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Healthcare

Newsletter | May 2017

Welcome to the May edition of the Baker McKenzie Ukraine Healthcare Industry Group Newsletter. This is your regular digest of legal developments affecting the life science and healthcare industries in Ukraine.

This edition covers, among other issues, pharmaceutical procurement in 2017 by specialized procurement agencies, the law on autonomization of healthcare institutions, abolishment of bylaws on licensing healthcare activities' use of foreign evidence-based clinical protocols. More details on these and other developments in the Ukrainian life science and healthcare industries are described below.

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In This Issue

Baker McKenzie named Law Firm of the Year in Medicine and Pharmaceutical Law by Ukrainian legal awards

Baker McKenzie has received three awards, including Law Firm of the Year in Medicine and Pharmaceutical Law at the 11th Annual Ukrainian Legal Awards Ceremony held in Kyiv on 17 May 2017. To see full press release, please follow the link.

Sanctions and Compliance

Baker McKenzie Webinar: the latest on compliance, sanctions and trade restrictions in Ukraine

On 25 April 2017, the Kyiv office of Baker McKenzie held a client webinar addressing compliance, sanctions and trade restrictions in Ukraine. In particular, the seminar covered the issue of implementing efficient compliance programs in Ukraine and Ukrainian sanctions and trade restrictions. You can access the recording of the webinar by clicking here. To download the presentation files, please click here.

US - OFAC updates list of medical supplies for Ukraine-related sanctions

On 23 May 2017, the Office of Foreign Assets Control ("**OFAC**") published a notice in the Federal Register with the updated list of items defined as medical supplies and generally licensed for exportation or re-exportation to the Crimea region of Ukraine pursuant to General License 4 under Executive Order 13685 of 19 December 2014, which is part of OFAC's Ukraine-related sanctions program. More details can be found here.

Currency Control Restrictions

Ukrainian Central Bank Continues to Relax Currency Control Restrictions

On 26 May 2017, the National Bank of Ukraine relaxed some of the temporary currency control restrictions that were imposed to stabilize the Ukrainian foreign exchange market, namely:

- 180-Day Settlement Rule
- Repatriation of Investment Proceeds
- Cross-Border Lending

For more details, please refer to our legal alert.

Public Procurement

Procurement via specialized procurement agencies in 2017

On 19 April 2017, the Cabinet of Ministers of Ukraine (the "**CMU**") approved Regulation No. 263-p "On Procurement of Pharmaceuticals, Medical Devices and Related Services by Engaging Specialized Procurement Agencies". By approving the abovementioned regulation, the CMU obliged the Ministry of Health of Ukraine (the "**MOH**") to ensure that procurement of pharmaceuticals, medical devices and related services with the state budget funds allocated to centralized healthcare activities is conducted through specialized procurement agencies.

As a reminder, as of 2015, centralized procurement of pharmaceuticals and medical devices has been conducted in Ukraine through the temporary mechanism of engaging specialized procurement agencies (ie, Crown Agents, UNICEF, UNDP).

Revised list of pharmaceuticals allowed for public procurement

On 5 April 2017, the CMU approved Order No. 368, which amends the list of pharmaceuticals produced domestically and abroad that can be purchased by healthcare institutions using full or partial financing from state or municipal funds (approved by CMU Resolution No. 1071, dated 5 September 1996). Specifically, several INNs have been added to this list. This order will become effective upon its official publication.

As reported in our previous legal alert, the abovementioned list should be cancelled as of 1 July 2017, and healthcare institutions financed with state or municipal budget funds will only be entitled to procure pharmaceuticals included in the National Essential Medicines List (with certain exceptions).

Draft procedure for calculating the demand for pharmaceuticals by healthcare institutions

On 24 April 2017, the MOH published for public discussion a draft procedure for calculating the demand for procurement of pharmaceuticals by healthcare institutions partly or wholly financed with state or municipal budget funds (the "**Draft Procedure**").

The Draft Procedure was developed to implement the requirements of CMU Regulation No. 152 "On Ensuring the Affordability of Pharmaceuticals" dated 17 March 2017, described previously in our legal alert. Based on this regulation, as of 1 July 2017, healthcare institutions financed with state or municipal budget funds will not be able to procure pharmaceuticals not included in the National Essential Medicines List (the "**NEML**"). Pharmaceuticals not included in the NEML may be procured when the full demand for pharmaceuticals listed in the NEML is satisfied. The scope of such demand should be determined in accordance with the Draft Procedure.

The Draft Procedure outlines the stages and methods for calculating the demand for pharmaceuticals. Specifically, it is proposed that healthcare institutions should use the methods of quantitative estimates (based on disease rates and/or consumption rates). The disease rate is recommended for planning public procurement, while the consumption rate is recommended for reimbursement.

The Draft Procedure will not apply to procurement procedures conducted using the approved budget allocations for the period of 1 July 2017 - 31 December 2017. Based on the public statements of MOH representatives, this provision will allow for procurement of non-NEML pharmaceuticals until the end of 2017, thus preventing the shortage of necessary non-NEML pharmaceuticals in healthcare institutions.

Healthcare Organizations

The Law on autonomization of healthcare institutions

On 6 April 2017, the Parliament of Ukraine adopted Law No. 2002-VIII "On Amending Certain Legislative Acts of Ukraine regarding Improvement of Legislation Governing Issues of Healthcare Institutions Activities" (the "**Law**").

Among other things, the Law provides for the following changes:

- possibility of reorganizing state and municipal healthcare institutions — budget organizations — into state non-commercial (*kazenny*) enterprises or municipal non-commercial enterprises (with exceptions for certain healthcare institutions of the Ministry of Defense of Ukraine, etc.)
- introducing a competitive process preceding the appointment of heads of state and municipal healthcare institutions
- detailing the requirements to agreements on medical care entered into between healthcare institutions and public-fund administrators
- possibility for healthcare institutions to provide medical services outside the scope of the abovementioned agreements based on separate fees

The Law will be enacted as of 6 November 2017, except for the provision concerning the financing of healthcare institutions, which will become effective as of 1 January 2017.

The MOH expects the reorganization of healthcare institutions to provide more autonomy in terms of budgeting and governance, and hopes that it will foster their commitment to provide a higher level of medical services.

Licensing Conditions

Abolishment of bylaws on licensing healthcare activities

On 21 May 2017, CMU Regulation No. 169-p dated 10 March 2017 (the "**Regulation**") became effective. Based on the Regulation, the following MOH orders were declared invalid:

- No. 724 dated 31 October 2011 "On Approval of the Procedure for Control Over Compliance with License Terms for Conducting Business Activities on Manufacturing, Wholesale, Retail Trade with Pharmaceuticals"
- No. 80 dated 10 February 2011 "On Approval of the Procedure for Control Over Compliance with License Terms for Conducting Certain Types of Licensed Business Activities in the Healthcare"
- No. 513 dated 11 July 2012 "On Approval of the Procedure for Inspection Before Issuing the License for Business Activities on Manufacturing, Wholesale, Retail Trade with Pharmaceuticals"
- No. 168 dated 27 February 2013 "On Approval of the Procedure for Inspection Before Issuing the License for Business Activities on Import of Pharmaceuticals"
- No. 244 dated 28 March 2013 "On Approval of the Procedure for Control Over Compliance with License Terms for Conducting Certain Types of Business Activities and of the Unified Acts Drawn Up Based On Results of Planned Inspections over Compliance with Certain Types of Licensed Business Activities in Healthcare by the Business Entity"
- No. 835 dated 26 September 2013 "On Approval of the Procedure for Control Over Compliance with License Terms for Conducting Business Activities on Import of Pharmaceuticals"

These orders were declared invalid as they are deemed non-complaint with the Law of Ukraine "On Main Principles of State Control (Surveillance) in the Area of Business Activities." Control over compliance with the licensing conditions will be performed based on the Law of Ukraine "On Main Principles of State Control (Surveillance) in the Area of Business Activities" and the Law of Ukraine "On Licensing Types of Business Activities."

Clinical Protocols

Use of foreign evidence-based clinical protocols in Ukraine

On 28 April 2017, changes to the Methodology of Development and Implementation of Medical Standards (Unified Clinical Protocols) of Medical Aid Grounded on Evidence-Based Medicine approved by MOH Order No. 751 dated 29 December 2016 became effective.

The changes provide for the possibility to use evidence-based clinical protocols selected by the MOH from a list without adjusting these protocols to the Ukrainian healthcare system's specifics. These clinical protocols may be approved by the MOH either as a text of a new protocol translated into Ukrainian or as a reference to the source of its publication in English. The MOH may approve the new clinical protocol if, among other things, it was developed by a national/profile medical association of an EU member, USA, Australia or Canada.

If the new clinical protocol is translated into Ukrainian and approved by the MOH, and there is no unified clinical protocol, use of the new clinical protocol is mandatory. If the new clinical protocol is set forth in English, the new clinical protocol may be used at the discretion of the healthcare institution (based on an internal order). If a new clinical protocol and the unified clinical protocol both exist, the new clinical protocol may be used subject to patient consent following a doctor's explanation of the differences between the two protocols, and if the use of the new protocol excludes the use of the unified protocol.

These changes are expected to enhance the level of medical services provided in Ukraine by facilitating patient access to treatment with the use of evidence-based clinical protocols.

Intellectual Property

Intermediaries now liable for third party online copyright infringements in Ukraine

On 20 April 2017, the draft law "On State Support of Cinematography in Ukraine" was signed into law by the President of Ukraine. It entered into force on 6 May 2017. Besides its main goal to regulate and support funding and production of Ukrainian motion pictures, the law also introduces, for the first time in Ukrainian history, a secondary liability regime for third party copyright and related rights infringements and a set of rules aimed at easing online enforcement. For more details, please refer to our legal alert.

State Intellectual Property Service of Ukraine is finally liquidated: what`s new for business?

By adopting Decree No. 320 (on May 11, 2017, effective as of May 18, 2017), the Cabinet of Ministers of Ukraine launched the next phase of the ongoing IP reform outlined in the Concept for Reforming the State Intellectual Property System in Ukraine (the "Concept") approved earlier (more on the IP reform here). This phase finalizes liquidation of the State Intellectual Property Service (SIPS) and transfer of all its functions to the Ministry of Economic Development and Trade of Ukraine (MEDT). For more details, please follow the link.

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The MapApp: Laws and Regulations

Baker McKenzies "MapApp" is a mobile application that provides access to real-time information on the laws and regulations impacting the healthcare industry, in a country-by-country format.

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