STRENGTHENING COUNTRIES' REGULATORY INFORMATION MANAGEMENT SYSTEMS

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Based on its decades of expertise in strengthening health systems to save lives and improve the health of people in low- and middle-income countries, USAID supports better governance and integrated, innovative, and sustainable strategies to strengthen pharmaceutical systems.

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WHY ARE STRONG REGULATORY INFORMATION MANAGEMENT SYSTEMS NECESSARY?

Strong regulatory information management systems (RIMS) are necessary for pharmaceutical regulatory systems to be able to regulate medical products circulating on the market. They enable national regulatory authorities (NRAs) to perform key functions, such as market authorization and pharmacovigilance. Strong RIMS improve the availability and accessibility of data to inform NRAs' decision-making; enhance the ability of NRAs to collaborate and share information with one another; and improve the consistency, efficiency, and accountability in their services. Such enhancements to an NRA's functionality improve the effectiveness of the regulatory system in controlling the medical products market.

As critical as RIMS are for helping countries to make evidence-based decisions, they often lack functionality and may lack interoperability in low- and middle-income countries. Additionally, in these contexts, paper-based systems may still be used for many functions of the regulatory system, creating inefficiencies and making them vulnerable to corruption or mismanagement. Digitalization, a key feature of strong RIMS, helps to address these inefficiencies by improving consistency, efficiency, and accountability in pharmaceutical regulatory service delivery.

MTAPS' APPROACH TO STRENGTHENING REGULATORY IMS

MTaPS' approach to strengthening RIMS entails improving local capacity for data governance, analytics, interoperability, and integration. MTaPS' activities include:

- Supporting regional harmonization of RIMS
- Building local capacity to analyze data requirements and infrastructure
- Creating data exchange systems
- Designing and improving pharmacovigilance systems
- Applying behavior change interventions
- Providing training and mentorship
- Collaboratively proposing minimum common standards for regulatory information management systems
- Implementing information management tools, such as Pharmadex for medicines registration, the PharmacoVigilance Monitoring System (PViMS) for active surveillance and spontaneous reporting on medicine safety, and the World Health Organization (WHO) Global Benchmarking Tool for assessment of regulatory systems

MOZAMBIQUE

In Mozambique, MTaPS is supporting the national medicines regulatory authority, ANARME, to become a functional authority with an effective RIMS and control of the medical products market. In-country capacity was strengthened by updating of the regulatory framework, capacity building for regulators, and the use of innovative systems like Pharmadex and PViMS for efficient delivery of services.

MTaPS is helping to enhance Pharmadex to meet context-specific needs. For example, Pharmadex will follow the common technical document format for the review of marketing authorization dossiers, in line with the country's requirements. The import and registration modules are expected to improve customer service and reduce registration processing timelines.

In Mozambique, PViMS allows active safety surveillance for newly introduced medicines, such as Tenofovir, Lamivudine, and Dolutegravir, in the national HIV and tuberculosis programs. As of December 2021, 3,217 participants were enrolled, with 7,447 follow-ups and 88 adverse events reported via the system. Through PViMS, data entered at the facility level are available at the central level for both monitoring and decision-making. MTaPS also collaborated with ANARME to finalize entry of incomplete data in PViMS and conduct data cleaning as part of its support to establish the active surveillance system.

NEPAL

In Nepal, MTaPS is also supporting the Department of Drug Administration (DDA) to become a functional authority with effective RIMS and control of the medical products market. Support has included the update of the legal and regulatory framework; reorganization of the structure of the DDA within the Ministry of Health; capacity building for assessors and inspectors; establishment of good practices for product registration and inspection; and the deployment of Pharmadex.

MTaPS is helping to customize Pharmadex to increase the DDA's efficiency and improve the department's use of data and is strengthening the capacity of system users. MTaPS finalized and implemented the registration module, which includes registration of medical devices and health technology products. The registration module, which was developed in line with WHO best practices, is expected to improve the department's registration functions. Country customizations are based on feedback received after a demonstration of Pharmadex for the DDA and user acceptance testing. MTaPS is training DDA staff, including the development and use of an eLearning course. The Nepalese government has established a help desk for Pharmadex.

ADDITIONAL RESOURCES

Management Sciences for Health. *OpenRIMS*. https://www.openrims.org/

USAID MTaPS. *Information for decision-making*. https://www.mtapsprogram.org/wp-content/uploads/2021/03/FactSheets_MTaPS_IS-in-Pharmaceutical-Services_052620.pdf

USAID MTaPS. *Pharmaceutical regulatory systems*. https://www.mtapsprogram.org/wp-content/uploads/2021/03/FactSheets_MTaPS_Pharmaceutical-Regulatory-Systems_051920.pdf

USAID MTaPS. *Pharmadex*. https://www.mtapsprogram.org/our-resources/pharmadex/

USAID MTaPS. *PViMS*. https://www.mtapsprogram.org/our-resources/pvims/

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The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to better health outcomes and higher-performing health systems. The program is implemented by a consortium of global and local partners, led by Management Sciences for Health (MSH), a global health nonprofit.

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