On Amendments to Order of the Minister of Health of the Republic of Kazakhstan No. ҚР ДСМ-11 as of 27 January 2021 “On Approval of the Rules for Marking of Medicines and Medical Devices”

Order No. ҚР ДСМ-49 of the Minister of Health of the Republic of Kazakhstan as of 30 May 2022 has been registered with the Ministry of Justice of the Republic of Kazakhstan on 1 June 2022 No. 28315

Notice of Legislation and Legal Information Institute!

For implementation, see Clause 4.

I HEREBY ORDER:

1. To amend Order No. ҚР ДСМ-11 of the Minister of Health of the Republic of Kazakhstan dated January 27, 2021 "On approval of the rules for marking of medicines and medical devices" (registered in the Register of state registration of regulatory legal acts under No. 22146) as follows:

the heading should be amended to read as follows:

"On approval of the rules for the marking and traceability of medicines and the marking of medical devices";

Preamble should be revised to read as follows:

"In accordance with Article 242(4) of the Health Code of the Republic of Kazakhstan “On Public Health and Health Care System" and subclause 2) article 7-2 of the Law of the Republic of Kazakhstan “On Regulation of Trade Activities" **I HEREBY ORDER**:";

Clause 1 shall be amended to read as follows:

"1. To approve:

1) rules for the marking and traceability of medicines according to Annex 1 to this Order;

2) rules for the marking of medical devices according to Annex 2 to this Order.";

Rules for marking of medicines, approved by Annex 1 to the aforementioned order, shall be amended in accordance with the annex to this order.

2. The Medical and Pharmaceutical Control Committee of the Ministry of Health of the Republic of Kazakhstan shall, in accordance with the procedure established by the legislation of the Republic of Kazakhstan, ensure:

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

2) posting this order on the website of the Ministry of Health 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 Health of the Republic of Kazakhstan information on the implementation of the measures provided for in subclauses 1) and 2) of this clause.

3. The supervising vice-minister of health of the Republic of Kazakhstan shall be entrusted with the control of execution of this order.

4. This Order shall take effect sixty calendar days after the date of its first official publication.

Minister of Health of the Republic of Kazakhstan *A.Ganiyat*

"AGREED BY"
Ministry of Trade and Integration
of the Republic of Kazakhstan

"AGREED BY "
Ministry of Finance of the
Republic of Kazakhstan

Annex to the Order of the Minister of Health of the Republic of Kazakhstan dated 30 May 2022 № ҚР ДСМ-49

Annex 1 to Order of the Minister of Health of the Republic of Kazakhstan as of 27 January 2021 № ҚР ДСМ-11

Rules for the marking and traceability of medicines

Chapter 1: General provisions

1. These Regulations on the marking and traceability of medicines (hereinafter referred to as the Regulations) have been developed in accordance with Clause 4 art. 242 of the Code of the Republic of Kazakhstan "On Public Health and Health Care System" (hereinafter referred to as the Code) and subclause 2) Article 7-2 of the Law of the Republic of Kazakhstan "On Trade Activities Regulation" (hereinafter - the Law on Trade Activities Regulation) and determine the order of medicines marking and traceability in the Republic of Kazakhstan.

2. The following terms shall be used in these Regulations:

1) business Identification Number (hereinafter referred to as the BIN) is a unique number formed for a legal entity (branch and representative office) and an individual entrepreneur engaged in joint business activities;
2) a single distributor is a legal entity operating within the scope of guaranteed scope of free medical care (hereinafter referred to as the GS of FMC) and/or in the system of mandatory social health insurance (hereinafter referred to as the MSHI) in accordance with Article 247 of the Code;
3) authorized body in the field of health care (hereinafter referred to as the authorized body) is the central executive body responsible for management and inter-sectoral coordination in the field of health care of citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of population, circulation of medicines and medical devices, quality of medical services (assistance);
4) bulk product of a medicine is a dosed finished medicine that has undergone all stages of the technological process, except for final packaging;
5) the package of a medicine is a means or set of means for ensuring the circulation of medicines by protecting them from damage and loss, as well as protecting the environment from contamination.

Package consists of primary (inner), intermediate (if any), and secondary (outer or consumer (if any)), transport (if any) package:

primary (inner) package is a package in direct contact with the medicine;

intermediate package is a package into which the primary package is placed for the purpose of additional protection of the medicine or on the basis of the specific use of the medicine;

secondary (outer or consumer) package is a package into which the medicine in the primary and intermediate package is placed;

transport package is a package combining sets of homogeneous (within the same GTIN product code) secondary (and in their absence - primary) consumer packages of medicines used for storage and transportation to protect them from damage during transportation and forming an independent transport unit. Transport package includes smaller transport packages (volume);

6) State body in the field of circulation of medicines and medical devices (hereinafter referred to as the state body) is a state body, responsible for management in the field of circulation of medicines and medical devices, control over circulation of medicinal products and medical devices;
7) State expert organization in the field of circulation of medicines and medical devices (hereinafter referred to as the expert organization) - an entity of the state monopoly which carries out production and economic activities in the field of healthcare to ensure safety, efficiency and quality of medicines and medical devices;

8) subjects in the field of circulation of medicines and medical devices - natural or legal persons engaged in pharmaceutical activities;
9) manufacturer of medicines is an organization carrying out activities for the production of medicines and holding a license for the production of medicines;
10) trade name of the medicine is the name under which the medicine is registered;
11) Individual Identification Number (hereinafter - IIN) is a unique number formed for a natural person, including an individual entrepreneur carrying out activities in the form of personal entrepreneurship;
12) tangible medium is a control (identification) mark or object made of any material, which contains or does not contain the elements (means) of protection against counterfeiting and is intended for the application, storage and transmission of the means of identification;
13) means of identification is a unique sequence of symbols in a machine-readable form presented in the form of a bar code or written on an RFID tag, or presented using another means (technology) of automatic identification;
14) batch number is a distinctive combination of numbers, letters and/or symbols allowing to specifically identify the series of a medicinal product and determine the complete sequence of manufacturing and control operations as well as trace the sale of the medicinal product;
15) sticker is an information carrier with consumer information in the Kazakh and Russian languages, attached to the secondary package by sticking;
16) marking is information affixed to the package of a medicinal product containing, inter alia, means of identification;
17) trademark, service mark (hereinafter referred to as trademark) is a designation registered in accordance with the Law Republic of Kazakhstan "On Trademarks, Service Marks and appellations of origin of goods" or

protected without registration by virtue of international treaties to which the Republic of Kazakhstan is a party, serving to distinguish goods (services) of certain legal entities or individuals from similar goods (services) of other legal entities or individuals;

18) information system (hereinafter referred to as IS) is an organizationally ordered 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 - the Operator) is a legal entity established in accordance with the legislation of the Republic of Kazakhstan, developing, administering, maintaining and supporting the information system of marking and traceability of goods, including development, maintenance and updating of the National Product Catalogue, and other functions defined by the Government of the Republic of Kazakhstan;

20) operator of fiscal data is a legal entity that ensures the transmission of data on money settlements in an operational mode to the tax authorities via public telecommunication networks, as determined by the state body responsible for ensuring tax revenues and payments to the budget, in agreement with the authorized body in the field of information;

21) electronic digital signature (hereinafter referred to as EDS) is a set of electronic digital characters created by means of electronic digital signature and confirming the authenticity of an electronic document, its ownership and invariability of its content;

22) traceability of medicines is an organization of accounting of medicines subject to traceability and operations related to their circulation, using the marking and traceability information system.

3. Layout of package marking, marks and stickers for a medicine shall be registered by a state authority during state registration of a medicine in the Republic of Kazakhstan carried out in accordance with the Rules of state registration, re-registration of a medicine or a medical device, making changes to the registration dossier for a medicine or a medical device approved by Order No. ҚР ДСМ - 16 of the Minister of Health of the Republic of Kazakhstan dated February 9, 2021 16 "On approval of the rules of state registration, re-registration of a medicine or medical device, introduction of amendments to the

registration dossier for a medicinal product or medical device" (registered with the Registry of State Registration of Regulatory Acts under No. 22175).

4. Information on the organization which accepts quality claims (offers) for medicines in the territory of the Republic of Kazakhstan shall be specified in the instructions for medical use of medicines.

Chapter 2: Procedures for Marking Medicines

5. Marking of medicines is carried out by a manufacturer (or a packaging company) of medicines for each unit of package (primary, intermediate, secondary) in the Kazakh and Russian languages.

In this case, the marking of medicines by means of identification is carried out by participants of circulation of medicines in accordance with paragraph 2 of this chapter of the Rules during circulation of medicines, including procurement (purchase), storage, import into the territory of the Republic of Kazakhstan, production, marking, transportation, sale of medicines.

Participants in the medicines circulation (hereinafter PMC) are entities in the field of circulation of medicines 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 subsidiaries of foreign medicine manufacturers.

The marking on the package is the same for each series of medicines, while the marking by means of identification is individual for each package.

The marking of medicines does not contradict or distort the information in the registration dossier documents and is not of a promotional nature.

The package of a medicine may, at the discretion of the PMC, bear:

1) holographic and protective signs, duplication of marking text in Braille (for the visually impaired), symbols or pictograms that help to explain information to the consumer;

2) the text of the instructions for medical use on the package of an over-the-counter medicinal product;

3) additional marking text in foreign languages, provided that the information is identical;

4) barcode (if any).

The colour design of the package of a medicine in the same dosage form containing different amounts of the active ingredient varies.

6. Marking of medicines with means of identification shall be carried out in accordance with the requirements of these Regulations:

1) in the manufacture of medicines on the territory of the Republic of Kazakhstan - in places where medicines are manufactured before transportation and (or) sale;

2) when importing medicines, including medicines 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 which are not members of the Eurasian Economic Union - in the territory of third countries, before importation to the territory of the Republic of Kazakhstan and (or) in customs warehouses, complying with good distribution practice standard before placing such medicines under customs procedures for release for domestic consumption or re-import;

3) when importing medicines 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 medicines registered and not registered in the Republic of Kazakhstan, imported according to the Rules of importing medicines and medical devices into the territory of the Republic of Kazakhstan and providing public service "Issuing approval and (or) conclusion (approval document) on the import (export) of registered and not registered in the Republic of Kazakhstan medicines and medical devices" approved by Annex 1 to Order of the Minister of Health of the Republic of Kazakhstan dated December 8, 2020 № ҚР ДСМ-237/2020 "On approval of the Rules of import to the territory of the Republic of Kazakhstan and export from the territory of the Republic of Kazakhstan medicines and medical devices and public service "Issue approval and (or) conclusion (approval document) on the import (export) of registered and not registered in the Republic of Kazakhstan medicines and medical devices" (registered in the Register of State Registration of Normative Legal Acts under No. 21749) (hereinafter referred to as the "Rules for Importation").

Marked medicines are medicines, which are marked with identification means in compliance with the requirements of these Rules, and information on which is contained in the IS for marking and traceability of goods, designed for information support of the marking and traceability of goods in circulation (hereinafter - IS MTG).

7. Marking of medicines by means of identification does not apply to:

1) medicines intended for the treatment of passengers and crew members of vehicles, train crews and drivers of vehicles entering the customs territory of the Eurasian Economic Union;

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

3) medicines made in pharmacies;

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

5) Pharmacopoeial medicinal plant material, including in collections and consumer package;

6) medicines manufactured in the Republic of Kazakhstan for export only;

7) samples of medicines and medical devices needed for exhibitions without the right to sell them further;

8) samples of medicines received for preclinical (non-clinical) and clinical trials and/or tests;

9) radiopharmaceutical medicines manufactured directly in health-care organizations at the point of use;

10) samples of medicines required for expert examination for state registration;

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

12) medicines manufactured and/or imported before the introduction of marking and traceability of medicines, which are stored and sold before the expiry date;

13) the cases provided for in Article 8 Agreement on marking of Goods by Means of Identification in the Eurasian Economic Union, ratified by the Law of the Republic of Kazakhstan “On Ratification of the Agreement on marking of Goods by Means of Identification in the Eurasian Economic Union”.

8. The expert agency, when carrying out expert examination of a medicine in accordance with the Rules for Expert Examination of Medicines, approved by Order Minister of Health of the Republic of Kazakhstan dated 27 January 2021 № ҚР ДСМ-10 "On approval of rules for expert examination of medicines and medical devices" (registered in the Register of state registration of regulatory legal acts under № 22144), carries out examination of authenticity of translation or translation into the Kazakh language of the general medical specifications, instructions for medical use

(package leaflet), packaging marking layouts, marks, marking stickers.

9. Marking on the package should be in clear, legible, easily legible and indelible letters, in legible script and should be retained throughout the shelf life of the medicine if the prescribed storage conditions are met.

10. The marking of the secondary package or, failing that, the primary package shall include the following information:

1) trade name of the medicines;

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

3) name of the manufacturer of the medicine, address. The name of the manufacturer and its address shall be indicated in full or in abbreviated form (city, country). A trademark shall be indicated if it is granted legal protection in the Republic of Kazakhstan.

If the manufacturer of the medicine is not the packer, the name of the packer, date and time of packing should be specified;

4) name of the holder of the registration certificate, his address (city, country);

5) dosage form;

6) dosage and/or activity and/or concentration (if applicable) of the active pharmaceutical substance(s);

7) the quantity of the medicines 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 medicine;

9) for medicinal plant preparations, which are packaged medicinal plant raw materials, the weight of medicinal plant raw materials and (or) active pharmaceutical substance of plant origin shall be indicated at a certain moisture content;

10) for medicines containing in their composition substances which are subject to control according to the Law of the Republic of Kazakhstan “On narcotic drugs, psychotropic substances, their analogues and precursors and measures of counteraction to their illicit circulation and abuse" (hereinafter referred to as Law), names of these substances and their content in units of weight or percentage are indicated.

In single-component medicines, provided that the name of the medicine and the active pharmaceutical ingredient are authentic and its dosage, concentration, activity - the composition of the active pharmaceutical ingredient is not specified;

11) list of excipients:

for parenteral, ophthalmic and topical preparations, a list of all excipients is indicated;

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

for other dosage forms, a list of antimicrobial preservatives, colorings as well as sugars and ethanol is indicated;

the list of excipients to be indicated on the marking of medicines for oral administration is given in Annex 1 to this Regulation;

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

13) method of administration and, depending on the dosage form, route of administration (the method of administration is not specified for tablets and capsules intended for oral administration);

14) precautions;

15) warning notices;

16) storage conditions, storage characteristics and transport conditions;

17) conditions for dispensing (prescription or non-prescription);

18) series number;

19) date of manufacture;

20) expiry date: "valid until (date, month, year)" or "(date, month, year)";

The expiry date "valid until (month, year)" or "(month, year)" shall be indicated, with the expiry date being up to and including the last day of the month indicated;

21) registration number of the medicine in the form of the symbol "РК-ЛС- " ;

22) barcode (if any);

23) a means of identification or a tangible medium containing a means of identification.

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

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

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

3) the name of the manufacturer of the medicine and/or its trade mark;

4) series number;

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

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

Intermediate package which does not allow the information on the primary packaging to be read without tampering with it, duplicates the information on the primary package.

12. When marking small primary package (one side area does not exceed 10 cm^2) enclosed in a secondary package (on an ampoule, insulin vial, syringe tube, dropper tube, cartridge, syringe pen), in accordance with clause 32 of the Technical Regulation "Requirements for marking product" approved by the order of Minister of Trade and Integration of the Republic as of May 21, 2021 № 348-Н Қ "On approval of technical regulations "Requirements for product marking" (registered in the Registry of state registration of regulatory legal acts under № 22836) specifies:

1) the trade name of the medicinal product, indicating the dosage, activity or concentration;
2) mass or volume;
3) series number;
4) expiry date "month, year".

13. The composition of homeopathic medicines is stated according to the terminology accepted in homeopathy: the names of homeopathic pharmaceutical substances are stated in Latin, indicating the scale and degree of dilution, the names of excipients are stated according to the documents of the registration dossier.

14. For herbal medicinal preparations, which are prepackaged herbal medicinal raw materials, the composition is indicated for the collections only and the procedure for preparing aqueous extracts, indicating storage conditions and shelf life of the aqueous extract is given.

15. Ampoules containing narcotic drugs, psychotropic substances and precursors listed in Table II of the list of narcotic drugs and psychotropic substances used for medical purposes and closely monitored, approved by the Resolution of the Government of the Republic of Kazakhstan as of July 3, 2019 No. 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 Attribution of Narcotic Drugs, Psychotropic Substances, their Analogues and Precursors Found in Illicit Circulation to Small, Large and Very Large Amounts, the List of Hydrogen Atoms, Halogens and (or) hydroxyl groups in the structural formulae of narcotic drugs,

psychotropic substances" specified in the Law have a clearly visible double red stripe on the capillary.

16. When marking a bulk product of medicines manufactured by foreign manufacturers and packaged in package (primary, secondary) by a manufacturing organization of the Republic of Kazakhstan, the secondary package, and in its absence, the primary package shall additionally indicate:

1) the name, trademark of the foreign manufacturing organization, country of the bulk product of the medicine;

2) the batch number of the prepackaged medicinal product assigned by the manufacturing organization that carried out the packaging, taking into account the date of manufacture of the bulk product of medicine;

3) the expiry date, which is calculated from the date of manufacture of the bulk product of medicine.

17. When marking a set of medicine with a solvent, the name, volume, concentration, composition, series number of the solvent or series number of the set should be additionally indicated on the secondary package. The expiry date is indicated by the lowest expiry date of the component (medicinal product, solvent) included in the kit.

18. The package (secondary and/or primary) of a medicine bears the following inscriptions:

1) "For children" - for medicines intended for children;

2) "Homeopathic remedy" - for homeopathic medicines;

3) "Radiation-tested and safe" - for medicinal plant material;

4) The product is controlled and safe against parenteral viruses, including human immunodeficiency viruses (types 1 and 2) and hepatitis B and C" - for medicinal products derived from human organs and/or tissues;

5) "Parapharmaceuticals" - for parapharmacists.

19. Medicines derived from genetically modified sources are marked as follows: "Genetically modified" or "Based on genetically modified sources", or "Containing components derived from genetically modified sources".

20. Marking on the package of a medicine (secondary and/or primary) requiring special conditions for storage, handling and use shall include the following warnings:

"Keep out of reach of children";

"Sterile" - for sterile medicines;
"No antibodies to human immunodeficiency virus", "No antibodies to hepatitis viruses" - for medicinal products obtained from human blood;
the insertion of sachets (tablets) with desiccant in the primary package of a medicine;
for parenteral medicines, indicate the route of administration ("Intravenous", "Intramuscular", "For infusion", "Subcutaneous"); if the medicinal product is administered by three or more routes, indicate "For injection".
On the primary package, the route of administration is abbreviated ("Intravenous (I.V.)", "Intramuscular (I.M.)", "Subcutaneous (S/K)", for a medicine which is administered by three or more routes - "For Injection (F/I)");
explaining safety requirements, precautions for transport, storage and use:
"Shake before use"; "Handle with care"; "Keep away from fire", "Do not freeze" (if necessary).
When sachets (or tablets) with desiccant are present in the intermediate or secondary package of a medicine, a warning mark is affixed to the sachets (or tablets) with the appropriate content.
21. For radiopharmaceutical medicines, package (primary and secondary) are marked in accordance with the Republic of Kazakhstan Law "On radiation safety of population" and the Law of the Republic of Kazakhstan "On Use of Atomic Energy" and meets the following requirements:
1) the marking on the protective container further explains the coding given on the primary package, indicates the number of radioactivity units in the dose or in the primary package for a given period of time and date, and the number of dosage forms (capsules) or the volume of the liquid dosage form in milliliters;
2) the marking on the primary package contains the following information:
the trade name or code of the medicine, including the name or chemical symbol of the radionuclide;
series number and expiry date;
the international symbol for radioactivity;
the name and address of the manufacturer of the medicine;
the number of radioactivity units in accordance with the approved regulation document.
22. Marking of immunobiological medicines shall, in addition to the information specified in paragraphs 10, 11, 12 of these Regulations, have the following additional information describing the immunobiological product:

1) for immune sera, the following is indicated:

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

species origin (human or species of animal used for extraction);

technology of receipt (e.g. purified, concentrated);

physical state (liquid, dry);

dosage;

expiry date (indicated as "date, month, year"), not indicated on the primary package of 1 milliliter or less, enclosed in the secondary package;

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

the name and dose of any antimicrobial preservative or other additive contained in the immuno-serum;

name of any excipient likely to cause an adverse reaction;

contraindications for use

2) for lyophilic-dried immune sera:

the name or composition and the amount of solvent needed;

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

3) for vaccines:

group name with the word "Vaccine" and specificity;

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

biological state (live, inactivated);

physical state (liquid, dry);

name and quantity of antimicrobial preservative (if needed);

name of antibiotic, adjuvant, flavouring agent or stabilizer in the vaccine;

the name of the excipient that may cause any adverse reaction and the contraindications for use;

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

4) For lyophilised vaccines, in addition to the information specified in sub-clause (3) of this clause, the following is specified:

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

the conditions and period of administration of the vaccine after dissolution;

5) for allergenic medicines:

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 lyophilised allergenic preparations, in addition to the information specified in sub-clause (5) of this clause, the following is indicated:

the name, composition and volume of the fluid to be added for rehydration;

storage conditions and the length of time for which the product is used after rehydration;

information on sterility (not specified for non-sterile preparations);

name and quantity of adsorbent;

7) for therapeutic and prophylactic phages:

the name, composition and activity of the phages;

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

for multi-component drugs - the specificity and activity of each phage;

8) for diagnostic immunobiological preparations: group name (e.g. diagnosticum, antigen, diagnostic serum);

indications for use, indicating the infection, pathogen or antigen for the diagnosis of which and by which methods (techniques) it is used;

the nature and technology of the active ingredient;

the designation of the antigens, antibodies, phages in the composition;

the physical state (liquid, dry);

for serum: species, group, monoclonal, polyvalent.

23. Medicines manufactured in the conditions of a pharmacy are dispensed to the public in primary package with an appropriate mark containing information for the consumer in the state and Russian languages and decorated with a medical emblem (a bowl with a snake) in accordance with paragraphs 25-31, 61-62 of these Rules.

24. Each mark is marked according to the mode of administration of the medicinal product. Marks with corresponding marking are divided into:

1) marks for internal dosage forms: "Internal", "Internal child";

2) marks for dosage forms for external use: "External";

3) marks for parenteral dosage forms: "For injection";

4) marks for eye medication: "Eye drops", "Eye ointment".

25. To reduce the risk of dispensing errors, the mark uses signal colours in the form of a coloured band on a white background:

1) on marks for dosage forms for internal use - green;

2) on marks for dosage forms for external use - orange;

3) on marks for eye medicine - pink;

4) on marks for parenteral dosage forms - blue.

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

27. Marks for the registration of individually manufactured medicines must contain the following information:

1) the name of the pharmacy;

2) the location (registered office) of the pharmacy;

3) prescription number;

4) name (if any) of the patient;

5) the designation according to dosage form and method of administration in accordance with paragraphs 25, 28 and 29 of this Regulation;

6) detailed method of application:

for mixutes: "a _____spoonful ___times a day ____meal";

for drops for internal use: " _____drops _____times a day_____meal";

for powder: "_____powder _____times a day____meal ";

for eye drops: "_____drops _____times a day____eye";

for other dosage forms, as well as externally applied, a space is left for indicating the mode of administration;

7) date of manufacture;

8) storage period (number of days);

9) price;

10) warning mark "Keep out of reach of children".

Marks for the designation of mixtures, drops for internal use, ointments, eye drops, eye ointments shall, in addition to the symbols listed, bear the symbols set out in clauses 8, 12 and the corresponding warning notices set out in paragraphs 11, 52 of this Regulation.

28. The marks of the different types of dosage forms additionally indicate the following information:

1) Intravenous (IV), intravenous (dropwise), intramuscularly, subcutaneously;

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

3) designed for disinfection: "For disinfection", "Handled with caution";

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

5) intended for infants: "For infants";

6) series.

29. Marks for registration of medicinal products manufactured for medical facilities shall, in addition to the information specified in clauses 27, 28 of these Rules, indicate:

1) the name of the health facility for which they are designated;

2) the name of the branch;

3) the signature of the person who prepared, checked and dispensed the medicinal product ("prepared____"; "checked____"; "dispensed____"));

4) analysis number;

5) composition of the dosage form.

30. All pharmacy marks are typographically printed with a warning mark corresponding to each dosage form:

1) for mixtures: "Keep in a cool and light-protected place", "Shake before use" ;

2) for ointments, eye ointments and eye drops, suppositories: "Keep in a cool and light-protected place;

3) for injections and infusions: "Sterile";

4) those requiring special conditions for storage, handling and use are additionally marked "Handle with care"; "Protect from fire".

31. Medicines containing poisonous substances (mercury dichloride, mercury cyanide, mercury oxycinide) have a black warning mark with an image of a skull and crossed bones and the words "Poison" and "Handle with Care" in white font. The mark indicates the name of the poisonous substance and its concentration.

Paragraph 1: Procedure for the formation of means of identification

32. The means of identification of medicines contain a marking code representing a unique sequence of characters comprising 4 groups of data identified by the application codes of the GS1 Data Matrix standard of the International Organization for Standardization in Accounting and Barcoding of Logistical Units.

The GS1, FNC1, ASC232 International Organization for Standardization of Accounting and Barcoding of Logistic Units barcode format characteristic is present at the beginning of the marking code line.

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

the first group is identified by application code 01 and contains the product code GTIN of the consumer package, consisting of 14 digits;

the second group is identified by application code 21 and contains an individual serial number of a consumer package of medicinal products consisting of a 13-character numeric or alphanumeric sequence (Latin alphabet letters). This group is terminated by a special separator character ASCII 29;

The marking code verification code forms the third and fourth data group:

the third group is identified by application code 91 and contains 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. ASCII delimiter character shall be used to terminate this group;

the fourth group of data is identified by application code 92 and contains the value of the verification code consisting of 44 characters (digits, lower and upper case Latin letters and special characters) generated by the Operator as part of the verification code.

33. Generation of the means of identification by the Operator in the IS MTG, after registration and signing contracts by PMC in the IS MTG with the help of EDS.

34. Registration of the PMC in the IS MTG and provision of access to a personal account is performed by the Operator on the basis of an application for registration in the IS MTG, signed by the EDS of a head or an individual entrepreneur.

PMC, who are not residents of the Republic of Kazakhstan, for registration in the IS MTG use a digital signature that meets the requirements of the Law of the Republic of Kazakhstan "On Electronic Document and Electronic Digital Signature".

35. The PMC is refused to registration in the IS MTG in the following cases:

1) IIN (BIN) or taxpayer identification (individual) number or international analogue (hereinafter - TIN), which is a unique taxpayer number of a non-resident legal entity of the Republic of Kazakhstan, assigned (issued) by the tax authority in the country of registration of the PMC, indicated upon receipt of EDS, do not correspond to the information indicated upon registration in the IS MTG;

2) The PMC is already registered in the IS MTG.

36. If the PMC is registered in the IS MTG, the Operator shall, within 1 (one) calendar day from the date of registration of the PMC:

1) include the PMC in the list of registered PMC in the IS MTG;

2) provides access to the personal account of IS MTG of PMC.

37. Registration of medicines in the IS MTG shall be carried out by PMC requesting marking codes to ensure the marking of medicines with identification means in accordance with Annex 2 of the Regulation.

38. The composition of the data of the product card intended for registration of a medicine in the IS MTG is provided to the Operator by the public authority.

39. For registration in the IS MTG of a medicine card which has state registration in the Republic of Kazakhstan, information shall be entered in accordance with the composition of data of the medicine card provided by the state body on the basis of information registered in the State Register of Medicines and Medical Devices.

40. The PMC automatically refuses to register medicines in the IS MTG in the following cases:

1) the medicine with the GTIN product code declared at registration is already registered in the IS MTG;

2) GTIN goods code according to GS Kazakhstan information system is not subject to use by PMC;

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

The PMC registering the medicine ensures that the data on the medicine entered into the IS MTG at the time of registration is correct.

41. Following the registration of medicinal products, the Operator shall, within three (3) working days, include the submitted information in the register of goods of the IS MTG and transfer all data on registration to the IS of the authorized body.

42. In order to ensure the marking of medicines with the means of identification by the PMC through the IS MTG, a request for marking codes in the form according to Annex 2 to these Regulations (hereinafter referred to as the request) shall be sent to the Operator.

43. The issuance of marking codes is automatically refused in the following cases:

1) PMC is not registered in the IS MTG;

2) the product identification code submitted has previously been registered in the IS MTG;

3) the GTIN goods code is not registered in the IS MTG goods register and/or is not subject to use by the PMC;

4) the goods code GTIN does not correspond to the product group "medicinal products".

44. If the information provided in the request complies with the requirements set out in these Regulations, the Operator shall, within one (1) working day from the date the request for marking codes is sent to the PMC:

1) issue (generate), for the number of marking codes specified in the request, using cryptographic protection algorithms based on the data received from the PMC;

2) include the relevant product identification codes in the register of means of identification;

3) provide information on the issuance of marking codes to the PMC in the form set out in Annex 3 to this Regulation.

45. Upon receipt of the marking codes, the PMC shall convert them into identification means, ensure their application to the package of the medicinal product, and transmit to the IS MTG information on product identification codes (application of identification means) contained in the identification means applied to the medicines, the date of application of identification means, as well as the series/batch number and expiry date of the medicine marked with identification means, as per the form in Annex 4 to these Regulations.

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

1) goods identification codes not available in the IS MTG register;

2) the details of the identification codes have not been submitted in accordance with the requirements stipulated in these Regulations.

3) there is no confirmation of the payment of the marking codes converted into means of identification, the application of which is communicated to the IS MTG by the PMC.

47. The marking code contained in the identification device applied to the medicine package is not re-generated (not formed) in the IS MTG.

Paragraph 2: Procedure for applying means of identification

48. The application of the means of identification is carried out:

in the manufacture of medicines on the territory of the Republic of Kazakhstan - by manufacturers of medicines;

in the manufacture of medicines outside the Republic of Kazakhstan (foreign production):

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

2) importers importing medicinal products into the territory of the Republic of Kazakhstan, if the foreign manufacturer does not have a representative office or a branch or a subsidiary on the territory of the Republic of Kazakhstan.

49. The medicine identification means is applied in the form of a two-dimensional Data 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 machine-readable data, with the obligatory indication in legible printed text of the GTIN product code and the unique serial number of this medicine contained in the means of identification.

The information on the GTIN goods code and the unique serial number of the medicine on a voluntary basis is preceded by the application codes, which are a set of two (2) or more characters, placed at the beginning of the item line and uniquely identifying the intended use, and the data field format, for use in the manual entry of the PMC goods identification code.

50. Identification means shall be applied by direct printing on the secondary package (in its absence - on the primary package) of a medicine or by printing on a tangible medium, which does not allow to separate the tangible medium containing the identification means 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 is not carried out on transparent wrapping film or any other external wrapping material.

In this case, the means of identification itself or the tangible medium containing the means of identification shall be placed so as not to compromise the integrity of the information applied to the package (secondary, and if not available, primary package) of a medicine in accordance with the requirements of the legislation of the Republic of Kazakhstan.

52. Specifications for the quality of the application of the means of identification on the package of medicine are:

1) printing using the ECC-200 error correction method;

2) use of ASCII coding;
3) print quality is class C or better.
53. The identification code of the transport package shall be formed by the PMC aggregating (combining) consumer packages of medicines into the transport package independently, in the form of a linear bar code compliant with the International Organization for Standardization standard for accounting and bar coding of logistical units ГС1-128, with a unique identifier of the transport package as a serial code, represented as a digital number SSCC code and identified by application code AI='00'.
54. The transport package identification code is printed on the front or side of each individual transport package at the discretion of the PMC to facilitate and simplify the aggregation of the goods.
55. In order to provide marking services, the Operator has contractual relationships with natural and legal persons owning:
1) sources ensuring 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 that meet the standard of good distribution practice, where PMC have the possibility of affixing means of identification to the tangible carrier.

Paragraph 3: Aggregation of medicines marked with the means of identification

56. Aggregation is carried out when there are several levels of nesting:
1) first-level aggregation - combining primary and/or secondary packages into a transport package;
2) second-level aggregation - combining transport packages into another transport package of a higher nesting level.
57. The PMC shall aggregate packages of medicinal products having one GTIN goods code into a transport package, as well as transport packages of medicinal products into a higher-level transport package, while maintaining information on the relationship between the identification codes of each nested package and the identification code of the package created in order to ensure traceability of medicines through the supply chain without the need to open the transport package created.

PMC prior to the transfer of an aggregated package to the next PMC, shall provide the IS MTG with information on the aggregation of packages in the form of Annex 5 to these Regulations.

The transmission by the PMC of information on the transport package shall be considered equivalent to the transmission of information on the consumer package contained in that transport package from the IS MTG.

58. When an PMC submits to the IS MTG information on the circulation or withdrawal from circulation of a part of the marked medicinal products contained in the transport package, the disassembly of the transport package containing the withdrawn medicines is registered in the IS MTG within 3 (three) working days.

59. When a medicine is transferred to another transport package, the information on aggregation shall be submitted to the IS MTG in accordance with the requirements stipulated by paragraph 57 of these Rules. At the same time, all packages containing withdrawn medicines shall be registered in the IS MTG.

60. The operator, upon receipt of the information on the aggregation of medicines under this chapter, shall automatically ensure that this information is reflected in the register of means of identification, and that this information is available to the PMC in the IS MTG.

Chapter 3: Procedures for marking medicines

61. Marking on stickers complies with the requirements of these Rules and is approved upon state registration of the medicinal product in the Republic of Kazakhstan.

62. Stickers on the package shall be applied by the organization-manufacturer of the medicinal product to each unit of the package (in case of first opening control only to the secondary package) in the Kazakh and Russian languages.

63. The sticker is placed on the package, leaving open the trade and/or international nonproprietary name and dosage of the medicine of the original mark.

64. The application of stickers on the package of medicines 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 manufacturing the medicine or a pharmaceutical market entity which carries out the importation of unregistered medicinal products.

Marks on stickers of medicinal products not registered in the territory of the Republic of Kazakhstan are placed in Kazakh and Russian.

Chapter 4. Traceability procedures for medicines marked with the means of identification

65. Traceability of medicines marked with identification means shall be ensured by submitting by the PMC and entities in the sphere of circulation of medicines and medical devices the information on putting into circulation, sale and (or) transfer, as well as withdrawal from circulation of marked medicines on the territory of the Republic of Kazakhstan in accordance with the requirements of these Rules.

Paragraph 1: Procedure for submitting information in the information system for marking and traceability when medicines marked with identification means are put into circulation in the Republic of Kazakhstan

66. Putting into circulation of medicines marked with the means of identification in the territory of the Republic of Kazakhstan shall be:

1) in production of medicinal products on the territory of the Republic of Kazakhstan - primary reimbursable or gratuitous transfer of medicines from a manufacturer of medicines to another PMC with 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 medicines from the territories of states which are not members of the Eurasian Economic Union - release of medicines for domestic consumption by the customs authorities of the Republic of Kazakhstan based on the results of sending a notice to the IS MTG on the importation of goods into the Republic of Kazakhstan from the territories of states which are not members of the Eurasian Economic Union;

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

67. PMC importing medicines to the Republic of Kazakhstan from the territories of the Eurasian Economic Union member states shall, prior to crossing the state border of the Republic of Kazakhstan, form a notification on the import of goods to the Republic of Kazakhstan from the territories of the Eurasian Economic Union member states according to the form of Annex 6 to the present Regulations, sign it with EDS and send it to the IS MTG to obtain a registration number.

Upon acceptance of the imported medicines at the importer's warehouse in the Republic of Kazakhstan, the PMC shall send to the IS MTG information on confirmation of the identification codes declared earlier in the notification on importation of goods into the Republic of Kazakhstan from the territories of the Eurasian Economic Union member states.

68. PMC importing medicines into the Republic of Kazakhstan from territories of states that are not members of the Eurasian Economic Union, upon acceptance of imported medicines into the importer's warehouse in the Republic of Kazakhstan, shall generate a notification on import of goods into the Republic of Kazakhstan from territories of states that are not members of the Eurasian Economic Union, in accordance with Annex 7 to this Regulation, sign it with EDS and send to the IS MTG to obtain a registration number.

69. The notification on import of medicines into the Republic of Kazakhstan shall be executed electronically, except for cases when the PMC executes the notification on paper upon confirmation of information on the Operator's Internet resource that the notification cannot be executed in the IS MTG due to technical errors in the IS MTG upon a forwarded request of the PMC to the Operator's technical support service. The Operator shall publish information on its own website about the occurrence of technical errors in the IS MTG not later than 24 hours from the moment of their occurrence.

After elimination of technical errors, the notification on import of medicines into the Republic of Kazakhstan, previously issued on paper, is sent by the importer to the IS MTG within 1 (one) working day from the date of publication on the Internet resource of the Operator of information on the elimination of technical errors in the IS MTG. The Operator publishes information on its own website about the elimination of technical errors in the IS MTG within 24 hours from the moment of their elimination.

Paragraph 2: Procedure for submitting information in the information system for marking and traceability of goods in circulation of medicinal products marked with identification means on the territory of the Republic of Kazakhstan

70. Circulation of medicines in the territory of the Republic of Kazakhstan, after the date of introduction of marking by means of identification according to the Law on Trade Activities Regulation, is carried out upon transfer of information on their sales to the IS MTG, with the condition of compliance with the stage of introduction of marking and traceability.

71. When selling and (or) transferring medicines marked with identification means to another PMC, the sender of the medicines shall draw up an acceptance (transfer) report according to the form in Appendix 8 to these Regulations, sign it with EDS and send it to the IS MTG to obtain a registration number, no later than the day of selling the medicines.

When a Single Distributor sells and (or) transfers medicines marked with identification means within the GS of FMC and (or) in the MSHI system, the Acceptance Report of medicinal products shall be formed and signed by authorized representatives of logistics companies providing storage and transportation services to the Single Distributor under a civil law contract, based on the power of attorney issued by the Single Distributor, information on which is contained in the IS MTG.

72. The operator, following the registration of the acceptance report of PMC medicines in the IS MTG, transmits to the Electronic Invoice Information System the information on this report, including information on the quantity of the goods transferred.

73. Acceptance of medicines marked with the means of identification is confirmed in the IS MTG by the subject in the field of circulation of medicines and medical devices.

In this case, a subject in the field of circulation of medicines and medical devices who performs acceptance of medicines from another subject in the field of circulation of medicines and medical devices marked with identification means, ensures signing of acceptance report of goods with EDS and transfer of information on acceptance of medicines to the IS MTG within 1 (one) working day from the date of acceptance until further operations.

74. Upon receipt from entities in the field of circulation of medicines and medical devices of information on acceptance of the acceptance report signed with an EDS, the Operator shall transfer information on acceptance of goods to the Electronic Invoice Information System.

75. If discrepancies in acceptance of medicines are identified, the recipient of the medicines shall generate a notification of identified discrepancies and send it to the sender who sold and (or) transferred the medicines to make changes to the previously sent acceptance report of goods. In this case, the previously sent acceptance report is automatically withdrawn in the IS MTG.

The withdrawal of the acceptance report by the sender shall take place within twenty (20) working days after the date of registration in the IS MTG, but before the confirmation by the recipient, without drawing up a new certificate,

except in the case provided for in part one of this clause.

76. The notification of discrepancies shall contain the following information:

1) vendor's IIN (BIN);
2) the recipient’s IIN (BIN);
3) list of identification codes for accepted packages of medicines;
4) list of identification codes of the packages of medicines for which information is missing in the acceptance report (if any);
5) details of the acceptance report of goods.

77. The acceptance report for medicines shall be drawn up in electronic form, except in the cases specified in clause 71 of the Rules.

78. The acceptance report for medicines should be drawn up on paper:

1) due to a technical failure in the IS MTG as confirmed by the Operator on its website;
2) due to force majeure;
3) due to the absence or interruption of electricity supply confirmed by the energy producing, energy supplying or energy transmitting organization, technical failure caused by an emergency breakdown.

79. The Operator shall post on its website information on the impossibility to draw up an acceptance report of medicines in the IS MTG due to technical errors in the IS MTG within 24 hours of the occurrence of technical errors in the IS MTG.

80. After the elimination of technical errors, the acceptance report of medicines previously issued in hard copy shall be entered by the subject in the field of circulation of medicines and medical devices into the IS MTG not later than 1 (one) business day from the date of publication of information on the elimination of technical errors in the IS MTG by the Operator on its own website. The Operator publishes information on its own website about the elimination of technical errors in the IS MTG within 24 hours of their elimination.

81. The change of ownership of the marking codes in the IS MTG is made on the basis of information confirmed by both parties from the report of acceptance of medicines in the IS MTG.

Paragraph 3: Procedure for submitting information to the Information System for the Marking and Traceability of Goods when withdrawing medicines marked with the means of identification from circulation

82. An entity in the field of circulation of medicines and medical devices that sells medicines in retail for cash, non-cash and (or) without payment by the

recipient, performs their withdrawal from circulation by scanning and recognizing the means of identification applied to the consumer package of the medicine by technical means interfaced with a cash register machine installed with him, registered in accordance with Order No 208 of the Minister of Finance of 16 February 2018 "On certain issues of application of cash register machines" (registered in the Register of State Registration of Legal Acts under No 16508).

Information on the identification code contained in the means of identification applied to the goods shall be included in the fiscal document "cashier's check" generated by the cash register and shall be transmitted to the operator of fiscal data.

83. The operator of fiscal data transmits real-time information to the IS MTG for each item sold, which includes the following information:

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

84. Withdrawal of medicines from circulation in the IS MTG is carried out at retail sales on the basis of the information referred to in clause 83 of these Rules, received from the Fiscal Data Operator.

85. An entity in the field of circulation of medicines and medical devices no later than 3 (three) working days following the day of withdrawal of medicines from circulation shall submit to the IS MTG a notification on withdrawal from circulation in the form according to Annex 9 to these Rules in case of withdrawal of medicines from circulation for reasons of:

1) reject;
2) loss;
3) damage;
4) destructions;
5) use for the company's own needs;
6) sampling;
7) for medical purposes;
8) dispensing, with a free prescription;
9) confiscations.

Paragraph 4. Procedure for Submission of Information to the Information System of Marking and Traceability of Goods upon Recurrent Putting Medicines into Circulation Marked with Identification Devices and Introduction of Changes in Information to the Information System of Marking and Traceability of Goods

86. In order to re-circulate medicinal products previously withdrawn from circulation for reasons specified in Clause 85 of these Rules, except for used medicines for medical assistance, as well as prescription medicines dispensed under the GS of FMC and (or) MSHI system, the PMC shall send to the Operator a notification on re-circulation of medicines in the form according to Annex 10 to these Rules.

87. Information of the PMC shall be sent to the Operator within three (3) working days from the date of recurrent putting medicines into circulation.

88. The operator shall, at the request of the public authority, within three (3) working days provide summary information on the traceability of medicines under the GS of FMC and MSHI.

89. The operator ensures the transfer of data to the authorized body's IS through integration with the authorized body.

90. The operator shall provide an automated workstation in the IS MTG for the authorized body and the public authority.

91. Amendments to the information previously submitted to the IS MTG shall not be made during a state body's inspection of a subject's activities in the field of circulation of medicines and medical devices.

92. The operator's access to information shall be provided in accordance with the Code of the Republic of Kazakhstan "On Taxes and Other Obligatory Payments to the Budget" (Tax Code), Law Republic of Kazakhstan "On Personal Data and its protection" and Law of the Republic of Kazakhstan "On Access to Information" and within the framework of current legislation of the Republic of Kazakhstan.

Annex 1 to
regulations on the
marking and traceability
of medicines

List of excipients used in the marking of medicines for oral administration

Name of the excipient	Substance code	Threshold content
Azo dyes:		
Sunset yellow	E110	0
Azorubin (carmoisine)	E122	
Punchy (Ponceau 4R, Wheat red A)	E124	

Brilliant black BN (shiny black 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 (macrohola glyceryl acinoleate, macrohola glyceryl hydroxystearate)		0
Preservatives		0
Xylitol (xylitol)		10 g
Sesame oil		0
Lactitol (lactite)	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
Inverted sugar		0
Saccharose		0
Soya oil		0
Sorbitol (sorbitol)	E420	0
Phenylalanine		0
Formaldehyde		0
Fructose		0
Ethanol (ethyl alcohol)		0

Annex 2 to regulations
on the marking and
traceability of medicines

Request for marking codes

Information on PMC:

1. IIN or BIN or TIN _____

2. General data:

1) the way the medicine is released _____

2) country of manufacture _____

3. Production data_____

4. List of products to be marked:

№	Product code	Number of marking codes	Method of generating individual serial numbers	Array of individual serial numbers	Type of package
1.	2	3	4	5	6
2.					
3.					
…					

Annex 3 to regulations
on the marking and
traceability of medicines

Information on the issue of marking codes

Information on PMC:

1. IIN or BIN or TIN _____

2. On request No. for the production site (code)_____ _____
marking codes are provided:

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

Annex 4 to regulations
on the marking
and traceability of medicines

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

Information on PMC:

1. IIN or BIN or TIN _____

2. General information:

1) production series number_____

2) expiry date_____

4. List of marking codes used:

№*	Array of marking codes (identification code + verification code)
1.	2
2.	
…	

Note:

* the number of marking codes does not exceed 30,000 codes.

Annex 5 to the Regulations
on the marking and traceability
of medicines form

Information on package aggregation

1. Information on PMC (general data):

IIN or BIN or TIN_____

2. Aggregate data:

Aggregate data					Array of aggregated cash registers
№	Identification code of the aggregation unit	Packaging capacity	Actual number of pieces per unit of aggregation	№	Identification code
1.	2	3	4	5	6
2.					
…					

Annex 6 to the Regulations
on the marking and traceability
of medicines form

Notification on the importation of medicines into the Republic of Kazakhstan from the territories of the member states of the Eurasian Economic Union №____as of _____

General information:

1. recipient's IIN (BIN)_____

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

_____

3. sender's name_____

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

5. Information on the document confirming the compliance of the goods with the requirements of the Republic of Kazakhstan (date of registration and registration number)

_____

6. Date and number of the primary document – Notification on importation *_____

7. Information on medicines:

№	Goods/package identification code
1.	2
2.	
…	

1. information on the results:

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

The document is signed with an EDS_____

Note:

* to be entered when entering information on a notice previously issued on paper.

Annex 7 to regulations
on the marking and traceability
of medicines

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

General information:

1. recipient's IIN (BIN)_____
2. Details of the goods declaration:

Number and date (column "A")_____

3. Decision on the goods declaration:

date and time of acceptance by the customs authority_____

decision code (in accordance with the classifier of decisions made by the customs authority)_____

4. Information on the document confirming the compliance of the goods with the requirements of the Republic of Kazakhstan (date of registration and registration number)
5. Date and number of the primary document - Notification of importation *_____
6. Product information:

№	Code of the nomenclature for foreign economic activities of the Eurasian Economic Union	Goods number on the goods declaration	Country of production of medicines	Goods/package identification code
1.	2	3	4	5
2.				
…				

The document is signed with an EDS _____

Note:

* to be entered when entering information on a notification previously issued on paper.

Annex 8 to the Regulations
on the marking and traceability
of medicines

Report on acceptance report of medicines №___as of ____

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 Report* №_____as of_____
4. Information on medicines:

№	Product/package identification code
1	2

5. Information on the results:

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

The document is signed with an EDS_____

Nota:

* to be specified when entering information on the acceptance report previously issued on paper.

Annex 9 to regulations
on the marking and traceability
of medicines

Notification of withdrawal of medicines

IIN or BIN or TIN _____

1. Reason for withdrawal: _____

2. Underlying document_____№_____as of _____

3. Information on products withdrawn:

№	Product/package identification code
1	2
2.	
…	

The document is signed with an EDS_____

Annex 10 to regulations
on the marking and traceability
of medicines

Notification of recurrent putting medicines into circulation

1. IIN or BIN or TIN _____

2. Underlying document__№_____as of _____

3. Reason for recurrent putting into circulation_____

4. Information on goods to be recovered in circulation:

№	Product identification code
1.	
2.	
…	

The document is signed with an EDS_____".