



## **MANDATE, OBJECTIVES AND RULES OF PROCEDURE FOR THE CVMP PHARMACOVIGILANCE WORKING PARTY (PhVWP-V)**

### **I. GENERAL CONSIDERATIONS**

The mission of the PhVWP-V is to provide advice on the safety of veterinary medicinal products authorised in the European Union and the investigation of adverse drug reactions, to enable effective identification, assessment, management and communication of risk to animal and/or public health, at any phase in the product life cycle. The CVMP agreed on 20 June 1995 for the creation of a Pharmacovigilance Working Party focused on the development of pharmacovigilance guidelines and on the provision of advice in relation to pharmacovigilance issues for specific veterinary medicinal products, in particular for centrally authorized veterinary medicinal products. The Member States requested in 2006 to re-confirm the role of the PhVWP-V for the overall surveillance of the adverse reactions of veterinary medicinal products authorised in the European Union in view of the legislative requirements for electronic reporting and the centralisation of the adverse reaction data for all veterinary medicinal products in one EU database (EudraVigilance Veterinary (EVVet)). The PhVWP-V has now a dual role in advising the CVMP as well as the Member States, ensuring the best use of pharmacovigilance resources available in the European Union as per the provisions foreseen in Regulation No 726/2004 Art.53. The responsibility for decision and action for centrally authorised products remains on CVMP and the responsibility for decision and action for products authorised by the national, mutual recognition or decentralised procedure remains on the Member States, and the reporting lines from PhVWP will reflect this.

### **II. MANDATE AND OBJECTIVES**

The key responsibilities of the PhVWP-V are:

- Evaluation of potential signals arising from spontaneous reporting of suspected adverse reaction reports to the EudraVigilance Veterinary database or other sources.
- Provision of advice to manage the risks identified in relation to signals generated by the data within the EudraVigilance Veterinary database or other sources. The advice includes options for regulatory action and/or risk management plans when appropriate.
- On request of the CVMP<sup>1</sup> or the Member States, to provide advice on issues related to pharmacovigilance, in particular but not limited to:
  - Periodic safety update reports,
  - Safety studies or signals generated during clinical trials for products under investigation in the pre- or post-authorisation phase, referral procedures, or procedures related to Art. 78 of Directive 2001/82/EC.
  - Wording for veterinary medicinal product information for the sections related to pharmacovigilance, for specific products or product groups in view of harmonised product information within the EU.
  - Scientific advice in relation to specific post-authorisation safety studies.
  - Risk management plans

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<sup>1</sup> Rapporteurs may also directly consult the PhVWP-V

- Pharmacovigilance systems for Member States and / or for marketing authorisation holders, when appropriate, in particular in relation to issues raised following pharmacovigilance inspections
- Preparation, review and update of pharmacovigilance guidelines on request of the CVMP
- Setting standards for procedures and methodologies to promote good pharmacovigilance practice.
- Advice on the harmonisation of terminology for adverse reaction reporting (e.g. VEDDRA), and codification of veterinary medicinal products
- Advice to the release of information to the stakeholders and the general public in view of the specific legal requirements on access to pharmacovigilance data.
- Advice on pharmacovigilance matters that are the subject of the negotiations within VICH or in the framework of international cooperation.
- Liaison with interested parties.
- Focus and catalyst for training to health professionals to increase better use of data, to improve the safety and efficacy of products on the basis of the evidences gained.”
- Catalyst and support of initiatives to increase reporting of adverse reactions by veterinarians within the EU.

### **III. COMPOSITION AND RULES OF PARTICIPATION**

The PhVWP-V is composed of nominated experts from the European experts' list according to their specific expertise.

The working party members (1 per Member State) are experts nominated by Heads of Agencies in liaison with CVMP members on basis of their expertise with the agreement to let him/her put resources into the work of the working party.

In order to ensure that the mandate and objectives of the working party can be accomplished the following areas of expertise are considered necessary:

- Involvement in a pharmacovigilance system on national level either in regulatory authority or at university
- Practical veterinary experience
- Epidemiology
- Pharmacoepidemiology
- Pharmacology, toxicology
- Immunological medicinal products for veterinary use
- Knowledge of regulatory requirements and procedures

Additional expertise in residues, environmental risk assessment, biostatistics and user safety (human adverse reactions) might be required occasionally in relation to specific topics. In cases where such expertise is not already available amongst the members of the working party additional European experts may be invited to participate in the work related to those specific topics.

Membership of a working party implies a commitment to participate actively in the work of that working party and to attend the meeting of the working party regularly as well as to communicate working party agreements and discussions effectively within their national agencies.

A member may nominate a replacement to participate in those exceptional cases where he or she is unable to attend a meeting.

Additional experts may attend the meetings of the PhVWP. Members who want to bring additional experts should notify the EMEA Secretariat in advance to the meeting, subject to the agreement of the Chairperson.

Representatives of the European Commission and the EMEA may attend the meetings of the PhVWP.

Representatives of Iceland, Liechtenstein and Norway are invited to attend the meetings of the PhVWP.

Observers from accession countries and MRA partners may have standing invitations to participate at certain working parties. Observers from other non-EEA countries may participate with the agreement of the chairperson, the EMEA and the HMA<sup>2</sup>.

Specific confidentiality rules will apply to observers.

CVMP members are encouraged to take an active role in the activities of the PhVWP-V.

#### **IV. MEETING FREQUENCY**

The PhVWP-V shall meet at least 6 times per year in accordance with the adopted Work Programme. The dates of the meetings shall be included in the work programme of the PhVWP-V.

The VEDDRA sub-group of the PhVWP-V shall meet once per year, with a possible second meeting if necessary. The date of the meeting shall be included in the work programme of the PhVWP-V.

#### **V. DURATION OF ACTIVITY (IN THE CASE OF TEMPORARY WORKING PARTIES)**

Not applicable.

#### **VI. RULES OF PROCEDURE**

##### **1. Mandate and Work programme**

a. The dual mandate of the PhVWP-V shall be agreed by the CVMP and Member States, respecting the divided responsibility for medicinal products according to authorisation routes. It shall be reviewed, at least every three years.

b. The PhVWP-V shall prepare an annual work programme with input from the Committee and the Member States. The work programme shall be adopted by the CVMP and Member States and regularly reviewed and updated as necessary.

##### **2. Election of Chairperson and Vice Chairperson**

The Chairperson, and Vice Chairperson if applicable, of the PhVWP-V shall be elected by the members of the CVMP for a term of three years, which may be renewed. A Committee member preferably, an alternate or a member of the PhVWP-V may be elected by the Committee to fulfil this responsibility.

A Vice-Chairperson may be elected by the Committee if the working party and CVMP consider it appropriate.

Nominations should be submitted in writing to the EMEA secretariat no later than the start of the Committee meeting at which election of the working party Chairperson is to take place.

Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.

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<sup>2</sup> Request to be submitted to the Chair of HMA-V

The election of the Chairperson and the Vice-Chairperson(s), where appropriate, shall follow the same procedure as that for the election of the Chairperson of Committee as stated in Article 3, paragraphs 1 to 4, of the Rules of Procedure of the CVMP.

## **2.1 Responsibilities of Chairperson**

The Chairperson, in his absence the Vice-Chairperson, is responsible for the efficient conduct of the business of the working party and shall in particular:

- Plan the work of the working party together with the EMEA Secretariat;
- Monitor, together with the EMEA 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 working party;
- Aim to achieve consensus on issues discussed by the working party;
- Decide in exceptional cases, when a vote is necessary;
- Ensure, together with the working party and the Secretariat, the regulatory and scientific consistency of the working party's recommendations;
  - Co-ordinate together with the EMEA secretariat the work of this working party with that of the other relevant working parties of the Agency;
  - Report on the activities of the working party to the CVMP or other working party as appropriate.

The Vice-Chairperson will deputise for the Chairperson when the latter is unable to chair either all or part of the working party meeting. On such occasions the Chairperson will seek the agreement of the Vice-Chairperson as early as possible, prior to the meeting and the EMEA Secretariat shall be informed immediately.

## **3. Organisation of meetings and reporting arrangements**

1. The dates of meetings are decided on an annual basis in consultation with the PhVWP-V and the CVMP.
2. The meetings will be held in English.
3. When a Member of the PhVWP-V is unable to participate to a meeting, part of meeting, or discussion topic due to conflict of interest, he/she must inform the Secretariat in advance in writing.
4. The draft agenda for every meeting shall be circulated, together with the relating documents, by the EMEA Secretariat, in consultation with the Chairperson, at least 14 calendar days before the meeting. The CVMP and the CMD(v) will receive a copy of the agenda.
5. The agenda shall be set-up in line with the key responsibilities and objectives identified under section II and should at least include separate sections to cover for the following topics;

### **a. Monitoring of suspected adverse reactions for veterinary medicinal products authorised within the EU**

This section includes items in relation to the continuous monitoring of suspected adverse reactions contained within EudraVigilance Veterinary in relation to all authorised Veterinary Medicinal Products within the EU.

The working party will conclude at each meeting on the potential signals identified within the data of EudraVigilance Veterinary and communicates its findings, without delay, including advice on possible regulatory actions, when appropriate, to the following stakeholders:

- in relation to centrally authorised products: the CVMP and in particular the rapporteur and Co-Rapporteur.
- in relation to products authorised via the mutual recognition procedure or the decentralised procedure: the coordination group for mutual recognition and decentralised procedures (CMD(v)) and also, for urgent matters, directly to the reference Member State or a competent authority designated as reference Member State and all concerned Member States.
- in relation to nationally authorised products: national competent authorities

#### **b. Requests for advice initiated by the CVMP**

The CVMP may decide to consult the PhVWP-V for their advice in relation to, but not limited to the following items:

- Specific questions in the field of pharmacovigilance with respect to procedures for Scientific Advice, applications for the authorisation of community marketing authorisation or applications for the renewal of a marketing authorisation.
- Periodic Safety Update Reports for centrally authorised products
- Specific obligations or follow-up measures related to pharmacovigilance issues for centrally authorised products
- Referrals related to pharmacovigilance issues
- Any other pharmacovigilance issues related to specific substances or veterinary medicinal products.

When considered appropriate by the PhVWP-V, oral presentations by companies can be made during working party meetings on matters directly related to the above activities, following agreement of the Committee.

The working party will communicate its findings and advice to the CVMP within the timeframe set by the CVMP.

#### **c. Requests for advice initiated by the Member States**

The Member States, preferably via their PhVWP-V member or alternatively via the Coordination group for mutual recognition and decentralised procedures CMD(v), may consult the PhVWP-V for their advice in relation to:

- Specific questions in the field of pharmacovigilance with respect to a national procedure, a mutual recognition procedure or a decentralised procedure for the authorisation of a veterinary medicinal product.
- Periodic Safety Update Reports for veterinary medicinal products authorised through the national procedure, the mutual recognition procedure or the decentralised procedure.
- Any other pharmacovigilance issues related to specific substances or veterinary medicinal products.

When considered appropriate by the PhVWP-V, oral presentations by companies can be made during working party meetings on matters directly related to the above activities, following agreement of the concerned Member States.

The working party will communicate its findings and advice to the CMD(v) or the specific Member States, when required.

#### **d. Guidelines / concept papers / SOPs**

This section includes discussion topics on specific guidelines, concept papers or SOPs in relation to pharmacovigilance that have been initiated by the CVMP. The working party may pro-actively

identify and propose topics for discussion under this section for consideration by the CVMP or the Member States.

1. The summary record is considered confidential and will be written in English. It will be circulated to the CVMP and the CMD-V at their next plenary meetings.
2. The Chairperson will be invited to attend plenary meetings of the CVMP and the CMD(v) to report on the activities on the PhVWP-V and ensure liaison with the CVMP and the CMD(v).

#### **4. Drafting Groups**

When further consideration is required in order to prepare proposals on specific topics the working party may convene drafting groups constituted of members of the working party or experts, as appropriate.

The drafting group will report to its working party in direct line.

#### **5. Participation of Experts in meetings**

1. When necessary, the working party 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 patient organisations or other health care professionals may act as experts.
2. The names of these experts shall be notified to the EMEA Secretariat before the meeting that they are due to attend.

#### **6. Guarantees of independence**

1. The members of the working party 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 interests. All indirect interests that could relate to the pharmaceutical industry shall be entered in a register held by the Agency, which is accessible to the public, on request at the Agency's office.
2. Members of the working party 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 made available to the public.
3. The specific provisions for handling declaration of interests and confidentiality undertakings as defined in the EMEA Policy on the Handling of Conflicts of Interests for Committee Members and Experts, adopted by the Management Board (EMEA/H/31653/03/Rev.1 Final) are applicable to members of the working party and experts participating in the activities of the working party.

#### **7. Code of conduct**

Members of the working party and experts participating in the EMEA's activities shall abide by the principles set out in the EMEA Code of Conduct.

## **8. EMEA Secretariat**

1. Under the authority of the Executive Director, the EMEA secretariat shall provide technical, scientific and administrative support to the working party. This includes the following:
  - Provide technical and scientific support to rapporteurs (guidelines), and other members of the working party;
  - Provide legal, regulatory and scientific support to the working party;
  - Prepare and co-ordinate the work of the working party in consultation with their Chairpersons;
  - Ensure, if appropriate, that the periods laid down by Community legislation for the adoption of the opinions are complied with;
  - Organise meetings of the working party ensuring timely circulation of meeting documents;
  - Facilitate the necessary contacts between the working party, the CVMP, the CMD(v) and the Member States.
  - Ensure adequate co-ordination of the work carried out within the working party, 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 working party in co-operation with the Chairperson or Vice-Chairperson, as appropriate;
  - Prepare the agenda, table of actions and minutes of the meetings of working party in consultation with the Chairpersons;
  - Communicate when necessary any CVMP recommendations relevant to the working party to interested parties;
  - Support the experts in the overall use and access to the EudraVigilance Veterinary data.
  - Contribute to the identification of experts.
2. The Executive Director of the Agency, members of the EMEA secretariat, and representatives of the Commission, may attend all meetings of the working party.

## **9. Contacts with Interested Parties**

1. Where relevant, the working party will establish contacts, on an advisory basis, with parties concerned with the use of medicinal products.
2. Draft guidelines and general regulatory developments will be subject to public consultation of all interested parties.
3. When considered appropriate by the working party, oral presentations by interested parties can be made during working party meetings in earlier stages of development of guidelines. The working party may also meet with interested parties to discuss general matters or specific scientific issues with the agreement of the CVMP and under specific conditions to be agreed by the CVMP.
4. In any case, the working party 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 working party members will communicate to the EMEA Secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the working party Chairperson and circulation by the EMEA secretariat.

## **10. General Provisions**

The Members of the working party 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.

When participating in international or other fora members of the PhVWP-V should adhere to the principles described in the 'Policy On Representation of EMEA Scientific Committees by CXMP Members' (EMEA/231477/05).

When participating in international or other fora not specifically on behalf of the CVMP, members shall make clear that the views expressed are their own views and not those of the CVMP.