7 December 2017
EMA/CVMP/SWP/278493/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Work plan for the CVMP Safety Working Party (SWP-V) 2018

Chairpersons	Status
Chair: E. Lander Persson Vice-chair: S. Scheid	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:	3 (per meeting: 23 members, 1.5 days) 1-2 February 2018 17-18 May 2018 29-30 November 2018
Other meetings:	
Drafting / Expert groups	2 physical meetings in the margins of plenary meetings as needed (6-8 participants), and virtual meetings as needed
Workshop / Focus group	None
Training	1 for assessors (User risk assessment of topically applied products)

Virtual meetings are mainly regarded as complementary to plenary meetings. However, if feasible 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
2	2

3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

3.1.1. User safety evaluation of topically applied veterinary medicinal products (EMA/CVMP/SWP/721059/2014)

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

Comments: None.

3.1.2. Guideline on DNA reactive impurities in veterinary medicinal products (EMA/CVMP/SWP/377245/2016)

Action: Draft guideline to be finalised following the public consultation (Q4 2018).

Comments: Multidisciplinary topic led by SWP-V and involving QWP and EWP-V (target animal safety).

3.1.3. Withdrawal time determination – review of approach for dealing with residues below the limit of quantification (EMA/CVMP/SWP/278493/2017)

Action: Revised Note for guidance: approach towards harmonisation of withdrawal periods, to be finalised following the public consultation (Q1 2018).

Comments: None.

3.1.4. 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 involving the ERAWP (ecological risk) and the SWP-V (risk to consumer health).

3.1.5. 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. Review of guideline on safety and residues data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market (EMA/CVMP/SWP/66781/2005-Rev.1) to take account of Commission Regulation (EU) 2017/880.

Action: Revised draft guideline to be released for one month public consultation (Q4 2018).

Comments: None

3.3. New topics/concept papers to be prepared

None

4. VICH guidelines and activities

4.1. Guideline on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing animals: residue studies in fish

Action: Contribute to EU position.

Comment: Current status of guideline: Step 4 of VICH process.

4.2. Guideline on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing animals: residue studies in honey

Action: Contribute to EU position.

Comment: Current status of guideline: Step 5 of VICH process.

4.3. VICH GL 23: studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing (EMA/CVMP/VICH/526/2000)

Action: Contribute to EU position for the revision of the guideline.

Comments: Current status of guideline: Step 2 of VICH process.

4.4. Revision of VICH GL 22: studies to evaluate the safety of residues of veterinary drugs in human food: reproductive toxicity testing (CVMP/VICH/525/00-FINAL)

Action: Develop EU position on the acceptability of the Extended One Generation Reproductive Toxicity Study and draft a proposal to VICH.

Comments: Current status of guideline: Step 9 of VICH process.

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

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

Comments: None.

5.3. EU position at Codex Alimentarius

Action: Preparation of CVMP/SWP comments as a contribution to the preparation of the EU position at Codex Alimentarius on issues related to safety of residues, as required.

Comments: None.

5.4. Assessor training

Actions: Contribute to the implementation of the veterinary training curriculum.

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

Comments: None.

5.5. Consideration of emerging concepts used in risk assessment

Action: Identify relevant risk assessment tools and investigate their applicability

Comments: None.

5.6. Other

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

Provide advice to CVMP on safety questions 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/Risk assessment bodies outside the EU

One meeting of SWP-V and JECFA experts to be determined.

7. Organisational matters

7.1. List of adopted organisational documents

Mandate, objectives and rules of procedure for the CVMP Safety Working Party (EMEA/CVMP/SWP/131613/2004-Rev.3).

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

Mandate, objectives and rules of procedure for the CVMP Safety Working Party (EMEA/CVMP/SWP/131613/2004-Rev.3).

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

Note for guidance for the determination of withdrawal periods for milk (and relevant parts of SPC guideline)

Overarching guideline on residues studies

Guideline on injection site residues