

Advancing Medicines Quality Assurance Systems in LMICs: Celebrating 10 Years of PQM Program Achievements

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Keynote Address

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- USAID recognizes the importance of ensuring the quality of medical products and why they underpin all other investments in health.
- Quality assurance systems protect people from the harms of substandard and falsified products.
- USAID's aim is to ensure sustainable local change and improve system performance in a way that promotes resilience, facilitates the journey to self-reliance, and reduces dependency on donor aid.
- PQM was built upon predecessor programs, including the Rational Pharmaceutical Management program and the Drug Quality Information program.
- PQM was part of USAID's response to a growing realization of the need to protect patients in LMICs from poor-quality medical products and to maximize USAID's investments in health systems and health supply chains.
- PQM was USAID's first program aimed at diversifying the sources of quality-assured priority products by helping manufacturers achieve World Health Organization (WHO) prequalification (PQ) and meet other stringent international standards.
- PQM's efforts to assess the quality of more than 30,000 medicine samples played a major role in recent publications by WHO that have helped to estimate the burden of poor-quality medicines in LMICs to be around 10 percent.
- Through PQM's support, several potential medicine shortages were averted by diversifying supply sources for quality-assured active pharmaceutical ingredients (APIs) and finished products.
- In total, the PQM program supported the PQ or approval (from a WHO-Listed Authority or Expert Review Panel) of 35 medicines used to treat HIV, tuberculosis (TB), and neglected tropical diseases (NTDs), and to address maternal and child health.
- PQM also worked to increase local access to quality-assured medicines, particularly for maternal and child health (e.g., chlorhexidine), which are beyond the current scope of the WHO PQ program.
- Looking forward, USAID remains committed to ensuring this progress continues and will seek to identify how innovation, partnership, and cross-sector collaboration can be leveraged to improve medical product quality for patients in USAID priority countries.