

Law of Ukraine

«On amendment of the certain Laws of Ukraine»

Verkhovna Rada of Ukraine ORDERS:

. To make the following changes to the following legislative acts of Ukraine:

1. Article 9 of Law of Ukraine «On medical drugs» of 4 April 1996 # 123/96-VR (Vidomosty Verkhovnoyi Rady (VVR), 1996, #22, p. 86 as amended under Laws #70/97-VR of 14.02.97, VVR, 1997, # 15, p. 115; # 783- (783-14) of 30.06.99, VVR, 1999, # 34, p.274), shall read as follows:

«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 a medical drug shall be conducted on the 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 the state registration of a medical drug shall contain: the 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, clinical trial, and their expert evaluations; 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; and a document confirming registration fee payment.

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 the 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.

The State Register of Drugs of Ukraine shall indicate: 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 the state registration of a medical drug, under provisions of this Law and other regulatory – legal acts of Ukraine, shall be subject to state protection against disclosure and unfair commercial use. In particular, the Ministry of Health of Ukraine or bodies

authorized by it, shall be required to protect confidentiality of such information and to prevent unfair commercial use of such information.

If a medical drug was registered, it shall be prohibited for the period of 5 years following the date of the registration of the medical drug in Ukraine to submit applications for state registration of medical drug, which contain information on safety and effects that is provided in the application for the state registration of the medical drug with respect to which registration was performed earlier, regardless of the period of validity of any patent that is connected with the medical drug, except for cases where an applicant has been given the right to use or refer to such information from a person or organization which itself derived that information, or that information was obtained directly by the applicant, or for the applicant.

Persons that violate provisions, which regulate disclosure or use of registration information, shall bear disciplinary, administrative, civil and/or criminal responsibility pursuant to applicable legislation of Ukraine.

For state registration of patented medical drugs an applicant shall be required to submit a copy of the patent or the licensing agreement which permits manufacturing and sale of the registered medical drug. All applicants shall submit statements indicating that the rights of the third parties, which are protected by the patent, are not infringed with respect to the registered product.

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 5 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 a full or temporary ban on its use.

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

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

The state registration may be disallowed in the event that the medical drug is referred to in a patent, except in cases where the patent's holder has given one's consent, or when after the examination performed by competent authorities it has been established that the patent is invalid, or that it will not be infringed upon in the course of manufacturing, use and sale of the medical drug with respect of which the application for state registration has been filed.

A rejection 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 as an official written reply within ten days. The decision to refuse registration may be appealed in accordance with established procedure.

A procedure for state registration (re-registration) of a medical drug and amounts of relevant charges 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 or on commission from health establishments are not subject to state registration.

2. Article 7 of Law of Ukraine «On pesticides and agrochemicals» dated 2 March 1995 #86/95-VR (Vidomosti Verkhovnoyi Rady Ukrainy (VVR), 1995, # 14 (04.04.95), p. 91 as amended by Laws #1628-IV of 18.03.2004, VVR, 2004, # 26 (25.06.2004), p. 362; #3078- IV dated 15.11.2005, VVR, 2006, #5-6 (10.02.2006), p. 74) shall read as follows:

«Article 7. State registration of pesticides and agrochemicals.

Subject to obligatory state registration shall be the preparative forms of pesticides and agrochemicals.

State registration of pesticides and agrochemicals shall be performed by the special authorized central executive government agency for environment protection issues in accordance with a procedure established by the Cabinet of Ministers of Ukraine, on the grounds of positive test results and examination materials.

A prerequisite of the state registration of pesticides and agrochemicals shall be availability of relevant documentation concerning safety of their use, including a positive finding of the state sanitary – epidemiology examination, and methodologies for determining residual quantities of pesticides and agrochemicals in agricultural products, feed, food, soil, water and air.

If a pesticide or an agrochemical was registered, it shall be prohibited for the period of 10 years following the date of the registration of the pesticide or the agrochemical in Ukraine to submit applications for state registration of a medical drug, which contain information on safety and effects that is provided in the application for the state registration of the pesticide or the agrochemical, with respect to which registration was performed earlier, except for cases where an applicant has been given the right to use or refer to such information from a person or an organization which itself derived that information, or that information was obtained directly by the applicant, or for the applicant.

After the state registration of pesticides or agrochemicals authorities administering the government control over their use shall be provided, pursuant to the procedure established by the Cabinet of Ministers of Ukraine, with standard sample quantities of pesticides and agrochemicals, and with methodologies for determining their residual quantities.

Pesticides and agrochemicals shall be registered for a period of up to ten years. The special authorized central executive government agency for environment protection issues may impose a final or temporary prohibition on the use of pesticides and agrochemicals in case new, earlier unknown data concerning lack of their safety have been received. In particular cases, in connection with a sanitary – epidemiological and environmental situation occurring in the country (a region), the special authorized

2921-III of 10.01.2002, VVR, 2002, N 16 (19.04.2002), .114, N 850-IV of 22.05.2003, VVR, 2003, # 35 (29.08.2003), p.271) shall read as follows:

«2. This Law shall not accord legal protection to a qualified indication of a product origin related to the geographical location in a foreign state, provided that:

1) rights to this qualified indication of the product origin are not protected in the foreign state in question;

2) legislation of the foreign state does not provide for protection of rights to qualified indications of goods originated in Ukraine.»

. Closing provisions

1. This Law shall take effect on the date of publication.

2. Within the three months the Cabinet of Ministers of Ukraine shall:
bring its regulatory – legal acts in conformity with this Law;
ensure a review and repealing by the ministries and other central executive government agencies of Ukraine of their regulatory – legal acts that are inconsistent with this Law.