



Pharmaceutical Sector News

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Pharmaceutical promotion and sampling prohibited

Today the Law of Ukraine "On Amendment of Fundamental Ukrainian Legislation on Healthcare Related to Imposing Restrictions for Officials and Employees of Medical and Pharmaceutical Institutions" No.5036-VI of 4 July 2012 (previously known as Draft Law No.10560) takes force.

According to the Law, during execution of their activities, medical and pharmaceutical employees have no right to accept rewards (fees) from legal entities engaged in the production and/or sale of pharmaceuticals or of pharmaceutical goods (pharmaceuticals and medical purpose goods). They also lack the right to receive pharmaceutical samples (pharmaceuticals and medical purpose goods). Prescriptions for pharmaceuticals using prescription forms that bear advertising information for such medical and pharmaceutical employees are also banned.

In addition, medical and pharmaceutical employees are prohibited from providing false information about the availability of pharmaceuticals with similar active substances at certain pharmaceutical institutions when the consumer asks about them (in particular, they are prohibited from hiding information about the availability of lower-priced pharmaceuticals).

The Law establishes that medical and pharmaceutical employees should bear liability for violating the above requirements. This liability could include civil, administrative and criminal liability.

Pharmaceutical import licensing implemented

The President of Ukraine signed the Law of Ukraine "On Amendment of Certain Laws of Ukraine on Licensing Activity for Import of Pharmaceuticals and Defining 'Active Pharmaceutical Ingredient'" No.5038-VI of 4 July 2012 (previously known as Draft Law No.10562).

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As we mentioned in our Newsletter of 22 June 2012, this Law amends the Law of Ukraine "On Licensing Certain Types of Economic Activities" and the Law of Ukraine "On Pharmaceuticals." Inter alia, it defines "active pharmaceutical ingredient," dosage forms and products "in bulk" and provides for licensing of pharmaceutical import.

The amendments make importing registered pharmaceuticals into Ukraine possible when there are available a certificate of quality series for the pharmaceutical and a license for pharmaceutical import. Please note that an importer does not need to obtain a license to import each pharmaceutical. The license has an appendix that lists the pharmaceuticals that the relevant importer is allowed to import.

The Law states that an entity must have the following to obtain a license to import pharmaceuticals: a material and technical base, a qualified staff and the conditions necessary for ensuring quality control of the pharmaceuticals that will be imported into Ukraine.

According to the Law, the regime for licensing import of pharmaceuticals will begin on 1 March 2013. The regime licensing the import of active pharmaceutical ingredients will begin on 1 January 2015.

The law in general will take force on the day subsequent to the day of its publication.

Legal liability for illegal distribution and adulteration of pharmaceuticals made more severe

The President of Ukraine signed the Law of Ukraine "On the Introduction of Changes to Certain Legislative Acts of Ukraine to Toughen Liability for Adulteration and Illegal Distribution of Pharmaceuticals" No.5065-VI of 5 July 2012 (previously known as Draft Law No.10561).

The Law amends the Code of Ukraine on administrative violations and the Criminal Code of Ukraine. In particular:

- ▶ administrative liability for violation of restrictions set for employees and officers of medical and pharmaceutical institutions has been established
- ▶ criminal liability for illegal distribution and adulteration of pharmaceuticals has been made more severe
- ▶ criminal liability for violation of the prescribed procedure for carrying out preclinical or clinical trials and state registration of pharmaceuticals has been prescribed.

The law will take force on the day subsequent to the day of its publication.

Criteria for banning pharmaceutical advertisement take force

On 30 July 2012 Order No.422 of 6 June 2012 of the Ministry of Healthcare of Ukraine "On Certain Questions of Banning Pharmaceuticals Advertisement" came into force. It approves the criteria for determining which pharmaceuticals should be prohibited from being advertised.

Criteria for banned pharmaceutical advertisement have been developed for the execution of the Law of Ukraine "On Amending Certain Laws of Ukraine in the Sphere of Healthcare on Reinforcement of Control over the Circulation of Pharmaceuticals, Food Products for Special Dietary Consumption, Functional Food Products and Diet Additives" No. 4196-VI dated 20 December 2011. According to this Law, advertising is allowed only for those pharmaceuticals that are released without a doctor's prescription and that are not on the list of pharmaceuticals that cannot be advertised, starting from 13 July 2012.

We will follow changes in legislation and keep you informed on further developments in the pharmaceutical industry.