AMENDMENTS TO REGULATION OF PRICES OF MEDICINES AND MEDICAL DEVICES IN KAZAKHSTAN, JULY 2023

Order of the Minister of Health of the Republic of Kazakhstan ("**RK**") No. 124 dated July 3, 2023 ("**Order**") introduced amendments into the Order of the Minister of Health of the RK No ҚР DSM-247/2020 dated December 11, 2020 "On Approval of the Rules on Regulation, Formation of Ceiling Prices and Mark-ups for Medicines, as well as Medical Devices within the Guaranteed Volume of Free Medical Care ("**GOBMP**") and (or) in the system of Obligatory Social Health Insurance ("**OSMS**")" (hereinafter referred to as the "**Rules**").

Amendments in relation to the medicines' price regulation

Pursuant to the amendments to the Rules, prescription medicines and those medicines with a registration certificate – market authorisation ("**MA**") within the Eurasian Economic Union ("**EAEU**") are subject to price regulation, whereas over-the-counter medicines are now excluded from price regulation for wholesale and retail sale.

Also, the requirement to provide a copy of the document confirming the current patent protection of the original medicine or biological original medicine according to the international non-proprietary name ("**INN**") or a letter from the manufacturer or marketing authorization holder ("**MAH**") confirming the originality of the medicine according to the INN was excluded from the list of documents required for registration of the ceiling price both within the framework of wholesale and retail sale and within the framework of the GOBMP (or) in the OSMS system.

In the absence of deliveries of imported medicines to the territory of Kazakhstan within the last 24 (twenty-four) months prior to the registration of the price, the registered price is registered or re-registered on the basis of not only an agreement on the purchase of medicines, but also on the basis of information about the Ex-works price in the reference countries or in country of origin (in case of absence of registration in the reference countries).

In addition, the previously established threshold margins in the amount of 30% for generic medicines and 10% for biosimilar medicines were lifted.

Further, the presence of medicines in the Kazakhstan National Medicinal Formular ("**KNF**") and (or) in the list of medicines and medical devices for free and (or) preferential outpatient care for certain categories of citizens with certain diseases (conditions) is no longer required in order to apply for registration or re-registration of the price within the framework of the GOBMP (or) in the OSMS system.

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Also, the Order added the ground for withdrawal of the registered price for medicines by the state expert organization based on acts of law enforcement agencies and judicial acts that have entered into force.

Amendments in relation to the medical devices' price regulation

The Rules have been amended not only with respect to the medicines' price regulation, but also with respect to the prices of medical devices.

The list of terms was supplemented with terms regarding units of measurement for devices for medical purpose ("**DMP**") as well as medical equipment ("**ME**").

Similar to medicine price regulation, the withdrawal of registered prices for DMP and ME can be carried out on the basis of acts of law enforcement agencies and judicial acts that have entered into force.

The Rules exclude the formation of ceiling prices for the trade name and technical characteristics of ME, while the formation of ceiling prices for DMP remains in force. In terms of ME the procedure consists of a price analysis carried out by the state expert organization. At the same time, at the request of the authorized body, the state expert organization can draft ceiling prices for the trade name and technical characteristics of the ME on the basis of the conclusions issued based on the results of the analysis of the prices of ME according to the list provided by the authorized body.

Now, if there is no supply of DMP within 24 (twenty-four) months (previously 12), instead of the projected costs for the purposes of registration and re-registration of the ceiling price of DMP, the prices in the DMP purchase agreement and information on related actual costs are taken into account.

The terms for consideration of an application for registration of the ceiling price for DMP have been clarified as follows:

- the application shall be considered by the state expert organization within 20 (twenty) business days from the date of the application registration;
- if there are repeated comments to the newly submitted documents, the expert organization sends the second notification to the applicant (in any form) within 15 (fifteen) business days;
- consideration of the submitted documents after the second notification by the state expert organization is carried out within 10 (ten) business days;
- the applicant submits the corrected documents to the expert organization within a period not exceeding 7 (seven) business days from the date of receiving the notification.

Previously, the term for consideration of the application and the analysis of prices for DMP by the state expert organization was regulated by one provision which established only a total period of 60 (sixty) calendar days from the date of the applicant's request.

Also, an additional condition was added for analysing and registering the ceiling price or re-registration of the registered price of DMP by the state expert organization, namely, the provided manufacturer's price within the framework of the GOBMP and (or) in the OSMS system for imported DMP should not exceed the price value per unit of measurement specified in the submitted documents confirming the price in the contract from the DMP manufacturer.

As well as in relation to DMP, the clause regulating general terms for conducting the analysis of marginal prices for ME within 60 (sixty) calendar days was removed from the Rules. Now, the terms for considering applications for the ME price analysis are regulated as follows:

- the term for considering application by the state expert organization is 25 (twenty-five) business days from the date of the application registration;
- if there are repeated comments to the newly submitted documents, the expert organization sends the second notification to the applicant (in any form) within 20 (twenty) business days (instead of the previously established 10 (ten) calendar days);
- consideration of the submitted documents after the second notification by the state expert organization is carried out within 15 (fifteen) business days.
- the applicant submits the corrected documents to the expert organization within a period not exceeding 7 (seven) business days from the date of receiving the notification.

When submitting documents for the analysis of prices for imported ME, namely, the contract between the applicant and the manufacturer, a requirement of a warranty service period of 37 (thirty-seven) months was lifted. Also, a number of clarifications and additions have been made to the list of documents to be submitted along with the application on ME price analysis:

- the requirement to provide a price list from the manufacturer or other companies selling ME is excluded;
- in the absence of a contract and a price list, it is no longer required to provide a document confirming the purchase price (price of the manufacturer) of ME (in the context of the configuration in accordance with the MA) with the terms of delivery under INCOTERMS;
- the power of attorney from the manufacturer indicates the right to sell at the prices of the manufacturer and the right to delegate rights to third parties with a validity period. The power of attorney for the applicant indicates the right to sell the ME and its validity period;
- in the absence of actual deliveries for the past 12 (twelve) months, copies of documents for the previous period of 12 (twelve) months should be provided. In the absence of actual deliveries within 24 (twenty-four) months prior to the registration of the declared ME under the GOBMP and (or) in the OSMS system on the territory of Kazakhstan, the price for imported ME under the GOBMP and (or) in the OSMS system is registered or re-registered

on the basis of a purchase agreement, as well as confirmed information on the associated actual costs.

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