KOSTA LEGAL

NEW LEGISLATION IN PHARMACEUTICS: AUGUST 2019

Dear Clients and Partners,

This legal alert highlights the most important legal developments of August 2019 that affect the Uzbek pharmaceutical industry as a whole and activities of foreign pharmaceutical producers and their representative offices in Uzbekistan in particular.

1. LICENSES & REGISTRATION CERTIFICATES

- *Regulations on the Licensing of the Pharmaceutical Activities, except for the Retail Sale of Medicines and Medical Products* have been amended. Among other things, medicines have been subdivided into 4 types (medicinal substances, sterile medical products, non-sterile medical products, and medical gases) with a particular category/categories having to be indicated when the license for the production of medicines and medical products is issued.
- The licensing requirements and conditions have been updated. Now, a licensee must be connected to the electronic system for the control and monitoring of pharmaceutical products. Additionally, by the fifth day of every month, standard form reports conating the information on the performance of a licensee over the past month must be submitted to the licensing authority – the Agency for the Development of the Pharmaceutical Industry under the Ministry of Healthcare.
- *Regulations on the Procedure for the State Registration of Medicines, Medical Devices and Medical Equipment and the Issuance of the Registration Certificate* have been amended. The state registration of medicines and equipment pre-qualified by the World Health Organization as for the *in vitro* diagnostics will now be carried out in a fast-track mode within 60 days.

Resolution of the Cabinet of Ministers No. 678 of August 17, 2019

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