



On approval of the Agreement on cooperation of the member States of the Eurasian Economic Community in the sphere of circulation of medicines (medical drugs), medical products and medical equipment (medical devices)

Unofficial translation

Decree of the Government of the Republic of Kazakhstan dated August 2, 2013 No. 766

Unofficial translation

The Government of the Republic of Kazakhstan RESOLVES:

1. To approve the attached Agreement on cooperation of the member states of the Eurasian Economic Community in the sphere of circulation of medicines (medical drugs), medical products and medical equipment (medical devices), completed in Yalta on September 28, 2012.

2. This resolution shall take effect from the date of signing.

*Prime Minister
of the Republic of Kazakhstan*

S. Akhmetov

Approved by
Order No. 766
of the Government
of the Republic of Kazakhstan
dated August 2, 2013

AGREEMENT

on cooperation of the member states of the Eurasian Economic Community in the sphere of circulation of medicines (medical drugs), medical products and medical equipment (medical devices)

The governments of the member states of the Eurasian Economic Community (hereinafter -EurAsEC), hereinafter referred to as the Parties, striving to maintain and develop cooperation of the EurAsEC member states in the sphere of circulation of medicines (medical drugs), medical products and medical equipment (medical devices)

based on the Treaty on the establishment of the EurAsEC of October 10, 2000, taking into account the provisions of the Activities for 2011-2013 and subsequent years on the implementation of the Priority directions for the development of the EurAsEC, approved by Decision of the EurAsEC Interstate Council (at the level of the heads of state) of December 9, 2010 No. 533, and in accordance with the laws of the States of the Parties,

recognizing the need to provide the population with safe, effective and high-quality medicines (medical drugs), medical products and medical equipment (medical devices)

have agreed as follows:

Article 1

The parties shall harmonize and unify the requirements for medicines (medical drugs), medical products and medical equipment (medical devices) during their pre-registration (registration) examination and post-registration monitoring, including standardization and quality control.

Article 2

The parties shall conduct examination of documentation and registration (re-registration or confirmation of state registration) of medicines (medical drugs), medical products and medical equipment (medical devices) in accordance with the procedure and tariffs established by the legislation of the states of the Parties, and considering the requirements established by:

Regulation on the basic requirements for state registration, re-registration or confirmation of state registration (hereinafter - state registration) of medicines (medical drugs) in the EurAsEC member states (Appendix 1);

Regulation on the basic requirements for state registration and re-registration (hereinafter -state registration) of medical products and medical equipment (medical devices) in the EurAsEC member states (Appendix 2), which are annexes to this Agreement.

Article 3

The parties shall acknowledge results of preclinical studies (research), clinical, bioequivalent and other tests (researches), medicines (medical drugs), medical products and medical equipment (medical devices), results of inspections of pharmaceutical enterprises, enterprises producing medical products and medical equipment (medical devices) carried out in the territories of the states of the Parties.

The parties shall reserve the right to assign additional tests, studies, inspections if necessary.

Article 4

The parties shall gratuitously exchange information on medicines (medical drugs), medical products and medical equipment (medical devices) about adverse side effects detected during their use, on withdrawal of medicines (medical drugs), medical products and medical equipment (medical devices) from circulation, on restriction of their use.

Article 5

The parties shall carry out cooperation in conducting research, research to practice conferences, seminars and other events on topical issues of examination, standardization and quality control of medicines (medical drugs), medical products and medical equipment (medical devices). Financing of these and other events, their topics, date and venue shall be made out in a separate protocol.

Article 6

This Agreement shall not affect the rights and obligations of each of the Parties arising from other international treaties to which they are parties.

Article 7

By mutual agreement of the Parties, this Agreement may be amended by separate protocols.

Article 8

Disputes between the Parties related to the interpretation and (or) application of the provisions of this Agreement shall be resolved through negotiations and consultations.

If the dispute is not resolved by the parties to the dispute through consultations and negotiations within six months from the date of the official written request for their conduct, sent by one of the parties to the dispute to the other side of the dispute, either party to the dispute may refer the dispute to the EurAsEC Court for consideration.

Article 9

This Agreement shall enter into force on the 30th day from the date of receipt by the depositary of the last written notice on completion by the Parties of the domestic procedures necessary for its entry into force.

Article 10

From the date of entry into force, this Agreement is open for accession by any state admitted to the EurAsEC membership. The instrument of accession shall be deposited with the depositary.

For an acceding state, this Agreement shall enter into force on the date of receipt by the depositary of the instrument of accession.

Article 11

Each Party may withdraw from this Agreement by notifying the depositary in writing.

The agreement shall terminate in respect of such Party upon expiry of six months from the date of receipt by the depositary of the relevant notification.

Executed in Yalta, September 28, 2012 in one original copy in the Russian language. The original copy of this Agreement shall be deposited with the EurAsEC Integration Committee, which, as the depositary of this Agreement, shall send a certified copy to the Parties.

*For the Government
of the Republic of Belarus*

*For the Government
of the Republic of Kazakhstan*

*For the Government
of the Kyrgyz Republic*

*For the Government
of the Russian Federation*

*For the Government
of the Republic of Tajikistan*

REGULATION

on basic requirements of state registration, re-registration or confirmation of state registration of medicines (medical drugs) in the member states of the Eurasian Economic Community

General Provisions

1. This regulation has been developed to unite and coordinate the efforts of the EurAsEC member states to further deepen cooperation in the given area, to develop their integration in the sphere of standardization, registration and quality control of medicines (medical drugs), also to provide the population with effective, safe and high-quality medicines (medical drugs) in the required volumes and assortment.

2. This Regulation is intended to improve the legislation of the EurAsEC member states governing the circulation of medicines (medical drugs), is based on recommendations of the World Health Organization, legislation of the EurAsEC member states and generally accepted international standards.

3. This Regulation is intended for mutual recognition, not contradictory to the legislation of the EurAsEC member states, of certain types of studies of medicines (medical drugs) with the aim of economical use of human and material resources, laboratory animals, also reducing the time for development and delivery of new medicines (medical drugs) to the market.

4. This Regulation contains minimum requirements for documents and data submitted at the state registration, re-registration or confirmation of state registration (hereinafter - state registration) of medicines (medical drugs), labeling and directions for use (package insert) in the EurAsEC member states that are not contradictory to their legislation.

Main terms and definitions

5. State registration of medicines (medical drugs) - system of accounting, determination of access to the sale and medical use of medicines (medical drugs), recognized as meeting the requirements for safety, efficacy and quality for humans. 6. The state register of medicines (medical drugs) - national information system containing data on medicines (medical drugs) registered in the state and authorized for medical use.

7. Medicine (medical drug) - a substance or combination of several substances of natural, synthetic or biotechnological origin, with pharmacological or immunological activity and used in a specific dosage form for prophylaxis, diagnosis (with the exception of substances or combinations of substances that are not in contact with the human body or animal body), and treatment of diseases, rehabilitation of patients, prevention of pregnancy.

Medicines include pharmaceutical substances and medical drugs.

8. Registration certificate (certificate) - a document issued by the authorized body on the state registration results and confirming permission for the sale and medical use of a medicine (medical drug) in the state.

State registration objects

9. All medicines (medical drugs), with the exception of cases provided for by the legislation of the EurAsEC member states shall be the state registration objects.

10. At the state registration, a medicine (medical drug) shall be entered on the state register of medicines (medical drugs) with assignment of the registration number (registry entry number) to it.

11. The applicant shall be issued a registration certificate (certificate) for a registered medicine (medical drug).

Basic requirements for documents and data submitted at the state registration of a medicine (medical drug)

12. For the state registration of a medicine (medical drug), the applicant shall provide the following documents and data:

- 1) application for the state registration of a medicine (medical drug);
- 2) name and legal address of the organization of the manufacturer of the medicine (medical drug);
- 3) name of the medicine (medical drug), including the international non-proprietary name, scientific name in Latin or chemical name, basic synonyms;
- 4) original name / trade name of the medicine (medical drug), if it is registered as a trademark;
- 5) list of active and auxiliary substances that are part of the medicine (medical drug), their number;
- 6) draft instruction for the medical use of the medicine (medical drug);
- 7) data on the manufacturer of the medicine (medical drug);
- 8) regulatory document / product specification file on the quality (a document containing quality indicators and quality control methods) of the medicine (medical drug);
- 9) quality control methods of the medicine (medical drug);
- 10) results of preclinical (nonclinical) trials of the medicine (medical drug);

11) results of clinical trials of the medicine (medical drug);

12) documents confirming the registration of the medicine (medical drug) in the country where it is manufactured - a certificate of pharmaceutical product (registration certificate (certificate), and in its absence - a certificate for free sale (notarized copy in the manufacturer country).

Samples of the medicine (medical drug) shall also be submitted for the examination of its quality.

13. Labeling of medicines (medical drugs) must contain the following mandatory information:

1) on the secondary packaging, and in its absence - on the primary packaging (label) the following information shall be indicated in Russian and the state languages:

state, name of the manufacturer, its trademark (if two or more manufacturers are involved in the production process, then they can be entered in accordance with the legislation of the EurAsEC member states);

trade (proprietary) name of the medicine (medical drug);

international nonproprietary name (the international nonproprietary name may be additionally indicated in English or Latin);

dosage form;

2) each individual package must be supplied by instruction for use (and / or package insert) in Russian and state languages. It is permissible to apply the full text of the instruction for use (package insert) directly to the primary or secondary packaging of a non-prescription medicine (medical drug);

3) the name and quantitative composition of active substances;

4) complete list of excipients (for medicines (medical drugs) intended for parenteral administration, for use in ophthalmology and for external application);

5) method of use, for parenteral medicines (drugs), the route of administration should be indicated if the medicine (drug) can be administered in three or more ways, it is allowed to indicate "for injection";

6) storage conditions, indicating the temperature range;

7) caution - "keep medicine (drug) out of the reach of children", "shake well before use", "do not freeze" and others;

8) series;

9) shelf life / expiration date;

10) dispensing conditions, if this requirement is provided for by the legislation of the EurAsEC member states.

On medicines (medical drugs) derived from human blood, blood plasma, organs and tissues, the inscription shall be applied: "No antibodies to HIV-1, HIV-2, to hepatitis C virus and surface antigen of hepatitis B virus".

Medicines (medical drugs) derived from plant materials (whole or crushed and packaged medicinal herbs, herbal preparations, herbal teas) must bear the inscription: "Radiation Safety Tested."

Sterile medicines (medical drugs) must be labeled "sterile".

Each individual package shall be supplied with instruction for medical use (and / or package insert) in Russian and the state languages. It is permissible to apply the full text of the instruction for use (package insert) directly to the primary or secondary packaging of a non-prescription medicine (medical drug)

For medicines (medical drugs) containing in the same dosage form a different amount of active substance, the color scheme of the design of the primary and secondary packaging should be different, if it is provided for by the legislation of the EurAsEC member states.

14. Instructions for the medical use of a medicine (medical drug) shall contain the following mandatory information:

- 1) trade name, international non-proprietary, chemical or other name;
- 2) dosage form indicating the quantitative content or activity of active substances and the names of excipients;
- 3) anatomical therapeutic chemical (ATC) classification;
- 4) description of the appearance;
- 5) pharmacological or immunological (biological) properties (pharmacokinetics, pharmacodynamics);
- 6) name, legal and actual address of the manufacturer's organization, including the legal entity in whose name the registration certificate has been issued;
- 7) indications for medical use;
- 8) contra indications;
- 9) dosing and route (method) of administration, duration of treatment, and if necessary, the time of administration of the medicine (drug);
- 10) precautions in medical use;
- 11) symptoms of an overdose, measures to help with an overdose;
- 12) instructions, if necessary, about the specifics of the action of the medicine (drug) at the first intake or its cancellation;
- 13) instructions, if necessary, on the actions of the doctor and patient when missing intake of one or more doses of the medicine (drug);
- 14) possible side effects, adverse effects and serious adverse effects during medical use of the medical drug;
- 15) interaction with other medicines (medical drugs) and (or) food products;
- 16) indication of the possibility of medicinal use by pregnant women, women during lactation, children under and over one year old, minors, adults with chronic diseases;

17) information on the possible effect of the medicine (medical drug) on the ability to drive vehicles, operate mechanisms that require increased concentration of attention and speed of the psychomotor reaction;

18) shelf life / expiration date, also an indication that the medicinal product must not be used after the expiration date;

19) storage conditions;

20) caution that the medicine (medical drug) should be kept out of the reach of children;

21) dispensing conditions;

22) Information on the organizations to which claims on the quality of the medicine (medical drug) can be directed and other information on the medicine (medical drug) (name, phone, fax, postal and email addresses).

The package insert shall contain the following required information:

1) the name of the medicine (medical drug), indicating the international non-proprietary name (if any), if the manufacturer uses the trade name of the medicinal product (medical drug) different from the international non-proprietary name, if the medicinal product (medical drug) contains only one active substance, if the medicinal product (medical drug) is available in several dosage forms and / or forms that differ in strength (for example, for newborns, children, adults), this information shall be indicated next to the trade name of the medicinal product (medical drug);

2) description of the medicinal product (medical drug) should contain a full description of active substances with quantitative and qualitative characteristics and the use of international names for each dosage form indicating the qualitative characteristics of the excipients;

3) information on the dosage form and composition of substances indicated in units of mass, volume or number of dose units;

4) anatomical therapeutic chemical (ATC) classification or type of action in the terminology understandable to a patient;

5) basic properties of the dosage form shall contain a brief description of the finished dosage form, including physicochemical properties (the information should correspond to the “description of the medicinal product” section of the regulatory document on quality control);

6) indications for use in the form of a list of diseases and conditions in which the medicine (medical drug) has an effect;

7) instructions for the proper use of the medicinal product (medical drug), namely:

contraindications

cautions in use;

interaction with other medicines (medical drugs) and other types of interaction (for example, with tobacco, alcohol, food), which can influence the effect of the medicine (medical drug);

usage advice;

8) the information provided shall take into account and contain the following:

features of certain categories of consumers (for example, children, pregnant or breast-feeding women, elderly people, patients with certain types of pathology);

information, if necessary, on the effect of the medicine (medical drug) on human behavior, ability to drive a car or operate mechanisms;

information about the excipients that are important for safe and effective use of the medicine (medical drug);

the following directions for the proper administration of the medicine (medical drug): dose; method and route of administration; frequency of administration, indicating, if necessary, time of the day when the drug should be taken, ratio with food intake, and also, if necessary, depending on the properties of the medicine (medical drug); duration of use without medical supervision, if it is limited; signs of an overdose, measures that must be taken in case of an overdose (for example, emergency care and symptomatic therapy); actions if a dose of the medicine (medical drug) was missed;

indications (if necessary) of the risk of developing a rebound effect of the medicine (medical drug);

9) description of adverse reactions that, when using a medicine (medical drug) in therapeutic or prophylactic doses can be observed, an indication of the need to contact the attending physician when they happen, and also in case of ensuing adverse reaction, which is not mentioned in the package insert;

10) expiration date indicated on the label;

11) caution not to use the medicinal product (medical drug) after the expiration date;

12) special storage conditions (if necessary);

13) indication of the storage of a medicinal product (medical drug) (storing in places not accessible to children and others);

14) caution about visual signs of the unsuitability of a medicinal product (medical drug) (if any);

15) dispensing conditions;

16) information about the organizations to which claims on the quality of the medicinal product (medical drug) and other information on the medicinal product (medical drug) can be sent (name, phone, fax, postal and email addresses);

17) name, legal and actual address of the organization manufacturing the medicinal product (medical drug).

It is possible to provide copies of the above documents drawn up in the prescribed manner

Documents issued by the competent authorities of foreign states shall be accepted if they are legalized or apostilled, unless otherwise provided by international treaties.

Documents drawn up in a foreign language shall be accompanied by notarized translation into the state or Russian languages, unless otherwise provided by law.

to the Agreement on cooperation
of the Member States
of the Eurasian Economic
Community
in the sphere of circulation of
medicines
(medical drugs), medical products
and medical equipment (medical
devices)
of September 28, 2012

REGULATION

on basic requirements of state registration and re-registration of medical products and medical equipment (medical devices) in the member states of the Eurasian Economic Community

General Provisions

1. This Regulation has been developed to unite and coordinate the efforts of the EurAsEC member states to further deepen cooperation and integration in the sphere of standardization, registration and quality control of medical products and medical equipment (medical devices) in order to provide the population with effective, safe and high-quality medical products and medical equipment (medical devices) in the required volumes and assortment.

2. This Regulation is intended to improve the regulatory legal acts governing the circulation of medical products and medical equipment (medical devices) in the EurAsEC member states, based on the recommendations of the World Health Organization, the legislation of the EurAsEC member states and generally accepted international standards.

3. This Regulation is intended for mutual recognition, not contradictory to the legislation of the EurAsEC member states, of certain types of trials for medical products and medical equipment (medical devices) with the aim of economical use of human and material resources, laboratory animals, also reducing the development and delivery time to market of new medical products and medical equipment (medical devices).

4. This Regulation contains requirements (minimum) for documents and data submitted during state registration and re-registration (hereinafter -state registration) of medical products and medical equipment (medical devices) in the EurAsEC member states that do not contradict the laws of the EurAsEC member states.

Main terms and definitions

5. State registration - procedure of determining the quality, efficacy and safety of medical products and medical equipment (medical devices), based on relevant trials and

assessments with the purpose of admitting medical products and medical equipment (medical devices) to manufacturing, import, export, sale and medical use.

6. The state register of medical products and medical equipment (medical devices) - a document containing information about medical products and medical equipment (medical devices), registered in the EurAsEC member states and authorized for production, import, export, sale and medical use.

7. Medical products - products, sets of reagents for diagnostics (in vitro) and excipients used for prevention, treatment, rehabilitation, prosthetics, research work.

8. Medical equipment - medical devices, instruments and appliances used separately, in complexes or systems for medical purposes for the prevention, diagnosis, treatment, rehabilitation, prosthetics, research work.

9. Safety of medical products and medical equipment (medical devices) - absence of unacceptable risk associated with harm to life, human health and the environment.

10. Quality of medical products and medical equipment (medical devices) - a set of properties and characteristics of medical products and medical equipment (medical devices) that affect their ability to act as intended, provided that they comply with the requirements of regulatory legal acts effective in the state.

11. Efficacy of medical products and medical equipment (medical devices) - a set of characteristics that ensure achievement of a preventive, diagnostic, therapeutic and (or) rehabilitation effect.

12. Registration dossier - a set of documents submitted for state registration (re-registration), amendments to the registration dossier for medical products and medical equipment (medical devices).

13. Registration certificate - a document confirming permission for manufacturing, import, export, sale and medical use of medical products and medical equipment (medical devices) issued upon the state registration results.

State registration objects

14. All medical products and medical equipment (medical devices) with the exception of cases provided for by the legislation of the EurAsEC member states shall be state registration objects. At the state registration the medical products and medical equipment (medical devices) shall be entered on the state register of medical products and medical equipment (medical devices) with assignment of a registration number (registry entry number) to it.

15. The applicant shall be issued a registration certificate (certificate) for a registered medical product and medical equipment (medical device).

Basic requirements for documents and data submitted at the state registration of a medical product and medical equipment (medical devices)

1. 16. The registration dossier shall contain the following documents:
2. 1) application for state registration (re-registration) of medical products and (or) medical equipment (medical devices), containing:
 3. name of the applicant (state, legal address);
 4. name of the manufacturer (state, legal address);
 5. name of the legal entity or individual entrepreneur in whose name the registration is made (state, legal address);
 6. name of the medical product and medical equipment (medical devices), indicating the name of the normative technical documentation in accordance with which the medical product and medical equipment (medical devices) were manufactured;
 7. scope of medical product and medical equipment (medical devices) use;
 8. information on analogues of the medical product and medical equipment (medical devices) ;
 9. complete set (composition) of the claimed medical products, medical equipment (medical devices) (with indication of the names);
 10. expiration date, warranty period for the medical product and medical equipment (medical devices) ;
11. 2) power of attorney of the manufacturer of medical products and medical equipment (medical devices), drawn up in the prescribed manner;
12. 3) documents certifying the quality of the claimed medical product and medical equipment (medical devices) issued in the state of the manufacturer (certificates of conformity for the quality management system, certificates of conformity for products, free sale certificates, manufacturer's declarations of conformity, registration certificates, etc.);
13. 4) normative technical document in accordance with which the medical product and medical equipment (medical devices) were manufactured;
14. 5) description (sample or layout) of labeling, packaging of medical products and medical equipment (medical devices);
15. 6) directions for the medical product use, a manual for the use of medical equipment (medical devices), passport for the medical product, medical equipment (medical devices), issued by the manufacturer of the claimed medical product, medical equipment (medical devices) in the prescribed manner;
16. 7) additional information confirming compliance of the medical product and medical equipment (medical devices) with safety, efficacy and quality requirements for humans, namely :
 17. protocols of required tests of medical products and medical equipment (medical devices) ;
 18. documents confirming the conduct of clinical trials in the state of the manufacturer or other documents confirming the clinical efficacy of medical products and medical equipment (medical devices).

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