



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8.2 Update on Opening Procedures at EMA to Non-EU authorities (OPEN) framework

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OPEN - Scope

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

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

1

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

2

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

3

[Opening procedures at EMA to non-EU authorities \(OPEN\) initiative | European Medicines Agency \(europa.eu\)](#)



OPEN - Update

- During the COVID-19 pilot phase ALL COVID vaccines and therapeutics were reviewed under OPEN from the moment the rolling review started to the evaluation of the marketing authorisation application.
- Three medicinal products currently under review under OPEN:
 - Arcturus COVID-19 vaccine
 - Moderna RSV vaccine
 - Valneva Chikungunya vaccine

OPEN – key messages

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



Health Canada



Swissmedic



TGA



MHLW/PMDA



WHO



ANVISA

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

- Companies are allowed to suggest for consideration, OPEN partners choices in their MAA application/Pre-Submission meetings for OPEN evaluation



Further reading:

[OPEN Q&A](#)

[One-year review of the OPEN pilot and recommendations \(europa.eu\)](#)

Any questions?