EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

International collaboration in the review of medicines

How can we optimize the use of reliance

Industry stakeholders meeting November 2022

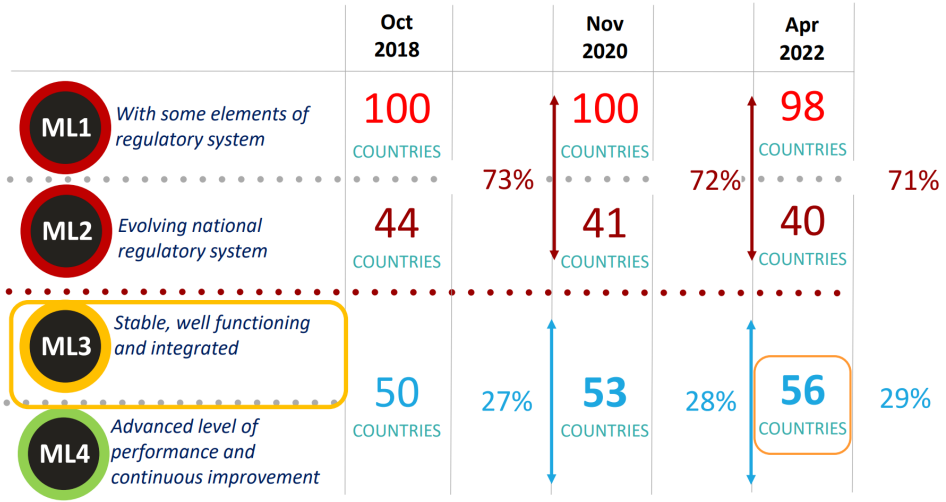
Presented by Martin Harvey and Victoria Palmi
International Affairs

An agency of the European Union

Need for global regulatory strengthening

Data from WHO

Global status of national regulatory systems, April 2022



Globally, 71% of countries have weak national regulatory systems

Inadequate legal framework to regulate medicines

Reduced human resources to conduct regulatory activities

Lack to technical capacity or expertise

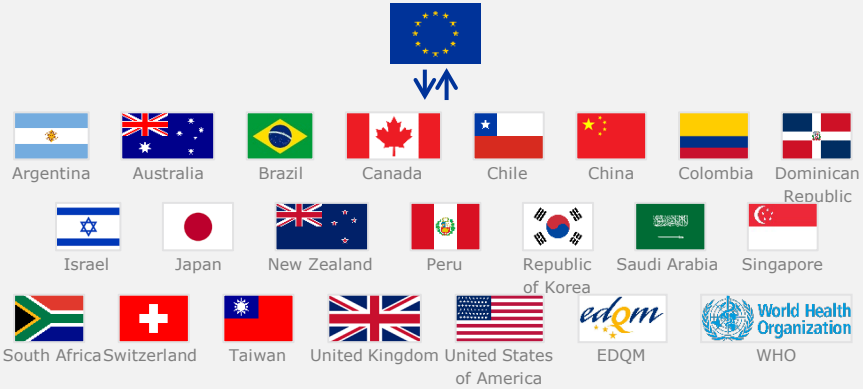
Reliance

"The act whereby the **regulatory authority in one jurisdiction** may take into account and give significant weight to – i.e. **totally or partially rely** upon – **evaluations performed by another regulatory authority or trusted institution** in reaching its own decision. The relying authority **remains responsible and accountable** for decisions taken, even when it relies on the decisions and information of others" – WHO (2020), Good Regulatory Practices Guidance

- Regulatory Harmonization
- Transparency and Trust
- Earlier access
- Capacity building
- Making best use of resources

Promoting harmonisation and trust

Bilateral relations



Multiple mechanisms for bilateral relations

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

Multilateral relations

ICMRA

OPEN pilot

IPA

Instrument for Pre-accession Assistance

ICH harmonisation for better health

EU-M4all

IPRP International Pharmaceutical Regulators Programme

CRP

PIC/S

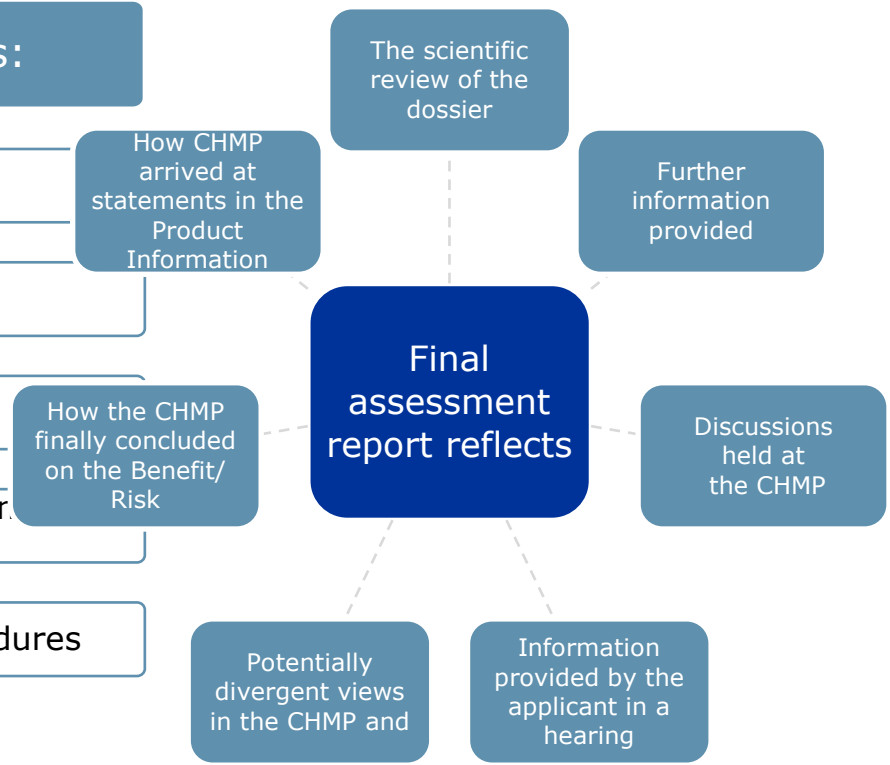
AMA

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

EMA assessment reports: a tool for Reliance

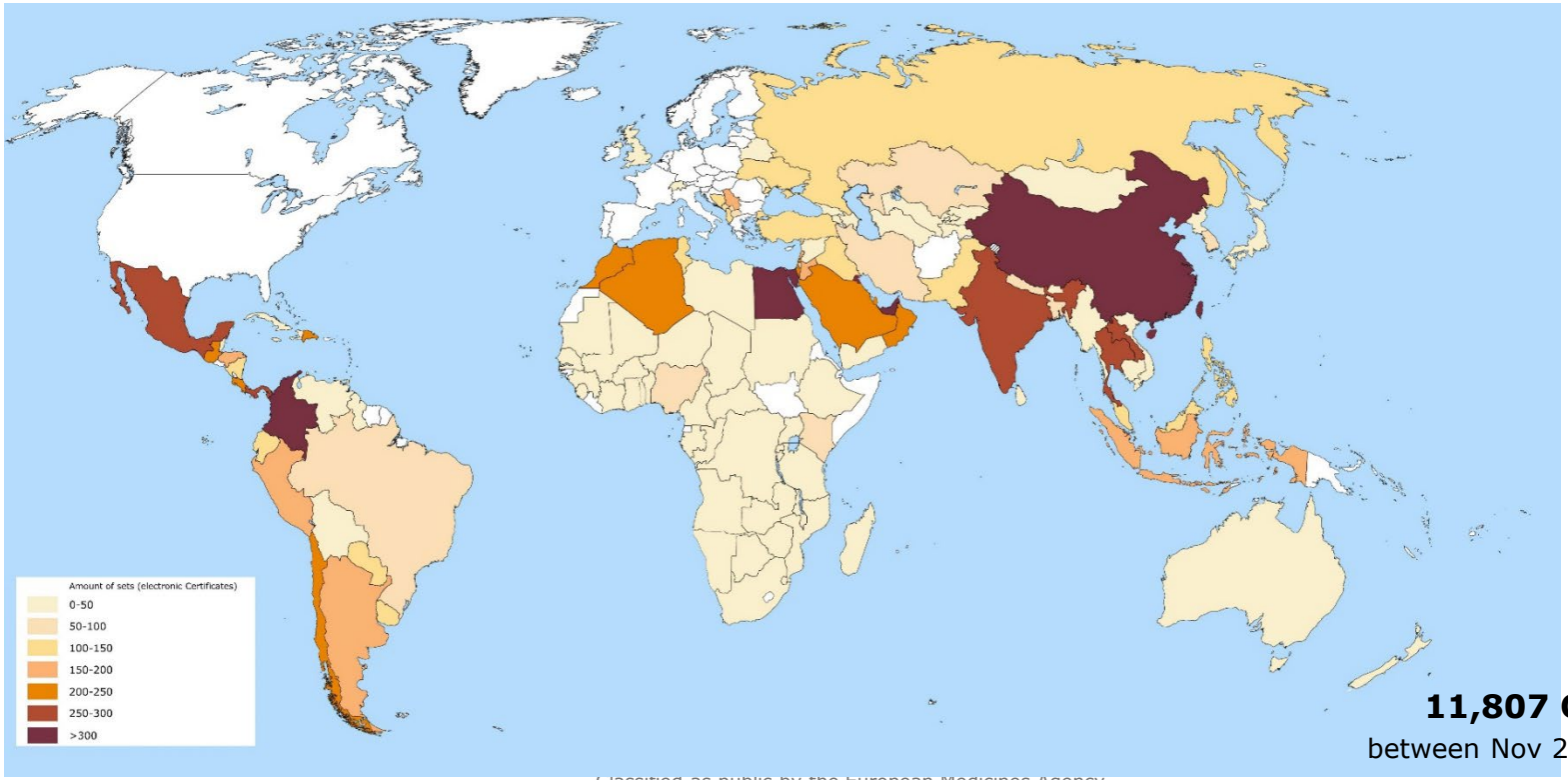
European Public Assessment report includes:

- information about the product
- approved product information
- conditions to the MA
- scientific discussion (based on CHMP assessr report)
- information on the post-authorisation procedures



EMA eCPPs: a tool for reliance

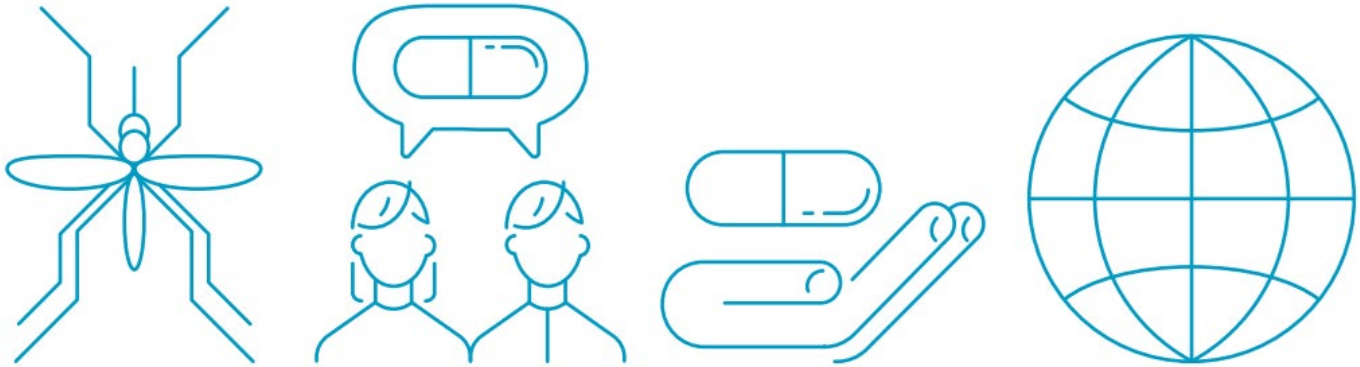
CPP confirm the marketing authorization status of the medicinal product and that is produced in accordance with GMP standards.



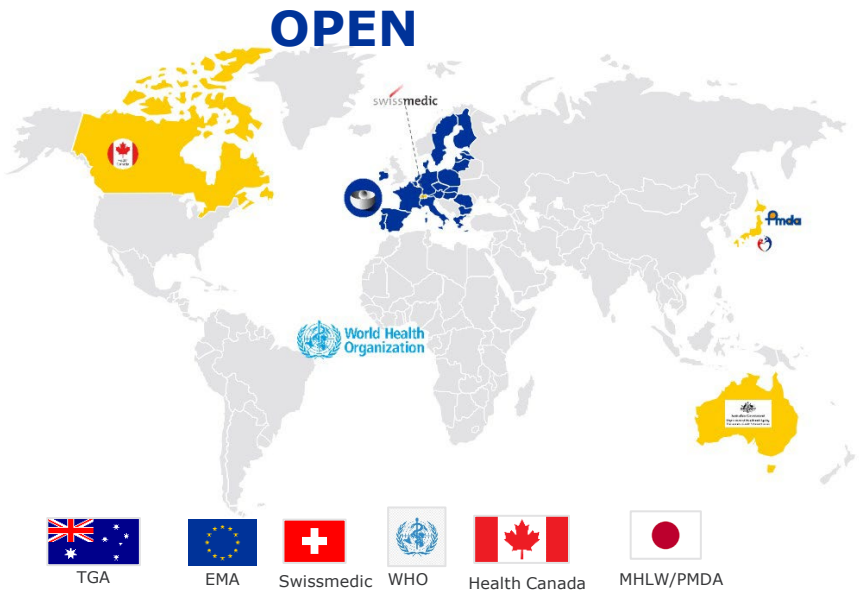
11,807 CPP
between Nov 21-Oct 22

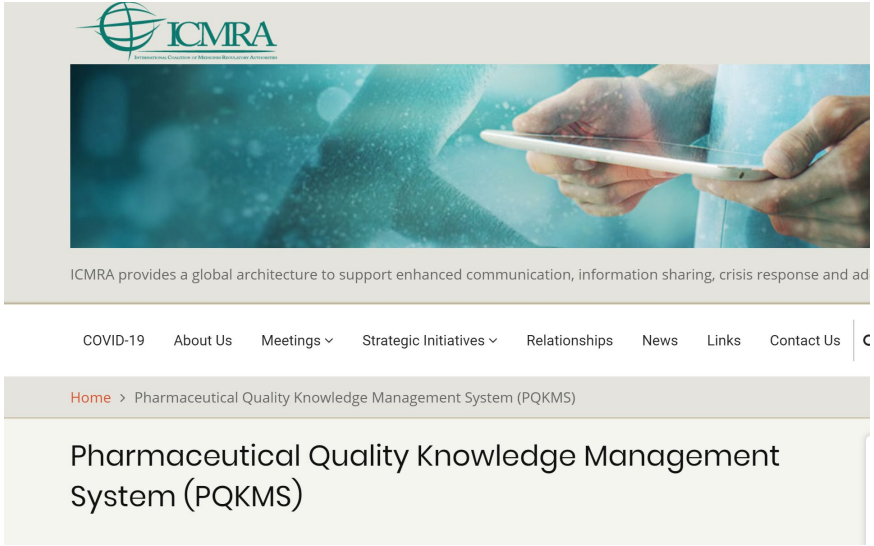
Supporting global regulatory system

EMA also collaborates **with WHO** to **support the global regulatory system** through EU-M4all, CRP and targeted meetings that facilitate registration and capacity building in low and middle income countries.



International collaboration and reliance – a tool for all agencies of any size





Take-home messages and next steps

Regulatory aspects are here to **protect patients**, but do **not** have to be **a barrier** to innovation and patient access to medicines.

International collaboration and **reliance mechanisms** bring **multiple benefits** to *regulatory authorities*, *developers*, and eventually to *patients* worldwide.

Reliance should by considered by any Agency, independent of their capacity/maturity and should be used for the whole lifecycle.

Understanding the barriers from industry will facilitate optimisation of Reliance

How can EMA help?

Email: EMAinternational@ema.europa.eu

Website: https://www.ema.europa.eu/en/partners-networks/international-activities