OPTIMIZING RESOURCES FOR SUSTAINABLE QUALITY ASSURANCE SYSTEMS

Medicine regulatory authorities (MRAs), as integral components of well-functioning health systems, must be configured and resourced to effectively and efficiently serve a country’s evolving public health priorities. Supporting MRAs in becoming increasingly self-reliant requires improving the generation, mobilization, and allocation of resources for maximum public health benefit. Broader, strategic plans and road maps help ensure that MRAs are configured and resourced to meet public health needs and enable MRAs to measure progress, identify successes, and make course corrections over time.

Using a health systems approach PQM+ supports regulatory authorities and national quality control laboratories to improve the use of financial and human resources, mobilize domestic resources, and apply risk-based approaches to ensure that MRAs can effectively respond to public health needs and an evolving pharmaceutical landscape.

Under PQM+, USP’s Insights team—comprising 39 strategy and analytics professionals globally—works to provide globally sourced and supported market research and insights through surveys and in-depth analysis of market trends. Additionally, PQM+ supports the implementation of best practices and approaches for strategic planning, organizational design, and realization of operational efficiencies across core regulatory functions.

Meaningful and sustained systems change will only occur if local leadership is engaged early and often and consensus is built before interventions are rolled out. As part of it’s program principles and implementation model, PQM+ prioritizes these critical steps as well as efforts to ensure ongoing transparency and accountability.

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

**Locally led governance, decision-making, and oversight**

- **Long-term strategic plan development**
- **Risk-based resource allocation**
- **Resource mobilization:**
  - Service fees
  - Government investment
  - Efficiency realization
- **Sustainable, efficient organization designed to reflect country’s public health priorities and objectives**

**Continuous improvement and institutional planning**

*Annual planning cycle | M&E system*

**Improving the allocation and use of resources**

- Map current product quality assurance systems and processes in partner countries to understand key activities and the use of resources involved in each activity.
- Conduct risk assessments to inform allocations, and support countries to reallocate and reinvest resources using risk-based approaches.
- Support the development of long-term strategic and financial plans to align quality assurance priorities with the broader national public health priorities and needs.
- Institutionalize sustainable systems for monitoring and evaluation and annual planning to ensure transparency, continuous improvement, and inform dynamic resource planning.

**Increasing domestic resource mobilization**

- Develop fee-for-service schemes and modeling tools (based on market tolerance and an analysis of MRA costs and configurations) to enhance domestic resource mobilization and self-reliance.
- Support countries to regularly review and refresh fee schedules, plan for the transparent rollout of new fee schedules and processes, and communicate and engage with relevant stakeholders through consultative processes.
- Develop the value proposition, return on investment, and public health benefit of strengthened quality assurance systems to support regulators in advocating for increased government investments.

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