15 January 2025
EMA/CVMP/PhVWP/274494/2024
Committee for Veterinary Medicinal Products (CVMP)

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

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

28-29 January*
26 February
25-26 March
23 April
20-21 May*
8-9 July
23-24 September*
29 October
25-26 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.

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Other meetings:

Workshops	Veterinary Good Pharmacovigilance Practice (VGVP) Joint Implementation Group (JIG) workshops to support implementation of Regulation (EU) 2019/6 (quarterly virtual meetings). Priority 1 (see CVMP Work Plan 2025 section 1.3.1 activity 2.3.3 and EMA/CVMP/SPG/223141/2024[1] section 2.3 activity 5). Focus groups (2) with veterinarians and healthcare professionals specialised in food-producing species (e.g. ruminants) and companion animals (TBC). Priority 2 (Q3-4 2025 (TBC) (see CVMP Work Plan 2025 section 1.3.1 activity 2.3.4 and EMA/CVMP/SPG/223141/2024[1] section 2.3 activity 4)).
Interested parties meeting	Annual joint PhVWP-V-PhV Inspectors Working Group (PhV IWG)[2] interested parties meeting with stakeholders. Priority 1 (21 May 2025 (TBC)) (see CVMP Work Plan 2025 section 1.3.1 activity 2.3.3 and 2.3.5 and EMA/CVMP/SPG/223141/2024[1] section 2.3 activities 3 and 5).
Training sessions	Please see section 5.

2. Guidelines

2.1. New EU guidelines

2.1.1. New guidance on post-authorisation measures to monitor safety and/or efficacy of novel therapy products under Annex II of Regulation (EU) 2019/6

Action:	Contribute to guidance on post-authorisation measures to monitor the safety and/or efficacy of specific novel therapy products according to the requirement in section V.1.1.6 of Annex II of Regulation (EU) 2019/6 for release for public consultation. Priority 1. Start date: Q1 2025, Completion date: Q4 2025.
Comments:	Activity led by CVMP novel therapies working party (NWTP). See CVMP Work Plan 2025 section 1.3.1 activity 2.3.2.

[1] Consolidated 3-year work plan for the veterinary domain (2025-2027) (EMA/CVMP/SPG/223141/2024)
[2] Meeting renamed to formalise the long-standing participation of the Pharmacovigilance Inspectors Working Group (PhV IWG) at PhVWP-V interested parties meetings.

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:	VeDDRA sub-group to conduct annual review. Priority 1. Start date: on-going, Completion date: Q2 2025.
Comments:	Deadline for comments: 1st March every year. Annual VeDDRA meeting: 1-2 April 2025 (TBC). Implementation in EudraVigilance Veterinary (EVV): 1st October every year.

2.2.2. Update VGVP module: Signal management (EMA/522332/2020)

Action:	Revise guidance in light of experience gained with Regulation (EU) 2019/6 and incorporate new signal management procedures to be developed following conclusions from pilot signal management expert group (P-SMEG) and including management of alerts related to pharmacovigilance data for release for public consultation. Priority 1. Start date: Q1 2025, Completion date: Q4 2025
Comments:	Pending outcome of P-SMEG initiative. See CVMP Work Plan 2025 section 1.3.1 activity 2.3.1 and EMA/CVMP/SPG/223141/2024[1] section 2.3 activity 1.

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: Q4 2025.
Comments:	See CVMP Work Plan 2025 section 1.3.1 activity 2.3.4 and EMA/CVMP/SPG/223141/2024[1] section 2.3 activity 4.

2.2.4. Update EudraVigilance Veterinary (EVV) best practice guide (BPG) (EMA/371192/2021)

Action:	Update BPG to incorporate new technical guidance on the use of the Union Veterinary Pharmacovigilance Database (specifically IRIS) to support signal management. Priority 1. On-going activity, subject to need NB. Completion date for incorporation of technical instructions for IRIS: Q1 2025.
Comments:	None.

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: TBD, Completion date: TBD.
Comments:	Pending outcome of P-SMEG initiative.

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).
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 best practice for use of the above systems. Priority 1.
Comments:	See CVMP Work Plan 2025 section 1.3.1 activity 2.3.1 and EMA/CVMP/SPG/223141/2024[1] section 2.3 activity 1.

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:	See CVMP Work Plan 2025 section 1.3.1 activity 2.3.1 and EMA/CVMP/SPG/223141/2024[1] section 2.3 activity 1.
Action:	Provide specialised scientific contribution and advice to CVMP and CMDv (including targeted signal management), 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: See CVMP Work Plan 2025 section 1.3.1 activity 2.3.1 and EMA/CVMP/SPG/223141/2024[1] section 2.3 activity 1.

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

Comments: None.

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

Comments: None.

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: Q2 2025.

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. Start date: Q2 2025, Completion date: Q4 2025.

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

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. This activity is partly reflected in EMA/CVMP/SPG/223141/2024[1] section 2.3 activity 2.

5.2. European activities

Action: Launch infographic for coordinated EU veterinary pharmacovigilance promotion and education for veterinarians.
Priority 1. Start date: Q1 2024, Completion date: Q1 2025.

Comments: Based on list of initiatives from January 2024 PhVWP-V break-out sessions (EMA/CVMP/PhVWP/277305/2024). The above activity takes into account input from the Federation of Veterinarians of Europe (FVE) (see CVMP Work Plan 2025

section 1.3.1 activity 2.3.4 and EMA/CVMP/SPG/223141/2024[1] section 2.3 activity 4).

Action: Finalise infographic to raise awareness for reporting lack of expected efficacy for antiparasitic veterinary medicinal products with CVMP Efficacy Working Party (EWP).
Priority 2. Start date: January 2024, Completion date: Q4 2025.

Comments: None.

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

Comments: None.

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.
Priority 1.

Comments: None.

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 the pharmacovigilance surveillance group[3] (superseding P-SMEG) – adopted in December 2024.

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

- Mandate, objectives and rules of procedure for the CVMP Pharmacovigilance Working Party (EMA/CVMP/PhVWP/133883/2004-Rev.3).
  Priority 1. Start date: Q3 2024, Completion date Q1 2025
- Finalise processes for support and management of the following:
  - EU veterinary signal management procedures (NB document title to be confirmed). Priority 1.

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

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

[3] NB name for group to be determined

- Guidance on considerations for requesting post-marketing surveillance studies under Regulation (EU) 2019/6 Article 76(3).