13 December 2024
EMA/CVMP/SWP/280825/2024
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Safety Working Party (SWP-V) 2025

Chairperson:	**Status**
C. Bergman	Adopted by CVMP in December 2024

The activities outlined in the work plan for 2025 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 2025

Plenary meeting:	3 meetings (Chair plus 12 members plus possible ad-hoc participants, 1.5 days)
	20-21 March 2025, virtual
	17-18 June 2025, face to face
	13-14 November 2025 virtual

Other meetings:

Drafting / Expert groups*	As needed
Workshop / Focus group	None
Training	1 (see section point 5.4)

* Drafting / Expert group meetings are mainly regarded as complementary to plenary meetings.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

None

3.2. Guidance documents to be released for consultation

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

Action: Guideline to be revised and released for public consultation.
Priority 2. Start date: ongoing, Completion date: 2025.

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. The revision of this guideline is planned in collaboration with 3RsWP.

3.2.2. Guideline on user safety for pharmaceutical veterinary medicinal products (EMA/CVMP/543/03)

Action: Guideline to be revised and released for public consultation.
Priority 2. Start date: Q4 2024, Completion date: 2026.

Comments: The guideline is planned to be updated regarding the references to the legislation and to the 3Rs. The revision would also include clarification on some wording from Annex II to Regulation (EU) 2019/6, and further guidance on adequate risk mitigation measures and on uncertainty factors. The revision of this guideline is planned in collaboration with 3RsWP.

3.3. New topics/concept papers to be prepared

3.3.1. Guideline on consumer safety of active substances of IVMPs acting against endogenous targets (reference to be completed)

Action: Concept paper to be prepared for public consultation.
Priority 2. Start date: ongoing, Completion date: Q1 2025.

Comments: This guideline is planned to be developed to address the consumer safety of the immunological active substances inducing immunity against endogenous antigens.

These antigens may be present in the body of the consumer, and consequently the consumer safety needs to be evaluated. This evaluation takes place during the assessment of the marketing authorisation application. There is currently no guidance in this matter. The development of this guideline is planned in collaboration with IWP and NTWP.

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

Action: Concept paper to be prepared for public consultation.
Priority 1. Start date: TBD, Completion date: TBD

Comments: This guideline is planned to be revised as needed by evolution of MRL regulation. The revision is planned in collaboration with NTWP.

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 the review of the guideline.
Priority 1. Start date: ongoing, Completion date: beyond 2025.

Comments: Current status of guideline: step 9/5 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 guideline.
Priority 1. Start date: ongoing, Completion date: beyond 2025.

Comments: Current status of guideline: step 9/5 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. Start date: ongoing, Completion date: beyond 2025.

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. Contributions EFSA

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

Comments: None.

5.2.2. Dietary exposure project

Action: Contribute to the development of the common calculation tool to estimate consumer exposure to residues of veterinary medicines, feed additives and pesticides, in food of animal origin. Priority 1. Start date: Q4 2024, Completion date: November 2026.

Comments: EFSA is the leading body, SWP-V and CVMP experts contribute.

5.3. EU position at Codex Alimentarius

Action: Prepare CVMP comments as a contribution to the preparation of the EU position at Codex Alimentarius on issues related to safety of residues, as required. Priority 1. Start date: ongoing, Completion date: Ongoing.

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 establishment of withdrawal periods.

SWP-V to reflect on needs for training for 2026.

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

5.5.1. Risk assessment tools

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.

5.5.2. Novel therapies

Action: Collaborate in the assessment of novel therapies.

Comments: In particular, the development of guidance on safety data requirements for veterinary medicinal products issued from nanotechnologies. On request of NTWP the SWP-V will be available to cooperate on the safety issues.

5.6. Other

5.6.1. 3RsWP

Actions: Collaborate with 3RsWP on topics common to SWP-V and 3RsWP

Comments: None

5.6.2. Contribution to other working parties

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.

5.6.3. Modelling, simulation and extrapolation

Actions: Work to increase capability in modelling, simulation and extrapolation within the European Regulatory Network (with applications in toxicological assessment and residue depletion), for example, by seeking out and developing relevant training materials

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 two years

None foreseen.

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

Development of guidance on user and consumer safety of biological non-immunological veterinary medicinal products.

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

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 2026 will be considered and agreed by the CVMP.*