On approval of the Rules for evaluation of the rational use of medicines

Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated May 6, 2019 No. ҚР ДСМ-67. Registered in the Ministry of Justice of the Republic of Kazakhstan on May 8, 2019 No. 18636

Unofficial translation

Footnote. Abolished by order of the Minister of Health of the Republic of Kazakhstan dated 03.11.2020 No. ҚР DSM-179/2020 (shall be enforced after ten calendar days after the day of its first official publication).

In accordance with subparagraph 70-2) of paragraph 1 of Article 7 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On people's health and healthcare system ", **I HEREBY ORDER**:

1. In accordance with the appendix to this order, to approve the Rules for evaluation of the rational use of medicines.

2. The Pharmacy Committee of the Ministry of Health of the Republic of Kazakhstan, in the manner prescribed by law, to ensure:

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

2) within ten calendar days from the date of the state registration of this order in the Ministry of Justice of the Republic of Kazakhstan, sending its copy in paper and electronic form in the Kazakh and Russian languages to the Republican state enterprise on the basis of the right of economic management "Institute of Legislation and Legal Information of the Republic of Kazakhstan" of the Ministry of Justice of the Republic of Kazakhstan for official publication and inclusion in the Reference Control Bank of regulatory legal acts of the Republic of Kazakhstan;

3) placement of this order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan;

4) within ten working days after the state registration of this order in the Ministry of Justice of the Republic of Kazakhstan, submission of information to the Department of Legal Services of the Ministry of Health of the Republic of Kazakhstan on implementation of measures provided for in subparagraphs 1), 2) and 3) of this paragraph.

3. Vice Minister of Health of the Republic of Kazakhstan K.T. Nadyrov shall be authorized to oversee the execution of this order.

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

Approved
by the order of the

Minister of health of the
Republic of Kazakhstan
dated May 6, 2019
№ ҚР ДСМ-67

Rules for evaluation of the rational use of medicines

Chapter 1. General provisions

1. These Rules for evaluation of the rational use of medicines are developed in accordance with subparagraph 70-2) of paragraph 1 of Article 7 of the Code of the Republic of Kazakhstan dated September 18, 2009 “On people’s health and healthcare system” (hereinafter referred to as the Code) and determine the procedure for evaluation of the rational use of medicines in healthcare organizations (hereinafter - the Rules).

2. The following basic terms and definitions are used in these Rules:

1) the authorized body in the field of health care (hereinafter - the authorized body) - the central executive body that provides management and inter-sectoral coordination in the field of public health, medical and pharmaceutical science, medical and pharmaceutical education, circulation of medicines and medical devices, control of quality of medical services;

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

3) medicine - a medicinal product that is either containing a substance or a combination of substances that comes into contact with the human body, intended for the treatment, prevention of human diseases or the restoration, correction or change of its physiological functions through pharmacological, immunological or metabolic effects, or for diagnosis of diseases and human condition;

4) rational use of medicines - medical treatment corresponding to 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 medicine - the name of the medicinal product recommended by the World Health Organization;

6) drug - a medicinal product in the form of a dosage form used for diagnosis, treatment and prevention;

7) adverse reaction - an unintentional, unfavorable reaction of the body associated with the use of a medicinal (test) drug and suggesting the existence of a possible relationship with the use of this medicinal (test) drug;

8) clinical pharmacologist - a specialist with a higher medical education in the fields of “ medical business”, “pediatrics”, “general medicine”, who has passed residency or retraining in clinical pharmacology and has a certificate of a clinical pharmacologist specialist;

9) clinical protocol - a document establishing general requirements for the provision of medical care to a patient in a particular disease or clinical situation;

10) Kazakhstan national drug formulary - a list of medicines with proven clinical safety and efficacy, as well as orphan (rare) medicines, which is an obligatory basis for development of drug formulary of medical organizations and formation of drug purchase lists within the guaranteed volume of free medical care and in the system of compulsory social health insurance;

11) trade name of a medicine - the name under which the medicinal product is registered;

12) formulary system - a system of periodic evaluation and selection of medicines for drug formulary, maintaining drug formulary and providing information in the form of an appropriate guide and list aimed at the rational use of medicines;

3. Evaluation of the rational use of medicines in healthcare organizations is carried out through an internal and external evaluation of the rational use of medicines.

Chapter 2. Procedure for conduct of internal evaluation of the rational use of medicines by healthcare organizations

4. Healthcare organizations annually during the 1st half year conduct an internal evaluation of the rational use of medicines (hereinafter referred to as the internal evaluation) for the previous year.

5. An internal evaluation is an assessment of the conformity of the use of medicines with the requirements of the current legislation of the Republic of Kazakhstan.

6. An internal evaluation is carried out by a structural unit of a healthcare organization that manages the quality of medical care at the level of a healthcare organization (hereinafter referred to as the structural unit) with the participation of a clinical pharmacologist. A clinical pharmacologist is recruited from outside if he is not available in a healthcare organization.

7. The structural unit and the clinical pharmacologist are provided with access to the medical information system of the healthcare organization.

8. The following shall be subject to internal evaluation of healthcare organization:

1) the activities of the formulary commission of a healthcare organization;

2) planning and procurement of medicines;

3) a system for monitoring the reasonability of prescribing medicines;

4) infection control system;

5) a system for collecting and monitoring medical errors;

6) a system for recording adverse drug reactions;

7) analysis of medicines consumption;

8) analysis of the rationality of the use of financial costs of medicines by distributing medicines into three classes depending on their consumption over a certain period (hereinafter - ABC) and evaluation of the effectiveness of the use of medicines: vital medicines, necessary (important) medicines to save and maintain life; essential medicines effective in treating less dangerous but serious diseases; minor (non-essential) medicines of doubtful effectiveness, expensive medicines used for symptomatic reasons (hereinafter - VEN).

9. To ensure the rational use of medicines, the healthcare organization develops and the head of the healthcare organization approves the following:

1) a document describing the procedure for the circulation of medicines in a healthcare organization, including standard operating procedures (SOPs) for the planning, purchase, storage, distribution and use of medicines, including the circulation of medicines with a high risk degree;

2) a list of medicines, when working with which there is an increased risk of harm to the patient and (or) medical workers (with a high risk degree), taking into account the profile of the healthcare organization.

10. The system for monitoring the reasonability of prescribing medicines includes collecting data to assess the reasonability of prescribing medicines and evaluating the reasonability of prescribing medicines in the forms in accordance with appendix 1 to these Rules.

The priority groups are determined to conduct a monitoring of the reasonability of prescribing medicines whose use has the greatest clinical and economic effect and indicators for their evaluation.

Priority groups include:

1) expensive ones;

2) those used in large quantities;

3) antimicrobial ones;

4) those used for the treatment of patients at risk (elderly, children, pregnant women, patients in the intensive care unit);

5) those having serious adverse reactions, narrow therapeutic index;

6) those used to treat the most common diseases;

7) those being considered for inclusion in the drug formulary of a healthcare organization;

8) new medicinal products included in the drug formulary of a healthcare organization.

Indicators for evaluation of the reasonability of prescribing medicines are:

1) the conformity of the indications for which the medicinal product was used with the indications of the medicinal product in the formulary articles of the Kazakhstan national drug formulary (hereinafter - KNF), instructions for the medical use of the medicinal product, clinical protocols, international clinical guidelines;

2) compliance with clinical restrictions on the use of the medicine;

3) compliance with the dosage regimen;

4) compliance of the administration route of the drug with the condition, age of the patient , pharmaceutical characteristics of the medicinal product;

5) the cost of the medicinal product.

11. The infection control system includes the creation and functioning of a multidisciplinary team on the use of antimicrobials, the examination of intra-hospital infections at the hospital level, and monitoring the reasonability of antimicrobial prescriptions .

In order to restrain antimicrobial resistance, the proportion of their prescription in all prescriptions of medicinal products is determined.

12. The system for collecting and monitoring medical errors includes collecting, filling out the reporting forms, analyzing the identified medical errors, developing measures to eliminate and prevent the reasons that cause them in accordance with appendix 2 to these Rules.

Messages about medical errors are submitted by all participants in the treatment process (doctor, pharmacist, nurse, patient, legal representative of a minor, guardian of a legally incapable person) for consideration to the structural unit, no later than 24 hours after the incident and (or) identification of a medical error.

The state medical organizations, to collect and record the reporting forms about medical errors once a year no later than October 25 of the current year, send the completed reporting forms about medical errors to the Republican State Enterprise on the basis of the right of economic management “Republican Healthcare Development Center” (hereinafter referred to as the Center).

13. The system for recording the adverse reactions of medicinal products includes the filling out and transmitting the reporting cards about a side effect or adverse reaction of a medicinal product to a state expert organization in the field of circulation of medicines and medical devices.

14. An analysis of the consumption of medicines is carried out taking into account the established daily dose and actual data on the number of medicinal products used.

The results of the analysis of the consumption of medicines are used for further monitoring and planning the purchase of medicinal products or individual pharmacological groups, as well as determining trends in their consumption.

15. ABC analysis is made to evaluate:

1) the procurement of various medicinal products or pharmacological groups at the level of a health care organization;

2) the use of medicinal products or pharmacological groups with a certain nosology;

3) the use of certain medicinal products within the same pharmacological group;

4) the reasonableness of the financial costs of the healthcare organization for medicinal products in accordance with the profile of the medical care provided;

5) compliance of financial costs with the structure of morbidity.

16. VEN analysis is made to rank the medicinal product according to the degree of clinical importance, which is determined by the level of evidence of the effectiveness of the medicinal product.

The results of ABC and VEN analyzes of the procurement of medicinal products are used in the development and formation of the drug formulary of a healthcare organization in accordance with the Procedure for formation of the Kazakhstan national drug formulary, a list of medicinal products and medical devices for free and (or) preferential outpatient care of certain categories of citizens with certain diseases (conditions), as well as the development of drug formulary of healthcare organizations approved in accordance with subparagraph 70) of paragraph 1 of Article 7 of the Code.

17. The results of an internal evaluation of the rational use of medicinal products are considered at a meeting of the formulary commission of a healthcare organization.

18. According to the decision of the formulary commission of the healthcare organization, measures are taken within three months to eliminate inconsistencies and further improve the rational use of medicines.

19. Measures to eliminate the identified inconsistencies are educational and (or) operational in nature and aimed at a group of individuals or at an individual specialist in whose work mistakes were made when using medicinal products.

20. Educational measures include training activities for medical and pharmaceutical workers in the form of the education courses on the rational use of medicinal products.

21. Operational measures include changes to the drug formulary of a healthcare organization, and (or) introduction of restrictions on the use of certain medicinal products, and (or) reviewing and introducing new treatment standards, and (or) purchasing medical equipment, and (or) introducing new laboratory methods, and (or) changes in the staffing specifications.

22. The results of an internal evaluation of the rational use of medicines are posted on the website of the healthcare organization upon expiry of 20 working days from the date of the evaluation.

Chapter 3. Procedure for conduct of an external evaluation of the rational use of medicines in healthcare organizations

23. An external evaluation of the rational use of medicines in healthcare organizations (hereinafter referred to as the external evaluation) is carried out in order to increase the effectiveness of the use of medicines by developing recommendations and training medical and pharmaceutical workers in the rational use of medicines.

24. An external evaluation is carried out by the Center with a frequency of once every two years.

25. For the conduct of an external evaluation, the Center has access to the information systems of the authorized body and the medical information systems of healthcare organizations.

26. An external evaluation is carried out on the basis of indicators for evaluating the rational use of medicines for organizations providing inpatient and outpatient care (hereinafter referred to as indicators), in accordance with appendixes 3 and 4 to these Rules.

27. Evaluation of compliance of indicators is carried out by studying and analyzing documents, monitoring and interviewing personnel.

28. The results of an external evaluation with recommendations are submitted to the appropriate health organization for review and action.

29. Summary information on the results of an external evaluation of healthcare organizations is submitted to the Formulary commission of the Ministry of Health of the Republic of Kazakhstan to develop recommendations to the authorized body to improve the rational use of medicines.

30. Based on the results of internal or external evaluations, the Center conducts training activities for medical and pharmaceutical workers. The term of study is at least 54 hours.

31. Health organizations ensure the rational use of medicines in accordance with paragraph 3 of Article 86-2 of the Code.

32. Through a unified free telephone line / contact center, the Center provides medical and pharmaceutical workers and the public with reliable information on medicines based on the principles of evidence-based medicine, as well as consulting services for complex cases of use and interaction of medicines.

Appendix 1
to the Rules for evaluation of the
rational use of medicines

Data collection to evaluate the reasonability of prescription of medicines

Date / period of data collection: _____

_____

_

(date, month, year)

Estimated medicine / pharmacological group of medicines / nosology:

_____

__

_____

__

_____

__

_____

Departments of healthcare organization where the evaluation to be conducted:

_____

_____

Data collection method:

☐ perspective

☐ retrospective

☐ current

Number of evaluated case records / prescriptions: _____

_____

Evaluated prescription period: _____

_____

(date, month, year)

Reason for selection of evaluated medicines / pharmacological group of medicines / nosology:

☐ possible adverse reactions

☐ possible adverse interactions

☐ difficulties with the prescription of this medicine / pharmacological group

☐ high risk drug

☐ high share of expenses for medicines / pharmacological group according to the results of ABC and VEN analyzes

☐ frequently prescribed medicine / pharmacological group

☐ staff recommendations

☐ other _____

The results of the conducted evaluation of the reasonability of prescribing medicine:

_____

_____

_____

_____

Measures taken to eliminate inconsistencies and further improvement of the rational use of medicines:

_____

_____

_____

_____

Evaluation sheet of reasonability of prescription of medicines

Department _____

№ of case record _____

Attending physician _____

(surname, initials)

Patient _____

(surname, name, patronymic (if any))

Date of birth ___. _____. _____ Sex:

☐ male

☐ female Weight (kg) _____

Primary diagnosis _____

Secondary diagnosis _____

Number of medicines prescribed to the patient _____

The prescribed medicines _____

_____

_____

_____

(names of medicines, dose, drug form)

Evaluation of reasonability for prescribing medicines Yes No

Not completely

Compliance of drug therapy with the diagnosis

☐

☐

☐

Compliance of drug therapy with KNF

☐

☐

☐

Compliance of drug therapy with clinical protocols

☐

☐

☐

Compliance of drug therapy with international clinical guidelines

☐

☐

☐

Taking into account the age, physiological / pathological condition of the patient

☐

☐

☐

Compliance of the drug dosage with the diagnosis and physiological state

☐

☐

☐

Compliance of the drug administration with the diagnosis and physiological state

☐

☐

☐

Combination of medicines was rational and (or) safe

☐

☐

☐

Reasonability of prescription of injectable drugs

☐

☐

☐

Reasonability of prescription of antimicrobials

☐

☐

☐

Achieving the goal of drug therapy

☐

☐

☐

Was the drug therapy monitored?

☐

☐

☐

Prescription / prescribing drugs under INN

☐

☐

☐

Compliance with maintenance standards of drug prescription leaflet

☐

☐

☐

No adverse drug reaction detected

☐

☐

☐

There are no medical errors

☐

☐

☐

Number of prescribed injection drugs
Number of antibiotics prescribed
Number of medicines included in the drug formulary
Conclusion*: prescription of medicines is justified / not justified
Date ____. _____ . ____
Doctor - Clinical Pharmacologist: _____ _____
_
(surname, name, patronymic (if any)) (signature)

* Quantitative evaluation of the results is carried out according to the following parameters:

1) Each indicator is rated on a 2 point scale, where:

- 2 points (answer “yes”) - full compliance with the indicator;
- 1 point (answer “not completely”) - partial compliance with the indicator;
- 0 points (answer “no”) - non-compliance with the indicator.

A qualitative evaluation of the results is carried out on a scale of evaluation equivalents, at that the maximum number of points is equal to 100%: - 90-100% - "prescription of medicines is justified"; - <90% - "prescription of medicines is not justified."

Evaluation sheet of examination of antibiotic prophylaxis

Department _____

№ of case record _____

_

Attending physician _____

__

(surname, initials)

Patient _____

__

(surname, name, patronymic (if any))

Date of birth ___. _____. _____ Sex:

☐

male

☐

female Weight (kg) _____

Primary diagnosis _____

_

Secondary diagnosis _____

_

Number of medicines prescribed to the patient _____

__

The prescribed antimicrobials _____

___

_____

__

_____

__

_____

(names of medicines, dose, drug form) _____

Evaluation of reasonability of prescribing antimicrobials Yes No
Not completely
Compliance of the prescribed antimicrobial drug with the diagnosis

☐

☐

☐

Presence of records on ongoing antibiotic prophylaxis in the prescription leaflet

☐

☐

☐

Antimicrobial dosage compliance

☐

☐

☐

Compliance with the route of administration of the antimicrobial drug

☐

☐

☐

Compliance with the time of administration of the antimicrobial drug

☐

☐

☐

Compliance with the frequency of administration of an antimicrobial drug

☐

☐

☐

Compliance with the duration of antibiotic prophylaxis

☐

☐

☐

Conclusion *: principles of antibiotic prophylaxis are observed / not observed

☐

☐

☐

Date ____. _____ . ____

Doctor - Clinical Pharmacologist: _____ _____

(surname, name, patronymic (if any)) (signature)

Head of Department: _____ _____

(surname, name, patronymic (if any)) (signature)

* Quantitative evaluation of the results is carried out according to the following parameters:

1) Each indicator is rated on a 2 point scale, where:

- 2 points (answer “yes”) - full compliance with the indicator;
- 1 point (answer “not completely”) - partial compliance with the indicator;
- 0 points (answer “no”) - non-compliance with the indicator.

A qualitative evaluation of the results is carried out on a scale of evaluation equivalents, at that the maximum number of points is equal to 100%: - 90-100% - "principles of antibiotic prophylaxis are observed"; - <90% - "principles of antibiotic prophylaxis are not observed."

Evaluation sheet of examination of antibiotic therapy

Department _____

№ of case record _____

Attending physician _____

(surname, initials)

Patient _____

(surname, name, patronymic (if any))

Date of birth ___. _____. _____ Sex:

☐ male

☐ female Weight (kg) _____

Primary diagnosis _____

Secondary diagnosis _____

Number of medicines prescribed to the patient _____

The prescribed antimicrobials _____

_____

_____

_____

(names of medicines, dose, drug form) _____

Evaluation of reasonability of prescribing antimicrobials Yes No

Not completely

Compliance of the prescribed antimicrobial drug with the diagnosis

☐

☐

☐

Compliance of the course of treatment with diagnosis

☐

☐

☐

Antimicrobial dosage compliance

☐

☐

☐

Compliance with the route of administration of an antimicrobial drug

☐

☐

- [ ]

Compliance with the time of administration of an antimicrobial drug

- [ ]
- [ ]
- [ ]

Compliance with the frequency of administration of an antimicrobial drug

- [ ]
- [ ]
- [ ]

Presence of clinical symptoms of infection

- [ ]
- [ ]
- [ ]

Presence of changes in the blood test (leukocytosis, ESR, CRP, a shift of the leukocyte formula to the left) / in the analysis of urine, indicating the presence of inflammation

☐

☐

☐

Presence of microbiological analysis

☐

☐

☐

Presence of microbial flora in microbiological analysis

_____

if available, indicate strain and titer

☐

☐

☐

Presence of sensitivity of the selected strain to the prescribed antimicrobial drug (s)

☐

☐

☐

Achieving recovery

☐

☐

☐

Conclusion *: antibiotic therapy is rational / irrational

Date ____. _____ . ____

Doctor - Clinical Pharmacologist: _____ _____

_

(surname, name, patronymic (if any)) (signature)

Head of Department: _____ _____

__

(surname, name, patronymic (if any)) (signature)

* Quantitative evaluation of the results is carried out according to the following parameters:

1) Each indicator is rated on a 2 point scale, where:

- 2 points (answer “yes”) - full compliance with the indicator;
- 1 point (answer “not completely”) - partial compliance with the indicator;
- 0 points (answer “no”) - non-compliance with the indicator.

A qualitative evaluation of the results is carried out on a scale of evaluation equivalents, at that the maximum number of points is equal to 100%: - 90-100% - “antibiotic therapy is rational”; - <90% - "antibiotic therapy is irrational."

Appendix 2
to the Rules for evaluation of the
rational use of medicines

Drug error reporting form

If you suspect a drug error, please fill out this reporting form. Please fill out all sections as fully as possible (blue / black ballpoint pen) or on a computer). Information about the patient and the person who submitted the reporting form will remain confidential.

Information about the person filling out the drug error reporting form

1. _____
__

(Surname, name, patronymic if any)

2. Phone / Fax (including area code) _____

3.

☐ doctor

☐ nurse

☐ pharmacist

☐ patient

☐ other.:_____

Information about the patient who underwent an adverse reaction due to a medical error

1. Who suffered an adverse reaction?

(Surname, name, patronymic (if any))

2. Sex:

☐ male

☐ female

3.Date of birth _____
(date, month, year)
4. Weight (kg)_____ 5. Height (cm) _____
_
6. Date and time of the drug error _____
(date, month, year, hour: minute)
7. Location of the medical error: _____
_____
__
(if important: department, office, etc.)
8. Features from the history of the patient: _____
__
_____
__

☐
allergy
☐
pregnancy ___ weeks
☐
kidney disease
☐
liver disease
9. Did the identified medical error lead to any of the following consequences?:

☐
No harm to health

☐
Help provided locally (cold, dressing, treatment)

☐
Splints are fixed, stitches are put in or the like

☐

Surgery

☐

Hospitalization

☐

Extension of hospitalization

☐

Intensive care (resuscitation)

☐

Sick leave (sick leave)

☐

Disability

☐

Defect _____

☐

Death

☐

None of the above.

Other _____

Suspected drug error information _____

Drug prescription related:

1. The drugs are prescribed to the patient:

☐

not according to indication

☐ in the presence of contraindications

☐ wrong dose

☐ not correct way of application

☐ incorrect speed, time and frequency of administration

☐ not taking into account the interactions with the medicines taken

2. Presence / absence of drugs in the Drug formulary of healthcare organization _____

(name of the drug, dose, drug form)

3. The illegible handwriting of the doctor / incomprehensible abbreviation _____

_____

4. Prescription is not fully written (drug form, dosage, method of application of the medicine are not indicated) _____

5. Prescription does not take into account the physiological condition of the patient, concomitant diseases and taking other drugs

_____

_____

(concomitant disease, names of drugs taken, dose, drug form)

6. Drug was prescribed if the patient is allergic to this drug _____

_____
__

(name of drug, dose, drug form)

7. Incorrect information is provided to the patient about the drug (indications, method of use, contraindications, special cases of use, adverse reactions)

_____
__

Related to drug administration:

1. The patient received:

☐ non-prescribed drug _____

_____

(name of drug, dose, drug form)

_____

☐ wrong dose _____

(specify)

_____

☐ wrong route of administration _____

(specify)

_____

☐ incorrect speed of drug administration

☐ expired drugs _____

(name of drug, dose, drug form, expiration date)

_____

2. The patient was not given the prescribed drugs _____

_____

Related to the storage and preparation of drugs:

☐ Drugs were improperly prepared (reconstitued, separated)

☐ Drugs storage conditions are not met

☐ No drug labeling (no label or signs)

☐ Incorrect labeling (sign, label)

Issued / released:

☐ other (not prescribed) drug in similar packaging (mistaken in appearance)

☐ other (not prescribed) drugs with a similar name (mistaken in name)

☐ drugs in a different dosage, drug form

_____

_____

_____

(describe the selected error)

Appendix 3
to the Rules for evaluation of the
rational use of medicines

Indicators for evaluation of the rational use of medicines for organizations providing inpatient care

No. Name of indicators

Those responsible for achieving indicators

Documents submitted for external evaluation

Evaluation scale

*1 2 3 4 5

Structure indicators

1 Availability of a document describing the procedure for the circulation of medicines in a healthcare organization. Chairman of the formulary commission, clinical pharmacologist, pharmacy manager. Document describing the procedure for the circulation of medicines in a healthcare organization

2 Availability of the Formulary Commission Chairman of the Formulary Commission, clinical pharmacologist. Order on establishment of the Formulary Commission;

Provision and work plan of the Formulary Commission for the current year;

Order on the composition / structure of the Formulary Commission.

3 Presence of a clinical pharmacologist in the Formulary Commission Chairman of the Formulary Commission, clinical pharmacologist. Order on appointment to the post of the clinical pharmacologist.

4 Availability of the drug formulary. Chairman of the formulary commission, clinical pharmacologist. The drug formulary for the current year, agreed with the local government health authority and approved by the head of the healthcare organization.

5 The presence of a medical information system (MIS) that provides access to patient data (including drug prescriptions) in the current mode.

Chairman of the Formulary Commission, clinical pharmacologist,

head of pharmacy. Medical Information System (MIS), providing access to patient data (including medical prescriptions) in the current mode.

6 Availability of forms of informed consent of patients on parenteral routes of drug administration and the use of high-risk drugs.

Chairman of the Formulary Commission, clinical pharmacologist, heads of departments. Forms of informed consent of patients on parenteral routes for drug administration and the use of high-risk medicines.

7 The presence of a multidisciplinary group on the use of antimicrobials. Chairman of the Formulary Commission, microbiologist,

epidemiologist,

clinical pharmacologist, head of pharmacy. Order on establishment of a multidisciplinary group.

8 Availability of a service for monitoring the reasonability of drug prescriptions. Chairman of the formulary commission; clinical pharmacologist.

Order on the composition of the service to monitor the drug prescriptions.

9 Availability of SOP defining a list of high-risk medicines, rules for storing and labeling of high-risk medicines (red mark).

Chairman of the Formulary Commission, clinical pharmacologist,

head of a SOP pharmacy defining a list of high-risk medicines, rules for storing and labeling of high risk medicines (red mark).

10 Registration of adverse drug reactions. Chairman of the formulary commission, clinical pharmacologist, head of pharmacy, heads of departments.

Order on appointment of a person responsible for pharmacovigilance; registration log of adverse reactions of drugs.

11 Availability of a system for collecting and monitoring drug errors Chairman of the Formulary Commission, clinical pharmacologist, epidemiologist, heads of departments. Drug error reporting forms

Process indicators

12 Frequency of revision of the drug formulary. Chairman of the formulary commission, clinical pharmacologist. Minutes of meetings of the Formulary Commission on the revision of the drug formulary

13 Number of meetings of the Formulary Commission per year. Chairman of the Formulary Commission, clinical pharmacologist. Minutes of meetings of the Formulary Commission; work plan of the Formulary Commission

14 Access of medical personnel to independent and reliable information about medicines. Chairman of the formulary commission, clinical pharmacologist, heads of departments. Access to reliable sources of information about medicines (KNF, etc.)

15 Availability of the drug formulary for medical personnel and the necessary information on providing medicines for patients

Chairman of the formulary commission, clinical pharmacologist, heads of departments, head of the pharmacy. Presence of the drug formulary at the workplace of medical personnel; accessible information for patients on drug provision in an accessible place.

16 Presence of a justified need for medicines for inclusion in the drug formulary, taking into account data on the incidence structure. Chairman of the formulary commission, clinical pharmacologist, heads of departments, head of pharmacy. The approved need for medicines with an indication of the quantity and amount for each drug

17 Functioning of the infection control system Chairman of the Formulary Commission, microbiologist, epidemiologist clinical pharmacologist, head of pharmacy. Minutes of meetings of a multidisciplinary group on the use of antimicrobials; referral to bacterial swab test;

Analysis of the incidence of nosocomial infections, an algorithm for the epidemiologically safe implementation of medical and diagnostic procedures, the sanitary-epidemiological regimen, the results of microbiological monitoring of nosocomial infections

18 Functioning of a system for recording the adverse reactions Chairman of the formulary commission, clinical pharmacologist, head of the pharmacy, heads of the departments of SOP / documented procedure / work instruction that defines the procedure for registering the adverse drug reactions;

Adverse reactions registration log

19 Functioning of monitoring of drug administration Chairman of the Formulary Commission, clinical pharmacologist, heads of departments.

Drug prescription leaflets

20 Functioning of the system for monitoring drug errors.

Chairman of the formulary commission, clinical pharmacologist, head of pharmacy, heads of departments. Internal audit protocols;

Measures in case of detection of drug errors (SOP)

21 Functioning of the system for monitoring the reasonability of prescribing medicines. Chairman of the formulary commission, clinical pharmacologist,

heads of departments. Internal audit protocols;

Plan of measures to identify drug errors;

Prescriptions / notes of doctors

Electronic cards (journals) of patients.

22 Frequency of training of medical personnel on the rational use of medicines. Chairman of the Formulary Commission, clinical pharmacologist, head of pharmacy. Schedule / training plan for medical staff on the rational use of medicines

Result indicators

23 Listing of medicines in the drug formulary according to international nonproprietary names. Clinical pharmacologist, head of pharmacy.

Drug formulary for the current year

24 Compliance of the drug formulary of the healthcare organization with the Kazakhstan national drug formulary. Clinical pharmacologist, head of the pharmacy. Drug formulary for the current year

25 Evaluation of knowledge of medical personnel of a healthcare organization on the rational use of medicines. Chairman of the formulary commission; clinical pharmacologist. Certificate of advanced training on the rational use of medicines, knowledge questionnaire

26 Conducting an evaluation of the use of medicines (ABC and VEN analyses) Chairman of the Formulary Commission, clinical pharmacologist, head of pharmacy. Results of the conduct of an evaluation of the use of medicines (ABC and VEN analysis)

27 Conducting an analysis of drug consumption using a method based on the determination of the established daily dose and analysis of actual data on the amount of drugs used. Chairman of the formulary commission, clinical pharmacologist, head of pharmacy

Results of analysis of drug consumption

28 Proportion of prescribing drugs with proven clinical efficacy. Chairman of the Formulary Commission

Prescriptions/notes of doctors

Electronic cards (journals) of patients

* Quantitative evaluation of the results is carried out according to the following parameters:

1) Each indicator is evaluated on a 2-point scale, where:

- 2 points - full compliance with the external evaluation indicator with all supporting documents, all processes are performed;

- 1 point - partial compliance with the external evaluation indicator, not all supporting documents are available, or the documents are available, but the process is not performed, or the process is performed, but there are no documents;

- 0 points - non-compliance with the external evaluation indicator, there are no supporting documents, processes are not performed or are partially performed.

2) The total number of points - 56.

Qualitative evaluation of the results is carried out on a scale of evaluation equivalents, at that the maximum number of points is equal to 100%:

- 90-100% - “Excellent”;
- 75-89% - "Good";
- 50-74% - "Satisfactory";
- <50% - "Unsatisfactory."

Appendix 4
to the Rules for evaluation of the
rational use of medicines

Indicators for evaluation of use of medicines for organizations providing outpatient care

No. Name of indicators
Those responsible for achieving indicators
Documents submitted for external evaluation
Evaluation scale
*1 2 3 4 5
Structure indicators

1 Availability of a document describing the procedure for the circulation of medicines in a healthcare organization. Chairman of the formulary commission, clinical pharmacologist, head of pharmacy. Document describing the procedure for the circulation of medicines in a healthcare organization

2 Availability of the Formulary Commission

Chairman of the Formulary Commission, clinical pharmacologist. Order on establishment of the Formulary Commission;

Provision and work plan of the Formulary Commission for the current year;

Order on the composition / structure of the Formulary Commission.

3 Presence of a clinical pharmacologist in the Formulary Commission

Chairman of the Formulary Commission, clinical pharmacologist. Order on appointment to the post of the clinical pharmacologist.

4 Availability of the drug formulary. Chairman of the formulary commission, clinical pharmacologist. The drug formulary for the current year, agreed with the local government health authority and approved by the head of the healthcare organization.

5 The presence of a medical information system (MIS) that provides access to patient data (including drug prescriptions) in the current mode.

Chairman of the Formulary Commission, clinical pharmacologist,

head of pharmacy. Medical Information System (MIS), providing access to patient data (including drug prescriptions) in the current mode.

6 Availability of forms of informed consent of patients on parenteral routes of drug administration and the use of high-risk drugs.

Chairman of the Formulary Commission, clinical pharmacologist, heads of departments. Forms of informed consent of patients on parenteral routes for drug administration and the use of high-risk medicines.

7 The presence of a multidisciplinary group on the use of antimicrobials. Chairman of the Formulary Commission, microbiologist, epidemiologist, clinical pharmacologist, head of pharmacy. Order on establishment of a multidisciplinary group.

8 Availability of a service for monitoring the reasonability of drug prescriptions. Chairman of the formulary commission; clinical pharmacologist.

Order on the composition of the service to monitor the drug prescriptions.

9 Availability of SOP defining a list of high-risk medicines, rules for storing and labeling of high-risk medicines (red mark).

Chairman of the Formulary Commission, clinical pharmacologist, head of a SOP pharmacy defining a list of high-risk medicines, rules for storing and labeling of high risk medicines (red mark).

10 Registration of adverse drug reactions. Chairman of the formulary commission, clinical pharmacologist, head of pharmacy, heads of departments.

Order on appointment of a person responsible for pharmacovigilance; registration log of adverse reactions of drugs.

11 Availability of a system for collecting and monitoring drug errors Chairman of the Formulary Commission, clinical pharmacologist, epidemiologist, heads of departments. Drug error reporting forms Process indicators.

12 Frequency of revision of the drug formulary. Chairman of the formulary commission, clinical pharmacologist. Minutes of meetings of the Formulary Commission on the revision of the drug formulary.

13 Number of meetings of the Formulary Commission per year. Chairman of the Formulary Commission, clinical pharmacologist. Minutes of meetings of the Formulary Commission; work plan of the Formulary Commission.

14 Access of medical personnel to independent and reliable information about medicines. Chairman of the formulary commission, clinical pharmacologist, heads of departments. Access to reliable sources of information about medicines (KNF, etc.)

15 Availability of the drug formulary for medical personnel and the necessary information on providing medicines for patients.

Chairman of the formulary commission, clinical pharmacologist, heads of departments, head of the pharmacy. Presence of the drug formulary at the workplace of medical personnel; accessible information for patients on drug provision in an accessible place.

16 Presence of a justified need for medicines for inclusion in the drug formulary, taking into account data on the incidence structure. Chairman of the formulary commission, clinical pharmacologist, heads of departments, head of pharmacy. The approved need for medicines with an indication of the quantity and amount for each drug

17 Functioning of the infection control system Chairman of the Formulary Commission, microbiologist, epidemiologist clinical pharmacologist, head of pharmacy. Minutes of meetings of a multidisciplinary group on the use of antimicrobials; referral to bacterial swab test;

Analysis of the incidence of nosocomial infections, an algorithm for the epidemiologically safe implementation of medical and diagnostic procedures, the sanitary-epidemiological regimen, the results of microbiological monitoring of nosocomial infections.

18 Functioning of a system for recording the adverse reactions Chairman of the formulary commission, clinical pharmacologist, head of the pharmacy, heads of departments of SOP that define the procedure for registering the adverse drug reactions;

Adverse reactions registration log.

19 Functioning of monitoring of drug administration Chairman of the Formulary Commission, clinical pharmacologist, heads of departments. Drug prescription leaflets.

20 Functioning of the system for monitoring drug errors.

Chairman of the formulary commission, clinical pharmacologist, head of pharmacy, heads of departments. Internal audit protocols;

Measures in case of detection of drug errors (SOP).

21 Functioning of the system for monitoring the reasonability of prescribing medicines. Chairman of the formulary commission, clinical pharmacologist, heads of departments. Internal audit protocols;

Plan of measures to identify drug errors;

Prescriptions / notes of doctors Electronic cards (journals) of patients.

22 Frequency of training of medical personnel on the rational use of medicines. Chairman of the Formulary Commission, clinical pharmacologist, head of pharmacy. Schedule / training plan for medical staff on the rational use of medicines

Result indicators.

23 Listing of medicines in the drug formulary according to international nonproprietary names. Clinical pharmacologist, head of pharmacy.

Drug formulary for the current year.

24 Compliance of the drug formulary of the healthcare organization with the Kazakhstan national drug formulary. Clinical pharmacologist, head of the pharmacy. Drug formulary for the current year.

25 Evaluation of knowledge of medical personnel of a healthcare organization on the rational use of medicines. Chairman of the formulary commission; clinical pharmacologist. Certificate of advanced training on the rational use of medicines, knowledge questionnaire.

26 Conducting an evaluation of the use of medicines (ABC and VEN analyses) Chairman of the Formulary Commission, clinical pharmacologist, head of pharmacy. Results of the conduct of an evaluation of the use of medicines (ABC and VEN analysis).

27 Conducting an analysis of drug consumption using a method based on the determination of the established daily dose and analysis of actual data on the amount of drugs used. Chairman of the formulary commission, clinical pharmacologist, head of pharmacy.

Results of analysis of drug consumption.

28 Prescription of medicines with the proven clinical efficacy

Chairman of the Formulary Commission Prescriptions /notes of doctors Electronic cards (journals) of patients.

29 Prescription of injectable medicines Chairman of the Formulary Commission Prescriptions /notes of doctors

Electronic cards (journals) of patients

30 Prescription of antibiotics Chairman of the Formulary Commission Prescriptions /notes of doctors Electronic cards (journals) of patients

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