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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from the European Union

-- Session III --

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- European Union --

Introduction

1. The distribution of pharmaceuticals is an essential part of the effort to deliver safe, effective and affordable medicines to patients. An efficient distribution of medicines is instrumental to ensure that patients everywhere in Europe have access to their medications in a timely manner, avoiding shortages, maintaining the optimal qualities of pharmaceutical products and guaranteeing the integrity of the supply chain to prevent the introduction of falsified medicines in it.

2. In the area of health care, the European Union shares competence with its Member States, the latter being responsible for the organisation and delivery of health services and medical care within their territories. As a consequence, the regulatory environment differs across Member States, for instance with respect to the pricing and reimbursement of medicines, to the restrictions on ownership and operation of pharmacies, and generally to the organisation of pharmaceutical distribution. Nevertheless, in carrying out their responsibilities, Member States and health care stakeholders such as national health services and pharmaceutical companies are affected by EU legislation.

3. Basic legislation relevant to pharmaceutical distribution includes the principles of Good Distribution Practice (GDP) stated in Directive 92/25/EEC and Title VII on Wholesale Distribution of Medicinal Products in Directive 2001/83/EC[1]. Recent developments include the adoption of Directive 2011/62/EU on prevention of the entry into the legal supply chain of falsified medicinal products[2] and the publication in November 2013 of revised Guidelines on GDP of medicines[3]. Ultimately, pharmaceutical distribution must be compliant with EC Treaty rules on competition in the Single Market.

1. Market structure of pharmaceutical distribution in the EU

4. Medicines produced by pharmaceutical manufacturers are dispensed to patients through a variety of channels. Prescription medicines are typically dispensed to patients in retail pharmacies. Non-prescription medicines (over-the-counter, OTC) are sold either in retail pharmacies or, in some countries, also by non-specialised retailers. A significant proportion of prescription and OTC medicines are dispensed and administered to patients in hospital settings. While wholesalers are the main providers of medicines to pharmacies and other retailers, pharmaceutical manufacturers tend to distribute their products directly to hospitals.

1.1 Wholesaling

5. The majority of countries have a mixture of national and regional wholesalers supplying medicines to retail pharmacies. This typically includes "full line wholesalers" operating at national

1 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0067:EN:PDF

2 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0074:0087:EN:PDF

3 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF

wholesalers that provide the full range of medicines and "short line wholesalers" distributing a limited set of medicines and that often operate at regional level. In most EU countries, national full line wholesalers represent the largest share of the wholesaling market, well above 60% of total pharmaceutical sales. However this is not the case in Greece, Portugal and Spain, where national wholesalers' share stands below 50%. In most countries, wholesalers' activities are subject to public service obligations establishing minimum requirements in terms of frequencies of delivery, product portfolio and geographical reach.[4]

1.2 Retailing

6. While pharmaceutical retailing is typically less concentrated than wholesaling, differences in the degree of pharmacies concentration are significant across EU countries. The number of pharmacies goes from one pharmacy per every ten thousand inhabitants in Denmark, Sweden, Slovenia and the Netherlands to more than five in Malta, Cyprus and Bulgaria, and almost eight in Greece. Most countries however have between two and four pharmacies per every ten thousand inhabitants. Country-specific regulations on pharmacy ownership and on the establishment of new pharmacies partially explain such differences.

7. Sixteen EU countries have some form of regulation of pharmacy establishment, often in the form of geographic and demographic criteria to limit the density of pharmacies. Thirteen countries regulate pharmacy ownership. The most restrictive ownership regulations are found in France, Greece, Italy and Spain, where only pharmacists may be owners (albeit in some countries as co-owners) and may only own one pharmacy.[5]

8. Entry regulations exist in many EU countries for various professional fields, not only pharmacies; including accountancy, legal and financial advice, architecture or engineering.[6]

1.3 Horizontal and vertical integration

9. The distribution chain has witnessed considerable consolidation in the past decade, which has manifested itself both through horizontal but also vertical integration. The degree to which consolidation has taken place often depended on national regulations.

10. In the last decade, nearly all EU countries have seen mergers in the wholesale sector and a decline in the number of operating wholesaler companies. On the retail side, pharmacy chains are becoming more prevalent. Some form of pharmacy chain is allowed in 19 EU countries. For instance, in Estonia, Lithuania and the UK more than 80% of the pharmacies belong to a chain. However, the diverse retail market structures and regulatory environments across the EU make it difficult to identify common patterns. The retail segment continues to be much fragmented in other countries where regulation is more restrictive on pharmacy ownership and establishment, like France, Greece, Italy and Spain. However, even in these cases there has been a trend towards joint procurement through cooperatives of pharmacies.

11. Vertical integration between wholesalers and retailers has also been in the rise, again constrained by certain regulations limiting ownership of pharmacies to pharmacists. Vertical integration is allowed, either with or without restrictions in 10 EU countries. [7]

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4 Figure 3.1 in *The Pharmaceutical Distribution Chain in the European Union: Structure and Impact on Pharmaceutical Prices*. EMINET, March 2011. (http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/structimpact_pharmaprices_032011_en.pdf)

5 Ibid., Figure 3.3.

6 *Economic impact of regulation in the field of liberal professions in different Member States*. IHS for DG Competition, January 2003, p. 51. (http://ec.europa.eu/competition/sectors/professional_services/studies/prof_services_ihs_part_1.pdf)

1.4 Direct-to-pharmacy (DTP) distribution

12. It is increasingly common to observe that pharmaceutical manufacturers deliver medicines directly to retail pharmacies, not only to hospitals. While the majority of sales continue to be supplied to pharmacies by wholesalers, in a number of EU countries the proportion of sales supplied to pharmacies directly by the manufacturer have significantly increased. They represent above 10 per cent of pharmacy sales in Denmark, Greece, Ireland, Luxemburg, Netherland and UK, and above 20% in the Czech Republic, France and Italy.[8]

13. DTP distribution can take place via a variety of schemes. It is not uncommon for manufacturers to have set up their own wholesale distribution channel for part of the portfolio. An alternative model is the so-called "sole agency", where the manufacturer sells directly to their customers with an exclusive wholesaler acting as a logistics provider. An intermediate option is the Reduced Wholesaler Model (RWM) schemes, in which the manufacturer selects a limited set of wholesalers (typically up to 3).[9]

14. Agency models limit wholesalers' ability to set their own commercial strategy and offer discounts, as they actually never own the stock. Less extreme models like RWM may also constraint wholesalers' decisions to some extent, depending on the terms of the agreement with the manufacturer. A consequence of these developments is a less clear-cut distinction between wholesalers and logistic providers than it had usually been the case.

2. The remuneration of pharmaceutical distribution

15. In recent years there has been considerable focus on the impact of the distribution chain on the total cost of prescription pharmaceuticals. Regulators have introduced changes in the remuneration of pharmaceutical wholesalers and pharmacies, with the aim of reducing the cost of distribution and increasing the efficiency of the distribution chain. The regulation of pharmaceutical prices, margins, and reimbursement and dispensation conditions creates incentives that distort the behaviour of market players, including wholesalers and pharmacists. The efficiency of market outcomes produced by such regulations remains in most of the cases a question to be assessed empirically.

16. The majority of EU countries regulate pharmaceutical wholesale and retail margins. Regulated margins can take different forms, including regressive mark-ups, proportional mark-ups and flat fees. Regressive mark-ups, the most common in the EU for both wholesaling and retailing, are typically designed as a percentage on ex-factory price that decreases as the price increases. Regulated margins are typically applied to reimbursable medicines, while they are less commonly applied to non-reimbursable medicines.

17. Data shows that most EU countries have average wholesale margins between 5% and 10%, although there is significant cross-country variability and the full range goes from the minimum observed margin of 3% in Sweden to the maximum of 23% observed in the Netherlands.[10] With respect to pharmacy margins, data shows most countries to apply margins ranging between 18% and 25%.[11]

18. Evidence suggests that wholesalers often offer a proportion of their allowable margin as a discount to pharmacies, to the extent that national regulations allow for it. The size of these discounts

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7 *The Pharmaceutical Distribution Chain in the European Union: Structure and Impact on Pharmaceutical Prices*. EMINET, March 2011, p. 31. (http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/structimpact_pharmaprices_032011_en.pdf)

8 Ibid., p. 32.

9 Ibid., p. 33-34.

10 Ibid., Figure 4.1.

11 Ibid., Table 4.2.

appears to be related to the relative bargaining power of wholesalers and pharmacies. Pharmacy chains and pharmacies' purchasing groups may have a greater bargaining power than single pharmacies, resulting in higher discounts obtained from wholesalers. On the contrary, evidence shows that maximum regulated margins for reimbursable medicines tend to be fully utilised by retail pharmacies when dispensing to patients, especially in Western European countries. As a result, retail pharmaceutical prices are largely homogeneous across pharmacies within the same country and price competition among retail pharmacies is therefore limited.[12]

19. In some countries, a significant proportion of pharmacy income comes from fixed fees, notably in Belgium, Denmark, Ireland, Netherlands and the UK. Usually these are dispensing fees linked to the volume of sales, not to pharmacy performance on value-added services to patients. There is an ongoing debate about the efficiency-enhancing incentives the could be generated by introducing fees for value-added services offered by pharmacies, like patient advice or therapy management, but there has been little regulatory development so far.[13]

3. Changing competitive dynamics in wholesaling and retailing

20. Developments in IT and logistics have triggered significant changes in the way wholesalers and pharmacies operate, with an impact in the competitive dynamics of the sector. Full line wholesalers have traditionally played a fundamental role in offering retail pharmacies the option of working with a few providers instead of a myriad of manufacturers, thus reducing their administrative burden and operating costs. However, having multiple providers has become less burdensome for pharmacies with recent advancements in IT and logistics. Also pharmacies' consolidation has increased their logistic capabilities. Manufacturers have identified this as an opportunity and show increased interest in establishing direct vertical links with retail pharmacies. This has resulted in DTP accounting for increasing shares of pharmacy sales, as discussed above.

21. Regulated distribution margins calculated as a proportion of the medicines prices imply that distributors obtain higher remuneration from supplying higher-price medicines. As a result, wholesalers and pharmacies obtain a large proportion of their remuneration from a limited number of medicines with high prices. For instance, data for France shows that wholesalers generate 80% of their revenue from only 12% of prescription medicines, while the remaining 88% generate just 20% of their revenue. This cross-subsidisation from high-price towards low-price drugs makes the current distribution models sustainable. To the extent that manufacturers decided to supply high-price drugs directly to pharmacies, wholesalers might find it increasingly difficult to cover the costs of meeting their public service obligations with respect to low-price drugs on which they make little profit.[14]

22. Wholesalers have faced increasing competitive pressure in recent years as a result of a number of developments, including advancements in IT and logistics, increased bargaining power of consolidated retailers, as well as a more active role of manufacturers in the distribution of medicines. Wholesalers have responded to these challenges granting larger discounts, seeking economies of scale through consolidation of existing entities. New distribution models like the sole agency model or the RWM are also redefining the traditional role that used to be played by full line national wholesalers.

23. Although the diverse retail market structure and regulatory environment across the EU makes it more difficult to identify common patterns, also the shape and role of pharmacies is adapting to this

12 Ibid., p. 40-48.

13 Ibid., p. 45.

14 Ibid., p. 41.

changing environment. This has included consolidation in some countries, the development of joint procurement in others. Competition among pharmacies may also lead to enhancing their role in health promotion, prevention, disease management and monitoring.

4. The impact of distribution on generic competition

24. Beyond competition among pharmaceutical distributors and its outcomes in terms of the cost and quality of their activities, the way in which medicines are distributed has also an impact on competition among pharmaceutical manufacturers. In particular, the design of regulations on pharmacy distribution has an impact on generic competition and uptake after patent expiry.

25. The analysis produced by the European Commission in the context of the Pharmaceutical Sector Inquiry showed that innovative drugs under patent protection typically enjoy higher prices than off-patent drugs facing generic competition. It also showed that often branded off-patent drugs manage to maintain higher prices than generic substitutable drugs well after patent expiry. Given the prevalent structure of distribution margins, this implies that wholesalers and pharmacies obtain higher remuneration from selling patented drugs and branded off-patent drugs than they do from selling generic drugs.[15]

26. Distributors therefore have a financial incentive to sell more expensive drugs. This has been identified as one of the features that may hinder the uptake of generic medicines in EU countries. The introduction of regressive margins instead of purely proportional margins has aimed at reducing this incentive, but not to the extent of fully counterbalancing it. Only fixed fees whose value is independent from the medicines prices could in fact fully counterbalance it. A number of EU countries have attempted to address this issue by introducing an obligation by the pharmacist to dispense always the cheapest generic version of a drug or by limiting reimbursement to the price of the cheapest versions of a drug. In the former, the formal obligation to dispense the cheapest drug should be the counterbalancing factor. In the latter, the patient is obliged to pay for the part of the price above the reimbursement level, in such a way that the patient has a financial incentive in the opposite direction to that of the pharmacist. Evidence shows that both types of measure have a positive effect on generic uptake.[16]

5. Concluding remarks from a patient and payer perspective

27. The structure of medicines distribution differs significantly across EU countries. A variety of models are used to achieve the fundamental objective of delivering safe, effective and affordable medicines to patients, complying with basic EU legislation in the field. Pharmaceutical distribution is regarded as part of the healthcare system and therefore subject to certain public obligations that are established by national regulators.

28. Recent developments in the sector may be seen as encouraging both from a payer and from a patient perspective: advancements in IT and logistics reducing operational costs, wholesalers facing increased competitive pressure, consolidation delivering efficiencies through economies of scale. These developments are already redefining the roles traditionally played by wholesalers and retail pharmacies.

29. Greater efficiency in the distribution of medicines will be achieved if ultimately patients get better services at a lower cost to payers. This is an objective that the Commission shares with national governments and which requires both well-designed regulations and the enforcement of competition rules.

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15 Pharmaceutical Sector Inquiry Final Report, European Commission, July 2009, Figures 25 and 28.

16 Pharmaceutical Sector Inquiry Final Report, European Commission, July 2009, p. 86.