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Healthcare

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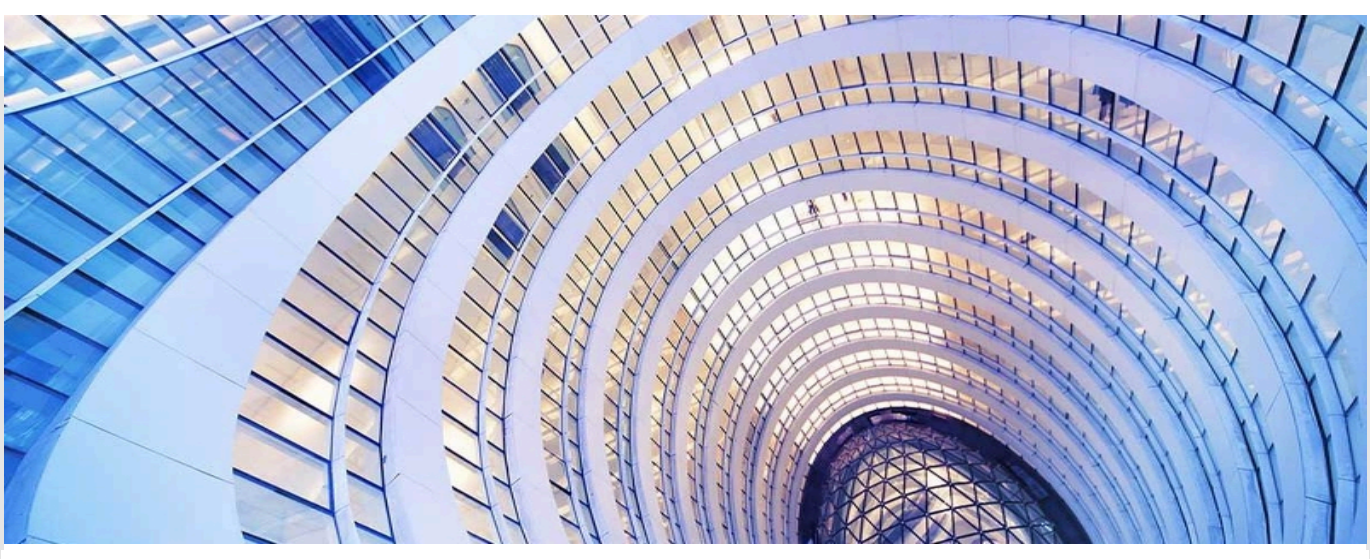

Welcome to the August edition of the Baker McKenzie Ukraine Healthcare Industry Group Newsletter. This is your regular digest of legal developments affecting the life science and healthcare industries in Ukraine.

This edition covers changes in the regulation of public procurement of pharmaceuticals, including changes that further extend the transition period for procurement based on the National Essential Medicines List, and establishment of the central procurement agency. This edition also covers changes in the list of orphan diseases, the comments of the regulator regarding the format of the conformity assessment body identification number for medical devices and the new requirements on reporting about donations received by healthcare organizations. 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

Transition period for procurement based on the National Essential Medicines List will be further extended

On 10 August 2017, the Ministry of Health of Ukraine (the "**MOH**") published the draft resolution of the Cabinet of Ministers of Ukraine (the "**CMU**") "On Amending Regulations of the Cabinet of Ministers of Ukraine dated 25 March 2009 No. 333 and 17 August 1998 No.1303" (the "**Draft**"). The Draft aims to introduce changes in the public procurement of pharmaceuticals and ensure free access to pharmaceuticals through pharmacies. The changes provide for yet another extension of the transition period for switching to procurement based on the National List of Essential Medicines (the "**NEML**"), which became effective on 25 March 2017. The previous timelines for implementing procurement based on the NEML were described in our July Newsletter. The new timelines stipulated in the Draft are as follows:

1. Until 1 January 2018, healthcare institutions will be allowed to procure registered pharmaceuticals not included in the NEML.
2. As of 1 January 2018, healthcare institutions will be allowed to procure registered pharmaceuticals not included in the NEML only when the full demand for pharmaceuticals listed in the NEML is satisfied. The procedure for calculating the demand for pharmaceuticals by healthcare institutions has not been approved (to learn more about the draft procedure, see our May newsletter).

Furthermore, as noted in our July Newsletter, procurement procedures initiated before 1 September 2017 can be finalized in accordance with the procedures that were effective before this date (eg, including procurement of pharmaceuticals not included in the NEML).

On a separate note, starting from 1 July 2017, obtaining pharmaceuticals at no charge through pharmacies is now only applicable to NEML-listed pharmaceuticals. 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. Previously, patients could receive pharmaceuticals that were listed in CMU Resolution No. 1071 "On the Procedure for Procurement of Pharmaceuticals by Healthcare Institutions Financed by the Budget," dated 5 September 1996, for free. As of 1 July 2017, CMU Resolution No. 1071 was abolished. As many pharmaceuticals listed in CMU Resolution No. 1071 were not included in the NEML, patients' access to such pharmaceuticals may be in jeopardy. To prevent any interruption of patients' treatment with such pharmaceuticals, the Draft provides for the temporary possibility, until 1 January 2018, for patients to obtain registered medicines not included in the NEML at no charge. As of 1 January 2018, free and preferential access will only be applicable to registered pharmaceuticals included in the NEML. Such access to non-NEML pharmaceuticals will only be allowed when the full procurement demand for pharmaceuticals listed in the NEML is satisfied.

It has been reported in the news that the CMU approved the Draft on 23 August 2017, but the official text of the approved resolution is not available yet. We will inform you once the official text is published.

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Establishment of the central procurement agency

On 23 August 2017, the CMU approved the Concept of Reforming Mechanisms for Public Procurement of Pharmaceuticals and Medical Devices by Regulation No. 582-p (the "**Concept**").

The Concept provides for the establishment of the central procurement agency (the "**Agency**"), which should be created by and be accountable to the MOH. Based on the Concept, the Agency will be established in the second half of 2017 and will assume the procurement function in 2018 (there is no indication of a specific date).

The Agency will ensure the procurement of pharmaceuticals and medical devices on the national, local and international levels as well as procurement from foreign suppliers and importing pharmaceuticals, if necessary. The Agency will use the electronic procurement system.

The establishment of the Agency is expected to ensure sustainable procurement by means of, among other things:

1. consolidation of procurement volumes
2. long-term procurement planning and use of long-term agreements
3. unification and transparency of procedures for (i) the selection of pharmaceuticals allowed to be procured and (ii) preparation of the bidding documentation and format of the request for procurement submitted by the budget holders to the Agency
4. development of the joint recommendations by the MOH, the Antimonopoly Committee of Ukraine, the State Audit Service and the Ministry of Economic Development and Trade (the "**MEDT**") on preparation of the bidding documentation for the procurement of pharmaceuticals and medical devices

The MOH must approve the action plan on implementing the Concept within a month, ie, by 23 September 2017. The MOH must also create an entity responsible for performing the Agency's functions.

We will provide further updates in our following newsletters on the status of the Agency's establishment and adoption of bylaws for the purpose of implementing the Concept.

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Orphan diseases

Updated list of orphan diseases

On 29 June 2017, the MOH approved Order No. 731 "On Amending the List of Rare (Orphan) Diseases Resulting in Reduction of the Life Duration or Disablement of Patients for which the Acknowledged Treatment Methods are Available."

Based on this order, the List of Rare (Orphan) Diseases Resulting in Reduction of the Life Duration of Patients or Disablement and for which the Acknowledged Treatment Methods are Available, approved by MOH Order No. 778 dated 27 October 2014, was amended and complemented with a number of new diseases, including specific epileptic syndromes, dystonia and others. The full updated list of orphan diseases is available here (In Ukrainian).

This order became effective as of 29 August 2017.

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Medical devices

The comments of the regulator on the format of the conformity assessment body identification number

As mentioned in our June Newsletter, as of 1 July 2017, the transitional period for partial application of technical regulations on medical devices came to an end and technical regulations became fully applicable to all medical devices (Technical Regulation on Medical Devices, the Technical Regulation on Medical Devices for In Vitro Diagnostics, the Technical Regulation on Medical Devices for Active Implantable Medical Devices approved by the regulations of the CMU No. 753-755, respectively (the "**Technical Regulations**")). Among other things, the Technical Regulations set out that the identification number of the conformity assessment body should be placed on the labeling of the medical device. At the same time, the Technical Regulations do not provide guidance as to the format of such number.

Prior to 1 July 2017, market players applied different approaches to labeling devices with this number, including the full format (UA.TR.YYY, where UA is the identity code of Ukraine in Latin, TR is the code of the assigned conformity assessment body, and YYY is the numerical order of the specific conformity assessment body), and the shortened YYY format. After the transitional period for partial application of the Technical Regulations expired, market players became concerned about the sanctions imposed on those players that have marked devices with an identification number in YYY format.

To address this concern, on 31 July 2017, the State Service of Ukraine on Pharmaceuticals and Control of Narcotics sent its local territorial bodies letter No. 5161-1/5.0/171-17 stating that it deems it possible not to use the restrictive (correctional) measures and sanctions to entities selling medical devices with an identity number in the YYY format before the respective official clarification of the MOH and MEDT is issued. Although the Letter is not binding, it may be taken into consideration by the Service's territorial bodies.

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Charity and donations

Disclosure of information on donations received by healthcare organizations

On 25 July 2017, the MOH approved Order No. 848 "On Taking Measures for Control over the Receipt and Use of Donations in Healthcare Organizations" (the "**Order**"). The Order will become effective upon its official publication.

Based on the Order, as of 1 January 2018, the state and municipal healthcare organizations must disclose information about the receipt and use of donations from legal entities and individuals.

Such information should include the name of the donator, the amount of the donation (both cash and in kind), the purpose for which the donation was used (expenditure items) and the balance of unused funds as of the end of the reporting period.

The data on donations must be published by healthcare organizations on a quarterly basis. The published data must be placed in a public place and on the official website of the healthcare organization and/or the state administration to which the healthcare organization is accountable.

The Order is aimed at enhancing transparency of funding of healthcare organizations. It is the state's first step towards introducing such disclosure requirements in the national legislation. To date, only voluntary disclosure by pharmaceutical companies of transfer of values to healthcare organizations under the industry self-regulation (eg, APRaD, EFPIA, AIPM codes) has existed in Ukraine.

To ensure compliance with new disclosure requirements, we recommend that companies review their template donation agreements prior to 1 January 2018.

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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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