16 December 2022
EMA/CVMP/ERA/828487/2022
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Environmental Risk Assessment Working Party (ERAWP) 2023

Chairpersons:	**Status**
Chair: R. Carapeto Vice-chair: B. Kolar	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:	3 (per meeting: Chair plus 10–12 members, 2 days) 29–30 March 2023 (virtual) 21–22 June 2023 (face-to-face) 11–12 October 2023 (virtual)
Other meetings:	
Drafting / Expert groups	10–15 meetings (mostly virtual; approximately 7–10 participants per meeting)
Workshop / Focus group	1 (related to the development of a guideline on the environmental risk assessment of veterinary medicinal products used in aquaculture; tentative)
Training	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.

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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	1

3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

3.1.1. Questions and answers on the implementation of the CVMP guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL38 (EMEA/CVMP/ERA/172074/2008 Rev. 7)

Action: Update of the questions and answers document to align its content with changes related to the inclusion of a list of input parameters for the FOCUS surface water models currently used for exposure calculation, as well as with other changes related to the implementation of Regulation (EU) 2019/6.

Priority 2. Start date: March 2023, completion date: December 2023.

Comments: None.

3.1.2. All published guidance documents within the remit of the ERAWP

Action: Update of relevant guidance documents in order to align them with provisions outlined in Regulation (EU) 2019/6, as applicable.

Priority 3. Start date: March 2023, completion date: December 2023.

Comments: None.

3.2. Guidance documents to be released for consultation

3.2.1. Development of a guideline on the environmental risk assessment of veterinary medicinal products intended for use in aquaculture

Action: Work on the guideline to be continued.

Priority 2. Start date: ongoing, completion date: December 2024.

Comments: This item is linked to action 5.3.1.b of the European Union strategic approach to pharmaceuticals in the environment (COM[2019] 128 final). The organisation of a (virtual) workshop bringing together relevant stakeholders in the field is envisaged for Q3/Q4 2023.

Comments: None.

3.2.2. Development of a concept paper for the development of a reflection paper on the environmental risk assessment of antimicrobial resistance in the environment

Action: Work on the concept paper to be initiated.

Priority 2. Start date: January 2023, completion date: June 2024.

Comments: None.

3.2.3. Development of a reflection paper on the environmental risk assessment of ectoparasiticidal veterinary medicinal products used in cats and dogs

Action: Work on the reflection paper to be continued.

Priority 1. Start date: ongoing, completion date: September 2023.

Comments: Development of a reflection paper considering the current approach for ERA for companion animals as well as documented environmental concerns.

3.2.4. Reflection paper on risk mitigation measures related to the environmental risk assessment of veterinary medicinal products (EMA/CVMP/ERAWP/409328/2010)

Action: Review of the reflection paper to include reference to the newest applicable legislation (e.g. Regulation (EU) 2019/6) as well as critical review of the adequacy/appropriateness of risk mitigation measures formulated/applied since the paper's initial release in 2012.

Priority 2. Start date: ongoing, completion date: December 2023.

Comments: None.

3.2.5. 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: Cooperation with AWP on the review of the reflection paper.

Priority 2. Start date: ongoing, completion date: Q4 2023.

Comments: None.

4. VICH Guidelines and activities

None foreseen.

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 and cooperation 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 (EC) as part of the "European Union Strategic Approach to Pharmaceuticals in the Environment" (COM[2019] 128 final), as required.

Provide advice to the EC and other EU Agencies on issues of mutual interest with regard to environmental risk assessment, 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.

Elaborate an EU-NTC veterinary environmental risk assessment sub-curriculum.

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

None.

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.6).

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

None.

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