Kazakhstan – July 2025

Amendments to the legislation of Kazakhstan on pharmaceuticals

Amendments to the List of Medicines Subject to Price Regulation for Wholesale and Retail Sale

By Order of the Minister of Health of the Republic of Kazakhstan dated June 18, 2025 No. 394 ("**Order No. 394**"), amendments were made to the List of Medicines Subject to Price Regulation for Wholesale and Retail Sale approved by Order of the Acting Minister of Health of the Republic of Kazakhstan dated December 1, 2022 No. KR DSM-150.

In accordance with the amendments, the number of medicines on the List Subject to Price Regulation for Wholesale and Retail Sale has been reduced from 6,060 to 5,408. Over-the-counter Medicines have been excluded from the list. Order No. 394 came into force on July 5, 2025.

Amendments to the Rules for Regulation of Prices for Medicines and Medical Devices

By the Order No. 59 of the Minister of Healthcare of the Republic of Kazakhstan dated June 24, 2025 ("**Order No. 59**"), amendments were made to the Rules for Regulating, Setting Maximum Prices and Markups for Medicines, as well as Medical Devices ("**MD**") within the Guaranteed Volume of Free Medical Care ("**GVFMC**") and/or in the Obligatory Social Medical Insurance ("**OSMI**") System approved by Order No. ҚР ДСМ-247/2020 of the Minister of Healthcare of the Republic of Kazakhstan dated December 11, 2020 ("**Rules for Regulation of Prices for Medicines and MD**"). The amendments related to Medicines concerned the following:

- One of the criteria for registering the price or re-registering the registered price for wholesale and retail sale, the price within the framework of the GVFMC and/or in the OSMI system has been changed[1]. Now, the provided manufacturer's price for imported Medicines shall not exceed the average (previously maximum) value of three minimum prices from the reference countries submitted in the application and shall not exceed the average value of 3 minimum prices obtained from the data of the websites of international organizations. If the number of reference countries is less than 3, the manufacturer's price for wholesale and retail sale, within the GVFMC and/or in the OSMI system shall not exceed the average (previously maximum) value of the prices in the presented number of reference countries. At the same time, when considering prices, their minimum value is taken into account from the websites of international organizations.
- According to the amendments, the maximum price for an international non-proprietary name (**"INN"**) of a Medicine must not exceed the average (previously maximum) value of

[1] sp. 1, p. 24, sp. 1, p. 51 of the Rules for Regulation of Prices for Medicines and MD as amended by Order No. 59;

the three minimum prices among the maximum prices for the trade name of the Medicine within the framework of the GVFMC and/or in the OSMI system[2].

- A rule has been introduced that when there's a change in the procedure of reference pricing and price registration, the recalculation of maximum prices for trade names of Medicines for wholesale and retail sale, within the framework of the GVFMC and/or OSMI shall be carried out by National Center for Expertise of Medicines and MD (the **"National Center"**) without the submission of an application from the applicant, using existing data and information systems[3].
- The provision has been excluded that if the re-registration of the registered price for wholesale and retail sale has not been completed between April 10 or October 10 of the current year, the National Center shall form a draft of maximum prices for the trade name of the Medicine for wholesale and retail sale based on previously approved maximum prices for the trade name of the Medicine for wholesale and retail sale[4].
- Annex 5 of the Rules for Regulation of Prices for Medicines, which defines the List of basic requirements for the provision of the public service named "Registration of the Price of Medicines and MD" has been updated.

MD

- A rule has been introduced that the revocation of registered prices for Medical Supplies shall carried out on the basis of acts of law enforcement agencies and judicial acts that have entered into legal force; and/or at the request of the applicant in no particular format[5].
- A rule has been introduced that when there's a change in the procedure for reference pricing and price registration, the recalculation of maximum prices for trade names of MD within the framework of the GVFMC and/or OSMI shall be carried out by the National Center at the initiative of an authorized body, without the submission of an application from the applicant, using existing data and information systems[6].
- Annex 3 of the Rules for Regulation of Prices for MD, which establishes a list of basic requirements for the provision of the public service "Registration of the price of medicines and MD" has been updated.

[2] p. 62, Rules for Regulation of Prices for Medicines as amended by Order No. 59;
[3] p. 41, 57, Rules for Regulation of Prices for Medicines as amended by Order No. 59;
[4] p. 42, Rules for Regulation of Prices for Medicines as amended by Order No. 110;
[5] sp. 1, p. 5, Rules for Regulation of Prices for Medicines as amended by Order No. 59;
[6] p. 26 Rules for Regulation of Prices for Medicines as amended by Order No. 59;

Amendments to the Rules for Registration and Examination of Medicines for Medical Use in the Eurasian Economic Union[7].

On June 21, 2025, amendments introduced by the Decision of the Council of the Eurasian Economic Commission (**"EEC"**) dated May 22 No. 34 (**"Decision No. 34"**) to the Decision of the Council of the EEC No. 78 dated November 3, 2016 "On the Rules for Registration and Examination of Medicines for Medical Use" ("**Decision No. 78"**) came into force.

In order to speed up the transition to EAEU regulation, restrictions on the simultaneous implementation of mutual recognition procedures and introduction of amendments to the registration dossier of a pharmaceutical product have been lifted.

Decision No. 34 contains clarifications of a number of provisions governing the procedure for registration of Medicines during the transition period. Thus, the registration certificates issued in accordance with the legislation of the EAEU member states remain in force until their expiration but not later than December 31, 2025. In the event that an application for bringing the registration dossier of a pharmaceutical product into compliance with the requirements of the EAEU has been submitted to the authorized body or expert organization of the reference state before December 31, 2025, the registration certificates shall be extended[8]:

- for the period of carrying out of this procedure, but no more than 3 years from the date of filing the application in the reference state;
- additionally - for a period of up to 2 years in each state of recognition from the date of filing applications in these states.
- In this case, the application to the state of recognition must be filed no later than the date of expiration of the 3-year period from the date of filing an application in the reference state.

If the procedure has already been completed in the reference state before 31 December 2025, marketing authorizations shall be extended in the recognition states for the period of completion of the procedure - but not more than for 2 years from 31 December 2025[9].

The authorized bodies of the Member States have the right to indicate information on the registration status of a pharmaceutical product in their registers[10].

In addition, the possibility of providing an alternative package of GMP supporting documents subject to inspection within 3 years of registration provided by paragraph 30 of Decision No. 78

[7] https://pharmreviews.kz/novosti/novosti-eaes/vstupili-v-silu-izmeneniya-uproshchayushchie-registratsionnye-protsedury-lekarstv-na-rynke-eaes ;
[8] sp. д, e, p.2, Decision No. 78;
[9] sp. e, p. 2, Decision No. 78;
[10] sp. ж, p. 2, Decision No. 78;

is now given indefinitely without a certain deadline. At the same time, paragraph 159 has been clarified on the consequences of failure to fulfill this obligation.

An updated structure of the expert report and its annexes, consistent with the practice of authorized bodies and expert organizations, has also been introduced. The provisions concerning the possibility of making changes to the registration dossier in the reference state during the recognition procedure in the recognition states being carried out, as well as approaches to making changes that relate exclusively to the recognition states, have been clarified.

Amendments to the Rules for the Procurement of Medicines and Medical Devices

By Order No. 58 of the Minister of Health of the Republic of Kazakhstan dated June 23, 2025 ("**Order No. 58**"), amendments were made to the Rules for the Organization and Conduct of Procurement of Medicines, MD and Specialized Medical Products within the Framework of the GVFMC, Additional Volume of Medical Care for Persons Held in Pre-trial Detention Facilities and Institutions of the Penal (Penitentiary) System, at the Expense of Budgetary Funds and/or in the OSMI system, Pharmaceutical Services, approved by Order No. 110 of the Minister of Health of the Republic of Kazakhstan dated June 7, 2023 ("**Procurement Rules**"). The amendments include the following:

- Amendments to definitions have been made (definition of the minimum reserve of Medicines and MD, definition of the component element of MD has been added)[11];
- A provision has been introduced that Medicines and MD shall be purchased at prices not exceeding those established by the Order of the Acting Minister of Health of the Republic of Kazakhstan dated August 27, 2021 No. КР ДСМ-94 "On Approval of the Maximum Prices of the Manufacturer for the Trade Name of the Medicine, Maximum Prices for the Trade Name of the Medicine for Retail and Wholesale Sale"[12].
- The provision that the orphan Medicines included in the Order of the Minister of Health of the Republic of Kazakhstan dated October 20, 2020 No. ҚР ДСМ - 142/2020 "On Approval of the List of Orphan diseases and (orphan) Medicines for Their Treatment may not be registered in order to be procured has been omitted[13].
- An exception has been introduced that if one domestic manufacturer (**"DM"**) and/or the EAEU manufacturer participates in the procurement for a lot, applications from other potential suppliers shall be automatically rejected, except for the procurement of medical equipment worth over 20 million tenge per unit, carried out through a Single Distributor (**"SD"**), while in this type of procurement, starting from July 31, 2025, the DM and/or the EAEU manufacturer will be provided with a conditional discount of 20% from the purchase price at the auction stage[14].

[11] p. 2 of the Procurement Rules;
[12] p. 4 of the Procurement Rules;
[13] sp. 1, p. 11 of the Procurement Rules as amended by Order No. 58;
[14] p. 14 of the Procurement Rules as amended by Order No. 58;

Tender

- A rule has been introduced that the SD carries out procurement by means of a tender[15]:
  1) if purchase from domestic and foreign manufacturers has been recognized as having failed;
  2) to purchase Medicines containing narcotic, psychotropic substances and precursors.

- A provision on the possibility of the procurement of Medicines and/or MD in the amount of a 3-year need, on the instructions of the Ministry of Health of the Republic of Kazakhstan, has been introduced into the chapter on the procedure for carrying out a tender[16].
- A rule has been introduced that upon submission of a single application for a lot which meets the terms of the announcement and the conditions of the Procurement Rules, a repeat tender shall be held[17].
- New grounds have been introduced for rejecting a potential supplier's application for a lot, such as exceeding the maximum price for an INN, exceeding the maximum price of the manufacturer for the trade name of a Medicine, the maximum price for the trade name of a Medicine for retail and wholesale sale, the characteristics of the Medicine and/or Medical Supply do not correspond to the expert opinion/conclusion etc.[18].
- A provision has been introduced that if a tender or any of its lots is declared as having failed, the content and terms of the tender may be changed, with the exception of the purchase of medical equipment, and the purchase may be conducted in accordance with Section 3 of the Procurement Rules. Section 3 covers tender, purchase by request for quotations from domestic or foreign manufacturers or through structural divisions of the United Nations (the **"UN"**), purchase from a single source, special purchase, purchase by request for quotations, purchase by concluding long-term supply contracts, etc. [19] Previously, if a tender or any of its lots was declared as having failed, the purchase was conducted in accordance with paragraph 2, Chapter 2, Section 3 of the Procurement Rules, i.e. by purchasing from a domestic or foreign manufacturer through a request for quotations[20].
- A rule has been introduced that domestic manufacturers do not provide the SD with security for the fulfillment of its obligations under supply contracts concluded in accordance with Chapter 2 of Section 3 of the Procurement Rules (procurement by

[15] p. 146-1 of the Procurement Rules as amended by Order No. 58;
[16] p. 146 -2 of the Procurement Rules as amended by Order No. 58;
[17] p. 197 of the Procurement Rules as amended by Order No. 58;
[18] p. 200 of the Procurement Rules as amended by Order No. 58;
[19] p. 210 of the Procurement Rules as amended by Order No. 58;
[20] p. 210 of the Procurement Rules as amended by Order No. 58;

requesting price quotations from domestic and foreign manufacturers or through international organizations established by the UN) [21].

- There is no longer a restriction that when purchasing from a foreign manufacturer, the SD must enter into a civil law contract for a period of *up to 3 years*[22].
- A rule has been introduced that if the purchase of Medicines and/or MD from a domestic or foreign manufacturer is declared as having failed, the SD shall conduct the purchase through a tender (previously through international organizations established by the UN) [23].

Purchase of Medical Equipment through Tender

- The period for reviewing applications and additions to them within a tender for the purchase of medical equipment has been extended, which now amounts to 15 working days instead of 10 working days[24].
- If the customer's technical specification corresponds to only 1 model of one manufacturer from those offered by potential suppliers for the lot, then the tender or any of its lots shall be considered as having failed.
- An exception to this rule, which existed for the purchase of medical equipment which did not have registered analogues in the Republic of Kazakhstan, has been excluded[25].
- A provision has been added stating that if a DM of medical equipment participates in the auction, the latter will be granted a conditional discount of 20% of the purchase price (current auction price), which will come into effect on July 31, 2025[26].

Purchase by Requesting Price Quotations from Domestic and Foreign Manufacturers or through International Organizations Established by the UN

- A rule has been introduced that if the procurement of Medicines and/or MD through international organizations established by the UN is recognized as having failed, the procurement shall be carried out in accordance with paragraph 2 of Chapter 2 of Section 3 of the Procurement Rules entitled “Procedure for Procurement from a Domestic or Foreign Manufacturer” (previously - through a special purchase procedure)[27].

Single Source Procurement

[21] p. 221 of the Procurement Rules as amended by Order No. 58;
[22] p. 221 of the Procurement Rules as amended by Order No. 58;
[23] p. 228 of the Procurement Rules as amended by Order No. 58;
[24] p. 153 of the Procurement Rules as amended by Order No. 58;
[25] p. 198 of the Procurement Rules as amended by Order No. 58;
[26] p. 206 of the Procurement Rules as amended by Order No. 58;
[27] p. 237-1 of the Procurement Rules as amended by Order No. 58;

- A rule has been introduced that if a single-source procurement fails, the purchase price of the Medicines and/or MD which haven't been purchased must not exceed the purchase price for the relevant financial year, in case the trade name, characteristics, unit of measurement, manufacturer and country of manufacture specified in the application (price offer) of the potential supplier are identical to the Medicine and/or MD, the single-source procurement of which was declared as having failed[28]. A rule has also been introduced that in the event of a full or partial refusal by the supplier to supply an additional volume, as well as in the event of unilateral termination of the supply agreement by the SD in the current financial year, a repeat purchase shall be made at a price not exceeding the fixed price established in the previously concluded supply agreement in the same financial year[29].

Purchase by Request for Quotations

- New grounds for conducting procurement by requesting price quotations have been added, such as[30]:

- • recognition of the purchase through tender as having failed;
- • receipt of notification from the SD in connection with:

- violation by the SD of delivery deadlines under a purchase agreement concluded between the SD and a customer;
- failed purchases of Medicines, MD or pharmaceutical services carried out by the SD in the ways established by the Procurement Rules. In this case, the purchase shall be carried out for up to a sixty-day need for Medicines or MD, as well as up to a ninety-day need for pharmaceutical services.

Conclusion of a Supply Contract

- A provision has been introduced that if the maximum price for the INN and/or trade name of a Medicine and/or MD changes upward during the supply contract being performed, the supply contract shall remain in effect until the parties have fully fulfilled their obligations at the previous price. If the maximum price for the INN and/or trade name of a Medicine and/or MD changes downward during the supply contract being performed, the SD shall negotiate with the supplier in order to reduce the price of the supply contract. In the event of disagreement regarding the reduction of the price of the supply contract or the supplier's refusal to negotiate, the SD has the right to

[28] p. 241 of the Procurement Rules as amended by Order No. 58;
[29] p. 241-1 of the Procurement Rules as amended by Order No. 58;
[30] sp. 5, 6, p. 245-1 of the Procurement Rules as amended by Order No. 58;

terminate the supply contract and conduct the procurement in the manner established by the Procurement Rules[31].

Competition for the Conclusion of Long-term Supply Contracts for the Creation and/or Modernization of the Production of Medicines and/or MD

- The requirement to provide the CT-KZ certificate in order to conclude an additional agreement for the relevant financial year has been omitted[32].

The Procedure for the Formation and Use of Medicines and MD of the Minimum Stock of the SD

- A rule has been introduced that when Medicines and MD have been excluded from the list of minimum stock of the SD or the list of the SD, a reduction and/or return to the supplier of the purchased volume of minimum stock of Medicines and MD shall be permitted[33].
- Medicines and MD of the minimum stock are replenished by the SD in the ways provided for in Chapters 1, 2 and 3 of Section 3 of the Procurement Rules (taking into account the remaining Medicines and MD) namely by tender, request for price quotations from domestic and foreign manufacturers or through international organizations established by the UN, from a single source (previously only by tender and from a single source)[34].

Amendments were also introduced to the annexes to the Procurement Rules, namely:

- Annex 5 “Standard contract for the purchase of goods (between the customer and the supplier)”;
- Annex 7 “Application for issuing a conclusion on the compliance of characteristics with the technical specifications for the purchase of medical equipment”;
- Annex 8 “Conclusion on the compliance of characteristics with the technical specifications for the purchase of medical equipment”;
- Annex 9 “Application for the purchase of medical equipment”;
- Annex 11 “Agreement for the purchase of Medicines and/or MD (between the SD and a customer)”;
- Annex 12 “Standard contract for the purchase of Medicines and/or MD (between the SD and a customer)”;

[31] p. 259 of the Procurement Rules as amended by Order No. 58;
[32] p. 344 of the Procurement Rules as amended by Order No. 58;
[33] p. 441-3 of the Procurement Rules as amended by Order No. 58;
[34] p. 445 of the Procurement Rules as amended by Order No. 58;

- Annex 13 “Standard gratuitous contract for the supply of Medicines and/or MD for outpatient Medicine provision. Standard gratuitous contract for the provision of pharmaceutical services”;
- Annex 15 “Technical specifications for the tender application of a potential supplier”;
- Annex 17 “Standard supply agreement dated _____ No. _____ (between the SD and a supplier)”;
- Annex 23 “Model Supplementary Agreement No. to the Model Long-Term Contract for the Supply of Medicines and MD dated _____ year No. _____ (between the SD and a supplier).”

The following new annexes have been added:

- Annex 9-1 “Information on medical equipment worth over 20,000,000 tenge”;
- Annex 9-2 “Information for _____ year based on monitoring of the purchase of medical equipment”.

The Order No. 58 entered into force on July 11, 2025, with the exception of the provisions that enter into force on July 31, 2025 (see the text of this Alert above).

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