16 December 2022
EMA/CVMP/EWP/817611/2022
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Efficacy Working Party (EWP-V) 2023

Chairperson	**Status**
Chair: C. Muñoz Madero	Adopted by CVMP in December 2022

The activities outlined in the work plan for 2023 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 2023

Plenary meetings:	3 (per meeting: Chair plus 12 members) 7-8 February 2023 (1.5 days) – virtual meeting 23-24 May 2023 (1.5 days) – virtual meeting 10-11 October 2023 (1.5 days) – physical meeting
Other meetings:	
Drafting / Expert groups	8-10 meetings (virtual; approximately 10 participants)
Workshop / Focus group	None
Trainings	- Guideline on data requirements for VMPs intended to reduce the risk of transmission of vector-borne pathogens in dogs and cats - Guideline on efficacy and TAS data requirements for applications for VMPs for limited markets eligible for Art. 23 - Bioequivalence - CVMP and VICH bioequivalence guidelines[1]

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.

[1] joint activity EWP-V & QWP

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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 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: January 2023, Completion date: Q4 2023.

Comments: Public consultation on the draft guideline ended on 31 August 2019; comments received from 6 stakeholders.

3.1.2. Guideline on conduct of pharmacokinetic studies in target animal species (EMEA/CVMP/EWP/133/1999-Rev.1)

Action: Guideline to be finalised following public consultation.
Priority 2. Start date: January 2023, Completion date: Q4 2023.

Comments: Public consultation on the draft guideline ended on 31 May 2018; comments received from 3 stakeholders.

3.2. Guidance documents to be released for consultation

3.2.1. Guideline on data requirements for veterinary medicinal products used for non-pathologic indications related to the reproductive system[2]

Action: Guideline to be developed.
Priority 2. Start date: January 2023, Completion date: Q2 2024.

Comments: Responsible group: EWP-V. Initial concept paper published in December 2016; revised concept paper published in July 2022.

3.2.2. Guideline on potential claims for products that can contribute to the reduction of the need for antimicrobials

Action: New guideline to be developed.
Priority 2. Start date: January 2023, Completion date: Q2 2024.

[2] Will replace the Guideline on veterinary medicinal products for zootechnical purposes (7AE7a).

Comments: Responsible group: EWP-V. Concept paper to be published in January 2023. Other working parties may also be involved, as needed.

3.2.3. Guideline on the flexibility of 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: New guideline to be developed.
Priority 1. Start date: ongoing, Completion date: to be determined.
Comments: Responsible group: EWP-V. Concept paper published in October 2021.

3.2.4. 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: Q2 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 demonstration of efficacy of ectoparasiticides (7AE17A)

Action: Concept paper to be developed.
Priority 2. Start date: January 2023, Completion date: July 2023.
Comments: Responsible group: EWP-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: 2023.
Comments: Guidelines under revision: General requirements (VICH GL7) and species-specific recommendations (VICH GLs 12-16, 19-21).
Current status of guideline: 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 2023.
Comments: VICH to elaborate a new GL on fixed combination products (pharmaceuticals).

4.3. VICH guideline on in vitro dissolution

Action: Contribute to EU position.
Priority 1. Start date: ongoing, Completion date: beyond 2023.

Comments: VICH to elaborate a new GL on *in vitro* dissolution.

5. EU regulatory activities

5.1. Art. 107(3) of Regulation (EU) 2019/6 - Use of antimicrobial VMPs for prophylaxis

Action: Elaborate guidance or criteria for determining 'exceptional cases' when antimicrobial administration for prophylaxis would be accepted.
Priority 1. Start date: ongoing, Completion date: to be determined.

Comments: A reflection paper on prophylactic use of antimicrobials is under development. Responsible groups: AWP, EWP-V.

Action: Contribute to the review of indications for existing centrally authorised products containing antimicrobial substances and determine the approach to ensuring that they are aligned with the guidance for determining 'exceptional cases' when antimicrobial administration for prophylaxis would be accepted.
Priority 1. Start date: Q1 2022, Completion date: to be determined.

Comments: This review is dependent on the recommendations of the reflection paper mentioned above. Responsible groups: CVMP, AWP, EWP-V.

5.2. 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 and in line with the Reflection paper on prophylactic use of antimicrobials in animals in the context of Article 107(3) of Regulation (EU) 2019/6.
Priority 2. Start date: January 2022, Completion date: to be determined.

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).

5.3. Art. 40(5) of Regulation (EU) 2019/6 - Rules on data protection

Action: Elaborate criteria that need to be satisfied to support a reduction in antiparasitic resistance to justify an extension to the period of data protection.
Priority 1. Start date: ongoing, Completion date: October 2023.

Comments: A reflection paper is being developed by a dedicated CVMP expert group. A subgroup composed of EWP-V experts is also working on this task. EWP-V might be consulted, if considered necessary.

5.4. Queries raised by CMDv

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

5.5. 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.

5.6. Assessor training

Action: Provide advice / active participation for training of assessors, as required. Training topics for 2023 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 2024 and consider the efficacy curriculum.

5.7. 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) (EMEA/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 on data requirements for veterinary medicinal products used for non-pathologic indications related to the reproductive system
- Guideline on potential claims for products that can contribute to the reduction of the need for antimicrobials
- 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 demonstration of efficacy of ectoparasiticides
- Revised guideline on veterinary medicinal products for fluid therapy in case of diarrhoea**

*The actual items to be included in EWP-V work plan for 2024 will be considered and agreed by the CVMP.

**Guidance documents on which EWP-V was working at the time of interruption of activity due to BCP.