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## Global Forum on Competition

### COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

#### Contribution from Lithuania

-- Session III --

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## COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

### -- Lithuania --

#### 1. Supply of drugs

1. The supply of affordable drugs in terms of price, quality and range is generally considered to be good in Lithuania. This has been confirmed, among others, also by the recent study commissioned by the state Compulsory Health Insurance Fund, which analysed the effects of the implementation of the European directives and regulations on the affordability of drugs to the Lithuanian citizens. The drugs supplied to the country have to meet the European requirements of quality, safety and effectiveness legal.

2. There are two sets of drugs – reimbursed drugs, where retail price (or a portion of it) is reimbursed to a patient by the state, and non-reimbursed drugs. The prices of non-reimbursed drugs, both generic and originator, are not regulated at the manufacturing level (*ex-factory*). Conversely, the manufacturing prices of reimbursed drugs cannot exceed the reference prices calculated as the average of relevant *ex-factory* prices in several selected reference countries in the EU. As to the generic drugs, their manufacturing-level prices must be by a certain percent lower than the prices of originator drugs (e.g., the price of a generic drug, which is the first one registered in the country, must be by at least 30% lower than the price of the cheapest originator drug; the price of the second and third registered generic drug must be at least by 10% lower than the price of the cheapest drug (originator or generic) already registered, and so on; all the subsequently registered generics must be lower in price than the existing ones by progressively diminishing amounts).

#### 2. Wholesaling

3. The share of drug production by local manufacturers is insignificant, therefore Lithuania has to rely on import of drugs. There are no explicit obstacles or barriers to trade and import of drugs to the country. The wholesale distribution and import of drugs is governed in accordance with the relevant European legal acts common to all the EU members.

4. Wholesalers buy drugs directly from manufacturers or from other wholesalers, and some manufacturers have their own wholesaling arms for the distribution of their own drugs. All wholesalers have to be registered and licensed. There are 111 licensed wholesalers in Lithuania at the moment, however, most of them are rather small, and there are 8 big wholesalers. Big wholesalers are integrated with the retail chains spread out throughout the country. The Competition Council has not specifically analysed the question of whether vertical integration may be harmful to competition in drug distribution. Several mergers have been notified in this area, however, the decisions by the Competition Council have been taken in the context of the facts of each particular case and market situation, and no conclusive inferences of a broader character have been made. No abuse of dominance cases have been found.

5. The margins of wholesalers are subject to regulation, both for non-reimbursed and for reimbursed drugs. E.g., the maximums of the margins for reimbursed drugs are fixed in the range of 5.5-14% (depending on the value of the drug). The Competition Council has not performed a specific study as to whether this wholesale margin (or retail margin) regulation has an impact on the prices paid or the

availability of drugs to final users. However, the Competition Council has recently looked at the regulation governing parallel imports into the country.

6. The Government regulation specifies that the prices of parallelly-imported reimbursed drugs have to be at least 4-10% lower than the prices of the same drugs distributed by marketing authorisation holders. Despite the fact that parallelly imported drugs are less expensive than the drugs sold by marketing authorisation holders, parallel importers cannot import those drugs unless they are not lower in price than the required minimum of 4-10%. The study evaluated economic impact that the liberalization of this limitation may have on drug prices for consumers. Although some negative aspects in terms of price increases may occur at the beginning, the overall effect can be expected to be positive due to generally lower prices of parallel imports, which potentially is capable to outweigh the negative effects in the longer term. The study also revealed that the existing requirement lessens competition, deprives the consumers of the freedom of choice of less expensive drugs. The Competition Council has proposed to the Government the abolition of this requirement.

### **3. Retailing**

7. Only licensed pharmacies can carry out activities related to retail drug distribution in Lithuania. Retail drug distribution licences are not categorized by drugs that are sold and are common for prescription and over-the counter drugs. In addition, all pharmacies sell drugs to both – paying out of their pocket and reimbursed patients. Hospital pharmacies are not allowed to sell to external patients, while doctors are not allowed to sell the medicines they prescribe at all.

8. In the meantime on-line pharmacies are not allowed, it will be possible in the near future: the legislative base is already in place but operating procedures still need to be prepared.

9. As there are no restrictions on the number and locations of pharmacies, those are often located in supermarkets. The supply of drugs to rural areas is ensured not by locating retailers there, but by supplying drugs to primary health care facilities. There are no restrictions on opening times of pharmacies.

10. Analysis of ownership shows that about 80 % of all operating pharmacies are part of different chains and there is only one publicly owned pharmacy. Moreover, neither NGOs, nor international donors are active in retail drug market, therefore they do not impact the affordability and availability of drugs or create any pressure on the prices of the medicines.

11. Most of pharmacy chains are vertically integrated with wholesale distributors and have high buying power. However at the moment, we do not have any concerns that this might reduce intra or inter brand competition. As there are few chains that have similar market shares, market conditions are more conducive for collusion than for abuse of dominance. Competition Council had only one collusion case, which was closed as no infringement was found. At the moment the Competition Council does not have information, indicating lack of price or service competition among pharmacies.

12. According to the information available, sales of generic drugs constitute up to 49 % of total drug sales. Although generic and originator drugs are subject to the same quality and safety control, there should be more information about the safety and efficiency of generic drugs, to encourage their use.

13. Although there are some indications that manufacturers may provide wholesalers and retailers with financial incentives for selling originator drugs rather than generics, the existing national regulation favours the sale of generics drugs. National patient treatment methodologies state that treatment must be started with drugs that have generic analogues. Furthermore, pharmacists are required to offer patients the cheapest alternative of a drug, and, if the drug is prescribed, to show patient all alternative drugs and indicate their prices.

14. Margin regulation at wholesale and retail level does not promote the use of generics, as while selling cheaper drugs, wholesalers and retailers can earn smaller margin in absolute value. This regulation might also cause distortions to parallel imports. However, the Competition Council of Lithuania has not performed a market study to look at this regulation.