26 January 2024
EMA/CVMP/AWP/381708/2023
Committee for Veterinary Medicinal Product (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Antimicrobials Working Party (AWP) 2024

Chairpersons	**Status**
Chair: D. Bouchard Vice-chair: TBD	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: 4 (per meeting: 11 members, 2 days)

5-6 March 2024 – virtual meeting
28-29 May 2024 – physical meeting
24-25 September 2024 – virtual meeting
26-27 November 2024 – 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: Q3 2024

Comments: Finalisation is dependent on contribution from the IDWP, harmonisation to the RP 40(5) and publication of the 7th revision of the WHO Medically Important Antimicrobial List.

3.2. Guidance documents to be released for consultation

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

Action: Revise the reflection paper on macrolides, lincosamides and streptogramins.

Priority 2, Start date: ongoing, Completion date: Q4 2024

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

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 2,** Start date: November 2023, Completion date: beyond 2024
Comments:	Responsible groups: AWP. 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.

3.3. New topics/concept papers to be prepared

3.3.1. Development of a 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: December 2024
Comments:	Responsible groups: ERAWP-V (AWP)

4. VICH guidelines and activities

4.1.1. Development of a concept paper for revision of VICH GL 27, to be submitted to the VICH SC

Action:	Development of a concept paper for revision of VICH GL 27, to be submitted to the VICH SC **Priority 1,** Start date: Q1 2024, Completion date: Q3 2024
Comments:	Responsible group: AWP

5. EU regulatory activities

5.1. 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: 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. List of priority candidate products for review and adjustment of dosage regimens

Action: At request of CVMP, contribute to the CVMP's implementation of the recommendations of the reflection paper on dose review and adjustment of established veterinary antibiotics by assisting with the task to establish a list of priority candidate products for review and adjustment of dosage regimens.

Priority 2, Starting date: Q1 2023, Completion date: Q2 2024

Comments: Responsible Group: CVMP drafting group, linked to the activity identified in the CVMP's work plan 2024.

5.3. Queries raised by CMDv

Action: Provide response to queries raised by CMDv via CVMP, as required.

Comments: None.

5.4. 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.

5.5. 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.

Comments: None.

5.6. 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

- Reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in food-producing animals in the European Union: development of resistance and impact on human and animal health.
- Reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals.

7.3.2. Guidance documents to be released for consultation

- Concept paper to develop a Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in companion animals.

[1] The actual items to be included in AWP work plan for 2025 will be considered and agreed by the CVMP.