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DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

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GENERIC PHARMACEUTICALS

-- Note by Ukraine --

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This document reproduces a written contribution from Ukraine submitted for Item VI of the 121st meeting of OECD Competition Committee on 18-19 June 2014.

More documents related to this discussion can be found at http://www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm.

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1. Approaches of the Committee to product market definition in pharmaceuticals industry

1. According to the National Register of Medicines, as of 12.05.2014 in Ukraine 12811 medicines were registered (including domestic – 3673 or 29%, foreign – 9138, or 71%). In the structure of retail sales in monetary terms the imported medicines are leading, and in physical - domestic ones.

2. Registered in Ukraine medicines form a large number of commodity markets, which in conditions of unfair competition can be monopolized.

3. In order to prevent the abuse of dominant position in the market of medicinal products there must be high quality and competitive analogs of the original (branded) drugs that will be pharmaceutically, therapeutically, biologically and toxicologically equivalent. Therefore, the main factor affecting the competitive situation in the pharmaceutical market is, above all, inadequate legal definition of interchangeability of drugs.

4. Therefore, the Committee introduces a methodological approach to defining the relevant product market on the basis of the molecular structure of the drug. In determining the interchangeability the Committee assumes that drugs must be therapeutically equivalent, contain the same amount of the same active substance, the same mode of administration, have the same dosage form, comply with the same or comparable standards, be bioequivalent, effective, qualitative and secure.

5. In addition there is also the concept of economic interchange based on the cost rate. So, among drugs with one active substance there is a big difference in prices, in other words, there are medicines with the same active ingredients with the large difference in price and various indicators of quality and efficiency on the market.

6. The consideration of long-term effects of drugs is also of high priority, as therapeutically active mount bring quick results, but often have a negative impact on patient health.

7. The Antimonopoly Committee of Ukraine has consistently maintain position on the need to determine in national legislation the terms "interchangeable drug", "generic medicinal product", "reference product" with the recommendations of the World Health Organization "Regulatory guidance on interchangeability of multisource (generic) drugs" («Multisource (generic) pharmaceutical products guidelines on registration requirements to establish interchangeability») / WHO Expert Committee on Specifications for Pharmaceutical Preparations / WHO Technical Report Series, No / 937, 2006).

2. Registration procedure of medicines and market entry of generics

8. The Government of Ukraine is taking measures to improve the provision of the population with qualitative medicines at affordable prices. Thus, the question of market access of quality imported generic medicines and stimulation of domestic pharmaceutical production is under scrutiny of the government agencies under their authority.

9. According to Article 9 of the Law of Ukraine "On Medicines" drugs are allowed for use in Ukraine after their state registration. State registration of medicinal products is carried out by the State Expert Center of the Ministry of Health of Ukraine on the basis of the submitted application, which should contain information on the drug manufacturer, indications and contraindications. Materials on pre-clinical study, clinical trial and their expertise, information on manufacturing process, drug samples etc. should be attached to the application. After reviewing the submitted materials the competent authority within one month should take a decision whether to register or refuse to register the drug.

10. The information contained in the application for the state registration of the medicinal product and the annexes (hereinafter – registration information) is subject to state protection from disclosure and unfair commercial use.

11. If a medicinal product registered under the submitted full registration information (hereinafter - the reference/original drug) in the Ukraine for the first time, the state registration of another drug containing the same active substance as the reference/original drug is possible not earlier than in five years from the date of first registration of the reference/original drug in Ukraine, unless otherwise provided by law. This requirement does not apply to cases where the applicant under the law acquired the right to refer and/or to use registration information of the reference/original drug or filed his own complete registration information that meets the requirements of the registration information for the reference/original drug.

12. The stated period may be extended to six years if within first three years after the state registration of the reference/original drug the central executive body, which implements the state policy in the matter of healthcare, allowed him the use of one or more indications that are considered to have particular advantage over existing ones. Guidelines and criteria for determining the indications of particular advantage over existing are set up by the central executive body that provides public policy in the health sector. This period is set if the application for state registration in Ukraine of the reference/original drug filed within two years from the date of its first registration in any country.

13. For state registration of medicinal products based on or related to the intellectual property that are in accordance with the laws of Ukraine granted a patent, the applicant shall submit a certified copy of the patent or license that allows the production and sale of registered medicinal products, as well as document that confirms the validity of the patent in Ukraine. Applicants submit a letter, which states that the rights protected by the patent or transferred under the license are not violated in connection with the registration of the drug.

14. For registered drug applicant receives a certificate that states the term, during which the drug is permitted to use in Ukraine.

15. The drug can be used in Ukraine for five years from the date of its registration. At the request of the person who filed an application for state registration of the medicinal product, the period, during which it is permitted for use on the territory of Ukraine, may be reduced by the decision of the registering authority.

16. At the end of 2013 there were changes in the legal framework, which is subject to the rules of medicines prescription. In particular, the mandatory prescription by INN of drug was established. The Antimonopoly Committee of Ukraine believes that these changes should have a positive impact on both consumers (who will be able to choose a drug, guided by the recommendations of a doctor, pharmacist, personal beliefs, level of material wealth, knowledge on medicinal products, etc.) and competitive situation in the pharmaceutical market.

3. Anticompetitive agreements

17. The Ukrainian pharmaceutical market is highly reliant on import and operates in strict vertical interaction (usually on an exclusive basis) between the foreign manufacturer of medical products, importer of its products in Ukraine and a small number of large distributors.

18. The Committee, due to the results of pharmaceutical market research, has found the existence of schemes of unjustified increase in prices of medicines due to the presence of vertical restraints imposed by manufacturers of drugs on the distribution channels of its goods. At the same time as the promotion in the market, based on the nominal price, takes place, under vertical relations on such promotion there are retro

cash flows, which determine the actual price of the product that is less than the nominal amount for a minimum of the amounts of discounts and bonuses.

19. As of today, the Committee considers a number of cases with the signs of violation of the law on protection of economic competition by economic entities - importers of drugs and wholesale distributors in the form of concerted actions relating to the supply of medicines.