



On approval of the rules for the formation of Kazakhstan national drug formulary, as well as the rules for the development of drug formularies of healthcare organizations

Unofficial translation

Order of the acting Minister of Healthcare of the Republic of Kazakhstan dated December 24, 2020 No. KR HM-326/2020. Registered in the Ministry of Justice of the Republic of Kazakhstan on December 25, 2020 No. 21913

Unofficial translation

In accordance with subparagraph 47) of Article 7, paragraph 2 of Article 264 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System"

I HEREBY ORDER:

1. To approve:

1) the rules for the formation of the Kazakhstan national drug formulary in accordance with Appendix 1 to this order;

2) the rules for the development of drug formularies of healthcare organizations in accordance with Appendix 2 to this order.

2. To declare invalid:

1) the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated June 14, 2019 No. KR HM-94 "On approval of the Rules for the operation of the formulary system" (registered in the Register of state registration of regulatory legal acts No. 18856, published on June 21, 2019 in the Standard control bank of regulatory legal acts of the Republic of Kazakhstan in electronic form);

2) order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated May 22, 2015 No. 369 "On approval of the Rules for the formation of Kazakhstan national drug formulary, a list of medicines and medical devices for free and (or) preferential outpatient provision of certain categories of citizens with certain diseases (states), as well as the development of drug formularies for healthcare organizations" (registered in the Register of state registration of regulatory legal acts under No. 11429, published in the Legal information system "Adilet" on July 03, 2015; "Kazakhstanskaya Pravda" dated June 25, 2016 No. 121 (28247); "Egemen Kazakhstan" on June 25, 2016 No. 121 (28849)).

3. The Department of drug policy of the Ministry of Healthcare of the Republic of Kazakhstan, in the manner established by the legislation of the Republic of Kazakhstan, shall ensure:

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

2) placement of this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

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

4. Control over the execution of this order shall be entrusted to the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan.

5. This order shall be enforced upon the expiration of ten calendar days after its first official publication

*Acting Minister of Healthcare
of the Republic of Kazakhstan*

M. Shoranov

Appendix 1
to the order of the
first Vice-Minister
of Healthcare of the
Republic of Kazakhstan
dated December 24, 2020
No. KR HM-326/2020

Rules for the formation of Kazakhstan national drug formulary

Chapter 1. General provisions

1. These rules for the formation of Kazakhstan national drug formulary (hereinafter-the Rules) have been developed in accordance with subparagraph 47) of Article 7 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System" (hereinafter-the Code) and shall determine the procedure for the formation of Kazakhstan national drug formulary.

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

1) State register of medicines and medical devices - an electronic information resource containing information on medicinal products and medical devices registered and permitted for medical use in the Republic of Kazakhstan;

2) a medicinal product - a product that is or contains a substance or a combination of substances that comes into contact with the human body, intended for the treatment, prevention of human diseases or restoration, correction or change of his/her physiological functions through pharmacological, immunological or metabolic effects, or for diagnosis of human diseases and state;

3) a medicinal drug - a medicinal product in the form of a dosage form;

4) international non-proprietary name of a medicinal product (hereinafter - INN) - name of a medicinal product recommended by the World Health Organization;

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

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

7) Kazakhstan national drug formulary (hereinafter - KNF) - a list of medicinal products with proven clinical safety and effectiveness, as well as orphan (rare) medicinal products, which is an obligatory basis for the development of drug formularies of medical organizations and the formation of lists of procurement of medicinal products within the guaranteed volume of free medical care and (or) in the compulsory social health insurance system.

Chapter 2. The procedure for the formation of Kazakhstan national drug formulary

3. The procedure for the formation of Kazakhstan national drug formulary includes the following:

1) submission of an application by the manufacturer or its official representative in the Republic of Kazakhstan (hereinafter-the applicant) to the subordinate organization of an authorized body, whose competence includes the issues of conducting an expertise, providing for the assessment of data on clinical safety and effectiveness of a medicinal product, confirmed by clinical researches, as well as in meta-analyses and (or) systematic reviews (hereinafter - the Centre);

2) conducting of professional expertise by the Center;

3) preparation of a conclusion based on the results of professional expertise by the Centre for the Formulary commission of the authorized body in the field of healthcare (hereinafter - the Formulary commission);

4) consideration and taking a decision by the Formulary commission on the basis of a conclusion based on the results of professional expertise;

5) formation of the KNF by the authorized body.

4. The applicant shall submit an application to the Centre in the form according to Appendix 1 to these Rules.

The application shall be drawn up in the Kazakh or Russian languages, signed by an authorized person of the applicant.

The application shall be attached by:

1) a dossier drawn up in accordance with the requirements provided for in Appendix 2 to these Rules;

2) materials (articles, summaries from scientific and medical publications), confirming the information contained in the dossier in the original language in the form of full texts, translated into Kazakh or Russian.

The materials specified in this paragraph shall be submitted in paper and electronic form in two copies.

A set of submitted paper documents shall be laced up, pages shall be numbered. On the reverse side of the last page, an entry shall be made: "Total laced, numbered ___ pages", which shall be certified by the signature of an applicant's authorized person.

The information provided by an applicant in the application and dossier shall be open and must be published on the website of the authorized body or Centre.

If an applicant provides information of a confidential nature in the application, such information shall not be subject to publication.

5. From the moment of receipt of materials specified in paragraph 4 of these Rules, the Centre shall check them for completeness and correctness of the documents submitted, within a period of not more than 5 (five) working days.

Based on the results of the check, the Centre shall draw up a conclusion indicating the identified comments (if any) in the form according to Appendix 3 to these Rules, which shall be sent to an applicant for elimination of the comments within 10 (ten) working days.

If the applicant fails to submit the requested materials or written justification within 10 (ten) working days within the framework of eliminating the comments, the Centre shall stop considering the application and the dossier for inclusion in the KNF.

In case of completeness and correctness of the submitted documents or elimination of comments within 10 (ten) working days, the materials shall be transferred for conducting professional expertise.

6. The Centre conducts a professional expertise within a period not exceeding 20 (twenty) working days, on the basis of a contract concluded with an applicant in accordance with civil law.

7. In the course of conducting a professional expertise by the Centre within the terms specified in paragraph 6 of these Rules, the following researches shall be carried out:

1) for finding the medicinal product in the State register of medicinal products and medical devices (hereinafter - the Register) and for finding the medicinal product in the List of orphan diseases and medicinal products for their treatment (orphan), determined in accordance with paragraph 3 of Article 177 of the Code (hereinafter – the List).

A corresponding extract from the Register shall be provided as a supporting document;

2) of clinical effectiveness of a medicinal product according to registered indications for the use, corresponding to the ratio of evidence levels I and II and gradations of recommendations A and B, according to the scale developed by the Oxford Centre for Evidence-Based Medicine in accordance with Appendix 4 to these Rules (hereinafter-the Scale), confirmed by the results of clinical researches of high methodological quality in Kazakhstani and internationally recognized sources.

Conducting of this research of clinical effectiveness of a medicinal product shall be confirmed by the relevant minutes drawn up by the Centre in any form;

3) safety of a medicinal product according to registered indications for the use, corresponding to the ratio of levels of evidence I and II and gradations of recommendations A

and B, according to the Scale, confirmed by the results of clinical researches of high methodological quality in Kazakhstani and internationally recognized sources.

Conducting of this research of safety of a medicinal product shall be confirmed by the relevant minutes drawn up by the Centre in any form;

4) for diseases that are registered indications for the use of a medicinal product, the level and structure of morbidity of the population of the Republic of Kazakhstan, according to the data of official electronic information resources and information systems created in accordance with subparagraph 30 of Article 7 of the Code, as well as published statistical collections of the authorized body or epidemiological researches;

Conducting of this research on diseases that are registered indications for the use of a medicinal product in the morbidity structure of the population of the Republic of Kazakhstan shall be confirmed by the relevant minutes drawn up by the Centre in any form;

5) for the presence of clinical protocols of the Republic of Kazakhstan in the recommendations;

6) for the presence in the recommendations of international (European) clinical guidelines and (or) clinical guidelines, protocols of the member countries of the Organization for Economic Cooperation and Development (OECD);

7) for the presence in the list of essential medicinal products of the World Health Organization and (or) in the British National Pharmaceutical Formulary (including for children) and (or) reimbursable lists and formularies of OECD countries;

8) for the availability of registration of medicinal products in the countries of the International conference on harmonization of technical requirements for registration of medicinal products for medical use (ICH) and (or) OECD or registration under a centralized procedure by the competent authority of the European Union, availability of a WHO re-qualification procedure or inclusion in the WHO list of prequalified medicinal products for HIV, tuberculosis, hepatitis and other diseases.

8. Based on the results of a professional expertise, the Centre, within a period of not more than 5 (five) working days, shall draw up a conclusion in the form according to Appendix 5 to these Rules, to which the supporting documents provided for in subparagraphs 1), 2), 3), 4), 5), 6), 7), 8) of paragraph 7 of these Rules (hereinafter - the conclusion) shall be attached.

The conclusion shall be sent to the Formulary commission within 1 working day, the activities of which shall be determined in accordance with paragraph 2 of Article 264 of the Code.

9. The Formulary commission shall consider the conclusion submitted by the Centre and assess the compliance of a medicinal product with subparagraphs 1), 2), 3), 4) and one of subparagraphs 5), 6), 7), 8) of paragraph 7 of these Rules, taking into account which a decision shall be made on the inclusion of a medicinal product drug in the KNF.

10. When a medicinal product used for the treatment of a socially significant disease is included in the KNF, the list of which is determined in accordance with subparagraph 158) of

paragraph 1 of Article 1 of the Code, the Formulary commission may consider the inclusion of a medicinal product in the KNF on the initiative of the authorized body, with the preparation of the dossier by the Centre in accordance with the requirements of Appendix 2 of these Rules.

11. Taking a decision on exclusion of medicinal products from the KNF by the Formulary commission shall be considered if one of the following grounds exists:

1) emergence of evidence-based recommendations on the lack of effectiveness of a medicinal product;

2) emergence of information about toxicity and (or) high frequency of undesirable side effects when using a medicinal product;

3) revocation of the registration certificate of a medicinal product by the authorized body or expiration of the registration period in the Republic of Kazakhstan within a period exceeding three years or exclusion from the List of orphan medicinal products, determined in accordance with paragraph 3 of Article 177 of the Code.

12. In accordance with the decisions of the Formulary commission, the authorized body in accordance with subparagraph 46) of Article 7 of the Code approves the Kazakhstan national drug formulary.

Changes and additions to the KNF shall be made with a frequency of no more than 1 (one) time per six months.

13. A medicinal product is entered into the KNF under the INN (in the absence of INN - by the grouped or chemical name) of a medicinal product, taking into account the dosage form, dosage, concentration and volume, indicating the code of anatomical-therapeutic and chemical classification of medicinal products (hereinafter - ATC), with the obligatory inclusion without consideration of each trade name of a medicinal product with a similar INN dosage form, dosage, concentration and volume, in accordance with the State register of medicinal products and medical devices.

14. When medicinal products for the treatment of orphan diseases are included, a note shall be made that this drug is orphan.

Appendix 1
to the Rules for the formation
of Kazakhstan national
drug formulary
Form

Application for the inclusion of a medicinal product in the Kazakhstan national drug formulary

1. Information about the applicant:

1) name of the organization;

2) Full name (if any) of a responsible person, position;

3) location of the organization-applicant (legal address, actual address);

4) BIN, bank details;

- 5) telephone and (or) fax number;
- 6) electronic address or e-mail address.

2. Data on the declared medicinal product (MP) in accordance with the State register of medicinal products and medical devices:

- 1) trade name of the MP;
- 2) international non-proprietary name;
- 3) composition of the MP (active and auxiliary substances), proposed for inclusion;
- 4) dosage form and dosage, concentration;
- 5) information on state registration of the declared MP in the Republic of Kazakhstan;
- 6) pharmacological action of the MP;
- 7) pharmacological group of MP and ATC code;
- 8) indications for the use according to instructions for the use of a medicinal product;
- 9) method of use.

If the dossier contains confidential information, indicate what information is confidential and provide a justification for the confidential nature of this information.

Position of the responsible person of an applicant _____ Signature

Full Name. (if any) _____

Date _____

Notes: The volume of an application does not exceed 2 pages and is based on summary information from the dossier;

Appendix 2
to the Rules for the formation
of Kazakhstan national
drug formulary
Form

Dossier of a medicinal product for inclusion in the Kazakhstan national drug formulary

1. Information on the medicinal product (MP) in accordance with the State register of medicinal products and medical devices:

- 1) trade name of the MP;
- 2) international non-proprietary name;
- 3) composition of MP (active and auxiliary substances), proposed for inclusion;
- 4) dosage form and dosage, concentration;
- 5) information on state registration of the declared MP in the Republic of Kazakhstan;
- 6) pharmacological action of MP;
- 7) pharmacological group of MP and ATC code;
- 8) indications for the use according to instructions for the use of a medicinal product;
- 9) method of use.

2. Data:

on registration status of the declared MP according to the indications specified in the application and dossier in the ICH and OECD countries (registered under the national procedure by the competent authority of the USA, Switzerland, Japan, Australia, Canada and other OECD countries or registered under the centralized procedure by the competent authority of the European Union);

on the passage of the declared MP through the WHO requalification procedure and its inclusion in the WHO list of prequalified medicinal products intended to combat HIV, tuberculosis, hepatitis and other diseases.

3. Information about clinical researches of high methodological quality in Kazakhstani and internationally recognized sources:

1) by clinical effectiveness according to registered indications for the use:

a description of the selection of publications containing data on effectiveness of MP;

description and summarization of results from selected relevant publications containing data on the effectiveness of MP;

list and links to relevant publications containing data on the effectiveness of MP;

materials (articles, summaries, from scientific and medical publications), confirming the effectiveness of MP in the original language in the form of full texts, with a translation in Kazakh or Russian;

2) for safety according to registered indications for the use:

a description of the selection of publications containing data on MP safety;

description and summarization of results from selected relevant publications containing data on MP safety;

list and links to relevant publications containing data on MP safety;

materials (articles, summaries, from scientific and medical publications), confirming the safety of MP in the original language in the form of full texts, with a translation in Kazakh or Russian.

4. Information on availability of the declared MP according to the registered indications, in the lists and formularies:

in the list of essential medicines of the World Health Organization (including for children)

;

in the British national drug formulary (including for children);

in reimbursable lists and formularies of OECD countries.

5. Information on availability of the declared MP for the registered indications, in clinical protocols and guidelines:

presence in the clinical protocols of the Republic of Kazakhstan;

presence in clinical guidelines, protocols and consensus of OECD countries;

presence in international (European) clinical guidelines.

6. Information about the need for MP for the healthcare system in accordance with the prevalence of disease and morbidity of the population according to official electronic

information resources and information systems created in accordance with subparagraph 30 of Article 7 of the Code, as well as published statistical collections of the authorized body or epidemiological studies.

Appendix 3
to the Rules for the formation
of Kazakhstan national
drug formulary
Form

Conclusion of the check of application and dossier for the inclusion of a medicinal product in the Kazakhstan national drug formulary

1. Information about the applicant:
 - 1) name of the organization;
 - 2) Full name (if any) of a responsible person, position;
location of the organization-applicant (legal address, actual address);
 - 3) BIN, bank details;
 - 4) telephone and (or) fax number;
 - 5) e-mail.
2. Data on the declared medicinal product (MP):
 - 1) trade name of the MP;
 - 2) international non-proprietary name;
 - 3) composition of MP (active and auxiliary substances), proposed for inclusion;
 - 4) dosage form and dosage, concentration;
 - 5) information on state registration of the declared MP in the Republic of Kazakhstan;
 - 6) pharmacological action of MP;
 - 7) pharmacological group of MP and ATC code;
 - 8) indications for the use according to instructions for the use of a medicinal product;
 - 9) method of the use.
3. Conclusion on the results of check for completeness and correctness of the submitted documents:
 - 1) assessment of completeness of the submitted documents and materials;
 - 2) assessment of registration of the application and the submitted materials;
 - 3) assessment of presentation of information in accordance with paragraph 4 of these Rules;
 - 4) consistency between the application and materials on paper and in electronic form.
4. Comments

Appendix 4
to the Rules for the formation
of Kazakhstan national
drug formulary
Form

The ratio of levels of evidence and gradations of recommendations developed by the Oxford Centre for Evidence-Based Medicine

Levels of evidence		Gradations of recommendations
Systematic review, clinical researches, individual clinical research	I	A
Systematic review of cohort researches, or individual cohort research	II	B
Research of "case-control" type (individual research or systematic review of several researches)	III	B
Description of series of cases, low quality cohort researches	IV	C
Experts opinion without accurate critical assessment	V	D

Scottish intercollegiate guidelines network. Developers guide. Quick reference guide. November 2015.

Appendix 5
to the Rules for the formation
of Kazakhstan national
drug formulary
Form

Conclusion of professional expertise for the inclusion of a medicinal product in the Kazakhstan national drug formulary

1. Information about the applicant:

- 1) name of the organization;
- 2) Full name (if any) of a responsible person, position;
- 3) location of the organization-applicant (legal address, actual address);
- 4) BIN, bank details;
- 5) telephone and (or) fax number;
- 6) e-mail;

2. Data on the declared medicinal product (MP):

- 1) trade name of the MP;
- 2) international non-proprietary name;
- 3) composition of MP (active and auxiliary substances), proposed for inclusion;
- 4) dosage form and dosage, concentration;
- 5) information on state registration of the declared MP in the Republic of Kazakhstan;
- 6) pharmacological action of MP;
- 7) pharmacological group of MP and ATC code;
- 8) indications for the use according to instructions for the use of a medicinal product;
- 9) method of the use.

3. Conclusion based on the results of professional expertise for inclusion in the Kazakhstan national drug formulary:

1) information on availability of a valid registration certificate of the Republic of Kazakhstan of a medicinal product in accordance with the State register of medicinal products and medical devices (a corresponding extract from the Register is attached);

2) information on availability of a medicinal product in the List of orphan diseases and medicinal products for their treatment (orphan), determined in accordance with paragraph 3 of Article 177 of the Code;

3) information on clinical effectiveness of a medicinal product for registered indications for the use, corresponding to the ratio of evidence levels I and II and gradations of recommendations A and B, according to the scale developed by the Oxford Centre for Evidence-Based Medicine in accordance with Appendix 4 to these Rules, confirmed by the results of clinical researches of high methodological quality in Kazakhstani and internationally recognized sources (the corresponding minutes for the research of clinical effectiveness of a medicinal product is attached);

4) information on the safety of a medicinal product for registered indications for the use, corresponding to the ratio of levels of evidence I and II and gradations of recommendations A and B, according to the scale developed by the Oxford Centre for Evidence-Based Medicine in accordance with Appendix 4 to these Rules, confirmed by the results of clinical researches of high methodological quality in Kazakhstani and internationally recognized sources (the corresponding minutes for the research of safety of a medicinal product is attached);

5) information on diseases that are registered indications for the use of a medicinal product in the morbidity structure of the population of the Republic of Kazakhstan, according to the data of official electronic information resources and information systems created in accordance with subparagraph 30 of Article 7 of the Code, as well as published statistical collections of the authorized body or epidemiological researches (the corresponding research minutes on diseases that are registered indications for the use of a medicinal product in the morbidity structure of the population of the Republic of Kazakhstan is attached)

6) information on availability in the recommendations of clinical protocols of the Republic of Kazakhstan in accordance with indications for the use;

7) information on availability in the recommendations of international (European) clinical guidelines

8) information on availability in the recommendations of protocols of the member countries of the Organization for Economic Cooperation and Development (OECD);

9) information on availability in the list of essential medicines of the World Health Organization (including for children);

10) information on availability in the British national drug formulary (including for children);

11) information on availability in the reimbursable lists and forms of OECD countries;

12) information on availability of registration of medicinal products in the countries of the region of the International conference on harmonization of technical requirements for registration of medicinal products for medical use (ICH);

13) information on availability of registration of medicinal products in OECD countries;

14) information on availability of registration of medicinal products in the countries of registration under a centralized procedure by the competent authority of the European Union;

15) information on availability of the WHO prequalification procedure or inclusion in the WHO list of prequalified medicinal products intended to combat HIV, tuberculosis, hepatitis and other diseases;

Conclusions.

Appendix 2
to the order of the
First Vice-Minister
of Healthcare of the
Republic of Kazakhstan
dated December 24, 2020
No. KR HM-326/2020

Rules for the development of drug formularies of healthcare organizations

Chapter 1. General provisions

1. These rules for the development of drug formularies of healthcare organizations (hereinafter-the Rules) have been developed in accordance with subparagraph 47) of Article 7 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System" and shall determine the procedure for the development of drug formularies of healthcare organizations.

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

1) a medicinal product - a product that is or contains a substance or a combination of substances that comes into contact with the human body, intended for the treatment, prevention of human diseases or the restoration, correction or change of his/her physiological functions through pharmacological, immunological or metabolic effects, or for diagnosis diseases and human state;

2) a medicinal drug - a medicinal product in the form of a dosage form;

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

4) a clinical pharmacologist - a specialist with higher medical education in the fields of “ medical care”, “pediatrics”, “general medicine”, who has mastered the residency or retraining program in clinical pharmacology and has a certificate of a healthcare specialist;

5) Kazakhstan national drug formulary (hereinafter - KNF) - a list of medicinal products with proven clinical safety and effectiveness, as well as orphan (rare) medicinal products, which is an obligatory basis for the development of drug formularies of medical organizations and the formation of lists for the purchase of medicinal products within the guaranteed volume of free medical care and (or) in the compulsory social health insurance system.

Chapter 2. The procedure for the development of drug formularies of healthcare organizations

3. Development of the drug formulary for healthcare organizations (hereinafter - the drug formulary) includes:

1) formation by a clinical pharmacologist or a pharmacist of a healthcare organization of the draft of a drug formulary according to INN and the volume of need for medicinal products on the basis of the KNF;

2) consideration of the draft of a drug formulary by the Formulary commission of a healthcare organization (hereinafter - the Formulary commission);

3) approval of the drug formulary by the first head of a healthcare organization.

4. A clinical pharmacologist or pharmacist of a healthcare organization, based on the KNF shall draw up the draft of a drug formulary taking into account:

1) the results of assessment of the use of medicinal products (ABC-VEN analysis) in the healthcare organization;

2) analysis of the consumption of medicinal products by a healthcare organization for previous years in a healthcare organization;

3) proposals of specialized specialists of a healthcare organization.

A medicinal product shall be entered into the draft of a drug formulary under the INN, indicating the dosage form, dosage, concentration, volume, code of the anatomical-therapeutic-chemical classification of medicinal products (hereinafter - ATC).

5. The Formulary commission shall consider the draft of a drug formulary for compliance with:

1) data from the medical information system of a healthcare organization, confirming a high proportion of diseases that are indications for the use for a certain medicinal product, in the structure of treated cases and (or) circulation for previous years in a healthcare organization;

2) proven advantages or clinical effectiveness of a medicinal product, in the appropriate dosage form, in comparison with the available analogues, confirmed by the results of clinical researches of high methodological quality in Kazakhstani and international recognized sources;

3) proven advantage or economic effectiveness of a medicinal product and (or) impact on the budget, in the appropriate dosage form, in comparison with the available analogues, confirmed by the results of pharmacoeconomic studies of high methodological quality in Kazakhstani and international recognized sources.

In the absence of compliance with one of the sub-paragraphs of this paragraph, the Formulary commission shall take a decision to refuse the approval.

The decision on approval or refusal shall be made in any form.

6. On the basis of a positive decision of the Formulary commission, the first head of a healthcare organization, in accordance with subparagraph 94) of paragraph 1 of Article 1 of the Code shall approve the drug formulary.

The revision of the drug formulary of a healthcare organization shall be carried out at least 1 (one) time per year.