7 December 2017
EMA/CVMP/ERA/289769/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Work plan for the CVMP Environmental Risk Assessment Working Party (ERAWP) 2018

Chairpersons:	**Status**
Chair: J. Weeks Vice-chair: S. Hickmann	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:	2 (per meeting: 12 members, 1.5 days)
	30-31 January 2018
	5-6 June 2018
Other meetings:	
Drafting / Expert groups	Virtual meetings, as needed
Workshop / Focus group	None
Training	None

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

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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
0	2

3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

3.1.1. Guideline on assessing the toxicological risk to human health and the environment from veterinary pharmaceuticals in groundwater (EMA/CVMP/ERA/103555/2015)

Action: To be finalised following the public consultation (Q2 2018).

Comments: Multidisciplinary topic led by the ERAWP (ecological risk) and involving the SWP-V (risk to consumer health).

3.1.2. Reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs (EMA/CHMP/CVMP/JEG-3Rs/164002/2016)

Action: Reflection paper to be finalised following the public consultation (Q1 2018).

Comments: Multidisciplinary project led by J3RsWG and involving QWP, SWP-V, IWP, ERAWP and EWP-V.

3.2. Guidance documents to be released for consultation

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

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

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

3.2.2. Reflection paper on environmental risk assessment of veterinary medicinal products used in aquaculture

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

Comments: The outcome of the workshop organised in 2016 on the environmental risk assessment of veterinary medicinal products used in aquaculture will be considered for the development of the reflection paper.

4. VICH Guidelines and activities

None.

5. EU Regulatory Activities

5.1. Queries raised by CMDv

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

Comments: None.

5.2. Collaboration with EFSA

Actions: Provide contribution to EFSA opinions in accordance with Article 59 of Regulation (EC) No 726/2004, as required.

Consultations with the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on environmental risk assessment issues, as required.

Comments: None.

5.3. Collaboration with ECHA

Action: Consultation with the ECHA PBT working group and with the biocides environment working group, as required.

Comments: None.

5.4. Assessor training

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

Comments: None.

5.5. Other

Actions: Provide comments to the European Commission as part of the development of a Commission strategy for managing risks to the environment related to the use of medicines, as required.

Provide contributions to guidelines and questions raised by other working parties and ad hoc expert groups, as required.

Provide advice to the CVMP on questions relating to environmental risk assessment arising from referral procedures, as required.

Comments: None.

6. Activities with external parties

6.1. Meetings with interested parties

None foreseen.

6.2. Regulatory authorities outside the EU

None foreseen.

7. Organisational matters

7.1. List of adopted organisational documents

Mandate, objectives and rules of procedure for the CVMP Environmental Risk Assessment Working Party (EMA/CVMP/ERA/705470/2009-Rev.3).

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

Mandate, objectives and rules of procedure for the CVMP Environmental Risk Assessment Working Party (EMA/CVMP/ERA/705470/2009-Rev.3).

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

None.