# Pharma Bulletin

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## Medicine registration procedure has been simplified

On 19 June 2016 the Law of Ukraine "On Amending Article 9 of the Law of Ukraine "On Medicines" Simplifing the Medicines State Registration Procedure" No.1396-VIII dated 31 May 2016 became effective (the "**Law No.1396-VIII**").

The Law No.1396-VIII provides for a simplified registration procedure of medicines in Ukraine provided that such medicines are registered by the respective state authorities in the strict-regulated jurisdictions, namely, the USA, Switzerland, Japan, Australia, Canada, the EU states. Terms envisaged for the Ministry of Health of Ukraine (the "**MHU**") for approval of the decision on the registration of the medicine have been reduced up to 10 business days (instead of a month).

Moreover, on 6 May 2016 the Regulation of the CMU No. 312 dated 20 April 2016 (the "**Regulation No.312**") amending Medicines State Registration Procedure, as well as registration (reregistration) charges due approved by the Resolution of the MHU No.376 dated 26 May 2005 became affective.

The Regulation No.312 reduces the medicines registration term in Ukraine provided that such medicines are registered by the respective authorities in the USA, Switzerland, Japan, Australia, Canada or the EU states. During the reduced term the following procedures should be completed:

- examination of the materials that should be performed by the State Enterprise "State Expert Center of the MHU" (the «**SEC**») within 20 business days;
- approval of the decision by the MHU either confirming or dening registration of the medicine within 10 business days.

If within the specified above deadlines the SEC does not provide any decisions or recommendations, the examination is deemed to be performed.

## Regulation on the Register of the Referential Prices on Insulin and Calculation Methods became effective

On 3 June 2016 the Order of the MHU No. 359 dated 13 April 2016 establishing Regulation on the Register of the Referential Prices (reimbursement prices) on Insulin (the "**Register**") and the Method for Calculation of the Referential Prices (reimbursement prices) on Insulin (the "**Regulation**") became effective.

The Regulation on the register of the referential prices establishes requirements for formation, maintenance and amendment of the data in the Register. The Register will be kept in the form of a specialized electronic database. Updates of the Register will be performed by the MHU twice a year – as of 1 February and 1 August of the current year. Any person can receive information about the insulin from the Register on the official website of the MHU.

The method of the calculation of the referential price on the insulin should apply to insulin medicines registered in Ukraine and recorded in the State Register of Medicines, according to the List of categories of diabetes mellitus for reimbursement of the price of the insulin.

Calculation mathod covers insulin medicines registered in Ukraine and recorded in the State Register of Medicines according to the List of the persons suffering from diabetes entitled to the reimbursement of the price of the insulin medicines approved by the Resolution of the CMU No. 239 dated 23 March 2016.

The referential price calculation of the full reimbursement of the insulin medicines produced by foreign producers should be made taking into account the mechanism of the external annotation of the wholesale prices obtained from the official databases and informational sources in the referential countries, sorting by the name of the insulin/ its analog. The referential states are Bulgaria, Moldova, Serbia and Hungary.

## Amendments to the Regulation on Maintenance of the State Register of the Medical Equipment and Medical Products

The Order of the MHU No. 361 dated 13 April 2016 (the "**Order No. 361**") amends the Regulation on Maintenance of the State Register of the Medical Equipment and the Medical Products (the "**Regulation**") approved by the Order of MHU No. 533 dated 16 July 2012.

Amendments are based on the mandatory technical regulations relating to the medical products effective as of 1 July 2015 approved by the Resolution of the CMU No. 753, 754,755 dated 2 October 2013. Accordingly, the state registration procedure of the medical products was abolished. Instead of the state registration procedure a new evaluation procedure of compliance of the medical products with the technical regulations was introduced.

However, presentation on the market and / or putting into operation of the medical products (including products used for in vitro diagnostics and effective medical products used for implantation) is allowed without passing any procedure relating to the assessment process of correspondence and marking the national conformity mark provided that:

(i) such medicins are registered and recorded in the State Register of the Medical Equipment and Medical Products (the "**Register**") allowed for the use on the territory of Ukraine, and
(ii) put into operation before the date of the mandatory use of the technical requirements.

In addition, the Regulation is supplemented with the provision according to which medical products duly recorded in the Register as of 30 June 2015 will be in the Register till the 30 of June 2020.

## Amendments to the Procedure of Control of the Compliance of the Immunobiological Medicines with Requirements of the State and International Standards were approved

On 29 April 2016 the Order of the MHU No. 343 dated 11 April 2016 amending the Procedure of control of the compliance of the relevant immunobiological medicines used in medicine practice with the state and international standards (the "**Procedure of Control**") approved by the Order of the MHU No. 698 dated 1 October 2014 became effective.

Amendments should supplement the Regulation with the provisions relating to the non-application of the Regulation to the immunobiological medicines that were reclassified by the World Health Organization and were procured via international organizations.

Accordingly, the Procedure of Control complies with the requirements of the current legislation and allows import of the respective medicines provided that such medicines have quality certificate issued by the producer.

## The Order defining the Ukrainian Customs Commodity Classification Codes for Foreign Trade to be specified on the documents issued by the MHU

On 27 May 2016 the Order of the MHU No. 341 dated 11 April 2016 abolishing the Order of the MHU "On Defining the List of the Ukrainian Customs Commodity Classification Codes for Foreign Trade (the "**UCCCCFT**") to be Specified in the Documents Issued by the MHU Required to Perform Customs Control and Customs Clearance of the Goods" No. 607 dated 22 September 2011 (the "**Order No.607**") became effective.

Abolishment of the Order No. 607 is closely related to the invalidity of the Regulation of the CMU "On the List of Documents Required to Perform Customs Control and Customs Clearance of the Goods and Vehicles Transferred Across the Customs Territory of Ukraine" No. 80 dated 1 February 2006 based on which the Order No. 607 was issued.

## Procedure on Coordination of the Information that could be Placed on the Advertising Materials of Medicines for Kids or Adolescents was abolished

On 13 May 2016 the Order of the MHU No. 304 dated 4 April 2016 abolishing the Order "On Approval of the Legislative Acts on Advertising of Medicines" No.177 dated 10 June 1997 (the "**Order No.177**") became effective.

The Order No. 177 approved the Regulation on Coordination of the Information that could be Placed on the Advertising Materials of Medicines for Kids or Adolescents, as well as the Regulation on Advertising of Medicines Intended for the Use by the Medical Institutions and Doctors.

Most of the provisions of the Order No. 177 coinside with the provisions of the existing draft of the Law of Ukraine "On Medicines" and the Law of Ukraine"On Advertising".