

STRENGTHENING PHARMACEUTICAL GOVERNANCE FOR IMPROVED MEDICAL PRODUCT QUALITY

The World Health Organization estimates that 3 of the top 10 sources of inefficiencies in health systems are attributable to medical products, including resources wasted on substandard and falsified medical products.¹ Poor governance and inefficient, opaque practices make health systems vulnerable to corruption and mismanagement, which can impede access to quality-assured medical products, have a negative impact on patients' health, waste health resources, and reduce trust in public institutions.

The Promoting the Quality of Medicines Plus (PQM+) program, a global program funded by the U.S. Agency for International Development and led by USP, works to increase access to quality-assured medical products by strengthening pharmaceutical governance and addressing other critical areas that help sustainably strengthen medical product quality assurance systems in low- and middle-income countries.

¹ WHO. 2010. The world health report: health systems financing: the path to universal coverage.

² WHO. 2018. Pharmaceutical System Transparency and Accountability Assessment Tool. Available at: <https://apps.who.int/iris/handle/10665/275370>.

Increasing transparency and accountability in the pharmaceutical sector and optimizing institutional processes decreases vulnerability to corruption and improves efficiency, credibility, and public trust in government institutions. Using globally recognized tools and measures—such as the Pharmaceutical System Transparency and Accountability Assessment tool²—PQM+ relies on the following strategies, customized as appropriate to each country context, to improve governance.

KEY PQM+ STRATEGIES

Promote systems that facilitate transparency and accountability

- + Develop consultative processes to engage industry, national health programs, and civil society in quality assurance rulemaking and strengthen the role of oversight committees to reduce the use of discretionary power.
- + Promote the use of integrated information systems to enhance transparency and information-sharing across different government agencies as well as with healthcare workers, pharmaceutical manufacturers, civil society, and the general public, as appropriate.



- + Strengthen good governance practices of medical product advisory committees by ensuring appropriate and documented processes for determining committee composition, developing and promoting use of committee terms of reference, establishing clear procedures for application decisions, and putting in place measures to eliminate or mitigate conflict of interest issues.

Address fragmentation and promote coordination across public and private sectors

- + Identify entities (e.g., government agencies, implementing partners, donors) involved in quality assurance functions and map quality assurance activities to elucidate fragmentation and identify redundancies.
- + Promote interagency committees to coordinate roles and responsibilities across government agencies involved in regulating different aspects of medical product quality assurance (e.g., licensing agencies, boards of pharmacy, customs, and enforcement agencies).

Develop, adapt, and implement evidence-based medical product quality assurance policies based on international standards and best practices

- + Work with key government stakeholders to conduct gap analyses for critical medical product quality assurance areas, including pharmaceutical policies, laws, and regulations, which will inform policy changes and revisions and promote harmonization with international or regional standards.
- + Support the adoption and application of good regulatory practices, including establishing transparent and accountable processes for the review and evaluation medical product applications.
- + Utilize the United Nations Conference on Trade and Development's Toolbox for Policy Coherence in Access to Medicines and Local Pharmaceutical Production³ to identify divergent and conflicting policies related to pharmaceutical development and to advocate for policy coherence.

³ UNCTAD. 2017. Tool Box for Policy Coherence in Access to Medicines and Local Pharmaceutical Production. Available at: https://unctad.org/en/PublicationsLibrary/diaepcb2017d2_en.pdf.

This fact sheet is made possible by the generous support of the American people through the U.S. Agency for International Development (USAID) under cooperative agreement number 7200AA19CA00025. The contents are the responsibility of the PQM+ program and do not necessarily reflect the views of USAID or the U.S. Government.

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