EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA and international affairs

Presented by Michiel Hendrix
International Affairs
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EMA in the global environment

Industry submits applications to **multiple regulatory authorities** worldwide, and those authorities **are all evaluating similar data**.

Clinical trials can be **conducted anywhere** in the world.

Safety and **quality signals** can originate from **anywhere**.

People need reliable information around the world.

Animal and human health are **intertwined**; animals/animal products **also travel** to and from the EU.

Approximately **80% of all active substances** in the medicines used in Europe **come from outside the EU**.

EMA in the global environment

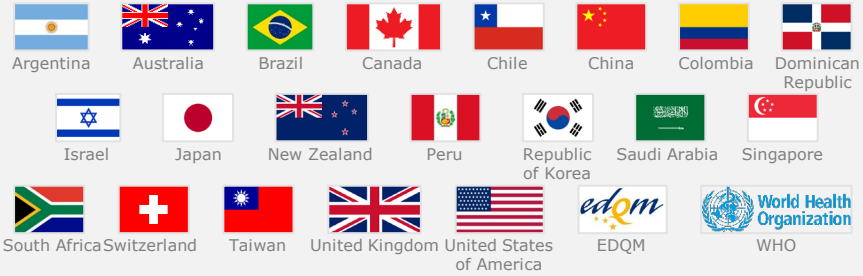
All Divisions/Departments are concerned and the exchange of information with international regulatory authorities is **part of EMA's daily work**.

International collaboration is **key** to:

- **Avoid duplication** of work
- **Release scarce resources** for more critical areas
- **Facilitate alignment** of regulatory approaches between international authorities
- **Speed up patient access** to new and/or affordable medicines
- **Support regulators** outside the EU who may **lack resources** and/or specific competences

Mechanisms for international collaboration

Bilateral relations



International Liaison Officers

Confidentiality Arrangements (CA)

Ad Hoc CA

Mutual Recognition Agreements (MRA)

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

VICH International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

IPA: Instrument for Pre-accession Assistance
AMA: African Medicines Agency

What is regulatory reliance?

WHO Good Reliance Practices (and Good Regulatory Practices) published April 2021

Focus on best use of resources and efficiency, with two core elements

- **rely wholly or in part on output of other (trusted) regulators** whenever possible
- allows **greater focus at national level on value-added regulatory activities**

… but what does it look like in practice?

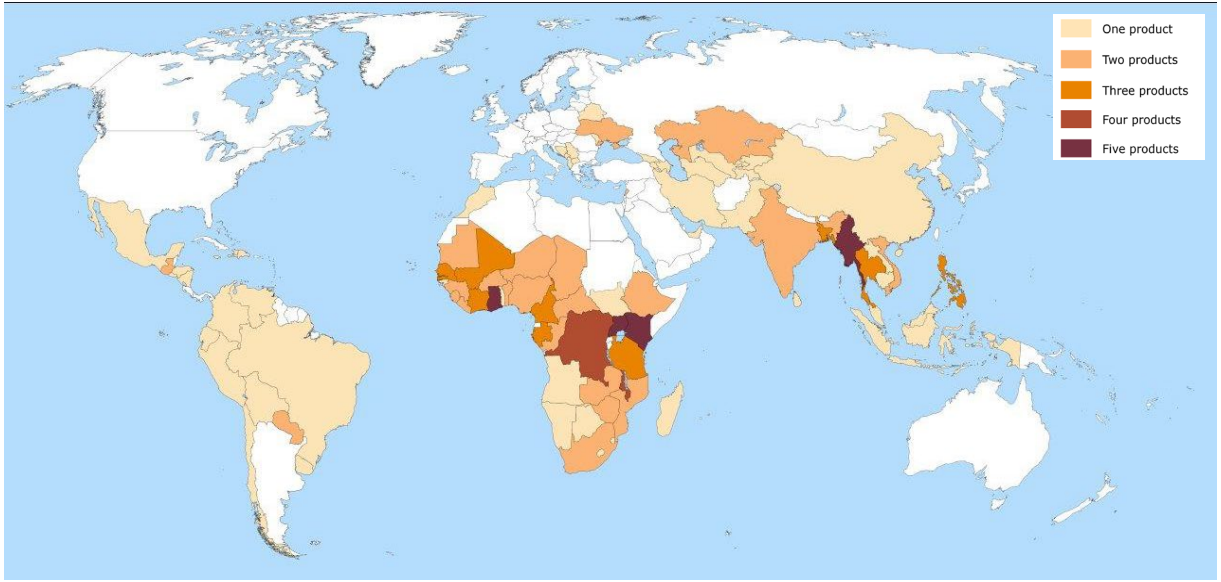
EU-Medicines for all (EU-M4all)

EMA supports the global regulatory system through its collaboration with **WHO** using two main regulatory mechanisms:

1. EU-M4all (Art. 58):

EMA evaluates and gives an opinion, in cooperation with **WHO**, 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.



15 medicines with an EU-M4all scientific opinion*

93 countries worldwide

158 Marketing Authorisations

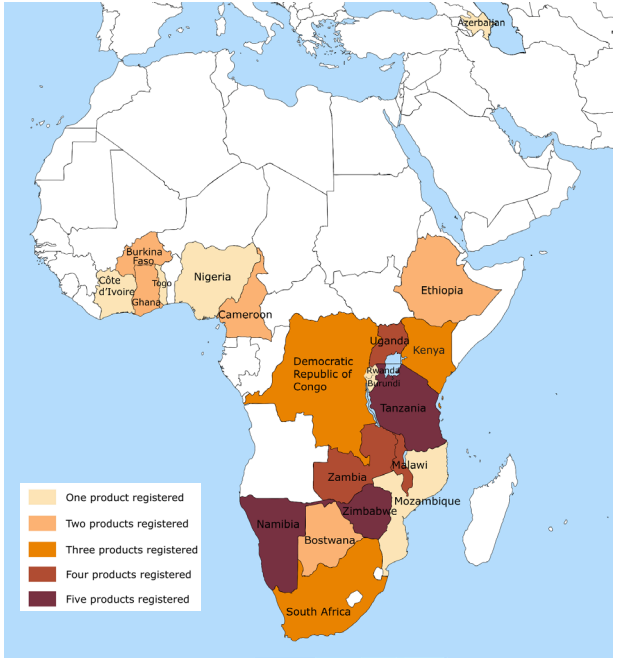
*7 of which have been withdrawn
As of January 2023

WHO Collaborative Registration Procedure (CRP)

2. WHO SRA CRP:

Accelerates national approval in countries where resources may be limited, based on the regulatory work already carried out by Stringent Regulatory Authorities (SRAs), such as EMA.

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



13 medicines with EU marketing authorisation

29 countries

53 marketing authorisations via CRP

48 pending/awaited approvals

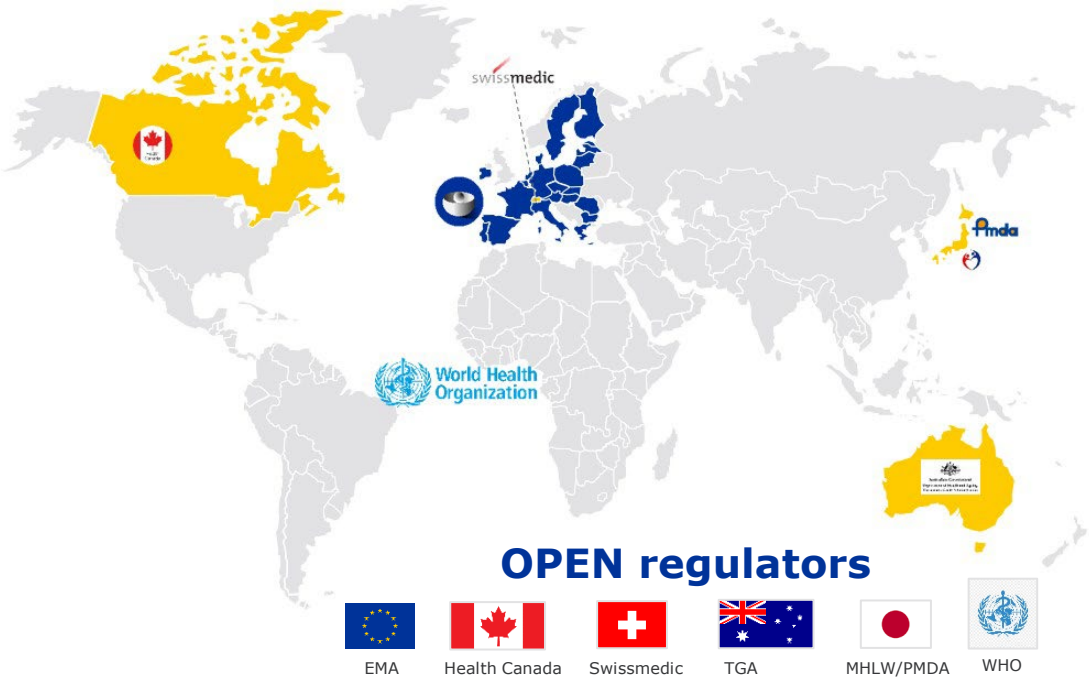
As of January 2023

‘OPEN’ initiative for non-EU regulators

Goal: Sharing scientific expertise to tackle common challenges on COVID-19 vaccines and therapeutics

Interaction: Participating non-EU experts are invited to **attend and contribute** to **ETF and CHMP evaluation** for COVID-19 vaccines and therapeutics.

OPEN experts follow **similar requirements** as the EU experts *(e.g., confidentiality, absence of conflict of interests).*



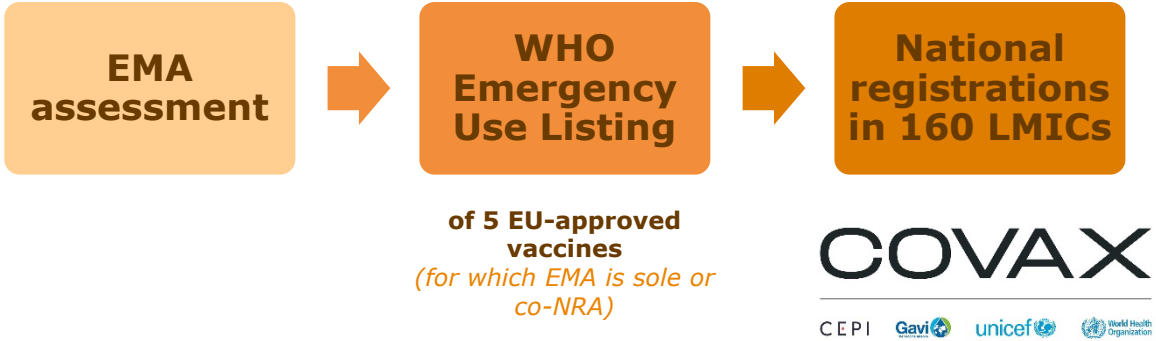
All participating under the terms of their Confidentiality Arrangement with the EU.

Reliance in action: 'OPEN' global health impact

Reliance significantly **accelerated decisions** from national regulatory authorities in **LMICs**.

EMA is regulatory authority of record for the **WHO Emergency Use Listing** (EUL) for the 5 of the COVID-19 vaccines approved in the EU.

The WHO EUL enabled LMIC national regulatory authorities to **speed the registration** of COVID-19 vaccines. It was also needed to allow **procurement** by UN agencies and World Bank Group partners.



LMIC = Low- and Middle-Income Countries

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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, and this has a **significant impact on global health**.

Almost all EMA departments have a **link** with one or more international stakeholders.

Any questions?

Further information

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International activities | European Medicines Agency (europa.eu) *(ema.europa.eu > Partners & networks > International activities)*