16 December 2022
EMA/CVMP/AWP/715896/2022
Committee for Veterinary Medicinal Product (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Antimicrobials Working Party (AWP) 2023

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

14-15 March 2023 – physical meeting
23-24 May 2023 – virtual meeting
19-20 September 2023 – virtual meeting
21-22 November 2023 – physical meeting (tbc)

Other meetings:

Drafting / Expert groups	4-6 (mostly virtual, 3-10 participants)
Workshop / Focus group	None
Trainings	None

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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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: Q4 2023

Comments: Finalisation is dependent on the harmonisation to the reflection paper on Article 40(5) and 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 2023

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: Q2 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.

3.3. New topics/concept papers to be prepared

3.3.1. Concept paper for the development of a reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals

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

Priority 2, Start date: January 2023, Completion date: Q2 2023

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.

3.3.2. 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

Comments: Responsible groups: led by EWP-V

3.3.3. Concept paper for the development of a reflection paper on the environmental risk assessment of antimicrobial resistance in the environment

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: June 2024

Comments: Responsible groups: led by ERAWP-V

3.3.4. Question and Answer document on inclusion of clinical breakpoints in generic SPCs for antibiotic VMPs

Action: New Q&A document to be developed.

Priority 2, Start date: January 2023, Completion date: Q2 2023

Comments: Additional guidance for NCAs regarding the necessity to include clinical breakpoints into the SPC of generic antibiotic VMPs and the suitability of available breakpoints.

4. VICH guidelines and activities

None foreseen.

5. EU regulatory activities

5.1. 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 antimicrobial 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 AWP experts is also working on this task. AWP might be consulted, if considered necessary.

5.2. 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: ongoing, 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.

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

Action: Contribute to the revision of existing guidelines and Q&A in line with the definitions in the Regulation (EU) 2019/6 for antimicrobial resistance, antimicrobial, antibiotic, metaphylaxis, prophylaxis and in line with the Reflection paper on prophylactic use of antimicrobials in the context of Article 107(3) of Regulation (EU) 2019/6.

Priority 2, Start date: January 2023, 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).

5.4. Recommendations of the reflection paper on dose review and adjustment of established veterinary antibiotics (EMA/CVMP/849775/2017)

Action: 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 dose review/adjustment.

Priority 2, Starting date: Q1 2023, Completion date: Q3 2023

Comments: Linked to the activity identified in the CVMP's work plan 2023.

5.5. Queries raised by CMDv

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

Comments: None.

5.6. 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.

5.7. 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.

Comments: None.

5.8. 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

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

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

7.3.2. Guidance documents to be released for consultation

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

[1] The actual items to be included in AWP work plan for 2024 will be considered and agreed by the CVMP.