March 2026

Veterinary Pharmacovigilance Cluster - Terms of Reference

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

1. Objectives and goals

The EMA/FDA/HC Veterinary Pharmacovigilance cluster has the following objectives:

- Achieve a common understanding of each Agency's approaches to pharmacovigilance surveillance and communication of safety issues;
- Provide a forum for discussion of adverse events collection and analysis systems;
- Offer a confidential forum for exchange of issue related to benefit-risk and safety of specific products.

The primary goals of the pharmacovigilance cluster are to foster the exchange of information related to topical pharmacovigilance issues as well as methodologies used in pharmacovigilance surveillance, which enable development of expertise. The confidential discussions may strengthen the surveillance procedures and may lead to earlier recognition of issues with the potential for informally coordinated actions when required.

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

2. Participants

From the EMA side, participants will be from the Pharmacovigilance Office within the Veterinary Surveillance and Regulatory Support Department.

The FDA participants will be from the Division of Pharmacovigilance and Surveillance within the FDA Center for Veterinary Medicine's Office of Surveillance and Compliance.

The HC participants are part of the pharmacovigilance team of the Veterinary Drugs Directorate (VDD).

The teleconferences will be chaired by the FDA.

EMA, FDA and HC agree that participants from other regulatory authorities (e.g. Center for Veterinary Biologics (CVB) or Canadian Centre for Veterinary Biologics (CCVB)) may participate in the trilateral

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

meetings subject to agreement and to appropriate confidentiality arrangements being in place. On an *ad-hoc* basis experts from the corresponding agencies responsible for immunological products may also be invited to attend these meetings, following a confidentiality undertaking for each participation.

3. Timing

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

The teleconferences are scheduled for 1-2 hours, depending on the amount of topics identified in the agenda and their complexity.

4. Working Arrangements

EMA will prepare the agendas by collecting topics from the other agencies and will circulate it several days ahead of 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 HC and reviewed at the next available meeting.

The need for additional *ad hoc* teleconferences may be identified for in-depth discussion of specific issues; 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 Cluster members are responsible for the implementation and maintenance of these arrangements.

Cluster members, as well as additional experts, 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 additional participants

6. Reporting

This cluster does not operate under a formal workplan or reporting framework; its activities are documented solely through regular meeting minutes and the actions resulting from information exchange.

No mandatory supporting documents are required for these meetings; however, additional materials may be shared as needed.