Legislative news in the field of medicinal products' circulation
Uzbekistan – July 2026

New Requirements for Documents Submitted for the State Registration of Medicinal Products

On 4 June 2026, the Minister of Health of the Republic of Uzbekistan adopted Order No. 3848 approving the Instruction on Requirements for Documents Submitted for the State Registration of Medicinal Products (the "**Instruction**"), aimed at establishing uniform requirements for registration dossiers in line with national requirements and the standards of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH CTD).

The Instruction was adopted pursuant to Decree of the President of the Republic of Uzbekistan No. UP-137 "On Additional Measures to Regulate the Circulation of Medicinal Products and Medical Devices" (the "**Decree No. UP-137**") and Resolution of the Cabinet of Ministers of the Republic of Uzbekistan No. 738 "On Approving the Regulations on the Procedure for State Registration of Medicinal Products and the Regulations on the Procedure for State Registration of Medical Equipment" (the "**Resolution No. 738**"). The Instruction will enter into force on **6 September 2026**.

Below is an overview of the key changes introduced by the Instruction to the procedure for the state registration of medicinal products ("**MPs**").

Requirements for the Application and Supporting Documents

The Instruction sets out detailed requirements for documents submitted as part of the state registration of MPs and clarifies practical aspects of document submission when applications are filed by foreign applicants.

Pursuant to clause 4 of the Instruction, the applicant must submit the application based on Annex 2 to the Resolution No. 738. When an application is submitted through an authorized representative, the document evidencing the *representative's authority (power of attorney)* must state the date of issue, the name and legal form of the representing legal entity.

It should also be noted that a power of attorney issued abroad must be notarially certified and legalized in accordance with the established procedure.

In addition, if the power of attorney submitted by foreign manufacturers is not issued in Uzbek, Karakalpak, Russian, or English, its accurate translation into Uzbek must be *notarized*. If the authorized person has changed, or a new power of attorney has been submitted, a copy of the new power of attorney must be attached to the application.

The Instruction requires that a payment document be issued by the applicant in the form of a payment order. In addition, foreign manufacturers must provide a *certificate of registration* issued by authorized state bodies, international or foreign organizations, and/or a *Certificate of Pharmaceutical Product (CPP)* (the "**Certificate**") in accordance with World Health Organization recommendations. If the submitted Certificate indicates that the MP is not registered in the country of manufacture, the applicant must provide a notarized or apostilled certificate of registration from other countries.

Pursuant to clause 3 of the Instruction, depending on the characteristics of the MP, the applicant may submit an *official letter (a substantiated explanatory letter)* where certain required documents or information are absent.

Labelling and Packaging Rules for MPs

The Instruction explains in detail the labeling requirements that apply to all types of packaging — *primary, secondary* (consumer) and *intermediate* packaging — as well as to labels and stickers. In accordance with clause 9 of the Instruction, information applied to these elements of packaging must strictly comply with the General Technical Regulation on the Safety of Medicinal Products, approved by Resolution of the Cabinet of Ministers of the Republic of Uzbekistan No. 365 "On Approval of the General Technical Regulation on the Safety of Medicinal Products" (the "**General Technical Regulation**").

The Instruction provides an exception for products registered under the recognition procedure: labeling of these products in the language of the country of manufacture is permitted without mandatory translation into the state language or Russian language.

The Instruction emphasizes the requirements for packaging layouts. Color samples of consumer packaging, labels and stickers must be submitted electronically in PDF or JPG format with a minimum resolution of 300 dpi. Layouts must indicate the Pantone color code, trim and fold lines, and the exact physical dimensions (length, width, height) of both primary and secondary packaging. These detailed technical requirements are intended to ensure uniformity and reproducibility of the appearance of MPs entering the market of the Republic of Uzbekistan.

Requirements for the Draft Summary and Package Leaflet of MP

Pursuant to clause 11 of the Instruction, the applicant must submit a draft of the product summary, the patient information leaflet, and the package leaflet in *Uzbek language*. Submission of the same documents in other languages is not mandatory.

The patient information leaflet must comply with clause 47 of the General Technical Regulation. The Instruction expressly permits inclusion in the leaflet of additional non-promotional information that conforms to international requirements and applicable law.

Requirements for Documentation Confirming the Quality of MPs

Clause 12 of the Instruction lists the documents required to demonstrate the quality characteristics of a MP.

First, the applicant must provide a *copy of the certificate of compliance* for the active pharmaceutical ingredient (substance) with the requirements of the *European Pharmacopoeia*, if such a certificate exists. The certificate must meet strict formal requirements: it must be submitted in full, including all pages unchanged, and be legible.

If the quality of the active substance is substantiated within the core dossier, the Center for Pharmaceutical Product Safety may require a letter of consent from the dossier owner permitting disclosure of the closed part of the dossier, including information on the manufacturing process and other confidential intellectual property.

A key element of the quality documentation is the draft in-house pharmacopeial monograph of the enterprise for the MP, developed based on the *State Pharmacopoeia of the Republic of Uzbekistan* and leading international pharmacopoeias. An explanatory letter that sets out the scientific rationale for the chosen quality specifications and control methods must accompany this draft.

When applying for renewal of the registration certificate, the applicant must additionally submit the current in-house pharmacopeial monograph.

Requirements for Manufacturing Documentation

Under clause 13 of the Instruction, the required manufacturing documentation varies depending on the manufacturer's location.

For domestic manufacturers, it is sufficient to submit a certificate of compliance with the national standard for *Good Manufacturing Practice (GMP)*, if available, together with the *manufacturing license* for the MPs.

For foreign manufacturers, the requirements are more extensive. In addition to a valid *GMP certificate* issued by a competent foreign state authority for the manufacturing site of the MP, the applicant must provide a *report* on the results of the most recent inspection of the manufacturing site. The inspection report must provide identified non-conformities, corrective actions taken, and the conclusion following the inspection. To verify the authenticity of submitted information, the Instruction allows the provision of references to the official websites of the competent authorities which issued the relevant documents.

Pharmacovigilance and Intellectual Property Documents

Clause 17 of the Instruction sets out the documentation required to demonstrate implementation of a pharmacovigilance system in the Republic of Uzbekistan. The applicant must include the core pharmacovigilance dossier prepared in accordance with the national

standard *Good Pharmacovigilance Practice (GVP)* (the "**GVP Standard**") and register a risk management plan for the MP.

The Instruction specifies qualification requirements for the local representative responsible for pharmacovigilance within the Republic of Uzbekistan. That person must hold a higher medical or pharmaceutical degree and possess specialized pharmacovigilance qualifications confirmed by a certificate. The dossier must contain the responsible person's full identification details, diploma information, appointment order, contact and work addresses, and the validity period of the qualification certificate.

When renewing the registration certificate or making amendments to the registration documents, a periodic *report* on pharmacovigilance, prepared by the applicant in accordance with the requirements of the GVP Standard, is additionally required.

Pursuant to clause 18, documents confirming the applicant's rights to intellectual property objects used in the MP (trademarks, industrial designs) form a separate part of the registration dossier. These documents may include a protection document (certificate or patent with annexes), an agreement on the use of objects of intellectual property, or an opinion from the competent intellectual property authority regarding the trade name and design of the MP.

Submission of Documents in ICH CTD Format

Clause 19 of the Instruction requires submission of the documents covered by Sections 2–5 of the List of Documents for State Registration of MPs (Annex 3 to Resolution No. 738) in the format of the *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH CTD)*. The Instruction aligns the sections of the registration dossier with the corresponding international modules as follows:

— Section 2, "General Technical Documents" — modules M4Q (R1) (quality), M4S (R2) (safety), M4E (R2) (efficacy).

— Section 3, "Information Defining the Quality of the MP" — module M4Q (R1).

— Section 4, "Information on Preclinical Studies" — module M4S (R2).

— Section 5, "Information on Clinical Studies" — module M4E (R2).

Introducing ICH CTD format requirements brings the regulatory practice of the Republic of Uzbekistan closer to international standards and creates conditions for potential mutual recognition of registration dossiers.

Rights to Appeal Actions of a Government Authority

The Instruction concludes with provisions that set out mechanisms for protecting the rights of interested parties and defining their liabilities. Under Clause 20, an interested party that disagrees with the requirements applicable to documents submitted for the state registration of MPs may challenge such requirements before a court or the competent authorities in accordance with the law.

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