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Newsletter

Pharmaceutical Sector: News overview

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Changes in state regulation of prices for pharmaceuticals and medical products

The Resolution of the Cabinet of Ministers of Ukraine (hereafter – "CMU") No. 449 dated 22 April 2015a (hereafter-- "Resolution No. 449") introduced a number of changes into legal acts governing the state regulation of prices for pharmaceuticals and medical products.

First, the Resolution No. 449 approved a new edition of the procedure for declaration of changes to wholesale prices for pharmaceuticals and medical products (hereafter – the "Procedure").[1]

The Procedure cancels the use of mechanism of determining comparative (referential) prices for declaring wholesale prices for pharmaceuticals.

Also the new Procedure amends the procedures for declaration of changes to wholesale prices for pharmaceuticals and medical products. In particular, the amendments are as follows:

- Reduction of a number of documents required for declaration of changes to wholesale prices

[1] By introducing new edition of the Procedure for Declaration of Changes to Wholesale Prices for Pharmaceuticals and Medical Products, approved by the CMU's Resolution No. 240 dated 2 July 2014.

- Cancelation of involvement of the State Price Control Inspection of Ukraine in the process of declaration of wholesale prices for pharmaceuticals
- Reduction of the term for making decision on declaring of change to wholesale price to 10 calendar days. Additionally, 2 days are envisaged for publishing relevant information on the web-site of the Ministry of Health of Ukraine (hereafter –the "Ministry")
- Adjustment of declared changes to wholesale prices due to UAH exchange rate fluctuations
- Cancellation of restriction to declare changes to wholesale prices not more than once a month. No new restriction for frequency of such declaration was set

Second, the Resolution No. 449 cancelled the differentiated levels of trade (retail) margin for pharmaceuticals and medical products (that are on the National List of Essential Pharmaceuticals and Medical Products (except for narcotic, psychotropic pharmaceuticals, precursors and medical gases) as well as on the Mandatory Minimum Range of (Socially Oriented) Pharmaceuticals and Medical Products for Pharmacy Institutions).[2]

Instead, it is established that the trade (retail) margin to purchase price for above pharmaceuticals and medical products should not exceed 25% (including taxes).

Third, the Resolution No. 449 introduced changes into the formula for calculation of wholesale prices for imported pharmaceuticals and medical products.[3]

The Resolution No. 449 is effective since 7 July 2015.

Mandatory Technical Regulations on medical products

On 1 July 2015 Technical Regulations on medical products became mandatory. The Technical Regulations were approved by the following CMU's resolutions dated 2 October 2013 (hereinafter – the "Technical Regulations"):

- Resolution "On Approval of Technical Regulation on Medical Products" No. 753
- Resolution "On Approval of Technical Regulation on Medical Products for In Vitro Diagnostic" No. 754
- Resolution "On Approval of Technical Regulation on Active Medical Products to Be Implanted" No. 755

The Technical Regulations were developed on the basis of the relevant EU directives in order to adapt the technical regulation on medical products.[4]

The Technical Regulations govern conformity assessment of medical products before their putting into circulation and before their marking with a national conformity mark.

The conformity assessment procedure depends on the characteristics and class of medical product (classes I, IIa, IIb and III). For production of class I medical products, only manufacturer's declaration on products' conformity with technical documentation, which is prepared in line with the technical regulation, is required. Conformity assessment of medical products of other classes is conducted by authorized body by reviewing the quality protocols or through the examinations.

The Technical Regulations do not apply to medical products that passed the state registration, are included to the State Register of Medical Equipment and Medical Products, and are allowed for use in Ukraine and putting into circulation and / or into operation without passing conformity assessment procedures and marking by national conformity mark:

- until 1 July 2016 - if the term of validity of the state registration certificate is unlimited or expires after 1 July 2016
- until the expiry date of the state registration certificate - if this term expires before 1 July 2016

Considering the mandatory force of the Technical Regulations, the State Fiscal Service of Ukraine (hereafter – "SFS") clarified some issues related to customs clearance of imported medical products. In particular, SFS specified documents based on which the custom clearance of such

[2] By amending the CMU's Resolution No. 955 dated 17 October 2008.
[3] By amending the Procedure on the Price Formation for Pharmaceuticals and Medical Products, approved by the CMU's Resolution No. 333 dated 25 March 2009.
[4] We refer to EU Council Directive No. 93/42/EEC dated 14 June 1993 , No. 98/79/EEC dated 27 October 1998 and No. 90/385/EEC dated 20 June 1990.

products is performed (Letter No. 23741/7/99-99-24-03-01-17 dated 2 July 2015).

State Fiscal Service clarified the procedure for determining VAT base for transactions with pharmaceuticals

SFS clarified the procedure for determining value added tax (hereafter – "VAT") base for transactions on supply of pharmaceuticals on the customs territory of Ukraine, which are allowed for production and use in Ukraine, included to the State Register of Pharmaceuticals, and which are subject to 7% VAT (Letters No. 10754/6/99-99-19-03-02-15 dated 21 May 2015 and No. 13835/6/99-99-19-03-02-15 dated 3 July 2015).

In particular, SFS underlined that VAT base for such transactions is determined based on pharmaceutical's contractual value (except for narcotic, psychotropic pharmaceuticals and medical gases) calculated considering national taxes and charges (including additional import duty) and established wholesale and trade (retail) margins.

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We will continue to monitor developments and will be happy to discuss with you any questions you may have.

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