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Committee for Medicinal Products for Veterinary Use (CVMP)

Work plan for the Committee for Medicinal Products for Veterinary Use (CVMP) Pharmacovigilance Working Party (PhVWP-V) 2020

Chairpersons	**Status**
Chair: E. Dewaele Vice-chair: E. Bégon	Adopted by CVMP in January 2020

1. Meetings scheduled for 2020

Plenary meetings are planned for the following dates:

- 28-29 January 2020
- 24-25 March 2020
- 12-13 May 2020
- 7-8 July 2020
- 22-23 September 2020
- 24-25 November 2020

The above-mentioned dates may be modified as needed. Additional virtual meetings may be organised ad-hoc to respond to time-sensitive requests on products and to progress guidelines, as required.

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2. Guidelines

2.1. New EU guidelines

Action: Pharmacovigilance Working Party (PhVWP-V)

2.1.1. Further development and improvement of methodologies for signal detection/surveillance

Leading group	Pharmacovigilance Working Party (PhVWP-V)/Secretariat
Target date	Ongoing activity throughout 2020
Comments	Improvements to develop methodology for signal detection taking into consideration potential strategy for future organisation of surveillance of veterinary medicinal products across the European Union considered at bi-monthly Adobe and PhVWP-V plenary meetings.

2.1.2. Determine the need for and initiate development of future guidance documents required to support implementation of implementing measures under Article 77(6) of Regulation (EU) 2019/6 on veterinary medicinal products regarding good pharmacovigilance practice

Leading group	Pharmacovigilance Working Party (PhVWP-V) (to be determined (TBD))
Target date	Expected start date: June 2020; completion date for entry into force of NVR in January 2022 following pubic consultation period
Comments	Pending mandate from Committee for Medicinal Products for Veterinary Use (CVMP) and the Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMDv) (TBD).

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)

Leading group	VeDDRA sub-group
Target date	Deadline for comments: 1 March every year. Annual VeDDRA review scheduled for 29 April 2020. Implementation in EudraVigilance Veterinary (EVVet): 1 October every year
Comments	None.

2.2.2. Determine the need for and initiate revision of existing guidance documents to support execution of implementing measures under Article 77(6) of Regulation (EU) 2019/6 on veterinary medicinal products regarding good pharmacovigilance practice

Leading group	Pharmacovigilance Working Party (PhVWP-V) (TBD)
Target date	Expected start date: June 2020; completion date for entry into force of NVR in January 2022 following pubic consultation period
Comments	Pending mandate from Committee for Medicinal Products for Veterinary Use (CVMP) and the Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMDv) (TBD).

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	Annual review of controlled list of terms and to review the proposed 'Acknowledgment message' standard
Comments	Adopted at step 7of the VICH process.

2.3.2. VICH Electronic standards implementation expert working group (ESI-EWG) on proposed solutions to specific elements of regional disharmonisation hereby identifying specific parts of the VICH pharmacovigilance guidelines that would require updating.

Action	Provide input to the ESI-EWG to investigate and propose specific solutions and necessary updates to the current VICH pharmacovigilance guidelines taking into account elements of regional disharmonisation as identified by industry
Comments	Discussions framed by the current legislative requirements implemented in the United States (US) as well as the ongoing discussions for the implementation of Regulation (EU) 2019/6.

3. Medicinal product-specific activities

3.1. Pre-authorisation activities

- Specialised scientific contribution related to pharmacovigilance to be provided to Committee for Medicinal Products for Veterinary Use (CVMP) and Member States upon request,

including recommendations for regulatory measures in relation to risk management.

Comments: None.

3.2. Evaluation and supervision activities

- Continuous evaluation of pharmacovigilance data for centrally and nationally authorised veterinary medicinal products on behalf of CVMP and Member States, respectively, to identify potential signals and/or the need for further investigations and recommendations for regulatory action.
- Publish the veterinary pharmacovigilance annual bulletin, which summarises data collected and pharmacovigilance activities from the preceding year (Q1-2 each year).
- Specialised scientific contribution and advice to be provided to CVMP or Member States, upon request, on marketing authorisation or post-authorisation evaluation procedures, including urgent union pharmacovigilance procedures, and identification and evaluation of potential safety issues and proposing recommendations for risk management measures for these.
- 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.

4. Input in European activities

4.1. Training for the network and knowledge building

- Provide veterinary training in line with the veterinary pharmacovigilance curriculum (pending Agency Brexit Reactivation Plan (BRP) including:
    - Organisation of an assessor training on processing adverse event reports (AERs) in EVWEB, veterinary signal management methodology and use of EudraVigilance Veterinary (EVVet) data warehouse (25-26 March 2020).
    - Bi-monthly virtual training meetings to support assessors on the use of the DWH and signal detection queries. Provide advice/active participation for other training sessions for assessors, as required.

4.2. Other input in European activities

- Provide responses to pharmacovigilance queries raised by CVMP, CMDv or Member States, as required.
- Provide contributions to CVMP on relevant actions of the Joint EMA and Heads of Medicines Agency (Veterinary) (HMA-V) action plan on pharmacovigilance, as required.

5. Input in international activities (beyond VICH guidelines)

None.

6. Contribution to dialogue and engagement with stakeholders and external parties

6.1. Workshops

- Focus group with veterinarians/healthcare professionals specialised in food-producing species: poultry (10-11 November 2020(TBC)) and fish (14-15 October 2020 (TBC)).

6.2. Other activities with stakeholders and external parties

- Annual PhVWP-V interested parties meeting with stakeholders (23 September 2020 (TBC)).

7. Organisational issues

7.1. Mandate

- Upon request from CVMP and CMDv and in collaboration with the Committees, reflect on principles for future mandate in line with new reporting lines and responsibilities in preparation for implementation of NVR as of January 2022.