

Abolition of licensing imports of APIs

On 15 January 2015 the Verkhovna Rada adopted the Law No. 126-VIII "On amendments to certain laws of Ukraine on the abolition of licensing imports of active pharmaceutical ingredients", which came into force on 1 February 2015.

The law abolishes licensing imports of active pharmaceutical ingredients (APIs), which was envisaged to become effective from 1 January 2015.

It bears reminding that the licensing of active pharmaceutical ingredients and imported raw materials for the production of drugs is inconsistent with the European and international practice, and Ukraine would become the only country in the world with the statutory requirement to license imports of APIs.

This provision in national legislation of Ukraine could lead to suspension of production at domestic pharmaceutical companies. It would be impossible for any domestic enterprise to get an import license, because foreign manufacturers of pharmaceutical substances do not have documents required to obtain a license.