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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Background Note by the Secretariat

-- Session III --

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Background Note * --

Executive summary

1. The market for prescription pharmaceuticals has some characteristics that render it very different from other markets in which consumer goods are sold. Supply is characterised by a considerable degree of market power, due to the presence of patents. Consumer demand is rather inelastic, because the one who makes the decision about the purchase (the doctor) is not the one who pays (the consumer or the insurer), and, hence, is less sensitive to price and often less informed about it. Demand by wholesalers and retailers is also rather rigid due to the must-have nature of many drugs, caused by the lack of alternatives for many drugs and by regulatory requirements on the range and level of the products that have to be made available to customers. These features imply that market competition cannot fully be relied upon to reach an efficient allocation of resources and that regulatory interventions to address these market failures are necessary.

2. In addition, drugs are essential to human health and survival. Hence, many governments consider drugs to be merit goods¹ that should be affordable and accessible to all citizens, notwithstanding their income or their place of residence. Further, the consumption of certain types of medicines, such as vaccines and medicines for infectious diseases, have a strong positive externality that can only be internalised by making these medicines within the reach of those who need them. Market competition cannot ensure that these equity and fairness concerns are met: ensuring accessibility, independent of one's geographic location, and affordability, independent of one's income, requires appropriate policy interventions.

3. For the above reasons the market for prescription pharmaceuticals is heavily regulated. Nevertheless, competition can and should play a role in ensuring that this market works well for consumers, so that these can benefit from higher quality, greater choice and variety, more innovation and lower prices.

4. This paper does not consider the market in its entirety, but focuses just on the distribution part of the market. Hence, this paper will not discuss competition issues related to patents and investments in innovation, nor agreements and mergers between drug producers, but it will concentrate on the wholesale and retail level of the value chain.

5. This paper looks only at prescription pharmaceuticals, since the market for over the counter medicines (OTC) tends to have different characteristics²; and it only consider the distribution of these drugs to final consumers, hence it does not consider the distribution to hospitals. Further, this paper tries to consider the issues both from the perspective of high income countries and of middle and low income countries. This last objective has proved the most complicated to meet since the existing economic literature tends to focus mostly on the first group of countries and there is limited information available on antitrust and merger cases investigated and market studies undertaken by competition agencies in low and middle income countries.

* This paper was written by Cristiana Vitale and Gianpiero Mattera from the OECD Competition division.

¹ The term merit good refers to a good that individuals should have on the basis of some concept of need, rather than ability and willingness to pay. The specific goods that society considers should fall in this category can change across countries and over time.

² Consumers do not need a doctor prescription to buy OTC drugs and hence can decide for themselves which product to purchase, though in some case the sale may have to be supervised by a pharmacist. In addition, OTC drugs are usually always paid for by the consumers themselves, as no private or public insurance covers them. Further, the sale of these medicines is increasingly being liberalised and numerous outlets, in addition to brick and mortar pharmacies, can stock them.

6. The distribution of prescription pharmaceuticals follows different models in different jurisdictions, and the amount and type of regulation that constraints the players active in it is also very varied. Considerable changes are also taking places: the drug market is becoming increasingly global and its players are consolidating at all level of the value chain, generics are a growing share of the prescription drugs sold around the world, manufactures are integrating downward to obtain great control over the sale of their drugs, and the retail sector is being increasingly liberalised. This is affecting the balance of sellers' and buyers' bargaining power and is creating new regulatory needs.

7. Both the variety of models and the changes that are happening have an impact on the type of competition issues that can arise in the distribution of prescription drugs. Hence, this paper does not intend to be comprehensive, it simply aims to highlight examples, problems and cases that could of interest to competition agencies and policy makers and to provide a set of valuable references of relevant academic papers and policy reports.

8. Chapter 1 provides an understanding of the regulatory framework within which the distribution of prescription pharmaceuticals takes place. It analyses the peculiar features of demand and supply for these goods and gives an overview of the regulation used to address the market failures these features gives raise to. It also examines the social objectives that many governments try to achieve, namely affordability and accessibility for all citizens, and the regulatory instruments used to do so. Only by understanding the constraints and the incentives that the regulatory framework creates it is then possible to consider what place competition can have in this market, how it can be fostered where beneficial and where threats to its proper working can arise.

9. Chapter 2 describes in more detail the distribution chain and its key players, touching on issues such as parallel imports, the various models of wholesale distribution that exist, and the complex relationships between pharmacies, wholesalers and manufacturers.

10. Chapter 3 delves more deeply into the competition issues that characterise the vertical and horizontal relationships between the various players active in the distribution chain. It discusses the efficiency incentives, the competition risks and the consumer protection problems that arise with greater vertical integration. It looks at horizontal mergers, in particular between pharmacies, and at collusion, usually triggered by industry associations. It also considers the issue of inappropriate incentives provided by manufacturers to doctors, which can considerably affect the nature and the level of the demand for drugs. Last but not least, it discusses the restraints to competition that can be caused by the excessive, obsolete and distortionary regulation in particular at the retail level.

1. Understanding the market for prescription pharmaceuticals

11. The market for prescription pharmaceuticals has several defining features which, when taken together, render it very different from most markets in which consumer goods are sold. Below we briefly discuss them.

- Pharmaceuticals are innovative products, which require high investments in R&D to be developed. If this innovation is not afforded some protection, there would be limited incentives to continue investing in R&D, because new products would be quickly copied, competition would drive prices close to marginal costs and innovators would not recover their investment. Hence, new medicines are usually given protection from competition for a certain number of years through the granting of patents.
- Pharmaceuticals are credence goods. They require specific knowledge to determine when and how they should be used. The transaction costs associated with the consumer having the same level of knowledge as the doctor is too high and, as a result, consumers cannot choose autonomously

which medicines to buy, but they need advice from a specialist – a doctor. This implies that the one who buys the product is not the one who makes the decision about the purchase.

- The market for pharmaceuticals is characterised by a considerable asymmetry of information, which characterises both the relationship between the doctor and the consumer, as discussed above, and the one between the manufacturer and the doctor, as the latter relies considerably on the former to obtain information on the effectiveness of drugs. This can create possibilities for manufacturers to manipulate how the choice is formed and leaves room for abuses if the incentives of the doctor and the patient are not aligned.
- The demand for drugs is rather price-inelastic. This is due to the fact that the one who makes the decision about the purchase, i.e. the doctor, is not the one who pays, i.e. the consumer or the insurer. And the doctor is less sensitive to its price and often less informed about it. Further, in some countries the consumer does not pay the full cost and, thus, is not sensitive to the price. The insurer, who pays in his place, would be sensitive to price but must often cannot interfere with the purchase decision. This overall lack of demand elasticity and the market power held by the manufacturers explain why in many countries pharmaceutical prices are regulated at various level of the supply chain.
- Drugs are essential to human health and survival. Hence, many governments consider them to be merit goods that should be affordable and accessible to all independent of their income and their place of residence. In addition, the consumption of certain types of medicines, such as vaccines and medicines for infectious diseases, have a strong positive externality that can only be internalised by making these medicines within the reach of those who need them. This requires policy interventions, which are particularly complex in low and middle income countries, where poverty and bad transport infrastructures exacerbate the accessibility and affordability problems.

12. These characteristics of the market for prescription pharmaceuticals imply that competition cannot be relied upon to reach an efficient allocation of resources. Supply is characterised by a considerable degree of market power, while consumer demand is rather inelastic. Unless these market failures are addressed competition cannot be relied upon to achieve an appropriate outcome. In addition, market competition cannot ensure that equity and fairness are met. For these reasons the market for prescription pharmaceuticals is highly regulated³.

13. Below we provide an overview of the regulation used to address the distortions just listed and to achieve the social objectives that characterise this sector. This is not meant to be an exhaustive description of all the regulation that exists in this sector, since this is outside the scope of this paper. This overview is meant to provide an understanding of the regulatory framework within which the distribution of pharmaceuticals takes place. Only by understanding the constraints and the incentives that this framework creates it is then possible to consider what place competition can have in this market, how it can be fostered where beneficial and where threats to its proper working can arise.

1.1 Innovation

14. Medicines are innovative products. To ensure that innovation continues to take place and that a constant flow of new drugs comes on the market, it is necessary to reward innovators for their effort. This is currently achieved through patents, which allow manufacturers of new drugs to be the only producer of that specific drug for a period of time and, through this temporary monopoly, to obtain additional profits that reward their investments in R&D.

³ For OTC drugs many of these concerns and problems are not present and this justifies the high degree of liberalisation and lack of regulation that characterises this market – tough issues about accessibility, information and quality persist.

15. Since our focus in this paper is on the distribution rather than on the production of pharmaceuticals, we shall not discuss whether patents are the most efficient way to foster innovation. What matters for us is to determine that some form of protection of IPRs is necessary and that this protection, as it is currently granted, leads to the creation of market power in the hands of the manufacturers⁴.

16. At this stage it is important to clarify that there are two types of medicines: originators and generics. Originators require high R&D investments, because they are the outcome of a long process of research, innovation and testing. Generics, instead, are “bioequivalent⁵” of existing originators based on their same active principle. Since there is no R&D involved in their production and much less testing, their costs are considerably lower than the ones of the corresponding originators.

1.2 Asymmetry of information

17. The market for prescription drugs is characterised by a high degree of complexity of the information concerning their therapeutic properties, side-effects and interaction with others drugs and medical conditions, which only technical experts can understand. This creates a high of degree of asymmetry between the various agents involved in the sale and purchase of drugs: manufacturers, doctors, and consumers. Pharmacists should also be included as they may have a role in influencing the decision of consumers, especially when regulation requires or allows them to substitute the products prescribed by the doctor with cheaper alternatives. Further in many low and middle income countries consumers cannot afford to go to the doctor and they often just rely on the advice of the pharmacist, who then supplies the medicine without a prescription (even if this is against the law). Hence, since their role is akin to that of doctors in terms of being able to provide technical advice, but it is integrated by a better knowledge of the prices of the drugs on sale, what is said with respect to doctors applies also to pharmacists.

1.2.1 Doctors and consumers

18. Because of the complexity of the relevant information, consumers cannot choose for themselves the drugs to buy and they need to rely on an agent acting on their behalf, the doctor, who has the expertise to evaluate this information⁶. Hence consumers, when they buy drugs, do not behave as in the purchase of most other goods - compare prices and features and decide what to buy – instead, they simply follow the instructions received from their doctor. In addition, since prescription drugs tend to be credence good consumers are not able to judge, even after the purchase, whether their doctor’s choice has been the most appropriate. This leaves the relationship between them open to distortions and abuses if the doctor’s and the consumer’s incentives are not aligned.

19. Regulation is therefore required to ensure that doctors maintain the necessary independence to choose the drug that is in the best interest of their patients’ health. In most countries doctors cannot derive any financial gain from selecting a specific drug over another. This prohibition covers receiving monetary and in-kind payments from manufacturers, though these are often masked, for example as (lavish) trips to conference and seminars.

⁴ See Jacobzone (2000) for a brief discussion of alternative ways of fostering innovation that could avoid the distortions caused by patents.

⁵ This means that they have the same active(s) ingredients, the same therapeutical indications and the same effects as the corresponding originator drugs.

⁶ In some cases clear instructions from the manufactures to the consumers are enough and this is why, some medicines can be sold without a doctor’s prescription. However, for all prescription drugs the complexity of the information requires that the choice is made by the doctor.

Box 1. Dispensing doctors

The issue of the independence of the doctor's choice of the drugs to prescribe becomes especially important in those cases where she is allowed to dispense the drugs she prescribes. This happens often in middle and low income countries, in Japan and in some rural areas of high income countries.

The ability to sell the drugs and make a profit from it generates a conflict of interest, since the financial gain the doctor makes from the sale gives her the incentive to over-prescribe medicines and, if its remuneration depends on the value of the drug, to prescribe more expensive ones (Lim et al. 2009). Moreover, it induces pharmaceutical manufacturers to make excessive investments in marketing to prescribing doctors (Kwon 2003).

For the above reasons the relationship between dispensing doctors and patients has attracted the attention of researchers. Dranove (1988) claims that there is a moral hazard problem inherent in such a relationship, but he also argues that reputation concerns can limit, though not remove, the extent of this problem. A physician who provides low quality services to her patient (i.e. by prescribing high priced drugs when cheaper alternatives exist) may lose clients and thus suffer from a reduction in her profits. This is especially likely to occur when patients engage in a repeated relationship with the physician, and, thus, can learn about the opportunistic behaviour of their doctor and punish her by no longer using her services.

Iizuka (2007) empirically investigates whether physicians' prescriptions are influenced by the size of the margin they can earn. He finds evidence that doctors are affected in their choice by the magnitude of this margin, which leads to over-prescription (too many medicines) and provision of sub-optimal (too expensive though cheaper alternatives exist) drugs. However, his results show that doctors are also sensitive to its patients' out-of-pocket costs. His overall conclusion is that, even though the mark-up affects their prescription choices, physicians appear more responsive to the patient's out-of-pocket costs than to their own profits.

Lim et al. (2009) review the existing literature on dispensing doctors and conclude that these doctors prescribe more drugs than their non-dispensing counterparts. But, they also find that there is only limited evidence that dispensing doctors prescribe less judiciously or have poorer dispensing standards. They also argue that patient convenience is an important factor and, therefore, that dispensing doctors can play an important role in areas where there is limited access to pharmacies.

1.2.2 Manufacturers and doctors

20. Before a drug can be launched on the market, it is necessary to perform numerous test and experiments. Manufacturers have all the information that is derived from this testing and research, but they have few incentives to release it in its entirety. While they want to make doctors aware of the existence of their drugs and of their main therapeutical properties, they are also interested in manipulating this information in order to increase their sales.

21. Some high income countries have made big strides to give doctors independent advice on prescribing, but in low and middle income countries there is still a considerable lack of independent sources of reliable information. Hence, doctors often have to rely, or find it easier to rely, on the information provided by manufacturers. This implies that doctors can be influenced by medical representatives and producers' marketing strategies, which can lead to a situation of "supply-induced demand" where doctors may prefer one drug over another, or may even prescribe drugs that are not really

necessary, because of the information they have been provided with. Manufacturers indeed invest very large sums to market their products to doctors⁷.

22. As a consequence, there exists (or should exist) regulation on the amount, quality and reliability of the marketing information received by doctors. Health experts consider that this should be complemented by incentives for more independent testing and research on the effects of drugs and for greater availability of their results.

23. In addition to manipulating the information they provide to doctors, manufacturers can also resort to other means to influence doctors' prescribing patterns. These can range from the provision of in-kind rewards for fidelity to their brand to financial kickbacks⁸. They may also charge much lower prices for drugs administered in hospital, thus exploiting doctors' inertia and risk-aversion and ensuring that these subsequently continue prescribing the same drugs to their patients once released.

**Box 2. The provision of branded medicines at lower prices
in the hospital sector to exploit consumers in the community sector in the UK**

In 1998 the UK Office of Fair Trading (OFT) imposed a fine of £3.2 millions on Napp Pharmaceuticals (Napp), a Cambridge-based pharmaceutical company, as well as some behavioural remedies⁹, for abuse of its dominant position in the market for the supply of sustained release morphine tablets and capsules in the United Kingdom¹⁰.

Sustained release morphine is commonly used in the treatment of cancer-related pain and Napp was found to have supplied its sustained release morphine product, MST, to patients in the community at excessively high prices while supplying hospitals at discount levels, with the effect of eliminating competition in the relevant market.

The OFT found that Napp had offered very high discounts when tendering for hospital contracts. Through these discounts, Napp had not only won numerous hospital contracts and excluded its competitors, but it had also been able to retain a high share of the much larger community market, because the prescribing practices of general practitioners were found to be strongly influenced by the brands used in hospitals.

The OFT also found that Napp's profits on these 'follow on' community sales were maximised, because Napp charged excessive prices on its sustained release morphine sold to the community, in some cases more than 10 times its hospital prices and up to six times its export prices.

⁷ OFT (2006) provides a quantitative estimate: these costs represent about 30% of total costs (See Annex D). Lexchin (2008) reports that the Pharmaceutical Research and Manufacturers of America, an industrial lobby group for research-based pharmaceutical companies, contends that these spend more on R&D than on marketing: US\$29.6 billion on R&D in 2004 in the US as compared to US\$27.7 billion for all promotional activities. He argues that these figures underestimate the actual marketing expenses and provides a number of justifications for this claim. See also Mossialos and Dukes (2001) and Liang (2001).

⁸ See Chapter 3 for some examples of these practices in high, middle and low income countries. And see Consumer International (2007) for a critical discussion of how drug companies influence health in the developing world.

⁹ The OFT required NAPP to reduce the price of MST to the community and imposed a limit on the extent to which community prices could exceed hospital prices.

¹⁰ See Decision of the Director General of Fair Trading No CA98/2/2001 from 30 March 2001. This decision was appealed to the Competition Appeal Tribunal on 29 May 2001. On 15 January 2002 the Competition Appeal Tribunal substantially upheld the OFT's decision.

1.3 *Drug price regulation*

24. The market power granted by the patents to the manufacturers of originators faces very few constraints. There is some competition from so-called therapeutic substitutes, i.e. other originators that can treat, at least to some extent, the same conditions, but this is rather limited¹¹. Hence, the demand for originators is highly inelastic at all levels of the distribution chain. Full-line wholesalers and pharmacies have to stock all originators, as their monopoly status makes them must-have products, and consumers are not price sensitive for a number of reasons already partially discussed:

- the choice of the drug is made by the doctor, who does not consider and often is not aware of its price;
- consumers have to follow their doctor's advice because they are not able to judge the validity of the doctor's choice;
- consumers may be shielded from the cost of purchasing the drugs by their (public or private) insurance.

25. This implies that manufacturers can earn very high profits from patented drugs, which can be well in excess of what is necessary to remunerate their R&D investments. For this reason many countries regulate the ex-factory price of patented drugs.

26. Once a patent expires, generic versions of the originator can enter the market. Generic drugs do not require investments in R&D, because they rely on the same active ingredient used in the corresponding originator, and undergo a much leaner authorisation procedure. Hence their costs are lower and they can be priced lower. In addition there is no constraint to the number of manufacturers that can produce them. Their entry, thus, engenders price competition among manufacturers.¹²

27. However, this competition reduces, but does not eliminate the need to protect consumers (and insurers when they pay for consumers) from excessive prices, as the effectiveness of this competition depends on the extent to which consumers consider the various drugs within a therapeutic class to be substitutes. Since drugs are credence goods, consumers' choice cannot be based on past experiences. Hence, consumers have to rely on technical advice from the doctor, on the authorisation and testing system of their country, and on other perceived signals of quality, such as the brand or the price. When there is limited information and guarantees on the quality of the generics, consumers can perceive originators to be more effective and reliable than subsequent "cheaper copies" and be resistant to the use of generics, especially unbranded ones (which are the cheapest)¹³. In addition, physicians may themselves not trust generics, often due to lack of reliable information on their bioequivalence, or may not be aware of their availability, or could be reluctant to switch when already prescribing an originator. Hence, a combination of lack or reliable testing requirements, ignorance, risk-aversion, and resistance to change weakens the degree of competition that generic can impose on originators. This is a major problem in low and middle income countries, where consumers are often paying for the drugs out of their pockets. In high income

¹¹ For example OFT (2006) claims that in the UK this competition is very limited. See also OECD (2008) in particular pag. 67.

¹² See Hollis (2010) for a more detailed discussion of the costs of producing and bringing generics to the market .

¹³ Some low and middle income countries do not require generics to prove their bioequivalence before entering the market. This clearly leads to a lack of trust in these products. See Danzon et al (2011).

countries, whether governments usually bear a large share of the expenditure on drugs, a greater effort is placed on fostering the use of generics¹⁴.

28. Indeed some studies show that price competition between generics and originators is rather weak. This evidence is not uncontroversial¹⁵. But, if this so-called “generics paradox” exists, it means that the price of originators drugs remain shielded from competition even once patents expire, allowing manufacturers to make profits that are no longer justified by their original R&D investments. Regulation is thus necessary to favour the take-up of generics and to constrain the price of originators even after their patent protection terminates.

29. Indeed Danzon et al. (2011) argue that of consumption of drugs in middle and low income countries is badly affected by this lack of trust in generics, as it directs demand towards the more expensive originators, despite the low income of the population and the lack of insurance that forces most patients to pay out of their pockets.¹⁶

30. Hence, there is a rationale for regulating the prices of originators even after the expiry of patents. In addition competition can be further fostered through policies that promote generic take-up.

Box 3: The so-called “generic paradox”

The competitive pressure of generics entry in the pharmaceutical market, after patents expire, is supposed to decrease the prices of originators to a point in which they are aligned with the prices of generics. Some economists, however, have found that this price alignment process does not always work. Wagner and Duffy (1988) and Grabowski and Vernon (1992) detect a considerable rise in originator drug prices after generic entry in the US drug market, Kanavos (2007) finds similar results in the European market. Frank and Salkever (1997) use data on the US market to show that prices of originators do not decrease following the expiration of their patents. Vandoros and Kanavos (2013) obtain a similar result using data from OECD countries and Lexchin (2004) with data from Canada. Similarly Rizzo and Zeckhauser (2005) and Wiggins and Maness (2004) find no evidence of decreases in originators’ prices after generics enter the market.

An answer to this phenomenon, often referred to as the generics paradox, may come from the characteristics of the demand for prescription drugs. As Frank and Salkever (1992, 1997) point out, demand for a specific drug is composed of two different segments, one that is price sensitive and another one that is much less so. Price sensitive consumers consist of patients not covered by health insurance plans, hospital managers and the like. The price insensitive segment includes insured consumers and hospital patients. The entry of generic drugs induces the price sensitive consumers to switch away from the more expensive originators, but not the price insensitive ones, who continue to buy originators. As a result, manufacturers of originators do not have to reduce their prices and can even increase them, since the demand they face becomes even more inelastic.¹⁷

Vandoros (2008) argues that some consumers may have a different perception of branded and non-branded drugs, although the latter are biologically equivalent to the former, and have greater trust in the former because of their manufactures’ brand image. Hence, after the patent expiration, brand-loyal consumers keep buying branded drugs, leading to a segmentation of the market.

¹⁴ This effort includes information campaigns, testing requirements, and obligations on physicians to prescribe drugs using the name of the active ingredient and on pharmacists to substitute originators for generics when purchases are made.

¹⁵ See OECD (2009) for discussion of evidence of the price reductions that can be brought about by generic entry.

¹⁶ See also evidence about India and the attitude of consumers and physicians towards generics in CUTS (2013).

¹⁷ See also Ferrara and Kong (2008) and Kong (2009).

31. Constraining prices and inducing competition is not just necessary to curb the manufacturers' market power, but also to keep pharmaceutical expenditure by public (and private) insurers under control. The size of this expenditure continues to rise as the result of a steadily growing life expectancy, an aging population, and greater availability of cures, but also high prices. The WHO (2011) reports an increase in per-capita median pharmaceutical consumption of 18,6% in high-income countries, 20,4% in upper-middle income countries, 22,9% in lower-middle income countries and 29,3% in low-income countries between 2000 and 2008. Public and private insurers are, therefore, under pressure to limit the amount spent to reimburse pharmaceuticals and similarly governments in those countries where consumers pay out of their pockets. Hence, many countries use regulation both on the supply and the demand side to cap prices and increase the price-elasticity of demand.

1.3.1 Supply side regulation of manufacturers' prices

32. The most commonly used forms of regulation of the ex-factory prices of originators and generics are:

- International Reference pricing - price is set on the basis of the prices charged in other countries for the same drug;
- Internal reference pricing - price is set on the basis of the prices of other drugs in the same therapeutic class within the same country; and
- Generic price ceiling - price of a generic is set as a percentage of the price of the corresponding originator (where the percentage may diminish for each new competing generic drug that enters the market).

33. These methods are not very information-intensive, but they generate a number of difficulties.

34. International reference pricing, which is often used to regulate originators, can distort launch decisions¹⁸. It gives manufacturers the incentives to introduce new drugs first in countries with laxer or no ex-factory price regulation and, subsequently, in countries that impose stricter regulation, so as to increase prices in the reference basket. In addition, the more countries adopt this system the less effective this becomes.

35. Internal reference pricing, formulary caps and generic price ceiling set the price of a drug with reference to the price of other drugs. This provides a distorted signal to manufacturers, as the production costs of different drugs may differ and the amount they are allowed to recover could be higher or lower than the effective costs. Further, the internal reference pricing approach provide a focal point on which prices within a class tend to converge and discourages further price competition, because no real benefit in terms of increased sales is derived from a price cut.

36. In the UK a more complex system is used, which comprises a cap on the overall rate of return that manufacturers can earn from the drugs they provide to the national health service (i.e. which are reimbursed) and some controls on price increases. This system, known as the PPRS¹⁹, does not set the prices of the originators, but poses constraints on their overall level and on their growth over time. The PPRS relies for its efficacy on an accurate and regular assessment of the cap to impose on profits, because

¹⁸ See Kyle (2007) and Danzon et al (2005).

¹⁹ Further details on the Pharmaceutical Price Regulation Scheme (PPRS) can be found in OFT (2006), which also includes recommendations on how to improve regulation of drug prices in the UK

too low a limit depresses the incentive to invest, but too high a cap defeats the purpose of constraining the monopoly power detained by the manufacturers.

1.3.2 Regulation of wholesale and retail prices

37. Prices at other levels of the value chain are also regulated. The most common approach is to limit the mark-ups that can be added to ex-factory list price by wholesalers and retailers. The rationale behind this regulation is not very clear, in some cases it seems to be meant to guarantee a profit for these players, while in others as a further constraint on prices. In addition, retailers margins are regulated also to achieve other policy objectives.

38. We will discuss this regulation in more detail in the next Chapter, but it is worth making a few general remarks. First the regulation of the margins wholesalers and retailers can add on the ex-factory prices of medicines takes a wide variety of forms across countries, as well as across drugs, and it is not always well enforced due to the limited transparency of these prices. These margins have sometimes a significant impact on retail prices. There is evidence that some countries have low ex-factory prices, but end up with rather high retail prices. Kanavos, Scurer and Vogler (2007) show some examples in the EU: they rank countries on the basis of the level of the price of a basket of drugs and they find that Greece, Italy and Luxembourg, for originators, and the Netherlands, for generics, experience dramatic changes in their ranking when moving from ex-factory prices to retail ones. The impact also varies across drugs, with generics often suffering more from the imposition of flat margins that increase their retail prices more in relative terms²⁰.

1.3.3 Demand side regulation of manufacturers' prices

39. Above we have discussed the traditional regulatory responses to unconstrained market power, which hinge upon regulating suppliers' prices. However, as we have explained before, a major cause behind the lack of competition and the high prices of drugs lies not just in the existence of market power on the supply side, but also in the price rigidity of the demand side. Hence, greater attention is being placed on the demand side of the market, and regulation aimed at providing incentives to doctors, pharmacists and patients to pay more attention to the financial costs of their choice has been introduced in many countries.

40. This regulation has been mostly targeted at avoiding the prescription and consumption of unnecessary drugs, and at favouring the consumption of generics over originators, whenever these are available.

41. Table 1 below lists some of the most common forms of demand-side regulation and interventions, considering separately the various actors involved in the purchase of the drugs.

²⁰ See Kanavos, Schurer and Vogler (2007)

Table 1. Examples of regulation and intervention aimed at increasing responsiveness to prices

Consumers	Co-payments
	Financial incentives for purchase of lower cost drugs, such as: <ul style="list-style-type: none"> ✓ offering consumers a lower co-payment if they accept to take a generic version of the prescribed drug ✓ limiting amount reimbursed to the price of the cheapest drug in the relevant therapeutic class
Physicians	Voluntary or mandatory prescriptions by substance name rather than by brand name
	Financial incentives for prescribing generics rather than originators
	Pharmaceutical budgets, coupled with financial incentives
	Benchmarking of physicians' prescribing patterns, coupled with financial incentives
	Formularies: <ul style="list-style-type: none"> ✓ Negative, which exclude from reimbursement the least cost-effective drugs ✓ Positive, which limit reimbursement to the most cost-efficient drug in each therapeutic class
Pharmacists	Voluntary or mandatory generic, or low-cost, equivalent substitution ²¹
	Margin regulation: <ul style="list-style-type: none"> ✓ Regressive margins that encourage the sale of cheaper drugs Margins that are not linked to the value of the drug sold
Insurers	Bulk-buying
	Tenders to procure drugs directly from manufacturers
	Formularies and discount for drugs flagged as "preferred drugs" (which incur lower co-payments)

42. Doctors, as they key decision makers, are the most important target of demand side regulation, but, while making them more sensitive to prices, it is important not to affect the impartiality of their advice to her patients. Hence, dispensing budget and prescription targets, which limit the value of the prescriptions doctors can issue, have attracted criticism, because they restrict doctors' freedom to select the best treatment for their patients. Further, doctors tend to have limited knowledge of the prices of the drugs they prescribe²²; hence they are not best placed to ensure that the cheapest option available is chosen. Pharmacists, instead, have good knowledge of the prices and the range of options available in each therapeutic class. Involving pharmacists alongside doctors can exploit the specialised knowledge of each one, making doctors responsible for identifying the appropriate active ingredient and pharmacists for selecting the cheapest drug based on that ingredient. The lack of information on prices that characterises doctors can also be addressed by providing them with a constrained choice. Formularies, i.e. positive or negative list of the medicines that have passed a cost-effectiveness test, have this aim.

43. Another mechanism adopted in some jurisdictions is that insurers acquire the medicines directly from the manufacturers. Since they are the ones who actually foot the bill, insurers have the greatest incentive to obtain the best price from the manufacturer and, since they need to acquire large quantities, they also have sufficient buyer power to be able to effectively negotiate with them. Indeed bulk-buying,

²¹ The rules disciplining the extent to which pharmacists can substitute originators with generics vary from country to country. In some cases substitution is possible only if the prescription is written generically (e.g. UK), while in others it is always possible unless the doctor specifically indicates that originator/higher cost drug cannot be substituted for therapeutical reasons (e.g. Italy).

²² OFT (2007) reports that a survey of 1000 general practitioners suggests these have weak knowledge of the prices of some of the most widely-prescribed drugs in the UK.

tenders and price negotiations are extensively used by hospitals to procure their medicines and public and private insurers are increasingly following this trend²³.

44. The US is probably the best example of how insurers can act as price sensitive intermediaries between manufacturers, physicians, pharmacies and consumers to reduce expenditure. Pharmacy Benefit Managers (PMBs) define through therapeutic committees the products that will be reimbursed by their insurance plan in each therapeutic class and include them in positive formularies. Through these formularies, and their network of physicians and contracted retail pharmacies, as well as co-payments, they channel the prescription and consumption patterns towards the selected drugs. This control over the demand and their ability to purchase bulk volumes of drugs empowers them to negotiate discounts with suppliers of generics and therapeutic substitutes.

1.4 Affordability of drugs

45. Merit goods are goods that should be available to all on the basis of some concept of need, rather than on basis of ability and willingness to pay. Medicines are often considered to be merit goods, though the number and types of medicines to which it is felt this definition should truly apply varies over time and across countries.

46. As for other merit goods, the provision of medicines cannot be completely left to the market, even once all the market failures previously discussed have been addressed, because the market is a mechanism that can ensure efficiency in the allocation of the resources, but not fairness nor equity.

47. In most of the Western world the need to ensure access to drugs (and health services) to all citizens despite income disparities has led to the creation of a system of public insurance²⁴. These systems were originally rather generous in their coverage. However, over time, concerns about the constantly raising level of pharmaceutical expenditure have led to reductions in the extent of their coverage. Nowadays reimbursements are increasingly based on the income and physical conditions of the patients, as well as on the nature of the drug, and, as we have seen above, greater incentives are provided to doctors and patients to favour the consumption of lower priced alternatives when these are available. Nevertheless the principle remains valid that consumers should be supported by third party payers when acquiring medicines.

48. This is true in most high income countries, but in low and middle income countries the limited resources available to governments considerably constrain the amount of financial help provided to finance the purchase of drugs by individuals²⁵. This implies that consumers have to rely on their own income to satisfy their needs.

Table 2. Private expenditure on health as share of total expenditure on health

WHO REGION	2000	2008
South-East Asia Region	67.9%	58.7%
African Region	56.3%	50.2%
Region of the Americas	54.9%	50.7%
Eastern Mediterranean Region	52.1%	46.8%
Western Pacific Region	36.3%	31.1%
European Region	25.7%	23.6%

Source: WHO – World Health Statistics (2011) check also OECD health statistics.

²³ See Vogler et al (2013) for a discussion on the use of rebates and discounts in European countries.

²⁴ A notable exception is the US where citizens receive a very limited coverage from national and federal governments and they must rely on expensive private insurances (that not everyone can afford).

²⁵ However, recently some middle income countries have been making considerable efforts to increase the coverage of their public health insurance, for example Indonesia.

49. This lack of public insurance, coupled with the very low income of most of the population, implies that access to drugs, even the most basic life-saving ones, is limited in many countries by the inability of consumers to pay for them. This is clearly a cause of concern since drugs are important, not just for the health, but also for the survival of human beings. In most low income countries pharmaceuticals are the largest household health expenditure, and the expense related to a serious family illness is a major cause of household impoverishment. According to the WHO (2000) in developed countries the amount spent on drugs represent between 7 and 30% of the total health expenditure, while in developing countries it ranges between 24 and 66%. The same database also shows that in Asia, Africa, Middle East and Latin America 65 to 75% of this expenditure is paid out of personal income. Nevertheless, the problem of access to drugs in low and middle income countries is not simply just one of insufficient financial resources, both public and private, but is due to a complex inter-relation of factors, ranging from corruption and lack of enforcement of price and margin regulation, to inefficiencies in the purchase and distribution systems, inappropriate use of drugs, poor drug quality and lack of adequate information. Some studies show that retail prices in low income countries are much higher than the prices for the same drugs in high income countries²⁶.

50. Indeed the WHO considers that 4 factors are key to ensuring access to medicines:

1. Rational selection and use
2. Affordable prices
3. Sustainable financing
4. Reliable health and supply system

51. Hence, the solution for ensuring access to drug in low and middle income countries does not simply lie in increasing the resources available for purchasing the drugs (3), but in ensuring that an efficient use is made of these resources, through a careful selection of the drugs to be used on the basis of cost effectiveness and actual need (1). Favouring a greater take up of generics would help in containing the costs, since low and middle income countries seem to rely considerably on the consumptions of imported originators²⁷. But a shift towards cheaper “copied” drugs would require reliable testing and authorisation procedures to dispel concerns about quality, as well as information campaign and demand-side incentives to prod doctors, pharmacists and consumers to change their consumption patterns. Addressing the issue of financial incentives from manufacturers to doctors should also play an important part in ensuring a more rational use of medicines, avoiding unnecessary and expensive prescriptions²⁸.

52. Curbing inefficiencies in the distribution chain and ensuring that price regulation is appropriately enforced (4) would also contribute by reducing the retail prices of medicines. High retail prices are due to a combination of lack of regulation and low capacity to enforce it when present, but also of inefficiencies, corruption and unfettered market power at various level of the distribution chain. For these reasons international donors rather than providing financial resources for the purchase of drugs, are increasingly taking control of the acquisition and distribution process. They identify the most pressing therapeutical needs, select the most cost efficient drugs, purchase them directly from the manufacturers (exploiting their buyer power, as they acquire very large quantities) and distribute them through their own network of pharmacies and health centres directly to those in real need.

53. Nevertheless, the issue of the level of prices (2) relative to income remains a major problem for these countries. Indeed many drugs, especially originators still covered by a patent, remain beyond the reach of a large share of the population in low and middle income countries.

²⁶ See Myhr (2000), who compares prices and availability of medicines in Eastern African countries (Ethiopia, Kenya, Uganda, and Tanzania) and finds that retail prices are sometimes twice those in European countries.

²⁷ See Everard (2003).

²⁸ See WHO (2003).

Box 4: How to ensure affordability in poorer countries

There is an extensive literature that addresses the issue of how to ensure that consumers in low and middle income countries have access to affordable drugs and suggests a wealth of solutions. This literature argues that since the pharmaceutical industry is international in its structure and ownership, the question of improving affordability in individual countries should be addressed at a global level.

Where on-patent drugs are concerned, many authors focus on how to reform the patenting and licensing regimes and on the use that could and should be made of the options included in the TRIPs²⁹. We shall not discuss this literature here³⁰.

Other authors consider that a way forward should be to encourage manufacturers to employ differential pricing across countries³¹. The argument is that, since the cost of producing pharmaceuticals tends to be composed of low variable production costs and high fixed development costs, prices could be set on the basis of the Ramsey-Boiteux pricing principle³². This pricing principle states that the fixed costs of producing a good should be recovered through mark-ups that are inverse to the price elasticity of demand: the more elastic the demand, the smaller price mark-up. Assuming that demand elasticities are related to income³³, this approach would be more efficient than uniform pricing and would generate lower prices for poorer countries. However, in the market for pharmaceuticals there seems to be very limited evidence of differential pricing based on countries' per capita income. A number of reasons have been put forward for this, e.g. that arbitrage through exports makes it unsustainable, that there is a high risk that lower prices would be forced on manufacturers in other countries through international price referencing, and that social and political malcontent could arise in high income countries, if these were asked to bear the greatest part of the R&D costs.

Hence, other proposals have been put forward to ensure lower prices for poorer countries. Danzon and Towse (2003) argue that the most promising approach is for payers/purchasers to negotiate purchase contracts on behalf of developing countries that include confidential rebates. With confidential rebates, final prices to purchasers can differ across countries, but list prices remain uniform (thus avoiding the problems mentioned above).

Tetteh (2008) suggest a slightly different approach, which he calls confidential bilateral contracting. He considers that prices of drugs are dictated more by demand condition than by cost of R&D and that if price-sensitive institutions were involved in the procurement of drugs also low and middle income countries could exercise bargaining clout and obtain discounts on drug prices. His approach relies on the buyer power that price-sensitive credible bulk buyers could exercise "rather than on differential programs that are designed on charity and public relation exercises and solely at the discretion of the drug suppliers"³⁴. Also in this approach confidentiality is key to avoid arbitrage, and external referencing.

²⁹ The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the World Trade Organization that sets down minimum standards for many forms of intellectual property regulation. In 2001, developing countries, concerned that developed countries were insisting on an overly narrow reading of the TRIPS, initiated a round of talks that resulted in a WTO statement clarifying the scope of this agreement (the Doha declaration).

³⁰ For reference see Nair (2012).

³¹ See Barton (2001), Danzon and Towse (2003), Lopert et al. (2002), Srivastava and McGuire (2013) and WHO (2001).

³² Ramsey-Boiteux pricing is a policy rule concerning what prices a monopolist should set, in order to maximize social welfare, when it has to recover high fixed costs and is subject to the condition of non-negative profit. The rule suggests that the mark-up on marginal cost that is necessary to recover fixed costs should be different for different groups of buyers of the good and it should be inversely related to the price elasticity of demand of each group: the more elastic the demand for the product, the smaller the price mark-up.

³³ The assumption that the elasticities of the demand for drugs are related to the level of income seems plausible since in poorer countries consumers' out-of-pocket expenditure accounts for a very large share of their income.

³⁴ See Tetteh (2008).

1.5 *Accessibility of drugs*

54. If drugs are merit goods that should be guaranteed to all, not only their affordability but also their accessibility should matter. This implies that patients should be able to obtain the drugs they need independently of where they are based. To achieve this objective the choice of the location of pharmacies cannot be left to the market, as poorer or more sparsely populated areas may not ensure enough profits to attract pharmacies. Remote or badly connected areas, where the cost of ensuring an adequate provision of drugs is higher, may also not be profitable enough and may remain under-served.

55. Various solutions have been adopted to achieve this objective: some more effective than others. Some countries impose restrictions on the number of pharmacies that can be located in a given area, based on population ratio and on minimum distance between pharmacies³⁵. These rules, it is argued, allow pharmacies to have a local monopoly and thus earn enough profits to support themselves. But these restrictions simply reduce competition in densely populated areas, while they are not necessarily sufficient to induce pharmacies to open in poorer and sparsely populated areas³⁶. More efficient mechanisms try to identify the non-profitable high-cost areas where accessibility could be a problem and to target only those areas, for example by allowing pharmacies therein located to charge higher margins or by giving them a higher remuneration for their pharmacy services³⁷. Another option is to offer a subsidy and tender the provision of pharmacy services in these areas to those bidders that ask the lowest subsidy.

56. The development of internet and mail-order pharmacies may lessen this problem, though access to drugs for older and poorer people may still remain an issue.

57. In some countries, especially low and middle income countries, dispensing doctors ensure the provision of drugs in otherwise underserved areas. Permitting doctors to sell the drugs they prescribe, however, affects the independence of the physician's therapeutical decision, because it gives her a financial interest in the prescription and this can lead to dangerous distortions in the choice of drugs (see Box 1). Nevertheless, in low income countries dispensing doctors may be the only option to ensure access to drugs in remote and poorer areas, as the lack of trained pharmacist and the limited profits these areas can afford, mean that the probability of these areas being served by pharmacies is very low. Hence, in these circumstances the downsides of the impact on doctors' impartiality have to be balanced against the need to ensure access to, often vital, drugs. In addition, in rural and poorer areas in low and middle income countries dispensing doctors are able to provide medical services, because of the margins they earn on the sale of medicines. If this practice was no longer allowed, their main source of financing would disappear and parts of the country would be left without access to both medical services and drugs.

58. To ensure the accessibility of drugs, regulation is also often imposed on wholesalers. This includes requiring wholesalers to offer the full range of medicines, to keep always a minimum stock of all medicines and to ensure delivery within a maximum delay³⁸.

³⁵ In Europe 14 countries impose restrictions on the location of pharmacies and 23 impose entry restrictions based on population criteria. See OECD (2013).

³⁶ See OFT (2003), OECD (2001) and OECD (2013) for a discussion how location restrictions may affect the quality and variety of services offered by pharmacy.

³⁷ For example this approach is used in Ontario (Canada), UK and Denmark.

³⁸ These obligations are very common in European countries.

1.6 Conclusions

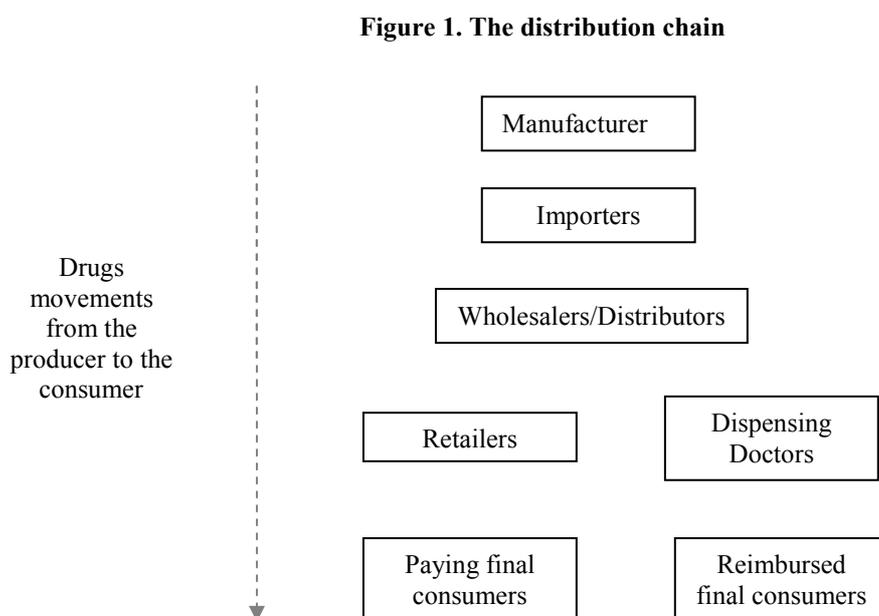
59. In this Chapter we have provided an overview of the pharmaceutical sector, highlighting all the reasons why the market left to its own devices would not be able to achieve an efficient allocation of resources and, therefore, that regulatory interventions are necessary. We have also shown that fairness and equity considerations further complicate the matter, especially in low and middle income countries where insurance coverage is very limited and the burden of paying for the pharmaceuticals falls on consumers. The Chapter includes a description of the main form of regulation aimed at addressing all these issues.

2. A description of the distribution chain

60. This Chapter describes the players involved in the distribution of pharmaceuticals and the constraints under which they operate, which provides the background for the discussion of the competition issues and concerns presented in Chapter 3.

2.1 The main players

61. Figure 1 below shows the main players involved in the distribution chain.



2.1.1 Manufacturers

62. Manufacturers produce prescription pharmaceuticals. They can be located in the country in which the drugs are finally sold, but they can also be located in other countries as the manufacturing sector is becoming more concentrated and global in nature, in particular for originators. As discussed in Chapter 2, manufacturers are subject to regulation on the quality of the drugs they produce and on the information they convey to doctors, pharmacists and consumers, as well as on the financial incentives they can provide to doctors and pharmacists. In addition, they are often subject to constraints on the level of the ex-factory prices of their drugs.

2.1.2 Importers and imports

63. If the drugs are manufactured outside the territory where they are sold and consumed, importers also play a role in the distribution chain. Sometimes these are large national wholesalers, sometimes these are firms specialising in obtaining the drugs from foreign manufacturers and selling them to local wholesalers.

64. Imports also happen when drugs are sold at different prices in neighbouring countries and, hence, there is possibility for arbitrage, even taking into account the costs of transporting and selling goods across borders. These import opportunities usually arise because of:

- Differences in national price regulations aimed at constraining ex-factory prices;
- Special discounts offered to governments in poorer countries;
- Bargaining and bulk buying by public bodies or private insurers;
- Price discrimination on the part of manufacturers, which enjoy sufficient market power to be able to set different prices in different locations according to local demand elasticity.

65. These types of imports are usually referred to as parallel imports (PIs). They differ from standard imports in that they concern goods that are authorised for sale in one country by the manufacturer that owns the relevant intellectual property rights, but which are subsequently imported in another country without the manufacturer's authorisation and compete in this market with authorised imports³⁹.

Box 5. Parallel Imports

Below we explore some of the main arguments in favour and against this practice.

PIs foster competition in the import market and constraint market power. In addition, by increasing competition, they also help to limit the opportunity for collusive behaviour.

Restrictions to PIs can be seen as non-tariff barriers to trade, which limit market integration⁴⁰.

PIs that originate from differences in price regulation allow countries with less stringent (or no) price regulation to obtain savings for consumers and insurers by placing on the market drugs that have lower prices (though one could say that they are freeriding on the effort made by the countries that have more stringent price regulation)⁴¹. However, these PIs may not lead to price convergence between lower priced and higher priced countries, but could just result in rents for parallel importers and for the pharmacies acquiring the products. In a recent paper Vandoros and Kanavos (2013) show, through a simple theoretical model, how prices in the less stringently regulated countries will remain high and any price differential will be split between the importers and the pharmacies, with no benefits for consumers and insurers. They also explain that result may change when there are policy interventions favouring PIs. Ganslandt and Maskus (2004) study data from the time when PIs were first allowed in Sweden and find that the rents gained by the importers were more than the gain to consumers from lower prices. In addition these PIs may lead to scarcity in the low-priced country since prices, due to the existence of regulation, cannot increase as a consequence of the rise in demand generated by the imports.

³⁹ Parallel imports only concern legitimate IPR-protected products and do not include the illicit import of unauthorised, pirated or counterfeited, goods. PIs are especially common for goods such as CDs, DVDs, cars and pharmaceuticals.

⁴⁰ This is the argument used by the European Union to support PIs among member countries.

⁴¹ This is the case between southern and northern EU member states.

PIs can disrupt any attempt to obtain reduced prices for essential medicines in low income countries. Any discount obtained by these countries may simply lead to a flow of imports to neighbouring richer countries. For this reason large international donors, who manage to procure drugs at low prices given their negotiation skills and buyer power, use their own distribution network (NGO-run pharmacies and dedicated health centres) to ensure that these (cheaper) medicines reach those and only those for which they have been bought.

PIs that originate from differences due to manufacturers pricing differently according to demand conditions may be welfare reducing, as prices would grow in price elastic countries and may become higher than most of local consumers' willingness to pay. These consumers would thus be priced out of the market, while under a regime of price discrimination they would be able to acquire the product. However, this loss in allocative efficiency may be compensated by gains in dynamic efficiency. PIs induced by price discrimination would also reduce prices in countries with inelastic demand. If these are countries where innovation takes place, lower prices can reduce local manufacturers' incentives to innovate⁴².

2.1.3 Wholesalers

66. Wholesalers are intermediaries that bulk-buy drugs from manufacturers and resell it in smaller quantities to retailers (or smaller wholesalers). Since retailers are too small to stock all the drugs they may require, wholesalers ensure regular delivery of the drugs and usually provide a number of related services, such as inventory and stock management, treatment of expired products and support in storing patient information. To ensure capillary distribution two or more layers of wholesalers can be present (e.g. large national and smaller local ones), especially in large countries where maintaining a single delivery network can be too complex.

67. Wholesalers can buy, stock and deliver the full assortment of medicines, in which case they are called full-line wholesalers, or they may focus only on a selected assortment of drugs (usually the most profitable ones), in which case they are referred to as short line wholesalers. The former tend to compete for customers by offering the ability to satisfy any request and by ensuring frequent deliveries, while the latter tend to offer fewer drugs with less frequent delivery and lower prices. In some countries regulation requires all wholesalers to be full-line to ensure regular availability of all drugs⁴³.

68. Wholesalers assume all the revenue risk for the drugs they have purchased from manufacturers. They then compete among themselves on price and level of service (i.e. frequency and timing of deliveries and ancillary services) to attract business from the retailers. Hence, manufacturers do not have any interaction with retailers. Wholesalers negotiate with the manufacturers the price they pay for the drugs, within the constraint posed by any price regulation that may exist. They then agree with retailers the price the latter will pay. Their revenues are given by the difference between these transactions and they depend on:

- the wholesalers' buyer power with respect to the manufacturers;
- the wholesalers' bargaining strength *vis-à-vis* the pharmacies;
- the degree of price elasticity of the final demand;
- the wholesalers' costs.

⁴² See Valletti and Szymansky (2006), Gaslandt and Maskus (2004), Rey (2003), Danzon (1998).

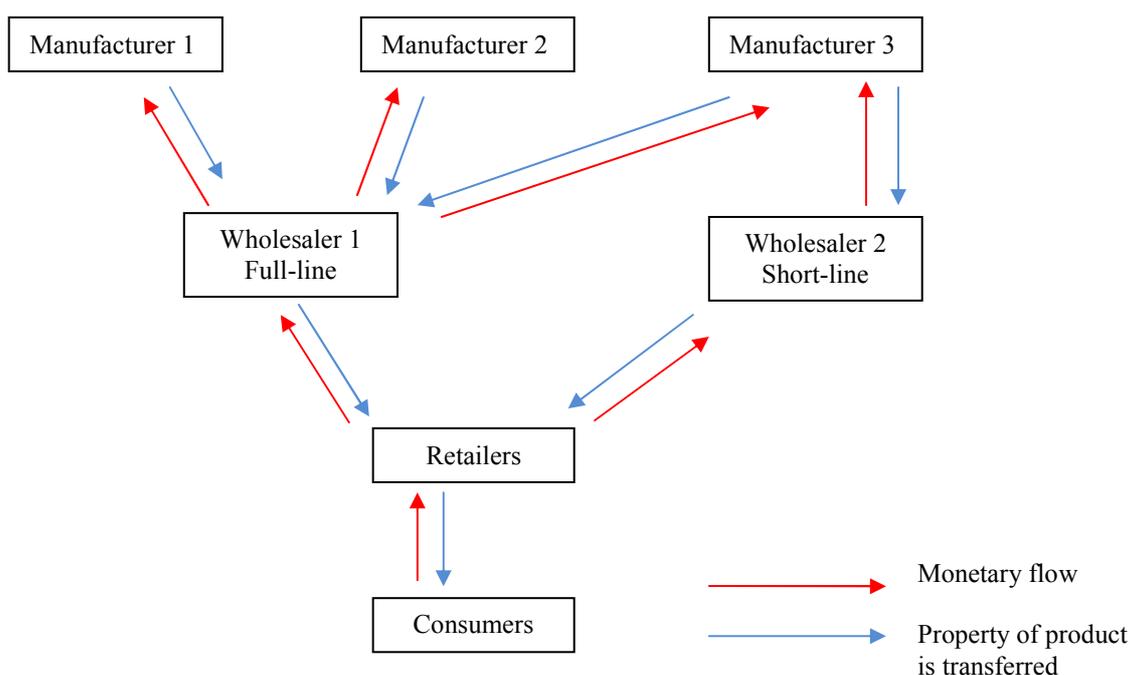
⁴³ This is sometimes coupled with other requirements on the minimum level of the stocks that has to be kept at all times and the frequency of deliveries. Many European countries have these requirements. See Girp (2005).

69. The relative importance of these factors depends on: the strength of the regulation on ex-factory prices and on their margins (and the extent to which this is enforced), the nature of the drug (whether an originator, hence a must have for the pharmacies, or a generic, hence substitutable with other products), the number of other wholesalers competing for the business, the type of pharmacies (whether small independent pharmacies or large chains with considerable buyer power), any obligation wholesalers need to meet in terms of stock and delivery, the quality of the transport infrastructure, and the extension and the geographical configuration of the territory they have to serve.

70. In many countries the pursuit of cost savings, the exploitation of economies scale (in warehouse facilities, electronic record keeping and data interchange systems for ordering medicines and stock keeping) and scope (inherent in a delivery network that has to cover a large territory with considerable frequency) have led to high level of concentration at the wholesale level of the distribution chain⁴⁴. This reduces competition between wholesalers on prices and level of services and can be a cause of concern, especially vis-a-vis smaller retailers.

71. Figure 2 below shows the financial relationships (red arrows) and the transfer of goods (blue arrows) between the various players.

Figure 2. Wholesalers



72. The margins wholesalers can earn from the sale of drugs to retailers are often regulated. Varying approaches are used, which range from fixed percentages, to fixed fees and maximum caps. A report from WHO-HAI (2011a) provides a detailed description of regulatory practice around the world and of the degree of their enforcement⁴⁵.

⁴⁴ See Philipsen (2003) and Mossialos et al (2004).

⁴⁵ See in particular Annex 2 and 4.

73. The rationale behind this regulation is often not very clear. It seems to vary from ensuring remuneration to wholesalers, especially when these are burdened with public service obligations that deprive them of buyer power, to constraining their market power, thus contributing to controlling the level of retail drug prices. The limited transparency of wholesale prices can render the enforcement of this regulation difficult to monitor, especially in low and middle income countries⁴⁶.

2.1.4 Distributors

74. There are growing incentives on manufacturers to perform internally at least some of the activities undertaken by wholesalers⁴⁷. Hence, in a growing number of countries, wholesalers as described above do not exist any longer⁴⁸; rather manufacturers have integrated all the activities relative to stock and demand management and sell directly to pharmacies. Wholesalers have thus become mere distributors, which have no direct ownership of the goods and no financial relationship with the retailers⁴⁹. Manufacturers manage the requests from the retailers and agree the selling price directly with them; and distributors only receive a delivery fee for their services from the manufacturers. As a consequence, distributors agree the level of service with manufacturers and no longer with pharmacies.

75. Distributors can be independent and deal with products of different manufacturers, or they can have exclusive agreements with specific manufacturers. Clearly in the first case pharmacies still have a choice among a number of distributors and hence can influence the level of service, but when distributors are exclusive they have no say in it. This can be a cause of concern because manufacturers have no real interest in keeping a very high level of service; given the cost of it and their market power (demand for their products would not decrease). This may have an impact on final consumers. OFT (2007) provides a detail discussion of this possible deterioration in the quality of distribution services.

76. Manufacturers, as we will see in more detail in the next chapter, claim that there are efficiencies from vertically integrating wholesaling activities, but it is not clear how much consumers and insurers benefit from these gains. In this set up, pharmacies have to bargain directly with manufacturers and they have no buyer power when negotiating with them the purchase of originators⁵⁰ and little market power in other cases (though they may form buyer groups). Further, pharmacies may see their administrative costs increase when they to switch from a system with full-line wholesalers to one with dedicated distributors, as they have to handle multiple financial relationships and multiple deliveries. In addition, even if pharmacies were to benefit from the efficiencies gained by the manufacturers they are under no pressure to pass them on to consumers.

⁴⁶ For an exhaustive discussion on the effectiveness of this regulation see again WHO-HAI (2011a).

⁴⁷ See Kanavos, Schurer and Vogler (2011) for a description of how this trend is happening in Europe, especially in northern Europe where wholesalers are less regulated.

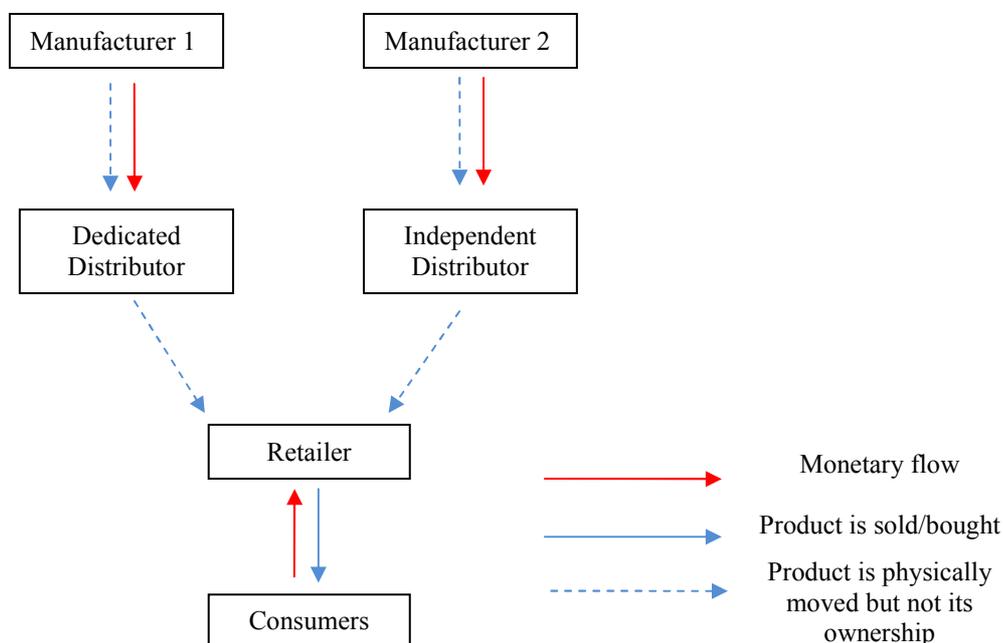
⁴⁸ For example in US, Canada, Chile, and increasingly so in Europe (see OFT, 2007).

⁴⁹ See for example the UK, US and Canada where this model is becoming prevalent.

⁵⁰ The degree of generics penetration is what affects this the most. To give an idea of the magnitude OFT (2007) shows that 75% of pharmacies sales relate to medicines for which no alternative is available (either because it does not exist or because no substitution was possible).

77. This model is shown in Figure 3 below.

Figure 3. Distributors



78. In some cases manufacturers may team up together to set up a joint distributor that deals only with their brands. Similarly, where large pharmacy chains are present, it is also possible for these to directly bargain with the manufacturers and then set up a distributor that is responsible for delivering the drugs from a central warehouse.

79. Hence, there are a number of different organisation models:

- Large number of wholesalers (a large choice for pharmacies)
- A reduced number of wholesalers (some choice for pharmacies)
- A reduced number of independent distributors (some choice for pharmacies)
- A small number of dedicated distributors (no choice for pharmacies)

80. In some countries one model may prevail, but it is also possible for more than one to be present, and sometimes for manufacturers to have different arrangements for different products.

Box 6. The OFT's market study on the distribution of pharmaceutical in the UK

In 2007 the OFT issued a report in which it analysed the possible competition effects of a new pharmaceutical distribution model that has been introduced by some manufacturers in the UK in the late 1990s.

Traditionally in the UK manufacturers sold their products to wholesalers at a conventional discount of 12.5 % on list prices. Wholesalers then competed to supply pharmacies and offered them an average discount on list prices of 10.5 %, keeping the difference as a reward for their services. Pharmacies were reimbursed at list prices and the NHS clawed-back some of these profits. Since the late 1990s, however, some manufacturers have looked for more efficient alternatives to their distribution systems in order to gain higher profits and have greater control over the supply chain.

This has led to the introduction of the so-called direct-to-pharmacy (DTP) model, already in use in other countries. The main difference between the DTP model and the traditional one is that in the former the ownership of the products goes directly from the manufacturer to the pharmacy and the price is agreed between them, no longer on the basis of the conventional discounts described above. Delivery of the good is ensured by distributors paid by the manufactures.

In its report the OFT recognises that the DTP model may bring efficiency benefits, but it also identifies a number of possible competition concerns. First, the OFT highlights that this scheme breaks the conventional discount scheme (12.5 % to wholesalers and 10.5 % to pharmacies) and may lead to an increase in the prices paid by pharmacies and of the cost of the NHS. Manufacturers have indeed a stronger bargaining position when dealing with pharmacies rather than wholesalers, because the former have much less choice over the medicines they must stock and buy much smaller quantities. As a result, in the DTP the manufacturers could reduce the discount traditionally offered to pharmacies, thus squeezing their margins and reducing the amount that NHS could claw-back.

In addition in the DTP model manufacturers could lower the service level provided to pharmacies (and as consequence to patients) by the distributors, since in this model they have the contractual relationship with the distributors and agree the relevant terms. In the traditional wholesale model, instead, the quality of the distribution services is agreed between wholesalers and pharmacies and is one of the main variables over which the former compete to gain business from the latter.

Finally, if all manufacturers use only one exclusive distributor, rather than rely on numerous wholesalers as in the traditional scheme, this may lead to a reduction in the number of distributors and to an increase in their market power. This may prove detrimental in the long run also for the manufacturers.

The OFT concluded the report by saying that it was too early to determine whether these concerns would become real problems, as the model had just been introduced and only by a few manufacturers.

2.1.5 Retailers

81. Retailers are those entities that obtain medicines from wholesalers, or directly from manufacturers, and dispense them to consumers. The only retailers authorised to sell prescription drugs are pharmacies⁵¹, i.e. shops where sales are supervised by trained pharmacists. As previously mentioned, in some countries, or in some geographic areas, doctors may also sell to patients the medicines they are prescribing.

82. There exist community pharmacies and hospital pharmacies. In this paper we shall only focus on the former. In some low and middle countries there are public and private pharmacies that cater for

⁵¹ There are other drugs (OTC drugs) whose sale requires neither a prescription from a doctor nor the supervision of a pharmacist. In some countries these can also be sold in a variety of other outlets, ranging from supermarket to corner shops and fuel stations

different consumers: public pharmacies provide free or subsidised medicines, while private pharmacies only cater for paying consumers. In some poorer areas there are also not-for profit pharmacies run by NGOs, which ensure the distribution of medicines provided by international donor agencies.

83. Depending on ownership regulation there are countries where there are only individually-owned pharmacies and other where also multi-chain pharmacies exist. As rules on ownership are being relaxed (see more on this in Chapter 3), chains are becoming more widespread.

84. Pharmacies can be subject to extensive regulation on their location, their ownership, and their opening hours. These constraints and their impact on competition at the retail level will be discussed in more details in Chapter 3.

85. Regulation also often constrains the prices at which pharmacies can sell medicines as well as the margins they can earn on these sales. These margins tend to be set as a fixed fee or as a percentage of the value of the medicines, though there are cases where the regulation sets a maximum fee or a capitation fee. The report from WHO-HAI (2011a) provides a detailed description of the different regulatory practices in place around the world.

86. Pharmacy margin regulation tries to achieve a number of different objectives, often simultaneously. Constraints on margins are used as a tool to limit final prices, as consumers are not very price sensitive. They are also used to provide incentives to pharmacists for substituting high-priced medicines with generics/lower costs ones. In addition, margins may be regulated to ensure sufficient profits to pharmacies located in poorer or less densely populated area.

87. A problem sometimes linked to margin regulation, is that it tends to be based on list prices. However, these may not always be the prices pharmacies actually pay for their products. Generic manufacturers have to compete to obtain shelf space in pharmacies, especially where the rate of take-up of generics is high. They do so by offering discounts, sometimes hefty ones, on list prices to pharmacies. These discounts do not get captured by margin regulation and are usually entirely retained by pharmacies in addition to the regulated margins. Since in many countries pharmacies tend not compete on prices (see Chapter 3 for a discussion of the reason why), they have no pressure to transfer these financial benefits to final consumers. Evidence of these practices is discussed in the CBC report on generics (CBC, 2007) with respect to Canada, and in Kanavos and Taylor (2007) for France. This problem has prompted some countries to prohibit discounts or to calculate regulated margins on effective rather than listed prices. However, due the very limited transparency of the prices paid by pharmacies, the enforcement of this type of regulation is extremely difficult⁵².

88. To some extent these extra profits can be competed away through the provision of other services consumers are effectively sensitive to⁵³. Location is still a primary concern for consumers, but this is not always a factor on which pharmacies compete, as there may be regulation that imposes constraints on their location. Competition on other dimensions can also be limited by regulation, for example there are countries opening hours are regulated and pharmacies have very limited freedom to depart from this timetable⁵⁴. See Chapter 3 for a detailed discussion of these regulatory restrictions that limit competition between pharmacies.

⁵² See Competition Bureau of Canada (2007) for a detailed discussion of this concern. See also Autorité de la Concurrence (2013) and Ordre national des pharmaciens (2013).

⁵³ See OFT (2003) and Ecorys (2007) for evidence that when competition on prices is restricted there is greater variety in the services offered by pharmacies.

⁵⁴ From the point of view of the society as a whole, one could question whether it is efficient to compete these profits away by providing additional services or whether it would be best to just lower prices.

2.2 *Conclusions*

89. This chapter has provided an overview of the key players in the distribution chain and of the role they play in it. It has also highlighted how they are regulated and how their role in the distribution chain is changing.

3. **Competition issues in the distribution of pharmaceuticals**

90. This Chapter discusses the competition issues that may arise in the distribution of pharmaceuticals by presenting some interesting examples. It discusses vertical integration and vertical agreements between players located at different levels of the distribution chain, as well as horizontal mergers. It considers collusion between wholesalers and between pharmacies; and it examines the restraints to competition that can be caused by excessive and distortionary regulation that tends to be present at the retail level.

3.1 *Vertical relationships and vertical integration*

91. Vertical integration and exclusive agreements are business strategies whose outcomes are very similar, because vertical contracts can be designed so as to mimic the same conditions that would prevail if the firms merged⁵⁵. Hence in the rest of this section we shall not distinguish between the two and refer generically to vertical integration.

92. Vertical integration may have an efficiency justification, as it may generate a number of benefits for the merged entity:

- cost savings from consolidating and rationalising certain activities,
- reduction in information asymmetries,
- elimination of double-marginalisation, and
- reduced risk of free-riding on investments.

93. However, vertical integration can also have anticompetitive effects in that it can reduce intra-brand competition or foreclose entry. Vertical integration is sometimes impossible due to regulation that restricts or prohibits this kind of agreements and concentrations.

3.1.1 *Vertical integration between manufacturers and wholesalers/distributors*

94. The integration of wholesale activities by manufacturers enables the latter to have more control on the drug flows at individual pharmacy level and thus to better co-ordinate production with distribution. This can lead to cost reductions and to a distribution system that is more efficient and more responsive to changes in demand (avoiding shortages due to bad or slow stock management on the part of wholesalers).⁵⁶ Greater visibility of the distribution chain also enables manufactures to better provide healthcare services to pharmacies⁵⁷.

⁵⁵ See Motta (2004), page. 305.

⁵⁶ See OFT (2007).

⁵⁷ See OFT (2007).

95. The presence of distortive regulation may also provide incentives towards vertical integration. The OFT (2007) has noted that when wholesalers receive a margin that is calculated as a percentage of the value of the medicine, manufacturers of high value medicines pay wholesalers more than the costs these actually incur in dealing with their medicines, as these costs are usually not related to the value of the product⁵⁸. They are thus subsidising the distribution of low value medicines and may achieve considerable savings by internalising these activities.

96. In addition when a manufacturer also undertakes the wholesaling activities, it will impose to retailers a final price that maximises the overall profits of the integrated entity, because it will internalise the demand-reducing effect of adding an additional mark-up⁵⁹. Whereas, when there is vertical separation between these activities, both the manufacturer and the wholesaler will add their own mark-ups above the costs, as they both enjoy some market power, and the retail price will not be the profit maximising one from the industry standpoint. This advantage may be mitigated by the presence of price regulation that constrains the price setting powers of both players.

97. Vertical integration between a manufacture and a distributor/wholesaler can reduce intra-brand competition if the manufacturer stops using other wholesalers (or charges them the same prices it asks from retailers). In addition, it can have a foreclosing effect at the upstream level if the wholesale market is very concentrated, as it deprives other manufacturers of access to an important resource. However, this may not happen if the vertically integrated wholesaler/distributor continues to provide services also to other manufacturers.

98. When the vertical agreement involves a number of manufacturers and a single wholesaler, different concerns may arise, in particular that the set-up could facilitate collusive agreements.

99. In South Africa, a group of manufacturers⁶⁰ established a jointly owned agency, called SAI, which carried out exclusive distribution operations for the products of its shareholders. In March 2000, SAI acquired the wholesale distributor DD and converted it into an exclusive distribution agency, Kinesis Logistics. As a distributor Kinesis was simply responsible for the delivery of the products of its shareholders without acquiring their ownerships.

100. A group of wholesalers complained to the Competition Tribunal on the ground that the joint-venture hid a collusive horizontal agreement between the manufacturers. The Tribunal concluded that the exclusive distributor could be a vehicle for collusive practices and the manufacturers had to sell Kinesis to a logistic service provider.

101. Subsequently each one of them concluded a separate contract for the exclusive distribution of their products with the now-independently owned Kinesis. Under these contracts the manufacturers could only sell their products through Kinesis, but the latter could also distribute the products of other manufacturers (non-exclusive provision/exclusive distribution).

102. The wholesalers complained again, arguing that, even though the distributor was now a legally separate entity, it had been sold only to circumvent competition rules and that the manufacturers' objective

⁵⁸ Usually distribution costs tend to be rather similar across medicines, unless a medicine requires special handling or conservation conditions.

⁵⁹ Spengler (1950) and Machlup and Taber (1960) show that the retail price is lower where there is vertical integration than when there is separation. See also Gil R. (2011) for an empirical study and Riordan (2008) for an exhaustive review of the literature on this topic.

⁶⁰ Glaxo Wellcome, Pfizer, Pharmicare limited, Smithkline Beecham and Warner Lambert.

was still to restrict competition at the wholesale level. The Competition Tribunal, however, argued that the existence of a set of separate exclusivity agreements did not prove the existence of horizontal collusion.

103. The wholesalers also alleged that the manufacturers, by means of those vertical agreements, had reduced intra-brand competition. The Competition Tribunal rejected the argument that exclusive distribution contracts by definition eliminate intra-brand competition⁶¹. It contended that, since there was insufficient evidence that competition at the wholesale level had been much more vigorous before the exclusive contracts were signed, it could not be claimed that the introduction of these contracts had reduced competition. In addition, the Competition Tribunal noted that any reduction in intra-brand competition is likely to be compensated for by more intensive inter-brand competition. The wholesalers contended that the pharmaceutical industry is characterised by unusually low levels of inter-brand competition because of the presence of patents on innovative products. The Competition Tribunal rebutted these arguments by stating that many patented products face competition from products applicable for the same broad therapeutic purpose.

3.1.2 *Wholesalers and retailers*

104. In those markets where there are no constraints on pharmacy ownership, there has been integration between wholesalers and retailers⁶². Vertical integration at this level of the supply chain can reduce transaction costs and increase efficiency, by exploiting synergies between the two businesses. Pharmacy chains, for example, have integrated backward to procure more efficiently⁶³. In addition, vertical integration can lead to an increase in the provision of services to pharmacies that may stimulate demand. The risk that other wholesalers may free ride on this effort stifles these investments and vertical integration may restore the wholesalers' incentives to invest.

105. However, vertical integration between a wholesaler and a group of retailers, in particular when the latter are independently-owned, may raise competition concerns, as it may facilitate information sharing and collusion, and it may soften competition at the retail level. It has also been argued that this type of integration may lead to conflict of interests, as the independence of pharmacists can no longer be guaranteed. The OBIG report (2006) emphasises the limited "professional freedom of pharmacists" in these settings, whose professional advice may be distorted by the need to reach business objectives. However this risk can be mitigated by introducing appropriate controls within the decision-making process, for example by requiring that a superintendent pharmacist sits on the board of directors and is legally liable for all the pharmacy related decisions taken within the organisation⁶⁴.

106. In 2008 in Hungary a wholesaler of pharmaceutical products, Hungaropharma, signed an agreement with several pharmacies. Under this agreement, the pharmacies were obliged to:

1. purchase at least 80% of their pharmaceutical products from Hungaropharma;
2. apply recommended prices during Hungaropharma's promotions;
3. notify Hungaropharma about any individual promotion activity.

⁶¹ See Competition Tribunal of South Africa, case no: 68/IR/JUN 00.

⁶² Vertical mergers between wholesalers and pharmacies have been observed in many countries. An example is the UK wholesalers Alliance that has integrated downward to become a major distribution-retail group under the brand Alliance-Boots.

⁶³ For example Sanacorp in Germany is a large wholesale company owned by a group of pharmacies.

⁶⁴ See the study by Ecorys (2007).

107. In return, the wholesaler committed to organise at least six promotions each year exclusively for those pharmacies that had signed the agreement, and to grant a 10% discounts during these promotions. The pharmacies that were part of the agreement also benefited from several other advantages, like discounts on third-party's products and the provision of laboratory equipment and materials at reduced prices.

108. Gazdasági Versenyhivatal, the Hungarian competition agency, investigated the agreement⁶⁵. The agency considered that point 1 (the quantity forcing) did not produce any anticompetitive effects. But it found that other elements of the agreement might lessen competition between the participating pharmacies. Point 2, by not allowing pharmacies to offer prices below the "recommended prices" during the promotions, limited their ability to compete on prices and violated Article 101 (1) of the TFEU. If the objective was to ensure that the pharmacies passed on any promotional discounts to consumers, the Gazdasági Versenyhivatal argued that the wholesaler could obtain it by imposing a maximum suggested price. As for point 3, the presence of pharmacies' representatives at Hungaropharma meetings transformed this obligation in an opportunity for competitors to share information about prices. Further, although firms were left free to choose the discounts they offered, Gazdasági Versenyhivatal considered that the obligation to notify the wholesaler about any individual promotional discount would reduce the pharmacies' incentives to propose discounts on their own initiative.

3.1.3 *Manufacturers, wholesalers and retailers*

109. In some countries vertical integration has extended to the whole supply chain. However links between manufacturers and retailers may generate conflicts of interests. Pharmacies are supposed to advice clients on the drugs to use and often are required to substitute prescribed drugs with the cheapest ones available, but when they sell their own drugs staying impartial becomes difficult.

110. In 2010 the government of the state of Ontario in Canada has amended the Drug Interchangeability and Dispensing Fee Act, which governs how prescription drugs are sold and reimbursed, to prohibit pharmacies from having their own private label generics included in the state's formulary. The government feared that allowing the listing of private label drugs in the formulary would increase prices and, hence, their expenditure in drug reimbursements. This restriction has basically prohibited the sale of private-label prescription drugs in Ontario.

111. Pharmacy chains have strongly fought this ban on the ground that private label drugs are cheaper to source than those produced by third parties. In 2011 the Ontario Superior Court of Justice gave them reason. This decision was later reversed by the Supreme Court of Canada, which argued that the government's decision was appropriate to maintain control over the costs of prescription drugs and to reduce price inflation.

3.2 *Horizontal integration*

112. Horizontal concentrations and horizontal agreements may not be possible due to regulation that imposes constraints on the nature of the owners, as is often the case for pharmacies. However, where such restrictions are absent, or have been removed, concentration both at the retail and wholesale level has raised due to mergers that have tried to exploit economies of scale and achieve greater buyer power.

⁶⁵ Gazdasági Versenyhivatal (2008), Case n° Vj-57/2008, *Hungaropharma*.

3.2.1 *Mergers between wholesalers*

113. Wholesale activities involve high fixed costs; especially as IT systems are becoming essential for managing stocks and storing information on consumers' needs, but also because of the economies of density involved in a capillary and frequent distribution network. This has brought about some consolidation at this level of the value chain in many high and middle income countries.

114. Sometimes mergers between wholesalers have also happened in order to take advantage of differences in price regulation across countries – so they can acquire medicines in countries where price regulation is more stringent and exporting them to countries where prices are higher because of no or laxer regulation.

Box 7. A three to two merger in the UK

In 1996 Gehe, at the time the largest wholesaler of pharmaceuticals in the UK, sought to acquire the control of Lloyds, the third largest one. Simultaneously Unichem, the second largest wholesaler, also made a bid to acquire Lloyds. Either of the two mergers would have reduced the number of national wholesalers from three to just two.

The two bids were assessed by the Monopolies and Merger Commission (MMC)⁶⁶, which concluded that both mergers would have raised competition concerns, especially in some local areas where the concentration of the three wholesalers was very high. The MMC added that a merger would have been cleared only if the successful bidder accepted to divest Lloyds' wholesaling depots located in the areas where competition would be most seriously affected.

The Director-General for Fair Trading⁶⁷ expressed a different view, arguing that it would be important to maintain a third national wholesaler of pharmaceuticals and expressed doubts on the possibility that suitable buyers for the divested depots could be found. Finally, the Secretary of the State declared that satisfactory undertakings relative to the divestiture of the depots had been obtained and the merger between Gehe and Lloyds was allowed on April 1996⁶⁸.

115. In analysing the impact of horizontal mergers at the wholesale level, one should also assess the relationships between the wholesalers involved in the operation and the final retailers. When there are contractual links between the wholesale and the retail sector, these mergers may also reduce competition at the downstream level.

116. This illustrated by a case investigated by the Spanish Tribunal de Defensa de la Competencia in 2006⁶⁹. The companies involved in the operation were Cofares and Hefame, two wholesalers active in the distribution of pharmaceutical and para-pharmaceutical products in Spain

117. Both these companies were, at the time, owned by co-operatives of pharmacies. According to the agreements regulating these co-operatives, each pharmacy had to comply with a number of clauses. These

⁶⁶ At the time the UK authority responsible for assessing mergers was the Monopoly and Merger Commission. The Competition Commission and the Office of Fair Trading replaced it in 1999.

⁶⁷ If the MMC finds that a merger operates or is likely to operate against the public interest, the Secretary of State can make orders or obtain undertakings from the parties to remedy the adverse effects the MMC has identified. Alternatively, if recommended to do so by the DGFT, the Secretary of State may - in lieu of a reference – accept undertakings from the parties to remedy adverse effects identified by the DGFT.

⁶⁸ DAFPE/CLP(99)23, "Competition Policy in OECD countries 1996-1997", p. 379.

⁶⁹ Tribunal de Defensa de la Competencia (2006), N/06026, *COFARES/HEFAME*.

clauses would remain in the statute of the merged entity. The two most important ones concerned: 1) a minimum purchase obligation - each pharmacy had to place orders from the merged entity at least for an amount equal to the minimum between 30% of the average purchases of all member pharmacies and 30% of each pharmacy's own purchases, and 2) a minimum membership term - all pharmacies had to be part of the co-operative agreement for at least five years.

118. The Tribunal was concerned that these clauses could represent a barrier to entry for new wholesalers, who would find it very difficult to gain business from the pharmacies involved in the agreement. The potential threat to competition was high given the large market share that the merged entity would have. As result, the Tribunal approved the merger under the conditions that: the minimum purchase requirement was lowered from 30% to 25%, and the minimum term of membership was reduced to one year.

3.2.2 *Mergers between pharmacies*

119. In those countries where no, or few, restrictions on the ownership of pharmacies are imposed, chains of pharmacies are rather common and when these start merging competition concerns may arise.

120. The market for retail pharmacy services is not a national market, as consumers tend to buy their drugs locally and do not travel far to obtain them. The OFT (2007) surveyed consumers and found that 78% of them travel less than 1 mile (1.6 km) to get to a pharmacy and 96% travel less than 3 miles (4.8 km) to get to a pharmacy. Hence, mergers between chains, even if these are not large ones, can raise concerns if competition between pharmacies in specific local areas is reduced. As already mentioned competition on prices between pharmacies can very restrained, but nevertheless these can compete on other dimensions (such as opening times, services available, store layout and the like).

Box 8. Assessing horizontal mergers between pharmacy chains

When assessing the merger between two retail chains, Boots and Unichem,⁷⁰ across the UK the OFT relied on the findings just mentioned to determine that a one-mile radius around a pharmacy was the appropriate geographic dimension for assessing the impact of the proposed concentration. It then assessed to what extent pharmacies competed between each other.

It found that location is the main factor that determines customers' choice, but that there is nonetheless competition on the prices for OTC drugs as well as on other service quality variables, such as waiting times, store layout, product availability and ease of shopping. Hence, it concluded that the merger could have a negative impact on consumers in those areas where after the merger there would be no competing pharmacies or only one.

It thus cleared the concentration under the conditions that around 100 pharmacies had to be divested in specific local areas and that Boots could not re-acquire any of these outlets without receiving a specific authorisation.

The Dutch competition authority performed a similar analysis when assessing the merger between the chains Brocacef and Lloyds Nederland⁷¹, and allowed it provided the parties divested four pharmacies in two specific areas.

⁷⁰ OFT (2006), anticipated acquisition by Boots plc of Alliance UniChem plc ME2134/05

⁷¹ Nederlandse Mededingingsautoriteit (2010), Case no. 6989, Brocacef/Lloyds Nederland.

3.3 *Collusion*

3.3.1 *Agreements between wholesalers*

121. The increased level of concentration in the pharmaceutical wholesale market in many countries has the raised ability of firms to form cartels.

122. In Germany, the Bundeskartellamt discovered a cartel between the four largest wholesalers in 2006⁷². This cartel had started after one of the four companies, Anzag, following a change in management, had started to compete aggressively on prices. When Anzag's management was again replaced in 2006, the price war terminated and the additional market share Anzag had acquired was shared among the other competitors.

123. The Bundeskartellamt denied the wholesalers' arguments that the end of the price war and the redistribution of Anzag's additional market share were the result of individually implemented business strategies and the four firms were accused of collusion. The Bundeskartellamt imposed fines of 500.000 euros on each of them.

124. Trade associations can play a role in helping wholesalers to co-ordinate their pricing strategies and sometimes even to agree strategies with manufactures and retailers⁷³. In India, for example, pharmaceutical wholesalers have colluded by means of their trade associations in three distinct occasions⁷⁴. In each of these cases associations of wholesalers signed agreements with Indian manufacturers and local retailers to fix the wholesale margins and the maximum number of wholesalers and retailers each manufacturer could contract with. In particular, some of these agreements forced manufacturers to appoint wholesalers only after receiving a "no-objection certificate" from the trade associations, and required them to obtain the trade associations' approval before launching any new drug on the market. Manufacturers were forced to sign these agreements under the threat that wholesalers would boycott their products.

125. The Competition Commission of India found that these agreements had two anticompetitive effects. First, they fixed the margins of all the wholesalers and retailers belonging to these associations. Since all the actors involved in the pharmaceuticals value chain were included in the agreements (manufacturers, wholesalers and retailers), this amounted to determining the final prices of the drugs. Second, by limiting the ability of manufacturers to appoint new wholesalers, these agreements impeded new entry in the market.

3.3.2 *Agreements between pharmacies*

126. Pharmacies are often too numerous to be able to co-ordinate their activities, but a number of different cases have emphasised the role played by trade associations in making co-ordination between pharmacies easier.

⁷² Bundeskartellamt (2006), Case n° B3 - 129/03, *Andrae Noris Zahn AG, Sanacorp Pharmahandel AG, Phoenix Pharmahandel Aktiengesellschaft & Co. KG and Gehe Pharma Handel GmbH*.

⁷³ See also OECD (2011).

⁷⁴ Competition Commission of India, New Delhi, Case No. 20/2011, *All India Organization of Chemists and Druggists* (AIOCD), MRTP Case No. C-87/2009/DGIR, *Chemists & Druggists Association of Baroda* (CDAB/BARODA) and MRTP Case No. C-127/2009/DGIR, *Varca Chemist and Druggist* (VARCA).

127. In 2004 in Germany the market for non-prescription drugs was further liberalised⁷⁵. The government introduced new legislation on OTC drugs that left complete discretion to pharmacies in setting the prices for some of these drugs. An association of manufacturers organised several meetings with the associations of pharmacies, in order to explain how the new legislation was going to be implemented and which challenges it would bring to the retail business. The Bundeskartellamt considered that these meetings allowed price-fixing practices among pharmacies and imposed a fine on the association of manufacturers⁷⁶.

128. This last fact is a rather interesting feature of this case. Indeed, even if it was the pharmacy associations who had colluded, these were not fined, while the association of manufacturers was fined for having facilitated the collusive behaviour.

129. In Greece, in 2012, the competition authority fined a number of trade associations, operating both at wholesale and retail level, for boycott activities. A reform in the pharmaceutical industry had allowed the sale of infant milk, not only in pharmacies but also in a wider range of retailers, like supermarkets and grocery stores. The pharmacist associations of Achaia, together with several wholesalers and other pharmacy associations, issued a letter to their members, in which they suggested not to distribute products of those manufacturers that did not comply with the trade associations' rules. The competition authority argued that this practice was restrictive of competition in the market for the distribution of infant milk.

130. In 2012, the Chilean competition agency fined three chains of pharmacies, Farmacias Ahumada S.A., Farmacias Cruz Verde S.A. and Farmacias Salcobrand S.A. for collusive practices⁷⁷. In 2007, these three chains, which jointly detained 90% of the retail market, had started a fierce price war making also use of comparative advertisings. This had led to a sharp decrease in their margins, especially for prescription drugs, that, at some point, had become negative. Towards the end of that year, the three firms changed strategy and started to collude. This led to upward adjustments of the prices of all the medicines' that had been affected by the previous price war. This prices adjustment process was slow but substantial: in some cases prices increased by 80% to 100%. The agency condemned the three pharmacy chains to pay fines of 14 million euros each.

3.3.3 *Illicit agreements between doctors and manufacturers*

131. As explained in Chapter 1, consumers cannot choose by themselves the drug that is most appropriate to treat their condition and they have to rely on their doctors' advice. For this reason pharmaceutical companies make huge investments in marketing campaigns in order to influence doctors' prescriptions. Sometimes, the nature of these campaigns has captured the attention of competition and consumer protection agencies.

132. In 2011, the South Korean Fair Trade Commission fined six pharmaceutical companies for having handed out illicit bribes⁷⁸. These companies repeatedly offered monetary and non-monetary incentives to doctors, hospitals and clinics in order to induce the prescription of some of their drugs. Non-monetary kickbacks were in the form of lavish free dinners, highly paid lectures and exorbitant

⁷⁵ In particular, the GKV-Modernisierungsgesetz, the health insurance modernisation Act, liberalized the distribution margins in the market for OTC products.

⁷⁶ Bundeskartellamt (2007), Decision B 3 - 6/05, WuW, Section E DE-V, p. 1539, *OTC pharmaceuticals*.

⁷⁷ Fiscalía Nacional Económica (2008), C 184-08, *Farmacias Ahumada S.A., Cruz Verde S.A. y Salcobrand S.A.*

⁷⁸ Korea Fair Trade Commission (2011), *Press Release from September 5*, CJ Cheiljedang Corp., Janssen Korea Ltd., Novartis Korea Ltd., Sanofi-Aventis Korea Ltd., Bayer Korea Ltd. and Astra Zeneca Korea Ltd

consultancy fees. The authority argued that these bribes had considerably altered market competition and had contributed to inflate medicine prices.

133. A similar case has involved GlaxoSmithKline in China. The manufacturer was heavily fined by the Chinese authorities of having trained its managers to offer monetary rewards and of having bribing hundreds of doctors and hospitals' procurement agents in return for drugs orders. In recent months three other major multinationals have been accused of using similar tactics to boost their sales in the country⁷⁹.

134. Higher income countries have also experienced similar cases. In 2012 GlaxoSmithKline was fined in the US after admitting to having bribed doctors, through lavish hospitality, trips and monetary rewards, to encourage the prescription of antidepressants to children⁸⁰. The company was also found to have cut research funding when sponsored doctors had refused to remove safety concerns from their articles about the company's drugs.

135. Recently, following these and other scandals, there have been welcome moves to self-regulation from the industry⁸¹.

3.4 Excessive regulation: the retail sector

136. Pharmacies are subject to extensive regulation, not just on prices at which they can sell medicines and on the margins they may earn on these sales but also on many other aspects of their business⁸². Some of these rules and restrictions are necessary, as discussed in Chapter 1 and 2, to protect consumers; however others appear at best obsolete and often anticompetitive. A serious reconsideration of these rules, by assessing their impact on competition and innovation would be necessary in many countries⁸³. Below we discuss some notable examples of these restrictions.

3.4.1 Restriction on entry

137. The constraints on the location of pharmacies, usually based on demographic criteria or on minimum distance between outlets, have already been discussed in Chapter 2. It is claimed that, by giving pharmacies a local monopoly, these constraints ensure that a sufficient number of pharmacies are set up across the country guaranteeing accessibility to all consumers. However, these restrictions seem unlikely to create the right incentives to locate pharmacies in poorer and rural areas, while they clearly restrict entry in more profitable areas thus limiting competition and harming consumers.

⁷⁹ See a study from CENTAD (2010) for a discussion on marketing techniques used in India.

⁸⁰ The United States Department of Justice (2012), C.A. No. 11-10398-RWZ, *GlaxoSmithKline Plc*.

⁸¹ For example in Finland the industry has a self-regulatory body – the Supervisory Commission for the Marketing of Medicinal Products.

⁸² See Ecorys (2007) for a good overview of pharmacy regulation in Europe.

⁸³ See OECD (2013).

Box 9. Changes to entry regulation in the pharmacy market in the UK

In 2003, the OFT⁸⁴ undertook a market study of the pharmacy sector in the UK and concluded that consumers would benefit from the elimination of the strict regulation on entry in place since 1987. The study noted that since the introduction of this regulation, there had been very little entry in the market and that the constraints it posed limited “the entry and expansion by pharmacies that offer consumers lower prices, more convenient opening times, or valued and innovative services⁸⁵”. The OFT argued that a deregulation of the market would lead to an increase in the quality of pharmacy services, in particular in terms of an increase in the number of pharmacies and in their higher opening hours⁸⁶.

In 2005 the UK government adopted the recommendations put forward by the OFT, though only partially. The Government kept the 'market entry' test, which prevents the granting of new licences in locations which are already “well” serviced by existing pharmacies, but introduced a number of exemptions to its strict requirements for, most notably the permission to set up new pharmacies if these undertook to stay open for more than 100 hours a week.

As reported by the OFT in its 2010 ex-post review of the impact of the intervention⁸⁷, the 100-hour exemption was effective in stimulating the entry of new firms in the market: it resulted in a 8.8% increase in the number of pharmacies. It also allowed consumers to have greater access to drugs and pharmacy services out of standard business hours. But these pharmacies were mostly opened in urban areas, where concentration was already high, while the liberalisation did not benefit rural and less densely populated areas.

The Government abolished the 100-hour exemption rule in September 2012.

3.4.2 *Restriction on opening hours*

138. In some countries opening hours are also regulated to ensure that consumers in each area have always some access to pharmacy services. Despite being aimed at protecting consumers, these rules can actually restrict the ability of pharmacies to really meet their customers’ needs, when setting short opening hours and limits on weekends and night shifts, or can raise costs and create barriers to entry, when setting excessively long hours. Ideally they should set minimum compulsory opening hours plus a shift system for out-of-hour services, to guarantee sufficient access, and leave individual pharmacies free to decide whether to offer longer opening hours.

Box 10. The regulation of pharmacies’ opening hours in Greece

In a recent report the OECD⁸⁸ has reviewed the regulation of a number of retail sectors in Greece, including pharmacies. It has found that pharmacies can only be open on Mondays and Wednesdays from 8:30 until 14:30, and on the remaining weekdays from 8:30 until 14:30 and from 18:00 until 21:00, while they must always close between 14:30 to 18:00 and on Saturdays, Sundays and during holidays when a shift system is applied. Pharmacies that wish to extend their opening hours are allowed to do so, only if:

- they notify their local pharmacist association and the prefecture every semester; and
- the extended hours coincide with one of two options (from 14.30 to 23 or from 14.30 to 8.30 of the following morning).

These provisions, as suggested by the OECD, excessively restrict consumers’ choice and raise their waiting time and the regime disciplining the extended operating hours is too restrictive and costly to really afford proper flexibility to the existing rules. The OECD has concluded that liberalising trading hours would increase consumers’ access to pharmacies, resulting in reduced transaction costs and significant time savings.

⁸⁴ See OFT (2003).

⁸⁵ See OFT (2003), page 7.

⁸⁶ Since prices of prescription drugs are regulated, the OFT argued that price competition could not have changed as a consequence of the regulatory changes.

⁸⁷ See OFT (2010), “Evaluating the impact of the 2003 OFT study on the Control of Entry regulations in the retail pharmacies market”.

⁸⁸ See OECD (2013).

3.4.3 *Restriction on products that can be offered and how they can be sold*

139. Regulation may also restrict the range of product that can be sold in pharmacies, as well as outside pharmacies. In France, for example, the law determines the products that a pharmacy can carry and in many European (and non-European countries) the sale of OTC drugs, whose sale does not require the supervision of a pharmacist, can only be sold in pharmacies. The latter is slowly changing and finally generating greater competition in a segment where no price regulation exists and, hence, where price competition is possible.

140. Regulation also restricts how drugs can be sold, as in many countries the online sale of medicines is prohibited or strongly limited, on the ground that the sale of medicines requires more careful supervision and advice, which cannot be provided in a virtual transaction. Hence while there are countries, such as the US and Australia, where online sales are rather unfettered and thriving, there are countries, such as Germany and France, where online sales are allowed but under very strong constraints that considerably reduce the benefit that this channel can bring to consumers.

141. Online sales can reduce the costs of having to physically go to a shop and queue, which can be especially high for older and sick people, as well as for patients that have repeated prescriptions. They ensure greater availability of products, because there are less physical constraints on the space available for stocking the drugs. Further, they can provide greater price transparency and lower prices, as these pharmacies tend to have lower running costs, thus providing savings for consumers.

Box 11. The on-line sale of medicines: the European Union's perspective

In 2000 in Germany, a pharmacy trade association filed a complaint against Doc Morris, a Dutch Internet pharmacy also active in the German territory. Doc Morris was accused of being in breach of the law when selling on-line prescription and non-prescription medicines to German patients. In Germany, the legislation did not allow to sell drugs that required a prescription without supervision by a pharmacist, which implied that the sale by mail order of prescription drugs was forbidden.

In 2001 the regional civil court in Frankfurt referred the case to the European Court of Justice (ECJ). In 2003 the ECJ issued its decision, in which it agreed with the Dutch online company that the on-line sale of non-prescription drugs, including those that can only be sold in pharmacies, should not be banned⁸⁹. But, the ECJ also stated that a stricter level of control on the sale of prescription drugs is justified, since it is important to ensure that those medicines are handed over to the consumer to whom they have been prescribed, or to a person entrusted by him, and that a valid prescription exists.

Hence, the ECJ only allowed the on-line sale of non-prescription medicines (as defined by the classification in the destination country). In addition, it stated that only brick and mortar pharmacies could run an on-line sale operation.

This decision, on the one hand, emphasises the importance of on-line sales as a mean to improve the availability of medicines and recognises that the German prohibition constituted an unnecessary barrier to the sale of these products. On the other hand, it still imposes considerable limit on the extent to which online sales are possible in European Union.

3.4.4 *Restriction on opening hours*

142. In many countries there are also restrictions on ownership: pharmacies have to be owned, at least partially by a pharmacist, and there is a limit (usually rather low) on the number of shops that a single pharmacist can own. The aim of such restrictions is claimed to be to avoid the dispersion of ownership control among non-specialists people, which could increase the risk of potential professional misconducts.

⁸⁹ European Court of Justice, Case C-322/01 "Deutscher Apothekerverband eV and 0800 DocMorris NV".

143. These restrictions, however, limit the opportunity for vertical integration with wholesalers, and for horizontal integration into chains, and do not allow the introduction of different business models (e.g. pharmacies in supermarkets). In addition, they limit the influx of new capitals and new management skills (as pharmacists may be skilled in advising on the use of medicines but not necessarily in running a business) in the sector. All these constraints in turn limit the exploitation of synergies and economies of scale, as well as innovation, leading to lower quality of services and higher costs.

144. A study by Ecorys (2007) shows that productivity in the retail market for drugs is negatively affected by regulation on the ownership of pharmacies, and that this type of regulation leads to higher prices and lower allocative efficiency. However, these conclusions are not uncontroversial, as shown by an assessment of ownership deregulation in Norway and Iceland (Anell 2005). This study examines the impact of removing pharmacy ownership restrictions in these two countries and argues that the overall effects are ambiguous. Deregulation can indeed lead to a considerable increase in concentration, which may generate cost savings and stronger buyer power, but can also weaken competition. In addition, the study argues that the efficiencies gained from the consolidation may not always be transferred to consumers in terms of lower prices or higher quality of services.

3.4.5 *Restriction on price transparency and advertisements*

145. Pharmacies compete to a limited extent on prices. This is due to three main factors. First is that in some countries consumers do not pay, or pay for a very limited share of, the price of the drugs. Hence, they have no incentives to select the pharmacy in which to make their purchase on basis of the prices it charges, but they only consider those factors that really affect them, such as location, opening hours, and other services on offer. Hence, pharmacies have no incentives to compete on prices. Second, prices are often regulated, even though regulation can leave scope for variation in final prices. Third, and more importantly, there are “ethical rules” that limit the degree to which pharmacies can publicise their prices. This lack of transparency limits the ability of pharmacists to publicise their prices and any discount they may wish to offer to attract consumers, thus reducing the incentives to compete on prices.

146. However it is interesting to note that in the US price competition between pharmacies is more common. This is partly due to the fact that insurance coverage is more limited and, hence, consumers are more price sensitive, but this is true also in many other countries, where such competition is much rarer. Another reason is that rules on price transparency and publicity are less stringent. An interesting example is that of the chain Walgreen, which in 2006 started offering a number of generic drugs at a price below the co-payment required by most insurance plans. Clearly this campaign was not directed at consumers that paid out of their pockets, since generics are usually reimbursed; its origin probably lied in a combination of: high co-payments, the possibility to advertise extensively and the ability of pharmacy chains to source generics at a low cost. Interesting lessons can be learnt from this example. A similar competitive outcome could and should be obtained for OTC drugs in all countries, as the prices of these drugs are neither regulated nor reimbursed⁹⁰. In addition, greater price competition could and should be obtained in those countries where consumers pay all or a share of the drugs out of their pockets and where prices are not stringently regulated.

3.5 *Conclusions*

147. This Chapter has discussed the most relevant competition issues in the distribution of prescription pharmaceuticals. It has given examples of vertical and horizontal agreements and mergers and of the kind of effects this may have on competition. In addition it has discussed how excessive regulation may stifle competition and therefore innovation and cost reductions.

⁹⁰ In a very recent report on competition in the distribution of pharmaceuticals, the French competition authority ([Avis 13-A-24 du 19 décembre 2013](#)) has discussed the issue of price transparency for OTC drugs, stressing how price competition is especially important for the development of on-line pharmacies.

BIBLIOGRAPHY

- Anell, A. 2005, Deregulating the pharmacy market: the case of Iceland and Norway, *Health Policy*, Elsevier, vol. 75(1), pages 9-17, December.
- Autorite' de la Concurrence (2013), Avis 13-A-24 du 19 décembre 2013 relatif au fonctionnement de la concurrence dans le secteur de la distribution du médicament à usage humain en ville.
- Barton, J. H. (2001): "Differentiated Pricing of Patented Products," mimeo, WHO.
- Competition Bureau of Canada (2007), *Generic Drugs Sector Study*.
- Consumer International (2007). *Drugs, doctors and dinners: How drug companies influence health in the developing world*. London, Consumer International.
- CUTS (2013), *Competition Issues in the Indian Pharmaceuticals Sector*.
- Danzon, P. (1998), 'The Economics of Parallel Trade', *Pharmacoeconomics*, Volume 13, 3:293–304.
- Danzon P. and Towse A. (2003), *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*. *International Journal of Health Care Finance and Economics*, Volume 3, No. 3: 183-205.
- Danzon P., Wang Y.R., and Wang L. (2005). *The impact of price regulation on the launch delay of new drugs-evidence from twenty-five major markets in the 1990s*, *Health Economics*, John Wiley & Sons, Ltd., Volume 14(3): 269-292.
- Danzon, P. M., Mulcahy, A. W. and Towse, A. K. (2013), *Pharmaceutical pricing in emerging markets: effects of income, competition, and procurement*. *Health Economics*. doi: 10.1002/hec.3013.
- Dranove, D. (1988), *Demand Inducement and the Physician/Patient Relationship*, *Economic Inquiry*, Volume XXVI: 281-298
- Ecorys (2007), *Study of regulatory restrictions in the field of pharmacies*.
- Everard M. (2003). *Access to medicines in low-income countries*. In: Dukes GMN, De Joncheere CP, Rietveld AH, Haaijer-Ruskamp FM (eds). *Drugs and money*. Amsterdam: IOS Press.
- Ferrara, I. and Kong, Y. (2008), *Can health insurance coverage explain the generic competition paradox?*, *Economics Letters*, Elsevier, Volume 101(1): 48-52.
- Frank, R.G., and D.S. Salkever, (1992), *Pricing Patent Loss and the Market for Pharmaceuticals*, *Southern Economic Journal*, October.
- Frank, R. G. and D. S. Salkever (1997), *Generic Entry and the Pricing of Pharmaceuticals*, *Journal of Economics and Management Strategy*, 6, 1, 75–90.
- Ganslandt, M. and K. E. Maskus (2004), 'The Price Impact of Parallel Imports in Pharmaceuticals: Evidence from the European Union', *Journal of Health Economics*, Volume 23, No. 5: 1035–57.
- Gil, R. (2011), *Does Vertical Integration Decrease Prices? Evidence from Paramount Antitrust Case of 1948*, mimeo, Johns Hopkins University.

- GIRP (2005), The European Association of Pharmaceutical Full-line Wholesalers response to the DG Competition Discussion paper on the application of Article 82 of the Treaty to exclusionary abuses, <http://ec.europa.eu/competition/antitrust/art82/011.pdf>.
- Grabowski H, and Vernon J. (1992). Brand loyalty and price competition in pharmaceuticals after the 1984 Drug Act. *Journal of Law and Economics*, volume 35, issue 2: 331-350.
- Hollis A. (2010), Generic drug pricing in Canada: components of the value-chain, University of Calgary Department of Economics Discussion Paper 2010-10.
- Iizuka, T. (2007), Experts' agency problems: evidence from the prescription drug market in Japan. *The RAND Journal of Economics*, 38: 844–862.
- Jacobzone, S. (2000), “Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals”, OECD, Labour Market and Social Policy Occasional Papers, No. 40, OECD Publishing.
- Kanavos (2007), France: is there room for further efficiency savings?. *Current Medical Research and Opinion*, volume 23 (10)
- Kanavos P., Schurer W. and Vogler S. (2011) The pharmaceutical distribution chain in the European Union: structure and impact on pharmaceutical prices. European Commission, Brussels, Belgium.
- Kanavos P., Taylor D. (2007), Pharmacy discounts on generic medicines in France: is there room for further efficiency savings?, *Current Medical Research & Opinion*, Volume 23, No. 10: 2467-2476.
- Kanavos P. and Vadoros S. (2011), ‘Determinants of Branded Prescription Medicine Prices in OECD Countries’, *Health Economics, Policy and Law*, Volume 6, Issue 3: 313–35.
- Kong, Y. (2009), Competition between brand-name and generics – analysis on pricing of brand-name pharmaceutical. *Health Econ.*, 18: 591–606. doi: 10.1002/hec.1392.
- Kyle, M. (2007) Pharmaceutical Price Controls and Entry Strategies. *The Review of Economics and Statistics*, 89 (1). pp. 88-99. ISSN 0034-6535
- Kwon, S. (2003), Pharmaceutical Reform and Physician Strikes in Korea: Separation of Drug Prescribing and Dispensing, *Social Science & Medicine*, Volume 57, Issue3: 529-538.
- Laing R.D. (2001), Health and pharmacy systems in developing countries. Paper delivered to the WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs, Høsbjør, Norway, 8–11 April, 2001.
- Lexchin, J. (2004), The effect of generic competition on the price of brand-name drugs, *Health Policy*, Volume 68, 1: 47–54.
- Lexchin, J. and Gagnon M. (2008), The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States, *PLOS Medicine* Lim D., Emery J., Lewis J., and Sunderland V.B. (2009), A systematic review of the literature comparing the practices of dispensing and non-dispensing doctors, *Health Policy*, Volume 92, Issue 1: 1-9.
- Lopert, R., Lang D., Hill S. and Henry D. (2002), Differential Pricing of Drugs: A Role for Cost Effectiveness Analysis?, *The Lancet*, Vol. 359: 2105-2107.
- Machlup F., Taber M. (1960), Bilateral monopoly, Successive Monopoly, and Vertical Integration, *Economica*, 27: 101-119.

- Mossialos, E. and Dukes, G. (2001), Affordably priced new drugs for poor populations: approaches for a global solution, *International journal of risk and safety in medicine*, 14 (1-2). 1-29. ISSN 0924-6479
- Mossialos E., Mrazek M., Walley T. (2004), *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality*, Open University Press.
- Mossialos E and Srivastava D. (2008), *Pharmaceutical policies in Finland: challenges and opportunities*, Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies; Ministry of Social Affairs and Health, Finland.
- Motta M. (2004), *Competition Policy: theory and practice*, Cambridge University Press.
- Myhr K. (2000), *Comparing prices of essential drugs between four countries in East Africa and with international prices*. Geneva: Médecins Sans Frontières.
- Nair M.D. (2012), TRIPS and Access to Affordable Drugs, *Journal of Intellectual Property Rights*, Volume 17: 305-314.
- OECD (2000), *Competition and Regulation Issues in the Pharmaceutical Industry*, DAF/COMP(2000)29.
- OECD (2001), *OECD Reviews of Regulatory Reform: Regulatory Reform in Ireland*, available at <http://www.oecd-ilibrary.org/docserver/download/4201071e.pdf?expires=1391002348&id=id&accname=ocid84004878&checksum=E9B3B4C8C3AEE38E9C612393E3151B4F>
- OECD (2008), *Pharmaceutical Pricing Policies in a Global Market*, OECD Health Policy Studies
- OECD (2009), *Generic Pharmaceuticals*, DAF/COMP(2009)39, also available at <http://www.oecd.org/daf/competition/abuse/46138891.pdf>
- OECD (2011), *Competition Issues in Trade Associations*, Background note by the OECD Secretariat, Latin American Competition Forum, Bogotá, DAF/COMP/LACF(2011)8.
- OECD (2013), *OECD Competition Assessment Reviews: Greece*, available at <http://www.oecd.org/daf/competition/greece-competition-review-2013.htm>
- OFT (2012), *Can 'Fair' Prices Be Unfair? A Review of Price Relationship Agreements*, A report prepared for the OFT by Lear, OFT 1438.
- OFT (2003), *The control of entry regulations in the retail pharmacies market - an OFT market study*.
- OFT (2007), *The Pharmaceutical Price Regulation Scheme - an OFT market study*.
- OFT (2010), *Evaluating the impact of the 2003 OFT study on the control of entry regulations in the retail pharmacies market - a study prepared for the OFT by DotEcon*.
- Ordre national des pharmaciens (2013), *Pour une transparence de la consommation et des coûts* http://www.ordre.pharmacien.fr/content/download/131173/683213/version/3/file/Medicaments_pour_une_transparence_de_la_consommation_et_des_couts-HDef.pdf.
- Perry, Martin K., (1989). Vertical integration: determinants and effects" *Handbook of Industrial Organization*, in: R. Schmalensee & R. Willig (ed.), *Handbook of Industrial Organization*, edition 1, volume 1, chapter 4, pages 183-255, Elsevier.
- Philipsen N.J. (2003), *Regulation of and by Pharmacists in the Netherlands in the Netherlands and Belgium: An Economic Approach*, Antwerp/Groningen: Intersentia.

- Rey, P. (2003), 'The Impact of Parallel Imports on Prescription Medicines', mimeo (Toulouse, IDEI).
- Riordan M.H. (2008), Competitive Effects of Vertical Integration, Handbook of Antitrust Economics, Paolo Buccirossi (ed.), MIT Press.
- Rizzo, J. A. and R. Zeckhauser (2005), 'Generic Script Share and the Price of Brand-Name Medicines: The Role of Consumer Choice', Working paper No. 11431 (Cambridge, MA: NBER).
- Scherer F. M. (2004), The pharmaceutical industry: prices and progress. The New England Journal of Medicine, 351(9).
- Spengler J.J. (1950), Vertical Integration and Antitrust Policy, Journal of Political Economy, Vol. 58, No. 4 (Aug., 1950), pp. 347-352.
- Srivastava, D. (2011), An analysis of the determinants of access to medicines and health care in developing country settings. PhD thesis, The London School of Economics and Political Science (LSE).
- Srivastava D. and McGuire (2013), Analysis of prices paid by low-income countries - how price sensitive is government demand for medicines?, LSE Health Working Paper 35/2013, London School of Economics and Political Science
<http://www.lse.ac.uk/LSEHealthAndSocialCare/pdf/Workingpapers/LSEHWP35.pdf>
- Tetteh E. (2008), Providing affordable essential medicines to African households: the missing policies and institutions for price containment, Social Science & Medicine 66, 569–581.
- Valletti, T. M. and S. Szymanski (2006), 'Parallel Trade, International Exhaustion and Property Rights: A Welfare Analysis', Journal of Industrial Economics, 54, 4.
- Vandoros, S. (2008) Generic policies and the 'generics paradox' Euro observer, 10 (2). 7-8. ISSN 1020-7481.
- Vandoros, S., Kanavos P. (2013), The generics paradox revisited: empirical evidence from regulated markets. Applied Economics, 45 (22). pp. 3230-3239. ISSN 0003-6846.
- Vogler S., Zimmermann N., Hahl C., Piessnegger J., and Bucsics A. (2013), "Discounts and Rebates granted to public payers for medicines in European countries", Southern Med Review, 5 (1)
- Wagner J.L., Duffy B.M. (1988), Containing the costs of prescription drugs: the U.S. experience, Paper Presented at the Symposium: Controlling Costs While Maintaining Health, Bonn.
- WHO (2000), Global Comparative Pharmaceutical Expenditures, EDM/PAR/2000.2.
- WHO (2001), Report of the Workshop on Differential Pricing & Financing of Essential Drugs, 8-11 April 2001, Høsbjør, Norway.
- WHO (2003), Drugs and Money, Edited by Dukes M.N.G., Haaijer-Ruskamp F.M., de Joncheere C.P., Rietveld A.H., IOS Press. WHO (2004), The World Medicine Situation.
- WHO (2011), The World Medicine Situation, Pharmaceutical Consumption.
- WHO –HAI (2011a), The Regulation of Mark-ups in the Pharmaceutical Supply Chain, WHO/HAI Project on Medicine Prices and Availability Review Series on Pharmaceutical Pricing Policies and Interventions Working Paper 3.
- Wiggins, S. N. and R. Maness (2004), Price Competition in Pharmaceuticals: The Case of Anti-infectives, Economic Inquiry, 42, 2, 247–62.