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## COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Poland --

### 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?*

1. Experience of the Polish competition authority (UOKiK) suggests that there is an adequate and reliable supply of affordable drugs of an acceptable quality. However, periodically some shortages of specific drugs happened. In 2012 new rules on public reimbursement of drugs were introduced. They aimed at reduction of prices of reimbursed drugs. The other rather unexpected results were temporal shortages of drugs.. Two possible reasons for this situation may be given. First, prices of some reimbursed drugs dropped which resulted in increase of parallel imports. Drugs were being bought in pharmacies and re-exported from Poland. In order to prevent this practice some manufacturers started to limit supplies and started to supply pharmacies directly in order to control the distribution chain. In response to that situation large wholesalers offered manufacturers more control over distribution of certain drugs and establishment of the “emergency channels” in order to avoid shortages of supply. Second, as some commentators suggested, the negative role of parallel imports was only an excuse for limitations of supplies. They pointed out that shortages resulted from defective reimbursement policy. The change of the policy that took place in 2012 consisted of fixed margins of pharmacies and wholesalers and lower regulated prices, which led to decreased volume of stocks of drugs at wholesalers and pharmacies. This caused shortages of certain drugs. Nowadays, the Ministry of Health is working on amendment of the Pharmacy Law and the act on reimbursement of drugs in order to create additional rules to secure supplies and limit uncontrolled parallel imports. However, the proposed changes are controversial, since the Ministry intends to establish a list of certain crucial drugs which will be object of close scrutiny so as to limit (or even eliminate completely) the possibility of parallel imports of those drugs.

*1.2 If not, can you describe the extent of the problem and possibly quantify it?*

2. The Polish competition authority has very rarely dealt with this issue. Until now, our experience suggests that this problem is rather limited in scope. Nonetheless, the Ministry of Health is trying to implement new regulatory measures.

*1.3 What are the main reasons for these problems? What solutions have you attempted?*

3. Analysis of complaints and past proceedings suggests that there are four basic reasons for periodical shortages of specific drugs:

- Merger between two producers and decision of the new owner to refrain from production of certain drugs. This is usually due to economical or technological reasons.
- Parallel importation or exportation of certain drugs prevented by official drugs producers.

- Change of distribution policy by one or several drug producers.
- Introduction of fixed margins for pharmacies and wholesalers which resulted in limitation of stocks of available drugs by pharmacies and wholesalers.

4. In 2012 and 2013 some shortages of certain drugs took place. It was due to the fact that some manufacturers wanted to reduce the possibilities of parallel imports and introduction of fixed margins for pharmacies and wholesalers. However, the Ministry of Health is proceeding with the amendment of the Pharmacy Law in order to limit the possibility of parallel imports of certain drugs. Those proposals are controversial since they focus only on parallel imports whereas shortages of drugs are also the effect of imperfect public policy on drugs reimbursement. It is doubtful whether introduction of barriers to parallel imports will improve the situation.

5. Last but not least, the Polish competition authority has conducted some antimonopoly proceedings regarding shortages of specific drugs. However, none of these proceedings led to levying sanctions upon manufacturers.

*1.4 What role can competition policy play to improve the situation (both through competition law enforcement and competition advocacy)?*

6. The role of the competition policy is to secure equal conditions for all the market players and competitive level playing field. The Polish competition authority is sensitive to complaints from consumers, market players or the Health Ministry regarding shortages of drugs and possible anticompetitive behavior of undertakings engaged in distribution of pharmaceuticals.

7. Furthermore, the Polish competition authority takes active role in consultations with the Ministry of Health on regulation of drugs distribution in Poland.

## **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?*

8. Manufacturers of original drugs, as well as manufacturers of generic drugs are free to set prices. However, fixed prices are set for drugs which are being refunded by the state insurer.

*2.2 Are you concerned that this regulation may be stifling price competition or innovation?*

9. The Polish competition authority believes that the above mentioned regulation strikes the right balance between freedom of enterprise and limited public funds for financing drugs.

10. In 2007 UOKiK conducted antimonopoly investigation against Jelfa – Polish generic producer, to verify if the company abused its market position by setting the price of their medicine. Since January 2007 Jelfa has been the only manufacturer and supplier of Cocarboxylasum on the Polish market. The medicine is used to treat deficiency of vitamin B1. Jelfa's only competitor, Polpharma Pharmaceutical Works, ceased to produce the drug in 2006 and, at the beginning of 2007, it also ceased the sales of this substance. The objective of the anti-monopoly proceedings initiated by the President of UOKiK was to check whether Jelfa did not abuse its market position by setting an excessive price. The information collected by UOKiK showed that for a few years (2001 - 2006) Jelfa would sell the medicine to wholesalers at PLN 7 per package. In the same period of time, Polpharma sold Cocarboxylasum for less. A month after Polpharma abandoned the production and sales of the product Jelfa quadrupled its price. The drug was not reimbursed by the public insurer so there was not fixed price established by the Ministry of Health. The investigation

proved that Jelfa did not enjoy dominant position. Despite preliminary assessment it turned out that two other companies were offering substitutes to drugs offered by Jelfa. Furthermore, the increase of price was objectively justified as the price of the imported active substance increased simultaneously. The proceedings were concluded without any sanctions.

2.3 *Have you ever performed a market study that has looked at this regulation?*

11. The Polish competition authority has not performed such a study.

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

12. Polish market for drugs is very specific due to rather strong position of generics and local producers. Overall import of drugs represents 70% market share when it concerns the value and only 35 % when it concerns the volume. This can be explained by the fact that 88% of local production is generics and 60% of imports are original drugs. Most of local manufacturers belong to large multinational drug producers like GSK, Aventis, Novartis or Teva. The strongest independent Polish producer is Polpharma.

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

13. In principle, there are no barriers for import of drugs. However, some manufacturers undertake actions in order to limit or eliminate parallel import of drugs by limiting domestic sales. Furthermore, the Ministry of Health intends to introduce further limitation of parallel imports for certain drugs. One may doubt whether this regulation will be effective in elimination of shortages of certain drugs but it will surely have adverse effect on parallel imports.

14. It is worth mentioning that in 2009 the Polish competition authority has conducted explanatory proceedings which led to preliminary conclusions that manufacturers may restrict competition. However due to the European dimension of the case, it was referred to the European Commission. The explanatory proceedings were carried out by UOKiK in order to make a tentative assessment of whether pharmaceutical manufacturers acted in compliance with antitrust law. The Office also carried out a survey and analysed contracts signed by the largest manufacturers and distributors with their wholesalers. The investigation covered i.a. the following companies: GlaxoSmithKline, Sanofi-Aventis, Servier, Novartis, AstraZeneca, Novo Nordisk, Pfizer, Eli Lilly, Roche and Bayer. The information obtained during the proceedings indicated that competition restricting practices may have been applied on the pharmaceutical market. The nature of the proceedings - especially the geographical scope of the companies' operations - indicated that the consequences may have affected the whole European Union. Therefore, the President of UOKiK decided to hand over the collected materials to the European Commission. The main problems which UOKiK highlighted to the European Commission were contract clauses limiting the wholesalers' trading area, imposed by manufacturers, as well as the practice of establishing quota restrictions for particular products. According to UOKiK, what was concerning was the fact that the analyzed documents contained certain signals indicating that manufacturers limited the wholesalers' trading area, for example, only to the countries of the European Economic Area and in some cases only to the territory of Poland. The manufacturers reserved themselves the right to impose sanctions, for example, to terminate the contract, if a wholesaler sold medicines outside the pre-defined area. The information collected during the explanatory proceedings also indicated that quota restrictions were becoming an increasingly common practice. Manufacturers established strict limits and refused to carry out orders from wholesalers who exceeded them. Such restrictions were most frequently used by manufacturers of innovative medicines. Consequently, this may have significantly limited the availability of medicinal products which had no substitutes. What also seemed controversial was limiting the possibility of carrying out parallel trade, for example by prohibiting the contracting parties from establishing trade relations with companies from other European Union countries, which was reported by enterprises operating on the market. The survey carried

out among pharmaceutical wholesales proved that manufacturers also applied other practices in order to limit parallel trade - they threatened to make the terms of cooperation less favourable or refused to deliver their products.

### 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?*

15. Wholesaling is a compulsory level in drug distribution chain. Most of the wholesalers are independent companies. Some of them are vertically integrated. In principle, wholesalers buy drugs from manufacturers and sell them to pharmacies. They perform the role of an important and independent intermediary between producers and pharmacies.

16. However, in recent years some producers started to sell drugs through their own wholesaling subsidiaries. At first, it was regarded as a serious threat to existing wholesalers but this trend turned out to be rather limited in scope. AstraZeneca was the first manufacturer to introduce such direct distribution. In 2009 UOKiK has conducted explanatory proceedings in order to establish whether AstraZeneca's model of direct distribution might have been a form of abuse of dominant position. However, the findings did not let the authority to bring a case against AstraZeneca. It turned out that the distribution model was based on objective and non-discriminatory criteria and did not lead to any quantitative limitations of supply.

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?*

17. There are more than 400 wholesalers in Poland. Most of them operate on regional or even local basis. However the market is dominated by three companies Neuca, Pelion and Farmacol which have over 75% market share. There are several medium size wholesalers like Hurtap, Slawex, OPDF or Galenica Nova which have 15% of market share. Even though they all operate on national basis, there are important regional differences as to market shares of particular wholesaler.

18. Most of the pharmacies cooperate with two - three wholesalers but usually the "first wholesaler" receives up to 70% orders from the pharmacy. In result two other wholesalers play supplementary role.

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?*

19. Exclusivity agreements between manufacturers and wholesalers are rather rare. Neither of major national wholesalers entered into such an agreement.

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?*

20. Some manufacturers establish wholesale subsidiaries to distribute their products. This is however limited in scope. Vast majority of wholesalers are independent and do not have links to producers. Two national players Pelion and Farmacol with combined market share over 40% are vertically integrated. They run two chains of pharmacies. However these chains are rather small – around 5% of all pharmacies belong to them. This suggests that vertical integration does not pose significant competition issues in Poland.

3.5 *Have you had cases of abuse of dominance or collusion? Are market conditions conducive to these types of infringements?*

21. Wholesaling market is still rather competitive. Market may be regarded as quite transparent. It is an attractive market and new players still have incentive to enter and to compete. Due to large number of independent pharmacies wholesalers are forced to compete. All pharmacies may check and compare offers of wholesalers on a daily basis which makes collusion between wholesalers rather difficult.

22. In the past there were several cases conducted against pharmaceutical wholesalers. Two decisions issued by the President of UOKiK in June 2004 may serve as good examples. Both decisions concerned the agreements concluded by Johnson & Johnson Poland with two pharmaceutical wholesalers: Compol and Hurtofarm, which restricted the sale of medicines based on erythropoietin and set sales prices. UOKiK imposed fines on the company for a total amount of almost 3.8 million PLN (around 900 thousand EUR). The decisions were the first effects of investigations by UOKiK concerning the market of drugs containing human recombinant erythropoietin (EPO). The pharmaceuticals are used by hospitals, clinics and dialysis stations to treat anaemia. In the Polish market, EPO is marketed as Eprex (offered by Johnson & Johnson) and NeoRecormon (sold by Roche Polska). Since they are not subject to regulations concerning refunds, their price is a market price determined by pharmaceutical companies and their distributors (wholesalers).

23. The first decision of the President of UOKiK concerned provisions in an agreement between Johnson & Johnson Poland and Compol as regards the wholesale distribution of pharmaceuticals. It described the principles applying to the distribution of Eprex. In accordance with the principles, the wholesaler was to buy the medicine from Johnson & Johnson Poland and offer it to the buyers (dialysis stations) at tenders at prices agreed with the producer. In the opinion of UOKiK, the provision was an example of unlawful imposing of sales prices on distributors and had to be considered as a competition restricting practice. Another example of an unlawful practice in the opinion of UOKiK was the provision in the distribution agreement designating to Compol the list of buyers of Eprex in the form of specific 18 dialysis stations. In the opinion of the Office, that was a prohibited agreement restricting the wholesaler's market and enabling Johnson & Johnson to control it and form it unlawfully.

24. The other decision of UOKiK concerned agreements between Johnson & Johnson Poland and Hurtofarm. In annexes to the General Sales Terms concerning the principles of Eprex distribution, the parties agreed that Hurtofarm would not offer the medicine to hospitals listed in the document. Besides, Hurtofarm undertook to refrain from selling Eprex to 11 clinics to be opened next year. Those hospitals and dialysis centres were to be supplied by Johnson & Johnson Poland on their own, or by a designated distributor. The sanction provided for failure to observe those provisions was non-payment of the contractual bonus, which as a matter of fact was the only remuneration for the wholesaler for the sale of Eprex. Considering the above, UOKiK discovered the existence of an illegal agreement to control and restrict by Johnson & Johnson the market for Eprex for Hurtofarm. This is a legally prohibited practice restricting competition.

25. In both decisions the President of the Office ordered the discontinuation of the questioned practices and imposed fines on the enterprises. By ordering discontinuation of those practices and imposing the fines, the President of the Office took into consideration the negative market effects resulting from such agreements and threatening competition. In effect, the freedom of distributors (pharmaceutical wholesalers) was limited in such important sphere of their business as setting the price of Eprex and designating a list of entities to which they can sell the medicine. The restrictions gave Johnson & Johnson Poland the possibility to control the sale of this drug. It is also important, that the agreements were harmful to buyers of the erythropoietin drugs, i.e. hospitals and dialysis stations. Pre-determined sales prices made it impossible to lower the prices, which was obviously against the economic interest of those

entities. Also, designation of the list of buyers to whom the wholesalers may not sell the product, caused a situation when potential buyers were forced to select the product from among a smaller number of offers.

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

26. There is no such special regulation. However, national wholesalers claim to deliver drugs to any place in Poland.

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

27. Wholesalers are free to set prices and margins except for drugs which are reimbursed by the state insurer. When distributing reimbursed drugs the maximum margin is 5%.

3.8 *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?*

28. Many wholesalers believe that 5% maximum margin is too low to cover costs of distribution. It has already led to decrease of stock of publicly financed drugs which resulted in temporary shortages of drugs. They demand increase of the margin up to 8%. However, the Ministry of Health is rather skeptical and resistant to those arguments.

3.9 *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)?*

29. As explained above, limitation of margin for distribution of drugs financed by the state insurer lowers incentives for the wholesalers to distribute those medicines. They decreased stocks of those drugs since they became less profitable. It is rather unlikely that the Ministry of Health will change it.

3.10 *Have you ever performed a market study that has looked at this regulation?*

30. In 2006 the Polish competition authority has published a report on the wholesale market for pharmaceuticals. It is a historical study but the short summary is given below.

31. At that time, there were 115 producers of medicines, over 660 pharmaceutical wholesalers and over 12 000 pharmacies operating in Poland. Due to intensive development of this sector, UOKiK surveyed the pharmaceutical market, paying special attention to wholesale trade in medicines. The survey showed that from among over 660 wholesalers operating on the Polish market, many operate within a small area or trade in only several products. There were five firms which played a significant role, holding a 60% share of the market. Gradual concentration was noticed. The number of pharmacies might have decreased within the next few years as well. The reason behind the collapse of smaller retailers who would be unable to withstand strong competition was first of all the expansion of retailing chains and financial difficulties - half of the smaller retailers were indebted, the debts of one in five of them exceed the value of the goods sold. Lack of competition in the form of a large number of pharmacies might have in turn led to the increase of the medicines prices. The limitations of competition which were noticed by UOKiK related to the barriers to parallel import which had been allowed in Poland since 1 May 2004. Parallel import consists in buying a medicine in one of the EU Member States and selling it in another at a higher price, which is nevertheless lower than the price offered on a given market. The condition is, however, that the medicine is registered and was allowed to be traded in the country to which it is imported. Such activity may be beneficial to consumers, who gain access to innovative medicines at lower prices. Nevertheless, UOKiK found that several distributors requested the wholesalers to conclude agreements limiting the

possibility to distribute medicines in Poland. On-line pharmacies were gaining popularity on the pharmaceutical market in Poland. Their number so far had reached about 70. Their operations might have stimulated competition, as they sold medicines 10-15% cheaper than traditional pharmacies. The situation of Polish e-pharmacies was not regulated by law - their owners pointed out to the judgment of the European Court of Justice, which ruled that mail-order sale of medicines is allowed in the EU Member States. However, only the draft amended Act "Pharmacy Law" provided that traditional pharmacies are allowed to sell medicines available without prescription via mail-order. On that account traditional pharmacies were reluctant to mail-order sale of medicines. Furthermore, consumers could not be sure whether the medicines offered on the Internet were completely safe. Pharmaceutical Chambers also made attempts to limit the activity of on-line pharmacies by filing requests to the Pharmaceutical Inspectorate for it to carry out inspections of the e-pharmacies. As a result, the Lekidodomu.pl e-pharmacy was closed down. These organisations claimed that competition on the retail market should be limited on account of its specificity - they opposed price competition and promotional activities of pharmacies. The conclusions of the report were reflected in UOKiK's comments to the draft amendment to the Act "Pharmacy Law". The Office expressed doubts as to the provisions introducing limitations to the number of pharmacy points and pharmacies that can operate within a given area. In the Office's opinion, the planned solutions would lead to the limitation of free competition which could result in smaller number of pharmacies and lesser degree of satisfaction of public needs. In consequence, consumers' interests could be disturbed as they would have to buy medicines at high prices only because of smaller number of pharmacies to choose from.

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

32. Parallel imports may be noticed in Poland but it is still relatively small and it represents 1% of the whole market for drug sales. State drug financing policy used to favor parallel imports but it changed in 2012. Even though, one may expect development of parallel imports in Poland.

#### **4. Retail distribution**

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

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

33. In principle, both prescribed medicines and OTC drugs may be sold exclusively in pharmacies. However, certain OTC drugs may be sold in ordinary outlets (supermarkets, chemistries, gas stations). The list of those OTC drugs is published by the Ministry of Health.

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

34. No. Generally all pharmacies are allowed to sell refunded and non-refunded drugs. Please note, that the pharmacy is obliged to sign certain agreement with the public insurer.

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

35. All pharmacies in Poland are private.

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

36. Doctors are not allowed to sell drugs in Poland. Only veterinaries may sell some drugs.



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

37. There are no restrictions for hospital pharmacies to sell drugs to any consumers.

4.1.6 *Are on-line pharmacies allowed?*

38. Internet sale of drugs is allowed. However there are some additional restrictions. Such pharmacy must be registered as an ordinary pharmacy. Furthermore, online sale is limited exclusively to OTC drugs. Nonetheless, it is possible for consumers to make online orders for any drugs. They are delivered and sold in the ordinary pharmacy. Such sale is not regarded as online sale. This kind of service is usually offered by chain pharmacies.

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

39. Yes. There are no restrictions in this regard.

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

40. In principle, creation of chains is limited. The Pharmacy Law precludes establishment of any chain consisting of more than 1% of all pharmacies within one region. However, this provision is easily escaped by pharmacies. Nonetheless, out of around 14 000 pharmacies in Poland only 10/% belongs to chains.

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

41. Each municipality sets minimum opening hours of pharmacies on yearly basis. Pharmacies may operate longer, if they wish so. Furthermore, each county designates pharmacies which are obliged to operate 24h. Those designated pharmacies are being changed periodically.

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

42. In principle there are no restrictions concerning the number and locations of pharmacies or other retail outlets of drugs. The only limitation is that Pharmacy Law precludes single owner to run more than 1% of pharmacies in the given region. However, this restriction is easily escapable by undertakings.

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

43. There are almost 14.000 pharmacies in Poland which secures easy access to pharmacies for consumers. To secure access to pharmacies in rural areas the county authorities are obliged to designate pharmacies which are compelled to operate 24/7. Furthermore, in remote areas there are so called pharmacy points which offer limited number of drugs.

4.5 *Do NGOs run retail outlets in your country? What impact does it have on affordability and availability? Does their presence spur price competition?*

44. The Polish competition authority is not aware of any such situation.

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

45. There are examples of vertical integration in pharmaceutical distribution. However, it does not pose a serious threat to competition. Only around 6,5% of all pharmacies belong to 5 vertically integrated companies. Pharmacies are usually run by independent pharmacists.

4.7 *Have retailers tried to obtain some buyer power through the creation of chains or by creating buyers groups?*

46. At the beginning of the 90's pharmacies tried to form buyer groups. However, it has never been a massive trend. Those groups lasted until mid of the first decade of XXI century. In the long run they did not manage to find an effective business strategy and they were gradually acquired by existing wholesalers. At the moment, there are not any viable buying groups formed by pharmacies.

4.8 *Have you had cases of abuse of dominance or collusion? Are market conditions conducive to these types of infringements?*

47. The Polish competition authority has conducted several antimonopoly proceedings against Pharmacists Association. In Poland every pharmacist is obliged to belong to such associations. They are functioning on regional and national basis. During the 90's several regional Pharmacists Associations tried to limit competition between pharmacies by amending the code of conduct of pharmacists. They tried to implement rules precluding prices competition between pharmacies and to eliminate advertising campaigns of pharmacies. UOKiK has repeatedly intervened against such restrictions.

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

48. Pharmacies are subject to strict regulation on prices and margins in relation to drugs financed by the public insurer. Those margins are as follows:

from	up to	Margin
-	5,00 PLN	40%
5,01 PLN	10,00 PLN	$2 \text{ PLN} + 30\% x^1 (x - 5,00 \text{ PLN})$
10,01 PLN	20,00 PLN	$3,50 \text{ PLN} + 20\% x (x - 10,00 \text{ PLN})$
20,01 PLN	40,00 PLN	$5,50 \text{ PLN} + 15\% x (x - 20,00 \text{ PLN})$
40,01 PLN	80,00 PLN	$8,50 \text{ PLN} + 10\% x (x - 40,00 \text{ PLN})$
80,01 PLN	160,00 PLN	$12,50 \text{ PLN} + 5\% x (x - 80,00 \text{ PLN})$
160,01 PLN	320,00 PLN	$16,50 \text{ PLN} + 2,5\% x (x - 160,00 \text{ PLN})$
320,01 PLN	640,00 PLN	$20,50 \text{ PLN} + 2,5\% x (x - 320,00 \text{ PLN})$
640,01 PLN	1.280,00 PLN	$28,50 \text{ PLN} + 2,5\% x (x - 640,00 \text{ PLN})$
1.280,01 PLN		$44,50 \text{ PLN} + 1,25\% x (x - 1.280,00 \text{ PLN})$

49. With regard to other drugs and items sold in pharmacies they are not covered by such restrictions.

<sup>1</sup> X stands for wholesale price of the drug.

4.10 *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)?*

50. Associations of pharmacies claim that fixed prices and margins decreased profitability of sale. It resulted in decreased stocks of those products kept in the pharmacy which sometimes may cause shortages of certain product or delay in supply. Fixed prices and margins result in higher costs for consumers since pharmacies are precluded from competition on prices for drugs which are refunded by the state insurer.

4.11 *Have you ever performed a market study that has looked at this regulation?*

51. The Polish competition authority has never performed such a study.

4.12 *Is there price competition between retail outlets? And service competition?*

52. The change of drug financing policy in 2012 resulted in elimination of price competition between pharmacies. Furthermore, the Pharmacy Law precludes pharmacies from any advertising of their services. These two changes aim at unification of conditions for consumers to acquire drugs at the same prices in all pharmacies and prevent them from buying more drugs than they actually need at that time. The main reason for those changes was to limit public expenditure connected to drugs and to rationalize buying policy of consumers. However, this leads to almost complete elimination of competition between pharmacies which cannot be regarded as beneficial. Service competition does not play important role.

## **5. International Donors**

5.1 *Are international donors of medicines active in your country?*

53. The Polish competition authority is not aware of any international donors of medicines to be present in our country.

5.2 *How they distribute medicines? Do they use the traditional distribution chain (local distributors and local pharmacies) or do they have their own channel? Does their presence create any pressure on the prices of the medicines not provided by donors?*

54. N/a.

## **6. Public and private insurers**

6.1 *Do public insurers try to exert control over the distribution chain in order to contain the price of drugs (e.g. do they run tenders to buy medicines)?*

55. The role of public insurer is limited due to the fact that it is the Ministry of Health that makes a decision which drugs will be financed and what will be the price caps for refunded drugs. No public tenders are organized by the public insurer.

6.2 *Do private insurers, if present, play a role in trying to exert control over the distribution chain in order to contain the price of drugs (e.g. do they run tenders to buy medicines)?*

56. The role of private insurers in Poland is very limited and they don't have any influence over the price of drugs.

## 7. Generics competition

7.1 *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?*

57. Generic drugs have a very strong position in Poland. Market share of generic drugs is around 65% (value of sales) and 85% (volume of sales.). This is a stable situation and changes of this market share are relatively small over the years. This situation may be perceived as an exceptional in comparison to other European countries. Many commentators are of the opinion that such a strong position of generics poses a competitive pressure over producers of original drugs and results in keeping prices of drugs in Poland on competitive level.

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

58. Registration of generic drugs is faster and simpler than original drugs. The production of original and generic drugs is subject to the same strict regulations.

7.3 *Does price or margin regulation at manufacturing, at wholesale and at retail level encourage the production and sale of generics? If so how? Could it be improved?*

59. The basic mechanism is connected with creation of a list of drugs that are financed by the National Health Fund. However, the list contains indication of active substances and the name of cheapest drugs in this category of drugs. Those indicated drugs set a maximum price cap. This means that if consumers choose other drug with the same active substance they will need to bare the additional cost which equals to price difference between the price of the drug on the list and the drug they intend to buy. Furthermore, if the manufactures of generics want their drugs to be included on the list they must prove that their drugs are at least 25% cheaper than original drugs.

7.4 *Does any other type of regulation favour/foster the sale and use of generics? For example are doctors required or incentivised to prescribe generics? Do doctors have maximum dispensing budgets? Are pharmacists required to substitute originators with generics whenever possible? Are there other types of financial incentives for doctors or pharmacists aimed at favouring the prescription and dispensation of generic drugs?*

60. The basic mechanism to encourage growth in the use of generics is provided in the article 44 of the Pharmacy Law. It requires any pharmacist to offer generic drug whenever original drug is prescribed by the doctor. The only exemption takes place when the doctor clearly stated on the prescription that the drug must not be exchanged to generic. This legal mechanism together with the growing knowledge of consumers who independently ask for cheaper generics guarantees such a strong position of generic drugs on the Polish market. However this applies only to pharmacists. Doctors are independent in their prescribing policy. In addition manufacturers are precluded from providing any economic incentives for doctors to prescribe original or generic drugs. Moreover, doctors in Poland do not have dispensing budgets.

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

61. The basic incentive for consumer is that generic drugs are generally cheaper than original drugs (from 20% to 90% cheaper).

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

62. Any financial incentives for doctor affecting their prescribing policy are forbidden in Poland.

7.7 *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?*

63. Some consumers do perceive original drugs as more effective even though they contain the same active substance as generic drugs. It applies both to modern and older drugs. Good example may be “Aspirin” by Bayer which is perceived by some group of consumers as the original drug with superior quality over generic drugs. Some producers advertise their drugs as “the only original ones” which may also influence potential consumers and sustain stereotypes about original and generic drugs. This perception of generic drugs concerns their inferior quality. Around 30% of consumers perceive generic drugs as less safe and effective. Usually it is older people who do not fully trust generic drugs. The problem of counterfeiting of drugs relates to drugs sold over the internet (and it usually concerns illegal sale of certain drugs). However, this “brand sensitivity” declines together with the increase of price of a particular drug. Furthermore, Polish consumers are much more aware of price differences between original and generic drugs in comparison to situation in the previous decade.