SUPPORTING REGIONAL HARMONIZATION FOR TIMELY ACCESS TO QUALITY MEDICAL PRODUCTS

In many low- and middle-income countries, access to essential, quality-assured medical products is often delayed by lengthy and ineffective product registration and approval processes. Delays in product registration, which can often stretch years, can act as a deterrent to manufacturers that might otherwise consider registering their products in a particular country. A number of challenges contribute to delays in product registration, including a lack of qualified regulatory staff, insufficient or inefficient use of financial resources, uncoordinated regulatory processes, and a lack of cooperation and information sharing among regulatory authorities.

By promoting the adoption of international quality assurance standards and supporting the implementation of policies that support convergence and harmonization, PQM+ helps improve work-sharing, collaboration, and mutual recognition. These efforts enable more rapid approval and access to essential medicines and also support countries on their journey to self-reliance. In partnership with the African Union Development Agency–New Partnership for Africa’s Development (AUDA–NEPAD), the technical arm of the African Union, PQM+ works to strengthen medicines regulatory harmonization initiatives across regional economic communities in Africa. PQM+ also draws expertise from the program’s technical resource partners to facilitate the harmonization of regulatory frameworks in Africa and Asia.

KEY PQM+ STRATEGIES

Endorse the uptake and use of international standards, guidelines, and best practices

+ Support adoption of good regulatory practices and related medical product quality assurance guidelines, including those that enable transparent and accountable product review and evaluation to enable work-sharing and mutual recognition.

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 advancing regional harmonization and convergence and by addressing other critical areas that help sustainably strengthen medical product quality assurance systems in low- and middle-income countries.
Endorse the adoption of risk-based approaches to improve the efficiency with which resources are allocated and used to improve medical product quality.

Deploy the Asia Harmonization Working Party Playbook for Implementation of Medical Device Regulatory Frameworks throughout the Asia region.

Promote and support harmonized policies and guidelines

- Assess medical product quality assurance guidelines, policies, and laws to identify opportunities for improved convergence and harmonization.
- Engage technical working groups within medicines regulatory authorities to strengthen governance and coordination and support the development and advancement of the African Medicines Agency with a phased financial plan toward self-sufficiency.
- Support development of guidelines for the regulation of active pharmaceutical ingredients, good clinical practices, bioequivalence, and quality assurance of diagnostics.

Promote the use of collaborative and cooperative mechanisms

- Map technical capacity for key medicines regulatory functions at local and regional levels to identify areas where mutual recognition would be particularly beneficial.
- Improve capacity to perform joint manufacturer inspections and dossier reviews to reduce registration backlogs and review times and support timely access to safe, effective, and quality-assured essential medicines.
- Encourage mutual recognition and work-sharing to facilitate regional post-marketing quality surveillance.
- Support the timely sharing and exchange of information among medicines regulatory authorities by promoting the use of shared data platforms.