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News Publications Legal Alerts



NEW LEGISLATION IN PHARMACEUTICS: JUNE 2019

Dear Clients and Partners,

This legal alert highlights the most important legal developments of June 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. CHANGES IN SOME REGULATORY LISTS OF MEDICAMENTS

Certain lists of medicaments, made to regulate the provision of particular tax or customs exemptions, for reference purposes for state treatment standards, or for other regulatory purposes, have been amended:

- A new *List of Orphan Drugs for the Treatment of Rare Diseases* (which are not subject to the state registration when being imported) has been approved with a number of items having been added and excluded.

The following generic names for medications have been added to the List: Mycophenolate sodium, Basiliximab, Ocrelizumab, Coagulation Factors II, VII and X, Tocilizumab (Actemra), Glecaprevir (100 mg) + Pilbrentasvir (40 mg), Laronidasum (Aldurazyme), medicines for the treatment of primary immunodeficiency (generic name for this medications is not provided).

The following generic names have been excluded from the List: Cyclophosphamidum Mesna, Procarbazine, Octanat, Immunate, Beriate, Glatiamer, Haemoctin, Octanine, Immunine, Natalizumabum.

- *The List of Medicaments Distributed on Preferential Terms during Outpatient Treatment* has been expanded. The following generic names has been inscribed on the List (the information in the brackets provides for the form of medicinal preparations): Omnopon (a solution for injections 2% 1 ml), Trifluoperazine (tablets 5 mg), Fluphenazine (solution for injection 25 mg/1 ml), Olanzapine (tablets 5 mg).

[Order of the Minister of Healthcare No. 3164 of June 6, 2019](#)

2. FREE ECONOMIC ZONE “ANDIJON-PHARM”

Boundaries for the free economic zone (FEZ) “Andijon-Pharm” have been defined and its Directorate has been established. Detailed information about the FEZ will soon be available on the [official website for FEZs](#).

The FEZ “Andijon-Pharm” has been created for attracting direct investment, primarily from India, for the implementation of projects for the creation of hi-tech pharmaceutical production enterprises for meeting local demand for medicaments. It is envisaged that management functions of the Directorate of the FEZ may be transferred to foreign companies with experience in the development and management of FEZs (Indian companies have priority) by decision of the Administrative Council for FEZs and Small Industrial Zones of the Andijan region.

[Resolution of the Cabinet of Ministers No. 480 of June 11, 2019](#)

3. STATE CONTROL OVER DEBTS UNDER FOREIGN TRADE CONTRACTS

The government has established the state commission and territorial working groups for examining foreign trade balances of entities engaged in foreign trade. Within 2 months from the date of their establishment, these working groups will carry out a full inventory of registered import and export contract, payments under which have not been made.

Within 2 months from the date of the legal act establishing the commissions above, a legal act will be drafted that will set rules for the maintenance of the List of Dishonest Traders, which may become subject to the following restrictive measures: (i) the order to use only guaranteed types of payment in carrying out foreign trade operations (ii) a temporary restriction of the right to engage into foreign trade activities.

[Resolution of the Cabinet of Ministers No. 464 of June 6, 2019](#)

4. USE OF ELECTRONIC INVOICES

The Regulation on the Use of Electronic Invoices has been adopted. It provides for detailed rules for using e-invoices;

Starting from July 1, 2019, business entities will be able to register, store and record invoices (a standard form document that confirms the sale and purchase of goods (works, services)) in electronic form. In 2020, such electronic handling will become mandatory. The Scientific Information Centre for New Technologies under the State Tax Committee is an authorized state body for e-invoicing.

[Resolution of the Cabinet of Ministers No. 523 of June 25, 2019](#)

5. IMPENDING LEGISLATION & EXPECTED CHANGES

This section contains the information prepared based on published draft laws, provides for review of such laws and explains what the proposed developments shall mean for entrepreneurs. All or some provisions of the draft laws may be changed and redrafted prior to its adoption.

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Development of the Pharmaceutical Industry under the Ministry of Healthcare published a [bill](#), in which the number of relevant medicaments has been increased from 76 to 104. It has also been clarified that the List relates to both ready and “in bulk” medicaments.



40a, Mustaqillik avenue,
Tashkent, 100000, Republic of Uzbekistan
www.kostalegal.com

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