



26 January 2024
EMA/CVMP/EWP/431047/2023
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Efficacy Working Party (EWP-V) 2024

Chairperson	Status
Chair: C. Muñoz Madero	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:	3 (per meeting: Chair plus 11 members) 20-21 February 2024 (1.5 days) – virtual meeting 28-29 May 2024 (1.5 days) – virtual meeting 15-16 October 2024 (1.5 days) – physical meeting
Other meetings:	
Drafting / Expert groups	8-10 meetings (virtual; approximately 10 participants)
Workshop / Focus group	None
Trainings	- Guideline on efficacy and TAS data requirements for applications for VMPs for limited markets eligible for Art. 23 - Guideline for the demonstration of efficacy for VMPs containing anticoccidial substances

If feasible and depending on the circumstances, some of the plenary meetings could be replaced by virtual meetings. 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 data requirements for veterinary medicinal products for zootechnical purposes (EMA/CVMP/EWP/37280/2023)**

Action: Revision of the guideline to be finalised following public consultation.
Priority 2. Start date: ongoing, Completion date: Q4 2024.

Comments: Responsible group: EWP-V. Draft revised guideline published for consultation in January 2024.

3.1.2. **Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6**

Action: Guideline to be finalised following public consultation.
Priority 1. Start date: ongoing, Completion date: Q2 2024.

Comments: Responsible group: EWP-V. Draft guideline published for consultation in July 2023.

3.1.3. **Guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances (EMA/CVMP/EWP/755916/2016)**

Action: Guideline to be finalised following public consultation.
Priority 2. Start date: ongoing, Completion date: Q2 2024.

Comments: Responsible group: EWP-V. Public consultation on the draft guideline ended on 31 August 2019; comments received from 6 stakeholders.

3.2. *Guidance documents to be released for consultation*

3.2.1. **Guideline for the evaluation of efficacy of ectoparasiticides - general requirements**

Action: Current guideline on demonstration of efficacy of ectoparasiticides (7AE17A) to be revised.
Priority 2. Start date: January 2024, Completion date: Q4 2024.

Comments: Responsible group: EWP-V. Concept paper published in July 2023.

3.2.2. Guideline on data requirements for post-authorisation studies for antimicrobial veterinary medicinal products under Article 36(2) of Regulation (EU) 2019/6

Action: New guideline to be developed.
Priority 2. Start date: Q1 2023, Completion date: beyond 2024.

Comments: Responsible groups: AWP, EWP-V. Concept paper published in September 2022.

3.3. New topics/concept papers to be prepared

3.3.1. Revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/2000-Rev.4)

Action: Concept paper to be developed.
Priority 1. Start date: Q1 2024, Completion date: Q2 2025.

Comments: Responsible groups: EWP-V, QWP.

3.3.2. Revision of the guideline on veterinary medicinal products controlling *Varroa destructor* parasitosis in bees (EMA/CVMP/EWP/459883/2008-Rev.1)

Action: Concept paper to be developed.
Priority 2. Start date: Q1 2024, Completion date: Q4 2024.

Comments: Responsible group: EWP-V.

3.3.3. Revision of the guideline on dossier requirements for anticancer medicinal products for dogs and cats (EMA/CVMP/28510/2008-Rev.1)

Action: Concept paper to be developed.
Priority 3. Start date: Q2 2024, Completion date: Q4 2024.

Comments: Responsible group: EWP-V.

3.3.4. Develop an infographic on lack of expected efficacy for antiparasitic veterinary medicinal products

Action: Infographic to be developed.
Priority 2. Start date: Q1 2024, Completion date: Q4 2024.

Comments: Responsible groups: EWP-V, PhVWP-V.

4. VICH guidelines and activities

4.1. Revision of VICH guidelines on efficacy of anthelmintics

Action: Contribute to EU position (revision of guidelines).
Priority 1. Start date: ongoing, Completion date: Q4 2024.

Comments: Guidelines under revision: General requirements (VICH GL7) and species-specific recommendations (VICH GLs 12-16, 19-21).
Current status of guidelines: Step 9/5 of VICH process.

4.2. VICH guideline on fixed combination products (pharmaceuticals)

Action: Contribute to EU position.
Priority 1. Start date: ongoing, Completion date: beyond 2024.

Comments: VICH to elaborate a new GL on fixed combination products (pharmaceuticals).

4.3. VICH guideline on between strength biowaivers

Action: Contribute to EU position.
Priority 1. Start date: ongoing, Completion date: beyond 2024.

Comments: VICH to elaborate a new GL on between strength biowaivers.

5. EU regulatory activities

5.1. Art. 4 of Regulation (EU) 2019/6 - Definitions

Action: Review and revise existing guidelines in line with the definitions in Regulation (EU) 2019/6 for antimicrobial resistance, antimicrobial, antibiotic, metaphylaxis and prophylaxis.
Priority 2. Start date: January 2022, Completion date: Q2 2024.

Comments: Responsible groups: EWP-V, AWP. Affected guidelines: 1) Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/627/2001-Rev.1); 2) Guideline on the conduct of efficacy studies for intramammary products for use in cattle (EMA/CVMP/344/1999-Rev.2).

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 Art. 59 of Regulation (EC) No 726/2004 as amended, as required.

Comments: None.

5.4. Assessor training

Action: Provide advice / active participation for training of assessors, as required. Training topics for 2024 are indicated under section 1 of this document.
Contribute to the evaluation of veterinary training curriculum.

Comments: EWP-V to reflect on needs for training for 2025 and consider the efficacy 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. Meetings with interested parties

None foreseen.

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 Efficacy Working Party (EWP-V) (EMA/CVMP/EWP/208686/2004-Rev.5) – last updated in 2020.

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

- Guideline for the evaluation of efficacy of ectoparasiticides - general requirements
- Guideline on data requirements for post-authorisation studies for antimicrobial veterinary medicinal products under Article 36(2) of Regulation (EU) 2019/6

7.3.2. Guidance documents to be released for consultation

- Revised guideline on the conduct of bioequivalence studies for veterinary medicinal products
- Revised guideline on VMPs controlling *Varroa destructor* parasitosis in bees
- Revised guideline on dossier requirements for anticancer medicinal products for dogs and cats

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