

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



Jinho Shin
Medical Officer
WHO

Regional Office for the Western Pacific
Manila, Philippines

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

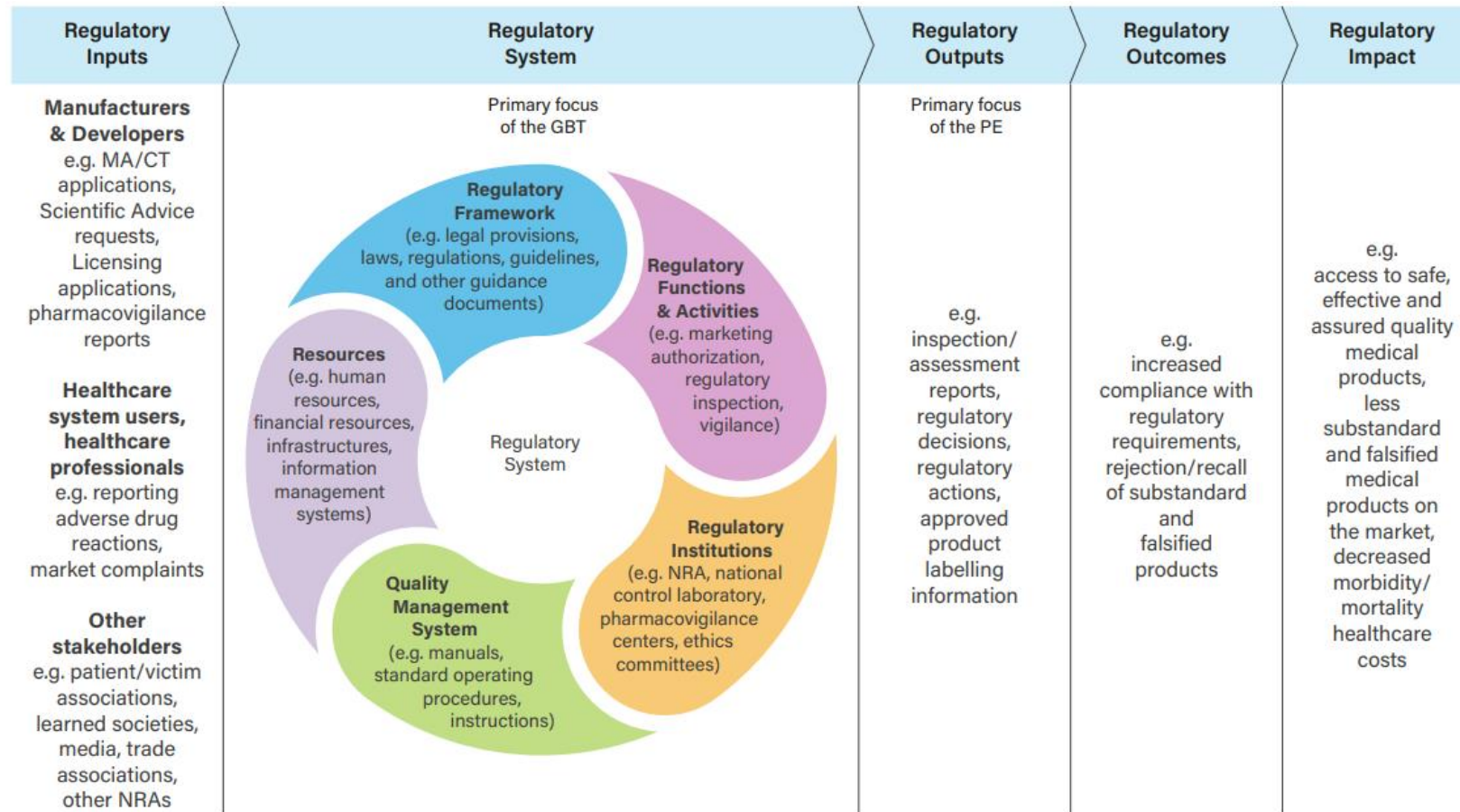
- **Nigeria:** National Agency for Food and Drug Administration and Control (NAFDAC)
- **Egypt:** Egyptian Drug Authority (EDA)
- **South Africa:** South African Health Products Regulatory Authority (SAHPRA)
- **Saudi Arabia:** Saudi Food & Drug Authority (SFDA)

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:

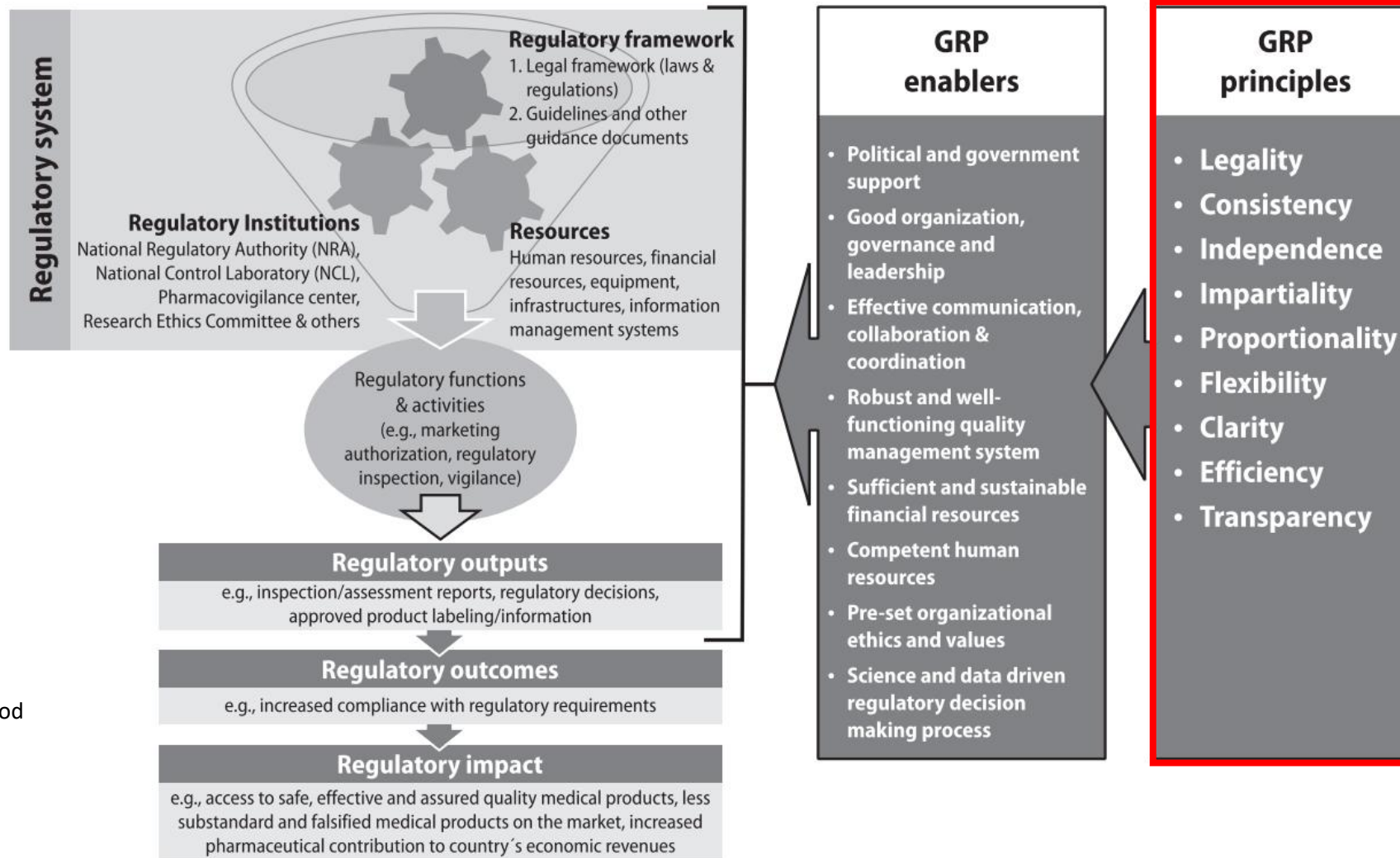
- Safe, Effective, and Quality-Assured Medical Products
- Timely Access to Medical Products
- Public Trust in the Regulatory System
- Compliance by Regulated Entities
- Efficient Regulatory Processes

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

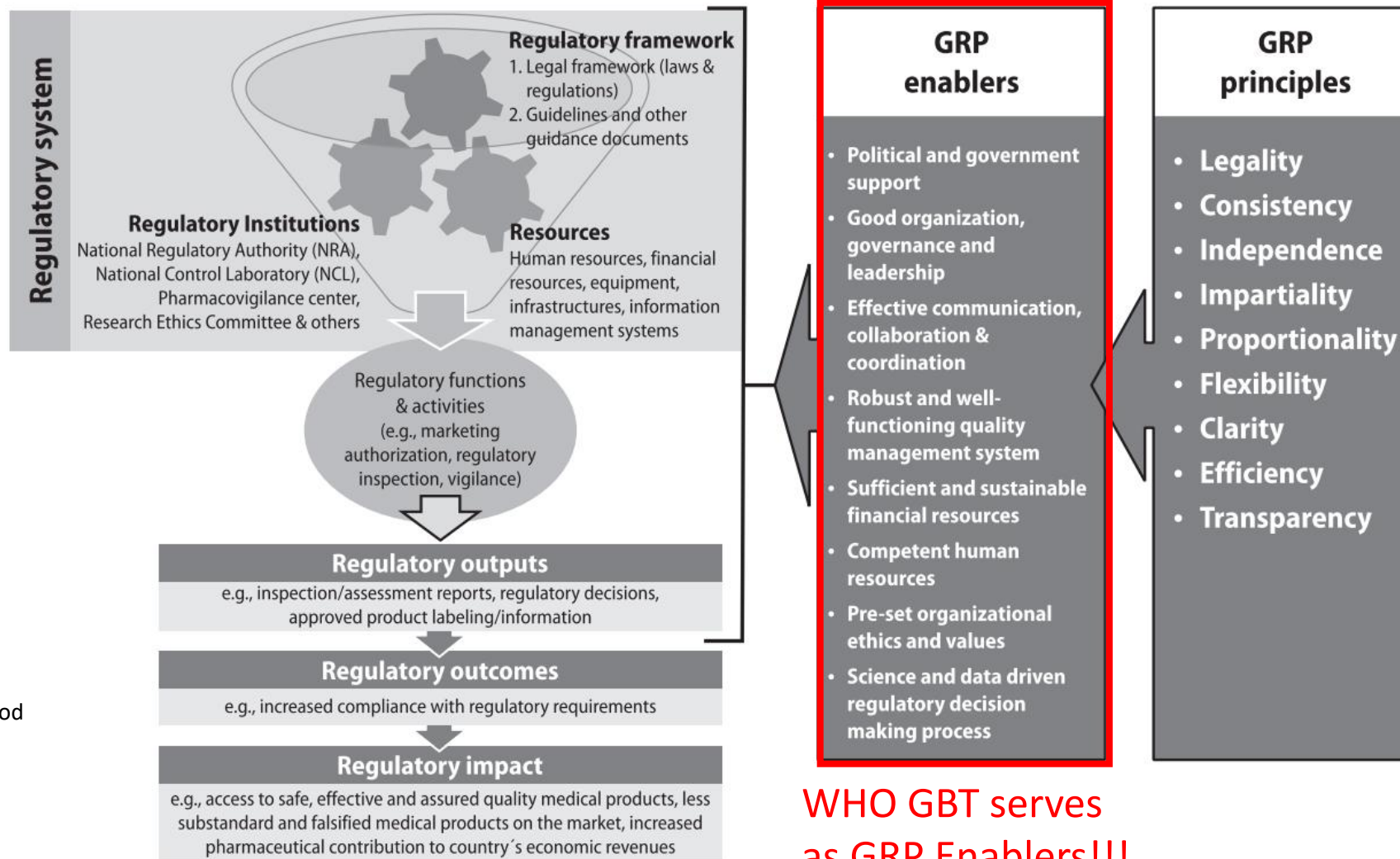


Source of the graphic: WHO good regulatory practices in the regulation of medical products

Good Regulatory Practice (GRP): Principles



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

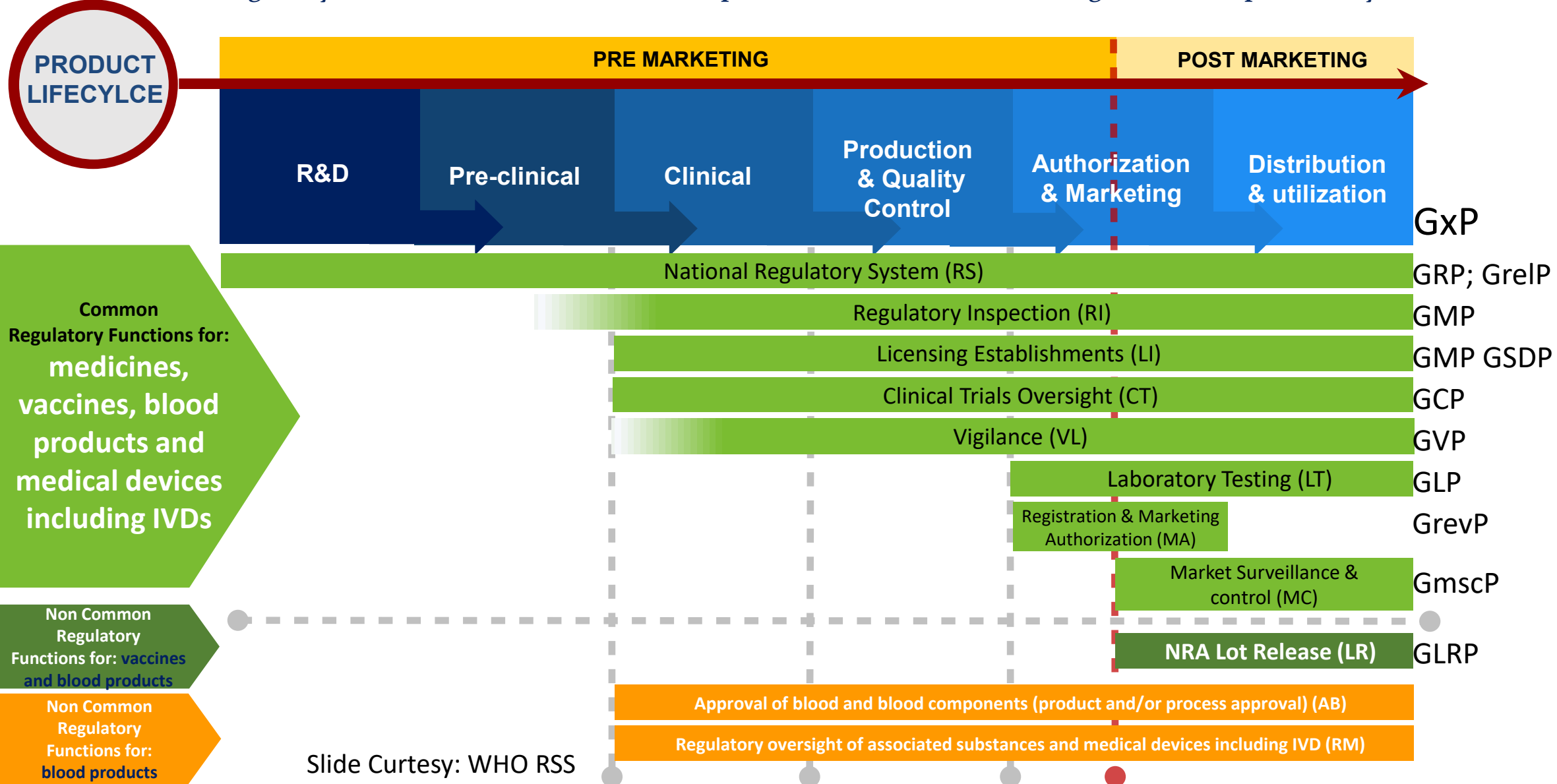
Maturity Level

- **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



Indicators' categories

cross-cutting across system & functions

RS	Indicators	MA	VL	MC	LI	RI	LT	CT	LR
○	Legal provisions, regulations and guidelines	○	○	○	○	○	○	○	○
○	Organisation and governance	○	○	○	○	○	○	○	○
○	Policy and strategic planning						○		
○	Leadership and crisis management								
○	Quality and risk management system								
○	Resources (HR, FR, infrastructure, and equipment)	○	○	○	○	○	○	○	○
	Regulatory process	○	○	○	○	○	○	○	○
○	Transparency, accountability and communication	○	○	○	○	○	○	○	○
○	Monitoring progress and assessing outcomes & impact	○	○	○	○	○	○	○	○

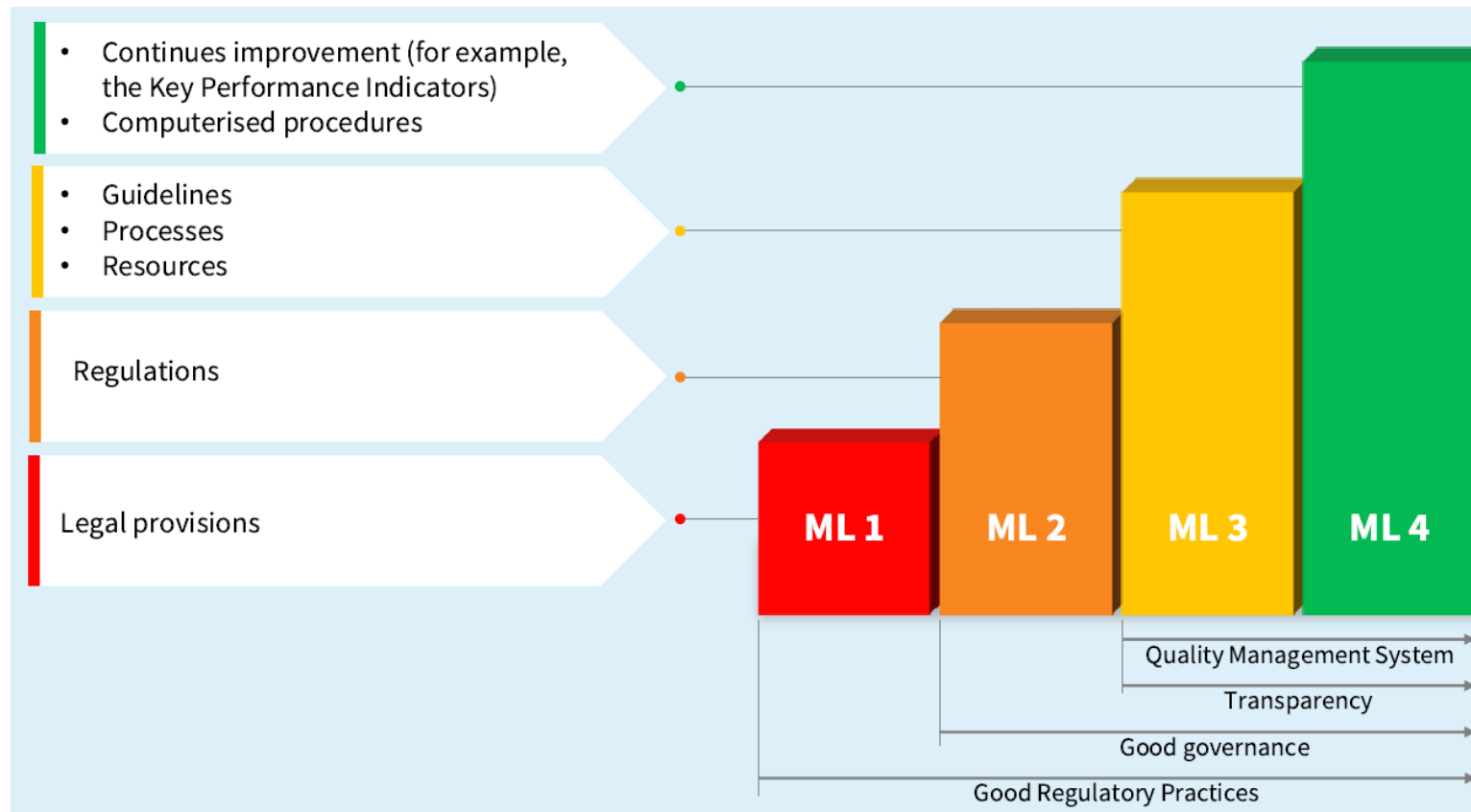
Updated Figures of the WHO GBT Revision VI

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

Allocation of a specific ML to each Sub-Indicator



Computerized GBT Dashboard

World Health Organization

computerized Global Benchmarking Tool (cGBT)

Country

Scope

Date of visit

Tool's version

Type of visit

Status

All

16.05.2022 - 20.05.2022

_GBT Rev VI, ver. 1 (E)

_cGBT Ver. 13.23 last update Oct 2024

Benchmarking

Draft

RS

4

01-NATIONAL REGULATORY SYSTEM (RS)

Contains data: Yes

Implementation Percentage 100

MA

4

02-REGISTRATION AND MARKETING AUTHORIZATION (MA)

Contains data: Yes

Implementation Percentage 100

VL

4

03-VIGILANCE (VL)

Contains data: Yes

Implementation Percentage 100

MC

4

04-MARKET SURVEILLANCE AND CONTROL (MC)

Contains data: Yes

Implementation Percentage 100

LI

3

05-LICENSING ESTABLISHMENT (LI)

Contains data: Yes

Implementation Percentage 96

RI

3

06-REGULATORY INSPECTION (RI)

Contains data: Yes

Implementation Percentage 96

LT

3

07-LABORATORY TESTING (LT)

Contains data: Yes

Implementation Percentage 97

CT

4

08-CLINICAL TRIAL'S OVERSIGHT (CT)

Contains data: Yes

Implementation Percentage 100

LR

4

09-NRA LOT RELEASE (LR)

Contains data: Yes

Implementation Percentage 100

What is WLA, Why is it Important

Definition of a WHO Listed Authority

Adopted by the ECSP 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 courtesy: WHO RSS

Main objectives of WLA initiative

01

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

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

02

Evaluating and publicly designating regulatory authorities as WHO listed authorities
Policy document

03

To **optimize use of limited resources** by **facilitating reliance**



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

First three WLAs

31st October 2023

SRA



Switzerland
Swissmedic

tWLA



Republic of Korea
MFDS

ML4 NRA



Singapore
HSA



Home / News / Landmark listing of first three countries as WHO-Listed regulatory Authorities



Landmark listing of first three countries as WHO-Listed regulatory Authorities

31 October 2023 | Departmental news | Reading time: 2 min (453 words)

The Health Sciences Authority (HSA), Singapore; the Ministry of Food and Drug Safety (MFDS), Republic of Korea; and the Swiss Agency for Therapeutic Products (Swissmedic), Switzerland are the first three countries to be listed as WHO-Listed Authorities.

A WHO-Listed Authority (WLA) is a regulatory authority or a regional regulatory system which has been documented to comply with all the indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process.

Members of the technical advisory group on WHO-Listed Authorities (TAG-WLA) met for the first time, 11 to 12 September 2023, at WHO headquarters in Geneva, Switzerland and reached a consensus to recommend the listing of HSA, MFDS and Swissmedic as WHO-Listed Authorities, after discussing the findings of the performance evaluations of these three regulatory authorities.

Media Contacts



Sarah Sheppard

World Health Organization
Telephone: +41 79 516 42 56
Email: sheppard@who.int

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



The screenshot shows a WHO News article titled "Largest number of regulatory agencies for medical products approved as WHO Listed Authorities". The article is dated 20 May 2024 and mentions a 2-minute video. The text states that WHO has approved the designation of 33 national and regional regulatory authorities (WLAs) that can be relied on for fulfilling the highest level of regulatory standards and practices for quality, safety and efficacy of medicines and vaccines. This listing makes a total of 36 regulatory authorities from 34 Member States now designated as WLAs since the launch of the initiative in March 2022. The newly approved WLAs include: the U.S. Food and Drug Administration (US FDA) and the European Medicines Regulatory Network (EMRN), which is composed of the European Commission, the European Medicines Agency (EMA) and the medicines regulatory authorities of the 27 European Union member states.

<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



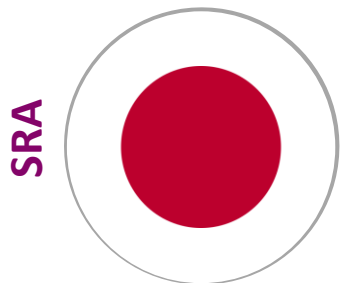
Canada

Health Canada



United Kingdom

Medicines and Healthcare products Regulatory Agency (MHRA)



Japan

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



Republic of Korea

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



Home / News / WHO designates new WHO-Listed Authorities, strengthening global access to quality-assured medical products



WHO designates new WHO-Listed Authorities, strengthening global access to quality-assured medical products

7 August 2025 | News release | Geneva | Reading time: 2 min (515 words)

The World Health Organization (WHO) has officially designated Health Canada, the Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency (MHLW/PMDA) of Japan, and the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom as WHO-Listed Authorities (WLAs), a status granted to national authorities that meet the highest international regulatory standards for medical products.

With these latest designations, WHO expands the growing list of WLAs, now involving 39 agencies across the world, supporting faster and broader access to quality-assured medical products, particularly in low- and middle-income countries (LMICs).



Media Contacts



WHO Media Team
World Health Organization
Email: media@who.int

<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 courtesy: WHO RSS



WHO-Listed Authority (WLA)

A Framework for evaluating and publicly designating regulatory authorities as WHO Listed Authorities (WLA)

The introduction of a framework for designating and publicly listing a regulatory authority as a WHO Listed Authority (WLA) responds to Member States' requests to develop a transparent and evidence-based pathway for regulatory authorities operating at an advanced level of performance to be globally recognized, thereby replacing the procurement-oriented concept of biologic regulatory authorities.

Implementation of the WLA framework is intended to promote access and supply of safe, effective and quality medical products. The framework also provides for the optimal use of limited resources by facilitating reliance on the work products and decisions of trusted agencies in the decision-making of regulatory authorities, the WHO Prequalification Programme and procurement agencies.

The WLA initiative is also expected to foster regulatory convergence, harmonization of approaches and international cooperation, thus contributing to the improvement in good regulatory practices.

- ✓ [List of National Regulatory Authorities \(NRAs\) operating at maturity level 3 \(ML3\) and maturity level 4 \(ML4\)](#)
- ✓ [List of WHO Listed Authorities \(WLAs\)](#)
- ✓ [List of transitional WLAs](#)

The WLA framework consists of the following components:

- ✓ [Policy](#) – Evaluating and publicly designating regulatory authorities as WHO-listed authorities
- ✓ [Manual for the performance evaluation of regulatory authorities seeking the designation as WHO-listed authorities](#)
- ✓ [Operational guidance for evaluating and publicly designating regulatory authorities as WHO-listed...](#)
- ✓ [Manual for the performance evaluation of regulatory authorities seeking the designation as WHO-listed...](#)

The TAG reviews the foundation for classifying regulatory systems according to maturity level, providing a structured approach to assessing how well a regulatory system is configured to achieve desired results. The WLA performance evaluation framework provides a more detailed picture of how a regulatory system operates through an extended set of measurements targeting key regulatory outputs and consistent adherence to international standards and good regulatory practices.

As set out in the Policy, regulatory authorities that have attained an overall maturity level 3 classification are eligible for consideration as a WLA. In addition, following public consultation on the draft WLA Operational Guidance and discussions with Member States, transitional arrangements were developed that afford all regulated authorities on the public WHO Informal List of National Regulatory Authorities the opportunity to be considered for WLA evaluation and being – as referenced by their placement on a list of transitional WLAs (TLAs).

The WLA framework replaces the WHO Informal List, which comprised categories of authorities recognized by WHO to have achieved levels of operation necessary for the regulation of medicines and/or vaccines. The WLA framework is valid for five years from the date of publication of the draft WLA Operational Guidance (17 March 2023) during which time the authorities will be evaluated against the requirements for designation as a WLA. A regulatory authority will move from the TLAs list to the permanent WLA list upon successful completion of the WLA evaluation process.

To ensure impartiality and transparency of the WLA decision-making process, the WHO Technical Advisory Group on WHO Listed Authorities (TAG-WLA) has been established. The TAG-WLA acts as an advisory body to WHO, by rendering an opinion on the listing/delisting of regulatory authorities as a result of the WLA evaluation process.

WHO will adopt a pragmatic and risk-based approach to evaluating performance that considers existing information and experience to ensure optimal use of resources and the efficiency of the process.

Links to the documents relevant to the WHO initiative for designation of WLAs are available on this page.

WHO will also be publishing additional documents and information related to the implementation of the WLA framework.

Note: The ultimate responsibility and decision for use of WLA and TLA lists rests with the governing regulatory authorities, procurement agencies and will depend on the specific context of its intended use. It is acknowledged that the World Health Organization is liable for any damages arising from its use.

Technical Advisory Group

[Technical Advisory Group on WHO Listed Authorities \(TAG-WLA\)](#)

The Technical Advisory Group on WHO Listed Authorities (TAG-WLA) provides an independent, strategic, evidential advice to WHO in the process of designating regulatory authorities as WHO-listed authorities.

Technical unit

[Regulatory system strengthening](#)

Q&A

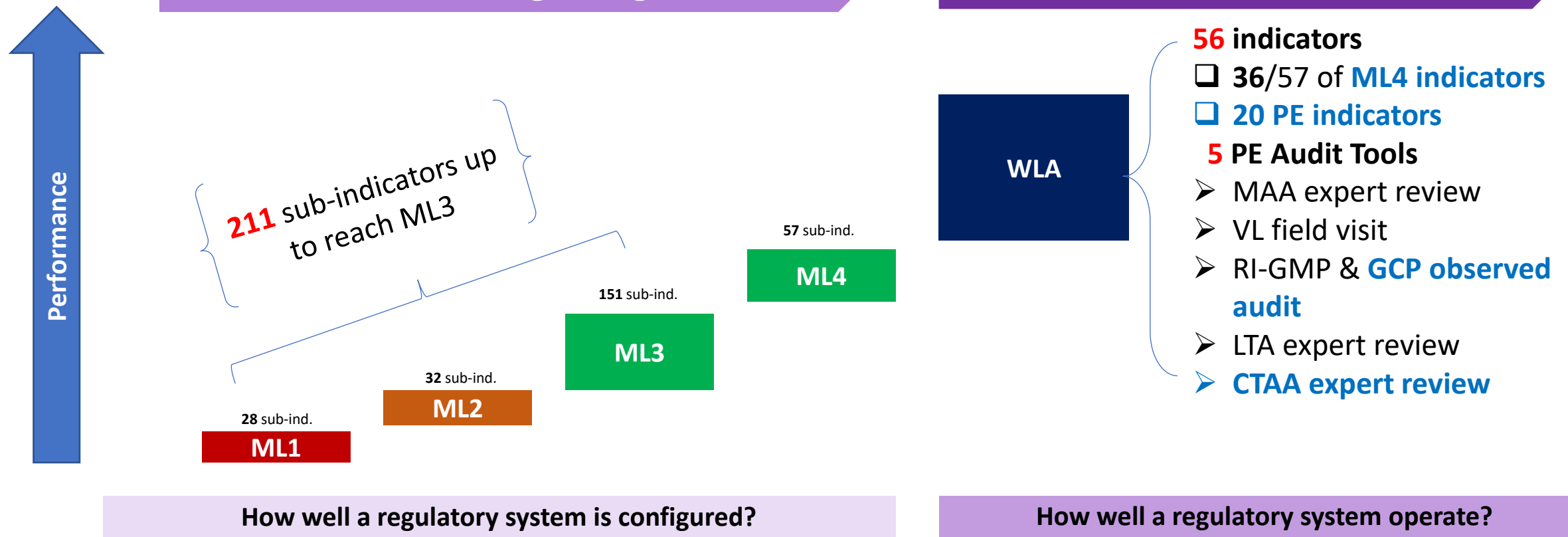
WHO Regulation & Prequalification

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

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

NRA Maturity Defined by Benchmarking using GBT

WHO Listed Authority Defined by PE Indicators and Tools



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

Jinho Shin

Medical Officer, Essential Medicines & Health Technologies,
Division of Health Systems and Services
WHO Regional Office for the Western Pacific
P.O.Box 2932, Manila, Philippines, 1000



Email: shinj@who.int



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