12 December 2025
EMA/CVMP/SWP/192449/2025
Committee for Veterinary Medicinal Products (CVMP)

Work plan for the Committee for Veterinary Medicinal Products (CVMP) Safety Working Party (SWP-V) 2026

Chairperson:	**Status**
C. Bergman	Adopted by CVMP in December 2025

The activities outlined in the work plan for 2026 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 2026

Plenary meetings:	3 meetings (Chair plus 12 members plus possible ad-hoc participants, 1.5 days)
	19-20 March 2026, virtual
	25-26 June 2026, face to face
	12-13 November 2026 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.

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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

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: 2026.

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: ongoing, 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. Finally, the general topics (e.g. considerations on toxicological reference values) would be transferred from the guideline on user safety of topically administered veterinary medicinal products addressed in 3.1.1. The revision of this guideline is planned in collaboration with 3RsWP.

3.2.3. Guideline on consumer safety of active substances of IVMPs acting against endogenous targets (EMA/CVMP/SWP/212933/2025)

Action: Draft guideline to be prepared for public consultation.
Priority 2. Start date: ongoing, Completion date: 2026.

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. New topics/concept papers to be prepared

None

3.4. Guidance documents to be amended for administrative reason

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

Action: Guideline to undergo a minor revision.
Priority 1. Start date: ongoing, Completion date: 2026

Comments: This guideline is planned to be revised in line with Commission Regulation (EU) 2025/1101 of 3 June 2025 amending Regulation (EU) 2018/782 concerning the assessment by the European Medicines Agency of maximum residue limits for chemical-unlike biological substances. The chemical-unlike substances which do not require a full MRL evaluation will be classified as 'No MRL required' instead of being included in an ad-hoc list published by the Agency. Since the revision is expected minor, no concept paper and no public consultation of the guideline are planned. The revision is planned in collaboration with NTWP.

4. VICH guidelines and activities

4.1. *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 2026.

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

4.2. *Questions and answers on waiving in vivo studies in VICH GL23 (studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing)*

Action: Q&A document to be developed to express the EU position on waiving *in vivo* genotoxicity studies
Priority 2. Start date: 1Q2026, Completion date: 4Q2026.

Comments: Refer to EFSA Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment (EFSA Journal 2011;9(9):2379). The development of this document is planned in collaboration with 3RsWP.

5. EU regulatory activities

5.1. Collaboration with EFSA

5.1.1. Contributions to EFSA

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

Comments: None.

5.1.2. 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: ongoing, Completion date: November 2026.

Start revision of the guidelines (e.g. withdrawal period guidelines) and other documents impacted by the change of model of consumer exposure. Priority 2. Completion date: tbd

Comments: For the development of the common calculation tool, EFSA is the leading body, SWP-V and CVMP experts contribute. For the revision of the documents specific to the field of veterinary medicines such as the guidelines, CVMP, SWP-V and EMA will be in charge.

5.2. *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.

5.3. *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 need for full MRL evaluation for chemical-unlike biologicals

SWP-V to reflect on needs for training for 2027.

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

5.4.1. 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.

5.5. Other

5.5.1. 3RsWP

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

Comments: None

5.5.2. 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.

5.5.3. 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 working parties under the quality, non-clinical, methodology, clinical and veterinary domains (EMA/299541/2025).

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

Revision of the guidelines on withdrawal periods, in relation to the calculation tool for consumer exposure (see also section 5.1.2) and in relation to eggs.

[**] *The actual items to be included in SWP-V work plan for 2027 will be considered and agreed by the CVMP.*