February 2026

Veterinary Medicinal Products Cluster - Terms of reference

The European Medicines Agency (EMA)[1] and the US Food and Drug Administration (FDA) agree on the following:

1. Objectives and goals

The veterinary medicines EMA-FDA bilateral meetings should fulfil the following objectives:

- Achieve a common understanding of each Agency's approaches and provide a forum for discussion on assessment of veterinary medicinal products in general and specifically those under assessment in either one or the other organisation;
- Offer a confidential forum for exchange of draft documents, policies in development, and more detailed information supporting the scientific basis for decision making;
- Be a collaborative platform for exchange of information on veterinary medicines topics;
- Promote the parallel scientific advice procedure;
- Enhance international cooperation on Antimicrobial Resistance (AMR) () and International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) activities;
- Coordinate the established clusters on pharmacovigilance and on novel therapies;
- Foster cooperation on GMP inspections for veterinary medicines (except vaccines).

The primary goal of the bilateral meetings is to facilitate the exchange of information related to veterinary medicinal products and to achieve greater international cooperation.

2. Participants

From the EMA side, participants will include a representation of the management team of the Veterinary Medicines Division, Heads of Services of the Veterinary Medicines Division and *ad hoc* subject matters' experts depending on the products/issues discussed at the meeting.

FDA participants will include representatives from the Center for Veterinary Medicine (CVM), including the Office of the Director, the Office of New Animal Product Evaluation, the Office of Surveillance and Compliance, Office of Minor Use and Minor Species Animal Drug Development, and the Office of Applied

[1] Participating in line with Art. 52 of Commission Regulation 726/2004 as amended

Science. Ad hoc subject matter experts may also participate, depending on the proposed discussion topics. The virtual meetings will be chaired by EMA and FDA alternately.

3. Timing

The meetings are held quarterly; dates are agreed at the last meeting of each year for the next year.

The videoconferences are scheduled for 1 hour, depending on the amount of topics identified in the agenda and their complexity.

4. Working arrangements

EMA will prepare the agendas by collecting topics and will circulate it a few days before the meeting. Topics should conform to the high level objectives detailed in section 1.

High level minutes will be recorded on the same agenda document by FDA and agreed at the following meeting.

The need for additional *ad hoc* meetings may be identified for in-depth discussion of specific issues; a specific agenda for such *ad hoc* meetings 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. Reporting

The cluster's priorities as well as any projects, ongoing and upcoming, are incorporated into meeting agendas and progress routinely supported by meeting minutes, and actions.

There are generally no supporting documents for these meetings. However, there is often an exchange of specific documents as follow up to the meetings.