REGISTRATION OF MEDICINES IN UKRAINE

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Introduction. The process of improving the regulatory framework regulating the procedure for state registration of medicines is carried out constantly, and today state registration under the main provisions is practically approximated to the legislation of the European Union

The aim. The purpose of the work is to study the Laws of Ukraine, the Cabinet of Ministers' decisions in the process of registration (re-registration) of medicines in Ukraine.

Materials and methods. Analysis of the scientific literature and the results of advanced research in the field of medicine and pharmacology.

Results and discussion. According to the decision of the Cabinet of Ministers of Ukraine from May 26, 2005 № 376 are not subject to state registration medicinal products, which are manufactured in pharmacies according to prescriptions of doctors (mainline formulas) and to the order of treatment and prophylactic establishments (officinal formulas) from authorized for the use of active and auxiliary substances. The state registration of the medicinal product is carried out by the Ministry of Health on the basis of the application and the results of examination of registration materials on such a remedy, conducted by the State Expert Center of the Ministry of Health (hereinafter - the Center) in the manner prescribed by the Ministry of Health.

In the case when the medicinal product is registered with the European Medicines Agency, the state registration of the original medicinal product is carried out without conducting the said examination on the basis of the application, registration materials, including the report on the evaluation of the registration dossier of the said Agency, and the Center's opinion on the compliance with the instructions for use and methods quality control of the medicinal product for registration materials. Verification of such compliance is carried out in the manner prescribed by the Ministry of Health.

The state registration of a medicinal product registered by the competent authority of the United States of America, Switzerland, Japan, Australia, Canada, under the centralized procedure of the competent authority of the European Union for use in the territory of such countries or member states of the European Union, is carried out on the basis of the application and conclusion of the Center compiled according to the results of the procedure for consideration of the attached materials attached to the statement in the Ministry of Health.

The information contained in the application for state registration of a medicinal product and its annexes (hereinafter - registration information), in accordance with the Law of Ukraine "About Medicines" and other regulations, is subject to state protection against disclosure and unfair commercial use. The Ministry of Health and the Center are obliged to protect such information from disclosure and to prevent the unfair commercial use of such information.

It is prohibited for a period of five years from the date of the state registration of a medicinal product (regardless of the term of validity of any patent related to the medicinal product) to use the registration information concerning safety and efficacy contained in the application and its annexes, the registered medicinal product for submission of an application for state registration of another medicinal product, except when the right to refer or use such information has been received in the manner prescribed by law from a person or body izatsiyi that provided the information or the information prepared by or for the applicant.

For the state registration of medicines based on or related to intellectual property objects which have been granted a patent in accordance with the laws of Ukraine, the applicant submits a copy of the patent or license that allows the production and sale of the registered medicinal product and the letter, which indicates, that the rights of a third party protected by a patent are not violated in connection with the registration of a medicinal product.

By the order of the Ministry of Health of Ukraine on the state registration of a medicinal product, a pharmacopoeial article or methods for controlling its quality, an instruction on the use of a medicinal

product (an instruction for medical use), approval of a technological regulation or technology of manufacture of a medicinal product shall be approved, and a registration number shall be assigned. to the State Medicines Register and interdepartmental database of registered medicinal products in Ukraine. The State Register shall include information on the possibility of advertising the medicinal product, as well as data on the prior registration, re-registration or cancellation of the registration of a medicinal product and the registration of a medicinal product in the United States of America, Switzerland, Japan, Australia, Canada.

The registration certificate, indicating the period during which the use of drugs in Ukraine is allowed, shall be issued within a ten-day period after the registration of the medicinal products.

Application in Ukraine is carried out within five years from the date of its state registration, if, in the event of the detection of previously unknown hazardous properties, the Ministry of Health of Ukraine will not decide on a full or temporary prohibition of its use.

In the case of registration of medicinal products, the applicant submits an application to the State Expert Center not earlier than a year, but not later than 90 calendar days before the expiration of the validity period of the registration certificate. In case of submission of an application after the specified time period, re-registration is usually carried out according to the new registration procedure.

Conclusions. The procedure for state registration of medicinal products is an important stage in the process of pharmaceutical provision of the population. The main objective of state registration of medicines is the guarantee of safety and efficacy of drugs, as well as further supervision of their use.