Certified for Success: Using the CEP Procedure to elevate quality and drive trust

23-24 September 2025, Budapest, Hungary

Reliance is key: perspective of WHO and good reliance practices

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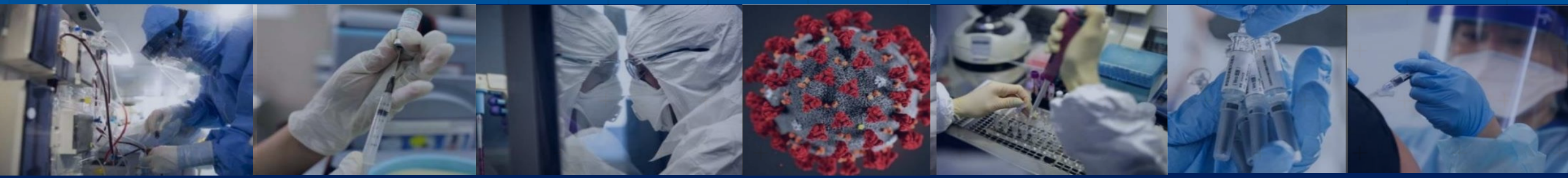
Health Systems, Access and Data Division



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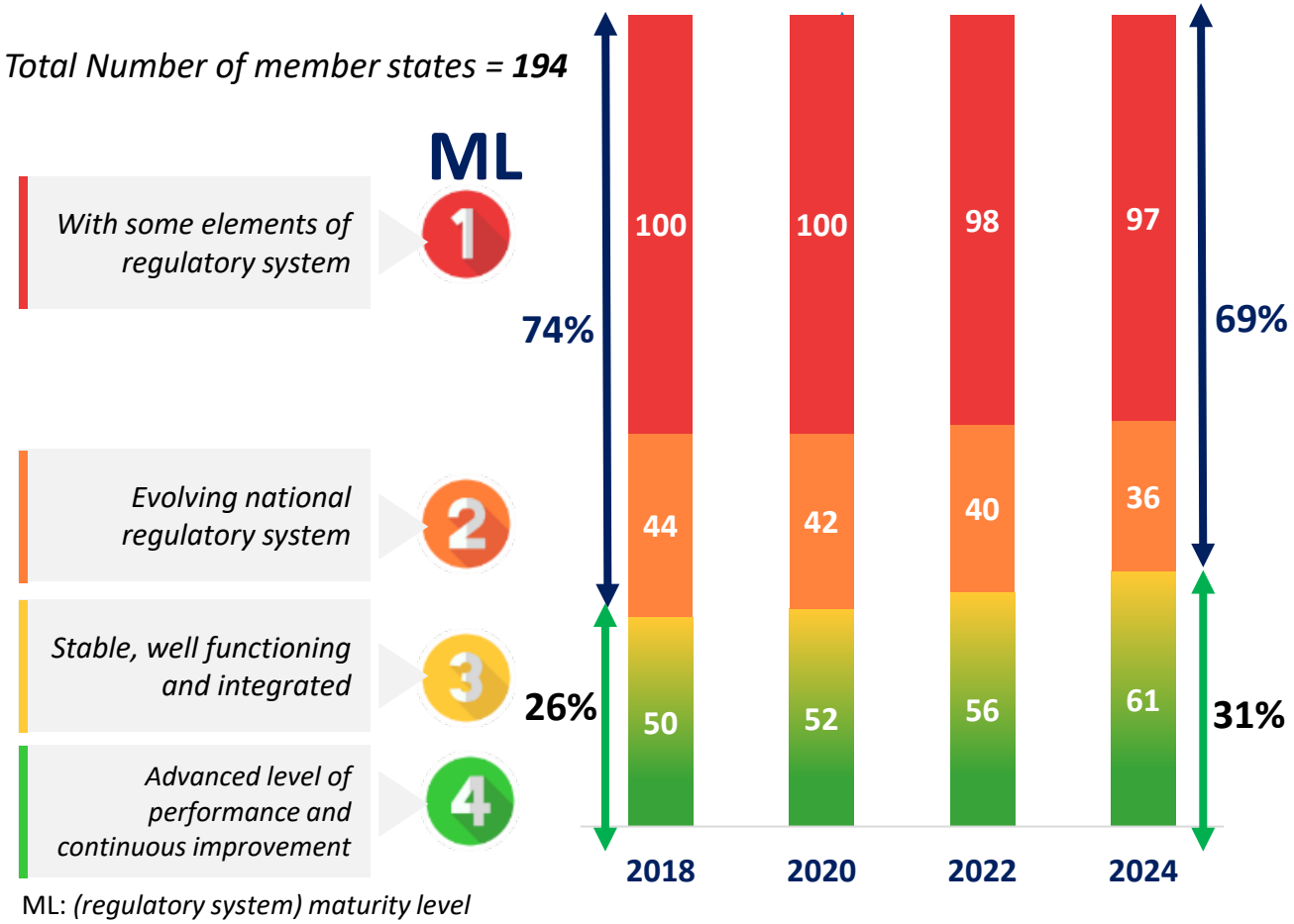
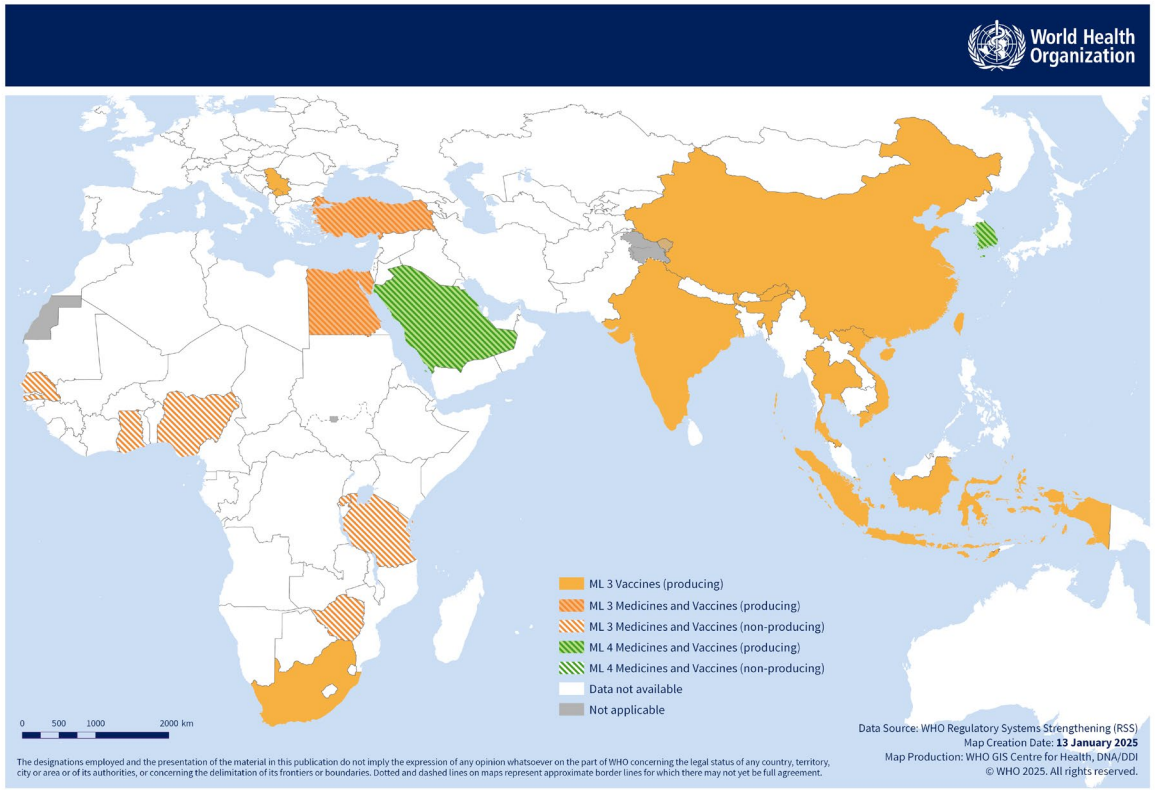
Global status of national regulatory systems

(includes WLAs & transitional WLAs for medicines and vaccines as of August 2025)



ML: *(regulatory system) maturity level*

NRAs benchmarked as ML3/ML4 using GBT



- **61 WHO member states (31%) have well-functioning regulatory systems**
  - ✓ **11 more NRAs achieved ML 3 or ML 4 since 2018 (22% growth)**
- **133 member states (69%) with NRAs still at ML 1 & ML 2**

- ***GBT:*** *Global Benchmarking Tool*
- ***NRA:*** *National Regulatory Authority*
- ***WLA:*** *WHO Listed Authority*

Source: WHO RSS database, August 2025

Regulatory Systems Strengthening and support to Member States

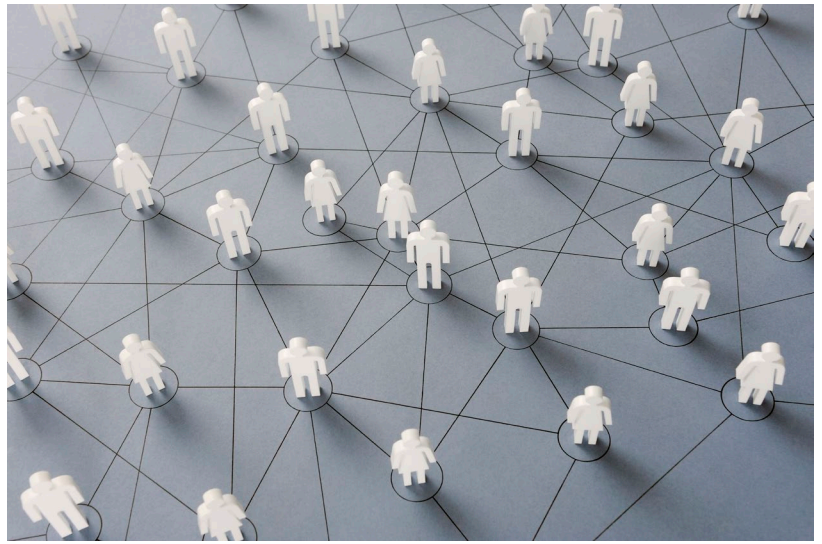
WHO Good regulatory practices, 2021

1 - Build regulatory capacity in Member States consistent with good regulatory practices

Legality	Consistency	Independence
Impartiality	Proportionality	Flexibility
Clarity	Efficiency	Transparency

WHO Good reliance practices, 2021

2 - Promote regulatory cooperation, convergence and transparency through networking, **work-sharing and reliance**



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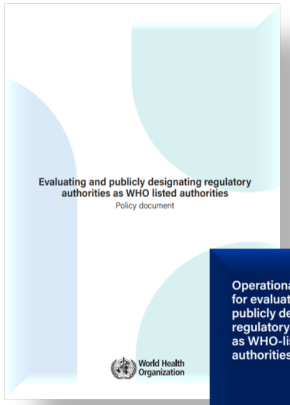
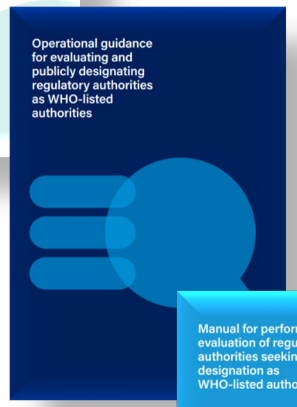
WHO Listed Authority

WLA Framework

36 Member States and 39 Regulatory Authorities evaluated and listed in 2023-2025

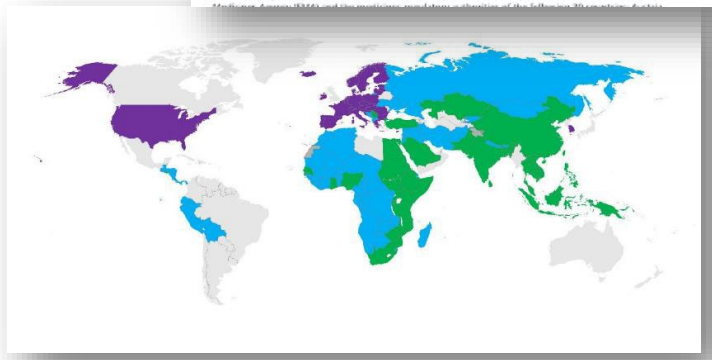


Policy document (2021)



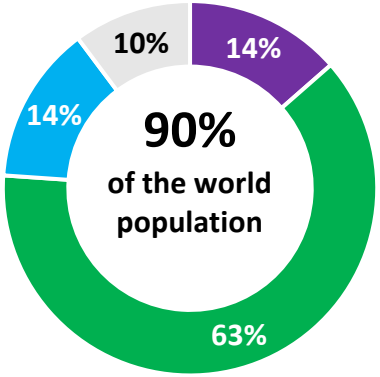
Operational Guidance (2023)

Manual for Performance Evaluation (2023)

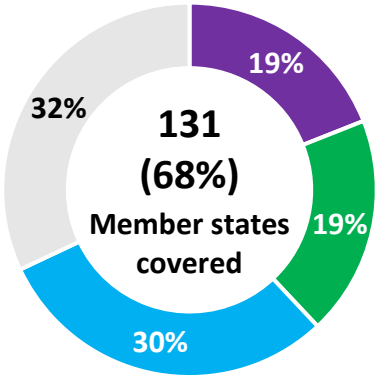


Global status of benchmarking and performance evaluation of regulatory systems (2016 – Sep 2025)

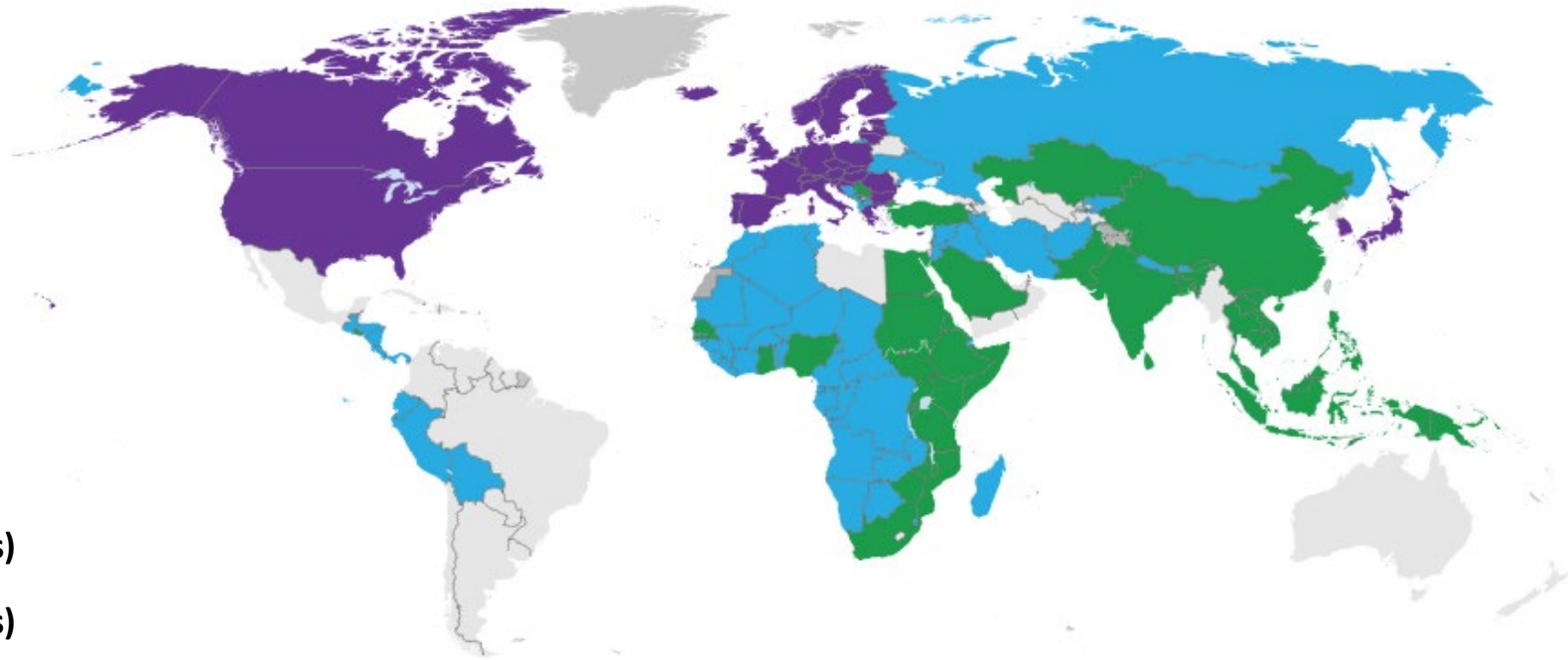
% of world population



% of member states



WHO Listed authority (WLA)	**(36 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.

Disclaimer: The designation of WHO-Listed Authority (WLA) status is granted for specific regulatory functions. Authorities may be listed for different functions. For the complete and updated scope and functions for each authority, please refer to the official WHO list

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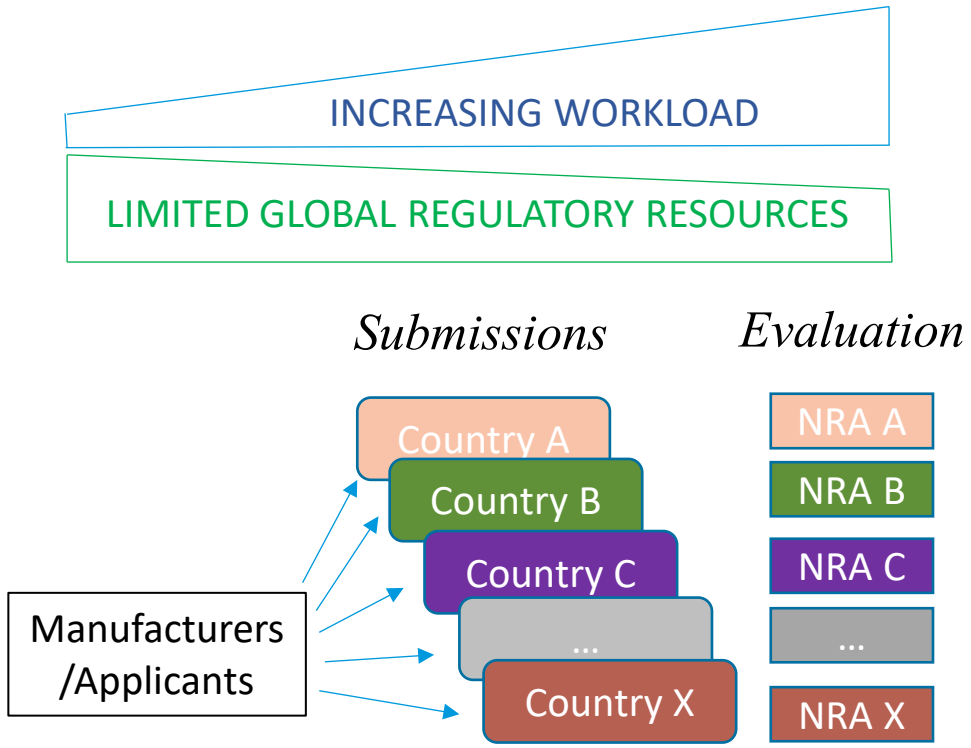
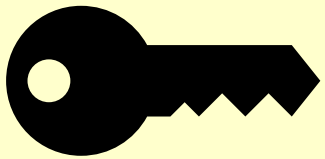
Reliance is key



SOLUTIONS



Work-sharing,
Joint assessment,
Abridged pathways,
Strengthened collaboration,
etc.

Implementation of reliance

- Voluntary participation
- Change mindset
- Start small, learning by doing
- Harmonisation facilitator but not pre-requisite

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Are we using the global regulatory resources as best as we can?

Growing use of reliance

Long history of improving efficiency through reliance (e.g. CPP)

Reliance embedded in the WHO Global Benchmarking Tool

WHO Good Reliance Practices, March 2021

Strengthen “informed” reliance

Reliance for more regulatory functions (**including PAC**) & worksharing

Develop more guidance for practical implementation (**including PAC**)

PAST

Emergency response as strong accelerator for reliance

Universality, regardless of maturity level or resources

PRESENT

FUTURE

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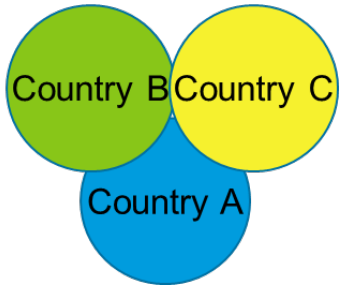
PAC: Post-Authorization Changes

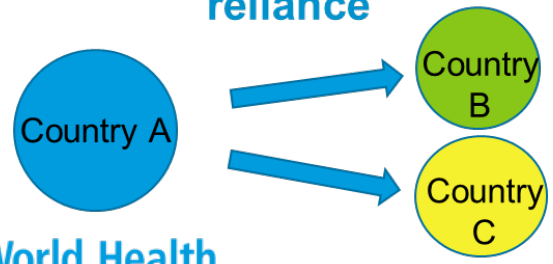
Reliance's many shapes and forms

"The act whereby the regulatory authority in one jurisdiction **takes into account and gives significant weight** to **assessments performed by another regulatory authority or trusted institution**, or to any other authoritative information, **in reaching its own decision**. The relying authority remains **independent, responsible and accountable** for the decisions taken, even when it relies on the decisions, assessments and information of others."

Work-sharing



Abridged pathway using reliance



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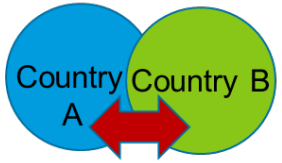
Recognition

Unilateral

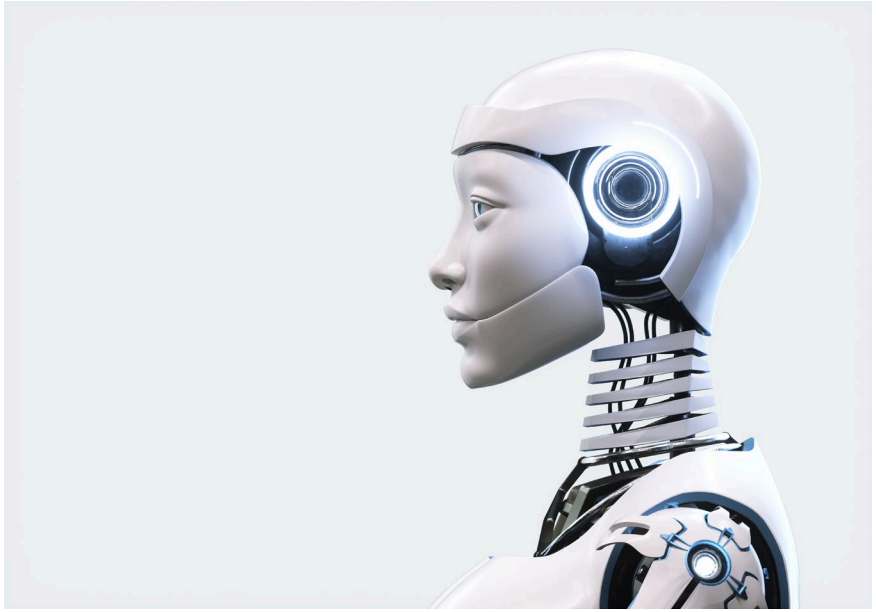


Mutual recognition

- Sovereignty maintained;
- More efficient use of global regulatory resources;
- Decrease duplication, increase trust and collaboration.

Ensuring quality of medical products globally through reliance for the regulatory oversight

- CEP 2.0
- Collaborative platforms (information sharing)
- Work sharing



- Electronic Certificate of Pharmaceutical Product (CPP)
- WHO Collaborative Registration Procedure
- Reliance on inspections

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Collaborative Registration Procedure (CRP)

WHAT it is and HOW does it work?

CRP facilitates exchange of information to accelerate national registrations in countries through the provision to NRAs of detailed assessment and inspection reports generated by reference NRAs/WHO PQ

Applicant

Single product dossier

\+

Prod. Assessment Reports from SRA/WHO PQ

To multiple CRP participating country(s)

Accelerated assessment and registration of quality-assured products in countries

Faster access to priority quality-assured products by the population

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WHO Collaborative Registration Procedure – participating countries

- Angola
- Armenia
- Azerbaijan
- Bangladesh
- Belarus
- Benin
- Bhutan
- Botswana
- Brunei Darrusalam
- Burkina Faso
- Burundi
- Cabo Verde
- Cameroon
- Caribbean Community (CARICOM)
- Central African Republic
- Chad
- Comores
- Côte d'Ivoire
- Democratic Republic of the Congo
- El Salvador
- Eritrea
- Ethiopia
- Gabon
- Gambia
- Georgia
- Ghana
- Guinea (Republic of)
- Honduras
- Jordan
- Kazakhstan
- Kenya
- Kyrgyzstan
- Lao People's Democratic Republic
- Lesotho
- Liberia
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Mauritania
- Mozambique
- Namibia
- Nepal
- Niger
- Nigeria
- Pakistan
- Papua New Guinea
- Paraguay
- Philippines
- Qatar
- Republic of Congo
- Republic of Moldova
- Rwanda
- Sao Tome and Principe
- Senegal
- Sierra Leone
- South Africa
- Sri Lanka
- Sudan
- Tanzania (Mainland)
- Tanzania (Zanzibar)
- Thailand
- Timor-Leste
- Togo
- (Tunisia)
- Türkiye
- Uganda
- Ukraine
- Uzbekistan
- Yemen (Sana'a)
- Yemen (Aden)
- Zambia
- Zimbabwe

CARICOM : Antigua and Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname, Trinidad and Tobago

PQ CRP Mx,Vx: 68 NRAs +

1 REC (CARICOM)

SRA CRP: 65 NRAs + 1 REC

(CARICOM))

PQ CRP IVD : 36 NRAs

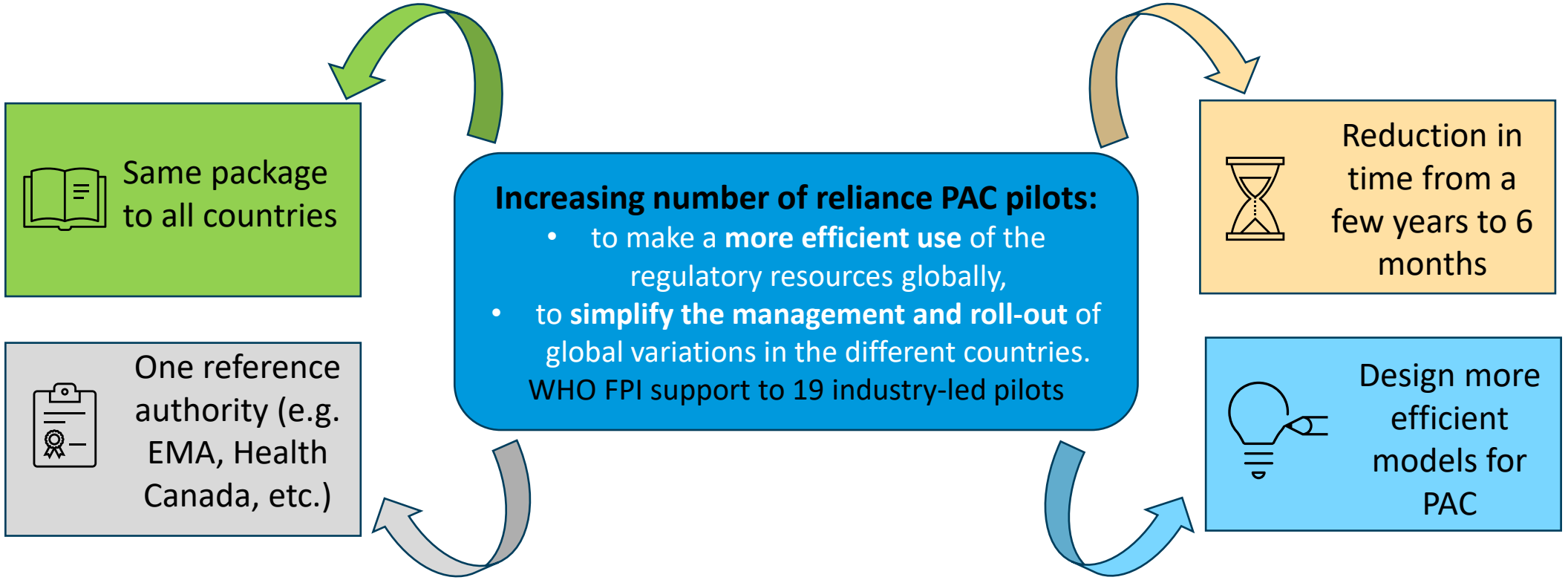
In green: PQ CRP Mx, Vx, IVD and SRA

In blue: PQ CRP Mx, Vx and SRA

In orange: SRA CRP only

In black: PQ CRP Mx, Vx only

PAC Evolving landscape with increasing use of reliance



Important to consider concomitant submissions for key supply-chain variations
Standard reliance for all/minor variations
Aim is also to harmonize/streamline requirements (same package for all)

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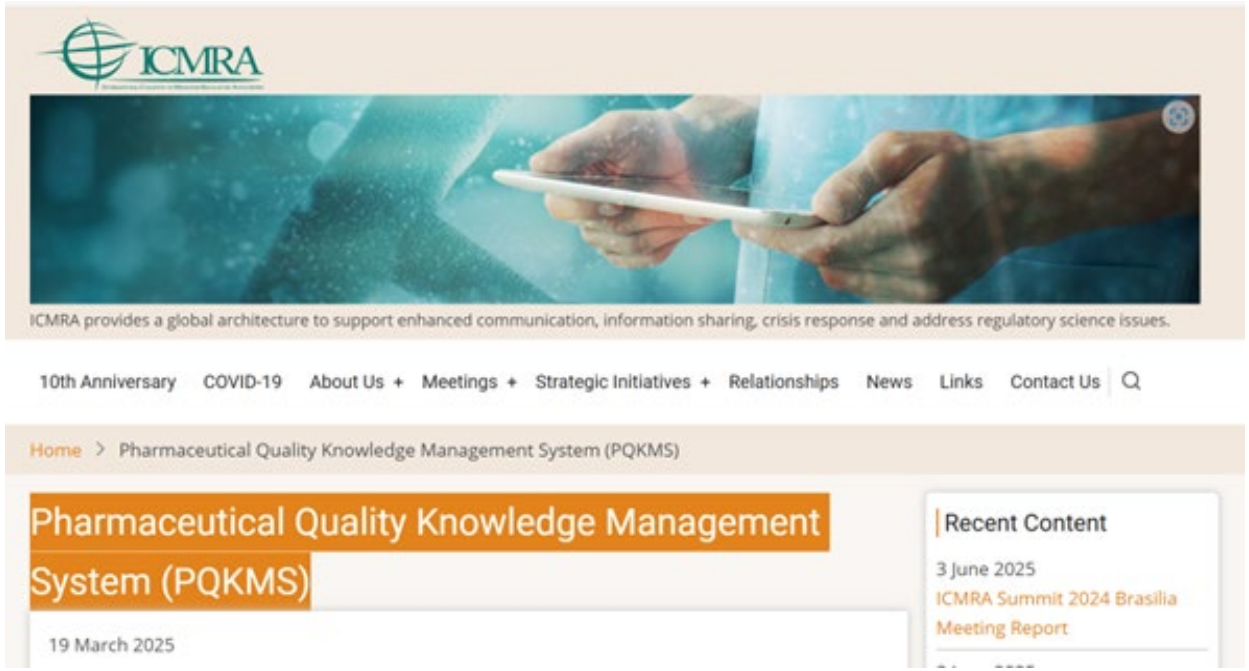
References: https://www.who.int/initiatives/who-listed-authority-reg-authorities, https://icmra.info/drupal/en/strategicinitatives/pqkms, https://pubmed.ncbi.nlm.nih.gov/37973190/, https://globalforum.diaglobal.org/issue/april-2024/unleashing-the-power-of-reliance-for-post-approval-changes-with-48-nras/?utm_source=db&utm_medium=email&utm_campaign=global_forum&utm_content=PUB_GF_April_2024-04-06_members, https://pubmed.ncbi.nlm.nih.gov/32467177/

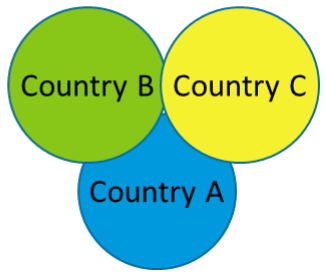
International Coalition of Medicines Regulatory Authorities

Pharmaceutical Quality Knowledge Management System (PQKMS)



https://icmra.info/drupal/en/strategicinitatives/pqkms

Work-sharing



Collaborative assessments and inspections

Two Pilot Programs focusing on:

- Collaborative assessment with initial focus on chemistry, manufacturing and control (CMC) post-approval changes and
- Collaborative Hybrid Inspections

Example for a Post Approval Change Management Protocol for Drug substance and Drug product for an oncology product

EMA as lead assessor, US FDA participate and PMDA Japan was observing

- Harmonized list of questions
- EMA & US FDA approval on the same day!

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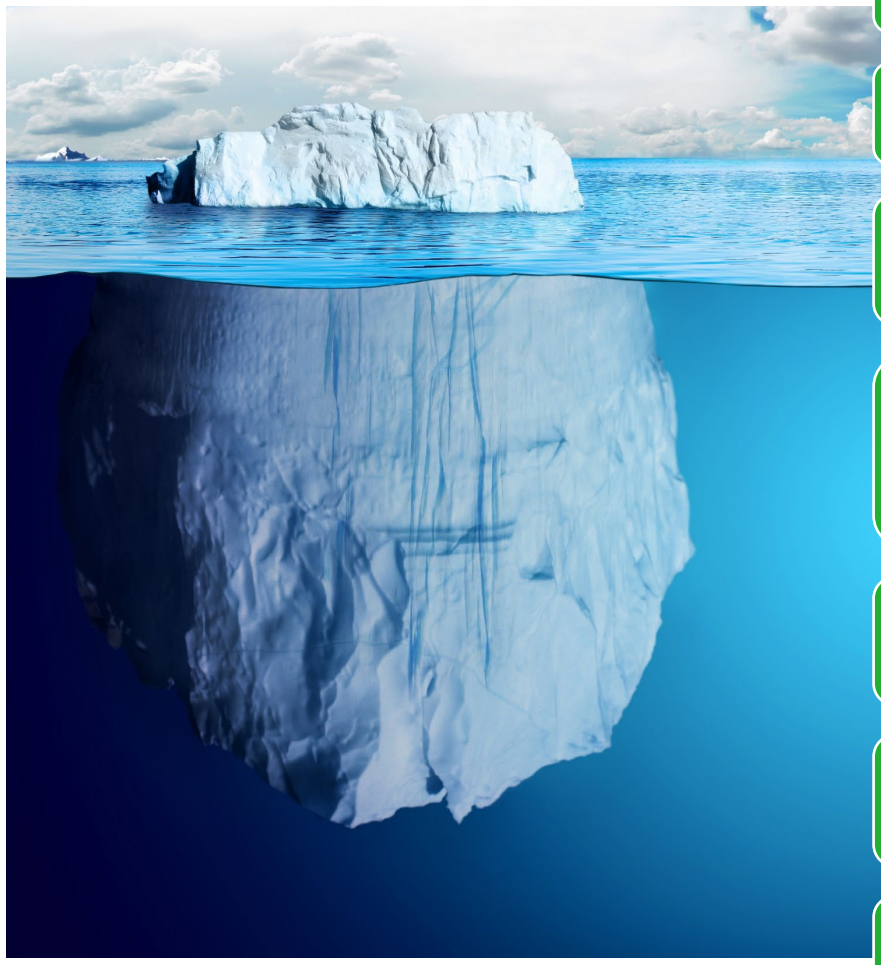
How can we collectively better manage Post-authorization Changes?

Initial authorization

Post-authorization changes



- Pragmatic approach
- More recognition for (minor) variations?
- Increase transparency of PAC assessment
- Accommodate new concept for product lifecycle management (e.g. ICH Q12)
- Simplification of regulatory frameworks
- More reliance and ensuring product sameness
- Build trust between stakeholders

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Regulation and Safety Unit