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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from Ukraine

-- Session III --

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Ukraine --

1. Legal framework

1. According to article 9 of the Law of Ukraine «On medicines» drugs should be approved for use after their state registration.

2. According to the National Register of medicinal products of Ukraine in November 2013 in Ukraine 13097 medicines were registered, including: 3693 – domestic production; 9404 – foreign production.

3. Import, production, wholesale and retail trade of medicinal products is subject to licensing.

4. The basis for the issuance of licenses for these activities is the availability of appropriate material and technical facilities, qualified personnel and conditions of the quality control of drugs.

5. The approximation of Ukrainian legislation in the sphere of production of medicines with EU legislation was carried out in recent years. Thus, in late 2009 the requirements of Good Manufacturing Practice (GMP) were introduced in the Licensing terms for production of medicines, which are harmonized with the requirements applicable in the EU.

6. For foreign manufacturers of drugs the obligation of compliance with the requirements of GMP actually was introduced in November 2011 by amending article 9 of the Law of Ukraine «On medicines». According to the amendments to the application for state registration of medicinal product (except API), in particular, a certified copy of the document confirming the compliance of conditions of manufacture of the medicinal product submitted for registration with the requirements for the production of drugs in Ukraine, issued by the central executive body for medicines in the manner specified by the central body of executive power in the health care industry.

7. Obligation of licensing the import of medicines, production of medicines, wholesale and retail trade of medicines and compliance with licensing conditions, mandatory compliance with the procedures before registration of medicines (preclinical study, clinical tests, examination of clinical trials etc.), obligation of compliance with the requirements of good manufacturing practice (GMP) is significant barriers to market entry.

8. According to article 3 of the Law of Ukraine «On medicines», the state ensures the availability of essential medicines. Thus, according to the resolutions of the Government:

- for medicinal products, which are purchased by the state and local budgets, declaring of changes in wholesale prices is introduced, marginal supply and sales allowances and marginal commercial (retail) allowances are set;

- for the medicines included in the National list of Essential medicines and medical devices and mandatory minimum assortment (socially oriented) medicinal products and medical devices for pharmacies, marginal supply and sales allowances and marginal commercial (retail) allowances are set.

9. The current legislation of Ukraine provides a mandatory declaring by manufacturers, importers and distributors of wholesale prices on medicines that belong to the National lists, and can be purchased at public expense.

2. Retail distribution

10. Participants of the markets of medicinal products retail are economic entities regardless of ownership forms, which have received the appropriate license and engaged in retail trade of drugs through pharmacies and pharmacy outlets.

11. As of November 2013 in Ukraine there are 21303 pharmacies.

Pharmacies in Ukraine by form of ownership in 2013

№	Form of ownership	Quantity	Structure, %
1	State and municipal	1878	12,1
2	Private	11927	76,6
3	Collective	1761	11,3
	Total	15566	100

12. Both prescription and non-prescription medicines are realized through pharmacies.

13. There are no restrictions on the work schedule of the pharmacies, the quantity of retail outlets allocation, the work of the pharmacy networks in Ukraine, however, the sale of medicines through Internet is prohibited.

14. In 2012, the Committee conducted researches of 138 regional drugs retail markets, and it was found that regional drugs retail markets in specific territorial boundaries in most cases have a structural features of individual or collective monopoly.

15. In 2013, the Committee conducted researches of regional drugs retail markets in the following directions:

- research of competition in markets, the participants of which are located in the medical institutions drugstores, and research of the activities of market participants for compliance with the legislation on protection of economic competition;
- research of the activities of regional retail market participants in the period of seasonal diseases for compliance with the legislation on protection of economic competition in case of fever-reducing medicines realization.

16. According to the results of research of the activities of regional retail market participants in case of fever-reducing medicines realization it was established that individual drugs retail companies, which have features of a monopoly (dominant) position on the regional markets of retail trade, significantly increase markups to those drugs that are in high demand. The highest level of markups (35-50%) applies to medicines, which cost up to 12 UAH and which are not subject to state regulation.

17. The research of regional pharmaceutical markets has revealed the following:

- the most common violations on retail pharmaceutical markets are price violations in the form of abuse of monopoly (dominant) position by setting such selling prices for the medicines that would be impossible to set in conditions of substantial competition in the market;
- the most common non-price violations of the legislation on protection of economic competition on the regional pharmaceutical retail markets are manifestations of unfair competition in the form of dissemination of information that misleads consumers in the form of dissemination of untruthful information about the lowest prices, information about discounts with the suppression that these discounts are not available on all goods, etc.;
- a decisive impact on the retail prices of medicines have wholesale prices;
- the existence of restrictions on offers on the wholesale market by foreign suppliers negatively affect the pharmaceutical retail market.

3. Manufacturing

18. In Ukraine 110 entities have license for manufacturing of medicines. The volume of sales of medicines by all producers in the estimation of experts is about 30% of the volume of the domestic pharmaceutical market in value terms. However, according to the specialists' research, sales of medicines in their natural form (packages) are about 70% of the domestic market in natural form (packages). The above indicates that domestic manufacturers operate in the low price segment of the pharmaceutical market, possibly due to the different range of products produced and imported.

19. According to the research of the activities of individual domestic producers of medicines, in 2013 bodies of the Committee began consideration of 6 cases on the grounds of committing violations of the law on protection of economic competition in the form of abuse of monopoly (dominant) position on the market of certain drugs. The essence of the violations was sale of drugs in the domestic market at prices higher than export ones, with high levels of profitability, and profitability levels above the level of profitability of the enterprise.

20. Ukrainian state selected rate to support production of innovative generic drugs with the aim of providing the population with quality medicines at affordable prices.

4. Wholesale distribution

21. Only registered in Ukraine drugs are allowed for wholesale distribution, except for the cases provided by the Law of Ukraine «On medicines», only under a certificate of quality issued by the manufacturer

22. Wholesale trade of medicines is conducted only through pharmacy base warehouses and cannot be conducted through any other institution other than pharmacies, and beyond them. An economic entity – distributor of pharmaceutical wholesale should ensure compliance of material and technical facilities, technological tools and quality insurance system of medicines during storage and distribution with the requirements of current legislation and good practice of storage and distribution of drugs.

23. Pharmacy warehouses should be composed of industrial premises: separate rooms, areas or zones for the reception and storage of medicines and their distribution, auxiliary materials and packaging with a total area of not less than 250 sq. m. The industrial premises include areas, where the medicines are received and stored, assembling and dispensing areas (freight forwarding), areas for storage of support materials and packaging, quality control of medicines, storage of quarantine products etc.

24. An entity that conducts the wholesale trade of medicinal products must ensure the compliance with the specified by manufacturer of medical products general and specific conditions of storage of medicines at all stages of technological process.

25. According to the information of the State Administration of Ukraine on Medicinal Products, the activities related to the sale of drugs in wholesale quantity are conducted by almost 500 economic entities that are licensed to conduct the wholesale trade of medicines.

26. According to the market research of the wholesale trade of medicinal products it was found that the largest sales volumes on the national market of wholesale trade of medicinal products have 4 entities and their combined market share exceeds 70%.

5. Exclusive distribution

27. The vast majority of foreign pharmaceutical companies work in Ukraine on the basis of supply of medicines in Ukraine through their representatives who have been granted the exclusive right to import goods in Ukraine.

28. Foreign manufacturer usually pays in the importer's favor funds for the promotion and distribution of goods in the territory of Ukraine.

29. Also, a number of foreign companies provide such importers bonuses and substantial discounts (attached percentage wise to the cost of drugs purchased by the importer). The discounts and bonuses for certain types of drugs amount to 50 %.

30. In turn, importers distribute goods in Ukraine through a very limited circle of wholesale companies.

31. Particular attention is required to the policy of bonuses and discounts for wholesale companies in case of purchasing of products for their further sale through tender procedures. In this case, in addition to the above bonuses applies a bonus in the amount of 15 to 25 % of the value of the sold on tenders products.

32. The above shows that almost during the sale of a significant volume of medicinal products of foreign production, distributors in Ukraine have a direct interest in purchasing more expensive drugs. Thus, trade allowance plays a less significant role in the formation of their income than the income received in the ratio to the value of the goods purchased.

33. In fact, foreign companies impose domestic distributors conditions under which they are forced to:

- act to a limited number of consumers;
- sell products to consumers at inflated prices.

34. Consequently, the use of schemes of exclusive distribution of goods in the markets of Ukraine by large multinational pharmaceutical companies (i.e. the situation when import of goods to Ukraine is conducted through the single representative of the company that is usually associated with it through relations of control) allows extending substantial market power freely directly on the markets of Ukraine. It allows foreign companies:

- to apply transfer pricing;
- to control the volumes of sales on the markets of Ukraine;

- to control the quality of the goods sold in the domestic markets;
- to create barriers to market access for domestic producers

35. The result of such actions of foreign pharmaceutical companies is reducing of the level of competition on the domestic markets and the possibility of setting unreasonably high prices for goods imported to Ukraine.

36. Subsequent to the results of pharmaceutical market research the Committee considers **5 cases** on violations of the law on protection of economic competition committed by importers and wholesale distributors of medicines in the form of anticompetitive concerted actions.

37. During the consideration of one of these cases the AMCU provided **recommendations** for the Ukrainian representative of one of the **world's leading drug company** and its distributors in Ukraine. The recommendations are about the necessity of taking measures to prevent unjustified pricing during disposal of medicines of the company in Ukraine and harmonization of contractual arrangements with the legislation on protection of economic competition.

38. In making these recommendations an authorized representative of the company confirmed their readiness to cooperate with the Committee concerning the elimination of actions that have signs of violation of the legislation on protection of economic competition.