News on pharmaceutical legislation

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New rules of state registration of medicinal products and medical devices in the Republic of Uzbekistan

Significant changes have been made to the regulation of state registration of medicinal products (hereinafter - "**Medicines**") and medical devices (hereinafter - "**MDs**") in the Republic of Uzbekistan (hereinafter - "**Uzbekistan**") with a view to simplifying the state registration of Medicine and MD. An overview of the key changes is provided below.

Resolution No. 738 of the Cabinet of Ministers of Uzbekistan dated November 24, 2025, approved new Regulations "On the Procedure for State Registration of Medicines" (hereinafter referred to as the "**Regulation-1**") and "On the Procedure for State Registration of MDs" (hereinafter – the "**Regulation-2**"). These documents provide for the procedure for state registration of Medicines and MDs, the issuance of certificates, as well as their extension and cancellation.

In addition, Resolution No. 738 repeals the Resolution No. 213 of the Cabinet of Ministers of Uzbekistan dated March 23, 2018, "On Approval of the Regulations on the Procedure for State Registration of Medicines, MDs and Medical Equipment and Issuance of Registration Certificates" (hereinafter referred to as the "**Resolution No. 213**").

Resolution No. 738 was adopted in pursuance of the Decree of the President of Uzbekistan "On Additional Measures to Regulate the Circulation of Medicines and MDs" No. UP-137 dated August 19, 2025, which strengthens the role of the Center for Pharmaceutical Products Safety" (hereinafter – the "**Centre**") under the Ministry of Health (hereinafter – the "**MH**") of Uzbekistan. Regulation 1 and Regulation 2 shall enter into force on 26 February 2026.

I. Regulation on the procedure for state registration of Medicines

1. Scope, concepts and scope of registration

The Regulation-1 defines the procedure for state registration of all Medicines – original, generic, biosimilar, biotechnological and others – and applies to developers, manufacturers, registration certificate holders and their authorized representatives.

The following basic terms are described in detail below.

Generic Medicine is a Medicine that has the same qualitative and quantitative composition and dosage form as the active substance of the original (patented) Medicine, but is manufactured after the expiry of the patent, and whose safety, potency, properties, area of application and bioequivalence have been confirmed in relation to the original Medicine. Different salts, esters, isomers, mixtures of isomers, complexes or derivatives of the active substances are recognized as the same active substance if they do not differ significantly in terms of safety and efficacy. Different dosage forms intended for oral administration and

having a rapidly released active substance are recognized as the same dosage form in bioavailability studies.

Biosimilar Medicine is a biological Medicine obtained from natural sources, containing the active substance of a registered original (reference) Medicine and proven to be similar to the original (reference) Medicine in terms of quality, biological activity, efficacy and safety based on comparative studies.

Original Medicine is a Medicine containing a new active substance or substances, registered first on the global pharmaceutical market, the quality, efficacy and safety of which are confirmed by the results of preclinical and clinical trials (hereinafter - "**CTs**").

Technology Transfer is the transfer of technological processes, data and experience in the development and/or production of Medicines, including from one pharmaceutical organization to the production site of another pharmaceutical organization without changing the qualitative and quantitative composition of the Medicines, apart from "in bulk" products.

Contract Manufacturing is manufacture of registered Medicines by one pharmaceutical organization on a contract basis for another pharmaceutical organization without changing the technologies at its facilities.

Pharmaceutical Organization is an authorized legal entity responsible for the safety, quality and efficacy of Medicines, which is the developer, manufacturer or purchaser of Medicine.

Notably, biotechnological Medicines have been added to clause 5 of the Regulation-1, defined as those produced on the basis of cell technology, previously registered in Uzbekistan, with changes to their type (autologous, allogeneic, combined), qualitative and/or quantitative composition (excluding the composition of excipients), as well as the biological and other properties of the cell line(s).

According to clause 3 of the Regulation-1, the registration of Medicines is carried out in two ways:

- In the general procedure,
- Through recognition, whereby Medicines, registered by the following foreign organizations, undergo state registration in Uzbekistan by means of recognition:
    - Regulatory authorities included in the World Health Organization (WHO) Listed Authorities.
    - Regulatory authorities with Maturity Level 4 according to the World Health Organization's Global Benchmarking Tool.

For the following Medicines, state registration will now not be required in accordance with clause 7 of the Regulation-1:

- radiopharmaceutical Medicines manufactured directly in medical institutions,
- Medicines intended for export,
- bone marrow stem cells,
- biotechnology products based on cell technology, specially manufactured and used in a medical institution for individual patients for the purpose of fulfilling an individual medical prescription.

At the same time, at the request of the applicant, substances used to produce Medicines intended for export may be registered.

In addition, according to clause 8 of the *Regulation-1*, the import of orphan Medicines, imported Medicines used in the prevention, diagnosis and treatment of particularly dangerous infections, as well as infections posing an epidemiological risk, at the request of the MH of Uzbekistan, may be carried out without state registration.

Medicines imported as foreign gratuitous and humanitarian aid may also be imported into the territory of Uzbekistan and used without state registration upon receipt of a positive conclusion from the MH on the import and use of these Medicine in the territory of Uzbekistan.

A priority registration procedure is introduced for the following Medicines:

- Medicines registered in Uzbekistan that have no analogues,
- orphan Medicines,
- Medicines in high demand on the domestic market based on the requirements of the MH of Uzbekistan,
- the first analogue of the original Medicines.

2. *Requirements and conditions, GMP/GVP*

An applicant who releases Medicines into circulation based on a registration certificate shall additionally be obliged to:

- ensure the accuracy and reliability of information in registration files and guarantee the quality, safety and efficacy of Medicines,
- regularly submit information on side effects to the Centre,
- ensure that Medicines are placed on the market in Uzbekistan for at least three years after their state registration (except for Medicines manufactured by domestic manufacturers for export).

3. *Documents and samples required for registration*

The following official documents obtained from abroad must be apostilled or legalized at the Consulate of Uzbekistan abroad:

- Certificate of registration and/or certificate of pharmaceutical products (CPP) in accordance with WHO recommendations, issued by authorized bodies, international or foreign organizations for foreign manufacturers,
- Certificate of compliance with the requirements of the Good Manufacturing Practice (GMP) standard and a report on the results of the last inspection (for foreign manufacturers),
- License for the manufacture of Medicine.

The authorized representative of the applicant must have a higher education degree in pharmacy, medicine, chemistry or biology.

4. *Expert review, deadlines and Medicines registration*

A fee will be charged for reviewing the application, which will not be refundable if the applicant withdraws the application and the Medicine registration is refused.

Applications will be reviewed within the following timeframes:

- for vaccines - ***30 days***.
- for medicinal substances (substances) - ***45 days*****.**

- for Medicines registered under the general procedure - ***210 days*****.**

These timeframes do not include ***45 days*** allocated for the elimination of deficiencies identified as a result of the initial examination; ***90 days*** allocated for the elimination of deficiencies identified as a result of a specialized examination; CTs periods (up to ***1 year*** for generics, up to ***3 years*** for original Medicines) and the time spent on verifying compliance with the GMP standard.

Changes in the Medicine registration procedure:

An expert opinion will be issued based on the results of the initial examination of registration documents and Medicine samples.

- *Specialized examination:*

Laboratory test reports and documents will be examined for compliance with registration requirements and conditions based on the substantiated conclusions of scientific commissions consisting of independent experts.

- *Conducting CT and examining their results*:

The Centre will issue a conclusion on the registration of Medicine with or without CTs.

Conducting CT during Medicines registration will not be required for medicinal substances (substances), biotechnological Medicines produced on the basis of cell technology, obtained as a result of processing human cells without significant changes, and oral generics whose bioequivalence to the reference product has been proven using validated in vivo or in vitro research methods, the results of which are presented in the form of quantitative indicators.

The need for inspections of bioequivalence studies to assess compliance with GCP requirements will be determined based on the following criteria:

- submission of unjustified data on the results of bioequivalence studies,
- inconsistency of the identified values specifically for this active substance,
- unreliability of one of the clinical, statistical or analytical data presented,
- obtaining results in pharmacokinetic studies that do not confirm bioequivalence.

From 1 January 2029, bioequivalence studies of oral generics based on ICH requirements will become mandatory.

Based on the results of the registration review of the Medicine, the Centre will make one of the following decisions:

- to register the Medicine,
- to refuse to register the Medicine.

5. Validity period of the registration certificate, changes and register

The registration certificate will be issued to all for a period of **5 years**.

II. Regulations on the procedure for state registration of MDs

1. Scope and risk classes

MD will be registered in accordance with the new the Regulation-2.

MD will now be registered according to the following safety levels:

- Class I - MDs with low risk,
- Class IIa - MD swith medium risk,
- Class IIb - high-risk MDs,
- Class III - MDs with the highest risk level.

According to clause 4 of the Regulation-2, MD registration will be carried out in two ways:

- In the general procedure,
- Through the recognition procedure.

MDs registered by the following foreign organizations will undergo state registration in Uzbekistan through recognition:

- Food and Drug Administration (FDA), USA,
- Authorities authorized to issue the European Certificate of Conformity (CE), European Union,
- European Medicines Agency (EMA), European Union,
- Pharmaceuticals and MD Agency (PMDA), Japan,
- Ministry of Food and Drug Safety (MFDS), Republic of Korea,
- Medicine and Healthcare Products Regulatory Agency (MHRA), United Kingdom.

According to clause 5 of the Regulation-2, registration is no longer required for:

- reagents included in the kit for in vitro diagnostic MDs that cannot be used as a diagnostic tool on their own,
- MDs manufactured based on individual order.

MDs intended for export may be registered in Uzbekistan at the request of the applicant.

The import of MDs used in the diagnosis and treatment of orphan diseases and used in the prevention, diagnosis and treatment of particularly dangerous infections, as well as infections posing an epidemiological risk, imported at the request of the MH of Uzbekistan, may be carried out without state registration of the imported MDs.

MDs imported as foreign gratuitous assistance, and humanitarian aid may be imported into the territory of Uzbekistan and used without state registration. In this case, the MH of Uzbekistan must issue a corresponding positive conclusion for the import into the territory of Uzbekistan and use of these MDs.

2. Documents, examination, and deadlines

Now, if the applicant withdraws the application and registration of the MD is refused, the fee paid for consideration is not refundable.

Applications for the state registration will be considered by the Centre within the following timeframes:

- within ***30 working days*** - MDs for in vitro diagnostics used during epidemics and pandemics of infections posing an epidemiological threat, registered once a year,
- within ***60 working days*** - MDs classified as Class I according to the safety classification,
- within ***90 working days*** - MDs classified as Class IIa according to the safety classification,
- within ***120 working days*** - MDs classified as Class IIb and Class III in the safety classification.

These periods shall not include ***30 days*** allocated for the elimination of deficiencies in the event of refusal to accept the application; ***60 days*** allocated for the elimination of deficiencies identified as a result of a specialized examination; the period of the CTs and the time spent on checking the MDs for compliance with the requirements of the national standard of Uzbekistan, harmonized with the international standard "ISO: 13485".

Changes in the procedure for registering MDs:

- *Laboratory tests:*

Laboratory tests for MD and their components registered through recognition and MDs of class I according to the safety classification (except for sterile, measuring and invasive MDs) will not be conducted.

- *Specialized expertise:*

Laboratory test reports and documents on compliance with registration requirements and conditions will be reviewed based on reasoned conclusions of scientific commissions consisting of independent experts.

- *Conducting CTs and reviewing their results:*

Conducting a CT during registration will not be required for Class I MDs according to the safety classification and for in vitro diagnostic MDs prequalified by the WHO and registered in cooperation with the WHO.

- *Inspection of manufacturing conditions*:

Production facilities will be inspected on site. The inspection will cover the quality management system, product traceability system and production environment. Inspections will be carried out in accordance with the national standard of Uzbekistan, harmonized with the international standard "ISO:13485". Based on the results of the inspection, the facilities are subject to certification in accordance with the established procedure.

Inspections of the production conditions of MDs not manufactured in Uzbekistan will be carried out on a priority basis, apart from the following:

- MDs registered by recognition,
- MDs for in vitro diagnostics, prequalified by the WHO and registered in cooperation with the WHO,
  MDs with a valid certificate in accordance with the requirements of the national standard of Uzbekistan, harmonized with the international standard "ISO: 13485".

3. Registration certificate and register

Based on the results of state registration, a corresponding registration certificate will be issued for ***5 years***.

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