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Healthcare

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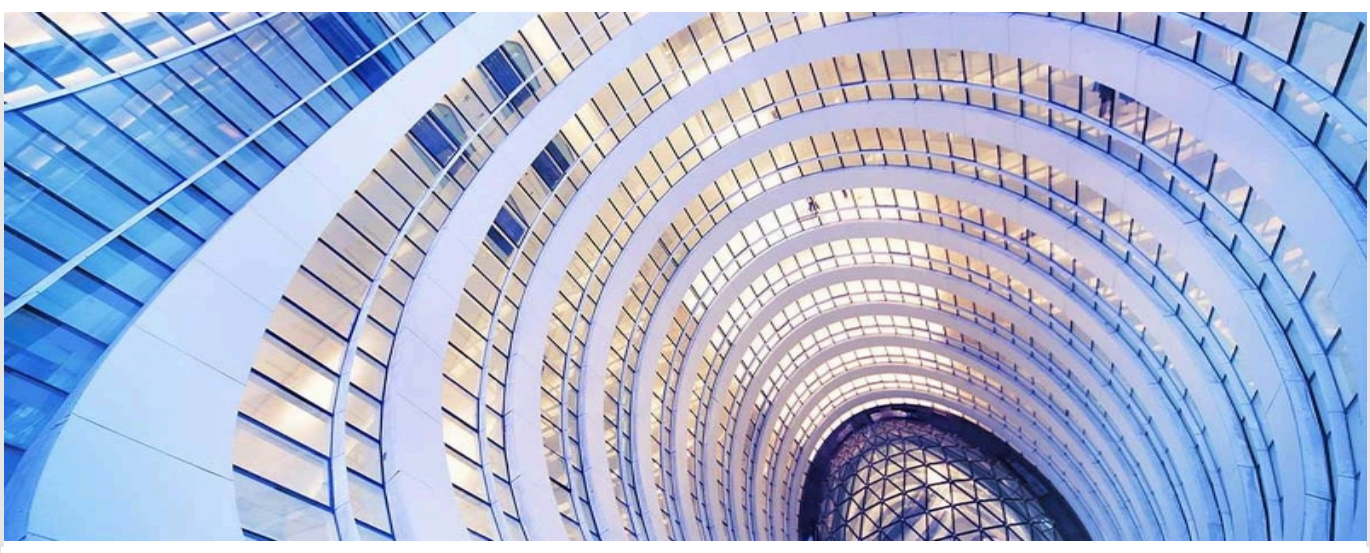

Welcome to the September edition of the Baker McKenzie Ukraine Healthcare Industry Group Newsletter. This is your regular digest of legal developments affecting the life science and healthcare industries in Ukraine.

This edition covers changes in the regulation of public procurement of pharmaceuticals, including changes that suspend procurement based on the National Essential Medicines List, and an update of the list of pharmaceuticals to be procured by specialized procurement agencies. This edition also covers an update of the register of reference (reimbursement) prices for insulin preparations, implementing bylaws regarding inspections of compliance with licensing conditions and expected changes to migration laws by the end of 2017. 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 of pharmaceuticals

Suspension of procurement based on the National Essential Medicines List

On 27 September 2017, the Cabinet of Ministers of Ukraine (the "**CMU**") adopted resolution No. 718 on "Certain Issues of Pharmaceuticals' Procurement" (the "**Resolution**"). The Resolution became effective on 30 September 2017.

The Resolution suspends procurement based on the National List of Essential Medicines (the "**NEML**"), which became effective on 25 March 2017. This is yet another bylaw aimed at prevention of interruption of patients' treatment with pharmaceuticals not included in the new NEML (the previous draft order described in the August issue of our newsletter has not been adopted by the CMU despite the public reports). The Resolution suspends the following until 31 December 2017:

1. Obligation of healthcare institutions to only procure NEML-listed pharmaceuticals
2. Obligation of healthcare institutions to satisfy full demand for NEML-listed pharmaceuticals before procuring non-NEML pharmaceuticals
3. Patients' free and preferential access to NEML-listed pharmaceuticals only (such access is guaranteed by the state under CMU regulation No. 1303 "On Regulation of Free and Preferential Access to Pharmaceuticals" dated 17 August 1998)

Until 31 December 2017, healthcare institutions are allowed to procure and provide patients with any registered pharmaceuticals, irrespective of their inclusion in the NEML.

Amended list of pharmaceuticals to be procured by specialized procurement agencies

On 23 August 2017, the CMU adopted Resolution No. 655 "On Amending the List of Pharmaceuticals and Medical Devices that Are Procured based on Procurement Agreements with Specialized Procurement Agencies with the Budget Funds Allocations in 2017 under the Budget Program 2301400 'Ensuring Medical Activities of Certain State programs and Complex Program Measures'" as approved by CMU Regulation No. 494 dated 12 July 2017 (the "**List**").

The List was supplemented with a number of pharmaceuticals and medical devices for treating pulmonary arterial hypertension and cardiovascular diseases, and performing blood donation and peritoneal dialysis, etc. As reported in our July newsletter, on 27 July 2017, the MOH signed procurement agreements for 2017 with specialized procurement agencies (Crown Agents, United Nations Development Program and UNICEF).

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Reference pricing and reimbursement

Updated register of reference (reimbursement) prices for insulin preparations and launch of the register of patients requiring insulin therapy

Based on order of the Ministry of Health of Ukraine (the "**MOH**") No. 359 "On Approval of the Regulation on Register of Reference (Reimbursement) Prices for Insulin Preparations and the Procedure for Calculation of Reference (Reimbursement) Price for Insulin Preparations" dated 13 April 2016, the MOH should update the Register of Reference (Reimbursement) Prices for Insulin Preparations twice a year — as of 1 February and as 1 August of the current year.

In compliance with the above requirement, on 4 September 2017, the MOH adopted the new version of the Register of Reference (Reimbursement) Prices for Insulin Preparations as of 1 August 2017, which includes 70 insulin preparations.

Furthermore, on 29 August 2017, the MOH announced that it has launched an electronic register of patients requiring insulin therapy in most Ukrainian regions. The register currently includes 174,000 patients.

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Licensing conditions

Implementing bylaws regarding inspections of compliance with licensing conditions

On 7 July 2017, by its order No. 759, the MOH approved bylaws required for conducting inspections of compliance with Licensing Conditions for Conducting Business Activities on Manufacturing, Wholesale and Retail Trade in Pharmaceuticals, Import of Pharmaceuticals (save for active pharmaceutical ingredients). New Licensing Conditions for Conducting Business Activities on Manufacturing, Wholesale and Retail Trade in Pharmaceuticals, Import of Pharmaceuticals (save for active pharmaceutical ingredients) became effective on 20 December 2016. In particular, the MOH approved templates of inspection acts to be drawn up by the State Service of Ukraine on Pharmaceuticals and Control of Narcotics based on results of scheduled (unscheduled) surveillance (control) measures of business entities' compliance with requirements of the Licensing Conditions for Conducting Business Activities on Manufacturing, Wholesale and Retail Trade in Pharmaceuticals, Import of Pharmaceuticals (save for active pharmaceutical ingredients). Specifically, the following templates were adopted:

1. The act to be adopted based on results of scheduled (unscheduled) surveillance (control) measures of business entities' compliance with requirements of the Licensing Conditions for Conducting Business Activities on Manufacturing, Wholesale and Retail Trade in Pharmaceuticals, Import of Pharmaceuticals (save for active pharmaceutical ingredients).
2. The act based on which a decision on license cancellation should be adopted.

The order became effective on 5 September 2017. The officials of the State Service of Ukraine on Pharmaceuticals and Control of Narcotics must use the approved templates when inspecting business entities for compliance with Licensing Conditions for Conducting Business Activities on Manufacturing, Wholesale and Retail Trade in Pharmaceuticals, Import of Pharmaceuticals (save for active pharmaceutical ingredients). As reported in our January newsletter, based on the Law of Ukraine "On Special Aspects of Conducting State Surveillance (Control) Measures in the Area of Business Activity" No. 1726-VIII, a moratorium on scheduled inspections of business entities is effective until 31 December 2017.

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Migration laws

Expected changes to migration laws by the end of 2017

On 2 September 2017, Decree of the President of Ukraine No. 256/2017, dated 30 August 2017, enacted the National Security and Defense Council of Ukraine's decision "On Strengthening Control over Entry into Ukraine and Departure from Ukraine of Foreign Nationals and Stateless Persons, Compliance with Rules of Stay in Ukraine" dated 10 July 2017 (the "**Decision**").

The Decision obliges the CMU to introduce significant changes to the existing regulations and, in particular, to necessitate the use of a biometric passport for entry into Ukraine. To learn more about this development, 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.