On approval of the rules for selection from the market, including in medical organizations, of pharmaceuticals and medical devices subject to quality control taking into account a risk-based approach

Unofficial translation

Order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated December 24 , 2020 no. ҚР ДСМ-323/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 26, 2020 no. 21923.

Unofficial translation

In accordance with subparagraph 20) of Article 10 of the Code of the Republic of Kazakhstan "On the health of the people and the health care system" **I hereby ORDER**:

Footnote. Preamble - in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 14.09.2022 № RK MH-100 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

1. To approve the attached Rules for selection from the market, including in medical organizations, of pharmaceuticals and medical devices subject to quality control taking into account a risk-based approach.

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

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

2) placement of 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, submission to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan of information about execution of measures stipulated by subclauses об 1) and 2) of this clause.

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

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

Acting Minister of Healthcare
of the Republic of Kazakhstan *M. Shoranov*

Appendix
to the order of the
Acting Minister of Healthcare
of the Republic of Kazakhstan

dated December 24, 2020
№ ҚР ДСМ-323/2020

Rules for selection from the market, including in medical organizations, of pharmaceuticals and medical devices subject to quality control taking into account a risk-based approach

Chapter 1. General Provisions

1. These Rules for selection from the market, including in medical organizations, of medicinal products and medical devices subject to quality control taking into account the risk-based approach (hereinafter referred to as the Rules) have been developed in accordance with subparagraph 20) of Article 10 of the Code of the Republic of Kazakhstan "On public health and the health care system" (hereinafter referred to as the Code) and shall establish the procedure for selecting from the market, including in medical organizations, medicines and medical devices subject to quality control taking into account a risk-based approach (hereinafter referred to as sampling).

Footnote. Paragraph 1 – in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 14.09.2022 № RK MH-100 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

2. For the purposes of these Rules, the following terms and definitions shall apply:

1) the state body in the field of circulation of medicines and medical devices (hereinafter referred to as the state body) shall be the state body exercising leadership in the field of circulation of medicines and medical devices, control over the circulation of medicines and medical devices;

2) state expert organization in the field of circulation of medicines and medical devices (hereinafter referred to as the expert organization) shall be a state monopoly entity engaged in production and economic activities in the field of health care to ensure the safety, effectiveness and quality of medicines and medical devices;

3) authorized body in the field of health care (hereinafter referred to as the authorized body) - the central executive body that exercises leadership and intersectoral coordination in the field of health protection of citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological well-being of the population, circulation of medicines and medical devices, quality of medical services (assistance);

4) products - medicines and medical devices registered in the manner prescribed by paragraph 3 of Article 23 of the Code and authorized for medical use in the Republic of Kazakhstan;

5) Internet resource of the expert organization - information (in text, graphic, audiovisual or other form) placed on a hardware and software complex having a unique network address and domain name of the expert organization and functioning in the Internet.

Footnote. Paragraph 2 – in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 14.09.2022 № RK MH-100 (shall enter into force upon expiry of ten calendar days after the day of its first official publication); as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 13.01.2025 № 3 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

3. Selection of samples is carried out by specialists of expert organization performing the assessment of quality of pharmaceuticals and medical devices in accordance with the procedure, stipulated by clause 1 of article 241 of the Code.

4. The state body shall, by October 1, send to the expert organization through the electronic document flow system information in any form on medicinal products and medical devices with identified non-compliances for the previous 3 years according to the results of pharmaceutical control, inspection, according to the Order of the Minister of Health of the Republic of Kazakhstan dated January 27, 2021 № ҚР ДСМ-9 " On approval of the rules for pharmaceutical inspections on good pharmaceutical practices" (registered in the Register of State Registration of Regulatory Legal Acts under № 22143) (hereinafter – Order № ҚР ДСМ-9), and the Order of the Minister of Health of the Republic of Kazakhstan dated December 23, 2020 № ҚР ДСМ-315/2020 "On approval of the Rules for inspections of medical devices" (registered in the Register of State Registration of Regulatory Legal Acts under № 21898) (hereinafter – Order № ҚР ДСМ-315/2020), pharmacovigilance in accordance with the Order of the Minister of Health of the Republic of Kazakhstan dated December 23, 2020 № ҚР ДСМ-320/2020 " On approval of the rules for conducting pharmacovigilance and monitoring the safety, quality and effectiveness of medical devices" (registered in the Register of State Registration of Regulatory Legal Acts under №21896) (hereinafter – Order № ҚР ДСМ-320/2020).

The expert organization shall annually by October 15 develop and send by means of electronic document flow system to the state body the plan of sampling for quality assessment of medicinal products and medical devices in circulation in the Republic of Kazakhstan for the next calendar year (hereinafter referred to as the Plan) in free form for approval.

In case of discrepancies with paragraph 5 of these Rules in terms of inclusion of medicinal products and medical devices in the Plan, the state body shall, within 5 working days from the date of receipt of the Plan, send the draft Plan for revision to the expert organization through the electronic document management system.

The expert organization shall, within 3 working days from the date of receipt of the request, send the Plan for approval by the state body.

The state body shall annually approve the Plan by November 1 and send it via the electronic document management system to the expert organization for posting it in open access on the official Internet resource of the expert organization.

The expert organization shall conclude an agreement with the manufacturer (marketing authorization holder of medicinal products, authorized representative of the manufacturer of

medical devices) or its authorized representatives (hereinafter referred to as the manufacturer) of the products included in the Plan for testing samples of products selected from the market, taking into account the risk-based approach, within 15 working days from the date of the manufacturer's request.

From the moment of conclusion of the agreement for testing samples of products selected from the market taking into account the risk-based approach, the expert organization within 10 working days shall form a schedule for sampling products and shall send it to the manufacturer for approval.

The manufacturer shall agree on the product sampling schedule within 30 calendar days from the date of its receipt. In the absence of approval by the manufacturer within 30 calendar days from the date of receipt of the request from the expert organization, the expert organization within 10 calendar days shall send a notification (in any form) to the state body on the adoption of appropriate measures.

Revision or adjustment of the product sampling schedule shall be carried out by the expert organization within 10 working days after receipt of a written request (in any form) from the manufacturer.

To make a decision on the suspension of current certificates of conformity of products issued in accordance with the Order of the Minister of Health of the Republic of Kazakhstan dated December 20, 2020 № ҚР ДСМ-282/2020 "On approval of the rules for assessing the quality of medicines and medical devices registered in the Republic of Kazakhstan" (registered in the Register of State Registration of Regulatory Legal Acts under № 21836), the expert organization, based on the results of the calendar year, by January 15 of the year following the reporting period, shall send information (in any form) on the product to the state body:

1) included in the plan but not selected due to the manufacturer's failure to enter into an agreement to test product samples selected from the market taking into account the risk-based approach;

2) included in the plan, under which a agreement has been concluded for testing product samples selected from the market taking into account a risk-oriented approach, but sampling has not been carried out in accordance with the terms of the agreement.

Footnote. Paragraph 4 as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 13.01.2025 № 3 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

5. The following shall be included in the Plan:

1) medicinal products requiring special storage conditions (stored at temperatures up to + 15 (degrees Celsius));

2) medicines by trade names purchased within the framework of the guaranteed volume of free medical care and (or) the system of compulsory social health insurance by a single distributor as of December 1 of the current year, with the exception of orphan medicines;

3) medicinal products registered for the first time in the Republic of Kazakhstan;

4) medicinal products of parenteral administration;

5) sterile medicinal products and medical devices, as well as medical devices that shall be personal protective equipment intended by the manufacturer for the protection of patients or medical personnel and used for medical purposes for personal protection, with the exception of implantable and medical devices for in vitro diagnostics, as well as medical equipment;

6) medicines and medical devices with detected non-conformities based on the results of pharmaceutical control, inspection in accordance with Orders № КР ДСМ-9, № КР ДСМ-315/2020 and № КР ДСМ-320/2020, selection from market for the previous 3 years, as well as in the presence of inconsistencies with quality requirements reported by regulatory authorities.

Selection from the market of medicinal products and medical devices subject to quality control taking into account the risk-based approach shall be carried out annually.

Footnote. Paragraph 5 as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 13.01.2025 № 3 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

Chapter 2. Procedure for selection from the market, including in medical organizations, of pharmaceuticals and medical devices subject to quality control taking into account a risk-based approach

6. Selection of samples is carried out in organizations manufacturing pharmaceuticals and medical devices, organizations engaged in the wholesale and retail sale of pharmaceuticals and medical devices (pharmacies, including those selling via the Internet, pharmacies in health care organizations, pharmacies, distribution warehouses, temporary warehouses for pharmaceuticals, medical products, optical stores, medical product stores), and also in healthcare organizations in the presence of a manufacturer's representative.

7. Selection of samples is carried out in the amount required for one-time laboratory tests.

When selecting samples, a product-sampling certificate is drawn up in the form according to the appendix to these Rules.

8. Simultaneously with the product sampling for testing, control sampling shall be carried out in the amounts equal to the amount of the selected samples.

9. Finished pharmaceuticals in consumer packaging are subject to selection of samples.

10. When sampling, precautions are taken to take into account the toxicity, explosion hazards, flammability, hygroscopicity of pharmaceuticals, and to keep them from contamination.

Selection of samples is carried out subject to the conditions that exclude deterioration in the quality of pharmaceuticals.

Methods of selection of samples ensure that the chemical composition of the product remains unchanged between collection and analysis.

Samples shall be taken among intact packaging units, which are sealed and packed in accordance with regulatory documentation.

11. To perform the test pharmaceuticals for compliance with the requirements of the regulatory document, a multistage selection of samples shall be carried out. Samples in each stage are taken at random in proportional amounts from units taken in the previous stage. The type of packaging shall determine the number of stages.

The first stage: selection of packaging units (boxes, boxes, bags, bottles, drums);

The second stage: selection of packaging units in packaging containers (boxes, vials, cans);

The third stage: selection of products in primary packaging (ampoules, tubes, blister packs).

The calculation of the amount of selected products at each stage is carried out according to the formula 0.4

$\sqrt{n}$

, where

n

is the number of samples of a given stage of one series (batch). The fractional number obtained as a result of calculation by the formula is rounded up to an integer, which is not less than 3 and not more than 30.

In case of insufficient number of samples for testing, samples shall be re-selected as described above.

From the packaging units selected at the last stage, after control in appearance, a sample is taken in the amount necessary for laboratory tests in accordance with the requirements of regulatory documents (taking into account tests for microbiological purity, sterility).

For solid dosage pharmaceuticals, the calculation of the number of units required for microbiological control is carried out by dividing the required amount of sample in grams (50 g) by the average weight of the tablet (dragee, capsule, suppository). Samples of pharmaceuticals for injection and eye drops are selected based on testing for particulate matter.

12. Selected samples are isolated from the principal product, packed, sealed off at the place of selection.

Selected samples of pharmaceuticals are sent for control in packaging provided by the regulatory document and ensuring its safety.

13. Finished medical devices in consumer packaging are subject to selection of samples.

14. Before sampling, an external examination of the package is performed, its quality, integrity, as well as the compliance of the container and packaging with the requirements of regulatory documents is determined. At the same time, the temperature conditions of storage of medical devices (temperature regime, humidity) are checked as applicable.

15. Selection of samples shall be carried out subject to the conditions that exclude deterioration of the quality of medical devices.

Samples are taken among intact packaging units, in accordance with regulatory documentation.

16. In the process of sampling medical devices, in general, the following shall be considered:

1) batch homogeneity;

2) representativeness of the sample by composition;

3) representativeness of the sample by amount;

4) compliance of samples with product identification characteristics.

17. The selected samples in terms of design, composition and manufacturing technology correspond to the products intended for sale.

18. The sampling according to the composition of samples reflects the entire set of homogeneous products, which are the object of quality assessment, taking into account the differences in the properties of individual types (brands, sizes, types, models) of such a set.

19. When taking samples of medical devices of a standard-size range of homogeneous products or a medical device included in a kit or set, the sampling shall include samples from different series, which are distributed for testing according to various quality indicators in accordance with the regulatory document on the quality of a medical device.

Appendix
to the Rules for selection from the
market, including in medical
organizations, of pharmaceuticals
and medical devices subject to
quality control taking into account
a risk-based approach
Form

Product-sampling certificate

From "___" _____ 20___ № _____

Name of organization:

_____

Place of selection:

_____

(address) Selection was performed by: _____

Surname, name, patronymic (if any) of the person, carried out selection of samples

Act was made by:

_____

Surname, name, patronymic (if any) representative of the expert organization, involving:

_____

Surname, name, patronymic (if any) of manufacturer or his/her representative
Samples of presented products were selected in accordance with

_____

(name of the regulatory document)
_____ for testing for the purposes of quality assessment of the products
Products were received according to:

_____

(consignment note; receipts №,

_____

under the contract №, date; agreement №, date)
Manufacturer:

_____

(country, organization and address)
Supplier:

_____

(country, organization and address)
The inspection established:

_____

Storage conditions:

_____

Appearance and condition of containers, packaging, vessels:

_____

Inscriptions on the packaging and labels:

_____

Samples taken from products presented under the name:

Name of samples of presented products	Measuring unit	Batch №	Batch size	Manufacturing date	Shelf life	Number of selected product samples
1	2	3	4	5	6	7

Control samples in quantities equal to the number of samples taken are selected, sealed and stored in appropriate conditions during the validity period of the certificate of conformity of products from an entity in the field of circulation of pharmaceuticals and medical devices.

Representative of the expert organization:

_____ _____

signature Surname, name, patronymic (if any)

Manufacturer

(Manufacturer's representative):

_____ _____

signature Surname, name, patronymic (if any)