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PROMOTING THE QUALITY OF MEDICINES PLUS (PQM+)

BACKGROUND

Since 2003, USAID/Mozambique has been providing technical assistance and support to the Government of Mozambique (GRM) and its Central Warehouse for Medicines and Medical Supplies (CMAM) including logistics and supply chain management for health, malaria, and HIV commodities, as well as providing in-kind donations of medicines and other supplies for malaria, HIV, and other health programs. However, until recently, USAID has provided very limited technical support to the Ministry of Health (MOH) to strengthen the medicines quality assurance and quality control systems. Initially, the National Quality Control Laboratory (LNCQM) had inadequate infrastructure, equipment and staff to provide full-fledged quality control services that meet internationally recognized pharmacopeial requirements. Laboratory infrastructure did not allow microbiological tests to be performed due to the inability to create sterile testing areas; which subsequently limits the ability of laboratories to perform common tests for injectables and other medicines requiring microbiological tests, of which there is great public health concern. Besides infrastructure shortages, there is a lack in human resources capability to execute full technical competence and quality management.

PROGRAM DESCRIPTION

PQM+ is implemented by the U.S. Pharmaceutical Convention (USP) to help assure the quality and safety of priority medicines by strengthening medical product quality assurance systems in Mozambique. The program's main objective is to strengthen the quality assurance and quality control capabilities of Mozambique's medicines regulatory authority, National Directorate of Pharmacy (NDP), now elevated to Autoridade Nacional Reguladora de Medicamento, Instituto Público (ANARME, IP) . Technical assistance is provided in order to build the capacity of medicine regulatory authorities and quality assurance systems in countries with weak health systems such as Mozambique. There is increasing recognition of the burden of poor-quality medicines and their threat to public health, especially in low-income countries like Mozambique.

EXPECTED RESULTS AND IMPACTS

Activities under PQM+ are anticipated to include:

- Governance for medical product quality assurance systems improved
- Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved
- Financial resources for medical product quality assurance optimized and increased
- Increase supply of quality assured essential medical products of public health importance
- Run tests on medicines purchased by GRM for quality to prevent fake and substandard medicines, which represent a threat to public health.
- Support the NLQCM to strengthen laboratory practices towards attainment of international standards ISO 17025. This will become mandatory requirement to meet WHO Global Benchmark Tool (GBT) for evaluation of national pharmaceuticals regulatory systems

- Provide technical assistance to strengthen the new DNF, functions established with the new law (e.g., inspections, post marketing surveillance). This will allow ANARME, IPF to have capabilities to take feasible regulatory actions for detected substandard medicines to protect public health
- Support Post Marketing Surveillance data dissemination events to increase awareness on the importance of quality assured medicines to Mozambique's health system
- Advocate and support ANARME, IP to identify feasible regulatory actions for detected substandard medicines to protect public health

IMPLEMENTING PARTNER: United States Pharmacopeial Convention, Inc	GOAL: Increase sustainable, predictable, and adequate financing for programs and health policy implementation to enable a health financing system that is equitable, sustainable, and efficient, and provides high-quality healthcare services to all Mozambicans.	LIFE OF ACTIVITY: September 2019 - September 2024	USAID CONTACT: Benedito Chaque bchaque@usaid.gov
USAID FUNDING: $3.67 million		GEOGRAPHIC FOCUS: National	