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Pharmaceutical Sector

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Law on state procurement of pharmaceuticals and medical products involving specialized organizations adopted

On 19 March 2015 the Verkhovna Rada of Ukraine adopted the Law of Ukraine "On Amending Certain Laws of Ukraine (Regarding Providing Patients with Timely Access to Necessary Pharmaceuticals and Medical Products for Budget Funds Involving Specialized Organizations Performing Purchases)" (hereinafter - "Law"). The Law was adopted on the basis of the draft law registered under No.2150 on 17 February 2015.

The Law regulates a number of issues relating to purchase of pharmaceuticals and medical products for state and local budget funds (hereinafter - "Pharmaceuticals" and "Medical Products") involving international specialized funds, organizations and mechanisms of the United Nations, the International Dispensary Association, the Crown Agents, the Global Drug Facility and the Partnership for Supply Chain Management (hereinafter - "Specialized Organizations").

The Law envisages, inter alia, the following:

- ▶ Introduction of a separate procedure for purchase of pharmaceuticals and medical products based on agreements with Specialized Organizations and in accordance with their internal rules and procedures without application of the procurement procedures established by the Law of Ukraine "On Public Procurement"

- ▶ Introduction of a simplified and free-of-charge procedure for registering pharmaceuticals purchased through Specialized Organizations
- ▶ Treatment of pharmaceuticals and medical products purchased through Specialized Organizations as vital products with the purpose of exempting them from additional import duty
- ▶ Shortened term for registration of pharmaceuticals purchased through Specialized Organizations, i.e., 14 business days (not more than seven business days to examine registration materials and not more than seven business days to approve or refuse registration)

If the President of Ukraine signs the Law it will take force on the day when it is officially published and will remain effective until 31 March 2019.

Please note that our comments are based on the text of the draft Law available in official sources as of today. Should the final edition of the Law contain rules different from those that we have outlined above, we will update you in due course.

Changes to procedure of state registration (re-registration) of pharmaceuticals adopted

On 18 March 2015 the Cabinet of Ministers of Ukraine (hereafter - "CMU") adopted a Resolution amending the Procedure for State Registration (Re-registration) of Pharmaceuticals and Fees of State Registration (Re-registration) approved by CMU Resolution No. 376 dated 26 May 2005.

As of today the CMU Resolution of 18 March 2015 has not been published. To the best of our knowledge this Resolution foresees, inter alia, the following:

- ▶ Simplification of the procedure for state registration of pharmaceuticals used for treatment of tuberculosis, HIV/AIDS, viral hepatitis, cancer and rare (orphan) diseases if these pharmaceuticals are registered by a competent body of the United States of America, Switzerland, Japan, Australia, Canada or the European Union
- ▶ After registration the term for the use of the pharmaceutical in Ukraine will not be limited, except in cases indicated in the list of grounds for a decision on the absolute or temporary prohibition of use of pharmaceuticals by the terminating of its registration certificate

VAT exemption of supply of pharmaceuticals and medical products purchased through specialized organizations proposed

On 17 February 2015 the draft Law of Ukraine "On Amending the Tax Code of Ukraine (Regarding Exemption of Import and Supply of Pharmaceuticals and Medical Products from Value Added Tax)" (hereafter - "Draft") was registered with the Verkhovna Rada under No. 2151.

The Draft foresees extension of the list of transactions that are exempt from value added tax (VAT). According to the Draft, the following transactions should be on this list: supply of pharmaceuticals listed in the State Register of Pharmaceuticals, supply of medical products listed in the State Register of Medical Equipment and Medical Products and/or released into circulation according to the law in the area of technical regulation and conformity assessment, based on agreements executed between suppliers of those pharmaceuticals and medical products and specialized organizations performing purchases, according to the definition established in the Law of Ukraine "On Public Procurement," if these agreements are made in order to fulfill the purchase contract between the central executive body of Ukraine that realizes the state health protection policy and the relevant specialized organization performing purchases.

As of today the Draft is on the agenda. To the best of our knowledge, the Verkhovna Rada will consider it in the nearest future.

Amendments to procedure for declaration of change of wholesale prices for pharmaceuticals and medical products planned

Ukraine's Minister of Health held a briefing meeting on 17 March 2015. The meeting was devoted to developments in and prospects for reforming the pharmaceutical sector. The issues discussed during the meeting included, among others, the unstable UAH exchange rate and the inefficient current Procedure for Declaration of Changes to Wholesale Prices for Pharmaceuticals and Medical Products, approved by CMU Resolution No. 240 dated 2 July 2014 "On Referential Pricing for Pharmaceuticals and Medical Products Purchased with Funds of State and Local Budgets" (hereafter - "Resolution No. 240").

During the meeting the proposal was made to cancel Resolution No. 240 and to approve a new, more liberal and flexible, mechanism for declaring changes to wholesale prices for pharmaceuticals and medical products.

However, as of today the Resolution No. 240 remains in force and the draft CMU Resolution "On Amending the Resolution of the Cabinet of Ministers of Ukraine No. 240 dated 2 July 2014" (hereafter - "Draft") has been placed on the official website of the Ministry of Health. The Draft was brought up for public discussion on 5 March 2015.

The Draft foresees the possibility of declaring changes to the wholesale price for a pharmaceutical or for a medical product in the national and in foreign currency with indication of the official National Bank of Ukraine exchange rate as of the date of the submitting of the wholesale price change declaration. Hence, the Draft means to regulate the declaration of wholesale price for foreign products not only in the national currency but in foreign one as well.

According to the information available to us, the Draft is at the discussion stage and the CMU has not yet considered it.

Establishment of 15% wholesale margin for pharmaceuticals and medical products proposed

On 13 March 2015 the draft Law of Ukraine "On Establishment of Ceiling Trade Margins for Certain Product Groups" (hereafter - "Draft") was registered with the Verkhovna Rada of Ukraine under No. 2368.

The Draft suggests establishing a ceiling trade and wholesale margin upon sale of pharmaceuticals and medical products to end customers at 15% of the wholesale domestic manufacturer price irrespective of the number of re-sale transactions.

As regards pharmaceuticals and medical products that are imported into Ukrainian customs territory, the Draft proposes establishing a ceiling trade and wholesale margin at 15% of customs value.

Also, the Draft suggests amending Article 13 of the Law of Ukraine "On Prices and Pricing" to include the Verkhovna Rada on the list of bodies responsible for state price regulation.

If the Draft is adopted, the law should take force on the day following the day of its publication.

As of today the Draft has been provided to the Verkhovna Rada for consideration.

Changes to license terms for production, wholesale and retail trade of pharmaceuticals adopted

We would like to remind you that the Order of the Ministry of Health of Ukraine (hereafter - "Ministry") No. 990 dated 22 December 2014 (hereafter - "Order No.990") took force on 20 February 2015.

The order foresees amendments to the License Terms for Production, Wholesale and Retail Trade of Pharmaceuticals, approved by the Ministry's Order No. 723 dated 31 October 2011 (hereafter - "License Terms") and to the Procedure for Examination Before Issuing a License for Conduction of Business Activity on Production, Wholesale and Retail Trade in Pharmaceuticals, approved by Ministry Order No. 513 dated 11 July 2012.

Order No. 990 establishes, inter alia, the following:

- ▶ Pharmacy institutions can store pharmaceuticals and related products that they do not own on their premises, provided that the License Terms are met
- ▶ Provisions according to which a pharmacy kiosk can be a subdivision of a pharmacy institution are excluded from the Licensing Terms
- ▶ The qualification requirements for employees engaged in the production of pharmaceuticals (in pharmacies), wholesale and retail trade are amended

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

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