



Kazakhstan – June 2022

Amendments have been introduced to the Rules of organization and conduct of the procurement of medicines, medical devices and specialized medical products, pharmaceutical services

The Rules of organization and conduct of the procurement of medicines ("**Medicine**"), medical devices ("**MDs**") and specialized medical products within the guaranteed volume of free medical care ("**GVFMC**") and/or in the system of obligatory social health insurance ("**OSHI**"), pharmaceutical services approved by Decree of the Government of the Republic of Kazakhstan dated June 4, 2021 No. 375 ("**Rules**") were amended on May 11, 2022, the amendments were published on May 26, 2022¹ and entered into force on June 6, 2022.

The amendments, inter alia, are aimed at increasing the use of the web-portal in a procurement process, as well as at automating some processes², namely:

- The procedure for automated tender has been introduced³. An automated tender is held if there is no need in obtaining an expert opinion⁴. An expert opinion is not required if the characteristics of the purchased Medicines and/or MDs comply with the characteristics of the registered Medicines and/or MDs in the "Unified Classifier of Medicines and Medical Devices" information system⁵;
- Tendering, procurement through request for quotations and procurement from one source are now carried out by the customer or the organizer of the procurement through a web-portal⁶;
- Tenders conducted by the customer, the procurement organizer or the Single Distributor are conducted through the web-portal and are regulated by a consolidated chapter of the Rules⁷. The chapter is based on the chapter that regulated procurement by the Single Distributor through the web portal in the previous version of the Rules⁸;

¹ Web site of the IS "Reference Normative Legislative Acts Control Bank of the Republic of Kazakhstan in electronic form": <http://zan.gov.kz/client/#/md/168075/rus>

² p. 5, 7 of the Rules

³ sp.2, p. 5; sp.2, p.7 of the Rules

⁴ p. 5, 7 of the Rules

⁵ p. 5, 7 of the Rules

⁶ Chapters 7, 10, 11 of the Rules

⁷ The previous version of the Rules contained a separate Chapter 8 regulating the procedure for procurement through tender by the customer or the organizer of the procurement and Chapter 13 regulating the conduct of the tender by the Single Distributor through the web portal

⁸ Chapter 13 of the previous version of the Rules



- The contest aimed at the conclusion of a long-term supply contracts ("**LSC**") among potential suppliers who intend to establish and/or modernize the manufacturing of Medicines and/or MDs is also now conducted by the Single Distributor through the web-portal⁹;
- The conclusion of the LSC for the supply of medical equipment with the potential suppliers that have the manufacturing of medical equipment is now carried out through the web-portal as well¹⁰;
- The bank guarantee is now provided only electronically and issued directly by the bank at the web-portal ¹¹.

In addition, the amendments also include the following:

- Ban on imposing additional qualification requirements for potential suppliers not provided for by the Rules in the process of procurement¹² was lifted;
- Medical equipment worth more than KZT 20,000,000 (twenty million) is purchased by a customer through the Single Distributor¹³ (previously the limit was KZT 50,000,000 (fifty million)¹⁴);
- The procedure for conclusion of the LSC for the supply of medical equipment by the contract manufacturing customer ("**CMC**") has been introduced¹⁵;
- The heads of the organizations which act as customers, organizer of the procurement or Single Distributor are now entitled to recognize the procurement as a whole or in relevant lots as invalid if violations, non-compliance with the requirements of the Rules in the procurement process are detected¹⁶.

The changes have also affected the procedure for conducting a contest aimed at the conclusion of an LSC between the potential suppliers that intend to establish and/or modernize the manufacturing of Medicines and/or MDs, as well as the procedure for concluding the LSC with the CMC:

- Applications by the potential suppliers intending to establish and/or modernize the manufacturing of Medicines and/or MDs within the process of conducting the contest for the purpose of formation of a draft nomenclature are now accepted by the Single Distributor annually no later than December 31¹⁷;

⁹ Chapter 20 of the Rules

¹⁰ Paragraph 5, Chapter 21 of the Rules

¹¹ sp. 2, p. 49, sp. 2, p. 172, p. 346 of the Rules

¹² p. 15 of the previous version of the Rules

¹³ p. 155 of the Rules

¹⁴ p. 155 of the previous version of the Rules

¹⁵ Chapter 23 of the Rules

¹⁶ p. 481 of the Rules

¹⁷ p. 242 of the Rules



- Within the process of conducting the contest between the potential suppliers intending to establish and/or modernize manufacturing of Medicines and/or MDs, the nomenclature no longer may include the Medicines and/or MDs registered by domestic manufacturers. Previously, only the Medicines and/or MDs registered by 2 (two) or more domestic manufacturers could not be included to the nomenclature¹⁸;
- To conclude an additional agreement to the LSC which has been entered into as a result of the contest between the potential suppliers intending to establish and/or modernize the manufacturing of Medicines and/or MDs, the Single Distributor establishes a commission that negotiates a reduction in the price of the agreement. In case the reduction of the price of Medicines and/or MDs has not been negotiated, the purchase of the Medicines and/or MDs is carried out by the Single Distributor in other ways provided for by the Rules¹⁹;
- The completion of the construction or modernization of the manufacturing facility is additionally confirmed by the act of the commission inspection²⁰;
- Now the CMC can enter into the LSC for the supply of not only original Medicines, but also for biosimilar Medicines²¹;
- Additional agreements to LSCs with the CMCs, are now subject to provision of a license for pharmaceutical activities and a certificate of origin of the Medicines for internal circulation CT-KZ²².

Conclusion of the supply contract by the Single Distributor

- Now amendments to the concluded supply agreement can be introduced in case of the change in the holder of the registration certificate (MAH)²³.
- In the event the authorized body in the field of health care changes the ceiling price for the trade name of Medicines and/or MDs during the execution of the supply contract, the supply contract remains valid until the parties fully fulfill their obligations at the previous price now except when the conclusion of an additional agreement is a result of procurement from a single source by the Single Distributor through the web-portal²⁴;
- The grounds for terminating the supply contract were clarified and supplemented, for example, the supply contract is terminated unilaterally if the fact of the supplier's affiliation is established (for example, affiliation with the representatives of the customer or the Single Distributor who have the right to directly and/or indirectly make decisions and/or influence decisions made by the commission²⁵), which, according to the Rules, is also a basis for potential supplier's rejection in the procurement procedure that preceded the conclusion of the contract, or if the delay in paying penalties and / or fines exceeds 15

¹⁸ p. 244 of the Rules, p. 270 of the previous version of the Rules

¹⁹ p. 321 of the Rules

²⁰ p. 298 of the Rules

²¹ p. 432 of the Rules

²² p.457 of the Rules

²³ sp.3, p. 342 of the Rules

²⁴ p. 343 of the Rules; p. 346 of the previous version of the Rules

²⁵ sp. 3, 6 of the p. 9 of the Rules



(fifteen) calendar days, etc.²⁶. Previously, such grounds for unilateral termination of the supply contract were already set out in the template contract for the supply of Medicines and/or MDs (between the Single Distributor and the supplier²⁷);

- Now the amount of the supplier's security for the fulfillment of obligations under the supply contract in monetary terms again amounts to 3 (three) percent of the price of the entire supply contract, and not of the amount of the individual lot²⁸;
- The rule exempting provision of a security for the fulfillment of obligations under the supply contract with the Single Distributor if the contract's price at the time of conclusion does not exceed 2 (two) thousand monthly calculation indices was excluded²⁹.

²⁶ sp. 4, 5, p. 344 of the Rules

²⁷ p. 61 of the Standard contract for the supply of Medicines and/or MDs (between the ED and the supplier), Appendix 25 to the Order of the Minister of Health of the Republic of Kazakhstan dated November 12, 2021 No. ҚР DSM-113 "On approval of forms of documents for the purchase and invalidation of certain orders of the Minister of Health and Social Development of the Republic of Kazakhstan"

²⁸ p. 345 of the Rules; p. 348 of the previous version of the Rules

²⁹ p. 350 of the previous version of the Rules