15 December 2017
EMA/CVMP/AWP/484533/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Work plan for the CVMP Antimicrobials Working Party (AWP) 2018

Chairpersons	Status
Chair: H. Jukes Vice-chair: C. Schwarz	Adopted by CVMP in December 2017

The activities outlined in the work plan for 2018 have been agreed considering the respective business priorities, as well as the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.

1. Meetings scheduled for 2018

Plenary meetings:	4 (per meeting: 13 members, 1.5 days)
	20-21 February 2018
	29-30 May 2018
	18-19 September 2018
	11-12 December 2018
Other meetings:	
Drafting / Expert groups	2-3 (approximately 7 participants, physical)
Workshop / Focus group	1 topic (risk assessment of antimicrobials)
Training	None

Virtual meetings are mainly regarded as complementary to plenary meetings. However, if feasible and depending on the workload, one or two of the plenary meetings could be replaced by virtual meetings.

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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
1	4

3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

3.1.1. Reflection paper on use of aminoglycosides in veterinary medicines in the EU (EMA/CVMP/AWP/721118/2014)

Action: Revision of the reflection paper on the use of aminoglycosides in the EU (Q1 2018).

Comments: The EMA advice to the European Commission on the impact on public health and animal health of the use of antibiotics in animals will be considered.

3.1.2. Reflection paper on off-label use of antimicrobials in selected domestic animals (EMA/CVMP/AWP/237294/2017)

Action: Revision of the reflection paper on off-label use of antimicrobials in selected domestic animals (Q2 2018).

Comments: The EMA advice to the European Commission on the impact on public health and animal health of the use of antibiotics in animals will be considered.

3.1.3. 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: Revision of the guideline following a focus group meeting with stakeholders (Q3 2018).

Comments: None.

3.2. Guidance documents to be released for consultation

3.2.1. Guideline on the summary of product characteristics for antimicrobial products (EMEA/CVMP/SAGAM/383441/2005)

Action: Revision of guideline, to be released for public consultation (Q1 2018).

Comments: Multidisciplinary topic led by AWP and involving EWP-V.

3.2.2. Reflection paper on use of extended-spectrum penicillins in veterinary medicines in the EU

Action: Development of a reflection paper on the use of extended-spectrum penicillins in the EU for release for public consultation (Q2 2018).

Comments: The EMA advice to the European Commission on the impact on public health and animal health of the use of antibiotics in animals will be considered.

3.2.3. Reflection paper on antimicrobial resistance due to presence of veterinary antimicrobials in the environment

Action: Contribute to the reflection paper to be released for consultation (Q2 2018).

Comments: Multidisciplinary topic led by ERAWP (ecological risk) and involving the AWP (antimicrobial resistance).

3.3. New topics/concept papers to be prepared

3.3.1. Summary of product characteristics harmonisation

Action: Contribute to the pilot project on dose optimisation for the harmonisation of SPCs for established veterinary antibiotics (Q1 2018).

Comments: The pilot project on dose optimisation is a joint CVMP and Industry project, led by CVMP.

4. VICH guidelines and activities

None foreseen.

5. EU regulatory activities

5.1. Advice following new mandate from the European Commission for further advice on the impact on public and animal health of the use of antibiotics in animals (AMEG)

Action: Provide advice to the follow-up request arising from the EMA advice to the questions from the European Commission on the impact on public health and animal health of the use of antibiotics in animals. The mandate relates to updating the categorisation of antimicrobials and development of an early hazard characterisation, as needed.

Comments: New mandate from the Commission received July 2017.

5.2. Advice following the EFSA/EMA scientific opinion (RONAFA)

Action: Provide advice to any follow up request arising from the report from the EFSA/EMA Joint Working Group on the "Reduction Of the Need to use Antimicrobials in Food-producing Animals" (RONAFA).

Comments: None.

5.3. Queries raised by CMDv

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

Comments: None.

5.4. Assessor training

Action: Provide advice / active participation for training of assessors, as required.

Comments: None.

5.5. 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.2).

7.2. List of organisational documents to be developed/revised in the forthcoming 2 years

Mandate, objectives and rules of procedure for the AWP (EMA/CVMP/AWP/749774/2012-Rev.2).

7.3. List of proposed scientific guidelines for the next work plan

Guidance on development of new formulations and extension of indications for AMEG Category 1[1] and lower risk antimicrobials.

[1] Antimicrobials used in veterinary medicine where the risk for public health is currently estimated as low or limited