EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Veterinary Use

Mandate, objectives and rules of procedure for the CVMP Scientific Advice Working Party (SAWP-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 Scientific Advice Working Party (SAWP-V) is therefore established to provide recommendations to the CVMP on all matters relating directly or indirectly to all aspects of veterinary medicinal products, including maximum residue limits (MRLs) and on questions of a more general scientific nature (including minor use minor species (MUMS) applications) pertaining to veterinary medicinal products irrespective of whether the product is eligible for the centralised procedure or not and to perform the tasks described under section 2.

2. Mandate and objectives

The SAWP-V is established to provide recommendations to the CVMP on all matters relating directly or indirectly to all aspects of veterinary medicinal products, including MRLs, and on questions of a more general scientific nature including but not limited to the tasks defined below:

- To formulate scientific advice regarding veterinary medicinal products in development/MRLs in response to specific questions from prospective applicants, for consideration by CVMP, within a defined timeframe and format.
- To assist the CVMP with the provision of scientific advice under the MUMS initiative in accordance with provisions laid down by the Management Board, e.g. the MUMS policy for free scientific advice for classified products with financial incentives.
- To give advice on general questions e.g. technical interpretation of a scientific question and to set principles on which a CVMP position will be based in the future, in particular where questions are not directly attributable to one of the other CVMP working parties.

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- To identify to the CVMP specific issues on which policy decisions may need to be taken by the CVMP on the advice of the working party, based on requests received for scientific advice in areas where there is a perceived lack of guidance and what advice to publish in more general terms.
- To review and update the procedure and existing guidance in relation to the provision of scientific advice.
- To liaise with other regulatory agencies, where agreements are in place (such as the US FDA), in the provision of parallel scientific advice when requested by applicants or judged appropriate in accordance with the provisions laid down in the practical arrangements established under the Confidentiality Arrangement.

The SAWP-V will ensure consistency of advice given, where appropriate, and also consistency in conjunction with current EU guidelines. The SAWP-V in its deliberations in the context of points above may identify the need for CVMP to develop new guidelines.

The SAWP-V will involve specialised experts in the provision of scientific advice whenever necessary.

At the specific request of the CVMP, the SAWP-V may develop appropriate contacts between the SAWP-V and the representatives of the pharmaceutical industry and other interested parties.

The SAWP-V is not responsible for the provision of regulatory advice.

3. Composition and rules of participation

The SAWP-V is composed of a limited number of experts, preferably between 15 and 18. These members are nominated by the CVMP and may be CVMP members, alternates or EU experts (included in the EU experts list).

Members are proposed to CVMP by CVMP members on the basis of their specific scientific expertise and/or regulatory experience on the subjects covered within the scope of the working party's mandate. The final composition shall be agreed by the CVMP with the objective of ensuring sufficient expertise in all areas covered by 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:

- Experience in assessment of pharmaceutical veterinary medicinal products
- Experience in assessment of immunological veterinary medicinal products
- Experience in assessment of maximum residue limits
- Knowledge of regulatory requirements

Members of the working party have general expertise on the topics identified above. Furthermore, they have the opportunity to involve appropriate additional experts for specific products requiring particular expertise. Membership of a working party implies a commitment to participate actively in the work of the working party and to attend the meetings of the working party regularly.

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 European Medicines Agency (the Agency) with the agreement of the Chairperson.

Observers from non-EEA countries may participate with the agreement of the Chairperson and the Agency. Specific confidentiality rules will apply to observers.

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

4. Meeting frequency

The SAWP-V shall meet at least 11 times per year in accordance with the adopted work plan. The dates of the meetings shall be included in the work plan of the SAWP-V.

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

Not applicable.

6. Rules of procedure

6.1. Responsibilities of Chairperson and Vice-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 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 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 secretariat shall be informed immediately.

6.2. Election of Chairperson and Vice-Chairperson

The Chairperson and Vice-Chairperson of the SAWP-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 or an alternate may be elected by the CVMP to fulfill this responsibility.

Nominations should be submitted in writing to the 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, 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 SAWP-V shall meet regularly at the Agency.
2. The dates of meetings are decided on an annual basis in consultation with the SAWP-V and the CVMP.
3. The meetings will be held and minuted 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 SAWP-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 SAWP-V may identify and propose topics for its consideration. Any proposal for a guideline, providing adequate justification, shall be transmitted to the CVMP for endorsement and shall be preceded by a concept paper to be endorsed by the CVMP.
7. Any recommendation from the SAWP-V shall be transmitted to the CVMP for adoption.
8. When considered appropriate by the SAWP-V, oral presentations by companies can be made during working party meetings on matters directly related to the scientific advice requests of the working party.
9. The SAWP-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 SAWP-V should be circulated to the CVMP.
11. The Chairperson will report on the activities on the SAWP-V and ensure liaison with the work of the CVMP.
12. The mandate and objectives of the SAWP-V shall be agreed by the CVMP. They shall be reviewed every three years by the CVMP.

6.4. Coordinators

For each scientific advice request, the working party appoints a coordinator amongst its members. To be appointed as co-ordinators, SAWP-V members shall provide the secretariat with a notification of interest prior to the SAWP-V meeting in writing. The SAWP-V shall appoint the coordinator according to expertise and equal opportunity for each member. For equal opportunities, the secretariat maintains a 36 month rolling count on coordinator-ships.

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 medicinal products or in their field of expertise and be included in the European Experts list. Where appropriate members from veterinary organisations or other health care professionals may act as experts.
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 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 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 European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts, adopted by the Management Board (EMA/626261/2014-Rev.1) 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 European Medicines Agency's activities shall abide by the principles set out in the European Medicines Agency Code of Conduct (EMA/385894/2012-Rev.1).

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 co-ordinators, 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 and the CVMP;
- Facilitate the necessary contacts between the SAWP-V and the applicants;
- 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;
- Carry out the validation of the applications;
- 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 Chairpersons;
- Communicate when necessary any CVMP recommendations relevant to the working party to interested parties;
- Contribute to the identification of experts;
- Organise pre-submission and briefing meetings with applicants.

2. The Executive Director of the Agency, members of the secretariat, and representatives of the 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 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. 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.