Approaches and Tools for Strengthening Pharmaceutical Systems

Strengthening Regulatory Systems

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Why is strengthening regulatory systems important?

National regulatory authorities (NRAs) are responsible for controlling the quality, safety, and efficacy of medical products (including medicines, vaccines, medical devices, and other health technologies) in their countries' jurisdictions. Effective national regulatory systems are comprised of eight key regulatory functions defined by the WHO Global Benchmarking Tool for Evaluation of National Regulatory System of Medical Products (GBT). These are product registration or marketing authorization, vigilance, market surveillance and control, licensing, inspection, testing, clinical trial oversight, and lot release. Together, these eight functions help ensure the availability and appropriate use of safe, effective, quality-assured, and affordable essential medicines and related services, a primary outcome of national pharmaceutical systems.

In low- and middle-income countries (LMICs), NRAs face challenges. A 2010 assessment of 26 NRAs in sub-Saharan Africa published by the World Health Organization (WHO) found that many countries had the necessary legal provisions, however, these laws and regulations were out of date and countries did not have the necessary capacity to maintain coherent control of the system.[1]

Capacity limitations include insufficient qualified personnel, inadequate financial resources, and inadequate information management systems. Such weaknesses can result in antimicrobial resistance, poor health outcomes, disability, or even patient deaths. Regulatory systems strengthening (RSS) addresses these gaps and improves countries' pharmaceutical regulatory capacity.

In this document, we present approaches and tools that MTaPS has found effective to address RSS and describe how other organizations can apply them in their context.

Approaches and tools to strengthen regulatory systems

USAID MTaPS applies a systemwide approach to supporting LMICs to improve their regulatory systems across various areas of the pharmaceutical system (figure 1). This includes strengthening governance of product quality, promoting accountability through appropriate legal provisions, improving human and institutional capacity to manage the system, advocating for adequate financing, and improving the availability of information that is needed to inform regulatory decision making.

[1] WHO. Assessment of medicines regulatory systems in sub-Saharan African countries: An overview of findings from 26 assessment reports. Geneva: WHO. 2010

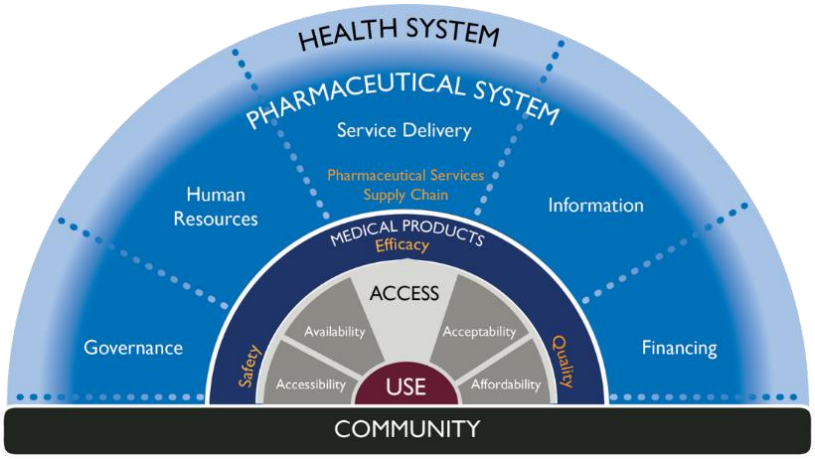

Figure 1. Components of the pharmaceutical system

MTaPS' RSS approach is based on the WHO GBT, which MTaPS uses in collaboration with NRAs, WHO, and other partners to first assess regulatory capacity. The GBT has 268 indicators across all 8 regulatory functions to classify each NRA's level of maturity from 1 to 4 (i.e., 1 = no formal approach, 2 = reactive approach, 3 = stable formal system approach, and 4 = continual improvement emphasized). Regulatory systems at maturity levels 3 and 4 are considered well-functioning.

MTaPS supports countries to use the gaps and weaknesses identified in the GBT assessment to develop and apply contextually tailored interventions and action plans (figure 2) laid out in institutional development plans (IDPs). Support to NRAs includes prioritizing areas for improvement in the action plans and supporting them to monitor progress and achievements against these plans. The standard that these regulatory systems aim to reach is maturity level 3 according to the GBT for regulation of medicines and ISO 9001:2015 certification, which indicates that they meet international requirements for quality management systems (QMSs).

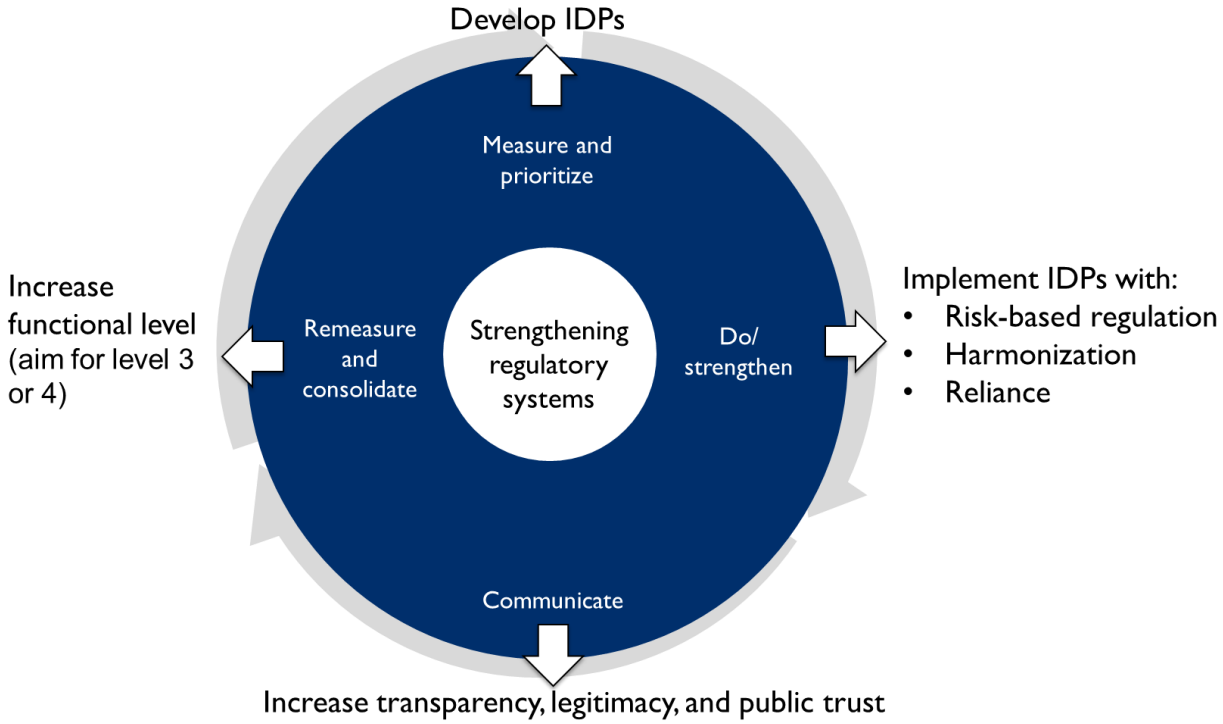

Figure 2. MTaPS' approach to strengthening regulatory systems

RSS interventions that are applied include:

- Drafting or updating evidence-based policies, laws, regulations, guidelines, norms, and standards
- Strengthening governance structures to better oversee and enforce legal provisions
- Building institutional and individual capacity in skills required to carry out NRAs' mandate
- Establishing QMSs and electronic information management systems in and across countries
- Supporting convergence and regional harmonization of pharmaceutical regulation

Case studies on RSS

Strengthening governance structures and establishing QMS for Rwanda FDA

In Rwanda, MTaPS applied this approach to supporting the government to ensure that an adequate regulatory framework is in place. This included developing a five-year business plan for growth and financial stability and an accompanying four-year strategic plan (2021 to 2024) that sets out the Rwanda FDA's vision, priorities, and strategic objectives. In the regulatory domain, MTaPS is supporting FDA in drafting and validating regulations, guidelines, and standard operating procedures (SOPs) for regulating products, such as medical gases (e.g., medical oxygen), vaccines, biological products, and generic medicines.

MTaPS is also supporting Rwanda in establishing a QMS for improving efficiency, consistency, and customer satisfaction while delivering regulatory services. The first step was to conduct a situational analysis to inform the approach. Based on findings, MTaPS then provided technical assistance to develop quality manuals and SOPs for specified regulatory functions. Activities included orienting FDA personnel at all levels on QMS principles, providing training in risk management and building the capacity of regulatory authorities to conduct internal quality audits. The QMS and internal audit will help prepare FDA for external audits, allow them to independently address gaps, facilitate ISO 9001:2015 certification, and fulfill QMS implementation requirements.

Improving regulatory competencies in Bangladesh, Nepal, and the Philippines

MTaPS provides regional- and country-level support to countries in the Asian region to strengthen their regulatory systems. Low maturity ratings as per the WHO GBT call for identifying existing competencies and developing adequate steps to meet competency gaps that will enhance NRAs' regulatory capacities in the region. MTaPS applied a combination of approaches, including regionally led networks, a bottom-up approach, and direct coordination with country representatives to jointly implement RSS capacity-building activities in Bangladesh, Nepal, and the Philippines.

This approach entailed:

- Developing a competency mapping questionnaire based on the WHO's Global Competency Framework and Implementation Tool and each country's needs
- Organizing workshop sessions in each country to collect data in response to the questionnaire
- Using the data collected to:
    - Identify key regulatory areas and map competencies in the areas of organizational requirements and requirements specific to each regulatory function or role
    - Identify gaps in knowledge, skills, and personnel experience
- Defining specific capacity-building needs, including training needs of regulatory personnel in the NRAs
- Disseminating findings for feedback and input via dissemination workshops in each country

The competency mapping demonstrated good understanding, knowledge, skills, and practices across the various competency areas. Pharmacovigilance was identified as an area needing critical intervention. Results also indicated that the countries needed varying degrees of regulatory environment development. Results are being used by the countries in collaboration with MTaPS to develop training plans that will build individual and organizational capacities and competencies.

How can organizations apply these approaches?

Below are resources that can equip organizations with the knowledge and tools to improve the effectiveness of regulatory systems in local contexts.

Tools

- GBT for Evaluation of National Regulatory System of Medical Products – Revision VI (WHO 2021): 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 the development of IDPs and help monitor countries' progress.
- OpenRIMS: OpenRIMS is an open-source, web-based tool that helps NRAs digitize and automate their work processes, such as medicine registration and licensing.
- Adopting Minimum Common Standards for Regulatory Information Management Systems (MTaPS 2022): These documents summarize the consultative process by which a set of minimum common standards for regulatory information management systems in LMICs was developed; the documents also provide advocacy tools and guidance so NRAs can adopt the standards for a regulatory information management system.
- Establishing Quality Management Systems for NRAs in LMICs (MTaPS, forthcoming)
- How to conduct competency gap assessments and develop capacity-building plans (MTaPS, forthcoming)
- WHO Global Competency Framework and Implementation Tool (forthcoming)

Additional readings and resources

- Improving Access to Maternal, Newborn, and Child Health Medical Products in Low- and Middle-Income Countries: Considerations for Effective Registration Systems (March 2021)
- Business Plan Development for Rwanda Food and Drugs Authority (December 2021)
- Making the Investment Case for National Regulatory Authorities (January 2021)
- Advancing Regulatory Systems for Improved Access to Safe, Effective, Affordable, and Quality-Assured Medical Products (January 2023)

eLearning resources

- Medicines to Markets: Building Effective Medicines Registration System in LMICs: This webinar recording from the Global Learning series shares MTaPS' approach and experience supporting countries to bolster their medicine registration in the context of the COVID-19 pandemic.
- 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 (PSS) 101 in English and French: This course developed by MTaPS teaches participants the basic principles of PSS.

Contact

Please contact MTaPS (Management Sciences for Health) if you would like further assistance.

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About USAID MTaPS:
The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2023) 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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