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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from Latvia

-- Session III --

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Latvia --

1. Supply conditions

1.1 Do you consider that in your country there is an adequate and reliable supply of affordable drugs of an acceptable quality? If not, can you describe the extent of the problem and possibly quantify it? What role can competition policy play to improve the situation (both through competition law enforcement and competition advocacy)?

1. We consider that in Latvia there is an adequate and reliable supply of affordable drugs of an acceptable quality. It is possible to import unregistered medicines. In exceptional cases the State Agency of Medicines issues a permission to wholesalers for the distribution of the medicines authorised in other countries.

2. However, there are some problems that should be noted.

3. First of all Latvia has to improve availability of reimbursable medicines for patients. In Latvia there is the third smallest drug consumption between the European Union countries. In addition, in Latvia there is the second lowest public expenditure on drug compensation - state paid (compensated). Only about a third of the population spendings on medicines are compensated. In 2012 introduced a new procedure of dispensing medicines - only the cheapest / reference drug prescribing and dispensing. For some patients that increased co-payments for drugs, as well as the majority of patients are now forced to buy medicine for their own money, if the cheapest / reference medicinal product was not available (doctor has no right to prescribe more expensive medications). Thus, patient choice is significantly limited, which is a significant lack of a system, because the patient does not always get the necessary pharmacy medicine with state-guaranteed compensation.

4. Secondly, experts (Association of International Research-based Pharmaceutical Manufacturers and Latvian Generic Medicines Association) are concerned about the lack of biological medicines in Latvia. Availability of medicines in Latvia can only be improved by increasing the funding for the health sector.

5. Thus improved legislation as well as avoidance of adoptions of anti-competitive provisions is improving the situation, however, the main problems is actually due to the lack of enough funding for health care.

2. Manufacturing level

2.1 *What kind of regulation, if any, exists on ex-factory prices of originator drugs? What kind of regulation, if any, exists on ex-factory prices of generic drugs? Are you concerned that this regulation may be stifling price competition or innovation? Have you ever performed a market study that has looked at this regulation?*

6. There is no regulation on ex-factory prices of originator or generic drugs. However, ex-factory prices in general are affected by the sale prices. In competitive environment, the company has to work with a profit, which in turn contributes to improving the quality and investment in new, innovative products.

7. The price is also affected by the buying power of the population and various secondary costs (relating to the registration of medicines and administrative costs). In addition, it is noted that in Latvia there is relatively high cost of medicine registration that may have impact on the price of medicines.

8. The market (on the demand side) in Latvia would be considered as small, so manufacturers must calculate whether and after how long time period the income from drug sales will reimburse drug implementation costs in Latvia.

2.2 *Do you rely mostly on local manufacturers of drugs or on foreign ones?*

9. Approximately 30% of Latvian residents would prefer their own country produced medicines. However, taking into account the local drug manufacturers offer, in accordance with established treatment foreign manufacturers medicine is selected. Latvian-produced drug proportion of all drug turnover in Latvia is not significant. Thus, the absolute majority of drugs in Latvia are foreign..

2.3 *Are there barriers to trade and import that constraint the availability of drugs in your country?*

10. The most significant barrier to trade and import is high administrative costs compared with profit opportunities. There are also other factors that could adversely affect trade, primarily attributable to market characteristics in Latvia - small market, low drug consumption and buying power. Limited patient's freedom of choice because of the ban on open-access to non-prescription medicines in pharmacies.

11. Several of the earlier listed administrative factors are made because of the public interest and should not be changed. The administrative barriers such as strict regulation of drug registration and distribution can be changed, only in case of upturn in the economic situation. The Competition Council has repeatedly drawn the attention of the responsible institutions about the financial barriers to entrance of new parallelly imported medical products in the market, created by Cabinet regulations - in some cases, there exist requirement for parallelly imported medical products (not only parallel imported) to be sold at least for 30 % lower price than the drug in another section (B) of the list of medicines to be reimbursed. Such procedures may lead to refusal of any parallel import of medicines in general, but there still are no observed negative trends.

3. Wholesale distribution

3.1 *How is wholesale distribution organised in your country? Are wholesalers buying drugs from manufacturers and selling them downstream or are they simply distribute of manufacturers? Is this changing and if so in what ways?*

12. Foreign manufacturers in Latvia have their own offices or affiliates, which in turn can also have their own wholesalers. Type of representation depends on the form of cooperation with the Latvian pharmaceutical wholesalers. If a foreign manufacturer have a company in Latvia (its own drug wholesaler),

usually other Latvian pharmaceutical wholesalers buys medicines directly from this wholesaler. In such cases, cooperation is actually the same as the Latvian manufacturers.

13. Supply chains: manufacturer → wholesaler → pharmacies, health care institutions, medical practitioners **or** wholesaler → wholesaler → pharmacies, health care institutions, medical practitioners.

3.2 *How many players are involved in wholesale distribution? Is it a very concentrated sector? Are there many layers (e.g. large national wholesalers who supply smaller local wholesalers)? Do retailers usually stock themselves from one wholesaler or do they rely on more than one?*

14. In 2013 there were 58 drug wholesalers in Latvia. In 2012, 46 wholesalers of human medicines distributed medicines to the pharmacies, medical practitioners, health care institutions, and other recipients. The remaining 11 wholesalers have either exported them or sold medicines to other wholesalers. Over the past 5 years, the number of wholesalers has increased.

3.3 *Are there vertical agreements in place between wholesalers and manufacturers (e.g. exclusive distribution, and exclusive territories)? What are the main characteristics of these agreements? Do you have concern that these agreements may reduce inter and intra brand competition?*

15. If a foreign manufacturer in Latvia and in the neighboring countries doesn't have their own wholesaler, following type of cooperation is common - to negotiate and cooperate with one Latvian wholesaler (resells the manufacturers drug to other wholesalers), including exclusive conditions in contracts.

16. The fact that a foreign manufacturer exclusively cooperate with one of the Latvian wholesalers, significantly contribute to the vertical co-operation between competitors - Latvian wholesalers.

17. Each of the merchants is able to supply all authorized products in Latvia, including those with which manufacturers exclusively supply only to one wholesale dealer. However, the vertical cooperation between wholesalers is often also an objective necessity for ensuring the availability of medicines.

18. Vertical agreements may affect intra brand competition, but at the same time pharmaceutical market is strictly regulated, including with the regard to the wholesalers' margins, therefore competition is affected minimally.

3.4 *Are wholesalers vertically integrated with retailers and/or manufacturers? Do you have concern that vertical integration may reduce inter and intra brand competition?*

19. In pharmaceutical distribution market competition among wholesalers occurs not only for customers (actually there's not a significant change in recent years due to the limited number of pharmacies), but in many cases also for the suppliers.

20. Each new contract with manufacturer, if it's directly or indirectly exclusive, can significantly increase merchant sales. At this level, the competition for new suppliers still exists and there is a possibility to enter into new contracts. The vertical and horizontal integration of recent 3-5 years have developed serious structures in Latvian pharmaceutical market, where the main role is played by wholesalers vertically integrated with retailers (pharmacies). Effect through vertical integration is also achieved through marketing and drug procurement programs.

3.5 *Are there special provisions or regulation in place to ensure that rural and sparsely populated areas are served by wholesalers?*

21. No.

3.6 *Are wholesalers subject to regulation on prices, profits or margins?*

22. Yes, wholesalers are subjected to regulation on prices, profits and margins. The principles for the determination of the price of the medicinal products are described in the national legislation. The manufacturer's prices are declared to the State Agency of Medicines by the manufacturers twice a year. The maximum wholesale mark-up is determined. This regulation does not apply to the determination of the price of those medicinal products, which are procured in accordance with the Public Procurement Law. The price of medicinal products included in the list of reimbursable medicinal products is determined in accordance with the regulatory enactments regarding the procedures for reimbursement of expenditures for the acquisition of medicinal products and medical devices in outpatient medical treatment.

23. The price for which a drug wholesaler sells medicinal products is determined by multiplying the manufacturer's price by the correction factor and adding the correction sum and the value of value added tax. The correction factor and correction sum is determined on the basis of the manufacturer's price. In order to determine the wholesaler's price, the following formula is used:

$$LC = RC \times k + X + PVN, \text{ where}$$

LC – wholesaler's price; RC – manufacturer's price; k – correction factor; X – correction sum; PVN – value added tax.

24. It should be taken into account that this created wholesaler price is the maximum price for the wholesaler, regardless of the number of wholesalers involved in particular drug distribution.

3.7 *Are they subject to any other type of regulation that may affect the prices paid by final consumers or the availability of drugs to final consumers? Does the existing regulation of wholesalers cause distortions that may limit the availability and affordability of drugs for final users (for example margin regulation favours the distribution of branded over generic drugs)?*

25. Existing regulation of wholesalers can cause distortions that may limit the drug availability, as the final price of drugs is determined. Manufacturer can make the choice not to supply medicines, taking into account the profit opportunities.

3.8 *Do wholesalers/importers source drugs in countries that have lower prices (often referred to as parallel imports)?*

26. Yes, wholesalers/importers source drugs in countries that have lower prices however, the quantity of drugs that are parallel imported is small.

4. Retail distribution

4.1 *How is retail distribution organised in your country?*

- *Who can sell prescription drugs and who can sell over-the-counter drugs?*

27. A retail trade of medicinal products is the distribution of medicinal products to the public by a pharmacy (including selling prescription drugs and over-the counter drugs).

- *Are there separate retail outlets for paying out of their pocket patients and for reimbursed/non-paying patients?*

28. There are no separate retail outlets for paying out of their pocket patients and for reimbursed/non-paying patients.

- *Are there publicly owned pharmacies and what is their role?*

29. There are no publicly owned pharmacies.

- *Are doctors allowed to sell the medicines they prescribe?*

30. No.

- *Can hospital pharmacies also sell to external patients?*

31. Closed type pharmacies or pharmacies of medical treatment institutions are not permitted to distribute medicaments to external patients.

- *Are on-line pharmacies allowed?*

32. Yes, but only non - prescription drugs can be distributed on the web.

- *Is it possible to locate pharmacies in supermarkets?*

33. No.

- *Are chains allowed? What percentage of all existing pharmacies are chains?*

34. Yes, pharmacy chains are allowed. Pharmacy chains currently owns about 80% of all pharmacies.

- *Are their restrictions imposed on opening hours of pharmacies?*

35. No.

4.2 *Are their restrictions on the number and locations of pharmacies? And other retail outlets of drugs?*

36. National regulation prescribes the criteria for the location of pharmacies and pharmacy branches, that is taken into account when issuing a special permit (licence) for the opening (operations) a pharmacy. Also the number of pharmacies is limited. The maximum permissible number of general type pharmacies in a populated area shall be calculated using the following formula:

$$A = \frac{P}{S} + k, \text{ where}$$

A – maximum permissible number of pharmacies; P – the number of inhabitants in the populated area;
S – minimum number of inhabitants per pharmacy; k – correction coefficient.

37. A general type pharmacy outside a populated area may not be opened within a radius of five kilometers from an already functioning general type pharmacy. A pharmacy branch may not be opened within a radius of five kilometers from an already functioning general type pharmacy or pharmacy branch.

4.3 *How is it ensured that a sufficient number of retailers are located rural and sparsely populated areas?*

38. When performing an assessment of access to pharmaceutical care in a specific populated area, the local government has the right to file an application with the State Agency of Medicines regarding the need for a general type pharmacy in the part of a populated where there is no functioning general type pharmacy within a radius of three kilometres. Local government can file an application regarding the need to open a general type pharmacy which operates 24 hours a day. After approval of State Agency of Medicines, local municipality is entitled to establish its own pharmacy.

39. At the same time, there is a limited availability of pharmacies located rural and in sparsely populated areas, because from the owner's point of view a pharmacy should be cost-effective and in these areas it is not always possible.

4.4 *Do NGOs run retail outlets in your country? What impact does it have on affordability and availability? Does their presence spur price competition? Are retail outlets vertically integrated with wholesalers and/or manufacturers? Do you have concern that vertical integration may reduce inter and intra brand competition? Have retailers tried to obtain some buyer power through the creation of chains or by creating buyers groups?*

40. Yes. Repeatedly received unofficial information indicates that retailers try to obtain some buyer power through the creation of chains, hospitals, health care institutions and medical practitioners. However, this information is very difficult to test and to prove.

4.5 *Are retailers subject to regulation on prices, profits or margins?*

41. Yes, retailers are the subject to regulation on prices, profits and margins. The principles for the determination of the price of the medicinal products are described in the national legislation.

42. The price for which a pharmacy sells medicinal products is determined, multiplying the price, for which the pharmacy procures medicinal products from drug manufacturer or drug wholesaler without value added tax, by the correction factor and adding the correction sum and the value of value added tax. The correction factor and correction sum is determined on the basis of the procurement price. In order to determine the price of pharmacy, the following formula is used:

$$AC = IC \times n + Y + PVN, \text{ where}$$

AC – pharmacy price; IC – procurement price; n – correction factor; Y – correction sum; PVN – value added tax.

43. This pharmacy price is the maximum price for pharmacies regardless of the number of pharmacies involved in the distribution process. Pharmacies can also apply lower markups.

4.6 *If so does this type of regulation cause distortions that may limit the availability and affordability of drugs for final users (for example margin regulation favours the distribution of branded over generic drugs)? Is there price competition between retail outlets? And service competition?*

44. System mentioned above does not encourage competition between pharmacies on the quality of service or a price.

5. Generics competition

5.1 *How extensively are generics used in your country? Has their usage increased in the last few years? Do you think it has had an effect on prices of originators?*

45. Generic drug consumption was tended to decline, but now it's starting to slowly grow. Yes, the competition in the generic drug market has also affected the price of the original drug.

5.2 *Are generics subject to the same quality and safety controls as originator drugs?*

46. Yes, generics are subjected to the same quality and safety controls as originator drugs. These requirements are as stringent as on the original medication.

5.3 *To what extent you consider that manufacturers affect the above incentives by providing wholesalers and retailers with financial incentives when they sell originators rather than generics?*

47. Theoretically, it is possible that manufacturers offer discounts to wholesalers, so they can choose to sell the original medicinal product rather than a generic medicine, however, on prescription drugs there are now strict rules related to the fact that doctor should write a common name in the prescription, but pharmacy will give the cheapest medicine of this common name. This in turn promotes the consumption of generic drugs because generic medicines are cheaper than most of the original products.

5.4 *Are there financial incentives on consumers to request generics rather originator drugs?*

48. The competent authorities have taken several measures to allow patients to be aware of the availability of generic medicines and the price differences, so yes, there is a financial incentives on consumer to request generics rather than originator drugs.

5.5 *To what extent you consider that manufacturers affect the above incentives by providing doctors with financial incentives when they sell originators rather than generics?*

49. There is a suspicion that the producers realize such a method, however, it has not been proved.

5.6 *Do consumers perceive generics as safe and effective drugs, or does the suspicion that these drugs may be sub-standard or counterfeit encourage consumers to require/buy originators? How aware are they of the price difference between generics and originators?*

50. Consumers perceive generics as safe and equivalent drugs. Consumers are aware of the price difference between generics and originators because of publicly available information in the mass media, and the educational work by the responsible authorities.