

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

Improved Access. Improved Services. Better Health Outcomes.

Approaches and Tools for Strengthening Pharmaceutical Systems

Strengthening **Regulatory Systems**

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Why is strengthening pharmaceutical regulatory systems important?

National regulatory authorities (NRAs) are responsible for controlling the quality, safety, and efficacy of medical products. NRAs have eight key regulatory functions:

- Product registration or marketing authorization
- Vigilance
- Market surveillance and control
- Licensing establishments
- Regulatory inspections
- Laboratory testing
- Clinical trial oversight
- Lot release

Together, these eight functions help ensure regulation of the medical products market and related services, as part of national pharmaceutical systems.



Why is strengthening pharmaceutical regulatory systems important?

WHO 2010 assessment of 26 NMRAs in Sub-Saharan Africa:

- Despite having the necessary legal provisions, the laws and regulations were out of date.
- Countries lacked the necessary capacity to maintain coherent control of the regulatory system.
- Capacity limitations include:
 - Insufficient qualified personnel
 - Inadequate financial resources
 - Poorly functioning information management systems
- These NRA challenges can result in poor health outcomes, disability, antimicrobial resistance, or even deaths.



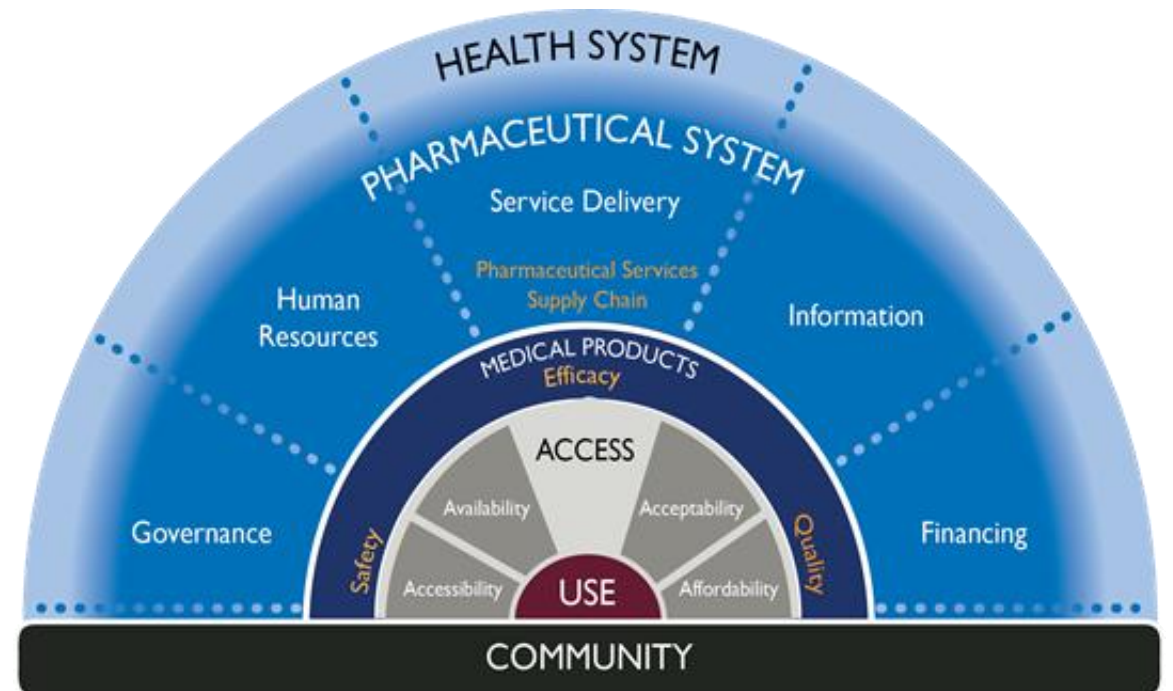
Regulatory systems strengthening (RSS) addresses these gaps and improve countries' pharmaceutical regulatory capacity.

Source: WHO 2010

Approaches and tools MTaPS has been using to strengthen RSS

A systemwide approach to improve regulatory systems across various components of the pharmaceutical system:

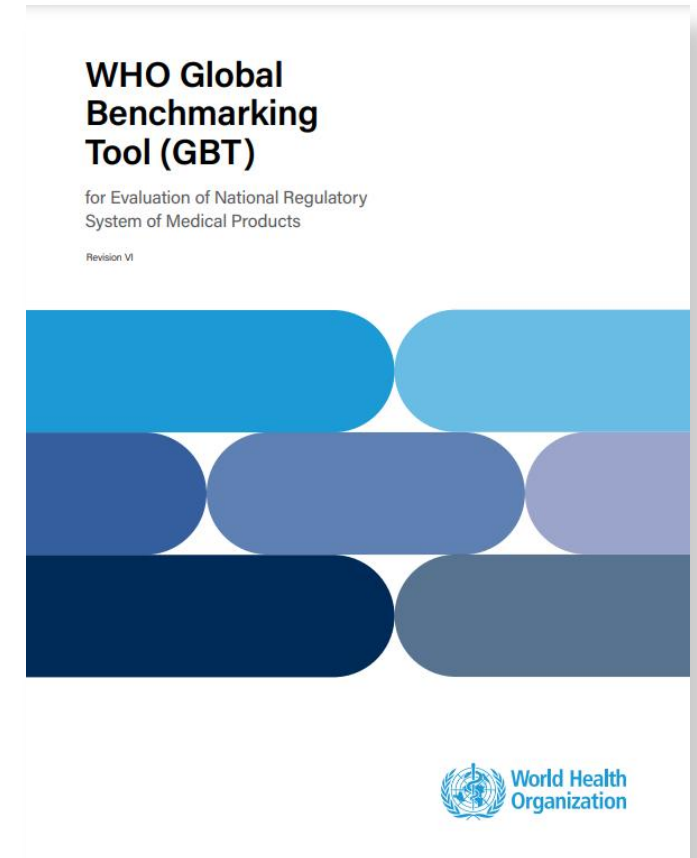
- Strengthening governance of product quality
- Promoting accountability through appropriate legal provisions
- Improving human and institutional capacity to manage the system
- Advocating for adequate financing
- Improving the availability of information that is needed to inform regulatory decision making



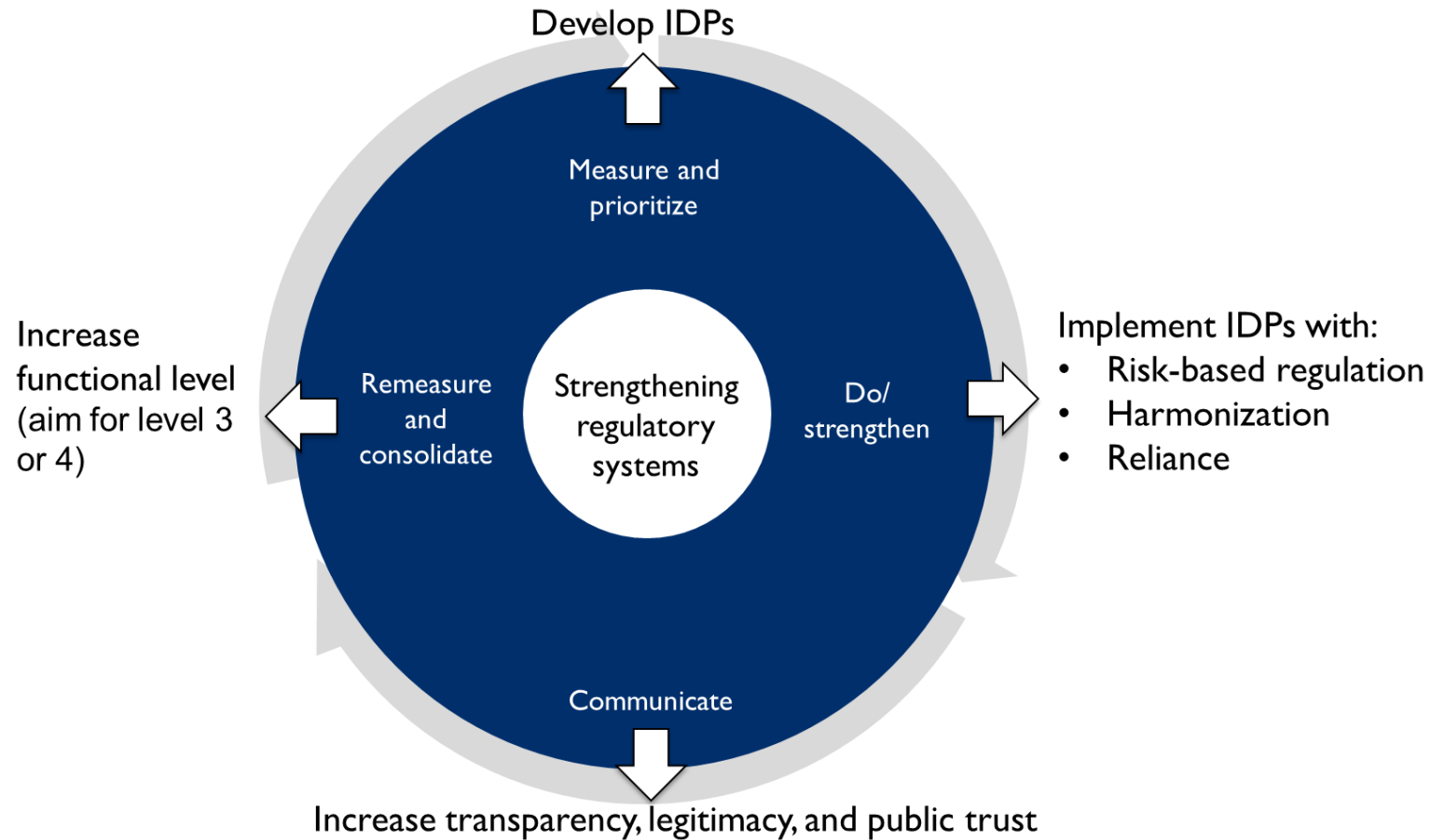
Approaches and tools MTaPS has been using to strengthen RSS

RSS approach involves assessment of the NRA functionality using the WHO GBT, which MTaPS uses in collaboration with NRAs, WHO, and other partners to determine the gaps and weaknesses.

- 268 indicators across all 8 regulatory functions to classify each NRA's level of maturity from 1 to 4
- Aim to reach maturity level 3 and ISO 9001:2015 certification.
- Use the gaps and weaknesses identified in the GBT assessment to develop Institutional Development Plans (IDPs).
- Prioritize areas for improvement and support monitor progress and achievements based on IDP.



Approaches and tools MTaPS has been using to strengthen RSS



This was extracted from February 2023 MTaPS RSS technical brief.

Case Study: Strengthening governance structures and establishing a QMS



MTaPS supported the **Rwanda Food and Drugs Authority (FDA)** to:

- Develop a five-year business plan and an accompanying four-year strategic plan (2021 to 2024)
- Draft and validate regulations, guidelines, and standard operating procedures (SOP) for regulating products
- Establish a quality management system (QMS)
 - Conduct a situational analysis to inform the approach.
 - Develop quality manuals and SOPs for specified regulatory functions.
 - Orient personnel 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 to prepare the FDA for external audits, allow them to independently address gaps, facilitate ISO 9001:2015 certification and fulfill QMS implementation requirements.

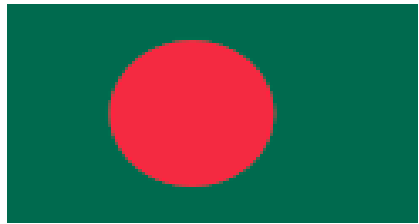
Case Study: *Improving regulatory competencies in the Asia region*



Low system GBT maturity levels call for identifying existing competencies and developing adequate steps to meet competency gaps that will enhance NRAs' regulatory capacities in the region.

MTaPS worked with a regionally led network to implement RSS capacity-building activities in **Bangladesh, Nepal, and the Philippines:**

- Conducted a competency mapping to identify:
 - Key regulatory areas and map the competencies in the areas of organizational requirements and requirements specific to each regulatory function or role
 - Gaps in knowledge, skills and personnel experience
- Defined specific capacity-building needs and implemented training courses in medicine registration and pharmacovigilance



- **Pharmacovigilance** needed critical intervention and regulatory environment needed development.
- MTaPS is working with countries to develop training plans that will build individual and organizational capacities and competencies.

How can you apply these approaches and tools?

- GBT for Evaluation of National Regulatory System of Medical Products – Revision VI (WHO, 2021): This tool assesses regulatory systems for the regulation of medical products. It provides WHO and regulatory authorities with information on areas of strength, and it identifies areas for improvement to facilitate the development of institutional development plans and help monitor countries' progress.
- OpenRIMS: OpenRIMS is an open-source, web-based tool that helps NMRAs to digitalize and automate their work processes, such as medicines registration and licensing.



How can you apply these approaches and tools?

- 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, and they provide advocacy tools and guidance for NMRAs' adoption of 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)



Resources

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](#) (Twesigye et al., 2021)
- [Advancing Regulatory Systems for Improved Access to Safe, Effective, Affordable, and Quality-Assured Medical Products](#) (January 2023)

Resources

e-Learning and video 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 medicines registration in the context of the COVID-19 pandemic.
- [OpenRIMS courses](#): This suite of courses educates developers, regulatory authorities, and business clients on the use of OpenRIMS for regulatory work processes.
- Pharmaceutical Systems Strengthening (PSS) 101 in [English](#) and [French](#): This course developed by MTaPS teaches participants the basic principles of PSS.



Whom to Contact



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