On approval of the Rules for the operation of the formulary system

Invalidated Unofficial translation

Order of the acting Minister of Health Care of the Republic of Kazakhstan No. KR DCM-94 as of June 14, 2019. Registered with the Ministry of Justice of the Republic of Kazakhstan on June 18, 2019, No. 18856. Abolished by the order of the Acting Minister of Health of the Republic of Kazakhstan dated 12/24/2020 No. KR DSM-326/ 2020

Unofficial translation

Footnote. Abolished by the order of the Acting Minister of Health of the Republic of Kazakhstan dated 12/24/2020 No. KR DSM-326/2020 (effective after the expiration of ten calendar days after the date of its first official publication).

In accordance with paragraph 2 of Article 86-2 of the Code of the Republic of Kazakhstan "On Public Health and Health Care System" as of September 18, 2009, I hereby ORDER:

1. To approve the appended Rules for the operation of the formulary system.

2. To invalidate Order No.1037 of the Minister of Health Care and Social Development of the Republic of Kazakhstan as of December 6, 2016 "On approval of the Regulations on the Formulary Commission of the Ministry of Health Care and Social Development of the Republic of Kazakhstan" (registered in the State Registration Register of Regulatory Legal Acts under No. 14641, published in electronic form on January 12, 2017 in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan).

3. In accordance with the procedure established by the legislation of the Republic of Kazakhstan, the Department of Drug Provision and Standardization of the Ministry of Health Care of the Republic of Kazakhstan shall:

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

2) within ten calendar days of the state registration of this order, send it in paper-based and electronic forms in Kazakh and Russian to the Republican State Enterprise with 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 its official publication and inclusion into the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan;

3) place this order on the website of the Ministry of Health Care of the Republic of Kazakhstan;

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

4. The control over the execution of this order shall be assigned to the vice-minister of health care of the Republic of Kazakhstan, K.T.Nadyrov.

5. This order shall take effect ten calendar days after its first official publication.

Acting Minister of Health Care of
the Republic of Kazakhstan

Approved by Order
No.KR DCM-94 of the
Minister of Health Care of the
Republic of Kazakhstan
as of June 14, 2019

Rules for the operation of the formulary system

Chapter 1. General provisions

1. These Rules for the operation of the formulary system (hereinafter referred to as the Rules) are developed in accordance with paragraph 2 of Article 86-2 of the Code of the Republic of Kazakhstan "On Public Health and Health Care System" as of September 18, 2009 (hereinafter referred to as the Code) and establish the procedure for the operation of the formulary system in the Republic of Kazakhstan.

2. The following terms are used in these Rules:

1) list of medicines and medical products for free and (or) preferential outpatient care for certain categories of citizens with certain diseases (conditions) - a list of medicines, medical products and specialized medical products purchased using budgetary funds and assets of the social health insurance fund within the guaranteed volume of free medical care and in the compulsory social health insurance system for the provision of outpatient care, which includes the names and characteristics of medicines, medical products and specialized medical products with a breakdown by certain categories of citizens with certain diseases (conditions);

2) medicine - a product that is either a substance, or contains a substance or a combination of substances coming into contact with the human body, intended for the treatment, prevention of human diseases or the rehabilitation, correction or change of its physiological functions through pharmacological, immunological or metabolic effects, or for diagnosing diseases and human condition;

3) rational use of medicines - medical treatment, according to clinical indications, in doses meeting individual requirements for a patient, during an adequate period of time and at the lowest cost;

4) proven clinical efficacy of a medicine - pharmacological effect for therapeutic purposes proven in meta-analyses and (or) systematic reviews, and (or) randomized controlled clinical trials;

5) international nonproprietary name of a medicine - the name of a medicine recommended by the World Health Organization;

6) health care entities – health facilities, as well as individuals engaged in private medical practice and pharmaceutical activity;

7) the authorized body for health care (hereinafter referred to as the authorized body) - the central executive body that provides leadership and intersectoral coordination in the field of public health, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, turnover of medicines and medical products, quality control of medical services;

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

9) clinical pharmacologist - a higher medical education specialist, who majored in " medical care", "pediatrics", "general medicine", who completed residency program or was retrained in clinical pharmacology and has a clinical pharmacologist certificate;

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

11) joint commission on the quality of medical services - a standing consultative and advisory body under the authorized body;

12) formulary system - a system of periodic evaluation and selection of medicines for medicines formularies, maintaining medicines formularies and presenting information in the form of appropriate guidelines and a list, aimed at the rational use of medicines.

3. The rational use of medicines is carried out to improve the quality of medical care and treatment results through the development of the formulary system.

Chapter 2. Procedure for the operation of the formulary system

Clause 1. Basic directions in the operation of the formulary system

4. The formulary system ensures the optimal use of safe, effective, cost-effective medicines.

5. The formulary system is represented by three levels:

1) the republican level is represented by the Formulary Commission of the authorized body, the Kazakhstan National Medicines Formulary and its website, the assessment of the rational use of medicines;

2) the regional level is represented by Formulary Commissions of local public health authorities of regions, cities of republican significance and the capital (hereinafter referred to as regional health authorities), consolidated medicines formularies of regional health authorities;

3) the local level is represented by Formulary Commissions, medicines formularies, and the assessment of the rational use of medicines of health facilities.

6. The main components of the formulary system are as follows:

1) formulary commission;

2) medicines formulary;

3) medicines formulary compendium;

4) recommendations for rational pharmacotherapy;

5) assessment of the rational use of medicines.

7. Medicines and medical products within the guaranteed volume of free medical care are provided:

1) for emergency, inpatient and hospital-replacing care – in accordance with the medicines formularies of health facilities;

2) for outpatient care – in accordance with the list of medicines and medical products for free and (or) preferential outpatient care for certain categories of citizens with certain diseases (conditions), approved in accordance with the current legislation of the Republic of Kazakhstan.

8. The procedure for the formation of the Kazakhstan National Medicines Formulary, the list of medicines and medical products for free and (or) preferential outpatient care for certain categories of citizens with certain diseases (conditions), and also for the development of medicines formularies of health facilities is established in accordance with subparagraph 70) of paragraph 1 of Article 7 of the Code.

9. The procedure for assessing the rational use of medicines is established in accordance with subparagraph 70-2) of paragraph 1 of Article 7 of the Code.

Clause 2. Main activities of the Formulary Commission of the authorized body

10. The Formulary Commission of the authorized body (hereinafter referred to as the Formulary Commission) coordinates and methodologically supports the operation of the formulary system.

11. The Formulary Commission is a consultative and advisory body of at least eleven people with a right to vote, which is set up by the authorized body and includes its representatives, subject-matter specialists, representatives of the pharmaceutical industry, non-governmental organizations with special knowledge in the field of turnover of medicines, clinical pharmacology and evidence-based medicine.

12. The purpose of the Formulary Commission is to develop recommendations for improving the provision of the population with medicines and medical products and submit them to the authorized body for consideration.

13. The main tasks of the Formulary Commission are as follows:

1) assistance in providing the population and health facilities with safe, effective, high-quality and affordable medicines and medical products;

2) maintaining and improving the medicines supply through the rational use of medicines by improving the formulary system.

14. The main functions of the Formulary Commission are as follows:

1) coordination of activities and provision of advisory and methodological assistance to formulary commissions of regional health authorities, health facilities;

2) promoting the introduction of evidence-based medicine in pharmacotherapy;

3) formation and regular review of the Kazakhstan National Medicines Formulary (hereinafter referred to as the KNMF);

4) consideration, approval and regular review of the list of medicines and medical products for free and (or) preferential outpatient care for certain categories of citizens with certain diseases (conditions) (hereinafter referred to as the List);

5) approval and regular review of the list of medicines and medical products purchased from the Single Distributor;

6) consideration and approval of recommendations for improving the medicines supply system;

7) approval of reference books on the rational use of medicines for doctors;

8) participation in the development and coordination of recommendations for the rational use of medicines;

9) assistance in the introduction of a program for assessing the rational use of medicines;

10) assistance in the ethical promotion of medicines with account of the criteria of the World Health Organization and the European Union;

11) evaluation of data on the interaction and adverse reactions of medicines, results of pharmacoeconomic and pharmacoepidemiological studies;

12) consideration of analyses of international experience and national standards for the pharmacotherapy of various diseases, the study of scientific evidence of clinical and economic efficiency;

13) consideration and introduction of proposals on the use of new technologies in the field of health care, including the use of medicines;

14) consideration of medicines' substitution with analogues;

15) participation in training on the rational use of medicines, evidence-based medicine;

16) consideration of a proposal for the prices of medicines, as well as for medical products within the guaranteed volume of free medical care and in the compulsory social health insurance system;

17) consideration of the nomenclature of medicines and medical products under long-term contracts.

15. The Formulary Commission consists of the chairperson, deputy chairperson, members of the commission and the secretary.

16. The chairperson is in charge of the commission's activities, approves its annual work plan, holds meetings and represents the Formulary Commission in state and public organizations.

17. The secretary is responsible for preparing meetings' agenda, sending materials to the members of the Formulary Commission, drawing up the minutes of the meetings , paperwork, maintaining the archive, he/she reports directly to the chairperson and deputy chairperson of the Formulary Commission and has no right to vote when decisions are made. The secretary shall send all materials on issues to be considered at an upcoming meeting to the members of the Formulary Commission at least 5 (five) working days before the meeting.

18. The working body of the Formulary Commission is a structural unit of the Ministry of Health Care of the Republic of Kazakhstan in the field of turnover of medicines and medical products (hereinafter referred to as the Working Body).

19. In order to select candidates for members of the Formulary Commission, the Working Body sets up a working group of at least five people of representatives of the authorized body, non-governmental organizations.

20. The authorized body posts an announcement on its website indicating its postal address, deadlines for submitting documents, and email addresses.

21. After the announcement is placed on the website, within fourteen working days, candidates submit to the working group that selects candidates such documents as:

1) an application in any form;

2) a CV with information on professional and (or) social activities, autobiographical data, a photo and contact information (phone, email address);

3) copies of an identity document, a higher national certificate (on higher medical, pharmaceutical education), a document confirming the employee's work experience in the field of health care for at least 5 years;

4) a document confirming the absence of a criminal record, including the absence of a criminal record for the commission of a corruption crime and (or) corruption offense.

22. The requirements of subparagraphs 3), 4) of paragraph 21 of these Rules do not apply to employees of state bodies, subordinate organizations of the authorized body, who are candidates for members of the Formulary Commission.

23. The working group takes decisions at its meetings by show of hands of a majority of attending members. In the event of a tie, the decision voted for by the head of the working group shall be deemed adopted.

24. Based on the results of consideration of candidates for members of the Formulary Commission, the working group makes recommendations on the approval of the composition of the Formulary Commission.

25. The head of the authorized body or a person acting for him/her approves the composition of the Formulary Commission and appoints the chairperson of the Formulary Commission by issuing a relevant order.

26. The authorized body replaces its representative without a selection procedure.

27. If a member of the Formulary Commission fails to attend its meetings without valid excuse more than thrice, the authorized body removes him/her from the Formulary Commission. Members of the Formulary Commission can prematurely leave the Formulary Commission by submitting an application in any form to the head of the authorized body.

28. In the cases provided for by paragraph 27 of these Rules, the authorized body shall announce the selection in accordance with paragraphs 19, 20, 21 and 22 of these Rules.

29. Members of the Formulary Commission:

1) comply with the procedure for the operation of the formulary system provided for by these Rules;

2) draw conclusions confirmed by reliable scientific data;

3) respect the rights of their colleagues and take into account their opinion in the course of joint discussions;

4) do not use their position in the Formulary Commission to obtain advantages and benefits;

5) do not disclose information for internal use on the activities of the Formulary Commission, if such a restriction is adopted by the Formulary Commission;

6) do not affect the objectivity of decision-making of the Formulary Commission, using professional activity related to the cooperation with government agencies, private and public organizations, associated with possible emergence of a conflict of interest;

7) do not participate in the examination, decision-making and voting on a medicine (medical technology, program) in the event of a conflict of interest;

8) make proposals to the work plan of the Formulary Commission and the meeting procedure;

9) leave the Formulary Commission on a voluntary basis, by written notice;

10) set out their special opinion to be recorded in the minutes of a meeting of the Formulary Commission.

30. Members of the Formulary Commission fill out the Declaration on the disclosure of a potential conflict of interest for a member of the Formulary Commission (invited subject-matter expert) (hereinafter referred to as the Declaration) in accordance with the form in Appendix 1 to these Rules.

31. The secretary, on the basis of the Declarations filled out by the members of the Formulary Commission (invited subject-matter expert), generates consolidated information on the presence of potential conflicts of interest, which is submitted to the Chairperson of the Formulary Commission for information.

32. Declarations completed by the members of the Formulary Commission (invited subject-matter experts) are stored and filed together with the minutes of the meeting, and are not subject to public discussion or publication.

33. The Formulary Commission works in accordance with its work plan approved by its chairperson for one calendar year. Unplanned issues are included in the agenda of a meeting of the Formulary Commission by decision of the chairperson or a person acting for him/her.

34. The work plan of the Formulary Commission is approved during the first month of a current year and is posted on the website of the authorized body 10 working days after its approval by the chairperson of the Formulary Commission.

35. Meetings of the Formulary Commission are held at least once a quarter and are considered valid if attended by two-thirds of the members of the Formulary Commission. Decisions are adopted if voted for by at least two-thirds of attending members. Controversial issues are submitted by the chairperson of the Formulary Commission for its consideration in order to make a compromise decision, in case of a failure to compromise, the decisions of the chairperson of the Formulary Commission are final. If necessary, the chairperson of the Formulary Commission schedules an extraordinary virtual meeting.

36. If necessary, subject-matter experts without a right to vote are involved in the work of the Formulary Commission.

37. The decisions of a meeting of the Formulary Commission are documented in minutes signed by all members of the Formulary Commission. Members of the Formulary Commission, within 10 working days of the meeting, sign the minutes submitted by the secretary.

38. The record of the decision of the Formulary Commission is posted on the website of the authorized body 20 working days after the meeting.

39. The termination of activities of the Formulary Commission is approved by order of the head of the authorized body or a person acting for him/her and is posted on the website of the authorized body.

40. Legal entities that applied to the Formulary Commission for the consideration of materials (hereinafter referred to as the applicant) send applications to the chairperson of the Formulary Commission in any form, which are registered by the Working Body. The Working Body sends official requests related to the activities of the Formulary Commission:

1) to the Republican State Enterprise with the right of economic management " Republican Center for Health Development" (hereinafter referred to as the Center) - for the evaluation and selection of medicines for medicines formularies and the List.

2) to health facilities engaged in activities related to the request for their consideration;

3) to the state expert organization in the field of turnover of medicines and medical products (hereinafter referred to as the expert organization) – with regard to issues of pricing of medicines and medical products;

4) to the single distributor – with regard to the procurement of medicines.

41. The Center, the state expert organization, the single distributor and health facilities send information to the Working Body within 50 working days of the request' s receipt.

Clause 3. Evaluation and selection of medicines for medicines formularies and the List

42. The medicines formularies of health facilities are developed on the KNMF basis.

43. The evaluation and selection of medicines for the KNMF are carried out in terms of proven clinical safety and efficacy of a medicine and provide critical assessment of the data submitted by the applicant on the clinical safety and efficacy of the medicine, proven in meta-analyses, and (or) systematic reviews, and (or) randomized controlled clinical trials.

44. Medicines for the KNMF are evaluated and selected pursuant to an application for evaluating and selecting medicines for the KNMF and the List (hereinafter referred to as the application) in accordance with the form in Appendix 2 to these Rules within 50 (fifty) working days, including:

1) initial analysis of the application - within 5 (five) working days;

2) evaluation and selection of medicines for the KNMF - within 40 (forty) working days;

3) preparation of recommendations for the Formulary Commission - within 5 (five) working days.

45. The applicant sends its application to the Center.

46. The initial analysis of the application for a medicine includes the assessment of the completeness, reliability and correct execution of submitted documents.

47. If there are comments on the results of the initial analysis of the application, it is necessary to draw up a statement on the results of the initial analysis of the application for evaluating and selecting medicines for the KNMF and the List according to Appendix 3 to these Rules, which is sent to the applicant within 5 (five) working days not included in the time frames established for the evaluation and selection of medicines for the KNMF, indicating identified failures such as:

improper execution of the application, and the documents and information attached thereto;

no electronic form of the application, and documents and information attached thereto;

presentation of incomplete documents and information;

identification of discrepancies between documents and information presented in paper-based and electronic forms;

submission of false or distorted information.

48. If necessary, the Center requests the applicant to clarify or specify particular provisions in the submitted documents.

49. In case of the applicant's failure to submit requested materials or written rationale for other time frames for their preparation within 10 (ten) working days, but no more than 20 (twenty) working days, the Center stops the evaluation and selection of medicines for the KNMF and rejects the application. The total number of working days required to submit the requested materials is not more than 20 (twenty) working days.

50. The following information sources are used for critical assessment of data on clinical safety and efficacy of medicines:

1) international evidence-based medicine data sources: the British National Formulary, the British National Formulary for Children, the Cochrane Library, the WHO Model List of Essential Medicines for Adults and Children, the Food and Drug Administration of the United States of America (hereinafter referred to as the USA), the European Medicines Agency, the Orphanet reference portal, Martindale (the complete drug reference), in the absence of information in the Cochrane Library - MEDLINE (PubMed).

2) international clinical guidelines and recommendations:

the core list: UK National Institute for Health and Care Excellence, Best Practice - British Medical Journal, Medscape, the Scottish Intercollegiate Guidelines Network;

additional list (in the absence of relevant (necessary) information in the core list):

for the provision of pulmonary care: clinical recommendations of the “Global strategy for asthma management and prevention”, the “Global strategy for the diagnosis, management, and prevention of chronic obstructive lung disease”;

in terms of gastroenterology: clinical recommendations of the American College of Gastroenterology, the British Society of Gastroenterology;

in terms of cardiology: clinical recommendations of the European Society of Cardiology, the American Heart Association;

in terms of nephrology: clinical recommendations “Kidney Disease: Improving Global Outcomes (Initiative to improve the care and outcomes of patients with kidney disease worldwide)”, the Renal Association, monthly peer-reviewed medical journal “ Nephrology Dialysis Transplantation”, the “Chronic Kidney Disease Management handbook” - Australia, the “National Kidney Foundation”;

in terms of endocrinology: clinical recommendations of the American Diabetes Association, the European Association for the Study of Diabetes;

in terms of urology: clinical recommendations of the European Association of Urology, the Infectious Diseases Society of America;

in terms of oncology: clinical recommendations of the European Society for Medical Oncology;

3) health technology assessment reports;

4) clinical protocols of the Republic of Kazakhstan approved by the Joint Commission on the quality of medical services.

51. To evaluate and select medicines for the KNMF in terms of proven clinical safety and efficacy of a medicine, it is necessary to use formal scales in accordance with the ratio of levels of evidence and grades of recommendations developed by the Oxford Center for Evidence-Based Medicine in accordance with Appendix 4 to these Rules.

52. To verify the accuracy of the data presented in the application for clinical safety and efficacy, if necessary, an independent search and analysis of clinical trials of drugs is carried out.

53. Based on the results of the evaluation and selection of medicines for the KNMF , it is necessary to draw up an opinion on the availability of proven clinical safety and efficacy of the medicine in accordance with Appendix 5 to these Rules, which is sent to the Formulary Commission for its consideration.

54. The evaluation and selection of medicines for the List are carried out in terms of proven clinical, and (or) pharmacoeconomic advantages and (or) equivalent efficacy , and (or) safety compared with other medicines used in the treatment of a particular disease or condition at the outpatient level in the health care sector of the Republic of Kazakhstan and provides for critical assessment of the data submitted by the applicant on the clinical safety and efficacy of the medicine, proved in the meta-analyses, and (or

) systematic reviews, and (or) randomized controlled clinical trials, as well as economic efficiency, presented in pharmacoeconomic studies in the economic context of the Republic of Kazakhstan.

55. Medicines are evaluated and selected for the List pursuant to an application within the time frames specified in paragraphs 44 and 45 of these Rules.

56. The initial analysis of the application is carried out in accordance with paragraphs 46, 47, 48 and 49 of these Rules.

57. The critical assessment of data on the clinical safety and efficacy of a medicine is carried out in accordance with paragraphs 50, 51, 52 of these Rules.

58. The analysis of economic efficiency of medicines means the analysis of presented pharmacoeconomic studies and the validity of data on the use of medicines in the health care sector of the Republic of Kazakhstan.

59. The applicant's pharmacoeconomic study on the analysis of the cost-effectiveness of medicines is presented in comparison with medicines with similar pharmacotherapeutic effects and indications for use, which are the medical therapy standard for a particular disease.

60. The economic analysis includes the analysis of the validity of the choice of the type of clinical trial, the selection of criteria for efficacy and safety, the validity of the choice of the object of comparison for the study, and the methods that underlie the pharmacoeconomic study in terms of costs and outcomes (results).

61. To verify the data presented in the application, if necessary, independent search and analysis of information on clinical and (or) pharmacoeconomic studies of the drug is carried out.

62. Based on the results of the evaluation and selection of medicines for the List, it is necessary to draw up an opinion on the availability of proven clinical and (or) pharmacoeconomic advantages, and (or) equivalent efficacy, and (or) safety compared with other medicines used in the treatment of a particular disease or condition at the outpatient level in the health care sector of the Republic of Kazakhstan in accordance with Appendix 6 to these Rules, which is sent to the Formulary Commission for its consideration.

63. The costs associated with the evaluation and selection of medicines for the KNMF and the List are borne by the applicants. In cases of rejection or withdrawal of the application by the applicant after the start of its implementation, the cost of the analysis is not returned to the applicant.

64. Requests for the selection of medicines included in the WHO List of Essential Medicines with regard to socially significant diseases are initiated by the authorized body and sent to the Center for the evaluation and selection of medicines for the KNMF and the List under the "Methodological support for health care reform" contract

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Clause 4. Main activities of formulary commissions of regional health authorities or health facilities

65. The formulary commission of a regional health authority or health facility is a consultative and advisory body whose main purpose is to introduce and maintain the formulary system and rational use of medicines, to manage, develop policy, and regulate important aspects of procurement, selection (prescription) and optimization of the use of medicines used in a respective region or health facility.

66. The formulary commission of the regional health authority is set up by the regional health authority and consists of at least eleven people having the right to vote, who are representatives of the regional health authority, subject-matter specialists, non-governmental organizations with special knowledge in the field of turnover of medicines, clinical pharmacology and evidence-based medicine.

67. The formulary commission of a health facility includes at least seven people having the right to vote, who are its clinical director, clinical pharmacologist, pharmacy manager, department heads and subject-matter specialists with relevant knowledge in the field of turnover of medicines, in clinical pharmacology and evidence-based medicine.

68. The composition and structure of the formulary commission of the regional health authority or health facility is approved by the head of the regional health authority or the head of the health facility.

69. The chairperson of the formulary commission of the regional health authority or health facility is elected from among the members of the formulary commission of the regional health authority or health facility.

70. The main tasks of the formulary commission of the regional health authority or health facility are as follows:

1) assistance in providing the population with safe, effective, high-quality and affordable medicines and medical products;

2) identification of the needs of the region, health facility for medicines and medical products;

3) rational use of medicines;

4) provision of informational, advisory and methodological assistance to medical personnel of health facilities on issues related to the use of medicines;

5) identification of the need for educational programs for staff development on the use of medicines, management of educational programs.

71. The main functions of the Formulary Commission of the regional health authority are as follows:

1) coordination of activities and provision of advisory and methodological assistance to formulary commissions of health facilities;

2) promoting the introduction of evidence-based medicine in pharmacotherapy;

3) formation of the consolidated medicines formulary of the region;

4) approval of medicines formularies of health facilities, except for health facilities administered by the authorized body and providing medical assistance, based on the results of the assessment of the use of medicines (ABC-VEN analysis) of the medicines formulary and analysis of medicines' consumption over a previous year within 1 (one) month;

5) consideration and approval of recommendations for improving the medicines supply system;

6) approval of reference books on the rational use of medicines for doctors;

7) promoting the introduction of the assessment of the rational use of medicines;

8) ethical promotion of medicines, taking into account the criteria of the World Health Organization and the European Union;

9) evaluation of data on the interaction and adverse reactions of medicines, results of pharmacoeconomic and pharmacoepidemiological studies;

10) consideration of analyses of international experience and national standards for the pharmacotherapy of various diseases, the study of scientific evidence of clinical and economic efficiency;

11) consideration and introduction of proposals on the use of new technologies in the health care sector, including the use of medicines;

12) consideration of medicines' substitution with analogues;

13) participation in training on the rational use of medicines, evidence-based medicine.

72. The functions of the formulary commission of a health facility include:

1) development of the medicines formulary of the health facility in accordance with subparagraph 70 of paragraph 1 of Article 7 of the Code;

2) consideration of proposals on entering in or removing from the medicines formulary;

3) evaluation of clinical data on new medicines proposed for use in the health facility;

4) planning of the procurement of medicines and medical products for this facility;

5) revision of the medicines formulary at least once a year;

6) introduction of programs that provide rational medical therapy at moderate and reasonable prices for a given health facility;

7) introduction of programs (including training ones) that ensure safe and effective medical therapy;

8) introduction of the fundamentals of pharmacoeconomic analysis and, if necessary, organization of training courses for specialists;

9) consideration of the results of the assessment of the rational use of medicines and determination of measures to eliminate inconsistencies and further improve the rational use of medicines;

10) provision of advisory, evaluating, educational support, as well as the organization and planning of training programs for medical personnel on issues related to the use of medicines;

11) keeping records and reporting on entering medicines in and removing them from the medicines formulary.

73. Members of the Formulary Commission of the regional health authority or health facility fill out the Declaration in accordance with the form in Appendix 1 to these Rules.

74. The formulary commission of the regional health authority or health facility works in accordance with the work plan approved by the chairperson of the formulary committee of the regional health authority or health facility. Meetings are held at least once a quarter and are considered valid if attended by more than half of the commission members. Decisions are adopted if voted for by at least two-thirds of attending members.

75. The decisions of the meeting of the formulary commission of the regional health authority and health facility are documented in the minutes signed by all the members of the formulary commission of the regional health authority and the health facility.

76. The record of the decision of the formulary commission of the regional health authority and health facility is posted on the website of the regional health authority and health facility 10 working days after the meeting.

Appendix 1
to the Rules for the
operation of the formulary system

DECLARATION
on disclosing a potential conflict of interest of a member of the Formulary Commission (invited subject-matter expert)

I (Surname, name, patronymic (if any) and position)

_____

_____trained as _____ undertake to strictly comply with the requirements of the Rules for ethical promotion of medicines and medical products and declare the presence or absence of the following potential conflicts of interest:

_____

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_____ _____

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I own (in whole or in part, in the form of shares or as a co-owner of a patent) the production of medicines, medical products, pharmacies or pharmaceutical distribution companies, health facilities (if so, indicate the name)

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I am a member of governing bodies (supervisory board, board of directors, other governing bodies) of manufacturing plants of medicines, medical products, pharmacies or distribution companies, health facilities, insurance companies engaged in health insurance (if so, indicate the name)

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Over the past three years, I have received payment for lectures or other educational programs, or received direct financial support for leisure or professional trips, including to conferences (excluding indirect sponsorship through the social organizations in which I am a member, the place of employment), from companies manufacturing medicines, medical products, other drugs, including dietary supplements, homeopathic medicines (if so, specify)

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Over the past three years, I have provided services to companies manufacturing medicines, medical products, other drugs, including dietary supplements, homeopathic medicines (it is necessary to indicate paid services, including direct research contracts) (if so, specify and indicate companies)

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I do not have other potential conflicts of interest; I understand the policy regarding the ethical promotion of medicines and medical products.

I take full responsibility for the accuracy of the information filled in this Declaration.

Date _____ Signature _____

Appendix 2
to the Rules for the operation of
the formulary system

APPLICATION
for the evaluation and selection of medicines for the Kazakhstan National Medicines Formulary and the List of medicines and medical products for free and (or) preferential outpatient care for certain categories of citizens with certain diseases (conditions)*

1. This application is intended for the evaluation and selection of medicines for the Kazakhstan National Medicines Formulary (hereinafter referred to as the KNMF) and the List of medicines and medical products for free and (or) preferential outpatient care for certain categories of citizens with certain diseases (conditions) (hereinafter referred to as the List).

2. Information on the applicant:

2.1 name of the facility_____
_____
__;

(in the national, Russian, English languages)

2.2. responsible person, position_____;

(Surname, name, patronymic (if any), position, telephone,
email)

2.3 address (registered address) _____
_____
__;

(legal address, actual address)

telephone (fax)_____;

email_____.

3. Information on the medicine:

3.1 trade name, dosage form and dosage, concentration:

_____
_____
__.

Methods of administration _____
_.

3.2 international nonproprietary name/composition (for medicines)

_____
__;
(in the national, Russian, English languages)
3.3 code of the Anatomical Therapeutic Chemical Classification (for medicines)
_____
__;
3.4. The medicine is:
3.4.1) with regard to a medicine (tick the right box):
original
generic
medical immunobiological preparations (MIBP)
biosimilar
3.4.2) With regard to a generic, biosimilar, indicate the name of the original medicine
_____;
3.5 declared indications for the use of the medicine
_____
__
_____
__
_____
__
_____
__;
3.6 state registration of the medicine in the Republic of Kazakhstan:
date (dd/mm/yyyy) _____;
registration certificate number_____;
date of confirmation of the state registration (if any) (dd/mm/yyyy)_____
_____;
name and address (location) of the legal entity having the registration certificate of the medicine used as a comparative one (if any)
_____
__
_____
__;
manufacturer of the medicine, which is used as a comparative one (if any)
_____
_____;
3.7 data on the manufacture of the medicine in the Republic of Kazakhstan (if any)

_____

_____
__

_____
__;

3.8 dosage forms/technical specifications of the registered medicine proposed for entering (indicate)

_____

_____
__

_____
__

_____
__;

3.9 information on generic medicines/technical analogues (if any)

_____

_____
__

_____
__

_____
__;

3.10 information on the availability of therapeutic equivalence and (or) bioequivalence for generic medicines _____

_____
__.

4. Information and data on the medicine:

4.1 evidence-based data on the need and validity of the use of the medicine for diagnosing, preventing, treating or rehabilitating diseases (conditions) that prevail in the structure of morbidity and mortality of citizens of the Republic of Kazakhstan based on statistical data (if any);

4.2 availability of evidence-based data on clinical and economic advantages of the use of the medicine compared with medicines used to provide inpatient, hospital-replacing, emergency or outpatient care, which are already included in the List ;

4.3 availability of evidence-based information on proven clinical safety and efficacy, advantages and (or) on features of the mechanism of action of the medicine

compared with its analogues, including those on the List, in the diagnosis, prevention or treatment of diseases (conditions), taking into account statistical data on the structure of morbidity and mortality in the Republic of Kazakhstan;

4.4 social significance of the prescription of the medicine and demand for it by the health care system and the population.

5. Evidence-based data for the analysis of the clinical and (or) economic effectiveness of the medicine:

5.1 epidemiological data (if any) - data on the morbidity, mortality, disability in relation to the disease (condition), for the diagnosis, prevention, treatment or rehabilitation of which the medicine is indicated (the data are presented on the basis of official statistics and epidemiological studies of the prevalence of the disease);

5.2 clinical data - full-text versions of clinical trials, articles, reports in the national or Russian language, or translated into the national or Russian language, certified by the applicant, it is necessary to indicate the authors, name, study design, the number of patients included in the study, observation period, indication for medical use of the medicine under the study, effectiveness (safety) criteria of the medicine with which the proposed medicine was compared (if any), placebo control or absence of treatment, the results of the study indicating quantitative data, opinion, a list of references according to the scheme: author, name of the study, imprint. Each medicine is assigned a level of evidence of effectiveness and recommendations;

5.3 data on therapeutic equivalence (if necessary) - full-text versions of comparative clinical trials (articles, reports in the national or Russian language or articles, reports translated into the national or Russian language, certified by the applicant) (it is necessary to indicate the authors, name, study design, number of patients included in the study, observation period, indication for medical use of the medicine, the results of the study indicating quantitative data, opinion, list of references according to the scheme: author, name of the study, imprint);

5.4 data on economic characteristics of the medicine - full-text versions of pharmacoeconomic studies in the health care sector of the Republic of Kazakhstan (articles, reports in the national or Russian language or articles, reports translated into the national or Russian language, certified by the applicant) (it is necessary to indicate information on the authors, name of the study, links to the study, the study design (retrospective, prospective, modeling**), type of analysis, information on medicines that are used for comparison with the proposed medicine, the costs taken into account in the study and the quantitative values of the costs in tenge, the effectiveness of the compared medicines (criteria for expert evaluation of effectiveness and quantitative values), study results, bibliography - author, title of the study, imprint);

5.5 data on the cost and price of the medicine:

5.5.1 the cost of one course of treatment (diagnosis, rehabilitation, etc. with the medicine)

_____

_____

__

_____

__;

5.5.2 the cost of treatment (diagnosis, rehabilitation, etc.) with the medicine over one year

_____

_____

_____

_____;

5.5.3 maximum price for the medicine (indicating the date of registration)

_____

_____

__;

5.5.4 possible discount from the manufacturer

_____

__

_____

__;

5.6 data on the actual sales volumes of the medicine in the Republic of Kazakhstan over a year preceding the filing of the application, in physical terms by dosage forms/ technical characteristics of registered medicines

_____

__

_____

__

_____

__

_____

_;

5.7 data of reports on the results of monitoring the safety of the medicine (in the Republic of Kazakhstan and (or) abroad)

_____

__

_____

__

_____
__;

5.8 data submitted at the applicant’s initiative _____

_____
__

_____
__.

6. The total number of documents submitted is_____
on _____ sheets.

The applicant’s signature _____ / _____
/

(signature) (print full name)

Date_____

* It is necessary to fill out all the application items. When filling out an application for the evaluation and selection of medicines for the KNMF, it is not required to enter the data on pharmacoeconomic advantages and (or) equivalent efficacy, and (or) safety compared to other medicines used in the treatment of a particular disease or condition at the outpatient level in the health care sector of the Republic of Kazakhstan. Documents and materials are submitted in the national or Russian language, if publications, documents and articles are submitted in foreign languages, it is necessary to additionally attach the translation of the summary of indicated materials into the national or Russian language, certified by the applicant.

** When using pharmacoeconomic modeling, all developed models are presented in electronic form, as well as assumptions for the development of appropriate models and calculation formulas used in the models.

Appendix 3 to the Rules for the operation of the formulary system

STATEMENT on the results of the initial analysis of the application for evaluating and selecting medicines for the Kazakhstan National Medicines Formulary and the List of medicines and medical products for free and (or) preferential outpatient care for certain categories of citizens with certain diseases (conditions)

1. This statement relates to the materials presented in the application for evaluating and selecting medicines for the Kazakhstan National Medicines Formulary and the List of medicines and medical products for free and (or) preferential outpatient care for certain categories of citizens with certain diseases (conditions).

2. Information on the medicine:

2.1 trade name: _____

_____
__;

2.2 international nonproprietary name_____

_____
__;
2.3 code of the Anatomical Therapeutic Chemical Classification _____
_____
__;
2.4 technical characteristics of the registered medicine (indicate):
_____
_____
__
_____
__
_____
__.
3. Time frames for the initial analysis:
from _____ to _____.
4. The application's initial analysis:
Required data.
Information on the submission of the required data by the applicant: _____
_____
__
1. Information on the applicant:

☐
presented in full;

☐
not presented in full (indicate): _____
_____
__

☐
not presented.
2. Information on the medicine:

☐
presented in full;

☐

not presented in full (indicate): _____

_____

__

☐

not presented.

3. Data on the medicine:

☐

presented in full;

☐

not presented in full (indicate): _____

_____

__

☐

not presented.

4. Evidence-based data:

☐

presented in full;

☐

not presented in full (indicate): _____

_____

__

☐

not presented.

5. Comments on the results of the initial analysis of the application (if any, tick as appropriate):

☐

improper execution of the application, and the documents and data attached thereto;

☐

no electronic form of the application, and the documents and data attached thereto;

☐

incomplete presentation of documents and data;

☐

identification of discrepancies between documents and data presented in paper-based and electronic forms;

☐

presentation of false or distorted information.

Comments:

_____

_____

6. Result:

☐

to send comments on non-compliance with the established requirements to the applicant to address them;

☐

to deny because of a failure to address failures in a timely manner.

_____ _____/_____

(date) (signature) (print full name)

Appendix 4
to the Rules for the operation
of the formulary system

Ratio of levels of evidence and grades of recommendations developed by the Oxford Center for Evidence-Based Medicine

Levels of evidence		Grades of recommendations
Systematic review, randomized controlled clinical trials, separate randomized controlled clinical trial	I	A

Systematic review of cohort studies, or a separate cohort study	II	B
Case-control study (separate or systematic review of several ones)	III	B
Description of the series of cases, low-quality cohort studies	IV	C
Expert opinion without accurate critical assessment	V	D

Scottish Intercollegiate Guidelines Network. Guideline Developer's Handbook. Quick Reference Guide. November 2015.

Appendix 5
to the Rules for the
operation of the formulary system

Opinion on proven clinical safety and efficacy of a medicine

1. This opinion relates to the materials submitted by the applicant for the evaluation and selection of medicines for the Kazakhstan National Medicines Formulary.

2. Information on the analysis of the application for the medicine (hereinafter referred to as the analysis of the application):

2.1 composition of experts (Surname, name, patronymic (if any), position)

_____
__
_____
__
_____
__;

2.2 additional technical or expert opinions taken into account

_____
__
_____
__.

3. Information on the medicine:

3.1 trade name: _____;

3.2. international nonproprietary name/composition:

_____
__;

3.3 dosage form: _____;

3.4 pharmacotherapeutic group: _____;

3.5 code of the Anatomical Therapeutic Chemical Classification: _____

_____
__;

3.6 registration in the Republic of Kazakhstan:

Registration number	Trade name	Registration date/ Expiration date	Manufacturer	Dosage form	Dosage

4. Time frames for the analysis of the application: from _____ to _____ _____.

5. The results of the analysis of proven clinical safety and efficacy of the medicine according to the applicant's application.

The results of the analysis of the medicine submitted by the applicant and (or) found independently by the organization for the analysis of the application:

5.1 In international evidence-based medicine data sources and international clinical guidelines:

In the British National Formulary and (or) the British National Formulary for Children (year of manufacture)

_____ __

_____ __

At the Cochrane Library _____ _____

_____ __ (describe in detail the availability of systematic reviews, meta-analyses, RCTs with a reference to SR, RCT, CT)

In the WHO Essential Medicines List (month and year of issue)

_____ __

_____ __

At the European Medicines Agency _____

_____ __

_____ __

At the U.S. Food and Drug Administration

_____

In MEDLINE (PubMed) _____(in the absence of information in the Cochrane Library, it is necessary to describe in detail the availability of systematic reviews, meta-analyses, RCTs with a reference to SR, RCT, CT)

In the "Best Practice" British Medical Journal _____

_____
_____

At the UK National Institute for Health and Care Excellence

_____
_____

_____
_____

If necessary, use other reliable sources of international clinical guidelines:

_____
_____

_____
_____

5.2 In clinical protocols of the Republic of Kazakhstan _____

_____
_____

_____
_____

6. Analysis of the application and opinions on the clinical efficacy of the medicine:

_____
_____

_____
_____

_____
_____

_____
_____

Signatures and full print name of the head of the organization that conducted the analysis:

_____
_____

(Surname, name, patronymic (if any) of the head of the organization)

Date "_____" _____20____

Appendix 6
to the Rules for the operation of
the formulary system

Opinion on the availability of proven clinical and (or) pharmacoeconomic advantage and (or)

equivalent efficacy, and (or) safety compared with other medicines in the treatment of a particular disease or condition at the outpatient level in the health care sector of the Republic of Kazakhstan

1. This opinion relates to the materials submitted by the applicant for the evaluation and selection of medicines for the List of medicines and medical products for free and (or) preferential outpatient care for certain categories of citizens with certain diseases (conditions) (hereinafter referred to as the List).

2. Information on the analysis of the application for the medicine (hereinafter referred to as the analysis of the application):

2.1 composition of experts (Surname, name, patronymic (if any), position)

_____
__

_____
__;

2.2 additional technical or expert opinions taken into account

_____
__

_____
__.

3. Information on the medicine:

3.1 trade name: _____;

3.2. international nonproprietary name/composition:

_____
__;

3.3 dosage form: _____;

3.4 pharmacotherapeutic group: _____;

3.5 code of the Anatomical Therapeutic Chemical Classification: _____

_____
__;

3.6 registration in the Republic of Kazakhstan:

Registration number	Trade name	Registration date/ Expiration date	Manufacturer	Dosage form	Dosage

4. Time frames for the analysis of the application: from _____ to _____
_____.

5. The results of the analysis of proven clinical safety and efficacy of the medicine according to the applicant’s application.

The results of the analysis of the medicine submitted by the applicant and (or) found independently by the organization for the analysis of the application:

5.1 In international evidence-based medicine data sources and international clinical guidelines:

In the British National Formulary and (or) the British National Formulary for Children (year of manufacture)

_____
__
_____
__

At the Cochrane Library _____
_____

_____
__ (describe in detail the availability of systematic reviews, meta-analyses, RCTs with a reference to SR, RCT, CT)

In the WHO Essential Medicines List (month and year of issue)

_____
__
_____
__

At the European Medicines Agency _____

_____
__

At the U.S. Food and Drug Administration

_____

_____
__

In MEDLINE (PubMed)_____

_____
__ (in the absence of information in the Cochrane Library, it is necessary to describe in detail the availability of systematic reviews, meta-analyses, RCTs with a reference to SR, RCT, CT)

In the “Best Practice” British Medical Journal_____

_____
__
_____
__

At the UK National Institute for Health and Care Excellence

_____
__

_____

If necessary, use other reliable sources of international clinical guidelines:

_____

_____

_____

5.2 In clinical protocols of the Republic of Kazakhstan _____

6. The results of the analysis of economic efficiency of the medicine according to the applicant's application:

Analysis criteria	Analysis result	Percentage of deviation
1. Presented price of the course/ administration or one-year treatment (diagnosis, rehabilitation, etc.) of the medicine	higher than the cost of the comparative medicine	
	equal to the cost of the comparative medicine	
	lower than the cost of the comparative medicine	
Analysis by the rating scale of presented costs		
2. Advantages in terms of economic efficiency of the medicine versus the comparative medicine	use of the medicine leads to a decrease in the total cost of providing medical care (budget impact)	
	use of the medicine does not require an increase in the total cost of providing medical care (budget impact)	
	use of the medicine requires an increase in the total cost of providing medical care as part of the state guarantee program for free provision of medical care (budget impact)	

7. The results of the analysis of other data on the applicant's application:

Analysis criteria	fits or not
Need to use medicines for the diagnosis, prevention, treatment or rehabilitation of diseases (conditions) that prevail in the structure of morbidity and mortality of citizens of the Republic of Kazakhstan (for inpatient, hospital-replacing and emergency care), as well as those managed at the outpatient level (for outpatient care) based on the statistics provided in the application	
Need to use medicines for the prevention, treatment and rehabilitation of socially significant diseases and diseases that are dangerous for others, managed at the outpatient level	

Need to use medicines for the prevention, treatment and rehabilitation of exclusively orphan (rare) diseases managed at the outpatient level	
Availability of generic medicines registered in the Republic of Kazakhstan	
Presence of the expert organization's confirmation of data on therapeutic equivalence and (or) bioequivalence for generic medicines with the similar mechanism of pharmacological action in the treatment of a particular disease (condition)	
Presence of analogues in the List	

8. Analysis of the application and opinions on the clinical and economic efficacy of the medicine:

_____

__

_____

__

_____

__.

Signatures and full print name of the head of the organization that conducted the analysis:

_____

_

(Surname, name, patronymic (if any) of the head of the organization)

Date "_____" _____20____