On approval of the Rules for drawing up and issuing instructions on medical use of medicines and medical devices and the general characteristics of the medicines

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan dated September 10, 2020 № RK HM-101/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on September 15, 2020 № 21200

Unofficial translation

In accordance with Article 242, paragraph 4, of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and healthcare system," **I hereby ORDER:**

1. To approve the attached Rules for drawing up and issuing instructions on medical use of medicines and medical devices and the general characteristics of the medicines.

2. To recognize as invalid:

1) Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated May 29, 2015 No. 414 "On approval of the Rules for the compilation and registration of instructions on medical use and general characteristics of medicines and medical devices" (registered in the Register of State Registration of Regulatory Legal Acts under No. 11495, published on July 14, 2015 in the information legal system "Adilet");

2) Order of the Minister of Healthcare of the Republic of Kazakhstan dated April 24, 2019 No. RK HM-48 "On introduction of amendments to the order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated May 29, 2015 No. 414 "On approval of the Rules for the compilation and registration of instructions on medical use of medicines and medical devices" (registered in the Register of State Registration of Regulatory Legal Acts under No. 18584, published on April 30, 2019 in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan in electronic form).

3. In accordance with the procedure established by the legislation of the Republic of Kazakhstan the Committee for Quality Control and Safety of Goods and Services of the Ministry of Healthcare of the Republic of Kazakhstan shall:

1) ensure the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) place this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

3) within ten working days after the state registration of this order, submit to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan information on the implementation of measures provided for in subparagraphs 1) and 2) of this paragraph.

4. Control over the execution of this order shall be entrusted to the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan.

5. This order shall enter into force upon expiry of ten calendar days after the date of its first official publication.

Minister of Healthcare
of the Republic of Kazakhstan *A. Tsoi*

Approved by order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated September 10, 2020 № RK
HM-101/2020

Rules for drawing up and issuing instructions on the medical use of medicines and medical devices and the general characteristics of medicines

Chapter 1. Procedure for drawing up and issuing instructions on medical use and general characteristics of medicines

1. The instruction on medical use of medicines (information leaflet) (hereinafter referred to as the M instruction) shall be prepared using clear and understandable terms for the patient reflecting medical and scientific data on the medicine and shall contain the following information:

1) identification data of the medicine:

the name of the medicine followed by the dosage and medicinal form. If the medicine contains only one active substance, then its international generic name (in the absence of a common name) should be indicated in parentheses immediately after the trade name of this medicine (it differs from the trade name); for medicines containing several active substances, they should be indicated in the form of a list under the name;

2) a therapeutic group or a description of activity readily understood by the patient;

3) indications for use shall contain a list of diseases and syndromes in which the drug shall be recommended for medical use; conditions of application in certain groups (children, pregnant and breastfeeding women, the elderly, persons with certain pathological conditions);

4) a list of information necessary before the medicine shall be used:

contra indications;

necessary precautions during application;

types of interactions with drugs and types of interactions that can affect the effects of the drug (with alcohol, tobacco, food); Information on the possible impact on the ability to drive or operate vehicles (if applicable);

special warnings;

5) recommendations for use:

dosing mode;

method and way of injection (if necessary);

frequency of use with indication of reception time (if necessary);

duration of treatment (depending on the properties of the medicine if it is necessary to limit it);

measures to be taken in case of overdose (symptoms, urgent procedures);

measures necessary when passing one or more doses of the medicine (if necessary);

indication of the risk of withdrawal symptoms (if necessary);

recommendations on health seeking consultation from a health professional to explain the use of the medicine;

6) a description of the undesirable reactions that are manifested in the standard use of the medicine and the measures to be taken in this case (if necessary);

7) standard text recommending patients to contact a medical officer, a pharmaceutical employee or directly to the information database on undesirable reactions (actions) to medicines, including reports of medicines inefficiency, and indicating various ways of such a message (e-mail, mail and/or other);

8) additional information:

complete qualitative (pharmaceutical substances and auxiliaries) and quantitative composition of pharmaceutical substances using their conventional names for each form of medicine release;

description of appearance, smell, taste;

9) expiry date, with indication of prohibition of medicine use after expiry date;

storage conditions;

warning of certain visible signs of quality degradation (if necessary);

10) information about the drug manufacturer:

full and abbreviated (if any) name, legal, (actual) address and contact details (telephone, fax, e-mail) of the manufacturer;

full and abbreviated (if any) name, legal, (actual) address and contact details (telephone, fax, e-mail) of the holder of the registration certificate (hereinafter referred to as HRC) (where appropriate, the name of the representative appointed by the HRC to represent his interests).

name and contact details (telephone, fax, e-mail) of the organization receiving claims (proposals) for a medicine from consumers in the territory of the Republic of Kazakhstan;

11) date of the last update of the M instruction.

2. The M instruction shall be developed on the basis of the general characteristic of medicines (hereinafter referred to as GCM) for each dosage form and shall be issued in the form of an insert in the package or its text shall be placed on the package without abbreviation.

3. The text of the M instruction shall be executed in Kazakh and Russian and shall correspond to the following:

headings and subheadings shall be arranged uniformly and in bold;

pictures and (or) pictograms (if necessary) shall be provided.

4. The text of the GCM shall contain information on a medicine for medical use and is being developed for each dosage form in accordance with the Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 No. 88 "On approval of requirements for the medical use of the medicine and the general characteristic of the medicine for medical use."

Chapter 2. Procedure for drawing up and issuing instruction on medical use of medical devices

5. The instruction on the use of the medical device (hereinafter referred to as the MD instruction) shall contain information provided by the manufacturer of the medical device regarding the purpose, proper and safe use of the medical device.

6. The MD instruction shall be compiled using the terms understandable for users. The MD instruction shall decrypt all symbols and symbols used in marking.

The MD instruction shall contain the following information:

1) the name of the medical device;

2) composition and description of a medical device:

technical and functional characteristics necessary for the user to use the medical device for the purpose specified by the manufacturer;

information on the presence of medicine, biological material and/or nanomaterial;

list of components for medical device (if any);

disposable or reusable (where necessary, specific guidelines for use);

the name (designation) of the regulatory document in accordance with which the medical device was manufactured.

3) the scope of use and the purpose of medical device with the indication of the user (for example, a patient, a medical specialist, an individual using medical device according to the purpose determined by the manufacturer);

4) information on precautions (safety) and restrictions when using a medical device:

prevention, precautions and/or measures taken in the event of malfunction of a medical device or abnormalities in its functioning that may affect the safety of the medical device;

prevention, precautions and (or) measures taken in the event of an impact on the functioning of medical device of external factors associated with the use of medical device in combination with medical devices and (or) equipment, or such factors as external electromagnetic fields, electrostatic discharges, radiation, atmospheric pressure and its differences, humidity and air temperature;

prevention, precautions and/or measures taken in the event of a foreseeable risk of electromagnetic interference caused by a medical device when conducting and evaluating the results of specific diagnostic studies, therapeutic treatment or its use (for example, electromagnetic radiation of a medical device affecting other equipment);

information on the limitations or incompatibility with a medical device of certain medicines or biological materials (if the medical device is intended for the introduction of medicines or biological materials);

prevention, precautions and/or limitations related to medicinal substances or biological materials that are part of a medical device;

prevention of carcinogenic, mutagenic or toxic materials in the medical device that may release or wash out, lead to sensitization, allergic reaction or adversely affect reproductive function;

prevention or precautions taken by the user when disposing of the medical device, accessories and consumables used with it (if any), including information about the infectious, microbial, environmental or physical hazard of the medical device.

5) contraindications for use, expected and foreseeable adverse events related to the use of a medical device, including information on the circumstances in which the user needs to consult a medical specialist (for medical devices intended for use by persons without a medical education), first aid measures in case of improper use;

6) information on the shelf life and storage conditions of the medical device;

7) information required to verify the correct installation of the medical device and its readiness for safe operation according to the purpose determined by the manufacturer, indicating the following information:

maintenance content and periodicity, including cleaning and disinfection of medical device;

availability of consumable components of the medical device and procedure for their replacement;

the need for calibration to ensure proper and safe operation of the medical device during its service life;

methods for mitigating the risks associated with the installation, calibration or maintenance of a medical device;

8) additional information required when using (maintaining) a medical device:

information on the procedure for installation and commissioning (if necessary), as well as on the need for preliminary preparation for the use of a medical device;

special requirements for premises, special training or special qualifications of the user and (or) third persons (if necessary);

information on the nature, type, and (if necessary) intensity and distribution of radiation emitted by a medical device and how to protect users or third persons from unintentional radiation during the use of a medical device (if the medical device creates a hazardous or potentially hazardous level of radiation for medical purposes);

information on the procedure in case of violation of sterile packaging of a medical device before its use (if the medical device is supplied sterile);

information on the method of sterilization of a medical device (if the medical device is supplied non-sterile, indicating the need to sterilize it before use);

information on the proper treatment of the medical device for reuse, including cleaning, disinfection, packaging and, if necessary, the method of re-sterilization (if the medical device is intended for reusable use), as well as criteria for the unsuitability of the medical device;

9) information about the manufacturer of a medical device and its authorized representative, including:

full and abbreviated (if any) name, legal, (actual) address and contact details (telephone, fax, e-mail) of the manufacturer;

full and abbreviated (if any) name, legal, (actual) address and contact details (telephone, fax, e-mail) of the authorized representative of the manufacturer in the territory of the Republic of Kazakhstan:

name and contact details (telephone, fax, e-mail) of the organization receiving claims (proposals) for medical devices from consumers in the territory of the Republic of Kazakhstan;

name and contact details (telephone, fax, e-mail) of the organization responsible for post-registration surveillance of the safety of a medical device in the territory of the Republic of Kazakhstan.

10) data on the release or last revision of the medical use instruction.

7. The MD instruction for in vitro diagnostics shall contain the following information:

1) the name of the medical device for in vitro diagnostics;

2) composition and description of a medical device:

test principle;

description of reagents, calibrators and control materials;

list of materials and special materials required for testing (analysis), but not contained in the delivery package medical device for in vitro diagnostics;

3) prescribing a medical device for in vitro diagnostics, including:

functional assignment;

a description of what shall be defined and/or measured (analyte);

a specific disorder, physiological condition or risk factor for detection, determination or differentiation of which the medical device shall be intended for in vitro diagnosis (if necessary);

the purpose of the medical device for in vitro diagnostics for qualitative, semi-quantitative or quantitative determinations;

the type of sample to be analyzed;

prescribing medical device for in vitro diagnosis with indication of the user (for example, a patient, a medical specialist, an individual using medical device according to the prescription determined by the manufacturer);

information on the purpose of the medical device for in vitro diagnostics for clinical laboratory diagnostics and (or) for self-testing;

information on the purpose of the medical device for in vitro diagnostics for disposable use;

special requirements for premises, special training or special qualifications of the user and (or) third persons (if necessary).

4) for medical devices for in vitro diagnostics intended for use in combination with other medical devices, including medical devices for in vitro diagnostics - information for the identification of medical devices in order to obtain a safe combination and/or information on known limitations on the joint use of medical devices;

5) information on the shelf life and storage conditions of a medical device: information on special storage conditions (air temperature and humidity, lighting) and (or) user handling of a medical device in vitro;

6) information on special transportation conditions;

information on the stability characteristics of the medical device for in vitro diagnostics (storage conditions, shelf life after the first opening of the primary container), as well as storage conditions and stability of working solutions (if necessary);

information on sterile condition, sterilization method and procedure in case of violation of sterile packaging (if medical device for in vitro diagnostics is supplied in sterile form);

7) information for users (warnings, precautions, limitations when using a medical device for in vitro diagnostics):

warning, precautions and/or measures taken in the event of malfunction or abnormalities in the functioning of the medical device for in vitro diagnostics determined by external signs;

prevention, precautions and/or measures taken with respect to predictable externalities such as external electromagnetic fields, electrostatic discharges, radiation, atmospheric pressure and pressure drops, humidity and air temperature;

prevention associated with in vitro diagnostic medical device materials that shall be carcinogenic, mutagenic or toxic, or result in sensitization, allergic reaction, or adversely affect reproductive function;

prevention, precautions and/or measures taken with respect to potentially infectious material contained in a medical device for in vitro diagnostics;

information on the proper treatment of the medical device for in vitro diagnostics for reuse, including cleaning, disinfection, packaging and, if necessary, a method of re-sterilization (if the medical device for in vitro diagnostics is for reusable use);

8) prevention and/or special precautions with regard to the safe disposal of the medical device for in vitro diagnostics and accessories (if available), which, if necessary, should cover the following factors:

infectious or microbial risks, including the possibility of contamination of consumables by infectious agents of human origin;

environmental risks associated with potentially hazardous materials and substances;

physical risks, including the possibility of explosion or fire;

9) information on conditions required for collection, processing and preparation of samples, data on stability of analyzed samples, including storage conditions and duration, transportation conditions, restrictions on freezing (defrosting) cycles;

10) detailed information on preparation for use of the medical device for in vitro diagnostics;

information necessary to verify the correct installation of the medical device for in vitro diagnostics and its readiness for safe operation as specified by the manufacturer, indicating the following information:

the need for calibration to ensure proper and safe operation of the medical device for in vitro diagnostics during its lifetime;

methods for mitigating the risks of installing, calibrating or maintaining a medical device for in vitro diagnostics;

11) recommendations on quality control procedures if necessary;

traceability information of values specified for calibrators or control materials, which shall be provided by available reference measurement methods (s) and/or benchmarks;

12) test procedure, including calculations and interpretations of test results, and, if necessary, information on the feasibility of conducting supporting tests;

characteristics of analytical effectiveness: sensitivity, specificity, correctness, repeatability , reproducibility, detection limit (detection) and measurement range, including information on the influence of known interferents, limitations of the method and the use of available reference materials and analysis methods (as applicable);

characteristics of clinical effectiveness: diagnostic sensitivity and diagnostic specificity (if necessary);

biological reference interval, if necessary;

information on interfering substances or limitations associated with the breakdown that may affect the outcome of the study;

13) with respect to an in vitro diagnostic medical device intended for self-testing by the user or testing in the vicinity of the user, also the following information:

detailed information on the test procedure (preparation of reagents, sampling (preparation) , procedure of performance and interpretation of test results)

recommendations for user actions in the event of a positive, negative, or undefined test result

information on test errors and the possibility of obtaining false positive or false negative test results, as well as on factors affecting the test result;

information about the inadmissibility of the user making medical decisions without prior consultation with a medical specialist;

information about the need to send a message to the manufacturer or its authorized representative about unwanted events that have signs of an adverse event (incident).

14) information about the manufacturer of the medical device for in vitro diagnostics and its authorized representative, including:

full and abbreviated (if any) name, legal, actual) address and contact details (telephone, fax, e-mail) of the manufacturer;

full and abbreviated (if any) name, legal, (actual) address and contact details (telephone, fax, e-mail) of the authorized representative of the manufacturer in the territory of the Republic of Kazakhstan;

name and contact details (telephone, fax, e-mail) of the organization receiving, claims (proposals) for medical devices for in vitro diagnostics from consumers in the territory of the Republic of Kazakhstan;

name and contact details (telephone, fax, e-mail) of the organization responsible for post-registration surveillance of the safety of the medical device for in vitro diagnostics in the territory of the Republic of Kazakhstan.

15) data on the issue or last revision of the instruction for use.

8. The instruction shall not allow recommendations on the use of medical devices from a particular manufacturer.

9. The text of the MD instruction shall be drawn up in Kazakh and Russian, shall be clear and understandable with indication of the sequence of actions for use. It shall be allowed to use separate information for professional and non-professional users.

The text of the MD instruction shall correspond to the following:

headings and subheadings shall be arranged uniformly and in bold;

pictures and (or) pictograms (if necessary) shall be provided.

10. The MD instruction shall be provided to the user on paper or in electronic form, both together with and separately from the medical device, including by placing information on a screen that shall be part of the medical device. The chosen method of providing the use instruction shall be suitable and accessible to users. If an instruction is provided on a medium other than paper, the manufacturer shall place information on how to obtain it:

1) viewing the instructions for use ;

2) obtaining an up-to-date version of the instructions for use;

3) obtaining a paper version of the instructions for use.