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Promoting the Quality of Medicines Plus (PQM+)

usp

Ensuring quality medical products to fight malaria

Since the launch of the U.S. President's Malaria Initiative in 2005, significant progress has been made in reducing global malaria deaths, but declines have slowed significantly in recent years, highlighting the need for renewed focus on prevention and treatment to address some of the more intractable root causes. In 2018 there were 228 million cases of malaria and 405,000 people died from this preventable disease globally[1], many of them pregnant women and children younger than five. Africa shoulders the highest malaria burden with 93 percent of cases and 94 percent of deaths in the world recorded in 2018. In Asia, more than 65 million people continue to be at risk for malaria infection.

Quality-assured medical products – such as antimalarial medicines, insecticide-treated bed nets, and rapid diagnostic tests – are essential tools for controlling malaria and progressing toward elimination. Widespread circulation of substandard or falsified (SF) medical products in local and global markets threatens to compromise efforts to reduce malaria morbidity and mortality. The seminal World Health Organization review[2] of the prevalence of SF medicines reports that 11.8 percent of the 18,764 antimalarials included in the systematic review failed testing. The data estimates conservatively that the use of SF antimalarials would result in an additional 31,000 to 116,000 deaths at a cost of $10.4 - $38.5 million annually, yet the true burden is likely much greater.

USAID's Promoting the Quality of Medicines Plus (PQM+) program works to sustainably strengthen medical product quality assurance systems in low- and middle-income countries (LMICs) to improve the quality of essential medical products that are used to help prevent and treat high-priority diseases, like malaria. PQM+ builds sustainability into medical product quality assurance systems by collaborating with national and regional public and private sector entities, using cross-sectoral and systems strengthening approaches, and applying international quality assurance standards across the pharmaceutical system.

PQM+ provides tailored technical assistance to countries so they can achieve their goals of reducing malaria morbidity and mortality. In particular, PQM+ interacts with key stakeholders in the pharmaceutical system – national regulatory authorities (NRAs), manufacturers, and national quality control laboratories (NQCLs) – to enhance their capacity to perform critical functions to increase the supply of good quality antimalarials and reduce the prevalence of SF antimalarial medicines from entering or circulating in countries.

PQM+ promotes **effective laboratory testing of medical product quality,** which is the cornerstone of assuring the quality of medical products on the market, by:

- Supporting NQCLs to sustainably strengthen their capacity to reliably detect and report SF medical products in the country.
- Improving the capabilities of NQCLs through the implementation of good laboratory practices (GLP) and subsequent achievement of ISO 17025 accreditation and/or WHO prequalification, which elevates the trust and confidence in the data the laboratory produces.

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PQM+ supports **NRAs** to protect the public from accessing SF medicines by working to:

- Establish and implement risk-based post-market surveillance (PMS) that include malaria medicines to identify and remove SF medical products from the market.
- Standardize processes, coordination, and advocacy for taking regulatory action for medical products found to be SF.
- Streamline the registration process for malaria products in-country through mutual reliance and joint reviews with other regulators and other processes that facilitate accelerated access to quality-assured antimalarials.
- Identify gaps and solutions to address bottlenecks in the import license approval process for antimalarials and align future approvals with national treatment guidelines.
- Establish a system and implement regulatory processes for GS1 standards, including barcodes, to improve 'track and trace' capabilities for medical products, such as rapid diagnostic kits, in the supply chain.
- Increase transparency and public dissemination of regulatory information (e.g., registration status, inspections, licensing, and PMS data/alerts) related to antimalarial medical products.

PQM+ helps to **expand the supply** of antimalaria medical products by **working with manufacturers** to:

- Facilitate domestic production of quality-assured antimalarial medicines.
- Implement good manufacturing practices to ensure manufacturers comply with local and international requirements to manufacture quality-assured antimalarial products.
- Ensure generic antimalarials are equally effective as the original brand products through bioequivalence studies for antimalarials, e.g., using reputable Contract Research Organizations that adhere to good clinical practices.
- Support dossier submission to WHO for prequalification.
- Adopt GS1 standards to support a framework for real-time medical product tracking, traceability, and supply chain optimization.

About the PQM+ Program

The PQM+ Program is a six-year cooperative agreement (No. AID-7200AA19CA00025) between the U.S. Agency for International Development (USAID) and the U.S. Pharmacopeial Convention (USP) to sustainably strengthen medical product quality assurance systems in LMICs as part of broader efforts to promote high performing health care. By sharing scientific expertise and providing technical support and leadership, PQM+ helps to create resilient and sustainable local health systems that ensure access to quality-assured essential medicines and other medical products for HIV/AIDS, tuberculosis, malaria, neglected tropical diseases, other emerging threats, and reproductive, maternal, newborn, and child health.

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Core partners

- African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD)
- 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.

1. https://www.who.int/publications/i/item/world-malaria-report-2019
2. A study on the public health and socioeconomic impact of substandard and falsified medical products. Geneva: World Health Organization; 2017. License: CC BY-NC-SA 3.0 IGO.

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