Kazakhstan – June 2026

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

The Minister of Healthcare of the Republic of Kazakhstan ("**Kazakhstan**") issued the Order No. 63 (the "**Order No. 63**"), which introduced amendments and additions to the Order No. 110 dated 7 June 2023 "On the Approval of the Rules for the Organization and Implementation of the Procurement of Medicines, Medical Devices, and Specialized Therapeutic Products within the Framework of the Guaranteed Volume of Free Medical Care, Additional Volume of Medical Assistance for Persons Held in Pre-Trial Detention Centers and Facilities of the Penal (Penitentiary) System, at the Expense of Budgetary Funds and/or within the Compulsory Social Medical Insurance System, as well as Pharmaceutical Services" (the "**Procurement Rules**").

The amendments regulate procedures for procurement of Medicines ("**Medicines**"), Medical Devices ("**MDs**"), and Specialized Therapeutic Products within the frameworks of the Guaranteed Volume of Free Medical Care, Additional Volume of Medical Care, and pharmaceutical services.

Specifically, the Procurement Rules have been amended as follows:

- **Amendments to the Procedure for Procurement of Medicines and MDs from Kazakhstani or Foreign Manufacturer**

The provisions governing the contract price for the supply of Medicines and/or MDs in foreign currency have been amended. Now, where a supply contract (agreement) for Medicines and/or MDs is concluded in a foreign currency, the contract price is determined using the exchange rate established by the National Bank of Kazakhstan applicable as of the date on which the price proposals and relevant documents are first submitted.

The amendments introduce an additional ground for declaring the procurement of Medicines and/or MDs from a Kazakhstani or foreign manufacturer as failed. Under the new provision, the procurement procedure shall be declared as failed where the relevant Kazakhstani or foreign manufacturer does not participate in the negotiations provided for under Section 225 of the Procurement Rules.

- **Amendments to the Rules Governing Single-Source Procurement from International Organizations Established by the United Nations**

The amendments introduce additional categories of Medicines and MDs that are excluded from the list of products eligible for procurement through this method. Specifically, the following Medicines and MDs shall not be included into the list of Medicines and MDs procured under agreements with international organizations established by the United Nations General Assembly:

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1) procured within a long-term supply contract or a supply contract based on an investment agreement, where the supplier has expressed its willingness and readiness to supply during the respective financial year;
2) containing narcotic substances, psychotropic substances, or precursors;
3) that are registered and manufactured by a Kazakhstani manufacturer, where the proposed price does not exceed 30% of the price proposed by the relevant international organization established by the United Nations General Assembly;
4) manufactured by a Kazakhstani manufacturer through the complete production cycle of the finished pharmaceutical product, including the stage of manufacturing the finished dosage form from the active pharmaceutical ingredient.

Amendments to the Special Procurement of Medicines and/or MDs by the Single Distributor, Customer, or Procurement Organizer

One of the procurement methods has been amended. Procurement from suppliers is now conducted through a single-source procurement method based on existing supply contracts or supplementary agreements concluded for the relevant financial year under a long-term supply contract and now also under a supply contract concluded pursuant to an investment agreement.

Amendments to the Rules Governing Procurement of Medicines and/or MDs through the Request for Quotations Method

One of the grounds for procurement through this method has been removed. Procurement of Medicines and/or MDs through the request for price quotations method shall no longer be carried out where the annual procurement volume of Medicines with the same international non-proprietary name (the "**INN**") and/or MDs, in monetary terms does not exceed two thousand times the monthly calculation index established by the legislation of Kazakhstan for the relevant financial year.

Amendments to the Procedure for the Conclusion and Performance of Supply Contracts by the Single Distributor, Customers, or Procurement Organizer

A new ground for amending a concluded supply contract has been introduced. Under the amended Procurement Rules, amendments to a concluded supply contract are now permitted upon issuance of a registration certificate for a medicine in the course of bringing the registration dossier into compliance with the requirements of international treaties and acts constituting the law of the EAEU.

The procedure for entering into long-term supply contracts for Medicines and/or MDs with potential suppliers intending to establish and/or modernize production facilities for Medicines and/or MDs has been amended. Under the amended Procurement Rules, for the purpose of

concluding these long-term supply contracts, the Ministry of Healthcare of Kazakhstan shall develop a draft list of Medicines and/or MDs to be procured by the Single Distributor under long-term supply contracts. The draft list shall specify, in respect of Medicines, the INN or composition, dosage form, dosage strength, release form, and unit of measurement, and, in respect of MDs, the name, technical specifications, and unit of measurement (the "**Draft List**").

The Formulary Commission of the Ministry of Healthcare of Kazakhstan shall review the Draft List within 15 (fifteen) business days.

If a long-term supply contract is terminated before the commencement of supply, the names of Medicines and MDs that were not supplied under this long-term supply contract shall be submitted by the Single Distributor to the Ministry of Healthcare of Kazakhstan for consideration by the Formulary Commission. Following approval by the Formulary Commission, the Single Distributor shall conduct a competitive procurement procedure.

The Formulary Commission of the Ministry of Healthcare of Kazakhstan may, where necessary, engage one or more experts with relevant expertise to provide opinions on matters requiring specialized knowledge and/or technical expertise.

Within 10 (ten) business days after approval of the Draft List by the Formulary Commission of the Ministry of Healthcare of Kazakhstan, the Ministry of Healthcare of Kazakhstan shall submit to the Single Distributor the approved List of Medicines and/or MDs to be procured by the Single Distributor under long-term supply contracts. The List shall specify, in respect of Medicines, the INN or composition, dosage form, dosage strength, presentation, and unit of measurement, and, in respect of MDs, the name, technical specifications, and unit of measurement (the "**List**").

The List shall exclude Medicines and/or MDs registered by Kazakhstani manufacturers, as well as Medicines and/or MDs covered by an existing long-term supply contract or a supply contract concluded pursuant to an investment agreement.

The composition of the commission established by the Single Distributor for conducting a competitive bidding process for the conclusion of long-term supply contracts has been amended. The commission shall now consist of an odd number of members, with at least nine members, a chairperson, a vice-chairperson, and members, including employees:

1) of the Ministry of Healthcare of Kazakhstan holding a position not lower than the head of the department responsible for oversight of the pharmaceutical and medical industries (subject to approval)
2) of the Ministry of Foreign Affairs of Kazakhstan, holding a position not lower than that of a department head (subject to approval);
3) of the Ministry of Industry and Construction of Kazakhstan (subject to approval);
4) of the Single Distributor at a level not lower than the head of a structural unit;

5) of the expert organization at a level not lower than the head of the structural unit responsible for specialized expert evaluation of Medicines and MDs (subject to approval);
6) of the State-Owned Enterprise "Salidat Kairbekova National Scientific Center for Health Care Development" under the Ministry of Healthcare of Kazakhstan (subject to approval);
7) of the National Chamber of Entrepreneurs of Kazakhstan "Atameken" (subject to approval);
8) from among pharmaceutical inspectors responsible for overseeing compliance with Good Pharmaceutical Practices (subject to approval).

The deadline for publishing the announcement of a competitive bidding process for long-term supply contracts has been amended, and provisions establishing the ground and deadline for extending the application submission period have been introduced. The announcement of a competitive bidding process shall now be published in Kazakh and Russian on the web portal within 5 (five) business days from the date of the Single Distributor's decision and at least 20 (twenty) business days prior to the opening date of the bids.

Where any amendments and/or additions are made to the List prior to the bid opening date, the deadline for submission of bid proposals shall be extended by no less than 20 (twenty) business days.

The requirements applicable to the announcement of the procurement of Medicines and MDs have been amended in relation to a competitive bidding process for long-term supply contracts. The announcement must now specify the name of the Medicines (including the lot number), their INN or composition, dosage form, strength, and unit of measurement, as well as the name of the MDs, their technical characteristics, and unit of measurement, in accordance with the List.

The requirements to the content of a potential supplier's bid for participation in a competitive bidding process for a long-term supply contract have been amended. A potential supplier's bid shall now include:

1) the INN or composition of the Medicines, their dosage form, dosage strength, release form, or the names of the active pharmaceutical ingredients (APIs), as well as the name of the MDs, their technical characteristics, and unit of measurement, in accordance with the List;
2) information on the implementation timeline and stages of the investment project aimed at establishing and/or modernizing production facilities for Medicines or MDs;
3) documents confirming compliance with the criteria established under the point-based evaluation system;
4) a business plan containing the following sections:

    - project summary;
    - technical section;
    - commercial section;
    - socioeconomic impact section;

- financial section.

At the same time, the Order No. 63 provides detailed requirements regarding the information to be included in each section. For instance, the technical section must contain, inter alia, a description of the investment project's technology, including details of the fixed assets planned for acquisition and use.

The commercial section shall include, inter alia, information on product distribution, specifying the regions, consumers, and foreign countries to which the products are planned to be supplied.

The socioeconomic impact section shall include, inter alia, the expected social outcomes and impacts associated with the implementation of the project.

The financial section shall include, inter alia, information on the project implementation costs and the sources of funding.

The evaluation criteria (point-based scoring system) for potential suppliers planning to establish or modernize pharmaceutical production facilities have been amended. While the criteria requiring confirmation of sufficient financial resources to fully finance the implementation of the investment project and confirmation of the availability of a land plot for the establishment of a pharmaceutical production facility remain in place, new criteria have been introduced to replace the previously applicable criteria:

- a plan for the localization of Medicines production;
- experience in Medicines production;
- an investment plan for research and development of Medicines, including cooperation with research institutes, higher education institutions of Kazakhstan, and/or laboratories, and/or Science Fund JSC for the purposes of joint development, based on the total cost of Medicines manufactured from the third year of the long-term contract;
- an export plan for a portion of the annual total volume of Medicines manufactured in Kazakhstan;
- a conditional discount on the prices of Medicines applicable during the supply period.

The above amendments and additions of the Order No. 63 entered into force on 20 June 2026.

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