The Global Benchmarking Tool:
Lessons learned strengthening national medicines regulatory systems

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Overview

- Context: Why does the regulation of medical products matter?
- The WHO Global Benchmarking Tool: A Game Changer
- Deploying the GBT: The Case of Rwanda
- Q&A
- Deploying the GBT: The Case of Bangladesh
- Reflection
- Knowledge check
- Q&A
- Closing Remarks

Regulation of medical products: Why does it matter?

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

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The WHO Global Benchmarking Tool: A Game Changer

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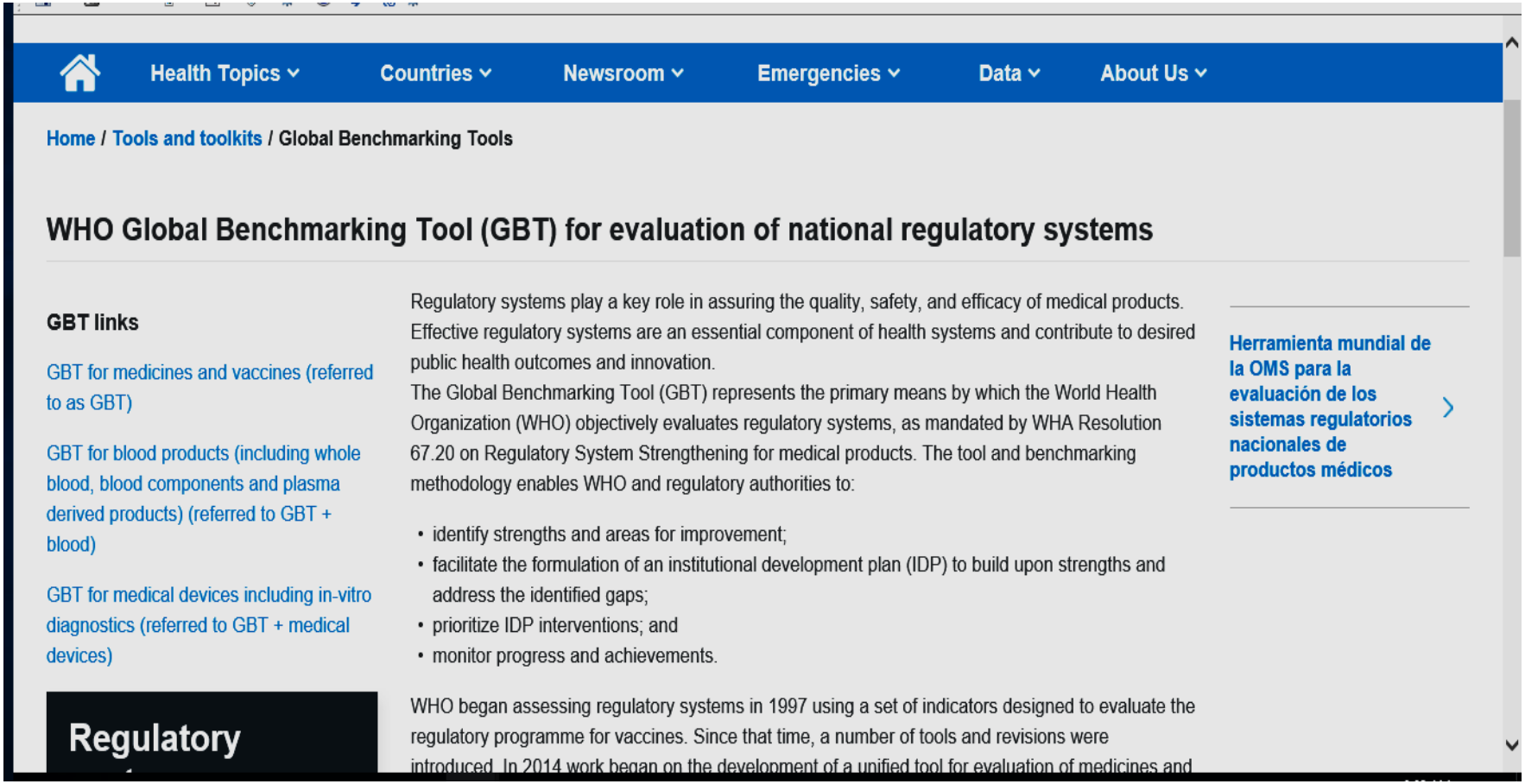
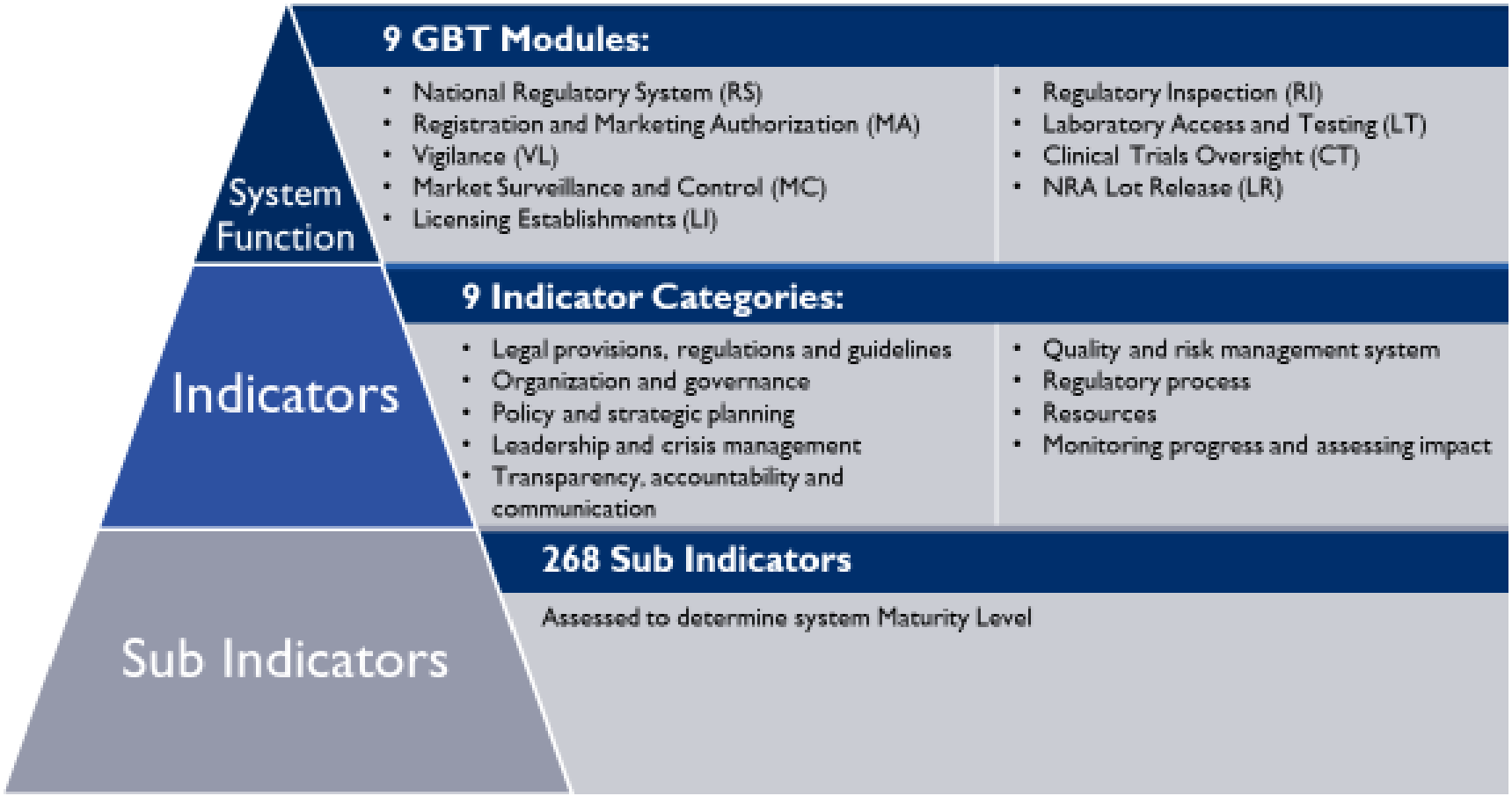
WHO Global Benchmarking Tool (GBT)



Source: https://www.who.int/tools/global-benchmarking-tools

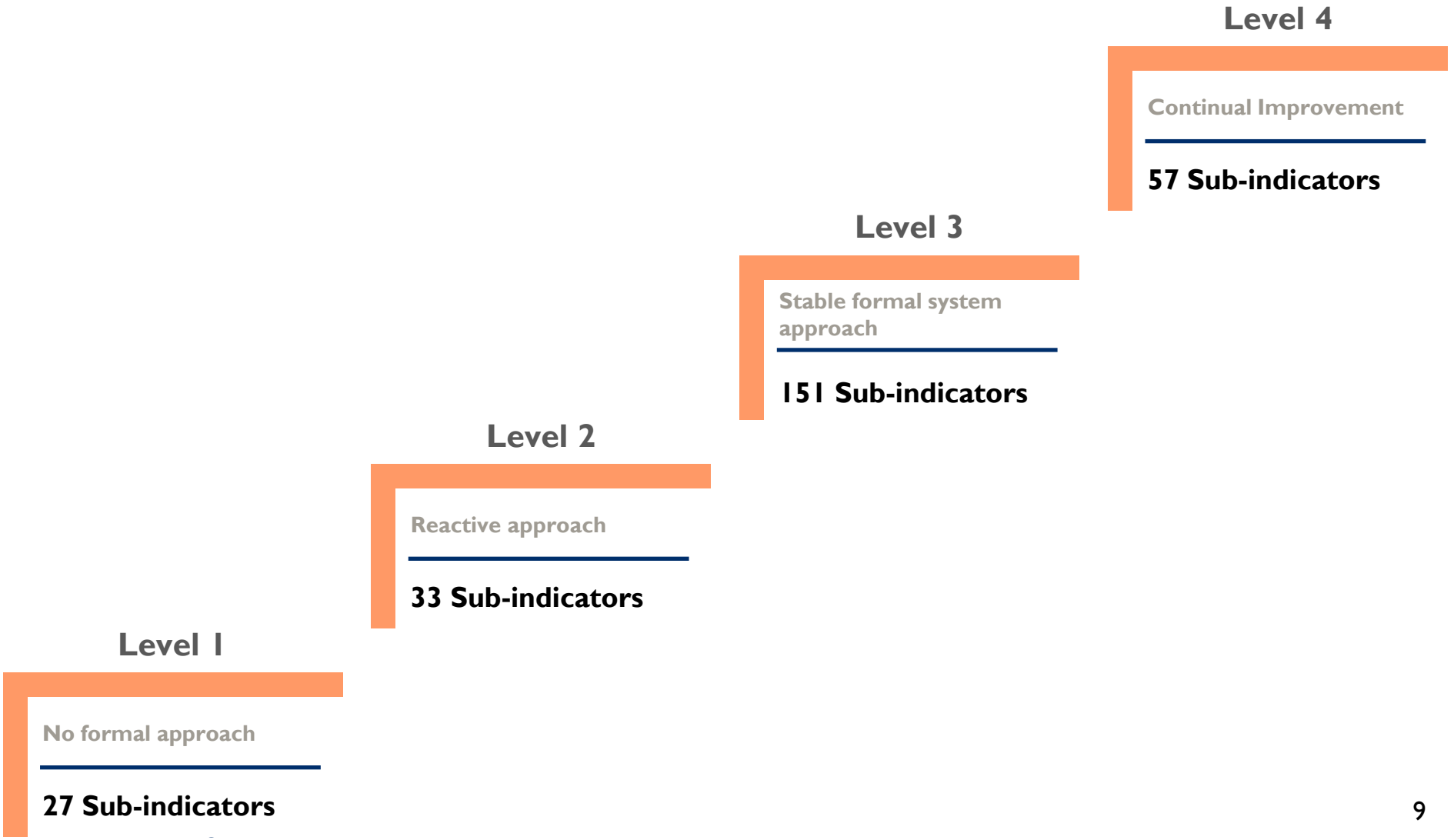
WHO Global Benchmarking Tool (GBT)



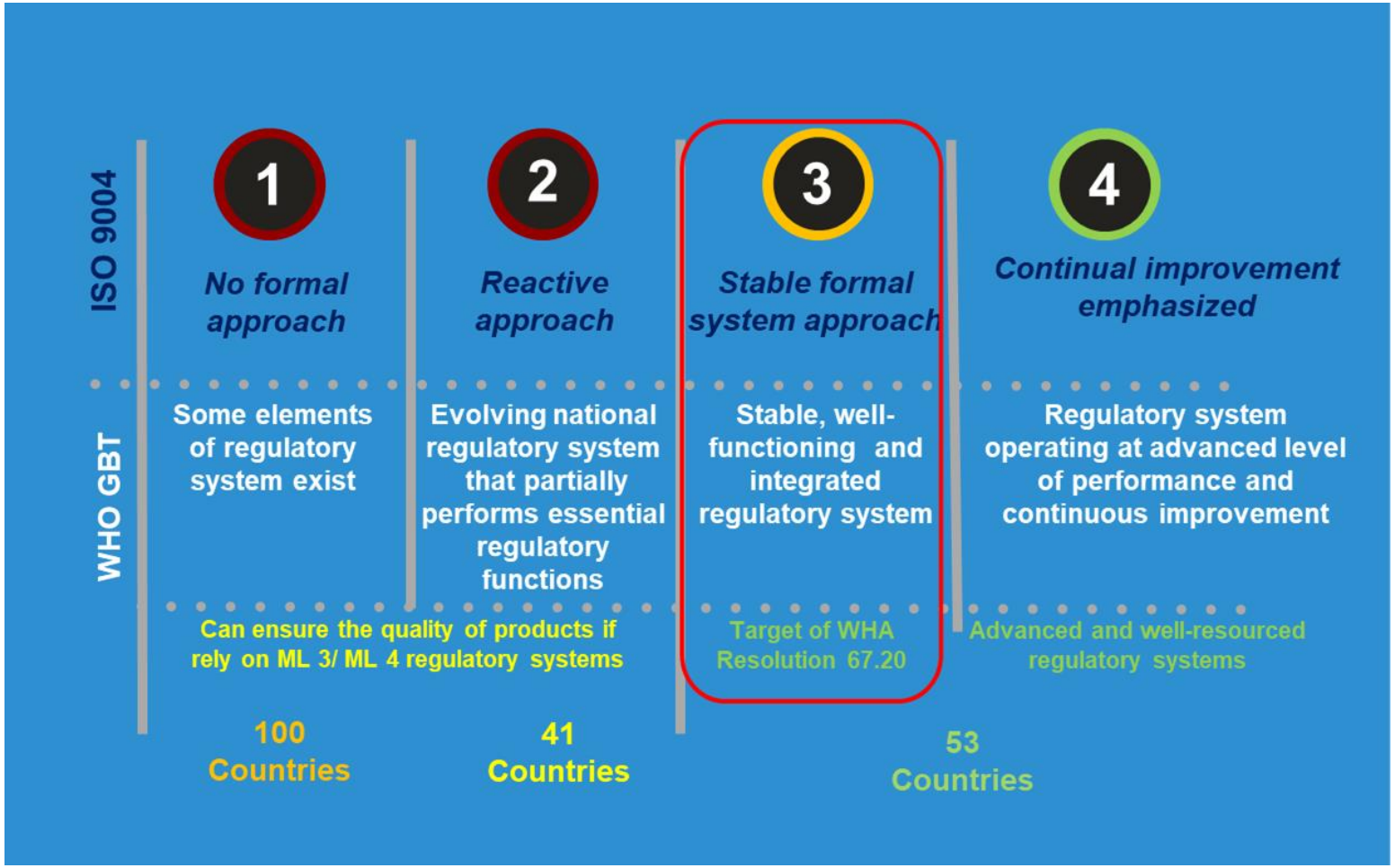
WHO-GBT Sub-Indicators

Item / Function	RS	MA	VL	MC	LI	RI	LA	CT	LR	Grand Total
# of Sub-Indicators	60	35	26	27	19	26	28	30	17	268
Maturity level 1	4	6	5	3	2	3	2	2	1	28
Maturity level 2	7	2	3	4	1	2	2	8	3	32
Maturity level 3 – Minimal capacity level	27	23	14	15	13	13	18	17	11	152
Maturity level 4 – Advanced/ reference NRAs	22	4	4	5	3	8	6	3	2	56

WHO-GBT Maturity Levels

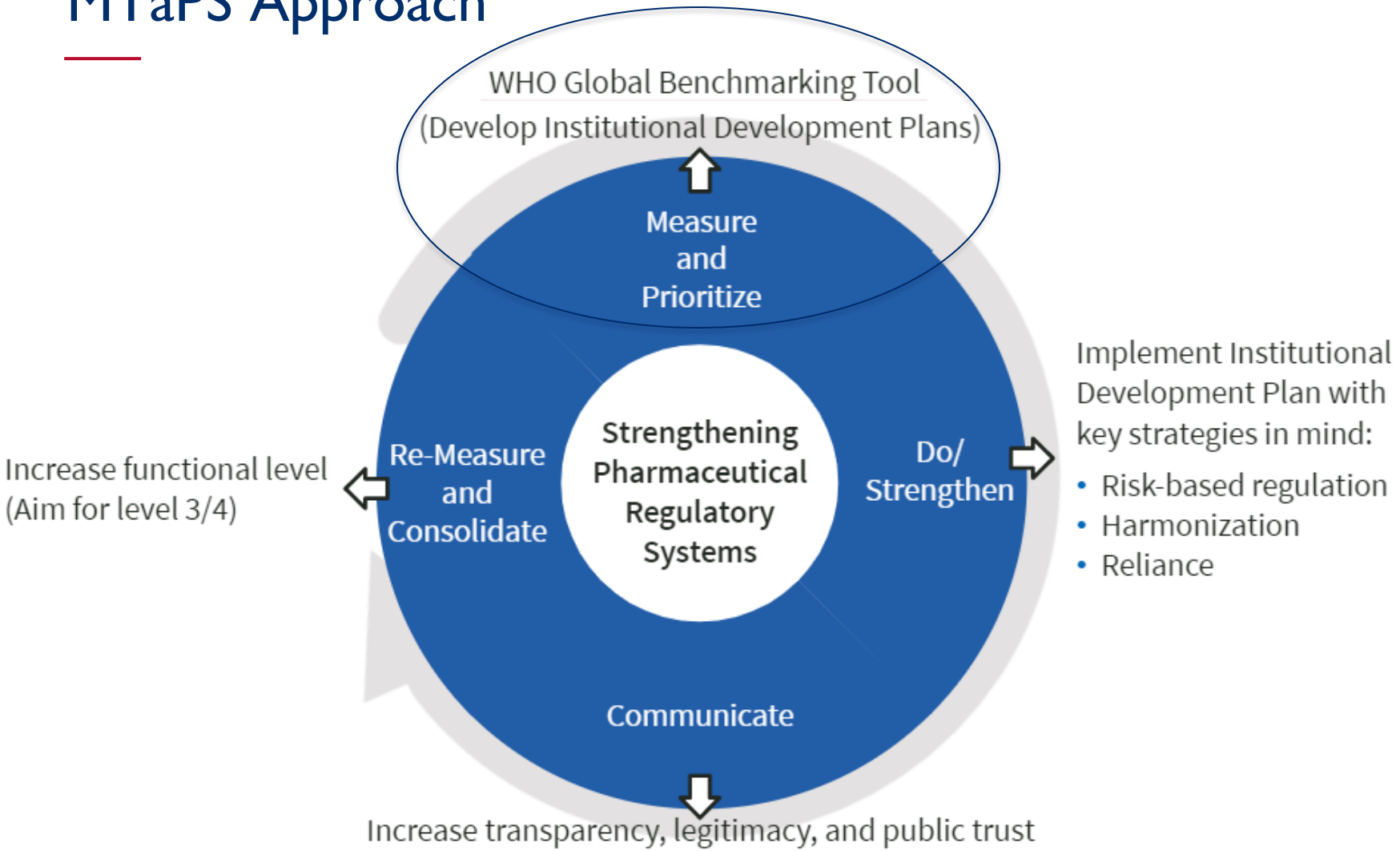


WHO GBT Performance Maturity Levels



Source: WHO RSS team

MTaPS Approach



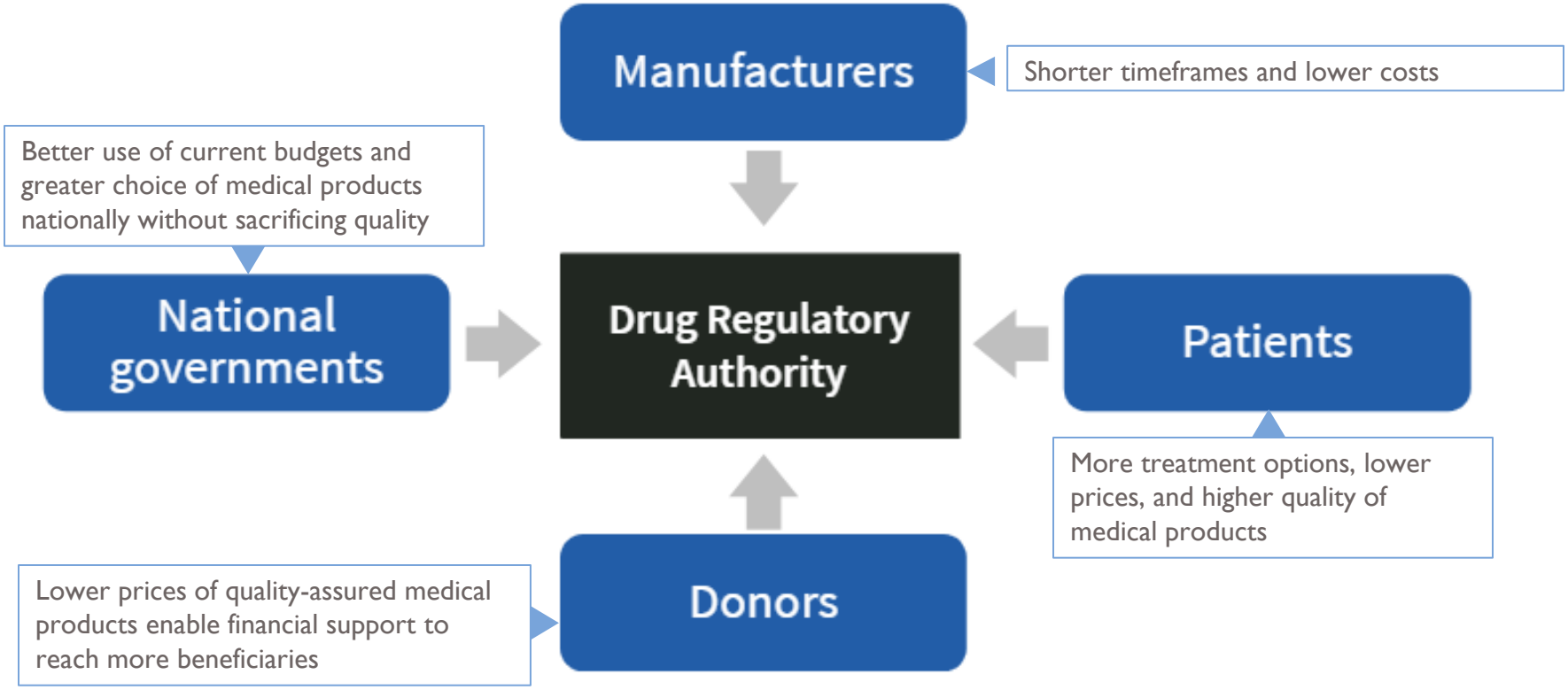
MTaPS RSS Strategic Approach (1)

Conduct NMRA assessments	Promote good governance	Strengthen legal and regulatory frameworks	Implement quality management systems
➢ Build consensus with NMRA leadership/ management ➢ Use of the WHO GBT ➢ Develop Institutional Development Plan (IDP) ➢ Implement with prioritization and options analysis	➢ Establish governance structure depts./ divisions responsible for registration of medicines ➢ Define organization and structure ➢ Establish/update job descriptions ➢ Establish functional technical committees	➢ Develop/ establish legal provisions, regulations, and guidelines ➢ Promote convergence, harmonization, and reliance	➢ Document and implement QMS (ISO 9001:2015 certification, development, and review of SOPs) ➢ Promote convergence, harmonization, and reliance

MTaPS RSS Strategic Approach (2)

Develop human resource capacity	Implement Good Review Practices (GRevP)	Install electronic management information systems
➢ Basic/advanced specialized training ➢ Establish/roll-out training policy and programs ➢ Develop training methodologies	➢ Establish GRevP principles ➢ Conduct reviews ➢ Establish project management processes/tools	➢ Provide customized solutions ➢ Implement and roll-out use of Pharmadex

Harmonization and Reliance



Source: Ndomondo-Sigonda and Ambali, 2011.

Considerations

- The **WHO GBT process provides a great window of opportunity** to strengthen regulatory systems in low- and middle-income countries.
- Governments, funders, and development partners **should support the WHO GBT deployment and work to further strengthen** the GBT framework and process.
- Explicitly **communicating the benefits related to public health and trade** might help convince decision makers to prioritize regulatory systems strengthening efforts.

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Journal of Pharmaceutical Policy and Practice

COMMENTARY Open Access

Making the investment case for national regulatory authorities

Gloria Twesigye, Tamara Hafner and Javier Guzman*

Abstract

Well-functioning national regulatory authorities (NRAs) ensure access to safe, effective, quality-assured, and affordable medical products. However, the benefits of their work are often unseen and difficult to attribute, thereby making NRAs undervalued and under-resourced, particularly in low- and middle-income countries. This paper offers three key arguments NRAs and other stakeholders can use to advocate for greater investment in regulatory systems strengthening—medical products regulation effectively safeguards public health; effective regulation improves health system's efficiency by increasing access to affordable medical products, contributing to universal health coverage; and robust regulation strengthens local pharmaceutical manufacturing and bolsters pharmaceutical trade. NRAs' critical role in health systems is indisputable, yet they need to better promote their value to receive the requisite resources to function effectively.

Keywords: Regulatory systems, National regulatory authorities, Health systems strengthening, Access to medicines, Quality-assured medicines

MTaPS publications promoting regulatory systems strengthening

Practice

BMJ Global Health

The WHO Global Benchmarking Tool: a game changer for strengthening national regulatory capacity

Javier Guzman [1], Erin O'Connell [2], Kate Kikule,[1] Tamara Hafner [1]

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ABSTRACT

Many low-income and middle-income countries lack the capacity to effectively and efficiently regulate medical products in their countries. To support countries in strengthening their capacity, WHO has developed the Global Benchmarking Tool (GBT) as the global standard for objectively assessing regulatory capacity for medicines and vaccines. The GBT is a game changer because it is the first globally accepted tool for assessing and strengthening national regulatory authorities. The inclusion of an institutional development plan in the GBT methodology provides context-specific actionable steps countries can take to advance their system's functionality and maturity. The GBT facilitates coordination and improves the effectiveness of regulatory strengthening efforts. The tool also facilitates regulatory reliance and harmonisation,

Summary box

- Effective regulation of medical products is critical for ensuring access to safe, effective and quality-assured medical products in a well-functioning health system.
- WHO's Global Benchmarking Tool (GBT) Revision VI is the first globally accepted tool for objectively assessing and strengthening regulatory capacity.
- The GBT provides countries with a systematic approach for strengthening their regulatory systems.
- The GBT fosters regulatory reliance and harmonisation, which increases timely access to quality-assured medical products and boosts pharmaceutical trade.

Deploying the GBT: The Case of Rwanda

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RWANDA FDA
Rwanda Food and Drugs Authority

1. Journey to Attaining

2018

- **WHO Benchmarking**

2019

- **More than 100 staff hired to fill the Structure**

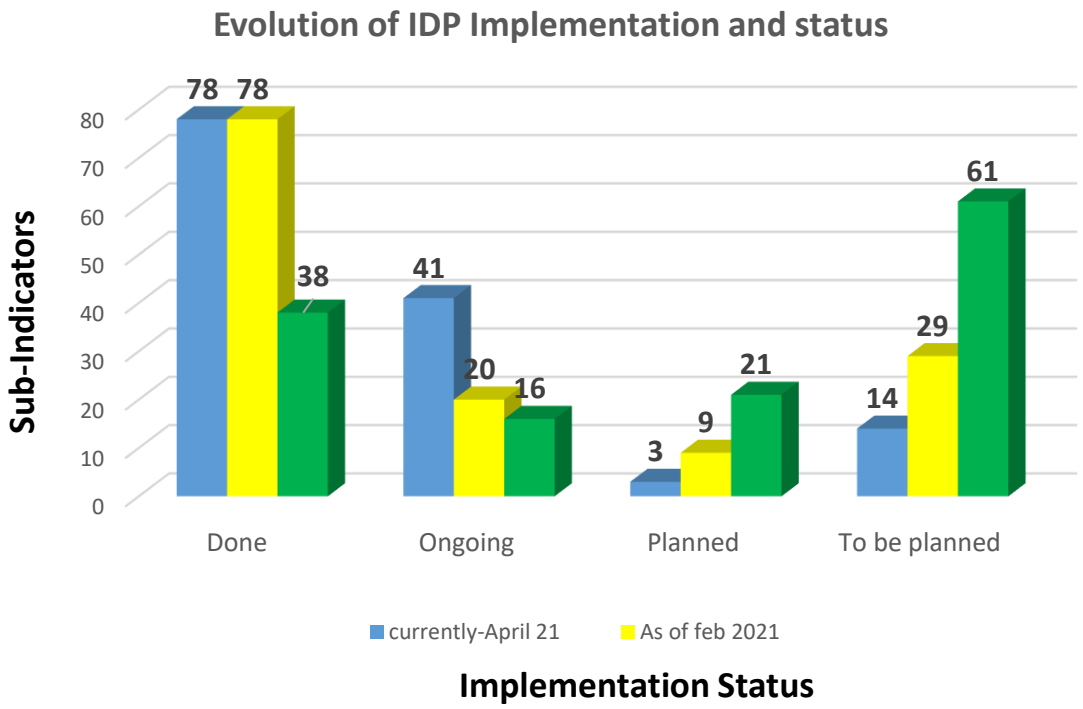
2020

- **1st Rwanda CIP Meeting**

2021

- **New Structure is approved by Cabinet**
- **WHO Benchmarking in August 2021**

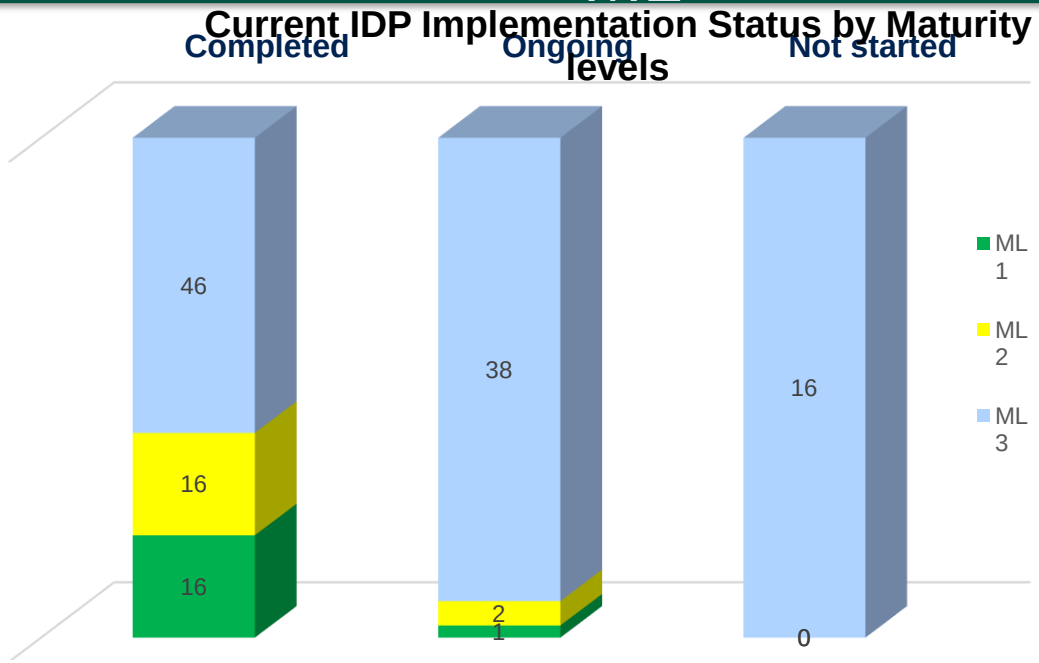
2. Progress on IDP Implementation (Sub-Indicators)



3. Summary on Implementation of IDP Recommendations based on ML

Maturity Level (ML)	Identified Number	Completed/ Implemented	Ongoing	Not started
ML 1	17	16	1	0
ML 2	18	16	2	0
ML 3	100	46	38	16

4. Current IDP Implementation Status by ML



5. Lessons learnt on the journey to attaining ML3

- **Using WHO GBT tool to guide regulatory processes and implementation is important**
- **Strong collaboration with partners and stakeholders is crucial**

6. Way Forward

- **Rwanda FDA is working to attaining Maturity Level 3 by August 2021**

Deploying the WHO GBT in Bangladesh

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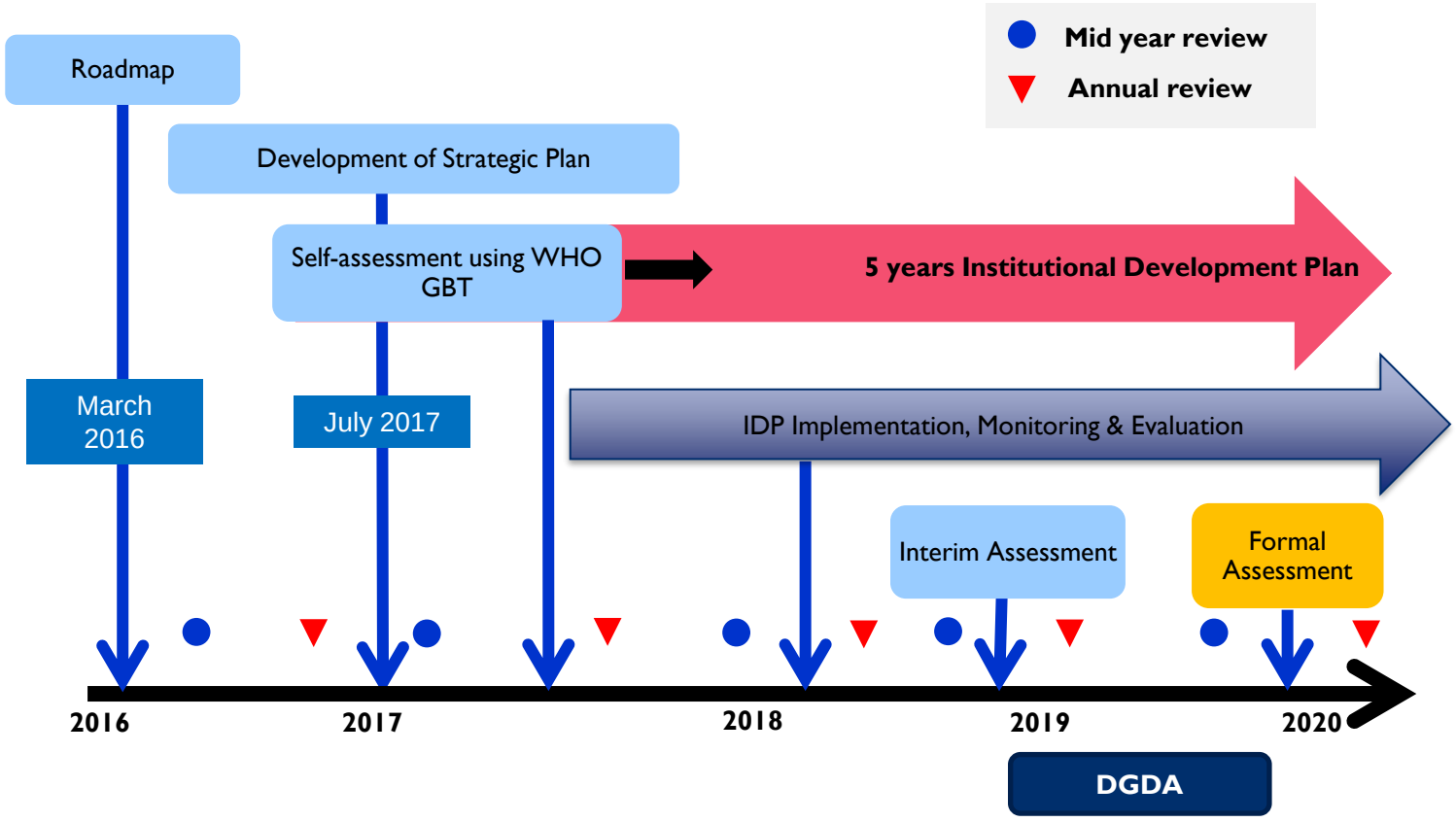
Bangladesh road map (2016-2020)



Benchmarking exercises using GBT

- Formal interim benchmarking – September 2018
  - Benchmark the status of the Bangladesh medicine regulatory system against the WHO GBT and measure the maturity of the system
  - Update the IDP to address existing and/or potential gaps and prioritize recommendations
  - Update the roadmap towards a maturity level three
- Desktop review by WHO – April 2020

Areas for improvement (Sept. 2018)

- Update the Drug Act and corresponding regulations
- Establish a comprehensive HR plan and capacity building program
- Promote QMS implementation for all regulatory functions
- Using best practices and experiences from the lab
- Improve communication among key stakeholders and accessibility to relevant information
- Public consultations on developed regulations and guidelines
- Need-based effective training for sustainable impact (mentoring and monitoring)
- Effective practice of recently developed regulations and procedures

MTaPS Achievements (1)

General Support:

- WHO GBT self-assessment and development of institutional development plan (IDP)
- Established a periodic monitoring mechanism of IDPs and its implementation
- Assisted Directorate General of Drug Administration (DGDA) in public consultation to adopt guidelines as per GBT, e.g., for GMP, dossier submission, and marketing authorization applications

Registration:

- Developed the action plan based on DGDA's 5-year strategic plan and quality management protocols
- Capacity building of 50 DGDA inspectors and 52 people from manufacturing industry
- Supported industry and DGDA in the submission, evaluation, and approval of electronic common technical document dossiers for cardiovascular drug registration

MTaPS Achievements (2)

Inspection and Licensing:

- MP/MMS inspection strategy developed with Better Health in Bangladesh
- Electronic inspection and licensing systems developed for pharmacies

Pharmacovigilance (PV):

- Scaled up to more health facilities and generated regulatory decisions on medicine safety
- Maintained WHO-UMC VigiFlow for global access to adverse drug reactions
- Developed: COVID-19 PV protocol developed, online adverse event following immunization reporting system

What's next for MTaPS and DGDA

- Continuing IDPs toward GBT maturity level 3
- Support the five-year strategic/action plan
- Streamline the registration system
- Implement Good Review Practices, focused on biologics and vaccines
- Pharmacovigilance scale up, decentralization, and developing direct patient reporting mechanisms
- COVID-19 regulatory support
- Automation of DGDA's regulatory functions

Lessons learnt

- Using the GBT enables measurement of progress on annual basis
- CIP provided an opportunity to garner support from various implementation partners
- Need to account for lengthy legislation approval process
- Electronic information management system improves transparency and efficiency
- Capacity building of assessors assures quality of assessments

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Reflections on deploying the GBT in Rwanda and Bangladesh

Knowledge Check!

True or False?

Question 1

The WHO Global Benchmarking Tool (GBT) assesses the performance of a national pharmaceutical system.

False!

Question 1

The WHO Global Benchmarking Tool assesses the performance of a national pharmaceutical system.

Correct answer:

Question 1

The GBT assesses the functionality of a national regulatory system.

True or False?

Question 2

The GBT facilitates coordination of regulatory strengthening efforts, reliance, harmonization, and creates incentives for trade.

True!

Question 2

The GBT facilitates coordination of regulatory strengthening efforts, reliance, harmonization, and creates incentives for trade.

True or False?

Question 3

The GBT is a necessary tool for creating strong and effective regulatory systems, which are critical for ensuring the efficacy, safety and quality assurance of medicines and populations' timely access to these medicines.

True!

Question 3

The GBT is a necessary tool for creating strong and effective regulatory systems, which are critical for ensuring the efficacy, safety and quality assurance of medicines and populations' timely access to these medicines.

True or False?

Question 4

Countries cannot deploy the GBT without assistance from WHO or development partners.

False!

Question 4

Countries cannot deploy the GBT without assistance from WHO or development partners.

Correct answer:

Question 4

Countries can deploy the GBT through a self-benchmarking process.

True or False?

Question 5

The preferred maturity level for a country's national regulatory system is maturity level 3.

True!

Question 5

The preferred maturity level for a country's national regulatory system is maturity level 3.

Closing Remarks

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Thank You