



22 May 2015
Rev 1¹

Guiding principles for the international pharmacovigilance cluster

The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (US FDA) have agreed the following:

1. Objectives and goal

The international pharmacovigilance cluster should fulfill the following objectives:

- Exchanging information on risk assessments (with special focus on emerging safety concerns, including those assessed in EU referral procedures) and informing the participating parties 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 authorization 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, in particular as regards timing of public communication. The main mechanism to achieve this goal will be regularly scheduled teleconferences for exchange of time-sensitive requests.

¹ The revision introduces additional quarterly teleconferences for exchanging views on impacts, priorities and goals for pharmacovigilance and includes identification of specific activities of mutual benefit to support improvements of pharmacovigilance activities as a further objective of the cluster. A number of procedural improvements have been included too. This document will be published jointly by the EMA and US FDA.

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It is recognised that it might be appropriate to agree at the regular teleconferences to arrange for in-depth discussions on specific product-related risk assessments, policies, guidance documents or regulations at separate ad hoc teleconferences. It might also be appropriate to arrange for participation of US FDA staff 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 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, quarterly teleconferences or in-person meetings separate from the exchanges of time-sensitive information will be arranged.

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

2. Participants

The participation builds on the long-standing collaboration between the EMA and the U.S. FDA under their confidentiality arrangements.

From the EMA side, participants will include: EMA staff members (including those providing the cluster secretariat), PRAC (vice) chairs and, depending on the topic and issue to be discussed, PRAC (co)rapporteurs.

The U.S. FDA will involve colleagues from their centres CDER and CBER.

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

The EMA and the US FDA agree that observers from regulatory authorities of other regions may participate in cluster activities subject to agreement of both the EMA and the U.S. FDA and appropriate confidentiality arrangements being in place.

3. Timing

The regular teleconferences to discuss time-sensitive information will be held on Wednesdays between the monthly (except August) PRAC meetings, normally for 90 minutes duration.

Teleconferences between senior members of the pharmacovigilance cluster to discuss views on impacts, priorities and goals for pharmacovigilance will be held quarterly.

Ad-hoc meetings, usually teleconferences, on product-related risk assessments, policies, guidance documents, or regulations can be held at any time.

4. Agenda setting

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 and the U.S. FDA 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 both agencies and that exchange on these topics is anticipated to be beneficial for both agencies.

The topics may concern medicinal products within the scope of EMA and U.S. FDA activities. For the EMA, in the pharmacovigilance area this includes the full range of items covered by the PRAC agenda.

For the purpose of agenda setting and discussion, regional differences in the signal terminology should be understood by all participants.

A proposed draft agenda will be sent by either the EMA or the U.S. 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 pharmacovigilance issues, and a specific agenda for such ad hoc teleconference will be set.

A separate agenda will be set for the quarterly teleconferences on views on impacts, priorities and goals for pharmacovigilance.

5. Records and supporting documents

The EMA and the U.S. FDA 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 U.S. FDA assessment reports.