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

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

1. Objectives and goals

The EMA/ FDA 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 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 share best practices on involving patients along the medicine's regulatory lifecycle within the respective agency's to support each'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 staff members to contribute to specific discussions via telephone link.

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

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2. Participants

From the EMA side, participants will comprise EMA staff members (from the Patients and Healthcare Professionals Department, including those providing the cluster secretariat, and International Affairs), 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 their centres OIP, OHCA (including those providing the cluster secretariat), CDER, CBER.

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

3. Timing

It is anticipated that teleconferences will occur 4 times per year, subject to need and predefined in advance, each lasting approximately 1hr 30 mins.

Ad-hoc teleconferences, on product-related assessments, of a more pressing nature can be held at any time.

4. Agenda setting

The EMA and the FDA will alternate in having responsibility to prepare the agenda, including mutually agreed topics 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. Records and supporting documents

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