EMA
EUROPEAN MEDICINES AGENCY

International collaboration and reliance in practice

CMC Strategy Forum Latin America 2025

Session I, 13 August 2025

Martin Harvey

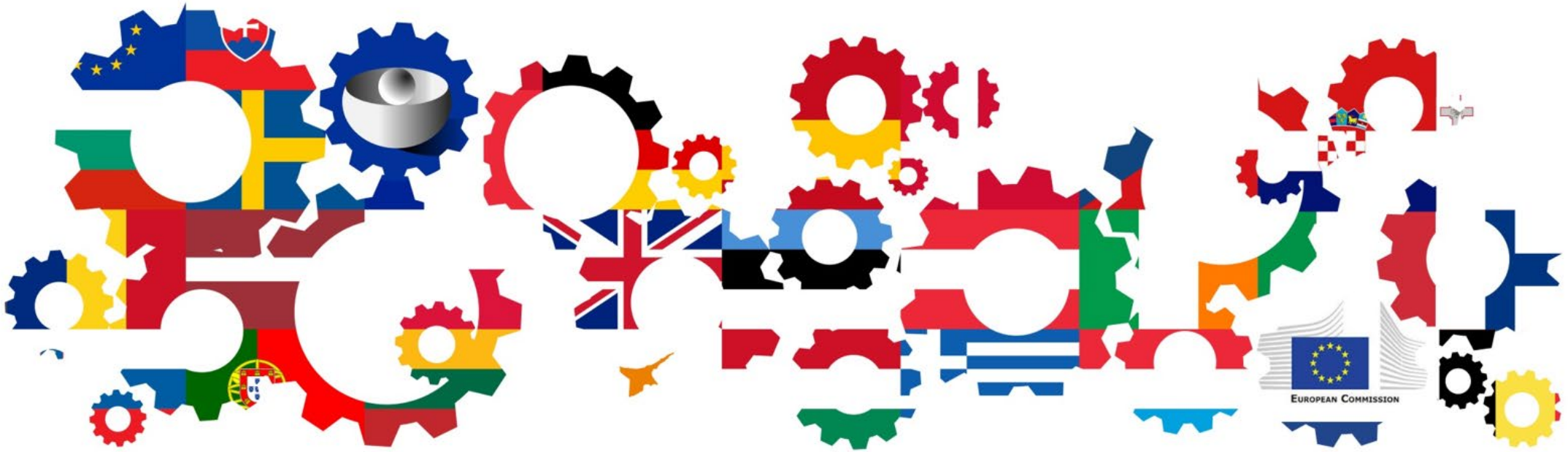
EMA international Affairs

Contents

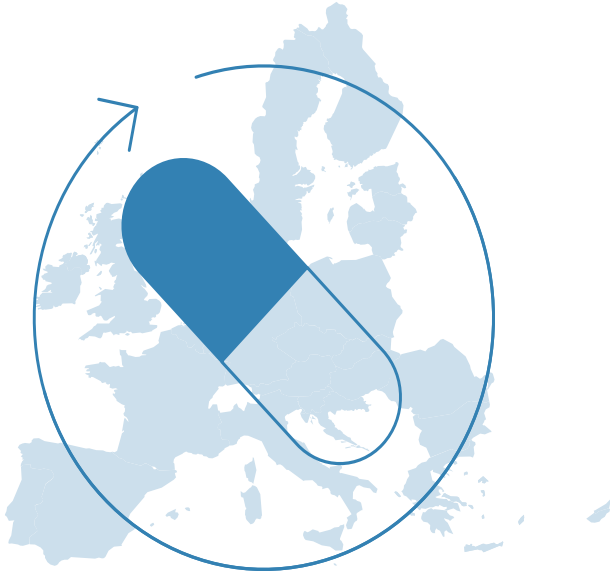
- EU network as a reliance system, and building blocks of reliance
- Understanding the EMA assessment
- International collaboration and reliance in practice
- Benefits of reliance and collaboration

EU network as a reliance system

European Medicines Regulatory Network: Collaboration and reliance is part of our DNA



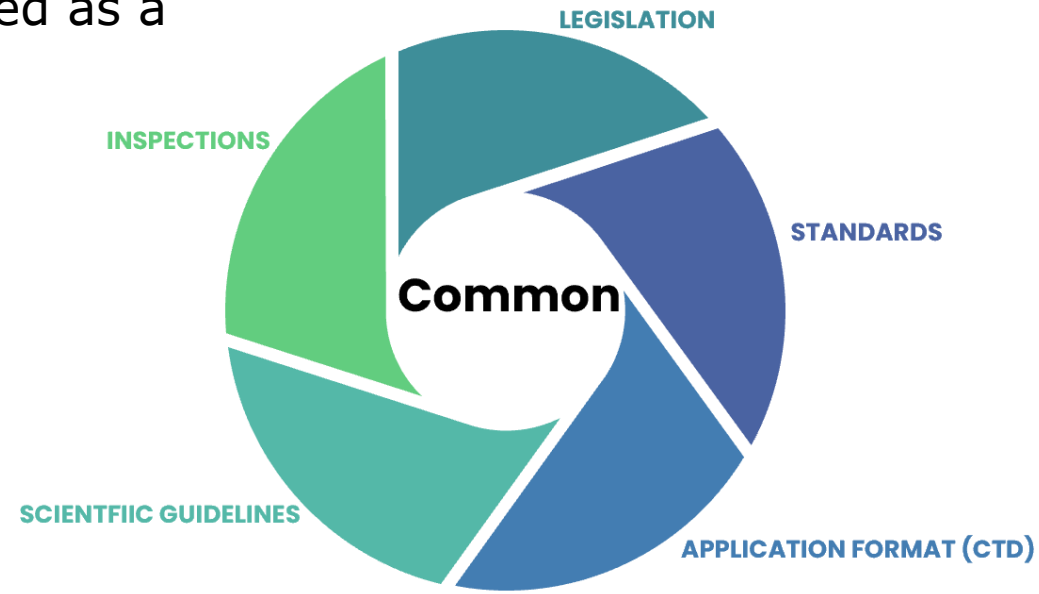
European medicines regulatory network: Reliance in action



EMRN is a unique system based on full **transparency, reliance, work-sharing and recognition**.

All European authorisation pathways are based on **single assessment**, that can be used as a basis for reliance by another agency.

Single assessment and Single Market is possible thanks to one set of **common legislation, rules and dossier requirements**.



European medicines network designated as WLA

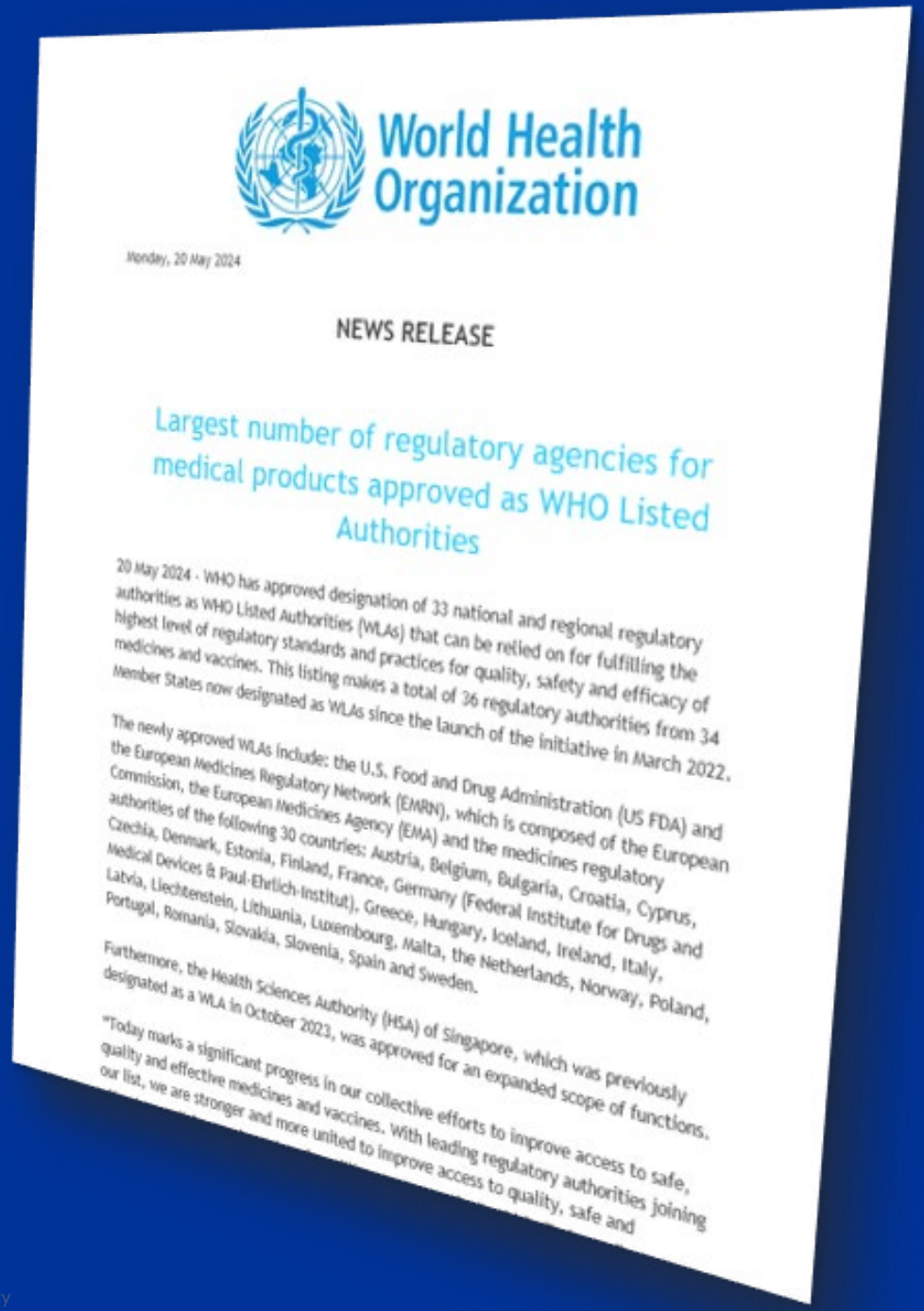
EMA, EC and all EU/EEA NCAs were designated as **WHO Listed Authorities (WLAs)** on 20 May 2024.

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.

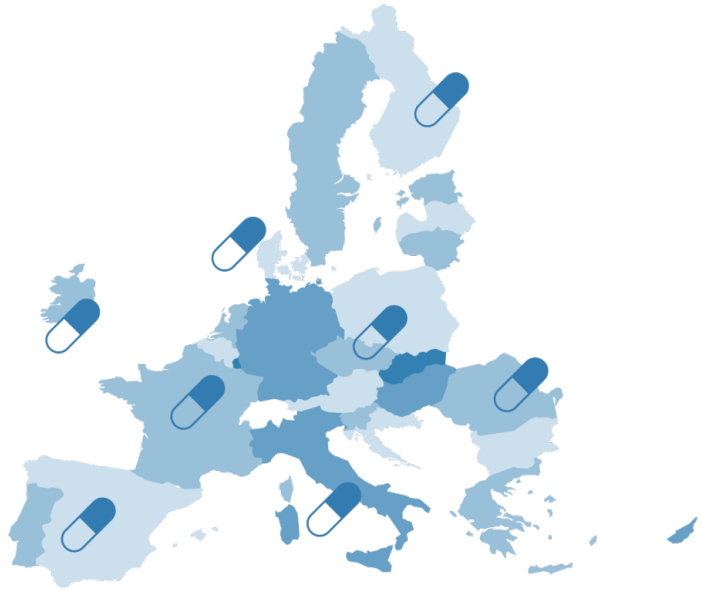
Furthermore, the Health Sciences Authority (HSA) of Singapore, which was previously designated as a WLA in October 2023, was approved for an expanded scope of functions.

"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

Understanding the EU assessment to support reliance

EU approval pathways
Different routes: one set of common rules

Centralised procedure (via EMA)



National procedures (via Member States)

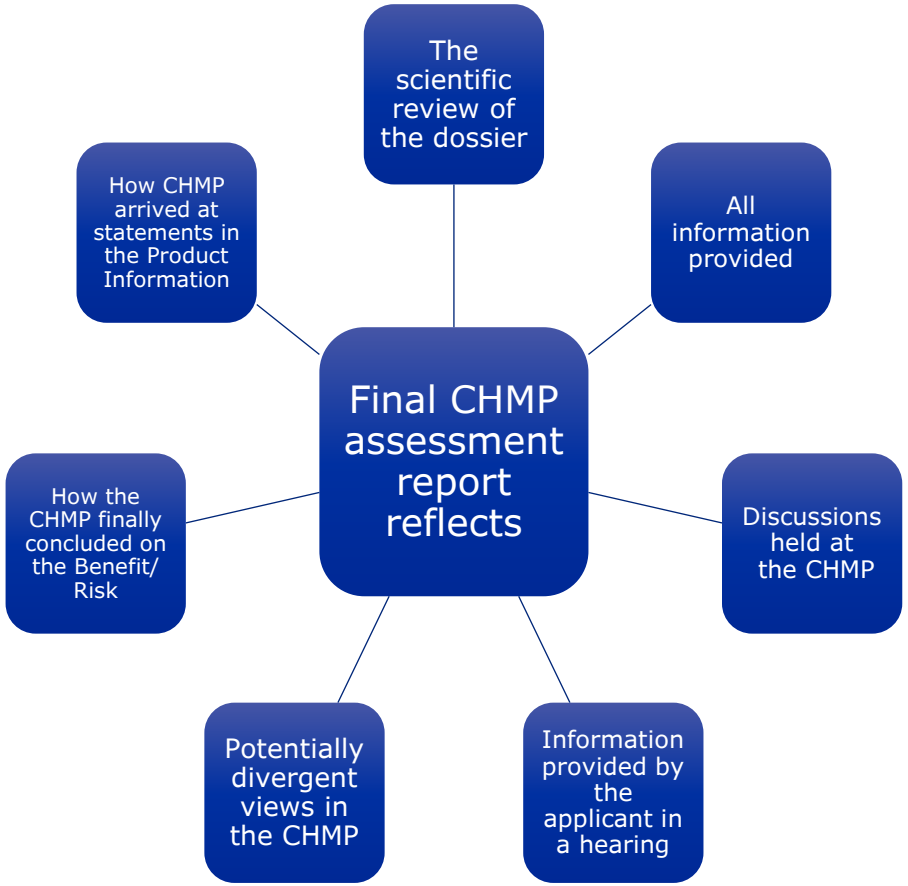
- Centralised procedure
- Mutual recognition procedure (MRP)
- Decentralised procedure (DCP)
- National procedure

One application, one assessment, one authorisation

The centralised procedure was established to streamline the approval process for medicines across the EU with a single submission and evaluation.

Another strength of the EU model is that a medicine could be authorised at the same time in all EU countries, helping improve access to medicines for patients, no matter in which EU country they lived.

CHMP Assessment Report



Final CHMP AR contains:

- comprehensive summary of Quality, Safety & Efficacy data submitted
- comprehensive summary of assessment discussions and conclusions
- Benefit/Risk discussion

Published in the European Public Assessment Report

What EMA publishes and when

Framework for transparency is embedded in EU legislation.

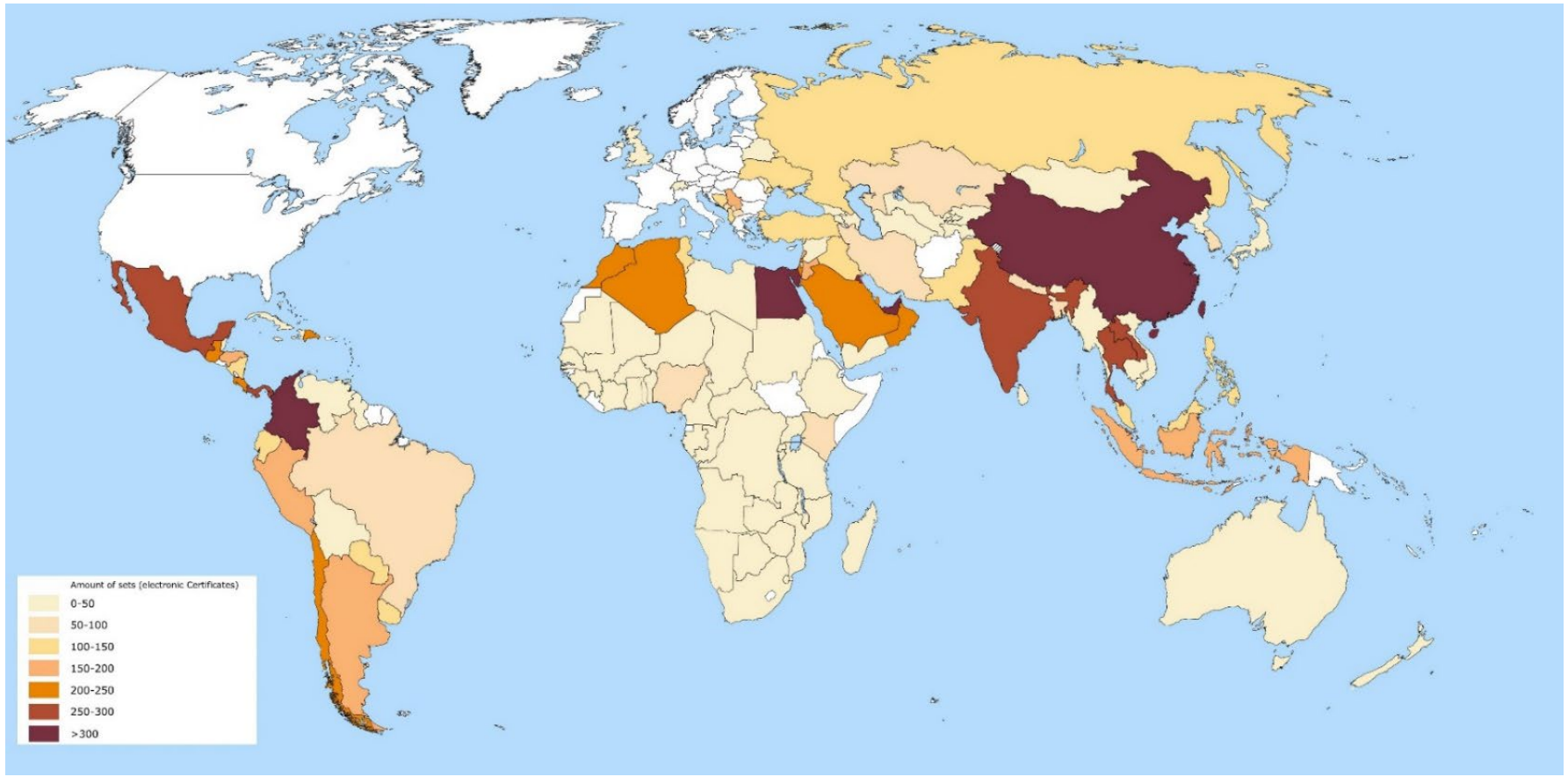
EMA publishes information on medicinal products at various stages of the life cycle.

EMA guidance tells stakeholders what kind of publications to expect on medicines undergoing evaluations and many other regulatory procedures.

This transparency enables many regulatory authorities to rely on EMA's assessment of medicines.

International collaboration and reliance in practice

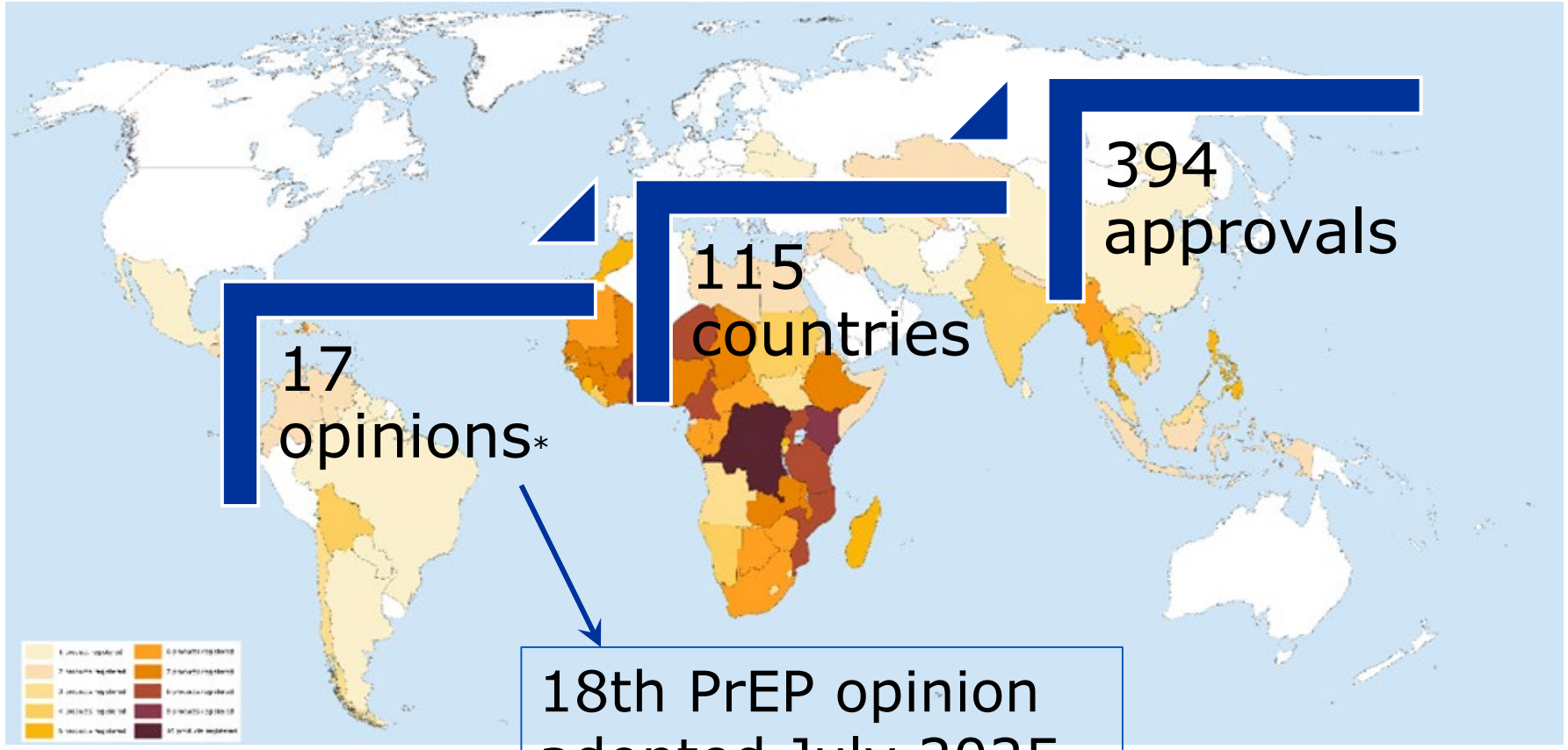
#1 Reliance in action: Certificates of Pharmaceutical Products



e-Certificates of Pharmaceutical Products (eCPP) provide assurance, confirm marketing authorisation status of a medicinal product and that is produced in accordance with GMP standards.

EMA is probably biggest issuer of (e)CPPs. EMA issues >11,000 certificates each year

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

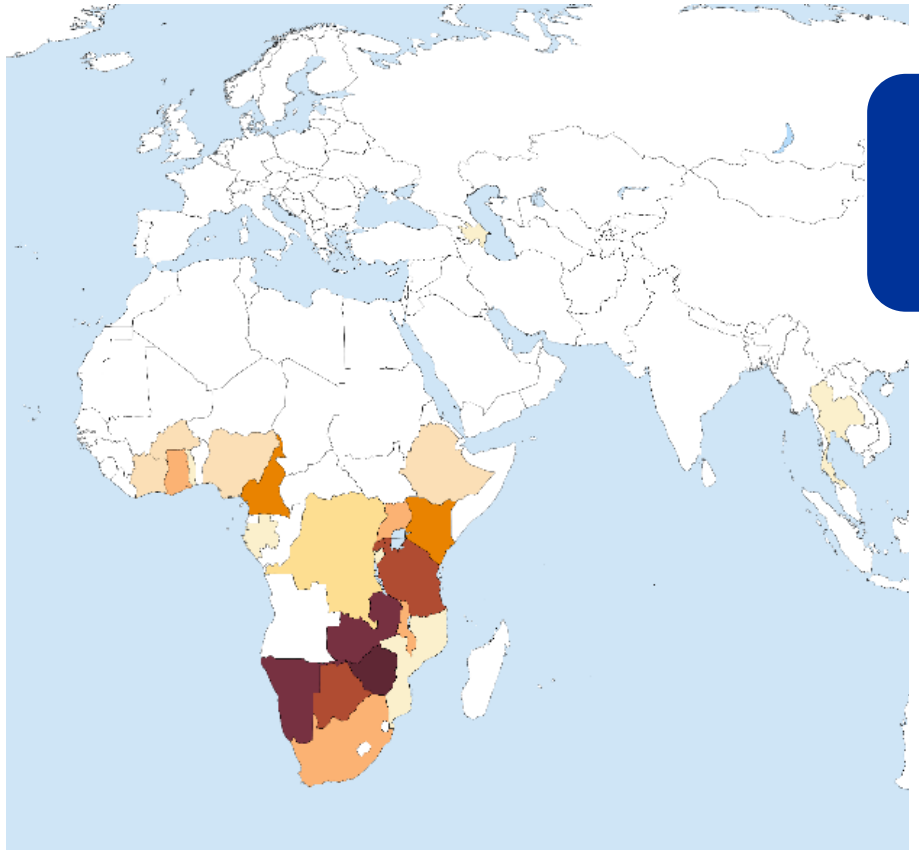


*7 of which are withdrawn or surrendered

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.

#3 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.

#4 Reliance in action: OPEN Pathway

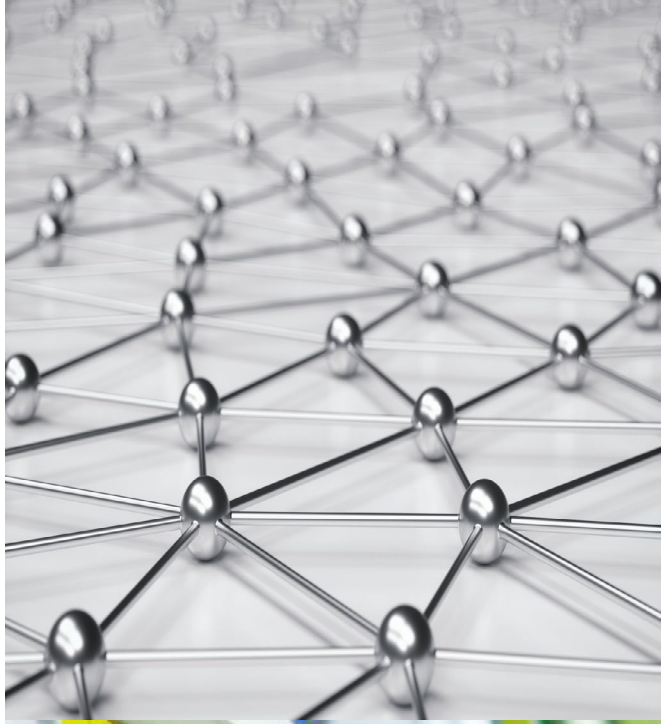
After success of COVID-19 pilot, OPEN pathway now expanded to identified areas:

- 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

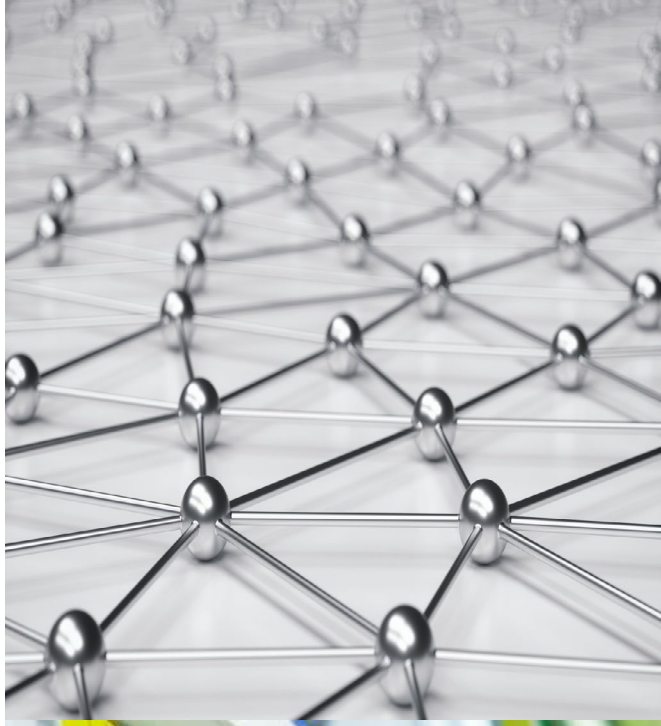
#5 Reliance in action: EMA/WHO post-approval reliance pilots

- Reliance approaches 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.
- EMA, with WHO, is supporting a pilot to submit EMA-approved variations to multiple non-EU national authorities.



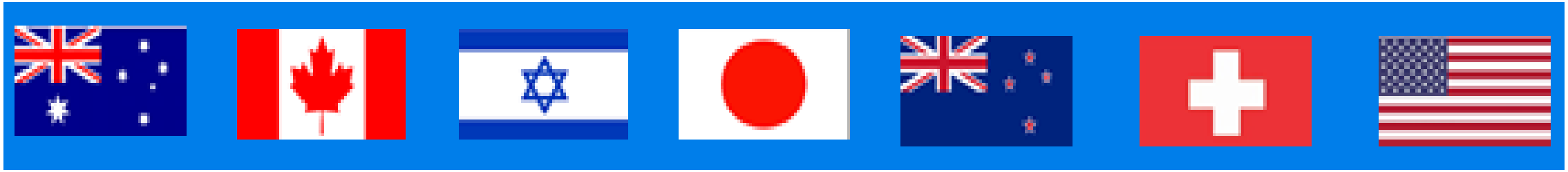
#5 Reliance in action: EMA/WHO post-approval reliance pilots

- Pilot aims at creating more efficient pathway for global roll-out of post-approval changes (‘variations’) through reliance
- Currently 12 active products (more in pipeline, review mid-2025)
- 11 = 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 some pilots show 83% participating NRAs approving variation withing 6.5 months.
- Promotes harmonisation of requirements; 75% reduction in country-specific documentation requirement.
- Ensures continuity of supply and patient access.



Inspections and reliance

Mutual recognition agreements (MRA) ensure the best use of resources by promoting mutual reliance and work-sharing for GMP with other international authorities



Broadly similar scopes, but with specific differences regarding product scopes or OMCL testing or recognition of third country inspections

Benefits for industry

- Fewer duplicative inspections
- Waiving of re-testing upon importation
- Encourage greater international harmonisation

Benefits for regulators:

- Better use of inspection resources
- Focus on manufacturers of higher risk
- Encourage greater international harmonisation

Quality control and laboratory testing recognition

- **Official Control Authority Batch Release (OCABR):**
  Batch release certificates by one OMCL (Official Medicines Control Laboratory) in the EU/EEA are valid across all Member States, eliminating repeat testing.
- **Harmonized testing network:**
  EDQM-coordinated network ensures consistent, high-quality testing via shared protocols and expertise.
- **Centralised data & transparency:**
  Test results and certificates are shared centrally to support surveillance and prompt regulatory actions.
- **Ongoing market surveillance:**
  Mutual recognition and data-sharing enable rapid detection and removal of substandard or falsified products (recognition and optimisation of network resources).

Making reliance happen

How can reliance be implemented in practice?

1

Framework

Legislation
Guidance
TRUST

2

Eligibility

Assessment of IMA
Post-approval changes
Inspections
Lot release/Lab testing

3

Requirements

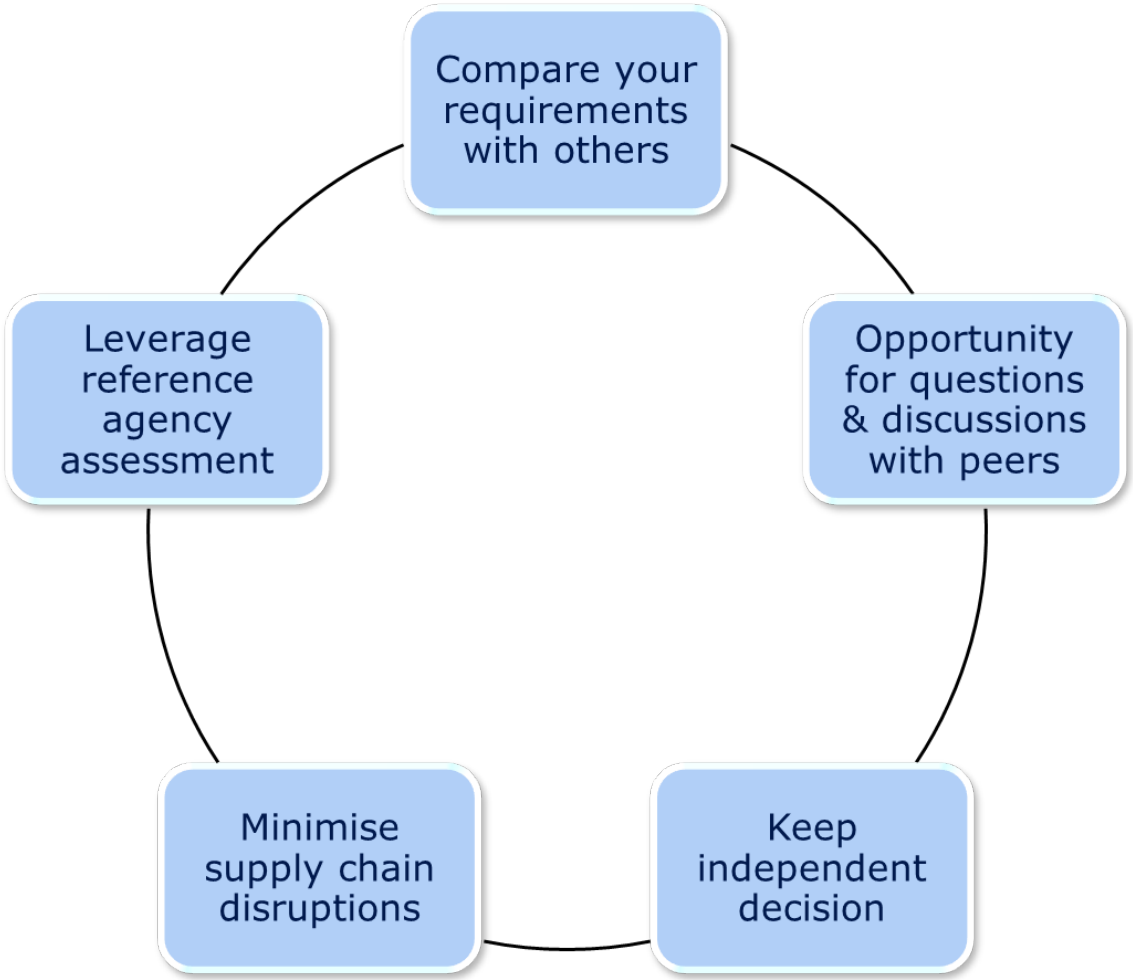
What data is needed to implement reliance in practice

4

Operational efficiency

Agency/assessors culture shift
Clear process in place
Measuring success

Opportunities and benefits



Other benefits:

- Promotes regulatory harmonization
- Promotes transparency and trust
- Promotes earlier access
- Supports capacity building
- Effective use of resources

Some reflections

- We all face many challenges, including increased workload and limited resources
- Reliance is not out-sourcing your decision, it is about **in-sourcing additional expertise**.
- Stakeholder engagement helps us to prioritize and decide what to do and how. Feedback from industry is key to focus and adjust.
- International collaboration and reliance is a **necessity**, not a choice. It brings benefits for regulators, industry and patients.
- No agency, no matter how well resourced, can do it all alone.

Thank you.

ema.europa.eu

linkedin.com/company/european-medicines-agency/

bsky.app/profile/ema.europa.eu

EMAinternational@ema.Europa.eu

Send a question via our website

EMA
EUROPEAN MEDICINES AGENCY