

## **State Initiatives to Stimulate Production and Enhance Research Activities in the Pharmaceutical Industry**

On 5 March 2026, the President of the Republic of Uzbekistan (“**Uzbekistan**”) signed the Decree «On Additional Measures to Stimulate Production and Improve Research and Development Processes in the Pharmaceutical Industry» No. UP-35 (the “**Decree No. 35**”), which came into force on 7 March 2026.

### **The key innovations introduced by Decree No.35 include:**

1. Establishing target indicators for the development of the pharmaceutical industry in 2026, including increasing production volume to UZS 8.5 trillion and raising exports of goods and services to USD 300 million,
2. Provision of tax incentives to business entities implementing investment projects in the pharmaceutical industry,
3. Introduction of specific regulations governing participation of pharmaceutical enterprises in public procurement,
4. Approval of an action plan aimed at improving production and research processes in the pharmaceutical industry, including the introduction of a “Regulatory Sandbox” regime,
5. Extension of certain customs benefits to enterprises producing dietary supplements (the “**DS**”) and cosmetic products,
6. Amendments to a number of regulatory legal acts, including those governing state registration of medicines, digital labeling, and financing of investment projects in the pharmaceutical industry.

Below is a more detailed overview of the key new developments introduced by Decree No. 35.

### **The following primary development targets for the pharmaceutical industry for 2026 have been established:**

- ❖ Increase in pharmaceutical production volume to UZS 8.5 trillion,
- ❖ Formation of prospective investment projects totaling USD 1 billion,
- ❖ Launch of new investment projects totaling USD 800 million,
- ❖ Increase in exports of goods and services to USD 300 million,
- ❖ Development and introduction of 350 new types of products,
- ❖ Expansion of the territory of the innovative scientific and industrial pharmaceutical cluster “Tashkent Pharma Park” with a view to transforming it into a regional research and manufacturing hub in biotechnology and pharmaceuticals – “BioPharma City”.

### **Support Measures have been Established for Pharmaceutical Manufacturers**

In order to stimulate the production of competitive and high-quality pharmaceutical products, as well as to attract investment into the pharmaceutical industry, Decree No. 35 provides for a number of state support measures.

In particular, manufacturers that establish production of original medicines in Uzbekistan within one year after expiration of the patent term for such medicines are eligible for compensation of the following expenses funded by the Pharmaceutical Industry Support and Development Fund:

- 50% of technology transfer costs, but not exceeding USD 50,000, or
- 50% of research and development expenses related to the creation of medicines, but not exceeding USD 100,000.

### **Improvement of Regulation of DS and Introduction of Additional Quality and Safety Requirements**

Pursuant to Decree No. 35, the Ministry of Health is tasked, by the end of May 2026, to develop requirements and procedures for issuing permits for the production of DS at enterprises holding a national GMP certificate.

Furthermore, as of 1 January 2027, enterprises holding a national certificate of “Good Manufacturing Practice – GMP” will be allowed to manufacture DS on their production lines for the duration of such certificate.

In addition, Decree No. 35 introduces additional requirements aimed at improving the quality and safety of DS. In particular, as of 1 January 2028:

- The issuance of permits for DS will require the implementation of a Hazard Analysis and Critical Control Points (HACCP) system,
- DS will be subject to mandatory digital labeling.

### **Tax Incentives for Implementation of Certain Investment Projects in the Pharmaceutical Industry**

According to Decree No. 35, until 2040, business entities implementing investment projects aimed at the production of pharmaceutical products, cultivation of medicinal plants, and their processing are granted the following tax incentives:

- exemption from land tax in respect of land plots used for implementation of investment projects for a period of three years from the commencement date of the investment project,
- exemption from corporate income tax within the framework of the investment project for a period of three years from the date the investment project is put into operation,
- exemption from property tax in respect of immovable property constructed within the framework of the investment project.

These tax incentives apply provided that the share of revenue derived from the sale of manufactured pharmaceutical products, cultivation of medicinal plants, or their processing constitutes at least 60% of the taxpayer's total revenue.

In addition, tax preferences are established for foreign holders of technologies and brands. In particular, for non-residents not operating in Uzbekistan through a permanent establishment, the corporate income tax rate on royalty income derived from technology transfer and brand use applied in the production of medicines and medical devices (“**MD**”) in Uzbekistan is set at 5% until 1 January 2030, unless otherwise provided by international treaties of Uzbekistan.

### **Compensation Measures for Manufacturers of Medicines and MD**

Decree No. 35 provides that, as of 1 June 2026, manufacturers of medicines will be reimbursed, at the expense of the Trade Promotion Fund, for 50% of expenses, but not exceeding USD 50,000, related to:

- engagement of foreign consulting services for the implementation of EU GMP and US FDA GMP standards,
- obtaining prequalification from the World Health Organization.

Additionally, compensation is provided to manufacturers of medicines and MD developed by research institutes and educational institutions and not previously produced in Uzbekistan. Such manufacturers are reimbursed for 80% of expenses related to state registration, clinical trials, and bioequivalence studies, after the commencement of industrial production and commercialization of the respective medicines but not exceeding USD 8,000.

Furthermore, business entities that, within three years, commission investment projects for the industrial production of high-tech medicines (as specified in Annex No. 1 to Decree No. 35) are entitled to compensation of interest expenses on loans attracted within such projects, for a period of two years, at the expense of the Pharmaceutical Industry Support and Development Fund.

### **Specific Aspects of Participation in Public Procurement and Distribution of Pharmaceutical Products**

Decree No. 35 establishes that, as of 1 June 2026, pharmaceutical and other manufacturing enterprises are, by way of exception, permitted to participate in public procurement where:

- tax and levy arrears do not exceed two times the base calculation amount (approximately USD 68), or
- such arrears exceed the specified threshold – within 10 days from the date such arrears arise.

Admission to participation in public procurement is based on information provided through the information system of the State Tax Committee.

In addition, it is established that until 1 September 2026, regardless of the level of localization of production, manufacturing enterprises producing pharmaceutical and other products and holding

a certificate of domestic origin are permitted to sell such products through the following mechanisms and electronic platforms:

- the electronic cooperation portal,
- the manufacturers' ecosystem,
- local auctions,
- the "national shop".

### **Approval of an Action Plan for Improving Production and Research Processes in the Pharmaceutical Industry**

In accordance with Annex No. 3 to Decree No. 35, an action plan aimed at improving production and research processes in the pharmaceutical industry has been approved.

#### *Introduction of a Special Legal Regime "Regulatory Sandbox"*

As part of the measures provided for in the action plan, it is envisaged to submit to the Cabinet of Ministers a proposal on the introduction of a special legal regime "Regulatory Sandbox," providing for a separate legal framework governing activities related to testing and registration of medicines, MD, new products and services, as well as intellectual property results – by September 2026. The Ministry of Health and the Pharmaceutical Industry Development Agency (the "**Agency**") have been designated as the responsible authorities for the implementation of this measure.

#### *Inventory of Mandatory Digital Labeling Codes for Medicines*

A phased inventory of mandatory digital labeling codes for medicines is envisaged within the following timeframes:

- Stage 1 – manufacturers of medicines – by July 2026,
- Stage 2 – wholesale distributors of medicines – by September 2026,
- Stage 3 – pharmacy organizations (retail sale of medicines) – by November 2026.

#### *Improvement of Post-Market Surveillance of Pharmaceutical Products*

Decree No. 35 provides for the improvement of the procedure for post-market surveillance of pharmaceutical products, to be implemented in two stages:

- Stage 1 – development of a draft regulatory legal act providing for improvements in post-market surveillance procedures – by May 2026,
- Stage 2 – coordination of the draft regulatory legal act with relevant ministries and authorities and submission thereof to the Cabinet of Ministers – by August 2026.

#### *Improvement of the Procedure for Distribution and Circulation of Medicines and MD*

In addition, by June 2026, it is envisaged to develop a draft regulatory legal act aimed at improving the procedures for wholesale and retail distribution of medicines and MD, as well as their write-off and destruction.

Coordination of this draft regulatory legal act with relevant ministries and authorities and its submission to the Cabinet of Ministers in accordance with the established procedure is scheduled for completion by September 2026.

### **Extension of Certain Customs Benefits to DS and Cosmetic Products**

In accordance with Decree No. 35, as of 1 April 2026, customs benefits provided under the Presidential Decree No. UP-55 dated 21 January 2022 “On Additional Measures for Accelerated Development of the Pharmaceutical Industry of the Republic in 2022–2026” are extended to enterprises producing DS and cosmetic products, in respect of the following equipment and goods:

- technological and laboratory equipment not produced in Uzbekistan, as well as components and spare parts thereto,
- “clean rooms,” sandwich panels, and ventilation systems for pharmaceutical production facilities, as well as raw materials and supplies, MD, and packaging materials used for maintaining laboratory animals, conducting preclinical studies, and manufacturing medicines (including extemporaneous compounding), imported by:
  - manufacturers of pharmaceutical products,
  - wholesale distributors of pharmaceutical products,
  - specialized research institutes and higher educational institutions for their own needs,
  - enterprises engaged in wholesale distribution of pharmaceutical products for the needs of pharmaceutical manufacturers,
  - enterprises engaged in wholesale and retail distribution of pharmaceutical products – for extemporaneous compounding of medicines.

### **Tax Treatment of Transfers of Medicines and MD as Humanitarian Aid**

In accordance with Decree No. 35, specific tax rules have been established for accounting of medicines and MD transferred as humanitarian aid. Such transfers, subject to compliance with the established requirements, are recognized as economically justified expenses of pharmaceutical organizations for tax purposes. Decree No. 35 also provides for rules on valuation of transferred products and establishes liability measures in cases of overstatement of value, fictitious transfers, re-circulation of transferred property, or non-compliance with the established transfer procedure.

### **Establishment of the National Research Institute of Biopharmaceuticals**

Pursuant to Decree No. 35, the National Research Institute of Biopharmaceuticals (the “**Institute**”) is to be established based on the following research organizations:

- the Uzbek Chemical and Pharmaceutical Research Institute,
- the Tashkent Research Institute of Vaccines and Serums,
- the “Sharq tabobati” Research Institute.

### **Amendments to Regulatory Legal Acts**

#### *Expansion of Grounds for Regulatory Control in the Pharmaceutical Industry*

In accordance with Decree No. 35, amendments have been introduced to the Presidential Decree No. UP-184 dated 14 November 2024 “On Measures to Ensure Reliable Protection of the Rights and

Legitimate Interests of Entrepreneurs,” expanding the grounds for exercising control over the production, manufacturing, wholesale, and retail distribution of medicines and MD.

Previously, such control could be conducted only upon availability of reliable information regarding the production, manufacturing, or sale of falsified or substandard products, as well as reliable information on retail sales of prescription medicines without a prescription. Under Decree No. 35, an additional ground for conducting control has been introduced, namely, a negative conclusion based on the results of post-market surveillance of pharmaceutical products.

Accordingly, post-market surveillance of pharmaceutical products has been included among the grounds for conducting control measures by the Safety Center.

#### *Expansion of the Scope of Participants in the Digital Labeling System for Medicines and MD*

Furthermore, amendments have been introduced to the Resolution of the Cabinet of Ministers No. 149 dated 2 April 2022 “On the Introduction of a Mandatory Digital Labeling System for Medicines and Medical Devices” (the “**Resolution No. 149**”), expanding the list of entities entitled to receive digital labeling codes for medicines and MD.

Under the revised version of the Resolution No. 149, importers have been additionally included among the entities entitled to receive such digital labeling codes.

In addition, Resolution No. 149 has been supplemented with a new provision requiring that, upon obtaining digital labeling codes for medicines and MD, importers must provide power of attorney from the foreign manufacturer, duly confirmed by the competent authorities of the foreign state, authorizing them to obtain such codes.

Moreover, while previously the labeling of medicines and MD – including ordering and obtaining labeling codes from the Operator, converting such codes into digital identification means, and applying them to consumer packaging – was ensured solely by manufacturers, it is now also ensured by importers.

#### *Simplification of Registration of Certain Medicines*

Decree No. 35 also introduces amendments to the Resolution of the Cabinet of Ministers No. 738 dated 24 November 2025 “On Approval of Regulations on the Procedure for State Registration of Medicines and the Procedure for State Registration of Medical Devices” (the “**Resolution No. 738**”).

According to the amendments, medicines containing identical active substances and produced by domestic manufacturers on a contractual basis under different trade names may be registered through recognition without conducting laboratory testing.

At the same time, it is established that such medicines must fully correspond to the reference medicine in terms of the manufacturer of the active pharmaceutical ingredient, composition of excipients, primary packaging materials, container-closure system, quality control methods and specifications, and manufacturing technology.

Changes are permitted only in the trade name, secondary packaging design, and instructions for use.

Simultaneously, it is provided that the first industrial batch of medicine registered under this procedure is subject to mandatory post-market surveillance.

*Specific Aspects of Conducting Clinical Trials for Registration of Original Medicines*

In addition, Resolution No. 738 has been supplemented with a new provision under which, upon state registration of original medicines, clinical trials may not be required if such medicines are supported by positive results of international multicenter clinical trials.

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