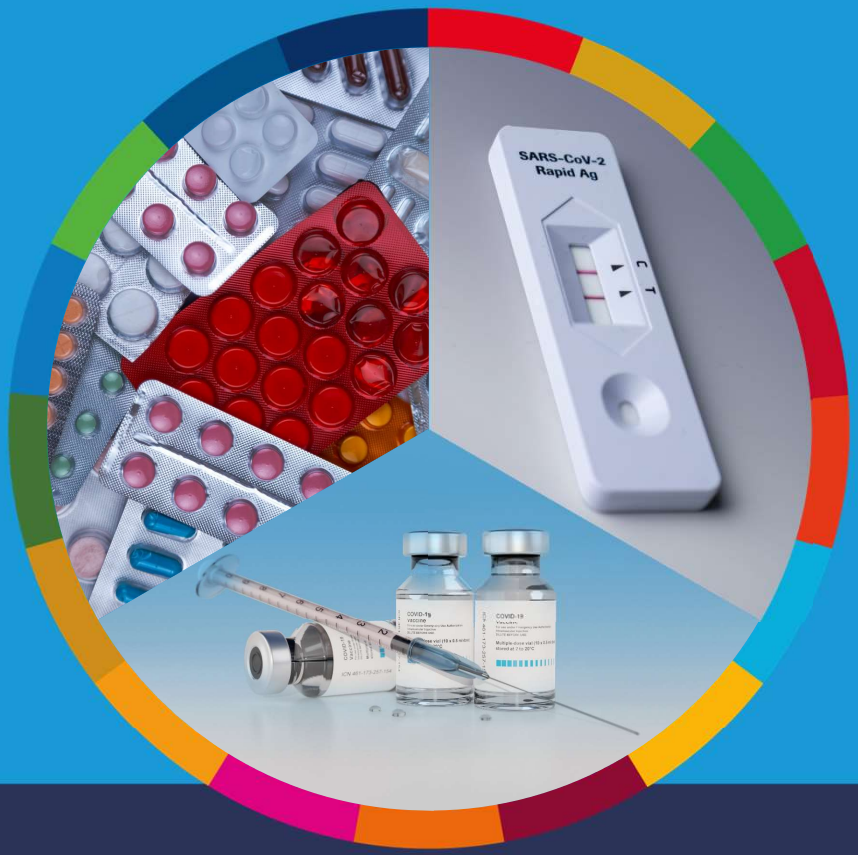


Reliance as an essential tool to promote efficient and robust global regulatory oversight

CASSS CMC Strategy Forum Latin America

Wednesday 20th August 2025

Marie Valentin
Team Lead
WHO Facilitated Product Introduction, Regulation and Prequalification (RPQ) Department

World Health Organization

Growing use of reliance

World Health Organization

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

FUTURE

Emergency response as strong accelerator for reliance

Universality, regardless of maturity level or resources

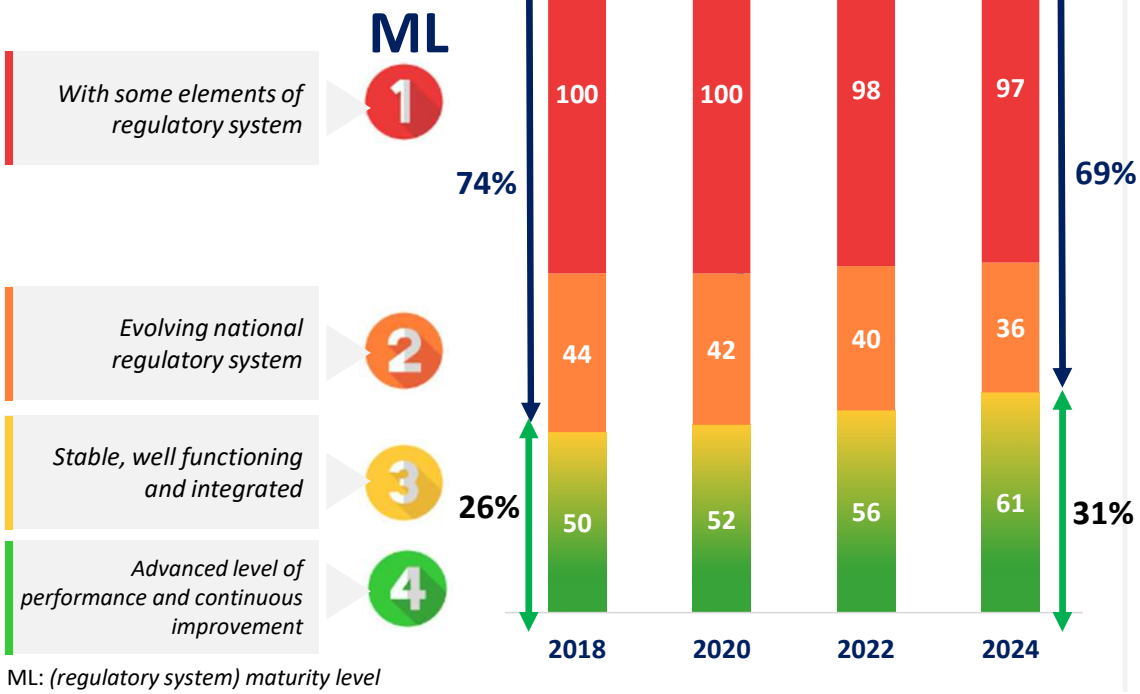
PRESENT

World Health Organization

Objectives of the WHO regulatory system strengthening programme

Why reliance?

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



ML: *(regulatory system) maturity level*

Source: WHO RSS database, Feb 2025

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

Good regulatory practices, 2021

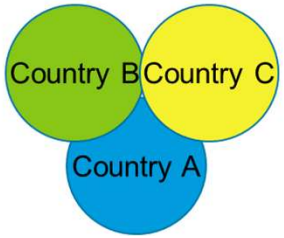
2 - Promote regulatory cooperation, convergence and transparency through networking, **work-sharing and reliance**

Good reliance practices, 2021

Reliance's many shapes and forms

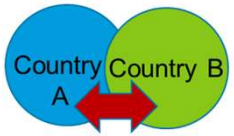
"The act whereby the regulatory authority in one jurisdiction **takes into account and gives significant weight** to **assessments performed by another regulatory authority or trusted institution**, or to any other authoritative information, **in reaching its own decision**. The relying authority remains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

Work-sharing



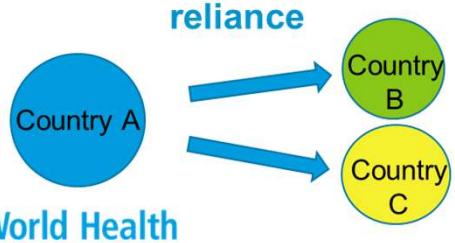
Recognition

Unilateral



Mutual recognition

Abridged pathway using reliance



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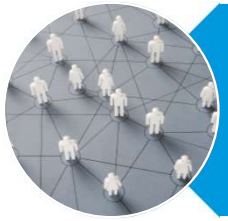
- Sovereignty maintained;
- More efficient use of global regulatory resources;
- Decrease duplication, increase trust and collaboration.

Examples of reliance facilitated procedures

1- WHO Collaborative Registration Procedure

2- Global Health Product Procedures

EU-M4all & Swissmedic MAGHP



3- Industry-led PAC reliance pilots

Access to quality-assured products

Collaboration & capacity buidling

Abridged pathway

Participation in the SRA Assessment

Unilateral reliance

World Health Organization

1- 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

World Health Organization

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

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

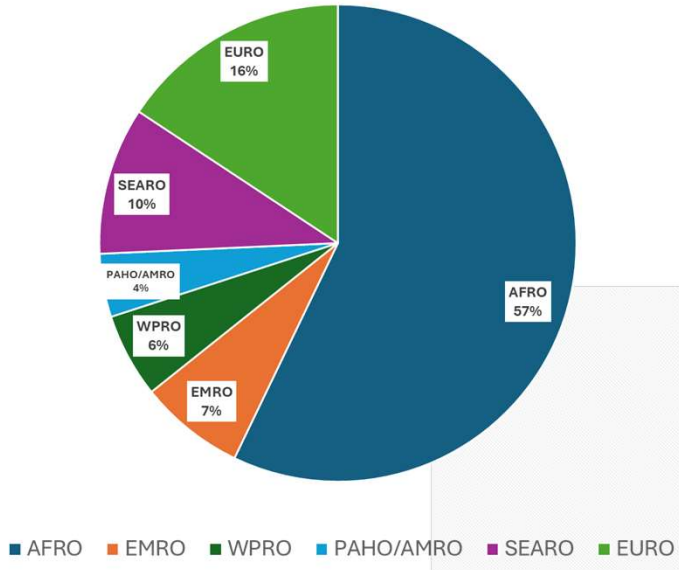
In orange: SRA CRP only

In black: PQ CRP Mx, Vx only

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

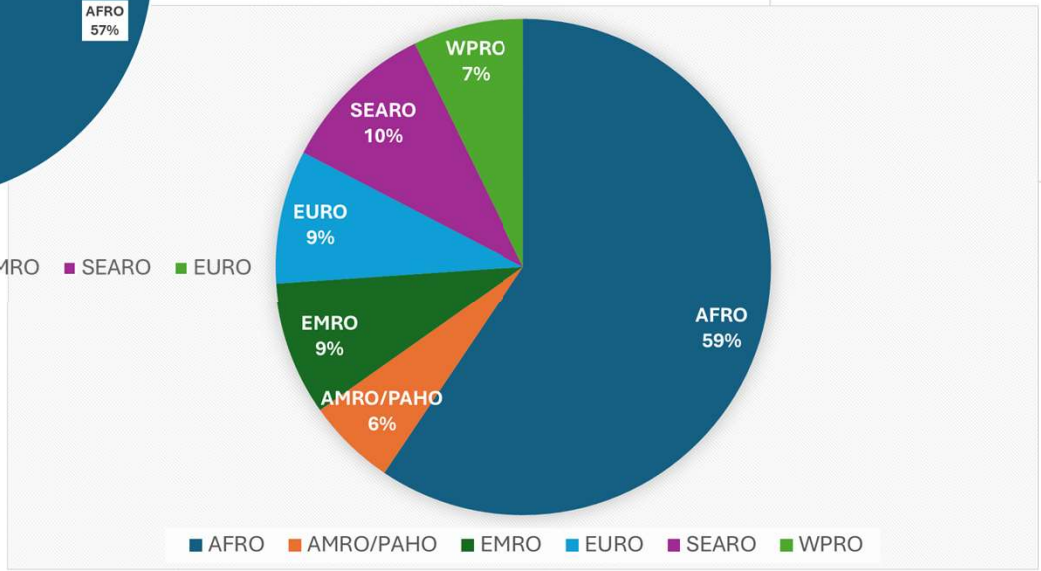
WHO Collaborative Registration Procedure – Regions participation

PQ CRP Medicine and Vaccines

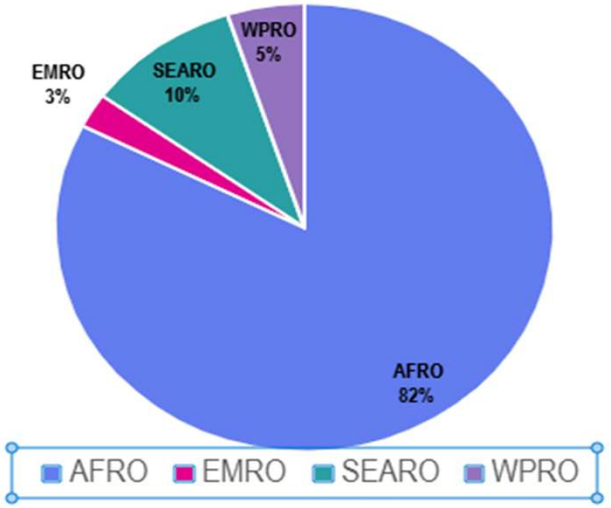


Increasing interest in CRP in the PAHO region

SRA CRP Medicine and Vaccines



PQ CRP IVDs



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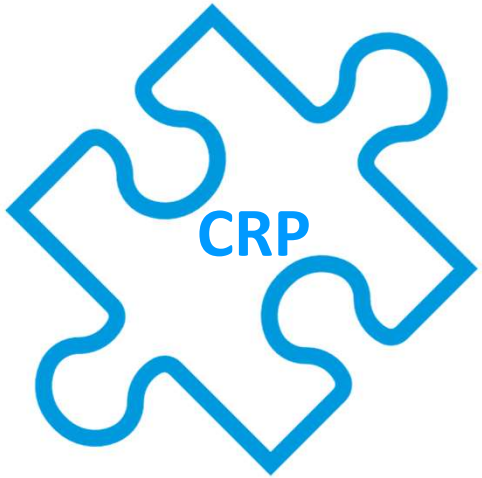
How can the WHO Collaborative Registration Procedure help?

Many NRAs already use reliance in the PAHO Region, CRP can be an **additional regulatory tool**

WHO CRP gives Access to **unredacted evaluation and inspection reports** from WHO PQ and SRA/WLA



Quality Information Summary validated **by SRA/WLA and WHO PQ – ensuring sameness of product**

Capacity building opportunities

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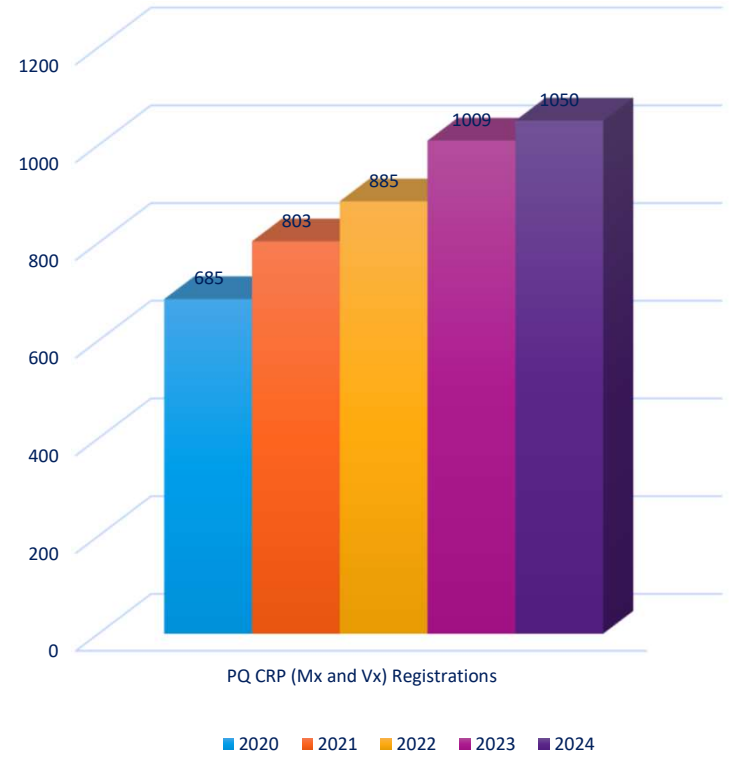
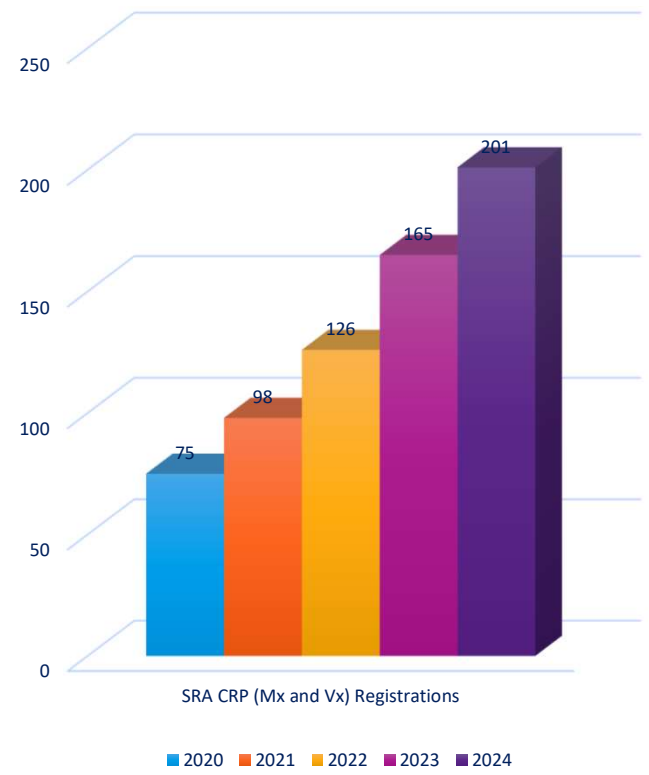
CRP data and progress 2025 (Q1) – Cumulative registration numbers

PQ CRP (Mx and Vx)



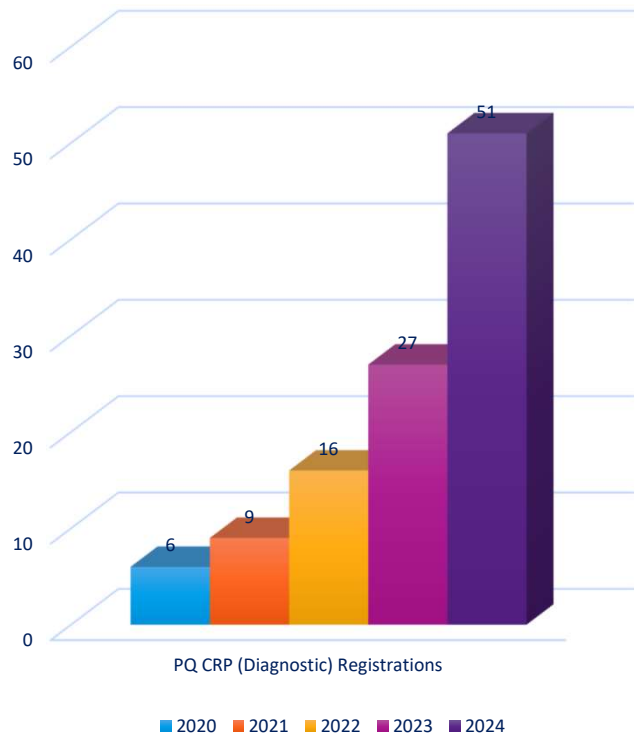
Number of prod. submissions: 1620

SRA CRP (Mx and Vx)



Number of prod. Submissions : 299

PQ CRP (IVDs)



Number of prod. Submissions : 74

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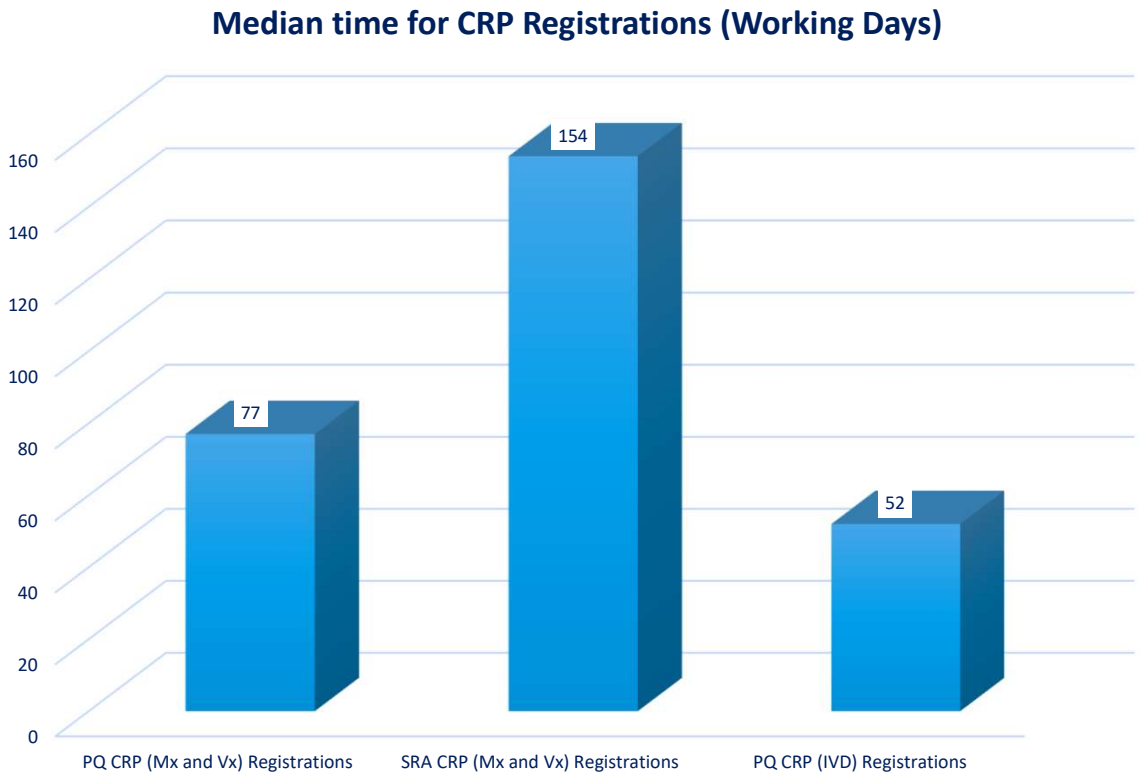
CRP data, progress and achievements 2024



- ✓ ***Conformity to CRP registration timelines : within 90 working days***
- ✓ ***Registration within 6 months: all CRP streams***
- ✓ ***Singificantly less than NRA timelines***
- ✓ ***Gross registration time (including applicants time)***

World Health Organization

2- Global Health Procedures (EU-M4all and MAGHP)

- Scientific evaluation from Stringent Regulatory Authorities for products to be used outside of the European Union and Switzerland
- Facilitate in-countries decisions
- Sharing expertise, capacity and trust building

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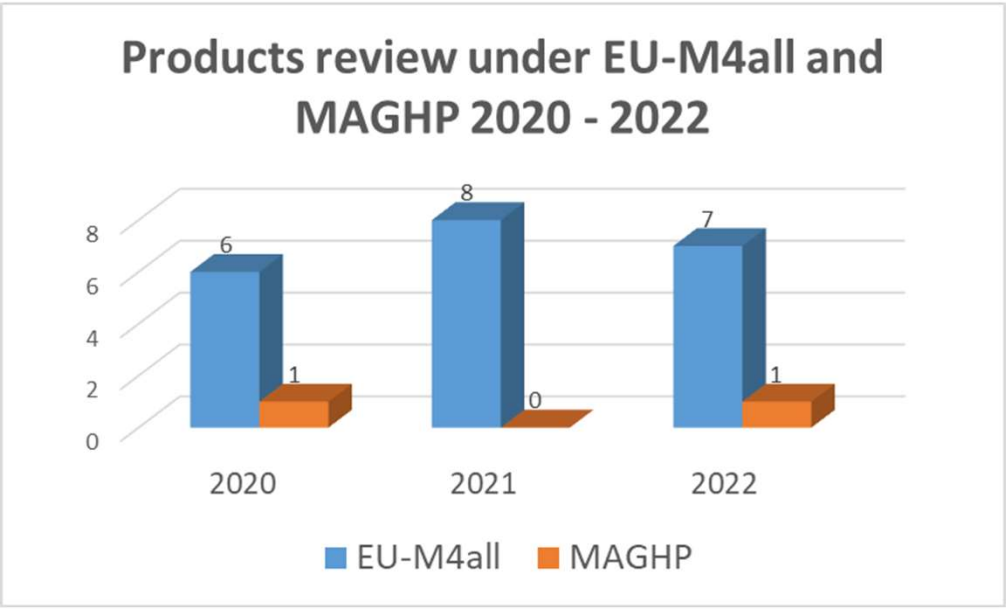
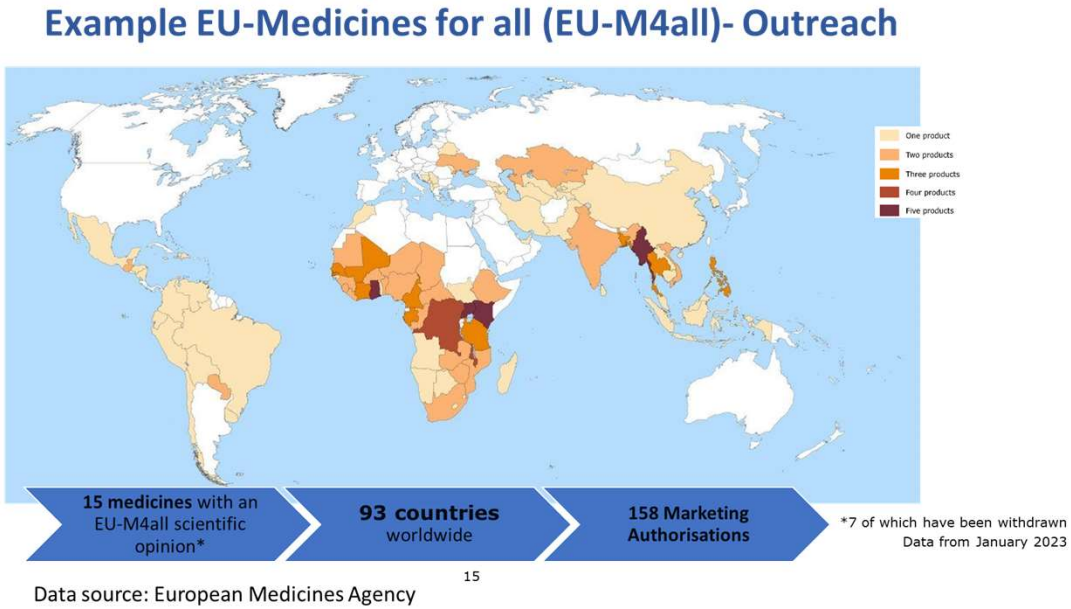
Global Health Procedures (EU-M4all and MAGHP) - Numbers





- WHO facilitate participation of WHO experts and target NRA experts in these procedures.
- Working closely with the European Medicines Agency and Swissmedic to advocate for these procedures, share lessons learned and promote best practices.

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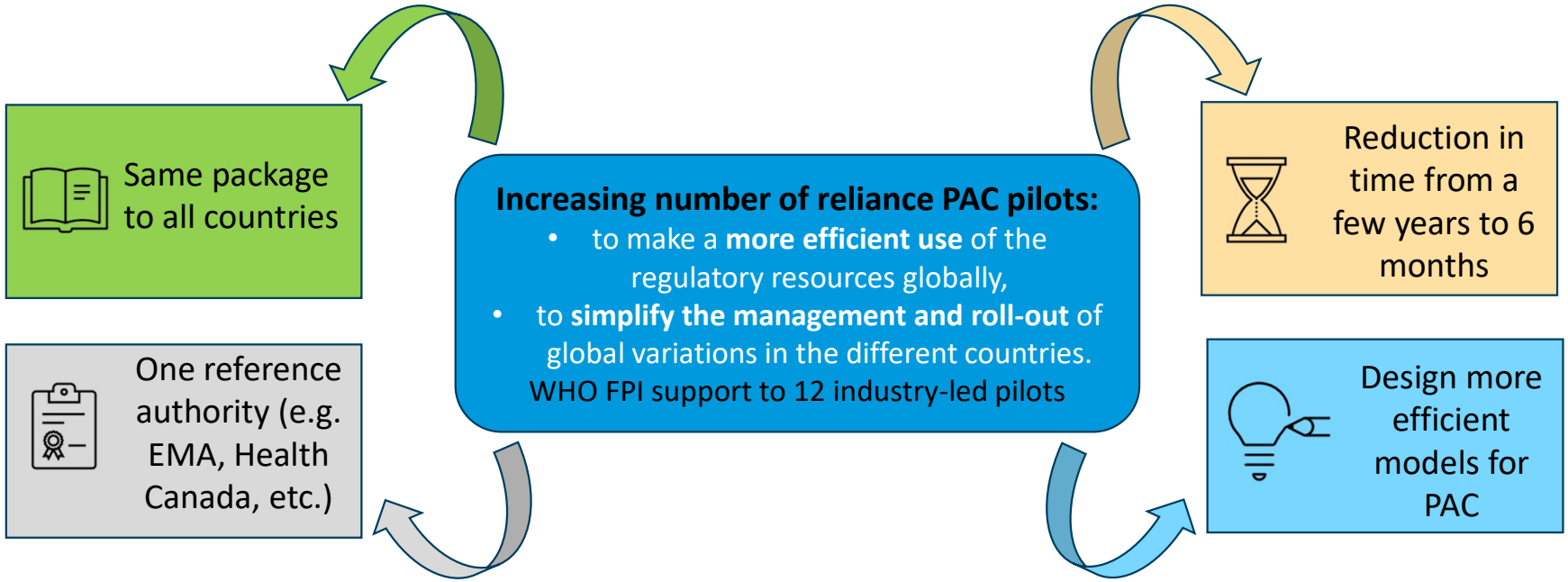
3- PAC Evolving landscape with increasing use of reliance

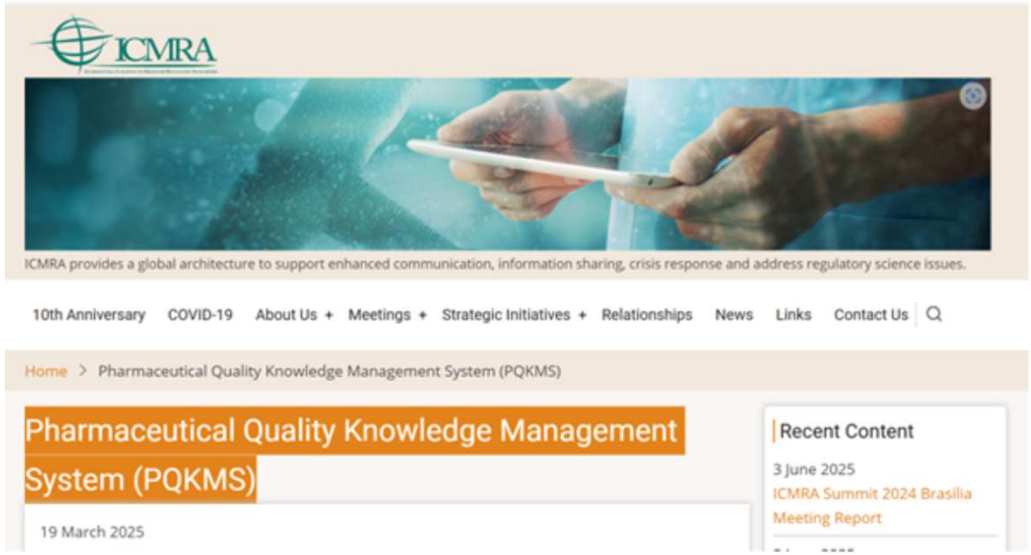


Important to consider concomitant submissions for key supply-chain variations
Standard reliance for all/minor variations
Aim is also to harmonize/streamline requirements (same package for all)

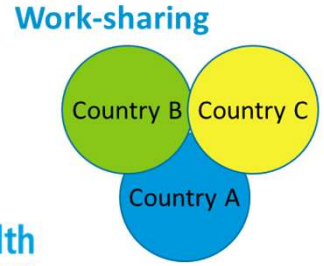
World Health Organization

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



Collaborative assessments and inspections

<u>Two Pilot Programs focusing on</u>:

- 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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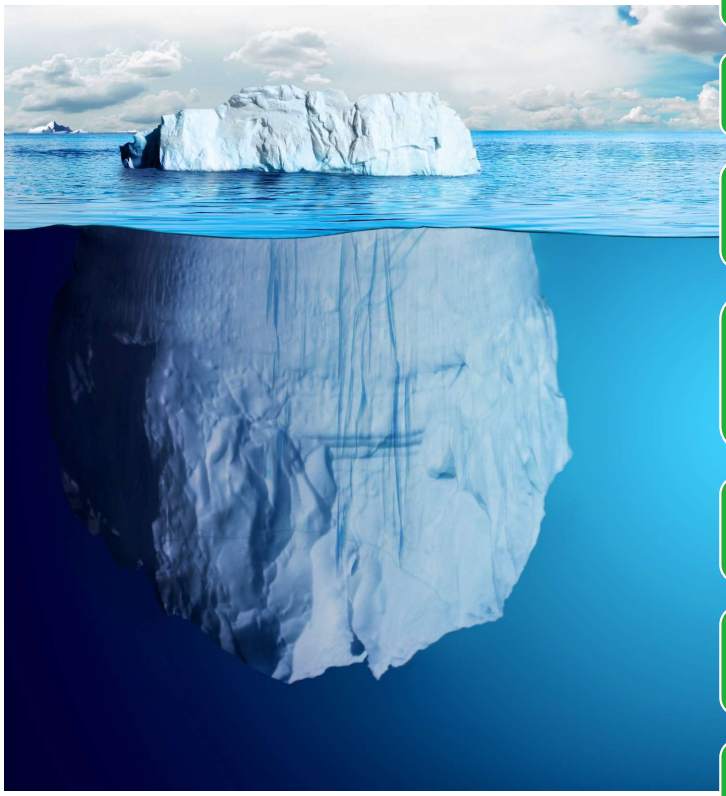
How can we collectively better manage PAC?

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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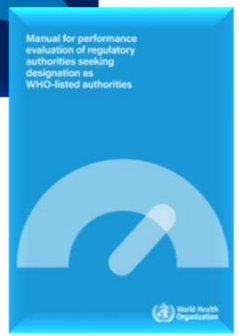
WHO Listed Authority

WLA Framework

Policy document (2021)

Operational Guidance (2023)



Manual for Performance Evaluation (2023)

33 Member States and 36 Regulatory Authorities evaluated and listed in 2023-2024

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.

Largest number of regulatory agencies for medical products approved as WHO Listed Authorities

26 May 2024 | News release [Reading time: 2 min (530 words)]

WHO has approved designations 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 marks 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

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Thank you

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