

**On approval of the Rules for the formation of the pharmaceutical inspectorate, maintaining the register of pharmaceutical inspectors of the Republic of Kazakhstan**

*Unofficial translation*

Order of the Minister of Healthcare of the Republic of Kazakhstan dated October 13, 2020 No. ҚР ДСМ-129/2020. Registered with the Ministry of Justice on October 15, 2020 No. 21435.

**Unofficial translation**

Under sub-paragraph 19) of Article 10 of the Code of the Republic of Kazakhstan “On the Public Health and the Healthcare System” **I HEREBY ORDER:**

**Footnote. The preamble as amended by order of the Acting Minister of Health of the Republic of Kazakhstan № KR DSM-79 of 10.08.2022 (shall be put into effect ten calendar days after the date of its first official publication).**

1. To approve the attached Rules for the formation of the pharmaceutical inspectorate, maintaining the register of pharmaceutical inspectors of the Republic of Kazakhstan.

2. To recognize as invalid the order of the Minister of Healthcare of the Republic of Kazakhstan dated April 15, 2019 № ҚР ДСМ-37 "On approval of the Rules for the formation of the pharmaceutical inspectorate, maintaining the register of pharmaceutical inspectors of the Republic of Kazakhstan" (registered in the Register of State Registration of Regulatory Legal Acts of the Republic of Kazakhstan as № 18530, published on April 18, 2019 in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan).

3. The Committee for Quality Control and Safety of Goods and Services of the Ministry of Healthcare of the Republic of Kazakhstan in accordance with the procedure, established 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) placement of this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

3) within ten working days after the state registration of this order, submission to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan, of information about implementation of activities, stipulated by subclauses 1), 2) of this clause.

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

5. This order shall come into force upon expiry of ten calendar days after the date of its first official publication.

*Minister of Healthcare  
of the Republic of Kazakhstan*

*A. Tsoy*

Approved

**Footnote. The text in the upper right corner is revised by order of the Acting Minister of Health of the Republic of Kazakhstan № KR DSM-79 dated 10.08.2022 (shall be enacted ten calendar days after the date of its first official publication).**

## **Rules for the formation of the pharmaceutical inspectorate, maintaining the register of pharmaceutical inspectors of the Republic of Kazakhstan Chapter 1. General Provisions**

1. These Rules for the Formation of the Pharmaceutical Inspectorate, Maintenance of the Register of Pharmaceutical Inspectors of the Republic of Kazakhstan have been elaborated under sub-paragraph 19) of Article 10 of the Code of the Republic of Kazakhstan “On Public Health and Healthcare System” and specify the procedure for the formation of the Pharmaceutical Inspectorate, maintenance of the Register of Pharmaceutical Inspectors of the Republic of Kazakhstan.

**Footnote. Paragraph 1 - as revised by order of the Acting Minister of Health of the Republic of Kazakhstan № KR DSM-79 dated of 10.08.2022 (shall become effective ten calendar days after the date of its first official publication).**

2. The following basic concepts are used in these Rules:

1) the register of pharmaceutical inspectors of the Republic of Kazakhstan - an electronic information resource of the authorized body containing information about pharmaceutical inspectors of the Republic of Kazakhstan;

2) pharmaceutical inspector for good pharmaceutical practices - a person authorized to exercise the functions of conducting pharmaceutical inspection for good pharmaceutical practices and included in the register of pharmaceutical inspectors of the Republic of Kazakhstan;

3) Pharmaceutical Inspectorate for Good Pharmaceutical Practices – structural subdivisions of the state body in the field of circulation of medicines and medical products, its territorial divisions (hereinafter 0 the state body) and (or) an organization determined by the authorized body that inspects compliance with good pharmaceutical practices for medicines and requirements for implementation, maintaining and evaluating the quality management system of medical products, depending on the potential risk of their use;

4) pharmaceutical inspection for good pharmaceutical practices (hereinafter referred to as the pharmaceutical inspection) - an assessment of a facility in the field of drug circulation in order to determine its compliance with the requirements of good pharmaceutical practices of the Republic of Kazakhstan and (or) the Eurasian Economic Union.

## **Chapter 2 Procedure for the formation of the pharmaceutical inspectorate of the Republic of Kazakhstan**

3. The formation of a pharmaceutical inspectorate requires:

- 1) a quality system;
- 2) quality manual (concept of management and development of the quality system of the entity to be inspected);
- 3) regulations on the pharmaceutical inspectorate stipulated by the quality system;
- 4) organisational structure;
- 5) standard operating procedures;
- 6) resources for the inspection.

**Footnote. Paragraph 3 as revised by order of the Acting Minister of Health of the Republic of Kazakhstan № KR DSM-79 of 10.08.2022 (shall apply upon expiry of ten calendar days after the day of its first official publication)..**

4. The quality guidance of the pharmaceutical inspectorate, covering all aspects of activities of the pharmaceutical inspectorate and including the adopted in the form of a written document, procedures of the quality system of the pharmaceutical inspectorate and (or ) reference to them, shall be approved by the head of the pharmaceutical inspectorate.

5. The quality guidance of the pharmaceutical inspectorate shall ensure the quality system and the procedures of the pharmaceutical inspectorate for the personnel of the pharmaceutical inspectorate, and shall be used for:

- 1) confirmation that the personnel of the pharmaceutical inspectorate have sufficient qualifications, knowledge and experience to fulfill the requirements established by the current legislation of the Republic of Kazakhstan in the field of circulation of medicines and medical products;

- 2) determination of conditions under which there is a need to conduct internal and external audits of the quality system of the pharmaceutical inspectorate.

6. organizational structure of the pharmaceutical inspectorate shall ensure impartiality of pharmaceutical inspectors when conducting pharmaceutical inspections.

Functional duties of the head and the personnel of the pharmaceutical inspectorate shall be determined by their job descriptions.

7. The quality system of the pharmaceutical inspectorate shall involve:

- 1) definition of the quality policy of the pharmaceutical inspectorate;
- 2) distribution of responsibilities and powers among the personnel of the pharmaceutical inspectorate;
- 3) allocation of resources required for the implementation of the quality policy of the pharmaceutical inspectorate;
- 4) procedures and order of scheduling, organising and conducting pharmaceutical inspections;
- 5) analysing the functioning of the quality system of the pharmaceutical inspectorate;
- 6) maintenance and upkeep of the documentation and records management system;

7) co-operation of the pharmaceutical inspectorate with accredited laboratories and involved experts.

**Footnote. Paragraph 7 as revised by order of the Acting Minister of Health of the Republic of Kazakhstan № KR DSM-79 of 10.08.2022 (shall become effective ten calendar days after the date of its first official publication).**

8. The personnel of the pharmaceutical inspectorate performs their duties, complies with the requirements of the quality manual of the pharmaceutical inspectorate and the procedures of the pharmaceutical inspectorate adopted in the form of a written document.

9. The head of the pharmaceutical inspectorate shall determine the person responsible for maintaining the quality system of the pharmaceutical inspectorate.

10. The pharmaceutical inspectorate is staffed to organize and conduct pharmaceutical inspections in accordance with the personnel schedule.

The personnel of the pharmaceutical inspectorate undergo continuous training to be able to perform their duties.

11. Requirements for education, qualifications, work experience, as well as tasks and functions of personnel are established in job descriptions.

12. Newly recruited pharmaceutical inspectors (involved in pharmaceutical inspection) shall participate as trainees in at least five inspections for each good pharmaceutical practice. Pharmaceutical inspectors shall be admitted to independent activities and included in the register of pharmaceutical inspectors (hereinafter - the register) as pharmaceutical inspectors following the quality manual of the pharmaceutical inspectorate.

Further training (education) of pharmaceutical inspectors shall be at least 10 calendar days (at least 60 academic hours) of participation in training events per year, including professional development. The pharmaceutical inspectorate shall regularly analyse the professional training of each pharmaceutical inspector.

**Footnote. Paragraph 12 as reworded by order of the Acting Minister of Health of the Republic of Kazakhstan № KR DSM-79 of 10.08.2022 (shall take effect ten calendar days after the date of its first official publication).**

13. The study of pharmaceutical inspectors and its results shall be documented.

Records of training completed and qualifications obtained are kept in the training document (personal file) of each pharmaceutical inspector.

14. The certificate of study (personal file) of each pharmaceutical inspector shall include the following personal information:

- 1) education and specialty according to diploma;
- 2) position;
- 3) qualifications;
- 4) work experience;
- 5) functional responsibilities;
- 6) specialization within the pharmaceutical inspectorate;

7) information on training (education), advanced training and final grades obtained in the course of training (education), advanced training;

8) information on participation in pharmaceutical inspections.

14-1. Pharmaceutical inspectors shall:

1) apply knowledge of the legislation regulating the circulation of medicines on the territory of the Republic of Kazakhstan and the Eurasian Economic Union;

2) apply the quality system of the pharmaceutical inspectorate;

3) apply the knowledge required to conduct pharmaceutical inspections, including knowledge of computerised systems and information technology;

4) issue professional opinions on the conformity of the inspected entity to the requirements of good pharmaceutical practices approved by order of the Acting Minister of Health of the Republic of Kazakhstan № KR DSM-15 “On Approval of Good Pharmaceutical Practices” of February 4, 2021 (recorded in the Register of State Registration of Regulatory Legal Acts under № 22167) and approved by Decision of the Council of the Eurasian Economic Commission № 77 of November 3, 2016 “On Approval of the Rules of Good Manufacturing Practices”.

**Footnote. The Rules are supplemented by paragraph 14-1 pursuant to order of the Acting Minister of Health of the Republic of Kazakhstan № KR DSM-79 of 10.08.2022 (shall be enacted ten calendar days after the date of its first official publication).**

### **Chapter 3. Procedure for maintaining the register of pharmaceutical inspectors**

15. The register is formed and is maintained by the state body.

16. The register shall be maintained by obtaining up-to-date data on pharmaceutical inspectors, storing, publishing the register data on the information resource of the authorised body in the field of healthcare, as well as granting access to the register data to interested organisations (regulatory authorities (pharmaceutical inspectors) of foreign countries).

**Footnote. Paragraph 16 as reworded by order of the Acting Minister of Health of the RK № KR DSM-79 of 10.08.2022 (shall come into effect ten calendar days after the day of its first official publication).**

17. The register shall be maintained in the Kazakh and Russian languages.

18. The register contains the following information to be published about the pharmaceutical inspector:

1) surname, first name, patronymic (if any);

2) contact information: phone number and email address (if any);

3) information on the availability of higher professional education;

4) the name of the specialty in accordance with the diploma of education;

5) information about the academic degree (if any);

6) information about the place of work:

full and abbreviated name of the legal entity with an indication of the organizational and legal form and the unique identifier of the legal entity in the register of legal entities;  
location (address) of a legal entity;  
contact information: telephone and fax numbers, e-mail address (if any) of the legal entity

;

Job title;

7) the date of commencement of activities related to the conduct of pharmaceutical inspections;

8) the date of the end of the implementation of activities related to the conduct of pharmaceutical inspections

**Footnote. Paragraph 18 as amended by order of the Acting Minister of Health of the Republic of Kazakhstan № KR DSM-79 of 10.08.2022 (shall be enforced ten calendar days after the date of its first official publication).**

19. The register contains the following, not subject to publication, information about the pharmaceutical inspector, access to which is provided only to regulatory bodies (pharmaceutical inspectorates) of foreign countries:

1) date of birth;

2) nationality;

3) place of residence;

4) information about higher vocational education: the name of the educational institution, dates of the beginning and end of training, qualification (degree), name, series and number of the document on higher vocational education;

5) information about additional education: name of the educational institution, dates of the beginning and end of training, name of the specialty in accordance with the document on additional education, qualification (degree), name, series and number of the document on additional education;

6) an indication of the names of good pharmaceutical practices for which the pharmaceutical inspector is authorized to conduct inspections;

7) information on labor activity in the last position:

employment date;

date of dismissal;

8) work experience in the field of assessment of organizations in the field of circulation of medicines (including healthcare organizations) in order to determine their compliance with the requirements of good pharmaceutical practices.

**20. Excluded by order of the Acting Minister of Health of the Republic of Kazakhstan № KR DSM-79 of 10.08.2022 (shall be implemented ten calendar days after the date of its first official publication).**

21. The pharmacy supervisor shall sign a confidentiality, non-disclosure and conflict of interest agreement upon employment.

Footnote. Paragraph 21 - as revised by order of the Acting Minister of Health of the Republic of Kazakhstan № KR DSM-79 of 10.08.2022 (shall become effective ten calendar days after the date of its first official publication).

22. Should the data on the pharmaceutical inspector to be included in the register be amended, they shall be forwarded by the pharmaceutical inspectorate to the public authority for the purpose of updating the register. Herewith, the information that has lost its relevance shall be subject to archiving with access to it for 10 years.

Footnote. Paragraph 22 - as revised by order of the Acting Minister of Health of the Republic of Kazakhstan № KR DSM-79 of 10.08.2022 (shall take effect ten calendar days after the date of its first official publication).

23. Information about the termination of activities by the pharmaceutical inspector is transferred to the state body for exclusion from the register and subsequent archival storage with access to them within 10 years.

24. Information on pharmaceutical inspector not subject to publication shall be disclosed to interested organisations by the public authority pursuant to the procedure established by the current legislation of the Republic of Kazakhstan, including in the field of protection of personal data and confidential information.

Footnote. Paragraph 24 - as revised by order of the Acting Minister of Health of the Republic of Kazakhstan № KR DSM-79 of 10.08.2022 (shall enter into force ten calendar days after the date of its first official publication).

25. As part of the maintenance of the register, the state body shall protect information about the pharmaceutical inspector, prohibited for publication, from unauthorized access.