09 February 2026

Terms of reference for the EMA/ FDA/ HC cluster on patient engagement

The European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and Health Canada (HC) agree on the following:

1. Objectives and goals

The EMA/ FDA/ HC cluster on patient engagement should fulfil the following objectives:

- Benchmark on practices and policies and identify areas of patient engagement within drug development, evaluation, post-authorisation and monitoring which could benefit from an exchange of EMA/ FDA/ HC experience;
- Exchange best practices with the overall aim to further enhance engagement activities, approaches and ideas;
- Exchange information on the different modalities in place for engaging with, and involving patients and their organisations within the work of the agencies;
- Exchange information on internal policies, guidance documents and regulations;
- Exchange information on high profile products/topics of mutual interest, especially those with potential high public interest and impact and which necessitate specific communication;
- Exchange views on priorities and goals regarding future proposals to enhance engagement;
- Exchange experience on challenging aspects identified.

The primary goal of this cluster is to share best practices on involving patients along the medicine's regulatory lifecycle within the respective agencies to support each other's aim to further improve and extend its current actives in this area. The main mechanism to achieve this goal will be regularly scheduled teleconferences for exchange of information and experience.

It may be appropriate to agree on additional in-depth discussions on specific topics during separate ad hoc teleconferences where it might also be applicable to arrange for participation of relevant EMA/ FDA/ HC staff members to contribute to specific discussions via telephone link.

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2. Participants

From the EMA side, participants will comprise EMA staff members (from the Public and Stakeholders Engagement Department, including those providing the cluster secretariat, and International Affairs),

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and, depending on the topic and issue to be discussed, colleagues from therapeutic teams and EU experts, other committee or working party members, as appropriate.

The FDA will involve colleagues from the Office of the Commissioner including (from the Public Engagement Staff and including those providing the cluster secretariat and the Office of Global Policy and Strategy) and the centres, the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and at times the Center for Devices and Radiological Health (CDRH).

Health Canada will involve participants from centres within the Biologics and Radiopharmaceutical Drugs Directorate (BRDD) including the Office of International Policy and Collaboration providing cluster secretariat, the Pharmaceutical Drugs Directorate (PDD), the Marketed Health Products Directorate (MHPD), and depending on the topic and issue discussed, experts from other Health Canada areas, as appropriate.
The teleconferences will be co-chaired by the EMA and the FDA.

3. Timing

It is anticipated that teleconferences will occur up to 3 times per year, subject to need and predefined in advance, each lasting approximately up to 90 mins.
Ad-hoc teleconferences, on product-related assessments, of a more pressing nature can be held at any time.

4. Working Arrangements

EMA and FDA alternate in having responsibility to prepare the agenda, including mutually agreed topics between all parties for discussion in line with the objectives described under section 1. The topics should be selected on the grounds that they are of mutual interest and are anticipated to be beneficial for both agencies.

A proposed draft agenda will be sent by either the EMA or the FDA about two weeks in advance of a teleconference for verifying topic proposals for mutual agreement. Urgent topics may be added shortly before the teleconference by mutual agreement.

Once the agenda has been agreed upon, the need for additional ad hoc teleconferences may be identified for in-depth discussion of specific issues, and a specific agenda for such ad hoc teleconference will be set.

5. Confidentiality

Confidentiality of the information shared within the cluster is covered under the bilateral information sharing Confidentiality Arrangements (CA) that exist between members and observers. Cluster members and observers are responsible for the implementation and maintenance of these arrangements.

Cluster members, as well as observers and guests, shall not disclose publicly or do anything that would lead to the disclosure of information shared or discussed during meetings without prior authorisation of the members that provide such information.

The chair will inform meeting attendees if there are participants from outside of member or permanent observer organisations.

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6. Reaching Agreement

The cluster will come to final decisions using the process of consensus, defined as general verbal agreement, to the greatest extent possible.

7. Workplan and Reporting

A joint annual/bi-annual workplan outlining the cluster's priorities is generated and routinely supported by meeting minutes, and actions.

A report highlighting the activities of the cluster will be prepared with a specified frequency.

No specific document other than agendas and action points will be generated, but the teleconferences may be supported by already existing EMA, FDA or HC documents.

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