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Healthcare

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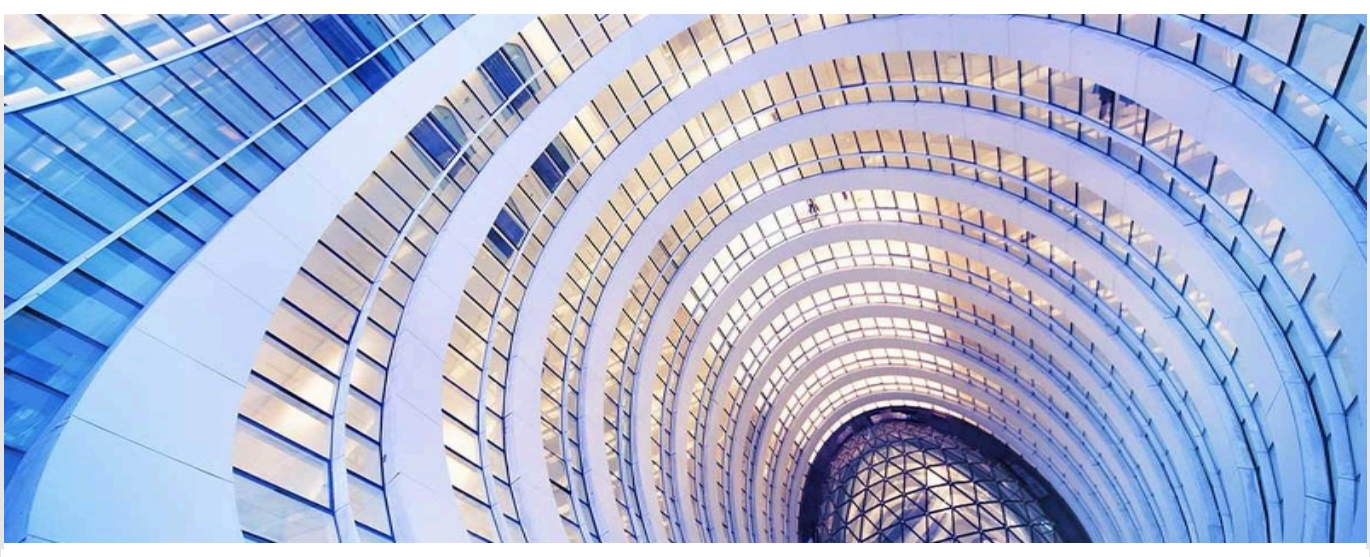

Welcome to the July edition of the Baker McKenzie Ukraine Healthcare Industry Group Newsletter. This is your regular digest of legal developments affecting the life science and healthcare industries in Ukraine.

This edition covers changes in the regulation of public procurement of pharmaceuticals, including changes that postpone procurement based on the National Essential Medicines List, approval of the list of products to be procured by the specialized procurement agencies in 2017, and update of the reimbursement register. This edition also covers proposed changes in the state registration of pharmaceuticals, adoption of rules for determining the cost of works on conformity assessment and the simplification of the procedure for issuing work permits and temporary residence permits for foreign nationals. More details on these developments affecting the Ukrainian life science and healthcare industries are provided below.

In This Issue

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Public procurement and reimbursement of pharmaceuticals

Procurement based on the National Essential Medicines List postponed

On 4 July 2017, the Cabinet of Ministers of Ukraine (the "**CMU**") adopted the Resolution No. 547 (the "**Resolution**") providing for substantial changes to the rules for procurement of pharmaceuticals stipulated in Regulation of CMU No. 333 dated 25 March 2009. For previous draft version of this Resolution, please refer to our newsletter for June. The changes include:

1. introduction of the possibility for healthcare institutions to finalize the procurement procedures initiated before 1 September 2017, in accordance with the procedures that were effective before this date
2. until 1 January 2018, delay of the provision allowing healthcare institutions to only procure registered medicines not included in the National List of Essential Medicines (the "**NEML**") when the full demand for pharmaceuticals listed in the NEML is satisfied
3. a number of technical amendments to the NEML

The Resolution became effective on 26 July 2017.

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List of products to be procured by the specialized procurement agencies in 2017 is adopted

On 12 July 2017, the CMU approved the list of pharmaceuticals and medical devices to be procured by the specialized procurement agencies in 2017. This list includes pharmaceuticals and medical devices divided into 23 areas.

On 27 July 2017, the MOH signed the procurement agreements for 2017 with specialized procurement agencies (Crown Agents, United Nations Development Program and UNICEF). It is expected that the MOH will shortly announce which specific procurement areas will be assigned to each of the engaged agency.

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Update of the reimbursement register

As set out in the Procedure for Calculating the Reimbursement Amount of Reimbursable Pharmaceuticals adopted by CMU Regulation No. 152 dated 17 March 2017, the MOH should update the register of wholesale prices for reimbursable pharmaceuticals, ie, pharmaceuticals within the list of 21 INNs for treating cardiovascular diseases, type II diabetes and asthma (the "**Reimbursement Register**"), twice a year — as of 1 January and as of 1 July.

On 26 July 2017, the MOH updated the Reimbursement Register by approving the order No. 856. The updated Reimbursement Register includes 199 pharmaceuticals (the previous version of the Reimbursement Register contained 157 pharmaceuticals).

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State registration of pharmaceuticals

Draft changes to the simplified procedure of state registration for pharmaceuticals registered by stringent regulatory authorities

On 24 July, the MOH published a draft Order on amending MOH Order No. 1245 "On Reviewing the Registration Materials for Pharmaceuticals Submitted for the State Registration (Re-Registration), and Materials for Variation of the Registration Materials During the Validity of the State Registration Certificate for Pharmaceuticals Registered by the Competent Authorities of the United States of America, Switzerland, Japan, Australia, Canada, Pharmaceuticals Registered under the Centralized Procedure by the Competent Authority of the European Union" dated 17 November 2016. This Order provides for a simplified and expedited procedure to register pharmaceuticals that were registered in the abovementioned countries.

The purpose of the changes is to enhance the current procedure of state registration for pharmaceuticals registered in the USA, Switzerland, Japan, Australia, Canada or the EU (see our previous newsletter) to encourage companies to use it for launching new products on the Ukrainian market.

The changes stipulated in the Draft include the following:

- the possibility to re-register the pharmaceutical under the simplified procedure
- the possibility for Ukraine's State Expert Center of the Ministry of Health to request additional documents or information during the review of submitted materials
- clarifications regarding the following issues:
  - the entity that shall be indicated as the manufacturer of the pharmaceutical during the registration (re-registration) and variations;
  - the entity that shall be indicated as the manufacturer on the product package;
  - product packages of the pharmaceutical that may be submitted for state registration under the simplified procedure;
  - the title of the pharmaceutical that may be submitted for state registration under the simplified procedure;
  - permissible variations in the title of the manufacturer indicated in the application for state registration compared to the title of the manufacturer in the reference country, which should not result in registration denial; and
  - the language of documents to be submitted by the applicant.

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Medical devices

Rules for determining the cost of works on conformity assessment were adopted

On 12 July 2017, the CMU adopted Regulation No. 514 on Approval of the Rules for Determining the Cost of Works on Assessment of Conformity with Requirements of Technical Regulations, Performed by the Appointed Conformity Assessment Bodies and Recognized Independent Organizations (the "**Rules**").

The Rules set out the formula for calculating the cost of works on assessment of conformity with requirements of technical regulations, performed by the appointed conformity assessment bodies and recognized independent organizations (the "**Cost of Works**"). The Cost of Works should be calculated based on, among other things, the cost of the estimated time unit. The latter should be calculated considering the net cost, revenue and the worktime fund of the performer of conformity assessment works. No maximum thresholds for revenue of the performer of conformity assessment works are established in the Rules.

The Rules also specify that the Cost of Works may include expenses related to the purchase of specific materials, component parts, business trips of the performers, transport and customs duties, etc. if such expenses are confirmed with documentary evidence. The existence of such expenses should be agreed between the customer and the performer of works before the performer proceeds to work. The cost of the estimated time should be revised not more often than once a year.

The Rules are expected to provide guidance and more transparency on establishing the Cost of Works, the reasonableness of which has been questioned by medical devices companies.

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Employment law

Procedure for issuing work permits for foreign nationals and temporary residence permits is simplified

On 27 September 2017, Law of Ukraine No. 2058-VIII "On Amendments to Certain Legislative Acts of Ukraine On Eliminating Barriers to Foreign Investments" dated 23 May 2017 (the "**Law**") will come into effect.

Among other things, the Law: (i) extends the list of grounds for applying for a temporary residence permit ("**TRP**"); (ii) amends the application documents for a work permit issued for employment of foreign nationals and stateless persons ("**Work Permit**"); (iii) extends the terms of the Work Permit and the TRP; (iv) establishes the minimum salary that must be paid to certain categories of foreign employees; and (v) provides for an option to amend the Work Permit. To read the full legal alert, please follow this 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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equivalent, in such a law firm. Similarly, reference to an "office" means an office of any such law firm.