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SCIENCE MEDICINES HEALTH

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Committee for Veterinary Medicinal Products (CVMP)

Procedural advice on appointment and responsibilities of the CVMP rapporteur and co-rapporteur in accordance with Article 140(6) of Regulation (EU) 2019/6, and peer reviewer

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This document has been updated (rev.4) to provide more clarity with regard to (co-)rapporteurship appointments taking into account case law and a European Ombudsman recommendation. The key elements of this revision are the requirement to consider the prior role of the (co-)rapporteur as coordinator for scientific advice for initial applications and changes in rapporteurship. This document is also revised to reflect minor amendments with regards to referral and related procedures.



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1. Introduction

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

The document has been updated to take into account Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products¹.

2. General

According to Article 140(6) of Regulation (EU) 2019/6, for the purpose of performing its tasks referred to in Article 141 of Regulation (EU) 2019/6, the Committee "[...]may appoint,one of its members to act as rapporteur. The Committee may also appoint a second member to act as a co-rapporteur."

Article 140(1) of the Regulation establishes that "The alternates....may also be appointed to act as rapporteurs". Article 7(1) of the CVMP Rules of Procedure² specifies that "For the purpose of performing its tasks referred to in Article 141 of Regulation (EU) 2019/6, the Committee shall appoint one of its members, alternates or co-opted members to act as rapporteur and may appoint a co-rapporteur from amongst its members, alternates or co-opted members".

According to Article 7(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 any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human use or veterinary medicinal products which is referred to it in accordance with the Union legislation relating to medicinal products".

For any appointment of rapporteurs or co-rapporteurs, the European Medicines Agency (EMA) policy on the handling of competing interests of scientific committees' members and experts (EMA/626261/2014-Rev.1)³ applies.

It should also be noted that since 2010 the CVMP has a peer review procedure. The aim of the peer review procedure is to enhance the scientific scrutiny of documents presented to the Committee thereby enhancing their scientific quality and consistency.

3. Role of the rapporteur and co-rapporteur

The CVMP rapporteur and co-rapporteur will:

- Take responsibility for the scientific assessment/evaluation undertaken by their assessment teams within the scope of the concerned procedure in accordance with the timeframes laid down in the EU legislation and the EMA regulatory procedures. The responsibilities of the rapporteur and co-rapporteur are summarised in section 7;
- Coordinate input from her/his assessment team;

¹ [EUR-Lex - 32019R0006 - EN - EUR-Lex \(europa.eu\)](#)

² CVMP Rules of procedure EMEA/CVMP/422/04-Rev.4
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004705.pdf

³ 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

- Review and integrate input from other groups, if applicable, e.g. Working Parties, Scientific Advisory Groups/Ad Hoc Expert Groups;
- Involve additional expertise, as considered necessary;
- Interact with the EMA procedure team;
- Ensure that all activities are performed in a transparent manner (informing accordingly the EMA procedure team);
- Establish interactions with representatives of animal owner organisations and veterinarians or other healthcare professionals' associations (in accordance with Article 7(7) of the CVMP rules of procedure);
- Conclude rapporteurship with the completion of required documentation as appropriate (assessment report, draft opinion, etc.).

4. Appointment of rapporteur and co-rapporteur

4.1. General principles

- All CVMP members, alternates and co-opted members can act as rapporteur/co-rapporteur.
- The rapporteur/co-rapporteur shall be supported by a team of assessors/experts (assessment team) during the various phases of the assessment. The resources of the rapporteur/co-rapporteur's assessment team shall be assessors/experts available not only from the rapporteur/co-rapporteur National Competent Authorities (NCAs)' level, but can be available from across the EEA. The use of multinational assessment teams (with provisions in place at level of EMA for division of fees (for initial applications at current time) between participating NCAs) is strongly encouraged, as a means of increasing capacity, competence and collaboration in the EU regulatory system.
- The appointment of the rapporteur/co-rapporteur shall be made on the basis of objective criteria, which will ensure the provision of objective scientific opinions and will allow the use of the best and available expertise in the EEA in the relevant scientific area, over the lifecycle of the medicinal product.
- In principle, the rapporteur(s) to be appointed should be member(s) or alternate(s) who have not acted as Scientific Advice coordinator for the same product.⁴ Exceptions to this approach could be justified in case that no other member or alternate with a comparable or equally adequate expertise for that product is available. However, this exception may be applied only in relation to either the rapporteur or to the co-rapporteur of the procedure at issue, to guarantee that at least one of them has not acted in the past as Scientific Advice coordinator for the same product.
- In order to ensure the provision of objective scientific opinions and to allow the use of the best and available expertise in the EEA in the relevant scientific area, offers to act as rapporteur/co-rapporteur should only be made when the criteria outlined in section 4.2 are satisfied.

⁴ Decision in the strategic inquiry OI/7/2017/KR on how the European Medicines Agency engages with medicine developers in the period leading up to applications for authorisations to market new medicines in the EU.

4.2. Objective criteria

For the purpose of this paper the objective criteria are identified as rapporteur/co-rapporteur's ability to fulfil their role, which refers mainly to their ability to take responsibility for the scientific assessment and evaluation undertaken by the assessment team, to ensure that the necessary assessors/experts are available and coordination input is provided in a timely manner.

4.3. Evaluation of applications for establishment of MRLs, marketing authorisations and variations requiring assessment

1. Following receipt of a notification to submit an application⁵, the EMA shall notify the CVMP by including it on the agenda.
2. No later than before the start of the CVMP meeting at which the rapporteur and co-rapporteur will be appointed, members, alternates or co-opted members wishing to be considered as rapporteur or co-rapporteur shall indicate this in writing to the EMA and CVMP using the 'All CVMP' Eudranet mailbox. If a member, alternate or co-opted member 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, alternates or co-opted members to be present at the meeting to be appointed rapporteur or co-rapporteur. A member and alternate from the same delegation should not both apply for rapporteurships relating to the same product or MRL application.
3. Before offering to act as rapporteur or co-rapporteur, the member, alternate or co-opted member 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 or co-rapporteur, the member, alternate or co-opted member should declare that he/she has:
 - Experience and expertise in the relevant area;
 - Access to appropriate experts as well as necessary administrative support;
 - Competence in the management of dossier assessment and undertaking of scientific risk assessment.

Where several CVMP members, alternates or co-opted members 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, alternate or co-opted member will be considered. The member and alternate are grouped together per delegation for counting purposes to assist in ensuring fairness. Co-opted members are counted separately. The intent is to appoint rapporteurs and co-rapporteurs as evenly as possible across the CVMP, amongst members, alternates or co-opted members willing to act as rapporteurs, while ensuring adequate expertise for assessment of the procedure.

4. At the plenary meeting, four months prior to the intended submission date, the CVMP chair will make the appointments of the rapporteur and co-rapporteur with the agreement of the CVMP. Proposals or preferences by applicants will not be considered for the appointment of rapporteur/co-rapporteur.

⁵ Details on timelines and forms see pre-submission guidance [Veterinary pre-authorisation guidance | European Medicines Agency \(europa.eu\)](https://www.ema.europa.eu/en/veterinary-pre-authorisation-guidance)

5. For a new application concerning the establishment of an MRL, 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.
6. For variations requiring assessment, a rapporteur is required and is the same as the rapporteur for the initial marketing authorisation. For those variations requiring assessment where it is considered that a co-rapporteur is needed, the co-rapporteur will be the same as that for the initial marketing authorisation.
7. For the purpose of transparency and to facilitate communication between assessors, the assessment teams acting on behalf of the rapporteurs (for new marketing authorisation applications, variations requiring assessment and MRL applications) 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.

4.4. Referrals and related procedures

In the case of procedures referred to the Agency's Committee for Veterinary Medicinal Products under Articles 54(8), 70(11), 82, 130(4) and 141(1)(c), (e) or (i) of Regulation (EU) 2019/6, the CVMP will adhere to the following general principles for appointment of rapporteur and co-rapporteur:

1. Normally, for the scientific evaluation of a referral procedure a rapporteur and a co-rapporteur shall be appointed. In the case of complex class referrals, when required, a lead rapporteur and more than one co-rapporteur could 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.
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, alternates and co-opted members and the principles set out below, and the CVMP will decide on the final appointment of rapporteur and 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.
4. In line with the principle of impartiality, the (co-)rapporteurship is not open to a CVMP member from a Member State that has adopted a decision on the same subject matter(s) identified in the referral notification (or request for opinion/scientific advice, in case of procedures under Article 141(1)(c), (e) or (i) of Regulation (EU) 2019/6), and/or has been involved in court proceedings related to the same subject matter(s) identified in said notification (or request for opinion/scientific advice). The foregoing does not apply to requests for clarification under Article 54(8) of Regulation (EU) 2019/6.

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 CVMP rapporteur/co-rapporteur as per the particular procedure:

Article 54(8) of Regulation (EU) 2019/6:

Rapporteur:	CVMP member or alternate from a concerned Member State having major concerns in the procedure for variation requiring assessment, mutual recognition procedure or decentralised procedure.
Co-rapporteur:	CVMP member or alternate from the reference Member State for the procedure for variation requiring assessment, mutual recognition procedure or decentralised procedure.

Article 70(11) of Regulation (EU) 2019/6:

Rapporteur:	CVMP member or alternate from the concerned Member State disagreeing with the proposed harmonised SPC.
Co-rapporteur:	CVMP member or alternate from the reference Member State in the SPC harmonisation procedure.

Article 82 of Regulation (EU) 2019/6⁶:

Referred by a Member State:

Rapporteur:	CVMP member or alternate from the referring Member State, normally.
Co-rapporteur:	Priority given to the CVMP rapporteur already identified for the CAP(s) ⁷ or if no CAP(s) involved, open to all CVMP members.

Referred by the European Commission or the Marketing Authorisation Holder:

Rapporteur and co-rapporteur:	Priority given to the CVMP rapporteur and co-rapporteur already identified for the CAP(s) ⁷ or if no CAP(s) involved, open to all CVMP members.
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⁶ The same principle will apply for Article 82 procedures based on Article 129(3).

⁷ If at least one CAP is involved in the referral, the CVMP rapporteur already identified for the CAP will be given priority to be appointed for the referral (at the discretion of the CVMP chair). If more than one CAP is involved, the CVMP referral (co-)rapporteur should be appointed from amongst the CVMP (co-)rapporteurs for the CAPs involved in the referral. Note: in case the referral procedure is not product specific, the CVMP chair may advise to open the rapporteurship to all CVMP members.

Article 130(4) of Regulation (EU) 2019/6:

Rapporteur and co-rapporteur:	Priority given to the CVMP rapporteur and co-rapporteur already identified for the CAP(s) ⁷ .
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Article 141(1)(c), (e) or (i) of Regulation (EU) 2019/6:

Rapporteur and co-rapporteur:	CVMP member or alternate having experience in CVMP procedures and relevant scientific expertise in particular.
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4.5. Re-examination of opinions

In accordance with Article 141(4) of Regulation (EU) 2019/6, 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 initial evaluation. These rapporteurs are to be appointed for the duration of the re-examination procedure only.

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 (marketing authorisation or MRL procedures) (co-)rapporteurships allocated to each available CVMP member, alternate and co-opted member. The re-examination procedure is described in the CVMP procedural advice to applicants/marketing authorisation holders on re-examination of CVMP opinions⁸.

5. CVMP peer reviewers

The aim of the peer review process is to ensure the scientific scrutiny of documents presented to the committee, thereby enhancing their scientific quality and the consistency of evaluations. Two peer reviewers will normally be appointed for applications for initial MRL, full marketing authorisation applications and referrals, one peer reviewer for abridged marketing authorisation applications, MRL extensions and more complex variations requiring assessment (e.g. new indication or new target species).

The peer reviewer is mainly expected to review the key document(s) indicating the CVMP's scientific recommendations, e.g. the scientific overview and list of questions (for initial and MRL applications) and the rapporteurs' assessment report (including for referrals). The peer reviewer should provide comments for the initial assessment phase as well as for any later assessment phase following responses to questions.

The peer reviewer should submit written comments according to the same timetable as other CVMP members. While a template for peer review comments will be made available by the EMA at the start of the assessment phase of the procedure, peer review comments provided in other formats will also be accepted. The formal nomination of CVMP member(s) as peer reviewer does not preclude additional CVMP members from providing their comments (using the same template) on a voluntary basis.

⁸ CVMP Procedural advice to applicants/marketing authorisation holders on re-examination of CVMP opinions ([link](#))

6. 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 experts who will form the respective assessment team(s). CVMP members, alternates and co-opted members responsible for the evaluation of applications shall rely on the scientific evaluation and resources made available by national competent authorities and the EMA. When participating at Committee meetings, rapporteurs' meetings or meetings with applicants/MAHs hosted by the EMA, 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.

7. 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 teams. Whilst it is not considered essential for the rapporteur or co-rapporteur to be a 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, alternate or co-opted member 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.

It may be considered appropriate that rapporteurs meet with an applicant/MAH directly at meetings organised by EMA, e.g. following adoption of a List of Questions/List of Outstanding Issues (LOQ/LoOIs) (clarification meeting) or following an oral explanation (to update the applicant on discussions at the CVMP). Direct contacts between an applicant/MAH and the rapporteurs or other members/alternates of the Committee during the assessment of their procedure(s) are not considered appropriate and should be avoided. If an applicant/MAH needs to contact the rapporteurs or other CVMP members/alternates, they must contact first the secretariat who will facilitate the organisation of such meeting. However, it should be noted that the aim of such meetings is primarily to clarify the CVMP LOQ/LoOIs and the views expressed during such meetings should be considered as individual views of persons expressing them and thus in no way they bind the CVMP. 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. For marketing authorisation and MRL applications, in addition to drafting their

initial assessment reports/critiques, they should finalise the list of questions by day 120, assess the applicant's responses, finalise the list of outstanding issues by Day 180, lead on discussions at an oral explanation should one take place and assist the EMA with the preparation of the CVMP assessment report and related product information for adoption by Day 210 of the procedure. For referral procedures and variations requiring assessment, 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, other members and alternates of the CVMP, working parties, SAGs/Ad Hoc Expert Groups (if applicable, see below), and the EMA.

Both the rapporteur and co-rapporteur, with the support from the EMA, 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 to the attention of CVMP members in advance of the plenary discussion, asking for specific comments.

During the relevant CVMP plenary session, the rapporteur with support from the co-rapporteur (or their nominated experts) will provide a brief overview of the procedure and 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 slides.

The CVMP can involve additional expertise (e.g. Working Parties, Ad Hoc Expert Groups) if considered necessary, and rapporteur and co-rapporteur should ensure that the input received is appropriately reflected in the assessment report. A decision on the involvement of additional expertise can be taken by the CVMP at any time before or during a procedure, e.g. at the time when rapporteurs are allocated prior to submission, or during the assessment if the need for additional expertise becomes apparent.

For procedures resulting in a CVMP opinion, the EMA will draft the CVMP opinion and CVMP assessment report, where applicable, based on the latest version of the Scientific Overview document or assessment report/critique prepared by the rapporteur and co-rapporteur (as applicable for the procedure). The documents should contain the grounds for the CVMP opinion, and should be prepared in collaboration with the rapporteur and co-rapporteur. All parties will ensure that the outcome of the 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 the CVMP assessment report, especially when divergent views are expressed or the outcome is not positive. The CVMP assessment report, where applicable, 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 will ensure that any other documents that have been identified as necessary to accompany the opinion are tabled and reviewed by the CVMP, as appropriate (e.g. question-and-answer documents, communication action plans, lines to take, etc.).

Subsequent to the adoption of the opinion, the rapporteurs will assist the EMA with the finalisation of the European Public Assessment Report, focusing 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 variations requiring assessment and general support. For pharmacovigilance, the rapporteur or a delegated expert is actively involved.

8. Changes affecting the appointment of rapporteur/co-rapporteur

The following issues may be encountered which may affect the appointment of rapporteur/co-rapporteur:

- Applicant informs the EMA of a revised intended MAA submission date:
 - Applicant informs the EMA in writing.
 - If appointed rapporteur and/or co-rapporteur and their assessment teams are no longer available, a new appointment procedure shall take place. Otherwise, the availability of appointed rapporteur/co-rapporteur and their assessment teams will remain as is.
- A previously withdrawn MAA is re-submitted:
 - A new appointment procedure of rapporteur/co-rapporteur shall take place.
- Member State appointed member informs the Committee, at any time, that she/he is no longer available to act as rapporteur/co-rapporteur:
 - Normally, the rapporteurship will be taken over by the successor Committee member or by her/his alternate to work with the previously identified assessment team.
 - If this is not feasible, then a new appointment procedure of rapporteur/co-rapporteur and her/his assessment team shall take place.
- Co-opted member informs the Committee, at any time, that she/he is no longer available to act as rapporteur/co-rapporteur:

Co-opted member affiliated to an EU National Competent Authority (NCA):

- The EU NCA to identify a member/alternate to take over the responsibility for (co)-rapporteurship and to work with the previously identified assessment team. The Committee shall confirm this appointment.

Co-opted member not affiliated to an EU National Competent Authority:

- A new appointment procedure of rapporteur/co-rapporteur and her/his assessment teams shall take place.