



USAID
FROM THE AMERICAN PEOPLE



PROMOTING THE QUALITY OF MEDICINES PLUS FACT SHEET

USAID Supports Kazakhstan in its Efforts to Ensure Quality of Medical Products

The USAID-supported Promoting the Quality of Medicines Plus activity, implemented by U.S. Pharmacopeia, provides technical assistance to sustainably strengthen medical product quality assurance systems in low- and middle-income countries through cross-sectoral and systems strengthening approaches. The Government of Kazakhstan considers the development of the domestic pharmaceutical industry a priority, providing safe and affordable medicines and products to the population. Currently, the pharmaceutical industry is undergoing the most ambitious reform in its history. In July 2020, the new edition of the Health Code on People’s Health and Healthcare System was adopted that emphasizes the importance of pharmaceutical sector development in Kazakhstan to ensure the quality of medicines in accordance with international standards and requirements. One success has been that the Kazakhstan National TB Program has made significant progress in recent years in fighting tuberculosis (TB), with TB incidence having fallen steadily since 2004 and the government ensuring universal treatment coverage for TB. To achieve this, Kazakhstan procures most of its TB medicines locally with domestic funding and continues to improve access to quality-assured medicines for TB and other essential medicines with a functional TB supply chain.

PROGRAM OBJECTIVES AND ACTIVITIES

In Kazakhstan, the Promoting the Quality of Medicines Plus activity is building on achievements of its predecessor, the Promoting Quality of Medicines activity and works closely with the national regulatory agency - the National Center of Expertise of Medicines and Medical Devices (NCEMMD) under the Ministry of Health, and other national counterparts to sustainably strengthen medicine quality assurance systems.

Objectives in Kazakhstan:

- Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved; and
- Supply of quality-assured essential medical products of public health importance increased.

To achieve these objectives, the activity implements the following initiatives:

- Provides technical assistance to the NCEMMD to strengthen their regulatory capacity for the registration, inspection, and quality control of laboratories;
- Ensures the use of the World Health Organization (WHO) Collaborative Registration Procedures (CRP) for expedited registration of WHO prequalified medicines;
- Strengthens the Quality Management System (QMS) of the Medicines Quality Control Laboratories (MQCLs) to comply with international standards to deliver reliable and accurate results of medical products testing;
- Strengthens the Good Manufacturing Practices (GMP) inspection system to achieve Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) membership; and
- Provides technical assistance to local manufacturers to improve their capacity to produce quality, priority, essential medicines.

ACCOMPLISHMENTS IN YEAR ONE

In program year one, the ongoing coronavirus pandemic and related travel limitations caused delays for several planned activities, which are now planned for the following year. Despite these restrictions, the Promoting the Quality of Medicines Plus activity has achieved the following:

- Worked with the NCEMMD toward operationalizing the WHO CRP. Activity staff trained five NCEMMD experts on CRP procedures to take advantage of the rapid registration process of WHO prequalified products and ensure increased availability of quality-assured medicines on the local market.
- Provided technical assistance to three of five MQCLs in Kazakhstan. Activity staff trained 83 laboratory specialists; providing technical assistance in the development of QMS procedures, standard operating procedures, and guidelines; and assisting with the WHO peer audit application and preparation. These are all necessary for the MQCLs to apply for WHO prequalification status, which is an achievement that requires high standards of quality control and expertise to ensure that the labs can accurately test the quality of medicines at an international standard. As a result, in January 2020 WHO officially included the Karaganda MQCL in the list of WHO prequalified laboratories becoming the first laboratory in Central Asia to achieve WHO prequalification.
- Held a cross-country, regional online forum for Kazakhstan's and Uzbekistan's staff of the medicines registration authorities and their MQCLs to share lessons learned from the Karaganda laboratory's journey to reach WHO prequalification status. More than 100 participants attended, including senior management and staff from the eight laboratories.
- Completed the assessment of the GMP Inspectorate in preparation for PIC/S membership. Of the 22 progress indicators or milestones toward PIC/S ascension (2020-2024), Kazakhstan met five milestones, which was 85 percent of the year one target.