Terms of reference for the EMA/HC/FDA cluster on Blood products

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

1. Objectives and goals

The EMA/HC/FDA cluster on Blood products should fulfil the following objectives:

- Achieve a common understanding of each Agency's regulatory approaches to blood product development as based on internal policies, guidance documents and regulations;
- Provide a forum for discussion of candidate blood products including issues such as:
  - regulatory pathways
  - pre-clinical evidence to support development programs
  - clinical trial design including trial end points and statistical analyses
  - clinical safety evaluation
  - labelling aspects
  - post marketing monitoring of blood products safety and effectiveness
  - as needed, issues related to manufacturing process and controls (excluding trade secret information)
- Offer a confidential forum for exchange of draft documents, policies in development, and more detailed information supporting the scientific basis for decision making.
- Address new issues and ensure a global discussion for novel blood products through confidential sharing of reports, with a view of achieving harmonised views across the Atlantic.

The primary goal of this cluster is to share scientific aspects pertaining to development, evaluation and post-marketing that affect products that the Agencies regulate in common for blood products indicated mainly for haematology indications but not exclusively. These aspects include clinical study design, endpoints, dosing, pharmacokinetics aspects and safety considerations. It also covers sharing of evaluation of marketing authorisation applications and discusses safety aspects in the post-marketing phase covering design and conduct of post-marketing studies. Guidelines and general strategic discussions on data requirements are also discussed. These discussions help understanding of the rationale behind respective regulatory approaches and facilitate convergence and harmonisation of regulatory decision.

The main mechanism to achieve these goals will be regularly scheduled teleconferences, including individuals from review divisions and therapeutic teams, for exchange of information and experiences.

It may be appropriate to agree to additional in-depth discussions on specific topics during separate ad hoc teleconferences when it might be relevant to include participation of appropriate EMA/HC/FDA staff members.

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

Cluster participants will discuss and determine which topics will be discussed at this cluster and which will be deferred to other platforms/clusters; e.g. Paediatric, Pharmacovigilance related topics. When topics are deferred to other platforms/clusters, a summary of discussions will be reported back to this cluster.

2. Participants

From the EMA side, participants will include EMA staff members (from the advanced therapies and haemato-oncology Office, who will also be providing the cluster secretariat, Paediatric medicines, Regulatory Affairs, Quality Office, Scientific Advice, pharmacovigilance, and International Affairs), and EU assessors from the Haematology Working Party. Depending on the topic and issue to be discussed, participants will include colleagues from other teams (Specialised Division), Statistics and EU assessors from other committee (e.g. CHMP or PDCO) or working party members (e.g. BWP), as appropriate. In addition, participation is also extended to colleagues working at the European Commission in the substances of human origin field and EDQM colleagues such as from Official Medicines Control Laboratories (OMCL), European Pharmacopeia or transfusions committee. When needed, colleagues from ECDC could also take part in specific topic relevant for the work of the blood cluster.

The FDA will involve colleagues from the Centre for Biologics Evaluation and Research (CBER) including the Office of Therapeutic Products (OTP), the Office of Compliance and Biologics Quality (OCBQ), the Office of Biostatistics and Pharmacovigilance (OBPV), Immediate Office of the Center Director, FDA Europe Office (Office of Global Policy and Strategy (OGPS), the Office of Blood Research and Review, and in some cases, review staff from other Centers in the Agency (e.g. Center for Drugs Evaluation and Research (CDER).

HC will involve colleagues from the Health Products and food Branch, including the Biologics and Radiopharmaceuticals Drugs Directorate and the Marketed Health Products Directorate. As required, colleagues from the Medical Devices Directorate, the Pharmaceutical Drugs Directorate, and/or the Regulatory Operations and Enforcement Branch.

The teleconferences will be chaired by the three Agencies in a rota system with acting chair responsibilities alternating at sequential meetings. High level minutes and action lists will be drafted by the Agency chairing the meeting and will be circulated to the other Agencies for comments within three weeks from the day of the meeting.

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

3. Timing

It is anticipated that teleconferences will occur three times per year, subject to need and predefined in advance, and each meeting to be conducted for up to 2 hours. Ad-hoc teleconferences, on product-related assessments or any other emerging concerns, of a more pressing nature can be held at any mutually agreeable time. As appropriate, some discussions will be moved to other clusters to expedite review.

4. Working Arrangements

The EMA, HC and the FDA will alternate the responsibility to prepare teleconference agendas, including mutually agreed topics for discussion in alignment with the objectives described under section 1. The topics should be selected on the grounds that they are of shared interest and are anticipated to be beneficial for all three agencies. Liaisons will play an administrative role in assigning topics to avoid duplication of efforts.

A proposed draft agenda conforming to the template will be sent by the organising Agency about one week in advance of a teleconference; however, proposals should be circulated via email at least 3 weeks in advance to verify topic 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 teleconferences will be set. Attendees for these ad hoc meetings will be limited to those actively working on the topic, subject matter experts and core Cluster members as needed.

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 authorization of the members that provide such information.

The chair will inform meeting attendees if there are participants from outside of member or permanent observer 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 stating the priorities of the cluster is generated on a specific frequency. A working group outcome report is encouraged.

No specific document other than agendas, high level summary of the discussion per topic and agreed upon action points will be routinely generated, although cluster member may decide to create documents that may be shared, as appropriate, with other clusters. The teleconferences may be supported by already existing EMA, HC or FDA documents.