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Regulation Of The Pharmaceutical Industry In Uzbekistan

Currently, the pharmaceutical industry in Uzbekistan is experiencing a modification of regulatory requirements. In recent years, the country has achieved positive results in the formation and development of the primary health care system for population. It is important to note that the network of republican specialized scientific and practical medical centers is being improved, and republican and regional screening centers have also been organized to prevent birth of children with hereditary and congenital diseases. Furthermore, in the country, there have been created pharmaceutical free economic zones and favorable conditions, while the organization of social drugstores, public-private partnerships, private health care, and medical tourism are being developed, and the competitive environment for the vast attraction of investments in the healthcare sector is being improved.

The central governmental body of healthcare control is the Ministry of Health of the Republic of Uzbekistan (hereinafter - the "Ministry of Health"). Moreover, the Ministry of Health also participates in the development and implementation of governmental programs in the field of drugs, and pharmaceutical activities, it carries out licensing of pharmaceutical activities, state registration and quality control of medical devices and medical equipment.

It should be noted that based on the Regulation "On the procedure for State registration of drugs, medical devices, and medical equipment and the issuance of a registration certificate", approved by the Cabinet of Ministers dated 23 March 2018 No.213 (hereinafter – "the Regulation on State registration"), the working body specialized in state registration, quality control, standardization and certification of drugs, medical devices, and medical equipment is the State center for examination and standardization of drugs, medical devices and medical equipment of the Agency for the development of the pharmaceutical industry under the Ministry of Health (hereinafter – "the State center").

Under the aforementioned Regulation, the following are subject to registration:

(i) drugs;

(ii) new combinations of drugs registered in Uzbekistan;

(iii) drugs previously registered in Uzbekistan but produced in other medical forms, dosages or by another manufacturer;

(iv) medical devices;

(v) medical equipment.

The Regulation on State registration also governs the registration of foreign drugs and medical devices. Besides, this Regulation provides non-registration of drugs with various medical substances under the same trade name, non-registration of drugs of the same manufacturer having the same composition of medical substances under different trade names.

It is necessary to note that as a result of registration, a certificate with the validity term of five years is issued. To obtain a certificate, applicants must submit the necessary documents directly to the State center via postal communication or in electronic form. Moreover, when considering the application and the attached documents, the Pharmacopoeia and Pharmacological committees, and the Committee on new medical equipment, conduct a number of examinations of the chemical, pharmaceutical, biological, and technical parts of the registration documents.

Another critical aspect of the pharmaceutical industry is the procedure for drug marking. Mandatory marking of drugs in the

Republic of Uzbekistan is regulated by the Resolution of the Cabinet of Ministers No.22 dated 5 February 2014 "On improving the procedure for marking and customs clearance of certain types of imported consumer goods" (hereinafter – "Resolution No.ПКМ-22") and the Resolution of the Cabinet of Ministers No.365 dated 27 October 2016 "On approval of the general technical Drug Safety Regulation" (hereinafter – "Resolution No.ПКМ-365"). These regulations clearly define the rules and procedures for applying the mark, as well as its form and language.

Resolution No.ПКМ-22 establishes that imported drugs should be marked by embedding the information for the consumer in consumer packaging in the form of a leaflet in the state language. The Main Department for quality control of drugs and medical equipment of the Ministry of Health is responsible for the approval of the text of drug marking in the State language. The marking must be complete and reliable, containing the main consumer properties and characteristics of the product in the State language. Accredited certification bodies examine the compliance of the marking in the State language to the requirements of regulatory documents on standardization of products.

It should be noted that from December 2019, in Uzbekistan, it is planned to launch a pilot project for the phased implementation of the procedure for marking of goods. This project will allow manufacturers to increase the efficiency of business processes, and the government will receive an effective method of combating the production and import of illegal products, as well as the ability to maintain a full record of manufactured and imported products.

Moreover, as per the Resolution of the President of the Republic of Uzbekistan No.ПП-4554 dated 30 December 2019 "On additional measures to deepen reforms in the pharmaceutical industry of the Republic of Uzbekistan" (hereinafter – "Resolution No.ПП-4554"), from 1 July 2020 there will be established a procedure of the phased implementation of the reference pricing system for drugs of local and foreign production.

This system provides for the selection of at least 10 reference countries belonging to the group of countries of high, above the average or below the average per capita incomes. According to the system, the holder of a registration certificate or its authorized representative provides the registration authority with the selling price of the drugs of the same manufacturer with the same active substance in the country of origin, reference countries and in Uzbekistan.

The authorized body for monitoring and analysis of the reference pricing system is the Agency for the Development of the Pharmaceutical Industry under the Ministry of Health.

In Resolution No.ПП-4554, there has also been approved the Concept for the Development of the Pharmaceutical Industry of the Republic of Uzbekistan in 2020-2024, which, among others, provides for the phased implementation of the requirements of Good Manufacturing Practices (GMP) and Good Vigilance Practices (GVP), as well as Good Distribution Practices (GDP), Good Laboratory Practices (GLP) and Good Clinical Practices (GCP), simplification of requirements for registration of medicinal substances, bringing the regulatory framework for the development, testing, and production of drugs under the requirements of good GxP practices with the involvement of international experience.

The approved Concept will be one of the important steps in the development of pharmaceuticals in Uzbekistan, the expected results of the implementation of which will be ensuring the drug safety of Uzbekistan, including immunobiological drugs, increasing the share of domestic pharmaceutical products in the domestic market, increasing the export of pharmaceutical products, and attracting additional direct investment.

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