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International Affairs

Questions and Answers on the 'OPEN' Framework

Opening our Procedures at EMA to Non-EU authorities

Questions and Answers on the OPEN framework allowing non-EU regulatory authorities ('OPEN partners') to participate in and contribute to EMA scientific assessment.

Introduction

International collaboration brings multiple benefits to regulatory authorities, and eventually to patients. It facilitates patient access through harmonisation or convergence, brings additional scientific expertise to the regulatory process, and simplification for the pharmaceutical industry.

EMA began a pilot in December 2020 to increase international collaboration and share scientific expertise on the evaluation of COVID-19 vaccines and therapeutics. All COVID-19 vaccines and therapeutics evaluated since the launch of the pilot have been assessed under the OPEN framework, from the moment the rolling review started to the evaluation of the marketing authorisation application. Regulators from Australia, Canada, Japan, Switzerland, and the World Health Organization participated in the pilot.
Experts as part of the OPEN pilot participated actively in Emergency Task Force (ETF) and CHMP meetings and exchanged comments and reviews with EMA product leads and assessment teams. Importantly, all regulators kept full scientific and regulatory independence in their decision making. The EMA policy on handling of competing interests of scientific committees' members and experts applied to involvement of OPEN partner experts in the concerned EMA activities.

Following the positive outcome of the pilot, the framework has been extended to other therapeutic areas. The following Q&A explains the principles of this collaboration.

1. What are the objectives and benefits of OPEN?

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OPEN provides a framework for near-concurrent review by one or multiple additional regulatory authorities, each conducting their own assessment in parallel to the EMA evaluation while sharing scientific expertise and maintaining their scientific and regulatory independence.

OPEN aims at:

- Facilitating sharing of scientific expertise to tackle common challenges
- Facilitating alignment of regulatory approaches between regulatory authorities
- Speeding up patient access to innovative medicines
- Enhancing transparency on regulatory decisions

2. Which regulatory authorities can participate?

The following authorities with whom EMA has a permanent confidentiality arrangement in place: Therapeutic Goods Administration, Australia (TGA), Brazilian Health Regulatory Agency (ANVISA), Health Canada (HC), Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency, Japan (MHLW/PMDA), Swiss Agency for Therapeutic Product (Swissmedic), and the World Health Organization (WHO).

3. Which scientific committees are involved?

This framework currently involves the CHMP and ETF and is not extended to other scientific committees. OPEN partners may continue to participate in other committee plenary meetings as observers under the confidentiality arrangements.

4. Which products are assessed under OPEN?

Products are eligible for assessment under OPEN if they fall into one of the following categories:

1. Antimicrobial resistance (AMR)
2. Priority medicines designated under the PRIME scheme (temporarily not including ATMPs products) and other products which address a high unmet need (e.g., RSV, Alzheimer, ALS)
3. Medicinal products responding to health threats or public health emergencies

For an eligible product to be selected for assessment under OPEN, both the CHMP and at least one OPEN partner must agree to collaborate on it. The dossier content/claimed indication and timing of submissions to both EMA and the OPEN partner(s) should also be aligned.
If submission of application is not aligned, OPEN partners can participate in CHMP discussions as observers.
EMA may decline including a submission in the OPEN framework on the grounds of overall workload.

The concerned marketing authorisation applicants will be informed of their participation by EMA.

5. What is the status of participants?

Each non-EU authority will conduct its assessment in parallel and appoint individuals considered

as 'OPEN experts' who should be able to present the compiled scientific evaluation and overall assessment of their authority. The participating OPEN experts are proposed by the participating authorities and appointed by EMA once they have met all criteria of the policies applicable to experts. This requires filling in a Declaration of Interests and confidentiality undertaking, as well as providing a CV and being included in the Experts database before any participation. The EMA policy on handling of competing interests of scientific committees' members and experts (link) is applicable to the involvement of these experts in the concerned EMA activities. The same safeguards of independence as for Committee members will apply to the experts.

Each non-EU authority will conduct its assessment in parallel and appoint individuals considered as 'OPEN experts' who should be able to present the compiled scientific evaluation and overall assessment of their authority. The experts can also discuss and report back within their authority (e.g. to their product team) on the discussions taking place at EMA.

The number of OPEN experts attending the CHMP is limited to 3 per OPEN partner, with possible justified exceptions based on area of expertise and need. In the case of WHO, participation is limited to WHO staff. WHO can also bring observers from non-EU regulatory authorities in the context of an OPEN procedure and the maximum number of observers will be three.

Note: the participation as OPEN experts is distinct and independent from participation as observers at any Committee meetings.

6. How are products assessed under OPEN?

Once a product has been selected to be assessed under the OPEN framework, the EMA product team will include experts from OPEN partners in the assessment procedure to ensure that comments will be received. The experts can also discuss and report back within their authority (e.g., to their product team) on the discussions taking place at EMA. EMA rapporteurs may contact OPEN experts when required.

OPEN experts will receive the Rapporteur's assessment reports (AR) and the list of questions (LoQs) from the applicant/MAH; applicants/MAHs will be asked to do this in a timely manner. They are then expected to review the documents and provide written comments on documents within the same timeframe as other members. OPEN partners will also actively share their preliminary and final reports, list of questions, applicant responses and any divergent analysis with the EMA. EMA rapporteurs and OPEN experts can request additional meetings for discussion.

Open experts' comments will be addressed during the assessment as any other EU experts' comment. OPEN experts are not permitted to contribute to the Committee's conclusions (or voting) on any key procedural milestone, in particular the adoption of opinions. They can still listen to these opinion-making steps, but are not allowed to contribute.

There is no obligation to align opinions, approvals or policies. Participation of OPEN partners should not limit or constrain the independence of the EMA scientific assessment. The participating authorities will retain their independence as well.

7. What information can be exchanged?

Under the terms of the confidentiality arrangements, authorities can receive the necessary outputs of the Committee. This includes (but is not limited to) Rapporteurs' assessment reports, list of questions, reader's guidance, joint assessment reports, interim and final opinions. OPEN partners should share their own documents with EMA, without prejudice to the CHMP assessment. EMA will not share companies' applications with OPEN partners.

8. How is collaboration under the OPEN framework communicated to the public?

CHMP assessment reports represent the view of the CHMP only.

EMA will indicate that a product is being assessed under the OPEN framework in the published CHMP agenda and minutes. As for any expert participating in the process, the OPEN experts and their domain of expertise are listed. Their names will appear in the list of participants in the minutes of the CHMP meeting that they attended, while observers are not listed. The following sentence is included in the Assessment report and EPAR, presenting the role of the OPEN experts from non-EU regulatory authorities, while highlighting the independence of the Committee: '*During the assessment of the application for marketing authorisation of <product name>, the following non-EU authorities were allowed to participate in and contribute to the scientific discussions of the CHMP: <OPEN partners>. These authorities had no influence on the final benefit/risk determination, which was decided by the Committee members only*.'

OPEN partners will give advance notice to EMA of any regulatory actions on corresponding applications. When publishing their decisions, both EMA and OPEN partners will refer to their participation in OPEN to promote this reliance framework.