12 December 2025
EMA/CVMP/IWP/298213/2025
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Immunologicals Working Party (IWP) 2026

Chairperson	Status
Chair: E. Werner	Adopted by CVMP in December 2025

The activities outlined in the work plan for 2026 have been agreed considering the respective business priorities and may be subject to further review and reprioritisation in accordance with the business plan of the Agency.

1. Meetings scheduled for 2026

Plenary meetings:

2* (per meeting: Chair plus 12 members)

21-22 April 2026 (1.5 days) – face-to-face

20-21 October 2026 (1.5 days) – virtual meeting

*An *ad hoc* plenary meeting (1.5 days) may be organised, if needed.

Other meetings:

Drafting / Expert groups: 6-8 (approximately 6 participants)

Workshop / Focus group: None

Training

- Data requirements and certification process for vaccine platform technologies master files; data requirements and assessment approach to applications for marketing authorisations for IVMPs in exceptional circumstances (22-23 April 2026)

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000
An agency of the European Union

© European Medicines Agency, 2025. Reproduction is authorised provided the source is acknowledged.

Drafting / Expert group meetings are mainly regarded as complementary to plenary meetings.

2. Product related issues

The following table provides the expected number per year of contributions (number of involvements in dossier) for scientific advice and product assessment, including pre- and post-authorisation issues.

Expected contribution in Scientific Advice	Expected contribution in Product Assessment
2	2

3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

3.1.1 Guideline on risk management requirements for elemental impurities in veterinary medicinal products

Action: Finalisation of draft guideline following public consultation.

Priority 2. Start date: Ongoing, Completion date: 2026

Comments: Responsible groups: QWP (lead), IWP, NTWP. Conversion of the Reflection paper on risk management requirements for elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/153641/2018) into a guideline covering also IVMPs and novel therapies. IWP to contribute to the drafting of the guideline.

3.2. Guidance documents to be released for consultation

3.2.1 Guideline on the requirements for combined vaccines and associations of immunological veterinary medicinal products (IVMPs)

Action: Draft revised guideline to be released for public consultation.

Priority 2. Start date: Ongoing, Completion date: Q1 2026

Comments: Responsible group: IWP. Concept paper published in December 2024.

3.2.2 Guideline on quality aspects of mRNA vaccines for veterinary use

Action: Draft new guideline to be developed and released for public consultation.

Priority 2. Start date: ongoing, Completion date: Q1 2026

Comments: Responsible group: IWP (lead), NTWP. Concept paper published in January 2025.

3.2.3 Guideline on consumer safety of active substances of IVMPs acting against endogenous targets

Action: Draft guideline to be prepared for public consultation.
Priority 2. Start date: ongoing, Completion date: 2026.

Comments: Responsible groups: SWP-V (lead), IWP, NTWP.

3.2.4 Guideline on the safety of nanoparticles

Action: Draft guideline to be discussed/adopted at CVMP for release for public consultation (Q4 2025)

Priority 1. Start date: March 2023, Completion date: Q3 2026.

Comments: Responsible groups: NTWP (lead), SWP-V, IWP, QWP, ERAWP.

3.3. New topics/concept papers to be prepared/other

3.3.1 Concept paper for the Revision of Guideline on data requirements for authorisation of IVMPs under exceptional circumstances (EMA/CVMP/IWP/251947/2021)

Action Develop a concept paper for the revision of the guideline. Revise the guideline accordingly. **Priority 2.** Start date: Q4 2025, Completion date: Q1 2026 (release of concept paper for consultation); Q4 2026 (release of the revised guideline for public consultation)

Comments Responsible group: IWP.

3.3.2 Concept paper for the Revision of Guideline on data requirements for the replacement of established master seeds already used in authorised IVMPs by new master seeds of the same origin (EMEA/CVMP/IWP/105504/2007), and merge with the Reflection paper on the replacement of cell lines used for the production of IVMPs (EMA/CVMP/IWP/37620/2014)

Action Develop a concept paper for the revision of the guideline. Revise the guideline accordingly. **Priority 2.** Start date: Q4 2025, Completion date: Q1 2026 (release of concept paper for consultation); Q4 2026 (release of the revised guideline for public consultation)

Comments Responsible group: IWP.

4. VICH guidelines and activities

4.1. Proposal for advancing the work on extraneous viruses in veterinary vaccines - Development of a guideline listing methods found suitable in different regions

Action	Contribution to EU position (development of guideline). **Priority 1.** Start date: ongoing, Completion date: to be defined.
Comments	Current status: Step 2 of VICH process.

4.2. Development of a guideline on principles for technical guidance for the transition to in vitro methods for batch potency tests in veterinary immunologicals

Action	Contribution to EU position (development of a concept paper). **Priority 1.** Start date: ongoing, Completion date: To be defined.
Comments	Current status: Step 2 of VICH process.

4.3. Proposal for revision of VICH GL34 (Biologicals: testing for the detection of Mycoplasma contamination) following revision of Ph. Eur. 2.6.7 Mycoplasmas

Action	Contribution to EU position (revision of the guideline). **Priority 1.** Start date: ongoing, Completion date: To be defined.
Comments	Concept paper endorsed at the March 2025 CVMP meeting. EU to take the lead if activity agreed by VICH steering committee.

5. EU regulatory activities

5.1. Review of existing IWP guidance

Action:	Review existing (old) IWP guidance for relevance and alignment to Regulation (EU) 2019/6; initiate revision if necessary, according to priority.
Comments:	None.

5.2. Collaboration with EFSA

Action:	Provide contribution to EFSA opinions in accordance with Article 59 of Regulation (EC) No 726/2004 as amended, as required.
Comments:	None.

5.3. Collaboration with EDQM

Action: Continue the collaboration with EDQM on guidance regarding the implementation of veterinary vaccine monographs and chapters.

Comments: None.

5.4. Assessor training

Action: Provide advice / active participation for training of assessors, as required. Training topics for 2026 are indicated in section 1 of this document.

Comments: IWP to reflect on needs for training for 2027 and consider the immunologicals curriculum.

5.5. Other

Action: Provide contributions to guidelines and questions raised by other working parties and *ad hoc* expert groups, as required.

Comments: None.

6. Activities with external parties

6.1. Meeting with interested parties

One meeting (Q4 2026).

6.2. Regulatory authorities outside the EU

As required.

7. Organisational matters

7.1. List of adopted organisational documents

Mandate, objectives and rules of procedure for working parties under the quality, non-clinical, methodology, clinical and veterinary domains (EMA/299541/2025).

7.2. List of organisational documents to be developed/revised in the forthcoming 2 years

None foreseen.

*7.3. List of proposed scientific guidelines for the next work plan**

*The actual items to be included in the IWP work plan for 2027 will be considered and agreed by the CVMP.