EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Agency OPEN pilot

International collaboration on Covid Vaccines and Therapeutics

Industry Stakeholder Platform on centralised procedure meeting
27 June 2022

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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**

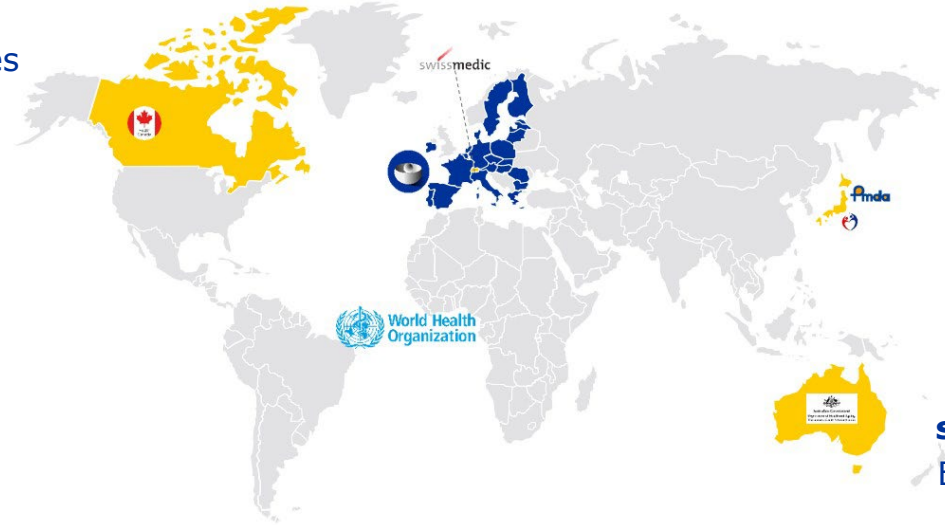
OPEN pilot

Launched in **December 2020**

Opening our Procedures at EMA to Non-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)*

OPEN regulators

TGA
EMA
Health Canada
Swissmedic
MHLW/PMDA
WHO

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

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

OPEN is **an international collaboration framework** of near-concurrent review among international regulators.

Before the pandemic some non-EU regulators participated as Observers in selected Committees/WP cluster meetings and requested EMA clarifications on questions or assessments.

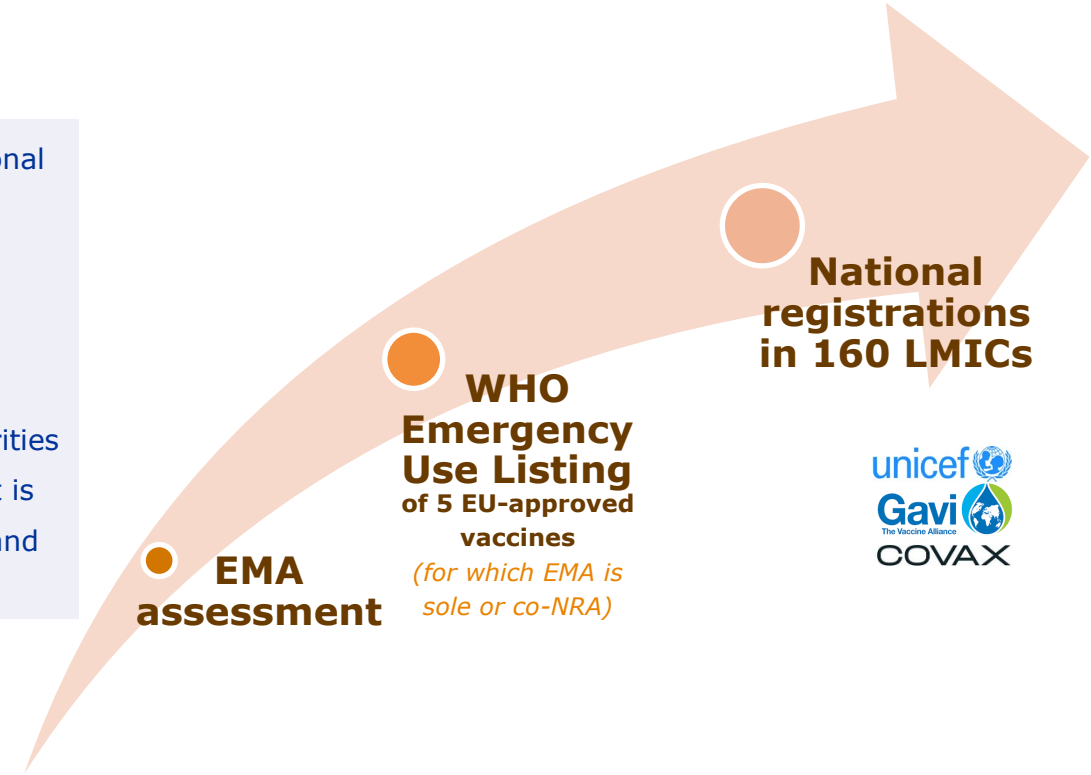
With OPEN :

- EMA conducted full review of applications but shared and discussed assessments on COVID vaccines and therapeutics in real time with OPEN experts.
- OPEN experts participated actively in Emergency Task Force (ETF) and CHMP meetings
- OPEN experts exchanged comments and reviews with EMA product leads and assessment teams.
- All Regulators kept full scientific and regulatory **independence.**

OPEN global health impact

Reliance 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 the registration** of COVID-19 vaccines. It is also needed to allow **procurement** by UN agencies and World Bank Group partners.



Products assessed under OPEN

All the COVID-19 vaccines and therapeutics evaluated since the launch of the pilot were assessed under OPEN, **from the moment the rolling review started** to the evaluation of the marketing authorisation application.

5 vaccines authorised*

8 therapeutics authorised*

4 under review* 3 under rolling review*

*As of June 2022.

In addition to **initial marketing authorisation**, **extensions of indications**, **major variations** and **inspections** were also part of the discussions.

There was **no requirement** from Industry **to submit** an application to all participating countries, and **all OPEN experts were invited to all EMA COVID-19 discussions**, even when submissions were not aligned.

Key success of the pilot

Enhanced communication channels and enabled **collaboration, discussions and exchanges**

Facilitated assessment of **similar data** by multiple authorities, reducing duplication of work and allowing the r**elease scarce resources** to other critical areas

Facilitated **alignment** 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

What could improve

More explicit **rules of engagement**
providing more clarity to all stakeholders.

Alignment of submissions or

Terms of reference with levels of engagement that are
adapted to eventual un-aligned timelines between regulators

Enhance **communication** and **visibility** of the OPEN framework

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 questions for industry and 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 is engaging with all stakeholders to consolidate OPEN in a stepwise approach

Any questions?

Further information

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