

On approval of the Rules for use of medicines and medical devices unregistered in the Republic of Kazakhstan for the provision of medical care according to the vital indications of a particular patient or provision of medical care to a limited contingent of patients with rare (orphan) diseases and (or) conditions

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 15, 2020 No. ҚР ДСМ-280/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 20, 2020 No. 21806

Unofficial translation

In accordance with clause 5 of article 196 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System" **I HEREBY ORDER:**

1. To approve the attached Rules for use of medicines and medical devices unregistered in the Republic of Kazakhstan for the provision of medical care according to the vital indications of a particular patient or provision of medical care to a limited contingent of patients with rare (orphan) diseases and (or) conditions.

2. To recognize as invalid the order of the Minister of Healthcare of the Republic of Kazakhstan dated December 25, 2019 No. ҚР ДСМ-151 "On approval of the Rules for use of medicines and medical devices unregistered in the Republic of Kazakhstan for the provision of medical care according to the vital indications of a particular patient or provision of medical care to a limited contingent of patients with rare and (or) especially severe pathology " (registered in the Register of State Registration of Regulatory Legal Acts as No. 19780, published on December 30, 2019 in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan).

3. The Department of Drug Policy 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) 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 implementation of measures stipulated by subclauses 1) and 2) of this clause.

4. Control over 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 force upon expiry of ten calendar days after the date of its first official publication.

*Minister of Healthcare
of the Republic of Kazakhstan*

A. Tsoy

Approved by the order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated December 15, 2020
No. ҚР ДСМ-280/2020

Rules for use of medicines and medical devices unregistered in the Republic of Kazakhstan for the provision of medical care according to the vital indications of a particular patient or provision of medical care to a limited contingent of patients with rare (orphan) diseases and (or) conditions

Chapter 1. General Provisions

1. These Rules for use of medicines and medical devices unregistered in the Republic of Kazakhstan for the provision of medical care according to the vital indications of a particular patient or provision of medical care to a limited contingent of patients with rare (orphan) diseases and (or) conditions (hereinafter referred to as the Rules) have been developed in accordance with clause 5 of article 196 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System" (hereinafter referred to as the Code) and shall determine the procedure for the use of medicines and medical devices unregistered in the Republic of Kazakhstan for the provision of medical care according to the vital indications of a particular patient or provision of medical care to a limited contingent of patients with rare (orphan) diseases and (or) conditions.

2. Basic concepts, used in the Rules:

1) pharmaceutical product - a product that is or contains a substance or a combination of substances that comes into contact with the human body, intended for the treatment, prevention of human diseases or recovery, correction or change of its physiological functions through pharmacological, immunological or metabolic effects, or for diagnostics diseases and human conditions;

2) authorized body in the field of healthcare (hereinafter referred to as the authorized body) is a central executive body that carries out management and inter-sectoral 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 pharmaceuticals and medical devices, the quality of healthcare services (assistance);

3) healthcare organization - a legal entity carrying out activities in the field of healthcare;

4) clinical pharmacologist - a specialist with higher medical education in the field of “General Medicine”, “Pediatrics”, “General Medicine”, who has mastered the program of residency or retraining in clinical pharmacology and has a certificate of a healthcare specialist ;

5) clinical protocol - scientifically proven recommendations for the prevention, diagnosis, treatment, medical rehabilitation and palliative care for a specific disease or condition of the patient;

6) Concilium - a medical examination of a person in order to establish a diagnosis, determine treatment tactics and prognosis of a disease with the participation of at least three doctors;

7) medical devices - medical devices and medical equipment;

8) patient - an individual who is (was) a consumer of healthcare services, regardless of the presence or absence of a disease or condition requiring medical care;

9) informed consent - a procedure for a person's written voluntary confirmation of his/her consent to receive medical care and (or) participation in a specific study after receiving information about all aspects of medical care and (or) research that are significant for his/her decision-making. The informed written consent shall be drawn up in the form approved by the authorized body.

Chapter 2. Procedure for the use of medicines and medical devices unregistered in the Republic of Kazakhstan for the provision of medical care according to the vital indications of a particular patient or provision of medical care to a limited contingent of patients with rare and (or) especially severe pathology

3. For the provision of medical care according to the vital indications of a particular patient or the provision of medical care to a limited contingent of patients with a rare and (or) especially severe pathology, it shall be allowed to use medicines and medical devices unregistered in the Republic of Kazakhstan, on the basis of the conclusion of a council of doctors of a healthcare organization on the ineffectiveness or impossibility of using specific patient of other registered medicinal products or medical devices and in accordance with the clinical protocol.

Local public healthcare bodies of regions, cities of republican significance and the capital, on the basis of the decisions of the council on the ineffectiveness or impossibility of using other registered medicines or medical devices in a particular patient, signed by the council of doctors, a clinical pharmacologist and the first head of the healthcare organization, shall form a consolidated application based on the calculated the needs of patients and the prevailing market price, and submit a consolidated application to the local representative and executive bodies of regions, cities of republican significance and the capital, to make a decision on the additional provision of a guaranteed volume of free medical care, to provide medicines and medical products.

4. Upon receipt of an agreement on the need, the import of medicines and medical devices unregistered in the Republic of Kazakhstan for the provision of medical care according to the vital indications of a particular patient or the provision of medical care to a limited contingent of patients with rare and (or) especially severe pathology shall be carried out in accordance with the procedure for the import of medicines and medical devices to the territory of the Republic of Kazakhstan, approved according to article 251 of the Code.

5. Before using an unregistered drug or medical device, the attending physician shall inform the patient or the patient's legal representatives (if any) about the expected efficacy and safety of the drug or medical device, the possible degree of risk to the patient, as well as about actions in case of adverse reactions to their use, and obtains informed consent from the patient or the patient's legal representatives (if available).

6. Consent to the use of an unregistered drug or medical device in relation to minors and citizens recognized by the court as legally incompetent shall be given by their legal representatives. In the absence of legal representatives, the decision on the use of an unregistered medicinal product or medical device shall be made by a consultation, if it is impossible to collect a consultation, the medical worker directly within one day with the subsequent notification of the officials of the medical organization shall send a notification in any form.

The use of an unregistered drug or medical device without the consent of citizens shall be carried out for medical reasons in relation to persons, who are:

- 1) in a shock, coma, which does not allow expressing their will;
- 2) suffering from diseases that pose a danger to others;
- 3) suffering from severe mental disorders (diseases);
- 4) suffering from mental disorders (diseases) and committed a socially dangerous act.

7. The healthcare organization shall ensure monitoring of side effects and analysis of the efficacy and safety of an unregistered drug and medical device in the manner prescribed by subclause 48) of article 7 of the Code.