13 December 2024
EMA/CVMP/AWP/341740/2024
Committee for Veterinary Medicinal Product (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Antimicrobials Working Party (AWP) 2025

Chairpersons	**Status**
Chair: Damien Bouchard Vice-chair: Boudewijn Catry	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: 4 (per meeting: 11 members, 2 days)

18-19 March 2025 – virtual meeting
27-28 May 2025 – physical meeting
23-24 September 2025 – virtual meeting
19-20 November 2025 – virtual meeting

Other meetings:

Drafting / Expert groups	4-6 (mostly virtual, 3-11 participants)
Workshop / Focus group	None
Trainings	Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals

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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	4

3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

3.1.1. Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals (EMA/CVMP/AWP/706442/2013)

Action: Finalise the guideline following the second public consultation.

Priority 1, Start date: ongoing, Completion date: Q1 2025

Comments: IDWP consultation finalised.

3.2. Guidance documents to be released for consultation

3.2.1. Reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/SAGAM/741087/2009)

Action: Finalise the reflection paper on macrolides, lincosamides and streptogramins following a period of public consultation.

Priority 2, Start date: ongoing, Completion date: Q4 2025

Comments: Responsible groups: AWP (ERAWP, SWP-V). IDWP consulted as well. During the review of the EMA/AMEG's advice on the 'Categorisation of antibiotics', it was recommended by the AMEG to update the reflection paper and consider the latest scientific knowledge published.

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

Priority 2, Start date: ongoing, Completion date: Q4 2025

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

This action is included in the CVMP's Strategy on Antimicrobials 2021–2025 under Aim 3, relating to measures to ensure the on-going availability and effectiveness of authorised veterinary antimicrobials.

3.2.3. Reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals

Action: Development of a reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antimicrobials in animals.

Priority 3, Start date: ongoing, Completion date: Q4 2025

Comments: This action is included in the CVMP's Strategy on Antimicrobials 2021–2025, carrying forwards the reflections in the European Medicines Agencies Network Strategy to 2025 and the EMA's Regulatory Science Strategy. Results of the EU survey launched in Q3 2024 to be taken into consideration.

3.2.4. Concept paper for the development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a VMP

Action: Provide comments on the concept paper for the development of a reflection paper on the environmental risk assessment of antimicrobial resistance in the environment

Priority 2, Start date: ongoing, Completion date: Q1 2025

Comments: Responsible groups: ERAWP-V (AWP)

3.3. New topics/concept papers to be prepared

3.3.1. Concept paper for the development of a guideline on the assessment of the risk to public health from antimicrobial resistance due to antimicrobial use in companion animals

Action: New concept paper to be developed.

Priority 2, Start date: Q2 2025, Completion date: beyond 2025

Comments: Responsible groups: AWP (consultation with IDWP). 'Reflection paper on the risk of antimicrobial resistance transfer from companion animals' published in 2015.

3.3.2. Development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a VMP

Action: Work on the reflection paper to be initiated.

Priority 2. Start date: Q3 2025, completion date: Q4 2026.

Comments: Responsible groups: ERAWP-V (AWP).

4. VICH guidelines and activities

4.1.1. Follow-up activities after the development of a concept paper for revision of VICH GL27

Action:	Follow-up activities after the submission to VICH SC of the concept paper for revision of VICH GL27 (EMA/CVMP/AWP/585799/2023). **Priority 1,** Start date: ongoing, Completion date: beyond 2025
Comments:	Responsible group: AWP

5. EU regulatory activities

5.1. CVMP Strategy on antimicrobials 2026 - 2030

Action:	To provide assistance to the CVMP in developing the strategy for 2026-2030. **Priority 1,** Start date: Q1 2025, Completion date: Q4 2025.
Comments:	The CVMP strategy will need to be completed in advance of 2026.

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

Action:	Contribute to the revision of existing guidelines in line with the definitions in the Regulation (EU) 2019/6 for antimicrobial resistance, antimicrobial, antibiotic, metaphylaxis, prophylaxis. **Priority 2,** Start date: ongoing, Completion date: Q1 2025.
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. Implement the CVMP's recommendations on the 'Reflection paper on dose review and adjustment of dosage regimens of established veterinary antibiotics in the context of SPC harmonisation'

Action:	At request of CVMP, contribute to the implementation of the recommendations of the 'Reflection paper on dose review and adjustment of established veterinary antibiotics in the context of SPC harmonisation' (EMA/CVMP/849775/2017). Initiate a trial scientific advice of selected active substance/route of administration/target species combination (based on survey results) under Article 141(1) of Regulation (EU) 2019/6 (or an alternative appropriate regulatory mechanism). **Priority 2,** Starting date: Q2 2025, Completion date: beyond 2025
Comments:	Responsible group: CVMP drafting group, linked to the activity identified in the CVMP's work plan 2025.

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 by Regulation (EU) 2019/5, as required.

Comments: None.

5.6. Assessor training

Action: Provide advice / active participation for training of assessors, as required. Training topics for 2025 are indicated under section 1 of this document.

Comments: None.

5.7. Other

Action: Work to increase capability in modelling, simulation and extrapolation within the European Regulatory Network (with applications in dose optimisation), for example, by seeking out and developing relevant training materials.

Comments: None.

6. Activities with external parties

6.1. Meetings with interested parties

Contacts with stakeholders on antimicrobials to exchange information on activities, as required.

6.2. Regulatory authorities outside the EU

Contacts with authorities on antimicrobials to exchange information on activities, as required.

7. Organisational matters

7.1. List of adopted organisational documents

Mandate, objectives and rules of procedure for the AWP (EMA/CVMP/AWP/749774/2012-Rev.4).

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[1]

7.3.1. Guidance documents to be finalised after the consultation period

- Concept paper for the development of a guideline on the assessment of the risk to public health from antimicrobial resistance due to antimicrobial use in companion animals.
- Concept paper for the development of a reflection paper on the use of tetracyclines in animals in the European Union

7.3.2. Guidance documents to be released for consultation

None foreseen.

[1] The actual items to be included in AWP work plan for 2026 will be considered and agreed by the CVMP.