European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Appointment and responsibilities of rapporteur and co-rapporteur for procedures regarding veterinary medicinal products

1. Introduction

This document describes the appointment of rapporteurs and co-rapporteurs and their respective responsibilities in the evaluation processes with regard to community procedures for veterinary medicinal products and was initially adopted by the Committee for Veterinary Medicinal Products in January 2003. The document has now been revised in order to take into account the new provisions of Council Regulation (EC) No. 726/2004.[1].

2. General

According to Article 62(1) of Council Regulation (EC) No. 726/2004, when the Committee for Medicinal Products for Veterinary Use is required to evaluate a veterinary medicinal product " … *it shall appoint one of its members to act as rapporteur for the co-ordination of the evaluation.. The Committee [concerned] may also appoint a second member to act as a co-Rapporteur"*. Article 61(1) of the Regulation establishes that "*the alternates.…may act as rapporteurs in accordance with Article 62*". The CVMP Rules of Procedure specifies the application of this requirement to applications for Community Marketing Authorisations and for the establishment of MRLs, as well as referrals and re-examination of opinions in respect to any of these procedures as follows: "*For any scientific evaluation in respect of a procedure a rapporteur shall be appointed from amongst the members or alternates*".

3. Appointment of rapporteur and co-rapporteur

a. On receipt of a letter of intent from an applicant, the Secretariat shall notify the Committee by including it on the agenda of the following meeting.

[1] The CVMP has on earlier occasions considered the role of rapporteur and co-rapporteur and summarised their conclusions in 3 previous position papers:

- Roles of rapporteurs and co-rapporteurs in the assessment of applications for the granting of a Community authorisation and for the establishment of MRLs (EMEA/CVMP/011/96-FINAL),
- Role of Rapporteur and Co-Rapporteur in preparation of the CVMP list of questions (EMEA/CVMP/221/96),
- Selection of Rapporteur and Co-Rapporteur and definition of each one's role in the assessment of applications for the granting of a Community Marketing Authorisation and for the establishment of Maximum Residue Limits (EMEA/CVMP/077/99), and in an SOP entitled Centralised Procedure: From Assessment Reports to European Public Assessment Report [EPAR], EMEA/SOP/005/96.

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b. Within the two weeks prior to the meeting, members and alternates wishing to be considered as rapporteur or co-rapporteur shall indicate this to the secretariat in writing via the member. It is not necessary for members and alternates to be present at the meeting to be appointed rapporteur or co-rapporteur. The member and alternate would not both apply for rapporteurships relating to the same product or MRL application.

c. At the plenary meeting, the Committee shall agree the appointment of the rapporteur and co-rapporteur.

d. Where several CVMP members and alternates indicate their availability to act as rapporteur or co-rapporteur for an application, the Chairman will normally make the appointments with the agreement of the Committee, taking into account objective criteria which will allow the use of the best available expertise in the EU on the relevant scientific area. These objective criteria are as follows:

- Experience and expertise in the relevant therapeutic area e.g. antimicrobials, NSAIDs, immunologicals etc
- Access to appropriate experts as well as necessary administrative support
- Competence in and management of dossier assessment and undertaking scientific risk assessment
- No conflict of interest with the product concerned and its development both for member/alternate and experts

CVs would need to be circulated as appropriate.

The number of rapporteur or co-rapporteurships allocated to each available CVMP member and alternate may also be considered. The member and alternate are grouped together per delegation for counting purposes to assist in ensuring fairness with co-opted members. The intent is to appoint rapporteurs and co-rapporteurs as evenly as possible across the Committee, amongst members/alternates willing to act as rapporteurs. Generally, only new rapporteurships or extensions of existing rapporteurships allocated in the actual 3-year period of the current CVMP should be counted. However, if this does not allow a decision the previous allocation could be considered.

e. When a full application concerning a new active substance is being considered for the establishment of MRLs, a rapporteur and a co-rapporteur will normally be appointed. For abridged applications (MRL extension or modification), the nomination of a co-rapporteur is not normally considered necessary.

f. In the case of centralised applications for products to be used in food-producing animals, the rapporteur and the co-rapporteur appointed for the assessment of the full dossier would normally remain the same as the ones appointed for the MRLs establishment. If there was a considerable time lapse between the receipt of the application for MRLs and a centralised procedure the Committee might appoint a different rapporteur or co-rapporteur.

g. A CVMP member or alternate who has previously acted as co-ordinator for scientific advice for the same product/substance will not automatically be appointed as the rapporteur or co-rapporteur for the application for the marketing authorisation or the establishment of maximum residue limits as the procedure for appointment of co-ordinator for scientific advice is independent of the procedure for appointment of rapporteurs for the application for the marketing authorisation or the establishment of maximum residue limits.

h. For Type IB variations a rapporteur is required and is the same as the rapporteur for the original applications for the granting of the community marketing authorisation. For Type II variations the rapporteur is the same as the rapporteur for the original applications, but a co-rappoteur may be appointed if it is considered appropriate, for example for a new therapeutic indication. For

extension applications the same rapporteur and co-rapporteur are normally appointed as per the original application.

4. Responsibilities of rapporteur and co-rapporteur

The rapporteur shall produce the assessment report according to the timeframe established for the respective procedures. The co-rapporteur shall prepare a detailed peer review of the rapporteur's report.

The rapporteur and co-rapporteur are required to co-ordinate the evaluation, by facilitating and supervising the compilation of each section of the assessment report through direct collaboration with the experts appointed to their team. Whilst it is not considered essential for the rapporteur or co-rapporteur to be a definitive scientific expert on all aspects of the dossier relating to the application, it is advisable that the person to be appointed has a familiarity with, and an understanding of, the scientific issues involved in the type and class of products involved in the centralised procedure. The rapporteur and co-rapporteur must be able to assure the Committee of the suitability of the experts chosen and their commitment to maintain the necessary timeframe.

In the centralised procedure, the scientific credentials of all the appointed members and alternates to the Committee should enable each member and alternate of the Committee to be appointed rapporteur or co-rapporteur for most classes of compounds. In practical terms, familiarity with certain classes of medicinal products will inevitably lead to the appointment of rapporteurs and co-rapporteurs with scientific expertise in those particular groups of compounds.

The responsibility of the rapporteur and co-rapporteur is not limited to their draft assessment reports produced during the evaluation phase within the time foreseen for the different procedures (days 70 and 85 for community marketing authorisation applications, days 45 and 60 for MRL applications, day 45 for referrals, and within 30 days of receipt of the grounds for appeal for appeal procedures). Their functional role is to apply their scientific expertise throughout the procedure supported by their respective experts. In addition to drafting their first reports, they finalise the list of questions at day 120 for community marketing authorisation applications, at day 90 for MRL applications, and day 60 for referrals), assess the applicant's responses, take account of all the input from members and alternates of the Committee at the various milestones including, if appropriate, summarising any conclusions which may arise from a hearing should it take place.

During validation of an application for a marketing authorisation for an antimicrobial substance the rapporteur and co-rapporteur decide on the need to involve the Scientific Advisory Group on Antimicrobials (SAGAM) after the Project Manager has verified if it fulfils the criteria for a referral to SAGAM. The rapporteur should take into account SAGAM comments in the draft list of questions circulated at day 115 as well as when discussing the need for an Oral Explanation.

For applications for products containing or consisting of GMOs, the rapporteur may wish to suggest appointing one of the Competent Authorities under 2001/18/EC to act as 'lead consulted Competent Authority', a contact point during the consultation as required by Article 28 of Council Regulation (EEC) No. 2309/93.

Based on the initial rapporteur's assessment report, the co-rapporteur's critique, the comments from CVMP members and alternates as well as the assessment report of the responses to the list of questions and oral explanations where appropriate, the EMEA secretariat will draft the CVMP assessment report containing the grounds for the CVMP opinion in collaboration with and under the direction of the rapporteur and co-rapporteur. The document will be adopted by the CVMP together with the CVMP opinion on the concerned procedure.

Subsequent to the authorisation of the product the rapporteur and co-rapporteur are actively involved in post marketing activities, including the processing of extensions, variations, pharmacovigilance

monitoring and general support. When a rapporteur leaves the Committee the rapporteurships should be reallocated to another member or alternate taking account of the suitability of the new rapporteur.

- For departure of a member or alternate consideration should be given to the replacement member from the same delegation.
- For departure of a co-opted member the co-rapporteur could be considered as he/she already has experience with the product concerned.

5. Appointment of rapporteur and co-rapporteur for referral procedures

In case of referrals to the CVMP the Committee shall appoint a rapporteur and a co-rapporteur for the procedure.

6. Rapporteurs for re-examination of opinions

When a re-examination procedure is initiated in relation to a CVMP opinion, a rapporteur and, where appropriate, a co-rapporteur specifically for this procedure shall be appointed. The rapporteur (and the co-rapporteur) for the re-examination procedure shall not be the same as the one(s) initially appointed for the evaluation.

7. Appointment of the European expert team

In order to accomplish the task of assessing an application, rapporteurs and co-rapporteurs will choose an evaluation team from the list of European veterinary experts placed at the disposal of the EMEA by Member States.

Each evaluation team shall be composed of as many experts as considered necessary for the rapporteur to make a proper evaluation of the dossier.

8. Other Responsibilities of the rapporteur and co-rapporteur

When preparing his/her assessment report, the rapporteur will follow the principles and guidance set out in the CVMP guidelines and templates available for this purpose.

Whilst the Committee has decided that there should be one rapporteur's report on the day established for the respective procedure, which is followed by a peer review of that report by the co-rapporteur, the rapporteur and the co-rapporteur may, with the CVMP's agreement, decide to produce two separate assessment reports. In this case, they should be circulated at the same time to the other members and alternates of the Committee. However, at the end of the procedure, the committee will have to base its opinion on a single assessment report, which is to be once endorsed by the Committee. Therefore, between the early stages of the procedure, where two assessment reports co-exist, and the end of it, where a single document is required, the EMEA project manager, in coordination with the rapporteur and co-rapporteur, will produce a single CVMP Assessment Report.