

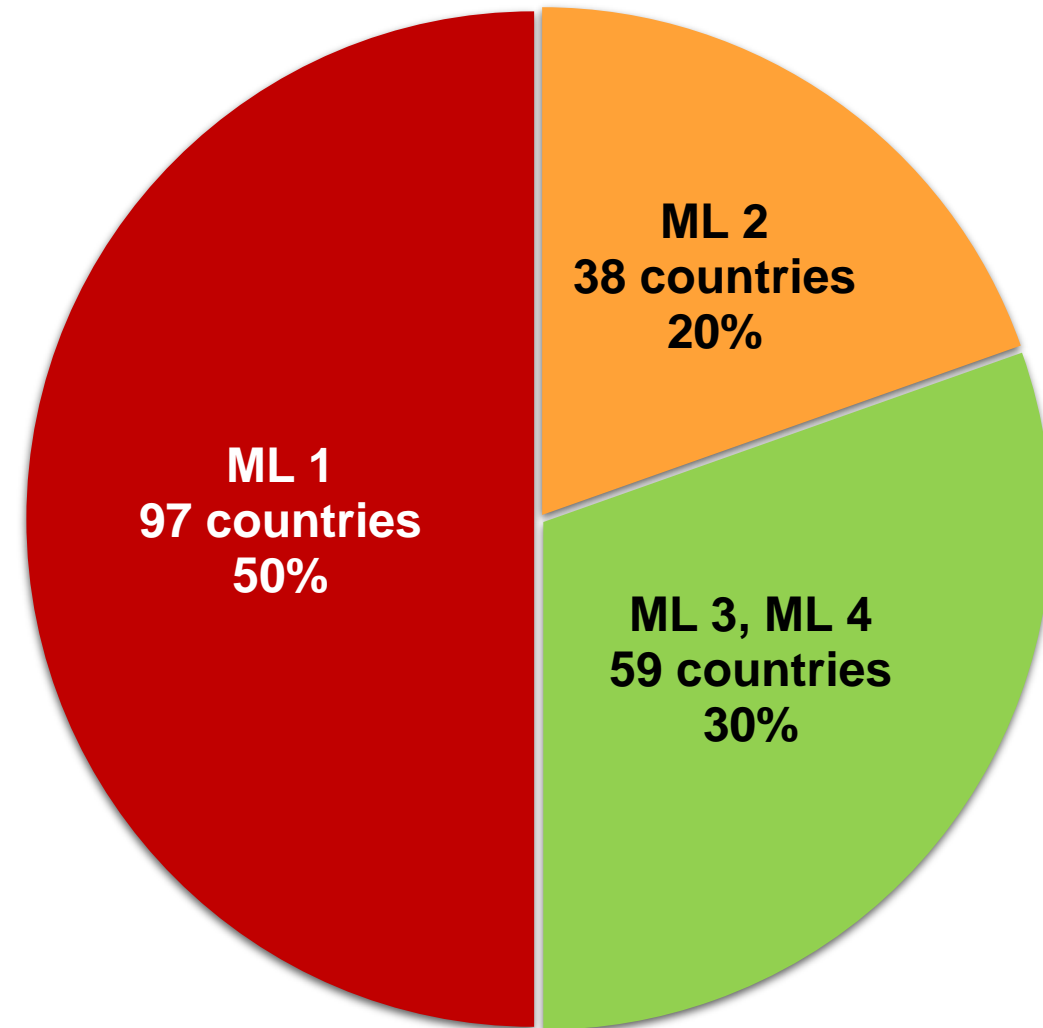
Overall regulatory systems' maturity level of WHO Member States and major challenges

Objectives of the RSS programme

- *Build capacity in Member States consistent with good regulatory practices*
- *Promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance*

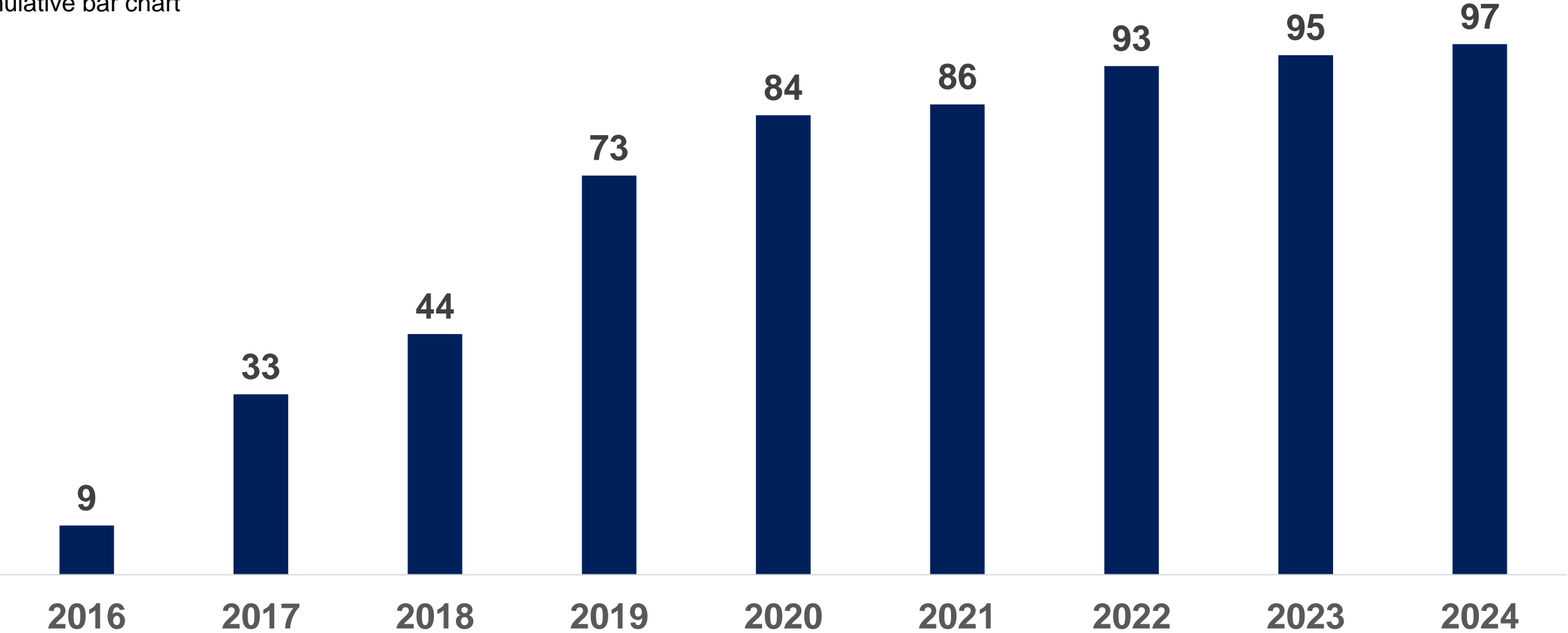
- **Resolution WHA 67.20 in 2014**

- ✓ Recognized the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of health-related SDGs and UHC



Number of Member States benchmarked by GBT by year

Cumulative bar chart



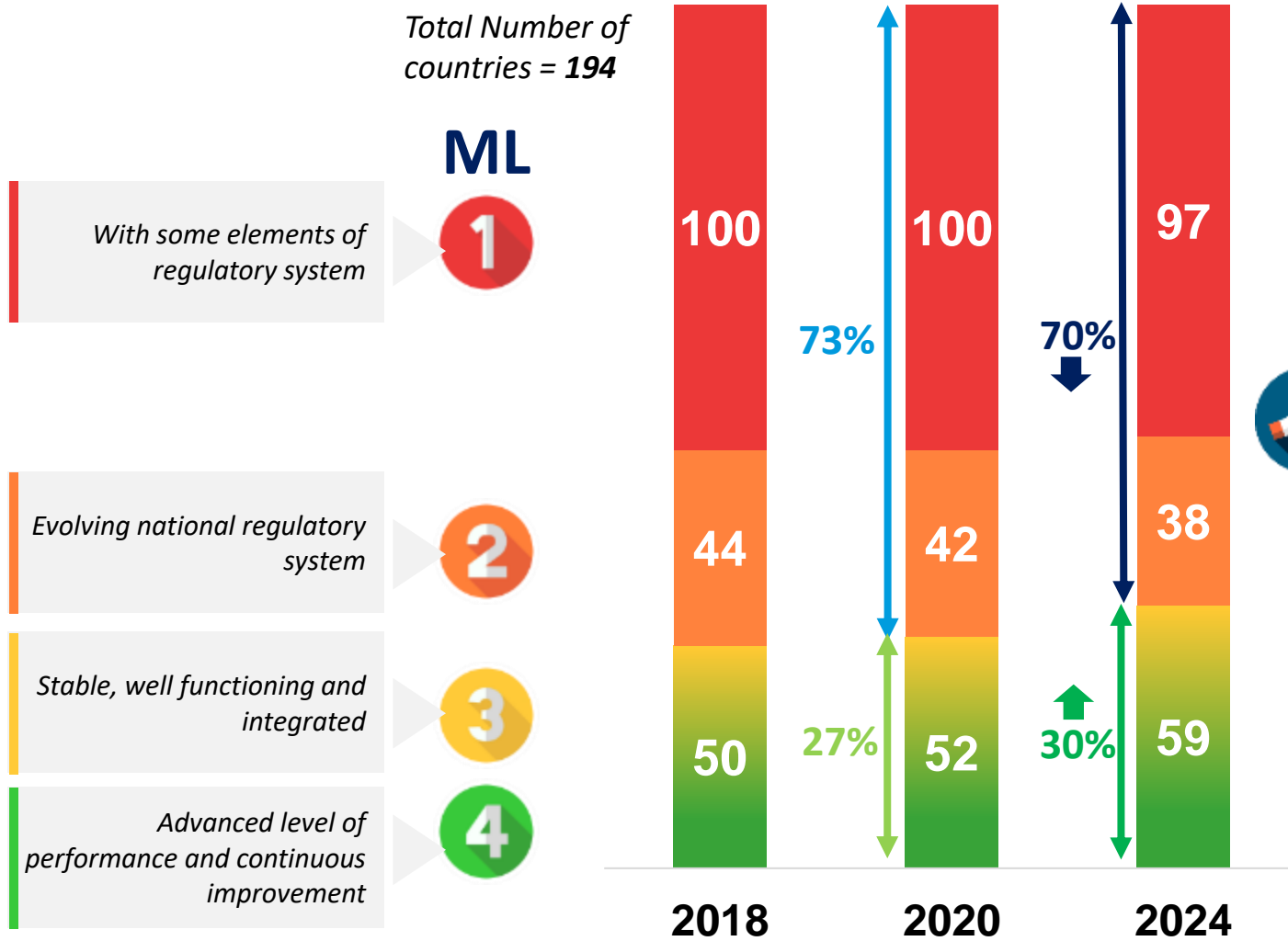
Source: WHO RSS database, Sep 2024

Global status of national regulatory systems

(medicines and vaccines regulation as of Aug 2024)



Total Number of countries = 194



- Vaccines produced in countries with ML 3/ML 4 NRAs eligible for EUL/prequalification
- NRAs at ML3/ML4 eligible for WLA PE process



Recent announcements

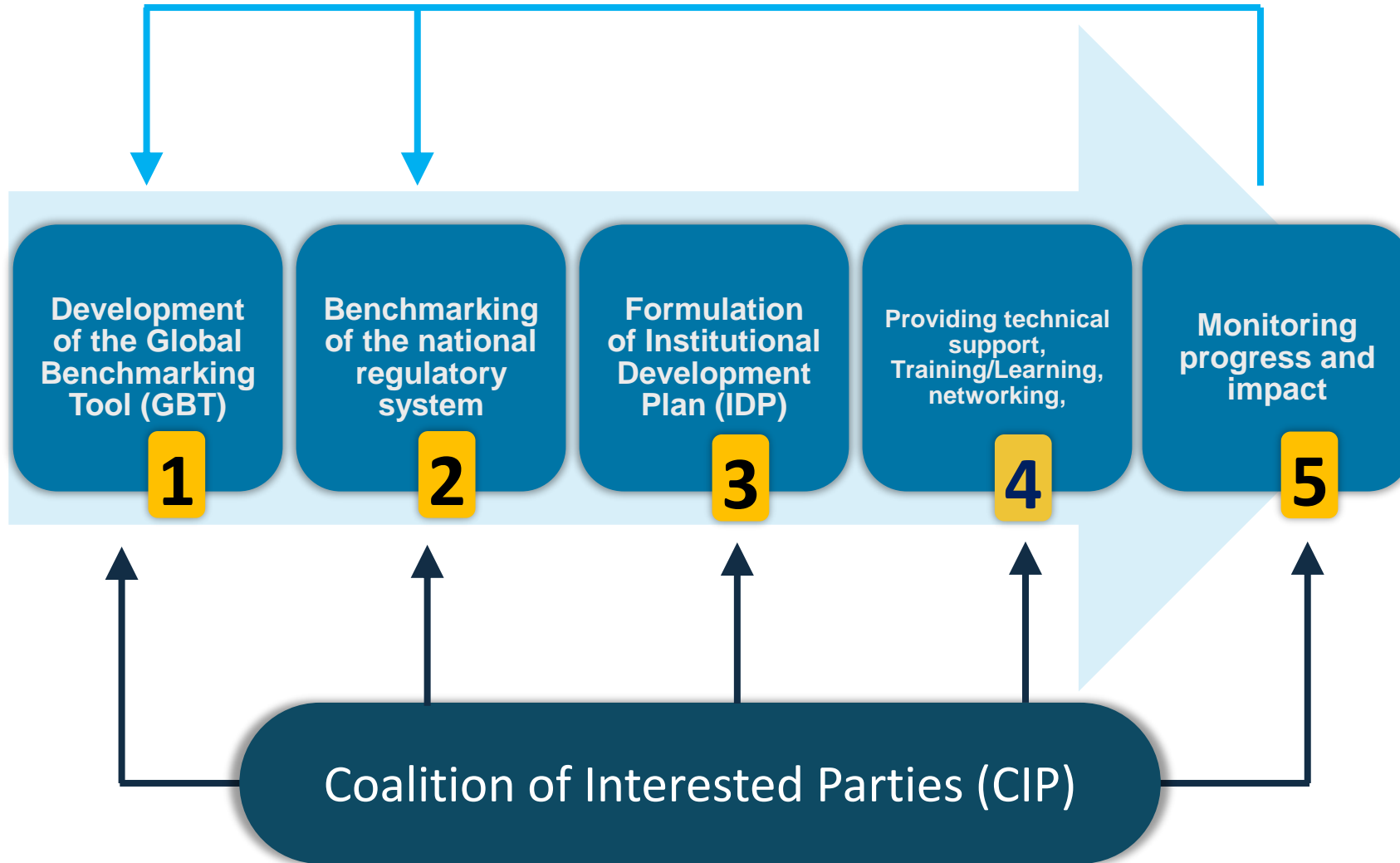


Zimbabwe becomes the sixth country in Africa to reach WHO maturity level 3 in regulation of medicines (14 June 2024)

ML: (regulatory system) maturity level

WHO Five-Step Capacity Building Model for National Regulatory Authorities (NRAs)

As per Resolution WHA 67.20 on Regulatory Systems Strengthening (2014)



- Target ML3
Stable, well functioning and integrated regulatory system
- Eligibility for:
 - vaccine PQ
 - PE for WHO listed authorities (WLA)

3	Contains data: Yes Implementation Percentage 94	3	Contains data: Yes Implementation Percentage 94	3	Contains data: Yes Implementation Percentage 97
MC	04-MARKET SURVEILLANCE AND CONTROL (MC)	LI	05-LICENSING ESTABLISHMENT (LI)	RI	06-REGULATORY INSPECTION (RI)
3	Contains data: Yes Implementation Percentage 94	3	Contains data: Yes Implementation Percentage 95	2	Contains data: Yes Implementation Percentage 83
LT	07-LABORATORY TESTING (LT)	CT	08-CLINICAL TRIALS OVERSIGHT (CT)	LR	09-NRA LOT RELEASE (LR)
2	Contains data: Yes Implementation Percentage 50	3	Contains data: Yes Implementation Percentage 97	3	Contains data: Yes Implementation Percentage 94



2016

Evaluation of national regulatory systems of medicines and vaccines

WHO Global Benchmarking Tool (GBT)



2019

Evaluation of national regulatory systems of blood products including whole blood, blood components and plasma derived products

WHO Global Benchmarking Tool + Blood (GBT + blood)



2022-2024

Evaluation of national regulatory systems of medical devices including in-vitro diagnostics

WHO Global Benchmarking Tool + Medical Devices (GBT + medical devices)



WHO Global Benchmarking Tools (GBT) for evaluation of national regulatory systems

Regulatory systems play a key role in assuring the quality, safety, and efficacy of medical products. Effective regulatory systems are an essential component of health systems and contribute to desired public health outcomes and innovation.

The Global Benchmarking Tool (GBT) represents the primary means by which the World Health Organization (WHO) objectively evaluates regulatory systems, as mandated by WHA Resolution 67.20 on Regulatory System Strengthening for medical products. The tool and benchmarking methodology enables WHO and regulatory authorities to:

- identify strengths and areas for improvement;
- facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address the identified gaps;
- prioritize IDP interventions; and
- monitor progress and achievements.

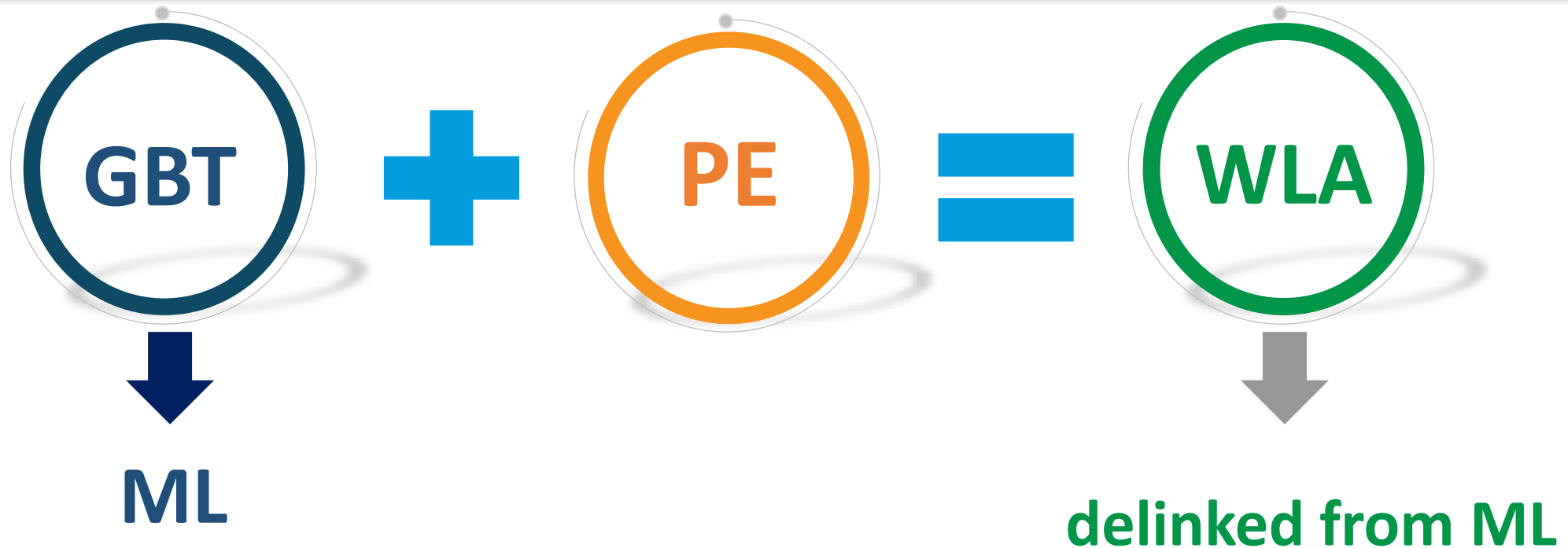
<https://www.who.int/tools/global-benchmarking-tools>

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



The 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 medical products

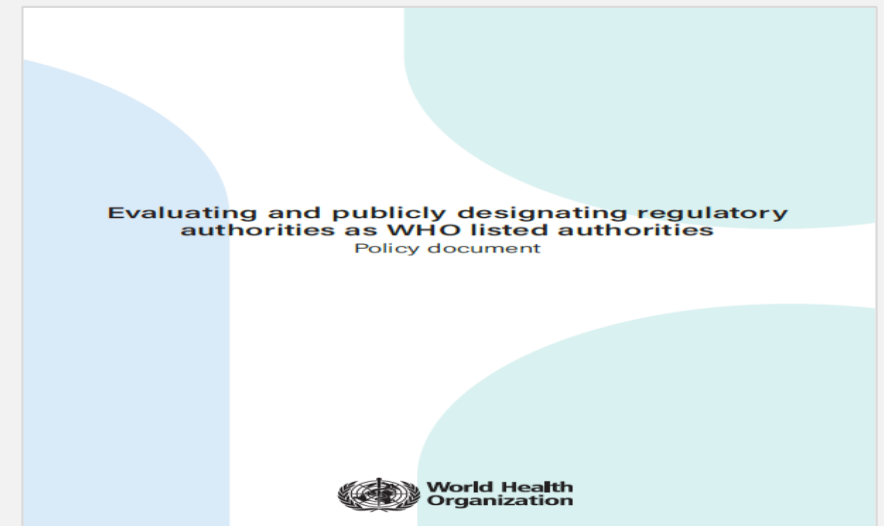
02

03

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

WLA Policy document:

The Policy describes the current scope (medicines and vaccines) purpose, definitions and high-level operating principles related to the evaluation and public listing of authorities



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

WHO Listed Authorities framework



NOV 2023 **WLA PE Manual**



NOV 2023 **WLA Operational Guidance**



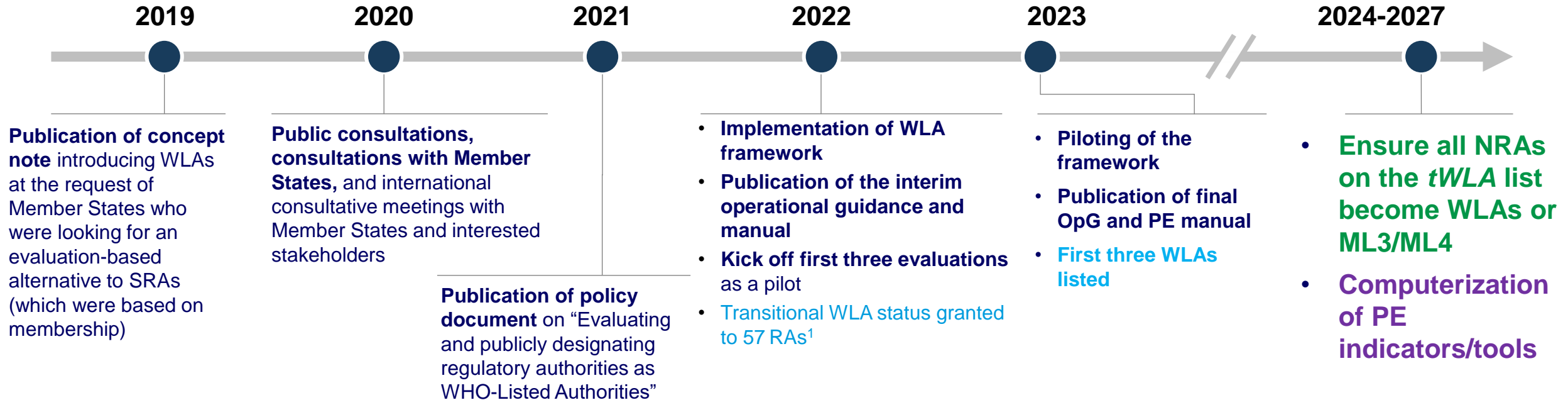
JULY 2021 **WLA Policy**



MAY 2019 **WLA Concept note**

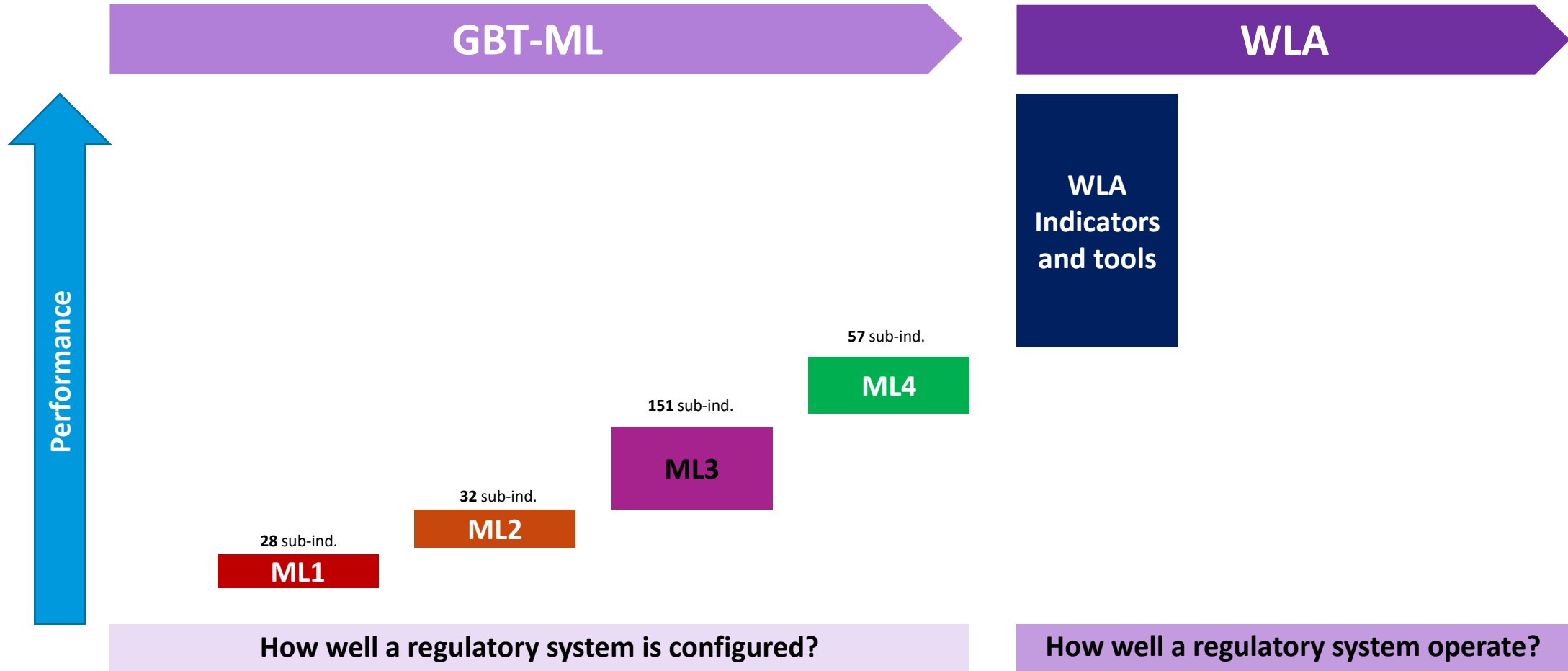
WHO Listed Authorities (WLAs)

Milestones and outlook for the future

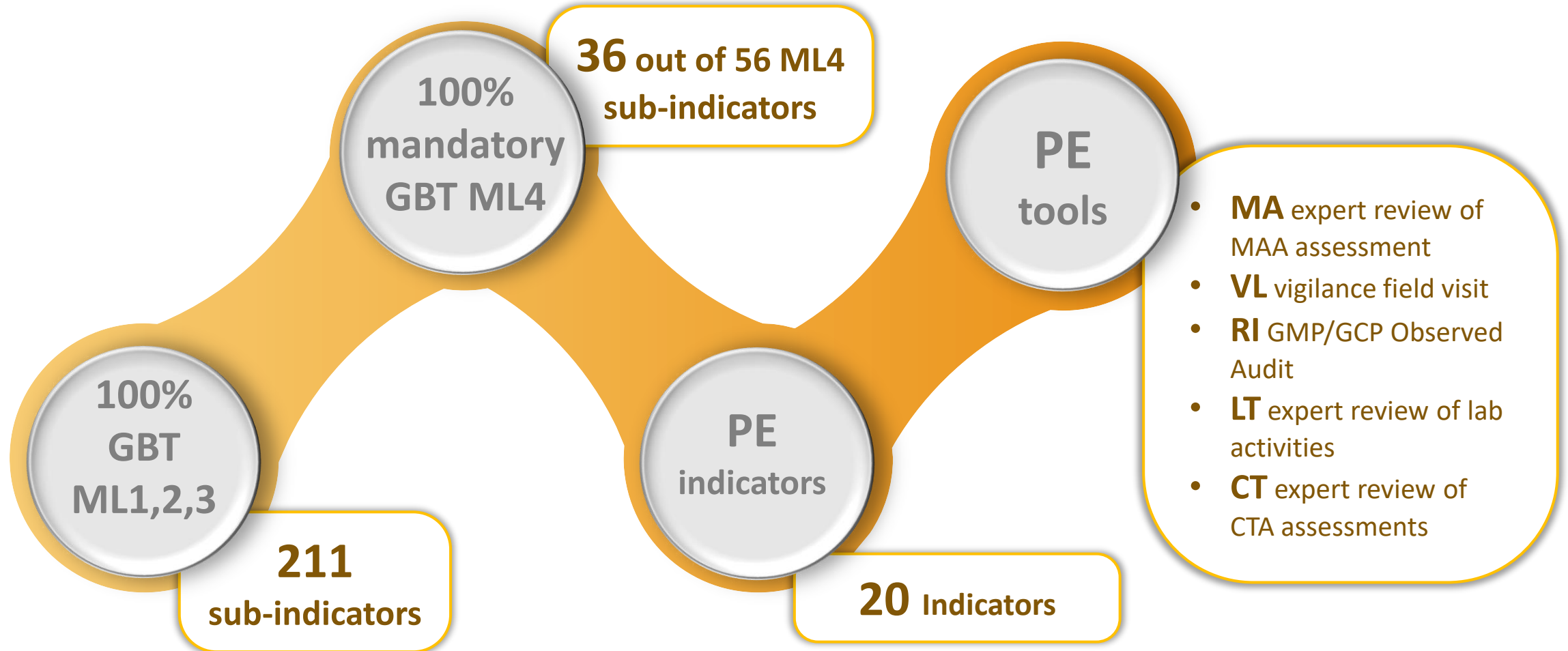


1. Includes one regional regulatory system – European Medicines Regulatory Network

What's being measured?



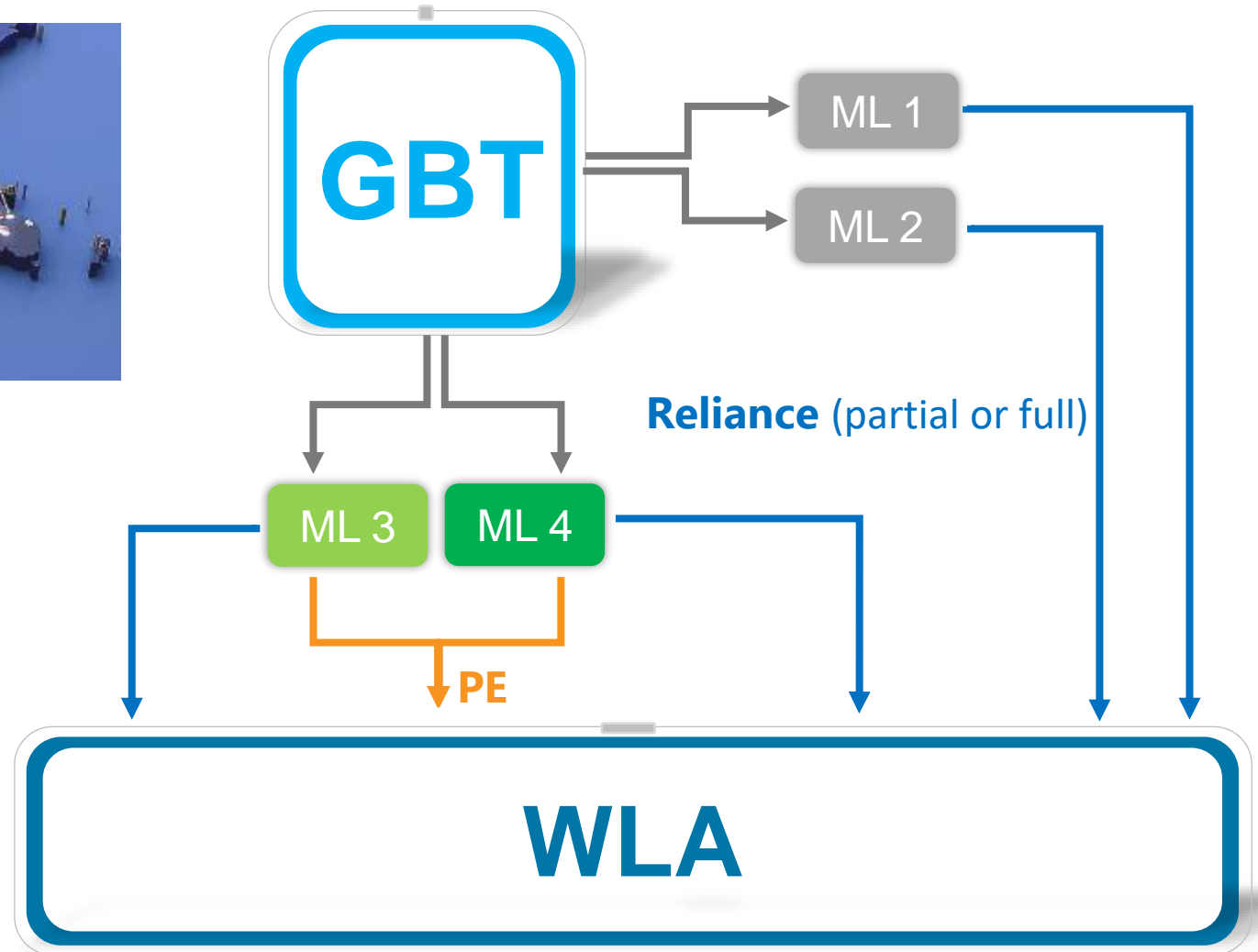
Components of PE process



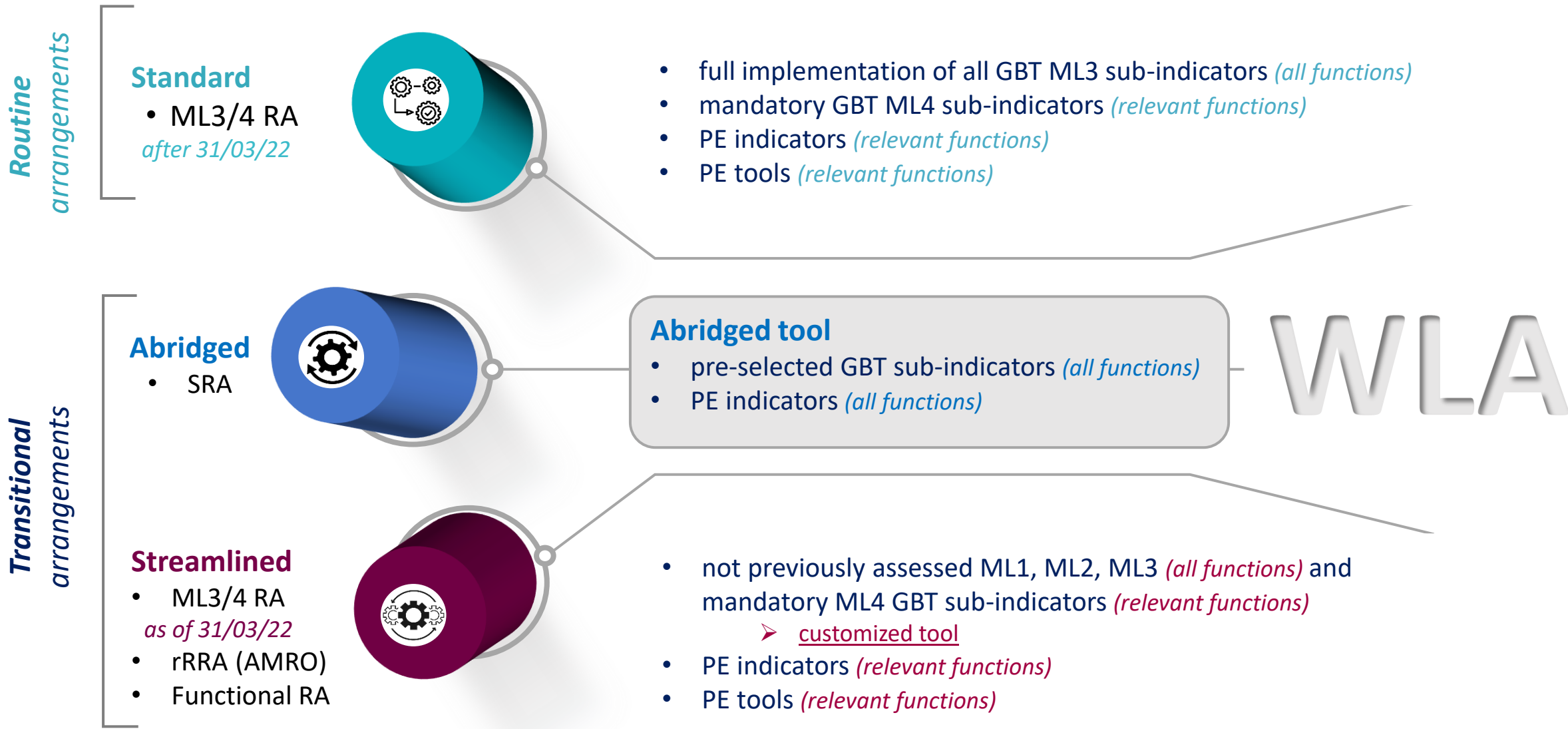
Fostering reliance through the WLA initiative



- Only ML3 and ML4 RAs are eligible for PE
- Reliance can be applied by all



Pathways for risk-based performance evaluation of candidate WLAs



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



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Email: sheppard@who.int

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

33 new WLAs

20th May 2024



*European Medicines
Regulatory Network*

**EC/EMA
+30 NCAs**



*United States
of America*

US FDA



Singapore

HSA*

* MC function



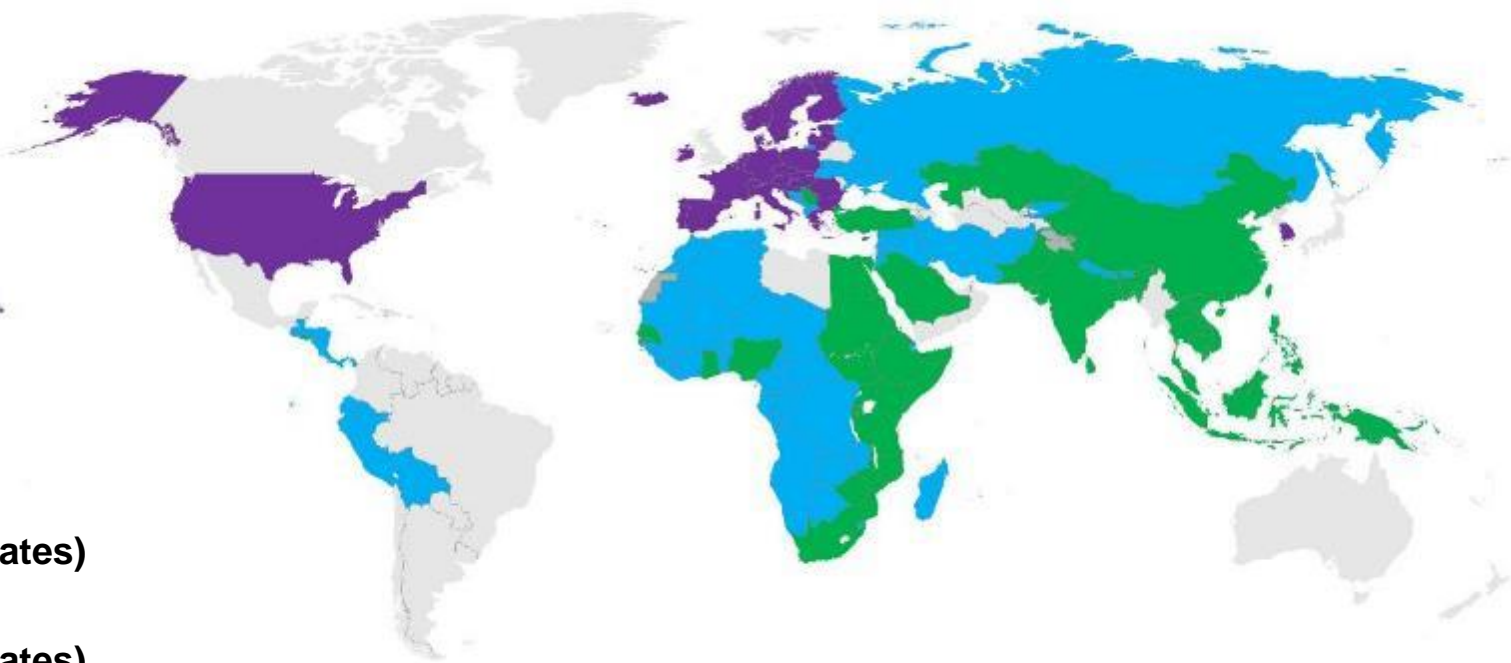
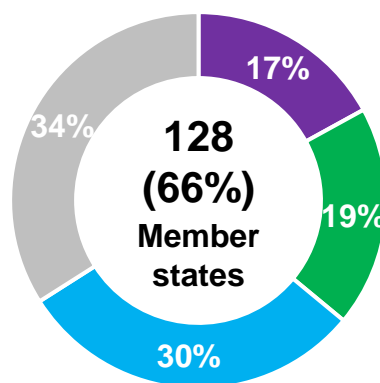
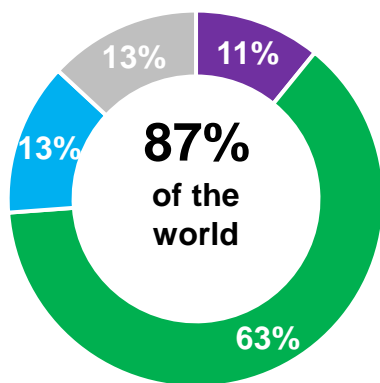
The screenshot shows a WHO news article page. At the top is the WHO logo and navigation menu. The main headline is "Largest number of regulatory agencies for medical products approved as WHO Listed Authorities". Below the headline is a photo of a woman holding a baby in a hospital setting. The article text states: "WHO has approved designation of 33 national and regional regulatory authorities as WHO Listed 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 following 30 countries: Austria".

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

Global status of benchmarking and performance evaluation of regulatory systems (2016 – Aug 2024)

% of world population

% of member states

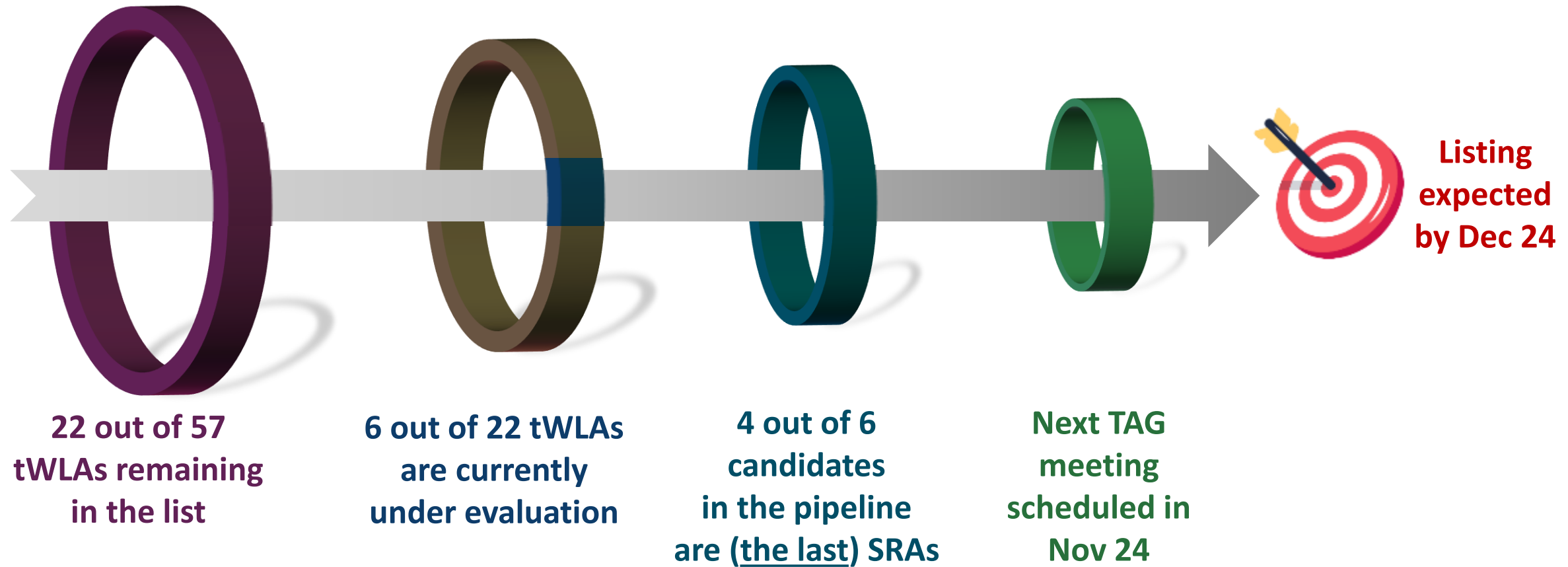


- WHO Listed authority (WLA) **(33 member states)**
- Benchmarking **(37 member states)**
- Self-benchmarking **(58 member states)**

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Source: WHO RSS database, Sep 2024

WLAs in the pipeline





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 foreign 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 Regulatory Programme and procurement agencies.

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

- ✓
- ✓
- ✓

- 27 October 2022
List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3) and maturity level 4 (ML4)
- 27 October 2022
List of WHO Listed Authorities (WLAs)
- 27 October 2022
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 authorities

14 November 2022

Operational guidance for evaluating and publicly designating regulatory authorities as WHO-listed...

Download Read More

14 November 2022

Manual for the performance evaluation of regulatory authorities seeking the designation as WHO-listed...

Download Read More

The G2T retains 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 consultations on the draft WLA Operational Guidance and discussions with Member States, transitional arrangements were developed that afford all regulatory authorities on the public WHO Inform List of National Regulatory Authorities the opportunity to be considered for WLA evaluation and being – as reflected by their placement on a list of transitional WLAs (TWLA).

The WLA list replaces the WHO Inform 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) list is valid for five years from the date of publication of the draft WLA Operational Guidance (17 March 2022) during which time the authorities will be evaluated against the requirements for designation as a WLA. A regulatory authority will move from the TWLA 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 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 WHO and WLA list rests with the country, regulatory authorities, procurement agencies and will depend on the specific context of its intended use. It is noted that the World Health Organization is liable for any damages arising there to 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, and technical advice to WHO in the process of designating regulatory authorities as WHO-listed authorities.

- ✓

Technical unit

Regulatory system strengthening

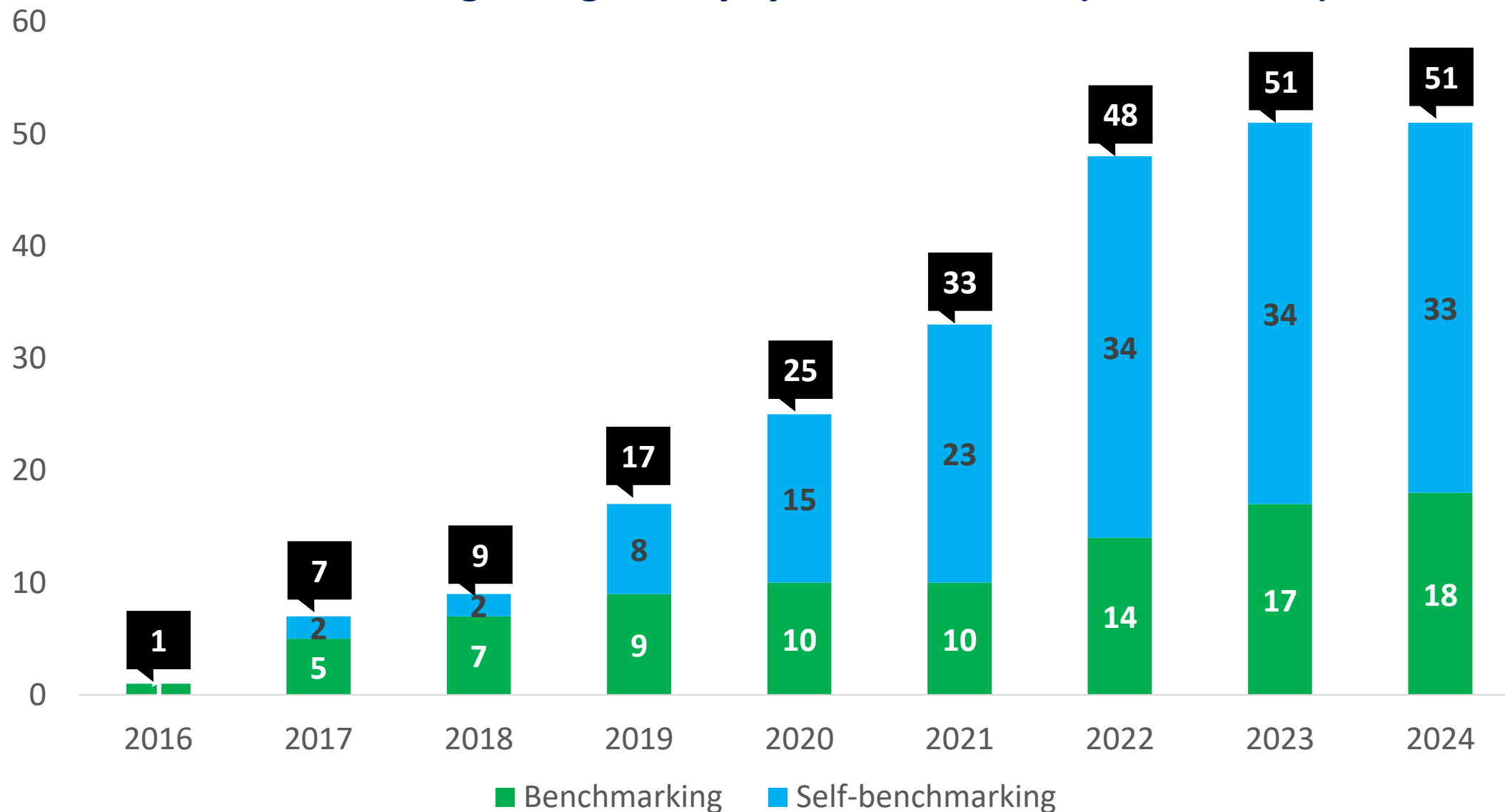
Q&A

WHO Regulation & Prequalification

WLA resources

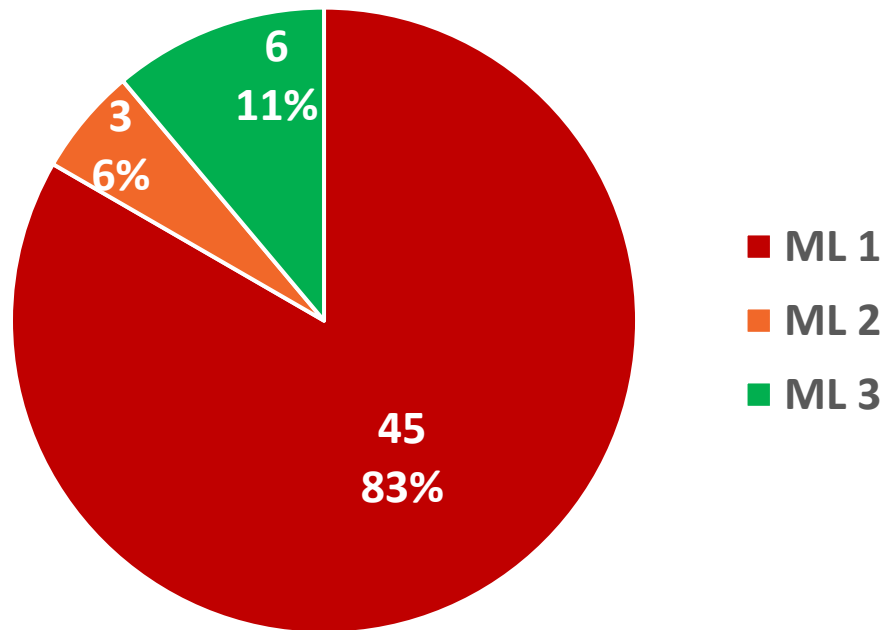
<https://www.who.int/initiatives/who-listed-authority-reg-authorities>

Benchmarking of regulatory systems in Africa (2016 – 2024)



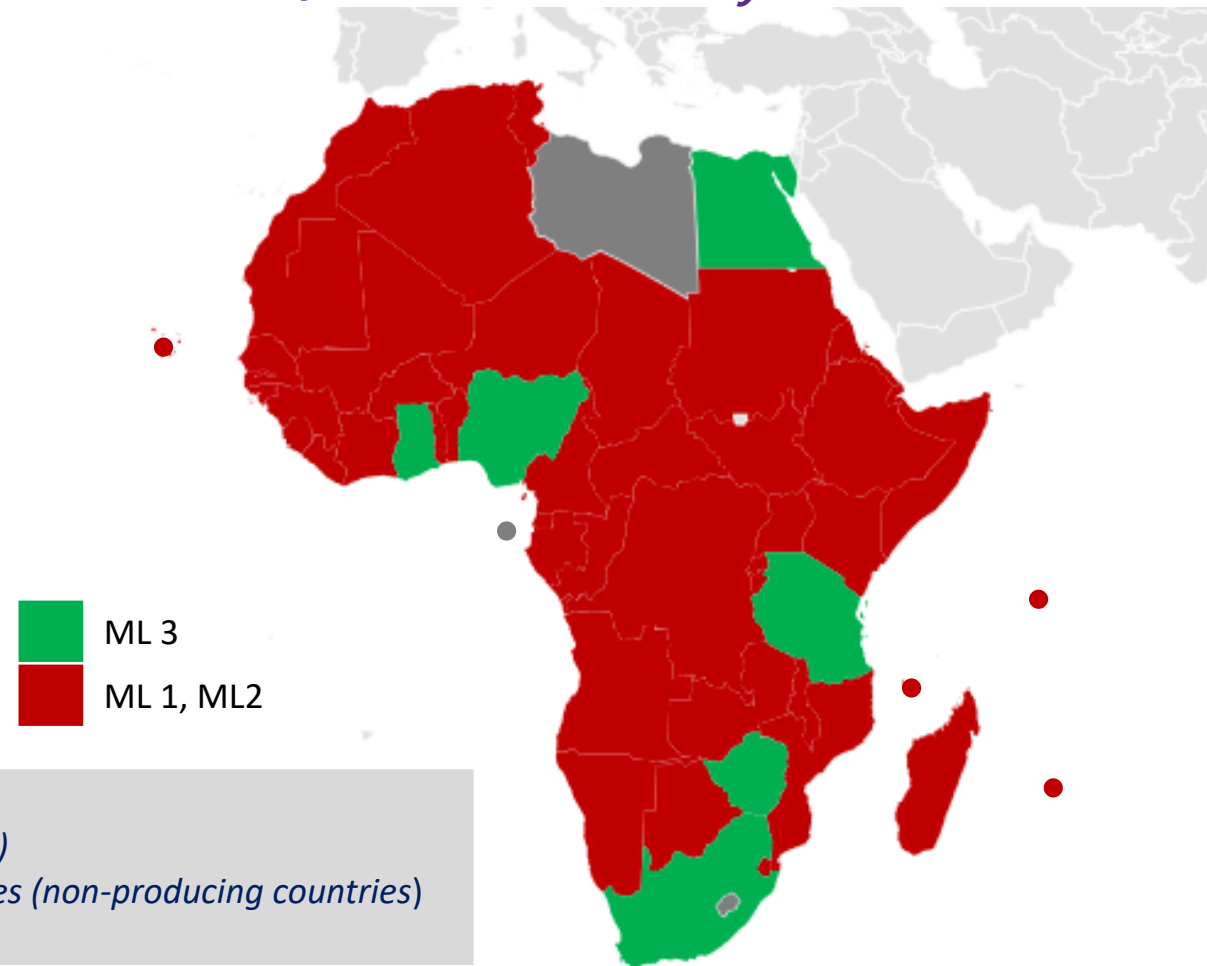
Six (6) countries have attained maturity level (ML) 3 according to WHO GBT

3 at ML 2 and several others expected to move to ML 2/ML 3 in the next 3-5 years



Results are based on NRA self-benchmarking and formal-benchmarking activities

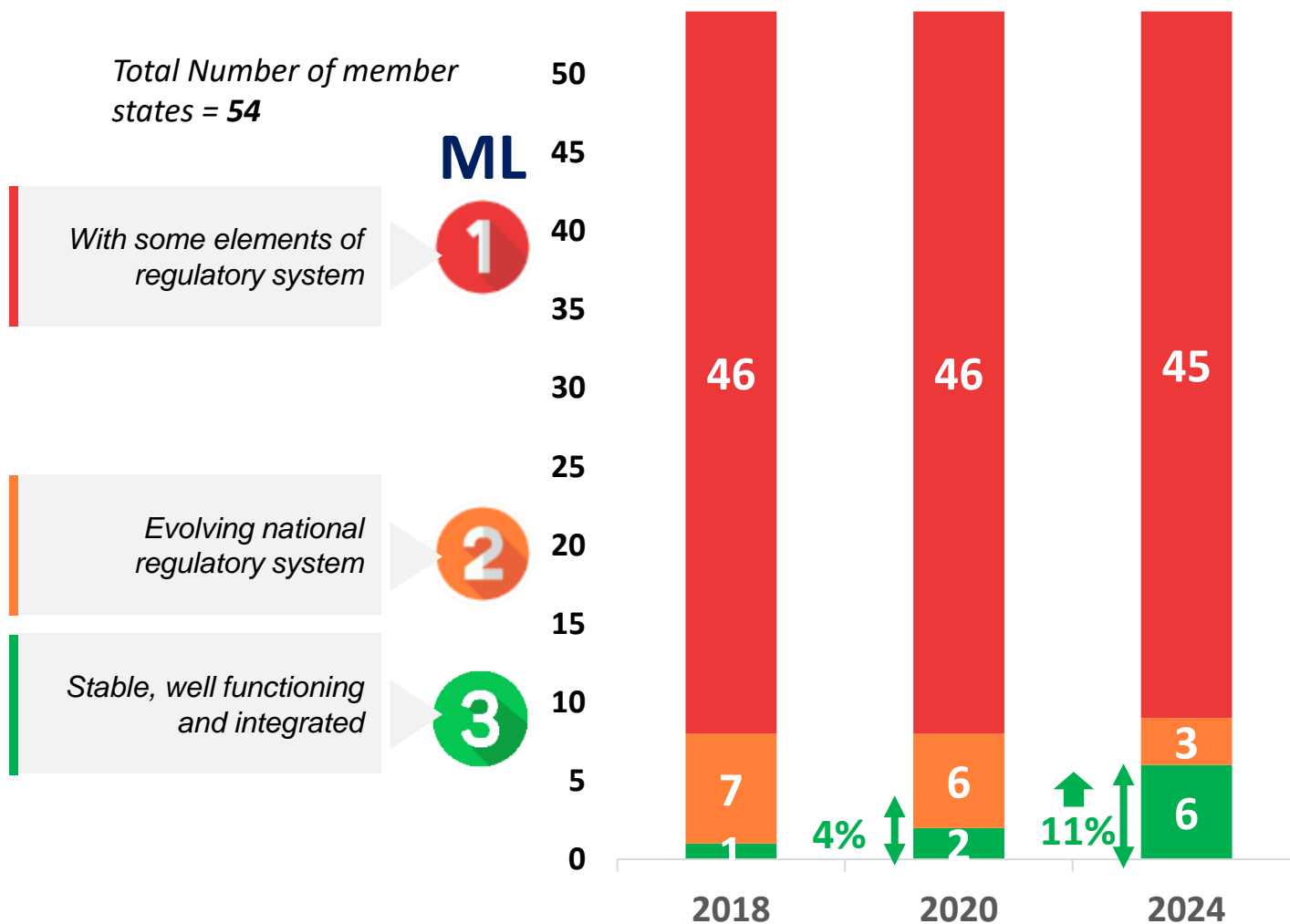
- Notes:**
- Egypt and South Africa are ML3 for regulation of vaccines (producing countries)
 - Ghana, Nigeria, and Tanzania are ML 3 for regulation of medicines and vaccines (non-producing countries)
 - Some island countries are referred to on the map as ● / ●



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization (WHO) concerning the legal status of any country, territory, city or area of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on map represent approximate border lines for which there may be not yet be full agreement.

Current status of national regulatory systems in Africa

(medicines and vaccines regulation, April 2024)



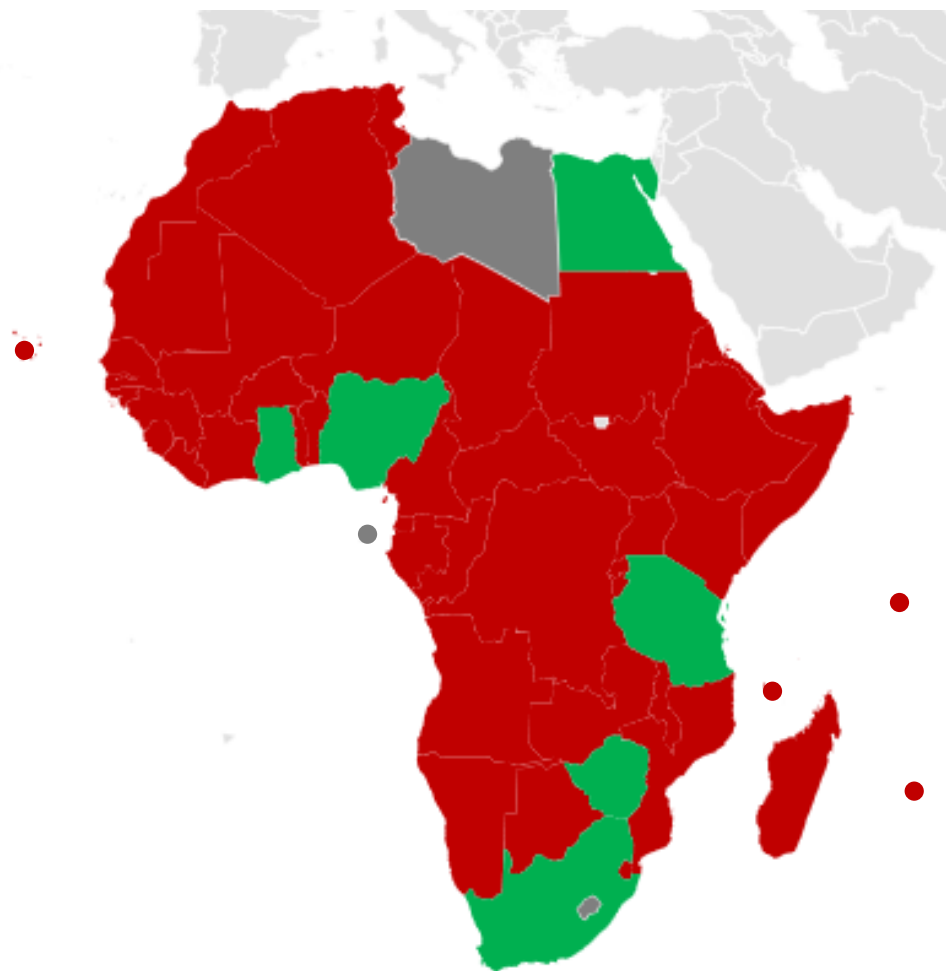
Countries with NRAs at ML 3

Country	Year
Egypt	2022
Ghana	2020
Nigeria	2022
South Africa	2022
United Republic of Tanzania	2018
Zimbabwe	2024
A?	2024
B?	2024

ML: (regulatory system) maturity level

Current status of national regulatory systems in Africa

Formal Benchmarking, 2016-2024



Country achieved ML 3 in Africa

- Egypt (Vaccine)
- Ghana
- Nigeria
- South Africa (vaccine)
- United Republic of Tanzania
- Zimbabwe

Re-benchmarking and maintenance of ML3

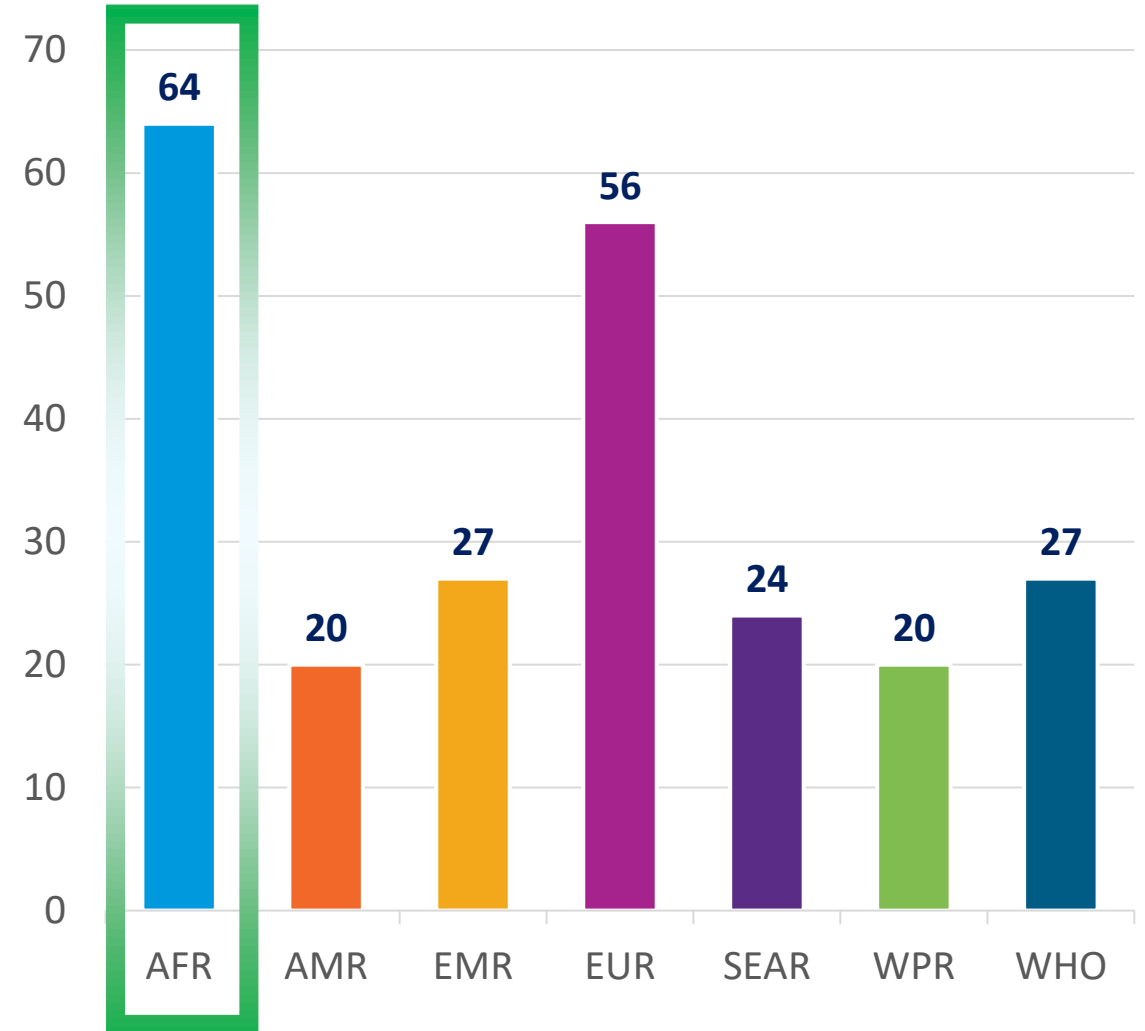
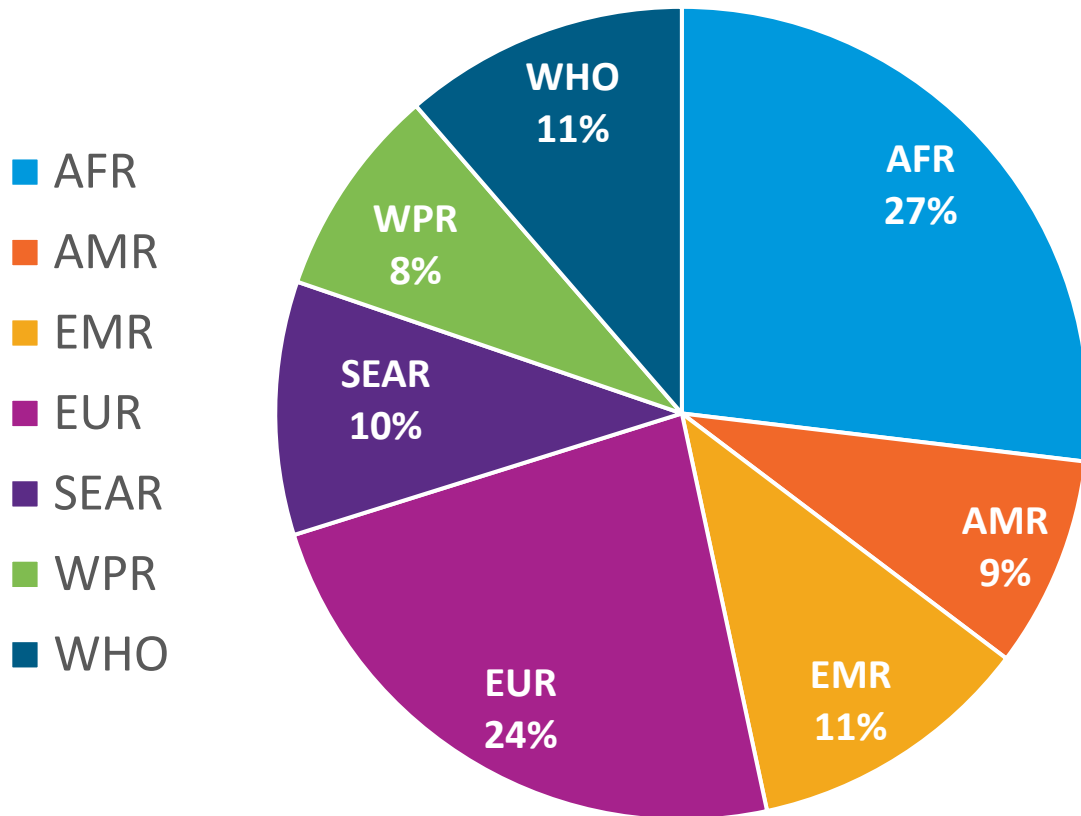
Country did not achieve ML 3 in Africa

- Burundi
- Eritrea
- Ethiopia**
- Kenya**
- Malawi
- Mozambique
- Rwanda**
- Senegal**
- Somalia
- South Sudan
- Sudan
- Uganda

IDP follow-up and technical support

Expanding a pool of experts for WHO GBT/WLA assessments from NRAs

A resource for countries to support self-benchmarking, IDP implementation, continuous improvement



WHO Workshop on GRP in the regulation of medical products

WHO – TRS No. 1033, Annex 11, 2021



First edition of GRP workshop

19-21 June 2024, Kunming, China

- Developed in 2023-2024
- Targeting Regulators and policymakers
- 2,5 Days including short theoretical sessions and extensive analysis of real case studies from BM and practical exercises



Excellent feedback received, mainly on:

- number and type of practical sessions
- modalities used to deliver theoretical and abstract concepts

WHO workshop on regulatory performance indicators (RPI)




- Developed in 2024
- To provide practical guidance on the development, implementation, and maintenance of RPIs
- Targeting regulators from QMS, technical regulatory and relevant administrative functions
- 3-day workshop composed of 8 modules

- **First edition: 24-26 June 2024, Kunming, China**
- **Second edition: Regional (AFRO and EMRO) 22-26 Sept. 2024, Amman, Jordan**



 **Performance indicators** developed for each regulatory function

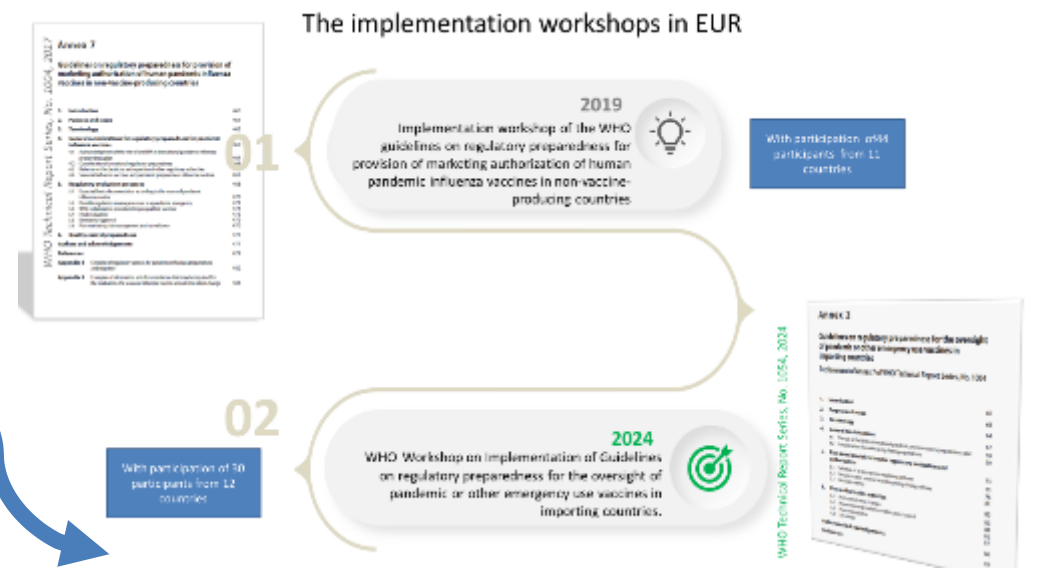
 **Very positive** feedback received

Guidelines on regulatory preparedness for the oversight of pandemic or other emergency use vaccines in importing countries

WHO academy course

The screenshot shows the course interface with a blue header, a title, a 'Register to start learning' button, and an 'Enroll' button. It also displays course details like 'Enroll by Jul 15th, 2024', 'Self-paced', 'English', and 'Started on Jul 15th, 2023'. Navigation tabs for 'Programme Overview', 'Modules', and 'Credentials' are visible.

The screenshot shows the WHO website page for 'TRS 1054 - Annex 2 - Guidelines on regulatory preparedness for the oversight of pandemic or other emergency use vaccines in importing countries'. It includes the WHO logo, navigation menu, and an 'Overview' section with a 'Download (228.5 kB)' button.



• <https://www.who.int/publications/m/item/trs1004-annex7-pandemic-influenza-vaccine>

WHO implementation workshops

Regulatory preparedness to authorize the use of pandemic vaccines in importing countries



The aim of this course is to improve national **competence in decision-making** to authorize the use and deployment of **pandemic vaccines** to address a public health emergency in a **timely and coordinated** manner in importing countries.



This course is based on the **WHO Guidelines on regulatory preparedness for the oversight of pandemic or other emergency use vaccines in importing countries**, published in TRS 1054, Annex 2, 2024, Replacement of Annex 7 of WHO Technical Report Series, No. 1004, 2017

The course is for:

- **National regulatory authorities.**
- **National disease control authorities** involved in disease control and response to public health emergencies.
- **National immunization programs** responsible for vaccine deployment.
- **WHO Country officers.**

Learning experience

This is a learner-centred, competency-orientated online course delivered in four self-paced modules:

- **Module 1 General considerations**
- **Module 2 Regulatory evaluation processes**
- **Module 3 Good regulatory practice, good reliance practice, risk assessment**
- **Module 4 Vaccine composition, quality control, safety and deployment**

Table-Top Simulation

a computer-simulation exercise with seemingly relevant realistic scenarios

Thank you

For more information, please go to our website:

<https://www.who.int/teams/regulation-prequalification/regulation-and-safety/rss>

Or contact: nra_admin@who.int

Regulatory Systems Strengthening [RSS] Team

Regulation and Safety [REG] Unit

Regulation and Prequalification [RPQ] Department

Access to Medicines and Health Products [MHP] Division

