16 December 2022
EMA/CVMP/PhVWP/593990/2022
Committee for Veterinary Medicinal Products (CVMP)

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

Chairpersons	**Status**
Chair: E. Dewaele Vice-chair: E. Bégon	Adopted by CVMP in December 2022

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

Month	**General**	**Product surveillance specific meetings (virtual)**
January	24-25	
February		22
March	28-29	
April		26
May	23-24	
June		14
July	4-5*	
August		30
September	26-27	
October		25
November	28-29*	
December		19

* Virtual meetings; NB March meeting may be virtual pending agenda content.
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). Focus group with veterinarians and healthcare professionals specialised in food-producing species: poultry and aquaculture (May and October 2023 (TBC)).
Interested parties meeting	Annual PhVWP-V interested parties meeting with stakeholders (27 September 2023 (TBD)).
Training sessions	Please see section 5.

2. Guidelines

2.1. New EU guidelines

2.1.1. New guidelines on veterinary good pharmacovigilance practice (VGVP) to support application of Commission Implementing Regulation (EU) 2021/1281 and responsibilities under Article 79 of Regulation (EU) 2019/6

Action:	Finalise (Q2 2023) guidance on regulatory review procedure for veterinary pharmacovigilance communication following public consultation in 2022. Subsequently develop guidance on post-marketing surveillance studies for release for public consultation (Q3 2023).
Comments:	None.

2.1.2. Develop guidance on methodology to collate, analyse and communicate information about the incidence of adverse events

Action:	Develop methodology to collate, analyse and communicate information about the incidence of adverse events using sales of veterinary medicinal products (VMPs) reported to the Union Product Database (UPD) (Q4 2023).
Comments:	None.

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 reactions in animals and humans to veterinary medicinal products (EMA/CVMP/10418/2009)

Action:	VeDDRA sub-group to conduct annual review (18 April 2023 (TBC)).
Comments:	Deadline for Comments: 1st March every year. Implementation in EudraVigilance Veterinary (EV): 1st October every year.

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

Action:	Update VGVP module subject to need, taking into account supplementary guidance provided in the questions and answers (Q&A) document under development in 2022 (Q2 2023).
Comments:	None.

2.2.3. VGVP module: Collection and recording of adverse events for veterinary medicinal products appendix: EV best practice guide (EMA/371192/2021)

Action:	Update guidance subject to need (throughout 2023).
Comments:	None.

2.2.4. VGVP module: Signal Management (EMA/522332/2020)

Action:	Update VGVP module subject to need, taking into account supplementary guidance provided in the questions and answers (Q&A) document under development in 2022 (Q2 2023).
Comments:	None.

2.3. VICH guidelines

2.3.1. VICH pharmacovigilance guidelines: GL30: controlled list of terms; GL35: electronic standards for transfer of data and GL42: data elements for submission of adverse event reports

Action:	Review and adopt the controlled list of terms.
Comments:	Reviewed annually.

2.3.2. VICH pharmacovigilance guidelines GL24 and GL29

Action:	Provide input to the VICH pharmacovigilance expert working group (EWG) to align GL24 and GL29 to address practical implementation in different VICH regions in particular for the implementation of Regulation (EU) 2019/6.
Comments:	The VICH Steering Committee agreed this Action: at its 31st meeting on the basis of a concept paper for minor revisions to GL24 and GL29. Lead for activity: EU regulatory representative.

2.3.3. VICH concept paper on pharmacovigilance signal detection and signal management practices

Action:	Provide input taking into account the guideline on VGVP in particular in relation to signal management.
Comments:	The concept paper should also address improving transparency and communication between regions on signals under investigation. Lead for activity: EU regulatory representative.

3. Electronic systems used for pharmacovigilance

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

Action:	Upon request, provide input on the development of additional functionalities for EVV, IRIS and UPD. Additionally, provide guidance to stakeholders related to day-to-day best practice for use of the above systems.
Comments:	None.

3.2. EV data warehouse

Action:	Review and propose additional queries necessary to improve signal detection and manage the corresponding regulatory procedures.
Comments:	None.

4. Medicinal product-specific activities

4.1. Pre-authorisation activities

Action:	Specialised scientific contribution related to pharmacovigilance to be provided to the CVMP and CMDv, upon request, including recommendations for regulatory measures in relation to risk management.
Comments:	None.

4.2. Evaluation and supervision activities

Action:	On behalf of CVMP and CMDv, continuously evaluate pharmacovigilance data of veterinary medicinal products currently on the basis of the recommendations from the pilot signal management expert group (P-SMEG) to identify potential signals and/or the need for further investigation and recommendations for regulatory action.

Comments: The outcome of signal management evaluation is discussed at dedicated product surveillance specific meetings (see section 1).

Action: Develop potential pharmacovigilance profile concept, summarising the latest status of pharmacovigilance data under evaluation for product users (in particular veterinarians) on the basis of data available in the electronic systems.

Comments: This activity will also entail identification of potential improvements to electronic system requirements related to pharmacovigilance.

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

Comments: None.

Action: Provide input to the pharmacovigilance inspectors working group (PhV IWG) and pharmacovigilance inspections teams, upon request.

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.

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.

Comments: None.

Action: Provide input to and participate in training in line with the veterinary pharmacovigilance curriculum including training sessions on VGVP (e.g. advanced signal management, adverse event collection and recording) for implementation of Regulation (EU) 2019/6

Comments: Q3-Q4 2023 (TBD).

5.2. Other input in European activities

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

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.
Comments:	None.

6. Input in international activities (beyond VICH guidelines)

None.

7. Organisational issues

7.1. Mandate

- Consider the need to refine the EU Veterinary Pilot Signal Management Pilot Expert Group's (P-SMEG's) terms of reference pending the review of the P-SMEG's performance and decision on the future of the P-SMEG (Q4 2023).

7.2. Procedural documents

- Finalise processes for support and management of the following:
  - EU Veterinary Pilot Signal Management Expert Group (P-SMEG) regulatory review (process description (EMA/112890/2022));
  - veterinary pharmacovigilance information exchange (pending development of EV functionality for management of pharmacovigilance alerts and non-urgent information (NUI));
  - regulatory review of veterinary pharmacovigilance communication; and
  - post-marketing surveillance studies requested by CVMP or CMDv.