EMA
EUROPEAN MEDICINES AGENCY

EMA international engagement and activities

PCWP/HCPWP meeting
18 November 2025

Martin Harvey, EMA International Affairs

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Deploy the EU’s strengths with unique regional bodies (like ECDC and **EMA**) that can collaborate with other regional initiatives worldwide, sharing EU data, science and knowledge, and benefit from non-EU expertise.

This would strengthen collaboration with bodies such as the Africa CDC, AMA, and similar entities in the neighbourhood and programmes in Latin-America, and the Indo-Pacific.

EU Global Health Strategy, 2022

EMA international engagement: what benefit for patients and health-care professionals?

International engagement contributes to:

- Faster and broader access to medicines
- Improved quality and safety of medicines
- Better crisis preparedness and response capacity
- Exchange of global scientific knowledge
- Promote our stakeholder engagement model

EMA bilateral international engagement

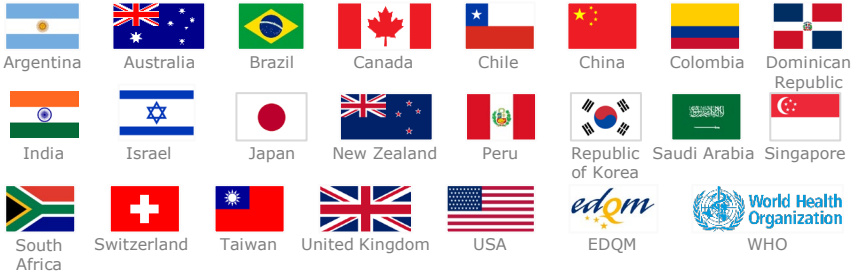
International bilateral engagements support global drug development, address safety issues, inspections, quality of medicines and supply chain issues.

Engage with trusted partners through Confidentiality Arrangements.

Support EC engagement and dialogue with other partners, including through MRAs, FTAs, etc.

IntCoP to support alignment, share information with EU member states.

Bilateral engagement



International Liaison Officers

Confidentiality Arrangements (CA)

Mutual Recognition Agreements (MRA)

Clusters

EMA multilateral international engagement

Multilateral engagements focus on access to and exchange of global scientific knowledge

They contribute to better crisis preparedness and response capacity

Take place usually alongside European Commission seeking global harmonisation or convergence, and promoting effective use of global regulatory resources

Multilateral engagement

African Medicines Agency

ICMRA

PIC/S

EU-M4all

SRA-CRP

OPEN

IPRP International Pharmaceutical Regulators Programme

ICH harmonisation for better health

VICH

Instrument for Pre-accession Assistance

Trusted partners

Main engagements and collaborations are with our trusted partners.

These make up majority of EMA international interactions.

Some current areas

USA

Key partner, half of all interactions

32 product and non-product clusters

Transition hiccups, now back on track

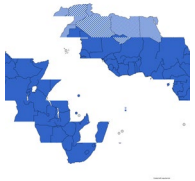
Long-term commitment

Candidate countries

DG ENEST funding (2024-2026)

Tailored access to EU NTC training, and selected CHMP & CVMP WPs, and IWPs

Training focus to support alignment



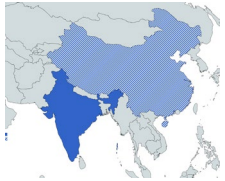
Africa

DG INTPA funding (2024-2027)

African Medicines Agency support

Delivering with NCAs, EU-NTC, EDQM

Continental, regional and national focus



India, China

Key non-EU sources of API and generics

GCP and GMP compliance issues

Working with DG SANTE to improve engagement

Latin America

DG INTPA exploring possible low-level EMA support for regional convergence

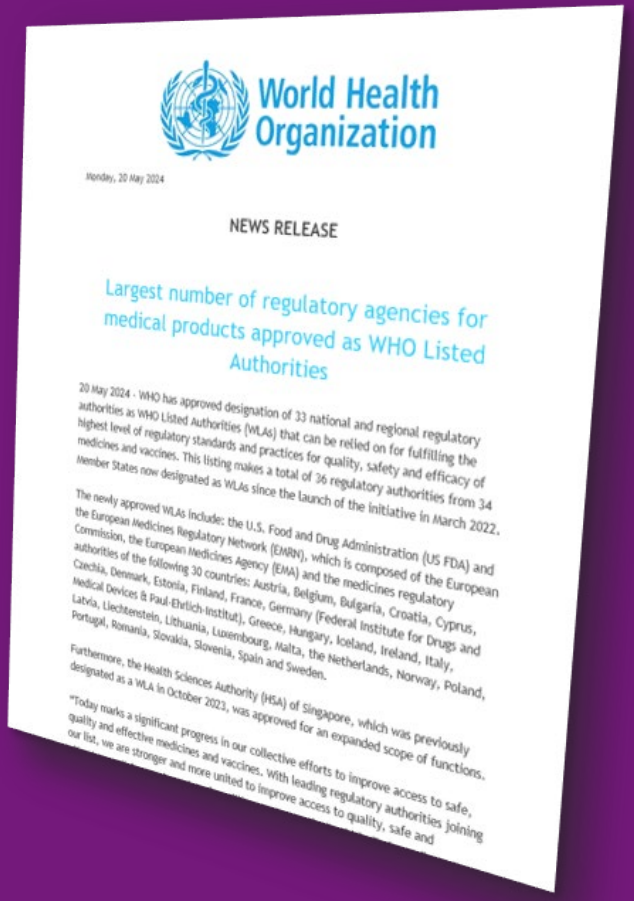
Caution over network capacity to resource

Reliance pathways and promoting the EU voice

**2020 EC Pharma Strategy:*
Pillar 4 Ensuring a strong EU voice globally

European medicines network designated as WLA

- EMA, EC and all EU/EEA NCAs were designated as WHO Listed Authorities (WLAs) on 20 May 2024.
- First and only regional network recognised.
- WLAs can be relied on as fulfilling the highest level of regulatory standards and practices for quality, safety and efficacy of medicines and vaccines.
- Enables informed reliance on trusted regulatory authorities, promoting confidence and fostering regulatory convergence, harmonization of approaches, and international cooperation.
- EMA and the network are already widely used as reference agency to apply reliance by other regulators and companies.



World Health Organization

Monday, 20 May 2024

NEWS RELEASE

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

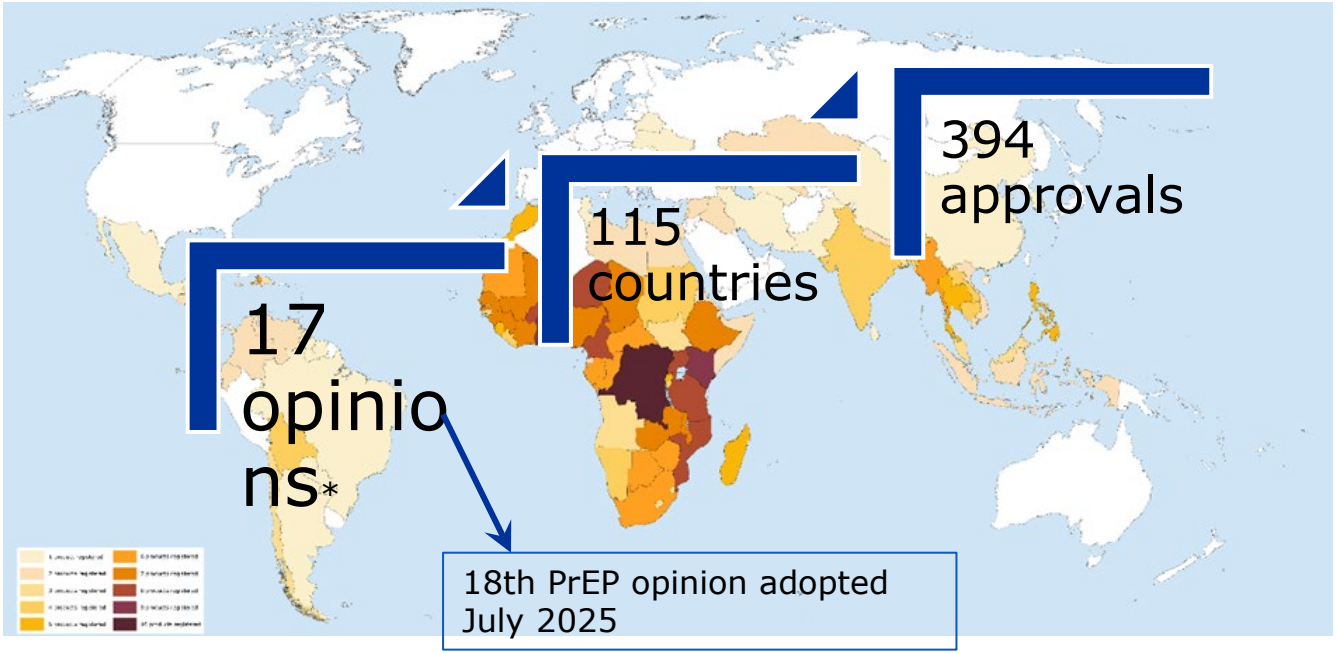
20 May 2024 - WHO has approved designation of 33 national and regional regulatory authorities as WHO Listed Authorities (WLAs) that can be relied on for fulfilling the highest level of regulatory standards and practices for quality, safety and efficacy of medicines and vaccines. This listing makes a 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 Medicines Agency (EMA) and the medicines regulatory authorities of the following 30 countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany (Federal Institute for Drugs and Medical Devices & Paul-Ehrlich-Institut), Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

Furthermore, the Health Sciences Authority (HSA) of Singapore, which was previously designated as a WLA in October 2023, was approved for an expanded scope of functions.

"Today marks a significant progress in our collective efforts to improve access to safe, quality and effective medicines and vaccines. With leading regulatory authorities joining our list, we are stronger and more united to improve access to quality, safe and

#1 Reliance in action: EU-Medicines4all *(aka Article 58)*

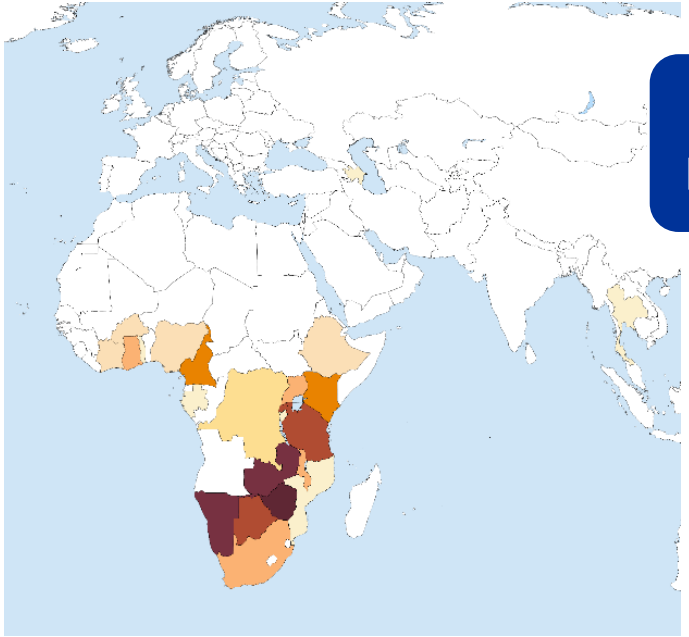


*7 of which are withdrawn or surrendered

EMA evaluates and gives an opinion, **in co-operation with WHO**, on medicinal products for human use intended for markets **outside the EU**.

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

#2 Reliance in action: Collaborative Registration Procedure



13 products

23 countries

83 approvals

Accelerates national approval in countries where resources may be limited, **based on regulatory work** already carried out by a stringent regulatory authorities (SRA, now **WLA**), such as EMA.

This facilitates **earlier access** to essential medicines for patients worldwide, improving global public health.

#3 Reliance in action: OPEN Pathway

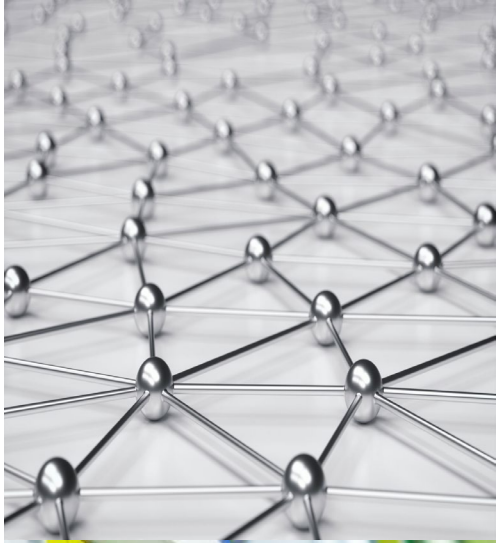
Scope expanded by Management Board in October 2025:

- Antimicrobial resistance (AMR)
- PRIME and any other products that target unmet medical needs, including ATMPs
- Vaccines or therapies for health threats or public health emergencies

OPEN can now also be used for PACs, including extension of indications

#4 Reliance in action: EMA/WHO post-approval reliance pilots

- Reliance is not just for initial authorisations, can also be used for post-authorisation activities – especially because of the substantial regulatory resources required during product lifecycle management.
- EMA assesses >8,000 applications for post-authorisation variations and renewals yearly, and industry tells us that 70% of their regulatory work is on post-approval changes.
- Post-authorisation changes can be complex, time-consuming, and unpredictability in approval timelines increases the risk of shortages. Contributes to continuity of supply and patient access.
- EMA, with WHO, is supporting a pilot to submit EMA-approved variations to multiple non-EU national authorities.
- Little to no resource requirement of NCA experts



#4 Reliance in action: EMA/WHO post-approval reliance pilots

- Pilot aims at creating more efficient pathway for global roll-out of post-approval changes through reliance, leveraging the EMA assessment to reduce review timelines by individual NRAs in a near-concurrent submission of same dossier
- Currently 17 active products (more in pipeline, review late-2025)
- 16 = CMC supply-critical variations; 1 = clinical variation
- Pilots involve between 5 to <100 non-EU regulatory authorities
- Accelerating timelines for approval of PACs: Preliminary data from early pilots show 83% participating NRAs approving variation withing 6.5 months
- Promotes harmonisation of requirements; 75% reduction in country-specific documentation requirements

4 successful reviews since COVID, currently for:

- Antimicrobial resistance (AMR)
- PRIME products (not ATMPs yet)
- Other products that address high unmet needs (e.g. RSV, Alzheimer's, ALS...)
- Vaccines or therapies for health threats or public health emergencies

OPEN to be expanded soon

Health in the EU is **strongly linked** with **health outside the EU**. Working to improve the EU population's health cannot be done without interacting with international partners.

EMA's unique way of working is **highly valued** on the international scene. What we do is leveraged outside of the EU through reliance mechanisms, transparency, and information sharing.

International engagement has a **significant impact on global health benefiting both patients and health-care professionals**.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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