

**On approval of the Rules for the wholesale and retail sale of medicines and medical devices**

***Unofficial translation***

Order of the Minister of Healthcare of the Republic of Kazakhstan dated September 17, 2020, No. ҚР ДСМ -104/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on September 19, 2020, No. 21229.

      *Unofficial translation*

      In accordance with subparagraph 15) of Article 10 of the Code of the Republic of Kazakhstan “On the public health and the healthcare system” **I HEREBY ORDER**:

      Footnote. Preamble - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      1. To approve the Rules for the wholesale and retail sale of medicines and medical devices in accordance with Annex 1 to this Order.

      2. To recognize as terminated some orders in the field of healthcare in accordance with Annex 2 to this Order.

      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) posting 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 with the Ministry of Justice of the Republic of Kazakhstan, submission to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan the information on the implementation of the measures provided for in subparagraphs 1), 2) of this paragraph.

      4. Control over the 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 effect upon the expiration of ten calendar days from the date of the first official publication.

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*Minister of Healthcare of the* *Republic of Kazakhstan*
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*A. Tsoi*
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|   | Annex 1 to the Order of the Minister of Healthcare of the Republic of Kazakhstan dated September 17, 2020 No. ҚР ДСМ-104/2020 |

 **The Rules for the wholesale and retail trade of medicines and medical devices Chapter 1. General Provisions**

      1. These Rules for the wholesale and retail sale of medicines and medical devices (hereinafter referred to as the Rules) were developed in accordance with subparagraph 15) of Article 10 of the Code of the Republic of Kazakhstan “On the health of the people and the healthcare system” (hereinafter referred to as the Code) and shall determine the procedure for wholesale and retail sales medicines and medical devices.

      Footnote. Paragraph 1 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 No. 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      2. These Rules shall use the following concepts:

      1) circulation of medicines - activities including the processes of development, preclinical (non-clinical) studies, testing, clinical studies, examination, registration, pharmacovigilance, quality control, production, manufacturing, storage, transportation, import and export, dispensing, sales, transfer, use, destruction of medicines;

      2) objects in the field of circulation of medicines and medical devices - a pharmacy, including those that sell via the Internet, a pharmacy in healthcare organizations and a mobile pharmacy for rural settlements, a pharmacy (distribution) warehouse, a temporary storage warehouse for medicines and medical products, optical store, medical device store, medical device warehouse, organizations for the production of medicines and medical devices;

      3) entities in the field of circulation of medicines and medical devices (hereinafter referred to as Entities) - individuals or legal entities engaged in pharmaceutical activities;

      4) retail sale of medicines and medical devices - pharmaceutical activities related to the acquisition (except import), storage, distribution, sale (except export) to the end consumer, destruction of medicines and medical devices;

      5) wholesale sales of medicines and medical devices - pharmaceutical activities related to the procurement (purchase), storage, import (importation), export (exportation), sale (except for sales to the public) without limiting volumes, transportation and destruction of medicines and medical products;

      6) circulation of medical devices - design, development, creation of prototypes, carrying out technical tests, research (studies) assessing the biological effect of medical devices, clinical studies, examination of the safety, quality and effectiveness of medical devices, registration, production (manufacturing), storage, transportation, sales, installation, adjustment, use (operation), maintenance, repair and disposal of medical devices;

      7) state body in the field of circulation of medicines and medical devices (hereinafter referred to as the State body) - a state body exercising management in the field of circulation of medicines and medical devices, control over the circulation of medicines and medical devices.

      Footnote. Paragraph 2 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 No. 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      3. Wholesale sales of medicines and medical devices shall be carried out by entities in the field of circulation of medicines and medical devices that have received an appropriate license for wholesale sales in pharmacy warehouses or have notified of the start of activities through a warehouse of medical products in the manner established by the Law of the Republic of Kazakhstan “On Permits and Notifications” "(hereinafter referred to as the Law on Permits and Notifications).

      Footnote. Paragraph 3 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 No. 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      4. Retail sale of medicines and medical devices shall be carried by entities in the field of circulation of medicines and medical devices that have received an appropriate license for retail sale in pharmacies, pharmacy branches, mobile pharmacies or notified of the start of activities through optical shops and medical devices stores in the manner prescribed Law on Permissions and Notifications.

      5. Entities of wholesale and retail sales shall provide:

      1) the presence of a sign indicating the name of the subject of pharmaceutical activity, its organizational and legal form, and mode of operation in the Kazakh and Russian languages;

      2) placement in a place convenient for acquaintance:

      copies of the license for pharmaceutical activities and annexes to it or a document (including a printed copy of an electronic document) informing on the beginning or termination of activities or certain actions;

      information on the telephone number and address of the territorial subdivision of the state body in the field of circulation of medicines and medical devices;

      book of comments and suggestions;

      information on telephone numbers of the pharmaceutical inquiry service;

      3) systematic training of personnel, at least once every five years, advanced training and retraining of pharmaceutical (medical) personnel.

      6. Wholesale and retail sales of medicines and medical devices shall not be permitted in the cases specified in paragraphs 4 and 4-1 of Article 233 of the Code.

      Footnote. Paragraph 6 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      6-1. To prevent the receipt of medicines and medical devices in accordance with paragraphs 4 and 4-1 of Article 233 of the Code and to prevent a decrease in their safety, effectiveness and quality during storage and sale, the following shall be ensured:

      1) quality control during acceptance and implementation;

      2) compliance with the rules and shelf life of medicines and medical devices, keeping records of medicines and medical devices with a limited shelf life;

      3) serviceability and accuracy of weighing instruments;

      4) checking the correctness of the prescribed prescription, its validity period, the compliance of the prescribed doses with the patient’s age, the compatibility of ingredients, and the norms for one-time dispensing;

      5) keeping records of the validity periods of certificates of conformity of products for quality assessment;

      6) pharmacies with the right to manufacture medicines shall be additionally provided with:

      all types of intra-pharmacy control;

      compliance with the manufacturing technology of dosage forms.

      Footnote. The Rules are supplemented by paragraph 6-1 in accordance with the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect ten calendar days after the day of its first official publication).

      7. Before they are sold, medicines and medical products shall be subject to unpacking, sorting, external inspection, cleaning, checking for completeness, assembly, and adjustment.

      Footnote. Paragraph 7 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      7-1. The acceptance of medicines and medical devices in terms of quantity and quality shall be carried out by specialists from wholesale and retail distribution facilities based on the supplier’s accompanying documents.

      Footnote. The Rules are supplemented by paragraph 7-1 in accordance with the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect ten calendar days after the day of its first official publication).

      7-2. When taking medicines and medical devices, the following shall be checked:

      1) compliance of quantity, completeness, the integrity of the container, compliance of packaging, labelling with regulatory documents, availability of instructions for the medical use of medicines and medical devices in Kazakh and Russian languages; availability of an operational document for medical products;

      2) compliance with the name, dosage, packaging, quantity, batch (series) of products specified in the accompanying documents;

      3) the presence in the accompanying documents of a certificate of conformity for the product or a reference to it in the invoice for the release of goods.

      Footnote. The Rules are supplemented by paragraph 7-2 in accordance with the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect ten calendar days after the day of its first official publication).

 **Chapter 2. The procedure for the wholesale of medicines and medical devices**

      8. The objects of wholesale sale of medicines and medical devices shall include:

      a pharmacy depot that carries out the wholesale of medicines and medical devices;

      a depot of medical devices, that carries out the wholesale of medical devices.

      9. Wholesale of medicines and medical devices shall be carried out in compliance with the following conditions:

      1) medicines and medical devices shall be purchased only from manufacturers or entities that have licenses for pharmaceutical activities and an annex to a license for the wholesale sale of medicines or who have notified about the commencement of activities through a depot of medical devices in the manner prescribed by the Law on Permissions and Notifications;

      2) medicines and medical devices shall be sold to entities that have a license for pharmaceutical or medical activities or have notified of the start of activities through optical stores and medical devices stores in the manner prescribed by the Law on Permissions and Notifications;

      3) medicinal products subject to dispensing without a doctor's prescription shall be sold to veterinary entities who have notified the start of their activities in accordance with the procedure established by the Law on Permissions and Notifications;

      4) medicines and medical devices shall be sold after receiving a certificate of conformity in accordance with subparagraph 44) of Article 7 of the Code;

      5) medical products related in accordance with the Law of the Republic of Kazakhstan “On Ensuring the Uniformity of Measurements” (hereinafter referred to as the Law on Ensuring the Uniformity of Measurements) to measuring instruments shall be sold in the presence of a certificate of approval of the type of measuring instruments or a certificate of metrological certification of medical products in accordance with legislation of the Republic of Kazakhstan on technical regulation;

      6) the premises, areas, and equipment comply with the Qualification Requirements established in accordance with subparagraph 80) of Article 7 of the Code;

      7) medicines and medical devices shall be stored and transported under conditions that ensure the preservation of their effectiveness and quality, in accordance with paragraph 1 of Article 250 of the Code;

      8) the availability and functioning of a documentation system shall be ensured, which makes it possible to trace the actions performed concerning the received and shipped batch (series) of products from the supplier to the buyer and to establish the location of medicines, medical devices;

      9) documentary recording of the facts of the discovery of medicines and medical devices is provided, in accordance with paragraphs 4 and 4-1 of Article 233 of the Code, notification of them, withdrawals from the market and informing the government body or its territorial divisions.

      Footnote. Paragraph 9 as amended by Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect ten calendar days after the day of its first official publication).

      10. The sale of medicines and medical products from a pharmacy (distribution) warehouse, a warehouse of medical products shall be accompanied by shipping documents in accordance with paragraph 3 of Article 443 of the Code of the Republic of Kazakhstan “On taxes and other obligatory payments to the budget (Tax Code)”, certified by the signature of the head or the person authorized by him/her, the chief accountant, as well as the signature of the person who sold the medicines and medical products.

      The shipping document for each item, batch (series) of products shall indicate:

      Name;

      dosage (for medicines);

      packaging;

      quantity, unit price;

      sum;

      series;

      best before date;

      number and validity period of the product conformity certificate (for a medicinal product or medical device).

      Corrections, additions, and blots in shipping documents shall not be allowed.

      Footnote. Paragraph 10 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      11. At the request of the subject, a copy of the certificate of product conformity for medicines and medical devices shall be provided in the form established in accordance with subparagraph 44) of Article 7 of the Code.

      Footnote. Paragraph 11 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

 **Chapter 3. Procedure for the retail sale of medicines and medical devices**

      12. Objects of retail sale of medicines and medical devices shall include:

      1) a pharmacy, including one that sells via the Internet;

      2) pharmacy in healthcare organizations providing primary health care, consultative and diagnostic care;

      3) mobile pharmacy for rural settlements.

      Footnote. Paragraph 12 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      13. Objects of retail sale of medical devices, including spectacle optics for vision correction, glasses for vision correction, as well as related products for their care and repair include:

      1) optics store;

      2) medical devices store.

      14. Objects of retail sale in a place visible to visitors shall place the information of the following nature:

      "Medicines and medical devices are not subject to return and exchange",

      "Medicines are not sold to children";

      "The sale of medicines subject to medical prescriptions is prohibited without a prescription";

      "Shelf life of medicinal products manufactured in a pharmacy" (for pharmacies with the right to manufacture).

      15. Retail sales facilities providing pharmaceutical services to provide the population with medicines and medical products within the framework of the guaranteed volume of free medical care (hereinafter referred to as the GVFMC) and (or) in the system of compulsory social health insurance (hereinafter referred to as CSHI) shall provide the population with access to information about list of medicines and medical products for free and (or) preferential outpatient provision for certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions).

      Footnote. Paragraph 15 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      16. Medicines subject to medical prescriptions shall not be subject to over-the-counter sales.

      16-1. Medicines and medical products shall not be subject to exchange and return in accordance with subparagraph 1 of paragraph 1 of Article 30 of the Law of the Republic of Kazakhstan “On Protection of Consumer Rights”, medicines and medical products shall not be subject to exchange and return, except for cases of sale of expired medicines and medical products expiration date or detection of defects by the consumer.

      Footnote. The Rules are supplemented by paragraph 16-1 in accordance with the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect ten calendar days after the day of its first official publication).

      16-2. Medicines shall not be sold to children.

      Footnote. The Rules are supplemented by paragraph 16-2 in accordance with the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect ten calendar days after the day of its first official publication).

      17. In the case of retail sale of medicines and medical devices, their delivery to the location of the consumer (customer) shall be carried out in a manner that does not allow changes in their properties during transportation, in accordance with paragraph 1 of Article 250 of the Code.

      18. Retail sale of medicines and medical devices shall be carried out in compliance with the following conditions:

      1) availability of appropriate premises, equipment;

      2) storage and transportation of medicines and medical devices under conditions that ensure the preservation of their safety, effectiveness and quality, in accordance with paragraph 1 of Article 250 of the Code;

      3) the acquisition of registered medicines and medical devices that have undergone quality assessment in the manner established in accordance with Article 241 of the Code, from entities that have a license for pharmaceutical activities, or who have notified the start of activities in the manner established by the Law on Permits and Notifications;

      4) sale of registered medicines and medical devices that have undergone quality assessment in accordance with the procedure established in accordance with subparagraph 44) of Article 7 of the Code, to the population, as well as to individuals engaged in private medical practice who have a license to practice medicine or who have notified the start of activities in the procedure established by the Law on Permissions and Notifications, as well as over-the-counter medicines and medical devices to third parties;

      5) the sale of medical devices related to measuring instruments in accordance with the Law On ensuring the unity of measurements, if they have a certificate of type approval of measuring instruments or a certificate of metrological certification of medical devices in accordance with the legislation of the Republic of Kazakhstan on technical regulation;

      6) implementation of interaction with healthcare entities on issues related to pharmacotherapy, health promotion, prevention of diseases of the population, and pharmacovigilance;

      7) participation in the promotion of the rational prescription of medicinal products;

      8) provision of reliable information by specialists regarding:

      correct and rational application or use;

      possible side effects and contraindications;

      interactions with other medicines, precautions for their use or use;

      shelf life and storage rules at home;

      operating rules, completeness of medical devices;

      9) provision of emergency medical care to the population in urgent cases.

      Footnote. Paragraph 18 as amended by Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect ten calendar days after the day of its first official publication).

      19. Excluded by Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      20. Excluded by Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      21. Excluded by Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      22. Excluded by Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      23. If medicinal products are sold in violation of the integrity of the consumer (secondary) packaging, except for blister (primary) packaging, the consumer shall be provided with instructions for medical use (a copy of the instructions).

      24. On a pharmacy trading floor, in the population service area of pharmacy, in the window shall be displayed the medicines, sold without a prescription.

      25. Medicines under the prescription of veterinarians are not subject to retail sale.

      26. Retail sales of medicines to the population within the framework of the GVFMC and (or) compulsory medical insurance shall be carried out according to a prescription written on prescription forms for free and (or) preferential dispensing in accordance with paragraph 5 of Article 233 of the Code.

      Footnote. Paragraph 26 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      27. Retail sale to the population of medicines containing narcotic medicines and psychotropic substances subject to control shall be carried out in accordance with the legislation of the Republic of Kazakhstan on narcotic medicines, psychotropic substances, their analogs, and precursors subject to control in the Republic of Kazakhstan.

      28. When prescribing medicine in a dose exceeding the highest single dose, the doctor in the prescription shall indicate the dose of the medicine in words and an exclamation mark. If the doctor fails to comply with this requirement, the retail sales facility specialist shall sell the prescribed medicine in half of the established highest single dose.

      Footnote. Paragraph 28 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      29. In the absence of a medicinal product prescribed by a doctor, a specialist at a retail facility shall offer the patient, without the consent of the doctor, synonyms of the medicinal product under the international nonproprietary name available in the assortment, starting with the medicinal product at the lowest price, or, in agreement with the attending physician, replace it pharmacological analogue.

      In this case, the back of the prescription shall indicate the trade name of the medicine sold, sign and date of selling.

      Footnote. Paragraph 29 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      30. A prescription that does not meet the requirements for its registration and (or) contains incompatible components for the individual manufacture of a medicinal product shall be considered invalid and shall be left in the pharmacy, pharmacy point, or mobile pharmacy.

      In this case, the specialist of the retail facility shall sell the prescribed medicinal product to the patient, except for an individually manufactured medicinal product containing incompatible components.

      Footnote. Paragraph 30 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      31. Invalid prescriptions shall be cancelled with the stamp “Prescription is invalid”, registered in the Register of Incorrect Prescriptions in the form according to the Annex to these Rules, numbered, laced and sealed with the signature of the manager and the seal (if any) of the pharmacy, pharmacy point, mobile pharmacy.

      Information about incorrectly written prescriptions shall be transmitted for information to the head of the relevant medical organization and (or) to the relevant local government health authorities.

      Footnote. Paragraph 31 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

      32. During the period of the state of emergency, restrictive measures, including quarantine, retail sale of medicines subject to prescription dispensing shall be carried out in accordance with paragraph 5 of Article 233 of the Code.

      33. Objects of retail sale shall be equipped with a first aid kit, the composition of which is approved in accordance with subparagraph 55) of Article 7 of the Code.

      34. The sale of medicines and medical products in settlements where there are no pharmacies shall be carried out in accordance with paragraph 6 of Article 233 of the Code.

      Footnote. Paragraph 34 - as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

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|   | Annex to the Rules of Wholesale and Retail Sale of Medicines and Medical Devices |
|   | Form |

 **Register of Incorrect Prescriptions**

      Footnote. The journal is as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 98 (shall be put into effect ten calendar days after the day of its first official publication).

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|
No. |
Date |
Name of healthcare organization |
Last name,
First name, Patronymic (if any) of the doctor |
Recipe Contents |
Identified violations |
Taken measures |
Last name, first name, patronymic (if any) of a pharmacy specialist, pharmacy point, mobile pharmacy point |

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|   | Annex 2 to the Order of the Minister of Healthcare of the Republic of Kazakhstan dated September 17, 2020 No. ҚР ДСМ-104/2020 |

 **List of some expired orders n the field of healthcare**

      1) Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated September 14, 2015 № 713 "On approval of the Rules for the wholesale and retail sale of medicines and medical devices" (registered in the State Register of Normative Legal Acts under № 12169, published on October 26, 2015, in the Legal Information System “Adilet”);

      2) Order of the Minister of Healthcare of the Republic of Kazakhstan dated April 25, 2019 № ҚР ДСМ-53 "On Amending the Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated September 14, 2015 № 713 " On approval of the Rules for the wholesale and retail sale of medicines and medical devices" (registered in the State Register of Normative Legal Acts under № 18612, published on May 13, 2019 in the Reference Control Bank of Normative Legal Acts of the Republic of Kazakhstan);

      3) Order of the Minister of Healthcare of the Republic of Kazakhstan dated March 16, 2020 № ҚР ДСМ-17/2020 "On amendments to some orders of the Minister of Healthcare and Social Development of the Republic of Kazakhstan and the Minister of Healthcare of the Republic of Kazakhstan" registered in the State Register of Normative Legal Acts under № 20130, published on March 18, 2020, the Reference Control Bank of Normative Legal Acts of the Republic of Kazakhstan).

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