

Promoting the Quality of Medicines Plus (PQM+)

USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.

Adopting Minimum Common Standards for Regulatory Information Management Systems—A Call to Action



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About the USAID MTaPS Program

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to higher-performing health systems. MTaPS focuses on improving access to essential medical products and related services and on the appropriate use of medicines to ensure better health outcomes for all populations. The program brings expertise honed over decades of seminal pharmaceutical systems experience across more than 40 countries. The MTaPS approach builds sustainable gains in countries by including all actors in health care—government, civil society, the private sector, and academia. The program is implemented by a consortium of global and local partners and led by Management Sciences for Health (MSH), a global health nonprofit.

About the USAID PQM+ Program

Promoting the Quality of Medicines Plus (PQM+) is a program operating under a USAID-funded cooperative agreement with the U.S. Pharmacopeial Convention (USP) with a goal to sustainably strengthen medical product quality assurance (QA) systems by providing technical assistance to manufacturers of priority health products and build in-country capacity of medicines regulatory authorities to improve product registration, inspection, and post-marketing surveillance for product quality. PQM+ support also includes accreditation of national drug quality control laboratories per ISO/IEC 17025 and/or World Health Organization (WHO) prequalification standards in low- and middle-income countries. PQM+ uses a systems strengthening approach to program implementation to enhance sustainability.¹ The program considers the entire system when designing and delivering technical assistance, focusing on the interaction among all health systems functions² as they relate to medical product quality assurance.

To implement PQM+, USP joined forces with a diversified consortium of four core partners, six field-led extension partners, and eight technical resource partners³ whose extensive technical expertise can be drawn on to achieve desired results.

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About the USAID MTaPS Program

Funded by the U.S. Agency for International Development (USAID) and implemented by a team led by Management Sciences for Health (MSH), the purpose of the five-year Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2023) is to provide pharmaceutical system strengthening assistance for sustained improvements in health system performance and to advance USAID’s goals of preventing child and maternal deaths, controlling the HIV/AIDS epidemic, and combating infectious disease threats, as well as expanding essential health coverage. The goal of MTaPS is to help low- and middle-income countries strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines, vaccines, and other health technologies and pharmaceutical services.

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¹ Chee G, Pielemeier N, Lion A, Connor C. Why differentiating between health system support and health system strengthening is needed. *Int J Health Plann Mgmt.* 2013; 28: 85-94. DOI: 10.1002/hpm.2122.

² Governance, human resources, service delivery, information systems, financing: <https://www.usaid.gov/global-health/health-systems-innovation/health-systems/strengthening-pharmaceutical-systems>

³ <https://www.usp.org/sites/default/files/usp/document/our-impact/pqm/pqm-plus-overview-brochure.pdf>

CURRENT SITUATION

National medicines regulatory authorities (NMRAs) are responsible for ensuring access to safe, effective, and quality-assured medical products by performing key functions as defined in the World Health Organization (WHO) Global Benchmarking Tool. These include product registration, inspection and licensing of pharmaceutical establishments, product quality testing, post-marketing surveillance, medicines safety monitoring/pharmacovigilance, clinical trials oversight, and lot release. In many low- and middle-income countries (LMICs), the regulatory information management systems (IMS) that support these functions are disjointed and poorly managed, not interoperable with other systems within or among countries, or even nonfunctional or nonexistent. A scoping study indicated that only 26 NMRAs (47%) of the 55 African Union member states have a regulatory IMS, and only 24 are used in daily operations.⁴ Many LMIC regulatory processes are still paper based, which makes for inefficient and inconsistent workflows and increases the likelihood of human errors in data management, backlogs and delays, lack of transparency, and corruption. Additionally, NMRAs struggle to fully operationalize both web- and paper-based IMS, which limits the availability of real-time data. Although some countries are addressing these challenges by digitalizing regulatory IMS, the variation in approaches to digitalization exacerbates issues of interoperability and complicates collaboration among NMRAs.

Several factors affect how efficiently NMRAs make regulatory decisions and bring quality, safe, and effective medical products to market. For example, if an NMRA lacks easy access to data on product quality or clinical trials to inform regulatory decision making, product registration is prolonged. In a recent study, manufacturers reported that registration of medical products takes an average of about six months in Asian countries and up to four years in African countries.⁵ As a result, the market entry of innovative products is slow if suppliers are deterred from submitting product dossiers to enter LMIC markets due to cumbersome approval processes and procedures. Additionally, a lack of standards makes data submission, exchange, and analysis difficult and can delay communication regarding product quality and safety issues as well as instances of cross-border theft and diversion.

Advantages to NMRAs that adopt common standards for regulatory IMS

- More efficient operations
- Expedited product assessments and facility inspections
- Easy information sharing, especially among harmonization initiatives
- Interoperability with international systems
- Common language for system design

Regional regulatory harmonization in Africa and Asia facilitates NMRAs' decision making processes and reduces workload and duplicative effort, thereby increasing operational efficiencies and lowering costs. These efforts rely on NMRAs and other related entities such as coordination within regional economic communities to use common standards and processes as well as fit-for-purpose regulatory IMS designed to gradually become fully interoperable and allow ready information exchange.

⁴ BEWSYS. 2020. Final Report. Consultancy for Scoping of a Continental Regulatory Information Management System Solution and Information Sharing Platform for the Member States in the African Union. Submitted to the World Bank Group. Washington DC.

⁵ Briggs J et al. 2021. The registration status of maternal, newborn and child health medical products: Evidence from nine countries. Arlington, VA: Management Sciences for Health.

Examples include the African Union’s Medicines Regulatory Harmonization initiative to standardize product registration, licensing of establishments, regulatory inspections, market surveillance and control, laboratory testing, pharmacovigilance, clinical trials oversight, and regulatory information management, which lightens the burdens of NMRAs. Similarly, the Association of Southeast Asian Nations promotes regulatory convergence and reliance, optimizes medical product manufacturing capability and resilience at the country and regional levels, and advances global medical product quality assurance learning and operational agenda in the region.

JUSTIFICATION FOR MINIMUM COMMON STANDARDS FOR REGULATORY IMS

Different standards for regulatory IMS exist, but by developing a set of minimum common standards, NMRAs could streamline workflows and regulatory processes, ensure uniform data capture, and enable data exchange within and among NMRAs and other stakeholders who support regulatory convergence and harmonization efforts. Minimum common standards would also enhance NMRAs’ ability to use mechanisms where countries can recognize or rely on WHO or stringent regulatory authorities’ regulatory assessments, inspection outcomes, or other regulatory decisions to speed up approval processes and prevent the need to duplicate evaluation of costly processes such as bioavailability assessment and safety studies.

A literature review was conducted that focused on existing IMS and regulatory standards required for data capture, data and information exchange, and enhancing interoperability. The search was organized around the eight regulatory functions outlined in the WHO Global Benchmarking Tool to evaluate national regulatory systems: registration or marketing authorization, vigilance, market surveillance and control, licensing establishments, regulatory inspection, laboratory testing, clinical trials oversight, and NMRA lot release. For the eight regulatory functions, 56 standards were collated and classified into three categories through a consultative process with expert stakeholders and NMRAs.

Identified common standards

- **Process standards** are prerequisites for standardizing regulatory functions. Examples include Good Regulatory Practices, Good Reliance Practices, Good Manufacturing Practices, and International Organization for Standardization standards.
- **Pharmaceutical standard dictionaries and knowledge trees** are reference lists for terminology, nomenclature, and hierarchies. Examples include Systematized Nomenclature of Medicine-Clinical Terms, Anatomical Therapeutic Chemical, and international nonproprietary name.
- **Data exchange standards** determine how data should be structured, defined, and formatted to share across computer systems. Examples include Structured Product Labeling and Portable Document Format and platforms such as Fast Health Interoperability Resources that define a common standard for health systems data exchange.

Within these three categories of standards, experts in regulatory systems strengthening and information management systems from 17 global, regional, and national organizations met to develop the use case and identify the selection criteria for the set of minimum common standards. Through extensive consultations, the group chose criteria to use to assess and select each standard.

Criteria for selecting common standards for regulatory IMS

- **Relevance:** Applicable to any of the eight core functions of the WHO Global Benchmarking Tool⁶ used to create more mature medicine regulatory systems
- **Feasibility of application:** Country capacity to apply the standard and the efficiency gained
- **Priority:** What countries would lose by not adopting the standard
- **Universality:** The standard is widely used or is recommended by WHO

ADVANTAGES TO NMRAS

Advantages of adopting a set of minimum common standards in the digitalization of regulatory IMS include:

- **More efficient internal operations**, such as workflow management, performance tracking, and reporting, that lower the cost of running a regulatory IMS
- **Expedited product assessments and facility inspections** that deliver to the market prompt access to safe, high-quality medical products
- **Easy sharing of information** about regulated medical products that may influence the health of the population, particularly regarding substandard and falsified medicines
- **Facilitated convergence and harmonization** of regulatory services both within and outside of an NMRA
- **Interoperability with the international systems** with which LMIC national systems must communicate
- Creation of a common language for system design and architecture that software developers can use to design IMS software for regulatory functions and make improvements to existing digitalized systems

OBSTACLES TO ADOPTING MINIMUM COMMON STANDARDS FOR REGULATORY IMS

Although NMRAs will clearly benefit from adopting minimum common standards for regulatory IMS, **barriers to implementation remain**. For example, **the maturity levels of NMRAs in LMICs vary, which makes adoption more difficult and lengthier for some**, and the lack of standards that exist across the regulatory functions that regulatory IMS support could impede implementation or serve as a disincentive. Although the IMS investment will likely pay for itself through efficiencies gained, the **high cost of initial adoption may be a limitation, particularly if the country aims to fully digitalize regulatory functions**. Some NMRAs may face challenges in obtaining adequate financial resources, especially in an environment of poor political will; in addition, **a country may not have sufficient skilled human resources to maintain the digitalized regulatory IMS and require additional technical assistance**. A solution to inadequate resources could be to prioritize gradual adoption.

⁶ WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory System of Medical Products - Revision VI

STAKEHOLDER CALL TO ACTION

The process to adopt minimum common standards for regulatory IMS should be stepwise and pragmatic. To determine the best path forward to achieve a stable, functional system, the country should assess its resources—financial, human, and infrastructure—and its regulatory maturity level according to the WHO Global Benchmarking Tool.

This call to action is made to global, regional, and national stakeholders:

- **Globally:** Recognize and adopt the identified set of minimum common standards for regulatory IMS and provide international guidance and support from development partners to help countries implement the standards in their efforts to digitalize their regulatory IMS
- **Regionally:** Integrate the concept of adoption of a set of minimum common standards for regulatory IMS into organizational strategic plans, particularly for promoting convergence and harmonization of medical product regulation, and collaborate to introduce the concept to member states
- **Nationally:** Provide feedback by participating in the discussions to finalize the common minimum standards and set a policy to adopt and integrate the standards as part of the medicines regulatory system digitalization transformation

Examples of Regulatory IMS Stakeholders

National: National medicines regulatory authority; government information technology agency

Regional: Regional economic communities such as the East African Community and Intergovernmental Authority on Development; regional health organizations

Global: Donors such as USAID, the Bill & Melinda Gates Foundation, Global Fund to Fight AIDS, Tuberculosis and Malaria, World Bank, and their implementing partners; global expert organizations/groups such as WHO