

On approval of the Rules for destruction by entities in the field of the circulation of medicines and medical articles, who possesses the medicines and medical articles that have become obsolete and have reached expiry date, counterfeited medicines, and medical products, and other products that do not comply with the requirements of the legislation of the Republic of Kazakhstan

Unofficial translation

Order of Acting Minister of Healthcare of the Republic of Kazakhstan dated October 27, 2020 No. №P DSM-155/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on October 29, 2020 No. 21533.

Unofficial translation

Footnote. The title in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 12.06.2023 № 114 (shall be enforced upon expiry of ten calendar days after its first official publication).

In accordance with paragraph 4 of Article 250 of the Code of the Republic of Kazakhstan "On public health and health care system", **I HEREBY ORDER:**

Footnote. The preamble as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 12.06.2023 № 114 (shall be enforced upon expiry of ten calendar days after its first official publication).

1. To approve the Rules for the destruction by entities in the field of the circulation of medicines and medical articles, who possesses the medicines and medical articles that have become obsolete and have reached expiry date, counterfeited medicines, and medical products, and other products that do not comply with the requirements of the legislation of the Republic of Kazakhstan.

2. To recognize as terminated:

1) Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated August 26, 2015, № 687 "On approval of the Rules for the destruction of medicines and medical articles that have become unusable, counterfeited, with an expired shelf life" (registered in the State Registration Register of Regulatory Legal Acts under № 12122, published on October 6, 2015 in the legal information system Adilet);

2) paragraph 9 of the List of amended orders of the Ministry of Healthcare of the Republic of Kazakhstan and the Ministry of Healthcare and Social Development of the Republic of Kazakhstan, approved by Order of the Minister of Healthcare of the Republic of Kazakhstan dated April 22, 2019 № ҚР ДСМ-44 "On 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 in the State Registration Register of

Regulatory Legal Acts under № 18582, published on May 2, 2019 in the Reference Control Bank of the Regulatory Legal Acts of the Republic of Kazakhstan).

3. The Committee for 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 ensure:

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

2) posting 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 the 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 come into effect upon the expiration of ten calendar days after the day of its first official publication.

*Acting Minister of Healthcare of the
Republic of Kazakhstan*

M. Shoranov

Approved
by Order of the Acting
Minister of Healthcare of the
Republic of Kazakhstan
dated October 27, 2020
№ ҚР ДСМ -155/2020

On approval of the Rules for destruction of medicines and medical devices that have fallen into disrepair, expired, counterfeit and other medicines and medical devices that do not meet the requirements of the legislation of the Republic of Kazakhstan

Footnote. Приложение 1 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 12.06.2023 № 114 (shall be enforced upon expiry of ten calendar days after its first official publication).

Chapter 1. General provisions

1. These Rules for destruction of medicines and medical devices that have fallen into disrepair, expired, counterfeit and other medicines and medical devices that do not meet the requirements of the legislation of the Republic of Kazakhstan (hereinafter – the Rules) have been developed in accordance with paragraph 4 of Article 250 of the Code of the Republic of Kazakhstan "On public health and health care system" and shall determine the procedure for destruction of medicines and medical devices that have fallen into disrepair, expired,

counterfeit and other medicines and medical devices that do not meet the requirements of the legislation of the Republic of Kazakhstan.

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

1) destruction of medicines and medical devices - the procedure of exposure (thermal, chemical, mechanical, or other) to medicine and a medical device, excluding the possibility of their further use;

2) entities in the field of circulation of medicines and medical devices (hereinafter referred to as Entities) - individuals or legal entities engaged in pharmaceutical activities;

3) the expiration date of a medicine - the date after which the medicine may not be used;

4) counterfeit medicines and medical devices - medicines, medical devices, unlawfully and deliberately supplied with inaccurate information about their composition or configuration and (or) manufacturer, as well as about supplies, including records and documents concerning the used supply channels;

5) medicines and medical devices unsuitable for sale and medical use - deteriorated, expired, counterfeit and other medicines and medical products that do not meet the requirements of the legislation of the Republic of Kazakhstan, the use of which poses a danger to human life and health.

Chapter 2. Procedure for destruction by entities in the sphere of circulation of medicines and medical devices of unusable, expired, counterfeit and other medicines and medical devices that do not meet the requirements of the legislation of the Republic of Kazakhstan

3. Destruction of medicines and medical devices unsuitable for sale and medical use (marriage, expiry date) and destruction of medical devices that have fallen into disrepair (physical and moral deterioration, as a result of natural disasters and accidents, breakage with impossible recovery) is carried out directly by the subjects in compliance with the requirements of the legislation of the Republic of Kazakhstan in the field of environmental protection and sanitary and epidemiological welfare of the population.

Destruction of medicines and medical devices shall be carried out by a standing commission, the composition of which shall be approved by the head of the subject (hereinafter referred to as the commission) and shall include at least 3 members of the commission.

Destruction of medicines and medical devices unsuitable for sale and medical use in the amount of more than 300 packages (pieces) shall be carried out through an organization carrying out destruction of medicines and medical devices on the basis of a relevant contract, in compliance with the requirements of the legislation of the Republic of Kazakhstan in the field of environmental protection and sanitary and epidemiological well-being of the population.

4. Medicines and medical devices not complying with accompanying documents, with expired shelf life, not passed state registration, quality assessment in the Republic of

Kazakhstan, counterfeit, unusable, not complying with the Rules of storage and transportation of medicines and medical devices approved by the order of the Minister of Healthcare of the Republic of Kazakhstan dated February 16, 2021 № KR DSM-19 "On Approval of Rules for Storage and Transportation of Medicines and Medical Devices" (registered in the Register of State Registration of Regulatory Legal Acts under № 22230) shall be isolated from other products and placed for storage in a specially designated protected place and provided with a label "Not to be sold until appropriate measures are taken".

As medicines and medical devices accumulate at least once a quarter, they shall be destroyed in the presence of the commission no later than the 10th day of the month following the reporting quarter.

5. Medicines and medical devices shall be destroyed in the following ways:

1) medical devices shall be destroyed by dismantling, disassembly, mechanical damage, including punching holes, tearing, causing damage by other means, provided that such damage precludes subsequent restoration of the medical device and the possibility of its use in its original form, unless otherwise specified in the operating document of the medical device developed by the manufacturing organization, as well as by incineration, unless otherwise specified in the instruction for medical use of the medical device developed by the manufacturing organization, as well as by incineration, unless otherwise specified in the instruction for medical use of the medical device developed by the manufacturing organization.;

2) liquid dosage forms (solutions for injection in ampoules, bags and bottles, mixtures, drops, liquids in aerosol cans) shall be destroyed by crushing with subsequent dilution of the contents with water at a ratio of 1:100 and pouring the resulting solution into the sewage system (holes shall be made in aerosol cans beforehand), the remains of ampoules, aerosol cans, bags and bottles shall be removed and destroyed by recycling;

3) solid dosage forms (powders, tablets, capsules) containing water-soluble substances of medicines are subject to dilution with water in the ratio of 1:100 after crushing to powdery state and draining into the sewage system;

4) solid dosage forms (powders, tablets, capsules) containing water insoluble substances of medicines, soft dosage forms (ointments, suppositories), transdermal forms of medicines, as well as pharmaceutical substances shall be destroyed by incineration;

5) immunological medicines shall be disinfected and destroyed by boiling for 30 minutes (anthrax vaccines - 2 hours) or by immersion in a disinfectant registered in the Unified Register of Certificates of State Registration of Products of the Eurasian Economic Union and shall be discharged into the sewerage system.

6. Destruction of medicines, empty vials and ampoules, raw materials, materials, residues of materials, samples, waste, semi-products containing narcotic drugs, psychotropic substances of Table II of the List shall be carried out in accordance with the order of the Minister of Health and Social Development of the Republic of Kazakhstan dated January 26,

2015 № 32 "On Approval of the Rules of medical use of narcotic drugs, psychotropic substances and their precursors subject to control in the Republic of Kazakhstan" (registered in the Register of State Registration of Regulatory Legal Acts under № 10404).

Footnote. Paragraph 6 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 11.07.2023 № 129 (shall be enforced upon expiry of ten calendar days after its first official publication).

7. Destruction of medical devices containing radioactive substances shall be carried out in accordance with the Sanitary Rules "Sanitary and Epidemiological Requirements for the collection, use, application, neutralization, transportation, storage and disposal of production and consumption waste" approved by the order of the Acting Minister of Health of the Republic of Kazakhstan dated December 25, 2020 № KR DSM-331/2020 "On Approval of Sanitary Rules "Sanitary and Epidemiological Requirements for Collection, Use, Application, Disposal, Transportation, Storage and Disposal of Production and Consumption Waste" (registered in the Register of State Registration of Regulatory Legal Acts under № 21934).

8. Flammable, explosive medicines, radiopharmaceuticals, as well as medicinal plant raw materials with increased radionuclide content shall be destroyed under conditions that exclude environmental contamination and impact on the health of personnel and the population.

9. When destroying medicines and medical devices unsuitable for sale and medical use, an act on destruction of medicines and medical devices unsuitable for sale and medical use shall be drawn up (hereinafter referred to as the act) according to the form according to Annex, to these Rules.

The Act shall be drawn up on the day of destruction of medicines and medical devices.

The Act shall be drawn up in triplicate and signed by all persons involved in the destruction of medicines and medical devices. If the destruction of medicines and medical devices is performed by an organization, the act shall be additionally certified by its seal (if any).

One copy of the act within 5 (five) working days from the date of its preparation shall be sent by the subject to the relevant territorial subdivision of the state body in the sphere of circulation of medicines and medical devices.

10. If medicines and medical devices imported into the territory of the Republic of Kazakhstan are recognized unsuitable for sale and medical use at the stage of customs clearance, such medicines and medical devices shall be exported from the Republic of Kazakhstan or placed under customs control until the actual destruction of the goods in accordance with the Code of the Republic of Kazakhstan "On Customs Regulation in the Republic of Kazakhstan".

Annex 1
to the Rules for destruction of medicines
and medical devices that have fallen into
disrepair, expired, counterfeit and other
medicines and medical devices that do not

The act on the destruction of medicines and medical devices unsuitable for sale and medical use

" _____ " _____ year, _____ (hour) _____

_____ (date) (time) (place of destruction)

We: _____

— (surname, name, patronymic (if any), place of work, position held

— (surname, name, patronymic (if any), place of work, position held

— (surname, name, patronymic (if any), place of work, position held

participated in the destruction) the following were destroyed

medicines and medical devices unsuitable for sale

and medical use in the amount of _____ items in the amount of _____ tenge,

whereof this act was made:

Item №	Name of medicine and (or) medical device	Medicine form, dosage	Series (model)	(Measuring unit	Price (tenge)	(Amount	Sum (tenge)	Name of the manufacturer of the medicine, medical device	Grounds for destruction / reason for destruction	Method of destruction
1.										
2.										
...										

persons who took part in the destruction

— Surname, name, patronymic (if any)

— Surname, name, patronymic (if any)

— Surname, name, patronymic (if any)

Signature: _____

Signature: _____

Signature: _____

Place for stamp (if any)

for organizations engaged in the destruction of medicines and medical devices".