



On approval of the rules for the formation of the register of healthcare entities engaged in wholesale and retail sales of medical devices, in a notification procedure

Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated October 19, 2020 No. ҚР DSM-139/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on October 23, 2020 No. 21486

Unofficial translation

In compliance with subparagraph 45) of Article 7 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On people's health and the health care system" **ORDER:**

1. To approve the attached rules for the formation of the register of healthcare entities engaged in wholesale and retail sales of medical devices, in a notification procedure.

2. To declare invalid:

1) order of the Acting Minister of Health of the Republic of Kazakhstan dated February 12, 2013 No. 75 "On approval of the Rules for the formation of the register of healthcare entities engaged in wholesale and retail sales of medical devices and medical equipment in a notification procedure" (registered in the Register of state registration of regulatory legal acts under No. 8385, published on August 24, 2013 in the newspaper "Egemen Kazakhstan" No. 197 (28136);

2) order of the Minister of Health of the Republic of Kazakhstan dated May 2, 2019 No. ҚР DSM-61 "On amendments to the order of the Acting Minister of Health of the Republic of Kazakhstan dated February 12, 2013 No. 75" On approval of the Rules for the formation of the register of healthcare entities engaged in wholesale and retail sales medical devices and medical equipment in a notification procedure "(registered in the Register of State Registration of Regulatory Legal Acts under No. 18640, published on May 17, 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 Health 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) posting this order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan after its official publication;

3) within ten working days after the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan; submission to the Legal Department of the Ministry of

Health of the Republic of Kazakhstan information on the implementation of the measures provided for in subparagraphs 1) and 2) of this paragraph.

4. Control over the execution of this order shall be entrusted to the supervising vice minister of health of the Republic of Kazakhstan.

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

*The Minister of Healthcare
of the Republic of Kazakhstan*

A. Tsoy

Approved by the order of the
Minister of Healthcare
of the Republic of Kazakhstan
October 19, 2020
№ RK MH - 139/2020

Rules for the formation of the register of healthcare entities engaged in wholesale and retail sales of medical devices, in a notification procedure

Chapter 1. General provisions

1. These rules for the formation of the register of healthcare entities engaged in wholesale and retail sales of medical devices, in a notification procedure (hereinafter referred to as the Rules), have been developed in accordance with subparagraph 45) of article 7 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On people's health and the healthcare system" and determine the procedure for the formation of the register of healthcare entities engaged in the wholesale and retail sale of medical devices, in a notification procedure (hereinafter - the Register).

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

1) a state body in the field of circulation of medicines and medical devices - a state body that exercises leadership in the field of circulation of medicines and medical devices, control over the circulation of medicines and medical devices (hereinafter - the state body);

2) applicant - an individual or legal entity who submits a notification to the state body in the field of circulation of medicines and medical devices on the implementation of wholesale and (or) retail sale of medical devices, including acting under a power of attorney.

Chapter 2. The procedure for the formation of the register of healthcare entities engaged in wholesale and retail sales of medical devices, in a notification procedure

3. Registers are formed in the form in accordance with the appendix to these Rules, on the basis of the notifications submitted by the applicant.

Registers are filled out in the state and Russian languages and are kept electronically in Excel format.

At the request of the interested state bodies of the Republic of Kazakhstan, information included in the registers is submitted.

If the territorial subdivisions of the state body receive a notification about a change in the address of the place of residence of an individual, the location of a legal entity, the address of the activities or actions specified in the notification, as well as registration data, the corresponding changes are made to the register on the day the notification is submitted.

4. The register is posted on the Internet resource of the territorial subdivision of the state body in the free access mode.

5. In case of suspension by the court of the activity or certain types of activity of an individual entrepreneur or legal entity, the relevant information shall be entered in the register

6. The register includes data on the change in the address (place of residence) of an individual, the location of the legal entity, the address of the activities or actions specified in the notification, as well as registration data (information is mandatory for notification).

7. The territorial subdivisions of the state body keep the register of health care entities engaged in wholesale and retail sales of medical devices in a notification manner in the form, in accordance with the appendix to these rules and quarterly submitted to the state body.

Appendix to the rules
formation of the register
healthcare entities,
carrying out wholesale and
retail sales
medical devices in
notification procedure

Form

Register of healthcare entities engaged in wholesale and retail sales of medical devices, in a notification procedure

№	Date and time of notification	Full name of the legal entity, BIN, surname, name, patronymic (if any) of an individual, IIN	Addresses of the place of residence of an individual or the location of a legal entity, addresses of activities or actions	Data on the start of an activity or certain actions, the termination of an activity or certain actions, changes in the data specified in the notification	Applicant's contacts (e-mail, telephones , fax)	Time and place of commencement of the activity (specific action)	Time and place of termination of the activity (certain action) (if it is provided by the laws of the Republic of Kazakhstan)
1	2	3	4	5	6	7	8

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