Legal alert
Uzbekistan – January 2024

Legislative changes in Pharma and Business Licensing in Uzbekistan

Amendments and supplements introduced into the pharmaceutical regulatory legal acts

On 22 November 2023, Uzbekistan President signed a Law, "On Amendments and Supplements to Certain Legislative Acts of the Republic of Uzbekistan in connection with the Improvement of Pharmaceutical Activity" No. ZRU – 879 (the "**Law No. 879**").

The Law No. 879 amended and supplemented the Law of the Republic of Uzbekistan "On Medicines and Pharmaceutical Activities" No. ZRU-399 dated 4 January 2016 (the "**Law on Medicines**") and the Law of the Republic of Uzbekistan "On Blood Donation and its Components" No. 402-II dated 30 August 2002 (the "**Law on Blood Donation**"). Law No. 879 came into force on 22 November 2023.

As per the amendments and supplements made to the Law on Medicines, healthy individuals can now participate in clinical trials of a pharmacological agent or medicine. Previously, only patients were allowed to participate as subjects in the clinical trials. According to the updated Law on Medicines:

- Participation of a subject in clinical trial of a pharmacological agent or medicine shall be carried out on a voluntary basis upon his/her written consent,
- The head of the clinical trial is obliged to give the subject a detailed explanation on the significance of the method, nature, and possible risks of the clinical trial,
- The subject of a clinical trial is entitled to refuse to participate at any stage of the clinical trial.

Besides, as per adopted supplements, in case of conducting a clinical trial involving a minor or legally incapable subject, before the start of the clinical trials, the parents or other legal representatives of the subjects shall give written consent.

Before conducting a clinical trial involving a minor, a similar clinical trial must be conducted with the participation of adults.

In addition, among other things, the Law No. 879 contemplates the following amendments and supplements:

- Now the same manufacturer can register several medicines having the same composition under different trade name.

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- Registration certificates for medicines, medical devices, and medical equipment issued to domestic manufacturers have become valid for indefinite term. Previously, the validity period of registration certificates for domestic manufacturers was 5 (five) years.
- Possessing an appropriate license, the third-party manufacturers are now allowed to manufacture medicines and medical devices based on a contract and in accordance with the purchase order of the customer (manufacturer of medicines and medical devices). The registration certificate is issued to the third-party manufacturer directly manufacturing medicines and medical devices in accordance with the purchase order. Notably, a separate regulatory legal act governing contract manufacturing has not been adopted yet.

In accordance with the amendments introduced into the Law on Blood Donation, manufacturers of pharmaceutical products from donor blood and its components are allowed to collect, prepare, process, and store donor blood and its components in a private capacity.

Improving the prevention and treatment of allergic diseases

The President signed the Decree “On Further Measures to Improve the Quality of Prevention and Treatment of Allergic Diseases” No. PP - 371 dated 23 November 2023 (the “**Decree No. 371**”).

According to the Decree No. 371, the proposals of the Ministry of Health of the Republic of Uzbekistan (the "**MoH**") were approved allowing further improvement of allergic diseases’ prevention and provision of allergological and immunological care to the population., The Decree No. 371 approved the following proposals of the MoH:

- Implementation of targeted screenings,
- Free provision of necessary medicines to the vulnerable groups of population,
- Early detection of the causes of the development and prevention of allergic and immunological diseases among children, adolescents, and pregnant women,
- Expanding the types of high-tech diagnostics and treatment, as well as introducing methods of molecular diagnostics of allergic diseases in the regions.

Starting from 2024, the MoH will carry out the following measures:

- Conducting mass and selective screenings in areas with high rates of allergic diseases (including seasonal allergies) at least 1 (once) a year,
- Organization of systematic monitoring and individual rehabilitation of identified patients suffering from allergic diseases and diseases of secondary immunodeficiency by allergists,
- Gradual increase from 10 (ten) to 20 (twenty) types of high-tech diagnostics and treatment modalities in the field of allergology and clinical immunology in the regions,
- Full provision of allergen reagents to the laboratories of territorial subdivisions of the Republican Scientific and Specialized Allergological Center at the expense of local budgets in cooperation with the Council of Ministers of the Republic of Karakalpakstan, the khokimiyats (regional government administrations) of the regions and Tashkent city.

Besides, Decree No. 371 stipulates that from 1 January 2024 the Republican Scientific and Specialized Allergological Center will be transformed into the Republican Specialized Scientific and Practical Medical Center for Allergology and Clinical Immunology (the "**Center**") with 140 (one hundred and forty) in-patient beds.

Moreover, the Decree No. 371 defines the following additional objectives and activities of the Center:

- Prevention, molecular diagnosis, and treatment of allergic and immunological diseases based on fundamental and practical research in the field of molecular allergology and clinical immunology,
- Implementation of screening programs for early detection and elimination of the causes of allergic diseases,
- Implementation of national programs for the prevention, early detection, and management of allergic diseases and secondary immunodeficiency diseases in primary healthcare.

Amendments to the legislation on business licensing

On 15 November 2023, the President signed a Law "On Amendments and Additions to Certain Legislative Acts of the Republic of Uzbekistan" No. ZRU-878 (the "**Law No. 878**"), which provides, among other things, amendments, and additions to the Law "On Licensing, Permits and Notification Procedures" No. ZRU-701 dated 14 July 2021. The Law No. 878 will come into force from 17 February 2024.

The Law No. 878 contemplates additional grounds for revocation of a license or a permit as a result of:

- Systematic (2 (two) or more times within 1 (one) year) violation by the licensee or the person who received the permit of licensing or permit requirements and conditions,
- A single gross violation by the licensee or a person who has received a permit of licensing or permit requirements and conditions, if these violations resulted in harm to the life and health of citizens, infringement of the rights and legitimate interests of individuals and legal entities, public safety and harm to the environment, damage to the interests of society and the state, creating a threat to peace and security.

In case of license revocation, the license is not reissued to the applicant based on a court decision within 1 (one) year for the types of activities determined by the legislation (including a license for pharmaceutical activities). This requirement also applies to new business entities created by the founder or beneficial owner of a business entity whose license has been revoked.

VAT exemptions have been canceled

On 28 December 2023, the President signed a Law of the Republic of Uzbekistan "On Amendments and Additions to Certain Legislative Acts of the Republic of Uzbekistan in

connection with the Adoption of the Main Directions of Tax and Budgetary Policy for 2024" No. ZRU – 891 (the "**Law No. 891**").

According to the Law No. 891, from 1 April 2024 VAT exemptions will be canceled with respect to the provision/sale of:

a) Medical services,
b) Veterinary services,
c) Medicines, veterinary medicines, medical and veterinary devices.

Besides, starting from 1 April 2024 VAT exemptions for the import of the following goods will be also cancelled:

a) Medicines, veterinary medicines, medical and veterinary devices,
b) Raw materials imported according to the list determined by legislation which are used to produce medicines, veterinary medicines, medical and veterinary devices.

The abovementioned amendments will come into force from 1 April 2024.

Maximum trade mark-ups for wholesale and retail sales of medicines are being canceled

The President signed the Decree "On Measures to Ensure the Implementation of the Law "On the State Budget of the Republic of Uzbekistan for 2024"" No. PP-422 dated 29 December 2023 (the "**Decree No. 422**"). The Decree No. 422 provides for the abolition of:

- Maximum trade mark-ups for wholesale and retail sales of medicines and medical devices,
- Sales of socially significant medicines and medical devices at fixed prices.

Nonetheless, there are several regulatory legal acts that remain in force under which the maximum trade mark-ups for wholesale and retail sales of medicines have not been abolished. Such regulatory legal acts include:

- Order of the MoH "On Approving the Regulation on the Procedure for Registration of Prices for Medicines in the Reference Price Formation System" No. 3242 dated 10 June 2020,
- Decree of the President "On Additional Measures to Deepen Reforms in the Pharmaceutical Industry of the Republic of Uzbekistan" No. PP-4554 dated 30 December 2019 (the "**Decree No. 4554**").

Moreover, the Pharmaceutical Industry Development Agency is currently considering developing new mechanisms to optimize the amendments adopted according to Decree No. 422, including the update of the regulation of reference prices of medicines, adopted based on the Decree No. 4554.

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