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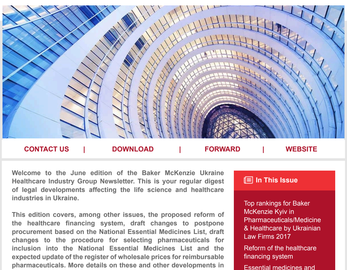
Healthcare
Newsletter | June 2017



Welcome to the June 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, the proposed reform of the healthcare financing system, draft changes to postpone procurement based on the National Essential Medicines List, draft changes to the procedure for selecting pharmaceuticals for inclusion into the National Essential Medicines List and the expected update of the register of reimbursable prices for reimbursable pharmaceuticals. More details on these and other developments in the Ukrainian life science and healthcare industries are provided below.

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Top rankings for Baker McKenzie Kyiv in Pharmaceuticals/Medicine & Healthcare by Ukrainian Law Firms 2017

The Kyiv office of Baker McKenzie has been highly ranked and recommended by the 2017 edition of Ukrainian Law Firms. A Handbook for Foreign Clients, an annual in-depth survey of the legal market in Ukraine. Specifically, Baker McKenzie is ranked in the top five firms in Pharmaceuticals/Medicine & Healthcare, having strengthened its position by climbing to second place. Counsel Olha Demianiuk is acknowledged as a Leading Individual in the industry. To read the full press release, please follow the link.

Reform of the healthcare financing system

Draft Law "On State Financial Guarantees of Providing Medical Services and Pharmaceuticals"

On 8 June 2017, the Parliament of Ukraine adopted in first hearing Draft Law No. 6327 "On State Financial Guarantees of Providing Medical Services and Pharmaceuticals" dated 10 April 2017 ("**Draft Law No. 6327**"). Draft Law No. 6327 provides for the recast of the healthcare financing system in Ukraine. The main changes that are proposed are as follows:

1. Establishment of the government guaranteed package

The government guaranteed package will include medical services and pharmaceuticals fully or partly financed with state budget funds. Certain medical services and pharmaceuticals will be provided free of charge; specifically, those required for provision of the following types of medical aid:

- emergency
- primary
- secondary (specialized)
- tertiary (highly specialized)
- palliative aid.

The exact list of pharmaceuticals and medical services to be provided fully or partly free of charge will be set out in the detailed description of the government guaranteed package (the "**Detailed Description**"). The Parliament of Ukraine should adopt the Detailed Description annually.

2. Establishment of co-payment

Medical services and pharmaceuticals not included in the government guaranteed benefit package will be fully paid by the patients, either using their own funds or voluntary medical insurance funds. Medical services and pharmaceuticals to be provided partly free of charge will be co-paid by patients based on co-payment rates, which should be annually approved by the Parliament together with the Detailed Description.

3. Establishment of the single national health purchaser

The single national health purchaser should enter into agreements on provision of medical services to the population and reimbursement of pharmaceutical costs. It will also be responsible for developing the draft Detailed Description and tariffs for co-payments as well as performing other functions.

4. New rules for financing pharmaceuticals

Draft Law No. 6327 sets out that pharmaceuticals may only be paid with state budget funds if they are included in both: (1) the National Essential Medicines List; and (2) the Detailed Description. It remains to be clarified in the implementing bylaws which mechanism will be used for state financing of pharmaceuticals, ie., reimbursement through pharmacies or centralized procurement followed by distribution through hospitals.

New rules for financing pharmaceuticals will not apply to financing pharmaceuticals with local budget funds. These procurements currently make up an insignificant amount of all pharmaceutical financing, as the major part of local procurement is funded using medical grants from the state budget.

If adopted, Draft Law No. 6327 will be implemented gradually. Most provisions, including those related to financing pharmaceuticals and medical services for primary medical aid provision, will become effective as of 1 January 2018. Until 1 January 2020 and pending the approval of the procedure for development of the Detailed Description and the methodology for development of tariffs, the detailed list of pharmaceuticals for primary medical aid provision will be adopted in accordance with a procedure yet-to-be adopted by the Ministry of Health of Ukraine (the "**MOH**"). Reimbursement of pharmaceuticals set out in the Detailed Description will be launched as of 1 January 2020. Until 31 December 2019, reimbursement will be available for a list of diseases to be defined by the Cabinet of Ministers of Ukraine (the "**CMU**").

Draft Law No. 6327 does not include provisions governing the financing of medical devices. The contemplated mechanism for financing procurement of medical devices is yet to be clarified.

Draft Law "On Amending the Budget Code of Ukraine"

Another essential element of the so-called healthcare reform package is amendments to the Budget Code of Ukraine. Implementation of the reform is impossible without adoption of these amendments, as they should allow the yet-to-be-created single national health purchaser to use state budget funds for the provision of primary, secondary and tertiary medical aid. On 8 June 2017, the Parliament of Ukraine failed to adopt in the first reading Draft Law No. 6329 dated 10 April 2017 "On Amending the Budget Code of Ukraine." We will keep you informed about any major developments related to this draft law.

Essential medicines and public procurement

Draft changes to postpone procurement based on the National Essential Medicines List

As discussed in a previous legal alert, as of 1 July 2017, the following changes in the system of public procurement of pharmaceuticals became effective:

- Cancelation of CMU Regulation No. 1071 "On the Procedure for Procurement of Pharmaceuticals by Healthcare Institutions Financed by the Budget" dated 6 September 1996 ("**Regulation No. 1071**"), which established the list of pharmaceuticals eligible for procurement with state or municipal budget funds.
- Prohibition for healthcare institutions financed with state or municipal budget funds to procure pharmaceuticals not included in the National Essential Medicines List (the "**NEML**"), subject to the following exceptions:
  - Pharmaceuticals not included in the NEML may only be procured when the full demand for pharmaceuticals included in the NEML is satisfied. The scope of such demand should be determined in accordance with a procedure yet to be approved by the MOH (which should be approved by 25 July 2017). In addition, within such procurement, preference should be given to pharmaceuticals included in the clinical protocols and other healthcare standards.
  - The requirements of Regulation No.180 do not apply to procurement of pharmaceuticals conducted by specialized procurement agencies (effective until 31 March 2018).
  - The requirements of Regulation No.180 do not apply to the pilot project on insulin reimbursement until 1 January 2019.

On 23 June 2017, the MOH published a draft CMU resolution (the "**Draft**") providing for the following changes to the above rules:

- Cancellation of Regulation No. 1071 delayed until 1 August 2017
- A number of technical amendments to the National List of Essential Medicines (the "**NEML**"), which will become effective on 1 August 2017
- Introduction of the possibility for healthcare institutions to finalize the procurement procedures started before 31 July 2017, ie, before the entry into force of the above-mentioned technical amendments to the NEML, in accordance with the procedures that have been effective before this date
- The effective date of the regulation allowing healthcare institutions to only procure registered medicines not included in the NEML when the full demand for pharmaceuticals listed in the NEML is satisfied delayed until 1 January 2018.

Although this is not expressly set out in the Draft, as follows from the explanatory note to the Draft, the purpose of the Draft is to introduce an additional transition period until 1 January 2018, during which healthcare institutions will be entitled to procure registered pharmaceuticals not included in the NEML without any restrictions. These changes are crucial for the market as the current version of the NEML includes substantially less pharmaceuticals than Regulation No. 1071. Unless the Draft is approved, healthcare institutions will only be entitled to procure pharmaceuticals included in the NEML and will only be allowed to procure non-NEML products upon satisfaction of the full demand for pharmaceuticals listed in the NEML. Given that the adoption of bylaws allowing for the procurement of non-NEML pharmaceuticals is still pending, patient access to a big number of innovative pharmaceuticals included in the current version of the NEML may be limited.

Draft changes to the procedure for selecting pharmaceuticals for NEML inclusion

On 12 June 2017, the MOH published a draft order proposing changes to the following bylaws:

- Regulation on the National Essential Medicines List and on the Expert Committee for Selection and Use of Essential Medicines approved by MOH Order No. 84 dated 11 February 2016
- Regulation on Conducting Selection of Medicines to be included in the National Essential Medicines List approved by MOH Order No. 1050 dated 7 October 2016

The most important changes provide for the following:

- extension of the timeline for reviewing applications for submission in the NEML from two months to 180 business days
- exclusion of the provision providing for equal treatment of generic and innovative pharmaceuticals within the procedure of NEML development (which means that the Expert Committee for Selection and Use of Essential Medicines (the "**Committee**") may only deny inclusion in the NEML on the basis of the innovative status of the pharmaceutical)
- possibility to engage the Committee in the procedure for preparing the nomenclature of pharmaceuticals to be procured with budget funds until 1 January 2019
- changing the timeline for NEML development, in particular:
  - by 1 August 2017, the Committee will approve the NEML based on the nomenclature of pharmaceuticals procured with budget funds, on the industry standards and on budget impact analysis
  - by 1 November 2017, the Committee should accept applications for amendment of the NEML
  - by 1 June 2018, the Committee should review applications for amendment of the received applications and submit the recommended version of the NEML for the MOH's approval
- exemption from the obligation to provide certain data on comparative safety and clinical efficacy for pharmaceuticals included in the latest version of the updated Model List of Essential Medicines of the World Health Organization

If adopted, the draft order will provide more clarity and guidance on the procedures and timelines for selecting pharmaceuticals to be included in the NEML. However, unequal treatment of generic and innovative pharmaceuticals and extension of timelines for including pharmaceuticals in the NEML may create additional impediments to the sale of innovative pharmaceuticals on the public procurement market. This is due to the new rules for the public procurement of pharmaceuticals, which become effective on 1 July 2017. In particular, healthcare institutions will only be entitled to procure non-NEML pharmaceuticals upon satisfaction of the full demand for pharmaceuticals listed in the NEML.

Pricing and reimbursement

Update of the reimbursement and maximum wholesale prices registries and launch of price monitoring for reimbursable pharmaceuticals

As set out in the Procedure for Calculating the Reimbursement Amount of Reimbursable Pharmaceuticals adopted by CMU Regulation No. 102 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 — as of 1 January and as of 1 July.

For updating the Reimbursement Register as of 1 July 2017, on 20 June 2017, the MOH announced that applications for inclusion of pharmaceuticals in the Reimbursement Register can be submitted from 3 July 2017 to 12 July 2017 (inclusive).

The MOH announced that the Reimbursement Register will be revised completely, so all applicants aiming to include their products in the Reimbursement Register will need to submit their applications, irrespective of their inclusion in the current version of the Reimbursement Register.

The Reimbursement Register should be adopted by an MOH Order on 24 July 2017. After that, the applicants will have five business days to submit applications for re-calculation of the reimbursement amount in case of a calculation mistake. The Reimbursement Register should be enacted as of 31 July 2017. Additionally, on 1 July 2017, the MOH published the new version of the maximum wholesale prices for reimbursable pharmaceuticals.

Lastly, the State Service of Ukraine on Safety of Foodstuffs and Consumer Protection, which is authorized to control compliance with legislation on state-regulated prices, has announced that it had launched permanent monitoring of prices for reimbursable pharmaceuticals by analyzing information on the prices and mark-ups for reimbursable pharmaceuticals sold by pharmacies.

Intellectual property

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

By adopting Decree No. 320 (on 11 May 2017, effective as of 18 May 2017), the CMU launched the next phase of the ongoing IP reform outlined in the Concept for Reforming the State Intellectual Property System in Ukraine.

This phase finalizes liquidation of the State Intellectual Property Service and transfer of all its functions to the Ministry of Economic Development and Trade of Ukraine. You can find out what to expect from the transition in our recent legal alert by following this link.

Medical devices

Full-scope application of technical regulations on medical devices

As of 1 July 2017, the transitional period for partial application of technical regulations on medical devices came to an end (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**")). During this transitional period, application of requirements of the Technical Regulations was not mandatory for medical devices that held registration certificates and had been registered in Ukraine. As of 1 July 2017, irrespective of whether they hold registration certificates or not, all medical devices must undergo conformity assessment procedures under the Technical Regulations before being placed on the Ukrainian market.

License terms

Abolishment of previous versions of license terms for conducting activities with pharmaceuticals

As of 13 June 2017, the License Terms for Conducting Business Activities for Manufacturing, Retail, Wholesale Trade with Pharmaceuticals, as approved by MOH Order No. 723 dated 31 October 2011, are no longer valid due to adoption of MOH Order No. 506 dated 11 May 2017.

As a reminder, the new Licensing Conditions for Conducting Business Activities on Manufacturing, Wholesale and Retail Trade in Pharmaceuticals, Import of Pharmaceuticals (save for active pharmaceutical ingredients) were adopted by the CMU on 30 November 2016, so the described change is merely a technicality.

At the same time, the Licensing Conditions for Conducting Business Activities on Import of Pharmaceuticals (save for active pharmaceutical ingredients) as adopted by MOH Order No. 143 dated 20 February 2013 remain valid.

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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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