EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3. Update on reliance and other collaborative pathways

7th Industry Standing Group (ISG) – 23 November 2023

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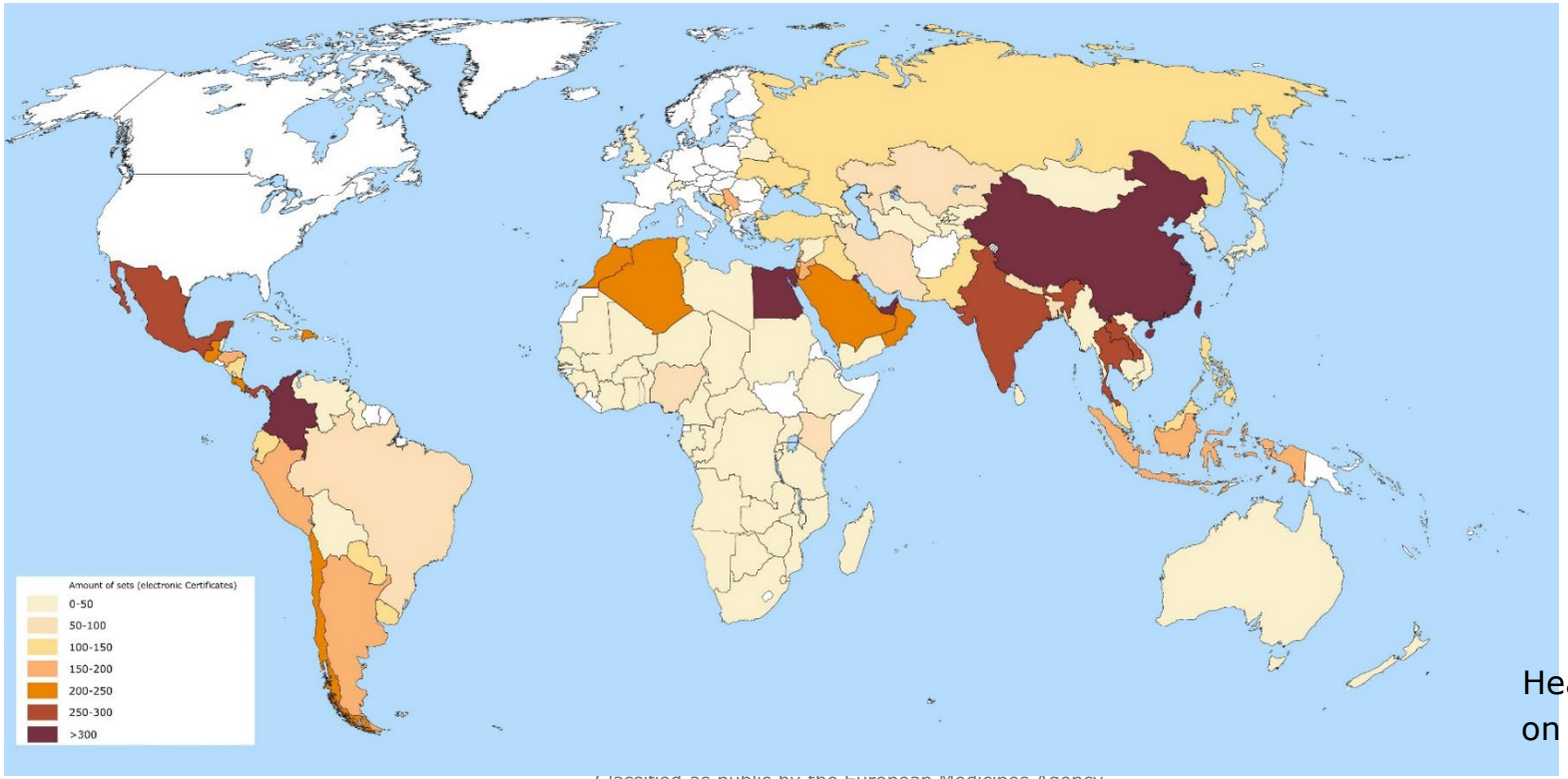
Reliance and collaboration are at the core of a more efficient use of global resources

- It's the job of every medicines regulator to protect public health in their own countries and regions, but health and medicine regulation is a cross-border concern and therefore we need to think and act both locally but also globally.
- We all face many challenges, including increased workload and limited resources
- Collaborative pathways and reliance also support regulatory harmonisation, capacity building, transparency and trust, and especially earlier access.
- EMA reliance and collaborative pathways with High-Income Countries (HICs) and Low- and Middle-Income Countries (LMICs)
  "Reliance is a modern 21st Century way of doing regulatory business"

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.

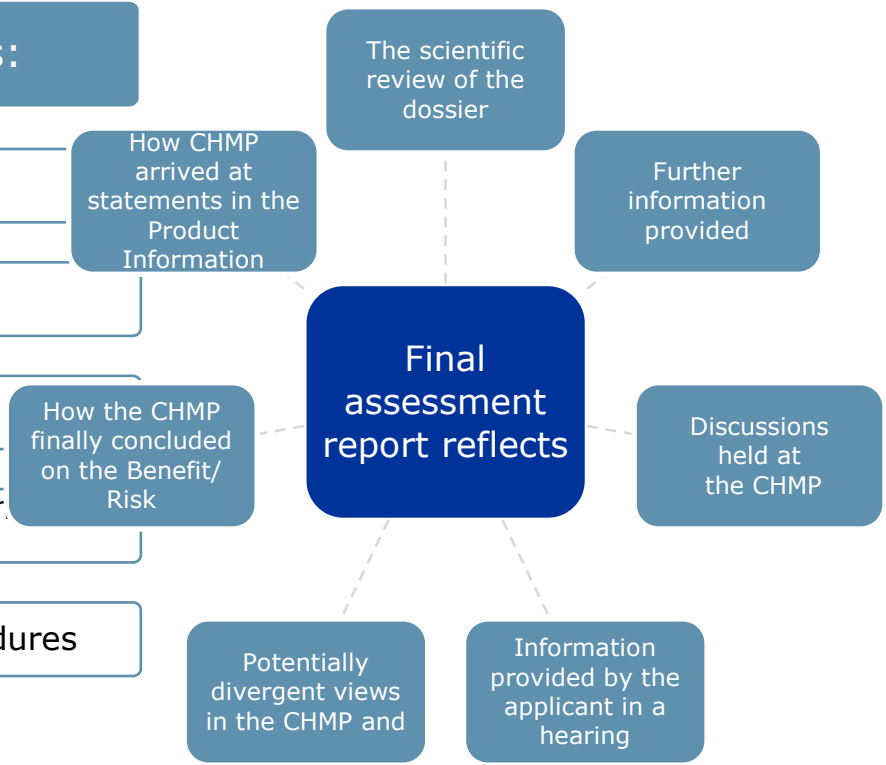


Heatmap based on 2022 figures

EMA assessment reports: a tool for Reliance

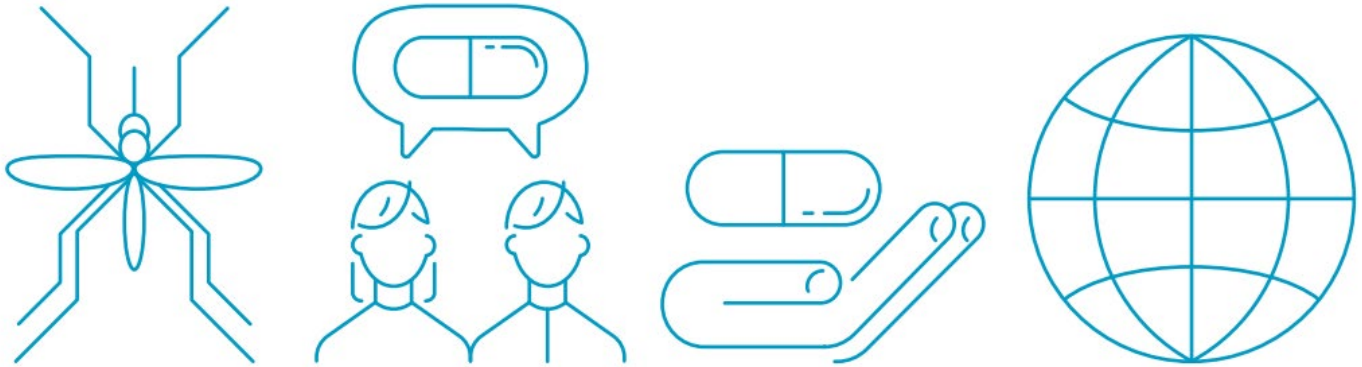
European Public Assessment report includes:

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



Supporting global regulatory system

EMA also collaborates **with WHO** to **support the global regulatory system** through EU-M4all, WHO Collaborative Registration Procedure and Facilitated Product Introduction – both facilitate registration and capacity building in low- and middle-income countries



OPEN - Update

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

1. **Antimicrobial resistance** (AMR) *global threat where progress requires a collective - effort for human and veterinary products*
2. Priority medicines designated under the **PRIME scheme (temporarily not including ATMPs products)** and PRIME-type products which **address high unmet need** (e.g. RSV, Alzheimer, ALS)
3. Medicinal products responding to health threats or **public health emergencies**

Engaged with all OPEN partners to:

- **Define terms of reference that promote RECIPROCITY and more active** participation
- Increase the **visibility** of the framework with more **systematic and coordinated communication**

OPEN - Update

- Two medicinal products currently under review under OPEN (2 vaccines)

- Engagement from OPEN partners to join the framework but applications not received


Health Canada


Swissmedic


TGA


MHLW/PMDA


WHO


ANVISA

- Need for industry stakeholders' regulatory submission alignment and early identification of OPEN partners

International collaboration, Reliance and convergence brings multiple benefits to *regulatory authorities*, *developers*, and eventually to ***patients*** worldwide.

Further reading:

OPEN - One-year review of the OPEN pilot and recommendations

EMA/6881/2022

One-year review of the OPEN pilot and recommendations (europa.eu)

Any questions?