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European Medicines Agency

Terms of reference for Biosimilars cluster

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

1. Objectives and goals

The EMA/FDA/HC/PMDA/Swissmedic cluster on Biosimilar products should fulfil the following objectives:

- Achieve a common understanding of each Agency's regulatory approaches to biosimilar product development as based on internal policies, guidance documents and regulations;
- Provide a forum for discussion of candidate biosimilar products including:
  - regulatory pathways
  - quality and clinical evidence to support development programs
  - PK,PD and immunogenicity evaluations
  - clinical efficacy/safety evaluation
  - quality evaluation (analytical and functional comparability)
  - product naming and other labelling aspects
  - post marketing monitoring of biosimilar products safety and effectiveness
  - as needed, issues related to manufacturing process and controls (excluding trade secret information)
- Offer a forum for confidential exchange of draft documents, policies in development, and more detailed information supporting the scientific basis for decision making.
- Address emerging issues and facilitate global convergence for biosimilar products through confidential sharing of reports/documents, with a view to achieve harmonised outcomes.

The cluster provides a forum for discussion on multidisciplinary aspects pertaining to development, evaluation and post-marketing of biosimilar products. These aspects include quality, efficacy and safety of biosimilar medicinal products, such as analytical and functional comparability, clinical study design, pharmacokinetics aspects and safety considerations. Participating Agencies can share marketing authorisation applications and related assessment reports for the initial and the post-marketing phase. Guidelines and other regulatory science topics are also discussed.

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The cluster will hold regular teleconferences, between members from relevant review teams.

Additional in-depth discussions on specific topics can be organised where relevant.

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

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

2. Membership

EMA participants will include staff members (mainly from Pharmaceutical Quality Office, Clinical Therapeutic Areas Offices, Scientific Advice), and EU assessors / members of the Biosimilar Medicinal Products Working Party (BMWP). In addition, depending on the topic and issue to be discussed, participants will include colleagues from other teams (Specialised Office e.g. Regulatory Affairs or International Affairs) and EU assessors from other committees (e.g. CHMP) or working parties (e.g. BWP, SAWP or MWP), as appropriate.

The FDA will involve colleagues from the Center for Drug Evaluation and Research (CDER), including the Office of Therapeutic Biologics and Biosimilars, the Office of Product Quality, the Office of New Drugs, the Office of Clinical Pharmacology and from other offices as needed for the topics being discussed.

HC will involve colleagues from the Health Products and Food Branch, including the Biologic and Radiopharmaceutical Drugs Directorate (BRDD), Marketed Health Products Directorate (MHPD), and include other biosimilars subject matter experts as appropriate.

PMDA will involve colleagues from the Office of Cellular and Tissue-based Products and other offices as appropriate.

Swissmedic will involve colleagues from the sector Medicinal products authorisation and vigilance and from the division Stakeholder Engagement, as appropriate.

3. Timing

It is anticipated that teleconferences will occur two 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 cluster secretariat is provided by the BMWP secretariat which resides in the Quality Domain.

The teleconferences will be chaired by the 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 in good time, e.g. within three weeks from the day of the meeting.

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

A draft agenda will be circulated one week in advance of a teleconference based on proposals, that should be shared at least 3 weeks in advance to allow identification of topic for mutual agreement. Urgent topics may be added shortly before the teleconference by mutual agreement. Agendas, high level summaries of the discussion per topic and action points agreed upon will be routinely generated as records. Subject to appropriate confidentiality agreements, cluster members may decide to share records with other clusters, as appropriate. Additionally, additional existing EMA, FDA, HC, PMDA and Swissmedic documents may be shared. The need for additional ad hoc teleconferences may be identified for in-depth discussion of specific issues. Attendees for such ad hoc teleconferences 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

In cases of conflicting feedback, 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 will be drawn up with a specific frequency (e.g. every 2 years).

A report highlighting the activities of the cluster will be drawn up with a specific frequency (yearly).