Kazakhstan – January 2025

Amendments to the Rules for procurement of medicines and medical devices in Kazakhstan

On December 27, 2024, in pursuance of the Roadmap for the Elimination of Corruption Risks identified in the operation of SK-Pharmacy LLP and the Action Plan approved based on the results of the audit by the Supreme Audit Chamber, the Minister of Health of the Republic of Kazakhstan issued the Order No. 112 (the "**Order No. 112**"), which introduced amendments and additions to the Order No. 110 dated June 7, 2023 (the "**Order No. 110**") "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 "**Rules**").

The amendments regulate procedures for procurement of Medicines ("**Medicines**"), Medical Devices ("**MD**"), 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 Rules have been amended as follows:

Amendments to Tender Rules Aimed at Promotion of Competition

The amendments are aimed at eliminating anti-competitive rules which provided an opportunity to recognize a potential supplier as the winner when only one application for participation in a tender (bid) for Medicines and MD was received, as well as preventing the selection of winners based on the application (bid) of only one participant and collusion between procurement participants.

The rules for determining a tender winner when one application has been received have been amended. Now, a potential supplier in the absence of competition for the lot shall be recognized as the winner when the repeated purchase for failed lots of Medicines and MD has been carried out (previously, a potential supplier in the absence of competition for the lot was recognized as the winner), with the exception of the purchase of medical equipment which does not have registered analogues in the Republic of Kazakhstan (**"Kazakhstan"**)[1]. A provision has been added according to which when purchase of medical equipment is carried out by the lessor, a potential supplier whose application (bid) has been recognized by the commission as meeting the terms

[1] p. 197 of the Rules as amended on 11.01.2025; p. 197 of the Rules as amended on 07.06.2023;

of the announcement and the terms of the Rules, in the absence of competition for the lot shall be recognized as the winner (previously - when carrying out a repeated purchase of medical equipment for failed lots, the potential supplier whose application (bid) was recognized as meeting the terms of the announcement and the Rules was considered to be the winner) [2].

A new ground for recognizing a tender as failed has been added: receipt of a single application (bid). A tender or any of its lots shall be deemed to have failed in the event of the submission of a single bid for the lot, except for the case provided for in paragraph 197 of the Rules (a potential supplier in the absence of competition for the lot shall be deemed a winner in the course of a repeated purchase for failed lots of Medicines and MD; when purchase of medical equipment is carried out by a lessor, a potential supplier in the absence of competition for the lot shall be deemed to be the winner)[3].

Amendments have been introduced to the rules for carrying out procurement after a tender or any of its lots have been declared as failed. If a tender or any of its lots has been declared as failed, it is allowed to change the content and terms of the tender, with the exception of the procurement of medical equipment, and to conduct procurement of Medicines and MD from a domestic or foreign manufacturer (previously - conduct procurement by request for quotations, tender, through a single source from domestic or foreign manufacturers, international organizations established by the United Nations)[4].

Amendments to the Provisions on Changing the Price of a Supply Contract

The rules for changing the contract price in connection with changes in maximum prices by the authorized body have been amended. A rule has been introduced according to which in case of a change of the maximum price for the international non-proprietary name (**"INN"**) and/or trade name (**"TN"**) of a Medicine and/or MD during the performance of a supply contract (standard supply contract between the SD and the supplier, standard contract for the purchase of goods between the customer and the supplier, standard contract for the provision of pharmaceutical services between the customer and the supplier) the contract remains in force at the previous price until the parties have fully fulfilled their obligations[5]. The provisions that, in the event of a reduction in the maximum price during the performance of a supply contract, the SD shall conduct negotiations with the supplier to reduce the price of the supply contract as well as the provisions that, in the event of disagreement regarding the reduction in the price of the supply contract or the supplier's refusal to conduct negotiations, the SD has a right to terminate the supply contract and conduct the procurement in the manner established by the Rules have been excluded[6].

[2] p. 197 of the Rules as amended on 11.01.2025;
[3] sp. 4, p. 198 of the Rules as amended on 11.01.2025;
[4] p. 210 of the Rules as amended on 11.01.2025 and of the Rules as amended on 07.06.2023;;
[5] p. 259 of the Rules as amended on 11.01.2025 and of the Rules as amended on 07.06.2023;
[6] p. 259 of the Rules as amended on 11.01.2025 and of the Rules as amended on 07.06.2023;

Amendments into Certain Terms of Template Contracts

Some conditions of the template contract for the purchase of goods have been amended. Now the available form of payment is a transfer only (previously - also in cash, through letter of credit and other payments)[7]. Now the quality guarantee provided by the supplier is valid for one year after delivery of the entire batch of goods or its part (previously - for an agreed number of days after delivery of the entire batch of goods or its part)[8]. Now the penalty is charged for each overdue day and is calculated based on the cost of goods not delivered or delivered in violation of the delivery schedule (previously, there was no clarification that the penalty is charged for each overdue day)[9].

Amendment have been made to the template long-term contract for the supply of Medicines and/or MD. Specifically, the supplier's right to refuse to supply the goods upon provision of a justification to the SD after the start of the supply period before signing the additional agreement to the contract, but not for more than 2 (two) years in a row has been excluded, and also the provision has been excluded stating that if the supplier refuses to supply (the goods) for the relevant financial year after it provides the notification of the start of the supply period, then the specified year of supply shall be included in the supply period[10]. The following ground for termination of a long-term contract for the supply of Medicines and/or MD has been omitted: the supplier's failure to comply with the investment project implementation schedule for a period exceeding 12 (twelve) months[11].

Certain conditions of the template contract for the provision of pharmaceutical services have been amended[12]. For example, a provision has been added stating that the advance payment shall be withheld monthly based on the volume of services rendered[13], as well as the provision that the supplier shall not be subject to VAT for the Medicines purchased under the contract[14].

The Rules for Procurement by Customers have been Amended

Amendments aimed at procurement by the Customers to be carried out through the Single Distributor have been introduced: A provision has been added stating that the Customers shall carry out the procurement of Medicines and MD not included in the list of the Single Distributor (the "**SD**") through the SD in accordance with Chapters 1 (a tender organized via a web portal), 3

[7] p. 5 of the Annex 5 of the Rules as amended on 11.01.2025 and of the Rules as amended on 07.06.2023;
[8] p. 21 of the Annex 5 of the Rules as amended on 11.01.2025 and of the Rules as amended on 07.06.2023;
[9] p. 31 of the Annex 5 of the Rules as amended on 11.01.2025 and of the Rules as amended on 07.06.2023;
[10] p. 16 of the annex 21 of the Rules as amended on 07.06.2023;
[11] sp. 5, p. 20 of the annex 21 of the Rules as amended on 07.06.2023;
[12] annex 6 of the Rules as amended on 11.01.2025;
[13] p. 5 of the annex 6 of the Rules as amended on 11.01.2025;
[14] p. 10 of the annex 6 of the Rules as amended on 11.01.2025;

(purchase from a single source via a web portal), 4 (special procurement), 4-1 (purchase by request for quotations) of Section 3 of the Rules[15].

A deadline by which the SD shall carry out purchases based on SD list has been clarified. Specifically, the SD annually no later than May 1 shall carry out the purchase of Medicines and/or MD[16].

The Procedure for Purchasing from Domestic or Foreign Manufacturers, Purchasing through Receiving Quotations has Changed

The procedure for purchasing from domestic or foreign manufacturers[17]. Such a ground for termination of a supply contract with a domestic or foreign manufacturer as registration in Kazakhstan of analogs of Medicines and/or MD under the same INN name (composition) and characteristics (when purchasing Medicines and/or MD which do not have registered analogs in Kazakhstan) has been omitted[18].In addition, such a ground for purchasing Medicines and/or MD from domestic or foreign manufacturers as the purchase of Medicines and/or MD which do not have registered analogs in Kazakhstan in terms of INN (composition) and/or characteristics has been omitted[19].

Amendments to the procedure of purchasing Medicines and/or MD through receiving quotations have been introduced[20]. For example, the grounds for purchase through requesting quotations have changed[21]. The deadline for publishing an announcement for a purchase by requesting quotations has changed - now it is set at no later than 3 business days before the deadline for submitting quotations ends (previously – no later than 7 calendar days)[22]. The provision that a request for quotations shall be requested from at least two unaffiliated potential suppliers has been omitted[23]. The rules have been introduced that a purchase by request for quotations shall be considered to have failed if no quotations have been submitted by suppliers, and that if a purchase by request for quotations is considered as failed, repeated purchase shall be carried out through request for quotations or tender[24]. A provision has been added that if a foreign manufacturer has an authorized representative within the territory of Kazakhstan, then

[15] p. 5-2 of the Rules as amended on 11.01.2025;
[16] p. 126 of the Rules as amended on 11.01.2025;
[17] p. 211 of the Rules as amended on 11.01.2025;
[18] sp. 1, p. 226 of the Rules as amended on 07.06.2023;
[19] sp. 1, p. 211 of the Rules as amended on 11.01.2025 of the Rules as amended on 07.06.2023;
[20] Chapter 4-1 of the Rules as amended on 11.01.2025;
[21] p. 245-1 of the Rules as amended on 11.01.2025;
[22] p. 245-3 of the Rules as amended on 11.01.2025; p. 74 of the Rules as amended on 07.06.2023;
[23] p. 73 of the Rules as amended on 07.06.2023;
[24] p. 245-5, 245-6 of the Rules as amended on 11.01.2025;

they shall provide a certificate of an authorized representative and a regulation on an authorized representative[25].

- **Amendments to the Rules on Carrying out Competition for Concluding Long-Term Supply Contracts among Potential Suppliers Intending to Create and/or Modernize the Manufacturing of Medicines and/or MD (for legal entities registered in Kazakhstan)**

The procedure for forming the list of Medicines and/or MD has been changed and the timeframes for reviewing the list by the formulary commission have been defined. Specifically, the draft list of Medicines and MD shall be formed on the basis of the analysis of the need for Medicines and MD of the healthcare system conducted by a scientific organization in the field of healthcare, no later than December 5 shall be reviewed by the formulary commission annually by January 31[26].

The grounds and criteria for issuing an industry opinion have changed. Now the industry opinion shall be issued only on the basis of a feasibility study (previously – also on the basis of a business plan) according to the following criteria: 1) market and industry analysis; 2) social aspects; 3) economic aspects[27].

The criteria for assessing an application to establish manufacturing of Medicines and/or MD have changed. Now one of the criteria is the provision of an expert opinion (previously a state expert opinion) on the design and estimate documentation for construction[28]. Further, a new criterion has been introduced – the share of local content[29].

The criteria for assessing an application submitted by a potential supplier intending to modernize the manufacturing of Medicines and/or MD have changed. Now, the experience of more than five years in pharmaceutical manufacturing in Kazakhstan of the founder (shareholder) of the potential supplier is not included in the criteria for evaluating the application of the potential supplier[30]. Further, a new criterion has been introduced – the share of local content[31].

New obligations for the supplier have been introduced for creation, modernization of the manufacturing of Medicines and/or MD. Specifically, the supplier is obliged to submit a semi-annual report on the progress of the Investment Project and on the process of product

[25] пп. 2, п. 215 of the Rules as amended on 11.01.2025;
[26] p. 266 of the Rules as amended on 11.01.2025;
[27] p. 295 of the Rules as amended on 11.01.2025;
[28] sp. 3, p. 301 of the Rules as amended on 11.01.2025, sp. 3, p. 301 Rules as amended on 07.06.2023;
[29] sp. 7, p. 301 of the Rules as amended on 11.01.2025;
[30] sp. 2, p. 302 of the Rules as amended on 11.01.2025;
[31] p. 8, 302 of the Rules as amended on 11.01.2025;

registration to the SD; is obliged to fill in the information reflecting the indicators of the manufacturing capacity and its main characteristics[32].

Purchase of Medical Equipment through Financial Leasing has been introduced

The rules on the purchase of medical equipment by the lessor have been introduced:

- Chapter 12 "Purchase of medical equipment by the lessor" has been added to the Section 3, and the list of definitions has been expanded, for example, the definitions of "lessor", "financial leasing agreement", etc. have been included[33];
- A provision has been introduced that the purchase of medical equipment by the lessor shall be carried out in paper form until September 30, 2025[34];
- A rule has been introduced that medical equipment costing from KZT 5,000,000 (five million) up to KZT 200,000,000 (two hundred million) may also be purchased using borrowed and/or the lessor's own funds based on the applications submitted by healthcare entities[35].

Investment Agreements

A provision has been introduced concerning investment agreements covering MD. Namely, within the framework of the implementation of the investment agreement the procurement of MD shall be carried out in accordance with the terms of the concluded investment agreement[36].

The Order No. 112 entered into force on January 11, 2025.

Contacts:

Zafar Vakhidov

Partner, Vakhidov & Partners
Uzbekistan/Kazakhstan
ZV@vakhidovlaw.com

[32] p. 322-1, p. 322-2 of the Rules as amended on 11.01.2025;
[33] sp. 70, 69, p. 2 of the Rules as amended on 11.01.2025;
[34] p. 5-1 of the Rules as amended on 11.01.2025;
[35] p. 99-1 of the Rules as amended on 11.01.2025;
[36] p. 454 of the Rules as amended on 11.01.2025.

Saltanat Zhakhina

Associate, Vakhidov & Partners
Kazakhstan
SaltanatZh@vakhidovlaw.com