EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

OPEN – International collaboration

Industry Stakeholder Platform on centralised procedure meeting
27 June 2023

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OPEN Pilot

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

Approach: Participating non-EU experts invited to **attend and contribute** to **ETF and CHMP evaluation**

OPEN experts follow **similar requirements** as the EU experts *(e.g., confidentiality, absence of conflict of interests).*

OPEN regulators

EMA, Health Canada, Swissmedic, TGA, MHLW/PMDA, WHO

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

OPEN products

All the COVID-19 vaccines and therapeutics evaluated since the launch of the pilot.

Implementation:

- **EMA conducted a full review** of applications but shared and discussed assessments 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.**

Closing off the pilot phase

- The OPEN pilot on COVID-19 vaccines and therapeutics is terminated.
- Any future COVID-19 vaccines or therapeutics will be assessed under the full OPEN framework
- Participation of representatives of non-EU regulatory authorities and selected international organisations at ETF will cease.
- Non-EU regulatory authorities/selected international organisations may continue to attend COVID-19 topics at CHMP as observers

Scope for extension of OPEN

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Expand 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 products which **address high unmet need** (e.g. RSV, Alzheimer, ALS)
3. Medicinal products responding to health threats or **public health emergencies**

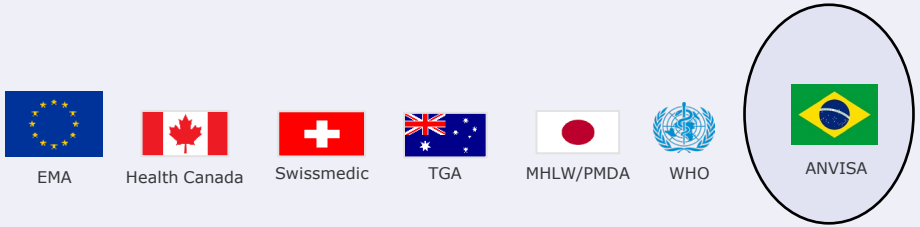
Update: Cross-regional collaborative assessment** of **CMC aspects addressed at ICMRA level

Consolidate the pilot's operation

- Engaged with all OPEN partners to:
  - **Define terms of reference that promote RECIPROCITY and more active** participation
  - Increase of the initiative **visibility** with more **systematic and coordinated communication** by all OPEN participants

Operationalisation of the OPEN framework – High level process

OPEN regulators



Principles

- OPEN experts invited to comment during the CHMP evaluation as any other EU MS.
- OPEN experts are not contributing to CHMP conclusions during the final benefit-risk decision.
- OPEN experts participate in ETF (when applicable) and CHMP meetings only

Selection of OPEN products

Criteria:

- CHMP and min. 1 OPEN partner interested in collaboration
- Alignment of dossier content/claimed indication, submission date

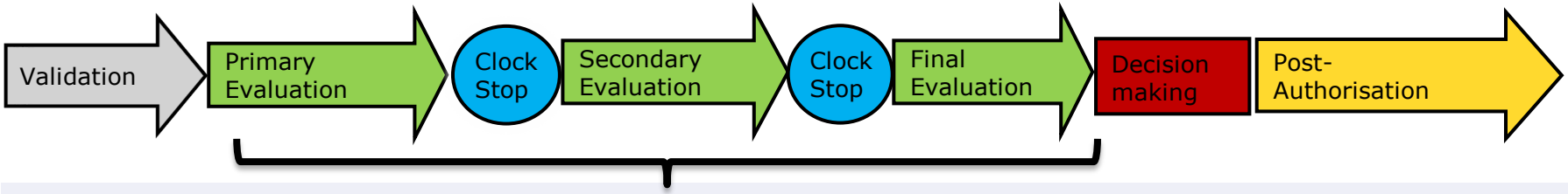
Procedure:

- Early Selection of OPEN products (so that OPEN partners can discuss timing of submissions with their applicants)

What are the expected benefits for industry and global health?

- Alignment of dossiers to improve regulatory convergence within OPEN partner countries
- Potential faster overall global approval through leveraging existing or ongoing assessments and expertise beyond the EU regulatory network (e.g. fewer questions for industry and labelling differences)
- Potential to align also the post-approval lifecycle management for major changes and/or also using reliance mechanism
- Promoting capacity optimisation and convergence of assessment standards
- Possibility to engage with EMA in a discussion to harmonise global standards of submissions

Operationalisation of the OPEN framework – High level process (cont'd)



During CHMP assessment:

- Comment during the evaluation as any other EU MS.
- Review EMA AR* (preliminary; updated; LoQ)
- Provide written comments on the AR (same timeframe as other CHMP members)
- Rapporteurs can interact with OPEN partners when required.

During parallel review:

- Actively share their preliminary / final reports/list of questions/applicant responses with the EMA.

During committee meetings:

- Provide comments when invited by the chair
- Are not contributing to CHMP conclusions during the final benefit-risk decision.

***Applicants circulate Rapporteurs ARs to OPEN experts – PLs either copied or receive a confirmation that the AR was shared with OPEN experts.**

Communication & visibility

EMA

- Publication of a revised Q&A + detailed communication plan
- Product assessed under OPEN indicated in the CHMP's published agenda and minutes
- EPARs of OPEN products to include statement on assessment under OPEN framework (same as during pilot phase)
- OPEN participation in press releases
- EMA will not share companies' applications with OPEN partners

OPEN partners

- Share with EMA divergent analysis and advance notice on regulatory actions on corresponding applications.
- When publishing their decisions, OPEN partners expected to give notice and refer to their participation in OPEN to promote this reliance framework

Message to applicants

- Companies encouraged to synchronize submissions as much as possible.
- Once the process is mature, companies will also be able to proactively ask for their product to be part of OPEN.

Further reading:

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

EMA/6881/2022

https://docs.eudra.org/webtop/drl/objectId/090142b2852c9d85

Any questions?