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## Pharmaceutical sector

### Content

#### ► Introduction of pharmaceutical import licensing

Recently Ukraine's Prime Minister Ukraine gave a press conference devoted to introduction of the law on pharmaceutical import licensing, in which Vice-Prime-Minister, directory of the Health Ministry of Ukraine, of the State Service of Ukraine on Pharmaceuticals and others took part.

At the event the Prime Minister of Ukraine ordered to elaborate all required legal acts, which would set precise conditions and rules of the new pharmaceutical import licensing regime. To the best of our knowledge so far the government adopted the Resolution "On introducing amendments to paragraph 5 of the list of licensing bodies" which foresees that the State Service on Pharmaceuticals shall be responsible for issuing pharmaceutical import licenses.

The press conference also announced that the decision had been made to implement pharmaceutical import licensing requirements in a step-by-step manner by the end of 2013 (please find information on the draft license provisions in our Newsletter of 17 January 2013). It is planned that the license provisions at the first stage will be very easy, the license issuance procedure - ultimately simplified. Importers will be able to obtain the license starting 1 March 2013.

In addition, two draft laws proposing to cancel the pharmaceutical import licensing procedure have been filed with the Verkhovna Rada of Ukraine:

- Draft Law "On Recognition as Invalid of the Law of Ukraine dated 7 May 2012 No. 5038 'On Introduction of Changes to Some Laws of Ukraine Regarding Pharmaceutical Import Licensing and Defining the Term "Active Pharmaceutical Ingredient"' (registered on 5 February 2013 as No. 2196)
- Draft Law "On Introduction of Changes to Some Laws of Ukraine (Regarding Guarantee of Adequate Medical Aid to the Population, Patient Rights Protection and Improvement of Access to Pharmaceuticals)" (registered on 8 February 2013 as No. 2251).

However, none of these drafts has been considered and adopted. As of 13 February 2013 both draft laws were provided for review to the Verkhovna Rada of Ukraine deputies.

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We will continue to monitor further developments and will be happy to discuss with you any issues related to this information.

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