IFPMA International Federation of Pharmaceutical Manufacturers & Associations

IFPMA webinar series on WHO facilitated regulatory pathways

Agenda

Welcome remarks	Janis Bernat
Principles of reliance and recent developments	Marie Valentin
Facilitated product introduction: Collaborative registration procedure and regional product assessments	Sunday Kisoma
Global health product procedures	Marie Valentin
International collaboration and reliance in practice	Victoria Palmi
Marketing Authorisation for Global Health Products (MAGHP)	Lodovico Paganini
Regional Joint Assessments	Sunday Kisoma & Marie Valentin
Q&A	All

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Reminder For Webinar Participants

The webinar is recorded, available on demand at events@ifpma.org

All participants are **muted.**

Please use the **“Q&A” function** to ask your questions to the panelists.

Scan the **QR code** on the screen to answer the Mentimeter question directly from your device.

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Instructions

Go to

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Enter the code

6459 4145

Or use QR code

Principles of reliance and recent developments

IFPMA Webinar on Facilitated Regulatory Pathways

Virtual Meeting, 19th September 2024

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

World Health Organization

Reliance is not a new concept…

Long history of improving efficiency through reliance e.g. Certificate of Pharmaceutical Products Scheme

"Regulate through reliance" as the hallmark of a modern and efficient regulatory authority.

Increasing role of reliance

Promoting "informed" reliance

WLA a new transparent and evidence-based system

COVID-19 response as a strong accelerator for the use of reliance

Flexibility/new ways of working

World Health Organization

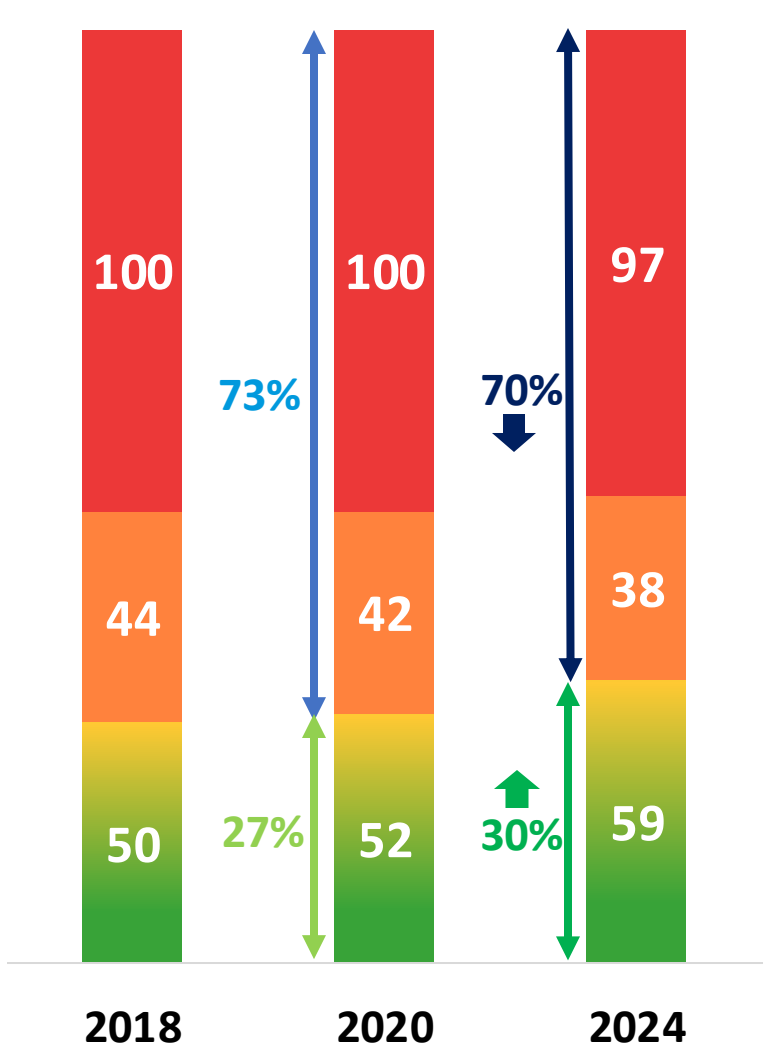
Objectives of the WHO regulatory system strengthening programme

Why reliance?

ML

- *With some elements of regulatory system* — 1
- *Evolving national regulatory system* — 2
- *Stable, well functioning and integrated* — 3
- *Advanced level of performance and continuous improvement* — 4

ML: *(regulatory system) maturity level*



*Total Number of countries = **194***

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

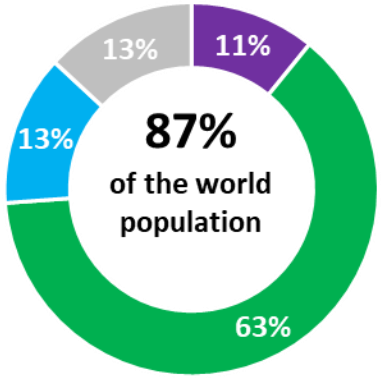
Good regulatory practices, 2021

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

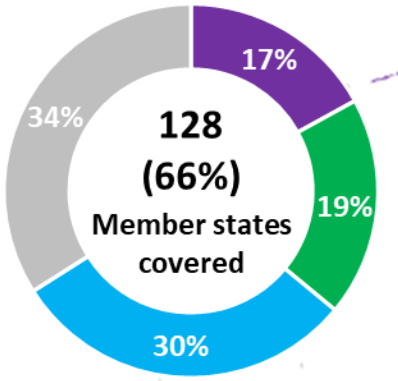
Good reliance practices, 2021

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

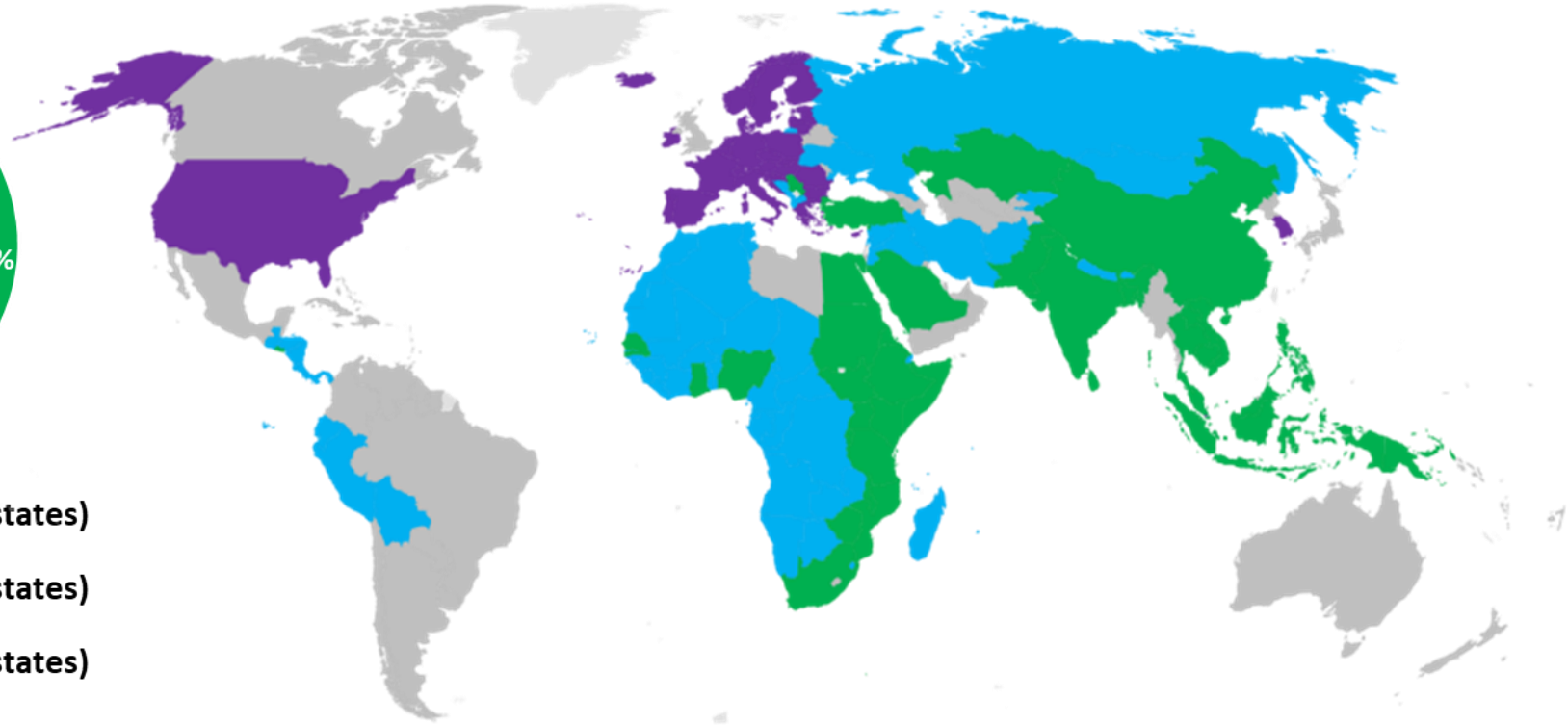
% of world population



% of member states



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



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.

Powered by Bing

Source: WHO RSS database, Sep 2024

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Reliance at the core of a more efficient use of global resources

70% of countries have weak national regulatory systems
Need to facilitate access to quality-assured medical products and to build capacity

Reliance to promote better use of limited resources and to strengthen global regulatory oversight

Apply a risk-based approach, avoid duplication where possible, full range of reliance options (work sharing, abridged pathways, etc.)

Implementation
Voluntary participation, change mindset, start small, learning by doing, harmonization facilitator but not pre-requisite

Evolving science and regulatory challenges
Globalization of markets and clinical trial programmes, complexity of supply chains, rapid evolution of science, transparency and growing public expectations etc.

WHO Listed Authorities
Transparent, evidence-based system to define trusted authorities

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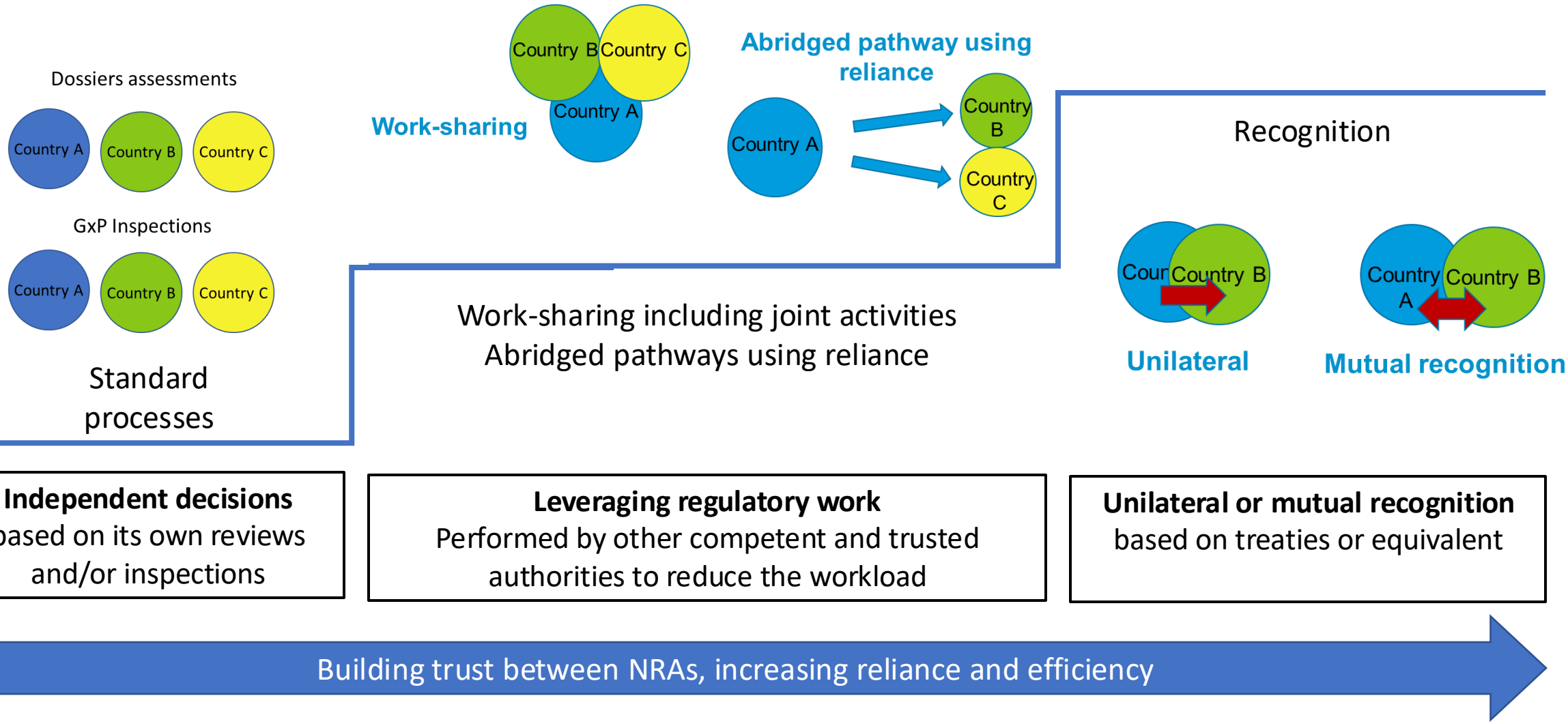
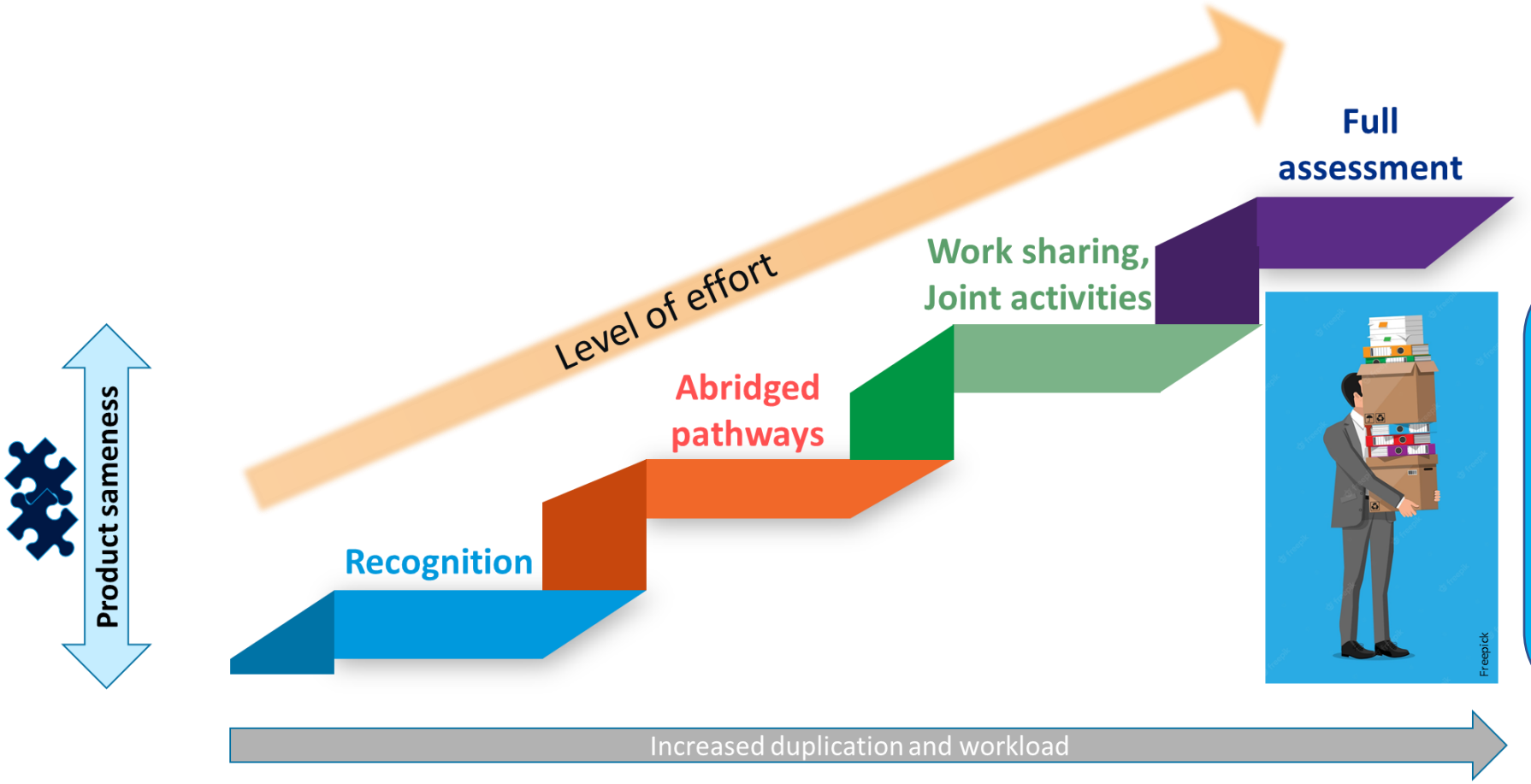
Key concepts of reliance



Promote collaboration and reduce duplication where possible



Regulatory activities

Where can I rely?

Where can I collaborate?

What shall I do alone?

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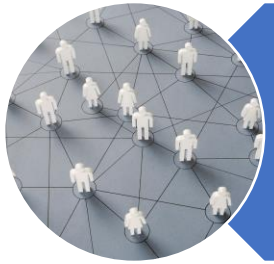
WHO Facilitated registration procedures

WHO Collaborative Registration Procedure

Global Health Product Procedures

EU-M4all & Swissmedic MAGHP



Regional Joint assessments in African Regional Economic Community & ASEAN

Access to quality-assured products

Collaboration & capacity buidling

Abridged pathway

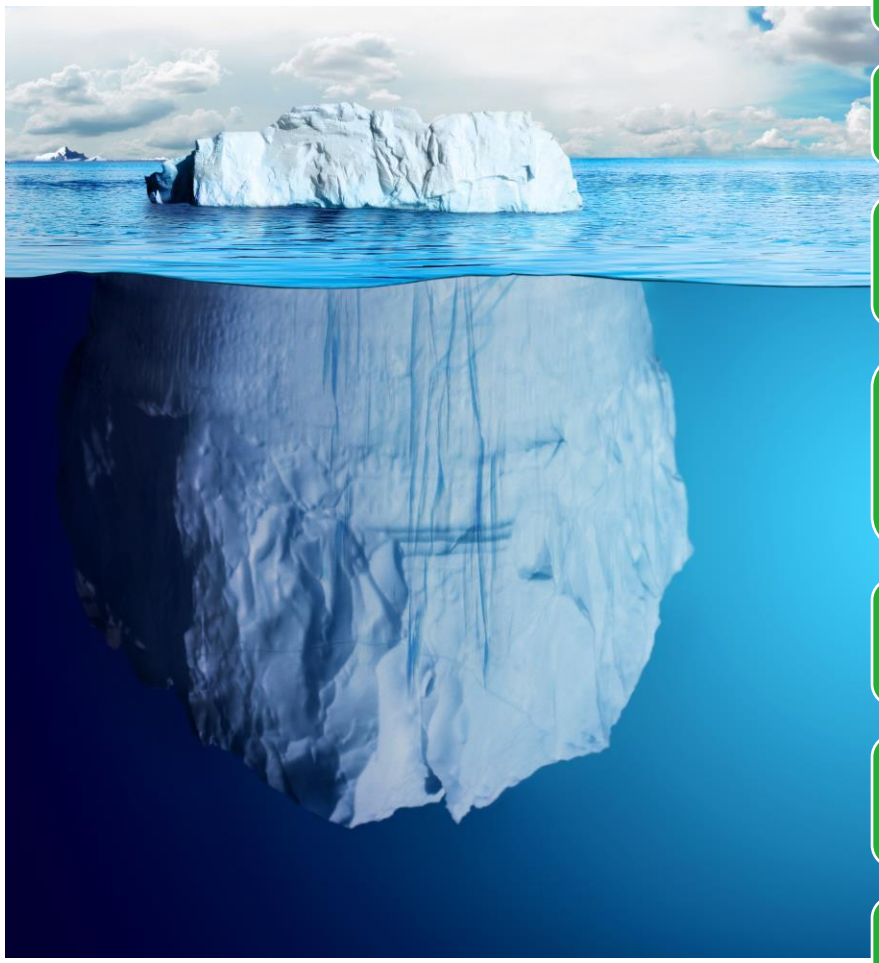
Participation in the SRA Assessment

Work-sharing

World Health Organization

Ideas for increasing role of reliance for 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

World Health Organization

WHO Facilitated registration procedures - Conclusions

Strategy of the manufacturer

Some of these tools can be combined

Considering also other initiatives e.g. ACESS, OPEN, Orbis, Pharmaceutical Quality Knowledge Management System, AMA pilot etc.

Many regulatory tools in the box!

WHO FPI Role

To clarify role/characteristics of the different pathways in collaboration with other stakeholders

Technical support

Advocacy and relevant trainings

World Health Organization

www.who.int/medicines

Thank you for your attention!

Marie Valentin, Team Lead, Facilitated Product Introduction, World Health Organization

valentinm@who.int

IFPMA Webinar Series on WHO Facilitated Regulatory Pathways

Thursday 19 September 2024

Facilitated Product Introduction : Collaborative Registration Procedure and Regional Product Assessments

Sunday Kisoma,
Technical Officer, Facilitated Product Introduction,
WHO/MHP/RPQ/REG/FPI

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Part I : Facilitated Product Introduction Collaborative - Registration Procedure

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 mechanisms and product scope

PQ CRP - products prequalified by WHO via full assessment:

- Medicines
- Vaccines
- Biotherapeutics
- IVDs
- Vector Control Products
- Applies to therapeutic areas in the scope of PQ

PQ CRP (Mx and Vx):

https://extranet.who.int/prequal/medicines/accelerated-registration-prequalified-fpps

PQ CRP (IVDs):

https://extranet.who.int/prequal/vitro-diagnostics/collaborative-procedure-accelerated-registration

SRA CRP:

https://extranet.who.int/prequal/medicines/accelerated-registration-fpps-approved-sras

SRA CRP - any product assessed or approved by an SRA:

- Innovative and generic products (chemicals or biologicals): Medicines/Pharmaceuticals, multisource/generics, vaccines, biosimilars, biotherapeutics, etc.
- Products Prequalified by WHO via Abridged review (SRA approved)
- Products approved by special routes or provided with positive scientific opinion: EU M4-all and Swissmedic Marketing for Global Health Products.

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CRP Steps – PQ CRP/SRA CRP

Participatin : 67 NRAs + 1 REC (CARICOM)

- Angola
- Armenia
- Azerbaijan
- Bangladesh
- Belarus
- Benin
- Bhutan
- Botswana
- Burkina Faso
- Burundi
- Cabo Verde
- Cameroon
- Caribbean Community (CARICOM)
- Central African Republic
- Chad
- Comores
- Côte d'Ivoire
- Democratic Republic of the Congo
- Eritrea
- Ethiopia
- Gabon
- Gambia
- Georgia
- Ghana
- Guinea (Republic of)
- 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
- Philippines
- Republic of Congo
- Republic of Moldova
- Rwanda
- Sao Tome and Principe
- Senegal
- Sierra Leone
- South Africa
- Sri Lanka
- Sudan
- Tanzania (Mainland)
- Tanzania (Zanzibar)
- Timor-Leste
- Thailand
- Togo
- 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

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List of SRAs as per WHO Guidelines

TRS 1003 - 51st report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations

WHO Technical Report Series 1003

14 June 2017 | Technical document

Overview

The WHO Technical Report Series makes available the findings of various international groups of experts that provide WHO with the latest scientific and technical advice on a broad range of medical and public health subjects. Members of such expert groups serve without remuneration in their personal capacities rather than as representatives of governments or other bodies; their views do not necessarily reflect the decisions or the stated policy of WHO.

- ✓ EMA
- ✓ FIMEA (Finland)
- ✓ MEB (The Netherlands)
- ✓ MHRA (UK)
- ✓ MPA (Sweden)
- ✓ Swissmedic (Switzerland)
- ✓ TGA (Australia)

Based on the above interim definition, the following is the list of the countries whose NRAs are designated as SRAs.

Australia	Germany	Netherlands
Austria	Greece	Poland
Belgium	Hungary	Portugal
Bulgaria	Iceland	Romania
Canada	Ireland	Slovakia
Croatia	Italy	Slovenia
Cyprus	Japan	Spain
Czech Republic	Latvia	Sweden
Denmark	Liechtenstein	Switzerland
Estonia	Lithuania	United Kingdom
Finland	Luxembourg	United States of America
France	Malta	Norway

+ EMA

WHO PQ CRP : Mechanism

1.
Source of Information to rely upon:

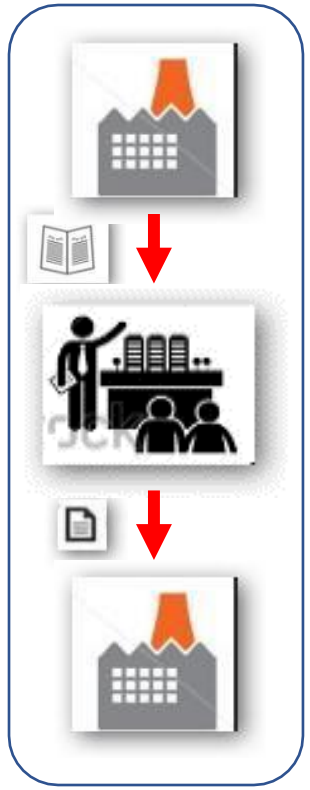
2.
Documentation to be shared:

3.
Actions for different stakeholders

WHO FPI

WHO PQT/SRA

a) Full Product Dossier (CTD format) : updated
b) Module 1 : Country specific
c) WHO QIS/SRA QIS
d) Detailed Assessment Reports: QOS PD (Initial, add. data) and Variations
d) GMP Inspection Reports (API + FPP)
e) GCP Inspections : CROs



Lifecycle management

Applicant

Submission

NRA

NRA Review: Recognition or Reliance - 90 working days (regulatory time)

Regulatory Decision

Variations
NRA Review: Recognition or Reliance - 30 working days (regulatory time)

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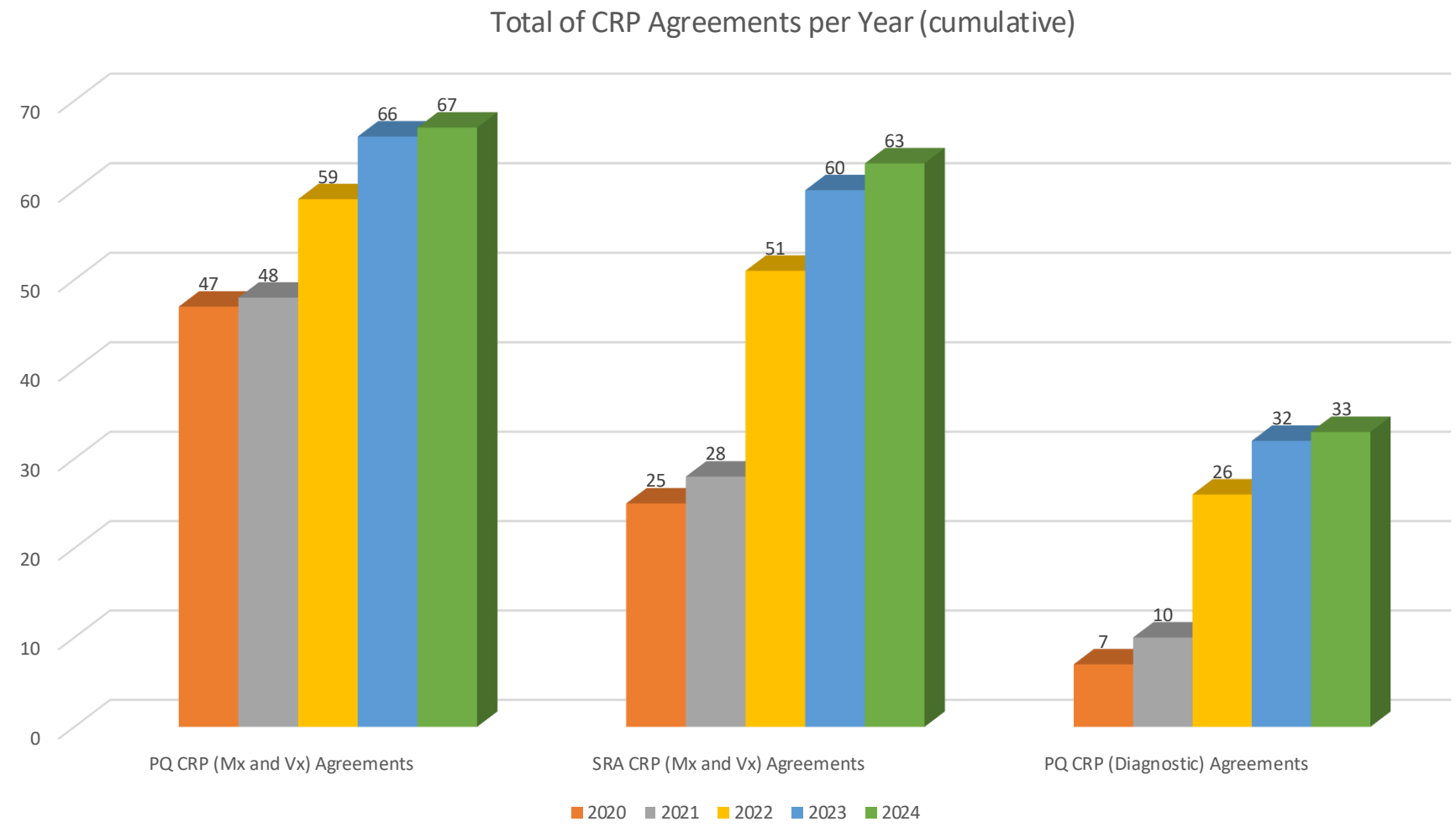
Progress on Countries Participation



1. **PQ CRP (Mx and Vx) – 67 NRAs (incl. 1 REC)**

2. **SRA CRP – 63 NRAs (incl. 1 REC)**

3. **PQ CRP (IVDs) – 33 NRAs**

4. **PQ CRP (VCP) – 6 NRAs (pilot)**

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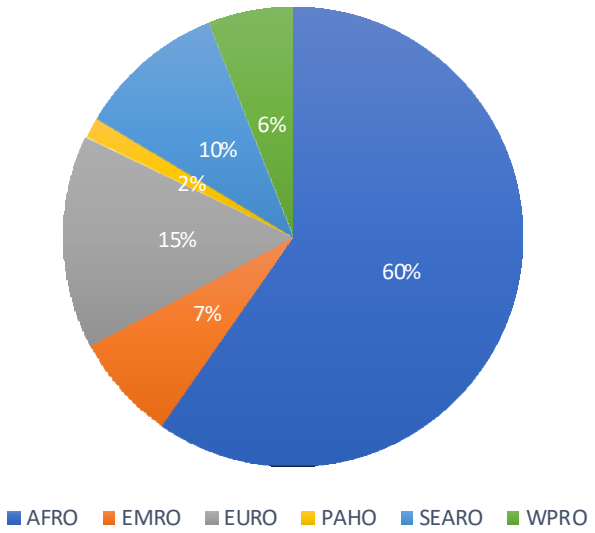
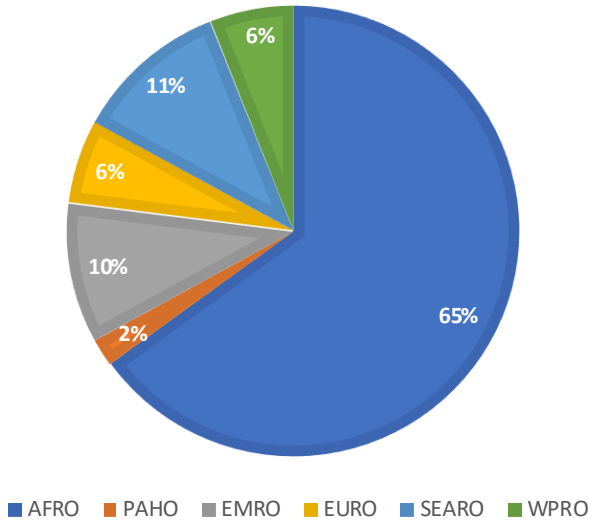
Progress on Countries Participation

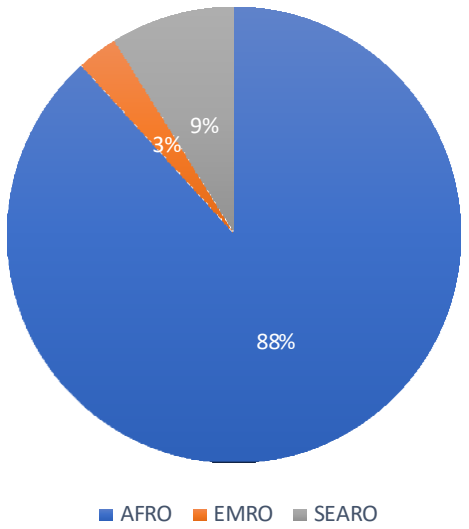
PQ CRP Agreements (Mx and Vx)



SRA CRP (MX & VX) AGREEMENTS BY REGION



IVDs CRP Agreements



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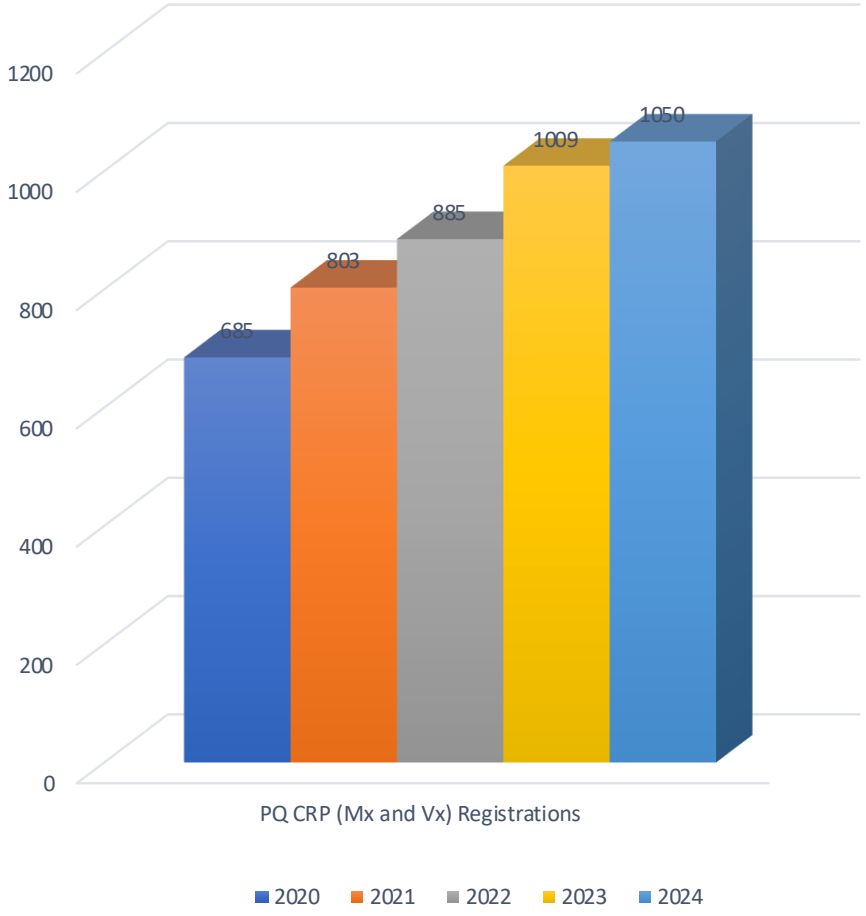
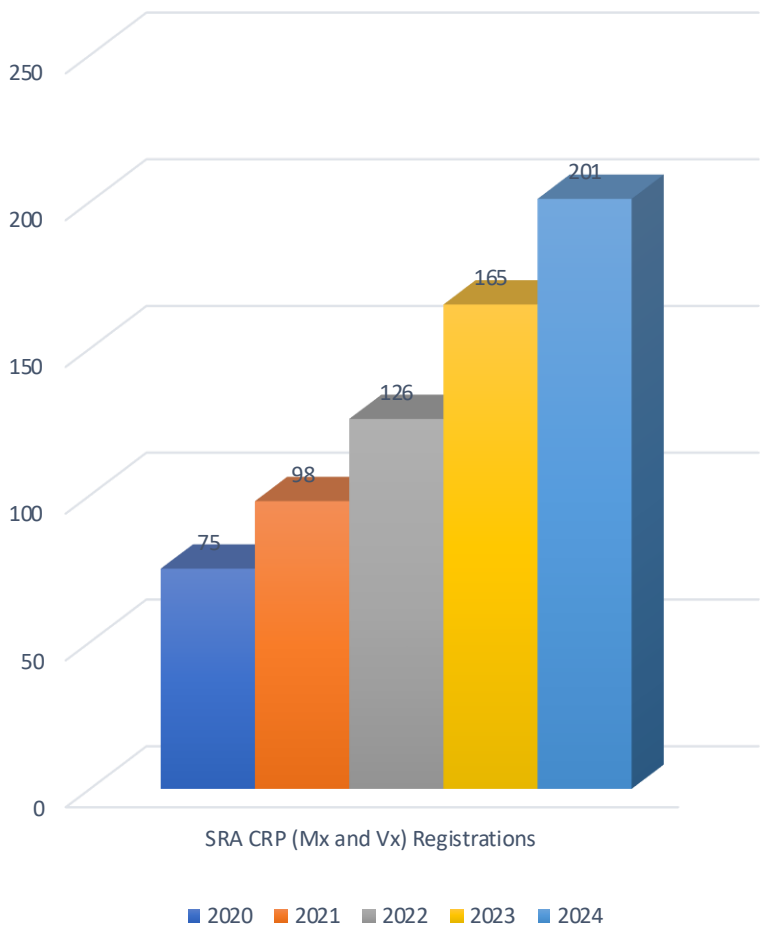
CRP data, progress and achievements 2024 (August)

PQ CRP (Mx and Vx)



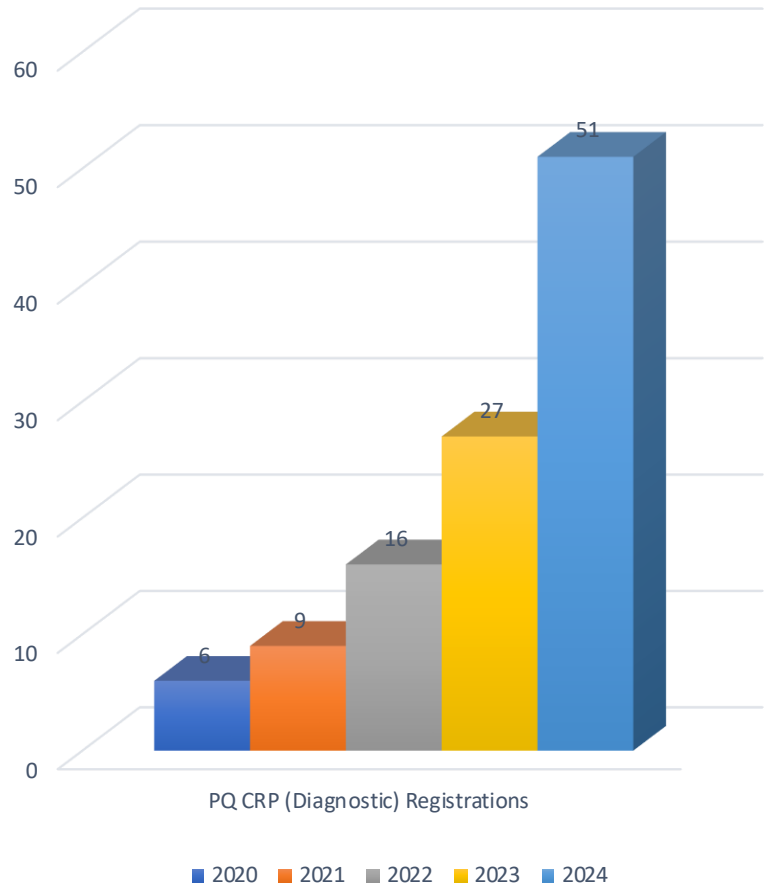
Number of prod. submissions: 1620

SRA CRP (Mx and Vx)



Number of prod. Submissions : 299

PQ CRP (IVDs)



Number of prod. Submissions : 74

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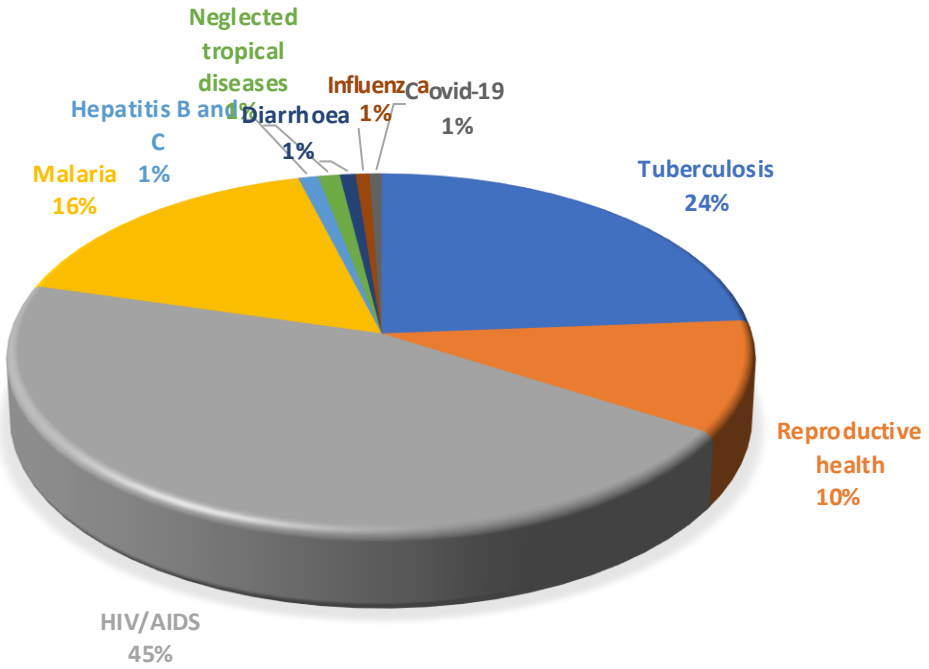
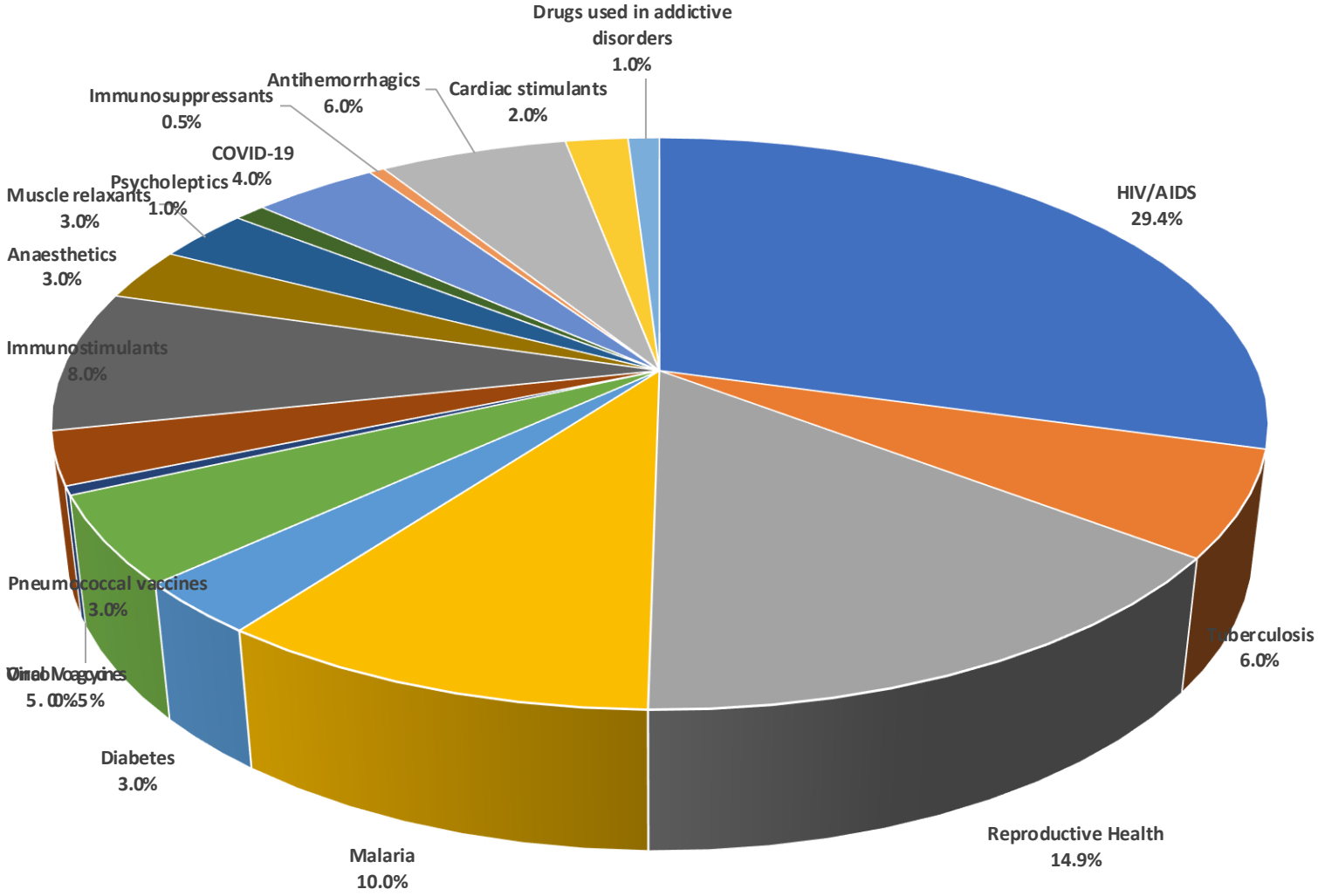
CRP data, progress and achievements





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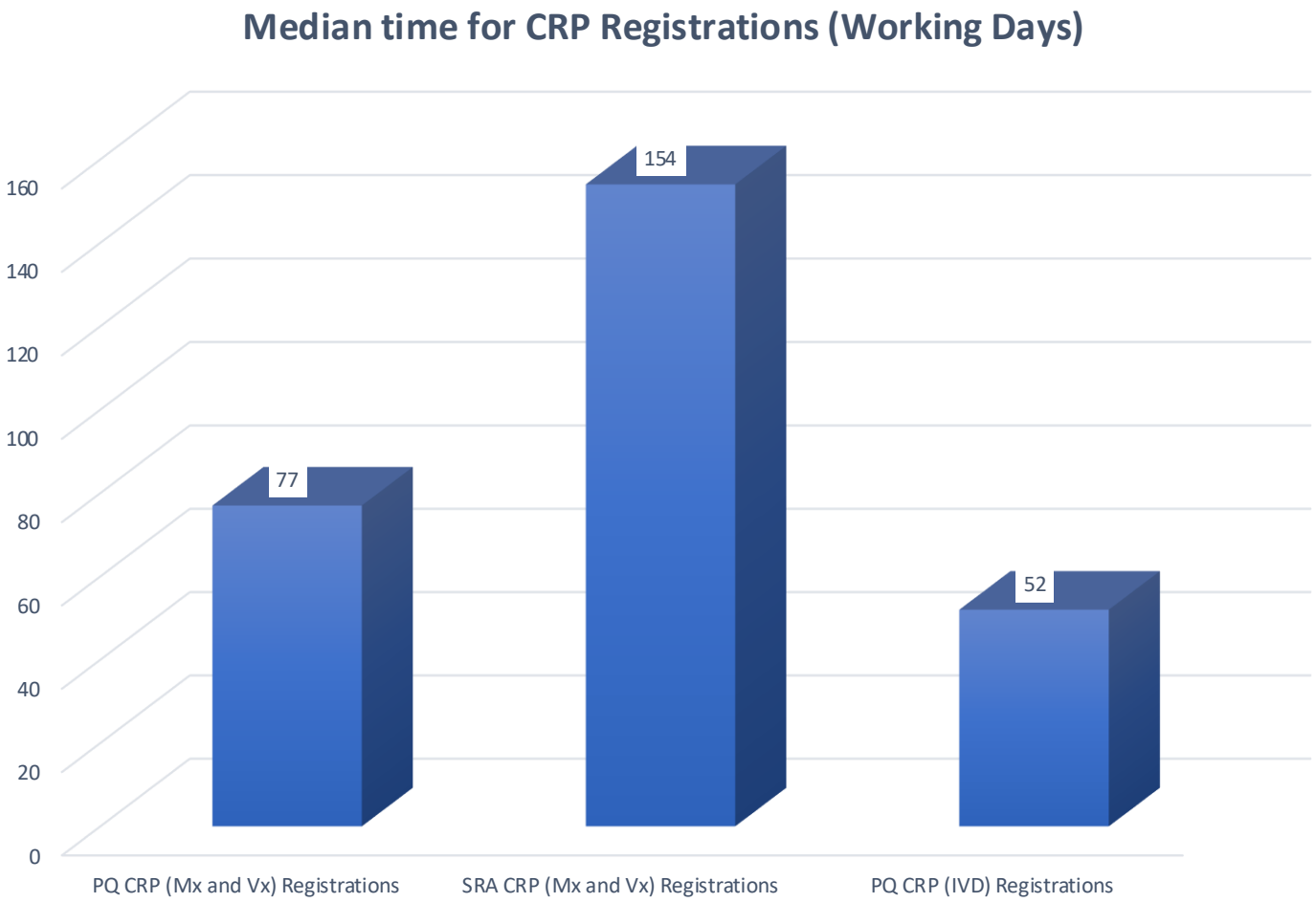
CRP data, progress and achievements 2024



- ✓ ***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)***

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Challenges and Interventions

Relatively Low uptake and utilization vs Opportunity

Lack/low responsiveness from NRAs

Information sharing and exchange

National regulatory requirements

Post Approval Changes management

National policies

- **Manufacturers/applicants: webinars, workshops, CRP Annual meetings, 1-on 1 meetings on regulatory pathways and specific NRA requirements**
- **NRAs : Regional workshops, CRP annual meeting, individual NRA trainings on reliance practices**
- **Centralized information sharing and exchange under dedicated platform (ePQS). NRA and manufacturers Pilot in Q4**
- **Strengthen Registration systems: Review of national requirements (guidelines and procedures) to enhance more reliance and minimize specific national requirements, communications with manufacturers, training and capacity buidling**
- **Product lifecycle : Reliance on PACs, support to specific PAC management initiatives, considerations to better define PAC in the context of CRP**
- **Procedure optimization : Review of Good Practices Guidelines to NRAs to align with current best practices**

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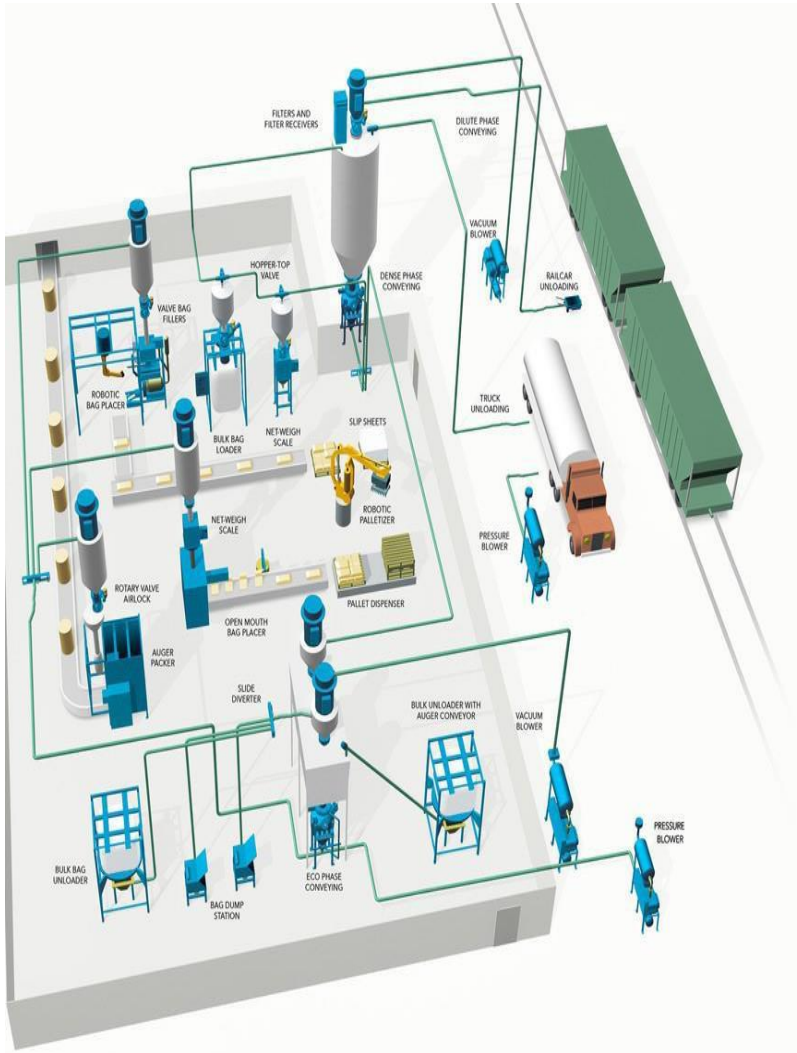
Take Away messages



- Evidence over 10 years demonstrationg reliance in assessment and MA in action : 1000+ MA facilitated
- CRP works effectively in all product streams : stakeholders to utilize this validated reliance mechanism
- Short timelines vs standard national process : access to patients, quick product introduction
- Supports harmonization and streamlining the submissions, predicted assessment styles and cycles
- Can facilitate reliance in PAC management : reduce manufacturers regulatory burden
- Continued growth : stakeholders committment, expansion to wider scope of product stream

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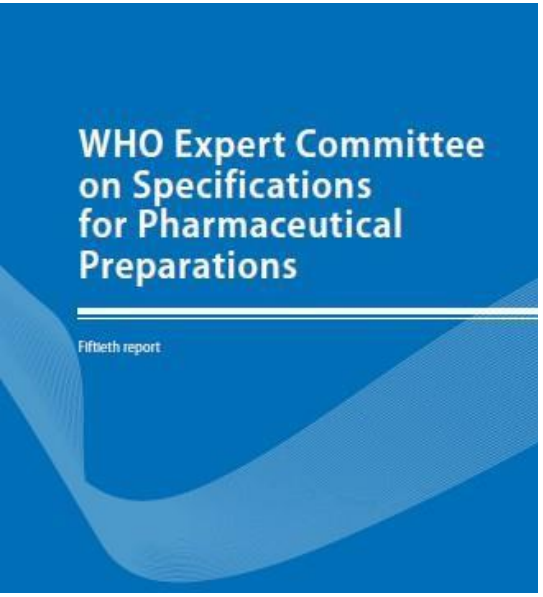
Relevant Tools and Resources

PQ CRP



Annex 8

Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines

https://iris.who.int/bitstream/handle/10665/255338/9789241209960eng.pdf?isAllowed=y&sequence=1#page=277&zoom=auto,-344,680

SRA CRP

Annex 11

Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities

https://iris.who.int/bitstream/handle/10665/272452/9789241210195eng.pdf?isAllowed=y&sequence=1#page=367&z_om=auto,-284,680

Global Health Products Procedures

Marie Valentin

Team Lead

Facilitated Product Introduction Team

Regulation and Safety Unit, Regulation and Prequalification Department, World Health Organization

IFPMA Webinar on Facilitated Regulatory Pathways

Virtual Meeting, 19th September 2024

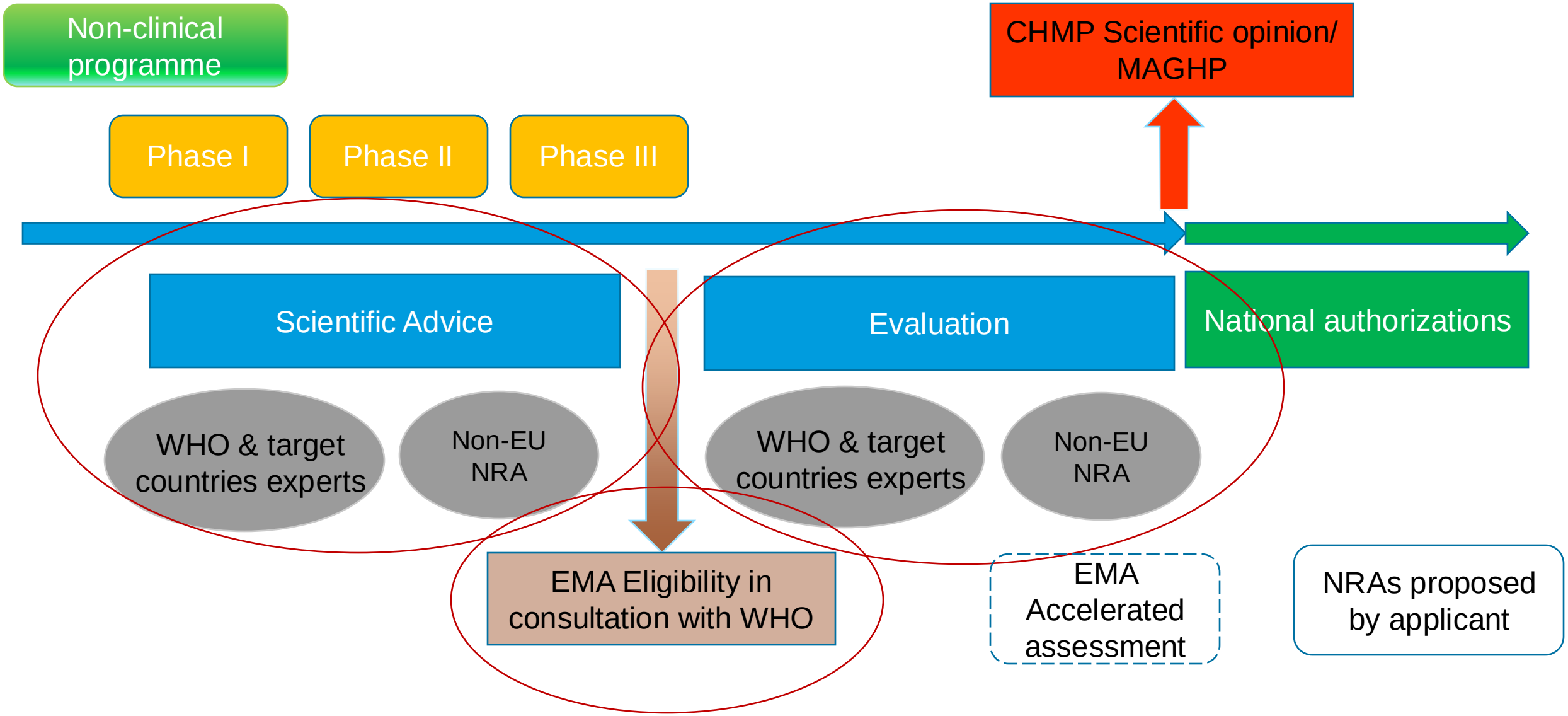
Global Health Products Procedures (EU-M4all and MAGHP)

- Scientific evaluation from Stringent Regulatory Authorities for products to be used outside of the European Union and Switzerland
- Involve target NRAs and WHO experts

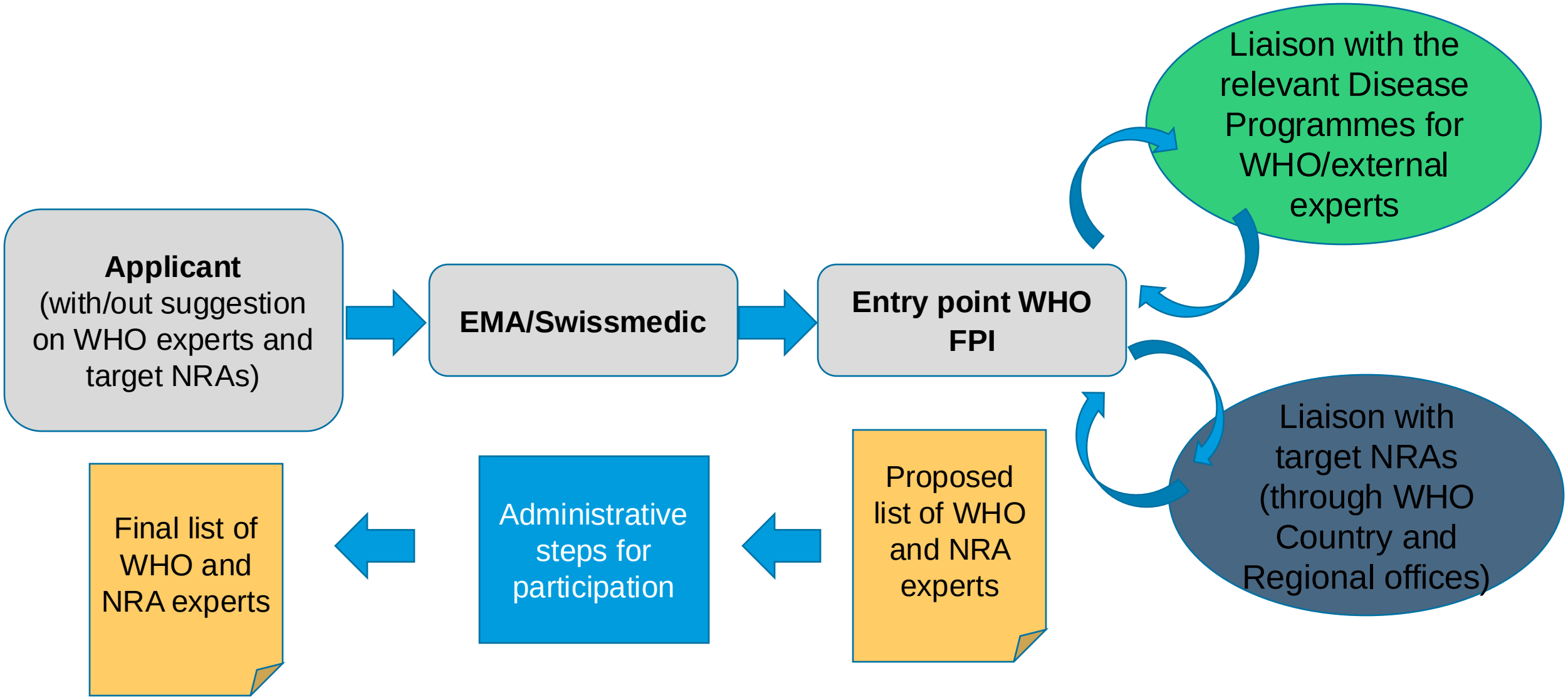
- Facilitate in-countries decisions

- Sharing expertise, capacity and trust building

WHO support to EU-M4all and Swissmedic MAGHP



Nomination process



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU-Medicines for all (EU-M4all)

International collaboration and reliance in practice

IFPMA WHO Webinar on Facilitated Regulatory Pathways

Presented by Victoria Palmi - EMA International Affairs

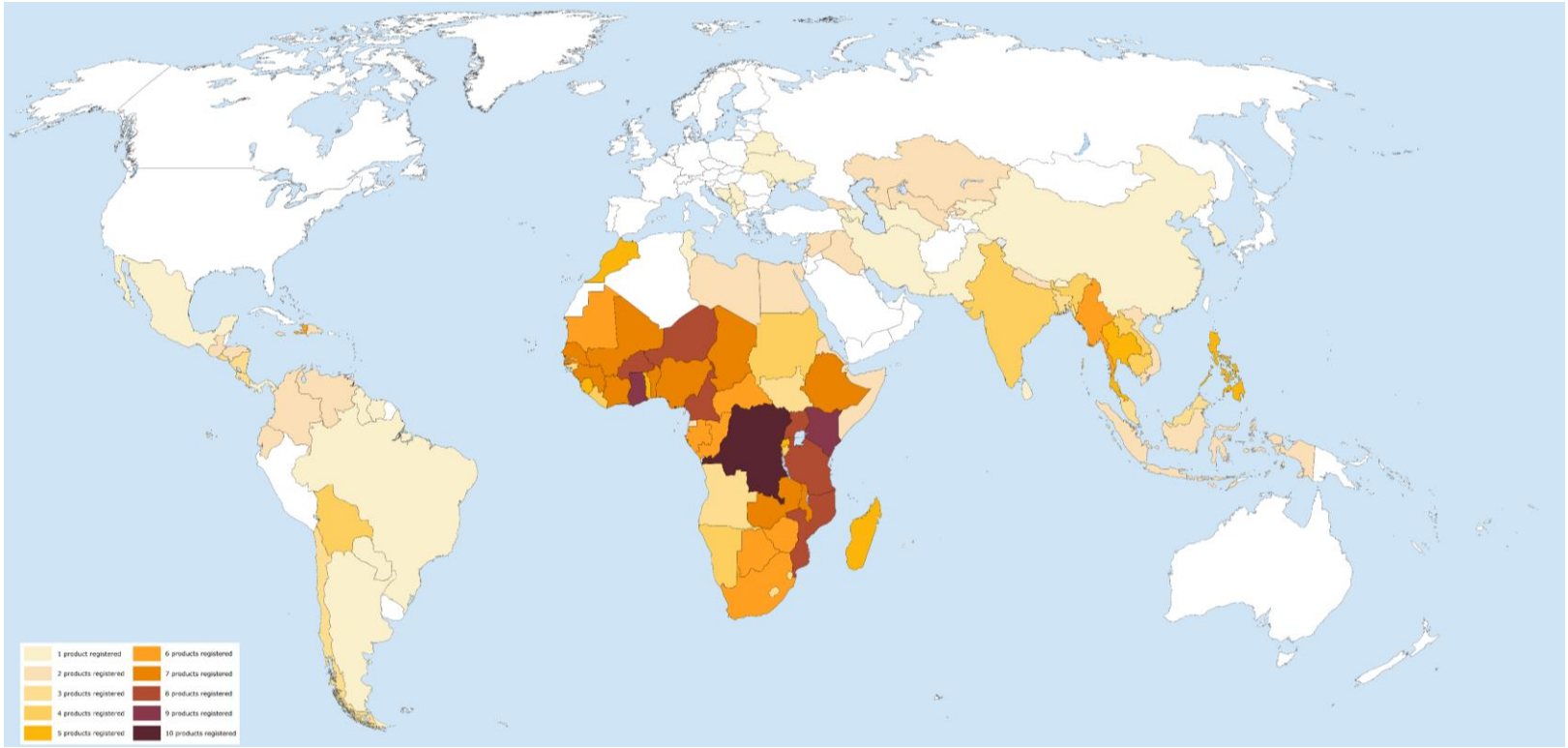
EU-Medicines for all (EU-M4all)

EMA supports the global regulatory system through its collaboration with **WHO** with this procedure

With EU-M4all

EMA evaluates and gives an opinion, in cooperation with **WHO and target NRAs**, on medicinal products for human use intended for markets outside of the EU.

Since 2021, this procedure can also be performed in parallel to a centralised procedure to accelerate medicines access at a global scale.



17 medicines with an EU-M4all scientific opinion*

115 countries worldwide

394 Marketing Authorisations

*7 of which have been withdrawn or surrendered and 1 pending as of September 2024

EUM4all

How does it work?

EMA can assess medicines and vaccines that address unmet medical needs or are of major public health interest **for use outside the EU**;

- Eligibility agreed with WHO
- Evaluation in **collaboration** with WHO/target NRAs:
- Same procedure as medicines for the EU (210days /150days for AA);
- Assessment Report/EPAR published on EMA website
- Same post-approval variations/PSURs/RMP
- National regulators remain **independent** in their decision making

What are the benefits?

- Same rigorous assessment as medicines for the EU;
- Epidemiology and disease expertise from WHO and national regulators in the countries where the products are expected to be used are included in the assement.
- Benefit-risk assessment tailored to intended non-EU population;
- **Capacity-building** for target NRAs promotes **confidence** in scientific process
- Streamlined assessment under the WHO prequalification programme;
- **Facilitated registration in target countries.**

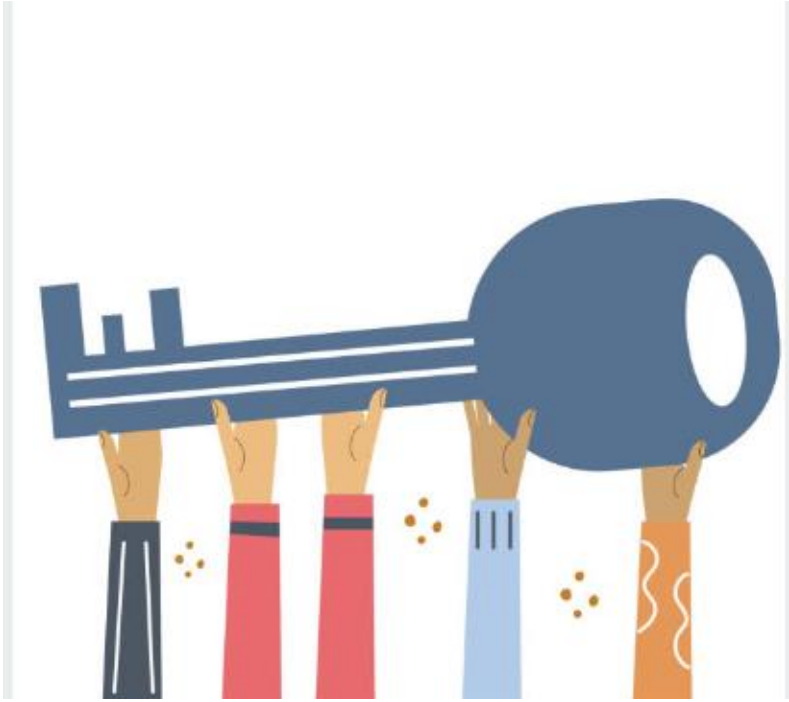
Role of WHO and national regulatory experts in EUM4all

- Act as **scientific experts** to contribute to SA or evaluation
- Invited to send their **comments** on the assessment reports
- **Participate** in PRAC/CHMP plenary **meetings**, ad-hoc expert groups, working parties or scientific advisory groups (SAG), as appropriate
- Participate in GCP and GMP inspections, if appropriate/possible.
- Benefit from awareness of scientific issues that are identified during assessment to speed up national registrations
- National registrations remain independent in their decision making but collective technical work as part of the evaluation facilitates reliance.

Pre-submission opportunities for EUM4all applicants

- Is my product regulated as a medicinal product within EU?
  - Innovation Task Force
- How do I get a handle on my product portfolio in EU?
  - Business Pipeline Project
  - Filing strategy
- How do I address my Paediatric obligations - PIP/deferral/waiver?
  - PIP
- How to best prepare for the evaluation procedure? When can I expect a GMP / GCP inspection
  - MAA Pre-Submission meeting
- Can I receive Scientific Advice regarding my development strategy?
  - SAWP
  - ETF
- Can my product be evaluated by the Agency?
  - CP eligibility request
  - Rapporteur appointment
- Am I eligible for product incentives in the EU?
  - SME Office
  - Orphan incentives
  - Fee reductions
- Am I eligible for PRIME?
  - PRIME
  - Accelerated assessment

Key take-away messages



- International collaboration and reliance is a necessity, not a choice.
- Increasing numbers of facilitated pathways show the impact of international collaboration and reliance in facilitating faster assessments.
- The EUM4all combines EMA's scientific review capabilities with the local epidemiology and disease expertise of WHO and national regulators in the target countries
- This bring benefits to regulators, industry and specially to **patients.**

Thanks for your attention

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Marketing Authorisation for Global Health Products (MAGHP)

IFPMA – WHO Webinar
on Facilitated Regulatory Pathways
19 September 2024

Lodovico Paganini, Scientific Officer
Stakeholder Engagement Division

Marketing Authorisation for Global Health Products

The MAGHP is based on the approach of involving regional National Regulatory Agencies (NRAs) and the WHO in the Swissmedic assessment process.

The procedure consists of two independent – ideally subsequent – components:

Scientific Advice

- To clarify scientific questions in the **development phase** regarding a planned submission
  - on quality of APIs and products
  - on the planning and organisation of preclinical investigations and clinical trials
  - on aspects of PV and RMP

Marketing Authorisation

- The procedure follows the regular Swissmedic marketing **authorisation procedure**
  - same time frames, procedural steps and evaluation criteria
  - results in an authorisation for the Swiss market
- with the difference that concerned NRAs and the WHO are involved

MAGHP Light

Background

- Pandemic brought up question, whether MAGHP is applicable/suitable for Covid-19 medicines
- Not directly applicable due to high urgency of corresponding requests
- Alternative suggestion: Leaner and more agile MAGHP procedure → MAGHP light
- Implementation incl. statement on webpage and Swissmedic Journal on 1st October 2020

Process

- Explicitly applicable to all submissions in the fast track and temporary authorisation procedures
- Not restricted to Covid-19 medicines/vaccines
- Modalities of interaction between Swissmedic and NRAs limited to access to information/documentation
  ➢shorter timelines set by the accelerated procedures
- No further requirements on the follow-up processes by the authorities involved

Scope and eligible products

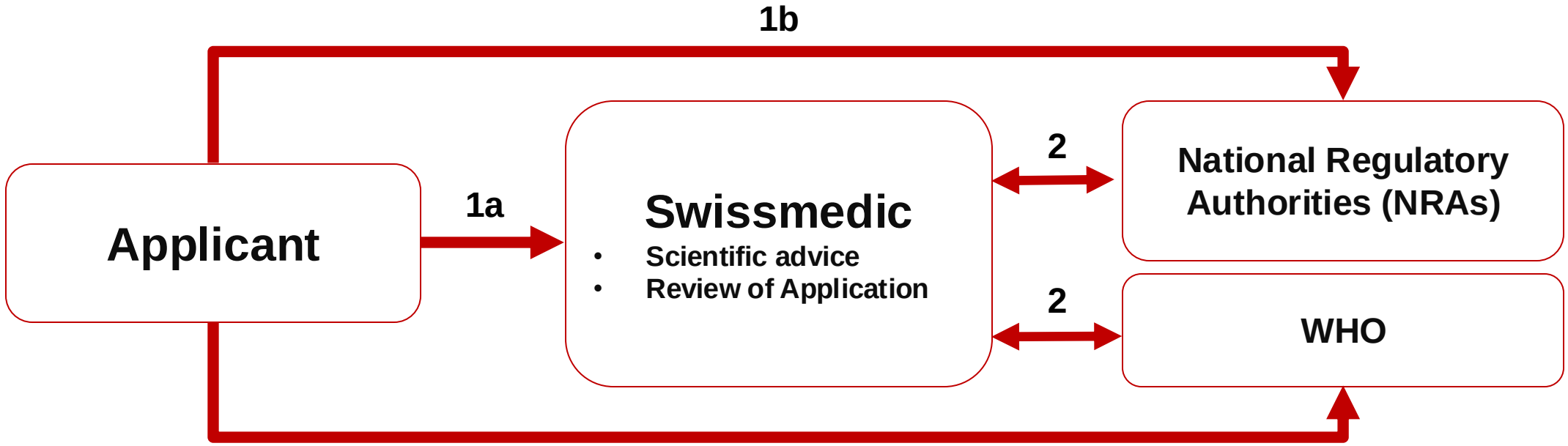
- Goal is to **accelerate access** to medicinal products targeting a concrete medical need in endemic regions

- Focus on **medical need** in global South

- Eligible medicinal products is limited to **new registrations/indications** of
  - ✓ medicinal products with a new active substance (**NAS**)
  - ✓ medicinal products with **a known active substance**

- **No restriction** to specific **therapeutic areas**.

Overview MAGHP procedure



1 Submission of documentation
2 Provision of MA application, list of questions, assessment reports, response packages on a secured «SharePoint» platform; interactions at defined milestones and ad-hoc (upon applicant's agreement to exchange confidential information)
3 Request for WHO Collaborative Registration Procedure / Prequalification

Involvement and interactions

NRAs and WHO are involved in the process as follows:

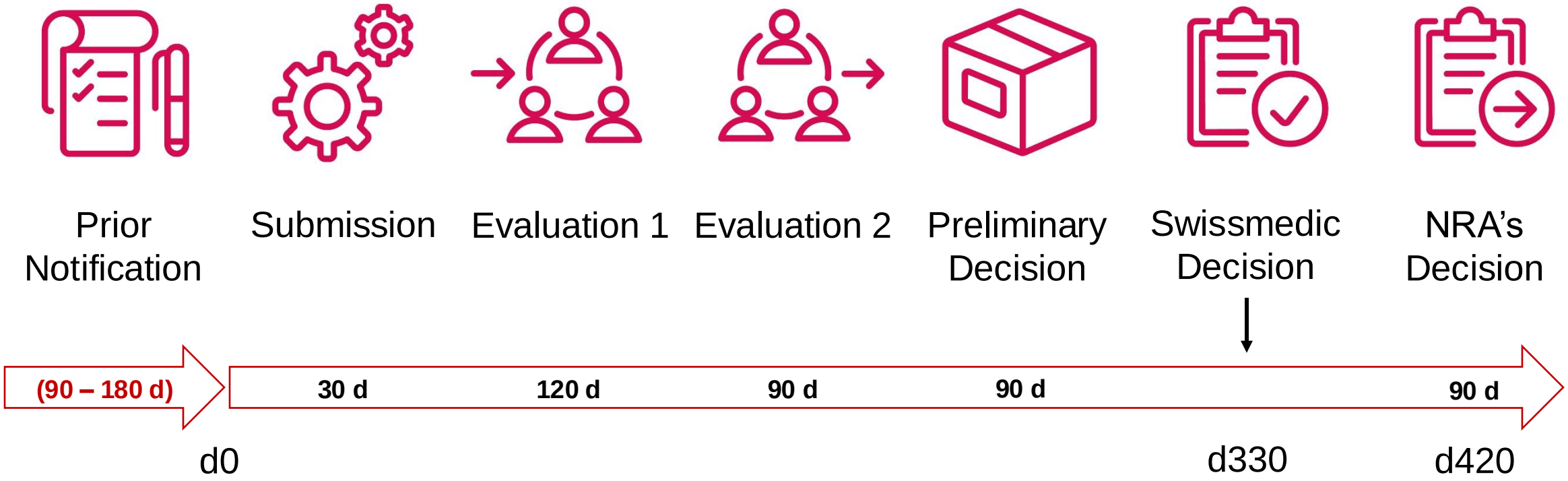
- **Get access to information**
  - Full documentation as submitted by the applicant (product dossier)
  - Swissmedic assessment reports and List of Questions (LoQ)
- **Provide input**
  - Evaluating/writing assessment reports
  - Adding questions to LoQ
- **Participate in meetings**
  - Scientific advice/pre-submission meeting
  - Case team meetings*
  - Experts review board*

*Internal meetings at Swissmedic

The choice about the NRAs/WHO to be involved follows the applicant's request.

NRAs/WHO decide about their participation.

Procedural Milestones



Scientific Advices - Updates

- Cryptosporidium - 2023
- Artemetherum-Lumefantrinum neonate - 2023
- Leishmaniasis - 2024
- Artemether-lumefantrine-amodiaquine - 2024

Icons designed by Freepik

New/ongoing MAGHP procedures

Ongoing procedure - ophthalmic anesthetic

- Submitted Q1 2024
- Assessment ongoing
- 1 targeted NRA from Africa involved

Ongoing procedure - malaria treatment in babies

- Submitted Q1 2024
- NRAs onboarding process ongoing
- 10 targeted NRAs from Africa
- + WHO disease programme

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MAGHP – Case Study

- Product for **prevention of postpartum uterine atony** following vaginal delivery approved
- 7 NRAs granted authorization, 3 of these within less than 90 days – **Median approval time = 5.5 months**
- Approval through **WHO Collaborative Registration Procedure** in Malawi, Ghana and Zambia
- Positive recommendation from **Carribbean Regulatory System**
- **WHO Prequalified**

- Advocacy/sensitisation events
- Feedbacks and lessons learned from Industry and targeted NRAs
- Cooperation and alignement with WHO
- Synergies and collaboration with EMA EU-M4-All

Cooperation with WHO and complementarity with WHO CRP

- Continous **exchange** with **WHO** and **optimization** of synergies
- Use of **SRA Collaborative Registration Procedure** is strongly encouraged as a vehicle to facilitate provisions of assessment and inspection reports following the MAGHP
- SRA CRP allows for an effective **management of the post-authorization changes**
- SRA CRP enables to **increase** the **outreach** of the procedure
- For prequalified products, the PQ-CRP should be used

Benefits

- **No restriction** to specific **indications**.
- The procedure helps building **trust** and **confidence** in the process.
- It helps **building capacitiy** at the involved NRAs.
- It produces **consolidated ARs**, with country-specific considerations.
- It is expected to **facilitate and speed up the granting of national marketing authorisations** following Swissmedic's approval (by "well-informed reliance").

Further information

Development Cooperation – Regulatory Systems Strengthening (swissmedic.ch)

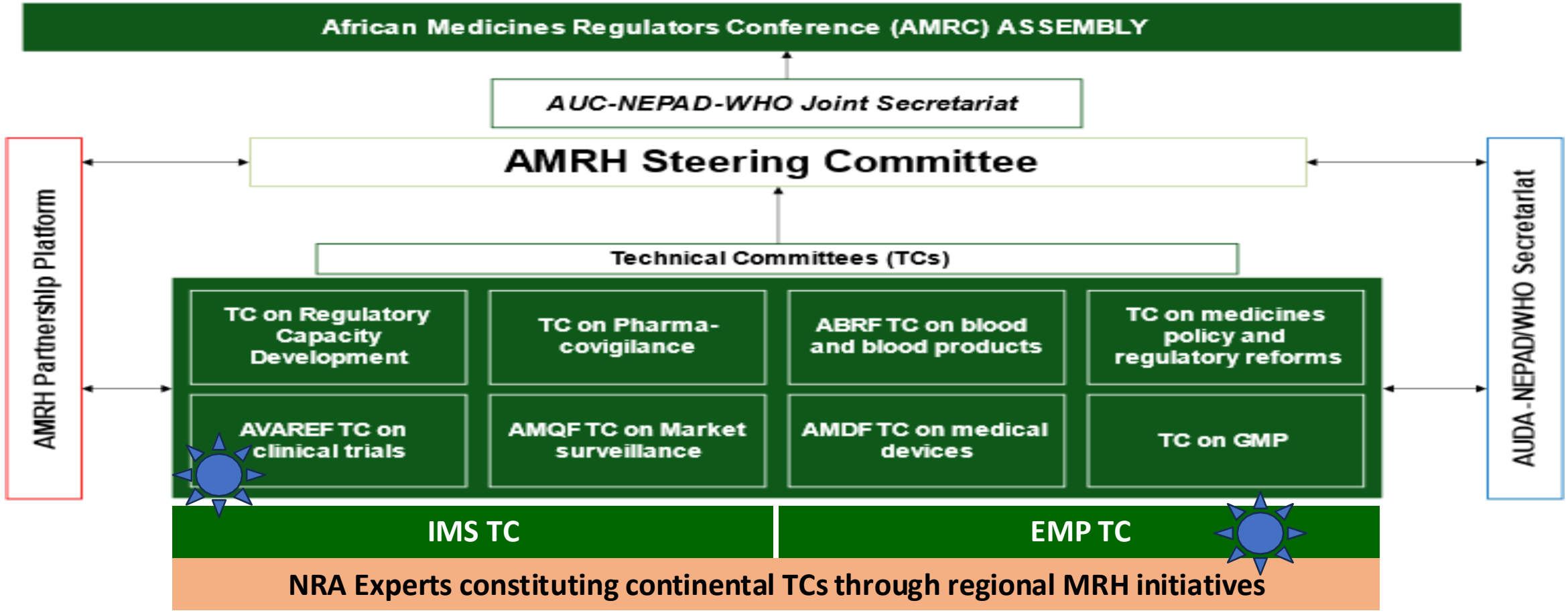
Dedicated sub-page on MAGHP Procedure

- Guidance Document Authorisation Procedure MAGHP
- Guidance Document Scientific Advice MAGHP

maghp@swissmedic.ch

Part II : Facilitated Product Introduction :Regional and Continental Product Assessments

Facilitated Product Introduction : African Medicine Regulatory Harmonization - Overview



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Medicines Regulatory Harmonization (MRH) Projects in Regional Economic Communities (RECs)

REC	Status	AMRH Lauch
EAC	Implementation	Launched March 2012
CEMAC-OCEAC	Implementation	Launch Nov. 2016
WAHO/UEMOA	Implementation	Launched Feb 2015
SADC	Implementation	Launched July 2015
IGAD	Implementation	Launched 2017

WHO : **Lead Technical Partner**

Partners mobilization : Coalition of Interested Partners (CIP)

Joint Secretariat

World Health Organization

Facilitated Product Introduction : Supporting Regional Product Assessments

Fundamental Principle : Common Applications in RECs NRAs (2 minimum)

Eligibility criteria (RECs priority), expression of interest , submission requirements of individual member states, common technical data (Module 2-5)

Dossier is reviewed by each agency in parallel and the scientific evaluation is discussed to have one single list of questions, and the outcome is discussed before a decision is taken. In country adoption in 3 months

WHO/FPI Technical support to :

- EAC joint assessment
- SADC joint assessment initiative (also known as ZAZIBONA),
- other RECs (upon specific requests).

Specific WHO FPI Support to RECs Joint Assessments

- Development of regional medicine registration guidelines and adoption of CTD format
- Domestication of regional CTD guidelines to support harmonization of product dossier formats and contents
- Tools for product application mapping across the member states : instrumental in early phase of SADC/ZaZiBoNa JA procedure
- Development of assessment guidelines, tools and templates to support uniformity in assessment and stakeholders' communication
- Information sharing platforms to support the sharing of assessment reports and product dossiers (when required)
- Facilitation and quality assurance in scientific assessments : adherence to international standards and consisteny in decision making
- Capacity building : on specific parts of product dossier assessment and specific product categories
- Process optimization : based on experience of implementation

Facilitated Product Introduction : Supporting Continental Product Assessments

Evaluation of Medicinal Products Technical Committee (EMP TC)

Scientific evaluation of human medicinal products at continental level and in **harmonizing assessment**, **registration** and **marketing authorization activities** at REC and NRA levels.

Comprehensive evaluation of the **quality**, **safety**, and **efficacy** of priority medicinal products

Towards operationalization of the African Medicine Agency (AMA). With other established TCs

Specific FPI Support for Continental Product Assessment (EMP TC)

Establishment of eligibility criteria for inclusion of priority essential medicinal products for continental assessment

Secretariat and Technical Support to the meetings of EMP-TC : 11 meetings to date

Technical Support to the Pilot Phase of Continental Product Dossier Assessment : 7 applications under consideration

Support on the establishment of Continental TWG on Bioavailability and Bioequivalence

Ongoing support : establishment of continental reliance Policy & Emergency Use Autorisation of Mpox medical products

Conclusion

- Regional Joint Assesment and Continental Product Assessment provides effective pathway for medical products introduction by manufactures and NRAs
- Facilitates harmonization and convergence : optimized use of NRA and manufacturers resources
- WHO continuos support : streamlined regulatory pathways and responsive regulatory systems
- Manufacturers to levarage to make optimal use of Joint Review pathways for shorter regulatory timelines and more predicable regulatory outcomes

Thank you

Sunday Kisoma,
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WHO/MHP/RPQ/REG/FPI

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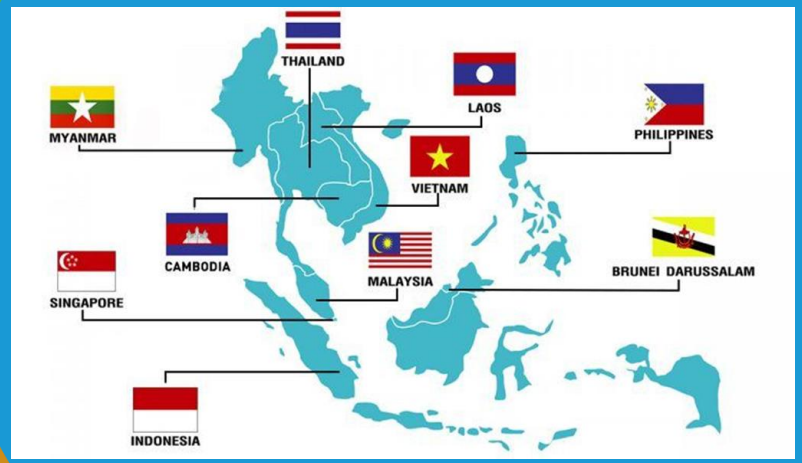
World Health Organization



ASEAN joint assessment procedures

IFPMA Webinar on Facilitated Regulatory Pathways

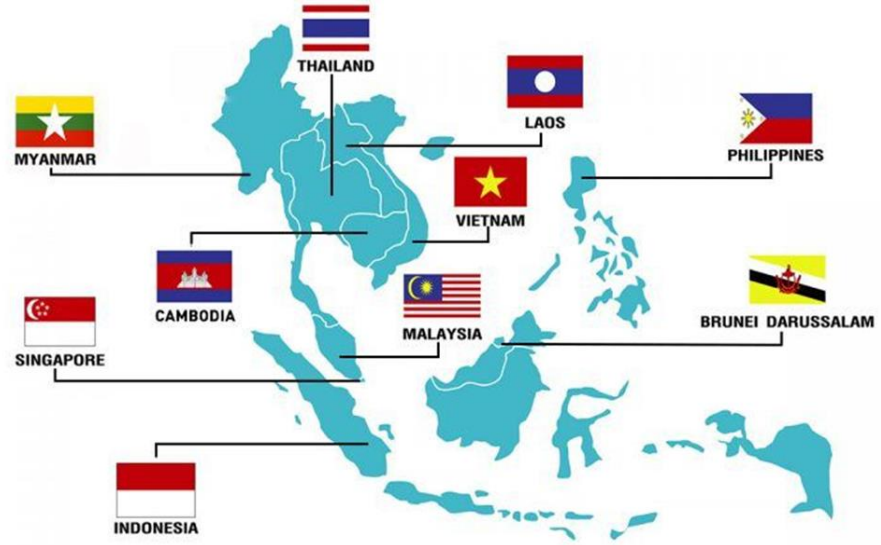
Virtual Meeting, 19th September 2024

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

World Health Organization

ASEAN Joint Assessment concept and principles

Same application



Technical assessment of modules (quality, safety and efficacy) **carried out jointly**

- Open to all 10 ASEAN NRAs on **a voluntary basis**
- **Minimum of 3 NRAs**
- Administrative/local submission/assessment is conducted by individual NRAs in parallel/before the technical assessment starts

- **Final regulatory decision taken by each NRA** (according to national timelines) based on joint assessment report and national-relevant considerations if applicable (30 to 90 days)

ASEAN Joint Assessment*

* Can be used by other ASEAN non-participating NRAs

ASEAN Joint Assessment - Achievements

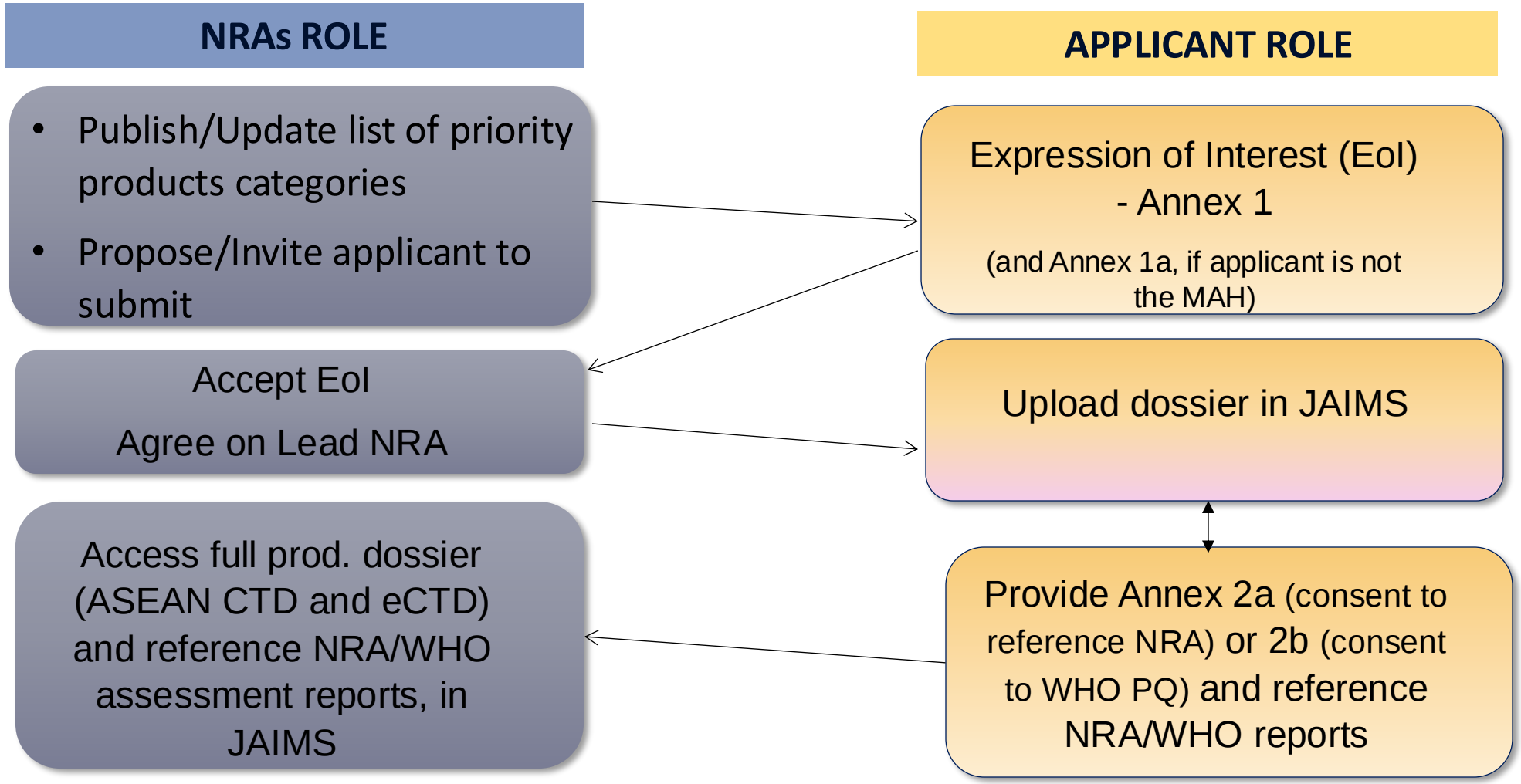
Five completed joint assessments

One JA on-going 2024

Product	Therapeutic area	NRAs	Technical support	Timelines	Year (JA)
Pyronaridine-artesunate	Malaria	**10 NRAs** **Lead Malaysia**	WHO &EMA (Art. 58)	Longer as pilot	2019
Tafenoquine succinate	Malaria	**4 NRAs**: Myanmar, Philippines, **Thailand,** Vietnam	WHO & TGA	< 5 months	2021
Two cabotegravir formulations (tablets and injectable)	HIV	**5 NRAs**: Malaysia, Myanmar, **Philippines**, Thailand, Vietnam,	WHO & TGA	~ 6 months	2023
Ocrelizumab (first biological product)	Multiple sclerosis	**6 NRAs:** Cambodia, Indonesia, Lao PDR, **Malaysia**, Philippines, Thailand	WHO & TGA	< 6 months	2023

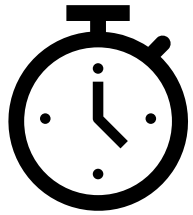
- Technical support of Australia TGA (unredacted assessment reports, TGA experts)
- JA reports can be used by other ASEAN NRAs that did not participate but may receive same application
- ASEAN successfully revised in 2022. Second revision starting in 2024.
- ASEAN JA information management system (JAIMS) developed to support applications process and provide a centralized platform for ASEAN joint assessment procedures.

ASEAN Joint Assessment – Application process



Reference NRAs are drawn from those defined by WHO as 'stringent' NRAs (SRAs): https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs
Occasionally, ASEAN NRAs may decide to rely on a different NRA if this is needed and justified.

ASEAN Joint Assessment – Timelines



Clock stop

Assessment up to **90 days**

Lead NRA shares **List of questions** with applicant

Applicants responses

NRA review up to **40 days**

10 days → New List of Questions

10 days → JA Meeting

10 days → JA Report

10 days → JA Report

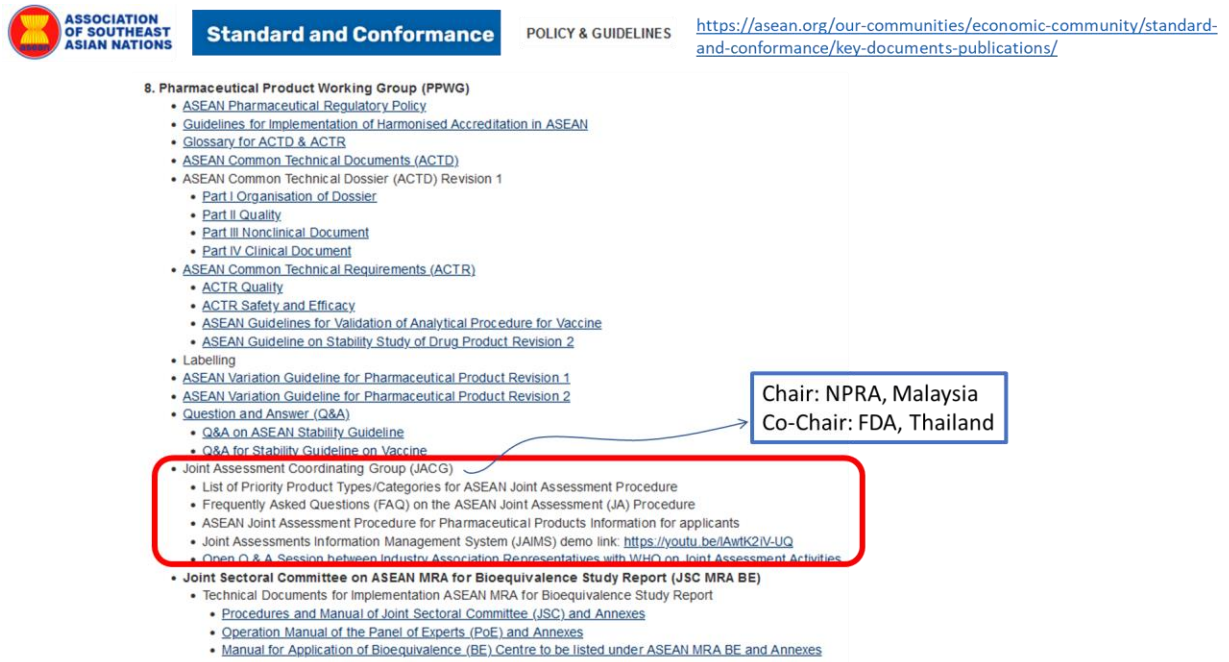
ASEAN Full JA process up to **150 calendar days**, 140 if JA meeting
ASEAN Expedited JA process **< 140 calendar days**

Duration of national Decision-making Process: Number of working days:
Brunei Darussalam 60 – Cambodia 90 – Indonesia 45 - Lao PDR 45 – Malaysia 30 – Myanmar 90 (standard)/60 (urgent) – Philippines 30 – Singapore 30 – Thailand 30 – Viet Nam 60

ASEAN Joint Assessment – Published information

ASEAN's Joint Assessments Coordinating Group periodically publishes a list of priority product categories eligible for the Joint Assessment Procedure, as referred in the document "Information for Applicants" available on this website.

No	**Pharmaceutical and Biological Products** (as applicable)
1	Products for the treatment of hepatitis B
2	Products for the treatment of hepatitis C
3	Products for the treatment of cancer[1]
4	Products for the treatment of HIV/AIDS
5	Products for the treatment of TB
6	Products for the treatment of Malaria
7	Products for the treatment of treatment-resistant depression
8	Products for the treatment of interstitial lung disease
9	Products for the treatment of chronic kidney disease
10	Products for the treatment of autoimmune diseases such as Crohn's disease, rheumatoid arthritis, psoriatic arthritis, generalized pustular psoriasis
11	Products for the treatment of Alzheimer's disease
12	Products containing new anti-infective substances
13	Products for Maternal and Reproductive Health
14	Products for the treatment of rare diseases (orphan drugs)
15	Vaccines



1. List of priority product categories eligible for joint assessment:
https://www.npra.gov.my/media/attachments/2022/04/11/proposed-list-of-priority-products_22mar2022.pdf
2. Detailed information about the procedure and submitting an application:
https://www.npra.gov.my/media/attachments/2022/04/20/information-for-the-applicants.pdf
3. Questions and Answers document on the JA procedure:
https://www.npra.gov.my/media/attachments/2022/04/20/frequently-asked-questions.pdf
4. JAIMS demo link:
https://youtu.be/IAwtK2iV-UQ

ASEAN Joint Assessment - Key messages going forward

1. Enhanced collaboration and understanding of regulatory process between ASEAN member states (AMS);
2. Reliance mechanisms and process understood and implemented by AMS;
3. Capacity building through learning and experience sharing between AMS;
4. Improvement in MA timelines;
5. Improve timely access to patients.

Thank you - Acknowledgement

Equitable access to affordable quality medicines and other health products requires **an integrated approach** with all stakeholders

World Health Organization

WORKING TOGETHER

Marie Valentin – valentinm@who.int, prequalreg@who.int
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