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Veterinary Medicines and Product Data Management

# Summary of procedures for consultation by CVMP of Scientific Advisory Groups (SAGs) and ad-hoc expert groups functioning as SAGs in relation to applications for authorisation of veterinary medicinal products

## 1. Scope

The policy in relation to scientific advisory groups (SAGs) and ad-hoc expert groups functioning as SAGs in the area of veterinary medicines follows the main principles of the Mandate and Rules of procedure for scientific advisory groups and ad-hoc expert groups as laid out in document EMA/117014/2010 adopted by CHMP. However there are a number of differences in the veterinary operations in relation to such groups. The scope of this document is to summarise the approach to be adopted when CVMP consults ad-hoc expert groups or SAGs in relation to applications for the authorisation of veterinary medicinal products and provide a brief description of the relevant CVMP related processes.

## 2. General considerations

Scientific Advisory Groups (SAGs) and ad-hoc expert groups are created by the CVMP to deliver answers, **on a consultative basis**, to specific questions or issues addressed to them in a defined area related to authorisation of medicines. The Committee, while taking into account the position expressed by the SAG or ad-hoc expert group, remains responsible for its final opinions. SAGs are established in situations where CVMP considers there is likely to be an ongoing need for consultation with experts in a particular area related to authorisation of medicines. Ad-hoc expert groups are created by CVMP on a temporary basis in response to a particular need. Ad-hoc expert groups can function as SAGs when they are created to provide advice on specific issues in relation to the consideration by the Committee of an application for authorisation in situations where no appropriate standing SAG exists.

The purpose of this document is to describe the operation and procedures mainly of ad-hoc expert groups when functioning as SAGs. For established SAGs, their operation will be detailed in the respective Standard Operation Procedure (SOP) and rules of procedure. Nevertheless, it is expected that SAGs will follow the approach described in this document in terms of assuring the independence of

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the advice provided to the Committee when consulted in relation to applications for the authorisation of veterinary medicinal products.

It is the decision of the CVMP whether or not to consult a SAG or an ad-hoc expert group in relation to any particular application. In order to ensure that consistent decisions are reached, the CVMP will give particular consideration to consulting a SAG or convening an ad-hoc expert group under any of the following circumstances:

- When highly specialised expert knowledge would be helpful in relation to certain aspects of an application and where such expertise is not present within the Committee or readily accessible through experts available to members at national level.
- When there are diverging views/split opinions within the Committee, or between the Committee and the applicant, and the submitted data critical to the outcome of the application requires highly specialised expert knowledge. In such circumstances, although adequate and appropriate expertise may already be available to the Committee, it may be appropriate for the diligence of the scientific process for the Committee to consult with an advisory group that is both highly knowledgeable in the required area and is also independent of both the applicant and the Committee. It follows that consultation with a SAG is not automatic in all cases of divergent opinion, or disagreement with the applicant on scientific issues, but only when such divergence arises from differing interpretation of data in a particular, defined area of specialised expertise and the Committee considers that additional, independent expertise may add value to the scientific consideration.
- After receipt of a request for consultation with a SAG by an applicant during a re-examination procedure.

When the issues refer to a therapeutic area for which no permanent SAG has been constituted, an ad-hoc expert group can be organised. Given the limited number of permanent SAGs for veterinary medicines this option is very relevant for CVMP as it allows a flexible, product-specific scope. Should the expertise of an ad-hoc expert group be considered useful to CVMP for further procedures, its mandate could be expanded to cover non product-specific issues and its duration prolonged where possible.

**Legal basis**

SAGs

The legal provisions for the consultation of CVMP by SAGs can be found in **Article 56 (2) of Regulation (EC) 726/2004:** *"The committees referred to in paragraph 1(a) and (b) may establish scientific advisory groups in connection with the evaluation of specific types of medicinal products or treatments, to which the committee concerned may delegate certain tasks associated with drawing up the scientific opinions referred to in Articles 5 and 30"*

and **Article 62 (1) of Regulation (EC) 726/2004** "*When consulting the scientific advisory groups referred to in Article 56(2), the Committee shall forward to them the draft assessment report(s) drawn up by the rapporteur or the co-rapporteur…..The applicant may request that the Committee consult a scientific advisory group in connection with the re-examination."*

**Article 16 of the CVMP rules of procedures** provides for the consultation of SAGs by the Committee: "*Scientific advisory groups shall be established to provide advice to the Committee in connection with the evaluation of specific types of medicinal products or treatments, as appropriate".*

Ad-hoc expert groups

**Article 62 (2) of Regulation (EC) 726/2004** states: "*The Agency shall keep an up-to-date list of accredited experts. The list shall include the experts referred to in the first subparagraph (national) and other experts appointed directly by the Agency. The list shall be updated*".

and **Article 62 (5) of Regulation (EC) 726/2004: "** *The Agency or any of the committees referred to in Article 56(1) may use the services of experts for the discharge of other specific tasks for which they are responsible*". The above Articles refer to the list of experts and the use of experts by the Committee, respectively. The **CVMP rules of procedures** provide for the consultation of experts before the authorisation of a veterinary medicinal product in **Article 6 (8)**: "*The Committee may consult the relevant working party and/or relevant experts from the European expert list as appropriate*".

and in **Article 11 (2)** in relation to re-examination procedures: "*The applicant may request that the Committee consult a scientific advisory group (if and when established) in connection with the re-examination. In this case, the Committee shall request the advice of additional available expertise*".

Ad-hoc expert groups can therefore be created to act as SAGs for consultation on specified issues in relation to the consideration by the Committee of an application for authorisation in situations where no appropriate standing SAG exists.

Timing for ad-hoc expert group consultation:

The CVMP can choose to consult an ad-hoc expert group at any stage of an application process.

If data or issues arise outside the expertise of Committee members or their experts, consultation may take place during all stages of the assessment (e.g. initial assessment or during assessment of the responses to questions). However, the most likely time point in the timetable for the Committee to identify issues on which consultation with an ad-hoc expert group would be useful is the stage after an Oral Explanation as this is the time when the applicant has exhausted all opportunities to provide information/clarifications to the Committee in relation to outstanding issues critical for the outcome of the application.

An ad-hoc group can also be convened by CVMP after the opinion for a product is adopted in the framework of a re-examination procedure, following a request by the applicant or if the Committee itself considers consulting such a group useful.

# 3. Mandate and objectives

An ad-hoc expert group is established or a standing SAG is consulted in order to provide an independent response on scientific/technical matters related to evaluation procedures under the responsibility of the CVMP (centralised marketing authorisation applications including post-authorisation procedures, MRL applications and referrals).

When agreeing on the need to consult an ad-hoc expert group, the CVMP should specify the List of Questions (LoQ) that the experts of the (ad-hoc) group need to address. The mandate of such a group would then be to provide responses to these questions (LoQ).

Dependant of the mandate of the ad-hoc expert group, it may have the opportunity to identify additional scientific issues that may need further discussion within the group, subject to the agreement by the CVMP.

For standing SAGs the procedure for consulting with CVMP should be reflected in the rules of procedure.

Any final opinions on issues discussed at ad-hoc expert groups or SAGs will be made by the CVMP.

# 4. Composition

Ad-hoc expert groups should be composed of independent experts selected according to their specific expertise required. The CVMP should decide on the field of expertise required, the approximate size of the group and the numbers of expert per field. The areas of expertise should be clearly defined, described and endorsed by the Committee.

For standing SAGs the relevant rules of procedure[1] and Standard Operating Procedures will be applicable[1].

For the purposes of responding to product specific issues raised by CVMP members of the ad-hoc expert groups will be independent experts and will not be members of an Agency Committee nor Agency staff nor staff employed by a National Competent Authority (NCA) responsible for the authorisation of veterinary medicines. Exceptionally, experts employed by NCAs responsible for human medicines, or joint agencies, may participate where their independence from the application under consideration can be assured. Experts from non-EEA countries may also be appointed by the CVMP. Concerned (co)-rapporteurs are expected to participate as observers in the product related meetings of the group. Members of the Agency's Committees and Working Parties, assessors from NCAs, national experts and regulators from non-EEA countries under confidentiality agreement with the Agency may also participate as observers subject to agreement of the group's chair and their presence should be notified to the CVMP. The independence of the advice at all stages of the SAG operation should be guaranteed and therefore the number of observers should remain limited.

### *Selection and appointment of experts:*

Experts should be proposed by CVMP members or the secretariat in line with the agreed field of expertise identified as required by CVMP and where possible should represent the best available expertise in their area. All experts must be included within the list of Euroepan Experts maintained by the Agency before they can participate in a group. Following their proposal therefore the secretariat will check if experts are already on the list and, if not, seek nomination to the list according to standard procedures. For new and existing experts, the secretariat will check for potential for conflicts of interest in line with Agency rules of procedure and eligible experts will be contacted for potential availability. The secretariat will then put forward the names and up-to-date CVs in English of those both eligible and available to the selection committee for the specific group for preparing a proposal to CVMP.

The selection committee for the ad-hoc expert group will normally consist of the rapporteur, co-rapporteur, secretariat and CVMP chair, vice-chair, and/or chair of the relevant CVMP Working Party. Additional members may be invited at the discretion of the CVMP chair where their expertise would be useful to the selection procedure. The selection committee should ensure that in the case of a surplus of candidates, those with the expertise closest to the ones described by CVMP should be proposed. This will be evaluated based on the CVs and publication lists that are provided at the time of the selection committee meeting. As a secondary parameter, a certain diversity of the group should be sought. The decision procedure in case of different opinions in the selection committee is by simple majority of those members of the selection committee that are present at the time the final recommendation to CVMP is drawn up.

[1] Available at http://www.ema.europa.eu/pdfs/vet/sagam/sagammandate.pdf

The CVMP will then formally endorse the composition of the ad-hoc expert group on the basis of the proposal from the selection committee. The chair will be elected by the group from among their members on the basis of a simple majority decision. The secretariat can assist in the identification of a potential chair where necessary and subject to confirmation by the group. As this role will involve the drafting and reporting of the group's conclusions to the CVMP, it should be ensured that potential candidates have adequate linguistic skills to deliver the group's considerations in a clear and precise manner and appropriate skills in chairing scientific groups.

For standing SAGs the respective rules of procedure will be applicable in relation to the selection and appointment of members.

The Agency conflict of interest rules apply to all ad-hoc expert groups and SAG participants. The Agency confidentiality rules apply to all participants, including observers.

A summary of procedures in relation to the selection and appointment of experts is provided in Annex I of the document.

# 5. Meeting frequency

Ad-hoc expert groups will meet on the request of CVMP. Ad-hoc groups are expected to meet formally at least once and the date will be decided by CVMP preferably the same week as a CVMP meeting in order to allow direct reporting of the group's conclusions by its chair. More meetings can be scheduled as deemed necessary (CVMP, secretariat and the group can propose additional meetings).

The frequency of standing SAG meetings will be decided by CVMP as considered appropriate and will be reflected in the rules of procedure and SOP.

# 6. Policy on communication with the company

When the formation of an ad-hoc expert group involves a specific product the applicant company will be informed. In such cases the applicant should be kept informed in relation to the adopted List of Questions (LoQ) that the CVMP will address to the group, the names of the group's experts once endorsed by CVMP, the updated timetable of the procedure and the list of the relevant data that the experts will review. The applicant should normally be invited to address the LoQ during the group's meeting and similar rules of procedure as the ones for oral explanations should apply. The applicant must refrain from contacting any of the experts of the group; should there be any contact it should then be reported by the expert to the secretariat to evaluate whether further participation of the expert is appropriate. The final recommendations of the ad-hoc expert group will be made available to the company.

# 7. Conduct of meeting for product related issues

For product related issues the CVMP rapporteur and the co-rapporteur can be invited to attend the ad-hoc expert group meeting(s), to present the List of Questions and to provide any additional information to the group, for practical reasons participation could be remote (virtual or teleconference). (Co)-rapporteurs can bring to the meeting their own experts to assist with any of the above. The rapporteur, co-rapporteur and their experts should normally attend the ad-hoc expert group's meeting in the role of observers. Observers do not participate in the group's discussions, but may be invited to express their point of view on the request of the group's chair. The chair should be responsible for coordinating the discussions during the meeting and for drafting the recommendations and conclusions at the end, with the support of group's experts as appropriate. Consensus should be reached, where possible; where consensus would not be possible the majority view should be expressed as the group's

view stating also the divergent views, as appropriate. Preparatory teleconferences are encouraged to assist the final discussions of the main meetings. Experts are expected to provide written input to the LoQ prior to the meeting addressing the LoQ. Should they not have the appropriate expertise to answer any of the raised questions they are expected to inform the secretariat and the chair of the group.

### *Documents for product related ad-hoc expert's groups*

The basic documents that should be produced following the agreement for the formation of the ad-hoc expert group are the following:

- LoQ raised by CVMP to be addressed by the group.
- Composition/Mandate: A document to describe the mandate of the group, to describe the expertise needed and the approximate numbers required, to briefly explain the selection procedure and to list the agreed documentation to be provided to experts.
- Agenda of the ad-hoc expert group meeting.
- Updated timetable of procedure including ad-hoc expert group steps.

The documents should normally be distributed electronically via Eudralink.

For standing SAGs the respective rules pf procedure will be applicable in relation to company policy and conduct of meetings for product related issues.

## 8. Summary of procedures

1. The rapporteur/co-rapporteur/any CVMP member/the secretariat can propose to the CVMP that an ad-hoc expert group should be consulted/convened.
2. Once it is agreed by CVMP that an ad-hoc expert group should be consulted, the CVMP should adopt: the mandate of the group, a List of Questions to be addressed by the group, the field of expertise required (and approximate numbers of participation), the data to be provided to the experts.
3. CVMP members/ Secretariat propose experts and seeks nominations from Competent Authorities for those experts not already included on the list of European Experts.
4. The secretariat checks their eligibility for inclusion on the list of European Experts and participation on the basis of conflict of interest / availability / requests up-to-date CVs.
5. Once a list of eligible and available experts is composed the selection committee makes recommendations to CVMP for the final composition.
6. CVMP endorses ad-hoc expert group's composition, draft agenda, updated timetable of procedure.
7. The secretariat provides the data to endorsed experts and assists in the identification of a chair following receipt of confidentiality undertaking from the experts.
8. Experts vote (by written procedure) for chair.
9. Chair is elected.
10. Preparatory teleconference of the group - submission of written responses by experts if necessary.

11. Main ad-hoc expert group meeting - production of recommendations and conclusions document by chair by the end of the meeting.

12. Chair reports to CVMP plenary on group's conclusions. The chair can delegate reporting to the CVMP to another member or observer of the ad-hoc expert group or the secretariat.

The above sequence of actions should be followed where relevant.

For standing SAGs the procedures will be described in the rules and standard operating procedures.

## *General Provisions*

The members of ad-hoc expert groups and SAGs 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. The Agency Guidance on Confidentiality and Discretion applies.

Ad-hoc expert group and SAG members, when participating in meetings or other fora on behalf of the Committee, shall ensure that the views expressed are those of the Committee. When they are participating not on behalf of the Committee, they shall make clear that the views expressed are their own.

**Annex I**

## Summary of procedures for the selection and appointment of experts:

**Stage: CVMP meeting where the need for a consultation of an ad-hoc group is agreed:**

1. Once it is agreed by CVMP that an ad-hoc expert group should be consulted, the CVMP should adopt a document where among other particulars (as described earlier), the specific fields of expertise required are clearly described together with approximate numbers per area. Usually the maximum total number of experts should be between 6 to 8 in order to allow multiple views to be expressed but also facilitate efficient decision making.

2. At the same meeting the selection committee is confirmed and it should normally consist of the rapporteur, co-rapporteur, secretariat and CVMP chair, vice-chair, and/or chair of the relevant CVMP Working Party.

3. CVMP members and the secretariat are requested to propose names of experts in the areas of the ad-hoc consultation agreed and contact their national competent authorities to provide nominations in case the proposed expert are not already included on the list of European Experts maintained by the Agency.

**Stage: Post CVMP where the need for an ad-hoc expert group was agreed:**

4. The secretariat receives proposals for experts from CVMP member and the secretariat.

5. The secretariat contacts the proposed experts in order to check their eligibility for inclusion on the list of European Experts and participation on the basis of conflict of interest / availability / requests up-to-date CVs. At this stage very limited information can be provided to the experts regarding the product and issues under consideration. Only a general description of the class of the product (e.g. vaccine against disease X) and nature of issue (safety/efficacy/other) can be communicated. A request is made for provision of their CVs in English and a completed Declaration of Interest form.

6. Once the required documents are present for all proposed experts, the selection committee should meet to decide on the selection of appropriate members.

7. When deciding the appropriate participants for the ad-hoc expert group the selection committee should take into account the following criteria:

    a) The required areas of expertise as agreed by the CVMP: Experts with the closest expertise to the required fields should be put forward.

    b) The desired number of experts per field as agreed by CVMP: If more than the required number are identified then those with the clearest leadership in the field of required expertise should be selected. This can be decided on the basis of the amount of relevant experience in the specific field and number of relevant publications.

8. The selection committee should decide by a simple majority of those members of the selection committee present on the final composition of the ad-hoc group which is then presented to CVMP for endorsement.

**Stage: CVMP meeting where endorsement of experts takes place:**

9. The CVMP will be asked to endorse the composition of the ad-hoc expert group on the basis of the proposal from the selection committee. Should there be any remaining disagreement among members of the selection committee, the CVMP can make the final decision.

**Stage: post CVMP meeting where endorsement of experts takes place:**

10. The secretariat should check that nominations from Competent Authorities have been received and all experts are included on the list of European Experts and their declarations of interest are in compliance with the relevant Agency's policy before they can participate in the group.

11. Following the official endorsement by the CVMP and confirmation of the inclusion of all experts on the list of European Experts, relevant information can be communicated to them for the preparation of the consultation.