

Promoting the Quality of Medicines Plus Program (PQM+)



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Reducing maternal, newborn, and child mortality by increasing the supply of and access to quality-assured medicines

Despite major strides toward improving maternal, newborn, and child health on a global level over the past few decades, an estimated 2.8 million pregnant women and newborns die every year, mostly from preventable diseases.¹ In 2019, 5.2 million children under age five died, with many of the leading causes (preterm birth complications, birth asphyxia/trauma, pneumonia, congenital anomalies, diarrhea and malaria) being either treatable or preventable.² According to the World Health Organization (WHO), 94 percent of all maternal deaths occur in low- and lower-middle-income countries, with sub-Saharan Africa accounting for nearly two-thirds and southern Asia about one-fifth.³

Access to skilled health professionals, timely case management, and quality-assured treatments, such as oxytocin, can make the difference between life and death for a mother and her baby. But the widespread circulation of substandard or falsified (SF) maternal, newborn, and child health (MNCH) medical products in local and global markets compromises efforts to reduce morbidity and mortality.

MNCH medicines, unlike medicines for other high-burden diseases, are largely not eligible for the WHO's prequalification (PQ) process and most already have an established market, making them less attractive for manufacturers.⁴ The PQ process ensures that medical products meet international standards for quality, safety, and efficacy through rigorous assessment and product approval. Other challenges impact the MNCH medicines market, including: inadequate standardized procedures for medicines regulatory authorities (MRAs) to review and approve medical products; local manufacturers' limited capacity to produce MNCH products; and few incentives for the private sector to boost production.

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USAID's Promoting the Quality of Medicines Plus ([PQM+](#)) program sustainably strengthens medical product quality assurance systems in low- and middle-income countries to improve the quality of essential medical products. PQM+ provides tailored technical assistance to help reduce MNCH morbidity and mortality. In particular, PQM+ interacts with key stakeholders in the pharmaceutical system – MRAs, manufacturers, and national quality control laboratories (NQCLs) – to enhance their capacity to perform critical functions to increase the supply of quality MNCH medical products and reduce the prevalence of SF medicines entering or circulating in countries. PQM+ works with manufacturers and donor-funded procurement agents such as USAID and UNICEF to ensure products meet required quality criteria.

PQM+ applies a multifaceted approach in its assistance to NQCLs, MRAs, and manufacturers. The program also supports global leadership efforts in collaboration with other MNCH partners to continue to advance USAID, global, and country MNCH agendas and increase access to quality-assured life-saving medicines for women and children in LMICs.

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 MNCH medical products in the country.
- + Improving the capabilities of NQCLs through the implementation of good laboratory practices (GLP) and subsequent achievement of internationally recognized accreditations for quality, such as ISO 17025 and WHO PQ, which elevates the trust and

confidence in the data the laboratory produces.

- + Develop public quality standards (monographs) for new and existing maternal health medicines, which do not yet have standardized testing monographs to assess the quality of the product.

PQM+ supports MRAs to protect the public from accessing SF medicines by:

- + Supporting MRAs post-market surveillance departments to develop standardized guidelines and protocols to detect and remove SF MNCH medical products from local markets.
- + Enhancing MRA registration departments' capabilities to align practices to international standards to streamline processes to improve efficiencies and staff capabilities for reviewing and approving MNCH medical products.

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

- + Optimize the manufacturing process of select MNCH medicines by providing technical assistance to align practices with international good manufacturing practices that optimize the quality, safety, and efficacy of these MNCH medicines.
- + Develop Product Information Reports, which are documents that provide critical technical information and guidance related to the manufacturing of MNCH products that utilize a more complex manufacturing process. These reports help increase local manufacturers' interest in the products and promote a quality manufacturing process.
- + Convene consultative meetings with key stakeholders, including procurement departments, to advocate for use of local manufacturers supported by PQM+ to bring MCH products to market.



About the PQM+ Program:

PQM+ is a five-year (2019-2024) 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 low- and middle-income countries as part of broader efforts to promote high-performing health care. By sharing scientific expertise and providing technical support and leadership, PQM+ helps 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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References:

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- 2 <https://www.who.int/news-room/fact-sheets/detail/children-reducing-mortality>
- 3 <https://www.who.int/en/news-room/fact-sheets/detail/maternal-mortality>
- 4 <https://www.who.int/topics/prequalification/en/>