Uzbekistan | November 2022

MEASURES TO PROVIDE POPULATION WITH QUALITY MEDICINES AND MEDICAL DEVICES

On October 27, 2022, the Resolution of the President of the Republic of Uzbekistan (hereinafter – "**Uzbekistan**") "On Additional Measures to Provide the Population with Quality Medicines and Medical Devices" No. PP-411 dated October 26, 2022 (hereinafter – the "**Resolution**") came into force. Please see below some of the key, from our standpoint, changes provided by the Resolution.

Amendments in the Registration and Certification Procedure of Medicines and Medical Devices

Starting from January 1, 2023, registration of new medicines is carried out:

- Based on the clinical trials positive outcome. Registration of certain medicines without clinical trials is carried out in accordance with the procedure established by the Ministry of Health of Uzbekistan (hereinafter – the "**Ministry**");
- after examining on-site compliance of the manufacturing conditions with the requirements of Good Manufacturing Practice – GMP.

The exceptions are the medicines specified in the Annex No. 1 to the Resolution[1], i.e.:

- Medicines that have been registered by other countries, international and foreign organizations[2], registration results of which are recognized by Uzbekistan;
- Medicines with the positive clinical trials and a certificate of pharmaceutical inspection conducted by other countries, international and foreign organizations, the registration results of which are recognized by Uzbekistan[3];
- Medicines prequalified by the World Health Organization.

Furthermore, from July 1, 2023, certification of medicines without registered reference price or with the price exceeding registered one will be prohibited.

[1] The list of drugs that are not subject to clinical trials and the study of production conditions compliance with the requirements of "Good Manufacturing Practice – GMP" during state registration in Uzbekistan.
[2] List of countries, international and foreign organizations whose results of registration of medicines are recognized in the Republic of Uzbekistan (Annex to the Resolution of the President of Uzbekistan "On Additional Measures to Improve the Procedure for State Registration and Turnover of Medicines" No. PP-3948 dated September 25, 2018) (hereinafter – the "**List**").
[3] The List.

In addition, by the end of 2022, the Ministry and the Pharmaceutical Industry Development Agency of Uzbekistan (hereinafter – the "**Agency**") shall approve a list of medicines and medical devices (hereinafter – the "**MD**") with no analogues registered in Uzbekistan, the introduction and application of which in medical practice is allowed up to January 1, 2025, subject to mandatory certification without state registration. It should be noted that within 3 months from state registration of the analogues of the abovementioned medicines and the MD in Uzbekistan, the non-registered foreign medicines and the MD will be excluded from the above list.

The Resolution cancels:

- State registration of medical substances;
- Requesting standard samples when recognizing results of medicines' registration carried out outside Uzbekistan.

Until December 2022, the Agency, *inter alia*, plans to:

- Introduce the possibility for business entities to submit applications for the state registration of medicines, the MD, medical equipment (hereinafter – the "**ME**") and their components electronically through the "Uzpharminfo" program;
- Post a register of medicines that have passed state registration on the Agency's official website.

Wholesale of Medicines and the MD

The Resolution introduces the following amendments to the procedure for the wholesale of medicines and the MD[4]:

- The purchase price of imported medicines and the MD is applied as the basis for regulating prices for imported products;
- The selling price of medicines and the MD of domestic production is considered as the basis for establishing a regulated price for manufactured products. It should be noted that manufacturers set the selling price of such medicines and the MD in accordance with the Regulation "On the Composition of Costs for the Production and Sale of Products (Works, Services) and the Procedure for Generating Financial Results"[5].

Provision of Medicines and the MD in the State Inpatient Medical Institutions of Uzbekistan

[4] Regulation "On the Procedure for the Wholesale of Medicines and Medical Devices" (Annex No. 1 to the Resolution of the Cabinet of Ministers of the Republic of Uzbekistan "On Measures to Implement the Law of the Republic of Uzbekistan dated January 4, 2016 No. ZRU-399 "On Amendments and Additions to the Law of the Republic of Uzbekistan" On Medicines and Pharmaceutical Activity" No. 185 of April 6, 2017).
[5] Approved by the Resolution of the Cabinet of Ministers of the Republic of Uzbekistan "On Approval of the Regulations on the Composition of costs for the Production and Sale of Products (Works, Services) and on the Procedure for the Formation of Financial Results" No. 54 dated February 5, 1999.

State inpatient medical institutions (hereinafter – the "**Hospitals**") of the republican level, which are funded from the State Health Insurance Fund, provide patients with medicines and the MD.

During 2023, provision of patients with medicines and the MD will primarily be carried out in republican level Hospitals as a pilot project.

Furthermore, the provision of medicines and the MD to patients in Hospitals is free of charge if those medicines and the MD were purchased as part of a guaranteed medical services and medicine package at the Hospitals' planned expenses. In other cases, the above provision is performed on a paid basis at prices that are recognized in Hospitals. The price of medicines and the MD purchased in Hospitals should not exceed the established wholesale reference prices.

Introduction of Public Control over Medicines' Retail Trade

Starting from May 1, 2023:

- Prices of medicines will be automatically compared with retail reference prices of medicines in the Agency's information system when individuals register the fiscal mark of the purchase receipt (by scanning QR-code) in a special mobile application of Uzbekistan tax authorities;
- The Consumer Protection Agency will be automatically notified to take appropriate measures if overstatement of established retail prices is detected while scanning QR-code;
- An inspection will be carried out if the medicine's price on the purchase receipt exceeds the registered retail reference price and the offender will be fined in accordance with the established procedure;
- Not specifying the full price of the purchased medicines and the MD in the purchase receipt will be considered as a violation of Uzbekistan legislation on the rules of trade or the provision of services.

Other Amendments

According to the Resolution, the procedure for the Ministry's approval of the over-the-counter (hereinafter – the "**OTC**") medicines list is canceled.

It should be noted that the Agency plans to:

- Develop and approve the procedure for including medicines into the categories of prescription and the OTC medicines. Post on the official state websites a register of medicines, the MD and the ME approved for use in medical practice, (with a separate indication of the OTC medicines), and to ensure its continious updating - in cooperation with the Ministry, until December 2022;

- Introduce until March 1, 2023 an Information System for Accounting and Control of Pharmaceutical Products to record the processes - from the manufacturing of medicines to their consumption;
- Develop instructions for the use of medicines that have passed state registration in Uzbekistan and an electronic catalog of biologically active additives (hereinafter – the "**BAS**") for their further postal on the official websites – in cooperation with the Sanitary and Epidemiological Welfare and Public Health Service, until June 1, 2023;
- Develop a mobile application that allows tracking the reference prices of medicines – until April 2023.

Additionally, it is planned to adopt the procedure allowing obtaining permits for the BAS, food additives, biological agents and materials' import and production via Unified Portal of Interactive Public Services.