OPEN framework

Industry Standing Group (ISG) meeting

11 December 2025

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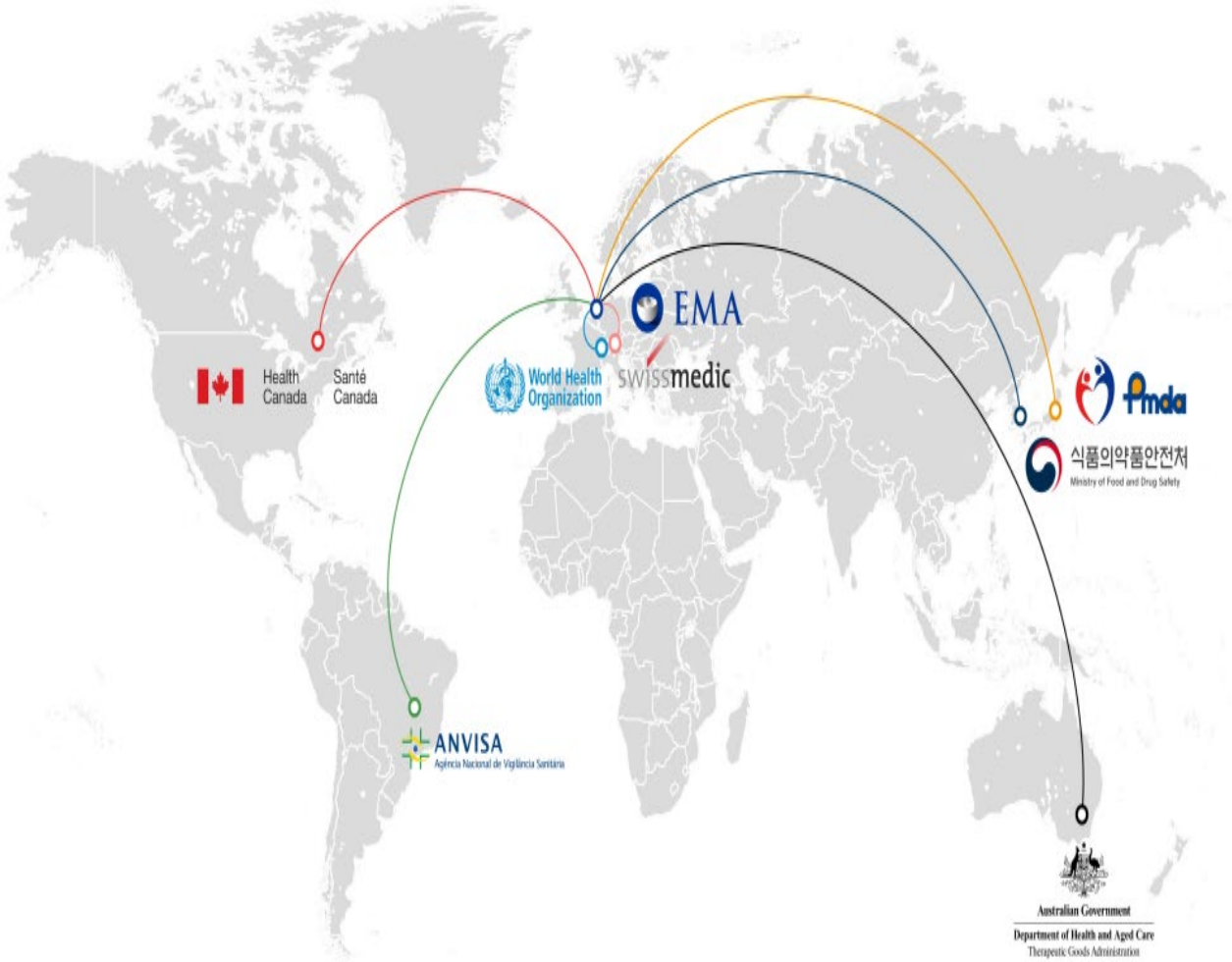
EMA



ISG feedback March – Key Barriers

- Strict eligibility criteria (e.g., antimicrobial products, PRIME-designated products, high unmet medical need) limit industry participation
- Exclusion of certain product types, such as ATMPs, reduces the potential impact.
- The framework should be opened to new indication
- Defined timelines, LOQ handling, and decision processes from OPEN partners
- Limited time savings, efficiency gains, or reduced resource burden for industry compared to other regulatory pathways and no assurance that questions aren’t repeated if already addressed.

OPEN framework updated – MB October 2025

- Broaden the range of products eligible under the OPEN framework to other medicines that target unmet medical need and ATMPs.
- Allowing ATMPs should address the gap between the submission in the different regions and links to the work done by WHO to promote ATMP regulatory framework beyond the main regions.
- Allow OPEN for post-authorisation changes (e.g. extension of indications and quality variations).
- Post-authorisation procedures for products within the scope of the OPEN framework may be submitted under this framework, irrespective of whether the initial marketing authorisation was assessed through OPEN.

OPEN – proposed revised scope

- Antimicrobial Resistance (AMR) response treatments and novel antimicrobials.
- Priority Medicines (PRIME) scheme products **~~(temporarily not including ATMPs products).~~**
- Other products that target **~~high~~** unmet medical needs **~~(e.g. RSV, Alzheimer), temporarily not including ATMPs.~~**
- Vaccines and medicines that respond to health threats or public health emergencies.

OPEN – process improvements

- Applications should be submitted to OPEN partner(s)≤ 1 month of EMA submission to ensure that the applications are reviewed in parallel

- OPEN partner to follow EMA's timetable (e.g. responses to the LoQ/LoOI/RSI to be submitted at the same time to EMA and the OPEN partners)

- OPEN partners should identify which questions are identical to the EMA ones and which ones are specific to their territory: to reduce the duplication of questions so that the applicant can provide the same answers to the identical questions raised by EMA and the OPEN partner(s)

OPEN Q&A

- Shared with ISG and comments included

- Will be published on the EMA website shortly

Key messages

- Updates implemented in response to feedback from industry stakeholders and OPEN partners.

- EMA is exploring opportunities to extend the framework to additional regulatory authorities.

- We strongly encourage all stakeholders to use the framework to gather more experience

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Thank you

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