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Simplification of procedures for drugs registration

On January 5, 2017, the Order of Ministry of Health of Ukraine came into force, which approved the procedure for examination of registration materials for drugs submitted for state registration (re-registration), and the material on changes to registration materials during the registration of certificate for drugs registered with the competent authorities of the United States, Switzerland, Japan, Australia, Canada, and the European Union member states.

Now the applicant must submit to the State Enterprise "State Expert Center of Ministry of Health of Ukraine of Ukraine", for the inspection of materials for drugs submitted for state registration, a registration dossier, on the basis of which the registration of drug is conducted to the competent authority of aforementioned countries. This shall include data on drugs registration in countries, including the name of country of registration, name of registration authority and the registration date, as confirmed by the applicant with all the changes made after the registration of the drugs.

In addition, the Ministry of Health also will inspect:

- materials about methods of quality control of the drug;
- samples of drug packaging and labeling into primary and secondary (if any) packages;
- instruction for medical use and a brief description of the drug;
- document, by which is confirming payment of the registration fee;
- duly certified copy of a document issued by the State Service of Ukraine on drugs and drug control and confirms the compliance of production conditions of drug, submitted for registration, to the GMP applicable in Ukraine, or manufacturer's written commitment to produce products suitable for drug delivery to Ukraine on the same production facilities used in the production of drugs intended for use in the United states, Switzerland, Japan, Australia, Canada or the European Union member states.

After receiving the materials for inspection, Ministry of Health of Ukraine, if necessary, conclude a contract with the applicant and conduct a review of registration documents, including check of the fact of drug registration according to the web site of the competent authorities that have registered this drug.

Term for review of registration materials shall not exceed 10 days. Re-registration of these medicines will be conducted 5 years after issuance of the registration certificate.

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