EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Veterinary Medicinal Products (CVMP)

Mandate, objectives, and rules of procedure for the Committee for Veterinary Medicinal Products (CVMP) Pharmacovigilance Working Party (PhVWP-V)

1. General considerations

Since 1995, the Committee for Veterinary Medicinal Products (CVMP) Pharmacovigilance Working Party (PhVWP-V) has provided advice on the safety of veterinary medicinal products authorised in the European Union (EU) to CVMP and Member States. Article 139(5) of Regulation (EU) 2019/6 provides that CVMP shall establish a standing working party for pharmacovigilance and this role will be conducted by the PhVWP-V. The PhVWP-V's remit includes evaluating potential signals in pharmacovigilance arising from the Union pharmacovigilance system, proposing the options for risk management to CVMP and the coordination group for mutual recognition and decentralised procedures for veterinary medicinal products (CMDv) and coordinating the communication about veterinary pharmacovigilance between the competent authorities and the Agency.

2. Mandate and objectives

The key responsibilities of the PhVWP-V include, but are not limited to, the following:

- evaluating potential signals in veterinary pharmacovigilance arising from the Union pharmacovigilance system or other sources and proposing options for risk management to CVMP and CMDv (Article 139(5));
- coordinating communication about veterinary pharmacovigilance between the competent authorities and the Agency (Article 139(5));
- coordinating the targeted signal management process for a given veterinary medicinal product or a group of veterinary medicinal products and allocation of tasks in relation to this (Article 81(3));
- providing advice to the regulatory network[1] on any question relating to veterinary pharmacovigilance issues, including, but not limited to:
    - signal management;
    - design and evaluation of specific veterinary pharmacovigilance data collection and post-marketing surveillance studies (Article 76(3); Article 76(4));

[1] CVMP, the CMDv or the competent authorities

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- Union referral procedures related to veterinary pharmacovigilance (referred to in Articles 82 and 129(3))
- wording for veterinary medicinal product information for the sections related to pharmacovigilance, for specific products or groups of products;
- veterinary pharmacovigilance systems for Member States or for marketing authorisation holders, when appropriate;
- communication on veterinary pharmacovigilance issues; and
- risk management plans for novel therapy veterinary medicinal products to detect early or delayed signals of adverse reactions, prevent clinical consequences of such reactions, to ensure timely treatment and to gain information on the long-term safety and efficacy of such products (Section V.1.1.6 of Annex II of Regulation (EU) 2019/6).

- preparing, reviewing and updating veterinary pharmacovigilance guidance and procedures for its implementation (including, but not limited to procedures referred to in Article 79(1) and Article 79(5));
- providing advice on pharmacovigilance issues to CVMP for VICH[2] or in the framework of international cooperation;
- providing input for preparation or follow-up of veterinary pharmacovigilance inspections;
- providing advice on the harmonisation of terminology for adverse event reporting (e.g. VeDDRA[3]) and coding of veterinary medicinal products and adverse events;
- providing advice on release of veterinary pharmacovigilance data to stakeholders and the general public;
- facilitating and providing veterinary pharmacovigilance workshops and training;
- liaising with interested parties (e.g. industry associations for veterinary medicinal products, veterinarians, pharmacists, learned societies);
- advising on requirements for veterinarians and other healthcare professionals in respect of the reporting of adverse events (Article 79(2));
- facilitating and supporting initiatives to encourage and improve reporting of adverse events by veterinarians, other healthcare professionals and the general public within the Union; and
- proposing criteria for the identification of the categories of veterinary medicinal products (VMPs) subject to risk-based monitoring.

3. Composition and rules of participation

The PhVWP-V members are experts included on the European list of accredited experts referred to in the second subparagraph of Article 62(2) of Regulation (EC) No 726/2004, with relevant expertise indicated. In view of the specific mandate and responsibilities of the PhVWP-V, which may involve both centrally and non-centrally authorised veterinary medicinal products, the PhVWP-V is composed of one member per Member State, nominated by CVMP members and endorsed by the CVMP, based on their expertise and capacity to actively contribute to the work of the PhVWP-V. The PhVWP-V, to

[2] International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
[3] Veterinary Dictionary for Drug Related Activities

complement its expertise, may appoint up to five additional members chosen on the basis of their specific scientific competence in surveillance and signal management. Experts are nominated by CVMP members, following a call for nominations circulated by the Agency, and agreed by the CVMP.

To ensure that the mandate and objectives of the PhVWP-V can be accomplished the following areas of expertise are considered necessary:

- involvement in a pharmacovigilance system at national level either in a regulatory authority or at a university;
- practical veterinary experience;
- epidemiology and/or pharmacoepidemiology;
- pharmacology and/or toxicology;
- immunological medicinal products for veterinary use;
- knowledge of regulatory requirements and procedures.

Additional expertise in, for example, residues, environmental risk assessment, biostatistics and user safety (human adverse events) might be required occasionally in relation to specific topics. In cases where such expertise is not already available amongst the members of the PhVWP-V additional European experts may be invited to participate in the work related to those specific topics, in accordance with Article 21 of the CVMP Rules of Procedure.

Membership of a working party implies a commitment to participate actively in the work of that working party and to regularly participate in the meetings as well as to communicate working party agreements and discussions effectively within their national agencies. Members should also adhere to the established routines associated with plenary meetings, including adherence to the established timings of mailings and preparation and responsibility of proposed agenda items.

A member may nominate a replacement to participate in those exceptional cases where they are unable to attend a meeting.

Members wishing to bring additional experts should notify the EMA secretariat in advance to the meeting, subject to the agreement of the chair.

Representatives of the European Commission and the EMA may attend the meetings of the PhVWP-V.

Observers from accession countries and mutual recognition agreement partners may have standing invitations to participate at PhVWP-V meetings. Observers from other non-EEA countries may participate with the agreement of the chair, the EMA, CVMP and CMDv chairs.

Specific confidentiality rules will apply to observers.

4. PhVWP-V operational expert group on surveillance

The PhVWP-V shall establish an operational expert group on surveillance to support the PhVWP-V in the evaluation of the results and outcomes of signal management and overall surveillance of veterinary medicinal products. The mandate, objectives and rules of procedure of the PhVWP-V operational expert group on surveillance shall be adopted by the PhVWP-V and shall be reviewed at least every three years.

As the PhVWP-V operational expert group on surveillance is established under the governance of the PhVWP-V, any requests to the PhVWP-V operational expert group on surveillance must be adopted by the PhVWP-V.

The recommendations of the PhVWP-V operational expert group on surveillance shall be transmitted to the PhVWP-V for adoption.

5. Meeting frequency

In accordance with the adopted work plan, the PhVWP-V shall meet at least 6 times per year. A proportion of these meetings can be held virtually, and members can participate in the meeting through a remote connection. Extraordinary meetings may be convened, if considered necessary and feasible to organise at short notice.

The PhVWP-V shall organise at least once a year, with additional sessions organised as necessary, a dedicated consultation on the revision of the standard terminology for electronic reporting of adverse events (the VeDDRA list), for which the PhVWP-V may liaise with the (external) stakeholders/interested parties it deems appropriate.

The PhVWP-V operational expert group on surveillance shall meet according to the frequency specified in its mandate, objectives and rules of procedure (EMA/CVMP/PhVWP/519892/2024)

The dates of the above meetings shall be included in the work plan of the PhVWP-V.

6. Duration of activity (in the case of temporary working parties)

Not applicable.

7. Rules of procedure

7.1. Mandate and work plan

1. The mandate, objectives and rules of procedure of the PhVWP-V shall be adopted by CVMP. It shall be reviewed, at least every three years, in accordance with Article 18(4) of the CVMP Rules of Procedure.
2. The PhVWP-V shall prepare an annual work plan with input from CMDv and CVMP. The work plan shall be adopted by CVMP, shall be reviewed at least annually (and updated as necessary) and will be made publicly available, in accordance with Article 18(4) of the CVMP Rules of Procedure.

7.2. Election of chair and vice chair

1. The chair and vice chair of the PhVWP-V shall be elected from amongst its members by the members of CVMP, each for a term of three years, which may be renewed once.
2. Nominations should be submitted in writing to the EMA secretariat no later than by the start of the CVMP meeting at which election is to take place.
3. Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.
4. The election of the chair and the vice chair shall follow the same procedure as that for the election of the chair of the Committee as stated in Article 3, paragraphs 1 to 4, of the CVMP Rules of Procedure.

7.3. Responsibilities of chair

The chair is responsible for the efficient conduct of the business of the PhVWP-V and shall in particular:

- plan the work of the PhVWP-V together with the EMA secretariat;
- monitor, together with the EMA secretariat, that the rules of procedure are respected;
- ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the PhVWP-V;
- aim to achieve consensus on issues discussed by the PhVWP-V;
- decide, in exceptional cases, when a vote is necessary;
- ensure, together with the PhVWP-V and the secretariat, the regulatory and scientific consistency of the PhVWP-V's recommendations;
- co-ordinate, together with the EMA secretariat, the work of the PhVWP-V with that of the other relevant working parties of the Agency; and
- report on the activities of the PhVWP-V to CMDv and CVMP or other working party as appropriate.

The vice chair will deputise for the chair when the latter is unable to chair either all or part of the PhVWP-V meeting. On such occasions the chair will seek the agreement of the vice chair as early as possible, prior to the meeting and the EMA secretariat shall be informed immediately.

7.4. Organisation of meetings and reporting arrangements

The dates of meetings are decided on an annual basis in consultation with the PhVWP-V, CMDv and CVMP.

1. The meetings will be held in English.
2. When a member of the PhVWP-V is unable to participate at a meeting, part of a meeting, or a discussion topic, e.g. due to conflict of interest, they must inform the EMA secretariat in advance in writing.
3. The draft agenda for every meeting will be written in English and shall be circulated, together with the related documents, by the EMA secretariat, in consultation with the chair, at least 14 calendar days before the meeting. CMDv and CVMP will receive a copy of the agenda.
4. Draft recommendations can, after approval of the chair, be submitted by the EMA secretariat to the PhVWP-V for adoption by written procedure. However, such written procedures should be restricted to measures required to be taken between scheduled meetings. Draft recommendations are addressed to members of the PhVWP-V, who may raise objections within a specified time-period, to be established in agreement with the chair. The secretariat shall present a full report on the outcome of the written procedure at the following meeting of the PhVWP-V. In the case of serious objections, the chair decides whether the written procedure should be suspended and the adoption of the draft recommendation postponed to the next meeting of the PhVWP-V.
    - Recommendations on veterinary pharmacovigilance matters from the PhVWP-V shall be transmitted to
    - For guidelines and other documents: to CMDv for endorsement and CVMP for adoption.
5. CVMP and/or CMDv, as appropriate, for their consideration and any necessary action in accordance with the rules governing the CVMP and/or CMDv, respectively.

6. When considered appropriate by the PhVWP-V, oral presentations by companies can be made during PhVWP-V meetings on matters directly related to its responsibilities and activities, following agreement of CMDv and CVMP, respectively, for non-centrally and centrally authorised veterinary medicinal products.
7. The summary record is considered confidential and will be written in English. It will be circulated to CMDv and CVMP at their next plenary meetings.
8. The chair will be invited to attend plenary meetings of CMDv and CVMP to report on the activities on the PhVWP-V and ensure liaison with CMDv and CVMP.

7.5. Drafting groups

When further consideration is required in order to prepare proposals on specific topics, the PhVWP-V may convene drafting groups constituted of members of the PhVWP-V or experts, as appropriate. The drafting group will report to the PhVWP-V.

7.6. Participation of experts in meetings

1. When necessary, the PhVWP-V may avail itself of the services of experts in specific scientific or technical fields. Such experts shall have proven experience in the assessment of medicinal products or in their field of expertise and be included in the European experts list. Where appropriate members from animal and/or public health organisations or other healthcare professionals may act as experts.
2. The names of these experts shall be notified to the EMA secretariat before the meeting that they are due to attend.

7.7. Guarantees of independence

1. The members of the PhVWP-V and experts referred to above shall not have any direct interests in the pharmaceutical industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner and shall make an annual declaration of their financial and other interests. All declarations of interests that could relate to the pharmaceutical industry shall be entered in a register held by the Agency and shall be made available to the public.
2. Members of the PhVWP-V and experts attending these meetings shall declare at the beginning of each meeting any specific interests which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be recorded.
3. The specific provisions for handling declaration of interests and confidentiality undertakings as defined in the EMA policy on the handling of declarations of interests of scientific committees, members and experts, adopted by the Management Board (EMA/136875/2022) are applicable to members of the PhVWP-V and experts participating in the activities of the PhVWP-V.

7.8. Code of conduct

Members of the PhVWP-V and experts participating in the EMA's activities shall abide by the principles set out in the 'EMA Code of Conduct' (EMA/385894/2012-Rev. 1).

7.9. EMA secretariat

Under the authority of the Executive Director, the EMA secretariat shall provide technical, scientific, and administrative support to the PhVWP-V. This includes the following:

- provide technical and scientific support to rapporteurs (guidance documents) and other members of the PhVWP-V;
- provide legal, regulatory and scientific support to the PhVWP-V;
- prepare and co-ordinate the work of the PhVWP-V in consultation with the chairs;
- ensure, if appropriate, that the periods laid down by Union legislation for the adoption of the opinions are complied with;
- organise meetings of the PhVWP-V ensuring timely circulation of meeting documents;
- facilitate the necessary contacts between the PhVWP-V, CVMP, CMDv and Member States;
- ensure adequate co-ordination of the work conducted within the PhVWP-V, the scientific Committee(s) and other concerned working parties and/or scientific advisory groups;
- contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the documents/recommendations of the PhVWP-V in co-operation with the chairs;
- prepare the agenda, table of actions and minutes of the meetings of the PhVWP-V in consultation with the chairs;
- communicate when necessary any CMDv or CVMP recommendations relevant to the PhVWP-V to interested parties;
- support the experts in the overall use and access to the Union veterinary pharmacovigilance database; and
- contribute to the identification of experts.

7.10. Contacts with interested parties

1. Where relevant, the PhVWP-V will establish contacts, on an advisory basis, with parties concerned with the use of veterinary medicinal products.
2. Draft guidance and general regulatory developments will be subject to public consultation of all interested parties.
3. When considered appropriate by the PhVWP-V, oral presentations by interested parties can be made during PhVWP-V meetings in earlier stages of development of guidance. The PhVWP-V may also meet with interested parties to discuss general matters or specific scientific issues with the agreement of CMDv and/or CVMP under specific conditions to be agreed by CMDv and/or CVMP, respectively.
4. In any case, the PhVWP-V shall neither conduct any deliberations nor reach any formal decisions in the presence of members of interested parties.
5. Before any consultation session, interested party representatives and PhVWP-V members will communicate to the EMA secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the PhVWP-V chair and circulation by the EMA secretariat.

7.11. General provisions

1. The Members of the PhVWP-V as well as observers and all experts shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by individual professional secrecy.
2. When participating in international or other *fora*, members of the PhVWP-V should adhere to the principles described in the 'Policy on scientific publication and representation for European Medicines Agency's scientific committees and their members' (EMA/231477/2005 Rev. 1).
3. When participating in international or other *fora* not specifically on behalf of the PhVWP-V, members shall make clear that the views expressed are their own views and not those of the PhVWP-V.