EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Veterinary Use (CVMP)

Appointment and responsibilities of the 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 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 and the possibility of rapporteurs or co-rapporteurs leading a multinational assessment team.

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 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[1] 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*".

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

[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
[2] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/11/WC500177253.pdf

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3. Appointment of rapporteur and co-rapporteur

3.1. Marketing authorisation and MRL procedures

a. Following receipt of an intention to submit an application[3] 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, their role and expertise. 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. At the plenary meeting, the CVMP shall agree the appointment of the rapporteur and co-rapporteur. Any proposals or preferences of applicants will not be considered for the appointment of rapporteur/co-rapporteur.

d. Where several CVMP members and alternates indicate their willingness to act as rapporteur or co-rapporteur for an application, the CVMP chair will normally make the appointments with the agreement of the CVMP, 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

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 CVMP, amongst members/alternates willing to act as rapporteurs. Generally, only new rapporteurships or extensions of existing rapporteurships allocated in the current 3-year mandate period of the CVMP member and alternate 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.

[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

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.

i. 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.

3.2. Referral procedures

In the case of referral procedures to the CVMP under Articles 33, 34, 35 and 40 of Directive 2001/82/EC, 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. 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.

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

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

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

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

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

Referred by the European Commission or the Marketing Authorisation Holder:

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

Article 34(2) of Directive 2001/82/EC (harmonisation of SPCs):

Rapporteur or Co-rapporteur:	The rapporteur **or** co-rapporteur to be appointed is a CVMP member being from a Member State where product is authorised, and the other is to be appointed from among all CVMP members

Article 35 of Directive 2001/82/EC[4]:

Referred by a Member State:

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

Article 40 of Directive 2001/82/EC:

Rapporteur:	CVMP member being from referring Member State
Co-rapporteur:	CVMP member being from Member State where product is authorised

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) initially appointed for the evaluation.

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.

[4] In case of a parallel procedure under Article 45 of Regulation (EC) No 726/2004, CAP rapporteur or CAP co-rapporteur is considered for rapporteurship for that Article 45 procedure.

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. The rapporteur and co-rapporteur must be able to assure the CVMP of the suitability of the experts chosen and their commitment to maintain the necessary timeframe.

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 Union marketing authorisation and MRL applications, assess the applicant's responses, take account of all the input from peer reviewers, members and alternates of the CVMP at the various milestones including, if appropriate, summarising any conclusions which may arise from an oral explanation 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 CVMP Antimicrobials Working Party[5] (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 EMA 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. 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 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.

[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)

- For departure of a co-opted member, the co-rapporteur could be considered as he/she already has experience with the product concerned.

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.