# Implementing the WHO-listed authority framework
## *Achievements – Challenges – Benefits*

Anna Laura Salvati
WHO/RPQ/REG/RSS

*Joint UNICEF, UNFPA and WHO meeting with manufacturers and suppliers*
*SESSION 11*
**December 05th, 2024**

# Achievements

# The WLA initiative

## Replacing the concept of SRAs

Following ICH structural changes in 2015, need for replacing the term Stringent Regulatory Authority (SRA) and eligibility criteria based on the pre-reform membership to ICH

## Objectives

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 medical products

03 To optimize use of limited resources by facilitating reliance

# Milestones

## *and outlook for the future*

**2019**

Publication of concept note introducing WLAs at the request of Member States who were looking for an evaluation-based alternative to SRAs (which were based on membership)

**2020**

Public consultations, consultations with Member States, and international consultative meetings with Member States and interested stakeholders

**2021**

Publication of policy document on "Evaluating and publicly designating regulatory authorities as WHO-Listed Authorities"

**2022**

- Implementation of WLA framework
- Publication of the interim operational guidance and manual
- Kick off first three evaluations as a pilot
- Transitional WLA status granted to 57 RAs[1]

**2023**

- Piloting of the framework
- Publication of final OpG and PE manual
- First three WLAs listed

**2024-2027**

Ensure all NRAs on the *tWLA* list become WLAs or ML3/ML4

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

# First three WLAs

- 31st October 2023

SRA

*Switzerland*

**Swissmedic**

tWLA

*Republic of Korea*

**MFDS**

ML4 NRA

*Singapore*

**HSA**

# 33 new WLAs

- 20th May 2024

RRS/SRAs

*European Medicines Regulatory Network*

**EC/EMA**

**+**


**31 EU NCAs**

SRA

*United States of America*

**US FDA**

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

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

# Global situation as of November 2024


*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.*

# 58th ECSPP meeting, October 2024

Considering the successful implementation of the WHO-listed authority (WLA) framework

- A soon as all SRAs will complete the transition

**1**

The term "Stringent Regulatory Authority" (SRA) will be read as "WHO-listed authority"

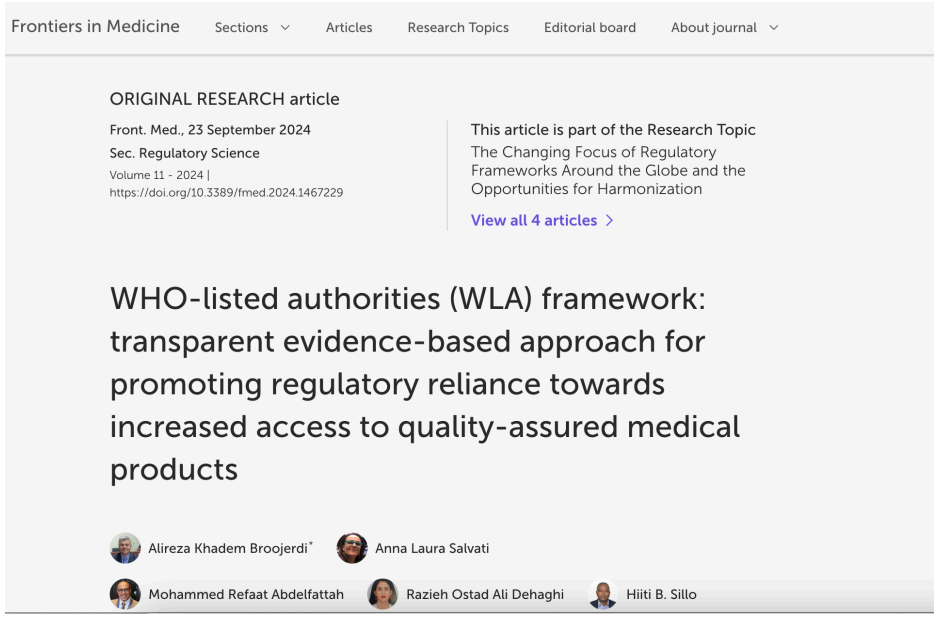
**2**

Applicable to all previously published norms and standards guidance, including all WHO Technical Report Series (TRS) and other documents endorsed by the **Expert Committee on Specifications for Pharmaceutical Preparations** (ECSPP), as well as any future updates or revisions of such documents

**3**

The terms SRAs (*medicines*) and highly performing NRAs (*vaccines*) will not be used in the future

# Challenges in implementing the framework




https://doi.org/10.3389/fmed.2024.1467229

# Challenges: *stakeholders' perspective*

## OTHER STAKEHOLDERS

**Unclear**
-ML *vs.* WLA

**Convoluted**
-Modular approach

**Risky**
-Limited time to transition

**Complex**

**Resource intensive**

## REGULATORY AUTHORITIES

# Challenge: UNCLEAR

*WLA Equations for reliance*

**UNCLEAR**
Understanding the difference between ML3/4 and WLA, specifically in terms of reliance and guiding procurement activities

The ultimate responsibility and decision for use of tWLA and WLA lists resides with the users (e.g., regulatory authorities, procurement agencies) and depends on the specific context of its intended use

**Reliance strategies should be:**

- scientifically sound
- evidence based
- proportionate to risks

**SRA/**

**Highly performing RA** = **WLA** *med. or vacc. all functions* > **ML3/4**

# Elements for performance evaluation of a regulatory system

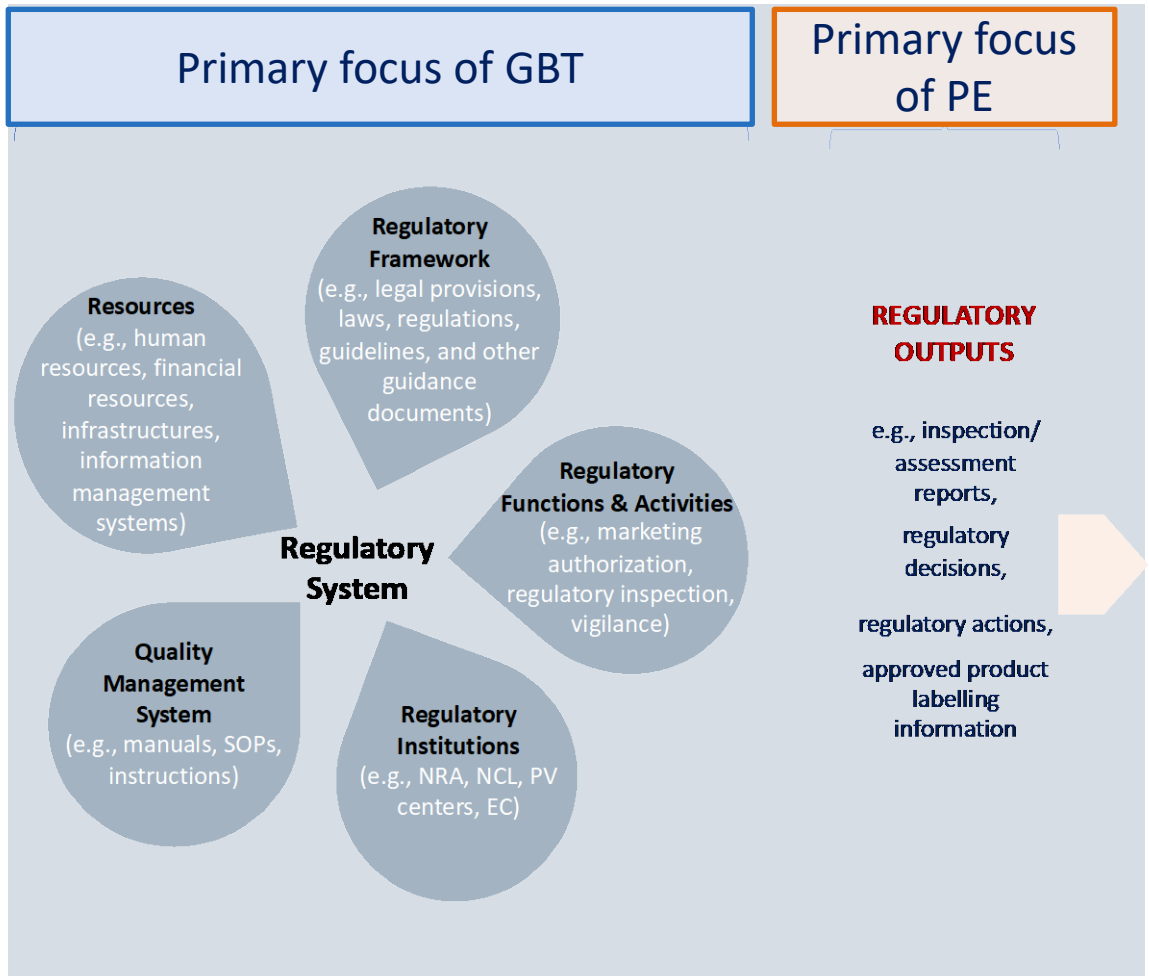
**UNCLEAR**
Understanding the difference between ML3/4 and WLA, specifically in terms of reliance and guiding procurement activities

**REGULATORY INPUTS**

**Manufacturers & Developers**
e.g.: MA/CT applications, Scientific Advice requests, Licensing applications, PV reports

**Healthcare system users, healthcare professionals**
e.g.: reporting ADR, market complaints

**Other stakeholders**
e.g.: patient/victim associations learned societies, media, trade associations, other NRAs




**REGULATORY OUTPUTS**

e.g., inspection/ assessment reports,

regulatory decisions,

regulatory actions,

approved product labelling information

**REGULATORY OUTCOMES**

e.g.,

increased compliance with regulatory requirements, rejection/recall of substandard and falsified products

**REGULATORY IMPACT**

e.g.,

access to safe, effective and assured quality medical products,

less substandard and falsified medical products on the market,

decreased morbidity/mortality

healthcare costs

**WLA**

# The example of MA

**UNCLEAR**
Understanding the difference between ML3/4 and WLA, specifically in terms of reliance and guiding procurement activities

## GBT

31 GBT sub-indicators (ML1, ML2 and ML3)

Legal provisions, Governance, Resources (HR, FR, infrastuctures and equipment), Regulatory processes, transparency, accountability and communication, M&E

## PE

3 mandatory ML4 GBT sub-ind
3 PE indicators
Expert review of 2-3 MAA assessments

Support to MAH (regulatory and scientific advice)
Compliance with timelines (efficiency)
Publication of regulatory actions (transparency)


| Evaluation Criteria | | No. of sub-indicators |
|---|---|---|
| 1. Application process | | 3 |
| 2. Assessment report | | |
| 2.1 | Quality of the report | 11 |
| 2.2 | Completeness of the report | 4 |
| 2.3 | Scientific rigour<br>2.3.1 Clinical<br>2.3.2 Quality<br>2.3.3 Non-clinical | 3 |
| 2.4 | Scientific opinions/Outcomes | 1 |
| 3. Assessment follow-up | | 2 |

# **Challenge:** CONVOLUTED
*the modular approach*

- Requested by Member States to ensure more **flexibility** in attaining the WLA designation

- Allows for the stepwise listing of specific regulatory functions or product categories

**CONVOLUTED**
**Modular approach**
- difficult to understand
- difficult tracking of listed functions and/or product categories
- acceptability for reliance?

COMPLEXITY
of decisions on reliance for stakeholders

COMPLEXITY
of the PE for candidate WLAs

# Modular approach towards listing

*Supporting reliance strategies through informed decisions*

CONVOLUTED
Modular approach
- difficult to understand
- difficult tracking of listed functions and/or product categories
- acceptability for reliance

**LISTING as WLA**

**PE**

**PE indicators**

ML4 mandatory

**GBT**

**ML3**

PE tools

PE ind.

mand. ML4

entry level

| RS | MA | VL | MC | LI | RI | LT | CT | LR |
|---|---|---|---|---|---|---|---|---|

# Modular approach towards listing: **MA**

CONVOLUTED
**Modular approach**
- difficult to understand
- difficult tracking of listed functions and/or product categories
- acceptability for reliance

**LISTING as WLA**

**PE**

| | |
|---|---|
| | **PE tools** |
| **PE indicators** | PE indicators |
| ML4 mandatory | ML4 mandatory |

**GBT**

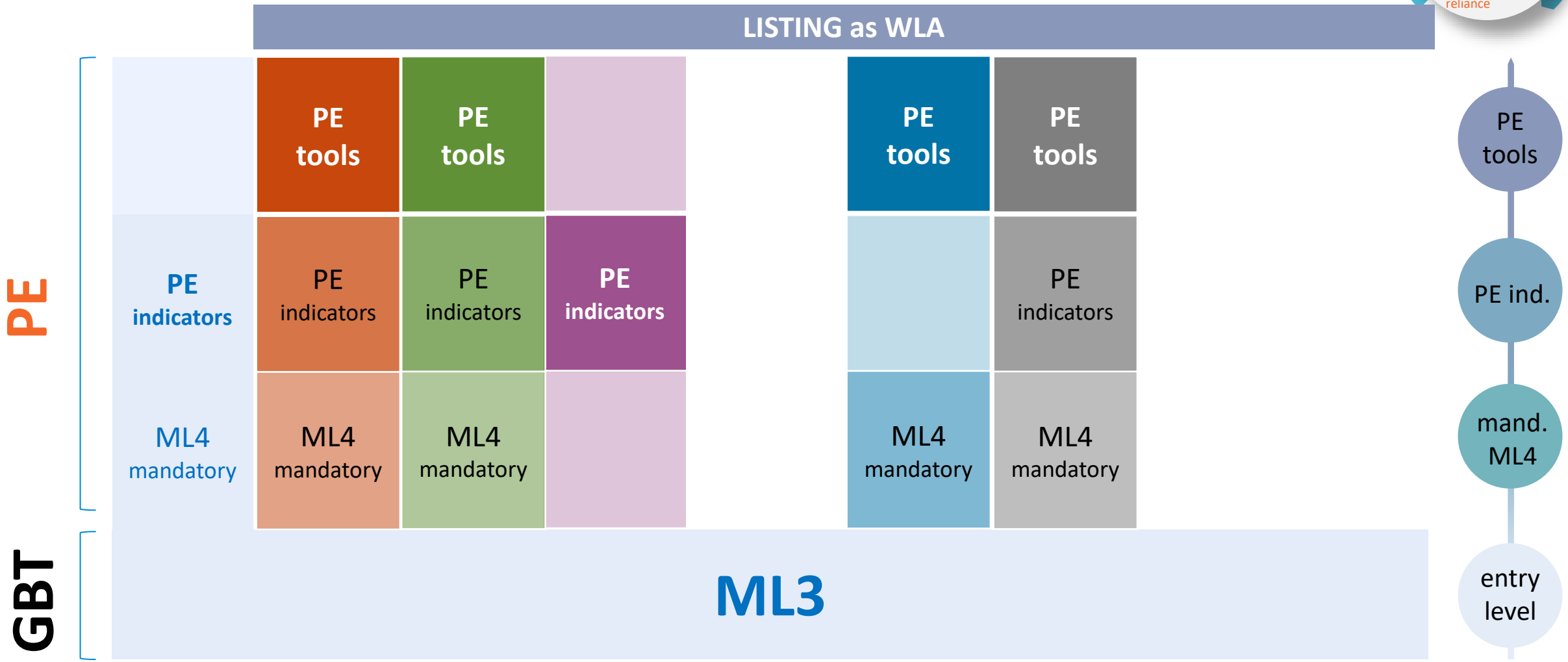
**ML3**

PE tools
PE ind.
mand. ML4
entry level

| RS | MA | VL | MC | LI | RI | LT | CT | LR |
|---|---|---|---|---|---|---|---|---|

# Modular approach towards listing: **MC**

CONVOLUTED
Modular approach
- difficult to understand
- difficult tracking of listed functions and/or product categories
- acceptability for reliance




| RS | MA | VL | MC | LI | RI GMP/GSDP | LT | CT | LR |
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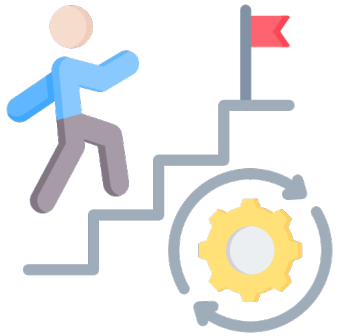
# Difficult tracking

CONVOLUTED
**Modular approach**
- difficult to understand
- difficult tracking of listed functions and/or product categories
- acceptability for reliance



May represent a challenge in the future

Currently, out of 36 WLAs:

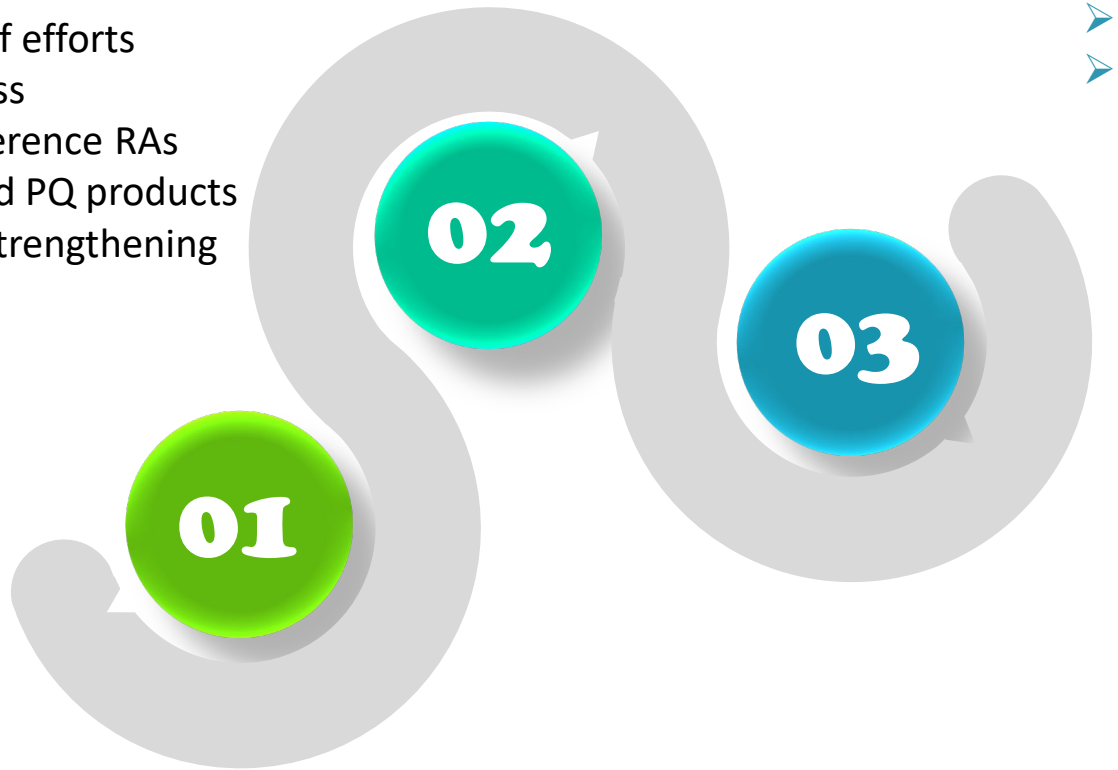
- 34 are listed in <u>all functions</u> in both product streams
- 1 is listed in <u>all functions</u> for medicines

# Challenge: RISKY

## *Considerations*

***PE prioritization of candidate WLAs***

- Chronology
- Anticipated level of efforts
- Estimated readiness
- Recognition of reference RAs
- Potential to expand PQ products
- Cooperation and strengthening of other RAs
- Transparency




***Risk-based evaluation pathways & recognitions***

- Routine arrangements (***standard*** pathway)
  *Vs*.
  transitional arrangements (***abridged*** and ***streamlined*** pathways)

**WHO advocacy for the framework**

- Actively promoting awareness
- Participating in several discussion *fora*
- Arranging *ad hoc* meetings/workshops
- Providing explanations and clarifications at each request

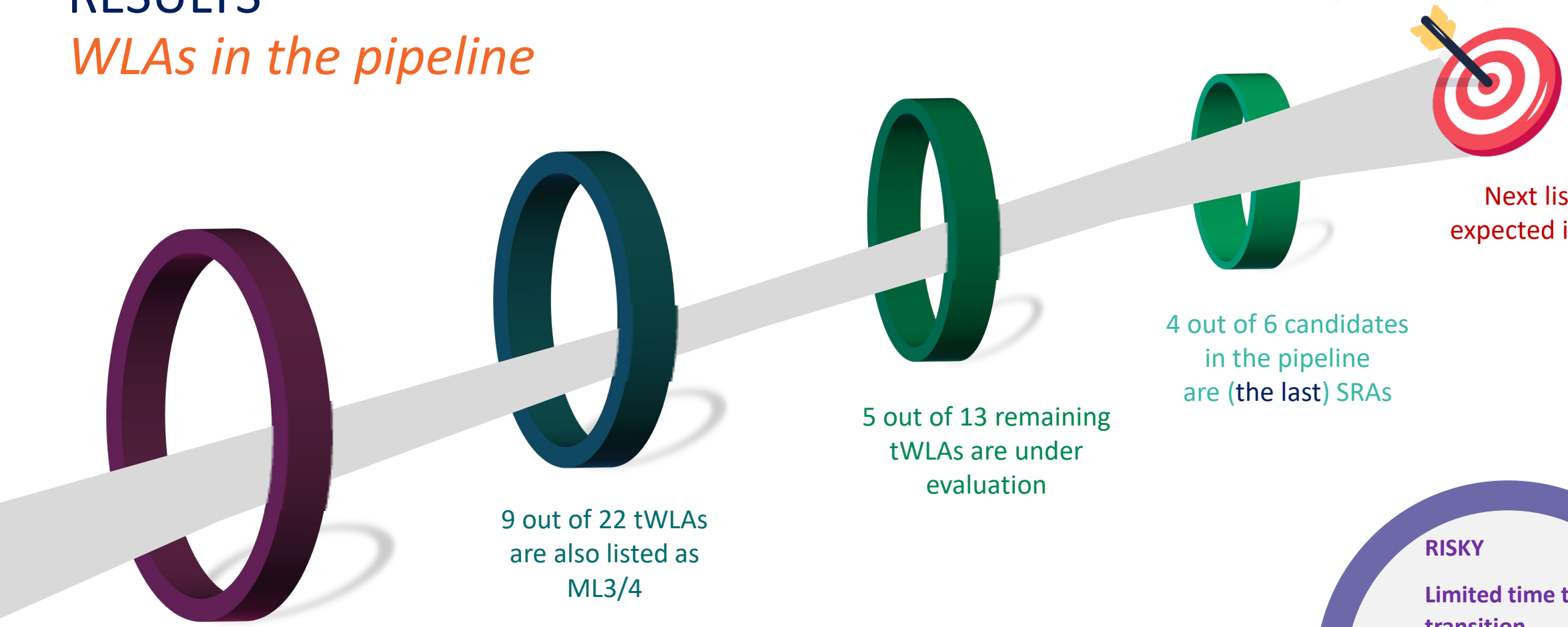
**RISKY**

**Limited time to transition**

- risk of procurement disruption
- impact on PQed products
- scarce resources or different priorities

# RESULTS

## *WLAs in the pipeline*



22 out of 57 tWLAs remaining in the list

9 out of 22 tWLAs are also listed as ML3/4

5 out of 13 remaining tWLAs are under evaluation

4 out of 6 candidates in the pipeline are (the last) SRAs

Next listing expected in 2025

**RISKY**

**Limited time to transition**

- risk of procurement disruption
- impact on PQed products
- scarce resources or different priorities

# **Challenges**: COMPLEX & RESOURCE INTENSIVE for candidate WLAs *(& for WHO)*

## Complex & resource intensive

- Granularity of requirements
- **Transparency *vs.* confidentiality**
- Inputs form multiple centers/depts
- Pressure to achieve (*political and from manufacturers*)
- Engagement of experienced staff (*task force*)
- Top management/gvt involvement
- Laborious

# Considerations

## Complex & resource intensive

- Granularity of requirements
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- Engagement of experienced staff (*task force*)
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## Rationale

1. Outcome of extensive **consultations**
2. Ensures **completeness** and **robustness** of the process
3. Promotes the **adoption of GRP**
4. **Transparency** leads to **trust** and **trust** leads to **reliance**
5. Focuses on the **regulatory system as a whole**
6. **Not all RAs are expected to become WLAs now**

# Benefits

# Perceived benefits and potentials

- Evidence-based, objective and transparent process
- Promotes investments in regulatory systems to reach higher standards
- Allows more equitable geographical distribution of trusted authorities adopting GRP
- Contributes to significantly strengthen trust among the population
- Allows abbreviated pathways (faster registration), increasing global access to medicines/vaccines
- Facilitates the adoption of recognition agreements, promoting awareness and confidence, with the potential to lead to regulatory convergence
- Potential to streamline procuring processes, shortening and improving the supply chain (reducing shipping times, mitigating risks of disruptions and increasing flexibility in meeting local demand)

# Resources

**WLA resources**

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


Regulatory Systems Strengthening **[RSS]** Team
Regulation and Safety [REG] Unit
Regulation and Prequalification [RPQ] Department
Access to Medicines and Health Products [MHP] Division
World Health Organization (Geneva, Switzerland)

# WLA impact on prequalification of medical products

## Session 11: Regulatory Updates from WHO and Partners

Joint UNICEF-UNFPA-WHO meeting
05 December 2024

Rogerio Gaspar
Unit Head, a.i., WHO Prequalification
Director, Department of Regulation and Requalification
Division of Access to Medicines and Health Products

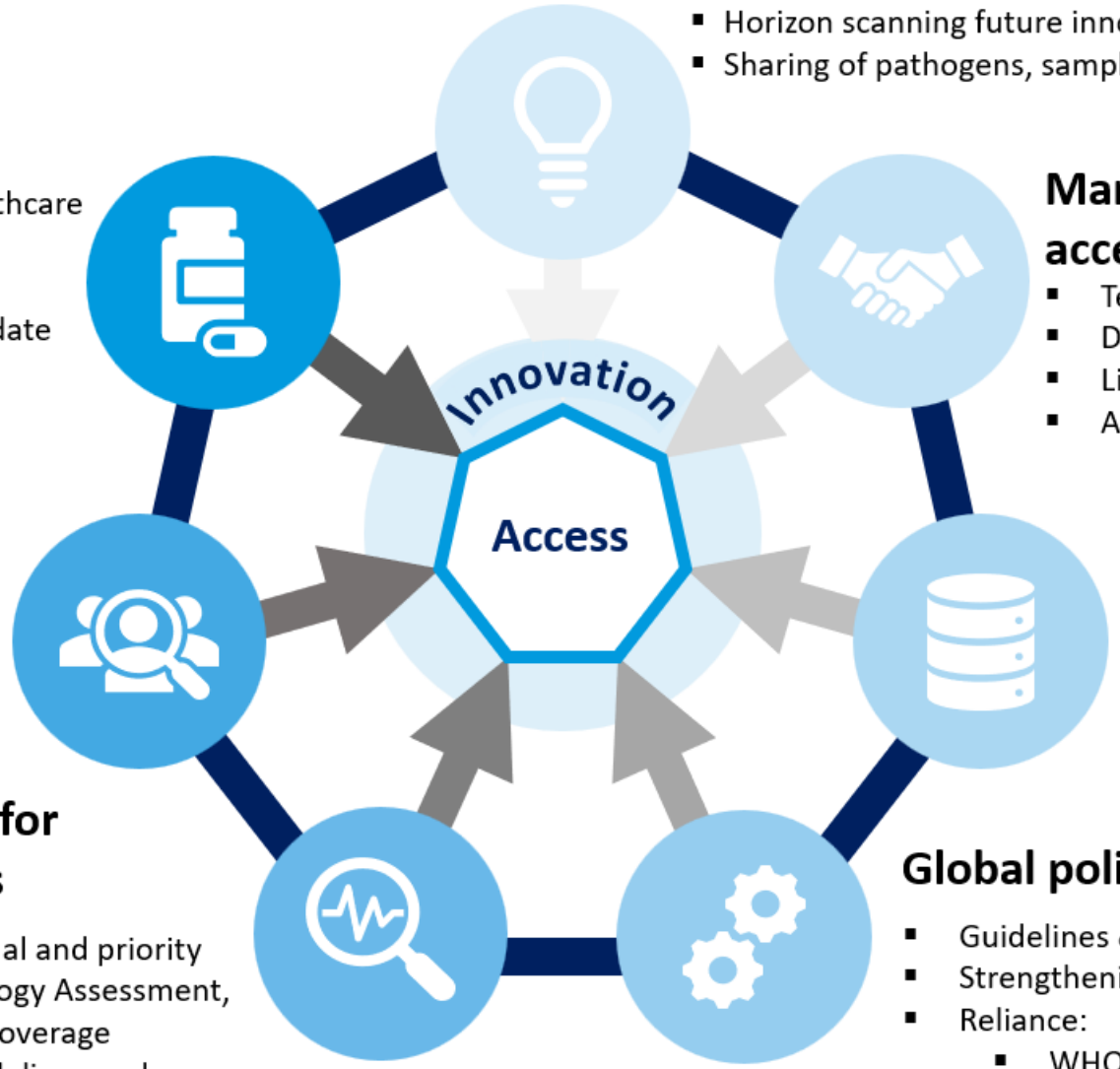
# WHO systematic approach for Accelerating Access

## Science, R&D & Innovation

- Convene and catalyze science
- Facilitate multi-centre trials
- Horizon scanning future innovation
- Sharing of pathogens, samples and access to products

## Impactful use

- Health-care Infrastructure
- Sustained capacity for healthcare workers
- Workflow integration
- Implementation research & update
- Digital Health and Innovation




## Management of IP & Market access

- Technology and knowledge transfer
- Design target product profiles
- Licensing
- Accelerated equitable access schemes

## Selection, procurement & supply

- Technical specifications
- Standardized Nomenclature
- Market shaping

## Manufacturing

- Sustained high quality manufacturing
- Training and quality assurance
- Regional production

## National Policy for health products

- Guidance for essential and priority lists, Health Technology Assessment, sustained financial coverage
- Integrate global guidelines and evidence into national policy

## Global policy & regulation

- Guidelines & normative functions
- Strengthening Regulatory Capacity
- Reliance:
  - WHO Listed Authorities
  - Pre-Qualification

# WHO Division of Access to Medicines and Health Products (MHP)

Assistant Director General
**Yukiko Nakatani**

## Dept. Health Products Policy and Standards (HPS)

**Deus Mubangizi**

| Technical Standards & Specifications<br>Deus Mubangizi (a.i.) | INN & classification of medical products<br>Raffaella Balocco | Access to Health Product Policies<br>Deus Mubangizi (a.i.) |
|---|---|---|
| Norms & Standards for Biological products | | Assistive Technology |
| Norms & Standards for Pharmaceuticals | | Medical Devices & Diagnostics |
| Blood & other products of human origin | | Essential Medicines List |
| Expert Committee on Drug Dependence | | |

## Dept. Regulation and Prequalification (RPQ)

**Rogério Gaspar**

Knowledge Management Advisor

Quality Management Advisor

| Prequalification<br>Rogério Gaspar (a.i.) | Regulation and Safety<br>Hiiti Sillo |
|---|---|
| Inspection Services | Regulatory Systems Strengthening |
| IVD Assessment | Regulatory Convergence and Networks |
| Medicines Assessment | Facilitated Product Introduction |
| Vaccines & Immunization Devices Assessment | Laboratory Network and Services |
| Vector Control Products Assessment | Pharmacovigilance |
| Medical Devices | Incidents and Substandard / Falsified Medical Products |

## Dept. Innovation and Emerging Technologies (IET)

**Deus Mubangizi (a.i.)**

| Local Production & Assistance<br>Jicui Dong | HTAP & mRNA Technology Transfer Team |
|---|---|
| | Heath Technology Access Management Team |
| | Special Assistance & Projects Team |

September 2024

**Access to Medicines & Health Products (MHP)**

Assistant Director General
**Yukiko Nakatani**

**Regulation and Prequalification (RPQ)**
**Rogério Gaspar**

Knowledge Management Advisor

Quality Management Advisor

**Prequalification**
**Rogério Gaspar (a.i.)**

- Inspection Services
- IVD Assessment
- Medicines Assessment
- Vaccines & Immunization Devices Assessment
- Vector Control Products Assessment
- Medical Devices

**Regulation and Safety**
**Hiiti Sillo**

- Regulatory Systems Strengthening
- Regulatory Convergence and Networks
- Facilitated Product Introduction
- Laboratory Network and Services
- Pharmacovigilance
- Incidents and Substandard / Falsified Medical Products

# Mandate:
# Regulation and Prequalification Dept.

To support Member States in strengthening robust, resilient and reliable regulatory systems through diverse, tailored approaches that ensure the quality, safety, effectiveness and accessibility of medicines, vaccines and other essential health products supplied to low-income countries, reaching populations in need.

# Prequalification: Ensuring quality-assured medical products (Dec 2023)

## Diagnostics

In vitro diagnostics (IVD), male circumcision device (MCD) & Emergency Use Listing (EUL)

- Cholera
- G6PD
- Glucose meter & test strips*
- HbA1c point of care test*
- Hep B
- Hep C
- HIV/AIDS
- HPV
- Malaria
- SARS-CoV-2
- Syphilis
- Tuberculosis

**113** IVDs, **1** MCD

EUL: **40** COVID-19, **6** Ebola, **4** Zika

* Completed the development of technical specifications

## Medicines

Finished pharmaceutical product (FPP), active pharmaceutical ingredient (API), quality control lab (QCL), biotherapeutic product (BTP) & similar biotherapeutic product (SBP)

- BTP/SBP (cancer, COVID-19, insulin)
- Child health
- COVID-19
- Diarrhoea
- Ebola virus diseases
- Hep B
- Hep C
- HIV/AIDS
- Influenza
- Malaria
- MDR bacterial infections
- Neglected tropical diseases
- New-born & young infants**
- Nicotine replacement therapy**
- Reproductive health
- Tuberculosis

**657** FPPs (inc. **15** BTPs, **12** SBPs), **168** APIs, **58** QCLs

** Call for expression of interest issued. No PQed product yet

## Medical devices

Immunization device (ImD) & cold chain equipment (CCE)

- Cold/freezer room
- Cold box & Vaccine carrier
- Cold chain accessory
- Coolant pack
- Injection device for vaccine
- Injection device for therapeutic
- Refrigerated vehicle
- Refrigerator & freezer
- Temperature monitoring device
- Waste management equipment

**443** ImDs/CCEs

## Vaccines

Vaccine (Vx), snake antivenom & Emergency Use Listing (EUL)

- 24 priority diseases, covering all vaccines required for routine immunization
- Cholera
- COVID-19
- Dengue
- Ebola virus diseases
- Malaria
- Snake antivenom

**151** Vx, EUL: **13** Vx

## Vector control

Vector control product (VCP) & active ingredient

- Aircraft disinfection product
- Indoor residual spraying product
- Insecticide-treated net
- Larvicide
- Space spraying product

**87** VCPs

## Inspection

- BTP, SBP
- FPP, API
- ImD
- IVD
- VCP
- Vaccine
- Bioequivalent study
- Clinical trial
- Laboratory

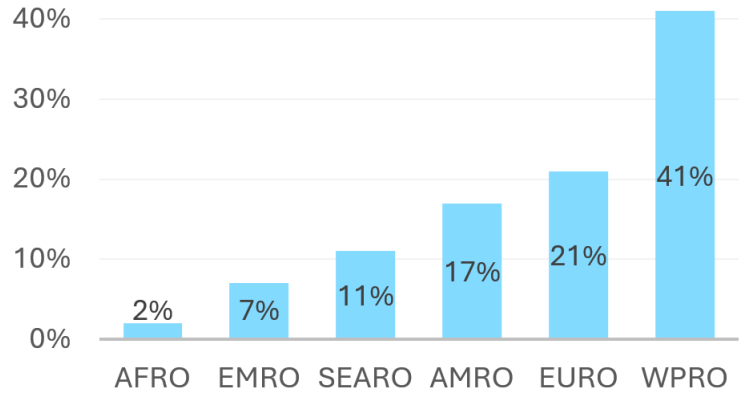
**636** inspections (2020–2023)

Cumulative numbers of PQed/EULed products as of December 2023

# Vaccine manufacturing capacity: limited in some regions

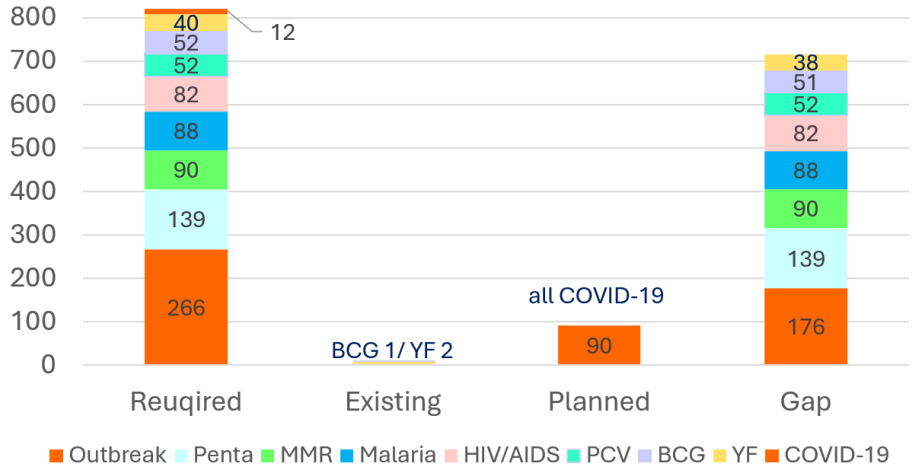
World Health Organization

**% Vx manufacturers based on their HQ locations[1]**




[1] WHO Global vaccine market report 2022

**African Vx manufacturing capacity**
**Required, existing, planned DS production and gaps[2]**

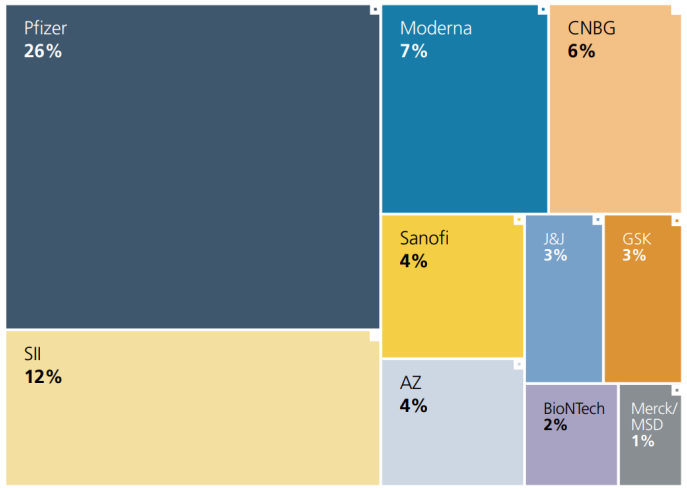



DS: drug substance

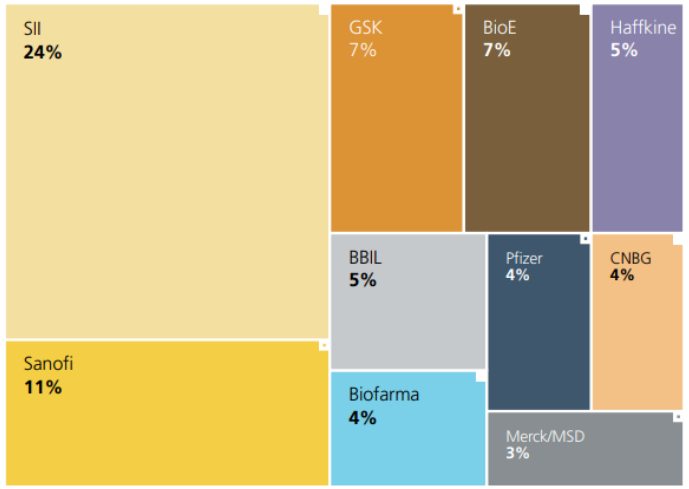
[2] Partnerships for African Vaccine Manufacturing (PAVM) 2022

**2022 Top 10 manufacturers by volume[3]**

including COVID-19



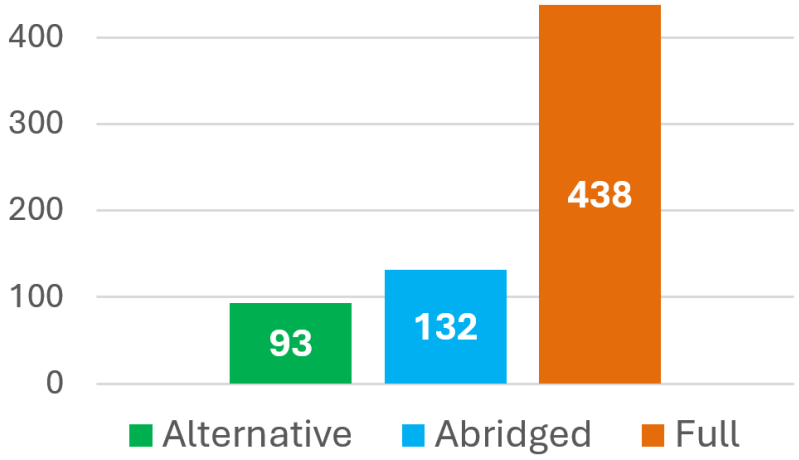

excluding COVID-19




[3] WHO Global vaccine market report 2023

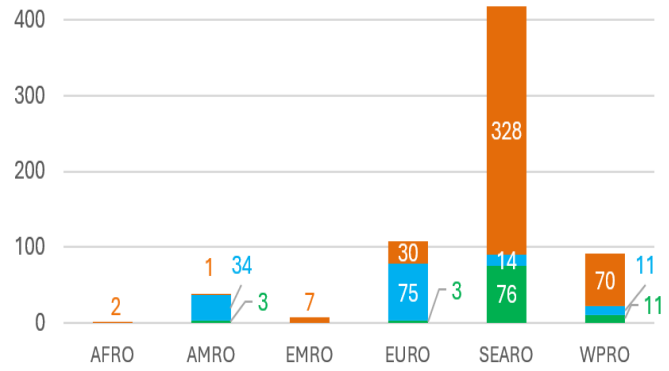
# **Prequalified FPPs:** (663 PQed FPPs as of 04 Dec 2024)

## PQ FPPs per assessment type

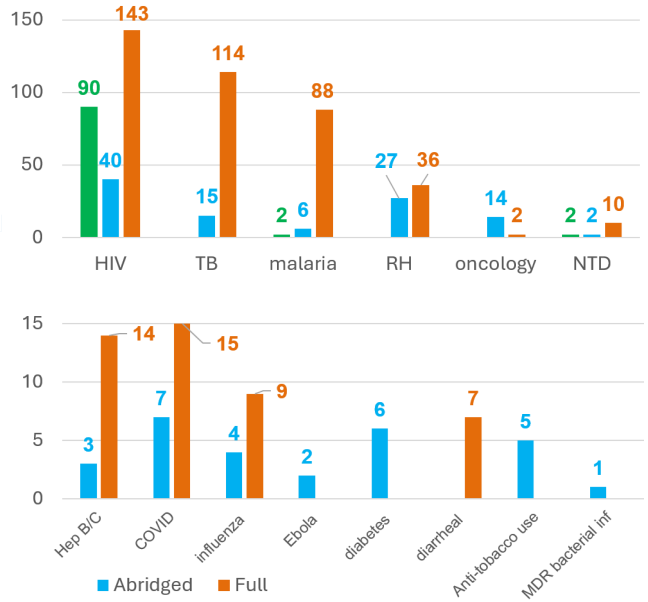



Alternative: EU-M4all, Health Canada Access programme, US FDA PEPFA

## PQ FPPs per WHO region




## FPPs: therapeutics area

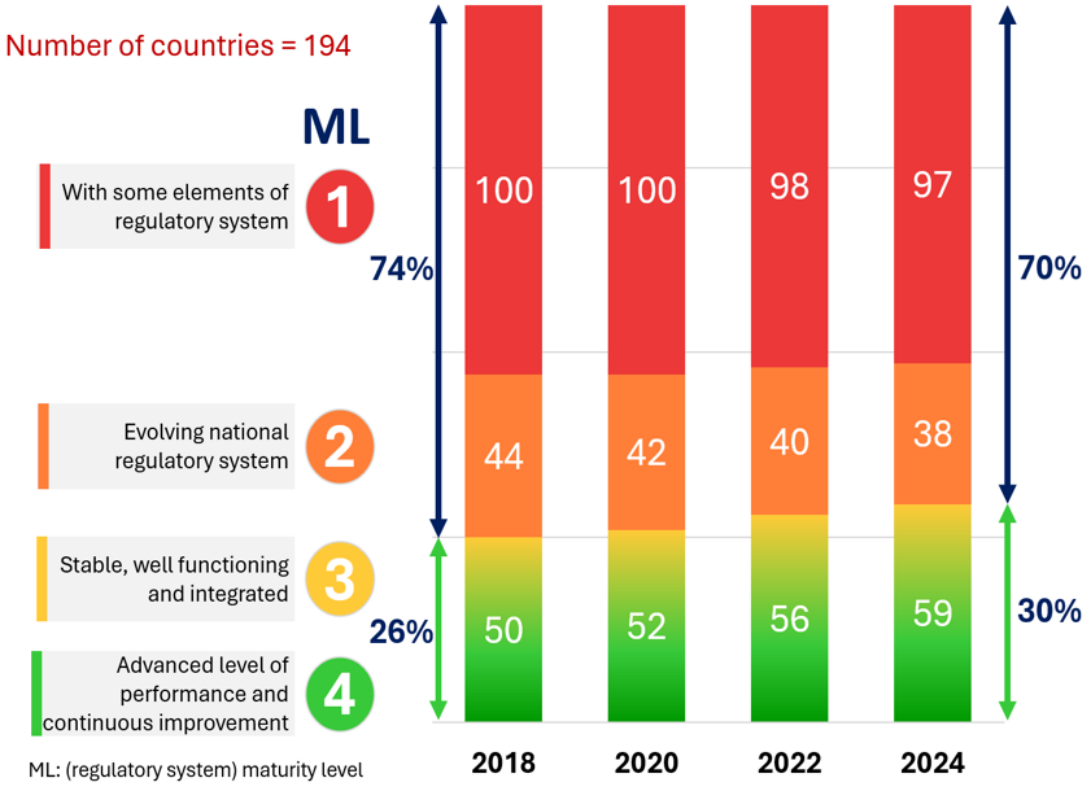



| FPPs: Abridged | |
|---|---|
| Country | # PQed FPPs |
| USA | 34 |
| Germany | 15 |
| India | 13 |
| UK | 9 |
| Romania | 8 |
| Switzerland | 8 |
| South Korea | 6 |
| Greece | 5 |
| Spain | 5 |
| Sweden | 5 |
| Denmark | 4 |
| Austria | 3 |
| Ireland | 3 |
| Portugal | 3 |
| Australia | 2 |
| Belgium | 2 |
| China | 2 |
| Italy | 2 |
| Bangladesh | 1 |
| France | 1 |
| Japan | 1 |
| Latvia | 1 |
| Slovenia | 1 |

| FPPs: Full assessment | | |
|---|---|---|
| Country | # PQed FPPs | # companies |
| India | 319 | 26 |
| China | 54 | 17 |
| Singapore | 11 | 1 |
| Spain | 7 | 2 |
| Switzerland | 5 | 4 |
| Bangladesh | 4 | 4 |
| France | 4 | 2 |
| Indonesia | 4 | 4 |
| Netherlands | 4 | 1 |
| Pakistan | 4 | 3 |
| South Korea | 4 | 2 |
| Ukraine | 4 | 3 |
| Egypt | 3 | 2 |
| Germany | 3 | 2 |
| Latvia | 3 | 2 |
| Nigeria | 2 | 1 |
| Brazil | 1 | 1 |
| Japan | 1 | 1 |
| Thailand | 1 | 1 |

# Global status of national regulatory systems

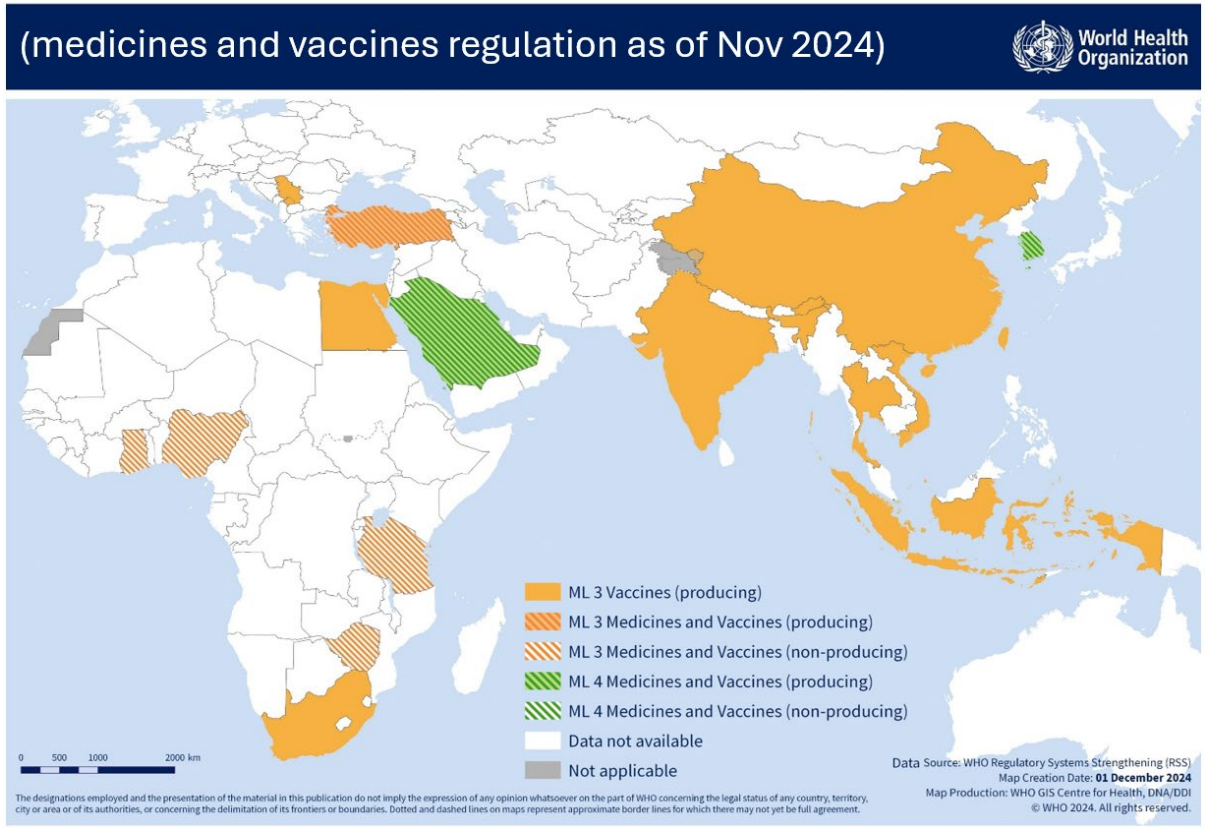
(medicines and vaccines regulation as of Nov 2024)




- Vaccines produced in countries with ML 3/4 NRAs are eligible for PQ or EUL
- ML3/4 NRAs are eligible for becoming WLAs

Source: WHO RSS database, June 2024

## NRAs benchmarked as ML3 / ML4 with GBT



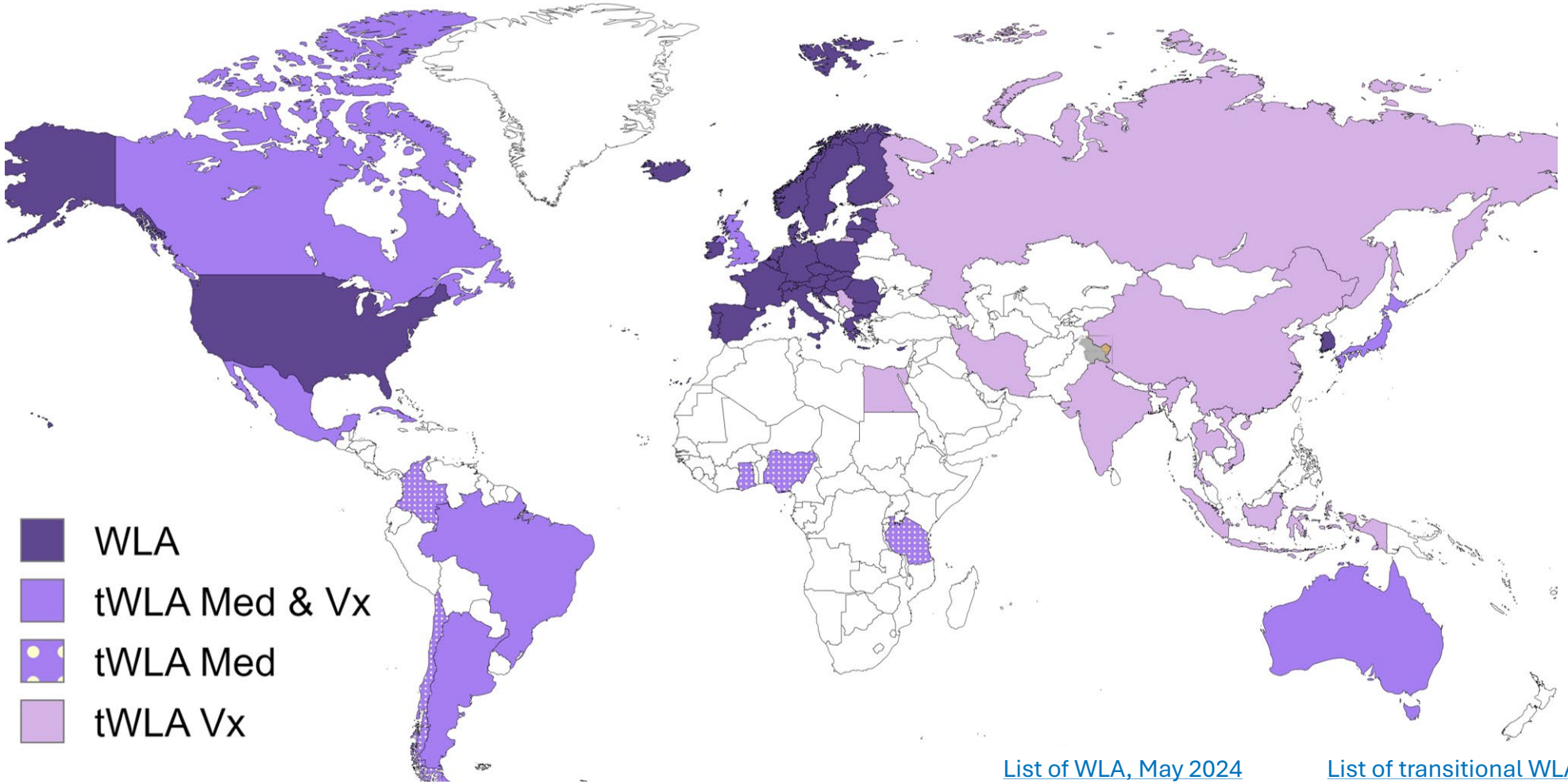

NRA: National Regulatory Authority
GBT: WHO Global Benchmarking Tools

List of ML3 and ML4 NRAs, June 2024

# WHO Listed Authorities (WLA) & transitional WLA (tWLA)

WLA: 36 regulatory agencies from 34 countries, 33 member states as of Nov 2024

tWLA ends on **31 March 2027**




List of WLA, May 2024

List of transitional WLA, May 2024

# Working together to build and strengthen Robust, Resilient and Reliable Regulatory Systems

as an enabler to access, from universal health coverage to emergencies response

## WHO Collaborative Registration Procedure

Global Health Products Procedures: EU-M4all / Swissmedic MAGHP

### Promoting / implementing

- Good regulatory practices
- Good **reliance** practices
- Regulatory collaboration, convergence & harmonization

## Partnership is key: Coalition of Interested Parties (CIP)

*Voluntary WHO-led Network for Regulatory systems Strengthening, launched in 2021*

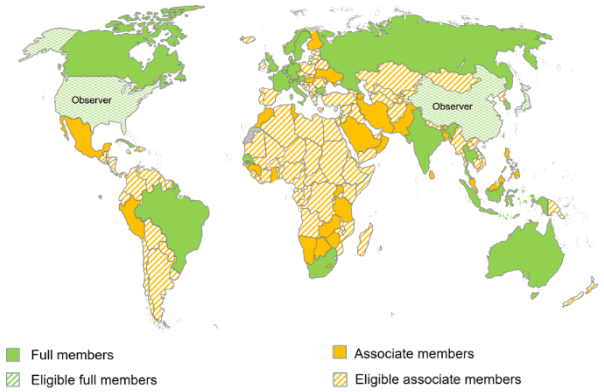
| 30 Members: *26 + 4 observers* | 6 Regions 36 Countries | 288 Activities | Over $125m investment |
|---|---|---|---|

*As of Nov 2024*

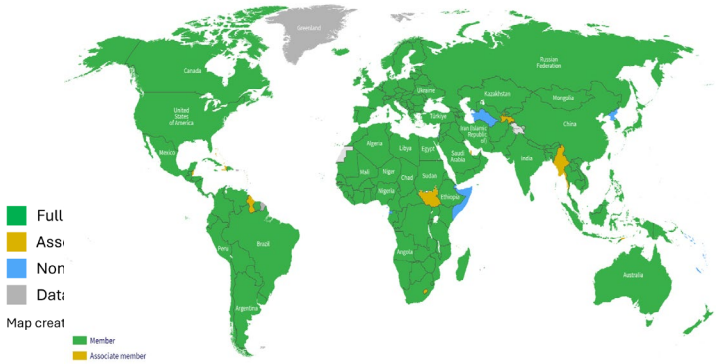
CIP Network website

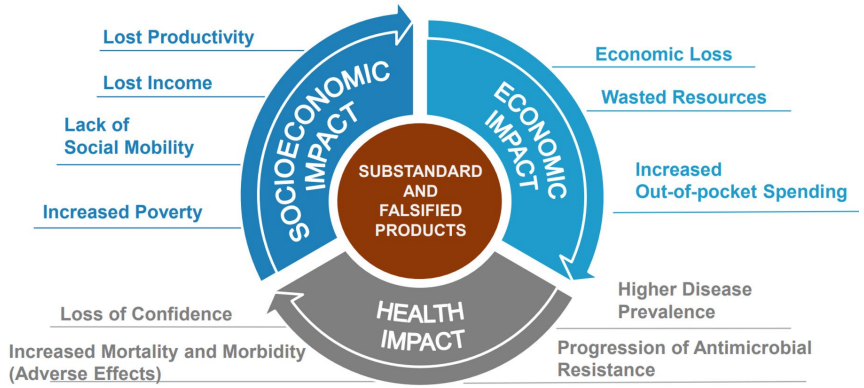
Observers: CIRS, IFPMA International Federation of Pharmaceutical Manufacturers & Associations, University of Hertfordshire UH

## WHO National Control Laboratory Network for Biologicals




## International Drug Safety – adverse events - Monitoring





# Working together !!!

**Subscribe to**
**WHO RPQ NEWSLETTER**

Regulation and Prequalification (who.int)

# WHO Coalition of Interested Parties Network

## *CIP updates and way forward*

**Engy Elhosary**
*Technical officer*
*WHO/RPQ/REG/RSS*

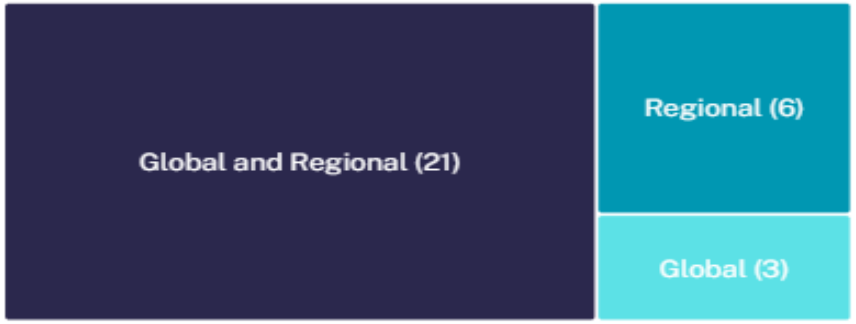
*Joint UNICEF, UNFPA and WHO meeting with manufacturers and suppliers*
*Session11*
*December 05th, 2024*

# CIP Network Members

**30 CIP NETWORK MEMBERS**

Participants: 26

Observers: 4




**NUMBER OF CIP MEMBERS**

By level of engagement

# CIP Network Members

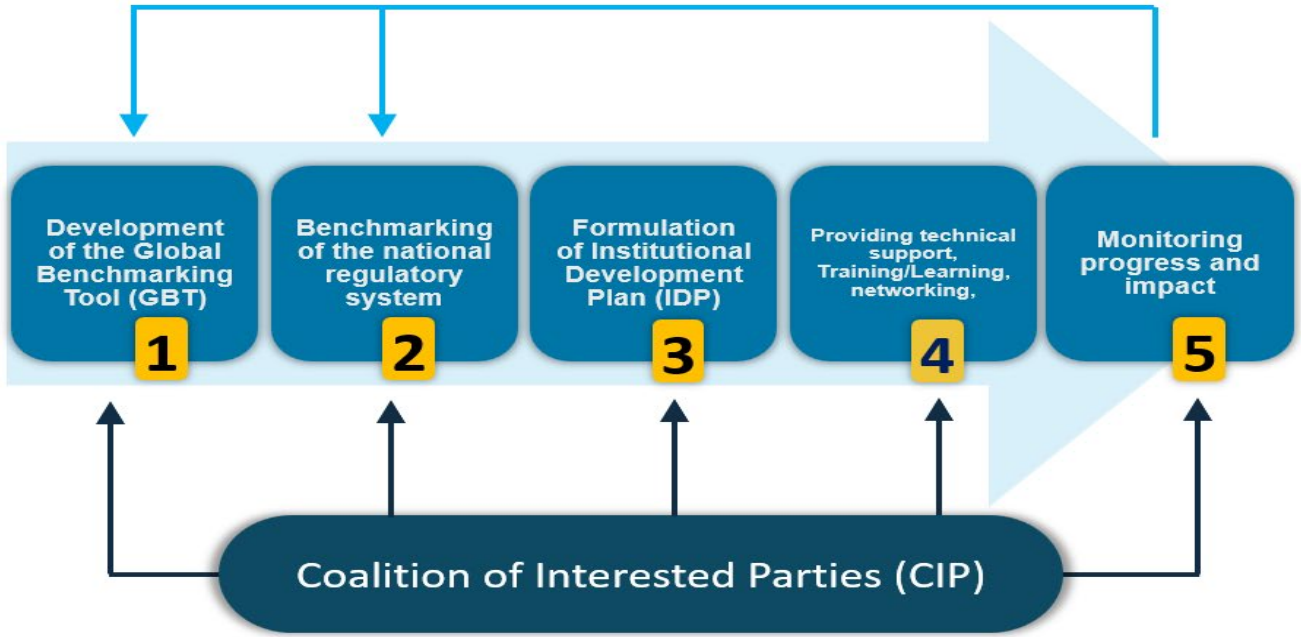
*Observers:*

# Scope of CIP Network activities

**1. The CIP Network's activities span the life cycle of regulatory systems strengthening activities**

**2. The WHO five-step capacity building model guide the roles and activities of CIP Networks members**

**3.The network and scope of collaboration between the NRA and the CIP Network members will be agreed upon and documented in CIP Toolkit**




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

# Benefits of Participation

## Enhanced regulatory capacity

- Capacity building
- Access to expertise and tools
- Financial resources
- Sustainability

## Strengthened international collaboration

- Harmonization and standardization
- Networking opportunities
- Joint projects and initiatives

## Improved public health outcomes

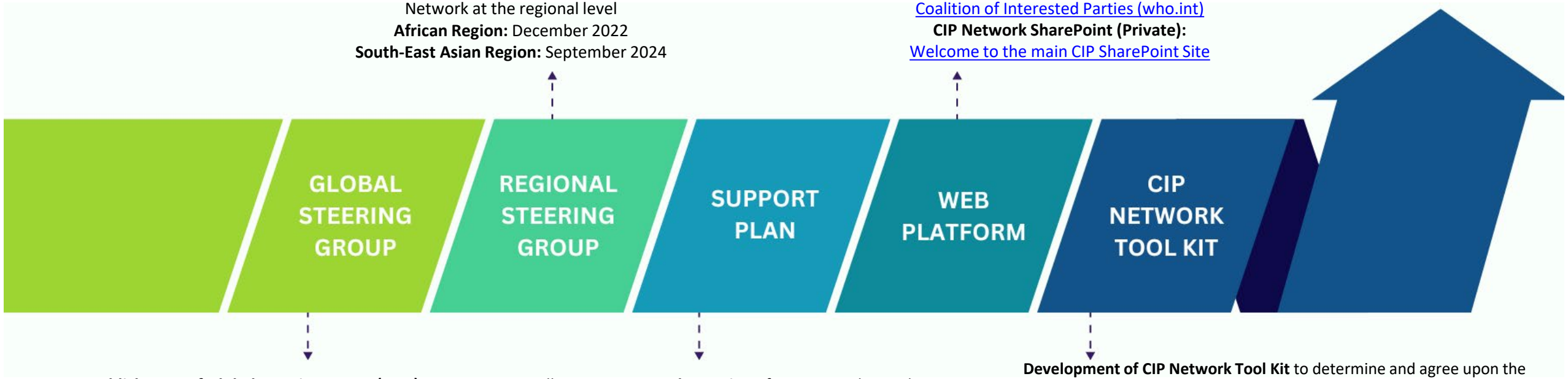
- Increased access to quality, safe, effective and affordable medical products
- Enhanced surveillance and response to public health threats and challenges

# Operationalization of the CIP Network

# Operationalization of the CIP Network

**Establishment of Regional Steering Groups (RSGs)** to oversee overall strategic direction, strategic planning, priorities and effectiveness of the Network at the regional level
**African Region:** December 2022
**South-East Asian Region:** September 2024

**Establishment of CIP Network web platform**, a central, secure repository for sharing confidential information
**CIP Network website (Public):**
Coalition of Interested Parties (who.int)
**CIP Network SharePoint (Private):**
Welcome to the main CIP SharePoint Site




**Establishment of Global Steering Group (GSG)** to oversee overall strategic direction, strategic planning, priorities and effectiveness of the Network at the global level
**1st GSG meeting:** Geneva, Switzerland, November 2022
**2nd GSG meeting:** The Hague, Netherlands, November 2023
**3rd GSG meeting:** Geneva, Switzerland, September 2024

**Annual mapping** of CIP Network member RSS activities to facilitate effective coordination
**1st Support Plan Meeting:** March 2023
**2nd Support Plan meeting:** April 2024

**Development of CIP Network Tool Kit** to determine and agree upon the nature, scope and timelines for RSS support activities

- **Consent Form:** Written consent obtained from NRAs to share country-specific information with the Network
- **Support Plan:** details nature, scope & timelines of support activities
- **Contact List:** Contact details of listed focal persons
- **Terms of Reference template** (Optional): used to define and agree upon collaboration between CIP Network member and NRA receiving support

# CIP Network support for regulatory system strengthening in 2024

**6**
Regions

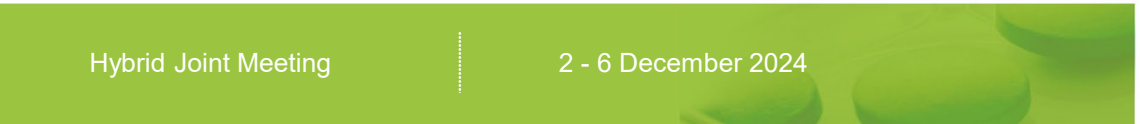
**38**
Countries

**Over 288**
activities

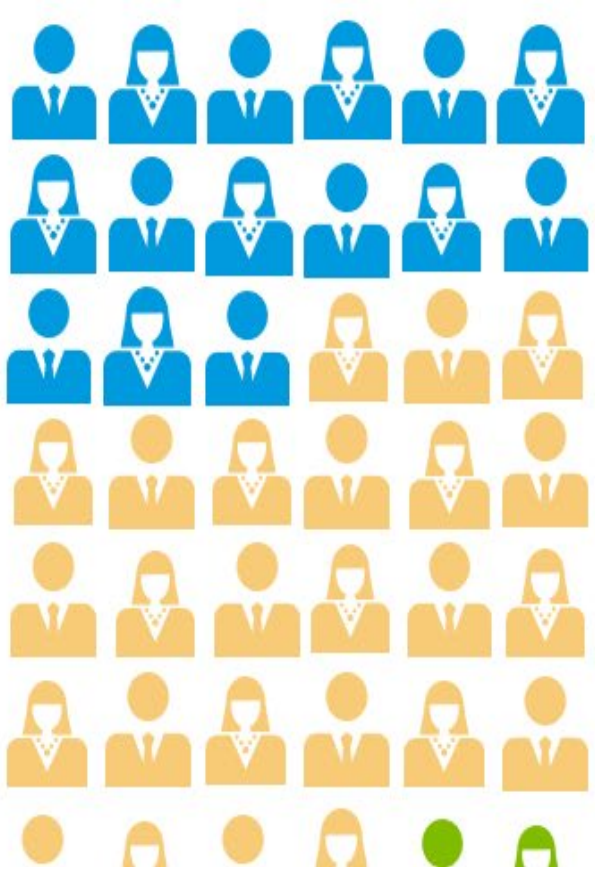
**Over 125 M**
USD

**70%**
TECHNICAL support

**30%**
FINANCIAL support




# CIP Network: Mapping Expertise & Tools



**136 Expertise**

In all Regulatory functions

**23 Tools**

e.g., Database, Training courses...

# Prioritization Model for CIP Network Engagement

- NRAs engaged in benchmarking activities using the WHO GBT
- Countries targeted by CIP Network members
- Countries with several partners
- Countries lacking partner support
- Targeting countries identified as regional leaders
- Countries engaged in regional reliance structures
- Countries earmarked for vaccine manufacturing or as technology hubs
- Countries more vulnerable to emergency situations
- ML3 NRA who require support to maintain ML3

# Priority Countries for 2025

## 20 Countries

# Success Story… Rwanda

Formal Benchmark

IDP follow up (onsite)

IDP follow up (onsite)

IDP follow up (virtual)

IDP follow up (virtual)

Finalization of Benchmark

IDP implementation

Dec 2022 | Sep 2023 | Feb 2024 | May 2024 | July 2024 | Aug 2024 | Sep 2024 | Oct 2024

CIP Network support for Rwanda FDA

1st CIP Network Coordination meeting (onsite)

2nd CIP Network Coordination meeting (virtual)

CIP Coordination Meeting Phase II (virtual)

3rd CIP Network coordination meeting (virtual)

# Success Story… Senegal

Self-bench marking verification workshop

IDP follow up (virtual)

Pre Bench marking

Formal Benchmark

Several IDP follow up (virtual)

Finalization of Benchmark

**IDP implementation**

Oct 2021

May 2022

Feb 2023

Mar 2023

Dec 2023

29 Apr-3 May 2024

July 2024

Aug 2024

Oct 2024

Nov 2024

**CIP Network support for Senegal NRA**

Pilot CIP Network coordination meeting

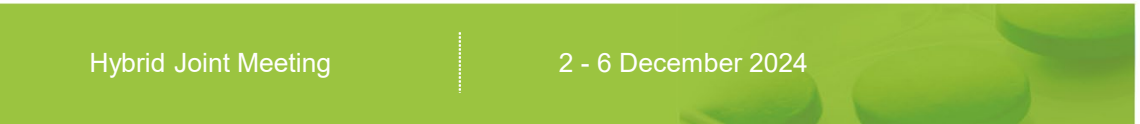
1st CIP Network coordination meeting (onsite)

2nd CIP Network coordination meeting (virtual)

CIP coordination meeting Phase II (virtual)

Hybrid CIP Network coordination meeting

3rd CIP Network coordination meeting (virtual)



# Keys for Success

- ✓ *Regular monitoring and feedback to ensure implementation of plans and tracking of support activities*
- ✓ *Enhanced Transparency and Communication across CIP members and Member states*

- ✓ *Resources and Expertise within the CIP Network supporting capacity-building efforts*

# Next Steps for 2025

- ✓ *CIP Network Expansion*
- ✓ *Foster Regional Support*
- ✓ *Expansion of the scope of CIP Network activities*


Regulatory Systems Strengthening **[RSS]** Team
Regulation and Safety [REG] Unit
Regulation and Prequalification [RPQ] Department
Access to Medicines and Health Products [MHP] Division
World Health Organization (Geneva, Switzerland)