EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Agency OPEN assessment pilot

International collaboration on Covid Vaccines and Therapeutics

PCWP/HCPWP meeting 2 June 2022

Presented by Martin Harvey
International Affairs, European Medicines Agency

COVID-19 regulatory challenges and EMA response

Regulatory context

Swift response to COVID-19 needed an **adaptation of our regulatory tools** and resources

Multiple regulatory authorities were facing the **same challenges** and were about to **assess the same medicines**

Resources were stretched worldwide

International collaboration

Bring **additional expertise** and **enrich scientific** discussions

Promote convergence to **increase public confidence**

Accelerate assessments and **patient access** to medicines

International collaboration and reliance **high on EMA agenda**

Potential challenges

additional workload and high number of meetings (ETF/CHMP)

Need for **maintaining** EU standards for **Personal Data protection**

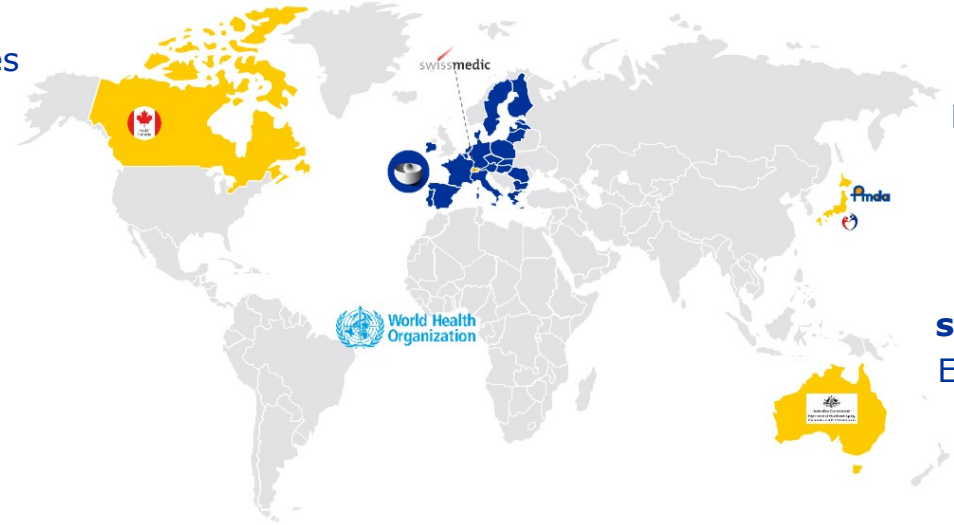
Keep the **independence** of all regulators' **decision-making**

OPEN pilot

Opening our **P**rocedures at **E**MA to **N**on-EU authorities

OPEN

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



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 Regulators kept full scientific and regulatory **independence.**

OPEN regulators

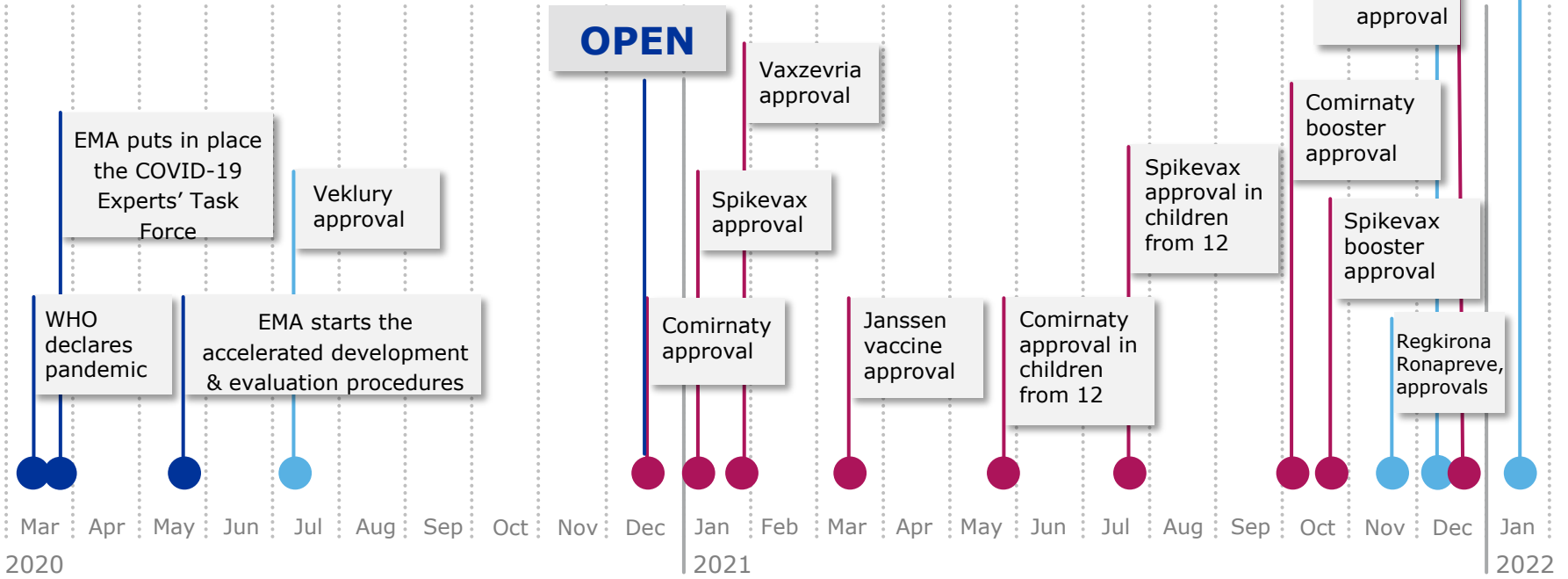
TGA
EMA
Health Canada
Swissmedic
MHLW/PMDA
WHO

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

Products assessed under OPEN

5 vaccines **8 therapeutics** 4 still under review

MAIN MILESTONES
FIRST YEAR



Vaccines Therapeutics

Key success of the pilot

Enhanced communication channels and facilitated **discussions and exchanges**

Assessment of **similar data** by multiple authorities and **fewer labelling differences**

Accelerated COVID-19 medicines assessments and **access to patients** outside of the EU

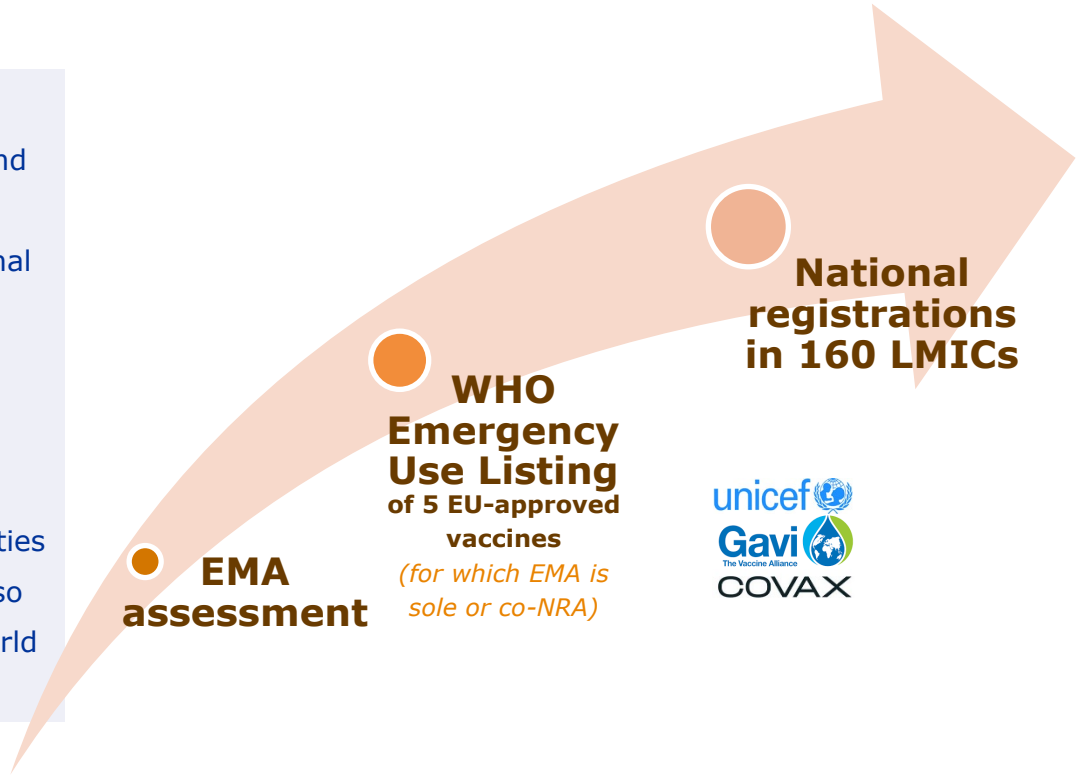
Global public health impacted through reliance pathways

Independence of decision-making

OPEN global health impact

Feedback shows positive impact for evaluation and **accelerated approvals** for participating regulators and applicants.
Has also significantly accelerated decisions from national regulatory authorities in **LMICs**.

The EMA is the regulatory authority of record
For the **WHO Emergency Use Listing** (EUL)
for the 5 vaccines approved in the EU.
The WHO EUL enables LMIC national regulatory authorities to **speed registration** of COVID-19 vaccines. It is also needed to allow **procurement** by UN agencies and World Bank Group partners.



OPEN pilot, what's next?

Consolidate the pilot's operation

Engagement with all stakeholders to define more detailed **terms of reference that promote more active** participation

Increase of the initiative **visibility** with more **systematic and coordinated communication** by all OPEN participants

Reduce the submission gap between applications to OPEN regulators **or envisage different types of engagement**

Expand to identified areas

Following a stepwise approach:

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

Cross-regional collaborative assessment
of **CMC aspects**
OPEN as a continuation of the ICMRA pilot

Explore other areas of interests

Some priority medicines designated under the **PRIME scheme**

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

EMA take-home message

International collaboration brings multiple benefits
to regulatory authorities, developers, and eventually to patients.

OPEN **facilitated the assessment** of the same data by multiple authorities, deepening the collaboration and moving the exchange of information to active engagement.

OPEN allowed regulators to **accelerate and align on decisions**, leading to fewer labelling differences, while **maintaining independence** in the decision making.

OPEN demonstrated the value of international collaboration to **avoid duplication of efforts**, improve **efficiency**, and bring vaccines and medicines to patients earlier in the **interest of public health**.

EMA will now engage with all stakeholders to consolidate OPEN in a stepwise approach

Any questions?

Further information

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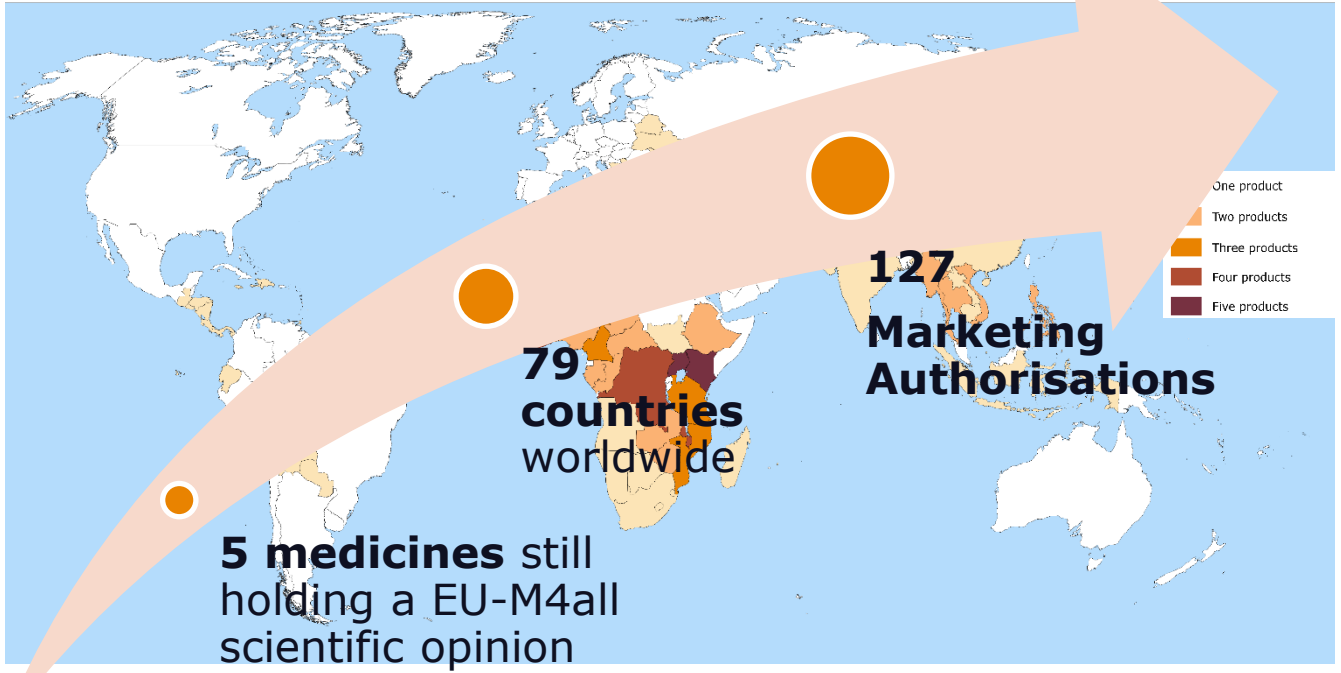
EU-Medicines for all (EU-M4all)

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

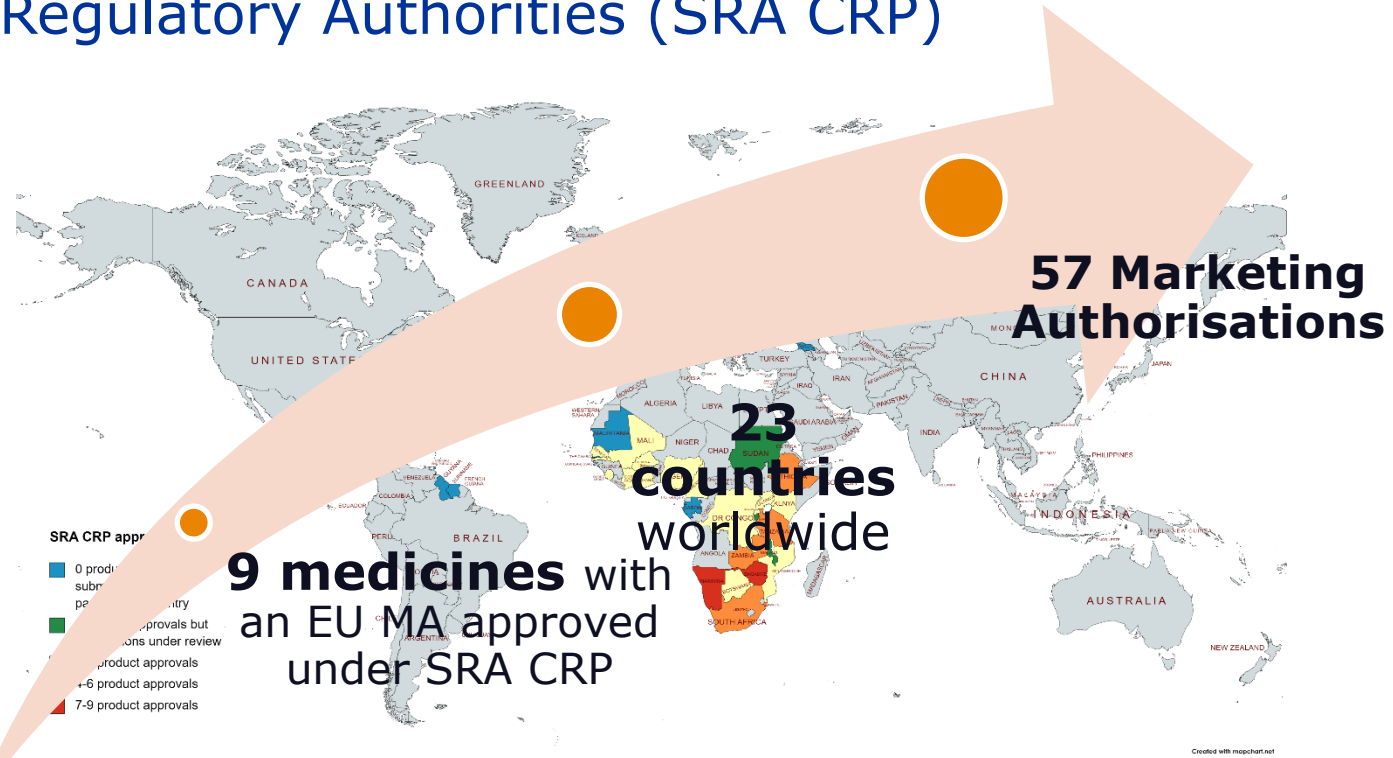
EMA evaluates and gives an opinion, in cooperation with WHO, on medicinal products for human use intended for markets outside of the EU



As of January 2022

WHO Collaborative Registration Procedure using Stringent Regulatory Authorities (SRA CRP)

Accelerates national approvals by allowing countries to rely on the scientific assessment carried out by Stringent Regulatory Authorities, such as EMA



As of December 2021