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COMPETITION COMMITTEE**

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Global Forum on Competition

COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Executive Summary --

27-28 February 2014

This Executive Summary by the OECD Secretariat contains the key findings from the discussion held during Session III of the 13th meeting of the Global Forum on Competition on 27-28 February 2014.

More documents related to this discussion can be found at www.oecd.org/competition/competition-distribution-pharmaceuticals.htm

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EXECUTIVE SUMMARY

*By the Secretariat**

From the discussion at the roundtable, the delegates' submissions and the invited presentations and papers, the following points have emerged:

- (1) *Regulatory needs and competition concerns in the market for the distribution of pharmaceuticals are shaped by the distinctive economic features of the pharmaceuticals sector, which are not shared by other industries. Policy-makers and enforcers need to understand these factors thoroughly to be able to intervene in this sector.*

The market for prescription pharmaceuticals has 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 designed to reward the high investments in R&D necessary to bring new drugs to market. However, the market power that patent protection confers requires some form of price regulation to ensure that the revenues are not excessive and consumers are protected. Moreover, originator drugs may continue to enjoy market power after the entry of generic equivalents due to various forms of inertia.

Prescription pharmaceuticals are credence goods. The decision about their purchase is delegated to an expert (a doctor) rather than being made by the consumer, implying an asymmetry of information between them. There is also an information asymmetry between manufacturers and doctors, as the latter rely 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.

Because the decision about the purchase is made by a third party (a doctor) rather than the one who pays (the consumer or insurer), the demand for drugs is rather price-inelastic. Doctors are usually insensitive to price, and in some countries the consumer does not pay the full cost of the medicines she buys and is thus similarly insensitive. Demand by wholesalers and retailers is also rather rigid due to the must-have nature of many drugs, caused by the lack of alternatives and by regulatory requirements on the range of the products that must be carried. 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 levels of the supply chain.

* This Executive Summary does not necessarily represent the consensus view of the Competition Committee. It does, however, encapsulate key points from the discussion at the roundtable, the delegates' written submissions, and the Secretariat's background paper.

Since drugs are essential to human health and survival, many governments consider them to be merit goods that should be affordable and accessible to all citizens, irrespective of their income or their place of residence: an outcome that market competition cannot guarantee. The consumption of some medicines, such as vaccines and medicines for infectious diseases, has a strong positive externality that can only be internalised by policy interventions making these medicines within the reach of those who need them.

These features of the pharmaceuticals sector imply that competition in an unregulated market cannot fully be relied upon to reach an efficient allocation of resources or to meet equity concerns. Regulatory interventions to address these market failures and to meet these policy objectives are therefore necessary. 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.

- (2) *Important differences exist between developed and less developed economies in the type of competition problems that arise in the distribution of pharmaceuticals. Better enforcement of regulation and of competition law, more consumer information, and greater control over the incentives provided by manufacturers to doctors could improve outcomes in less developed countries.*

While most of the literature tends to focus on high income countries, the situation in middle and lower income countries is often very different. Limited resources available to governments and the lack of extensive public or private insurance coverage mean that consumers in such countries typically have to pay for medicines out of their own pocket. Doctors, operating privately, often both prescribe and dispense medicines and are therefore subject to a potential conflict of interest. Reliable and independent information to consumers is lacking, resulting in, among other things, a mistrust of cheaper generic alternatives. Price and margin regulation is often weakly enforced.

As a result, retail prices in lower income countries are sometimes much higher than in high income countries. Since medicines account for a very large fraction of total out-of-pocket expenditures by consumers in such countries (86% in India according to a World Bank study in 2011-12, for example), high prices aggravates poverty. Prescribing standards are often poor since doctors are susceptible to inducements from manufacturers.

Various measures can, however, mitigate these problems, at least to some extent. Public awareness campaigns supported by improved testing and authorisation procedures can help to shift consumption patterns towards cheaper generic drugs. Audits of prescription practices, or the threat of such audits, can combat misprescribing on the part of doctors. Addressing the issue of financial incentives from manufacturers to doctors could also help ensure a more rational use of medicines, avoiding unnecessary and expensive prescriptions.

- (3) *Mechanisms used to regulate or otherwise constrain drug prices can have varying effects on competition. Competition authorities have a legitimate interest in these effects and the competence to help guide the choice of the most appropriate mechanisms.*

Constraining prices and inducing competition at the various level of the distribution chain is necessary to constrain the market power held by manufacturers and pharmacies and thus to keep pharmaceutical expenditure by consumers and by public (and private) insurers under control.

Various methods of regulating the ex-factory and retail prices (or reimbursements) of originator and generic drugs are used. In many cases wholesale prices are also regulated, either to ensure remuneration to wholesalers operating under public service obligations to carry a full range of drugs, or to curb the effects of market power in the supply chain.

Despite their practical advantages, there are a number of difficulties with the most commonly used forms of regulation of ex-factory prices. International reference pricing, which is often used to regulate originator drugs, can distort launch decisions by giving manufacturers an incentive to launch first in countries with less stringent price regulation in order to establish a high reference price elsewhere (and hence defeat the purpose of price benchmarking). Internal reference pricing and generic price ceilings, in which prices are set by reference to either drugs in the same therapeutic class or to the originators corresponding to generics, may not reflect underlying costs, and can provide a focal point for pricing that discourages further price competition.

Margin regulation at the retail level tends to be based on list prices, but prices actually paid may include substantial discounts as manufacturers of generics compete to obtain shelf space in pharmacies. This problem has prompted some countries to calculate regulated margins on effective rather than listed prices, although the enforcement of this type regulation is difficult because of the very limited transparency of the prices paid by pharmacies. Other countries have instead prohibited discounts, even though they may be considered pro-competitive in certain circumstances.

Evidence presented at the roundtable indicates no clear relationship between the form of ex-factory price regulation and the prices of comparable drugs, and that final prices can vary substantially across countries even where ex-factory prices are the same. This indicates that institutional details matter, but also suggests that regulation may not always be effective. Competition authorities can and should contribute to the design of regulatory pricing regimes to ensure that this provides the right incentives and effectively restrain prices.

- (4) *Drug price regulation and limited patent length are not sufficient to ensure vigorous competition between originators and generics. Competition, public cost-efficiency and private affordability can be further fostered by measures to promote generics, including demand-side measures.*

Competition from the entry of generics after the expiry of patents on originator drugs reduces, but does not eliminate, the need to protect consumers and payers from excessive prices. Some studies find that price competition between generics and originators is surprisingly weak despite their bioequivalence. Various reasons might explain this “generics paradox” including demand segmentation into price-sensitive and non-price-sensitive payers, different perceptions of branded and non-branded drugs, and limited information on the part of doctors and consumers as to the availability and quality of generics.

Regulation is thus necessary to favour the take-up of generics. Higher consumption of these drugs would help constrain the price of originators after their patent protection expires, and would decrease drug expenditure as generics are much cheaper than any originator drugs.

Such regulation includes not only price regulation, but demand-side measures to combat price rigidity and make doctors, pharmacists and patients take into account the costs of their choice. These measures include higher co-payments for consumers that do not select generics or lower-cost equivalents; formularies and budget constraints on prescribing doctors; voluntary or mandatory generic substitution by dispensing pharmacists; and bulk buying by price-sensitive insurers (an approach well exemplified by the US).

- (5) *The traditional pharmaceutical supply chain involves three levels: manufacturers, wholesalers and retailers (pharmacies). Forward integration by manufacturers and backward integration by pharmacy chains are changing this structure and are raising new competition issues.*

Increasingly manufacturers are performing, at least some of, the activities traditionally undertaken by wholesalers, with the result that in some countries (e.g. the US, Canada, Chile and increasingly many European countries) manufacturers have a direct commercial relationship with pharmacies and wholesalers have become mere distributors. In some cases manufactures are also acquiring wholesalers.

Manufacturers claim that these arrangements generate efficiencies, such as cost savings, reduced information asymmetries and elimination of double marginalisation, but it is not clear how much consumers and insurers benefit from these gains. In addition vertical integration may also have anti-competitive effects. Refusal by an integrated manufacturer/wholesaler to supply its products to other wholesalers can reduce intra-brand competition, while refusal to distribute other manufacturers' products can foreclose rivals' access to retail markets.

Since the pharmacy sector is less concentrated than the traditional wholesale sector, manufacturers are in a stronger bargaining position when they deal directly with pharmacies. In some cases pharmacies have responded by forming buying groups or (where permitted) consolidating into retail chains to improve their bargaining power with manufacturers, but this does not ensure that efficiencies from upstream integration are passed on to consumers and insurers (who pay for the drugs).

Vertical agreements between wholesalers and retailers (including mergers where there are no ownership restrictions) are also being observed. Vertical integration at this level of the supply chain can reduce transaction costs and increase efficiency, but may again raise competition concerns, as it may facilitate information sharing and collusion, and soften retail competition. A case investigated by the Hungarian competition authority in 2008 involved a wholesaler signing agreements with several pharmacies committing them to purchase most of their products from it and to comply with its recommended prices in exchange for discounts and other inducements.

- (6) *Where restrictions on ownership are absent or have been lifted, mergers aimed at exploiting economies of scale and achieve greater buyer power have increased concentration at the wholesale and retail levels.*

Horizontal mergers at the wholesale level are motivated partly by the economies of scale present in wholesale activity, which may be increasing due to the growing importance of IT systems that carry large fixed costs. In analysing wholesale mergers, one should also assess whether contractual links between the wholesale and the retail sector might reduce competition at the downstream level.

Concentration may also raise the ability of firms to form cartels. A cartel involving the four largest wholesalers in Germany was uncovered in 2006, while in 2012 the Chilean competition authority fined three pharmacy chains for collusive practices. In both instances the cartel had been formed in the aftermath of a price war.

In those countries with few or no restrictions on pharmacy ownership, retail mergers may reduce competition. Even though pharmacies do not compete on the price of prescription drugs, as these tend to be regulated, pharmacies nevertheless compete on other dimensions such as opening times, quality of service, store layout and the price of over-the-counter drugs. If the number of

fascia is reduced in a specific area this may reduce competition on these dimensions, leaving consumers worse off. Hence, as shown by two presentations, the effects of pharmacy mergers on the affected geographic markets need to be carefully examined.

Even where ownership is fragmented, industry groupings can provide a means for collusive arrangements, as demonstrated in India by three cases in which associations of retailers have acted to impede the entry of new wholesalers and to determine final prices to consumers. In Germany in 2008, a manufacturers' association was fined for having hosted meetings among pharmacy associations, ostensibly to discuss the imminent deregulation of the pricing of certain OTCs envisaged for 2004, but which were found to have facilitated price-fixing among retailers. In 2012 the competition authority of Greece fined several wholesale and retail trade associations for colluding to restrict the distribution of infant milk.

- (7) *The extensive historic regulation of the retail pharmacy sector in many countries should be assessed considering its impact on consumer welfare.*

In many countries around the world pharmacies are subject to extensive regulation governing market entry, ownership and opening hours.

Constraints on the number and location of pharmacies, based on demographic criteria or a minimum distance between outlets, are claimed to be necessary in order to ensure an optimal coverage of the population. However, such 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, harming consumers and generating economic rents for incumbents. The wide variation in the density of pharmacies in Europe reported at the roundtable (from one per 18,000 people in Denmark to one per 2000 in Spain and one per 1000 in Greece) seems to be due more to differences in historical legacy than to differences in the optimal level of coverage among countries.

Only limited deregulation of market entry has occurred so far. In the UK, the Office of Fair Trading in 2003 recommended removing the strict regulation of entry that had been in place since 1987. This was only partially implemented in 2005 by allowing an exemption for new pharmacies undertaking to stay open for more than 100 hours a week. Despite an increase in the number of pharmacies and improvements in access, the reform was abolished in 2012. Likewise, a partial deregulation of the pharmacy market in Hungary in 2007 was reversed in 2010.

Regulation of ownership, where it exists, places restrictions on who can own pharmacies and how many outlets a single owner can have. Relaxing these rules can lead to a substantial increase in concentration that may generate cost savings and improve buyer power, but this must be weighed against a potential lessening of competition and the risk that such efficiencies may not be transferred to consumers and payers. The decision on whether to maintain such restrictions should be based on an assessment of the likely balance of these effects.