Pharmacovigilance Cluster – Terms of Reference

28 January 2026

The European Medicines Agency (EMA), the US Food and Drug Administration (FDA), Health Canada and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan agree on the following:

1. Goal and Objectives

The international Pharmacovigilance Cluster should fulfil the following objectives:

- Exchanging information on risk assessments and emerging safety concerns, and informing the participants of anticipated regulatory action, including public information and communication, prior to decision-making and publication;
- Exchanging information on policies, guidance documents and regulations;
- Exchanging information on concerns over marketing authorisation holder's pharmacovigilance systems and inspection findings;
- Exchanging views on impacts, priorities and goals for pharmacovigilance activities, especially in areas of emerging science of mutual interest; and
- Identifying specific activities of mutual benefit (e.g. jointly sponsored scientific symposia) to support the improvement of pharmacovigilance activities.

The primary goal of the international Pharmacovigilance Cluster is to support regional risk assessment with a view to enriching the decision-making phase and to facilitate international coordination of regulatory action, including timing of public communication. The main mechanism to achieve this goal will be regularly scheduled teleconferences for exchange of time-sensitive requests. The topics may concern medicinal products within the scope of EMA, FDA, Health Canada and PMDA activities. For the EMA, in the pharmacovigilance area this includes the full range of items covered by the PRAC agenda.

Should the need arise, in-depth discussions on in relation to the above objectives could be organised as separate ad hoc teleconferences. In specific situations, participation of Cluster standing members (''core members'') as observers in discussions of the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) or Committee on Human Medicinal Products (CHMP) on product-related safety concerns could be arranged via telephone link.

To meet the objective of exchanging views on impacts, priorities and goals for pharmacovigilance and identifying specific activities of mutual benefit to improve pharmacovigilance, dedicated teleconferences or in-person meetings separate from the exchanges of time-sensitive information may be organised.

The work of the cluster is conducted within the confidentiality arrangements in place between the participants.

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2. Participants

The standing members of the Cluster (''core members'') are the EMA, the FDA, Health Canada and PMDA. Their participation builds on their long-standing collaboration under confidentiality arrangements.

From the EMA side, participants include EMA staff members, PRAC (vice) chairs and, depending on the topic and issue to be discussed, PRAC (co)rapporteurs.

The FDA participants include colleagues from The Centre for Drug Evaluation and Research (CDER) and The Centre for Biologics Evaluation and Research (CBER).

Health Canada participants include colleagues from the Bureau of Biologics, Radiopharmaceuticals and Self-Care Products and from the Marketed Pharmaceuticals Bureau.

PMDA participants include colleagues from the Office of Pharmacovigilance II.

The teleconferences will be co-chaired by the EMA and the FDA.

Observers from other regulatory authorities may participate in Cluster activities subject to agreement of both the EMA and the US FDA and appropriate confidentiality arrangements being in place.

3. Timing

The Pharmacovigilance Cluster regular teleconferences to discuss time-sensitive information are routinely held on Wednesdays between the monthly (except August) PRAC meetings, usually for up to 2 hours duration.

Separate ad hoc teleconferences, including participation of additional EMA/FDA/PMDA/HC staff members

4. Working arrangements

Cluster Leads - Clusters are primarily run by the subject matter experts within the EMA and the various FDA Centres. They are responsible for scheduling meetings, drafting agendas, following action items, and maintaining membership lists.

For each regular teleconference for the exchange of time-sensitive information, normally up to 6 topics should be selected by mutual agreement of the EMA, FDA, Health Canada and PMDA for discussion in line with the objectives described under section 1. The topics should be selected on the grounds that they are of major relevance to all agencies and that exchange on these topics is anticipated to be beneficial for all agencies.

Topics for discussion in the teleconference will be proposed by either the EMA, FDA, Health Canada or PMDA on the week before a teleconference, followed by the circulation of a proposed draft agenda 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 pharmacovigilance issues, and a specific agenda for such ad hoc teleconference will be set.

The platform for hosting the Pharmacovigilance Cluster is Microsoft Teams.

The EMA, FDA, Health Canada and PMDA will co-develop short action points as the summary record of the teleconference, and these will be recorded in a tracking table.

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

Some topics can also be addressed in writing (e.g. topics not necessitating lengthy discussion, or emerging topics of interest in between Cluster teleconferences).

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 potential observers. Cluster members and potential 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 authorization of the members that provide such information.

The chair will inform meeting attendees if there are participants from outside of member organizations.

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 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 yearly and shared with the participants to the Cluster.