Changes to Rules for establishment of maximum prices for medicines under GVFMA and OSMI framework

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In brief

The Pharmacy Committee sent NCE "Atameken" the draft of the Rules for establishment of maximum prices for medicines under the frameworks of the Guaranteed Volume of Free Medical Assistance ("**GVFMA**") and the Obligatory Social Medical Insurance ("**OSMI**"), (the "**Rules**"). If approved, the Rules will introduce significant amendments to the current rules for establishment of prices for medicines approved by the Order No. 639 dated 30 July 2015 ("**Order No. 639**").

In details

Below are the key changes to be introduced by the Rules to the procedure for establishment of maximum prices under the frameworks of GVFMA and OSMI.

Establishment of manufacturers' registered prices

- *Applying Ex Works Prices*

Unlike the current Order No. 639, the Rules will apply Ex Works prices as a basis for establishment of a manufacturer's registered price by taking into account expenses incurred, including on marketing and running the manufacturer's representative office in Kazakhstan.

Ex Works price means a manufacturer's sale price for medicines to its distributor in the manufacturer's country of incorporation (excluding any risks and expenses related to transfer of the goods from the seller's territory to the place of destination). However, the Rules do not specify what types of expenses can be recognized as expenses on marketing and running representative offices in Kazakhstan and how these expenses shall be confirmed.

- *Comparing with External reference pricing*

The Rules provide the list of countries for reference in order for foreign manufactures to establish registered prices.

Unlike the Order No. 639, there is no division of countries into main and reserve countries. The list refers to Ex Works prices in the following countries for comparative analysis: Belarus, Hungary, Latvia, Czech Republic, Bulgaria, Russia, Turkey, Slovenia, Poland, Austria, Netherlands, Belgium, Spain, Greece and Israel.

Moreover, the Rules exclude the possibility for manufactures to negotiate Ex Works prices for establishment of a registered price even if the proposed price is higher than the comparable reference prices. As such, if an applicant's price exceeds the average of the lowest five Ex Works prices in the above-mentioned list, the application for price registration will be rejected.

- *Registered price for reproduced medicines (generic and biosimilar)*

The Rules establish that the registered price for biosimilar should be 10% lower than the price of the manufacturer of the original biological medicines. Whereas, the Order No. 639 stipulates that the price of biosimilar should not exceed 70% of the price of the original medicine.

In addition, the Rules cancel the requirement that the registered price for reproduced medicines should be reduced if two or more generics or biosimilars of the same kind have been registered.

- *Currency of the registered price*

Manufacturers' registered prices should be determined in KZT. When applying for price registration, conversion of a manufacturer's price into KZT should be based on the official rate of the National Bank of Kazakhstan on the last complete business day preceding the date of filing the application.

At the same time, unlike the Order No. 639, the Rules do not provide any indexation provision for the case of change in the official exchange rate of KZT to USD by more than 15%, for establishment of the maximum prices.

It should also be noted that the Rules shorten the period from six months to three months during which it is restricted to change the registered prices of medicines.

Wholesale markup

To cover expenses on and make profits from wholesale realization of medicines, the Rules allow manufactures to charge wholesale markups on the registered prices of medicines which are to be procured under the frameworks of GVFMA and OSMI on a regressive scale.

The regressive scale of the wholesale markup determines the amount of a wholesale markup in percentage, which depends on the value of the registered price of medicines, namely:

Registered price of medicines	Regressive scale of wholesale markup
up to KZT 1,000	20%
from KZT 1,001 to KZT 3,000	19%
from KZT 3,001 to KZT 5,000	18%
from KZT 5,001 to KZT 30,000	17%
from KZT 30,001 to KZT 100 000	16%
more than KZT 100,001	15%

Establishment of maximum prices for medicines to be procured under GVFMA and OSMI framework

In accordance with the Rules, maximum prices for medicines of each trademark are determined based on their registered prices with consideration of wholesale mark-ups.

The Rules provide that the maximum prices for the international non-proprietary name ("**INN**") are formed on the basis of the maximum value of the lowest three maximum wholesale prices for trade names.

Taking into account all the above mentioned, the Ministry of Healthcare will approve the list of maximum prices for medicines, on the basis of which the lists of medicines to be procured in the frameworks of GVFMA and OSMI will be developed and approved for the next calendar year.

The Rules will become effective ten calendar days after the day of their first official publication.

[Source: Draft Order «On Introduction of Amendments to the Order of the Acting Minister of Healthcare and Social Development of the Republic of Kazakhstan dated 30 July 2015 No. 639 «On Approval of the Rules for the Establishment of Prices Assessment for Medicines and Medical Products under the Guaranteed Volume of Free Medical Assistance»]

Let's discuss

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