New Pricing Regulations and Amendments to Import and Use of Medicines and Medical Devices in Uzbekistan

Overview of Key Amendments to the Reference Pricing System for Medicines in Uzbekistan

On December 10, 2025, the Minister of Health of the Republic of Uzbekistan ("**Uzbekistan**") issued the Order "On Approval of the Regulation on the Procedure for Registration of Prices for Prescription Medicines within the Reference Pricing System" (the "**Regulation**") in a new edition registered with the Ministry of Justice of Uzbekistan on December 25, 2025 under registration No. 3735 (the "**Order No. 3735**").

Order No. 3735 enters into force on March 28, 2026.

Below is an overview of the key changes introduced to the regulation of reference pricing for prescription medicines as set forth in Order No. 3735.

Clarification of the Scope and Subject Matter of the Regulation

The revised edition of the Regulation introduces a direct reference to the official list of medical devices ("**MDs**") and products intended for the diagnosis and treatment of orphan diseases (Register No. 3258 dated June 30, 2020) that are explicitly excluded from the scope of the reference pricing regulation.

Amendments and Additions to Key Definitions

The new edition of the Regulation revises the terminology used to define price categories. The term "maximum prices" has been replaced by two separate terms: "reference price" and "maximum prices".

A reference price is defined as a price registered within the reference pricing system, while maximum prices are defined as wholesale and retail prices calculated by applying maximum trade mark-ups to the reference price.

In addition, the Regulation introduces three new definitions: "original medicine," "generic medicine," and "biosimilar medicine."

Change of the Working Body

The new edition of the Regulation removes references to the state institution "The Center for Pharmaceutical Products Safety" (the "**Center**") as the working body, thereby excluding this institution from exercising the relevant powers.

Instead, the working body is defined as the responsible division of the authorised body (the Agency for the Development of the Pharmaceutical Industry under the Ministry of Health (the "**MOH**") of Uzbekistan, - the "**Agency**") for reference pricing.

Update of the List of Reference Countries

In accordance with Order No. 3735, Annex No. 2 to the Regulation, which contains the list of reference countries, has been set out in a new edition.

In particular, the Republic of Belarus has been replaced with the Republic of Moldova.

Exclusion of Excessively High Reference Country Prices

Under Order No. 3735, Annex No. 2 to the Regulation has been supplemented with a note providing that if the price of a medicine in any reference country exceeds by more than 50 percent the prices established for the same medicine in two or more other reference countries, the prices established in such reference country shall not be taken into account.

Changes to the Procedure for Submission of Data for Registration and Re-registration of Reference and Maximum Prices

According to the new edition of the Regulation, the type of data to be submitted by applicants in respect of imported medicines for price registration has been revised.

Instead of delivery prices to reference countries and prices for distributors in the country of manufacture, the new edition now requires the submission of official prices established for manufacturers in reference countries, as well as the official price established for the manufacturer in the country of manufacture.

In addition, the time period for which data on imported medicines is taken into account has been extended: whereas previously data for the preceding six months were used, data for the preceding twelve months are now taken into account based on information provided by the Customs Committee under the Ministry of Economy and Finance of Uzbekistan on Incoterms CIP terms.

Revision of the Alternative Procedure for Price Confirmation in the Absence of Key Pricing Data

The new edition of the Regulation introduces a revised procedure for confirming prices in cases where key pricing data, namely information on official prices established for the manufacturer in reference countries and in the country of manufacture, are unavailable.

In these cases, the applicant shall submit official prices for medicines with the same active substance and in the same dosage form that are applied in the country of manufacture, in member countries of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), as well as in Uzbekistan.

In this process, a step-by-step procedure for determining a comparable price is established. First, the lowest price of a medicine with the same dosage of the active substance, in the same packaging and in the same quantity is used. If these data are unavailable, a proportionally adjusted price of a medicine with the same dosage of the active substance in the nearest larger package size is applied. If this option is also unavailable, the price of a medicine with the same dosage of the active substance in the nearest smaller package size is used.

Regulatory Establishment of Pricing Principles for Generic and Biosimilar Medicines

The Regulation establishes that:

- the reference price of a generic medicine may not exceed 80% of the reference price of the original medicine.
- the reference price of a biosimilar medicine may not exceed the reference price of the original medicine.
- where the original medicine is not registered in Uzbekistan, the price of the original medicine is calculated based on the average prices in reference countries.

Introduction of a Pre-Trial Mechanism for Appealing Registered Prices

The Regulation provides for a special appeal procedure under which the applicant is entitled to appeal a registered price before the Agency's Appeals Board within ten working days.

The Appeals Board shall consider the appeal within ten working days and may either leave the price unchanged or amend it. The decision of the Appeals Board may be appealed to a higher authority or to a court.

Revised Methodology for Calculating Wholesale and Retail Prices

Whereas previously the purchase cost of medicines was calculated based on the contract price, the new edition of the Regulation establishes specific formulas for determining maximum wholesale and retail prices based on the reference price. In calculating these prices, customs payments, other expenses (2% of the reference price), value added tax, as well as fixed trade mark-ups (15% wholesale and 20% retail) are now expressly taken into account.

In addition, the Regulation for the first time establishes a procedure for calculating maximum wholesale and retail prices for domestically produced medicines. The prices are formed on the basis of the reference price, including value added tax and applying fixed trade mark-ups, without considering customs payments and other expenses typical for imported medicines.

Reforms in the Mandatory Price Review Procedure

A new requirement has been introduced into the Regulation for regular analysis of the register of reference and maximum prices, to be carried out by the authorized body every six months. The threshold for reducing actual prices compared to fixed prices, at which mandatory re-registration is initiated, has also been changed from 20% to 15%. In addition, it is specified that maximum retail prices are adjusted three months after re-registration.

Overview of Key Changes in the Issuance of Permits for the Import and Use of Medicines and MDs in Cases of Temporary Shortage in Uzbekistan without State Registration

In Uzbekistan, a Regulation has been adopted establishing the procedure for issuing authorization for the import and use in medical practice of medicines and MDs without state registration, subject to mandatory certification in cases of temporary shortage of medicines and MDs in Uzbekistan, approved by Order of the Minister of Health of Uzbekistan No. 3749 dated January 9, 2026 (the "**Regulation No. 3749**"). Regulation No. 3749 covers both the procedure for

confirming a temporary shortage and the process to be followed by healthcare authorities and importers in organizing the supply of such medicines and MDs.

Below is an overview of the key provisions affecting pharmaceutical companies and suppliers of medicines and MDs.

Clarification of Scope of Application and Key Definitions

Regulation No. 3749 applies to medicines and MDs that are temporarily unavailable or available in limited quantities to meet the needs of the population and state medical institutions of Uzbekistan. The document introduces the key definitions of "temporary shortage" and "importing organization".

Where a temporary shortage is confirmed, the import and use in medical practice of medicines and MDs without state registration are permitted, while the requirement for mandatory certification remains in force (except for MDs not subject to mandatory certification).

Mechanism for Identifying Shortages and the Role of the Working Group

The organization of supply in cases of temporary shortage is based on the analysis of information submitted by republican-level medical institutions, specialized medical associations, wholesale pharmaceutical organizations, Agency, as well as structural subdivisions of the MOH based on data from the "Electronic Healthcare" information system.

The above entities submit to the Permanent Working Group on the Provision of Medicines and MD in Cases of Temporary Shortage, approved by the Minister of Health of the Republic of Uzbekistan (the "**Working Group**"), information on the clinical significance of the product, risks to therapy, planned termination of import or production, the minimum three-month volume required to cover the shortage, indicating the INN, dosages, pharmaceutical forms, and technical requirements for medical equipment. The Working Group reviews the submitted information within ***three working days*** and forwards it to Agency and the state institutions – Center and "Procurement Center" for sector-specific analysis.

Assessment of the Shortage and Possible Decisions of the Working Group

Within ***five working days***, Agency examines the availability or absence of the relevant medicines or MDs on the Uzbekistan market, the status and plans of local production, as well as the availability of stock in the warehouses of customs authorities and wholesale organizations. In parallel, Center analyzes data on the state registration of the shortage medicines and substitute medicines, their comparability in terms of dosage, pharmaceutical form and route of administration, while "Procurement Center" reviews their inclusion in public procurement plans and the delivery timelines.

Based on the results obtained, the Working Group, within five working days, adopts one or more of the following decisions:

- on the redistribution of available stock between medical institutions,
- on issuing recommendations to republican-level medical institutions to procure shortage products from local manufacturers or wholesale pharmaceutical organizations,

- on permitting import without state registration subject to mandatory certification and determining the minimum volume required, as well as allowing the import of registered medicines in packaging differing from that approved in Uzbekistan (also subject to mandatory certification).

Publication of the List and Requirements for Importing organizations' Proposals

Following the meeting of the Working Group, the list of medicines and MDs permitted for import without state registration, subject to mandatory certification due to a temporary shortage, shall be published on the official website of the MOH within ***one working day***.

Importing organizations, within 15 days from the date of publication of the list (with a possible extension for an additional 15 days if no proposals are submitted), shall submit to the MOH proposals including:

- a copy of the registration certificate issued in the country of manufacture or in another country,
- documents required for quality control (pharmacopoeial monograph/standard/specification; batch quality certificate; packaging mock-ups; instructions for use in the state language),
- information on price and delivery timelines,
- a commitment to implement mandatory digital marking,
- confirmation of available stock held by the manufacturer or other entities,
- a transport and logistics plan and a letter of guarantee.

Review of Proposals, Certification, and Customs Clearance

The Working Group reviews the proposals submitted by importing organizations within ***three working days*** after the expiry of the prescribed period and issues a conclusion in favor of one or several organizations, taking into account the priorities established by Regulation No. 3749. The decision is recorded in the form of minutes and approved by the Chairman of the Working Group.

From the date of receipt of the conclusion, the importing organization is required to ensure delivery within the specified timelines and to apply to the certification bodies for obtaining a certificate of conformity in accordance with the Rules for Certification of Pharmaceutical Products, except for MDs not subject to mandatory certification. The certification body is entitled to conduct quality control based on the submitted documents and to issue the certificate regardless of the reference price. For placement under the import customs regime , the importing organization submits the certificate of conformity and other required documents, after which the goods are released for free circulation within the timeframes established by law.

Shortage medicines imported into the territory of Uzbekistan or manufactured by local producers are subject to mandatory digital marking in accordance with Resolution of the Cabinet of Ministers No. 149 dated April 2, 2022 "On the Introduction of a Mandatory Digital Marking System for Medicines and MDs". Information on medicines and MDs imported for the

purpose of eliminating the shortage is subject to continuous publication on the official website of the MOH.

Supply volumes, Price Markups, and Import Priorities

Regulation No. 3749 allows the import of medicines and MDs in volumes up to twice the established minimum volume required to eliminate the shortage.

For wholesale and retail trade of prescription medicines, maximum mark-ups are established, similar to those applied under the reference pricing framework: up to 15 percent of the purchase (base) price at the wholesale level and up to 20 percent at the retail level, regardless of the number of intermediaries involved.

At the same time, medical institutions are not obliged to procure medicines and MDs imported under this mechanism and may carry out procurement only within the limits of their own financial capacity.

For the purposes of determining import priorities, Regulation No. 3749 establishes a list of priority areas, including:

- services for the prevention, diagnosis and treatment of socially significant diseases,
- emergency and resuscitation care,
- combating infectious diseases and epidemiological risks,
- maternal and child healthcare,
- oncology,
- critical cardiovascular and cerebrovascular conditions,
- chronic life-threatening diseases,
- renal failure,
- surgical interventions and anesthesiology and resuscitation,
- transfusion therapy,
- rare (orphan) and other high-risk conditions.

In the event of competing proposals for the same type of medicines or MDs, priority is given to the importing organization capable of ensuring delivery within the shortest possible timeframe. If the selected importing organization fails to meet the delivery deadlines, the conclusion of the Working Group is revoked, and proposals of other organizations are considered in accordance with the general procedure.

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