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Newsletter

Pharmaceutical Sector

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Contacts at EY

+380 (44) 490 3000
kyiv@ua.ey.com

Industry expert

Pavlo Moroz
Pavlo.Moroz@ua.ey.com

+380 (44) 490 3049

Changes regarding active pharmaceutical ingredients and products in bulk to the procedure for quality control of pharmaceuticals imported to Ukraine took force

On 18 November 2014 a resolution of the Cabinet of Ministers of Ukraine (hereafter – "CMU") No. 601 dated 12 November 2014 (hereafter – "Resolution No. 601") took force. It introduces amendments to the Procedure for State Quality Control of Pharmaceuticals Imported to Ukraine, approved by CMU's resolution No. 902 dated 14 September 2005.

The amendments envisaged by Resolution No. 601 are as follows:

- Cancellation of the requirement that residents must provide the products in bulk being imported to Ukraine for their own manufacture to the state quality control. This refers to the residents that are licensed to manufacture pharmaceuticals and have their own laboratories certified according to the procedure established by the Ministry of Health of Ukraine (hereafter - the "Ministry") or cooperate with such laboratories under contracts. Such residents will perform their own laboratory analysis and quality control and bear responsibility for the quality of the said products.

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- Granting of the right to place active pharmaceutical ingredients (substances) and products in bulk being imported for sale in full to a manufacturer of pharmaceuticals that will use them in its own manufacturing and has its own laboratory certified according to the procedure established by the Ministry, or that cooperates with such laboratories under contract, in the manufacturer's licensed warehouse, from where the manufacturer is able to carry out samples for laboratory analysis.
- Clarifying one of the grounds for laboratory analysis, namely the ground regarding information about pharmaceuticals' quality. Such information should be official and obtained from competent international regulatory bodies.

Please note that the procedure for state quality control of pharmaceuticals imported into Ukraine applies to all entities that import pharmaceuticals into the country.

Introduction of state regulation of prices for domestically produced pharmaceuticals and medical products that cost less than UAH 12 is anticipated

According to the state authorities' public statements the Ministry elaborated and provided the Government with a draft resolution amending the CMU's resolution "On Measures to Stabilize the Prices for Pharmaceuticals and Medical Products" No. 955 dated 17 October 2008.

The amendments extend from 1 January 2015 state regulation of prices for pharmaceuticals and medical products of domestic manufacture, the wholesale price for which is under UAH 12 per package. This refers to pharmaceuticals and medical products that are on the National List of Essential Pharmaceuticals and Medical Products (except for narcotic, psychotropic pharmaceuticals, precursors and medical gases) and in the Mandatory Minimum Range of (Socially Oriented) Pharmaceuticals and Medical Products for Pharmacy Institutions as defined by the Ministry.

According to the draft resolution published on the Ministry's website, the calculation of price for these pharmaceuticals and medical products is subject to margin trade (retail) mark-up not exceeding 30% of the purchase price.

Timelines for prepayments on purchase of pharmaceuticals and medical products for budget funds are increased

On 8 November 2014 there amendments to the CMU's resolution "On Pre-Payment for Goods, Works and Services Purchased for Budget Funds" No. 117 dated 23 April 2014 (hereafter – "Resolution No. 117"), took force. These amendments were introduced by CMU's resolution No. 589 dated 22 October 2014.

Hence, from 8 November 2014 increased maximum terms for pre-payment on purchase of pharmaceuticals and medical products for budget funds apply. These terms are:

- No more than six months for pharmaceuticals and medical products
- No more than one year for vaccines for prophylactic immunization of individuals

The previous version of Resolution No. 117 established the maximum pre-payment period for these products as not more than three months.

Changes to procedure for examination of registration materials for pharmaceuticals are proposed

The Ministry has published on its website the draft order "On Amending the Procedure for Examination of Registration Materials on Pharmaceuticals That Are Filed for State Registration (Re-registration) and for Examination of Materials Introducing Changes to Registration Materials During the Validity Period of the Registration Certificate[1]" (hereafter – the "Draft Order").

The Draft Order envisages *inter alia* the following novelties:

- *Narrowing the grounds for state registration (re-registration) of pharmaceuticals*, namely excluding the quality control of pharmaceuticals that is performed by the State Expert Centre of the Ministry (hereafter – "the Centre") from these grounds. State registration (re-registration) of pharmaceutical should be conducted by the Ministry based on results of examination of

[1] Procedure for Examination of Registration Materials on Pharmaceuticals That Are Filed for State Registration (Re-registration) and for Examination of Materials Introducing Changes to Registration Materials During the Validity Period of the Registration Certificate, approved by the Order of the Ministry No. 426 dated 26 August 2005.

registration materials (registration dossiers) for those pharmaceuticals performed by the Centre.

- *Extending the list of possible additional examinations*, namely adding examination on confirmation of quality and reproducibility of quality control methods to that list.

Currently the Draft Order is under public discussion. The Ministry has established that the comments and suggestions should be filed by 5 December 2014.

Draft procedure for reimbursement of insulin pharmaceutical costs is developed

The Ministry has published the draft CMU resolution "Issues Relating to the Procedure for Reimbursement of Insulin Pharmaceutical Costs and on Amending Certain Resolutions of the Cabinet of Ministers of Ukraine Concerning Improvement of Pilot Projects on Introduction of State Regulation of Prices for Pharmaceuticals and Partial Reimbursement of Their Cost" (hereafter - the "Draft Resolution").

According to the Draft Resolution starting 1 March 2015 the cost of insulin pharmaceuticals will be reimbursed to business entities that conduct business activity based on licenses for retail trade of pharmaceuticals, regardless of ownership and subordination, if these entities' pharmacies are located within the relevant administrative-territorial unit. The reimbursement should be made for insulin pharmaceuticals that these business entities provided to diabetes patients, and for this purpose special funds from local budgets should be used. The procedure for this reimbursement is foreseen in the Draft Resolution.

Additionally, the Draft Resolution envisages amendments to certain CMU's resolutions concerning pilot projects on introducing state regulation of prices for pharmaceuticals and partial reimbursement of their cost.

Currently, the Draft Resolution is under public discussion. The Ministry has established that comments and suggestions should be filed by 10 December 2014.

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We will continue to monitor developments and will be happy to discuss with you any questions you may have.

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