Concept of National Regulatory Authority's Maturity Level, WHO-Listed Authority's Performance in the Context of Clinical Trials Oversight: **Part I**

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Learning Objectives

1. Why is strengthening regulatory systems for medical products important?
2. What are the core roles and responsibilities of National Regulatory Authorities (NRAs)?
3. How do regulatory outputs, outcomes, and impact contribute to public health and global health security?
4. How do Good Regulatory Practices (GRP) and enablers drive regulatory performance?
5. What is the WHO Global Benchmarking Tool (GBT), and how does it support regulatory system improvement?
6. What is a WHO Listed Authority (WLA), and why is WLA status significant?
7. What are the main challenges in achieving higher maturity levels and WLA recognition?

Why Regulatory System Strengthening is Important

National Regulatory Authority for Medical Products: Examples

Asia-Pacific

- **Japan:** Pharmaceuticals and Medical Devices Agency (PMDA)
- **Republic of Korea:** Ministry of Food and Drug Safety (MFDS)
- **Singapore:** Health Sciences Authority (HSA)
- **Philippines:** Food and Drug Administration (FDA)
- **India:** Central Drugs Standard Control Organisation (CDSCO)
- **Australia:** Therapeutic Goods Administration (TGA)

Americas

- **United States:** Food and Drug Administration (FDA)
- **Canada:** Health Canada
- **Brazil:** Brazilian Health Surveillance Agency (ANVISA)
- **Mexico:** Federal Commission for the Protection against Sanitary Risk (COFEPRIS)
- **Argentina:** National Administration of Drugs, Foods and Medical Devices (ANMAT)

Europe

- **European Union:** European Medicines Agency (EMA)*
- **United Kingdom:** Medicines and Healthcare products Regulatory Agency (MHRA)
- **Switzerland:** Swiss Agency for Therapeutic Products (Swissmedic)
- **France:** National Agency for the Safety of Medicine and Health Products (ANSM)
- **Germany:** Federal Institute for Drugs and Medical Devices (BfArM)

Africa & Middle East

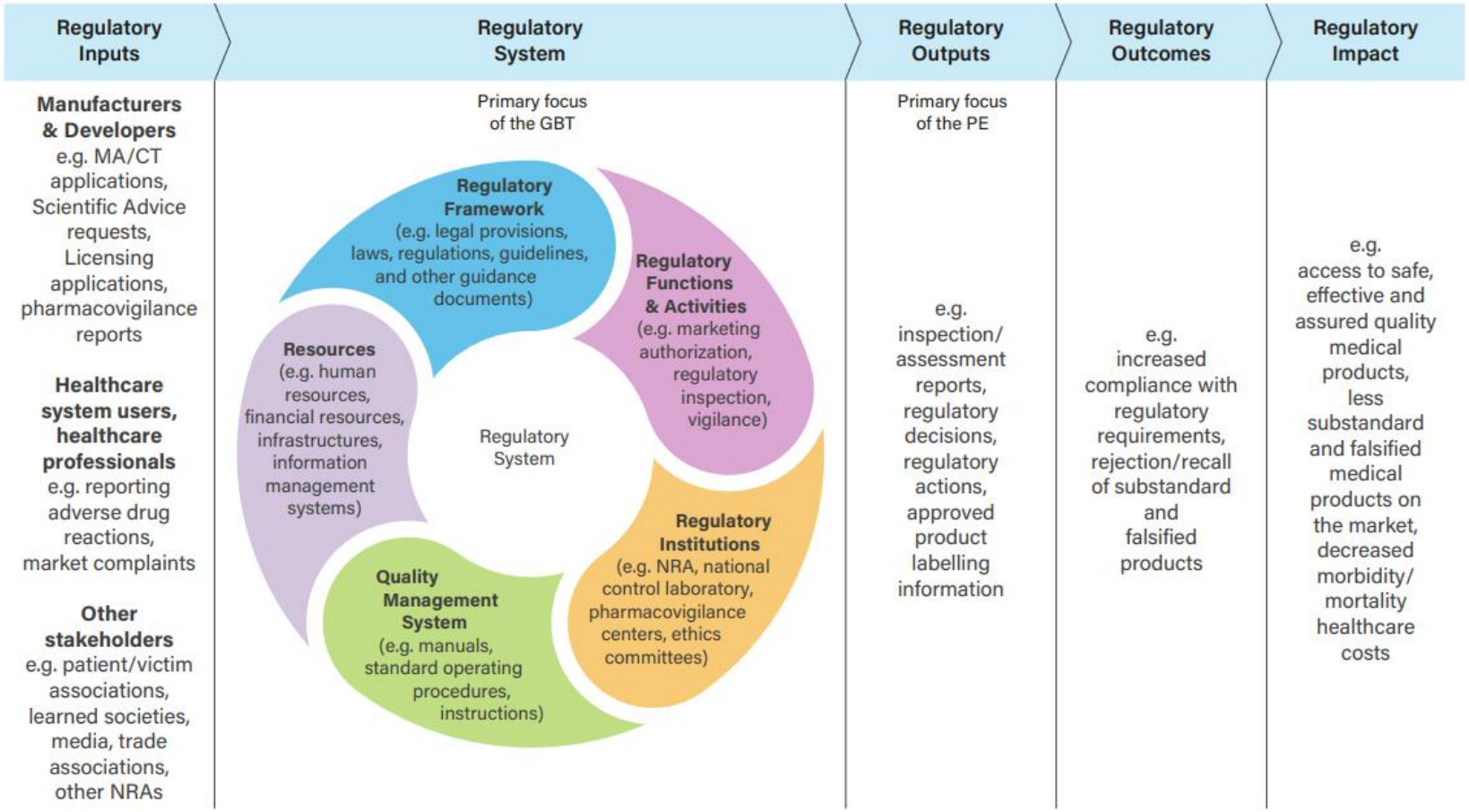
- **Nigeria:** National Agency for Food and Drug Administration and Control (NAFDAC)
- **Egypt:** Egyptian Drug Authority (EDA)
- **South Africa:** South African Health Products Regulatory Authority (SAHPRA)
- **Saudi Arabia:** Saudi Food & Drug Authority (SFDA)

Caution: The examples are not an exhaustive list
EMA is defined as a regional regulatory authority

National Regulatory Authority for Medical Products: Roles and Responsibilities

- Ensuring that regulatory decisions are **transparent, science-based, impartial, consistent, timely**, and **risk-proportionate**.
- Operating under a **robust legal and institutional framework**.
- Applying **quality management systems** to strengthen oversight.
- Participating in **international harmonization** and **reliance mechanisms** where appropriate.
- Supporting the availability and accessibility of safe, effective, and quality-assured medical products as part of a **strong health system**.

National Regulatory Authorities for Medical Products: Theory-of-Change Logic Model



Source: WHO operational guidance for evaluating and publicly designating regulatory authorities as WHO-listed authorities

Regulatory Inputs

- **Manufacturers & Developers**:
  - Including MA/CT applicants, scientific advice requests, inspections, and market complaints.
- **Healthcare System Users**:
  - Such as hospitals, clinics, trade associations, and other NRAs.
- **Other Stakeholders**:
  - This may include government agencies, professional associations, and the general public.

Regulatory System & Functions

Regulatory System

- **Regulatory Framework**
  - ✓ Legal Framework (Laws and Regulations)
  - ✓ Guidelines and Guidance Documents
- **Regulatory Institutions**
  - ✓ National Regulatory Authority (NRA)
  - ✓ National Control Laboratory
  - ✓ Pharmacovigilance Centres
  - ✓ Research Ethics Committees
- **Resources**
  - ✓ Human Resources
  - ✓ Financial Resources
  - ✓ Infrastructure and Equipment
  - ✓ Information Management Systems

Regulatory Functions

- Clinical Trials Oversight
- Marketing Authorization
- Vigilance
- Market Surveillance and Control
- Licensing of Establishments
- Regulatory Inspection
- Laboratory Testing
- Lot Release for Vaccines and Biologicals
- …

Regulatory Outputs

- Inspection Reports
- Assessment Reports
- Regulatory Decisions
- Product Labels

Regulatory Outcomes

Increased compliance with regulatory requirements:

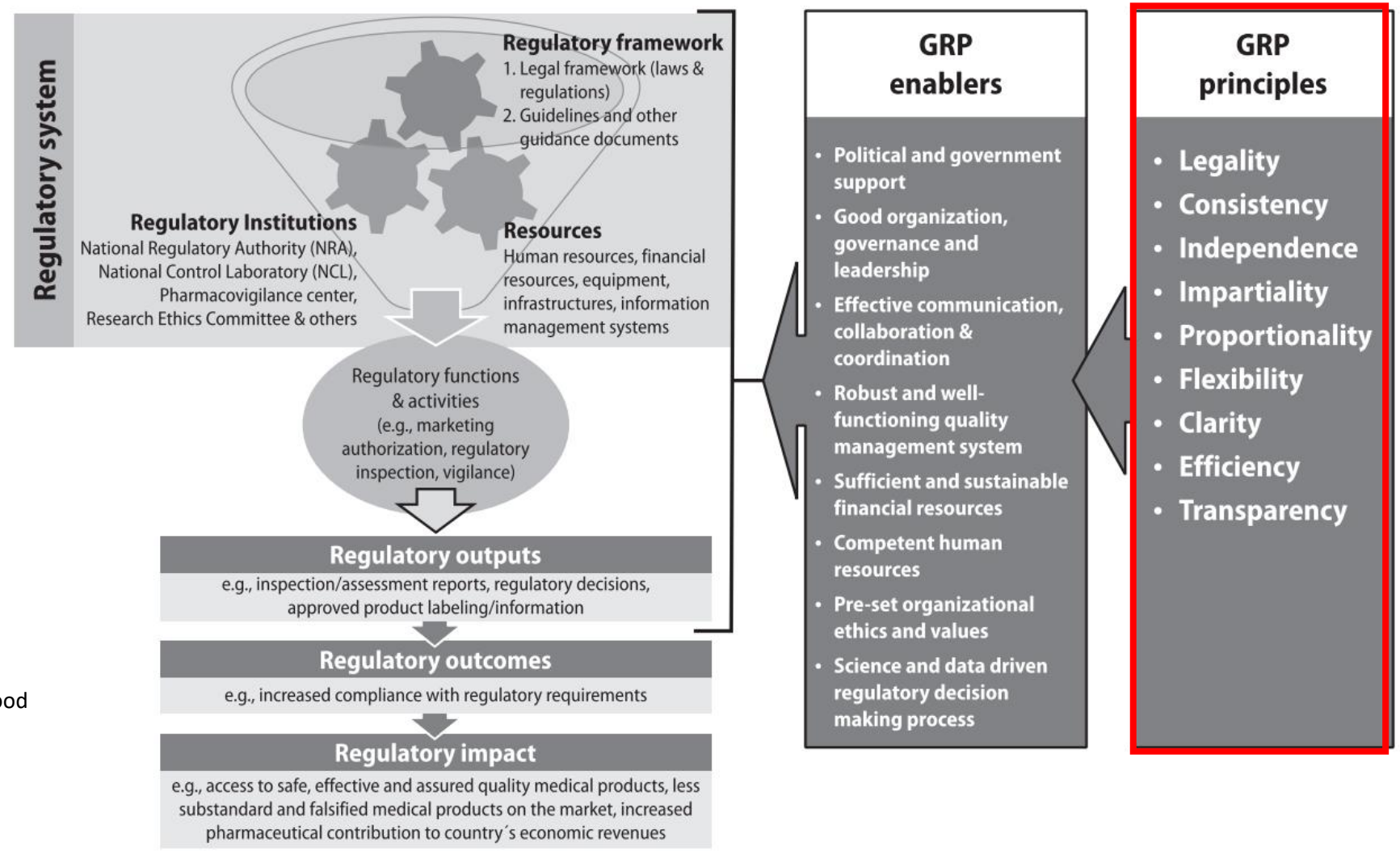
- Safe, Effective, and Quality-Assured Medical Products
- Timely Access to Medical Products
- Public Trust in the Regulatory System
- Compliance by Regulated Entities
- Efficient Regulatory Processes

Regulatory Impact

These reflect the **broader effects** of a well-functioning regulatory system:

- Improved Public Health Outcomes
- Strengthened Health Systems
- Enhanced Global Health Security
- Support for Innovation and Access
- Contribution to Universal Health Coverage (UHC)

Theory-of-Change Logic for Regulatory System: Linking with GRP Principles & Enablers

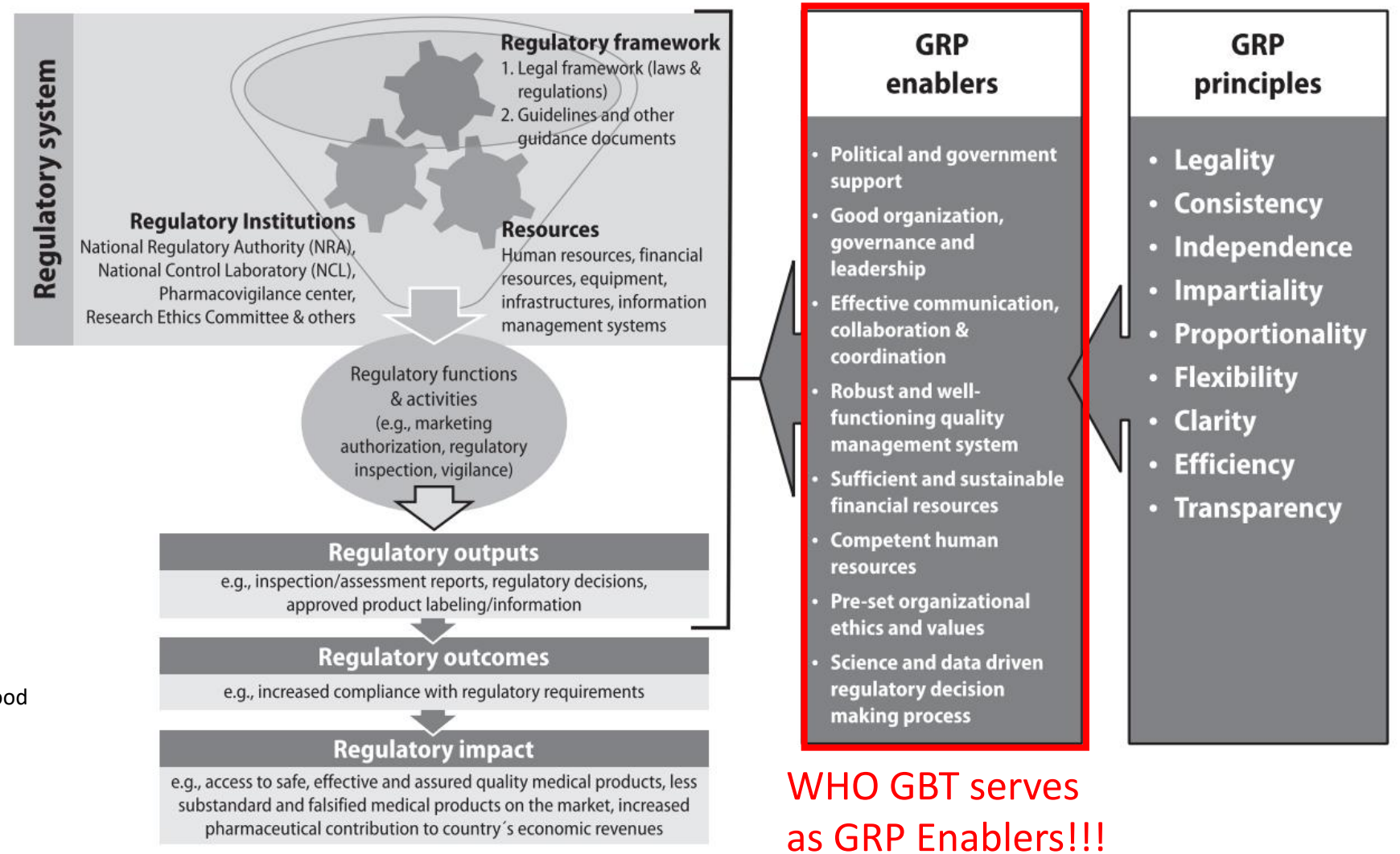


Source of the graphic: WHO good regulatory practices in the regulation of medical products

Good Regulatory Practice (GRP): Principles

1. Legality
2. Impartiality
3. Consistency
4. Proportionality
5. Flexibility
6. Effectiveness
7. Efficiency
8. Clarity
9. Transparency

Theory-of-Change Logic for Regulatory System: Linking with GRP Principles & Enablers



Source of the graphic: WHO good regulatory practices in the regulation of medical products

WHO GBT serves as GRP Enablers!!!

Good Regulatory Practice (GRP): Enablers

- Political and Government-wide Support
- Effective Organization and Governance
- Communication, Collaboration, and Coordination
- Quality Management System
- Sustainable Financial Resources
- Competent Human Resources
- Organizational Ethics and Values
- Science- and Data-driven Decision-making

What is WHO GBT for, Why is it Important?

What is WHO GBT for?

WHO's primary instrument for evaluating and strengthening **national regulatory systems** for medical products

Purpose

- To **objectively assess** the capacity and performance of national regulatory authorities (NRAs).
- To **identify strengths and gaps**, and guide countries in developing **Institutional Development Plans (IDPs)**.
- To promote **regulatory system strengthening**, **harmonization**, **convergence** and **reliance** across countries.

Structure

- **System & Functions**, **indicators** and **sub-indicators**
- **Each of Regulatory System & Functions** consists of a set of indicators of **nine cross-cutting categories**.
- Each **sub-indicator** is pre-defined with a maturity level
- **Fact sheet** provides detailed guidance on each sub-indicator

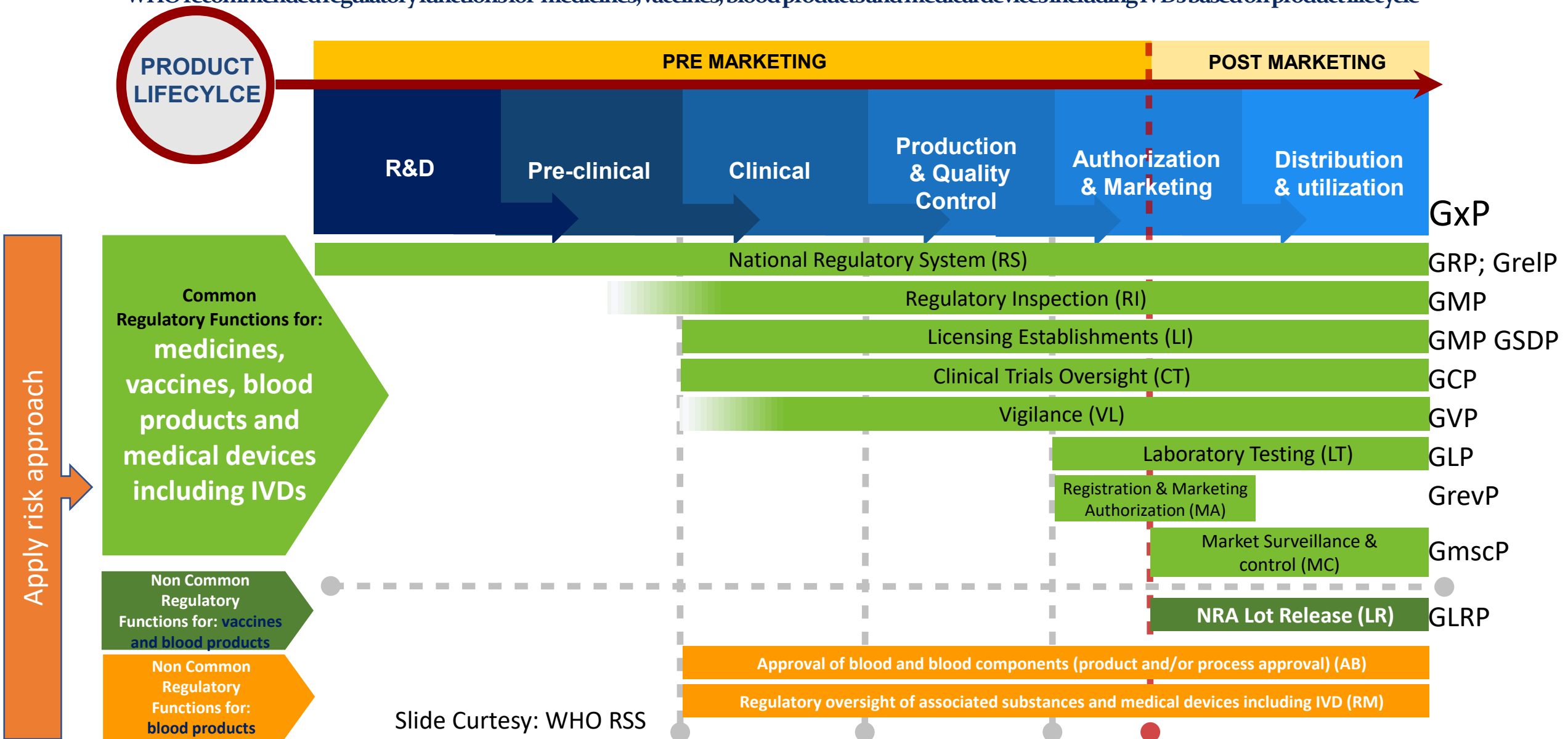
Maturity Level

- **ML1**: Some elements exist
- **ML2**: Evolving system
- **ML3**: Stable, well-functioning system
- **ML4**: Advanced system with continuous improvement.

Global Impact

- **Unified global tool** for regulatory benchmarking.
- Facilitates **international cooperation**, **technical support**, and **capacity building**.
- Supports **universal health coverage** by ensuring access to **safe, effective, and quality-assured medical products**

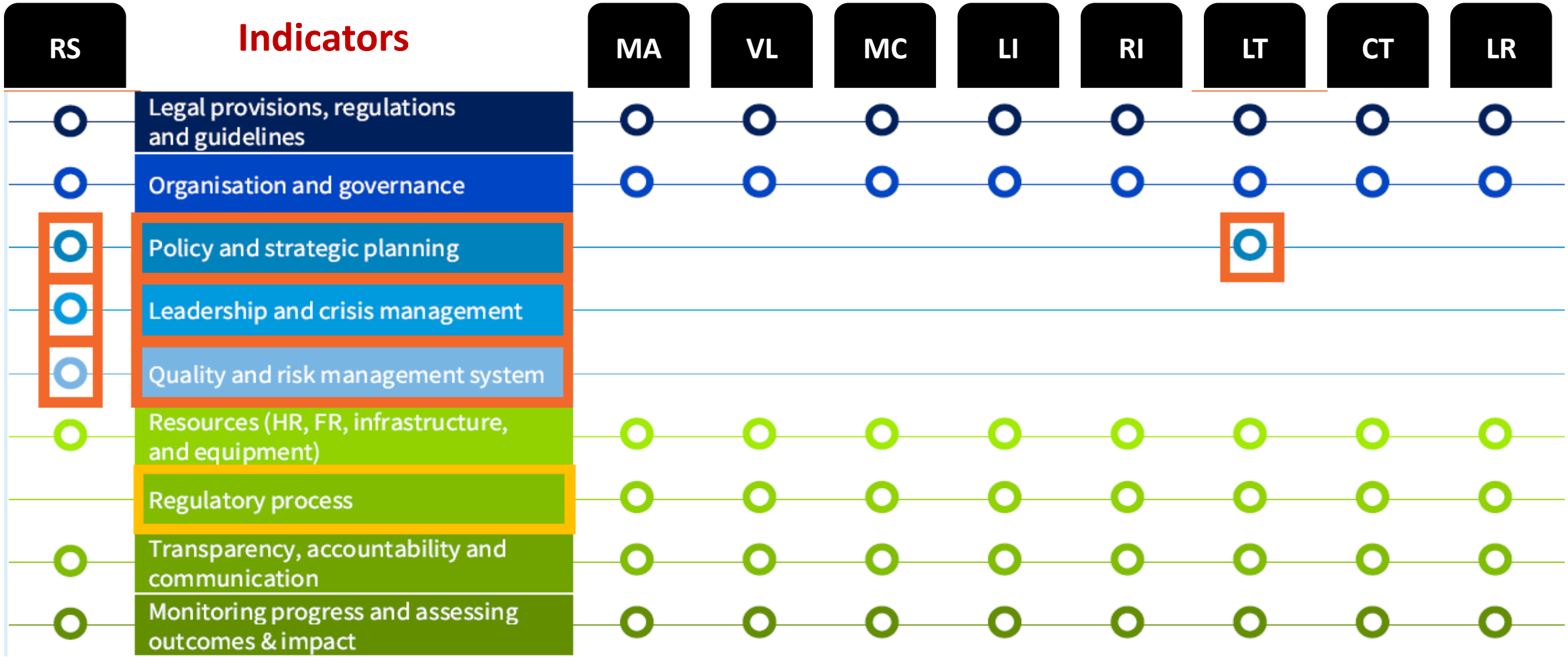
WHO recommended regulatory functions for medicines, vaccines, blood products and medical devices including IVDs based on product lifecycle



Slide Curtesy: WHO RSS

Indicators' categories

cross-cutting across system & functions



Source: WHO Academy

Updated Figures of the WHO GBT Revision VI

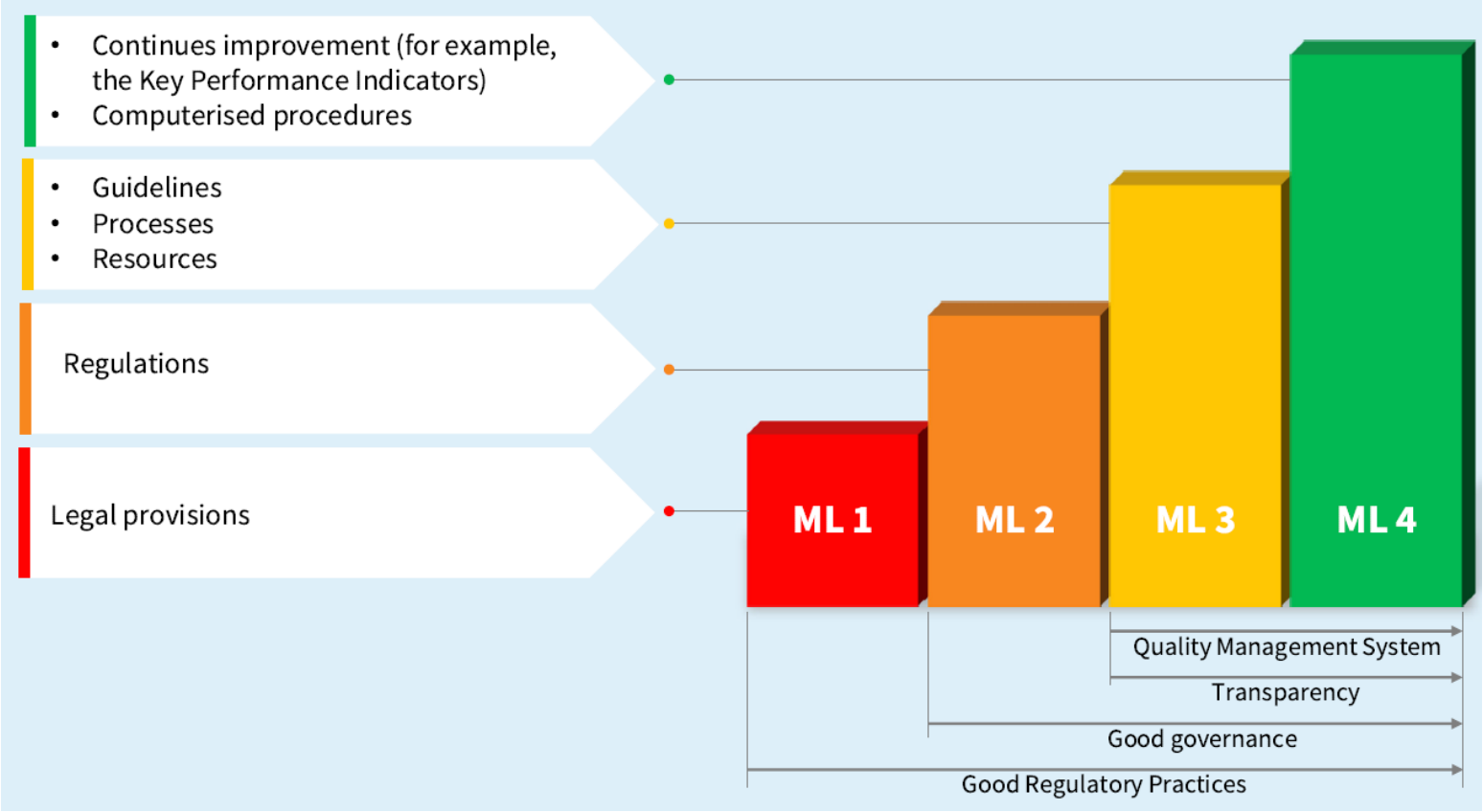
Item / Function	RS	MA	VL	MC	LI	RI	LA	CT	LR	Grand Total
Number of Sub-Indicators	60	35	26	27	19	26	28	30	17	268
Sub-Indicators measuring maturity level 1	4	6	5	3	2	3	2	2	1	28
Sub-Indicators measuring maturity level 2	7	2	3	4	1	2	2	8	3	32
Sub-Indicators measuring maturity level 3	27	23	14	15	13	13	18	17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

Minimal capacity

Advanced/reference NRAs

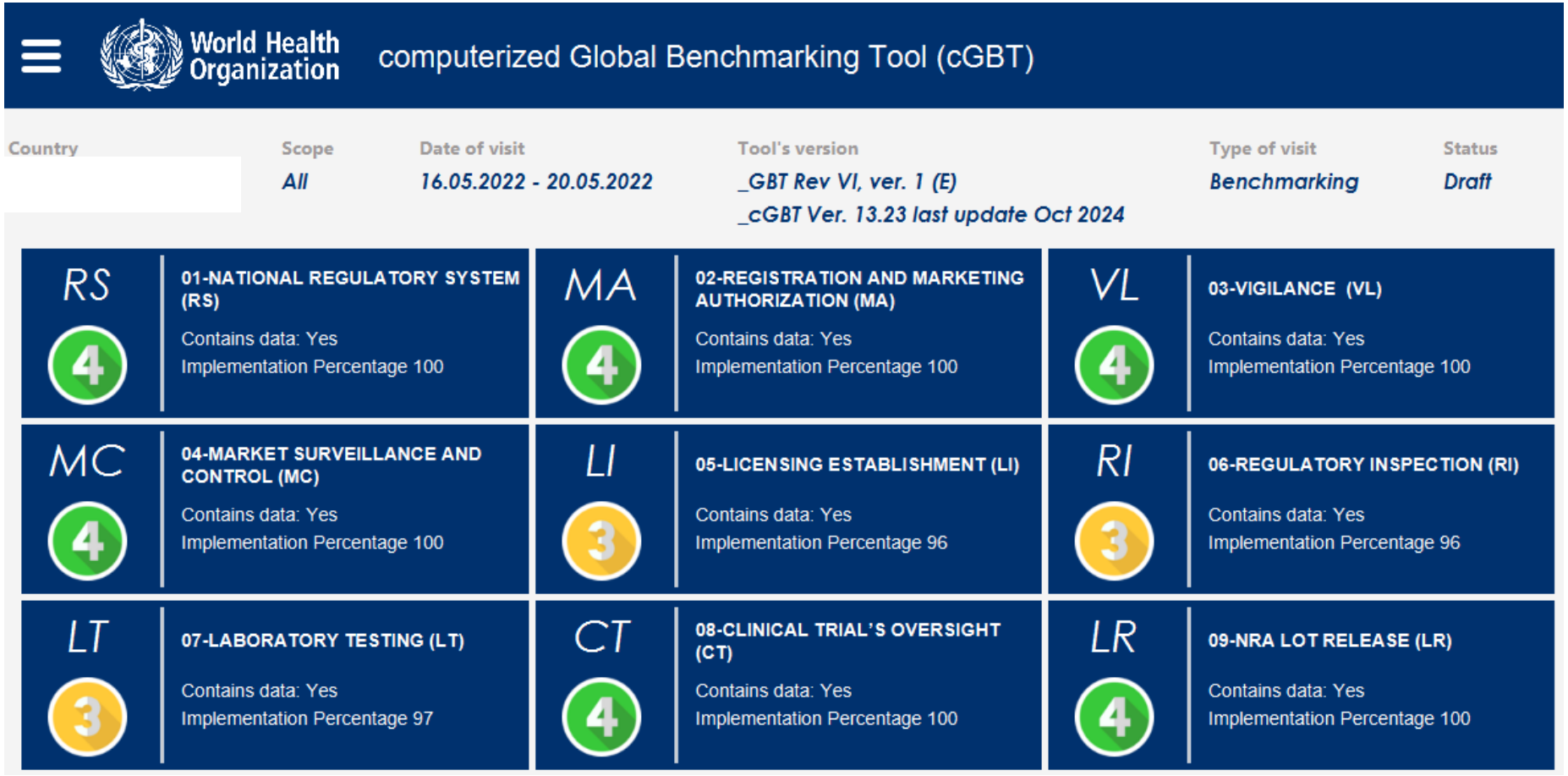
Slide Curtesy: WHO RSS

Allocation of a specific ML to each Sub-Indicator



Source: WHO Academy

Computerized GBT Dashboard



What is WLA, Why is it Important

Definition of a WHO Listed Authority

Adopted by the ECSPP in October 2020, TRS 1033

A WHO Listed Authority (WLA) is a regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on

an **established benchmarking (GBT)** **AND** a **performance evaluation (PE) process**

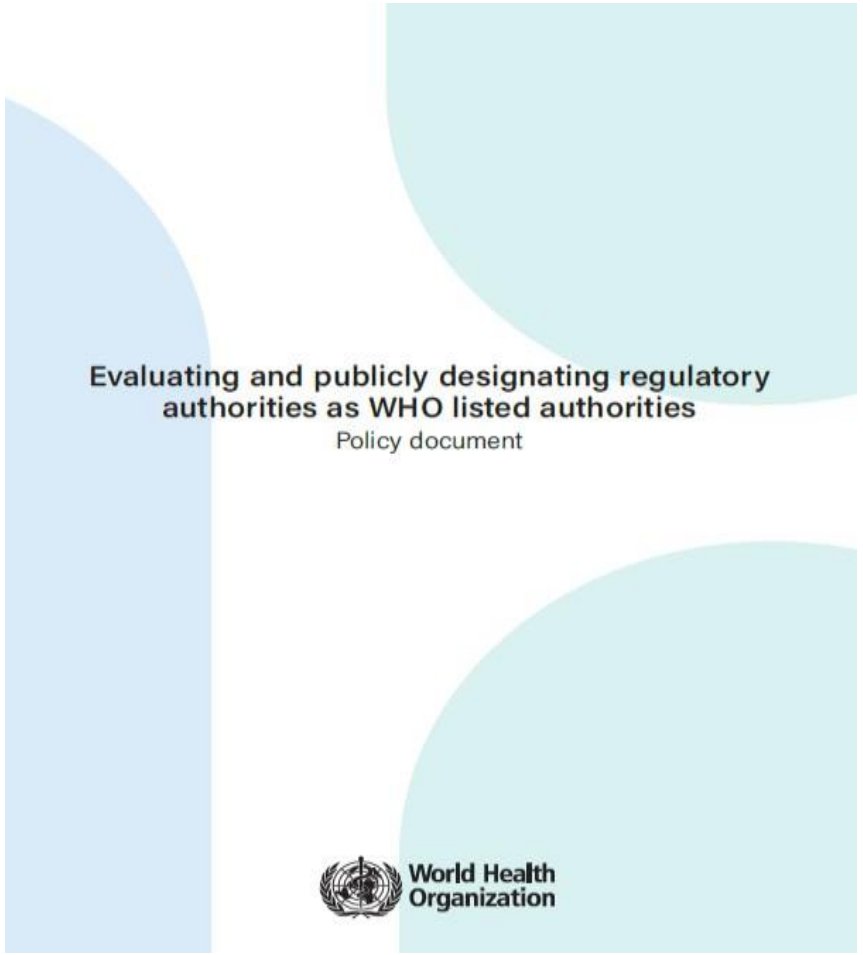
Slide curtesy: WHO RSS

Main objectives of WLA initiative

01 To provide a transparent and evidence-based pathway for RAs to be globally recognized

02 To promote access and the supply of safe, effective and quality-assured medical products

03 To optimize use of limited resources by facilitating reliance



Link: https://www.who.int/publications/i/item/9789240023444

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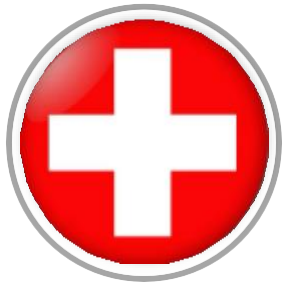
First three WLAs

31st October 2023

SRA



Switzerland

Swissmedic

tWLA

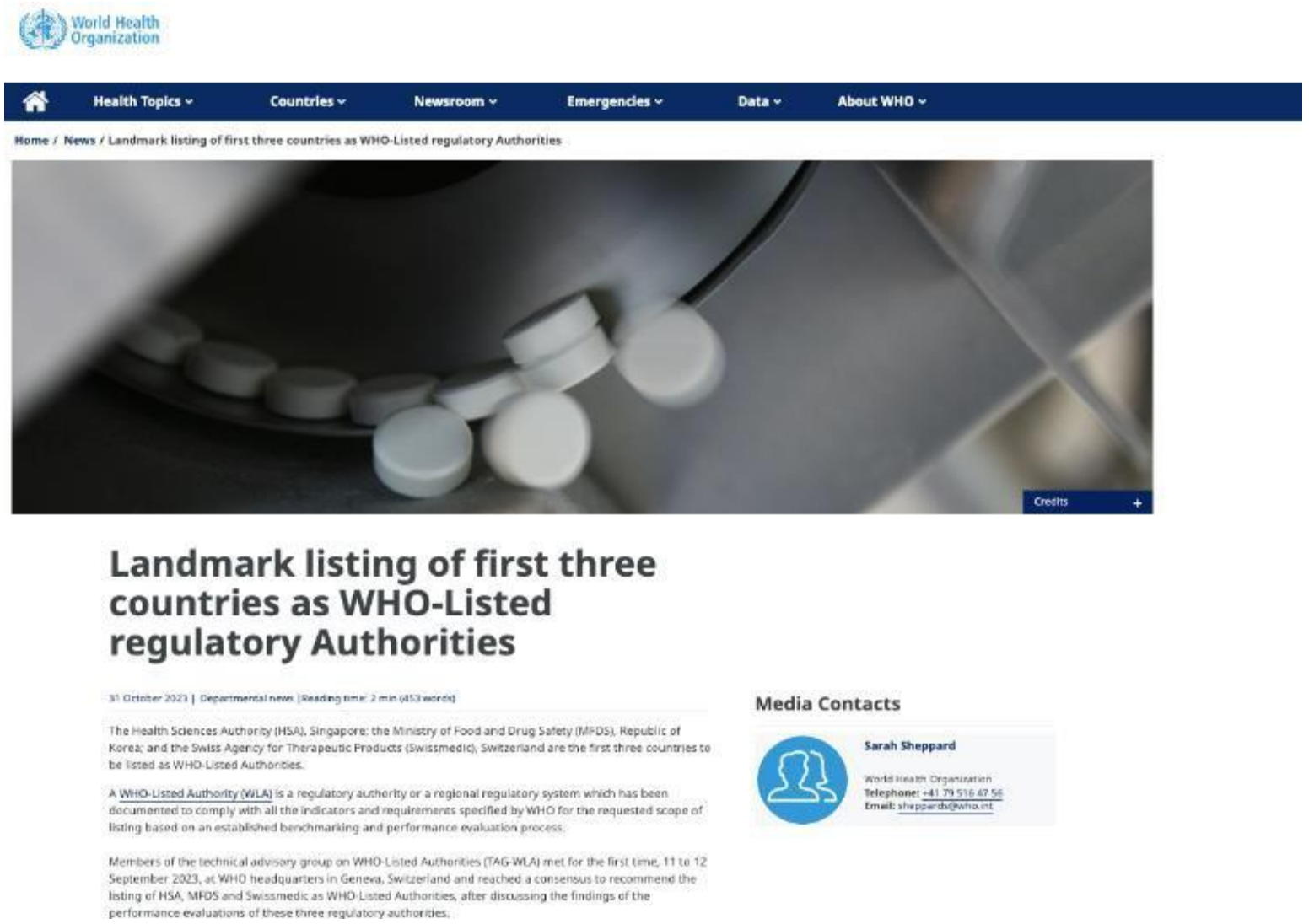
Republic of Korea

MFDS

ML4 NRA

Singapore

HSA



https://www.who.int/news/item/31-10-2023-landmark-listing-of-first-three-countries-as-who-listed-regulatory-authorities

33 new WLAs

20 May 2024

RRS

European Medicines Regulatory Network

EC/EMA

+30 NCAs

SRA

United States of America

US FDA

ML4 NRA

Singapore

HSA*

* MC function

https://www.who.int/news/item/20-05-2024-largest-number-of-regulatory-agencies-for-medical-products-approved-as-who-_listed-authorities

39 WLAs from 37 Member States

7 August 2025

SRA

Canada

Health Canada

SRA

United Kingdom

Medicines and Healthcare products Regulatory Agency (MHRA)

SRA

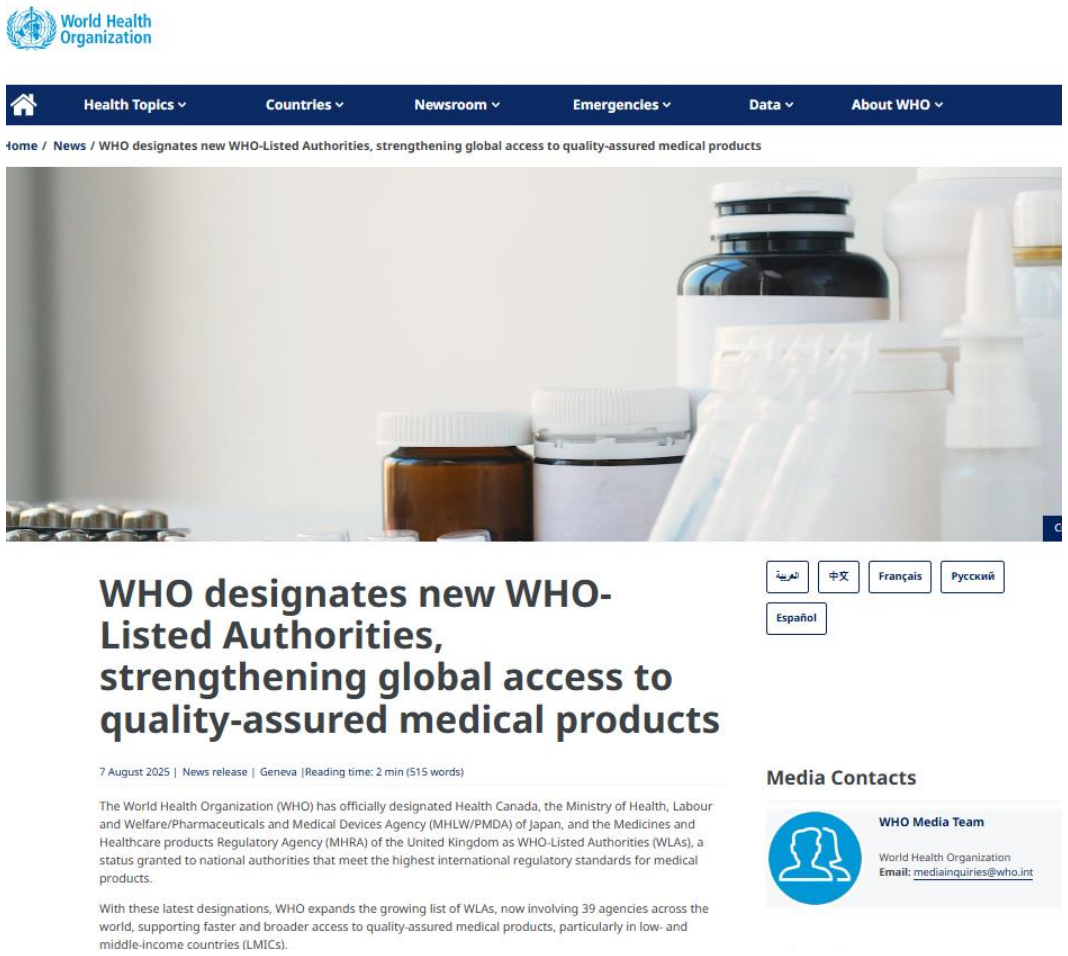
Japan

Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency (MHLW/PMDA)

WLA

Republic of Korea

Ministry of Food and Drug Safety (MFDS) – full scale for Medicines, Vaccines

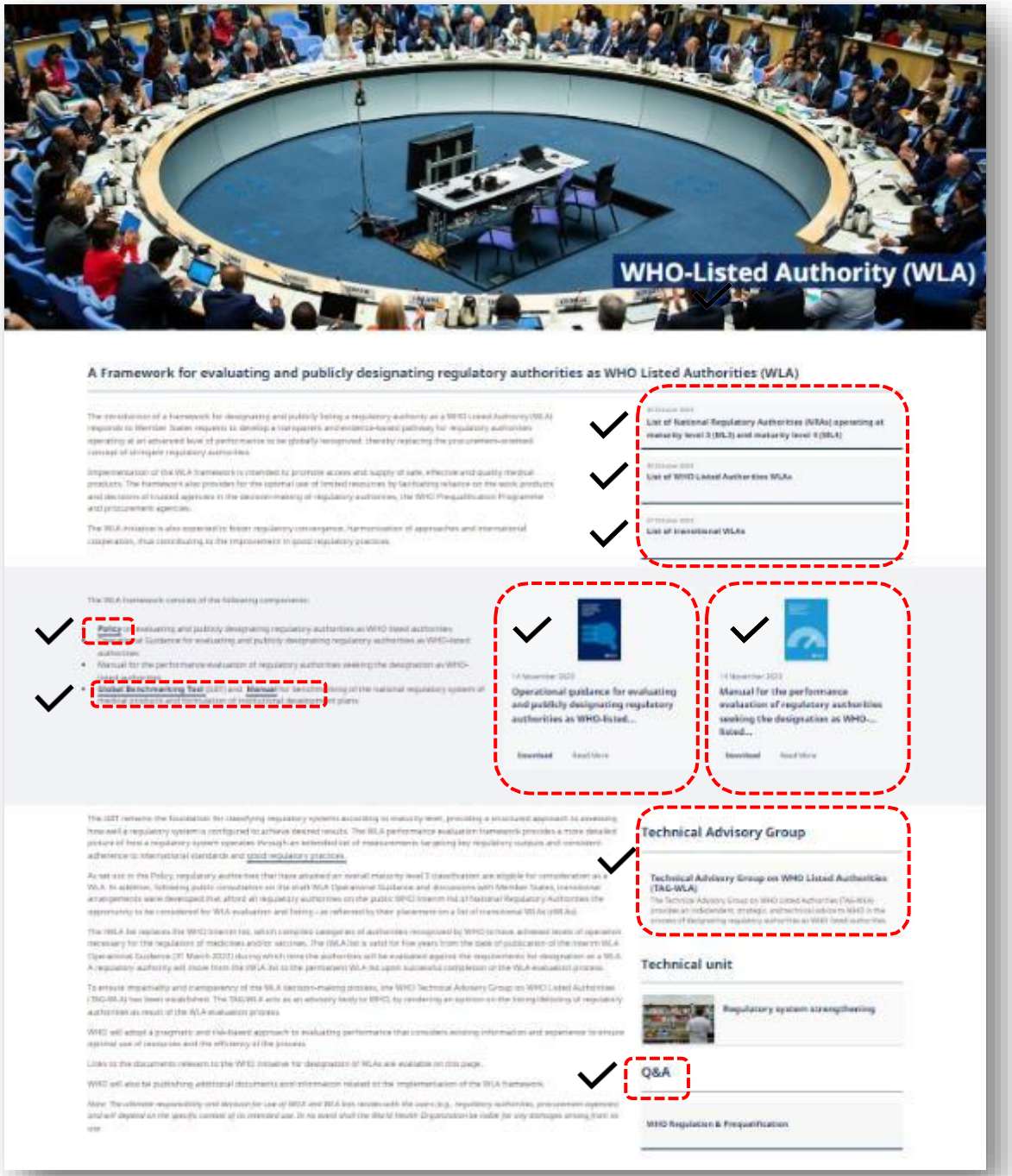


https://www.who.int/news/item/07-08-2025-who-designates-new-who-listed-authorities--strengthening-global-access-to-quality-assured-medical-products

WLA resources

https://www.who.int/initiatives/who-listed-authority-reg-authorities

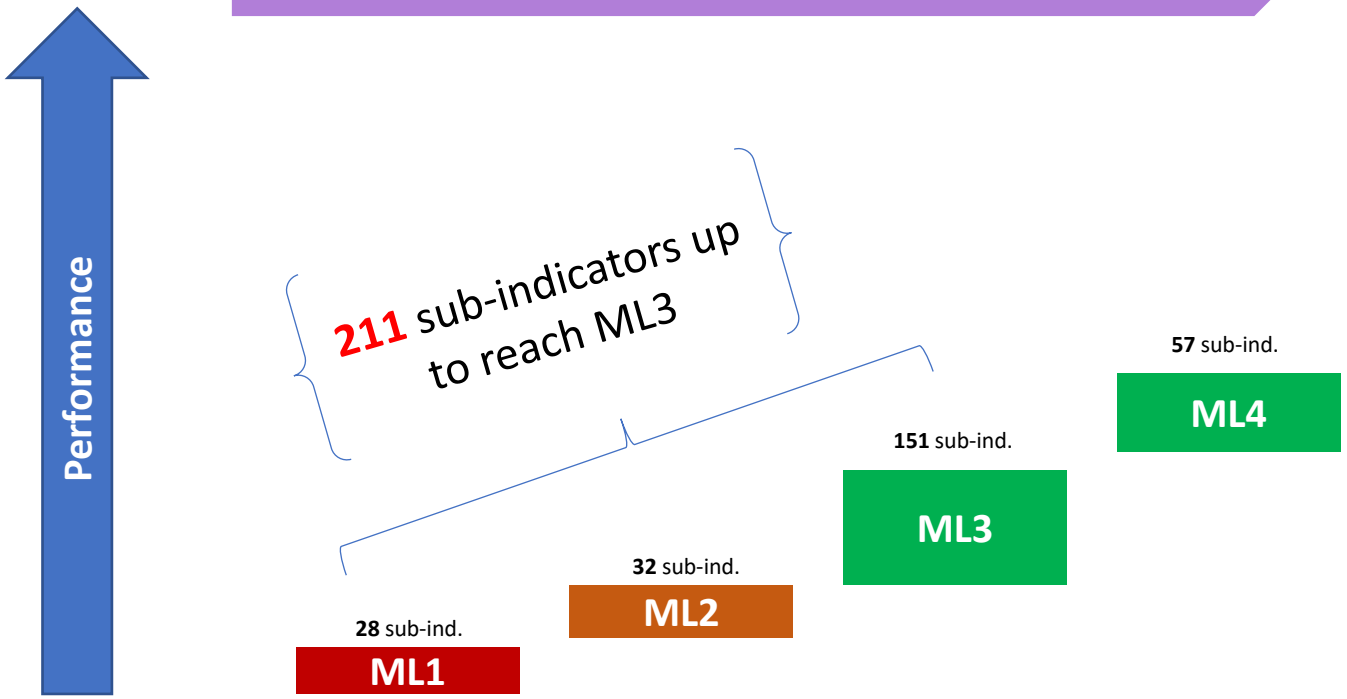
Slide curtesy: WHO RSS



Summary: GBT & WLA - NRA-ML & WLA: What's being measured?

NRA-ML & WLA: What's being measured?

NRA Maturity Defined by Benchmarking using GBT



How well a regulatory system is configured?

WHO Listed Authority Defined by PE Indicators and Tools

WLA

- **56 indicators**
  - ❑ **36**/57 of **ML4 indicators**
  - ❑ **20 PE indicators**
- **5 PE Audit Tools**
  - ➢ MAA expert review
  - ➢ VL field visit
  - ➢ RI-GMP & **GCP observed audit**
  - ➢ LTA expert review
  - ➢ **CTAA expert review**

How well a regulatory system operate?

ML: maturity level; **PE:** performance evaluation; **MA:** registration & marketing authorization; **VL:** vigilance; **RI**: regulatory inspections; **LT:** laboratory testing; **CT:** clinical trial oversight; AAR: application assessment report

Source: WHO RSS

Key Takeaways

Strong regulatory systems are essential for ensuring the **safety, efficacy, and quality of medical products**, directly impacting **public health** and **global health security**.

National Regulatory Authorities (NRAs) play a central role in implementing **good regulatory practices**, making **science-based, transparent, and timely decisions**.

Good Regulatory Practices (GRP) and **enablers**—such as effective governance, quality management, and collaboration—drive **regulatory performance and continuous improvement**.

WHO Global Benchmarking Tool (GBT) provides **a structured approach** to assess and strengthen regulatory systems, **guiding countries toward higher maturity levels**.

WHO Listed Authority (WLA) status is **a globally recognized mark of regulatory excellence**, promoting **international trust and reliance**.

Achieving higher maturity and WLA recognition requires overcoming **challenges** such as resource limitations, system complexity, and the need for ongoing capacity building.

Collaboration, stakeholder engagement, and commitment to quality are vital for **advancing regulatory systems and supporting universal health coverage**.

Reference Resources

- Global Benchmarking Tool (GBT) https://apps.who.int/iris/handle/10665/341243
- WHO Listed Authorities (WLA) initiative https://www.who.int/initiatives/who-listed-authority-reg-authorities
- Good regulatory practices in the regulation of medical products (GRP) https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf
- Good reliance practices in the regulation of medical products: High level principles and considerations (GRelP) https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf
- WHO guideline on the implementation of quality management systems for national regulatory authorities - TRS 1025 - Annex 13 https://www.who.int/publications/m/item/trs-1025-annex-13-qms-nra
- Quality management system requirements for national inspectorates https://www.who.int/publications/m/item/trs-1025-annex-5-qms-national-inspectorates
- Implementing quality management systems in national regulatory authorities: Examples and practices https://www.who.int/publications/i/item/9789240022379

Contact to the speaker for questions and feedback

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