

On approval of the Rules for labeling of medicinal products and medical devices

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan dated January 27, 2021 No . ҚР DSM-11. Registered with the Ministry of Justice of the Republic of Kazakhstan on February 2, 2021 No. 22146.

Unofficial translation

Footnote. The title as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 30.05.2022 № ҚР ДСМ-49 (shall be enforced upon expiry of sixty calendar days after its first official publication).

In accordance with paragraph 4 of Article 242 of the Code of the Republic of Kazakhstan "On Public Health and Healthcare System" and subparagraph 2) of Article 7-2 of the Law of the Republic of Kazakhstan "On regulation of trading activities" **I HEREBY ORDER:**

Footnote. The preamble as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 30.05.2022 № ҚР ДСМ-49 (shall be enforced upon expiry of sixty calendar days after its first official publication).

1. To approve:

1) Rules for labeling and traceability of medicinal products according to Annex 1 to this Order;

2) Rules for labeling of medical devices according to Annex 2 to this Order.

Footnote. Paragraph 1 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 30.05.2022 № ҚР ДСМ-49 (shall be enforced upon expiry of sixty calendar days after its first official publication).

2. To recognize as invalid:

1) order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated April 16, 2015 № 227 "On approval of the Rules for labeling of medicinal products and medical devices" (registered in the Register of State Registration of Regulatory Legal Acts under № 11088, published on June 5, 2015 in the information and legal system "Adilet");

2) order of the Minister of Healthcare of the Republic of Kazakhstan dated April 22, 2019 № KR DSM-44 "On introduction of amendments to some orders of the Ministry of Healthcare of the Republic of Kazakhstan and the Ministry of Healthcare and Social Development of the Republic of Kazakhstan" (registered with the Register of State Registration of Regulatory Legal Acts under № 18582, published on May 2, 2019 in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan).

3. The Committee of medical and pharmaceutical control of the Ministry of Healthcare of the Republic of Kazakhstan, in accordance with the procedure established by the legislation 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 with the Ministry of Justice of the Republic of Kazakhstan, submit to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan of information on the implementation of the 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 day of its first official publication.

*Minister of Healthcare
of the Republic of Kazakhstan*

A. Tsoy

Annex 1
to the order of the Minister
of Healthcare of the
Republic of Kazakhstan
dated January 27, 2021
№ KR ДСМ-11

Rules for labeling and traceability of medicinal products

Footnote. The Rules as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 30.05.2022 № ҚР ДСМ-49 (shall be enforced upon expiry of sixty calendar days after its first official publication).

Chapter 1. General provisions

1. These Rules for labeling and traceability of medicinal products (hereinafter referred to as the Rules) have been developed in accordance with paragraph 4 of Article 242 of the Code of the Republic of Kazakhstan "On Public Health and Healthcare System" (hereinafter referred to as the Code) and subparagraph 2) of Article 7-2 of the Law of the Republic of Kazakhstan "On regulation of trading activities" (hereinafter referred to as the Law on regulation of trading activities) and shall determine the procedure for labeling and traceability of medicinal products in the Republic of Kazakhstan.

2. The following concepts shall be used in these Rules:

1) business identification number (hereinafter referred to as the BIN) - a unique number generated for a legal entity (a branch and a representative office) and an individual entrepreneur carrying out activities in the form of joint entrepreneurship;

2) a single distributor - a legal entity, carrying out activities within the guaranteed volume of free medical care (hereinafter referred to as the GVoFMC) and (or) in the system of compulsory social medical insurance (hereinafter referred to as the CSMI), in accordance with Article 247 of the Code;

3) authorized body in the field of healthcare (hereinafter referred to as the authorized body) - a central executive body exercising management and inter-sectoral coordination in the field of healthcare of citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, circulation of medicinal products and medical devices, quality of medical services (assistance);

4) bulk product of a medicinal product - a dosed medicinal product that has passed all stages of the technological process with the exception of the final packaging;

5) packaging of the medicinal product - a product or a complex of products that ensure the process of circulation of medicinal products by protecting them from damage and loss, as well as protecting the environment from pollution.

Packaging shall consist of primary (internal), intermediate (if any) and secondary (external or consumer) packaging:

primary (internal) packaging - packaging directly in contact with the medicinal product;

intermediate packaging - a package in which the primary packaging shall be placed for the purpose of additional protection of the medicinal product or based on the characteristics of the use of the medicinal product;

secondary (external or consumer) packaging - packaging in which the medicinal product shall be placed in the primary and intermediate packaging;

transport package - a package combining sets of homogeneous (within one GTIN (GTIN) commodity code) secondary (and in their absence - primary) consumer packages of medicinal products used for storage and transportation in order to protect them from damage during movement and forming an independent transport unit. A transport package includes transport packages of smaller size (volume);

6) the state body in the field of circulation of medicinal products and medical devices (hereinafter referred to as the state body) - the state body leading in the field of circulation of medicinal products and medical devices, control over circulation of medicinal products and medical devices;

7) state expert organization in the field of circulation of medicinal products and medical devices (hereinafter referred to as the expert organization) - a state monopoly entity carrying out production and economic activities in the field of healthcare to ensure the safety, effectiveness and quality of medicinal products and medical devices;

- 8) subjects in the sphere of circulation of medicinal products and medical devices - individuals or legal entities carrying out pharmaceutical activities;
- 9) manufacturer of medicinal products - an organization engaged in the production of medicinal products and having a license for the production of medicinal products;
- 10) trade name of medicinal product - name under which the medicinal product is registered;
- 11) individual identification number (hereinafter referred to as the IIN) – a unique number, generated for an individual, including individual entrepreneurs, operating in personal business;
- 12) material carrier - a control (identification) sign or an object made of any materials, which contains or does not contain anti-counterfeiting elements (means) and is intended for application, storage and transmission of the means of identification;
- 13) means of identification - a unique sequence of symbols in machine-readable form, represented in the form of a bar code, or recorded on a radio-frequency tag, or represented using another means (technology) of automatic identification;
- 14) batch number - a distinctive combination of numbers, letters and (or) symbols that allows to specifically identify a batch of medicinal product and determine the complete sequence of manufacturing and control operations, as well as to trace the realization of the medicinal product;
- 15) sticker (sticker) - a storage medium on which the marking with information for the consumer in the state and Russian languages shall be applied, attached to the secondary packaging by gluing;
- 16) labeling - information applied to the packaging of the medicinal product, containing, in addition, means of identification;
- 17) trademark, service mark (hereinafter referred to the trademark) - a designation registered in accordance with the Law of the Republic of "On trademarks, service marks and names of goods' places of origin" " or protected without registration by virtue of international treaties in which the Republic of Kazakhstan participates, which serves to distinguish goods (services) of some legal entities or individuals from homogeneous goods (services) of other legal entities or individuals;
- 18) Information system (hereinafter referred to as the IS) – Organizationally arranged set of information and communication technologies, service personnel and technical documentation, implementing certain technological actions through information interaction and designed to solve specific functional tasks;
- 19) single operator of marking and traceability of goods (hereinafter referred to as the Operator) - a legal entity established in accordance with the legislation of the Republic of Kazakhstan, which carries out development, administration, maintenance and operational

support of the information system of marking and traceability of goods, including development, maintenance and updating of the National Catalogue of Goods, and other functions determined by the Government of the Republic of Kazakhstan;

20) fiscal data operator - a legal entity that ensures the transmission of data on cash settlements in operational mode to the tax authorities via public telecommunication networks, determined by the state body in charge of ensuring the collection of taxes and payments to the budget, in coordination with the authorized body in the field of informatization;

21) Electronic digital signature (hereinafter referred to as the EDS) - a set of electronic digital symbols created by means of electronic digital signature and confirming reliability of an electronic document, its belonging and invariability of its content;

22) traceability of medicinal products - Organization of accounting of medicinal products subject to traceability and operations related to their circulation using the information system for labeling and traceability.

3. Mockup of labeling of packages, labels and stickers for medicinal products shall be registered by a state body during state registration of the medicinal product in the Republic of Kazakhstan, carried out in accordance with the Rules for state registration, re-registration of a medicinal product or a medical device, amendments to registration dossier of a medicinal product or a medical device, approved by the order of the Minister of Healthcare of the Republic of Kazakhstan dated February 9, 2021 № ҚР ДСМ-16 "On approval of the Rules for state registration, re-registration of a medicinal product or a medical device, amendments to registration dossier of a medicinal product or a medical device" (registered in the Register of State Registration of Regulatory Legal Acts under № 22175).

4. Information on the organization accepting claims (proposals) on the quality of medicinal products in the Republic of Kazakhstan shall be indicated in the instructions for medical use of medicinal products.

Chapter 2. Procedure for labeling medicinal products

5. Labeling of medicinal products shall be applied by the manufacturer (or packaging company) of medicinal products for each packaging unit (primary, intermediate, secondary) in Kazakh and Russian languages.

At the same time, marking of medicinal products with means of identification shall be carried out by participants of medicinal products turnover in accordance with paragraph 2 of this Chapter of the Rules during medicinal products turnover, including purchase (acquisition), storage, importing into the territory of the Republic of Kazakhstan, production, marking, transportation, sale of medicinal products.

Participants of medicinal products turnover (hereinafter referred to as the PoMPT) shall be entities in the sphere of circulation of medicinal products and medical devices, representative offices and (or) branches of foreign manufacturers of medicinal products, authorized individuals and legal entities of foreign manufacturers, holders of registration

certificates and foreign manufacturers of medicinal products, as well as subsidiary organizations of foreign manufacturers of medicinal products.

The labeling on the packaging shall be the same for each batch of medicinal products, at the same time, labeling with means of identification shall be individual for each packaging.

Labeling of medicinal products shall not contradict or distort the information contained in the registration dossier documents and shall not be advertising in nature.

According to the decision of PoMPT, it shall be allowed to apply the following on the packaging of the medicinal product:

1) holographic and protective signs, duplicate the labeling text using Braille (for persons with visual disabilities), symbols or pictograms that help explain the information to the consumer;

2) the text of the instructions for medical use for packaging of a medicinal product dispensed without a doctor's prescription;

3) additional text of labeling in other languages, provided that the information shall be fully identical;

4) barcode (if any).

The color design of the packaging of a medicinal product of the same dosage form containing different amounts of active substances shall vary.

6. Labeling of medicinal products with means of identification shall be carried out in accordance with the requirements of these Rules:

1) when medicinal products are manufactured in the territory of the Republic of Kazakhstan - in places of production of medicinal products prior to transportation and (or) sales;

2) when importing medicinal products, including import of medicinal products registered and unregistered in the Republic of Kazakhstan, imported in accordance with the Rules of import, export to the territory of the Republic of Kazakhstan from the territory of states that are not member states of the Eurasian Economic Union - in the territory of third countries, before import to the territory of the Republic of Kazakhstan and (or) in customs warehouses that comply with the standard of good distribution practice, before placing such medicinal products under the customs procedures of exportation;

3) when importing medicinal products into the territory of the Republic of Kazakhstan from the territory of the member states of the Eurasian Economic Union - outside the state border of the Republic of Kazakhstan, including when importing medicinal products registered and not registered in the Republic of Kazakhstan, imported according to the Rules of importing of medicinal products and medical devices into the territory of the Republic of Kazakhstan and provision of the state service "Issuance of approval and (or) conclusion (authorization document) for import (export) of registered and not registered medicinal products", approved by Annex 1 to the order of the Minister of Healthcare of the Republic of Kazakhstan dated December 8, 2020 № ҚР ДСМ-237/2020 "On Approval of the Rules for

importing into the territory of the Republic of Kazakhstan and exporting from the territory of the Republic of Kazakhstan of medicinal products and medical devices and provision of the state service "Issuance of approval and (or) conclusion (authorization document) for import (export) of medicinal products and medical devices registered and not registered in the Republic of Kazakhstan" (registered in the Register of State Registration of Regulatory Legal Acts under № 21749) (hereinafter referred to as the Rules for Import).

Labeled medicinal products are medicinal products, which are labeled with means of identification in compliance with the requirements of these Rules, and information about which is contained in IS labeling and traceability of goods, designed for information support of the processes of labeling of goods with means of identification and their further traceability in the process of circulation (hereinafter referred to as the IS LTG).

7. Labeling of medicinal products with means of identification shall not apply to:

1) medicinal products intended for the treatment of passengers and members of vehicle crews, train crews and drivers of vehicles arriving in the customs territory of the Eurasian Economic Union;

2) medicinal products necessary for the treatment of participants of international cultural, sporting events and participants of international expeditions;

3) medicinal products manufactured in pharmacies;

4) pharmaceutical substances (active pharmaceutical substances) produced under conditions of good manufacturing practice;

5) pharmacopoeial medicinal plant raw materials, including as part of collections and consumer packaging;

6) medicinal products produced in the Republic of Kazakhstan for export only;

7) exhibition samples of medicinal products and medical devices necessary for holding exhibitions without the right of their further realization;

8) samples of medicinal products received for preclinical (non-clinical) and clinical studies and (or) trials;

9) radiopharmaceutical medicinal products manufactured directly in healthcare organizations at the place of their use;

10) samples of medicinal products required for expert examination during state registration;

11) medicinal products of advanced therapy, produced for individual use using autologous biological materials of the patient or his/her donor, selected directly for him/her;

12) medicinal products manufactured and (or) imported before the introduction of labeling and traceability of medicinal products, which are stored and sold before expiration date;

13) cases, provided for in Article 8 of the Agreement on Marking Goods with Means of Identification in the Eurasian Economic Union, ratified by the Law of the Republic of

Kazakhstan "On Ratification of the Agreement on Marking Goods with Means of Identification in the Eurasian Economic Union".

8. Expert organization in conducting expertise of medicinal product in accordance with the Rules for Expert Examination of Medicinal Products approved by the order of the Minister of Healthcare of the Republic of Kazakhstan dated January 27, 2021 № ҚР ДСМ-10 "On approval of the Rules for expertise of medicinal products and medical devices" (registered in the Register of State Registration of Regulatory Legal Acts under № 22144), shall verify the authenticity of translation or translation into the Kazakh language of the general characteristics of the medicinal product, instructions for medical use (leaflet-insert), package marking mockups, labels, stickers with labeling.

9. The packaging shall be marked with clear, legible, easily visible and indelible letters, a well-readable font and maintained for the entire shelf life of the medicinal product subject to compliance with the specified storage conditions.

10. Labeling of secondary packaging, and in its absence - primary packaging shall include the following information:

- 1) trade name of the medicinal product;
- 2) international non-proprietary name (if any) in Kazakh, Russian and English;
- 3) name of the manufacturer of the medicinal product, address. The name of the manufacturing organization and its address shall be indicated in full or in short (city, country). The trademark shall be indicated if it is granted legal protection in the Republic of Kazakhstan.

If the manufacturer of the medicinal product shall not be its packer, the name of the packer, the date and time of packaging shall be indicated;

- 4) the name of the marketing authorization holder, its address (city, country);
- 5) dosage form;
- 6) dosage, and/or activity, and/or concentration (if applicable) of the active pharmaceutical substance (active pharmaceutical substances);
- 7) amount of the medicinal product in the package by weight, volume or number of dosage units depending on the dosage form and type of package;
- 8) information on the composition of the medicinal product;
- 9) for medicinal herbal products, which are packaged medicinal herbal raw materials, the mass of medicinal herbal raw materials and/or active pharmaceutical substance of plant origin shall be indicated at their certain humidity;
- 10) for medicinal products containing substances subject to control in accordance with the Law of the Republic of Kazakhstan "On narcotic medicinal products, psychotropic substances, their analogues and precursors and measures to counter their illegal trafficking and abuse" (hereinafter referred to as the Law), the names of these substances and their content in units of weight or percentage shall be indicated.

In single-component medicinal products, subject to the authenticity of the name of the medicinal product and the active pharmaceutical substance and the indication of its dosage, concentration, activity, the composition of the active pharmaceutical substance shall not be indicated;

11) list of excipients:

the list of all excipients for parenteral, ocular and external medicinal products shall be indicated;

for infusion solutions, the qualitative and quantitative composition of all excipients shall be indicated;

for other dosage forms, the list of antimicrobial preservatives, dyes, as well as sugars and ethanol shall be indicated;

the list of excipients indicated during the labeling of medicinal products for oral administration shall be given in Annex 1 to these Rules;

12) for infusion solutions containing more than one active pharmaceutical substance, the value of osmolarity and/or osmolality shall be indicated;

13) the mode of use and depending on the dosage form, the route of administration (the method of use for tablets and capsules intended for oral administration shall not be indicated);

14) precautions;

15) warning signs;

16) storage conditions, storage features and, if necessary, transportation conditions;

17) conditions of dispensing (on prescription or without a doctor's prescription);

18) batch number;

19) production date;

20) shelf life: "valid to (day, month, year)" or "(day, month, year)";

Specify the shelf life "valid to (month, year)" or "(month, year)," while the shelf life is determined until the last day of the specified month inclusive;

21) registration number of the medicinal product in the form of the designation "RK-MP-";

22) barcode (if any);

23) means of identification or material carrier, containing the means of identification.

11. The primary packaging enclosed in the secondary packaging shall indicate:

1) trade name of the medicinal product, indicating dosage, activity or concentration;

2) international non-proprietary name (if any) in the state, Russian and English languages;

3) the name of the manufacturing organization of the medicinal product and (or) its trademark;

4) batch number;

5) expiry date "month, year" or "day, month, year".

Пазм Additional information identical to the information printed on the secondary package shall be placed.

Intermediate packaging, which does not allow reading the information on the primary packaging without violating its integrity, repeats the information indicated on the primary packaging.

12. When marking a primary package of small size (the area of one side does not exceed 10 sm²) embedded in a secondary package (on an ampoule, an insulin vial, a syringe tube, a tube dropper, a cartridge, a syringe pen), in accordance with paragraph 32 of the Technical Regulations "Product Labeling Requirements," approved by the order of the Minister of Trade and Integration of the Republic of Kazakhstan dated May 21, 2021 № 348-HK "On approval of the technical regulations"Product Labeling Requirements" (registered in the Register of State Registration of Regulatory Legal Acts under № 22836) the following shall be specified:

- 1) trade name of the medicinal product, indicating dosage, activity or concentration;
- 2) weight or volume;
- 3) batch number;
- 4) shelf life "month, year".

13. The composition of homeopathic medicinal products shall be indicated according to the terminology adopted in homeopathy: the names of homeopathic pharmaceutical substances shall be given in Latin with an indication of the scale and degree of their dilution, the names of excipients, shall be given according to the registration dossier documents.

14. For medicinal herbal products, which are packaged medicinal herbal raw materials, the composition shall be indicated only for collections and the procedure for preparing aqueous extracts is given, indicating the storage conditions and shelf life of the aqueous extraction.

15. Ampoules containing narcotic medicinal products, psychotropic substances listed in Table II of the List of narcotic medicinal products and psychotropic substances, used for medical purposes and under strict control, approved by the Resolution of the Government of the Republic of Kazakhstan dated July 3, 2019 № 470 "On Approval of the list of narcotic drugs, psychotropic substances and precursors subject to control in the Republic of Kazakhstan, the Summary Table on the classification of narcotic drugs, psychotropic substances, their analogs and precursors found in illicit trafficking to small, large and especially large sizes, the List of substituents of hydrogen atoms, halogens and (or) hydroxyl groups in the structural formulas of narcotic drugs, psychotropic substances", specified in the Law, shall have a clearly visible double red stripe on the capillary.

16. When labeling a bulk product of a medicinal product manufactured by foreign manufacturing organizations and packaged in packaging (primary, secondary) by the manufacturing organization of the Republic of Kazakhstan, the following shall be additionally indicated on the secondary, and in case of its absence – on the primary packaging:

- 1) name, trademark of a foreign manufacturer, country of the bulk product of the medicinal product;

2) batch number of the packaged medicinal product, assigned by the manufacturing organization who performed the packaging, taking into account the date of manufacture of the bulk product of the medicinal product;

3) shelf life, which shall be calculated from the date of manufacture of the bulk product of the medicinal product.

17. When labeling a kit of medicinal product with a solvent on the secondary packaging, the name, volume, concentration, composition, and batch number of the solvent should be additionally indicated. The shelf life shall be indicated by the shortest shelf life of the component (medicinal product, solvent) included in the kit.

18. The following inscriptions shall be applied on the packaging (secondary and/or primary) of the medicinal product:

1) "For children" - for medicinal products intended for children;

2) "Homeopathic remedy" - for homeopathic medicinal products;

3) "The products have passed radiation control and are safe" - for medicinal plant raw materials;

4) "The medicinal product has passed control and is safe in relation to viruses transmitted by parenteral route, including human immunodeficiency viruses (types 1 and 2) and hepatitis B and C" - for medicinal products obtained from human organs and (or) tissues;

5) "Parapharmaceuticals" - for parapharmaceuticals.

19. Medicinal products derived from genetically modified sources have corresponding labels: "Genetically modified" or "Based on genetically modified sources," or "Containing components derived from genetically modified sources".

20. The labeling on the packaging of the medicinal product (secondary and, if necessary, primary), requiring special conditions for storage, handling and use, shall include the following warning labels:

"Keep out of reach of children";

"Sterile" - for sterile medicinal products;

"No antibodies to human immunodeficiency virus" "No antibodies to hepatitis viruses" - for medicinal products obtained from human blood;

on the inclusion of bags (tablets) with a desiccant in the primary packaging of the medicinal product;

for parenteral medicinal products, the method (route) of administration ("Intravenous," "Intramuscular," "For infusions," "Subcutaneous") shall be indicated, if the medicinal product is administered by three or more methods it is allowed to indicate "For injections".

On the primary packaging, the method (route) of administration shall be indicated in abbreviations ("Intravenous (IV)," "Intramuscular (IM)," "Subcutaneous (SC)," "For injection (F/I)" - if three or more routes of administration are allowed for the medicinal product;

explaining safety requirements, precautions for transportation, storage and use:

"Shake before use"; "Handle with care"; "Keep away from fire," "Do not freeze" (if necessary).

If bags (or tablets) with a desiccant are present in the intermediate or secondary packaging of the medicinal product, warning labeling of the corresponding content shall be applied to them.

21. For radiopharmaceutical medicinal products, the packaging (primary and secondary) shall be labeled in accordance with the Law of the Republic of Kazakhstan "On Radiation safety of the population" and the Law of the Republic of Kazakhstan "On the use of atomic energy" and shall meet the following requirements:

1) the labeling on the protective container further explains the coding given on the primary packaging, indicates the number of units of radioactivity in a dose or in the primary packaging for a given time period and date, as well as the number of units of the dosage form (capsules) or the volume of the liquid dosage form in milliliters;

2) labeling of primary packaging shall contain the following information:

trade name or code of the medicinal product, including the name or chemical symbol of the radionuclide;

batch number and shelf life;

international symbol of radioactivity;

name and address of the manufacturing organization of the medicinal product;

number of radioactivity units in accordance with the approved regulatory document.

22. The labeling of medical immunobiological preparations, in addition to the information specified in paragraphs 10, 11, 12 of these Rules, has the following additional information characterizing this immunobiological preparation:

1) for immune sera, shall indicate:

group name (e.g. serum, immunoglobulin) with specificity;

species origin (human or animal species used for production);

production technology (e.g. purified, concentrated);

physical condition (liquid, dry);

dosage;

shelf life ("number, month, year" shall be indicated), shall not be indicated on primary packaging with a volume of 1 milliliter and less, embedded in secondary packaging;

for multi-dose packages - conditions and period of use after the first opening;

name and dose of any antimicrobial preservative or other adjuvant contained in the immune serum;

name of the excipient capable of causing a side reaction;

contraindications when used;

2) for lyophilic-dried immune sera:

the name or composition and the amount of solvent required;

indication of the need for immediate use after dilution or conditions and period of use after rehydration;

3) for vaccines:

group name indicating the word "Vaccine" and specificity;

production technology (e.g. culture, allantoic, recombinant, purified, concentrated, adsorbed);

biological state (living, inactivated);

physical condition (liquid, dry);

name and amount of antimicrobial preservative (if necessary);

name of the antibiotic, adjuvant, flavor or stabilizer present in the vaccine;

name of the excipient capable of causing any adverse reaction and contraindications when used;

for multi-dose primary packages - conditions and period of use after the first opening;

4) for lyophilized vaccines, in addition to the information specified in subparagraph 3) of this paragraph, shall indicate:

name (or composition) and volume of the liquid or liquid components of the complex vaccine added to the lyophilizate;

conditions and period of administration of the vaccine after dissolution;

5) for allergenic medicinal products:

biological activity and/or protein content and/or extract concentration;

name and amount of antimicrobial preservative added;

for multi-dose primary packages - conditions and period of use after the first opening;

6) for lyophilized allergenic preparations, in addition to the information specified in subparagraph 5) of this paragraph, shall indicate:

name, composition and volume of liquid added for rehydration;

storage conditions and the period of time during which the product shall be used after rehydration;

sterility information (for non-sterile products not specified);

the name and quantity of the adsorbent;

7) for treatment and prophylactic phages:

name, composition and activity of phages;

for multi-dose primary packages - conditions and period of use after the first opening;

for multicomponent medicinal products - specificity and activity of each phage;

8) for diagnostic immunobiological products: group name (for example, diagnosticum, antigen, diagnostic serum);

indications for use, indicating the infection, causative agent or antigen, for the diagnosis of which and with the help of which methods (methods) shall be used;

the nature and technology of producing the active ingredient;

designation of antigens, antibodies, phages in the composition;

physical condition (liquid, dry);

for serum, the following is additionally indicated: species, group, monoclonal, polyvalent.

23. Medicinal products manufactured in a pharmacy shall be dispensed to the population in primary packaging with an appropriate label containing information for the consumer in the state and Russian languages and a decorated medical emblem (a bowl with a snake) in accordance with paragraphs 25-31, 61-62 of these Rules.

24. Each label shall have a corresponding designation depending on the method of use of the medicinal product. Labels with corresponding inscriptions shall be divided into:

- 1) labels for medicinal forms of internal use: "Internal," "Internal children's";
- 2) labels for medicinal forms of external use: "External";
- 3) labels for parenteral dosage forms: "For injection";
- 4) labels for eye medicinal products: "Eye drops," "Eye ointment".

25. To reduce the risk of errors when dispensing the medicinal product on the label, signal colors in the form of a colored stripe on a white background shall be used:

- 1) on labels for internal medicinal forms - green;
- 2) on labels for dosage forms of external use - orange;
- 3) on labels for eye medicinal products - pink;
- 4) on the labels for parenteral dosage forms - blue.

26. Depending on the dosage form, labels for internal or external use shall be divided into the following types: "Mixture," "Drops," "Powders," "Ointment," "Nasal drops," "Eye drops," "For injection".

27. The following information shall be indicated on the labels for the design of individual medicinal products:

- 1) name of the pharmacy;
- 2) location (legal address) of the pharmacy;
- 3) prescription number;
- 4) Full name (if any) of the patient;
- 5) designation depending on the dosage form and method of use in accordance with

paragraphs 25, 28 and 29 of these Rules;

6) detailed method of use:

for mixtures: " ____ spoon ____ times a day ____ meal";

for internal drops: " ____ drops ____ times a day ____ meal ";

for powders: " ____ powder ____ times a day ____ meal ";

for eye drops: " ____ drops ____ times a day eye ____ ";

for other dosage forms, as well as those used externally, space shall be left to indicate the method of use;

- 7) date of manufacture;
- 8) shelf life (number of days);
- 9) price;

10) warning inscription "Keep out of the reach of children".

Labels for mixtures, drops for internal use, ointments, eye drops, eye ointments, in addition to the listed designations, shall bear the designations given in paragraphs 8, 12, as well as the appropriate precautionary notes given in paragraph 11, 52 of these Rules.

28. The following information shall be additionally indicated on the labels of various types of dosage forms:

1) intended for injection - the route of administration of the medicinal product: "Intravenous," "Intravenous (drip)," "Intramuscular," "Subcutaneous";

2) intended for therapeutic enemas: "For enemas";

3) intended for disinfection: "For disinfection," "To handle with care";

4) intended for children: "Children's";

5) intended for newborns: "For newborns";

6) series.

29. In addition to the information specified in paragraphs 27, 28 of these Rules, the labels for registration of medicinal products manufactured for medical organizations shall indicate:

1) the name of the medical organization for which they are intended;

2) name of the department;

3) signature of the person who prepared, checked and released the medicinal product ("prepared _____"; "checked _____"; "dispensed _____");

4) analysis number;

5) composition of the dosage form.

30. All pharmacy labels shall be printed with warning labels corresponding to each dosage form:

1) for mixtures: "Store in a cool and keep away from sunlight," "Shake before use";

2) for ointments, eye ointments and eye drops, suppository: "Store in a cool place and keep away from sunlight";

3) for injections and infusions: "Sterile";

4) requiring special conditions of storage, handling and use are formalized with additional labels "Handle with care"; "keep away from fire".

31. Dosage forms containing poisonous substances (mercury dichloride, mercury cyanide, mercury oxyanide) shall be decorated with a black warning label with an image of a skull and crossed bones and with an inscription in white in the font "Poison" and "Handle with care" The label shall indicate the name of the poisonous substance and its concentration.

Section 1. Procedure for formation of means of identification

32. Means of identification of a medicinal product, contains a labeling code, representing a unique sequence of symbols, including 4 groups of data identified by the application codes provided by the standard of the international organization in the field of standardization of accounting and bar coding of logistic units GS1 (GS1) Data Matrix (Data Matrix).

In this case, at the beginning of the labeling code line there is a sign of bar code format symbols of the international organization in the field of standardization of accounting and bar coding of logistic units GS1 (GS1), FNC1 (FNC1), ASC232 (ASC 232).

The first 2 groups of labeling code data form the product identification code:

the first group shall be identified by application code 01 and shall contain the product code GTIN (GTIN) of the consumer package consisting of 14 digits;

the second group shall be identified by application code 21 and contains the individual serial number of the consumer package of medicinal products consisting of 13 characters of numeric or alphanumeric sequence (letters of the Latin alphabet). A special ASCII (ASCII) delimiter character 29 shall be used as a termination for this group;

The labeling code verification code shall be formed by the third and fourth data groups:

the third group shall be identified by application code 91 and shall contain the identifier (individual serial number) of the verification key consisting of 4 characters (digits, lowercase and uppercase letters of the Latin alphabet) formed by the Operator as part of the verification code. A special ASCII delimiter character (ASCII) is used as a termination for this group;

the fourth data group shall be identified by application code 92 and shall contain the value of the verification code consisting of 44 characters (digits, lowercase and uppercase letters of the Latin alphabet, as well as special characters) generated by the Operator as part of the verification code.

33. Formation of means of identification by the Operator shall be carried out in IS LTG, after registration and signing of PoMPT contracts in IS LTG by means of EDS.

34. Registration of PoMPT in IS LTG and granting access to the personal account shall be carried out by the Operator on the basis of the application for registration in IS LTG, signed by EDS of the manager or individual entrepreneur.

PoMPT that are not residents of the Republic of Kazakhstan, for registration in IS LTG shall use EDS that meets the requirements of the Law of the Republic of Kazakhstan "On Electronic Document and Electronic Digital Signature".

35. PoMPT shall be refused to register with IS LTG in the following cases:

1) IIN (BIN) or taxpayer identification (individual) number or its international analog (hereinafter referred to as the TIN), which is a unique taxpayer number of a non-resident legal entity of the Republic of Kazakhstan, assigned (issued) by the tax service in the country of registration of PoMPT, specified upon receipt of EDS, do not correspond to the information specified upon registration in IS LTG;

2) PoMPT is already registered in IS LTG.

36. In case of PoMPT registration in IS LTG, the Operator within 1 (one) calendar day from the date of PoMPT registration shall:

1) include the PoMPT in the list of registered PoMPTs in IS LTG;

2) provide access to the personal cabinet of IS LTG to PoMPT.

37. Registration of medicinal products in IS LTG shall be carried out by PoMPTs making a request for labeling codes to ensure labeling of medicinal products with means of identification, according to Annex 2 of the Rules.

38. The composition of the data of the product card intended for registration of the medicinal product in IS LTG shall be provided to the Operator by the state authority.

39. For registration in IS LTG of a medicinal product card having state registration in the Republic of Kazakhstan, information shall be entered in accordance with the data composition of the medicinal product card provided by the state body on the basis of information registered in the State Register of Medicinal Products and Medical Devices.

40. PoMPT shall automatically refuse to register medicinal products in IS LTG in the following cases:

1) the medicinal product with the product code GTIN declared during registration is already registered in IS LTG;

2) the product code GTIN (GTIN) according to the information system of the association GS Kazakhstan (GS Kazakhstan) is not subject to PoMPT;

3) according to the data of the information system of the international organization GS1 (GS1) the code of goods GTIN (GTIN) does not exist.

The PoMPT registering the medicinal product shall ensure that the medicinal product data entered into the IS LTG at the time of registration is accurate.

41. According to the results of medicinal product registration the Operator within 3 (three) working days includes the submitted information in the IS LTG product register and transfers all registration data to the IS of the authorized body.

42. To ensure labeling of medicinal products with PoMPT identification means through LToG, IS sends to the Operator a request for obtaining labeling codes in the form according to Annex 2 to these Rules (hereinafter referred to as the request).

43. It shall be automatically refused to issue the labelling codes in the following cases:

1) PoMPT is not registered in IS LTG;

2) the submitted goods identification code has been previously registered in IS LTG;

3) the goods code GTIN (GTIN) is not registered in the goods register of IS LTG and (or) is not subject to PoMPT;

4) the product code GTIN (GTIN) does not correspond to the product group "Medicinal products".

44. If the information specified in the request complies with the requirements set forth in these Rules, the Operator shall, within 1 (one) working day from the date of sending the request for labeling codes to PoMPT:

1) issues (generates) for the number of labeling codes specified in the request using cryptographic protection algorithms based on the data received from PoMPT;

2) includes the corresponding codes of goods identification into the register of means of identification;

3) provides PoMPT with information about emission of labelling codes in the form according to Annex 3 to these Rules.

45. PoMPT after receipt of labeling codes convert them into means of identification, shall ensure their application on the medicinal product package, and transmit to IS LTG information on product identification codes (application of means of identification) contained in means of identification applied to medicinal products, date of application of means of identification, as well as series/batch number and expiration date of medicinal product labeled with means of identification, in the form according to Annex 4 to these Rules.

46. Registration of information on the application of means of identification shall be automatically refused in the following cases:

1) codes of identification of goods, are absent in the register of means of identification IS LTG;

2) information on identification codes is submitted in violation of the requirements stipulated by these Rules.

3) there is no confirmation of payment for the labeling codes converted into means of identification, about the application of which PoMPT transmits information to IS LTG.

47. The labeling code contained in the means of identification applied to the medicinal product packaging shall not be re-formed (not generated) in IS LTG).

Section 2. Procedure for application of means of identification

48. Application of means of identification shall be carried out:

when medicinal products are manufactured in the territory of the Republic of Kazakhstan
- by manufacturers of medicinal products;

when medicinal products are produced outside the Republic of Kazakhstan (foreign production):

1) holders of registration certificates of medicinal products or foreign manufacturers of medicinal products or their authorized representative offices and (or) branches or subsidiaries in the territory of the Republic of Kazakhstan;

2) by importers who import medicinal products into the territory of the Republic of Kazakhstan, if the foreign manufacturer has no representative office or branch or subsidiary organization in the territory of the Republic of Kazakhstan.

49. Means of identification of a medicinal product shall be applied in the form of a two-dimensional matrix barcode in Data Matrix format, representing black and white elements or elements of several different degrees of brightness, applied in the form of a square, placed in a rectangular or square group, designed to encode text or other types of data, suitable for machine reading, with mandatory indication in the form of legible printed text of information on the product code GTIN (GTIN) and unique serial number of the medicinal product.

Before the information in the form of readable text about the product code GTIN (GTIN) and the unique serial number of the medicinal product, on a voluntary basis, application codes are indicated, which are a set of 2 (two) or more characters, located at the beginning of the element line and unambiguously defining the purpose, and the format of the data field, for the use of manual entry of the product identification code PoMPT.

50. Application of means of identification shall be carried out by direct printing on the secondary package (in its absence - on the primary package) of a medicinal product or by printing on a tangible medium that does not allow separation of the tangible medium containing the means of identification from the package of the medicinal product without damage.

51. The application of the means of identification or the tangible medium containing the means of identification shall not be performed on transparent wrapping film or any other external wrapping material.

At the same time, the means of identification or material carrier containing the means of identification shall be positioned in such a way that the integrity of the information applied to the package (secondary, and in case of absence - to the primary package) of the medicinal product in accordance with the requirements of the legislation of the Republic of Kazakhstan is not violated.

52. Technical conditions for quality of application of means of identification on the package of medicinal products shall be as follows:

- 1) application by printing using the error correction method ESS-200 (ECC-200);
- 2) use of ASCII (ASCII) coding;
- 3) the quality of printing corresponds to class C or higher.

53. The code of identification of the transport package shall be generated by PoMPT, who aggregate (combine) consumer packages of medicinal products into a transport package, independently, in the form of a linear bar code complying with the standard of the international organization in the field of standardization of accounting and bar coding of logistic units GS1-128, with a unique identifier of the transport package in the form of a serial code, represented in the form of a digital number SSCC code (SSCC code) and identified by the application code AI='00'.

54. The transport package identification code shall be printed on the front or side of each individual transport package at the discretion of PoMPT for convenience and ease of aggregation of the goods.

55. In order to provide labeling services, the Operator has contractual relationships with individuals and legal entities that own:

- 1) resources ensuring the processes of marking and traceability of goods, including branches, representative offices and (or) other structural subdivisions up to the level of administrative centers of districts throughout the territory of the Republic of Kazakhstan;

2) customs warehouses complying with the standard of good distribution practice, where PoMPTs have the possibility to apply means of identification on a tangible medium.

Section 3. Aggregation of medicinal products labeled with means of identification

56. Aggregation shall be carried out in the presence of several levels of nesting:

- 1) first-level aggregation - combining primary and (or) secondary packages into a transportation package;
- 2) second-level aggregation - combining transport packages into another transport package of a higher nesting level.

57. PoMPT performs aggregation of packages of medicinal products having the same GTIN (GTIN) commodity code into a transport package, as well as transport packages of medicinal products into a transport package of a higher level with preservation of information on the relationship of identification codes of each nested package with the identification code of the created package in order to ensure traceability of medicinal products circulation along the commodity distribution chain without the need to open the created transport package.

The PoMPT shall submit information on the aggregation of packages to the IS LTG before transferring the aggregated package to the next PoMPT in the form according to Annex 5 to these Rules.

The transfer by PoMPT of information on a transport package shall be considered equivalent to the transfer of information on the consumer packages contained in that transport package according to the IS LTG.

58. When PoMPT submits to IS LTG information on circulation or withdrawal from circulation of a part of labeled medicinal products contained in a transport package, IS LTG shall register disbanding of the transport package containing withdrawn medicinal products within 3 (three) working days.

59. In case of transfer of medicinal products into another transport package, submission of information on aggregation to IS LTG shall be performed in accordance with the requirements stipulated by paragraph 57 of these Rules. In this case, the IS LTG shall record the disbanding of all packages containing seized medicinal products.

60. The operator shall, upon receipt of the medicinal product aggregation information under this Chapter, automatically ensure that it is reflected in the register of means of identification and that this information is made available to PoMPT in the IS LTG.

Chapter 3. Procedure for medicinal product stickering

61. Labeling on stickers shall comply with the requirements of these Rules and shall be approved during state registration of a medicinal product in the Republic of Kazakhstan.

62. Application of stickers on the package shall be carried out by the manufacturer of the medicinal product for each unit of the package (if there is a control of the first opening only on the secondary package) in Kazakh and Russian.

63. The sticker shall be placed on the package, leaving open the trade and/or international non-proprietary name and dosage of the medicinal product of the original label.

64. Application of stickers on the packaging of medicinal products not registered in the territory of the Republic of Kazakhstan and imported in accordance with the Rules of Importation shall be carried out by the organization-manufacturer of the medicinal product or a subject of the pharmaceutical market that imports unregistered medicinal products.

Labeling on stickers of medicinal products not registered in the territory of the Republic of Kazakhstan shall be placed in Kazakh and Russian languages.

Note!

The validity of Chapter 4 was suspended until 01.07.2024 by the order of the Minister of Healthcare PK dated 01.02.2023 № 20 (shall be enforced upon expiry of ten calendar days after its first official publication).

Chapter 4. Procedure for traceability of medicinal products labelled with means of identification

65. Traceability of medicinal products labeled with means of identification shall be ensured by submission of information on introduction into circulation, sale and (or) transfer, as well as withdrawal from circulation of labeled medicinal products on the territory of the Republic of Kazakhstan according to the requirements of these Rules by PoMPT and entities in the sphere of circulation of medicinal products and medical devices.

Section 1. Procedure of providing information in the information system of labelling and traceability when introducing medicinal products labelled with means of identification into circulation of the Republic of Kazakhstan

66. Introduction of medicinal products labelled with means of identification into circulation in the territory of the Republic of Kazakhstan shall be:

1) in the production of medicinal products in the territory of the Republic of Kazakhstan - primary compensated or gratuitous transfer of medicinal products from a manufacturer of medicinal products to another PoMPT for the purpose of alienation to such person or for subsequent sale, which makes them available for distribution and (or) use in accordance with the requirements of the legislation of the Republic of Kazakhstan;

2) when importing medicinal products from the territory of states that are not member states of the Eurasian Economic Union - release by customs authorities of the Republic of Kazakhstan of medicinal products for domestic consumption based on the results of sending to IS LTG the notification on importation of goods to the Republic of Kazakhstan from the territories of states that are not members of the Eurasian Economic Union;

3) when importing medicinal products from the territory of the member states of the Eurasian Economic Union - acceptance of imported medicinal products at the importer's warehouse in the Republic of Kazakhstan based on the results of sending to IS LTG the information on confirmation of identification codes declared by the importer in the notification on importation of goods to the Republic of Kazakhstan from the territories of the member states of the Eurasian Economic Union.

67. PoMPT, importing medicinal products to the Republic of Kazakhstan from the territories of the Member States of the Eurasian Economic Union, before crossing the State border of the Republic of Kazakhstan shall form a notice of import of goods to the Republic of Kazakhstan from the territories of the Member States of the Eurasian Economic Union in the form according to Annex 6 to these Rules, shall sign it with EDS and shall submit to IS LTG for obtaining a registration number.

Upon acceptance of imported medicinal products at the importer's warehouse in the Republic of Kazakhstan, PoMPT shall send to IS LTG information on confirmation of identification codes declared by it earlier in the notification on import of goods to the Republic of Kazakhstan from the territories of the Eurasian Economic Union member states.

68. PoMPT, importing medicinal products to the Republic of Kazakhstan from the territories of states that are not members of the Eurasian Economic Union, upon acceptance of imported medicinal products to the importer's warehouse in the Republic of Kazakhstan, shall form a notification of importation of goods to the Republic of Kazakhstan from the territories of states that are not members of the Eurasian Economic Union, in the form according to Annex 7 to these Rules, shall sign it with EDS and shall submit to IS LTG for obtaining a registration number.

69. Notification on importation of medicinal products into the Republic of Kazakhstan shall be executed in electronic form, except for the cases when PoMPT executes notification on paper when confirming information on the Operator's Internet resource about impossibility to execute notification in IS LTG due to technical errors in IS LTG according to PoMPT's application to the Operator's technical support service. The Operator shall publish information on its own Internet resource about the occurrence of technical errors in IS LTG not later than one day from the moment of their occurrence.

After elimination of technical errors, the notice on importation of medicinal products into the Republic of Kazakhstan, previously issued on paper, shall be sent by the importer to IS LTG within 1 (one) working day from the date of publication of information on elimination of technical errors in IS LTG on the Operator's Internet resource. The Operator shall publish information on its own Internet resource about elimination of technical errors in IS LTG within 24 hours from the moment of their elimination.

Section 2. Procedure for submission of information in the information system of labeling and traceability of goods in circulation of medicinal products marked with means of identification on the territory of the Republic of Kazakhstan

70. Circulation of medicinal products in the territory of the Republic of Kazakhstan, after the date of introduction of labeling with means of identification according to the Law on regulation of trading activities shall be carried out when transferring information on their realization to IS LTG, subject to compliance with the stage of introduction of labeling and traceability.

71. When selling and (or) transferring medicinal products labeled with identification means to another PoMPT, the sender of medicinal products forms an act of acceptance (transfer) of goods in the form according to Annex 8 to these Rules, signs it by EDS and sends it to IS LTG for obtaining a registration number, not later than on the day of sale of medicinal products.

In case of sale and (or) transfer of medicinal products marked with means of identification by a Single Distributor within GVoFMC and (or) in the CSMI system, the act of acceptance (transfer) of medicinal products shall be formed and signed by authorized representatives of logistics companies providing services to the Single Distributor for storage and transportation of medicinal products under a civil law contract on the basis of a power of attorney issued by the Single Distributor, information about which is contained in the IS LTG.

72. Upon the results of registration of the act of acceptance (transfer) of PoMPT medicinal products in IS LTG, the Operator shall transfer the information on this act, including information on the quantity of the transferred goods to the Electronic Invoice Information System.

73. Acceptance of medicinal products labeled with means of identification shall be confirmed in IS LTG by an entity in the field of circulation of medicinal products and medical devices.

At the same time, a subject in the sphere of circulation of medicinal products and medical devices, who accepts medicinal products from another subject in the sphere of circulation of medicinal products and medical devices labeled with means of identification, shall ensure signing of the act of acceptance (transfer) of EDS goods and shall transfer information on acceptance of medicinal products to IS LTG within 1 (one) working day from the date of acceptance before performing further operations.

74. Upon receipt from subjects in the sphere of medicinal products and medical devices circulation of information on acceptance of the acceptance (transfer) act signed by EDS, the Operator shall transfer information on acceptance of goods to the Electronic Invoice Information System.

75. If discrepancies are detected during acceptance of medicinal products, the recipient of medicinal products shall form a notice of the detected discrepancies and send it to the sender

who sold and/or transferred medicinal products to make changes to the previously sent acceptance (transfer) certificate of goods. In this case, the previously sent acceptance (transfer) report shall be automatically revoked in IS LTG.

Revocation of the acceptance (transfer) act by the sender shall be carried out within 20 (twenty) working days after the date of registration in IS LTG, but before confirmation by the recipient, without execution of a new act, except for the case provided for in part one of this paragraph.

76. The notice of detected discrepancies shall contain the following information:

- 1) IIN (BIN) of the supplier;
- 2) IIN (BIN) of the recipient;
- 3) list of codes of identification of accepted packages of medicinal products;
- 4) list of codes of identification of medicinal product packages, information on which is missing in the act of acceptance (transfer) of goods (if any);
- 5) details of the act of acceptance (transfer) of goods.

77. The act of acceptance (transfer) of medicinal products shall be executed in electronic form, except for cases specified in paragraph 71 of the Rules.

78. The act of acceptance (transfer) of medicinal products shall be executed on paper:

- 1) due to technical failure in IS LTG, confirmed by the Operator on its Internet resource;
- 2) due to force majeure circumstances;
- 3) due to absence or suspension of electric power supply, confirmed by the energy producing, energy supplying or energy transmitting organization, technical failure caused by an emergency breach.

79. The Operator shall post on its Internet resource information on impossibility to execute the act of acceptance (transfer) of medicinal products in IS LTG due to technical errors in IS LTG not later than 24 hours from the moment of occurrence of technical errors in IS LTG.

80. After elimination of technical errors the act of acceptance (transfer) of medicinal products executed earlier on paper shall be entered by the subject in the sphere of circulation of medicinal products and medical devices into IS LTG not later than 1 (one) working day from the date of publication by the Operator of information on elimination of technical errors in IS LTG on its own Internet resource. The Operator shall publish information on its own website on elimination of technical errors in IS LTG within 24 hours from the moment of their elimination.

81. Change of the owner of labeling codes in IS LTG shall be performed on the basis of information confirmed by both parties from the act of acceptance (transfer) of medicinal products in IS LTG.

Section 3. Procedure for submission of data to the information system for labeling and traceability of goods when medicinal products marked with means of identification are withdrawn from circulation

82. The subject in the sphere of circulation of medicinal products and medical devices, selling medicinal products in retail for cash, cashless payment and (or) without payment by the recipient, shall withdraw them from circulation by scanning and recognizing the means of identification applied to the consumer package of the medicinal product by technical means interfaced with the cash register machine registered in accordance with the order of the Minister of Finance of the Republic of Kazakhstan dated February 16, 2018 № 208 "On Some Issues of the Sale of Medicinal Products and Medical Devices" (registered in the Register of State Registration of Regulatory Legal Acts under № 16508).

Information on the identification code contained in the means of identification affixed to goods shall be included in the fiscal document "cash voucher" generated by a cash register and transmitted to the Fiscal Data Operator.

83. The fiscal data operator shall transfer information in real time to IS LTG for each realized goods unit, including the following information:

- 1) IIN (BIN) of the seller;
- 2) registration number of the cash register machine;
- 3) details of the fiscal document (check number and date);
- 4) sale date and price;
- 5) identification code of goods contained in the means of identification affixed to the commodity.

84. Withdrawal of medicinal products from circulation in IS LTG shall be performed at retail sale on the basis of information specified in paragraph 83 of these Rules, received from the Fiscal Data Operator.

85. Subject in the field of circulation of medicinal products and medical devices not later than 3 (three) working days following the day of withdrawal of medicinal products from circulation shall submit to IS LTG a notice of withdrawal from circulation in the form according to Annex 9 to these Rules in case of withdrawal of medicinal products from circulation for the following reasons:

- 1) defect;
- 2) loss;
- 3) damage;
- 4) destruction;
- 5) use for the enterprise's own needs;
- 6) sampling;
- 7) for medical purposes;
- 8) dispensing, on a free prescription;

9) confiscation.

Section 4. Procedure for submission of data to the information system for labeling and traceability of goods in case of reintroduction into circulation of medicinal products labeled with means of identification and making changes to the data contained in the information system for labeling and traceability of goods

86. For reintroduction into circulation of medicinal products, previously withdrawn from circulation for reasons specified in paragraph 85 of these Rules, except for used medicinal products for medical care, as well as the release of medicinal products on prescriptions issued under the GVoFMC and (or) CSMI system, PoMPT shall send to the Operator a notice of reintroduction of medicinal products into circulation in the form according to Annex 10 to these Rules.

87. The information of PoMPT shall be sent to the Operator within 3 (three) working days from the date of re-entry of medicinal products into circulation.

88. The Operator, upon request of the state body, provides generalized information on traceability of medicinal products within GVoFMC and CSMI within 3 (three) working days.

89. The Operator shall ensure data transfer to the IS of the authorized body through integration with the authorized body.

90. Operator shall provide an automated workstation in IS LTG for the authorized body and state body.

91. Amendments to the information previously submitted to the IS LTG shall not be made during the period when the state body conducts an audit of the subject's activities in the sphere of circulation of medicinal products and medical devices.

92. The access to information, shall be provided by the Operator, in accordance with the Code of the Republic of Kazakhstan "On taxes and other obligatory payments to the budget" (Tax Code), the Law of the Republic of Kazakhstan "On personal data and their protection" and the Law of the Republic of Kazakhstan "On access to information" and within the framework of the current legislation of the Republic of Kazakhstan.

Annex 1
to the Rules for labeling and traceability
of medicinal products and labeling of
medical devices

List of auxiliary substances for the labeling of oral medicinal products

Name of auxiliary substance	Substance code	Threshold content
Azo dyes:		
sunny sunset yellow	E110	0
azorubine (carmuazine)	E122	
punz (ponso 4R, cochineal red A)	E124	

diamond black BN (black shiny BN, black PN)	E151	
Peanut butter		0
Aspartame	E951	0
Galactose		0
Glucose (dextrose)		0
Glycerol (glycerine)		10 g/dose
Isomalt (isomaltite)	E953	0
Potassium-containing compounds		39 mg/dose
Polyethoxylated castor oils (macrogol glycerylricinoleate, macrogol glyceryl hydroxystearate)		0
Preservatives		0
Xylitol (xylitol)		10 g
Gingelly oil		0
Lactitol (Lactitol)	E966	0
Lactose		0
Latex (natural rubber)		0
Maltitol (maltitol)	E965	0
Mannitol (mannitol)	E421	10 g
Urea		0
Sodium-containing compounds		23 mg/dose
Propylene glycol and its esters		400 mg/kg for adults 200 mg/kg for children
Wheat starch		0
Invert sugar		0
Sucrose		0
Soybean oil		0
Sorbitol (sorbit)	E420	0
Phenylalanine		0
Formaldehyde		0
Fructose		0
Ethanol* (ethyl alcohol)		0

Annex 2
to the Rules for labeling and traceability
of medicinal products and labeling of
medical devices

Request for the receipt of labeling codes

Information about PoMPT:

1. IIN or BIN or TIN _____
2. General data:

1) Method of releasing the medicinal product in circulation _____

2) Country of origin _____

3. Manufacturing data _____

4. List of products for labeling:

№	Product code	Number of labeling codes	Method of generation of individual serial numbers	Array of individual serial numbers	Packaging type
1.	2	3	4	5	6
2.					
3.					
...					

Annex 3
to the Rules for labeling and traceability
of medicinal products and labeling of
medical devices

Information about emission of labeling codes

Information about PoMPT:

1. IIN or BIN or TIN _____

2. According to order № for production site (code) _____

labeling codes are provided:

№	Product code GTIN (GTIN)	Array of labeling codes (identification code + verification code)
1.	2	3
2.		
...		

Annex 4
to the Rules for labeling and traceability
of medicinal products and labeling of
medical devices

Information about product identification codes (on application of means of identification)

Information about PoMPT:

1. IIN or BIN or TIN _____

2. General information:

1) production series number _____

2) shelf life _____

4. List of labeling code used:

№*	Array of labeling codes (identification code + verification code)

1.	2
2.	
...	

Note:

* the number of labeling codes do not exceed 30 000 codes.

Annex 5
to the Rules for labeling and traceability
of medicinal products and labeling of
medical devices
Form

Information about aggregation of packaging

1. Information about PoMPT (General data):

IIN or BIN or TIN _____

2. Aggregate data:

Aggregate data					Array of aggregated LC
№	Identification code of a unit of aggregation	Packaging capacity	Actual amount of pieces in a unit of aggregation	№	Identification code
1.	2	3	4	5	6
2.					
...					

Annex 6
to the Rules for labeling and traceability
of medicinal products and labeling of
medical devices
Form

Notification on importation of medicines to the Republic of Kazakhstan from the territories Of Member States of the Eurasian Economic Union №__ from _____

General information:

1. IIN (BIN) of recipient _____

2. Originator's identification number (or equivalent in the originating country)

3. Originator's name _____

4. Member State of the Eurasian Economic Union, from the territory of which the goods are imported _____

5. Information about the document, confirming the conformance of goods with the requirements of the Republic of Kazakhstan (registration date and number)

6. Date and number of the primary document – Notifications

on Import* _____

7. Information about medicines:

№	Product / package identification code
1.	2
2.	
...	

1. Information about results:

Product code GTIN	Number of consumer packages by product code
1	2
2	
...	

Document is signed with EDS _____

Note:

* is specified when entering information on a notification previously issued on paper.

Annex 7
to the Rules for labeling and traceability
of medicinal products and labeling of
medical devices

Notification on the import of medicines into the Republic of Kazakhstan from the territories of states that are not members of the Eurasian Economic Union №_____ from _____

General information:

1. IIN (BIN) of the recipient _____

2. Details of the goods declaration:

Number and date (column "A") _____

3. Decision on the goods declaration:

date and time of adoption by the customs authority _____

decision code (in accordance with the classifier of decisions

adopted by the customs authority) _____

4. Information on the document confirming the compliance of the goods with the requirements

of the Republic of Kazakhstan (registration date and registration number) _____

5. Date and number of the primary document - Notification of import* _____

6. Information on the goods:

№	Code of the commodity nomenclature of foreign economic activity of the Eurasian Economic Union	Product number in the goods declaration	Country of origin of medicinal products	Product / package identification code

1.	2	3	4	5
2.				
...				

Document is signed with EDS _____

Note:

* is specified when entering information on a notification previously issued on paper.

Annex 8
to the Rules for labeling and traceability
of medicinal products and labeling of
medical devices

Acceptance/transfer certificate of medicinal products №_____ dated _____

General information:

1. IIN or BIN or TIN of the sender _____

2. IIN or BIN or TIN of the recipient _____

3. Date and number of the primary document – Acceptance/transfer certificate* №_____ from _____

4. Information on medicines:

№	Product / package identification code
1	2

5. Information about results:

Product code GTIN (GTIN)	Number of consumer packages by product code
1	2

The document is signed with EDS _____

Note:

* is indicated when entering information on the acceptance (transfer) certificate, previously issued on paper.

Annex 9
to the Rules for labeling and traceability
of medicinal products and labeling of
medical devices

Notification of withdrawal of medicinal products from circulation

IIN or BIN or TIN _____

1. Reason for withdrawal: _____

2. Document of title _____ №_____ from _____

3. Information about withdrawn products:

№	Product / package identification code
1	2
2.	
...	

The document is signed with EDS _____

Annex 10
to the Rules for labeling and traceability
of medicinal products and labeling of
medical devices

Notification on reintroduction of medicinal products into circulation

1. IIN or BIN or TIN _____
2. Document of title _____ № _____ from _____
3. Reason for the reintroduction into circulation _____
4. Information about recovered goods in circulation:

№	Product identification code
1.	
2.	
...	

The document is signed with EDS _____

Annex 2 to order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated January 27, 2021
№ RK ДСМ-11

Rules for labeling medical devices

1. These rules for labeling medical devices (hereinafter referred to as the Rules) have been developed in accordance with paragraph 4 of Article 242 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On People's Health and Healthcare System" (hereinafter referred to as the Code) and shall determine the procedure for labeling medical devices in the Republic of Kazakhstan.

2. The following concepts shall be used in these Rules:

1) the state body in the field of circulation of medicinal products and medical devices (hereinafter referred to as the state body) - the state body leading in the field of circulation of medicinal products and medical devices, control over circulation of medicinal products and medical devices;

2) state expert organization in the field of circulation of medicinal products and medical devices (hereinafter referred to as the expert organization) - a state monopoly entity carrying out production and economic activities in the field of healthcare to ensure the safety, effectiveness and quality of medicinal products and medical devices;

3) operational document of a medical device - a document developed by the manufacturer of a medical device for consumers, containing information about the design, principle of operation, parameters, characteristics (properties) of the medical device, its components;

instructions required for correct and safe operation of the medical device (intended use, maintenance, storage and transportation); information on disposal; information about the manufacturer, supplier of the product and their warranty obligations;

4) labeling - information applied to the packaging of a medical device.

3. Labeling of medical devices shall be approved by the state body during the state registration of medical devices in the Republic of Kazakhstan, carried out in accordance with Article 23 of the Code.

4. Information for the consumer (operational document of a medical device, instructions for medical use of medical devices) shall contain complete and reliable information that does not mislead them regarding the composition, properties, nature of origin, method of manufacture (production) and use, as well as other information that directly or indirectly characterize the quality and safety of medical devices.

Information on the organization accepting claims (proposals) on the quality of medical devices in the territory of the Republic of Kazakhstan shall be indicated in the instructions for medical use of the medical device and the operational document of the medical device.

Chapter 2. Procedure for labeling medical devices

5. Labeling shall be applied by the medical device manufacturing organization directly to each medical device unit, package (container), label (mark, container), stated in a compressed form, complete enough to transfer the necessary and reliable information to the consumer.

6. Labeling of medical devices containing information in accordance with the instructions for medical use of the medical device or the operational document of the medical device approved during state registration, in the form of text, individual graphic, color signs (symbols) and (or) pattern and their combinations, shall be applied directly to the medical device, package (container) or label (sticker), label, container.

When applying graphic signs, the following requirements must be observed:

signs are easily recognizable and understood, different from other signs;

the same signs applied to a medical device have the same meaning regardless of their functions or purpose and type of application;

symbols and designations used in labeling are deciphered in the instructions for medical use of the medical device and in the operating document of the medical device.

7. Labeling shall be unified for each series (batch) of medical device and shall be indicated in the state and Russian languages.

The expert organization, when conducting an examination in accordance with the procedure established by paragraph 4 of Article 23 of the Code, shall verify the authenticity of the translation or translation into Kazakh of labeling of mock-ups of packages, labels, stickers, instructions for medical use, as well as the requirements of these Rules.

8. The labeling of the medical device shall be clearly and intelligibly executed, and shall be also distinguished or placed against a background contrasting with the color of the surface on which it is located.

9. Labeling shall be maintained during the entire permissible period of application (operation) of the medical device, methods of application and manufacture of labels (signs), marks, containers take into account the features of the medical device and ensure the necessary image quality.

10. Safety requirements for storage, transportation, sale, use, disposal (recycling), destruction of medical devices shall be highlighted from the rest of the information for the consumer in another font, color.

11. If the package (container) in which the medical devices are embedded is placed in an additional package, then the external package does not interfere with the internal label (sticker) of the package for reading, or a similar label (sticker) is applied to the external package.

If it is impossible to apply the necessary labeling text on the package (container), label (sticker), label, small-size container (the area of one side does not exceed 50 sm²), then the marking is placed on the group package (container).

12. The labeling means in contact with the medical device ensure the stability of the applied information during their storage, transportation, sale, use and impact of climatic factors, without affecting the safety and quality of the medical device.

13. The safety of the labeling used in the conditions of active exposure to the environment or in special conditions (high or low temperature, aggressive environment and other similar conditions) shall be ensured by one of the following methods or their combination:

- 1) application of a material-carrier resistant to action (moisture-resistant, heat-resistant);
- 2) application of the appropriate application method (extrusion, etching);
- 3) application of a resistant shell (transparent film, bag, box).

14. The labeling for consumers, applied directly to the medical device, package (container), label (sticker), label (tag), container, contains the following data:

1) name of the medical device (if the size of the label is less than 50 cm², it is possible to indicate the name in Latin letters or in the manufacturer's language);

2) the name of the country-manufacturer;

3) name and/or trademark of the manufacturer (if any);

4) name and location (legal address) of the manufacturer and/or license holder, if the medical device is manufactured under a license;

5) the main properties and characteristics that are specified in the metric system of measures (International System of Units): indication of mass (net, gross), basic dimensions, volume and capacity;

6) information necessary for the user to identify a medical device: if possible, a bar code identifying medical devices placed in a place convenient for reading by scanning devices;

7) shelf life (month, year) and/or operation up to which safe use of a medical device is allowed;

8) the year of manufacture of the active medical device (in accordance with the state standards of the Republic of Kazakhstan). The production year is indicated together with the batch number or serial number;

9) special conditions for storage and (or) use (operation): for example, indication of temperature and light modes;

10) indication of sterility (for sterile medical devices);

11) batch number (batch) and/or batch code, and/or symbol;

12) information that the medical device is intended for disposable use, in the form of an inscription: "For disposable use";

13) on a medical device made to order, the inscription: "Made to order";

14) on a medical device intended for clinical studies, indication ("Only for clinical research");

15) precautions to be taken during storage, transportation, sale, operation, use;

16) trademark (if any).

15. The labeling of medical devices shall not contradict or distort the information contained in the registration dossier documents and is not advertising in nature.

It is allowed to apply the following on the medical device packaging:

1) holographic and protective signs, duplicate the labeling text using Braille (for persons with visual disabilities), shall place symbols or pictograms that help explain the information to the consumer;

2) in addition, the labeling text in other languages, provided that the information is fully identical.