Registration of medicinal products procured by the specialized organization

The Cabinet of Ministers by virtue of its Resolution No. 597 dated 12 August 2015 amended the Procedure for state registration (Re-registration) of medicinal products. The changes became effective on 1 September 2015 and are valid until 31 March 2019.

According to the amendments, the Ministry of Health performs the state registration of a medicinal product, which is subject to procurement, upon the results of procurement procedure conducted by the specialized organization (e.g., specialized funds, organizations and mechanisms of the UN, the International Dispensary Association) on the basis of the application and conclusion of the State Expert Center of the Ministry of Health following expert evaluation of the registration materials.

The following shall be attached to such application submitted to the Ministry of Health:

- materials of the drug master file submitted for registration of the medicinal product to the regulatory authority of the country where such product is registered or to the World Health Organization (WHO) in case of requalification of the medicinal product;
- assessment report on the medicinal product issued by the regulatory authority of the country where such product is registered or by the WHO in case of requalification of the medicinal product;
- methods of the quality control (information on control) of the medicinal product (final product);
- instruction for use of the medicinal product or information on use of the medicinal product;
- translations of the labelling text on the drug package and instruction for use of the medicinal product or information on use of the medicinal product in Ukrainian, certified by the authorized person of the applicant.

No duty for the state registration of such medicinal product shall be paid.

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