9 September 2020
EMA/CVMP/EWP/208686/2004-Rev.5
Committee for Medicinal Products for Veterinary Use (CVMP)

Mandate, objectives and rules of procedure for the CVMP Efficacy Working Party (EWP-V)

1. General considerations

According to the Committee for Medicinal Products for Veterinary Use (CVMP) rules of procedure, the CVMP may consult its working parties on any scientific issue related to their specific fields of expertise. The CVMP may also delegate certain tasks associated with the scientific evaluation of applications or drafting of guidelines to the relevant working parties. The tasks identified by the CVMP should be included in the work plan of each working party to be adopted by the CVMP.

The CVMP Efficacy Working Party (EWP-V) is therefore established to provide recommendations to the CVMP on all matters relating directly or indirectly to efficacy and target animal safety of veterinary medicinal pharmaceutical products and to perform the tasks described below.

2. Mandate and objectives

The EWP-V is established to provide recommendations to the CVMP on all matters relating directly or indirectly to efficacy (including target animal safety) of veterinary medicinal pharmaceutical products including, but not limited to the tasks defined below:

- Preparation, review and update of guidelines,
- Support to dossier evaluation,
- At the request of the CVMP, provision of scientific advice on general and product specific matters related to efficacy,
- Liaison with interested parties (pharmaceutical industry associations such as AnimalhealthEurope, EGVVP and other specific interested parties, as appropriate), see “rules of procedure”,
- International cooperation on efficacy-related matters, e.g. VICH,
- Liaison with other working parties on efficacy-related matters,
- Advice, through the CVMP, to the European Commission on efficacy-related issues,
- On request, advice, through the CVMP, to CMDv on efficacy-related matters,
- Contribution to and organisation of workshops and training related to efficacy assessment of veterinary medicinal pharmaceutical products.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

3. Composition and rules of participation

The EWP-V is composed of a limited number of experts, ideally between 10 and 12, identified by the CVMP on the basis of their specific scientific expertise, on basis of the subjects covered within the scope of the working party and based on nominations from the CVMP or the European Medicines Agency (EMA).

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

1. Clinical trials
    - Experimental models;
    - Practical clinical expertise (e.g. knowledge of disease mechanisms, diagnostic skills, genetic epidemiological factors, treatments and animal patient care);
    - Study design (e.g. knowledge of appropriate diagnostic methods and, when applicable, bacteriology, virology and parasitology to determine proper in- and exclusion criteria, knowledge of factors that reduce bias);
    - Trial monitoring;
    - Assessment (e.g. knowledge of guidelines, continued professional education);
    - Statistics (e.g. biometrics for designing and evaluating field trials);
    - Population kinetics.
2. Pre-clinical studies
    - Experimental models;
    - Resistance (in relation to efficacy and target animal safety, e.g. mechanisms, risk management strategies both in Europe and elsewhere, including antimicrobials and antiparasitics);
    - Tolerance (e.g. pharmacology, toxicology, clinical pathology and histopathology);
    - Pharmacology (e.g. pharmacodynamics, pharmacokinetics, PK/PD modelling);
    - Bioequivalence testing, including understanding of the statistical tests used.
3. Knowledge of regulatory requirements

Additional expertise might be required occasionally in relation to particular areas, certain animal species, speciality medicines or other 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 meetings of the working party regularly. Given the restricted membership of this working party, if a member does not participate in 3 consecutive meetings without reasonable justification, the CVMP Secretariat will ask the CVMP, in consultation with the WP Chairperson, to reconfirm his/her membership or to nominate a new one.

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

Members who want to bring additional experts should notify the Secretariat in advance to the meeting, subject to the agreement of the Chairperson.

Meeting documentation will be distributed to an agreed list of recipients drawn up by the Secretariat with the agreement of the Chairperson.

Observers may participate with the agreement of the Chairperson and the EMA.

Specific confidentiality rules will apply to observers.

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

4. Meeting frequency

The EWP-V shall meet at least 2 times per year in accordance with the adopted work plan. The dates of the meetings shall be included in the work plan of the EWP-V.

Drafting group meetings might be required according to the annual work plan.

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

Not applicable.

6. Rules of procedure

6.1. Responsibilities of Chairperson

The 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 Secretariat;
- Monitor, together with the 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 Secretariat the work of this working party with that of the other relevant working parties of the EMA;
- Report on the activities of the working party to the CVMP or other working party, as appropriate.

6.2. Election of Chairperson and Vice-Chairperson

The Chairperson of the EWP-V shall be elected by the members of the CVMP for a term of three years, which may be renewed once. A CVMP member (preferably), alternate or a member of the EWP-V may be elected by the CVMP to fulfil this responsibility.

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

Nominations should be submitted in writing to the EMA Secretariat no later than the start of the CVMP 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.

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

6.3. Organisation of meetings and reporting arrangements

1. The EWP-V shall meet regularly. Physical meetings will be held at the EMA.
2. The dates of meetings are decided on an annual basis in consultation with the EWP-V and the CVMP.
3. The meetings and written records will be in English.
4. The draft agenda for every meeting shall be circulated, together with the relating documents, by the Secretariat, in consultation with the Chairperson, at least 14 calendar days before the meeting.
5. When a member of the EWP-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.
6. The working party may identify and propose topics for its consideration. Any proposal for a guideline, providing adequate justification, shall be transmitted to the CVMP for endorsement.
7. Any recommendation from the EWP-V shall be transmitted to the CVMP for adoption.
8. When considered appropriate by the EWP-V, oral presentations by stakeholders can be made during working party meetings on matters directly related to the activities of the working party, following agreement of the CVMP.
9. The EWP-V shall prepare an annual work plan for adoption by the CVMP which shall include topics identified in accordance with point 6 above and any specific tasks identified by the CVMP. The work plan shall be regularly reviewed and updated as necessary with the agreement of the CVMP.
10. Agenda and minutes of the meetings of the working party should be circulated to the CVMP.
11. The Chairperson will be invited to attend plenary meetings to report on the activities of the EWP-V and ensure liaison with the work of the CVMP.
12. The mandate and objectives of the EWP-V shall be agreed by the CVMP. They shall be reviewed every three years by the CVMP.

6.4. 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.

6.5. 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 veterinary medicinal products or in their field of expertise and be included in the European Experts list.
2. The names of these experts shall be notified to the Secretariat before the meeting that they are due to attend.

6.6. Guarantees of independence

1. The members of the working party and experts referred to above shall not have any 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 interests that could relate to the pharmaceutical industry are entered in a register held by the EMA, which is accessible to the public.
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 EMA policy on the handling of competing interests of scientific committees' members and experts, adopted by the Management Board (EMA/626261/2014), are applicable to members of the working party and experts participating in the activities of the working party.

6.7. Code of conduct

Members of the working party and experts participating in the EMA's activities shall abide by the principles set out in the EMA Code of Conduct (EMA/385894/2012).

6.8. EMA Secretariat

1. Under the authority of the Executive Director, the 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 the Chairperson;
    - 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 and the CVMP;
    - 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 and minutes of the meetings of working party in consultation with the Chairperson;
- Communicate, when necessary, any CVMP recommendations relevant to the working party to interested parties;
- Contribute to the identification of experts.

2. The Executive Director of the EMA, members of the Secretariat, and representatives of the European Commission, may attend all meetings of the working party.

6.9. Contacts with Interested Parties

1. Where relevant, the working party will establish contacts, on an advisory basis, with parties concerned with the use of veterinary medicinal products.
2. Draft concept papers, 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 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 Secretariat.

6.10. 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* on behalf of the CVMP, members shall ensure the views expressed are those of the CVMP.

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.