28 January 2022
EMA/CVMP/AWP/605507/2021
Committee for Veterinary Medicinal Product (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Antimicrobials Working Party (AWP) 2022

Chairpersons	**Status**
Chair: C. Schwarz Vice-chair: D. Bouchard	Adopted by CVMP in January 2022

The activities outlined in the work plan for 2022 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 2022

Plenary meetings: 4 (per meeting: 10 members, 2 days)

22-23 March 2022 (virtual)
24-25 May 2022 (tbc)
20-21 September 2022 (tbc)
22-23 November 2022 (tbc)

Other meetings:

Drafting / Expert groups	4-6 (mostly virtual, 3-10 participants)
Workshop / Focus group	None
Trainings	- GL on the SPC for VMPs containing antimicrobial substances[1] - RP on prophylactic use of antimicrobials - Art. 107(3)[2] - GL on Risk Assessment of antimicrobial VMPs (if applicable)

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 led by AWP; EWP-V to provide support as necessary
[2] joint activity AWP & EWP-V

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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. Completion date: Q2 2022.

Comments: Finalisation is dependent on the Commission's adoption of the implementing act under Article 37(5) of the Regulation.

3.2. New topics/concept papers to be prepared

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: Q1 2022, completion date: September 2023.

Comments: 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. Concept paper at public consultation until 31 January 2022.

3.2.2. Article 36(2) of Regulation (EU) 2019/6 - Concept paper on post-authorisation studies for antimicrobial VMPs

Action: Development of concept paper on post-authorisation studies for antimicrobial VMPs to ensure the benefit-risk remains positive in case of development of antimicrobial resistance.

Priority 2. Start date: Q2 2022, completion date: July 2022.

Comments: 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.

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. Completion date: May 2022

Comments: This action being undertaken by a dedicated CVMP expert group including members of AWP.

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: June 2022.

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: June 2022.

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 use of antimicrobials – Art. 107(3).

Priority 2. Start date: January 2022, Completion date: December 2022.

Comments: Responsible groups: EWP-V (AWP). Concept paper to be developed and published for consultation. 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 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. Completion date: December 2022.

Comments: Linked to the activity identified in the CVMP's work plan 2022.

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 2022 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[3]

7.3.1. Development of a concept paper on the availability and characteristics of diagnostic tests

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

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.

[3] The actual items to be included in AWP work plan for 2023 will be considered and agreed by the CVMP.