



# PROMOTING THE QUALITY OF MEDICINES PLUS FACT SHEET

USAID supports Uzbekistan in its efforts to ensure quality of medical products

In recent years, the Government of Uzbekistan has demonstrated a significant commitment to developing the pharmaceutical industry and achieving international standards for medicines quality assurance systems. This commitment was reflected in a number of presidential decrees and resolutions, including two from 2019 – the Presidential Decree (UP-5707) on further measures for the accelerated development of the pharmaceutical industry in the Republic of Uzbekistan (2019-2021) and the Resolution of the President of the Republic of Uzbekistan (PP-4554) on additional measures for the strengthening of reforms in the pharmaceutical industry of the Republic of Uzbekistan.

This high-level commitment is important from a public health as well as an economic development standpoint. Transparent and predictable medicines regulatory systems following international standards, could attract increased investments in Uzbekistan’s pharmaceutical sector. Uzbekistan has made significant strides in reducing tuberculosis (TB) incidence and mortality and is transitioning from donor-supported procurement to domestic procurement of TB medicines. Access to quality-assured medicines is essential in the fight against TB and multidrug-resistant TB (MDR-TB).

USAID, through the Promoting the Quality of Medicines Plus program, is supporting this transition and economic growth. Implemented by U.S. Pharmacopeia (USP), the program supports sustainable strengthening of medical product quality assurance systems in low- and middle-income countries to achieve desired health objectives.

## PROGRAM OBJECTIVES AND ACTIVITIES

In Uzbekistan, the Promoting the Quality of Medicines Plus program works closely with the Agency for the Development of the Pharmaceutical Industry (ADPI) and other national counterparts to sustainably strengthen these medicines quality assurance systems. The objectives of the program in Uzbekistan are:

- Improve country regulatory systems to assure the quality of medical products in the public and private sectors;
- Increase the supply of quality-assured essential medical products of public health importance;
- Strengthen the pharmaceutical sector workforce.

To achieve these objectives, the program implements the following activities:

- Provide technical assistance to the ADPI to strengthen its product evaluation and registration procedures for essential medicines. Accountable product evaluation and timely registration are important in ensuring access to critical quality assured medicines. In addition, USAID will help ADPI to operationalize the World Health Organization's (WHO) collaborative procedure for accelerated registration, which will allow expedited registration and access to WHO prequalified medicines.
- The program will support Uzbekistan in strengthening the Good Manufacturing Practices (GMP) inspectorate and achieve Pharmaceutical Inspection Cooperation Scheme (PIC/S) membership standards. PIC/S is an internationally accepted cooperative mechanism for ensuring the harmonization of the standards in the field of GMP. Ultimately, a country's participation in PIC/S impacts patients' ability to access quality-assured medicines.
- The program assists the medicines quality control laboratory in Tashkent as well as regional laboratories to strengthen their quality management systems to ensure they meet internationally recognized standards set forth by the WHO prequalification program.
- The program will continue to provide technical assistance to the local manufacturer of TB medicines to achieve WHO prequalification for their TB products. Prequalification would allow Uzbekistan and potentially other countries in the region to have access to quality-assured TB products.
- Provide technical assistance to train the regulatory authority and pharmaceutical manufacturers workforce.

## ANTICIPATED RESULTS

- The ADPI achieves WHO maturity level 3 of the Medicines Regulatory Authority;
- The ADPI's GMP Inspectorate achieves the Pharmaceutical Inspection Cooperation Scheme standards;
- At least two medicines quality control laboratories achieve WHO prequalification;
- Risk-based post-marketing surveillance is established;
- At least two second-line TB medicines are produced by local manufacturers that are WHO prequalified;
- Students of the pharmaceutical universities are trained according to a curriculum that complies with high international standards; and
- Pharmaceutical scientists attain certification in long-term stability studies, formulation science, bioequivalence studies, and clinical research that follows good clinical practices.