

On approval of the Rules for development, registration, amendment, coordination, approval and enforcement of the State Pharmacopoeia of the Republic of Kazakhstan

Invalidated Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated April 29, 2019 No . ҚР ДСМ-57. Registered with the Ministry of Justice of the Republic of Kazakhstan on May 3, 2019 No. 18621. Abolished by Order of the Minister of Health of the Republic of Kazakhstan dated November 5, 2020 No. KR DSM-183/2020

Unofficial translation

Footnote. Abolished by Order of the Minister of Health of the Republic of Kazakhstan dated November 5, 2020 No. KR DSM-183/2020 (effective from 06/01/2021).

In accordance with paragraph 7 of Article 66-1 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On the health of the people and the healthcare system", I HERBY ORDER:

1. To approve the attached Rules for development, registration, amendment, coordination, approval and enforcement of the State Pharmacopoeia of the Republic of Kazakhstan.

2. The Pharmacy Committee of the Ministry of Healthcare of the Republic of Kazakhstan, in the manner prescribed by the legislation of the Republic of Kazakhstan, shall ensure:

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

2) within ten calendar days from the date of the state registration of this order, the direction hereof both in Kazakh and Russian languages to the Republican State Enterprise on the right of economic management "Republican Center for Legal Information of the Ministry of Justice of the Republic of Kazakhstan" for official publication and placement in the Reference Control Bank of the regulatory legal acts of the Republic of Kazakhstan;

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

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

3. The control over the execution of this order shall be assigned to the Supervising Vice-Minister of Healthcare of the Republic of Kazakhstan.

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

Approved
by order of the
Minister of Healthcare of the
Republic of Kazakhstan
dated April 29, 2019
No. ҚР ДСМ-57

The Rules for development, registration, amendment, coordination, approval and enforcement of the State Pharmacopoeia of the Republic of Kazakhstan

Chapter 1. General Provisions

1. These Rules establish the procedure for the development, registration, amendment, coordination, approval and enforcement of the State Pharmacopoeia of the Republic of Kazakhstan.

2. For the purposes of this document, the following concepts shall be used:

1) main pharmacopoeias of the world - pharmacopoeias, the standards of which are the basis of the State Pharmacopoeia of the Republic of Kazakhstan (hereinafter referred to as the State Pharmacopoeia of the Republic of Kazakhstan). The leading pharmacopoeias of the world include the European Pharmacopoeia, the British Pharmacopoeia and the United States Pharmacopoeia (hereinafter referred to as the United States Pharmacopoeia). Therein the European Pharmacopoeia is the basic pharmacopeia for the State Pharmacopoeia of the Republic of Kazakhstan (hereinafter referred to as the Basic pharmacopeia)

2) general monograph (general pharmacopoeial article) - a pharmacopoeial article containing general requirements and provisions for the quality and packaging of medicines and other products for pharmaceutical use, as well as tests and methods for their implementation;

3) private monograph (private pharmacopeia article) - a pharmacopeia article containing particular requirements for the quality of specific medicines and other products for pharmaceutical use;

4) The State Pharmacopoeia of the Republic of Kazakhstan - a set of minimum requirements for the safety and quality of medicines and medical devices.

Chapter 2. The procedure for development of the State Pharmacopoeia of the Republic of Kazakhstan

3. Development of the State Pharmacopoeia of the Republic of Kazakhstan shall be carried out on the basis of the following principles:

1) harmonization with the leading pharmacopoeias of the world, as well as international and interstate standards for medicines and medical devices (hereinafter referred to as the Leading pharmacopoeias of the world);

2) updating in connection with current editions of the main pharmacopoeias of the world, changes in the pharmaceutical market of the Republic of Kazakhstan and new requirements for the quality of medicines;

3) the continuity of the development and improvement of pharmacopeia requirements based on modern scientific knowledge and the technique of analytical experiment.

4. Harmonization of the State Pharmacopoeia of the Republic of Kazakhstan shall be carried out according to perspective and retrospective types. Prospective harmonization shall be carried out for medicines and certain types of medical devices, as well as methods for testing them, which were not previously the subject of pharmacopoeial standardization. Retrospective harmonization shall be carried out for sections and monographs included in the pharmacopeia.

5. Harmonization of the State Pharmacopoeia of the Republic of Kazakhstan shall be carried out using the full and selective (partial) borrowing mechanism. The full mechanism shall provide for borrowing in full, excluding any significant changes. The selective (partial) mechanism shall be reduced to the borrowing of selected parts, which implies coordinated changes.

6. The full harmonization mechanism of the State Pharmacopoeia of the Republic of Kazakhstan shall be carried out by the following methods:

1) copying the texts of the basic pharmacopeia;

2) adaptation of the texts of the basic pharmacopoeia to facilitate their understanding;

3) inclusion (incorporation) of the own texts in the content of the State Pharmacopoeia of the Republic of Kazakhstan.

7. The selective (partial) mechanism of harmonization of the State Pharmacopoeia of the Republic of Kazakhstan allows the use of other methods of harmonization. In this case, the borrowed and own text should be consistent with each other.

8. The full mechanism shall be used in harmonizing the State Pharmacopoeia of the Republic of Kazakhstan with the standards of the basic pharmacopeia. In harmonization with the British Pharmacopoeia and the United States Pharmacopoeia, both full and selective (partial) mechanisms shall be used.

9. Monographs (articles), borrowed from the leading pharmacopoeias of the world, contain both theoretical principles and test methods. The borrowing of test methods given in the texts of the leading pharmacopoeias of the world does not require their validation.

10. The style of presentation of the monograph (article) of the State Pharmacopoeia of the Republic of Kazakhstan, the name of the sections should correspond to the basic pharmacopoeia.

11. Own (national) monographs (articles) of the State Pharmacopoeia of the Republic of Kazakhstan may be presented in the form of:

- 1) a national monograph;
- 2) a separate national part in the structure of the monograph;
- 3) fragments included (incorporated) in the borrowed texts of the monograph (article).

12. The inclusion of their own texts in the form of a separate national part, possibly in cases of copying and adaptation of the texts of the leading pharmacopoeias of the world. The national part may contain additional information or additional requirements. The content of the national part should not contradict texts borrowed from the leading pharmacopoeias of the world.

13. When incorporating their own texts shall be included in the borrowed texts of the leading pharmacopoeias of the world. Their content shall logically follow from the borrowed text, shall reveal and supplement or detail the content of the borrowed text.

14. Own (national) test methods may be either alternative to the methods of the leading pharmacopoeias of the world, or flexible, supplementing, but not replacing them. The inclusion of such techniques in the monograph of the State Pharmacopoeia of the Republic of Kazakhstan should be justified by the corresponding validation characteristics.

15. Harmonization shall provide for the marking (indexing) of pharmacopoeial texts. Marking allows us to differentiate texts borrowed from the leading pharmacopoeias of the world from our own (national) texts of the State Pharmacopoeia of the Republic of Kazakhstan.

16. Marking of pharmacopoeia texts shall:

1) confirm the harmonization of the State Pharmacopoeia of the Republic of Kazakhstan with the leading pharmacopoeias of the world and the degree of its implementation;

2) identify its own (national) texts of the State Pharmacopoeia of the Republic of Kazakhstan, which does not exclude the possibility of their borrowing by other pharmacopoeias of the world;

3) not violate the copyright of pharmacopoeial authorities that are their owners.

17. When incorporating their own (national) texts into texts borrowed from the basic pharmacopoeia, the marking of national texts shall be carried out using the signs "at the beginning and" at the end of the text.

18. Texts borrowed from the British Pharmacopoeia and the US Pharmacopoeia shall be marked with a special sign (symbol) "BP" and "USP", respectively.

19. In addition to the texts of the leading pharmacopoeias of the world, the State Pharmacopoeia of the Republic of Kazakhstan may include texts of the Pharmacopoeia of the Eurasian Economic Union (hereinafter referred to as the EEU), harmonized on the basis of the national pharmacopoeias of the EEU member states and the leading pharmacopoeias of the world.

20. Standard samples of the leading pharmacopoeias of the world, with which the Global Pharmacopoeia is harmonized, and our own (national) standard samples shall be accepted as standard samples of active substances and impurities of State Pharmacopoeia of the Republic of Kazakhstan.

Chapter 3. Registration of the State Pharmacopoeia of the Republic of Kazakhstan

21. State Pharmacopoeia of the Republic of Kazakhstan shall be published both in Kazakh and Russian languages.

22. The design of the texts of the State Pharmacopoeia of the Republic of Kazakhstan, including visual material, must comply with the leading pharmacopoeias of the world.

23. The numbering of the texts of the State Pharmacopoeia of the Republic of Kazakhstan (general information, general sections, general monographs, private monographs, annexes) shall be carried out in accordance with the basic pharmacopoeia.

24. The numbering of tables, diagrams and figures of the State Pharmacopoeia of the Republic of Kazakhstan shall be carried out in accordance with the basic pharmacopoeia.

25. The chemical formulas of substances, including molecular and structural, as well as mathematical formulas shall be indicated in accordance with the basic pharmacopoeia.

26. The names of the substances shall be given in accordance with the basic pharmacopoeia.

27. The use of fonts in the text, especially in cases where this font indicates the pharmacopoeial status shall be carried out in accordance with the basic pharmacopoeia.

Chapter 4. Amendments to the State Pharmacopoeia of the Republic of Kazakhstan

29. Amendments to the texts of the State Pharmacopoeia of the Republic of Kazakhstan shall be carried out in connection with:

1) with the revision and updating of texts in the leading pharmacopoeias of the world;

2) with changes in the pharmaceutical market of the Republic of Kazakhstan;

3) with a reasonable request from the manufacturer and/or holder of the registration certificate of the medicinal product.

30. Amendments to the texts of the State Pharmacopoeia of the Republic of Kazakhstan shall be carried out in accordance with the principles of updating the basic pharmacopoeia:

- 1) in the framework of the current publication;
- 2) in each subsequent edition.

31. Within the framework of the current publication, amendments to the texts shall be included in additions to the main volumes of the State Pharmacopoeia of the Republic of Kazakhstan.

32. In each subsequent edition, changes to the texts shall be included in both the main volumes and the amendments to the State Pharmacopoeia of the Republic of Kazakhstan.

Chapter 5. Coordination, approval and enforcement of the State Pharmacopoeia of the Republic of Kazakhstan

33. The approval of the main volume and amendments to the State Pharmacopoeia of the Republic of Kazakhstan for their publication shall be carried out by decision of the Expert Council established under the state expert organization in the field of circulation of medicines and medical devices (hereinafter referred to as the Expert organization).

34. The decision of the Expert Council of the expert organization shall be made on the basis of the results of public discussion of draft monographs of the State Pharmacopoeia of the Republic of Kazakhstan.

35. After publication, the main volume and (or) annex of the State Pharmacopoeia of the Republic of Kazakhstan shall be sent for approval to the state body in the field of circulation of medicines and medical devices.