



USAID's Promoting the Quality of Medicines Plus Program

In low- and middle-income countries (LMICs), at least 1 in 10 [medical products](#) are estimated to be substandard or falsified with the true burden likely much greater. Nearly 70 percent of national [regulatory authorities](#), many in LMICs, do not have adequate capacity to perform the oversight functions required to ensure the quality of medical products. These circumstances put millions of people at risk of harm. The Promoting the Quality of Medicines Plus (PQM+) program, which is funded by the U.S. Agency for International Development (USAID), works to improve systems that assure the quality of essential medical products in LMICs to help prevent maternal and child deaths, control the HIV epidemic, and combat infectious diseases through high-performing health systems.

PQM+ program goal, objectives and expected results

Funded by USAID and implemented by the U.S. Pharmacopeial Convention ([USP](#)) and its consortium of partners, the [PQM+](#) program (2019-2024) is designed to sustainably strengthen quality assurance systems by providing technical assistance to **manufacturers** of priority health products and support to **Medicines Regulatory Authorities** to improve product registration, inspection, and post-marketing surveillance for product quality. This includes accreditation of **national drug quality control laboratories** per ISO 17025 and/or WHO prequalification standards.

Building on the success of USAID's [PQM](#) program (2009-2019), PQM+ will help to expand the supply and improve the quality of essential medical products to help prevent and treat diseases such as tuberculosis, malaria, and neglected tropical diseases, and to improve maternal, newborn, and child health by achieving the following objectives.

1 Governance for medical product quality assurance systems improved.

- + Evidence-based medical product quality assurance legislation, policies, and regulations developed/updated and/or implemented.
- + Systems that facilitate transparency and accountability promoted.
- + Fragmentation addressed and coordination across entities (public and private) with medical product quality assurance responsibilities promoted.
- + Links among the medical product quality assurance systems and other sectors developed and fortified.

2 Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved.

- + Sustainable systems for market authorization/registration, inspection, and licensing functions of medical product regulatory agencies improved.
- + Sustainable post-marketing surveillance systems and medical product quality control laboratory capacity strengthened.
- + Regional harmonization to strengthen medical product quality assurance regulatory capacity and networks supported.
- + Adoption of data standards and integrated information systems to support regulatory medical product quality assurance functions supported.
- + Competence, efficiency, and expansion of the medical product quality assurance workforce improved.

3 Financial resources for medical product quality assurance optimized and increased.

- + Allocation and use of investments for medical product quality assurance systems strengthening optimized.
- + Sustainable resources mobilized.

4 Supply of quality-assured essential medical products of public health importance increased.

- + Pharmaceutical manufacturers for Good Manufacturing Practices and medical product regulatory submissions/dossiers supported.
- + Capacity to conduct bioequivalence studies for dossier submissions strengthened.
- + Capacity for market intelligence and analytics of public health pharmaceutical markets increased.
- + Health coverage schemes that incorporate medical product quality requirements supported.
- + Monograph development and use supported.

5 Global medical product QA learning and operational agenda advanced.

- + Evidence-based approaches and tools developed and/or applied.
- + Research and analysis to support medical product quality assurance systems strengthening conducted.
- + Advocacy on the importance of medical product quality assurance for public health, including the link between poor product quality and antimicrobial resistance supported.

Guiding principles

PQM+ uses a systems strengthening approach, through which technical assistance will be implemented using the following guiding principles:

- + Build on and strengthen existing systems
- + Strengthen capacity of local organizations
- + Prioritize and optimize allocation and use of resources
- + Support integration
- + Support country-led coordination and ownership
- + Develop strategic partnerships
- + Provide global technical leadership

The PQM+ consortium

For 200 years, USP has helped to ensure the quality of medicines in the United States and hundreds of countries around the world. For PQM+, USP has assembled a consortium of internationally-recognized leaders to address the most critical quality assurance challenges in LMICs. Core partners each bring specialized expertise to bear on achieving PQM+ objectives. Core Field-Led Extension (Core-FLEX) partners are local entities that bring on-the-ground expertise and are intended to assume increasing levels of direct technical assistance provision. Technical Resource partners support targeted areas such as quality of medical devices, risk-based approaches, and civil society engagement.

CONSORTIUM LEAD USP

CORE PARTNERS

African Union Development Agency-New Partnership for Africa's Development
IntraHealth International
IQVIA Government Solutions, Inc.
Panagora Group

CORE-FLEX PARTNERS

Addis Ababa University School of Pharmacy Regional Bioequivalence Center in Addis Ababa, Ethiopia
Association of Southeast Asian Nations Network for Drugs, Diagnostics and Vaccines Innovation in Taguig City, Philippines
Center for Drug Discovery, Development and Production in Ibadan, Nigeria
Ecumenical Pharmaceutical Network in Nairobi, Kenya
Mahidol University Center for Analysis of Product Quality in Bangkok, Thailand
Muhimbili University of Health and Allied Sciences in Dar es Salaam, Tanzania

TECHNICAL RESOURCE PARTNERS

Asia Pacific Leaders Malaria Alliance • Boston Consulting Group • BroadReach Consulting Group • Centre for Innovation in Regulatory Science • Harvard Pilgrim Health Care • Howard University • the International Diagnostics Centre at the London School of Hygiene and Tropical Medicine • Purdue University • University of Washington

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