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Newsletter

Pharmaceutical sector

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This newsletter briefly reviews certain legislation regulating the pharmaceutical sector that was approved in 2012 and takes force in 2013.

Pharmaceutical import licensing developments

The Law of Ukraine "On the Introduction of Changes to Certain Legislative Acts of Ukraine on Licensing Activity for Import Pharmaceuticals and Defining 'Active Pharmaceutical Ingredient'" No.5038-VI dated 4 July 2012 (hereinafter – the Law) foresees introduction of a pharmaceutical import licensing regime. According to the Law the regime shall take force on 1 March 2013. Starting then, import of registered pharmaceuticals into the customs territory of Ukraine must be supported with an import license issued to the importer and by a quality certificate issued by the manufacturer.

An attachment to the import license should list the pharmaceuticals that the licensee has accepted for import and the special terms according to which the activity is to be conducted. To obtain the license the importer must have the relevant material and technical base, a qualified staff and the conditions necessary to ensure quality control of pharmaceuticals imported into Ukraine. The licensing state authority will audit compliance of these criteria with the law.

As of today, a sufficient legislative base on obtaining the license's has not been yet developed. Given this, the issues connected with the pharmaceutical import licensing regime are still opened for discussions. It cannot be ruled out that introduction of the pharmaceutical import licensing regime could be postponed. We are aware on proposals to postpone this regime to 1 September 2013.

New rates for wholesale and retail trade margins

We remind readers that the Cabinet of Ministers of Ukraine approved the Decree "On Introduction of Amendments to Paragraph 1 of the Decree of the Cabinet of Ministers of Ukraine dated 17 October 2008 No.955" dated 24 September 2012 No.880 (hereinafter – Decree No.880). It takes force on 1 January 2013.

Decree No.880 has changed the rates of wholesale and retail trade margins for pharmaceuticals and medical purpose products on the National List of Main Pharmaceuticals and Medical Purpose Products (excepting narcotic and psychotropic drugs, precursors and medical gas) and for Mandatory Minimal Assortment (Social Oriented) Pharmaceuticals and Medical Purpose Products for Pharmacy Institutions as determined by the Ministry of Health of Ukraine (hereinafter – MOZ).

The table below shows the comparative rates of wholesale trade margins and retail trade margins:

<table>
<tr><th colspan="3">Wholesale trade margins</th></tr>
<tr><td colspan="2">before 01.01.2013</td><td>after 01.01.2013</td></tr>
<tr><td colspan="2">≤12% of wholesale price</td><td>≤10% of wholesale price</td></tr>
<tr><th colspan="3">Retail trade margins</th></tr>
<tr><td>before 01.01.2013</td><td colspan="2">after 01.01.2013</td></tr>
<tr><td rowspan="6">≤25% of retail price</td><td>Retail price, UAH</td><td>Margin rate</td></tr>
<tr><td>up to 100 inclusive</td><td>≤25%</td></tr>
<tr><td>from 100 to 300 inclusive</td><td>≤23%</td></tr>
<tr><td>from 300 to 500 inclusive</td><td>≤20%</td></tr>
<tr><td>from 500 to 1000 inclusive</td><td>≤15%</td></tr>
<tr><td>more than 1000</td><td>≤10%</td></tr>
</table>

Please also note that on 5 October 2012 the Order of the MOZ "On Approval of the Mandatory Minimal Assortment (Social Oriented) of Domestically Produced Pharmaceuticals and Medical Purpose Products for Pharmacy Institutions" No.1000 dated 29 December 2011 was changed. The words "Domestically Produced" were excluded from the header of this order; consequently, foreign pharmaceuticals were included in the Mandatory Minimal Assortment, meaning that the amount of pharmaceuticals covered by statutory price control increased.

Obtaining local confirmation of compliance with GMP

Decree of the Cabinet of Ministry of Ukraine No.793 dated 8 August 2012 (hereinafter - Decree No.793) has amended the Order of the Statutory Control of the Quality of Pharmaceuticals Imported into Ukraine.

The list of documents that the business entities must submit to obtain a conclusion about the quality of imported pharmaceuticals has now changed. Starting 1 January 2013 importers of pharmaceuticals have a five-day period after the execution of customs formalities pertaining to pharmaceutical cargo to file with the local state authority a copy of the document confirming compliance with the terms of pharmaceutical production in Ukraine (with Good Manufacturing Practice (GMP)).

According to letter of the State Service of Ukraine on Pharmaceuticals No.23050-1.1/3.1/17-12 dated 1 November 2012 such a document can be (i) a conclusion confirming compliance with the requirements of good manufacturing practice (if a certificate issued by the authorized regulatory authority of a country-member of PIC/S is provided) or (ii) a GMP certificate.

To the best of our knowledge the term by 1 January 2013 is not sufficient for the most international producers to comply with the new requirements and to obtain local confirmation of GMP compliance.

Given this the MOZ working group and public business association representatives have initiated postponement of implementation of this provision until 1 July 2013.

Excluding medical equipment from the list of goods subject to mandatory certification in Ukraine

Order of the Ministry of Economic Development and Trade of Ukraine No.162 dated 25 October 2011 "On Introducing Amendments to the List of Goods Subject to Mandatory Certification in Ukraine" has excluded Section 8 "Medical Equipment" from the list. The changes take force on 1 January 2013.

Starting then, inter alia, customs clearance of medical equipment must take place without the filing of a conformity certificate (a certificate on recognition of conformity).

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We will be glad to answer any of your questions about these topics.

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