12 December 2025
EMA/CVMP/PhVWP/189306/2025
Committee for Veterinary Medicinal Products (CVMP)

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

Chairpersons	**Status**
Chair: J. Mount Vice-chair: A. Bottger	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:

27-28 January*
25 *February*
24-25 March
22 *April*
26-27 May*
7-8 July
29-30 September*
28 *October*
24-25 November

* Face to face meetings. Meetings *in italics* to be held only when necessary (e.g. urgent matters or topics circulated via written procedure in advance only). Meeting dates may be modified as needed and additional virtual meetings be organised *ad-hoc* to address time-sensitive requests.

Other meetings:

Workshops	Workshop with Federation of Veterinarians of Europe (FVE) Medicines Working Group on improvement of pharmacovigilance communication

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	to veterinarians (Q2 – Q3 2026 (TBC)). **Priority 1**[1]
Interested parties meeting	Annual joint PhVWP-V-PhV Inspectors Working Group (PhV IWG) interested parties meeting. **Priority 1**[1]
	PhVWP-V industry stakeholders meeting to support implementation of Regulation (EU) 2019/6 (quarterly virtual meetings). **Priority 1**[1]
Training sessions	Please see section 5.

2. Guidelines

2.1. New EU guidelines

2.1.1. Guidance and template on the risk management plan for novel therapy veterinary medicinal products according to the requirement in section V.1.1.6 of Annex II of Regulation (EU) 2019/6

Action:	Contribute to guidance and template on the risk management plan for novel therapy veterinary medicinal products for release for public consultation. **Priority 1**. Start date: Q3 2025, Completion date: Q3 2026.
Comments:	Activity led by CVMP novel therapies working party (NTWP)[1].

2.2. EU guidelines under revision

2.2.1. Combined Veterinary Dictionary for Drug Related Affairs (VeDDRA) list of clinical terms for reporting suspected adverse events in animals and humans to veterinary medicinal products (EMA/CVMP/10418/2009)

Action:	Annual VeDDRA review. **Priority 1**. Start date: on-going, Completion date: Q2 2026.
Comments:	Deadline for comments: 14 February every year. Annual VeDDRA meeting: 14-15 April 2026 (TBC). Implementation in EudraVigilance Veterinary (EVV): 1 October every year [1]

2.2.2. Concept paper for revision of VGVP module: Signal management (EMA/522332/2020)

Action:	Develop concept paper for revising the VGVP. Initiate the revision of the guidance accordingly, considering experience gained with Regulation (EU) 2019/6 and incorporating new signal management procedures **Priority 1**. Start date: Q4 2025, Completion date: Q2 2026 (finalisation of concept paper following public consultation); Q3 2026 (initiate revision of VGVP)

[1] see CVMP Work Plan 2026 section 1.3.1 (EMA/CVMP/210842/2025)

Comments: None[2]

2.2.3. VGVP module: Communication (EMA/63454/2021)

Action: Update guidance in light of experience gained since Regulation (EU) 2019/6 came into force and incorporate new guidance on coordination of communication on pharmacovigilance within the regulatory network for release for public consultation.

Priority 1. Start date: on-going, Completion date: Q2 2026.

Comments: None[2].

2.2.4. Update Union veterinary pharmacovigilance database best practice guide (BPG) (EMA/371192/2021)

Action: Update BPG to incorporate new technical guidance on the use of electronic systems for veterinary pharmacovigilance
Priority 1. On-going activity, subject to need.

Comments: None[2].

2.2.5. VGVP module: Signal management Appendix 1 Medically Important (MI) VeDDRA terms list (EMA/522332/2020)

Action: Update appendix subject to need.
Priority 1. Start date: Q3 2026 (initiate revision of VGVP pending finalisation of concept paper for revision of VGVP module: Signal management following public consultation)

Comments: None[2]

2.2.6. VGVP module: Collection and recording of suspected adverse events for veterinary medicinal products (EMA/306663/2021)

Action: Consider the need to update guidance considering experience gained since Regulation (EU) 2019/6 came into force for release for public consultation.

Priority 1. Start date: Q2 2026, Completion date: Q4 2026.

Comments: None[2].

2.3. VICH guidelines

2.3.1. VICH pharmacovigilance guidelines: GL30: controlled list of terms

Action: Review and adopt the controlled list of terms.
Priority 1. Start date: on-going, Completion date: ongoing (continuous activity).

[2] see CVMP Work Plan 2026 section 1.3.1 (EMA/CVMP/210842/2025)

Comments: Reviewed annually.

3. Electronic systems used for pharmacovigilance

3.1. Union pharmacovigilance database (EudraVigilance Veterinary (EVV)), EVV data warehouse (DWH), IRIS (EMA's regulatory and scientific information-management platform) and Union Product Database (UPD) technical issues

Action: Provide guidance to stakeholders related to day-to-day veterinary pharmacovigilance best practice for use of the above systems.
Priority 1.

Comments: None[3]

4. Medicinal product-specific activities

4.1. Evaluation and supervision activities

Action: Evaluate potential signals in veterinary pharmacovigilance arising from the Union pharmacovigilance system and propose options for risk management.
Priority 1.

Comments: None[3].

Action: Provide specialised scientific contribution and advice to CVMP and CMDv (including targeted signal management[4]), upon request, on pre- and post-authorisation procedures, including Union referral procedures concerning pharmacovigilance; identification and evaluation of potential safety issues and recommending risk management measures to address these.
Priority 1.

Comments: None[3].

Action: Provide input to the PhV IWG and pharmacovigilance inspections teams, upon request.
Priority 1.

Comments: None[3].

Action: Upon request, contribute to the supervision and approval of pharmacovigilance data to be released proactively to veterinarians, other healthcare professionals and the public.
Priority 1.

Comments: None[3].

[3] see CVMP Work Plan 2026 section 1.3.1 (EMA/CVMP/210842/2025)
[4] Regulation (EU) 2019/6 Article 81(3)

5. Other input in European activities

5.1. Training for the network and knowledge building

Action: Revise EU network training centre (EU NTC) pharmacovigilance curriculum (EMA/694832/2016) in line with requirements of Regulation (EU) 2019/6 and Commission Implementing Regulation (EU) 2021/1281.
Priority 1. Start date: Q1 2024, Completion date: Q1 2026.

Comments: None.

Action: Organise, provide input to and participate in training for the regulatory network, including pharmacovigilance inspectors, in line with the veterinary pharmacovigilance curriculum for implementation of Regulation (EU) 2019/6.
Priority 1. Ongoing.

Comments: Training sessions will take into account the revision of guidance documents described above, with particular focus on signal management[5].

Action: Upon request, support the continued implementation of the HMA-EMA Joint Big Data strategy 2022-2027, specifically the use of real-world data sources and the establishment of a data quality framework within the domain of veterinary pharmacovigilance.
Priority 3.

Comments: Current support is provided through PhVWP-V members participating in the EU Veterinary Data Hub and engagement at Big Data Stakeholder forums.

5.2. European activities

Action: Contribute to Veterinary Medicine Safety Day 2026 (8 April 2026 (TBC)) and encourage and facilitate promotion and participation in the initiative.

Comments: None[5].

Action: Finalise infographic to raise awareness for reporting lack of expected efficacy for antiparasitic veterinary medicinal products to promote prudent and responsible use of antiparasitics in the EU.
Priority 2. Start date: ongoing, Completion date: Q2 2026.

Comments: In conjunction with CVMP Efficacy Working Party (EWP)[5].

Action: Provide responses to veterinary pharmacovigilance queries raised by CVMP, CMDv or Member States, as required.
Priority 1.

Comments: None[6].

Action: Provide contributions to CVMP and CMDv on relevant actions of the Joint EMA and Heads of Medicines Agency (Veterinary) (HMA-V) action plan on veterinary pharmacovigilance, as required.

[5] see CVMP Work Plan 2026 section 1.3.1 (EMA/CVMP/210842/2025)

Priority 1.

Comments: None[6].

6. Input in international activities (beyond VICH guidelines)

None.

7. Organisational issues

7.1. Adopted organisational document(s)

- Mandate, objectives, and rules of procedure for working parties under the quality, non-clinical, methodology, clinical and veterinary domains (EMA/299541/2025)
- Mandate, objectives and rules of procedure for the pharmacovigilance operational expert group on surveillance group (EMA/CVMP/PhVWP/519892/2024)
- Call for comments on VeDDRA (EMA/CVMP/123352/2004 – Rev.16)

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

- Finalise processes for support and management of the EU veterinary signal management process (EMA/CVMP/PhVWP/559490/2024) and risk-based monitoring process (EMA/CVMP/PhVWP/579052/2024).
  Priority 1.
- Develop process for support and management of targeted signal management processes in accordance with Article 81(3-6) of Regulation (EU) 2019/6.
  Priority 1

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

- N/A

[6] see CVMP Work Plan 2026 section 1.3.1 (EMA/CVMP/210842/2025)