

**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

In accordance with subclause 19) of article 10 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and Health Care System", I HEREBY ORDER:

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 No. 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 No. 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  
the Order of the Minister of  
Healthcare of the  
Republic of Kazakhstan

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

## **Chapter 1. General Provisions**

1. The Rules for the formation of the pharmaceutical inspectorate, maintaining the register of pharmaceutical inspectors of the Republic of Kazakhstan have been developed in accordance with subclause 19) of article 10 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and Health Care System" and determine the procedure for the formation of the pharmaceutical inspectorate, maintaining the register of pharmaceutical inspectors of the Republic of Kazakhstan.

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) quality guideline;
- 2) organizational structure;
- 3) quality system;

4) resources.

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 provides for:

1) determination of the quality policy of the pharmaceutical inspectorate;

2) distribution of duties and powers between the personnel of the pharmaceutical inspectorate;

3) allocation of resources required for the implementation of the quality policy of the pharmaceutical inspectorate.

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 (recruited to carry out pharmaceutical inspections) participate as trainees in at least five inspections for each good pharmaceutical practice. The admission of pharmaceutical inspectors to independent activities shall be carried out in accordance with the quality guideline of the pharmaceutical inspectorate.

Further training (study) of pharmaceutical inspectors shall be at least 10 days (at least 60 academic hours) of participation in training events per year. The head of the pharmaceutical inspectorate regularly shall analyze the professional training of each pharmaceutical inspector and shall determine the needs for his further training (study).

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.

### **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 is maintained by obtaining up-to-date information about pharmaceutical inspectors, storing, publishing the register information on the information resource of the authorized body in the field of healthcare, as well as providing access to the register information to interested organizations.

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, 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.

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. The inclusion of persons on the register as pharmaceutical inspectors shall be carried out by the head of the pharmaceutical inspectorate in accordance with the quality guideline.

21. The pharmaceutical inspector shall sign an agreement on confidentiality, non-disclosure of information and no conflict of interest.

22. In the event of amendments to the information about the pharmaceutical inspector to be included in the register, they are transferred to the state body in order to update the register . At the same time, information that has lost its relevance is subject to archival storage with access to them within 10 years.

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. The provision of information about the pharmaceutical inspector that is not subject to publication to interested parties shall be carried out by the state body in the manner prescribed by the current legislation of the Republic of Kazakhstan, including in the field of protection of personal data and confidential information.

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.