Antivirals Cluster – Terms of Reference

25 November 2025

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

1. Goal and Objectives

The joint EMA-FDA antiviral cluster collaboration aims to promote a harmonized global regulatory framework, to the extent possible, for antiviral drug development.

The EMA-FDA antiviral cluster's key objectives include fostering mutual understanding of each agency's regulatory practices, providing a platform for discussing specific drug candidates and scientific advice, and enabling confidential exchange of scientific rationale to support regulatory decisions.

The specific objectives of the antivirals cluster are:

- Exchange information and discuss topics related to antiviral product development for treatment or prevention of illness caused by viral infections such as HIV, respiratory viruses, viral hepatitis, herpes viruses and emerging viral infections, including medical countermeasures.
- Discuss each agency's scientific advice for investigational antiviral drug development programs and authorized/approved products
- Share information on post-marketing safety or efficacy concerns
- Share scientific rationale to support regulatory decisions

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

- EMA's participation in this cluster includes EMA staff members from, but not limited to, the Vaccines and Therapies for infectious diseases office, International Affairs, ETF or Committee or Working Party members and other EU experts as relevant.
- FDA's participation in this cluster includes FDA staff from, but not limited to, the Office of Infectious Disease/Division of Antivirals and other FDA experts as relevant.

EMA and FDA agree that guests (e.g. observers from other regulatory authorities or organisations) may participate in cluster activities, subject to the prior agreement of all four parties. The scope of topics discussed in the presence of guests will be determined based on the existence of appropriate confidentiality arrangements.

3. Timing

The Antivirals Cluster meetings are expected to be conducted remotely (1hour teleconferences) and will be chaired by the agencies in a rotational system.

The meetings occur with a frequency of approximately one meeting every quarter of the year.

EMA and FDA may agree to schedule additional discussions on specific topics through ad hoc meetings, which can be set up including participation of additional EMA/FDA staff members or experts as needed.

4. Working Arrangements

EMA and FDA collaborate equally to prepare cluster meeting's agenda and meeting notes for each meeting, including mutually agreed topics for discussion in alignment with the objectives of the cluster and actions.

A proposed draft agenda conforming to the template will be sent by the organising Agency about one week in advance of a teleconference. 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.

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 membership.

6. Meeting Outcomes

At the conclusion of each antiviral cluster meeting, FDA and EMA will verbally summarize each respective position on each topic discussed to the extent possible.

7. Workplan and Reporting

A joint annual/bi-annual workplan outlining the cluster's priorities is generated and routinely supported by meeting minutes, and actions.
A report highlighting the activities of the cluster will be prepared with a specified frequency.