20 January 2026
EMA/303082/2025
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 leverage scientific expertise on the evaluation of COVID-19 vaccines and therapeutics. All COVID-19 vaccines and therapeutics evaluated since the launch of the pilot were 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 (PL) 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 and procedures. The following Q&A explains the principles of this collaboration.

1. **What are the objectives of the OPEN Framework?**

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

2. What are the benefits of the OPEN Framework

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.
- Predictability for industry in terms of assessment timelines and similar list of questions.
- Streamlined, consolidated Lists of Questions from regulators.
- Coordinated regulator input during the MAA review.
- More expedient regulatory decision timelines.
- More rapid responses to applicant's/MAHs questions.

3. 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 and Food Safety, Republic of Korea (MFDS), 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).

4. Which scientific committees are involved?

Experts from participating authorities are invited to attend the CHMP, CAT and ETF (where appropriate) and may be extended to other scientific committees and working parties (e.g. BWP, QWP).

5. Which medicines can be assessed under OPEN?

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

1. Antimicrobial Resistance (AMR) response treatments and novel antimicrobials.
2. Priority medicines designated under the PRIME scheme.
3. Other medicines which address an unmet need.
4. Medicines, including vaccines, that respond either to health threats or public health emergencies.

OPEN framework applies to initial marketing authorisation applications and post-authorisation procedures.

6. Which procedures are reviewed under the OPEN Framework

The OPEN Framework applies to Marketing Authorisations Applications (MAA), and post-authorisation procedures (e.g. Extensions of marketing authorisations, Extension of Indications (EoI),quality variations (e.g. post-approval change management).
Applicants are strongly encouraged, specifically for life cycle management procedures, to involve as many OPEN partners as possible in applications submitted through the OPEN Framework to promote regulatory alignment.

7. Is it mandatory for the applicant/MAH to submit their application to all interested parties?

Applications should be submitted in parallel to EMA and the selected OPEN partner(s) by the applicant/MAH. These applications are not shared between EMA and the OPEN partner(s).

8. Will the dossiers content and proposed indications need to be harmonized across countries?

The dossiers content and proposed indications need to be harmonized across countries part of the OPEN Framework.

9. How applicants/marketing authorisation holders (MAHs) can request the review of their application under OPEN?

For MAA and quality variations, applicants can request for their product to be part of the OPEN Framework provided that the application is submitted ≤ 1 month of EMA submission in at least one "OPEN partner".
When submitting the "Letter of Intent Request" through the EMA service desk, applicants will have to specify in the pre-submission request form if they want their application to be reviewed under the OPEN Framework and which OPEN partner(s) will review the application in parallel.
The applicant/MAHs is expected to ensure their proposed OPEN partner(s) agree with participating in the procedure prior to submitting the "Letter of intent request" via the EMA service desk.
EMA can also facilitate engagement with OPEN partners at applicants/MAHs' request.

For Extensions of marketing authorisations and EoIs, the MAHs should contact the product lead and cc the dedicated OPEN mailbox (OPEN@ema.europa.eu) .

EMA may decline including a submission in the OPEN Framework.
Applicants/MAHs are advised to consult their company country leads internally to confirm their willingness to file in respective OPEN partner jurisdictions before signalling their interest (e.g. through the Letter of Intent request) to the EMA.

10. Will EMA and OPEN partners follow the same timetable during the assessment?

OPEN partner should follow the EMA's assessment timetable (e.g. responses to the List of Questions/List of Outstanding Issues/Request for Supplementary Information to be submitted at the same time to EMA and the OPEN partners).

11. What is the status of participants?

Each OPEN partner will conduct its assessment in parallel and appoint individuals considered as 'OPEN experts'.
OPEN experts are invited to comment during the assessment of the application as any other EU member state (MS). OPEN experts 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.
WHO may only nominate WHO staff as experts. WHO may also nominate other non-EU regulators as observers. These observers can provide their comments on the application (via the nominated WHO staff expert) and attend any EMA scientific committee discussions (without intervening, just as observers).

12. What are the guarantees of independence of the OPEN experts?

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 curriculum vitae (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 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.
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.
While the OPEN Framework aims at facilitating alignment between participating authorities there is no obligation to align opinions, approvals or policies between EMA and OPEN partners. Participation of OPEN partners should not limit or constrain the independence of the EMA scientific assessment. The participating non-EU authorities also retain their independence.
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/CAT meeting that they attended.

13. How many OPEN experts can participate in the OPEN Framework?

The number of OPEN experts attending the scientific committee meetings is limited to 3 per OPEN partner, with possible justified exceptions based on area of expertise and need.

14. What happens after an application is accepted for the OPEN?

Once an application has been accepted 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. EMA will confirm to the applicants/MAHs that their product will be reviewed under the OPEN Framework and provide the name of the OPEN experts involved in the Framework.

Upon agreement by the Rapporteurs, a meeting between EMA and the OPEN experts, could take place before the submission of the application to discuss general information about the product, regulatory steps, assessment timetables, data package to support the application, and any other topic to be followed up with the applicant/MAH. Written communication to share information and plans can be an alternative option.

15. What information is exchanged?

Under the terms of the confidentiality arrangements, OPEN partners can receive the necessary outputs of the Committee as well as administrative documents issued by EMA. This includes (but is not limited to) Rapporteurs' assessment reports, list of questions, product information, 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.

16. How are assessment reports shared during the assessment?

As for any other procedure, EMA will circulate to the applicant/MAH the Rapporteurs Assessment Reports (AR) (preliminary; updated) and Committee outcome packages to the applicant/MAH.
Applicant/MAH are responsible for sharing application dossiers, and EMA assessment reports/LoQ to the OPEN experts after applicant's/MAH's redaction of personal data.
OPEN partners will also actively share their assessment reports, list of questions, product information, applicant/MAH responses and any divergent analysis with the EMA.

17. What are the expectations with regard to the comments provided by OPEN experts?

OPEN experts are then expected to review the EMA assessment reports and any other relevant documents and provide written comments on documents within the same timeframe as other EMA scientific committee members.
Open experts' comments will be addressed during the assessment as any other EU MS comment.

18. What is the process for list of questions (LoQ) and the timeframe requirements for applicants/MAHs to respond?

EMA and OPEN partners will send independently their respective list of questions to the applicant/MAH.
OPEN experts should identify which questions are identical to the EMA ones and which ones are specific to their territory.
The applicant/MAH is asked to send standalone parallel answers to EMA and the OPEN experts.

19. How is collaboration under the OPEN Framework communicated to the public?

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.

EMA will indicate that a product is being assessed under the OPEN Framework in the published CHMP agenda and minutes, in the press releases, if applicable. The following statement 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 this application for <product name>, the following non-EU authorities participated as part of the OPEN Framework and contribute to the scientific discussions of the CHMP: <OPEN partner name(s)>. This/these authority/ies did not participate in the overall benefit/risk determination, which was decided by the CHMP."

20. What happens if your application cannot be submitted in parallel to EMA and other non-EU regulatory authorities?

If your application cannot be submitted in parallel to EMA and other non-EU regulatory authorities using the OPEN Framework, there are still mechanisms to facilitate regulatory convergence and reduce duplication of effort. Reliance pathways allow non-EU regulators to leverage EMA's scientific assessments when making their own decisions. EMA actively encourages industry to share its assessment reports and related documentation with these authorities to support reliance-based reviews. This approach helps accelerate access to medicines in multiple jurisdictions, minimizes resource burden for both regulators and applicants, and promotes global regulatory alignment.

The OPEN Framework can also be used for life-cycle management: post-authorisation procedures for products within the scope of the OPEN Framework may be submitted under this Framework, irrespective of whether the marketing authorisation application was assessed through OPEN.

21. Can an applicant/MAH opt-out from OPEN framework once the assessment of the application has started?

While strongly discouraged, applicants/MAHs may formally request to withdraw from the OPEN framework once the assessment of the application has started. To do so, the applicant/MAH must submit in advance written notice accompanied by a comprehensive justification, addressed both to the EMA and to the OPEN partners involved. The EMA and OPEN partners will review the request and issue a formal acknowledgment, specifying any implications for the ongoing process. When an application is withdrawn, EMA and OPEN partners will not refer to this collaboration within the OPEN framework when publishing their final decisions.