Terms of reference for the ATMP Cluster

23 April 2026

Participants: European Medicines Agency (EMA), Health Canada (HC) and the US Food and Drug Administration (FDA), Japan Pharmaceutical and Medical Device Agency (PMDA), Swissmedic (SM) agree on the following:

1. Objectives and goals

The ATMP Cluster should fulfil the following objectives:

- Achieve a common understanding of each Agency's regulatory approaches for ATMP development as based on internal policies, guidance documents and regulations.
- Offer a confidential forum for exchange of draft documents, policies in development, and more detailed information supporting the scientific basis for decision making.
- Provide a forum for discussion of candidate ATMPs including issues such as:
  - regulatory pathways
  - product manufacturing (excluding trade secret information)
  - clinical trial design, including trial endpoints
  - clinical safety evaluation
  - labelling aspects
  - post marketing monitoring of ATMPs for safety and effectiveness

The primary goal of this cluster is to share scientific aspects pertaining to development, evaluation, and post-marketing of ATMPs. ATMPs include cell therapy, gene therapy, tissue engineered products, and xenotransplantation products. Data provided to regulators by manufacturers often differs. This forum provides an opportunity for information sharing that affects regulatory decision making. Novel regulatory approaches for ATMPs, guidance and guidelines and general strategic discussions help facilitate convergence and harmonisation of regulatory decisions.

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.

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

The ATMP Cluster is a product-specific cluster that may have overlapping discussions with other clusters such as the Oncology Cluster, Rare Disease Cluster, and Paediatric Cluster. Agency leads will discuss appropriate clusters. At times, other cluster participants may be invited to the ATMP Cluster for information sharing purposes.

2. Participants

From the EMA side, participants will include EMA staff members and members from the Committee for Advanced Therapies (CAT), Committee for Human Medicinal Products (CHMP), Biologics Working Party (BWP) and other specialized teams as appropriate.

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, Office of Biostatistics and Epidemiology, Immediate Office of the Center Director, Office of International Programs.

HC will involve colleagues from the Health Products and Food Branch, including the Biologic and Radiopharmaceutical Drugs Directorate and the Marketed Health Products Directorate and from the Regulatory Operations and Enforcement Branch.

PMDA will involve colleagues from the Office of Cellular and Tissue-based Products, with additional ad hoc participants from the Center for Pediatric Drugs, Office of Pharmacovigilance, Office of International Programs.

Swissmedic will involve colleagues from the Division Advanced Therapy Products with ad hoc participants from the Divisions Marketing Authorisation, Clinical Trial and Stakeholder engagement.

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

3. Timing

It is anticipated that teleconferences will occur bimonthly, subject to need and predefined in advance, and each meeting to be conducted for up to 1 hour.

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.

4. Working Arrangements

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 topics 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 annual/bi-annual workplan outlining the cluster's priorities is generated and routinely supported by agendas, high level summary of the discussion per topic and agreed upon action points. Cluster members 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, PMDA or SM documents.