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Committee for Medicinal Products for Veterinary Use (CVMP)

Procedural advice on appointment and responsibilities of the CVMP rapporteur and co-rapporteur in accordance with Article 62 (1) of Regulation (EC) No 726/2004

1. Introduction

This document describes the appointment of rapporteurs and co-rapporteurs and their respective responsibilities in the different scientific evaluation procedures with regard to veterinary medicinal products under the responsibility of the Committee for Medicinal Products for Veterinary Use (CVMP).

The document has been updated to take into account procedural amendments that have taken place over the years, the possibility of rapporteurs or co-rapporteurs leading a multinational assessment team and recent case law in 2019 in order to provide more clarity with regard to the (co-)rapporteurship appointments for referral procedures.

2. General

According to Article 62(1) of Regulation (EC) No. 726/2004, when the CVMP is required to evaluate a veterinary medicinal product " ... it shall appoint one of its members to act as rapporteur, taking into account existing expertise in the Member State. The Committee concerned may appoint a second member to act as 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 Procedure¹ specifies the application of this requirement to applications for Union marketing authorisations and for the establishment of maximum residue limits (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*".

According to Article 6(1) of the CVMP Rules of Procedure, the appointment of rapporteurs is to be made on the basis of objective criteria in accordance with the notion of 'best available expertise'. This is in keeping with Article 57(1) of Regulation (EC) No 726/2004 which states that "*The Agency shall provide the Member States and the institutions of the Union with the best possible scientific advice on*

¹ CVMP Rules of procedure EMEA/CVMP/422/04-Rev.1 / EMEA/MB/47098/2007
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004705.pdf



any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use which is referred to it in accordance with the provisions of Union legislation relating to medicinal products.”.

For any appointment of rapporteurs or co-rapporteurs, the European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts (EMA/626261/2014-Rev.1)² applies.

3. Appointment of rapporteur and co-rapporteur

3.1. Marketing authorisations and MRL procedures

- a. Following receipt of an intention to submit an application³ from an applicant, the secretariat shall notify the CVMP by including it on the agenda of the following meeting for information. The appointment of rapporteurs will take place at the subsequent meeting.
- b. Within the two weeks prior to the meeting when the rapporteur and co-rapporteur will be appointed, members and alternates wishing to be considered as rapporteur or co-rapporteur shall indicate this to the secretariat in writing via the member. If a member or alternate wishing to be considered as rapporteur or co-rapporteur acts as lead of a multinational team, he/she will need to indicate also the participants of the team. 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 from the same delegation would not both apply for rapporteurships relating to the same product or MRL application.
- c. Before offering to act as rapporteur, the member or alternate shall satisfy themselves that they have available to them the resources, in terms of expertise and capacity, required for a particular application. Therefore, when offering to act as rapporteur, the member or alternate is declaring that he/she has:
 - Experience and expertise in the relevant therapeutic area;
 - Access to appropriate experts as well as necessary administrative support;
 - Competence in and management of dossier assessment and undertaking scientific risk assessment.

Where several CVMP members and alternates indicate their willingness to act as rapporteur or co-rapporteur for an application, the number of rapporteur or co-rapporteurships allocated to each available CVMP member and alternate will 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 CVMP, amongst members/alternates willing to act as rapporteurs, while ensuring adequate expertise for assessment of the procedure. Generally, only new rapporteurships or extensions of existing rapporteurships allocated in the previous 3 years should be counted.

² European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts https://www.ema.europa.eu/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees_en.pdf

³ Details on timelines and forms see pre-submission guidance http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000171.jsp&mid=WC0b01ac058002d9ab

- d. At the plenary meeting, the CVMP chair will make the appointments of the rapporteur and co-rapporteur with the agreement of the CVMP. Any proposals or preferences of applicants will not be considered for the appointment of rapporteur/co-rapporteur.
- 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 CVMP 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 MRLs, 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 MRLs.
- h. For extension applications, the same rapporteur and co-rapporteur are normally appointed as per the original application. For Type II variations, the rapporteur is the same as the rapporteur for the original applications, but a co-rapporteur may be appointed if it is considered appropriate, for example for a new therapeutic indication. 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.
- i. For the purpose of transparency and to facilitate communication between assessors, the assessment teams acting on behalf of the rapporteurs (for new product applications, extensions, MRL applications and referrals) should be communicated to the CVMP at the start of the procedure/before Day 1 of the procedure. Similarly, any change in assessment teams during the procedure should be communicated to the CVMP.

3.2. Referral procedures

In the case of procedures referred to the CVMP under Article 13 of Commission Regulation (EC) No 1234/2008, Articles 33, 34, 35 and 78 of Directive 2001/82/EC, and Article 30(3) and 45 of Regulation (EC) No 726/2004, the CVMP will adhere to the following general principles for appointment of rapporteur and co-rapporteur:

1. Normally, for the scientific evaluation in respect of a referral procedure a rapporteur and a co-rapporteur shall be appointed. In the case of class referrals, when required, a lead rapporteur and more than one co-rapporteur shall be appointed. The role of the lead rapporteur would primarily be to prepare an overall assessment report, taking into account the assessment from each co-rapporteur. This approach may be useful also in other types of referrals to allow for input from and use of specific scientific expertise.
2. The CVMP chair will make a proposal for the rapporteur and co-rapporteur to the CVMP, taking into account the scientific expertise of the CVMP members and the principles set out below, and will decide on the final appointment of rapporteur/co-rapporteur.

3. If no CVMP member(s) volunteer(s) in the rapporteur/co-rapporteur nomination procedure, the CVMP chair will designate the rapporteur/co-rapporteur, taking into account the members' experience in CVMP procedures and their relevant scientific expertise. It is expected that those CVMP members with the resources and capacity to take on fee-paying rapporteurships (MA or MRL procedure) will also have some capacity for non-fee paying activity; therefore the number of fee paying rapporteur or co-rapporteurships allocated to each available CVMP member will also be taken into account.
4. The (co-)rapporteurship is not open to CVMP members from Member States that have adopted a decision on the same subject matter(s) identified in the referral notification (or request for opinion, in case of procedures under Article 30(3) of Regulation (EC) No 726/2004), and/or is involved in court proceedings related to the same subject matter(s) identified in said notification (or request for opinion). The foregoing does not apply to referral procedures initiated under Article 13 of Commission Regulation (EC) No 1234/2008 and Article 33 of Directive 2001/82/EC.

The paragraph above also applies to the appointment of (co-)rapporteur in re-examinations for referral procedures, where applicable.

For the purpose of the above:

- 'Decision' means any formal act adopted by a national competent authority before the start of the referral procedure, affecting negatively the status of a marketing authorisation of a veterinary medicinal product involved in the referral procedure. For example, a decision refusing the granting of the marketing authorisation(s), a decision not renewing the marketing authorisation(s), a decision on the suspension/revocation of the marketing authorisation(s) or a decision to remove indication(s). Temporary measures taken in the course of the referral procedures are not considered as 'decisions'.
- 'Same subject matter(s) identified in the referral notification' means any scientific issue concerning the quality, safety and/or efficacy raised in the referral notification and involving the same veterinary medicinal product(s) covered in the referral procedure.
- 'Temporary measure' means the actions taken by Member States at any stage of the referral procedure, in exceptional cases, where urgent action is necessary to protect the interests of human or animal health or of the environment and until a definitive decision is adopted at EU level through the adequate referral procedure.

The following shall be considered for the appointment of rapporteur/co-rapporteur as per the particular referral:

Article 13 of Commission Regulation (EC) No 1234/2008:

Rapporteur:	CVMP member from the concerned Member State having major concerns in the variation procedure.
Co-rapporteur:	CVMP member being from the reference Member State for the variation procedure.

Article 33(4) of Directive 2001/82/EC:

Rapporteur:	CVMP member from the concerned Member State having major concerns in the mutual recognition procedure or decentralised procedure.
Co-rapporteur:	CVMP member from the reference Member State of the mutual recognition procedure or decentralised procedure.

Article 34(1) of Directive 2001/82/EC:*Referred by a Member State:*

Rapporteur:	CVMP member from the referring Member State.
Co-rapporteur:	CVMP member from a Member State where a divergent decision has been taken.

Referred by the European Commission or the Marketing Authorisation Holder:

Rapporteur:	CVMP member from a Member State where a divergent decision has been taken.
Co-rapporteur:	CVMP member from a Member State where product is authorised.

Article 35 of Directive 2001/82/EC⁴:*Referred by a Member State:*

Rapporteur:	CVMP member from the referring Member State, normally.
Co-rapporteur:	CVMP member having experience in CVMP procedures and relevant scientific expertise in particular.

Referred by the European Commission or the Marketing Authorisation Holder:

Rapporteur and co-rapporteur:	CVMP member having experience in CVMP procedures and relevant scientific expertise in particular.
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Article 78 of Directive 2001/82/EC:

Rapporteur:	CVMP member from the referring Member State.
Co-rapporteur:	CVMP member from a Member State where product is authorised.

Article 30(3) of Regulation (EC) No 726/2004:

Rapporteur and co-rapporteur:	CVMP member having experience in CVMP procedures and relevant scientific expertise in particular.
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Article 45 of Regulation (EC) No 726/2004:

Rapporteur and co-rapporteur:	CVMP rapporteur and co-rapporteur already identified for the centrally authorised product(s).
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⁴ In case of a parallel procedure under Article 45 of Regulation (EC) No 726/2004, the rapporteur or co-rapporteur for the centrally authorised product is considered for rapporteurship for that Article 35 referral procedure.

3.3. 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) appointed for the initially evaluation.

If no CVMP member(s) volunteer(s) in the rapporteur/co-rapporteur nomination procedure, the CVMP chair will designate the rapporteur/co-rapporteur, taking into account the members' experience in CVMP procedures, their relevant scientific expertise and the number of fee paying (MA or MRL procedure) rapporteur or co-rapporteurships allocated to each available CVMP member.

4. Appointment of the European expert team

In order to accomplish the task of assessing an application or a referral, rapporteurs and co-rapporteurs will choose an evaluation team from the list of European veterinary experts placed at the disposal of the EMA by Member States. The rapporteur and co-rapporteur will ensure that all members of their assessment teams are included in the EMA Expert database with an updated declaration of interest, confidentiality undertaking form and curriculum vitae.

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

5. 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 critique 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 procedure. When offering to act as rapporteur, the member or alternate is declaring that they have the necessary resources (in terms of capacity and expertise) for the procedure in question and can commit to maintain the necessary timeframe.

The rapporteur shall act as a committee representative/spokesman in liaison with Applicant/MAH, although all such contact should be made initially through the secretariat. It may be considered appropriate that rapporteurs meet with an Applicant/MAH pre-submission (to review technical/scientific aspects of a MAA dossier, in particular where there are concerns about incomplete/premature submissions), following adoption of a List of Question/List of Outstanding Issues (LOQ/LoOIs) (clarification meeting) or following an oral hearing (to update the applicant on discussions at the CVMP). The secretariat should be aware of and/or participate in all such contacts with the Applicant/MAH. All such contacts should be documented and declared to CVMP.

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.

It is expected that the rapporteur and co-rapporteur will have available an adequate quality management system at the level of the national competent authority to ensure optimal quality of scientific assessment and regulatory consistency.

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. 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 marketing authorisation and MRL applications, assess the applicant's responses, finalise the list of outstanding issues at Day 180, lead on discussions at an oral explanation should it take place and assist the secretariat with the preparation of the CVMP assessment report and related product information for adoption at Day 210 of the procedure. For referral procedures, the role is the same according to the given timetable.

At each stage of the procedure, the rapporteurs will update their scientific overview/assessment report as appropriate taking account of the input from peer reviewers, members and alternates of the CVMP and the EMA secretariat.

Both the rapporteur and co-rapporteur, with the support from the secretariat, should liaise in advance of the CVMP meeting where the relevant LoQ will be adopted in order to find agreement (in discussion with CVMP members) on key issues and to identify any contentious issues or areas of disagreement. Such issues should be brought out to the attention of CVMP members in advance of the plenary discussion, asking for specific comments.

The rapporteur with support from the co-Rapporteur (or their nominated experts) will submit a brief Reader's Guidance (cover note) summarising the stage of the procedure and the issues identified when circulating their assessment report and subsequent revisions. During the relevant CVMP plenary session, the rapporteur with support from the co-Rapporteur (or their nominated experts) will present the proposed LOQ/LoOIs. Due to time constraints, it is essential that presentations to the Committee are focused on the key issues identified in the dossier and on the areas of disagreement/controversy. Redundancy and excessive background information should be avoided. Presentations should generally not exceed 10-15 slides.

The rapporteur and co-rapporteur will involve additional expertise (e.g. Working Parties, Ad Hoc Expert Groups) as considered necessary and ensure that the input received is appropriately reflected in the assessment report. For example, 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 CVMP Antimicrobials Working Party⁵ (AWP). The rapporteur should take into account AWP 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 Genetically Modified Organisms (GMOs), the rapporteur suggests 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 31(3) of Regulation (EC) No 726/2004.

The secretariat will draft the CVMP assessment report based on the Scientific Overview document prepared by the rapporteur and co-rapporteur, containing the grounds for the CVMP opinion in collaboration with the rapporteur and co-rapporteur. All parties will ensure that the outcome of the

⁵ SOP/V/4042 on Involvement of the CVMP Antimicrobials Working Party in the evaluation of applications for centralised marketing authorisations for veterinary medicinal products containing antimicrobial substances (http://www.ema.europa.eu/docs/en_GB/document_library/Standard_Operating_Procedure_-_SOP/2009/09/WC500003107.pdf)

scientific assessment is sufficiently substantiated and that the data/information underpinning the conclusions reached are accurately reflected in the final assessment report and product information. Rapporteurs have a responsibility to provide clear justifications for the finalisation of CVMP assessment report especially when divergent views are expressed. The document will be adopted by the CVMP together with the CVMP opinion on the concerned procedure. When finalising the opinion, the rapporteurs, CVMP members and EMA staff will ensure that any communications that have been identified as necessary to accompany the opinion are tabled and reviewed by the CVMP as appropriate (question-and-answer documents, communication action plans, lines to take, etc.). Subsequent to adoption of the opinion, the rapporteurs will assist the secretariat with the finalisation of the European Public Assessment Report, focussing in particular on accuracy/factual correctness.

Subsequent to the authorisation of the product, the rapporteur and co-rapporteur are actively involved in post authorisation activities, including the processing of extensions, variations and general support. For pharmacovigilance, the rapporteur or a delegated expert is actively involved.

When a rapporteur leaves the CVMP, 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, reallocation to the CVMP member representing the MS NCA that supports the co-opted member can be considered. Alternatively, the co-rapporteur could be considered as he/she already has experience with the product concerned.