Approaches and Tools for Strengthening Pharmaceutical Systems

Strengthening Regulatory Information Management Systems

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Why are RIMS important?

National regulatory authorities (NRAs) ensure access to safe, effective, quality-assured, and affordable medical products, which is a primary outcome of national pharmaceutical systems (figure 1). Well-functioning regulatory information systems (RIMS) enable NRAs to perform key regulatory functions, such as marketing authorization and pharmacovigilance, by improving the availability and accessibility of data to inform NRAs' decision making. Critical decisions include the approval of new products or product withdrawal from the market. As important, RIMS enhance NRAs' ability to collaborate and share information with one another and improve the consistency, efficiency, and accountability in regulatory services provision.

Despite their importance, low- and middle-income countries often have RIMS that are disparate and lack interoperability. In some countries, RIMS are nonexistent, partially implemented, or nonfunctional.[1] Further, many regulatory processes are still paper-based (e.g., drug application dossier processing, lists of registered products, licensing of pharmacy establishments), resulting in inefficient workflows, lack of transparency, mismanagement, and vulnerability to corruption.

Digitalization—a key feature of well-functioning RIMS—often improves consistency, efficiency, and accountability in pharmaceutical regulatory service delivery. However, RIMS digitalization can only be beneficial if manual processes and information flow are first clearly defined and strengthened.

Improving the functionality of RIMS is an essential aspect of strengthening regulatory systems and as part of broader pharmaceutical systems strengthening efforts.

Figure 1. Pharmaceutical system components

In this document, we present approaches and tools that MTaPS uses to strengthen RIMS using digital solutions and describe how organizations can apply them in their context.

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[1] BEWSYS. 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. 2020. https://documents1.worldbank.org/curated/en/468801613316844205/pdf/Final-Report.pdf

Approaches and tools for strengthening RIMS

MTaPS' approach to strengthening RIMS entails improving local capacity for the generation, governance, analysis, interoperability, and integration of pharmaceutical data in NRA workflows. Specific tools and approaches include:

- Designing and improving NRA data-generating processes, which may then be suitable for digitalization
- Developing and implementing RIMS
  - OpenRIMS: A free and open-source software (FOSS) that enables NRAs to digitalize and automate their work processes, such as medicines registration and licensing, without the routine need of a software developer
  - PharmacoVigilance Monitoring System (PViMS): A web-based application used by clinicians, regulatory bodies, and implementing partners to monitor the safety of medicines. It supports both passive surveillance and spontaneous reporting. PViMS support includes capacity building through local training and mentorship on generating and using regulatory information.
- Developing minimum common standards for RIMS and promoting their adoption to align regulatory processes, the uniform capture of information, and the exchange of data within and among NRAs
- Providing training and mentorship to strengthen capacity to use RIMS to generate and use data to improve regulatory processes

MTaPs has supported countries' implementation of RIMS modules pertaining to marketing authorization and vigilance, with other modules added in phases as implementation of RIMS progresses. Together, OpenRIMS and PViMS will ultimately support the work processes aligned with the range of regulatory functions (product registration or marketing authorization, vigilance, market surveillance and control, licensing, inspection, testing, clinical trial oversight, and lot release) outlined in the World Health Organization's Global Benchmarking Tool (GBT).

Case studies on improving pharmaceutical RIMS

Mozambique: OpenRIMS and PViMS

MTaPS is supporting the NRA, Autoridade Nacional Reguladora de Medicamentos (ANARME), to increase its GBT score with an effective RIMS that will facilitate control of the medical products market and increase functionality. In-country capacity was strengthened by updating the regulatory framework, building regulators' capacity, and using innovative systems, like OpenRIMS and PViMS, for efficient delivery of integrated regulatory services.

MTaPS is helping enhance OpenRIMS to meet context-specific needs. For example, OpenRIMS will be configured to follow the common technical document format for reviewing pharmaceutical marketing authorization dossiers, in line with the country's requirements. The import and registration modules are expected to improve customer service, reduce registration processing timelines, and allow important data for decision making, e.g., key performance indicators to be available in a dashboard.

OpenRIMS in Nepal

MTaPS is supporting the Department of Drug Administration (DDA) to digitalize its RIMS and increase its GBT maturity level. Digitalization will improve the registration and regulation of medical products, health technology products, manufacturers, pharmacies, wholesalers, and importers. Support has included updating the legal and regulatory framework; the proposed reorganization of the DDA; building the capacity and competency of DDA staff; revising workflows and practices in line with WHO best practices; establishing a quality management system in support of ISO certification; and deploying OpenRIMS, initially for registration and inspection, followed by developing inspection and import/export modules.

MTaPS is helping customize OpenRIMS to the Nepal context and increase DDA's efficiency through better use of management information and reporting capacity.

MTaPS finalized and deployed the registration module, which includes registration of pharmacies and wholesalers. The manufacturer, product, import, HTP, and inspection registration module prototype has been developed and is awaiting implementation after successful review and user acceptance testing by DDA. The registration module, which was developed in line with WHO best practices, is expected to improve the department's registration functions and dossier review practices. Country customizations are based on feedback received after a demonstration of OpenRIMS for DDA and user acceptance testing. MTaPS has trained DDA staff, prepared user manuals for the system, and established a help desk to facilitate the transition from the existing system (DAMS) to the new and better OpenRIMS. To ensure sustainability after MTaPS closes, a local vendor is being hired, so that after sufficient training, long-term support for OpenRIMS can be provided.

How can organizations apply these approaches?

Below are resources that can equip organizations with the knowledge and tools to improve pharmaceutical RIMS in local contexts.

Tools

- WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory System of Medical Products – Revision VI: This tool assesses systems for regulating medical products. It provides WHO and regulatory authorities with information on areas of strength as well as areas for improvement to facilitate development of institutional development plans and monitor countries' progress.
- OpenRIMS: This is a FOSS that enables NMRAs to digitalize and automate their work processes, such as medicines registration and licensing, without the routine need of a software developer.
- Adopting Minimum Common Standards for Regulatory Information Management Systems: This document summarizes the consultative process by which a set of minimum common standards for RIMSs in low- and middle-income countries was developed and provides advocacy tools and guidance for NMRAs' adoption of the standards for a RIMS.

Additional readings and resources

- Advancing Regulatory Systems for Improved Access to Safe, Effective, Affordable, and Quality-Assured Medical Products (January 2023)
- Making the Investment Case for National Regulatory Authorities (January 2021)

eLearning resources

- OpenRIMS courses: This suite of courses educates developers, regulatory authorities, and business clients in regulatory authorities on using OpenRIMS for regulatory work processes. For instance, business clients can receive training on how to submit applications for marketing authorization, export license, pharmacy registration, and other regulatory processes.
- Pharmaceutical Systems Strengthening 101 (available in English and in French): This course introduces learners to the basic principles of PSS, including how addressing pharmaceutical system problems advances universal health coverage; combats AMR, HIV and AIDS, malaria, tuberculosis, and other public health threats; and promotes maternal and child health.

Contact

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