EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Understanding EU-M4all

Solving challenges by working together
IAS Industry Liaison Forum, 25 November 2025

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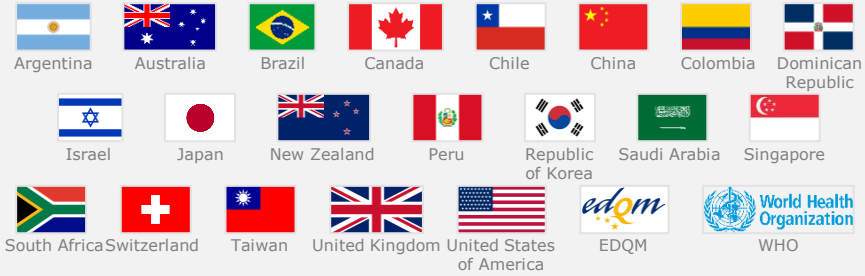
Head of International Affairs

EMA international collaborations

Bilateral relations



International Liaison Officers

Confidentiality Arrangements (CA)

Ad Hoc CA

Mutual Recognition Agreements (MRA)

32 Clusters

Multilateral relations

ICH harmonisation for better health

OPEN

PIC/S

IPA project

ICMRA

EU-M4all

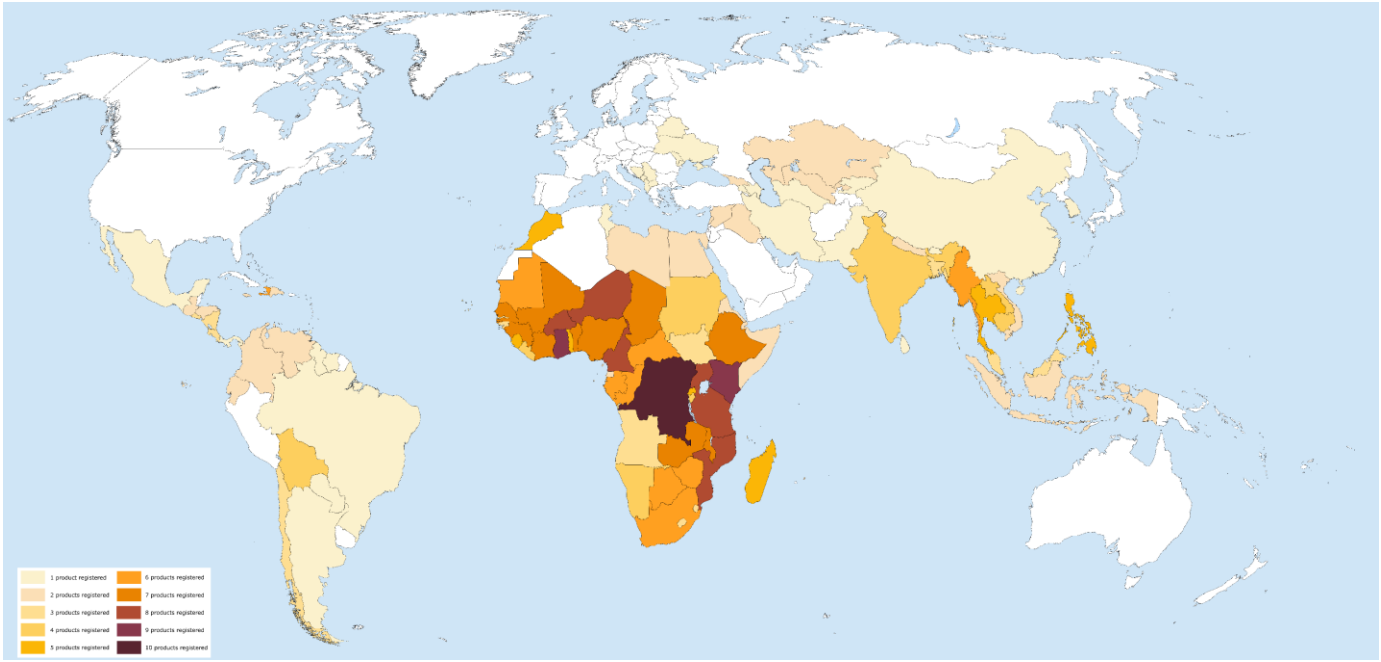
IPRP International Pharmaceutical Regulators Programme

SRA CRP

AMA project

IPA: Instrument for Pre-accession Assistance

EU-Medicines for all (EU-M4all)



18 medicines with an EU-M4all scientific opinion*

>115 countries worldwide

c.400 Marketing Authorisations

*7 of which have been withdrawn or surrendered

Collaborative Review: Under EU-M4all, EMA works with WHO and target countries, combining EU regulatory expertise with local disease knowledge and epidemiology.

Global Reliance: Non-EU regulators can rely on EMA scientific assessments to decide on the use of the medicine in their country.

EUM4all: 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 (+ clinical trials engagement)
- 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
- National regulators remain **independent** in their decision making

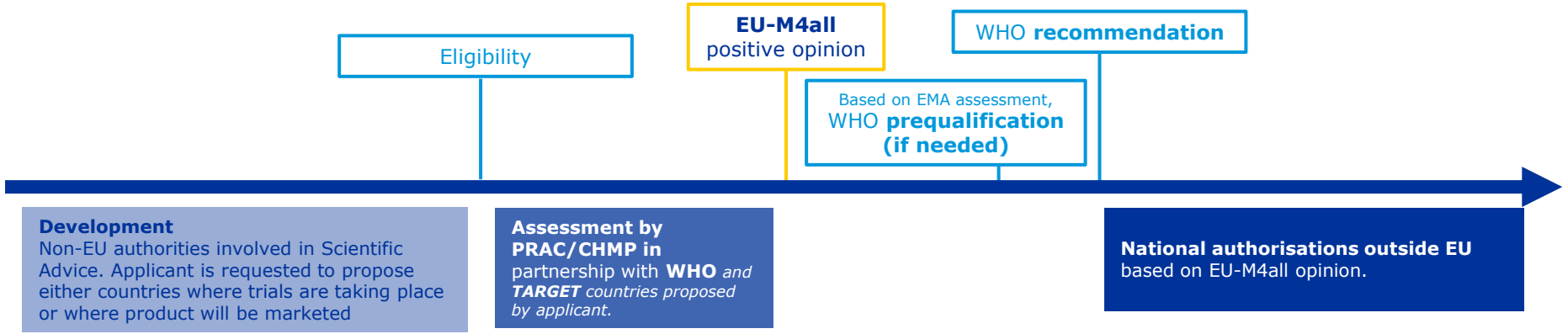
Pre-submission opportunities for EU-M4all applicants

- 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 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?
  - Eligibility request
  - Rapporteur appointment
- Am I eligible for product incentives in the EU?
  - SME Office
  - Fee reductions
- Am I eligible for PRIME?
  - PRIME
  - Accelerated assessment

WHO/NRA interaction timelines

EU-M4all

WHO/NRAs ensure that specific disease expertise and local knowledge are taken into account



EU-M4all medicines can be included in the **WHO Prequalification List** through the 'alternative listing procedure' without any further review by the WHO Prequalification Program-> **Facilitated registration in target countries**
WHO prequalification programme

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 authorities always remain **independent** in their decision making

Post-authorisation responsibilities

EMA may request additional post-authorisation measures to the Opinion Holder

EMA oversees the entire post-authorisation lifecycle

Opinion holder must:

- Notify EMA of any medicine changes and submit variations.
- Update product information as needed.
- Comply with agreed pharmacovigilance requirements:
  - Record and report serious adverse reactions within set timelines.
  - Submit periodic safety update reports.
  - Manage safety signals.

Some reflections

- We all face challenges, including increased workload and limited resources
- Inclusive approach of EU-M4all supports regulatory harmonisation and strengthens global capacity
- EMA assessment of lenacapavir included experts from WHO, and national regulatory authorities from Kenya, Nigeria, South Africa, Thailand, Uganda, Vietnam, Zambia and Zimbabwe in our assessment
- Lenacapavir had accelerated EMA assessment, reducing review time to 120 days (vs. 210): facilitated by strong efficacy & favorable safety data, prior knowledge of Sunlenca, and the applicant's rapid responses
- National registration steps for products assessed under EU-M4all pathway can be done independently country by country or via the WHO CRP
- EMA commitment to transparency and publication of EPAR facilitates reliance

Useful links

EU-M4all Article:

The European Medicines Agency facilitates access to medicines in Low and Middle Income Countries

Medicines for use outside the European Union

https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/medicines-use-outside-european-union

Obtaining and maintaining a scientific opinion on a medicine for use outside the European Union

https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/medicines-use-outside-eu-article-58/obtaining-maintaining-scientific-opinion-medicine-use-outside-european-union

EMA procedural advice for medicinal products intended exclusively for markets outside the European Union under Article 58 of Regulation (EC) No 726/2004 in the context of co-operation with the World Health Organisation (WHO)

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-procedural-advice-medicinal-products-intended-exclusively-markets-outside/2004-context-cooperation-world-health_en.pdf

Support for applications on Article 58

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/support-applications-article-58_en.pdf

Accelerated assessment

https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-scientific-application-practical-arrangements-necessary-implement-procedure-accelerated/2004_en.pdf

Parallel submission. https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/public-guidance-parallel-application-eu-m4all-article-58-opinion-and-centralised-marketing-authorisation-procedure_en.pdf

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Thank you

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