26 January 2024
EMA/CVMP/IWP/444036/2023
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Immunologicals Working Party (IWP) 2024

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

The activities outlined in the work plan for 2024 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 2024

Plenary meetings:

2* (per meeting: Chair plus 12 members)

24-25 April 2024 (1.5 days) – face-to-face

22-23 October 2024 (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	– Guideline on data requirements for vaccine platform technology master files – Guideline on plasmid DNA vaccines for veterinary use

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– Guideline on quality data requirements for applications for biological VMPs intended for limited market products not deemed eligible for authorisation under Article 23

– Guideline on safety and efficacy data requirements for applications for IVMPs intended for limited market products not deemed eligible for authorisation under Article 23

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 quality data requirements for applications for biological VMPs intended for limited market products not deemed eligible for authorisation under Article 23 (EMA/CVMP/IWP/228730/2022)

Action: Finalise guideline following public consultation (ending on 31 January 2024).

Priority 1. Start date: Ongoing; Completion date: Q2 2024.

Comments: None.

3.1.2 Guideline on safety and efficacy data requirements for applications for immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6 (EMA/CVMP/IWP/224724/2022)

Action: Finalise guideline following public consultation guideline (ending on 31 January 2024).

Priority 1. Start date: Ongoing; Completion date: Q2 2024.

Comments: None.

3.1.3 Guideline on plasmid DNA vaccines for veterinary use (EMA/CVMP/IWP/365817/2022)

Action: Finalise guideline after public consultation.

Priority 2. Start date: Ongoing, Completion date: Q1 2024.

Comments: None.

3.2. Guidance documents to be released for consultation

3.2.1 Guideline on live recombinant vector vaccines for veterinary use (EMEA/CVMP/004/04-FINAL)

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

Priority 2. Start date: Ongoing, Completion date (release of draft guideline for public consultation): Q1 2024; expected finalisation of guideline: Q4 2024.

Comments: Comments received during the public consultation of the concept to be considered

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

Action: Release of draft guideline for public consultation.

Priority 2. Start date: Ongoing, Completion date: Release of the draft guideline for public consultation by Q4 2023.

Comments: Activity led by QWP. 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. IWP to contribute to the drafting of the guideline.

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

3.3.1 Guideline on the requirements for combined vaccines and associations of immunological veterinary medicinal products (IVMPs) EMA/CVMP/IWP/594618/2010

Action: Prepare concept paper for the revision of the guideline.

Priority 2. Start date: Q2 2024, Completion date (release of concept paper for public consultation): Q4 2024

Comments: None.

3.3.2 Development of a new guideline on quality aspects of mRNA vaccines for veterinary use

Action: Prepare concept paper for the development of the new guideline.

Priority 2. Start date: Q2 2024, Completion date (release of concept paper for public consultation): Q4 2024

Comments: None.

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 CVMP accepted the revised concept paper at the September 2019 meeting. The concept paper was subsequently adopted by VICH Steering Committee in November 2019. First draft from the topic leader (USDA) received in September 2023.

4.2. 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/revise existing (old) IWP guidance for relevance and alignment to Regulation (EU) 2019/6.

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.

Comments: In particular in key areas such as requirements for non-conventional veterinary vaccines.

5.5. Assessor training

Action: Provide advice / active participation for training of assessors, as required. Training topics for 2024 are indicated in section 1 of this document.

Comments: IWP to reflect on needs for training for 2024 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 2024).

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**

*The actual items to be included in the IWP work plan for 2025 will be considered and agreed by the CVMP.