EMA
EUROPEAN MEDICINES AGENCY

International collaboration and reliance

WCBP 2026 – Session 5A

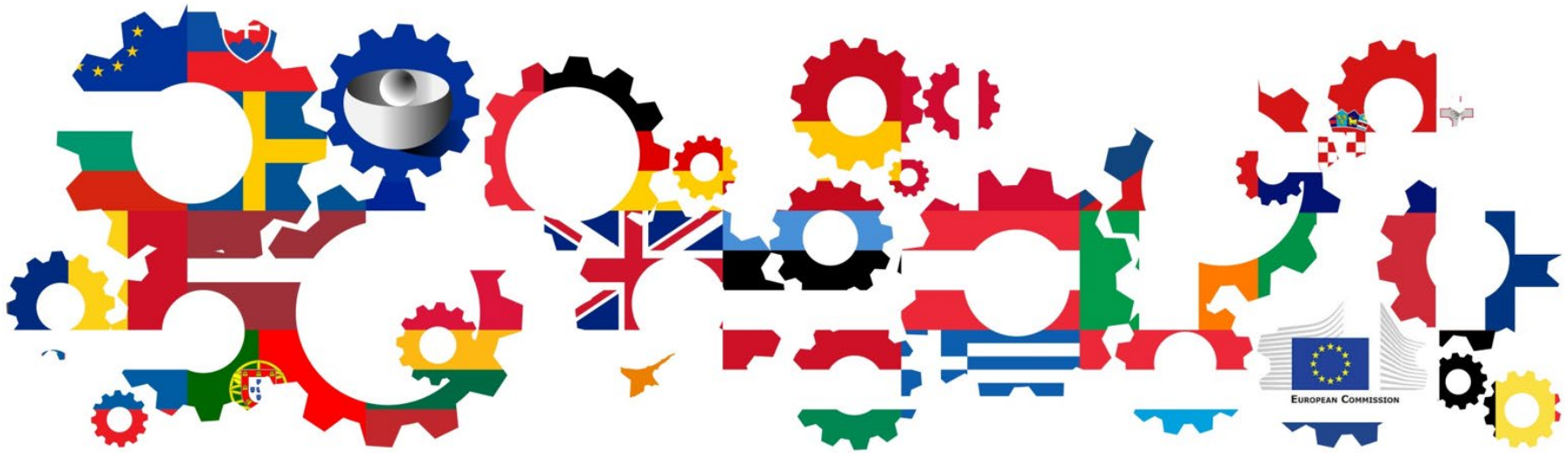
28 January 2026

Brian Dooley

Pharmaceutical Quality Senior Specialist, EMA

The importance of international collaboration

International collaboration and reliance is part of the European's Network DNA



An effective and efficient way of regulating medicines through reliance, work-sharing and recognition.

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

Mechanisms that facilitate and alignment and trust with international partners

Bilateral relations

Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Dominican Republic

Israel, Japan, New Zealand, Peru, Republic of Korea, Saudi Arabia, Singapore

Switzerland, Taiwan, United Kingdom, United States of America, EDQM, WHO

- International Liaison Officers
- Confidentiality Arrangements (CA)
- Ad Hoc CA
- Mutual Recognition Agreements (MRA)
- Clusters

Multilateral relations

African Medicines Agency

ICMRA

PIC/S

EU-M4all

SRA-CRP

OPEN

IPRP International Pharmaceutical Regulators Programme

ICH harmonisation for better health

VICH

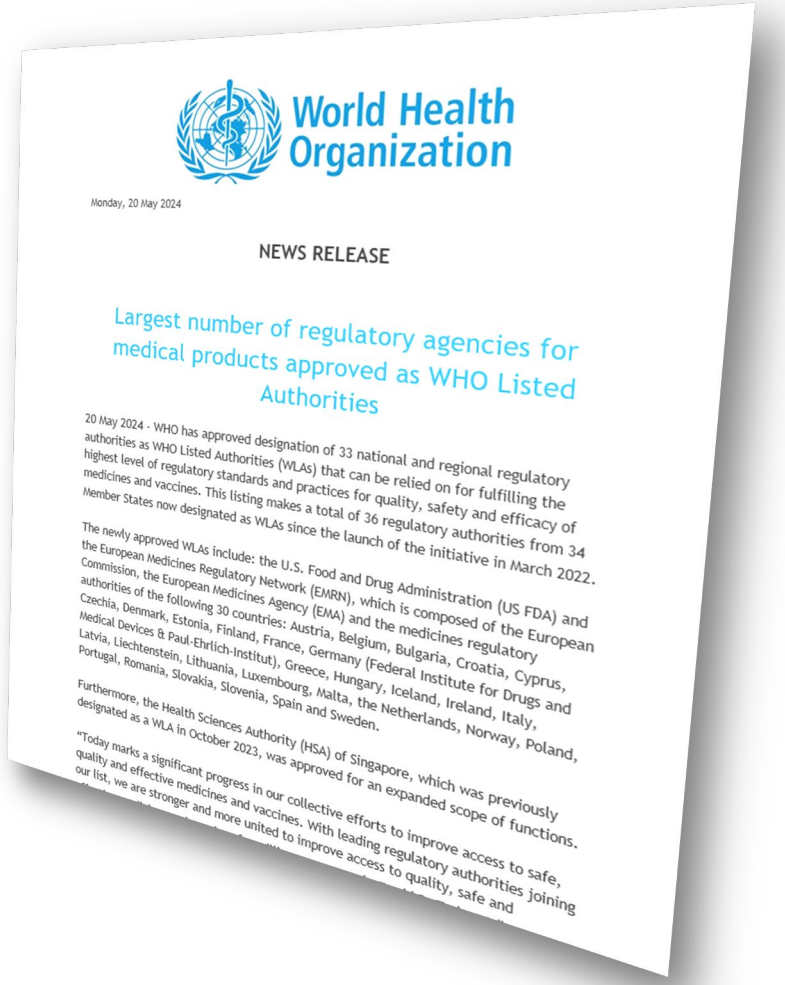
Instrument for Pre-accession Assistance

EMA

International collaboration and reliance

European medicines network designated as WHO listed authority

- On 20 May 2024, EMA, EC and 30 NCAs were designated 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.
- Decision was based on technical evaluations by WHO, confirming consistency of advanced performance by all these authorities.
- This recognition enables reliance on trusted regulatory authorities, promoting confidence and fostering regulatory convergence, harmonization of approaches, and international cooperation.
- Currently, EMA and the network are already widely used as reference agency to apply reliance amongst 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

EMA

International collaboration and reliance in practice

‘OPEN’ framework for non-EU regulators

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

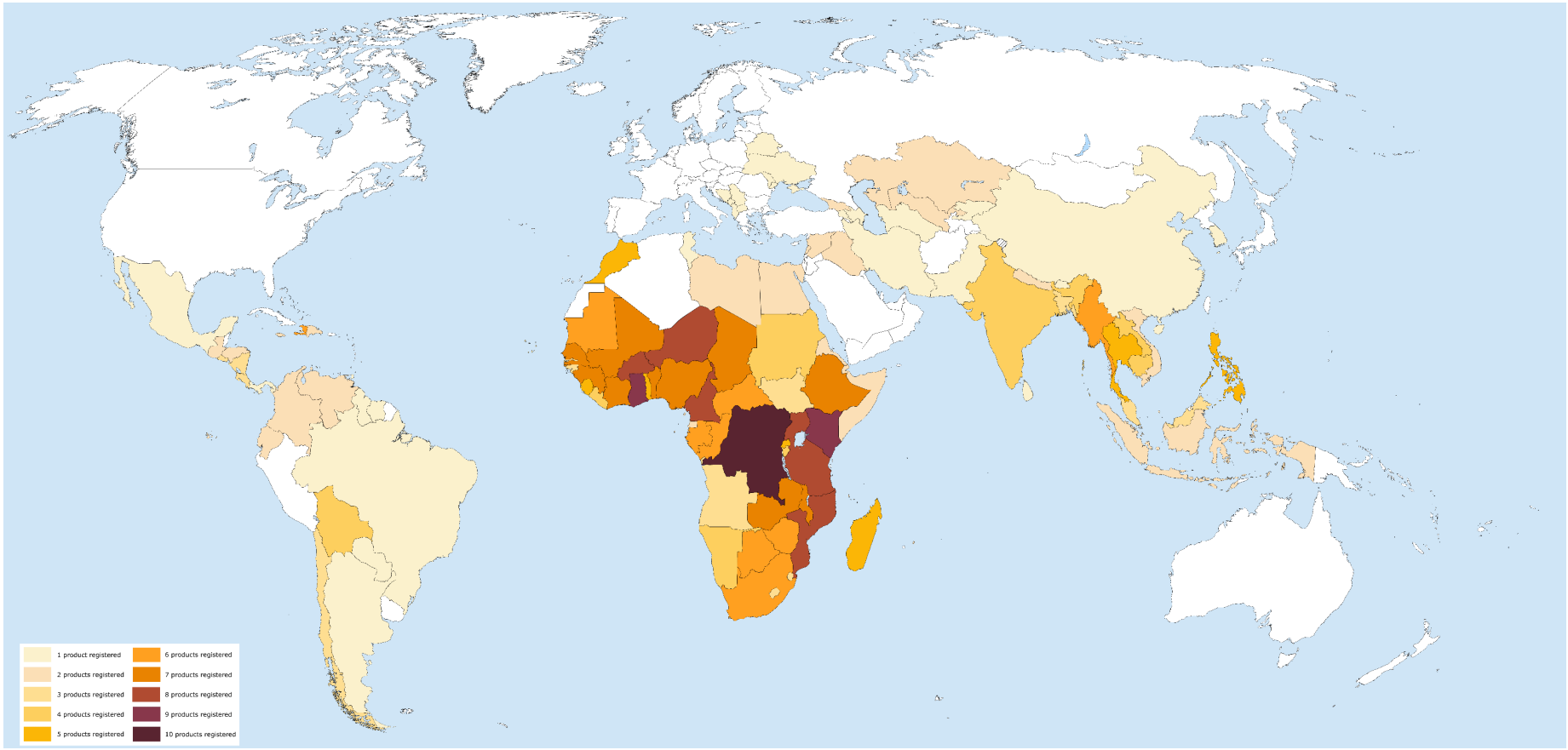
- **Antimicrobial resistance** (AMR) global threat where progress requires a collective effort for human and veterinary products

- Priority medicines designated under the **PRIME scheme (temporarily <u>not</u> including ATMPs products)** and PRIME-type products which **address high unmet need** (e.g. Alzheimer,)

- Medicinal products responding to health threats or **public health emergencies**

EMA

EU-Medicines for all (EU-M4all)



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

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.

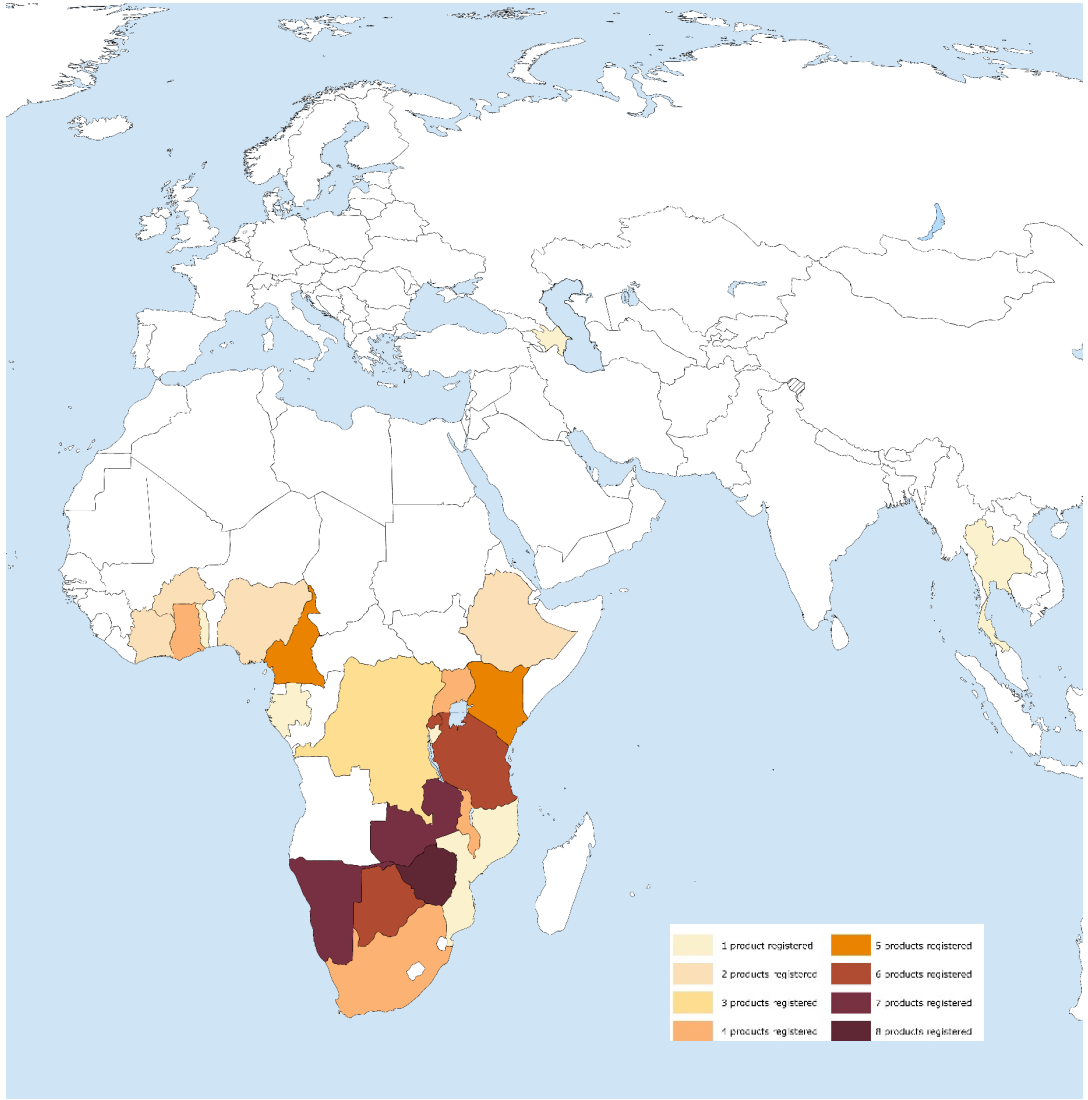
EMA

WHO Collaborative Registration Procedure (CRP)

13 medicines with EU marketing authorisation

23 countries

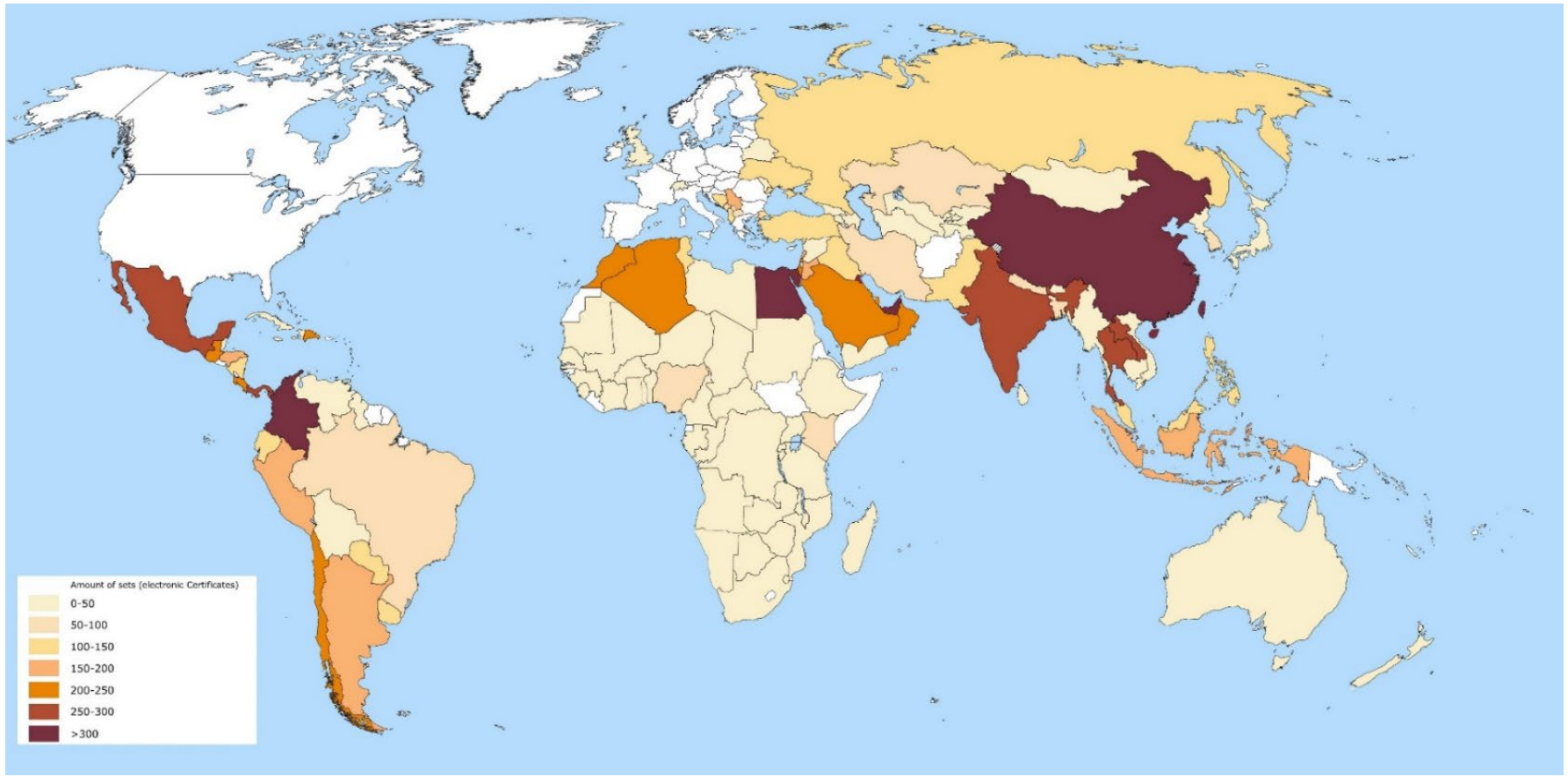
83 marketing authorisations via CRP



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.

Certificates of Pharmaceutical Products

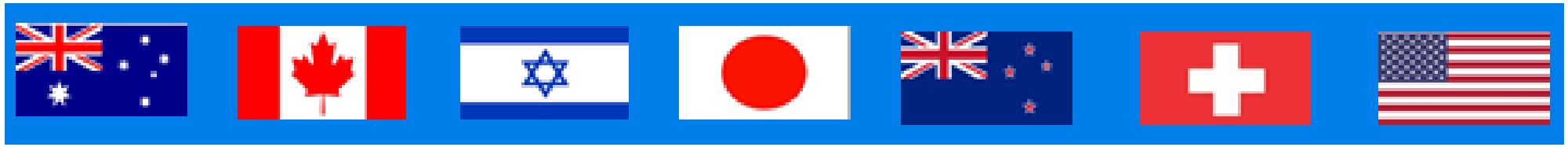


e-Certificates of Pharmaceutical Products (eCPP) provide assurance, confirm marketing authorisation status of a medicinal product and that is produced in accordance with GMP standards.

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

Inspections and compliance

EMA ensures the best use of resources by promoting mutual reliance and work-sharing with other international authorities.



Impact on existing EU MRAs on GMP

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

Piloting reliance applied to post-authorisation changes

- EMA collaborates with non-EU regulatory authorities, WHO and the pharmaceutical industry in running pilots to test a more efficient model for handling major post-authorisation changes.
- Applicants must submit the same Variation package, as used in the EU to all participating national authorities together with EMA CHMP final assessment report
- NRA is encouraged to align country-specific requirements to EMA's documentation requirements.
- NRA have the option to fully or partially rely on EMA's assessment.
- National authorities keep full scientific and regulatory independence in their decision-making
- EMA invites pharmaceutical companies interested in participating in a pilot to contact EMA at emainternational@ema.europa.eu.
- Overall, the results of this pilot are overwhelmingly positive and suggest that the pilots were effective and well-perceived by NRAs. With the analysis of the learnings we hope to have data-driven results that promote trust in reliance for PACs.

ICMRA Collaborative Assessment Pilot – Overview

- **Scope**

Multi-agency collaborative assessment of Post Approval Change Management Protocols (PACMPs)

Focused on medically important treatments, including chemical and biological products, but excluding vaccines

- **Application Process**

14 applications received

Prioritised based on impact to supply of critical medicines & potential for agreed regulatory approach

- **Pilot implementation**

5 proposals accepted

Identical submissions sent to all participating agencies

ICMRA Pilot cases

Application	Product	Indication	Proposed change	Lead Authority	Participating Authorities	Observer Authorities
Pilot Case 1	Monoclonal antibody	Follicular lymphoma	Additional active substance manufacturing site and additional QC testing site	EMA	FDA	PMDA
Pilot Case 2	Small molecule	Hyperkalaemia	Additional drug product manufacturing site	FDA	EMA	PMDA, Health Canada, HSA, ANVISA
Pilot Case 3	Small molecule	Non-small cell lung cancer	Additional active substance manufacturing site	PMDA	FDA, EMA, MHRA, Swissmedic	HSA, Health Canada, TGA
Pilot Case 4	Antibody drug conjugate	Metastatic triple-negative breast cancer	Additional active substance intermediate manufacturing site and additional QC testing site	FDA	EMA, MHRA, Swissmedic	Health Canada
Pilot Case 5	Monoclonal antibody	Multiple cancer indications	Improvements to the manufacturing process	EMA	FDA, PMDA, Health Canada	HSA, Swissmedic

Lead Authority

- Assess application
- Propose IRs
- Coordinate all activities
- Lead on project calls
- Consolidates IRs
- Applicants' main contact

Participating Authorities

- Conduct independent assessment
- Participate in discussion meetings
- Propose IRs

Observer Authorities

- Participate in discussion meetings
- Cannot raise IRs

Key achievements

Streamlined Timelines

- Agreed a common **120 day assessment timetable**
- **Near-simultaneous approvals** — a global first!

Overall duration (days)	Max difference in approval dates between participating authorities
115	0
118	0
105	0
122	2
119	12

Efficiency & Harmonisation

- **88% of all assessment IRs** harmonized via intensive discussions
- Harmonisation achieved across all sections of Module 3
- **~25% reduction** in total IRs due to collaborative review meetings
- All 5 collaborative assessments completed successfully with **harmonised outcomes**
- No increase in standard expectations → the regulatory bar remained unchanged
- **Positive feedback** from industry and regulators (based on survey results)
- Increased resource requirements, especially for regulators

Regional Specificities

- Some region-specific IRs (e.g. method transfer data, validation report requirements)
- A few region-specific administrative questions (e.g. applicant forms, GMP documentation)

Pilot extension

Based on positive results and feedback, pilots have been extended for **1 extra year.**

- A detailed report is now publicly available

ICMRA website 

Summary Report 

Scope includes:

- ✓ High impact changes for medically important treatments
- ✓ Innovative manufacturing technologies
- ✓ PACMPs that impact supply
- ✓ Generics and biosimilars

- Applicants are encouraged to contact the PQKM Pilot Coordination Group to discuss potential applications
- **Informal discussions** are welcomed prior to application

Email contacts for queries
icmra-pac-pilot@fda.hhs.gov
icmra-pac-pilot@ema.europa.eu
icmra-pac-pilot@pmda.go.jp

Some reflections

- All regulators face many challenges, including increased workload and limited resources
- Collaborative pathways and reliance support regulatory harmonisation, capacity building, transparency and trust, and especially earlier access.
- Active engagement from industry and all other stakeholders is key.
- Reliance is not out-sourcing your decision, it is about **in-sourcing additional expertise**.
- 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.

EMA
EUROPEAN MEDICINES AGENCY

ema.europa.eu

European Medicines Agency

European Medicines Agency

brian.dooley@ema.europa.eu

Send a question via our website