

THE LAW OF UKRAINE

No. 362-V of 16 November 2006

On Amendment of Article 9 of the Law of Ukraine “On Medical Drugs”

The Verkhovna Rada of Ukraine hereby **decrees to:**

I. State Article 9 of the Law of Ukraine “On Medical Drugs” (Vidomosti Verkhovnoyi Rady Ukrayiny, 1996, No. 22, p. 86) in the following wording:

“Article 9. State Registration of Medical Drugs

Except for cases stipulated by this Law, medical drugs shall be allowed for use in Ukraine after their state registration.

State registration of medical drugs shall be effected on grounds of an application filed with the Ministry of Health of Ukraine or a body authorized by the Ministry for that purpose.

An application for registration of a medical drug shall contain: name and address of the manufacturer; the name of the medical drug and its trade name; the name of the active ingredient (in Latin); synonyms; form of manufacture; full composition of the medical drug; indications and contraindications; dosage; terms of dispensing; route of administration; expiry date and storage conditions; information about the packaging; and information on the registration of the medical drug in other countries.

Attached to the application shall be: materials of the preclinical study and clinical trial, and expert evaluations thereof; the relevant pharmacopeial article or materials on methods of quality control of the medical drug, a draft of the technical regulations or information on the technology of its manufacture; specimens of the medical drug; packaging of the medical drug; and a document confirming payment of registration fee.

Based on the results of its examination of the above materials, the Ministry of Health of Ukraine or a body authorized by the Ministry for that purpose, shall make a decision to register or refuse to register the medical drug in question within one month.

The decision on state registration of a medical drug shall approve the pharmacopeial article or methods of control of quality of the medical drug, approve the regulations or technology of manufacture, and assign to the medical drug a registration number to be entered in the State Register of Drugs of Ukraine.

Indicated in the State Register of Drugs of Ukraine shall be: the trade name of the medical drug; its manufacturer; international non-proprietary name; synonyms; chemical name or composition; pharmacological effect; pharmaco-therapeutic group; indications; contraindications; precautions; interactions with other medical drugs; modes of application and dosages; side effects; forms of manufacture; expiry date and storage conditions; and terms of dispensing.

Information provided in an application for state registration of a medical drug and in attachments to it (hereinafter “registration information”), under provisions of this Law and other regulatory – legal acts of Ukraine, shall be subject to state protection against disclosure and unfair commercial use. The

Ministry of Health of Ukraine or bodies authorized by it, shall be required to protect such information against disclosure and to prevent unfair commercial use of such information.

If a medical drug was registered, it shall be prohibited for the period of five years following the date of such registration (irrespective of the term of any patent that is connected with the medical drug) to use the registration information to submit applications for state registration of another medical drug, except for cases where an applicant has been given the right, in the course of the relevant established procedure, to use such information or to refer to it.

Persons guilty of disclosure or unfair use of registration information, shall bear disciplinary, administrative, civil and / or criminal responsibility pursuant to applicable legislation of Ukraine.

For state registration of medical drugs based on or relating to intellectual property objects on which a patent was issued pursuant to Ukrainian law, an applicant shall submit a copy of the patent or the license which permits manufacturing and sale of the registered medical drug. All applicants shall submit statements indicating that rights of the third parties protected by the patent, are not infringed in connection with registration of the medical drug concerned.

For a registered medical drug, the applicant shall be issued a certificate specifying the period during which the medical drug will be allowed for use in Ukraine.

A medical drug may be used in Ukraine during five years following the date of its state registration. Based on the request of the person who submitted an application for state registration of a medical drug, the period during which it is allowed for use in the territory of Ukraine, may be reduced by decision of the registering body.

If a medical drug is found to have earlier unknown dangerous properties, the Ministry of Health of Ukraine or a body authorized by the Ministry for that purpose may adopt a decision on complete or temporary ban on its use.

When a period for which a registered drug was approved for use in Ukraine expires, the medical drug may be used provided it is re-registered.

A decision to refuse to grant state registration to a medical drug shall be made if findings about its effectiveness and safety are not confirmed.

State registration may be refused in the event where such registration would result in the infringement of valid intellectual property proprietary rights protected by a patent, including in the course of manufacturing, use, and sale of medical drugs.

A refusal to register a medical drug shall be communicated to the applicant by the Ministry of Health of Ukraine or a body authorized by the Ministry for that purpose, within ten days, as a reasoned written reply. A decision to refuse registration may be appealed in accordance with the procedure established by law.

The procedure for state registration (re-registration) of a medical drug and the amount of state registration (re-registration) fee shall be established by the Cabinet of Ministers of Ukraine.

Medical drugs prepared in pharmacies from authorized active and auxiliary substances on a doctor's prescription and on commission from health - prophylactic establishments, are not subject to state registration".

II. Final Provisions.

1. This Law shall take legal effect from the date of its publication and is applied to the cases that arose after its entering into force.

2. The Cabinet of Ministers of Ukraine shall within three months:

Bring its normative - legal acts into line with this Law;

Provide for review and abrogation by ministries and other central bodies of executive power in Ukraine of their respective normative - legal acts that are at variance with this Law.