Kazakhstan– July 2022

On the amendments to the Rules for the Price Regulation of the Medicines and Medical Devices

On July 9, 2022 the amendments to Order of the acting Minister of Health of the Republic of Kazakhstan dated June 23, 2022 No. ҚР ДСМ-56 "On the amendments and additions to Order of the Minister of Health of the Republic of Kazakhstan dated December 11, 2020 No. ҚР ДСМ-247/2020 "On approval of the Rules for Regulation, Formation of the Ceiling Prices and Markups for Medicines, as well as Medical Devices within the Guaranteed Volume of Free Medical Care and/or in the system of Obligatory Social Health Insurance" ("**Order No. 56"**) took effect[1].

Why were the Rules for Regulation of the Prices for Medicines and Medical Devices (the "Rules")[2] changed?

The changes are mainly related to the amendments made to the Code of the Republic of Kazakhstan "On the Public Health and the Healthcare System" dated July 7, 2020 ("**the Health Code**") in accordance with the Law of the Republic of Kazakhstan dated January 3, 2022 No. 101-VII ЗРК "On Amendments and Additions to Certain Legislative Acts of the Republic of Kazakhstan on the Matters Relating to the Development of Competition".

The changes to the scope of price regulation to Medicines were among the most important novelties. According to the amendments the price regulation applies to the Medicines within the Wholesale and Retail Sales channel included in the list approved by the Ministry of Health as opposed to the previous version of the Code where the prices for all Medicines were subject to regulation[3]. The Rules have been amended so that they reflect the changes to the Health Code.

What has changed with respect to Medicines?

The main changes to the Rules include the following:

(1) The Rules establish the categories of Medicines within the Wholesale and Retail Sales channel that are subject to price regulation.

Now the following categories of Medicines are subject to price regulation[4]:

[1] p. 4, Order No.56

[2] Order of the Minister of Health of the Republic of Kazakhstan dated December 11, 2020 No. ҚР ДСМ -247/2020 "On approval of the Rules for Regulation, Formation of Ceiling Prices and Markups for Medicines, as well as Medical Devices within the Guaranteed Volume of Free Medical Care and (or) in the system of Obligatory Social Health Insurance"

[3] sp. 3, p.7 of the Law of the Republic of Kazakhstan dated January 3, 2022 No. 101-VII ЗРК "On Amendments and Additions to Certain Legislative Acts of the Republic of Kazakhstan on the Matters Relating to the Development of Competition"

[4] p. 13-1 of the Rules for Regulation of Prices for Medicines

- RX (Prescription) Medicines;
- OTC (Over-the-counter) Medicines:
  - included in the draft list of Medicines and Medical Devices ("**MD**") to be purchased from Single Distributor and/or in the list of Medicines and MDs for free and/or subsidized outpatient provision of Medicines to certain categories of citizens with certain diseases (conditions);
  - having less than three Medicine Trade Names («**TN**») within one International Non-proprietary Name («**INN**»);
  - having less than three Manufacturers of the Medicine TNs within one INN;

(2) The requirement to provide data on forecasted costs for Medicines for Wholesale and Retail Sales that were not sold or supplied to the territory of the Republic of Kazakhstan ("**Kazakhstan**") prior to the registration of the price[5], as well as for the imported Medicines within the Guaranteed Volume of Free Medical Care ("**GVFMC**") and/or in the System of Obligatory Social Health Insurance ("**OSHI**") which were not supplied to the territory of Kazakhstan before the registration of the price [6] has been excluded;

(3) Currency adjustment of the price specified in a contract on the purchase of Medicines in addition to the currency adjustment of the price indicated in the documents confirming the actual price of the supplies has become possible [7];

(4) A requirement to provide a separate application and accompanying documents for each registered Medicine (e.g., having different numbers of registration certificates, dosages, forms, packages) when registering prices for the TN of the Medicine has been introduced[8];

(5) A new criterion for registration (re-registration) of prices for Wholesale and Retail Sales has been introduced. Now the costs of transportation of Medicines from the manufacturer to the border of Kazakhstan specified in an application should not exceed 15% of the manufacturer's price[9];

(6) The number of documents submitted together with the application for registration (re-registration) of the price of Medicines for Wholesale and Retail Sales as well as within the framework of the GVFMC and/or OSHI has been reduced. Now the provision of the ceiling price of the manufacturer of Medicines on the applicant's letterhead, the table of Ex Works

[5] p. 18, Rules for Regulation of Prices for Medicines
[6] p. 47, Rules for Regulation of Prices for Medicines
[7] p. 10, Rules for Regulation of Prices for Medicines
[8] p. 16, p. 45, Rules for Regulation of Prices for Medicines, p.16, p. 45 of the previous version of the Rules for Regulation of Prices for Medicines
[9] sp. 5, p. 24,Rules for Regulation of Prices for Medicines

prices in the reference countries, as well as information on Ex Works prices in the country of manufacture is no longer required[10];

(7) The provided manufacturer's price within the framework of the GVFMC and/or in the OSHI system for imported Medicines should not exceed the prices indicated in the submitted documents confirming the price of Medicines (a copy of the invoice) of the last import, minus the discount, and in the contract for the purchase of Medicines (previously the manufacturer's price had not to be higher than the maximum value of the three minimum prices per unit of measurement) [11];

(8) An application for registration or re-registration of the registered price for the Wholesale and Retail Sales for the TN of the Medicine in Kazakhstan should be submitted no later than April 10 or October 10 of the current year (in the previous version no later than March 10 or September 10 of the current year)[12].

What has changed with respect to MD?

The changes affect inter alia the following:

(1) The requirement to convert foreign currency prices has been clarified and now applies to the price in the price list from the manufacturing plant, as well as in documents confirming the actual price of supplies, in the copies of the invoice as well as in the contract on the purchase of MD[13];

(2) When submitting an application for registration (re-registration) of prices for imported MD, medical equipment ("**ME**"), the requirement to provide apostilled powers of attorney has been established, and the required factory price may now be provided not only based on Ex-Works terms[14];

(3) The possibility of providing a copy of the permission of the Ministry of Health of Kazakhstan for the import and use of goods on the territory of Kazakhstan, obtained through the web portal of the "Electronic Government" for the imported MD that do not have a registration certificate, has been omitted[15];

(4) The rule establishing the procedure for calculating the cost of additional (on top of 37 months) maintenance of ME has been omitted[16];

[10] p. 18, p. 47 Rules for Regulation of Prices for Medicines
[11] sp. 2,4, p. 53, Rules for Regulation of Prices for Medicines, sp. 2, p. 53, previous version of the Rules for regulation of prices for medicines
[12] p. 15, Rules for regulation of prices for medicines, p.15, previous version of the Rules for Regulation of Prices for Medicines,
[13] p. 6, Rules for Regulation of Prices for MD
[14]sp.1, p. 13, sp. 1, 2 p. 35, Rules for Regulation of Prices for MD
[15] p. 17, the previous version of the Rules for Regulation of Prices for MD
[16] p. 41, the previous version of the Rules for Regulation of Prices for MD

(5) The ceiling prices and markups for MD for diagnostics (in vitro) are not set, however an exception has been added for devices, equipment, as well as MD manufactured in Kazakhstan[17];

(6) A requirement has been introduced that in case the exchange rate of KZT against foreign currencies changes by 10% or more over the period of a month and/or in case the actual annual inflation rises (decreases) by more than 1.5 times compared to the upper limit of the target corridor, the ceiling prices are formed for the TN of the Medical Products by way of addition/deduction of a percentage value provided by the Ministry of Health of Kazakhstan ("**MoH**") to the manufacturer's price[18];

(7) An application for the provision of services for the analysis of ceiling prices for the TN and technical characteristics of medical equipment as well as the documents submitted with it can now be submitted electronically[19];

(8) A new criterion has been added for registration of the ceiling price or re-registration of the registered price for imported Medical Products under the GVFMC framework and/or in the OSHI system:

- The provided manufacturer's price within the framework of the GVFMC and/or in the OSHI system for imported Medical Products must not be higher than the maximum value of 3 (three) minimum prices per unit of measurement indicated in the provided documents confirming the price of Medical Products (copy of the invoice, customs declaration) minus the discount, and in the contract or agreement on the purchase of Medical Products[20];

(9) For the imported ME and the ME purchased within the projects for the healthcare organization facilities construction or design, the total cost of the supplier's expenses should not exceed 10% of the purchase price of ME delivered under the EXW, FCA, FAS, DAT, DAP terms[21] (previously under the EXW, FCA, FAS, SAR (SAR was mentioned only for the imported MT) CFR, CIF, CPT terms[22]). Now, under the terms of delivery of CFR, CIF, CPT, CIP to the destination of Kazakhstan, 10% is not included in the price of ME[23].

(10) The changes with regard to the deadlines:

- Now, in case of submission of the incomplete package of documents, an application for registration (re-registration) of the price is not formed on the portal[24]. The deadline for providing missing information, clarifying information (for ME - the deadline for providing

[17] p. 22, the Rules for Regulation of Prices for MD
[18] p. 23, 24, Rules for Regulation of Prices for MD
[19] p. 28, Rules for Regulation of Prices for MD
[20] sp. 2, p 19, Rules for Regulation of Prices for MD
[21] p. 38, p. 41 , Rules for Regulation of Prices for MD
[22] p. 37, p. 40 , the version of Rules for Regulation of Prices for MD dated 11.12.2020
[23] p. 38, p. 41, the Rules for Regulation of Prices for MD
[24] p. 15, p. 31, the Rules for Regulation of Prices for MD

missing information after the first notification is received) when submitting documents for registering the price has changed from 20 calendar days[25] for Medical Products and 10 calendar days[26] for ME in the old version to 10 business days for both Medical Products and for ME in the new version[27]. According to the amendments, such information is provided in writing on the applicant's letterhead via the Portal and is certified by an electronic digital signature, without providing paper documents;

- The validity period of the conclusion based on the results of the analysis of ceiling prices for the ME imported and produced in Kazakhstan is 12 months from the date of its issuance[28];
- The state expert organization develops the project of ceiling prices for the list of Medical Products within the framework of the GVFMC and/or in the OSHI in accordance with the list approved by the MoH formed based on the applications submitted no later than December 31[29].

Government Resolution No. 501 dated July 18, 2022

Pursuant to the Resolution of the Government of Kazakhstan No. 501 dated July 18, 2022 in order to ensure uninterrupted supply of Medicines and MD the MoH shall through September 3, 2022 adopt acts enabling procurement of registered in Kazakhstan Medicines and MD without the ceiling price for TN within the GVMC and/or OSHI. Until the MoH adopts the acts it is unclear in which cases procurement of Medicines and MD will be allowed without a ceiling price.

[25] p. 18, the version of the Rules for Regulation of Prices for MD dated 11.12.2020
[26] p. 30, the version of the Rules for Regulation of Prices for MD dated 11.12.2020
[27] p. 15, p. 31, the Rules for Regulation of Prices for MD
[28] p. 44, p. 54 the Rules for Regulation of Prices for MD
[29] p. 25, the Rules for Regulation of Prices for MD