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NEW LEGISLATION IN PHARMACEUTICS: APRIL 2019

Dear Clients and Partners,

This legal alert highlights the most important legal developments of April 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. CERTIFICATION AND LICENSES

Licenses for pharmaceutical activities, except for the license for retail trade in medicines and medical products, are no longer issued by the Ministry of Healthcare, but by the Agency for the Development of the Pharmaceutical Industry under the Ministry. Previously issued licenses remain valid until their expiration date.

By 1 January 2022, (a) all local manufacturers of medicinal products will have to undergo the mandatory certification of compliance with the requirements of the national standard Good Manufacturing Practices, whereas (b) all enterprises engaged in wholesale trade in medicines and medical products will have to undergo the mandatory certification of compliance with the requirements of the national standard Good Distribution Practices.

By 1 June 2019, the Cabinet of Ministers will introduce regulations on the procedure for conducting inspections for ensuring compliance with the above standards.

Presidential Decree No. UP – 5707 of April 10, 2019

2. IMPORT OF MEDICINES AND MEDICAL PRODUCTS

Starting from July 1, 2019, the fee for customs clearance of imported medicines and medical products (except for medicinal substances) will increase to 1.2% of the customs value. The currently applied rate is 0.2% of the customs value, but not less than USD 25 and not more than USD 3,000.

The list of medicines that cannot be exempted from the import VAT is now applicable to “in bulk” pharmaceutical production and is prepared solely by the Agency for the Development of the Pharmaceutical Industry without the Cabinet

Until January 1, 2022, technological and laboratory equipment, components and spare parts for such equipment, raw materials used for keeping laboratory animals, preclinical studies, and the production of medicines and medicinal products, not produced within Uzbekistan, are exempted from the import VAT, the excise tax and import customs duties. Relevant lists of exempted items will be approved by the Cabinet of Ministers. Manufacturers of medicines and medical products, specialized research and higher educational institutions as well as enterprises engaged in wholesale and retail trade in pharmaceutical products for the production of medicines in pharmacies are eligible for the exemption.

Presidential Decree No. UP – 5707 of April 10, 2019

3. PUBLIC PROCUREMENT OF MEDICINES AND MEDICAL PRODUCTS

As an experiment, from July 1, 2019 to December 31, 2020, while considering applications for procurement of medicines and medical products, state institutions will be obliged to reject proposals for the supply of imported medicines and medical products, if applications from two or more local producers of similar local products (as compared by the international non-proprietary name) have been received.

Presidential Decree No. UP – 5707 of April 10, 2019

4. PUBLIC-PRIVATE PARTNERSHIP IN HEALTHCARE

The Regulations on PPP in Healthcare have been adopted. Project agreements in the sphere may relate to either providing services related to healthcare infrastructure (the design, construction, reconstruction, creation, equipping, modernization, financing, operation of healthcare facilities) or the provision of related healthcare goods and services. The term of a PPP agreement cannot be less than 3 years or exceed 49 years.

Private partners may be selected on a tender basis or after direct negotiations. Investors in PPP projects are eligible to get preferential loans from the Fund for Reconstruction and Development for purchasing modern foreign medical equipment. All state assets transferred to private investors in PPP projects must be returned to the state upon the completion of respective projects.

Private investors may initiate a PPP project in the sphere by applying to the Ministry of Healthcare.

Presidential Decree No. PP – 4290 of April 16, 2019



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