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Reliance as an essential tool to promote efficient and robust global regulatory oversight

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Globalization of markets requires global regulatory oversight

Medical products are crossing borders

Globalization of markets and of clinical trial programme development

Promotion of "informed reliance"

Ideally regulators should have access to all the quality, safety and efficacy information and to the source evaluation/inspection reports

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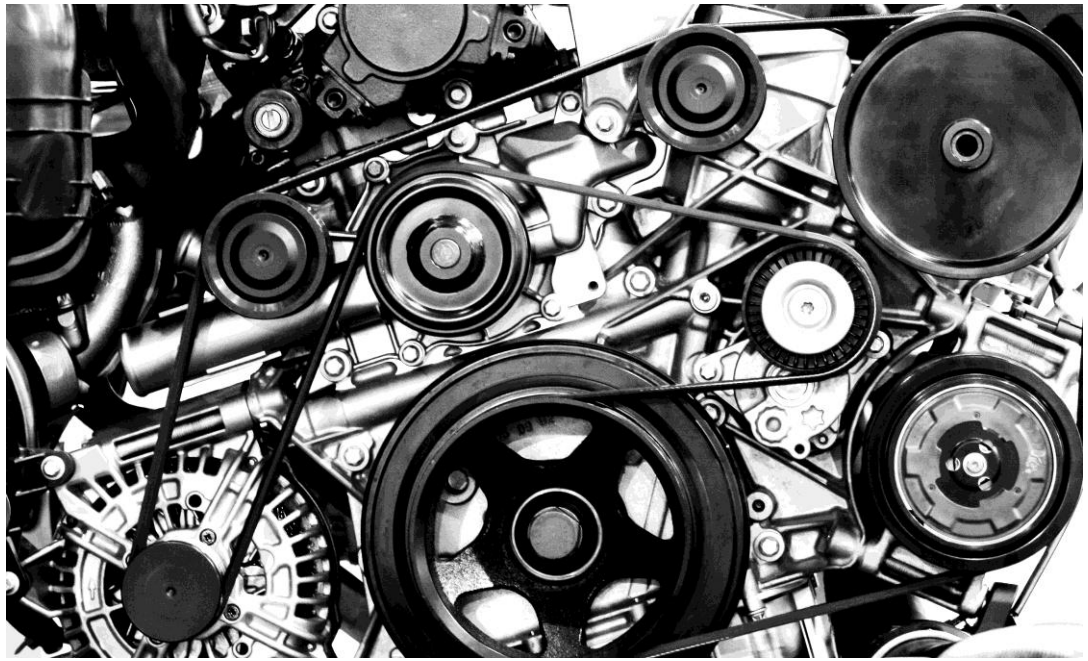
Blue-Sky Thinking: Transparency by default between regulators? A secure **regulators platform** for all regulators to exchange in the future?

Reliance promoted for all regulatory functions

Regulatory functions as per WHO Global Benchmarking Tool



Successful examples

NRA Lot release: WHO-NNB to facilitate access and ensure efficient testing of vaccines

Clinical Trials: AVAREF

Inspections: PIC/s, Mutual Recognition Agreement and joint inspections

Marketing Authorization: WHO Collaborative Registration Procedure

Vigilance: Regional RMP review

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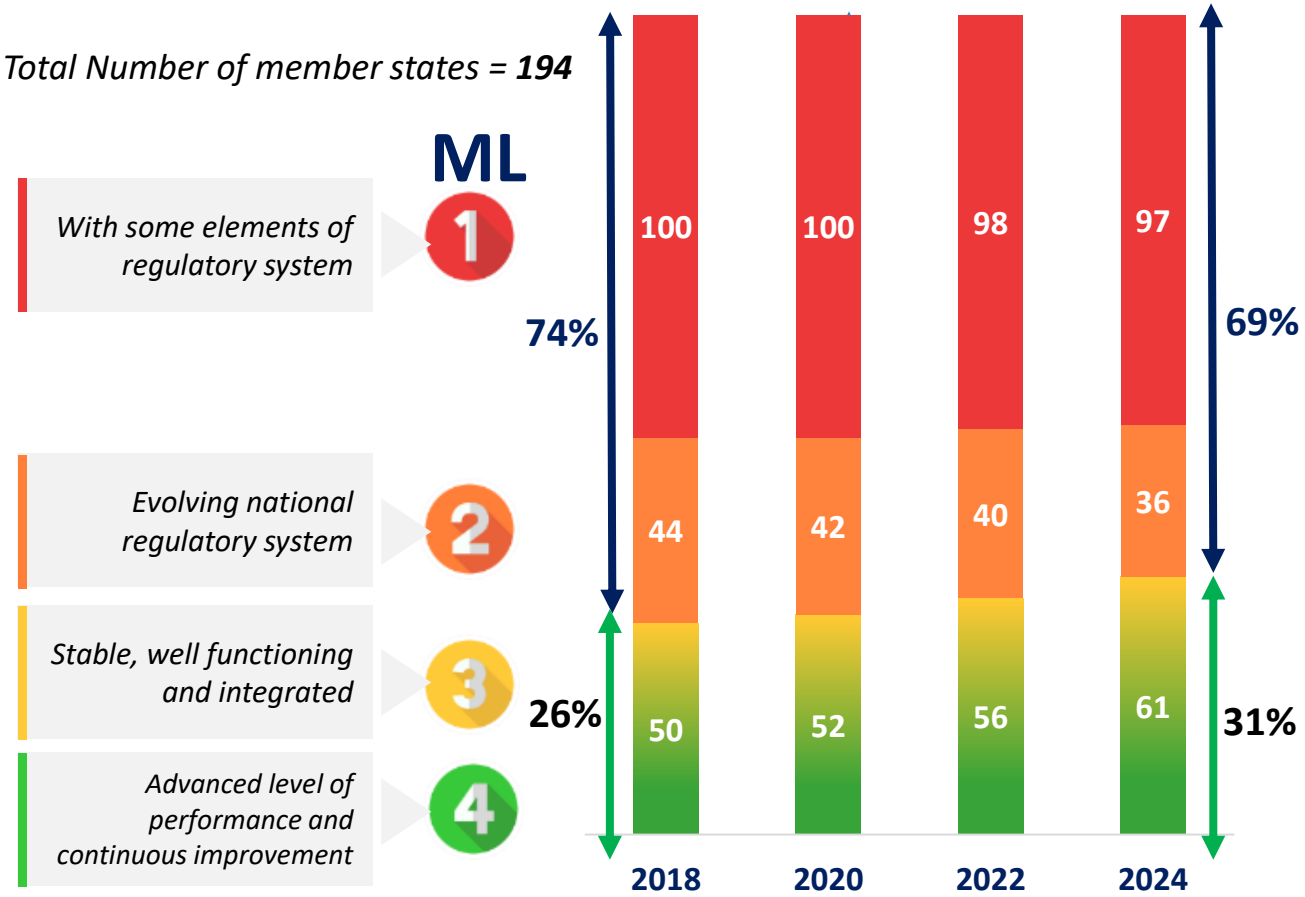
Global status of national regulatory systems

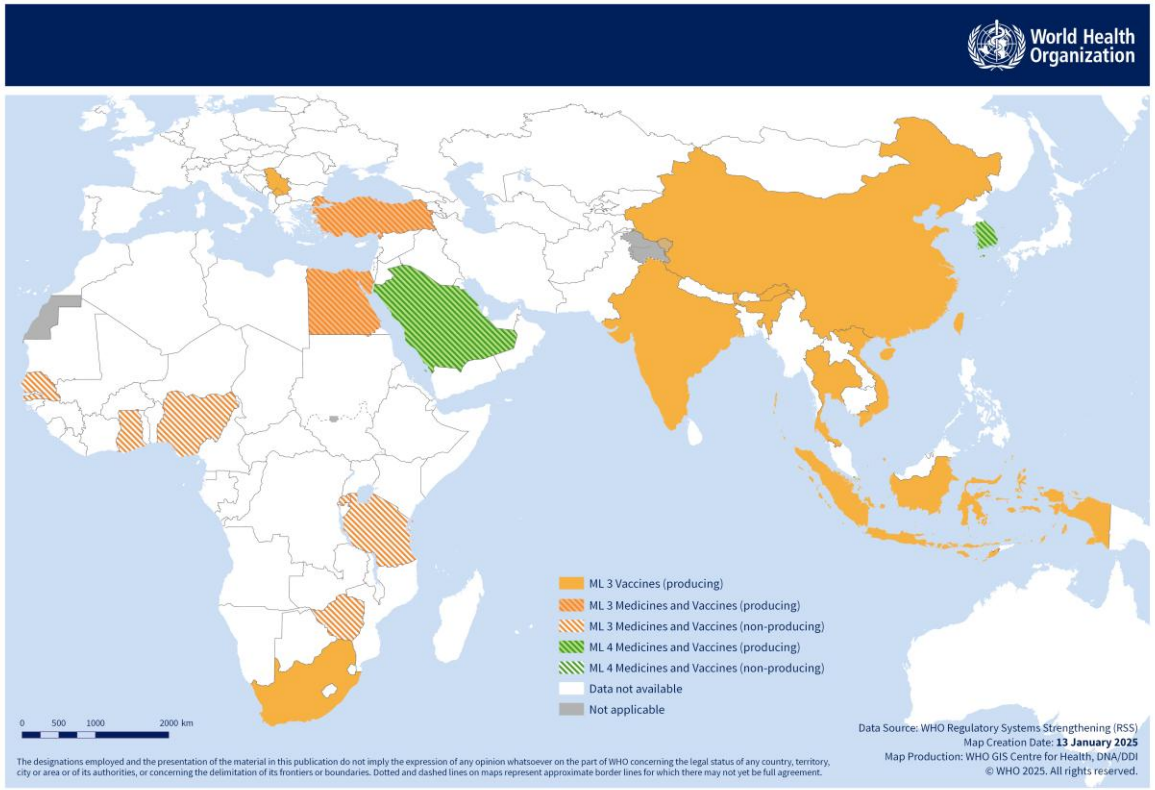
(includes WLAs & transitional WLAs for medicines and vaccines as of August 2025)

*Total Number of member states = **194***



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

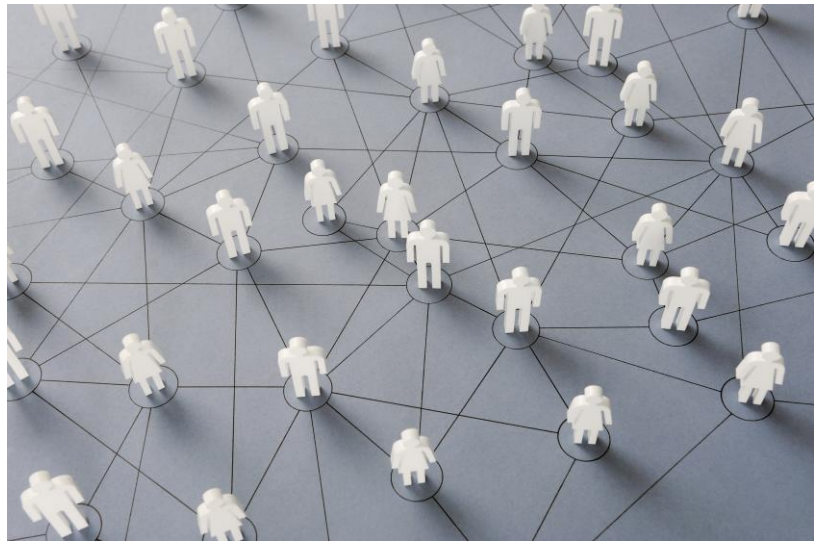
WHO Good regulatory practices, 2021

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

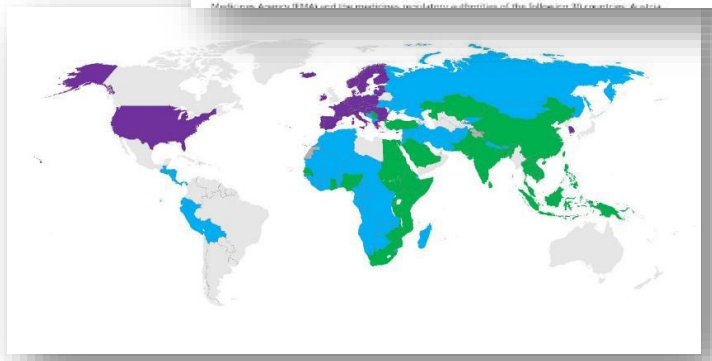
WLA Framework

Policy document (2021)

Operational Guidance (2023)

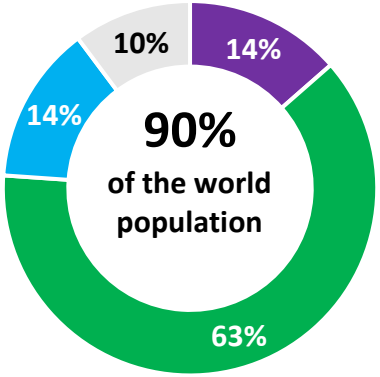
Manual for Performance Evaluation (2023)

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

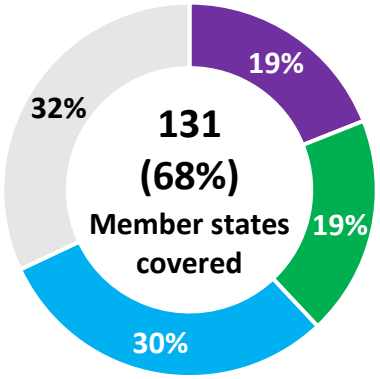


Global status of benchmarking and performance evaluation of regulatory systems (2016 – Sep 2025)

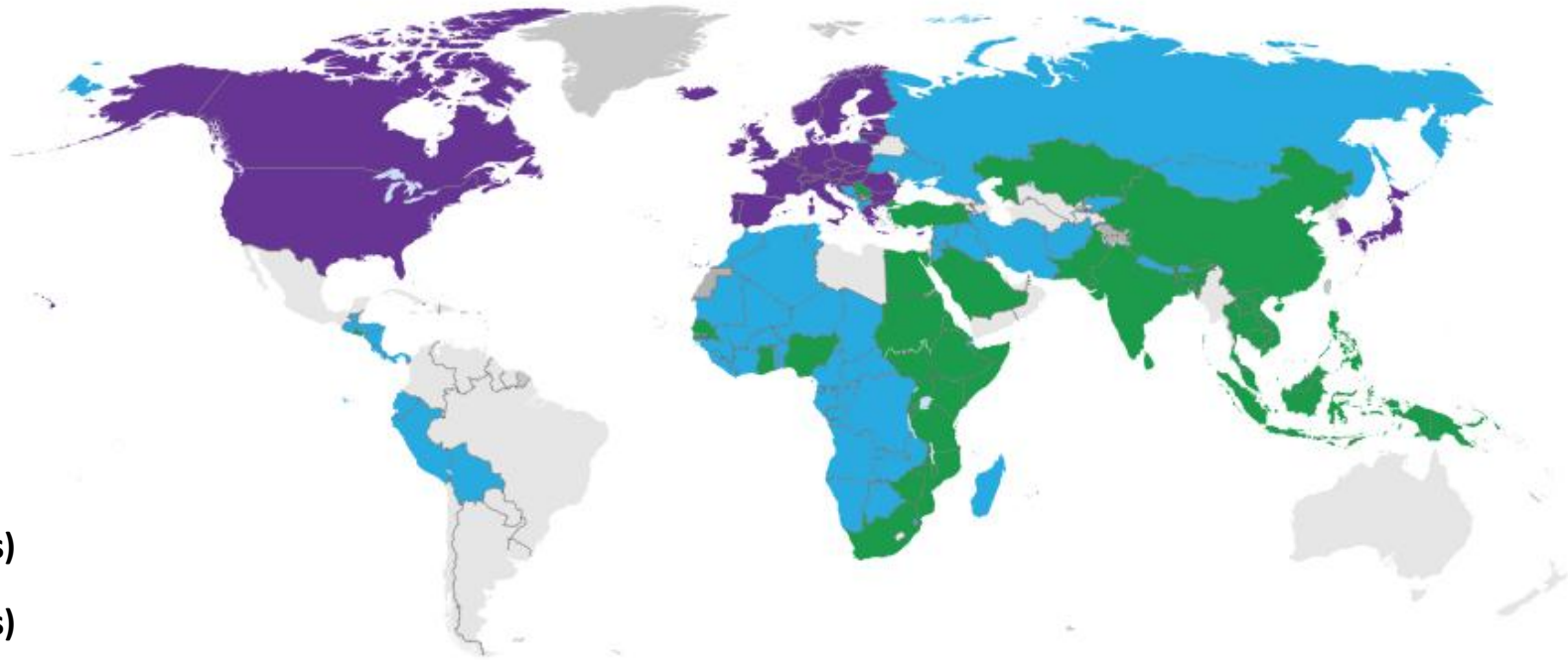
% of world population



% 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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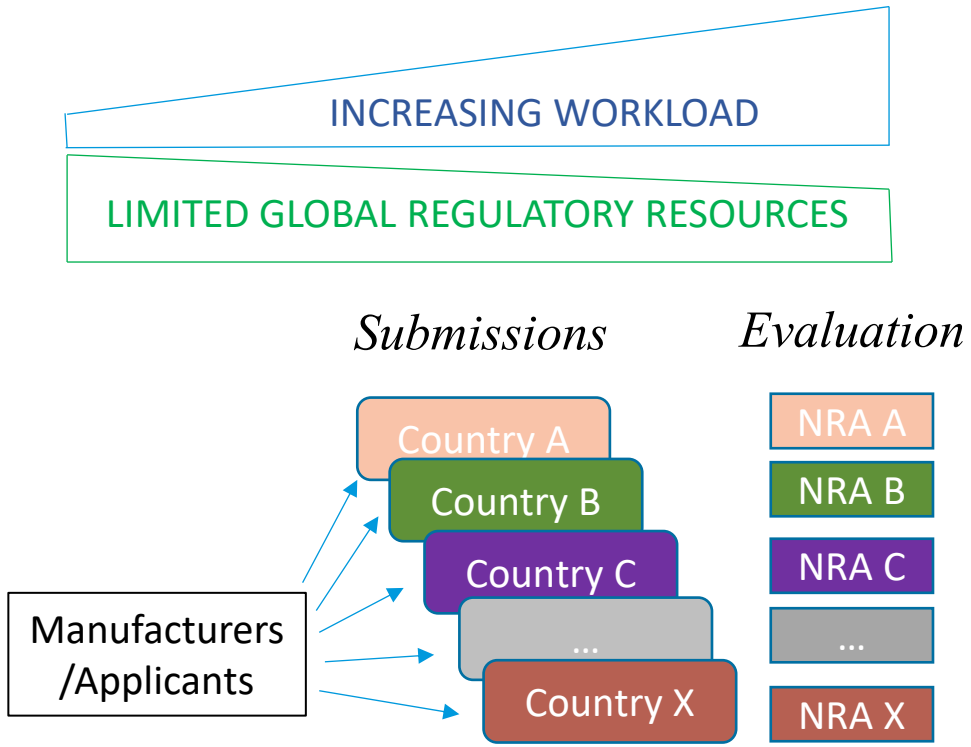
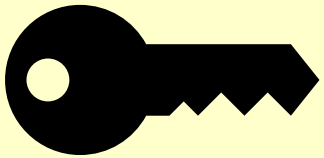
Reliance is key



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?

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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CRP Participating countries – Medicines and vaccines

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

Agreements signed

PQ CRP: 68 agreements for 65 countries & 1 REC

SRA CRP: 68 agreements for 65 countries & 1 REC

Key :
- PQ CRP only
- SRA CRP only
- PQ CRP and SRA CRP

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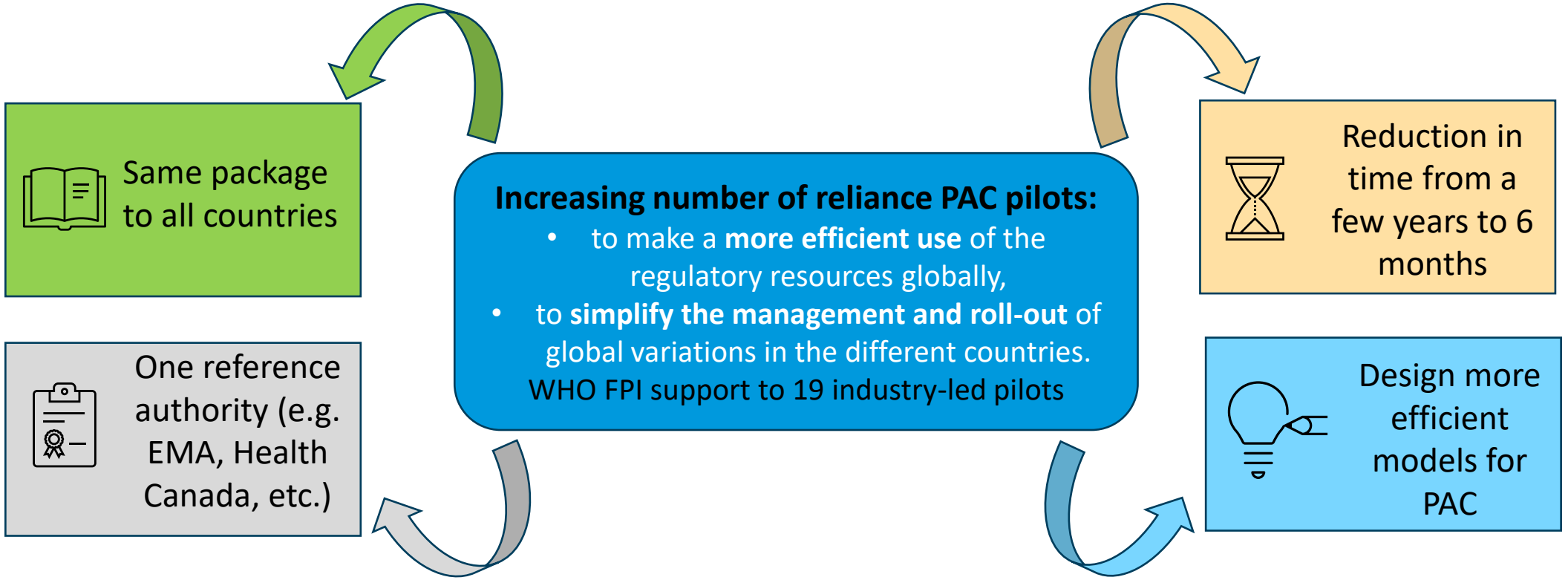
** Caribbean Community, CARICOM
15 Member States: Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago
Associate Member States: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands

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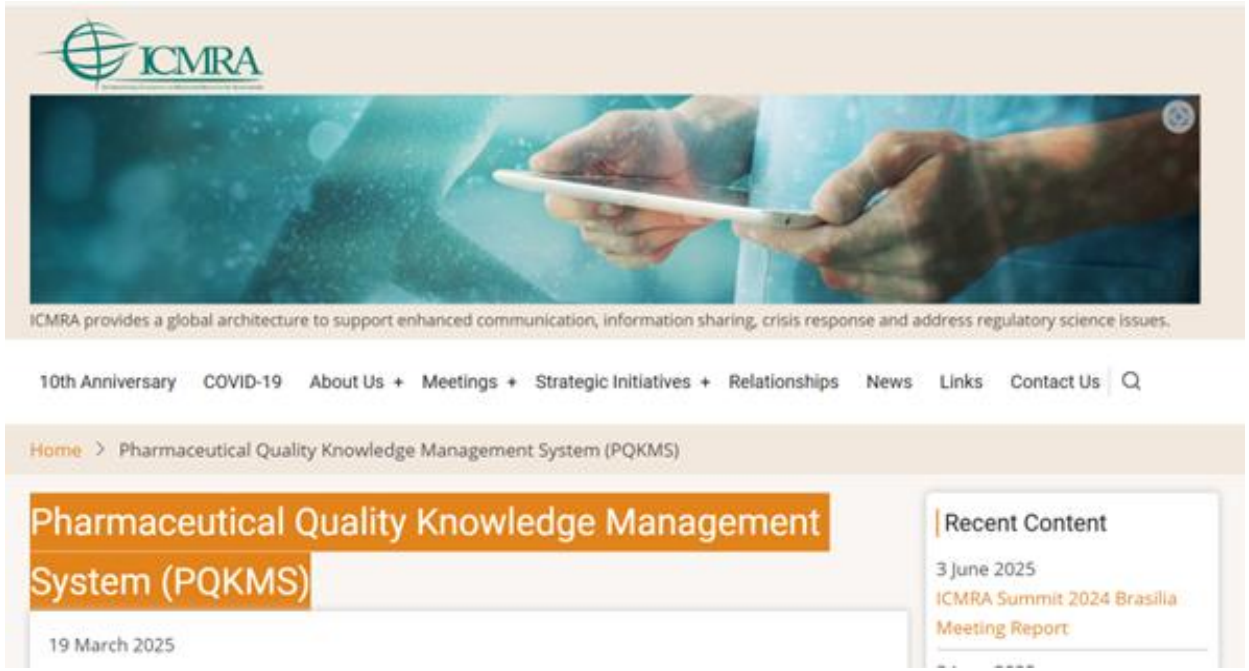
References: https://www.who.int/initiatives/who-listed-authority-reg-authorities, https://icmra.info/drupal/en/strategicinitatives/pqkms, https://pubmed.ncbi.nlm.nih.gov/37973190/, https://globalforum.diaglobal.org/issue/april-2024/unleashing-the-power-of-reliance-for-post-approval-changes-with-48-nras/?utm_source=db&utm_medium=email&utm_campaign=global_forum&ut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

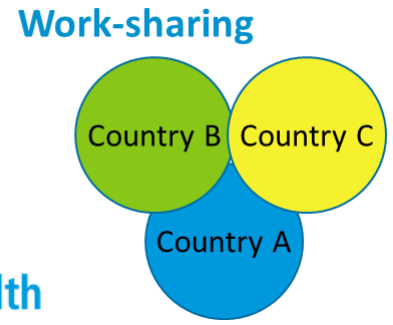
Two Pilot Programs focusing on:

- 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!



Collaborative assessments and inspections

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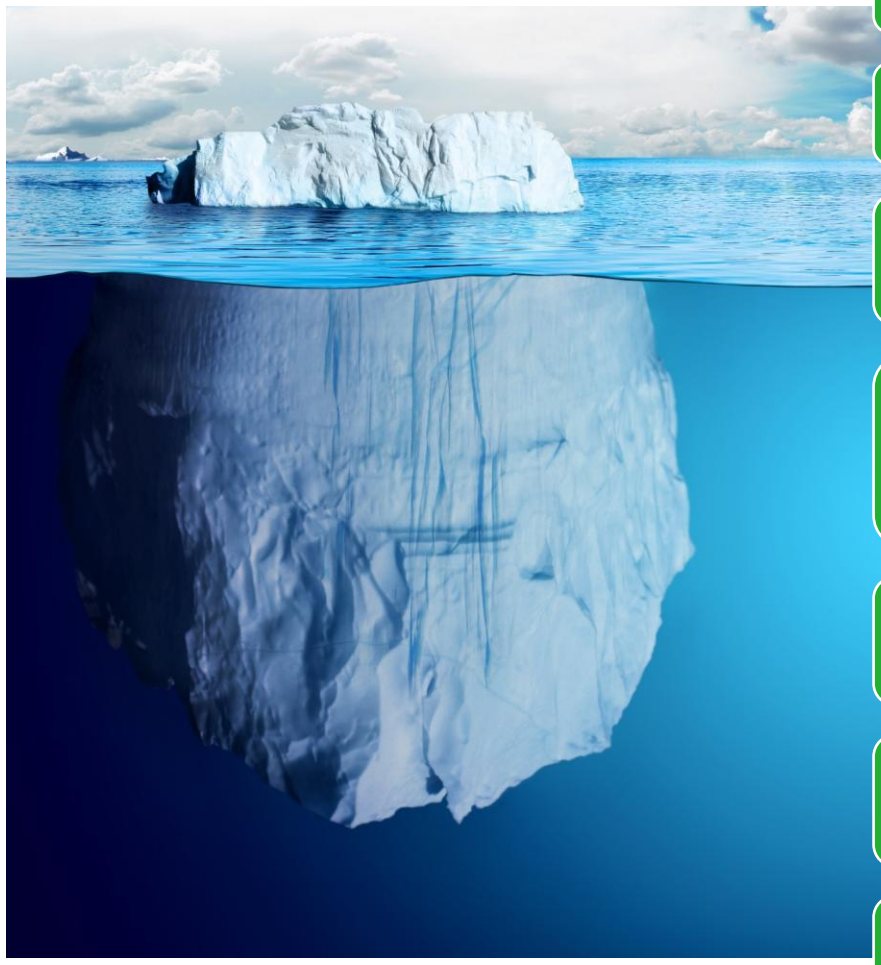
How can we collectively better manage Post-authorization Changes?

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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