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

Invalidated Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan dated April 15, 2019 № KR MHC-37. Registered in the Ministry of Justice of the Republic of Kazakhstan on April 16, 2019 № 18530

Unofficial translation

Footnote. Abolished by order of the Minister of Health of the Republic of Kazakhstan dated October 13, 2020 No. ҚР DSM-129/2020 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

In accordance with Article of subparagraph 71) of paragraph 1 of Article 7 of the Code of the Republic of Kazakhstan "On Public Health and Health Care System" dated September 18, 2015, **I ORDER**:

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

2. The Committee of pharmacy of the Ministry of Healthcare of the Republic of Kazakhstan in the established legislative manner shall ensure:

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

2) within ten calendar days from the date of state registration of this order, sending its copy in paper and electronic form in the Kazakh and Russian languages to the Republican state enterprise on 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 official publication and inclusion to the Standard control bank of regulatory legal acts of the Republic of Kazakhstan;

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

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

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

4. This order shall be enforced upon expiry of ten calendar days after its first official publication.

Minister of Healthcare
of the Republic of Kazakhstan *E. Birtanov*

Appendix to the order
Minister of Healthcare
of the Republic of Kazakhstan
dated April 15, 2019
№ KR MHC-37

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

Chapter 1. General provisions

1. These Rules for formation of pharmaceutical Inspectorate, maintaining the register of pharmaceutical inspectors of the Republic of Kazakhstan are developed in accordance with subparagraph 71) of paragraph 1 of Article 7 of the Code of the Republic of Kazakhstan dated 18 September 2009 "On Public Health and Health Care System" and shall determine the procedure for formation of pharmaceutical inspectorate, maintaining the register of pharmaceutical inspectors of the Republic of Kazakhstan.

2. For the purposes of these Rules, the following basic concepts shall be used:

1) pharmaceutical inspection for appropriate pharmaceutical practices (hereinafter-pharmaceutical inspection) - assessment of an object in the sphere of circulation of medicines in order to determine its compliance with the requirements of appropriate pharmaceutical practices of the Republic of Kazakhstan and (or) the Eurasian Economic Union;

2) a pharmaceutical inspector for appropriate pharmaceutical practices – a person authorized to perform the functions on conducting pharmaceutical inspection for appropriate pharmaceutical practices and included in the register of pharmaceutical inspectors of the Republic of Kazakhstan;

3) pharmaceutical inspectorate for appropriate pharmaceutical practices - a structural division of the state body in the sphere of circulation of medicines and medical products and its territorial divisions (hereinafter- the state body), carrying out pharmaceutical inspection;

4) register of pharmaceutical inspectors of the Republic of Kazakhstan – information resource of the authorized body containing information about pharmaceutical inspectors of the Republic of Kazakhstan;

Chapter 2. Procedure for formation the pharmaceutical inspectorate of the Republic of Kazakhstan

3. For formation of the pharmaceutical inspectorate, it is necessary:

1) a quality manual;

2) organizational structure;

3) quality system;

4) resources.

4. A quality manual of the pharmaceutical inspectorate, covering all aspects of pharmaceutical inspectorate activity and including the procedures of the pharmaceutical inspectorate quality system adopted in the form of a written document and (or) references to them, shall be approved by the head of the pharmaceutical inspectorate.

5. A quality manual of the pharmaceutical inspectorate establishes the requirements and procedures of the quality system for pharmaceutical inspectorate for the staff of the pharmaceutical inspectorate and involved experts and shall be used for:

1) confirmation that the staff of the pharmaceutical inspectorate has sufficient qualifications, knowledge and experience to meet the requirements established by the current legislation of the Republic of Kazakhstan in the sphere of circulation of medicines and medical products;

2) determining the 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 complies with the tasks set and guarantees the impartiality of pharmaceutical inspectors during conducting pharmaceutical inspections.

Functional responsibilities of the head and the staff of the pharmaceutical inspectorate are determined by job instructions.

7. Quality system for pharmaceutical inspectorate establishes the procedure for cooperation of the pharmaceutical inspectorate with other divisions of state body and other organizations (including accredited laboratories for quality control of medicines), carrying out licensing of production of medicines and control in the sphere of circulation of medicines and medical products.

8. A standard operating procedure for cooperation of the pharmaceutical inspectorate with the pharmaceutical inspectorates of other countries for the exchange of information and joint pharmaceutical inspections in accordance with the current legislation of the Republic of Kazakhstan shall be adopted in the form of a written document in the quality system of the pharmaceutical inspectorate.

9. Quality system of the pharmaceutical inspectorate provides:

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

2) distribution of responsibilities and powers among the staff of the pharmaceutical inspectorate;

3) allocation of resources necessary for implementation of the policy in the field of quality of the pharmaceutical inspectorate.

10. The staff 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.

11. The head of the pharmaceutical inspectorate determines the person responsible for maintaining the quality system of the pharmaceutical inspectorate.

12. The pharmaceutical inspectorate is staffed with the necessary personnel for organization and conducting pharmaceutical inspections in accordance with the staffing table.

The staff of the pharmaceutical inspectorate receives appropriate continuous training in order to be able to perform their duties.

13. Requirements for education, qualifications, work experience, as well as tasks and functions of the staff are established in job instructions.

14. Pharmaceutical inspectors newly hired (involved for conducting pharmaceutical inspection) participate as trainees in at least five inspections for each appropriate pharmaceutical practice. Admission of pharmaceutical inspectors to independent activity shall be carried out after checking their knowledge by the head of the pharmaceutical inspectorate in accordance with the quality manual of the pharmaceutical inspectorate.

Further training (education) of pharmaceutical inspectors is at least 10 days (at least 60 academic hours) of participation in training events per year. The head of the pharmaceutical inspectorate regularly analyzes professional training of each pharmaceutical inspector and determines the needs for his /her further training (education).

15. Training of pharmaceutical inspectors and its results shall be documented.

Records of completed training and received qualifications shall be stored in the training document (personal file) of each pharmaceutical inspector.

16. The training document (personal file) of each pharmaceutical inspector includes the following personal information:

1) education and specialty by diploma;

2) qualification;

3) work experience;

4) functional responsibilities;

5) specialization within the pharmaceutical inspectorate;

6) information about training(education), professional development and final grades, received during training (education), professional development.

17. The personal file of the involved expert includes information about the position and qualification, as well as information about his/her participation in pharmaceutical inspections.

Chapter 3. Procedure for maintaining the register of pharmaceutical inspectors

18. The register shall be formed and maintained by the state body.

19. Maintaining of the register shall be carried out by obtaining up-to-date information about pharmaceutical inspectors, storing and 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.

20. Maintaining of the register shall be carried out in the Kazakh and Russian languages.

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

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

2) contact information: phone number and e-mail address (if any);

3) information about availability of higher professional education;

4) 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 indication of organizational-legal form and unique identifier of the legal entity in the register of legal entities;

location (address) of the legal entity;

contact information: phone and fax numbers, e-mail address (if any) of the legal entity;

name of the position;

7) date of commencement of activity, related to conducting pharmaceutical inspections;

8) date of completion of activity related to conducting pharmaceutical inspections .

22. The register contains the following non-public information about the pharmaceutical inspector, access to which is provided only to regulatory bodies (pharmaceutical inspectorates) of foreign countries:

1) date of birth;

2) citizenship;

3) place of residence;

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

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

6) indication of the names of appropriate pharmaceutical practices for compliance of which the pharmaceutical inspector is authorized to carry out inspections;

7) information about the last position of employment:

date of employment;

date of dismissal;

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

23. After making a decision by the state body on appointment of a person as a pharmaceutical inspector, information about such a person shall be included in the register.

24. In case of changing of information about the pharmaceutical inspector to be included in the register, it shall be transferred to the state body for the purpose of updating the register. At the same time, information that has lost its relevance shall be subject to archival storage with access to it for 10 years.

25. Information about termination of activity by the pharmaceutical inspector shall be transferred to the state body for deletion from the register and subsequent archival storage with access to them for 10 years.

26. Provision of information about the pharmaceutical inspector that is not subject to publication to the interested persons shall be carried out by the state body in the manner established by the current legislation of the Republic of Kazakhstan, including in the sphere of protection of personal data and confidential information.

27. Within the framework of maintaining the register, the state body ensures protection of non-published information about the pharmaceutical inspector from an unauthorized access.