

Simplification of state registration of drugs

On 18 March 2015, the Cabinet of Ministers of Ukraine adopted Resolution No. 125 and amended the Procedure of state registration (renewal) of drugs.

The adopted resolution cancelled the requirement of registration renewal of drugs every 5 years, and also simplified procedure for expert evaluation of the registration file for the original drugs registered with the European Medicines Agency.

Also, the resolution simplified the state registration of drugs designed exclusively for treatment of tuberculosis, HIV/AIDS, viral hepatitis, cancer and rare (orphan) diseases which are registered as drugs with the competent authorities of the USA, Switzerland, Japan, Australia, Canada or EU.

Decision on registration or registration refusal for such drugs is made by the Ministry of Health of Ukraine within seven days following conclusion of documentation expert evaluation, except for cases specified as grounds for full or partial prohibition of application of a drug by way of termination of the registration document.