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LEGAL ALERT

The Procedure of Declaring Wholesale Prices (for Medicinal Products and Medical Devices) Becomes Simpler

On July 7, 2015 an amended Regulation on declaring wholesale prices (**“Resolution No.240”**) came into force, based on the Cabinet’s Resolution No. 449 dated April 22, 2015 (**“Resolution No.449”**).

The Resolution No.449 establishes the following key changes:

1. Currency issues are taken into account

The regulation provides that prices for imported medicines and medical devices are to be declared in UAH, but with indication of the Central Banks’ official rate at the date of declaring.

The new mechanism obliges Ministry of Health of Ukraine (**“MOH”**) to **automatically review** and update in the Register prices for imported products in case the Central bank’s official rate for the currency of declaration (EUR or USD) fluctuates for more than 5% during the current calendar month. In such cases, MOH shall update the prices by the 10th of the following calendar month by either **increasing or decreasing** the prices in the Register.

2. Simplification of the mechanism

Deregulation. The amended mechanism becomes actually declaring of prices per se, and is no longer restricted with the level of reference prices.

No State Price Inspection. The only authority involved into declaring of wholesale prices is MOH.

Resolution No.449 significantly shortened list of documents needed to declare wholesale prices for the medicinal products and medical devices.

To declare price for a medicine, an applicant shall only submit application and power of attorney.

To declare price for a medical device, a document confirming registration or conformity assessment is required as well.

3. Shortened timeframes

MOH decides on declaring the wholesale prices within **10 business days**. Then within **2 business days** MOH shall publish prices on its official website.

Thus, the procedure of declaring wholesale prices shall formally take up to **12 business days** compared to (formally) 20-25 or (practically) 40-120 business days, as it was before.

Resolution No. 449 sets no restrictions regarding frequency of declaring updated wholesale prices (in case of relevant grounds, being out of the applicant's control).

4. Mark-ups

Resolution No.449 replaced the regressive scale of retail mark-ups, previously established by the Cabinet's Resolution No. 955, with the single 25% rate.

5. Clear provision on Interbank Rate application for mark-ups calculation

As of now, for calculation of wholesale mark-ups for imported products, the average Interbank rate of UAH established on the banking day preceding the day of supply of product, shall be used. The Central Bank publishes the rate in question on daily basis.

For full implementation of the updated mechanism, MOH shall amend its regulations on the Register in part of automatic review of prices in case of currency fluctuation.

If you have any questions, please, contact:

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