



On approval of the Rules for Assessing the Rational Use of Pharmaceuticals

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan No. KR DSM-179/2020 dated November 3, 2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on November 5, 2020 under No. 21586

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In obedience to sub-paragraph 48 of Article 7 of the Code of the Republic of Kazakhstan of 7 July 2020 “On Public Health and the Healthcare System”, **I HEREBY ORDER:**

1. That the attached Rules for Assessing the Rational Use of Pharmaceuticals shall be approved.

2. That order of the Minister of Healthcare of the Republic of Kazakhstan No. KR DSM-67 of May 6, 2019 “On Approval of the Rules for Assessing the Rational Use of Pharmaceuticals” (registered with the Register of State Registration of Regulatory Legal Acts under No. 18636, published on May 20, 2019 in the Reference Bank of Regulatory Legal Acts of the Republic of Kazakhstan) shall be deemed to have lost force.

3. That in the manner prescribed by the legislation of the Republic of Kazakhstan, the Department of Drug Provision and Standardization of the Ministry of Healthcare of the Republic of Kazakhstan shall ensure:

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

2) placement hereof on the web-site of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

3) within ten working days after state registration hereof 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 information on execution of actions stipulated by sub-paragraphs 1) and 2) of this paragraph.

4. The supervising vice-minister of Health of the Republic of Kazakhstan shall be charged with the control of execution hereof.

5. This order shall be put into effect upon expiry of ten calendar days from the date of its first official publication.

*Minister of Healthcare
of the Republic of Kazakhstan*

A. Tsoy

Annex to order
of the Minister of Healthcare
of the Republic of Kazakhstan
No. KR DSM-179/2020
dated November 3, 2020

Rules for Assessing the Rational Use of Pharmaceuticals

Chapter 1. General provisions

1. These Rules for Assessing the Rational Use of Pharmaceuticals have been developed in compliance with sub-paragraph 48) of Article 7 of the Code of the Republic of Kazakhstan of July 7, 2020 “On Public Health and the Healthcare System” (hereinafter - the Code) and determine the procedure for assessment of rational use of pharmaceuticals in healthcare organisations (hereinafter - the Rules).

2. The following key terms and definitions shall be used in these Rules:

1) an authorized body in the field of healthcare (hereinafter referred to as authorized body) - central executive body carrying out management and interdepartmental coordination in the field of healthcare of citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of population, circulation of medicines and medical devices, quality of healthcare services (assistance);

2) drug formulary of a healthcare organization - a list of medicinal products for providing medical care within the guaranteed volume of free medical care and (or) within the compulsory social health insurance system, which was formed on the basis of the Kazakhstan national drug formulary and approved by the head of a healthcare organization in the manner prescribed by the authorized body;

3) pharmaceutical - a product representing or containing a substance or a combination of substances coming into contact with the human body, intended to treat, prevent human diseases or restore, correct or change human physiological functions through pharmacological, immunological or metabolic effects, or to diagnose human diseases and conditions;

4) rational use of pharmaceuticals - medicinal treatment in accordance with clinical indications, in doses that meet the individual needs of the patient, for a sufficient period of time and at the lowest cost;

5) international non-proprietary name of the pharmaceutical - the name of the medicinal product recommended by the World Health Organisation;

6) trade name of the pharmaceutical - the name under which the medicinal product is registered;

7) adverse reaction - unintentional, unfavourable reaction of the body which is related to the use of the pharmaceutical (investigational product) and suggesting possible interrelation with the use of this medicinal product (investigational product);

8) clinical pharmacologist - a specialist with higher medical education in "general medicine", "paediatrics", "general medicine", who has completed a residency or retraining programme in clinical pharmacology and has a certificate of specialist in healthcare;

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

10) Kazakhstan National Drug Formulary - a list of pharmaceuticals with proven clinical safety and efficacy, as well as orphan (rare) pharmaceuticals, which is a mandatory basis for development of drug formulary of medical organizations and formation of lists of procurement of pharmaceuticals within the guaranteed volume of free medical care and in the mandatory social health insurance system;

11) medicinal product - a medicinal product in a dosage form;

12) formulary system - a system of periodic evaluation and selection of medicinal products for drug formularies, maintenance of drug formularies and provision of information in the form of an appropriate guide and list, aimed at rational use of medicinal products.

13) State expert organisation in the field of circulation of pharmaceuticals and medical devices - an entity of state monopoly that performs production and economic activities in the field of health care to ensure safety, efficiency and quality of medicinal products and medical devices.

3. The assessment of the rational use of pharmaceuticals in healthcare organisations shall be carried out via internal and external evaluation of the rational use of medicines carried out as part of the accreditation of healthcare organisations to recognise the compliance of healthcare services provided with established health requirements and standards, in compliance with Article 25 of the Code.

Chapter 2: Procedures for assessing the rational use of pharmaceuticals

4. Health care organisations shall ensure the rational use of pharmaceuticals and conduct, on an annual basis, an internal evaluation of the rational use of medicines (hereinafter referred to as internal evaluation), in obedience to Article 264 of the Code.

5. Internal assessment shall be carried out by a structural subdivision of a healthcare organization engaged in healthcare quality management activities at the level of a healthcare organization (hereinafter referred to as a structural subdivision) with the participation of a clinical pharmacologist. A clinical pharmacologist shall be involved from outside in case of his/her absence from the health care organization.

6. Structural unit and clinical pharmacologist shall be provided with access to medical information system of healthcare organization.

7. Internal evaluation of a healthcare organisation shall be conducted in compliance with indicators determined pursuant to accreditation standards approved by the authorised body in conformity with Article 25 of the Code, as well as the formulary system procedure developed in accordance with paragraph 2 of Article 264 of the Code, the standard for the organisation of clinical pharmacology care in the Republic of Kazakhstan approved in compliance with

Article 138 of the Code and the procedure for developing drug formularies of healthcare organisations developed in obedience to paragraph 47 of Article 7 of the Code:

- 1) availability of a document describing the procedure for the circulation of pharmaceuticals in a healthcare organisation;
- 2) ensuring the activities of the Formulary Commission of a medical institution;
- 3) availability of a clinical pharmacologist in the Formulary Commission;
- 4) compliance with the Drug Formulary of the medical institution;
- 5) accessibility of the medicine formulary to healthcare staff and necessary information on the provision of pharmaceuticals to healthcare staff and patients;
- 6) availability of access to independent and reliable information on pharmaceuticals for medical staff;
- 7) availability of training of medical staff in the rational use of pharmaceuticals;
- 8) availability of pharmaceuticals for patients;
- 9) availability of a medical information system (MIS) that provides access to patient data (including medication prescriptions) on an ongoing basis;
- 10) availability of a system for collecting and monitoring medication errors;
- 11) provision of high-risk pharmaceuticals;
- 12) ensuring informed consent of patients for parenteral routes of administration and use of high-risk pharmaceuticals;
- 13) recording adverse drug reactions;
- 14) assessment of the knowledge of healthcare staff of a healthcare organisation about the rational use of pharmaceuticals;
- 15) proportion of prescribing of medicines with proven clinical efficacy;
- 16) rationality of prescribing injectable medicines;
- 17) rationality of prescribing antimicrobial medicines;
- 18) drug utilisation evaluation (ABC and VEN analyses).

8. Based on the results of the internal evaluation, an internal evaluation report on the rational use of medicinal products shall be prepared in accordance with the Annex to these Rules.

9. The internal evaluation report on the rational use of pharmaceuticals shall be considered by the Formulary Commission of the healthcare organisation.

10. Following a decision of the Formulary Commission of a health care organisation within three months, measures shall be taken to eliminate non-compliances and further improve the rational use of pharmaceuticals.

11. Corrective actions to address non-compliances identified in the internal evaluation shall include the following:

- 1) conducting training activities for medical and pharmaceutical workers on rational use of medicinal products;
- 2) changes in a health care organisation's formulary;

- 3) introduction of restrictions on the use of certain pharmaceuticals;
- 4) revision and introduction of new treatment approaches;
- 5) procurement of medical equipment;
- 6) introduction of new laboratory methods;
- 7) changes in staff schedule.

12. External evaluation of the rational use of pharmaceuticals in healthcare organizations shall be carried out in accordance with the rules of accreditation in the field of healthcare developed in conformity with paragraph 9 of Article 8 of the Code.

Annex to the Rules for Assessing
the Rational Use of Pharmaceuticals

Internal assessment report form on the rational use of pharmaceuticals

Healthcare organisation _____		Period _____				
No.	Name of indicators	Supporting documents	Assessment (points)	Corrective actions	Responsible persons	Due date
1	Availability of a document describing how medicines are handled in a healthcare organisation	Policy or other document governing the management of pharmaceuticals (hereafter Policy)			Chief Medical Officer or Director Chairperson of the Formulary Commission	
2	Activities of the Formulary Commission	Order on the establishment of the Formulary Commission; Regulation and work plan of the Formulary Commission; Order on the composition or structure of the Formulary Commission Minutes of meetings of the Formulary Commission (once a quarter)			Chief Medical Officer or Director Chairperson of the Formulary Commission	
3	Presence of a clinical pharmacologist on the Formulary Commission	An appointment order for a clinical pharmacologist			Chief Medical Officer or Director	
4	Drug formulary	Drug formulary for the current year, agreed with the local public health authority or authorised body and approved by the head of the health care organisation Conformity of the drug formulary of a healthcare organisation with the Kazakhstan National Drug Formulary Listing of medicines in the formulary by international non-proprietary names			Chief Medical Officer or Director Chairperson of the Formulary Commission	

5	Availability of drug formulary for health-care staff and necessary information on the provision of medicines for health-care staff and patients	The medicine formulary shall be available at the workplaces of medical staff Information for patients on medicines shall be available in accessible places (information boards, website of healthcare providers)			Chairperson of the Formulary Commission Heads of departments	
6	Availability of independent and reliable information on medicines to health-care staff	Treatment protocols Kazakhstan National Formulary Instructions for the use of pharmaceuticals registered in Kazakhstan			Chief Medical Officer or Director Chairperson of the Formulary Commission Clinical Pharmacologist	
7	Training of medical staff in the rational use of medicines	Training plan for health-care staff on the rational use of medicines Report on training of medical personnel in the rational use of medicines Certificates of refresher courses, participation in conferences			Chairperson of the Formulary Commission Clinical Pharmacologist	
8	Drug provision	Reports on the provision of medicines to patients within the framework of the statutory free medical assistance and Compulsory Social Health Insurance Drug utilization assessment (ABC and VEN analyses) Approved requirement (requisition) for medicines stating the quantity and amount per medicine Proper storage Drugs with expiry date			Chief Medical Officer or Director Pharmacy Clinical Pharmacologist	
9	Availability of a medical information system (MIS) that provides access to patient data (including medication prescriptions) on an ongoing basis	A medical information system (MIS) that provides access to patient data (including medication prescriptions) on an ongoing basis			Chief Medical Officer or Director	
10	System for collection and monitoring of medication errors	Form of incident, including medication errors Clinical and pharmacological review of medication prescriptions Internal audit protocols or formulary committee minutes			Head of Patient Support and Internal Audit Service	

		Interventions in case of medication errors (standard operating procedures)			Clinical Pharmacologist	
11	High-risk pharmaceuticals	SOP defining a list of high-risk pharmaceuticals Rules for storage and labelling of high-risk pharmaceuticals (red sign)			Pharmacy	
12	Informed patient consent for parenteral routes of administration and use of high-risk pharmaceuticals	Patient informed consent form for parenteral ways of administration and use of high-risk medicines			Head of Patient Support and Internal Audit Service	
13	Registration of adverse drug reactions	Order appointing a person responsible for pharmacovigilance SOP, regulating the procedure for registering adverse reactions of medicinal products in a medical organisation Minutes of meetings of the Formulary Commission			Clinical Pharmacologist Head of Departments Pharmacy	
14	Assessment of knowledge of health-care staff about the rational use of pharmaceuticals	Knowledge surveys (if carried out) Surveys, studies (if carried out)			Chairperson of the Formulary Commission Clinical Pharmacologist	
15	Percentage of pharmaceuticals prescribed with proven clinical efficacy	Clinical and pharmacological assessments Interviews, studies (if any)			Clinical Pharmacologist	
16	Prescribing injectable medicines	Assessment of the reasonableness of prescriptions for injectable medicines Percentage of injectable medicines prescribed to total prescriptions Interviews, surveys (if conducted) Training sessions for health-care staff and patients Formulary committee minutes			Head of the Formulary Committee	
17	Prescribing antibiotics	Guidelines on the use of antibiotics Assessment of appropriateness of antimicrobial prescribing Percentage of antimicrobial prescriptions to total prescriptions Interviews, surveys (if conducted) Training sessions for health staff and patients Formulary Commission			Chairperson of the Formulary Commission Clinical Pharmacologist	

		protocols Multidisciplinary team for antibiotic use			Head of Departments Pharmacy	
18	Conducting drug utilisation assessments (ABC and VEN analyses)	Results of drug utilisation assessment (ABC and VEN tests)			Chair of the Formulary Committee, Clinical Pharmacologist , Head of Pharmacy	
	TOTAL		Number of points:	Percentage o f compliance :		

Note: 0 points - no or full compliance, 5 points - partial compliance, 10 points - full compliance. The qualitative assessment of the outcomes shall be based on a grading equivalents scale, with a maximum score of 100%: 90-100% - “Excellent”; 75-89% - “Good” ; 50-74% - “Fair”; <50% - “Failed”.

Conclusion:

Commission:

1. Chairperson of the Formulary Commission
2. Clinical Pharmacologist
3. Head of the Patient Support and Internal Audit Service
4. Head Nurse
5. Pharmacy Manager(s)