EMA
EUROPEAN MEDICINES AGENCY

OPEN Framework

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‘OPEN’ framework for non-EU regulators

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

-**Antimicrobial Resistance (AMR)** response treatments and novel antimicrobials.

- Priority medicines designated under the PRIME scheme.

- Other medicines which address an **unmet need**.

- Medicines, including vaccines, that respond either to **health threats or public health emergencies**.

OPEN framework is used for **IMAA** and **post-authorisation changes** (e.g. extension of indications and quality variations).

Aims of OPEN framework

- Make it possible to share expertise and tackle common challenges.
- Leverage broader scientific insights (e.g. AMR) leading to more robust and globally aligned evaluations.
- Speed up the access to new therapies.
- Harmonised regulatory approaches for medicines.
- Increase the transparency of regulatory decision-making.

OPEN principles

- OPEN initiative currently relies **on permanent arrangements** between EMA and OPEN partners.
- OPEN experts are **invited to comment** during the evaluation, as any other EU Member States.
- OPEN experts to follow **EMA's timetable.**
- OPEN experts can **participate in relevant EMA scientific meetings.**
- OPEN partners should identify which questions **are identical** to the EMA ones and which ones **are specific** to their territory.
- OPEN experts **do not contribute to committee meetings (or voting)** during the final/overall benefit-risk balance decision.

OPEN framework - Communication

- All scientific committee documents (e.g. Assessment reports and LoQs) are shared to OPEN experts by the applicant.
- When publishing their decisions, both EMA and OPEN partners will refer to their participation in OPEN to promote this collaborative Framework.
- OPEN partners to mention their participation in the OPEN Framework participation in press releases at opinion, if applicable.

Applications reviewed under OPEN

- All COVID-19 vaccines and therapeutics during pandemic.
- Under ‘new OPEN’ 4 iMAA + 1 Type II.
- Mix of both vaccines and therapeutics.
- OPEN partners so far: ANVISA (Brazil), PMDA (Japan), Swissmedic and WHO.
- Commitment from other partners to participate (i.e. align timetables), but need industry to synchronise regulatory strategy.

More information on the OPEN framework can be found here

Opening procedures at EMA to non-EU authorities (OPEN) framework

OPEN Q&A

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Thank you

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