30 January 2018
EMA/CVMP/PhVWP/384293/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Work plan for the CVMP Pharmacovigilance Working Party (PhVWP-V) 2018

Chairpersons	Status
Chair: E. Dewaele Vice-chair: E. Bégon	Adopted by CVMP in December 2017

The activities outlined in the work plan for 2018 have been agreed considering the respective business priorities, as well as the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.

1. Meetings scheduled for 2018

Plenary meetings:

5 (per meeting: 28 members, 1 day)

23-24 January 2018

20-21 March 2018

29-30 May 2018

25-26 September 2018

20-21 November 2018

Other meetings:

Topic virtual meetings	Pharmacovigilance surveillance meeting July 2018
Drafting / Expert groups	5 physical meetings in the margins of plenary meetings as needed (4-5 participants)
Workshop / Focus group	1 focus group with specialised veterinarians/healthcare professionals for poultry on promotion of pharmacovigilance to improve reporting and provision of feedback

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Training	1 for assessors (advanced EudraVigilance Veterinary (EVVet), data warehouse (DWH)/signal detection) Bi-monthly virtual training meetings to support assessors on the use of DWH and the signal detection queries.

Virtual meetings are mainly regarded as complementary to plenary meetings. However, if feasible and depending on the workload, one of the plenary meetings could be replaced by a virtual meeting.

2. Product related issues

Undertakings on behalf of or upon request from CVMP

On behalf of the Committee for Medicinal Products for Veterinary Use (CVMP), the Pharmacovigilance Working Party (PhVWP-V) systematically and continuously reviews pharmacovigilance data for centrally authorised veterinary medicinal products to identify potential problems and/or the need for further investigations and recommendations for regulatory action.

Upon request, the PhVWP-V will review and advise on periodic safety update reports (PSURs), referral procedures and other specific scientific requests related to pharmacovigilance of products, including recommendations for regulatory measures in relation to risk management. Furthermore the PhVWP-V will address any specific scientific requests relating to veterinary pharmacovigilance in general.

The PhVWP-V is also expected to have a role in the supervision and pre-evaluation of the data to be released to healthcare professionals and the general public.

The following table provides the expected number of contributions (number of involvements) per year for product assessment, including pre- and post-authorisation issues, in addition to the ongoing surveillance of centrally authorised products.

Expected contribution in scientific advice	Expected contribution in product assessment
0	0-1

Undertakings on behalf of or upon request from Member States

On behalf of the Member States, the PhVWP-V also reviews pharmacovigilance data for nationally authorised veterinary medicinal products, including products authorised via the mutual recognition or the decentralised procedure.

Upon request, the PhVWP-V will review and advise on PSURs, CMD(v) referral procedures and other specific scientific requests related to pharmacovigilance of products, including recommendations for regulatory measures in relation to risk management. Furthermore the PhVWP-V will address any specific scientific requests relating to veterinary pharmacovigilance in general.

The PhVWP-V is also expected to have a role in the supervision and pre-evaluation of the data to be released to healthcare professionals and the general public.

The following table provides the expected number of contributions (number of involvements) per year for product assessment, including pre- and post-authorisation issues.

Expected contribution in scientific advice	Expected contribution in product assessment
N/a	3-4

EVVet and the EVVet DWH will be used for the systematic surveillance of adverse events across the European Union. The increased availability of product data in a central database (EU veterinary medicinal product database[1] (EU VMPD)) will facilitate and enhance surveillance on an EU-scale which, in particular, will be of benefit to smaller Member States with limited resources.

3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

3.1.1. 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: Annual review of the standard lists used for reporting adverse events by the VeDDRA sub-group with industry participation and involving VICH partners (Q3 2018). Additionally, input will be given into Controlled Term Lists for the European Union Telematics Controlled Terms (EUTCT) project (as contained within the EU Telematics Master Plan endorsed by the European Medicines Agency Management Board and Heads of Medicines Agency (HMA)) as necessary.

Comments: Revision of existing guidance. Deadline for comments: 1 March every year. Annual VeDDRA review scheduled for April 2018. Implementation in EVVet: 1 October every year.

N.B. The update of VeDDRA will be suspended for 2019, due to reduction of Agency activities as part of the Brexit Business Continuity Plan.

3.1.2. Revised recommendation for the basic surveillance of EudraVigilance Veterinary (EVVet) data for centrally authorised products (CAPs) (EMA/CVMP/PhVWP/471721/2006-Rev.1)

Action: Finalise revised recommendation (Q2 2018).

Comments: Following public consultation (Q2 2017) and taking into account experience gained during pilot to implement the revised recommendation (pilot: Q3 2017 – Q1 2018).

3.2. Guidance documents to be released for consultation

None.

3.3. New topics/concept papers to be prepared

3.3.1. Promotion of pharmacovigilance reporting

Action: Develop concept for strategy for handling promotion of pharmacovigilance reporting and providing feedback to reporters on food producing animals (Q2 2018).

Comments: Pending further input from HMA-V ESS and stakeholders i.e. veterinarians/healthcare professionals, in particular specialised in food-producing species, via a series of focus

[1] http://vet.eudrapharm.eu

groups to establish potential collaborative network and continue dialogue with specialist stakeholders to identify gaps and potential opportunities, including practical measures for improving pharmacovigilance reporting and providing feedback to reporters. The first focus group will consider poultry (Q3 2018) and future focus groups will address other food-producing species groups.

3.3.2. Pharmacovigilance communication

Action: Reflect on how to improve communication on Pharmacovigilance issues (Q3-Q4 2018).

Comments: None.

4. VICH guidelines and international standards activities

4.1. Review of 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: None.

4.2. Support the work of the 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: The discussions will be framed by both the current implemented United States (US) legislative requirements as well as the draft proposals foreseen as part of the upcoming revision of the EU legislative framework.

5. EU regulatory activities

5.1. For CVMP

5.1.1. Veterinary pharmacovigilance public bulletin

Action: Publish the veterinary pharmacovigilance annual bulletin, which summarises data collected in 2017 and pharmacovigilance activities from that year (Q1 2018).

Comments: The annual summary has a specific focus on CAPs.

5.1.2. Targeted analysis of anti-parasitic adverse event data

Action: Conduct an active substance class-based analysis of anti-parasitic CAPs including developing methodology and undertaking a critical evaluation of the analytical tools for best use of the data available in EVVet (Q4 2018).

Comments: Pending endorsement of mandate by CVMP.

5.1.3. CVMP pharmacovigilance issues

Action: At the request of CVMP, provision of advice on individual pharmacovigilance issues concerning CAPs for identification and evaluation of potential safety concerns and risk management relating to these.

Comments: Advice will be provided as necessary.

5.2. For Member States

5.2.1. Member States' pharmacovigilance issues

Action: At the request of Member States (including CMDv), provision of advice on individual pharmacovigilance issues on the basis of information provided concerning NAPs for identification and evaluation of potential safety concerns and risk management relating to these. In addition, advice may also be requested regarding the new EU legislative proposals, when available.

Comments: Advice will be provided as necessary.

5.3. Assessor training

5.3.1. Veterinary training curriculum

Actions: Provide veterinary training in line with the Pharmacovigilance curriculum (EVVet Data Warehouse) Provide advice/active participation for other training sessions for assessors, as required.

Comments: None.

5.3.2. EVVet Data Warehouse and signal detection

Action: Bi-monthly virtual training meetings to support assessors on the use of DWH and the signal detection queries. Provide advice/active participation for other training sessions for assessors, as required.

Comments: This ongoing activity is distinct from the advanced EVVet training course (see section 1 Other meetings (training)).

6. Activities with external parties

6.1. Meetings with interested parties

One with pharmaceutical industry, public health stakeholders, learned societies.

6.2. Regulatory authorities outside the EU

None foreseen.

7. Organisational matters

7.1. List of adopted organisational documents

Mandate, objectives and rules of procedure for the CVMP Pharmacovigilance Working Party (EMA/CVMP/PhVWP/133883/2004-Rev.3).

7.2. List of organisational documents to be developed/revised in the forthcoming 2 years

Mandate, objectives and rules of procedure for the CVMP Pharmacovigilance Working Party (EMA/CVMP/PhVWP/133883/2004-Rev.3).

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

Development of concept paper outlining principles and tools for surveillance of NAPs in line with the methodology outlined in revised recommendation for the basic surveillance of EVVet data for centrally authorised products (CAPs).