

Uzbekistan | June 2022

## BENEFITS AND PREFERENCES FOR THE PHARMACEUTICAL INDUSTRY

According to the Decree of the President of the Republic of Uzbekistan (hereinafter referred to as “**Uzbekistan**”) “On Additional Measures for the Accelerated Development of the Pharmaceutical Industry of the Republic in 2022–2026” No. UP-55 dated 21.01.2022 (hereinafter referred to as the “**Decree No. UP-55**”), from 01.04.2022 it is planned to introduce a mechanism for guaranteed procurement of pharmaceutical products subject to localization (hereinafter referred to as the “**Procurement**”) by concluding a contract for a 3 years period. The Procurement will be carried out at the expense of the State budget, which will be allocated for the procurement of pharmaceutical products.

The Procurement procedure:

- Contracts on the Procurement of substances, medicines, medical products (hereinafter referred to as “**MP**”) and medical equipment (hereinafter referred to as “**ME**”) will be concluded on the basis of an open competition:
- The open competition is held in relation to substances, medicines, MP and ME, provided in the list of international nonproprietary names of substances, medicines, MP and ME not produced previously in Uzbekistan that are subject to localization in perspective (hereinafter - the “**List**”).
- The List will be posted and annually updated on the Special public procurement information portal, as well as on the websites of the Ministry of Health of Uzbekistan (hereinafter referred to as the “**Ministry of Health**”) and the Pharmaceutical Industry Development Agency under the Ministry of Health (hereinafter referred to as the “**Agency**”). Currently, the List is generated by the Ministry of Health along with the Agency, the Ministry of Finance of Uzbekistan (hereinafter referred to as the “**Ministry of Finance**”) and the Ministry of Investments and Foreign Trade of Uzbekistan (hereinafter referred to as the “**MIFT**”);
- The state customer and the beneficial owner of the procured objects is the Ministry of Health;
- Furthermore, the Ministry of Health and organizations within its structure are allowed to make advance payments preliminarily under the Procurement agreements.



In addition, on 12.04.2022, the President of Uzbekistan held a conference on the matters related to the development of the pharmaceutical industry in Uzbekistan (hereinafter referred to as the "**Conference**"), according to the results of which the Ministry of Health and the Ministry of Finance were instructed to conclude contracts for 3 years with domestic manufacturers on guaranteed procurement of 120 types of frequently requested medicines in Uzbekistan by 01.07.2022. Herewith, from 01.07.2022 it was planned the Procurement of 25 types of medicines, and from 2023 - the production and further Procurement of 70 types of medicines. The primary focus will be on reducing the cost of medicines, especially used in the treatment of oncological, hematological, endocrine and viral diseases. Presently, legislative act adopting the above Conference's results has not been published yet.

Additionally, the Decree No. UP-55 establishes measures for further support of pharmaceutical manufacturing organizations:

- It is expected that new pharmaceutical products produced by domestic manufacturing organizations will be registered for an unlimited period. Furthermore, previously issued registration certificates will be exchanged for perpetual certificates within 15 days without requiring additional documents after their expiration date;
- It was planned to cancel from 01.07.2022 the procedure for mandatory certification of medicines, MP and ME produced by domestic manufacturing organizations that have Good Manufacturing Practice (GMP) certificate (hereinafter referred to as the "**GMP**") for medicines and ISO: 13485 certificate for MP and ME issued by authorized organizations of Uzbekistan. However, as of the date of publication of this Legal Alert, respective procedure has not been adopted.

The following was also suggested on the Conference:

- To compensate the expenses of domestic manufacturing organizations for obtaining a GMP certificate by the Agency in prospect;
- Establish that the list of raw materials for the production of medicines and MP exempt from VAT will be approved by the MIFT, the Agency and the State Customs Committee of Uzbekistan (instead of the five bodies that approve this list).

In addition, the Decree No. UP-55 also cancels:

- Prohibition on the collection of donated blood and the production of pharmaceutical products on its basis in private capacity;
- Restriction on conducting clinical trials of medicines on healthy volunteers;
- Restriction on production of medicines that have the same ingredients and are produced by the same manufacturer under different trade names.



To implement the requirements of Good Practices (GxP) (hereinafter referred to as the "GxP"):

- From 01.04.2022 newly established manufacturing enterprises, wholesale and retail trade organizations in the pharmaceutical industry of Uzbekistan shall comply with the following requirements:
  - ✓ GMP;
  - ✓ Good Distribution Practice (GDP) (hereinafter referred to as the «GDP»);
  - ✓ Good Pharmacy Practice (GPP);
- Until 01.01.2024, the obligation of pharmaceutical industry organizations' mandatory certification for compliance with GxP requirements has been delayed;
- From 01.02.2022, 75% of the expenses of domestic pharmaceutical manufacturers on the registration of pharmaceutical products in foreign countries shall be covered from the Fund for Support and Development of the Pharmaceutical Industry under the Agency, if the document confirming the registration is available;
- From 01.01.2023, only organizations operating in accordance with the following standards are allowed to participate in public procurement tenders for pharmaceutical products:
  - ✓ for medicines manufacturing organizations – GMP standard;
  - ✓ for organizations-manufacturers of MP and ME - ISO: 13485 standard;
  - ✓ for wholesale pharmaceutical distributors - GDP standard.

According to the Decree No. UP-55, until 01.01.2025 technological and laboratory equipment not produced in Uzbekistan, its components and spare parts, "clean rooms", sandwich panels and ventilation systems for pharmaceutical production premises, raw materials, MP and packaging materials used for keeping laboratory animals, preclinical studies, medicines production (including in-pharmacy production), imported by:

- ✓ manufacturers of pharmaceutical products, wholesale pharmaceutical companies, specialized research institutes and higher educational institutions - for their own needs;
- ✓ wholesale and retail pharmaceutical distributors - for in-pharmacy manufacturing of medicines on the basis of the lists approved by the Cabinet of Ministers of Uzbekistan,

will be exempt from customs duties.

Additionally, the MIFT along with the Agency for the Promotion of Export under the MIFT will implement the following measures to support organizations manufacturing medicines in accordance with GMP requirements:



- For the period until 01.01.2025, the provision of subsidies to cover up to 50 % of costs for transportation by road and rail (excluding transportation costs) when exporting pharmaceutical products to all countries, including neighboring states, in the amount not exceeding 5 % - when transported by road, and 7 % - when transported by rail, of the product's export value;
- Provision of interest-free financial resources to commercial banks for financing revolving loans to replenish the working capital of pharmaceutical exporting organizations when they export products with the condition of deferred payments. The abovementioned revolving loans are provided for up to 1 year at 4 % interest rate per year (including the bank's margin) for a grace period and in the amount of the of exported products' value in the equivalent of not more than 3,000,000 US Dollars.

## Medicinal Herbs

To organize and develop the industry of cultivating and processing medicinal herbs, as well as create a value chain, the Decree of the President of Uzbekistan "On Measures for Creation of a Value Chain through the Effective Utilization of the Raw Materials Base and Support the Processing of Medicinal Herbs" No. UP-139 (hereinafter referred to as the "**Decree No. UP-139**") and the Resolution of the President of Uzbekistan No. PP-251 "On Measures for Organization the Cultural Cultivation, Processing and Widespread Utilization of Medicinal Herbs in Treatment" (hereinafter referred to as the "**Resolution No. PP-251** ") were adopted on 20.05.2022.

According to the Decree No. UP-139, it is established that in 2022-2026 plantations for cultivation of medicinal herbs should be based on the area of 36,000 hectares. The cultivation of other types of agricultural crops on these plantations is prohibited.

Furthermore, the Decree No. UP-139, provides, *inter alia*, the following benefits and subsidies:

- Subsidies from the State budget in the amount of 600,000 Uzbek Soums per meter, but not exceeding 120,000,000 Uzbek Soums, for every 10 hectares of constructed medical herbs' plantations - with the purpose of drilling wells for water extraction and construction of pumping stations for pumping stations for water drain from rivers, canals and other reservoirs. It should be noted, utilization of water-saving technologies is a mandatory requirement;
- Loans provided by commercial banks in the amount of up to 2,000,000,000 Uzbek Soums at 10 % interest rate per year for up to 3 years - to enterprises cultivating medicinal herbs with the purpose to increase the cultivation of export-oriented medicinal herbs. Besides,



the State Fund for Support of Entrepreneurship will act as a guarantor - up to 75 % of the loan amount;

- Until 01.01.2025, exemption from customs duties for technological and laboratory equipment imported for own needs, its components and spare parts, sandwich panels and ventilation systems, raw materials, packaging materials used for the production of biologically active additives, not produced in Uzbekistan - for manufacturers of biologically active additives, essences and extracts from medicinal herbs materials (according to the lists formed in accordance with the established procedures);
- Granting deferred payment of VAT for a period of 180 days - if importing technological and laboratory equipment, its components and spare parts, sandwich panels and ventilation systems, tools and instruments, raw materials, chemicals and protective equipment used for cultivation and processing of medicinal herbs;
- Compensation of transportation costs in the amount of up to 50 % by the Agency for the Promotion of Export under the MIFT - for business entities exporting by road, rail and air transport medicinal herbs materials and biologically active additives, essences and extracts produced from them.

To finance manufacturing of finished production based on the deep processing of medicinal herbs within the framework of the "Modernization of Agriculture" and "Development of Rural Entrepreneurship in the Ferghana Valley" World Bank's projects and "Diversification and Modernization of Agriculture" International Fund for Agricultural Development's project, the Ministry of Agriculture of Uzbekistan and the Ministry of Finance will allocate funds in the amount of 20,000,000 US Dollars to commercial banks, which will be placed as assets in Uzbek Soums at 14 % interest rate per year. Thus, commercial loans will be provided by commercial banks at 17 % interest rate per year for a period of 10 years, including 3 % of bank margin and 5 years' grace period.

Furthermore, it is expected that from 01.09.2022, the Ministry of Health and the Agency will establish additional conditions for licensing medicines and MP's retail sale activities, i.e., at least 10 % of pharmacy sales floors' counters will need to be filled with biological active additives and medicines produced from medicinal herbs raw materials.