13 December 2024
EMA/CVMP/IWP/466054/2024
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Immunologicals Working Party (IWP) 2025

Chairperson	Status
Chair: E. Werner	Adopted by CVMP in December 2024

The activities outlined in the work plan for 2025 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 2025

Plenary meetings:

2* (per meeting: Chair plus 12 members)

19-20 March 2025 (1.5 days) – face-to-face

21-22 October 2025 (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	- Procedural and technical guidance on requirements for vaccine platform technologies master files

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

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 after public consultation.

Priority 2. Start date: Ongoing, Completion date: Q2 2025

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: Q4 2025

Comments: Responsible group: IWP.

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: Q4 2025

Comments: Responsible group: IWP (lead), NTWP.

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

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

Action: Concept paper to be prepared for public consultation.
Priority 2. Start date: ongoing, Completion date: Q1 2025.

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

3.3.2 Guideline on the safety of nanoparticles

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

Priority 1. Start date: ongoing, Completion date: Q1 2026.

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

3.3.3 Provide guidance on what is considered a new indication within the context of Article 38(3) of Regulation (EU) 2019/6

Action: Concept paper to be prepared for public consultation.
Priority 2. Start date: ongoing, Completion date: Q1 2025.

Comments: Responsible groups: EWP-V (lead), 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 October 2023 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. Queries raised by CMDv

Action:	Provide response to queries raised by CMDv via CVMP, as required.
Comments:	None.

5.3. 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.

5.4. Collaboration with EDQM

Action:	Continue the collaboration with EDQM on guidance regarding the implementation of veterinary vaccine monographs and chapters.
Comments:	None.

5.5. Assessor training

Action:	Provide advice / active participation for training of assessors, as required. Training topics for 2025 are indicated in section 1 of this document.
Comments:	IWP to reflect on needs for training for 2025 and consider the immunologicals curriculum.

5.6. 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 2025).

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 the CVMP Immunologicals Working Party (EMEA/CVMP/IWP/208689/2004-Rev.5).

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**

7.3.1. Guidance documents to be finalised after the consultation period

- Revised guideline on the requirements for combined vaccines and associations of immunological veterinary medicinal products
- Guideline on quality aspects of mRNA vaccines for veterinary use

*The actual items to be included in the IWP work plan for 2026 will be considered and agreed by the CVMP.