27 January 2023
EMA/CVMP/SWP/618508/2022
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Safety Working Party (SWP-V) 2023

Chairpersons:	**Status**
Chair: C. Bergman	Adopted by CVMP in January 2023

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 meeting: 3 meetings (Chair plus 12 members plus possible ad-hoc participants, 1.5 days)

30-31 March 2023 – virtual meeting

22-23 June 2023 – physical meeting

16-17 November 2023 – virtual meeting

Other meetings:

Drafting / Expert groups*	As needed
Workshop / Focus group	None
Training	2

*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
2	2

3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

3.1.1. Guideline on determination of the need for an MRL evaluation for biological substances (EMA/CVMP/SWP/591282/2021)

Action: Guideline to be finalised further to public consultation.
Priority 1. Start date: On-going, Completion date: tbc.

Comments: Guideline on how to determine the need for an MRL assessment of biological substances relevant to the field of veterinary medicines, in collaboration with NTWP.

3.2. Guidance documents to be released for consultation

3.2.1. Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted but not eligible for authorisation under Article 23 of the Regulation (EU) 2019/6

Action: Guideline to be finalised following the public consultation.
Priority 1 Start date: On-going, Completion date: tbc.

Comments: The elaboration of the guideline is carried out by the SWP-V and coordinated by an 'oversight' group, including in its membership the chair of the SWP-V and other relevant working party chairs.

3.2.2. Guideline on user safety of topically administered veterinary medicinal products (EMA/CVMP/SWP/721059/2014)

Action: Guideline to be released for public consultation.
Priority 2. Start date: Q2 2023, Completion date: 2024.

Comments: This guideline is planned to be revised in relation to possible inclusion of a reference to current EU-standards in the assessment of dermal absorption, i.e. EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873) and to updated OECD guidance notes on dermal absorption No. 156. The revision could also include developments on NOELs and exposure calculations (e.g. absorption factors, appropriateness of the default values and of the wipe test), and mitigation measures.

3.2.3. New topics/concept papers to be prepared

None foreseen.

4. VICH guidelines and activities

4.1. Review of VICH GL22: studies to evaluate the safety of residues of veterinary drugs in human food: reproductive toxicity testing (CVMP/VICH/525/00-FINAL)

Action: Contribute to EU position on use of the Extended One Generation Reproductive Toxicity Study.
Priority 1.

Comments: Current status of guideline: step 9/2 of the VICH process.

4.2. Review of VICH GL23: studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing (CVMP/VICH/526/2000)

Action: Contribute to EU position on the review of the standard battery of tests.
Priority 1.

Comments: Current status of guideline: step 9/2 of the VICH process.

4.3. Review of VICH GL49: Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing animals: validation of analytical methods used in residue depletion studies

Action: Contribute to EU position on the review of the guideline.
Priority 1.

Comments: Current status of guideline: step 9/2 of the 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

5.2.1. **Action:** Provide contribution to EFSA opinions in accordance with Art. 59 of Regulation (EC) No 726/2004 as amended, as required.
Comments: None.

5.2.3. **Action:** Assess the possible impact of any change in approach to consumer exposure estimation on CVMP guidance, approach to MRL assessment and existing MRLs and initiate the necessary preparatory and follow-up work.
Priority 1. Completion date: end 2023
Comments: None.

5.3. EU position at Codex Alimentarius

Action: Preparation of CVMP 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 development of the veterinary training curriculum.

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

Provide training on the safety assessment of mutagenic impurities, in association with QWP.

Provide training on data requirements for limited market products eligible for Article 23, in association with EWP, IWP and ERAWP.

SWP-V to reflect on needs for training for 2024.

5.5. Consideration of emerging concepts and issues related to harmonised application of risk assessment approaches

5.5.1. **Action:** Identify relevant risk assessment tools and investigate their applicability. Exchange of experience gained with risk assessment tools with a view to improve and harmonise use of methods.
Comments: None.

5.5.3. **Action:** Collaborate in the assessment of novel therapies if necessary
Comments: In particular the development of guidance on quality and safety of veterinary medicines containing nanomaterials is planned at NTWP in cooperation with other working parties as needed. On request of NTWP the SWP-V will be available to cooperate on the safety issues.

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

None foreseen.

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.6).

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

None.

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

Development of a guideline on the conduct of studies related to the determination of the need for MRL evaluation for biological substances.

Development of a guideline on the user and consumer safety of biological non-immunological veterinary medicinal products.

Revision of the guidelines impacted by a change of model of consumer exposure as needed.

**The actual items to be included in SWP-V work plan for 2024 will be considered and agreed by the CVMP.*