulsory licensing under which the patent holder would be required to sub-license the right to manufacture and market a drug to any requesting firm. The requesting firm would pay the patent holder a royalty fee determined by regulation. Secretariat's Note at 34.

1. While emphasizing the "advantages" of this approach, including controls on profit and limits on the likelihood of anticompetitive behavior (e.g., tying of drug products and exclusive contracts with pharmaceutical distributors) by drug companies, the Note fails to describe the disadvantages to compulsory licensing.

2. The essence of the patentee's patent right is the right to exclude others from the use of the invention for a period of years. Compulsory licensing would severely weaken intellectual property rights by abolishing this right and consequently would diminish pharmaceutical manufacturers' incentives to innovate. Limiting profits would further diminish incentives to innovate. In addition, having a government panel establish royalty rates would add more regulatory intrusion and, consequently, more market distortion. Finally, as noted above, the goal of eliminating anticompetitive conduct by pharmaceutical manufacturers is best achieved by relying on antitrust enforcement.

B. The Note identifies as an "ideal R&D policy" one that would reward only those innovations for which the total value to the economy exceeds the R&D costs. The Note also suggests that it may be inappropriate for small, inexpensive innovations to receive the same intellectual property protection as large, expensive innovations. Secretariat's Note at 18-19. This policy presumably would offer rewards only for successful products and would ignore the high cost of R&D failures, thereby diminishing incentives to innovate.

C. The Note proposes mechanisms to "reduce the negative impact of market power," including having national health insurers pay a fixed annual fee in exchange for purchasing a brand-name drug at its marginal cost. The fee would "compensate the manufacturer for its market power (and therefore its R&D expenditure) while, at the same time, eliminating the distortionary effect of pricing above marginal cost." Secretariat's Note at 20. Alternatively, the Note proposes that governments or large insurers could buy out a manufacturer's patent rights and then manufacture the drug directly and distribute it at marginal cost. *Id.* These proposals would compensate the manufacturer only for its success on the purchased product and would ignore the high cost of R&D failures, thereby diminishing incentives to innovate.

D. The Note appears to favor a greater role for government-funded R&D. Secretariat's Note at 20. This proposition ignores the fact that industry members are almost always better-suited to make drug development decisions than are bureaucrats.

E. Other proposals discussed in the Secretariat's Note, including using price controls more extensively and allowing parallel trade, would further distort market mechanisms and weaken intellectual property rights, and therefore should be rejected as well. For example, the current patchwork of EU Member State reimbursement and price control legislation, in conjunction with the principle of free movement of goods among Member States, distorts the market, limits patient choice and impedes innovation. The unintended effect is the partitioning of the EU market, the enrichment of price arbitrageurs engaged in parallel trade, and the attendant loss of scarce Member State healthcare resources.

F. In the final analysis, as stated by Raymond V. Gilmartin, Chairman, President and Chief Executive Officer of Merck & Co., Inc:

> "Evidence shows that by supporting the five enabling conditions necessary for pharmaceutical innovation, namely continued government support of basic biomedical research; a free market for pharmaceuticals based on competition and choice; effective intellectual property protection; efficient and effective regulatory systems; and a global business environment conducive to free trade and medical innovation, countries can develop and maintain strong, globally competitive pharmaceutical industries that excel at breakthrough research. Support of those enabling conditions also will ensure that citizens have access to the latest innovative medicines . . . .
>
> It is important to continue to advocate policies that support innovation and to build and cultivate environments worldwide that encourage investment in exploratory basic research and drug development efforts. If society is to make major advances against diseases that cause so much suffering and economic hardship, diseases such Alzheimer's, depression and cancer, new innovative medicines must be brought to market."

Raymond V. Gilmartin, Chairman, President and CEO, Merck & Co., Inc., *The Impact of Political and Economic Factors on Pharmaceutical Innovation*, Before the Royal College of Physicians, London, England (July 14, 1998).

BIAC

Europe Economics, United Kingdom

1. Introduction

Europe Economics was commissioned to provide a critique of the OECD paper "Competition and Regulation Issues in the Pharmaceutical Industry" (DAFFE/CLP/WP2(2000)4).

The OECD paper was prepared by the OECD Secretariat ahead of a roundtable meeting on the pharmaceutical industry on 7 June 2000. Participants at the meeting included the Secretariat, representatives from OECD Member States, and industry representatives from the Business and Advisory Committee to the OECD.

The OECD paper is wide-ranging. It emphasises the extent to which the pharmaceuticals market is subject to regulation. On the demand side, regulation includes widespread social insurance; the control of product availability through doctors and pharmacists; and the regulation of prices and reimbursement conditions. On the supply side, it includes licensing controls for safety and efficacy; and the award of patents to protect the rewards to innovative effort.

But the core of the paper is an analysis of the effectiveness of competition in the pharmaceuticals sector. Section 2 of this paper focuses on what we consider to be the central economic issue raised by that analysis:

- the nature of competition in pharmaceuticals, including whether patents generate a degree of market power that is not balanced by corresponding market power of the purchasers.

- We take the view that in crucial respects the argument of the OECD paper is unbalanced. While the Secretariat's paper recognises that some form of intellectual property protection is necessary to reward the substantial and risky investment that goes into new products, its argument emphasises the risk that patents may give pharmaceutical companies excessive market power in particular therapeutic classes. Their proposals offered for discussion focus on solutions to this perceived "problem". This analysis by Europe Economics therefore focuses on the nature and vigour of competition in the pharmaceuticals sector. It includes comment on:

- the evidence on whether the pharmaceutical sector has been able to earn super-normal profit (as suggested in paragraphs 28-29); and

- the suggestion (paragraphs 42-47, 53-55, and elsewhere) that patents allow anti-competitive behaviour.

- Two suggestions for institutional reform set out in the OECD paper that relate directly to the rewards of pharmaceutical R&D are analysed in Section 3 below. These are:

- that for many OECD countries the private sector may be able to better manage the procurement and use of pharmaceuticals than the current public sector agencies (paragraph 71, and emphasised in the conclusions in paragraphs 168-169); and

- that patents might usefully be replaced by a system of compulsory licensing and royalties (paragraphs 48, 114-116).

2. Competition in pharmaceuticals

2.1 The dynamic nature of competition in pharmaceuticals

The conclusions of the OECD paper underplay the importance of innovation to the competitive process in pharmaceuticals. The fortunes of the major pharmaceutical companies turn on new products, particularly on the small minority of products that are major sellers. These breakthroughs typically offer improved health care and reduce other medical costs associated with illness such as, for example, the way pharmaceutical treatment for stomach ulcers largely eliminated the need for expensive and dangerous surgery. These points are recognised in the OECD paper (paragraphs 19-23 on risk and 9 on the contribution to health care), but are not reflected in the paper's recommendations.

Analysis by IMS Health of sales profiles for 670 molecules launched since 1983 (reported in the IMS Health *Strategic Management Review* for 1998) suggests that revenues peak about ten years after product launch and then tend to decline until patents expire, when revenues fall more sharply. The biggest-selling drugs in any year are unlikely to be amongst the world's biggest selling drugs ten years later.[3] Companies' relative sales and profitability ten years from now will depend on drugs that have recently been launched and those in the late stages of development. In this context, static analyses of the shares of leading brands in particular therapeutic categories (as reported in paragraphs 30-33) are a poor basis for making policy recommendations.

Those responsible for competition policy in both the EU and US have emphasised the importance of competition in innovation, more than of price competition between the current generation of products, when assessing proposed mergers between pharmaceutical companies. [4] In the words of John Lang, a Director in the European Commission's Competition Directorate General:

> "In [high-technology] markets price is often less important than the technical or other advantages of the product. These advantages are usually due to an innovation, which is likely to be a recent innovation because all or almost all the features of these products are changing".[5]

Relevant measures of competition in innovation would include:

- measures of inter-class competition, such as change over time in the rate at which classes of therapeutic products are superseded and the revenue declines;

- measures of intra-class competition, such as change over time in the rate at which further branded products enter a new therapeutic category[6]; and change over time in the rate at which market share and revenue fall away on the entry of competitor brands; and

- measures of the vigour of generic competition, such as change over time in the rate at which market share and revenue fall away on generic entry.[7]

The OECD paper does not provide any such analysis, and therefore cannot be seen as providing a fully rounded analysis of the nature of competition in pharmaceuticals.

2.2 Market power from patents

The second serious imbalance in the OECD Secretariat's argument is over market power. The market power arising from patents is overstated, while the degree of monopsony (sole buyer) power of purchasers is understated.

The Secretariat's paper expresses concern that the temporary exclusivity provided by patents may give a degree of market power to pharmaceutical companies that is undesirable in terms of society more widely. Several sources or forms of distortion are cited:

- treatment choices being distorted or denied by having price above marginal cost (paragraph 46);
- weak competition in R&D, such that the patent protection given by legislation is more generous than required (paragraph 44); and
- companies being able to devise secondary patents to prolong an underlying patent for longer than legislators intended (paragraphs 44-45);
- studies of the importance of patents have consistently found that patents are more important to innovation in pharmaceuticals than in other industrial sectors.[8] With almost universal agreement on the need for effective intellectual property protection to encourage the development of new medicines, the first point requires an alternative method of providing such protection if prices are to be reduced to marginal costs of production. The Secretariat's proposals here are considered in Section 3.2 below.

The key evidence on the second of these points consists of evidence of change over time in the effective degree of patent protection and the market power it confers; and evidence on the underlying rate of return on capital invested in the pharmaceutical sector compared to that in other industries. As noted above, there is no evidence in the report on change in competition over time. The key point that remains – the evidence on whether the pharmaceutical sector has consistently earned supernormal profits – is considered in Section 2.5 below.

2.3 Optimal patent length and patent renewal

The third point, the question of whether innovators should be able to extend the protection of intellectual property by secondary patents, remains unresolved from the economic literature.

A long patent life increases the inventor's appropriability at the cost of a longer period of monopoly pricing, likewise a shorter life reduces appropriability but brings about efficient pricing sooner. The natural implication is that an optimal patent life lies somewhere in between the two extremes.[9]

Even though all countries impose a uniform statutory patent life, most patent systems require that patentees pay annual renewal fees in order to maintain patent protection up to a statutory patent life. Even if these fees (variable across countries and usually rising with patent age) are relatively low, they have effectively created a degree of differentiation in patent lives.

Patent renewal fees are currently often used simply as a fiscal device to fund patent offices, but some economists argue that patent renewal fees can be designed strategically by the government in order to improve economic efficiency. The disadvantage of a uniform patent life is that it may provide *ex ante* excessive incentives to carry out R&D to the low productivity firm and insufficient incentives to high productivity firms. For this reason it may be welfare-increasing to differentiate patent life across inventions[10]. The differentiated scheme is implementable through renewal fees that endogenously determine an optimal pattern of patent life. The optimal pattern of patent life spans depends on the degree of heterogeneity in R&D productivity across firms, the ability of patentees to appropriate the potential rents generated by R&D and the learning process about the value of innovation.

A related debate has focused on the conditions under which innovators of incremental improvements should be able to obtain patent protection. This has focused on the conditions under which other companies should be able to patent products that rely on the basic innovation, typically concluding that the ability to do so should be restricted.[11]

No clear conclusion emerges from this literature on the extent to which innovating companies should be able to develop secondary patents to prolong the effective lives of their own products. One important point, however, is that the focus of debate should be on the appropriateness of the intellectual property protection in general, not on that for particular products. This is because the distribution of returns across products is highly skewed, with most returns coming from a small proportion of products – Grabowski and Vernon's analysis showed 70 percent of returns coming from a fifth of products, and most products not breaking even. [12]

2.4 Market power of purchasers

The understating of the market power of purchasers is a third serious imbalance in the OECD paper. The most the Secretariat acknowledges is that:

> "It is possible that some national health insurers are sufficiently large to have sizeable bargaining power with respect to certain manufacturers" (paragraph 118).

This is an obvious understatement of the current situation. The real position is that within most OECD Member States, the main purchasing authority is in the public sector and has a high degree of monopsony (single buyer) power backed by statutory control over price levels and reimbursement schedules.

Many EU Member States countries, including Belgium, France, Greece, Italy and Portugal, impose legal controls on manufacturers' maximum selling prices of drugs, either individually or by therapeutic category.[13] Various criteria are used for determining prices such as allowable costs, the prices of existing drugs with comparable therapeutic effects, or the prices charged in other countries.

Health insurers in OECD countries, whether private or, as in most cases, public, then set reimbursement prices for particular products. Reimbursement prices may be directly related to the manufacturer's selling price ceiling or they may be separately determined by other characteristics, such as perceived therapeutic benefit.

These price and reimbursement controls are powerful limits on the market power conferred by the possession of a patent. Companies are not free to set the prices of their products. The companies are unable, in practice, to simply refuse to supply a vital medicine, and this further weakens their negotiating position. Within the EU, companies typically cannot raise the price of medicines above the initial level,

and indeed in many countries such prices are subject to arbitrary cuts. This can also create serious distortions in pricing behaviour.

- The free movement of goods within the EU means that a low price set by purchasing authorities in one Member State affects the value of patents in all Member States. This is particularly important given that individual Member States have strong incentives to set low prices and free-ride on the willingness of others to fund R&D investment. Such parallel trade can prevent the efficient recovery of sunk costs and lead to reduced access to important medicines for patients in countries with lower per-capita incomes.[14]

- Some forms of price control encourage the introduction of "new" products that are marginal improvements or line extensions merely to gain approval for a higher price. Hence the evidence cited by the OECD that most new products in Germany in the 1980s did not represent significant therapeutic advance (footnote 35 to paragraph 43) is as likely to be a result of price and reimbursement controls as it is to constitute an argument for them.

2.5 Does the pharmaceutical industry earn super-normal profits?

The OECD paper reports that inter-industry comparisons show the pharmaceutical industry to have consistently earned higher profits than an average of other industries, and that this result is robust to the necessary accounting adjustments. If this conclusion were shown to be sound, this would be a powerful result suggesting either an excessive degree of intellectual property protection for pharmaceuticals or some other source of continuing market power.

As reported by the OECD, comparisons using simple versions of standard accounting ratios usually suggest that the profitability of the pharmaceutical sector over time has been higher than that of other sectors. [15] For instance, Scherer (1996) notes that over a 32 years period, the return on equity averaged 18.4 percent for pharmaceuticals and 11.9 percent for 500 largest industrial companies. This study is cited by the OECD report, but not Scherer's comment that accounting profits are likely to overstate actual profits in the drug industry. The issue of the appropriate accounting adjustments is central to the debate.

Research-based pharmaceutical companies invest substantial sums in R&D. These sums are investment in intangible capital, creating valuable assets, such as patents, trademarks, know how, brand loyalty and skilled workforce that may generate cash flows for many years. Such investments, in accounting statements, are usually treated as an expense rather than as a capital investment. As a consequence, for the pharmaceutical industry, as for any other industry with significant intangible investments, accounting measures of capital are downward-biased and estimates of returns on capital (usually calculated as ratios of income to assets) are upward biased. This bias fuels the perception that the pharmaceutical industry earns abnormally high profits, which in turn leads to pressure for lower prices.

In analysing more precisely the expected effects of switching from expensing research to capitalising and depreciating it, two different cases should be considered:

- A steady-state: in this case annual research expenditure should equal the annual depreciation of the research assets, so as to maintain the stock of those assets. Removing research expenditure from costs and adding research depreciation should leave annual costs, and hence annual profits, unchanged. Capitalising research expenses will add a new element to assets without reducing anything else. Hence a switch from expensing to capitalising research must reduce the return on assets.

- Growth: in this case current research expenditure will exceed the depreciation on past expenditure. Hence capitalising research will reduce costs and so increase profits. Since assets will also increase, the effect on the rate of return will be indeterminate, depending on the actual magnitudes involved.

Clarkson conducted an analysis of Merck & Company accounting records to correct accounting rates of return in order to remove some of the differential effects of unrecorded intangible capital.[16] He found that the accounting return on book equity over the period 1980-1993 dropped from 27.5 percent to 14.3 percent after correcting for the investment outlay and correcting equity for the omission of intangible assets.

In a comparison across US industries for 1980-93, Clarkson found an unadjusted "accounting" rate of return for pharmaceuticals to be 24.4 percent, highest of 14 sectors and twice the 14-industry average of 12.3 percent. Under his corrected rates of return, the comparative figures were 13.3 percent and 10.3 percent, and the rate of return in pharmaceutical industry was fourth of the 14 sectors.

These are not the "small" reductions suggested by the OECD. Clarkson's analysis suggests that once accounting rates of return are adjusted for intangible capital, the pharmaceutical industry no longer stands out as having particularly high returns on capital that other industries. Scherer also reported that there may be downward pressures on the rate of return in pharmaceuticals, a view supported by more recent evidence. For example, the US Congressional Budget Office concluded that the net effect of the rise in generic competition since 1984 and the patent life extensions under the Hatch-Waxman Act has been a fall in the average returns from a branded medicine in the US of about 12 percent.[17]

A full analysis of relative profitability of different industries also needs to take account of risk. Myers and Shyam-Sunder explain why the cost of capital for pharmaceutical R&D is higher than the cost of capital for producing and selling established drugs.[18] Differences in the underlying riskiness of returns across industries may also provide part of the explanation for the higher average rates of return observed in pharmaceuticals.

Other measures also cast doubt on the view that pharmaceutical companies earn super-normal profits. Zweifel and Breyer cite studies that calculated the internal rates of return of pharmaceutical innovations in the United States to be an average of 6.1 percent.[19] In addition, they estimate that half of the innovations that were introduced in the United States during the period 1962-1977 would not have paid back their development costs even after 36 years.

3. The Secretariat's main recommendations

As noted in the Introduction, the Secretariat follows through its analysis of competition and market power with two main recommendations.

3.1 Privatising the regulation of pharmaceutical pricing and reimbursement

The OECD paper suggests that in many OECD countries the private sector may be better able to manage the procurement and use of pharmaceuticals than the current public sector agencies (paragraph 71, and emphasised in the conclusions (paragraphs 168-169)). "The tendering process would be designed to keep pharmaceutical costs down to a minimum and to innovate in techniques for monitoring and controlling pharmaceutical expenditure." (paragraph 71).

This proposal builds on what is viewed by the Secretariat as the successful development of new models of health care management in the US. The US economic literature shows that over the last 15 years, the pricing and other competitive strategies of pharmaceutical companies have been altered by developments in information technology, new state drug substitution laws, federal legislation and the emergence of market institutions that include health maintenance organisations ("HMOs")[20] and pharmacy benefit managers ("PBMs"). The industry has also undergone significant structural changes that include growth of the generic drug segment and substantial horizontal and vertical consolidation such as acquisitions of PBMs by drug companies.

Whether the market power of US health plans with monopsony powers as purchasers of health care services and market power as health insurers may lead to socially unattractive outcomes has long been the subject of debate in the US.[21] The evidence is that such power may well have been used to reduce the cost of health care, but it remains much less clear whether this has been accompanied by reductions in the quality of care.

There are several respects in which the direction of reform outlined by the Secretariat may be less promising than it first appears. These include the following:

- The Secretariat's paper does not explain what would happen to the statutory powers most OECD member state governments have taken to set prices and reimbursement rates. Would this market power simply be delegated? One study that found no evidence of abuse of market power in the US from the development of HMOs and PBMs (such as reducing services, shifting costs or forcing consumers to take over-specified plans) suggested that this result may reflect the threat of competitive entry. [22] If so, it cannot be relied on as a precedent for the behaviour of European firms given a statutory monopsony.

- Reductions in pharmaceutical expenditure can lead to higher costs elsewhere in the health care system, or in later years. It needs to be made clearer how contracts could be drawn up requiring private firms to reduce pharmaceutical costs without generating such undesirable side-effects.

- If private sector companies with strong monopsony positions were charged with keeping down pharmaceutical expenditures over a certain time period, what steps would be taken to ensure they recognised in their behaviour that the sunk costs of R&D expenditures need to be recovered through pharmaceutical prices? The long lags in the development of new products would mean that even in the extreme case of refusing to recognise any need for intellectual property protection and forcing prices down to marginal production costs, it would be several years before the supply of new medicines dried up.

- Companies charged with minimising pharmaceutical expenditures could be expected to seek to exclude expensive categories of treatments from what was provided, even where the benefits of the treatment could be shown to outweigh the costs. They could also be expected to seek to exclude from benefits, patients who were likely to be expensive eg the elderly or those with expensive-to-treat medical conditions. How would governments write contracts that prevented such exclusions?

4. Replacing patents with other forms of intellectual property protection

It is common ground that R&D investments in the pharmaceutical industry need to be protected through intellectual property rights. Without this protection, the expectation would be that that the price of

a product, once developed, would be bid down to marginal production cost. Under such conditions, investment in the development of new medicines would simply stop. As noted in Section 2, empirical evidence shows that the pharmaceutical sector relies more on patent protection than most other sectors.

Section 2 above reviewed the Secretariat's argument that patents grant an excessive degree of market power, and found it unconvincing. However, the point remains valid that by allowing prices to be set above marginal cost, patent protection introduces an economic distortion. The effects of this distortion could be significant. For instance, if the price of a pharmaceutical is above the cost of certain alternatives, patients may be forced to incur in the cost of surgery, even if the cost of a pharmaceutical, based on its marginal cost, is higher than the cost effectiveness of these alternative treatments.

Besides patents there are other techniques for protecting intellectual property rights such as awards (eg for scientific achievements), contracts (eg for defence research), or copyright. The Secretariat notes other possible mechanisms but emphasises compulsory licensing (paragraph 48 and the subsequent box).

The main proposal put forward for discussion by the Secretariat is to control the purchasing contracts between manufacturers and national health insurers, replacing patent rights by a royalty paid under a compulsory licensing system. Insurers would offer to pay a fixed annual fee in exchange for purchasing a brand-name drug at its marginal cost. The level of the fee should be chosen so that it would compensate the manufacturer for the loss of market revenue (therefore its R&D expenditures), while eliminating at the same time the distortionary effect of pricing above the marginal cost. Presumably, a government agency would also take over the role of informing medical professionals about the availability and characteristics of the new product.

Such a compulsory licensing system would presumably have to be introduced for all products simultaneously, otherwise the value of patents in products competing with those subject to compulsory licensing would be destroyed. Within the EU, they would also have to be introduced in all countries simultaneously if parallel trade was not to undermine the value of patents in countries where they were still valid.

To encourage efficiency in production, the Secretariat suggests that several companies might also compete for the right to produce the licensed product, (see especially paragraphs 113-117) but that is a secondary issue to that of the effects of compulsory licensing on the development of new medicines.

The technical economics literature does not establish that patents dominate prizes or research contracts as a form of reward. Wright (1983) shows how different forms of information asymmetry between firm and government make different forms of intellectual property rights socially optimal. [23] In his model, the key difference of patents from prizes or research contracts is that they allow information held by researchers but not by government about the potential value of successful inventions to be incorporated into the allocative process.

The primary advantages of patent protection are its efficient use of information and the fact that the patent process makes new innovation public information. The economic and social value of a new innovation is extremely difficult to assess in advance. The Secretariat does not explain how, even at the point at which a product was ready for market, governments would estimate its likely potential commercial value to determine the royalty.

Indeed, in a world of compulsory licensing there would be no such concept as the potential commercial value of a new medicine. Instead, the royalty would in practice have to be determined by what

governments could measure: their estimate of the degree of therapeutic advance, or their estimate of the savings in health care costs.

As noted by Grabowski and Vernon (see reference above), the value of patents in pharmaceuticals is skewed.[24] Most of the returns come from a small minority of patents. Suppose that with the samples of patents studied in these references, governments following the OECD Secretariat's recommendations had placed caps on the maximum royalty payable at the level of the 25th percentile of the distribution ie the upper quartile. Such a move would have greatly reduced the total returns.

The expected value of a patent on a new medicine, and changes in this value over time, provide an important indicator and guide during the development of new products. What would take its place in that role if patents were abolished? Under compulsory licensing, products already well advanced in the pipeline would be brought to marketable stage. But for the longer term, a critical question would be the following:

> "At the time it first synthesised a new product and developed a notion of its therapeutic potential, would the returns a company expected to make on developing the product and undertaking clinical trials make that investment worthwhile?"

If not, then governments may need to plan and carry out trials themselves, paying companies royalties simply in respect of initial innovations rather than of marketable products.

This suggestion by the Secretariat is incomplete, as it does not specify any solution to the central issue of the information the royalty decision would be based on and how that information would be used.

5. Conclusions

This paper has provided a brief review of the OECD paper on regulation and competition in pharmaceuticals. Our main conclusions on the Secretariat's analysis are as follows:

- The Secretariat's conclusions on competition in pharmaceuticals do not give enough weight to the central role of innovation in competition. The readily available evidence suggests that competitive pressures may be reducing the value of pharmaceutical patents over time.

- The Secretariat's paper significantly understates the extent of monopsony (single buyer) power held by national health authorities.

- The argument on whether companies seeking to extend patents is an abuse or not, is not as clear-cut as the Secretariat's paper suggests.

- The evidence we have seen does not suggest that rates of return in the pharmaceutical industry, once measured correctly, are significantly out of line with those in other industries.

The Secretariat's argument that patents give an excessive degree of market power in pharmaceuticals is therefore less than wholly convincing. Its weakness is made more serious by the minimal treatment in the OECD paper of market power on the demand side of the pharmaceuticals market. The two main proposals put forward by the Secretariat do not seem to have been adequately considered:

- the proposal to privatise the management of the procurement and use of pharmaceuticals does not take into account the market power of health insurers or the difficulties of contracting to

avoid short-termist or otherwise opportunist behaviour by private companies charged with reducing the drugs bill; and

- the proposal to replace patents for pharmaceuticals with compulsory licences fails to spell out the information and processes that would be used to determine the value of these compulsory licences, and does not consider what the longer-term consequences of such a move might be for the development of new medicines.

NOTES

1. . To properly consider regulation consistent with consumer welfare, one should examine the full range of factors that affects this market, such as health insurance.

2. In fact, the US Congress repeatedly has modified the patent laws as they relate to pharmaceutical products. For example, the US Congress has enacted term extensions, modifications to the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), exceptions from patent infringement for R&D, and a number of other changes designed to address concerns about competition in the pharmaceutical industry.

3. . From the IMS Health analysis, only four of the top 15 selling drugs in 1987 were in the top 15 in 1997.

4. . For US policy, see for example, "Antitrust Guidelines for the Licensing of Intellectual Property", US Department of Justice and Federal Trade Commission, April 1995, with the emphasis on future-generation products: here the market definition refers to goods and services which ultimately flow from R&D.

5. . See European Community Antitrust Law-Innovation Markets And High Technology Industries, by John Temple Lang LL.D, Fordham Corporate Law Institute, 17/10/1996, New York.

6. . Evidence for the UK shows a marked acceleration in the rates of subsequent entry Towse, A. and Leighton, L. "The Changing Nature of NCE Pricing of Second and Subsequent Entrants." *Risk and Return in the Pharmaceutical Industry*. OHE, (1999).

7. . H. Grabowski and J. Vernon found that 11 branded drugs whose US patents expired between 1988 and 1992 had an average generic market share of 50 per cent in the first year after patent expiry, compared to 38 per cent for a sample whose patents expired in 1986-7. (Longer Patents for Increased Generic Competition in the US: the Hatch-Waxman Act after One Decade." *Pharmacoeconomics* 1996.

8. . A 1986 study by Edwin Mansfield, through a survey of firms from 12 industries, found that only 14 percent of innovations overall (in a period from 1981-83) would not have been developed without patent protection. However, this figure was 30 percent for chemical inventions and as high as 65 percent for pharmaceutical inventions: most of the pharmaceutical innovations in his study would not have taken place without patent protection.

9. . As Zweifel and Breyer view it, the optimal length of patent protection can be regarded as the result of a noncooperative game between the Patent Office and the innovator. Zweifel, P. and Breyer, F. *Health Economics*, Oxford University Press, 1997, p. 317.

10. . Cornelli F, Schankerman M. (1996), "Optimal Patent Renewals" Paper to the LSE Economics Industry Group, ISSN 0969-4447.

11. . See two articles in the *Rand Journal of Economics*: Scotchmer, S "Protecting early Innovators: should second-generation products be patentable?" RJE, Vol 27. no.2 (summer 1996) pp322-331; and O'Donoghue ,T "A patentability requirement for sequential innovation" RJE Vol 29 No. 4 (winter 1998) pp 654-679.

12. . Grabowski HG, Vernon JM "Returns to R&D on New Drug introductions in the 1980s" *Journal of Health Economics*,13 (1994) pp 383-406.

13. . A detailed description of price and reimbursement control in these countries is contained in Europe Economics: (2000) "Access to Important New Medicines: Where and Why do Patients Wait? *Two Studies*".

14. . The economic analysis that shows that for products with high sunk costs (such as research and development costs) and consumers with different willingness to pay, allowing parallel trade is likely to reduce, rather than increase, economic welfare, is set out in an article published earlier this year by staff at Europe Economics: Tim Booer, Peter Edmonds, Dermot Glynn and Claudia Oglialoro, *Economic Aspects of the Single Market in Pharmaceuticals*, European Competition Law Review, Volume 20 Issue 5, May 1999.

15. The most common indicators of profitability are ROE (return on equity) and ROI (return on investment). The former is the ratio between earnings and average equity, while the latter is the ratio of after tax operating income to the net (depreciated) book value of assets.

16. Clarkson KW "The effects of research and promotion on rates of return". In Helms R, editor. Competitive strategies in the pharmaceutical industry. Washington, DC: The American Enterprise Institute Press.

17. . CBO "How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry" July 1998.

18. Myers, SC and Shyam-Sunder, L. Measuring Pharmaceutical Industry Risk and the Cost of Capital in RB Helms ed. "Competitive Strategies in the Pharmaceutical Industry" AEI press, Washington, 1996.

19. Zweifel, P. and Breyer, F. *Health Economics*, Oxford University Press, 1997, p. 309.

20. HMOs provide health care coverage and services for roughly 11 percent of the US population. They generally offer relatively extensive coverage for prescription pharmaceuticals.

21. . See Pauly, MV "Market Power, Monopsony and Health Insurance Markets", *Journal of Health Economics* 7 (1988) pp111-128.

22. . Monopoly, Monopsony and Contestability in Health Insurance: A Study of Blue Cross Plans: S Foreman, J Wilson and R Scheffler, *Economic Inquiry* October 1996 pp 662-677.

23. Wright , Brian D (1983) "The Economics of Incentives: Patents, Prizes, and Research Contracts" *American Economic Review* Vol 74 no.4 pp 691-707.

24. See also Schankerman, M : "How Valuable is Patent Protection: Estimates by Technology Field " *Rand Journal of Economics* Vol 29 No.1., Spring 1998. pp 77-107

AIDE MEMOIRE OF THE DISCUSSION

1. Introduction

The Chairman introduced the roundtable noting that the pharmaceutical industry is quite different from the other industries analyzed in this Working Party. It is an industry which is heavily regulated, but not because the industry cannot sustain competition. The pharmaceutical industry is regulated for three primary reasons: First, to guarantee a return on research and development; second, to ensure that the products that are brought to market are safe and will not harm consumers; third, to offset the effects of health insurance on the pharmaceutical demands of individuals.

The roundtable was organised into four topics: (*a*) intellectual property rights and the drug approval process; (*b*) health insurance controls on quantity and quality of health expenditure; (*c*) regulation of pharmacies; and (*d*) antitrust enforcement in the pharmaceutical industry.

2. Intellectual property rights and the new drug approval process

Turning to the first part of the roundtable, the Chairman observed that despite the fact that all OECD countries are signatories to the TRIPs agreement (which introduces a minimum period of patent protection of 20 years from filing) countries differ in terms of the effective period of commercial exploitation of pharmaceutical patents because of the different way they take into account the time required for approval of new drugs. Many countries (New Zealand is an exception) extend the basic period of 20 years from filing to take into account the time for new drug approval. But the extension is not the same in all jurisdictions and leads to differing times of effective patent protection among countries.

The United States described their policies with regard to new drug approvals. The approval process of the US Food and Drug Administration ("FDA") can last up to 15 years. This process proceeds in a series of three phases, labelled phases I, II, and III, which involve increasing numbers of human subjects. These phases involve tests for safety, efficacy and dosing.

Since patent protection starts from the time of filing (prior to commencing the process of market approval) the effective life of a patent (i.e., the time during which the patent can be commercially exploited) is significantly reduced. In 1984 the US Congress passed the Hatch-Waxman Act which tried to accommodate the lengthy drug approval process by providing for an extension of the patent term. The patent term is extended by taking into account the time spent in clinical testing (phases I, II and III) and the time that the FDA itself takes to approve the drug. However, the total extension cannot be more than five years and the total effective patent life cannot be more than 14 years (which approximates the average period of effective protection for other patents subject to a simpler approval process).

In exchange for this patent extension, Congress provided incentives to speed the approval and entry of generic drugs by establishing an Abbreviated New Drug Application ("ANDA") process for generic manufacturers. Provided they could demonstrate bio-equivalency and that the generic drug was for the same use, conditions and dosage as the original branded product, generic manufacturers were allowed to rely on much of the research material that the manufacturer of branded product had already submitted to

the FDA. In order to benefit from the ANDA process the generic manufacturer must certify that when it gets to market it will either not be infringing the patent of an existing branded manufacturer, that the patent has expired or that the patent was invalid.

The US delegate concluded by recalling some points that emerged from FTC hearings in 1995 on intellectual property rights. Although in many industries firms may be able to use alternatives such as being the first to market or trade secrets to protect or benefit from their investment in R&D, in the pharmaceutical industry in particular, patents are essential to stimulate innovation and to encourage research and investment.

The European Commission agreed with the United States about the important and legitimate role that intellectual property rights play in this sector. In addition to the standard patent protection of 20 years from filing granted by international treaty, the EC delegate highlighted two further points. The first related to the Supplementary Protection Certificate legislation, which the European Union agreed in the early 1990s, mirroring the provisions in United States which allow up to five years extension on top of the 20 years from filing period, to compensate for time taken in the research and development process. The general mechanics of how that legislation works is very similar to the US. The second point related to the provisions for data protection in the medicines licensing process. Companies are effectively given a form of property right in the clinical trial data that they produce in support of the first application for a product. In the case of an application through the centrally authorized licensing procedure these rights last ten years. The effect of this data protection is that generic companies cannot rely on the original data when they make an application for the right to market products. This means they have to conduct clinical trials themselves, even if the original patent has expired.

There are two processes by which companies obtain an authorisation to market a drug. The first is through what is called a “centrally authorized” process, where the company makes the application to the European Medicines Evaluation Agency (“EMEA”). The EMEA works in conjunction with the competent national authorities to come up with a scientific assessment of the product which is then passed to the European Commission as the formal licensing agency. The second process is the “mutual recognition” route where a company makes an application to an individual competent authority in one of the member states but declares in which other member states it wishes that license to be valid. The license which is ultimately issued is valid in all of those member states. The aims of the licensing process are: entry to the market in one process; a focus on safety, quality and efficacy and not pricing and other issues; and contribution to the creation of the single market, particularly through product harmonisation.

Italy described why a situation arose whereby patent protection in Italy was longer than in other EU countries. Just before the European regulation on supplementary patent protection, Italy passed a law which allowed up to 18 years of supplementary protection. After the European regulation was passed, the Italian legislation was adjusted to fall into line with the European legislation. But during the short period when the longer patent protection was in force almost 400 products received supplementary protection. As a result there are products in Italy still under protection which in other countries are off patent. The Italian antitrust authority has twice signalled this problem to the government. Italian pharmaceutical firms do not investment substantially in research and development, so this kind extended patent protection does not protect Italian research.

The statutory time periods for approval of drugs in Mexico are very short. The length of the approval process depends on whether a drug is already patented and approved in other countries. If it is approved in other countries Mexico relies on the efforts of other countries and has a very short procedure for approval. If a drug is completely new and not approved in other countries, approval may take up to 90 days to obtain in Mexico. This is very short compared to other countries.

The Chairman then gave the floor to BIAC who expressed a number of concerns about the background paper. These concerns were summarised as follows: First, concerns that the background paper promoted a dilution of intellectual property rights through compulsory licensing (associated with a system of guaranteed rate of return on the IPR investment) reducing incentives for research and development and the availability of high-quality drugs in sufficient quantities for consumers. Second, BIAC was concerned that price controls and other forms of regulatory intrusions to stimulate competition in the pharmaceutical industry are inferior and counterproductive relative to rational antitrust enforcement and the promotion of market welfare. Third, the background report suggests that collusion is common in the pharmaceutical industry, citing the 1996 opinion of the District Court in the "brand-name pharmaceutical" litigation, but neglects to point out that subsequently, the judge on reviewing the evidence more fully states that any evidence of collusion was based on speculation and conjecture.

Another member of the BIAC delegation (from Europe Economics) commented that the background paper is wide-ranging but reaches conclusions that are unbalanced and not soundly based. In the view of the delegate, the key issue that the paper addresses is whether pharmaceutical companies benefit from excessive market power. The background paper fails to consider that in capital intensive industries profitability needs to be assessed by comparing prices not to variable costs, but to total cost, i.e. taking into account a "normal" rate of return on investment, including R&D investment. Clarkson has quantified the discrepancy between accounting and "corrected" profits in a detailed study. The difference after corrections is a few percentage points.

Second, the delegate questioned whether a high market share was a problem or something to be welcomed. A company would presumably only have such a position if its drug represented a major medical breakthrough, which is the objective of the intellectual property rights system. No compulsory licensing should be imposed, as argued in the background paper, in such circumstances. Compulsory licensing would require that a value be set by some public authority on an innovation that had been made which would in the opinion of the delegate be an intolerable task.

Third, the paper touches upon but does not do justice to the importance of competition for innovation. John Temple-Lang, Director in the EC Competition Directorate, has said: "In [high-technology] markets price is often less important than the technical or other advantages of the product. These advantages are usually due to an innovation, which is likely to be a recent innovation because all or almost all the features of these products are changing". This aspect of the industry – where the major companies are competing to get to the major products – is at the heart of competition and, in the opinion of the delegate, is not adequately dealt with in the background paper.

Fourth, the paper understates the extent of competition in the market and how it is changing. Recent work, which is mainly UK based, suggests that follow-on or me-too products are coming along faster and pricing more keenly compared to the path-breaking first products.

Fifth, with regard to purchasing power, the paper states that "it is possible that some national health insurers are sufficiently large to have sizeable bargaining power with respect to certain manufacturers". In the opinion of the delegate this is an understatement of the real situation. In most OECD countries the main purchasing agent is the state in one form or another.

Sixth, the paper omits any major discussion of international trade issues in pharmaceutical products. It does correctly say that prices in one country are sometimes set with respect to prices in other countries, but it does not explicitly state that a low price set by a country which has no interest in the continuation of research and development might lead to increased exports into other countries, undermining R&D expenditures.

BIAC then passed the floor to a representative of Merck who commented that the paper focuses on concentration in individual therapeutic classes. The delegate claimed that correct statistics in relevant markets would show that this is a competitive industry, especially in view of the large number of pharmaceutical companies which exist around world. The delegate noted that there have been a large number of decisions rendered by antitrust authorities in recent years and these authorities have frequently come to the view that mergers do not create an antitrust issue. In very few mergers are conditions imposed on the parties. This contrasts significantly with other industries in which mergers are either prohibited or abandoned because of the heavy conditions that are imposed by antitrust authorities on the parties.

The delegate emphasised that focus should be placed on the inefficiencies of state regulation in the pharmaceutical industry, both regulations regarding product approval and also price and reimbursement negotiations. The delegate noted he was aware of many cases in which innovative drugs could not be put on the markets in a number of countries in the EC. Such as might be the case when a company cannot agree a price with authorities in Belgium even though the same drug is available in France. There are examples of new innovative products not coming on the markets while many off-patent products remain on the formularies in OECD countries. The delegate noted he found it difficult to see how compulsory licensing could be introduced with the royalty determined by the government.

The delegate concluded by noting that the statements and statistics in the paper on the profitability of the industry contrasted with observations regarding how long it takes to bring a product to the market. Pharmaceutical companies face significant risks. Very few discoveries ever result in products that come to the market and when you have a marketable product you are faced with price and reimbursement negotiation delays. In the view of the delegate it seems quite contradictory to say that this could be an industry which is enjoying profits which are significantly higher than other sectors.

BIAC then passed the floor to a representative of Glaxo Wellcome who emphasised that a judgement that is made about the level of pharmaceutical prices and the level of pharmaceutical company profitability ultimately involves a social judgement about levels of research and development. Pharmaceutical companies finance all of their research and development internally from their own revenues and profits. In addition, as budgetary pressures on pharmaceutical companies increase, the impact on R&D is not only quantitative but also qualitative. The first projects that an R&D company would eliminate from its budget are the most risky projects which are also, in the view of the delegate, the projects which may bring the most benefits for consumers.

The delegate went on to discuss the extent to which pricing policies by governments pursuing different social objectives can be distorted or exported by different systems of regulation that are adopted. Reference pricing is a moderate form of this phenomenon. A clearer example within the European Union is the effect of the rules on freedom of movement of goods and the effect they have on the creation of parallel trade. Price regulation within the European Union is a national affair - prices are not regulated by the European Commission but by national governments, each of which has its own perception about the trade-off between price and quality. That system would work reasonably well except that the rules on the freedom of movement of goods create a situation in which the pricing decisions of low-price countries in the EU get exported to the high price countries. This creates a significant distortion in the market and a significant distortion of competition. Governments are monopolist purchasers – they determine the prices that can apply and they also regulate access to the market. The interplay of that function, when combined with rules on free movement of goods can give rise to very significant competitive distortions in the market.

In response to the BIAC comments the United States delegate noted that background papers try to be fair, blunt and honest. The BIAC interventions give the impression that the paper claims that pharmaceutical companies are rapacious and the most profitable companies in the world. The background

paper attempts to make creative proposals about how one might get pharmaceutical services to citizens when the alternative of surgery will be (in some cases) much more expensive. The delegate raised a question whether existing prices are the only prices that adequately compensates R&D – if pharmaceutical companies received a little less compensation what products would be lost?

France congratulated the Secretariat for the quality of this document and noted that it found the paper balanced and not taking a position opposed to the pharmaceutical industry.

The EC delegate also congratulated the Secretariat for the paper and noted that the intention of the paper was to give a broad picture of the pharmaceutical market (both the antitrust and regulation issues) in order to provide a basis for the discussion. The delegate emphasised to BIAC that competition authorities will never punish an industry for being profitable. Neither would they punish a company for having market power, even 100 percent market share in one therapeutic class. Competition law is about preventing the use of that market power to restrict competition. In regard to parallel trade and the export of low prices, the paper points out that the European Court of Justice has an extensive case law on that (supporting free movement of goods) which the industry delegates did not mention.

The Switzerland delegate, echoing the views of the US and France, noted that the background document was well balanced. The document reflects well the situation in Switzerland (which has some substantial experience in the field of pharmaceuticals). The delegate also expressed his wish that the discussion did not focus on expressing doubts about the analysis set out in the Secretariat document.

Canada picked up on the concern about the market share figures in the background paper, noting that it was misleading in a paper destined to a competition audience to set out market share figures in various therapeutic classes when those therapeutic classes may not be relevant markets for the purpose of competition analysis (as the disclaimer in the paper points out).

In response to these interventions BIAC noted that it would also like to thank the Secretariat for its work. BIAC emphasised the importance of research, recalling that that five years ago people with AIDS were viewed as people who were going to die, while nowadays many millions of AIDS sufferers live thanks to the medicines that have been discovered by the pharmaceutical industry. BIAC noted that before discussing the regulation of prices of a drug it is necessary to have the drug in the first place. The creation of a drug requires confidence. The delegate concluded that it is not by using out-of-date economic models that we encourage research and progress.

France thanked the BIAC for emphasising the importance of innovation. France noted that competition authorities are very sensitive to the need to encourage innovation. In regard to use of an out-of-date economic model, competition authorities base their analysis on a certain number of principles or concepts. The delegate recalled a roundtable on intellectual property rights and innovation markets that was held in October 1997. That roundtable tried hard to understand in what cases the competition law might limit innovation as little as possible. In the context of that roundtable three options were presented. The first option was to correct the weaknesses which result from the protection of intellectual property rights by fixing a price at which the intellectual property must be licensed. In this case it was recognised that such actions might be detrimental to the dynamic processes of innovation in the economy. The second option consisted of limiting the rights of usage linked to intellectual property rights. This option was also put aside by economists as being undesirable in the light of certain detrimental consequences. The third option which emerged in the context of that roundtable was for competition authorities to content themselves with limiting the abusive usage of intellectual property rights. This was suggested by the economists as the best means in which to encourage innovation while not limiting the intervention of competition authorities. The delegate emphasised that this is the approach of most of the competition

authorities at this roundtable and that to describe an economic model which is out-of-date is not to describe the practice of competition authorities.

TUAC made three points. On the need for compulsory licensing the delegate noted that the option of compulsory licensing should be available to national governments in cases where pharmaceutical companies are negligent in the development phase of production of a new drug. In regard to mutual recognition by different national states of the approval of a new drug, it is important that mutual recognition does not lower standards to the lowest common denominator. On parallel importing, this is a difficult problem to resolve. It is worth noting that parallel importing is inefficient on environmental grounds.

3. Health insurance controls on quantity and quality of health expenditure

The Chairman introduced the second part of the roundtable noting that the demand side of the drug market is profoundly affected by health insurance. All OECD countries have some form of health insurance, either private or public, which covers, fully or partially, pharmaceutical expenditures. The problem with health insurance is that final consumers, being insured, do not have the right incentives to save on the price of the medicines that they purchase. Neither does the prescribing physician have the right incentives. So health insurance companies and governments try to provide incentives both for the patients to demand low-cost medicines and for doctors to prescribe low-cost medicines.

Introducing the discussion on price regulation, the Chairman noted that many countries fix drug prices using an average of foreign prices. But, if every country looks at every other country, the system can lead to any level of prices – the outcome is indeterminate.

Pharmaceutical prices in Spain are set by government through negotiation with Farmaindustria, the association for pharmaceutical firms. Until very recently, these prices were set on the basis of the costs of the industry plus an agreed level of profit. In addition, at the last revision of prices, prices were reduced by an average of six percent. Pharmacists are allowed a margin of 27 percent of the final consumer price without taxes. Prices in Spain are lower than in the rest of Europe, so there is strong incentive for parallel trade, particularly export from Spain to high-priced areas like Denmark and Germany. In a recent case a multinational company set a two-tier price structure –one price for the domestic market and one for the rest of the European Union. Wholesalers and retailers complained to the competition authority in Spain and also to EC. In January of this year, the Spanish government passed a law to allow pharmaceutical companies to have different prices for the domestic market and for export.

The Chairman observed that co-payments are one of the tools by which insurers and governments create incentives for patients to demand low-cost drugs but it appeared that such a system does not exist in the Netherlands. In addition, the Dutch Cabinet put forward proposals to Parliament in April 2000 which seem to give much greater control to Dutch insurers over pharmaceutical expenditure.

The Netherlands noted that there had been a system of co-payments in the past but it was abolished. Previously, there was an excess payment of up to 200 Guilders per person but after patients spent the excess payment, coverage rose rapidly. Since the policy had little effect it was stopped. There was also a system of co-payments for pharmaceuticals but the administration costs were enormous so that also was stopped.

In regard to efforts by health insurance companies to control costs, there are around 26 public health insurers in the Netherlands providing compulsory public health insurance. As elsewhere, they use formularies as part of the effort to control the costs. But, there is not just one national formulary, but each insurance company is trying to develop its own list. So there is a “battle of the formularies”. This might

even have an anti-competitive effect – it is not clear what pharmaceutical companies have to do to get on a list, what prices and discounts must be offered and so on. The decisions to list or not list a drug are not checked by an independent committee. It might be better to have one uniform national formulary. There is an interesting parallel with the cases in the US submission involving vertical integration between pharmaceutical companies and PBMs as the Netherlands has similar concerns over the effect of leaving control of formularies to private companies.

The 26 health insurance companies are private undertakings with a long social tradition, that are now being asked to act as entrepreneurs. Historically, they were geographically based but that distinction has been abolished. They now all operate nationally. But their historical base remains very important. Each has a very big market share in its home area. Only ten percent of all insurance is supplied outside the home area. They are funded 90 percent from public authorities and ten percent from their own budget. This provides some stimuli to control costs. If they go over the budget one year they have to adjust their premiums in the future.

In the Czech Republic the expenditure of prescribing physicians is controlled by means of a pre-set budget. The value of this budget is determined by analysis of physician prescriptions over the comparable time period of the previous year. In addition, the average financial expenditure of physicians in the same professional activity is taken into consideration. If the physician exceeds his budgeted limits, it is possible to impose penalties.

The Chairman noted that Hungary has a computerised system linking pharmacies in order to monitor drug consumption and prescribing practices.

The delegate from Hungary (Ministry of Health, Department of Pharmaceuticals) responded that this system was built for financial reasons – so as to be able to reimburse pharmacists for the costs not covered by patients. Pharmacies report on a monthly basis and receive a reimbursement within two weeks. In regard to pricing and reimbursement policies in Hungary, there is a price negotiation meeting which is held on an annual basis. There is a governmental decree which prescribes what kind of reimbursement level can be assigned to certain therapeutic categories. Pharmaceuticals for less severe diseases are not reimbursed at all. There is a 50 percent reimbursement is for many acute conditions and 100 percent reimbursement for all drugs used for the treatment of severe and chronic diseases.

The Chairman observed that in Korea (and Japan) there is no distinction between the prescribing doctor and the pharmacist. However, starting from 4 July 2000 there will be a separation between prescribing and dispensing in Korea.

In Korea the health insurance prices of drugs are controlled by fixing the price which is reimbursed. After consultation with the Medical Reimbursement Committee the Minister of Health and Welfare determines the ceiling price of each item and price at which it will be released onto the pharmaceutical reimbursement schedule. A combination of criteria are used to fix the price of drugs. Prices of innovative new drugs which are technically improved and are cost-effective in comparison with existing pharmaceuticals are set on the basis of the average factory prices of the same pharmaceuticals in seven advanced (G7) countries. These prices are collected using commercial suppliers of offshore pharmaceutical formularies listing the price of drugs for reimbursement and insurance. The national health insurance scheme covers drugs prescribed by doctors and non-prescribed (or OTC) drugs which are listed in the pharmaceutical reimbursement schedule. Drugs used for non-therapeutic purposes such as promoting convenience in daily life are not covered.

The United Kingdom drew an important distinction between price regulation on the one hand and procurement negotiations on the other. The UK has a system of profit controls which gives pharmaceutical

companies some degree of liberty to seek their own prices within and overall profit cap. Rather than characterise this system as price regulation, the delegate emphasised that this is better characterised as a process of negotiation between a dominant buyer on the one hand and a dominant seller on the other. The pharmaceutical market is, in this respect, no different from any other procurement relationship between a dominant buyer and seller. This relationship often arises in the defence industry or between a dominant supermarket and its suppliers. In each case the buyer wishes to obtain the best price, guaranteed supply and some assurance of innovation as well.

The UK pharmaceutical pricing scheme, known as the PPRS, sets at a reference level rate of return at around 21 percent, based on an assessment of historic capital costs. Pharmaceutical companies cannot go over above a proportion of this reference level, or below a certain proportion. If they go above the reference profit level to a certain degree then they have to adjust their profits downwards. If they go below, they are afforded liberty to raise prices to some degree. The cap was renegotiated in 1999. Prices were generally reduced by 4.5 percent in the context of that renegotiation.

The Chairman asked the UK how costs are calculated since a multinational pharmaceutical company may undertake research in Canada, produce in the US and sell in the United Kingdom. The Chairman asked if the cap only applied to UK functions and activities?

The United Kingdom responded that the cap is based on an assessment of the historic capital costs (including R&D costs) incurred in the preparation off drugs sold to the NHS in the UK. Inevitably that raises problems because you have to divide capital costs between exports and sales to the NHS. To some extent this is a criticism against the system – the division of capital costs between exports and domestic sales is rather arbitrary.

4. Regulation of pharmacies

The Chairman observed that while the regimes governing intellectual property rights are relatively similar across countries we find large differences in the way pharmacies organised in different jurisdictions. In some countries the number of pharmacies is fixed. In other countries pharmacies are government-owned (e.g., Sweden). In other countries pharmacies are completely free and unregulated (e.g., Mexico). Furthermore in some countries pharmacies are restricted to selling prescription and non-prescription drugs. In other countries pharmacies are allowed to sell a number of other products such as cosmetics or health or well-being products.

In Sweden the pharmaceutical sector is heavily regulated. Although private pharmacies existed until the beginning of the 1970s, at that time a legal monopoly was granted to a state company. It was considered that this was the only way to guarantee universal service and to have uniform prices. The competition authority and other actors have suggested that pharmacies should be privatized but at present there is no sign of change in this monopoly.

The Chairman underlined the contrast with Mexico. In Mexico the pharmacy distribution system is completely unregulated with no restrictions whatsoever on the number pharmacies, on the type of goods sold in pharmacies and there is occupational regulation of pharmacists. The reason given in the Mexican submission is that Mexican pharmacists don't provide any additional processing of medicines – they just sell boxes. But this is common practice even with countries where there is a strong limitation on the number pharmacies. The Chairman asked Mexico to explain if there is a problem serving high-cost, low demand areas?

Mexico replied that entry barriers in retail pharmaceutical distribution in Mexico are very low indeed. Any person can open a pharmacy in Mexico – no special qualifications are needed. This may be

due to the fact that pharmacies only sell medicines – they do not prepare them or mix them in any way. Medicines leave pharmacies exactly the same form as they enter it. The consequence is that there are many, many pharmacies in Mexico. An association of small pharmacies in Mexico claims that each consumer has at least one pharmacy within a walking distance of five minutes from his or her home. The delegate admitted that system in Mexico does not completely work for many rural areas – in some rural areas the retail distribution of drugs is not completely present.

Norway began with some information on the determination of drug prices in Norway. In the budget of the Ministry of Health and Social Affairs, this year, the government has revised the way that maximum pharmaceutical purchase prices are determined. In future the Norwegian medicines control authority will determine the maximum pharmacy purchase price on the basis of the equivalent price in nine specific EU countries. In general, the maximum price of the pharmaceutical in Norway will be calculated on the basis of the average of the price in the three cheapest EU countries. The pharmaceutical companies, and especially the parallel importers are not very pleased about this new pricing system.

In Norway pharmacies have the exclusive right to retail trade in pharmaceuticals. Because of the pharmacies' market position the government regulates the gross profit margins for prescription sales and hence the maximum retail price. Since 1994 the prices of non-prescription drugs have not been regulated. It is the opinion of the Norwegian Competition Authority that it should be easier to establish pharmacies in Norway. Norway has among the lowest number of pharmacies per capita in Europe. The NCA has argued for establishing more pharmacies and for allowing certain non-prescription drugs to be sold through other outlets and to allow direct delivery to hospitals and other health institutions. The new Pharmacy Act, which comes into force in March 2001, will make it somewhat easier to establish pharmacies in Norway because it will no longer be required that the owner is a pharmacist.

In the United States pharmacies are primarily regulated by the individual States. At the federal level the FTC has brought enforcement actions against pharmacists for fixing prices or seeking to raise reimbursement rates in an anticompetitive or collusive way. The US submission describes a case brought against an association of pharmacists in Oregon. These were institutional pharmacists that mostly supplied medicines to long-term institutions and were resisting a cut in the Medicaid reimbursement rate. The delegate questioned whether some of these concerns expressed by other countries could be addressed through the use of the Internet or mail-order. The FTC is beginning to see on-line pharmacies and the prescription of medicines are over the Net. This might be one way to open up markets and address some concerns about restrictions on pharmacies.

Switzerland echoed these comments, noting that mail-order sales of pharmaceuticals represent a new and effective method for strengthening competition with traditional pharmacies. The Swiss competition authority has attempted to introduce an amendment to the law on health insurance to ensure that mail-order sales of pharmaceuticals are permitted. Of course, there are security obligations that are imposed on companies engaging in mail-order sales, just like the obligations imposed on traditional pharmacies.

In Spain, pharmacies are the only outlets allowed to sell pharmaceuticals. They have to be owned by pharmacists with a University degree. The regional government fixes the location and density of pharmacies. In the event of zoning changes on a site to allow a new pharmacy to be built, the price of the site rises many times.

The delegate from Ireland emphasised the pervasive nature of competition restrictions in this sector. The delegate noted that competition authorities feel powerless in the face of all the rules that reduce competition in this particular sector. There is a defeatist attitude, rather than join with health authorities and Treasury authorities to jointly combat this protectionism. The delegate then asked a number of

questions. In what ways do pharmacies compete? By and large, they don't. What conditions would make effective competition between pharmacies possible? One way might be to loosen the entry restrictions, not just in relation to location but also entry to the profession. How many countries like Ireland allow the pharmacy profession itself to restrict the number of education and training places available for the pharmacy profession and to limit the supply of graduates? The competition authority in Ireland is very opposed to this practice. If there were more graduates and more pharmacists available this would create at least social, if not economic, pressure for restrictions to be lifted. Other than easing entry restrictions, which is the classic response of competition authorities, there are other ways that the anti-competitive restrictions in this industry could be and should be tackled.

Responding to Ireland, Australia underlined that the pharmaceutical industry and the pharmaceutical distribution chain, in particular, is one of the best examples of a regulatory structure which overlaps in different areas and which is interlocking and self-reinforcing. In Australia regulation of the physical delivery of drugs at the retail level is a responsibility of the states. The states regulate ownership structures, entry, requirements that only pharmacists can own pharmacies, limitations on the number of pharmacies they can on and so on. The result is an industry structure which is small-scale and geographically widely distributed. You cannot have, for example, prescription drugs sold in supermarkets. These are restrictions on competition on the supply side. At the federal level, the federal system regulates the financial delivery of pharmaceuticals through the so-called pharmaceutical benefits which effectively set the price for pharmaceuticals that consumers face. Consequently, federal regulation establishes the level of margins that pharmacists can charge and also introduces a cap on the overall pharmaceutical prices. This is an interlocking structure. You cannot deregulate one part without another because the structure would not fit together.

Responding to the Mexican intervention, the delegate from Ireland noted that the Mexican regime sounds almost too good to be true. He wondered what it is that pharmacists do behind their glass screen. The delegate asked what percent of prescriptions are filled without any processing by the pharmacist. This percentage might be very high indeed. This raises a question about the legitimacy of dispensing fees or prescription fees which accounts for a sizeable proportion of the costs of pharmaceuticals. If dispensing is simply a question of reading what the doctor has prescribed and handing out a box the expertise required does not seem to be high. Perhaps the pharmacist profession has been consistently overstating the qualifications required.

Following up, the Secretariat observed that the regime in Mexico cannot necessarily be adopted in other countries for the following reasons. We can distinguish between occupational regulation on the pharmacist on the one hand and controls on prices and controls on entry of pharmacies on the other. Apparently Mexico has neither sorts of controls. The delegate from Ireland made a strong case that perhaps the need for occupational regulation on pharmacists is less than conventionally assumed. But, on the question whether there is a need for regulation of the quantity of pharmacies, their location, and the prices charged – this depends upon the incentives on consumers to shop around between pharmacies, which depends in turn on the level of co-payments. In countries which have no co-payment consumers do not have any incentive to choose an efficient drug or to choose a low-priced pharmacy. In these countries we cannot rely upon traditional competition to ensure that pharmacies are efficient and to keep drug prices down. The system works in Mexico because there is very little public insurance coverage of medicines, similar to non-reimbursed medicines in the rest of the OECD countries. When medicines are reimbursed 100 percent, it is necessary to control the prices of pharmacies and then when you control prices, you need to control the quantity and location and you get the hierarchy of regulation described in the Australian intervention.

5. Competition policy and competition law enforcement

The Chairman introduced the last session noting that there have been a number of substantial mergers among R&D-based pharmaceutical companies. These mergers have raised issues both with respect to competition among existing drugs and also with respect to competition between future drugs. The Chairman invited the European Commission to discuss their approach for market definition and some of the issues that came up in mergers between large R&D based pharmaceutical companies.

The European Commission agreed that they have investigated some huge mergers in the past, including Glaxo/Wellcome, SmithKline/Beecham, Pfizer/Warner-Lambert and so on. What is the economic rationale for these mergers? The delegate focused on two factors – changing technology for drug development and the need for strengthening marketing capabilities. New methods of drug development such as biotechnology may revolutionise the industry. There will be a new gene-to-disease approach which will allow pharmaceutical companies to target drugs more precisely. The market leaders of today cannot be sure that their competitive advantage will last. In addition, it is important not just to create a new drug, but also to have the possibility of effectively marketing the drug. It seems that larger firm size means that more resources that can be devoted to developing and marketing drugs.

In regard to taking into account future products, even with conventional merger analysis we have only a glimpse of the market situation today. If we look at the pipeline products (products that will likely be approved in the next few years) you still cannot get an accurate picture of future competition. It is difficult to predict the impact the products that are currently in phase III trials will have on the market. Even in phase III the probability that a drug will not be successful is 50 percent. In addition, there is the impact of national price regulation. It is not easy to simply increase prices 20 percent after a merger.

The United States responded that they look at pharmaceutical mergers and joint ventures in the same way that they look at mergers and joint ventures in other sectors, using their regular antitrust guidelines. These guidelines involve the assessment of pro-competitive and anti-competitive effects – whether the merger will lead to an increase in prices, reduction in consumer information, reduction in the quality of drugs and/or reduction, delay or elimination of research and development. As BIAC said earlier, most pharmaceutical mergers are not anti-competitive. The industry is not that concentrated. There tend to be overlaps only in particular products, which can be remedied through the divestiture of intellectual property rights, technology or manufacturing information.

The US expressed optimism about the usefulness of looking at pipeline products. For example, in the Glaxo/Wellcome case there was a migraine drug that was only available in injectable form. Both Glaxo and Wellcome were developing oral versions of this product. Information from the FDA shows which companies are in phase III trials and likely to have products on the market in six months. If other companies are five years behind it may be that in the next five years these “phase III” firms are the only potential competitors that you will have in the oral migraine drug market. The merger may lead to collapse of all research into one drug and/or a delay until a second drug comes to market. The FTC in this case required the divestiture of Wellcome’s oral migraine drug-related assets. This divestiture was successful – the assets were divested to AstraZeneca which now produces a competing oral migraine drug on the market.

The delegate then moved to discuss vertical mergers, particular mergers between pharmaceutical companies and Pharmacy Benefit Managers (PBMs). PBMs are companies who, on behalf of health insurers, select and monitor physicians who prescribe drugs and select drugs to put in the formulary. They do this in order to control the costs of pharmaceuticals – they therefore play a middle-man role. If a pharmaceutical company acquires one of these pharmaceutical benefit manager firms there are obvious incentives for that company to want its products on the PBM's formulary and to have its products favoured

over the competitors' products. Also, if the formulary is selling the products of the pharmaceutical firm's competitors, there is a concern that the formulary may pass on price information that it gets from the competitors to the pharmaceutical company itself and may be able to facilitate a form of collusion among pharmaceutical manufacturers. Although the FTC has had a number of concerns, it has only placed conditions and limitations on these acquisitions that seek to preserve the incentives for the PBM to negotiate aggressively with all pharmaceutical manufacturers. The PBM is not allowed to carry only the pharmaceutical products of the pharmaceutical manufacturer that is acquiring it. It is also required, when competitors give bids for rival products at lower prices, to accept those bids. There are also information firewalls so that any confidential information that the pharmaceutical benefit manager receives will not be passed on to the parent company.

The Chairman invited France to describe an interesting case involving abuse of dominance to restrict the rise of generic substitutes.

France acknowledged that in this case the Conseil de la Concurrence considered that the practice (which consisted of preventing customers from purchasing from other more competitive suppliers in a generic market and tying the sale of a patented product) was an abuse of a dominant position. In 1988 Lilly France produced a product, Vancomycine, which held a dominant position in the market for the treatment of Staphylococcus. When the patent expired in 1988 two enterprises began manufacturing generic alternatives. One was American Cyanamid with nine percent of the market and the other Dakato-Pharm with a very small market share. Eli Lilly had also developed a medicine for the treatment of cardiac problems called Dobutrex. This medicine was held to be indispensable in hospitals for the treatment on a number of diseases. Starting in 1988 when the patent in Vancomycine expired Lilly offered a very substantial discount on Dobutrex on the condition that the hospitals also bought Vancomycine while, at the same time, increasing the price of Dobutrex by 64 percent. In the opinion of the Conseil this was a case of abuse of a dominant position. The anti-competitive practices were carried out for a period of three years between the time when the Conseil began its investigation and the time when it issued its decision. The Cour d'Appel quantified the super-competitive profits that resulted from this anti-competitive action and found they amounted to 90 million francs, while the penalty that was imposed only amounted to one-third of the amount. The total net profit after the penalty therefore was still 60 million francs.

Japan described a bid-rigging case which it had prosecuted. The case involved manufacturers of nitrogen suboxide. Nitrogen suboxide is used as a general anaesthetic in surgical procedures. It is sold in pressurised containers. The standard price of nitrogen suboxide is sent by the Minister of Health and Welfare under the health insurance law. In this case national universities and the National Defence Medical College selected suppliers of nitrogen suboxide through competitive bidding. Six companies that were manufacturing or selling nitrogen suboxide for medical services participated in these tenders, either directly or through their agents and thereby supplied to the majority of the nitrogen suboxide that the universities were purchasing. The six manufacturers held a meeting in March 1994 and decided to set the bidding price at 262 000 yen per 30 kg container as the standard price was to be raised from nine yen to ten yen per gram in 1994. Simultaneously they decided to keep the price of nitrogen suboxide for medical services to 2 60 000 yen per 30 kg container in order to prevent the standard price of nitrogen suboxide from being reduced when the Ministry of Health and Welfare reviewed market prices and revised standard prices of pharmaceuticals in 1995. In 1997 the Japan Fair Trade Commission issued a cease and desist order to the six companies and imposed approximately 53 million yen ($US 500 000) fines.

The European Commission then raised the issue of horizontal co-operation in the pharmaceutical industry. The EC observed that pharmaceutical companies enter into an increasing number of horizontal co-operation agreements, especially in R&D, co-marketing, co-promotion and joint ventures. These different forms of co-operation are usually linked - partners come together first for R&D and then later for commercialisation of the resulting products. Unfortunately they start their R&D up to 12 years before

market entry, so it is difficult to assess market conditions that far in advance. The principles that will be used by the EC in assessing these agreements are set out in their draft Horizontal co-operation Guidelines, published on 27 April. The factors that will be examined when assessing an R&D agreement include the number of R&D pools around, and whether they are credible R&D pools; i.e., whether they have the market power, assets and knowledge, that give them a good chance to ultimately bring a product to the market. Of course, this is a subjective assessment. The EC is not necessarily worried if two parties come together and have a 100 percent market share, although in this case they may want to limit exemptions to a period of five years to give a chance to re-examine the market structure.

In regard to joint marketing (co-promotion and co-marketing), the view of the delegate was that co-promotion agreements is not as threatening as co-marketing. As set out in the guidelines the EC will look at the market power of the parties involved, whether they will tie-up the market, whether they are holding a "gold standard", whether other competitors are forceful enough to come in into time. In the case of co-marketing agreements, before giving an authorisation for the second trademark the EC will also look at all the standard competitive issues such as whether it is a secret market sharing agreement and whether there is any unwanted foreclosure effect.

TUAC pointed out that one of the main driving forces of mergers in the pharmaceutical sector is shareholder satisfaction, which is paramount. That normally means a drive for cost savings, which usually feeds on to job losses. Competition authorities usually pay no account to labour markets. This could lead to an opportunity for collusion in the labour markets. The trade union movement believes that the labor market is an important market which does need to be looked at when mergers take place.

The United Kingdom noted that it may be difficult to distinguish between anti-competitive behaviour and a rational reaction to incentives of the pricing and reimbursement systems. In a number of cases investigated by the OFT, behaviour that appears anti-competitive (for example, collusion or abuse of dominance) can also be explained by ineffective purchasing on the demand side. In these cases the issue is whether competition policy provides the solution to the problem or whether a better solution lies on the demand side - such as creating structures or incentives for GPs to substitute drugs more effectively.

6. Conclusion

The Chairman brought the roundtable to a close making the following observations. The roundtable highlighted the importance of ensuring the right incentives to control demand – e.g., the right incentives for physicians to prescribe the less expensive drugs including generics and for the patients to look for the least expensive pharmacy. As for physicians, formularies (private or public) should impose on the physician the obligation to prescribe the least expensive drug. Furthermore pharmacists should be obliged to sell the least expensive drug, unless they are directed not to explicitly by the physician. Furthermore the roundtable brought out how important it is to open up pharmacy markets to competition. This can only be done when patients have incentives to buy the least expensive medicines, which would be possible when there are some co-payments that they have to incur. This means that one solution could be for governments, when they regulate prices of medicines, to regulate wholesale prices instead of final prices, so as to leave pharmacies open to compete among themselves and leaving the margin to be paid by consumers.

The Chairman emphasised that we cannot disregard the importance of antitrust enforcement. The cases presented, including the EC discussion on joint ventures, co-marketing and co-promotion agreements, show that there are many ways in which antitrust enforcement may contribute to increasing competition in the pharmaceutical industry. This could be the topic of a roundtable in the future.

The Chairman concluded the roundtable by thanking all the participants including those countries which had made submissions, the industry specialists and the business and trade union representatives.

AIDE MÉMOIRE DE LA DISCUSSION

1. Introduction

Le Président remarque en introduction de la table ronde que l'industrie pharmaceutique se distingue sensiblement des autres industries étudiées par le Groupe de travail. Il s'agit d'une industrie fortement réglementée. Cette circonstance ne tient pas à une incapacité à faire face à la concurrence mais aux trois raisons essentielles suivantes : tout d'abord, la nécessité de garantir un certain degré de rentabilité des investissements en recherche et développement ; ensuite, la nécessité de s'assurer que les produits qui sont mis sur le marché sont sûrs et ne présentent pas de risques pour la santé des consommateurs ; enfin, la nécessité de contrebalancer les effets des systèmes d'assurance maladie sur la demande de produits pharmaceutiques des consommateurs.

La table ronde est organisée autour de quatre thèmes : (*a*) les droits de propriété intellectuelle et la procédure d'autorisation des médicaments ; (*b*) la régulation par les organismes d'assurance maladie du volume et de la qualité des dépenses de santé ; (*c*) la réglementation des pharmacies ; (*d*) la mise en œuvre de la législation antitrust dans l'industrie pharmaceutique.

2. Droits de propriété intellectuelle et procédure d'autorisation de mise sur le marché

S'agissant du premier des thèmes proposés, le Président observe qu'en dépit du fait que tous les pays Membres de l'OCDE sont signataires de l'accord ADPIC (qui fixe à 20 ans à compter du dépôt de la demande la durée minimale de protection conférée par un brevet), il existe des divergences en ce qui concerne la durée effective d'exploitation commerciale des brevets protégeant les produits pharmaceutiques en raison de la façon différente dont les pays prennent en considération le temps nécessaire à l'autorisation de nouveaux médicaments. De nombreux pays (la Nouvelle-Zélande faisant figure d'exception) prolongent la période de base de 20 années à compter du dépôt de la demande afin de tenir compte de cet élément. Toutefois, l'allongement de la durée de protection conférée par un brevet n'est pas le même dans toutes les zones de juridiction et se traduit par des différences dans la durée effective de protection, en fonction des pays.

Les Etats-Unis décrivent leur politique en matière d'autorisation de mise sur le marché. La procédure d'autorisation de la FDA peut durer jusqu'à 15 ans. Cette procédure se déroule en trois phases ("phase I", "phase II" et "phase III") comportant la participation d'un nombre croissant de sujets humains. Chacune de ces phases comprend des tests de sécurité, d'efficacité et de dosage.

Dans la mesure où la protection conférée par le brevet prend effet à la date de dépôt de la demande, avant, donc, la mise en œuvre de la procédure d'autorisation de mise sur le marché, la durée de vie effective d'un brevet, à savoir la période au cours de laquelle celui-ci peut être exploité commercialement, se trouve sensiblement réduite. En 1984, le Congrès a par conséquent voté la loi Hatch-Waxman qui vise à contrebalancer la longueur de la procédure d'autorisation des médicaments en permettant un allongement de la durée de validité des brevets. Aux termes de cette loi, la durée des brevets est prolongée en fonction du temps consacré aux essais cliniques (phases I, II et III) et du délai à

l'issue duquel la FDA elle-même délivre son autorisation. La prolongation totale accordée ne peut toutefois pas excéder cinq ans, la durée totale de vie effective du brevet ne pouvant quant à elle pas dépasser 14 années, ce qui correspond approximativement à la durée moyenne de protection effective conférée par d'autres brevets qui donnent lieu à une procédure d'autorisation moins complexe.

En contrepartie de cette extension de la période d'exclusivité, le Congrès a adopté des mesures incitatives visant à accélérer l'autorisation et l'entrée sur le marché de médicaments génériques, sous la forme d'une procédure de demande d'autorisation de médicaments nouveaux simplifiée [Abbreviated New Drug Application ("ANDA")] à l'attention des fabricants concernés. A condition qu'ils puissent démontrer la bio-équivalence de leurs médicaments et le caractère identique des indications, des conditions d'utilisation et du dosage par rapport à ceux des médicaments princeps, les laboratoires producteurs de médicaments génériques ont ainsi été autorisés à utiliser pour leur propre compte une grande partie des dossiers de recherche déjà soumis à la FDA par les laboratoires producteurs de médicaments princeps. Pour pouvoir bénéficier de cette procédure d'autorisation simplifiée, les laboratoires ont l'obligation de certifier qu'un médicament générique, lorsqu'il est mis sur le marché, ne viole pas le brevet protégeant un médicament de marque existant, que ce brevet est échu ou bien qu'il était non valide.

Le délégué des Etats-Unis conclut en rappelant certains points que des audiences tenues par la FTC en 1995 à propos des droits de propriété intellectuelle ont fait émerger. Ainsi, bien que dans un grand nombre de secteurs industriels, les entreprises du secteur puissent recourir à d'autres solutions telles que le fait d'être le premier à commercialiser des secrets commerciaux pour protéger leur investissement en recherche et développement et en retirer un avantage, dans l'industrie pharmaceutique, en particulier, les brevets constituent un moyen essentiel de stimulation de l'innovation et d'encouragement des activités de recherche et développement.

La Commission européenne s'accorde avec les Etats-Unis pour reconnaître le rôle important et légitime que jouent les droits de propriété intellectuelle dans le secteur considéré. Au-delà de la durée standard de protection par brevet de 20 années à compter du dépôt de la demande, garantie par traité international, le délégué européen souligne deux points. Le premier a trait à la législation relative au Certificat complémentaire de protection, qui a fait l'objet d'un accord entre les Etats membres de l'Union européenne au début des années 90. Cette législation fait pendant aux dispositions en vigueur aux Etats-Unis qui autorisent un allongement d'une durée maximale de cinq années de la période de 20 ans à compter du dépôt de la demande de brevet, de façon à compenser le temps consacré aux travaux de recherche et développement. Le fonctionnement général de cette législation est très similaire à ce qui existe aux Etats-Unis. Le second point évoqué par le délégué concerne les dispositions relatives à la protection des données dans le cadre de la procédure d'agrément des médicaments : les entreprises se voient conférer une forme de droit de propriété sur les données afférentes aux essais cliniques qu'elles fournissent à l'appui de la première demande d'autorisation d'un produit. Pour une demande présentée dans le cadre de la procédure d'agrément centralisée, ces droits sont valables dix ans. La protection des données ainsi organisée a pour effet d'empêcher les entreprises productrices de médicaments génériques de s'appuyer sur les données originellement fournies lorsqu'elles présentent une demande d'autorisation de commercialisation. Ces entreprises doivent par conséquent procéder elles-mêmes à des essais cliniques, même lorsque le brevet original a expiré.

Il existe deux procédures d'obtention de l'autorisation de commercialiser un médicament. La première est la procédure "centralisée" ; dans ce cas, les entreprises déposent leur demande auprès de l'Agence européenne pour l'évaluation des médicaments ("AEEM"). L'AEEM travaille de concert avec les autorités nationales compétentes pour réaliser une évaluation scientifique des produits, laquelle est ensuite transmise à la Commission européenne en tant qu'agence détentrice du pouvoir formel d'agrément. La seconde procédure est celle dite de la "reconnaissance mutuelle" : les entreprises présentent alors leur demande à l'autorité compétente de l'un des Etats membres et indiquent parallèlement les noms des autres

Etats membres dans lesquels elles souhaitent que l'agrément soit valide. L'agrément finalement délivré est valable dans l'ensemble de ces pays. Les objectifs poursuivis au moyen de la procédure d'agrément sont les suivants : entrée des médicaments sur le marché en une seule étape, priorité accordée à la sécurité, la qualité et l'efficacité plutôt qu'à la fixation des prix et autres éléments et, enfin, contribution de cette procédure à l'instauration du marché unique, particulièrement au moyen de l'harmonisation des produits.

L'Italie décrit les raisons qui ont conduit à ce que la protection conférée par un brevet puisse être plus longue dans ce pays que dans d'autres Etats membres de l'Union européenne. Juste avant que le règlement européen relatif à la durée supplémentaire d'exclusivité ne soit adopté, l'Italie avait voté une loi autorisant jusqu'à 18 ans de protection complémentaire. Après l'adoption du règlement européen, la législation italienne a été modifiée de façon à être en conformité avec le texte considéré. Toutefois, pendant la brève période au cours de laquelle une durée de protection supérieure était en vigueur dans le pays, près de 400 produits se sont vus accorder cette protection complémentaire. En conséquence, certains produits restent protégés par un brevet en Italie alors qu'ils ne le sont plus dans d'autres pays. L'autorité italienne chargée de la législation antitrust a par deux fois attiré l'attention du gouvernement sur ce problème. Il faut noter que les laboratoires pharmaceutiques italiens n'investissent pas de manière importante dans les activités de recherche et développement, de sorte que ce type d'extension de la protection conférée par un brevet ne protège pas la recherche italienne.

Au Mexique, le délai légal pour l'autorisation d'un médicament est très limité. La durée de la procédure d'autorisation dépend du fait de savoir si un médicament est déjà breveté et autorisé dans d'autres pays. Si le médicament est déjà autorisé dans d'autres pays, le Mexique s'appuie sur le travail effectué dans ces pays et applique une très courte procédure d'autorisation. Dans le cas où un médicament est complètement nouveau et non encore autorisé dans d'autres pays, le délai d'obtention de l'autorisation est au Mexique de 90 jours au maximum. Il s'agit là d'un délai très court par comparaison à la situation existant dans d'autres pays.

Le Président donne ensuite la parole au BIAC, qui exprime un certain nombre de réserves quant à la note de référence. Ces réserves sont résumées par le BIAC de la façon suivante. Premièrement, la note de référence prônerait la dilution des droits de propriété intellectuelle par le biais d'une concession obligatoire de licence (assortie d'un système de taux de rendement garanti de l'investissement faisant l'objet des droits de propriété en question), ce qui aurait un effet anti-incitatif en ce qui concerne les travaux de recherche et développement et aboutirait à une moindre disponibilité sur le marché de médicaments de haute qualité en quantité suffisante pour les consommateurs. Deuxièmement, le BIAC estime que les contrôles exercés sur les prix et autres formes d'intrusions à caractère réglementaire destinées à stimuler la concurrence dans l'industrie pharmaceutique sont moins efficaces, voire contreproductifs, comparativement à l'application rationnelle de la législation antitrust et à la promotion de conditions favorables au développement du marché. Troisièmement, le rapport de référence suggère que les cas de collusion sont chose fréquente dans l'industrie pharmaceutique, citant à cet égard la motivation du jugement de la District Court dans la procédure dite "du médicament de marque déposée", mais omet de souligner qu'après examen plus approfondi des éléments de preuve, le juge indique dans la suite du jugement que tous les éléments tendant à prouver la collusion reposent sur la spéculation et la conjecture.

Un autre membre de la délégation du BIAC (appartenant à Europe Economics) remarque que la note de référence traite de façon extensive du sujet examiné mais débouche sur des conclusions non équilibrées et qui ne reposent pas sur des bases valides. De l'avis du délégué, la question centrale abordée dans ce document est celle de savoir si les laboratoires pharmaceutiques ont un pouvoir de marché trop important. Le document de référence ne tient à cet égard pas compte du fait que, dans les industries à forte intensité capitalistique, la profitabilité doit être évaluée en comparant les prix, non pas aux coûts variables, mais aux coûts totaux, c'est-à-dire en tenant compte d'un taux "normal" de rentabilité des investissements, y compris ceux qui touchent à l'activité de recherche et développement. Clarkson a à cet égard mis en

évidence l'écart existant entre le bénéfice comptable et le bénéfice "corrigé" dans une étude détaillée, la différence après correction représentant quelques points de pourcentage.

Deuxièmement, le délégué pose la question de savoir si le fait de détenir une part de marché importante constitue véritablement un problème ou bien plutôt un élément positif. De son point de vue, une entreprise ne peut selon toute vraisemblance occuper une telle position sur le marché que si son médicament représente une avancée majeure sur le plan médical, cas de figure qui se trouve être celui sur lequel repose le système des droits de propriété intellectuelle. En pareil cas, il ne devrait pas être question d'imposer une concession obligatoire de licence comme le suggère le document de référence. L'octroi obligatoire d'une licence nécessiterait en effet qu'une autorité publique détermine la valeur d'une innovation, ce qui constituerait aux yeux du délégué une tâche irréalisable.

Troisièmement, le document n'évoquerait que de façon incomplète l'importance de la concurrence pour l'innovation. Selon les termes de John Temple-Lang, directeur de la Direction Générale de la Concurrence de la Commission européenne, "sur les marchés [de haute technologie], le prix est souvent moins important que les avantages, techniques ou autres, attachés aux produits ; ces avantages sont habituellement le fruit d'une innovation, le plus souvent récente, dans la mesure où toutes, ou pratiquement toutes, les caractéristiques de ces produits sont modifiées". Cet aspect du fonctionnement de l'industrie – à savoir le fait que les plus grandes entreprises sont en concurrence pour créer les meilleurs produits –, qui est au cœur des questions de concurrence, n'est, selon le délégué, pas traité comme il conviendrait dans le document de référence.

Quatrièmement, le document minimise le niveau de concurrence existant sur le marché ainsi que les évolutions en cours. Des travaux récents, principalement menés au Royaume-Uni, suggèrent que les produits suiveurs ("follow-on") ou "me-too" font leur apparition sur le marché à un rythme plus soutenu et sont assortis d'une politique de prix plus fine que cela n'est le cas pour les produits précurseurs premiers arrivés sur le marché.

Cinquièmement, s'agissant du pouvoir d'achat, le document indique qu'"il est possible que certains assureurs nationaux aient un poids suffisant pour avoir un "pouvoir de négociation" appréciable auprès de certains fabricants". Du point de vue du délégué, il s'agit là d'un euphémisme, qui ne décrit pas la réalité. En effet, dans la plupart des pays de l'OCDE, le principal acheteur du marché est l'Etat, sous une forme ou une autre.

Sixièmement, le document ne traite en aucun point de manière approfondie des questions liées au commerce international de produits pharmaceutiques. Il indique justement que les prix dans un pays sont parfois fixés par référence à ceux qui sont pratiqués dans d'autres pays mais il ne mentionne pas explicitement le fait qu'un prix bas déterminé par un pays qui n'a pas intérêt à la poursuite de l'activité de recherche et développement est susceptible de se traduire par un renforcement des exportations de ce pays à destination d'autres pays et d'avoir ainsi un effet négatif sur les dépenses de recherche et développement.

Le BIAC donne ensuite la parole à un représentant de la société Merck, qui remarque que l'analyse présentée dans le document, s'agissant des questions de concentration, est centrée sur certaines classes thérapeutiques. Le délégué fait valoir à cet égard que des statistiques exactes concernant des marchés pertinents feraient apparaître que le secteur pharmaceutique est un secteur concurrentiel, compte tenu, en particulier, du nombre important de laboratoires pharmaceutiques existant à travers le monde. Le délégué note qu'un grand nombre de décisions ont été rendues par les autorités antitrust au cours des dernières années, et que lesdites autorités ont fréquemment conclu que les fusions ne créent pas de difficulté relativement à la législation antitrust, très peu de fusions nécessitant l'imposition de conditions restrictives aux parties concernées. Cette situation contraste de façon très nette avec celle que l'on observe

dans d'autres industries, dans lesquelles les fusions sont soit interdites, soit abandonnées en raison des conditions draconiennes imposées aux parties par les autorités antitrust.

Le délégué souligne que l'analyse devrait porter en priorité sur les inefficiences de la réglementation par l'Etat de l'industrie pharmaceutique, qu'il s'agisse de la réglementation concernant l'autorisation des produits ou des négociations sur les prix et les niveaux de remboursement. Le délégué dit connaître de nombreux exemples de médicaments innovants qui n'ont pas pu être mis sur le marché dans certains pays de l'Union européenne ; ainsi, par exemple, une entreprise n'est-elle pas parvenue à un accord de prix avec les autorités belges, alors que le même médicament était disponible en France. Il existe des exemples de nouveaux produits innovants qui ne sont pas commercialisés, tandis que de nombreux produits non brevetés restent sur les formulaires des pays de l'OCDE. Le délégué observe qu'il lui est difficile d'imaginer comment une procédure de concession de licence obligatoire, impliquant la détermination des royalties par le gouvernement, pourrait être introduite.

Le délégué conclut en remarquant que les observations et les statistiques figurant dans le document relativement à la profitabilité de l'industrie pharmaceutique s'opposent à ce qui est dit concernant le délai nécessaire à la mise d'un produit sur le marché. Les laboratoires pharmaceutiques ont à faire face à des risques importants. Très peu de découvertes se traduisent par la mise de produits sur le marché, les industriels étant par ailleurs confrontés à des retards dus aux négociations sur les prix et le niveau de remboursement lorsqu'ils sont en possession d'un produit commercialisable. Aux yeux du délégué, il paraît contradictoire avec cet état de fait de soutenir que l'industrie pharmaceutique engrangerait des bénéfices substantiellement plus élevés que ceux d'autres secteurs d'activité.

Le BIAC donne ensuite la parole à un représentant de la société Glaxo Wellcome qui souligne que le fait d'émettre un jugement sur le niveau de prix des produits pharmaceutiques ainsi que sur le niveau de profitabilité des laboratoires pharmaceutiques revient en dernière analyse à émettre un jugement à caractère social sur les niveaux de recherche et développement. Les laboratoires pharmaceutiques financent la totalité de leurs travaux de recherche et développement à partir de leurs propres revenus et bénéfices. En outre, le renforcement de la pression budgétaire pesant sur les laboratoires pharmaceutiques a un impact non seulement quantitatif mais également qualitatif sur l'activité de recherche et développement. Les premiers projets qu'une société de recherche et développement va éliminer de son budget sont les plus risqués, lesquels se trouvent être aussi, de l'avis du délégué, ceux qui sont susceptibles de profiter le plus aux consommateurs.

Le délégué poursuit en examinant dans quelle mesure les politiques de fixation des prix adoptées par des gouvernements poursuivant des objectifs sociaux différents peuvent être faussées ou exportées par les divers systèmes de régulation qui sont adoptés. La fixation de prix de référence représente une forme atténuée de ce phénomène. Au sein de l'Union européenne, l'effet des règles relatives à la libre circulation des biens sur l'émergence d'un commerce parallèle en constitue un exemple plus évident. La réglementation des prix dans les pays de l'Union est une affaire nationale ; les prix ne sont en effet pas réglementés par la Commission européenne mais par les gouvernements nationaux, qui ont chacun leur propre perception du compromis qui doit être réalisé entre le prix et la qualité. Ce système fonctionnerait relativement bien si ce n'était que les règles relatives à la libre circulation des biens créent une situation dans laquelle les décisions en matière de prix des pays à bas niveau de prix de l'Union européenne sont exportées vers les pays à niveau de prix élevé. Cette circonstance crée une distorsion importante, à la fois de l'état du marché et de la concurrence. Les gouvernements sont des acheteurs monopolistiques : ils déterminent les prix qui peuvent être appliqués, tout en réglementant l'accès au marché. L'interaction de cette double fonction avec les règles relatives à la libre circulation des biens peut donner lieu à des distorsions de concurrence considérables.

En réponse aux observations formulées par le BIAC, le délégué des Etats-Unis observe qu'un document de référence vise à être équitable, honnête et sans détour. Les interventions du BIAC donnent selon lui l'impression que le document considéré affirme que les laboratoires pharmaceutiques, avides, sont les entreprises qui réalisent le plus de bénéfices au monde. Le document de référence tente de formuler des propositions créatives quant au moyen d'offrir aux citoyens des services pharmaceutiques qui permettent d'éviter le recours à la solution (dans certains cas) beaucoup plus onéreuse de la chirurgie. Le délégué pose la question de savoir si le niveau de prix actuellement pratiqué est le seul qui puisse rémunérer de manière adéquate les travaux de recherche et développement, ou, en d'autres termes, quels seraient les produits qui disparaîtraient si les laboratoires pharmaceutiques recevaient une compensation un peu moins importante.

La France félicite le Secrétariat pour la qualité de son document et souligne qu'à son avis, le contenu de celui-ci est équilibré et ne comporte pas de prise de position défavorable à l'industrie pharmaceutique.

Le délégué de la Commission européenne félicite également le Secrétariat pour son document et observe que l'objet de ce dernier est de proposer une vue d'ensemble du marché pharmaceutique (questions ayant trait à la réglementation antitrust ainsi qu'à la concurrence) de façon à fournir une base de discussion. Le délégué souligne à l'attention du BIAC que les autorités en charge de la concurrence ne sanctionneront jamais une industrie en raison du fait qu'elle réalise des bénéfices, ni une entreprise au motif qu'elle dispose d'un pouvoir de marché, quand bien même elle détiendrait une part de marché de 100 pour cent dans une classe thérapeutique donnée. Le droit de la concurrence vise à empêcher l'utilisation de ce type de pouvoir de marché aux fins de limitation de la concurrence. S'agissant du commerce parallèle et de l'exportation de prix bas, le document met en avant le fait qu'il existe une jurisprudence très importante de la Cour européenne de justice à cet égard (en faveur de la libre circulation des biens) que le délégué de l'industrie n'a pas mentionnée.

Le délégué de la Suisse observe, en écho au point de vue exprimé par les Etats-Unis et par la France, que le contenu du document de référence est équitable. Le document reflète fidèlement la situation existant en Suisse (qui possède une expérience non négligeable dans le domaine des produits pharmaceutiques). Le délégué énonce également le souhait que la discussion ne soit pas centrée sur l'expression de doutes quant à la validité de l'analyse présentée dans le document du Secrétariat.

Le Canada revient sur la réserve exprimée à propos des chiffres concernant les parts de marché qui figurent dans le document et note que le fait de présenter, dans un document destiné à un groupe de travail sur la concurrence, de chiffres relatifs aux parts de marché pour certaines classes thérapeutiques déterminées lui paraît sujet à caution, dans la mesure où ces classes thérapeutiques peuvent ne pas constituer des marchés pertinents aux fins de l'analyse de la concurrence (ce que souligne d'ailleurs l'avertissement figurant à cet égard dans le document).

En réponse à ces interventions, le BIAC indique qu'il souhaite également remercier le Secrétariat pour son travail. Le BIAC souligne l'importance de la recherche, rappelant qu'il y a cinq ans de cela, les personnes atteintes du SIDA étaient considérées comme vouées à une mort certaine, alors qu'aujourd'hui des millions de malades du SIDA sont en vie grâce aux médicaments qui ont été découverts par l'industrie pharmaceutique. Le BIAC observe qu'avant de discuter de la réglementation du prix d'un médicament, il faut pouvoir disposer de ce médicament. La mise au point de médicaments exige que l'on soit placé dans une situation de confiance. Le délégué conclut en indiquant que ce n'est pas en utilisant des modèles économiques dépassés que l'on encourage la recherche et le progrès.

La France remercie le BIAC d'avoir souligné l'importance de l'innovation et remarque à ce propos que les autorités en charge de la concurrence sont très sensibles à la nécessité d'encourager l'innovation. S'agissant du modèle économique utilisé, jugé dépassé par le BIAC, il faut savoir que les autorités de la concurrence fondent leurs analyses sur un certain nombre de principes et de concepts. Le délégué évoque à ce sujet une table ronde consacrée aux droits de propriété intellectuelle et aux marchés d'innovation qui s'est tenue en octobre 1997. Les participants à cette table ronde ont longuement débattu pour déterminer de quelle façon utiliser le droit de la concurrence pour réduire au minimum le risque de limitation de l'innovation. Trois options ont été examinées à l'occasion de cette table ronde. La première consistait à corriger les inconvénients qui sont le corollaire de la protection des droits de propriété intellectuelle en fixant un prix à partir duquel la propriété intellectuelle doit faire l'objet d'une licence. Les participants à la réunion ont reconnu qu'une telle mesure risquait de nuire à la dynamique de l'innovation à l'intérieur de l'économie. La deuxième option consistait quant à elle à limiter les droits d'usage afférents aux droits de propriété intellectuelle. Cette option a elle aussi été écartée par les économistes présents en raison d'un certain nombre de conséquences négatives. Aux termes de la troisième option, apparue au cours de la table ronde, il était suggéré que les autorités de la concurrence se contentent de limiter l'usage abusif des droits de propriété intellectuelle. Cette proposition a été formulée par les économistes comme étant le meilleur moyen d'encourager l'innovation sans restreindre la capacité d'intervention des autorités de la concurrence. Le délégué souligne que c'est là l'approche adoptée par la plupart des autorités en charge de la concurrence représentées à la présente table ronde, et que décrire un modèle économique en le qualifiant de "dépassé" n'est pas décrire la pratique des autorités en question.

Le TUA**C** fait valoir les trois points suivants. S'agissant de la nécessité d'introduire une procédure de concession obligatoire de licence, le délégué observe que l'option de la licence obligatoire devrait être offerte aux gouvernements nationaux dans les cas où les laboratoires pharmaceutiques se montrent négligents dans la phase de développement de nouveaux médicaments du processus de production. En ce qui concerne la reconnaissance mutuelle, par différents Etats nationaux, de l'autorisation délivrée pour un nouveau médicament, il est important que ce dispositif ne réduise pas les normes en vigueur à leur plus petit commun dénominateur. Le commerce parallèle, enfin, est un problème difficile à résoudre. A cet égard, il y a lieu de noter que les importations parallèles sont inefficaces pour des raisons tenant à l'environnement.

3. Contrôle du volume et de la qualité des dépenses de santé par le biais de l'assurance maladie

Le Président introduit la deuxième partie de la table ronde en notant que la demande sur le marché du médicament est profondément influencée par les systèmes d'assurance-maladie. Tous les pays de l'OCDE possèdent une forme quelconque d'assurance maladie, soit publique, soit privée, qui couvre, partiellement ou en totalité, les dépenses pharmaceutiques. Le problème soulevé par l'existence de tels systèmes tient au fait que les consommateurs finals, étant assurés, ne sont pas incités comme ils le devraient à être attentifs au prix des médicaments qu'ils achètent. L'incitation n'existe pas davantage pour le médecin prescripteur. En conséquence, les organismes d'assurance-maladie et les gouvernements tentent, au travers de mesures incitatives, de pousser à la fois les patients à exiger des médicaments à faible coût et les médecins à prescrire ces mêmes médicaments.

En introduction de la discussion sur la réglementation des prix, le Président note qu'un grand nombre de pays fixent le prix des médicaments en utilisant une moyenne de prix pratiqués hors de leurs frontières. Toutefois, si chaque pays examine ce qui se fait dans chacun des autres pays, le système peut aboutir à n'importe quel niveau de prix ; autrement dit, l'issue de cet examen est imprévisible.

Les prix des produits pharmaceutiques en Espagne sont fixés par le gouvernement dans le cadre de négociations avec Farmaindustria, l'association qui regroupe les entreprises du secteur pharmaceutique. Jusqu'à une date très récente, ces prix étaient déterminés sur la base des coût encourus par l'industrie pharmaceutique, majorés d'un niveau de bénéfice convenu. En outre, il faut noter que, lors de la dernière révision des prix, ceux-ci ont été réduits de six pour cent en moyenne. Les pharmaciens sont pour leur part autorisés à appliquer une marge correspondant à 27 pour cent du prix final au consommateur hors taxes. Les prix en Espagne sont inférieurs à ce qu'ils sont ailleurs en Europe, ce qui constitue une forte incitation au commerce parallèle, et particulièrement aux exportations à partir de l'Espagne vers des zones de prix élevés comme le Danemark ou l'Allemagne. Récemment, une société multinationale a mis en place une structure de prix à deux niveaux : un prix pour le marché intérieur, un autre pour le reste de l'Union européenne, à la suite de quoi grossistes et détaillants ont déposé une plainte auprès des autorités espagnoles en charge de la concurrence et également auprès de la Commission européenne. En janvier de cette année, le gouvernement espagnol a finalement voté une loi autorisant les laboratoires pharmaceutiques à pratiquer des prix différents pour le marché intérieur et pour les marchés d'exportation.

Le Président observe que la participation aux coûts constitue l'un des instruments au moyen desquels les assureurs et les gouvernements incitent les patients à demander des médicaments à faible coût. Il semble toutefois qu'un système de cette nature n'existe pas aux Pays-Bas. Au demeurant, le cabinet néerlandais a soumis au parlement en avril 2000 des propositions qui paraissent donner aux assureurs du pays un contrôle très sensiblement accru sur les dépenses pharmaceutiques.

Les Pays-Bas indiquent qu'un système de participation aux coûts a existé par le passé mais qu'il a été supprimé. Ce système prévoyait le paiement d'une somme d'un montant maximal de 200 florins par personne en dépassement des dépenses encourues ; cependant, une fois que les patients avaient dépassé cette somme, la couverture de leurs dépenses augmentait rapidement. Cette politique produisant peu d'effets, elle a été abandonnée. Il a aussi existé un système de participation aux coûts pour les produits pharmaceutiques mais l'énormité des frais d'administration a également conduit à son abandon.

S'agissant des efforts des organismes d'assurance-maladie pour maîtriser les dépenses, il faut noter qu'il existe aux Pays-Bas quelque 26 assureurs publics qui fournissent des prestations au titre du système public obligatoire d'assurance-maladie. Comme c'est le cas ailleurs, ils ont recours aux formulaires comme instrument de régulation des dépenses. Toutefois, au lieu qu'il existe un formulaire national unique, chaque assureur tente d'élaborer sa propre liste, ce qui conduit à une "bataille des formulaires". Cette situation pourrait avoir des conséquences préjudiciables à la concurrence dans la mesure où il n'est pas clairement précisé quelles conditions les laboratoires pharmaceutiques doivent remplir pour que leurs médicaments figurent sur une liste, quels prix et remises ils doivent proposer, etc. La décision d'inclure ou non un médicament dans une liste n'est pas contrôlée par une commission indépendante. Il pourrait par conséquent être préférable de se doter d'une liste nationale uniforme. On peut à cet égard établir un parallèle intéressant avec les affaires d'intégration verticale impliquant des laboratoires pharmaceutiques et des sociétés de gestion de soins pharmacothérapeutiques (Pharmacy Benefit Managers ou PBM), mentionnées dans la contribution américaine, étant donné que les Pays-Bas éprouvent des inquiétudes de même nature quant aux conséquences que pourrait avoir le fait de laisser le contrôle des formulaires à des sociétés privées.

Les 26 caisses d'assurance-maladie sont des entreprises possédant une longue tradition sociale, auxquelles on demande aujourd'hui d'agir dans un esprit d'entreprise. Ces caisses étaient autrefois spécialisées par zone géographique, mais cette particularité a été supprimée et toutes opèrent désormais à l'échelle nationale. Toutefois, cette base d'intervention historique demeure un élément essentiel. En effet, chacune d'entre elles possède une part de marché très importante dans sa zone d'implantation d'origine ; seul dix pour cent de l'ensemble des prestations d'assurance est fourni hors de cette zone. Le financement de ces sociétés est assuré à 90 pour cent par les autorités publiques et pour dix pour cent à partir de leur

propre budget. Ce système comporte ainsi une certaine incitation à contrôler les coûts, un dépassement du budget annuel se traduisant par la nécessité d'ajuster les primes ultérieurement.

En République tchèque, les dépenses des médecins prescripteurs sont contrôlées au moyen d'un budget préétabli. L'importance de ce budget est déterminée grâce à l'analyse des prescriptions réalisées par le médecin au cours de la même période de l'année précédente. La moyenne des dépenses des médecins exerçant dans la même spécialité est également prise en compte. Lorsqu'un médecin dépasse son budget, des sanctions peuvent lui être imposées.

Le Président observe que la Hongrie dispose d'un système informatisé reliant les pharmacies entre elles de façon à contrôler la consommation de médicaments et les habitudes de prescription.

Le délégué de la Hongrie (Ministère de la Santé, Département des Produits pharmaceutiques) indique en réponse que ce système a été mis en place pour des raisons financières, précisément dans le but de rembourser les pharmaciens du coût non supporté par les patients. Les pharmaciens rendent compte aux autorités tous les mois et reçoivent le remboursement qui leur est dû dans un délai de deux semaines. En ce qui concerne la politique de prix et de remboursement en Hongrie, une négociation sur les prix a lieu une fois par an ; un décret gouvernemental détermine par ailleurs le niveau de remboursement affecté à certaines classes thérapeutiques. Les produits pharmaceutiques destinés au traitement de maladies bénignes ne sont pas remboursés du tout ; le taux de remboursement est en revanche de 50 pour cent pour un grand nombre de maladies aiguës et de 100 pour cent pour tous les médicaments utilisés dans le traitement des maladies chroniques graves.

Le Président remarque que la distinction entre médecin prescripteur et pharmacien n'existe pas en Corée (ni au Japon). Néanmoins, une séparation entre les activités prescriptrice et dispensatrice doit être introduite à compter du 4 juillet 2000.

En Corée, le prix des médicaments aux termes du système d'assurance-maladie est contrôlé au moyen de la fixation du prix donnant lieu à remboursement. A l'issue d'une consultation avec la Commission médicale de remboursement, le Ministère de la Santé et des Affaires sociales détermine le prix plafond de chaque spécialité ainsi que le prix auquel elle sera intégrée dans le programme de remboursement des produits pharmaceutiques. Plusieurs critères sont utilisés en combinaison pour déterminer le prix des médicaments. Le prix de nouveaux médicaments innovants qui représentent un progrès technique par rapport aux spécialités pharmaceutiques existantes et ont une plus grande efficacité par rapport au coût est fixé sur la base du prix d'usine moyen de ces spécialités dans sept pays avancés (pays du G7). Ces prix sont collectés par le biais de fournisseurs commerciaux de formulaires étrangers comportant la liste des prix des médicaments aux fins de remboursement et d'assurance. Le système national d'assurance-maladie couvre à la fois les médicaments prescrits par les médecins et les médicaments non soumis à prescription (médicaments en vente libre) dont la liste figure dans le programme de remboursement des produits pharmaceutiques. Les médicaments utilisés à des fins non thérapeutiques telles que l'obtention d'un meilleur confort de vie ne sont pas couverts.

Le Royaume-Uni établit une importante distinction entre les notions de réglementation des prix, d'une part, et de négociation portant sur un marché d'achat, d'autre part. Le Royaume-Uni a un système de contrôle des bénéfices qui laisse aux laboratoires pharmaceutiques une certaine liberté leur permettant de déterminer leurs propres prix dans la limite d'un niveau de bénéfice global plafonné. Le délégué souligne que, plutôt que de système de réglementation des prix, il conviendrait ici de parler de processus de négociation entre un acheteur dominant et un vendeur dominant. Le marché des produits pharmaceutiques ne se distingue à cet égard en rien d'une autre relation d'approvisionnement réunissant un acheteur et un vendeur dominants. Ce type de relation s'observe souvent dans l'industrie de la défense ou entre un hypermarché occupant une position dominante et ses fournisseurs. Dans tous les cas, l'acheteur cherche à

obtenir le meilleur prix, une garantie d'approvisionnement et, dans une certaine mesure, également une assurance d'innovation.

Le mécanisme de fixation du prix des produits pharmaceutiques en vigueur au Royaume-Uni (Pharmaceutical Pricing Scheme ou PPRS) détermine un taux de rentabilité de référence d'environ 21 pour cent, taux basé sur une évaluation des coûts d'investissement historiques. Les laboratoires pharmaceutiques ne peuvent aller au-delà d'une fraction donnée de ce niveau de référence, ni descendre en deçà d'une certaine fraction. S'ils dépassent le niveau de rentabilité de référence d'un certain pourcentage, ils doivent ajuster leur bénéfice à la baisse. Dans le cas contraire, ils ont la liberté de relever leurs prix dans une certaine proportion. Le plafond applicable a été renégocié en 1999 ; dans le cadre de cette renégociation, les prix ont généralement été réduits de 4.5 pour cent.

Le Président demande au délégué du Royaume-Uni de quelle façon les coûts sont calculés, étant donné qu'une société multinationale peut fort bien entreprendre des travaux de recherche au Canada, produire aux Etats-Unis et vendre au Royaume-Uni. Le Président pose par ailleurs la question de savoir si le plafond existant s'applique uniquement aux activités se déroulant au Royaume-Uni.

Le délégué du Royaume-Uni répond que le plafond est basé sur une évaluation des coûts d'investissement historiques (y compris les dépenses de recherche et développement) liés à la préparation des médicaments vendus au NHS à l'intérieur du Royaume-Uni. Inévitablement, ceci soulève certains problèmes en raison de la nécessaire division de ces coûts d'investissement entre ce qui concerne l'export et ce qui concerne les ventes au NHS sur le marché intérieur. Dans une certaine mesure, il s'agit là d'une faiblesse du système, la division effectuée étant relativement arbitraire.

4. Réglementation des pharmacies

Le Président note que, si les régimes qui gouvernent les droits de propriété intellectuelle sont relativement similaires d'un pays à l'autre, on observe en revanche d'importantes différences dans la façon dont les pharmacies sont organisées. Ainsi, dans certains pays, le nombre de pharmacies est précisément fixé. Dans d'autres pays, les pharmacies sont la propriété du gouvernement (cas de la Suède). Dans d'autres pays encore, les pharmacies ne font l'objet d'aucune réglementation (cas du Mexique). En outre, dans un certain nombre de pays, les pharmacies ne sont autorisées à vendre que des médicaments nécessitant une prescription médicale ou en vente libre, tandis qu'ailleurs, les pharmacies peuvent vendre d'autres produits tels que des cosmétiques ou des produits liés à la forme physique ou au bien-être.

En Suède, le secteur pharmaceutique est très fortement réglementé. Bien qu'il ait existé des pharmacies privées jusqu'au début des années 70, à la même époque, un monopole légal a été concédé à une entreprise d'Etat. On a alors estimé que c'était là la seule façon de garantir un service universel et d'avoir des prix uniformes. Les autorités en charge de la concurrence ainsi que d'autres acteurs du système ont depuis lors suggéré que les pharmacies soient privatisées mais il n'existe pas à l'heure actuelle de signe indiquant un changement relativement au monopole en vigueur.

Le Président souligne à ce propos le contraste existant avec le Mexique. Dans ce pays, le système de distribution dans le secteur des pharmacies n'est soumis à aucune réglementation ; aucune restriction de quelque nature que ce soit ne s'applique au nombre de pharmacies ou au type de produits vendus dans celles-ci. Il n'y a pas non plus de réglementation concernant la qualification des pharmaciens. D'après la contribution mexicaine, la raison en est que les pharmaciens au Mexique n'effectuent aucune intervention sur les médicaments : ils se contentent de les vendre en l'état. Toutefois, c'est là une pratique courante, même dans des pays où le nombre de pharmacies est strictement limité. Le Président demande par

conséquent au Mexique d'expliquer si le système en vigueur engendre des difficultés d'approvisionnement des zones où la demande est faible et les coûts élevés.

Le Mexique répond au Président que les barrières d'entrée dans le circuit de distribution de détail de produits pharmaceutiques au Mexique sont effectivement très peu élevées. N'importe qui peut ouvrir une pharmacie : aucune qualification spécifique n'est requise. Ceci est sans doute dû au fait que les pharmacies ne font que vendre les médicaments ; elles ne les préparent ni ne les associent en aucune façon. Les médicaments sortent de la pharmacie exactement sous la même forme qu'ils y sont entrés. Par voie de conséquence, il existe un nombre considérable de pharmacies dans le pays. Une association de petites pharmacies affirme que chaque consommateur a au moins une pharmacie à une distance de cinq minutes à pied de son domicile. Le délégué admet que le système mexicain ne fonctionne pas complètement pour un grand nombre de zones rurales ; dans certaines de ces zones, la distribution de détail de médicaments n'est pas réellement présente.

La Norvège fournit tout d'abord quelques informations relatives à la détermination du prix des médicaments dans ce pays. Dans le cadre de l'établissement du budget du Ministère de la Santé et des Affaires Sociales, le gouvernement a cette année révisé les modalités de détermination des prix maximaux d'achat de produits pharmaceutiques. Dorénavant, l'autorité de contrôle des médicaments en Norvège déterminera le prix maximal d'achat sur la base du prix équivalent dans neuf pays spécifiques de l'Union européenne. En règle générale, le prix maximal des produits pharmaceutiques sera calculé à partir de la moyenne des prix dans les trois pays de l'UE les moins chers. Les laboratoires pharmaceutiques, et particulièrement les importateurs parallèles, ne voient pas l'introduction de ce nouveau système de fixation des prix d'un œil très favorable.

En Norvège, les pharmacies bénéficient d'un droit exclusif en matière de commerce de détail de produits pharmaceutiques. En raison de la position de marché des pharmacies, le gouvernement réglemente la marge brute bénéficiaire applicable aux médicaments vendus sur ordonnance et, par conséquent, le prix de vente maximal au détail. Depuis 1994, le prix des médicaments en vente libre n'est plus réglementé. L'Autorité Norvégienne de la Concurrence estime pour sa part que les conditions d'ouverture d'une pharmacie en Norvège devrait être assouplies : le pays fait en effet partie de ceux qui comptent le plus faible nombre de pharmacies par habitant en Europe. L'ANC plaide en faveur de l'installation d'un plus grand nombre de pharmacies et pour que la commercialisation de certains médicaments en vente libre par d'autres canaux ainsi que la vente directe aux hôpitaux et autres établissements de santé soient autorisées. La nouvelle loi sur les pharmacies, qui entre en application en mars 2001, facilitera quelque peu l'ouverture de pharmacies en Norvège dans la mesure où il ne sera plus exigé que le propriétaire soit pharmacien.

Aux Etats-Unis, les pharmacies sont essentiellement réglementées par les Etats eux-mêmes. Au niveau fédéral, la FTC a dû prendre des mesures coercitives contre des pharmacies au motif qu'elles avaient fixé des prix ou tenté de relever les taux de remboursement de manière anticoncurrentielle ou collusoire. La contribution des Etats-Unis décrit à cet égard une procédure engagée contre une association de pharmaciens de l'Oregon. Il s'agissait de pharmaciens "institutionnels" fournissant principalement des établissements de long séjour et qui s'opposaient par leur action à une diminution du taux de prise en charge par Medicaid. Le délégué s'interroge par ailleurs sur le fait de savoir si un certain nombre des difficultés exposées par d'autres pays participants ne pourraient pas être résolues par le biais d'Internet ou de la vente par correspondance. Cela pourrait constituer un moyen d'ouvrir les marchés et de mettre fin à certaines inquiétudes concernant les restrictions qui affectent les pharmacies.

La Suisse fait écho à ces commentaires, en observant que la vente par correspondance de produits pharmaceutiques représente un instrument nouveau et efficace de renforcement de la concurrence face aux pharmacies traditionnelles. Les autorités suisses de la concurrence ont tenté d'introduire un amendement à

la loi sur l'assurance-maladie afin d'autoriser la vente par correspondance des produits pharmaceutiques. Bien entendu, les sociétés qui pratiquent ce type de vente dans ce secteur d'activité se voient imposer les mêmes obligations en matière de sécurité que celles qui s'appliquent aux pharmacies traditionnelles.

En Espagne, les pharmacies sont les seuls points de vente qui sont autorisés à vendre des produits pharmaceutiques. Le propriétaire doit en outre être un pharmacien diplômé de l'Université. Ce sont les gouvernements régionaux qui déterminent le lieu d'implantation et la densité des pharmacies. Dans le cas où une modification du zonage intervient sur un site pour permettre la construction d'une nouvelle pharmacie, la valeur de ce site est multipliée plusieurs fois.

Le délégué de l'Irlande met l'accent sur la multiplicité des restrictions s'exerçant en matière de concurrence dans le secteur pharmaceutique. Le délégué remarque à cet égard que les autorités de la concurrence ont un sentiment d'impuissance face à l'ensemble des règles qui limitent la concurrence dans ce secteur. Elles adoptent une attitude défaitiste, plutôt que de conjuguer leurs efforts avec ceux des autorités en charge de la santé et du Trésor pour lutter contre ce protectionnisme. Le délégué pose ensuite une série de questions. De quelle manière la concurrence s'exerce-t-elle entre les pharmacies ? Pour l'essentiel, il n'y a pas concurrence. Quelles sont les conditions qui permettraient l'instauration d'une concurrence effective entre les pharmacies ? Une solution pourrait consister à assouplir les restrictions à l'exercice de la profession de pharmacien, et ce, non seulement pour ce qui concerne l'emplacement des pharmacies mais aussi pour ce qui touche à l'entrée dans la profession. Combien de pays autorisent comme l'Irlande la profession elle-même à limiter le nombre de places disponibles dans les établissements de formation ainsi que le nombre de diplômés ? Les autorités de la concurrence du pays sont fermement opposées à cette pratique. Si les diplômés et les pharmaciens étaient plus nombreux, il se créerait une pression, sinon économique, du moins sociale pour que les restrictions existantes soient levées. Au-delà de l'assouplissement des restrictions à l'exercice de la profession de pharmacien, qui est la réponse classique des autorités en charge de la concurrence, il y a d'autres moyens par lesquels on pourrait et devrait s'attaquer aux restrictions anticoncurrentielles frappant l'industrie pharmaceutique.

En écho à l'intervention de l'Irlande, l'Australie souligne que l'industrie pharmaceutique et le circuit de distribution des produits pharmaceutiques, en particulier, offrent l'un des exemples les plus caractéristiques d'une structure réglementaire qui déborde son propre cadre et dont les différents éléments s'imbriquent les uns dans les autres et se renforcent mutuellement. En Australie, la réglementation concernant la livraison physique des médicaments au niveau du commerce de détail est du ressort des Etats. Ceux-ci régulent ainsi les formes juridiques de propriété d'une pharmacie et l'accès au marché, de même qu'ils restreignent aux seuls pharmaciens la possibilité d'être propriétaire d'une pharmacie, limitent le nombre de pharmacies qu'ils sont autorisés à ouvrir, etc. La conséquence en est une structure de distribution à petite échelle et géographiquement diffuse. Les supermarchés ne sont par exemple pas autorisés à vendre des médicaments délivrés sur ordonnance. Comme on le voit, ce sont là des restrictions à la concurrence qui affectent l'offre. Le système fédéral réglemente quant à lui la délivrance des produits pharmaceutiques sur le plan financier au moyen des "allocations pharmaceutiques"[1] qui déterminent dans les faits le prix des produits pharmaceutiques pour le consommateur. La réglementation fédérale définit par voie de conséquence le niveau de marge autorisé aux pharmaciens, tout en plafonnant le prix total des produits pharmaceutiques. Il s'agit là d'une structure imbriquée dans laquelle il est impossible de déréguler un élément isolément sous peine de déséquilibrer tout l'édifice.

En réaction à l'intervention du Mexique, le délégué de l'Irlande note que le régime mexicain semble trop beau pour être vrai. Il s'interroge sur le fait de savoir ce que font les pharmaciens dans leur arrière-boutique. Il demande à cet égard quel pourcentage de prescriptions est exécuté sans aucune intervention du pharmacien et estime pour sa part que ce pourcentage pourrait bien être très élevé. Ceci pose la question de la légitimité des frais de dispensation et de prescription, lesquels représentent une part non négligeable du coût des produits pharmaceutiques. Si l'acte de dispensation consiste simplement à lire

l'ordonnance du médecin et à remettre une boîte, les compétences requises ne paraissent pas devoir être très importantes. On pourrait alors penser que la profession exagère systématiquement le niveau de qualification requis.

Pour faire suite à l'intervention précédente, le Secrétariat observe que le régime en vigueur au Mexique ne peut pas nécessairement être adopté ailleurs, et ce, pour les raisons suivantes. Il convient de distinguer entre la réglementation touchant à la qualification professionnelle des pharmaciens, d'une part, et les contrôles exercés sur les prix ainsi que sur l'ouverture de pharmacies, d'autre part. Apparemment, le Mexique n'applique aucun de ces deux types de contrôles. Le délégué de l'Irlande a fait valoir de manière tout à fait convaincante qu'il était possible que la nécessité de réglementer la qualification professionnelle des pharmaciens soit moins impérieuse qu'on le croit habituellement. Quant à la nécessité de réglementer le nombre de pharmacies, leur emplacement et les prix pratiqués, elle dépend de la mesure dans laquelle les consommateurs sont incités à comparer les prix, cet élément dépendant à son tour du niveau de participation aux coûts. Dans les pays où il n'y a pas de participation aux coûts, rien n'incite les consommateurs à choisir un médicament efficace ou une pharmacie pratiquant des prix peu élevés. Dans ces pays, il n'est pas possible de s'appuyer sur le jeu normal de la concurrence pour garantir l'efficience des pharmacies et maintenir le prix des médicaments à un bas niveau. Le système mexicain fonctionne en raison du fait que la couverture des médicaments au titre de l'assurance publique est très limitée, puisqu'elle est comparable à celle des médicaments non remboursés dans les autres pays de l'OCDE. Lorsqu'au contraire, les médicaments sont remboursés à 100 pour cent, il est nécessaire de contrôler les prix pratiqués par les pharmacies et il devient dès lors également nécessaire de contrôler le nombre et l'emplacement des pharmacies : on obtient alors la structure réglementaire pyramidale décrite par le délégué australien dans son intervention.

5. Politique de concurrence et application du droit de la concurrence

Le Président introduit la dernière session en notant que l'on a observé au cours de la dernière période un nombre substantiel de fusions parmi les laboratoires pharmaceutiques axés sur la recherche et le développement. Ces fusions ont suscité des interrogations sur le plan de la concurrence, à la fois dans le cas des médicaments existants et dans celui des médicaments à venir. Le Président invite à ce propos la Commission européenne à exposer son approche en matière de définition des marchés et à évoquer certains des problèmes qui sont advenus à l'occasion de fusions entre grands groupes pharmaceutiques axés sur la recherche et le développement.

La Commission européenne indique qu'elle a effectivement effectué dans le passé des enquêtes à l'occasion de certaines fusions de très grande ampleur, dont Glaxo/Wellcome, SmithKline/Beecham, Pfizer/Warner-Lambert, parmi d'autres. Quelle est la justification économique de fusions de cette nature ? Le délégué met en avant deux facteurs d'explication : premièrement, les évolutions technologiques dans le domaine du développement de médicaments ; deuxièmement, la nécessité de renforcer la capacité de commercialisation. Les nouvelles techniques de développement des médicaments, telles que la biotechnologie, sont susceptibles de révolutionner l'industrie pharmaceutique. On va assister à la naissance d'une nouvelle approche "gène/maladie" qui permettra aux laboratoires pharmaceutiques de cibler plus précisément les médicaments à développer. Les entreprises occupant aujourd'hui les premières places sur le marché ne peuvent pas être assurées que leur avantage concurrentiel va persister. Par ailleurs, il est important de ne pas se contenter de créer de nouveaux médicaments mais de disposer également des moyens de commercialiser efficacement ces derniers. Or, il semble que l'augmentation de la taille des entreprises entraîne un accroissement des ressources qui peuvent être consacrées au développement et à la commercialisation de médicaments.

Pour ce qui est des produits à venir, les outils conventionnels d'analyse des fusions ne permettent eux-mêmes que d'avoir une vision parcellaire de la situation actuelle du marché. Il n'est pas non plus possible d'obtenir une image précise de la concurrence future en examinant le cas des produits en voie de commercialisation (c'est-à-dire les produits qui sont susceptibles d'être autorisés au cours des prochaines années). Il est en effet difficile de prévoir quel sera l'impact sur le marché de produits qui sont actuellement en phase III d'essais [cliniques] dans la mesure où, même en cette dernière phase d'essais, la probabilité qu'un médicament ne démontre pas son utilité est de 50 pour cent. Il faut ajouter à cela l'impact des réglementations nationales en matière de prix, la solution consistant à simplement augmenter les prix de 20 pour cent après une fusion étant difficilement applicable.

Les Etats-Unis réagissent en indiquant qu'ils ont à l'égard des fusions et des coentreprises du secteur pharmaceutique la même approche que celle qui est la leur dans ce domaine s'agissant d'autres secteurs, c'est-à-dire en appliquant les lignes directrices habituelles en matière de politique antitrust. Ces lignes directrices impliquent l'évaluation des effets à la fois favorables et défavorables à la concurrence et notamment le fait de savoir si la fusion va entraîner une augmentation des prix, une diminution de l'information du consommateur, une baisse de la qualité des médicaments et/ou une diminution, un ralentissement, voire même l'élimination de l'activité de recherche et développement. Comme le BIAC l'a fait observer plus tôt, la plupart des fusions dans le secteur pharmaceutique n'ont pas un caractère anticoncurrentiel, l'industrie pharmaceutique n'étant pas concentrée à ce point. En règle générale, il n'y a présence sur le même segment de marché que pour certains produits, ce problème pouvant être résolu au moyen du transfert de droits de propriété intellectuelle, de technologie ou d'information relative à la fabrication.

Les Etats-Unis se montrent optimistes quant à l'utilité du suivi des produits en cours de commercialisation. S'agissant de la fusion Glaxo-Wellcome, par exemple, on a le cas d'un médicament contre la migraine qui n'était disponible que sous forme injectable. Aussi bien Glaxo que Wellcome étaient en phase de développement d'une version de ce produit administrable par voie orale. Or, l'information détenue par la FDA indique quels sont les laboratoires qui sont en phase III d'essais et susceptibles de mettre un produit sur le marché dans un délai de six mois. Si d'autres laboratoires mènent la même recherche avec cinq ans de décalage, il se peut qu'au cours des cinq années à venir, ces laboratoires en phase III soient les seuls concurrents potentiels des premiers sur le marché du médicament contre la migraine par voie orale. Une fusion peut alors conduire à l'abandon de toute recherche concernant un médicament et/ou à une mise en sommeil des travaux de recherche jusqu'à ce qu'un second médicament fasse son apparition sur le marché. Dans le cas évoqué, la FTC a ordonné que Wellcome se voit dessaisi de son actif relativement au médicament contre la migraine par voie orale. Ce dessaisissement s'est avéré positif puisque l'actif a été transféré à AstraZeneca qui a désormais un produit concurrent sur le marché.

Le délégué aborde ensuite le sujet des fusions verticales, fusions à caractère particulier associant des laboratoire pharmaceutiques et des sociétés de gestion de soins pharmacothérapeutiques (Pharmacy Benefit Manager ou PBM). Les PBM sont des sociétés agissant pour le compte des assureurs des régimes d'assurance-maladie qui sélectionnent et contrôlent les médecins prescripteurs et déterminent quels seront les médicaments qui figureront dans le formulaire. Elles jouent par conséquent le rôle d'intermédiaires dont l'action vise à contrôler le coût des produits pharmaceutiques. Si un laboratoire pharmaceutique acquiert une de ces sociétés de gestion, il sera bien évidemment tenté de vouloir que ses produits soient inscrits dans le formulaire de ladite PBM et qu'ils soient favorisés par rapport à ceux de ses concurrents. En outre, si les produits des concurrents du laboratoire pharmaceutique figurent sur le formulaire, on peut craindre que la société de gestion ne transmettent au laboratoire concerné des renseignements sur les prix qui lui viennent de ces mêmes concurrents et facilite ainsi une forme de collusion entre fabricants de produits pharmaceutiques. Ainsi, bien qu'un certain nombre d'autres points aient posé question, la FTC s'est limitée à imposer des conditions restrictives à celles des acquisitions du type considéré ici qui font en sorte de préserver les éléments incitant la PBM à négocier de façon agressive avec l'ensemble des

fabricants. Ladite PBM n'est pas autorisée à inscrire sur son formulaire les seuls produits pharmaceutiques du fabricant qui est son acquéreur ; elle a à l'inverse obligation d'accepter les offres à meilleur marché qui peuvent être faites par des concurrents pour des produits rivaux. Il existe enfin un dispositif de cloisonnement qui permet d'éviter que des renseignements confidentiels qui parviennent à la société de gestion de soins pharmacothérapeutiques ne soient transmis à la société mère.

Le Président invite la France à présenter une affaire intéressante d'abus de position dominante visant à freiner l'émergence de médicaments génériques de substitution.

La France indique que, dans cette affaire, le Conseil de la Concurrence a estimé que la pratique en cause (laquelle consistait à empêcher les consommateurs d'acheter à des fournisseurs plus compétitifs sur un marché générique et à lier la vente d'un produit breveté) constituait un abus de position dominante. En 1988, Lilly France produisait un produit, la Vancomycine, qui se trouvait en position dominante sur le marché du traitement du staphylocoque. Lorsque le brevet est venu à expiration cette année-là, deux entreprises se sont lancées dans la fabrication de médicaments génériques de substitution. L'une d'entre elles était American Cyanamid, qui détenait neuf pour cent du marché ; l'autre, Dakato-Pharm, ne possédait, quant à elle, qu'une très petite part de marché. Eli Lilly avait par ailleurs développé un médicament pour le traitement des affections cardiaques du nom de Dobutrex, médicament considéré comme indispensable dans les hôpitaux pour le traitement d'un certain nombre de maladies. A partir de l'expiration du brevet protégeant la Vancomycine, en 1988, la société Lilly a offert une remise très substantielle sur le Dobutrex à la condition que les hôpitaux achètent également de la Vancomycine, tout en augmentant dans le même temps le prix du Dobutrex de 64 pour cent. Le Conseil de la Concurrence a estimé qu'on était là en présence d'un cas d'abus de position dominante. Les pratiques anticoncurrentielles décrites se sont déroulées sur une période de trois années entre le moment où le Conseil a commencé son enquête et celui où il a rendu sa décision. La Cour d'appel a chiffré après examen les bénéfices extraconcurrentiels résultant de l'action délictuelle en question à 90 millions de francs. L'amende infligée à la société Lilly ne représentant qu'un tiers de cette somme, le bénéfice net total réalisé s'élève à 60 millions de francs.

Le Japon décrit pour sa part une affaire de détournement d'appel d'offres qui a fait l'objet d'une procédure judiciaire, affaire dont les protagonistes étaient des fabricants de sous-oxyde d'azote. Ce produit est utilisé comme anesthésiant général dans des protocoles chirurgicaux et vendu dans des conteneurs sous pression. Le prix de référence du sous-oxyde d'azote est déterminé par le Ministère de la Santé et des Affaires sociales dans le cadre de la loi relative à l'assurance-maladie. Dans le cas considéré, les universités nationales et le Collège médical de la défense nationale avaient sélectionné des fournisseurs de sous-oxyde d'azote par le biais d'un appel d'offres concurrentiel. Six entreprises fabriquant ou commercialisant ce produit pour un usage médical avaient participé à cette procédure, soit directement, soit par l'intermédiaire de leurs agents, et se trouvaient donc en position de fournir la majeure partie du sous-oxyde d'azote acheté par les universités. Ces six fabricants ont tenu une réunion en mars 1994, à l'occasion de laquelle ils ont décidé de fixer le prix de soumission à 262 000 yens par conteneur de trente kilos dans la mesure où le prix de référence devait être augmenté et passer de neuf à dix yens par gramme au cours de la même année. Ils ont parallèlement décidé de maintenir le prix du sous-oxyde d'azote à usage médical à 260 000 yens par conteneur de trente kilos de façon à empêcher que le prix de référence du sous-oxyde d'azote ne soit diminué lorsque le Ministère de la Santé et des Affaires sociales procéderait à l'examen des prix de marché et réviserait les prix de référence des produits pharmaceutiques l'année suivante. En 1997, la Commission sur la loyauté des pratiques commerciales a délivré une ordonnance de cesser et de s'abstenir et décidé d'une amende d'un montant approximatif de 53 millions de yens ($US 500 000).

La Commission européenne soulève ensuite la question des coopérations horizontales dans l'industrie pharmaceutique. La Commission souligne à ce propos que les laboratoires pharmaceutiques concluent entre eux un nombre croissant d'accords de coopération horizontale, en particulier dans les

domaines de la R&D, du co-marketing, de la co-promotion et des coentreprises. Ces diverses formes de coopération sont habituellement liées : le partenariat se forme originellement autour de la recherche et développement puis évolue vers la commercialisation des produits issus de cette dernière. Malheureusement, les entreprises partenaires commencent leurs travaux de recherche et développement jusqu'à douze ans avant que les produits résultants ne fassent leur entrée sur le marché, un tel décalage dans le temps rendant l'évaluation des conditions du marché difficile. Les principes que la Commission européenne mettra en œuvre pour examiner ce type d'accord sont exposés dans son projet de lignes directrices sur les coopérations horizontales, publié le 27 avril. Les facteurs dont il sera tenu compte lors de l'examen d'un accord de recherche et développement incluent le nombre de pôles de recherche et développement existants et le degré de crédibilité de ces pôles, c'est-à-dire le fait de savoir s'ils disposent du pouvoir de marché, des actifs et du savoir qui leur permettront selon toute vraisemblance de mettre en dernier ressort un produit sur le marché. Bien entendu, il s'agit là d'une évaluation subjective. La Commission européenne n'est pas nécessairement opposée à ce que l'association de deux parties leur confère une part de marché de 100 pour cent, bien qu'il est probable qu'elle souhaite dans ce cas limiter les exemptions accordées à une durée de cinq années, de façon à se ménager la possibilité de procéder à un nouvel examen de la structure du marché à l'issue de ce délai.

S'agissant de la commercialisation en commun (co-promotion et co-marketing), le délégué estime que les accords de co-promotion ne constituent pas une menace aussi sérieuse que le co-marketing. Comme le précise les lignes directrices, la Commission européenne étudiera la position de marché des parties intéressées, ainsi que la question de savoir si leur action conjointe comporte un risque de fermeture du marché, si elles détiennent un "étalon-or" et s'il existe des concurrents assez puissants pour accéder au marché avec le temps. Pour ce qui est des accords de co-marketing, avant d'autoriser la seconde marque déposée, la Commission étudiera en outre l'ensemble des points qui font classiquement l'objet d'un examen en matière concurrentielle et, notamment, le fait de savoir si l'on se trouve en présence d'un accord secret de répartition du marché ou si le partenariat envisagé comporte un effet de forclusion non désirable.

Le TUAC fait observer que l'un des principaux éléments moteurs dans les fusions opérées dans le secteur pharmaceutique est la satisfaction des actionnaires, qui prime toute autre considération. Ceci génère dans la majorité des cas une action tendant à diminuer les coûts, laquelle entraîne habituellement des pertes d'emplois. Les autorités en charge de la concurrence ne se préoccupent généralement pas de ce qui se produit sur les marchés du travail, cette circonstance pouvant créer des conditions favorisant les cas de collusion sur ces marchés. Le mouvement syndical estime que le marché du travail est un marché important qu'il est nécessaire de prendre en considération lorsqu'une fusion est réalisée.

Le Royaume-Uni souligne à ce propos qu'il peut s'avérer difficile de faire la distinction entre un comportement anticoncurrentiel et une réaction rationnelle face aux éléments incitatifs que comportent les systèmes de fixation des prix et de remboursement. Dans un certain nombre d'affaires ayant donné lieu à investigation de la part de l'OFT (Office of Fair Trading), un comportement qui paraît anticoncurrentiel (collusion ou abus de position dominante, par exemple) peut également s'expliquer par le rôle insuffisant joué par la demande en ce qui concerne les achats. En pareil cas, la question qui se pose est celle de savoir si la solution réside dans la politique de régulation de la concurrence ou bien plutôt du côté de la demande, sous forme de mise en place de structures ou de mesures incitatives permettant aux médecins généralistes de substituer un médicament à un autre de façon plus efficace.

6. Conclusion

Le Président met fin à la table ronde en formulant les observations suivantes. La réunion a mis en évidence l'importance de s'assurer de la mise en place de mesures incitatives efficaces pour contrôler la

demande, à savoir des mesures qui poussent les médecins à prescrire les médicaments les moins onéreux, y compris des médicaments génériques, et les patients à rechercher les pharmacies les moins chères. S'agissant des médecins, il conviendrait ainsi que les formulaires (publics ou privés) leur imposent l'obligation de prescrire le médicament dont le prix est le moins élevé, les pharmaciens étant quant à eux tenus de vendre le médicament le moins cher, à moins que le médecin ne leur précise explicitement le contraire. La table ronde a par ailleurs fait ressortir la nécessité d'ouvrir le marché des pharmacies à la concurrence. Ceci ne peut se faire qu'à la condition que les patients soient incités à acheter les médicaments les moins chers, ce qui devrait être possible dans les cas où il leur est demandé une participation aux coûts. Une solution pourrait par conséquent consister à ce que, dans le cadre de la réglementation du prix des médicaments, les gouvernements fassent porter leur action sur les prix de gros plutôt que sur les prix finals, de manière à laisser aux pharmacies la possibilité d'instaurer une concurrence entre elles, la marge étant à la charge des consommateurs.

Le Président insiste sur le fait que les parties concernées ne sauraient méconnaître l'importance que revêt l'application de la législation antitrust. Les affaires présentées, notamment l'exposé de la Commission européenne concernant les coentreprises et les accords de co-marketing et de co-promotion, montrent bien que la mise en œuvre de cet appareil législatif peut contribuer à renforcer la concurrence dans l'industrie pharmaceutique de nombreuses façons. Ce thème pourrait faire l'objet d'une prochaine table ronde.

Le Président remercie en conclusion l'ensemble des participants, y compris ceux des pays membres qui ont présenté une contribution, les spécialistes de l'industrie et du monde économique, ainsi que les représentants des syndicats.

1. Ndt : "pharmaceutical benefits" dans le texte original.