07 January 2022
EMA/CVMP/422/04 - Rev. 4
Committee for Veterinary Medicinal Products

Committee for Veterinary Medicinal Products

Rules of Procedure

Article 55 of Parliament and Council Regulation (EC) No 726/2004 of 31 March 2004 establishes the European Medicines Agency ('the Agency') with the responsibility for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products for human use and of veterinary medicinal products.

Article 139(1) of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC establishes the Committee for Veterinary Medicinal Products ('the Committee') within the Agency.

The Committee, being part of the Agency, is responsible for carrying out tasks conferred on it under Regulation (EU) 2019/6, and Regulation (EC) No 726/2004, most recently amended by Regulation (EU) 2019/5.

Since the Committee is part of the Agency, the Integrated Quality Management System, endorsed by the Management Board of the Agency on 11 March 2004, applies to the Committee, its working parties and its scientific advisory groups.

Each national competent authority shall monitor the level and independence of the evaluation carried out and facilitates the activities of nominated members and experts. Members States shall refrain from giving Committee members and experts any instruction, which is incompatible with their own individual tasks or with the tasks of the Committee and responsibilities of the Agency.

Having regard to Article 139(6) of Regulation (EU) 2019/6;

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council, as amended by Regulation (EU) 2019/5 of 11 December 2018;

Having regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin;

Having regard to the EEA Joint Committee Decision No 74/1999 of 28 May 1999 regarding the participation of the EEA-EFTA States in the work of the Agency;

The Committee adopts the following rules of procedure:

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

Composition

Article 1

1. The Committee consists of:
    - a chairperson;
    - one member appointed by each of the EU Member States, after consultation of the Management Board, for a term of three years, which may be renewed;
    - one member appointed by each of the EEA-EFTA States, after consultation of the Management Board, for a term of three years, which may be renewed.
2. The Committee, in order to complement its expertise, may appoint up to five co-opted members chosen on the basis of their specific scientific competence, among the experts nominated by Members States or the Agency. Co-opted members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.

Responsibilities of chairperson and vice-chairperson

Article 2

1. The chairperson, and in her/his absence the vice-chairperson, is responsible for the efficient conduct of the business of the Committee and shall in particular:
    - plan the work of the Committee meetings, together with the EMA secretariat;
    - monitor, together with the EMA secretariat, that the rules of procedures are respected;
    - ensure, at the beginning of each meeting, that any potential conflict of interest regarding any particular agenda item to be discussed by the Committee is declared;
    - decide when a vote is necessary;
    - ensure, together with the Committee and the EMA secretariat, the regulatory and scientific consistency of opinions or advices;
    - ensure that scientific grounds are adequately reflected in the Committee opinions;
    - coordinate, together with the EMA secretariat, the work of this Committee with that of the other Committees of the Agency and the coordination group for mutual recognition and decentralised procedures for veterinary medicinal products set up pursuant to Article 142 of Regulation (EU) 2019/6.
2. The vice-chairperson will deputise for the chairperson when the latter is unable to chair, either for the whole or part of the Committee meeting. On such occasions, the chairperson will seek the agreement of the vice-chairperson as early as possible, prior to the meeting, and the EMA secretariat shall be informed immediately.
3. If the vice-chairperson takes the chairperson, her/his place and vote will be assigned to her/his alternate.

Election of chairperson and vice chairperson

Article 3

1. The chairperson and the vice-chairperson of the Committee shall be elected by and from amongst its members for a term of three years, which may be renewed once. Without prejudice to paragraph 5 of the present Article, the chairperson may be elected for a second mandate if a nomination for a renewed term is submitted before the end of his/her first mandate.
2. Nominations for the chairperson and the vice-chairperson should be submitted in writing to the EMA secretariat, no later than by the start of the meeting at which the election is due to take place.
3. Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.
4. The election of the chairperson and the vice-chairperson shall be by absolute majority of the members (i.e. favourable votes by more than half of the total number of Committee members eligible to vote) and by secret ballot. At each round, the candidate(s) with the lowest number of favourable votes shall withdraw. If there is a tie amongst the candidates with the lowest number of votes, all tied candidates are eliminated, and a further voting round is organised with the remaining candidate(s) only. In the case of a tie when only two candidates remain, a new voting round is organised with these two remaining candidates. If, during the new round, the candidate with the highest number of votes does not get an absolute majority, a further voting round is organised with this candidate only. If there is only one (remaining) candidate, she/he needs favourable votes from more than half of the total number of Committee members eligible to vote, to be elected chairperson or vice-chairperson, as the case may be. If the remaining candidate(s) do(es) not get an absolute majority, the election is annulled, and a new election is convened for the next scheduled meeting of the Committee following the same procedure as stated in paragraphs 2 to 4 of the present Article.
5. Once a chairperson has been elected, the chairperson shall lose her/his vote as member from the start of the mandate as chair. If a member is elected as chairperson, the Member State who appointed her or him will appoint a new member of the Committee. If a co-opted member is elected as chairperson, the Committee shall appoint a new co-opted member in accordance with Article 4, of these Rules of Procedure.
6. In the event of resignation of the chairperson, the vice-chairperson shall take the chairperson until a new election has been completed.
7. The members appointed by the EEA-EFTA States may neither vote nor be elected chairperson or vice-chairperson of the Committee.

Appointment of co-opted members

Article 4

1. The Committee shall decide if co-opted members should be appointed and shall agree on their profile and number. The Committee shall also agree on the procedure for the selection of co-opted members.
2. The Committee shall take the necessary steps to identify and appoint any such co-opted members forthwith on the basis of their specific scientific competence.

3. The members and alternates appointed by EEA-EFTA States may not be elected co-opted member. This applies also to experts nominated by EEA-EFTA States.

Alternates to nominated Committee members

Article 5

1. Each member of the Committee referred to under Article 1, paragraph 1 shall have an alternate appointed by their Member State or EEA-EFTA State for a term of three years, which may be renewed.
2. Alternates shall represent and vote for the nominated member from the same Member State, in the absence of said member.
3. Alternates may act as rapporteurs at any time.
4. At the request of the member, the alternate may respond on behalf of the member, in case of written procedures or requests for urgent advice from members between meetings.
5. Alternates may not be elected as chairperson or vice-chairperson of the Committee, but may vote for the election of the chairperson or vice-chairperson in the absence of the member.

Delegation of tasks

Article 6

1. On the basis of Article 140(3) of Regulation (EU) 2019/6 a Member State may delegate its tasks within the Committee to another Member State. Each Member State may represent no more than one other Member State.
2. Delegation is subject to mutual agreement between two Member States.
3. The delegation period will run for an unlimited period until the Member State withdraws it.
4. Delegation can be withdrawn at any time and a Member State always retains the right to withdraw the delegation and take up its tasks at the CVMP itself at any given time.
5. A delegate representing another Member State in the CVMP will have two votes and will be counted as two present members. Alternates shall represent and vote for the nominated member from the same Member State, in the absence of said member.

Rapporteur, co-rapporteur and assessment team

Article 7

1. 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. The appointment of the rapporteur and the co-rapporteur shall be made on the basis of objective criteria, which will allow the use of the best available expertise in the EU on the relevant scientific area.
2. The role of the rapporteur, and when appropriate, the co-rapporteur, is to perform the scientific evaluation and to prepare an assessment report to the Committee according to the timetable

agreed for the evaluation procedure, taking into account the timeframe laid down in the relevant legislation.

3. For the evaluation of new marketing authorisations, establishment of maximum residue limits for new substances as well as for referral procedures the rapporteur is supported by one co-rapporteur, as agreed by the Committee. A co-rapporteur shall be appointed from amongst the members of the Committee or alternates and shall prepare a critique of the rapporteur's report or prepare a separate full report at the discretion of the Committee. A co-rapporteur may also be appointed for variations requiring assessment. The Committee may also appoint (a) peer reviewer(s) from amongst the members and alternates. In addition, the Committee may at any time ask for a peer review of any critical issues by the appropriate Committee's working party or scientific advisory group.

4. The Committee shall establish its own rules for appointment and responsibilities of the CVMP rapporteur(s), co-rapporteur(s) and peer reviewer(s).

5. The rapporteur, and when appropriate co-rapporteur, chooses the experts who will form the respective assessment team(s). Members of the Committee, including co-opted members, or alternates and experts responsible for the evaluation of applications shall rely on the scientific evaluation and resources made available by national competent authorities and the EMA.

6. Whenever meetings between rapporteurs or co-rapporteurs, and applicants or marketing authorisation holders take place, the meetings shall be minuted. The minutes of all contacts shall be made available to the rapporteur, co-rapporteur and the EMA secretariat. Contacts between applicants and marketing authorisation holders with other members of the Committee or alternates during the assessment of their procedures are not considered appropriate and should be avoided. Should such contacts take place, they shall be reported to the rapporteur and co-rapporteur and to the EMA.

7. Rapporteurs may establish contacts on an advisory basis, with representatives of animal owner organisations and veterinarians or other healthcare professionals' associations relevant to the indication of the veterinary medicinal product concerned. Any such contacts should be organised in liaison with the EMA secretariat with the prior agreement of the Committee. The rapporteur should provide a report on the outcome of such contacts to the Committee.

8. The provision of services by rapporteurs or experts shall be governed by written contract between the Agency and the person concerned, or, where appropriate, between the Agency and the employer of the person concerned. The person concerned, or the employer, shall be remunerated in accordance with a scale of fees established by the Management Board of the Agency, to be included in the financial arrangements of the contract.

9. The Committee may (if and when established) consult the relevant scientific advisory group, in particular in relation to the evaluation of a specific product, without prejudice of the legal deadlines established. In such cases, the draft assessment report(s) prepared by rapporteur and co-rapporteur, where appropriate, shall be forwarded to the group for advice in accordance with the procedure agreed by the Committee.

10. The Committee may consult the relevant working party or relevant experts from the European experts list, as appropriate, in particular in relation to the evaluation of a specific product or establishment of maximum residue limits.

11. The format and quality of the assessment report should be determined and judged by the Committee.

Scientific Advice

Article 8

1. The Committee shall establish a standing working party with the sole remit of providing scientific advice to undertakings.
2. The Executive Director, in consultation with the Committee, shall set up the administrative structures and procedures allowing the development of advice for undertakings on maximum residue limits, conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of veterinary medicinal products, including advice on the use of novel methodologies and tools in research and development, particularly regarding the development of novel therapy veterinary medicinal products.
3. For any procedure regarding the provision of advice for undertakings on maximum residue limits, conduct of tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products the Committee shall liaise with its working party on scientific advice, which shall appoint (a) co-ordinator(s) amongst its members for the evaluation.
4. The provisions under Article 7, paragraphs 8 to 11 equally apply regarding the provision of services of co-ordinators, consultation with the scientific advisory groups and assessment reports.

Pharmacovigilance

Article 9

The Committee shall establish a standing working party for pharmacovigilance, as mandated by Article 139(5) of Regulation (EU) 2019/6, with a remit including evaluating potential signals in pharmacovigilance arising from the Union pharmacovigilance system, proposing the options for risk management referred to in Article 79 of Regulation (EU) 2019/6 to the Committee and to the coordination group, and coordinating the communication about pharmacovigilance between the competent authorities and the Agency.

Scientific opinions, scientific advice or recommendations

Article 10

1. The quorum required for the adoption of scientific opinions, scientific advice or recommendations by the Committee, fulfilling the tasks conferred to the Committee in Article 141 of Regulation (EU) 2019/6, shall be reached when two thirds of the total number of members of the Committee eligible to vote are present, either directly, or by having (temporarily) conferred their responsibilities to another member of the Committee (nominated proxy), or by having conferred their responsibilities to another Member State on the basis of Article 140(3) of Regulation (EU) 2019/6. For virtual meetings in order to cope with emergency situations, the quorum required for the adoption of scientific opinions, scientific advice or recommendations by the Committee shall be reached when an absolute majority of the Committee members is connected remotely as foreseen under Article 15(8) of these Rules of Procedure.
2. One member of the Committee (nominated proxy), or the respective alternate, may represent only one other member, when this member and the respective alternate are unable to participate in a meeting. The member that is being represented shall inform the EMA secretariat in advance

including the name of the Committee member delegated to vote on the represented member's behalf.

3. The votes shall be positive or negative (unless the provision concerning the conflicts of interest is applied in line with the EMA policy 0044 on the handling of competing interests of scientific committees' members and experts).

4. Whenever possible, scientific opinions, scientific advice or recommendations given by the Committee shall be delivered by consensus. If consensus cannot be reached, the scientific opinion, scientific advice or recommendation will be adopted if supported by an absolute majority of the members of the Committee (i.e. favourable votes by more than half of the total number of Committee members eligible to vote).

5. When a scientific opinion, scientific advice or recommendation is adopted by vote, the divergent position(s) of the member(s) expressing divergent views and their names shall be mentioned in the scientific opinion, advice or recommendation and in the minutes of the Committee meeting. Members having divergent positions to the scientific opinion, advice or recommendation of the Committee shall provide these in writing before the end of the Committee meeting at which the vote takes place, clearly stating the reasons on which they are based.

6. The opinions of the Committee and where applicable the divergent position(s) to the opinions of the Committee shall be publicly accessible, in accordance with Article 139(8) of Regulation (EU) 2019/6.

7. The members from the EEA-EFTA States may participate to the meeting either directly or by nominated proxy given to another EEA-EFTA member. They may not vote but their positions (given either directly or by nominated proxy) shall be stated in the opinion, and where relevant in the minutes of the Committee. In case of divergent positions, these and their grounds on which they are based, should be stated in writing and will form part of the Committee's opinion.

8. In the event of no absolute majority position in favour of the concerned opinion, the Committee's opinion is deemed to be negative.

9. For Union interest referral procedures in accordance with Regulation (EU) 2019/6 if the Committee cannot achieve a majority vote in support of the question(s) presented, the Committee's opinion will be to maintain the initial regulatory position.

Scientific opinions for international organisations for animal health

Article 11

The Committee may give scientific opinions, in the context of cooperation with international organisations for animal health, for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union. For that purpose, an application shall be submitted to the Agency in accordance with Article 8 of Regulation (EU) 2019/6. The Committee may, after consulting the relevant organisation, draw up a scientific opinion.

Procedure for urgent adoption of opinions

Article 12

1. In some instances, particularly in relation to the provisions of Regulation (EU) 2019/6 on market surveillance and pharmacovigilance, it may be necessary to take urgent decisions. This may be done by:

    - adoption of an opinion during a scheduled meeting (using an accelerated timeframe if necessary), when the need for adoption of the urgent opinion has been identified in the course of said meeting (or within 48 hours before said meeting);
    - the convening of an extraordinary meeting, if considered necessary and if feasible to organise within the available timeframe. Such meetings require the same quorum foreseen under Article 10(1) or Article 15(8) of these Rules of Procedure, if meetings are held virtually. A full report on such an extraordinary meeting will be prepared, formally recording the adoption of the opinion;
    - written procedure in accordance with Article 13.

2. Where the opinion recommends urgent action to be taken in the form of an urgent change in product information, this may be carried out by an urgent safety restriction either within a scheduled meeting, if the timeframe allows, or by written procedure.

3. The decision on the need for the adoption of an urgent opinion outside of a scheduled Committee meeting will be taken by the EMA secretariat in discussion with the chairperson and vice-chairperson of the Committee. The procedure for the adoption of such urgent opinions should be in line with the EMA incident management arrangements.

Written procedure

Article 13

1. Draft opinions can, after approval of the chairperson, be submitted by the EMA secretariat to the Committee for adoption by written procedure. However, such written procedures should be restricted to measures required to be taken between scheduled meetings.

2. Members of the Committee, or alternates in the absence of said members, may raise objections to the draft opinion within a specified time period that is established in agreement with the chairperson. The EMA secretariat shall present a full report on the outcome of the written procedure at the following scheduled meeting of the Committee.

3. In case of serious objections, the chairperson decides whether the written procedure should be suspended, and the adoption of the draft opinion be postponed to the next meeting of the Committee.

Re-examination of opinions

Article 14

1. For the re-examination of opinions mentioned in Article 44(4), Article 66(10) and Article 83(6) of Regulation (EU) No 2019/6, and in Article 8(3) of Regulation (EC) No 470/2009, a different rapporteur and, where previously appointed, a different co-rapporteur from those appointed for the

opinion for which re-examination is requested, will be appointed by the Committee to assess the grounds for the re-examination of the opinion.

2. This re-examination shall be carried out by using best endeavours to ensure a new examination, independent from the initial opinion.

3. The re-examination may deal only with the points of the opinion initially identified by the applicant and is based only on the scientific data available when the Committee adopted the initial opinion. The applicant may request that the Committee consult a scientific advisory group/ad hoc expert group in connection with the re-examination. In this case, the Committee shall request the advice of additional available expertise.

Organisation of meetings

Article 15

1. The Committee shall meet monthly at the Agency except for the month of August, during which no meeting is convened unless explicitly required. The Committee may hold in-person or virtual meetings. In the event of virtual meetings, members participate through a remote connection. The meetings shall be convened by Executive Director or her/his representative, after consultation with the chairperson.

2. The dates of meetings are decided on an annual basis in consultation with the Committee. In exceptional circumstances and on motivated grounds agreed with the chairperson an extraordinary meeting may be convened at short notice.

3. The meetings will be held and minuted in English.

4. Upon agreement with the chairperson and EMA Secretariat, the Committee may hold virtual meetings.

5. The draft agenda for every meeting shall be circulated together with the relating documents by the EMA secretariat in consultation with the chairperson at least 14 calendar days before the meeting. This draft agenda shall enable the Committee to perform its duties as defined in Article 141 of Regulation (EU) No 2019/6.

6. Agendas and minutes of the Committee's meetings shall be made publicly available at pre-defined time points, according to the Agency's policy on transparency.

7. When a member of the Committee is unable to participate in a meeting, part of a meeting, or a discussion topic due to conflict of interest, the member must inform the EMA secretariat in advance. Such declarations will be recorded in the minutes of the respective meeting.

8. In order to cope with emergency situations, possibly coupled with the activation of the Agency's Business Continuity Plan in compliance with the Agency internal guidelines, the following rules shall apply:

8.1. In case of in-person meetings, members who are prevented from participating in person, can participate through a remote connection. The quorum required for the adoption of scientific opinions, scientific advice or recommendations by the Committee shall be reached when an absolute majority of the Committee members is connected remotely (i.e. more than half of the total number of the Committee members eligible to vote), either directly (in person or remotely), represented by their alternate, or by having (temporarily) conferred their responsibilities to another member of the Committee (nominated proxy), or by having conferred their responsibilities to another Member State on the basis of Article 140(3) of Regulation (EU) 2019/6.

The votes shall be positive or negative (unless the provision concerning the conflicts of interest is applied in line with the EMA policy 0044 on the handling of competing interests of scientific committees' members and experts). The members from the EEA-EFTA States may participate to the meeting either directly or by nominated proxy given to another EEA-EFTA member.

8.2. Whenever possible, scientific opinions, scientific advice or recommendations of the Committee shall be taken by consensus. If consensus cannot be reached, the scientific opinions, scientific advice or recommendations will be adopted if supported by an absolute majority of the Committee members (i.e. favourable votes by more than half of the total number of the Committee members eligible to vote). The members from the EEA-EFTA States may not vote but their positions (given either directly or by nominated proxy) shall be stated separately in the opinion, where relevant, in the minutes of the Committee and in case of divergent opinions appended to the Committee's opinion. Their position is not taken into consideration for the purpose of counting the votes for the adoption of the Committee's opinion.

8.3. Members connected remotely can cast their votes remotely. In case a Committee member or alternate temporarily faces difficulties to connect remotely, it is acceptable that her/his vote is cast via email, to be sent before the voting is closed. In this latter scenario, the email must clearly indicate the member who is casting the vote, the opinion, advice or recommendation on which the vote is being cast, as well as the vote cast (in favour or not in favour). For reasons of transparency, the vote cast by email shall be brought immediately to the attention of the chairperson and the other members or alternates of the Committee.

Oral Explanations

Article 16

1. The Committee shall invite an applicant or marketing authorisation holder to provide oral explanations in person or remotely in connection with an evaluation procedure where requested by the applicant or marketing authorisation holder, unless urgent measures need to be adopted for reasons of public or animal health. The Committee may also invite on its own initiative an applicant or marketing authorisation holder to provide oral explanations in person or remotely. Oral explanations may also be provided by the applicant or marketing authorisation holder to working parties or scientific advisory groups/ad hoc expert groups when the Committee has delegated tasks associated with the scientific evaluation to a working party or a scientific advisory group/ad hoc expert group.
2. The Committee may also invite on its own initiative or may consider a request of any other relevant third party for an oral explanation in person or remotely in connection with an evaluation procedure. With the agreement of the Committee, oral explanations may also be provided by any other relevant third party in connection with an evaluation procedure to working parties or scientific advisory groups.
3. Oral explanations shall be indicated clearly in the draft agenda of the meeting.
4. The Committee, working party or scientific advisory group as appropriate shall not make any conclusions during these oral explanations in the presence of the company representatives or the third parties.
5. In all cases the applicant/marketing authorisation holder is informed, at an appropriate time, of the trend at CVMP level following the scientific discussion ahead of any formal vote to conclude the evaluation process.

Coordination with national authorities

Article 17

In addition to their task of providing objective scientific opinions to the Union and Member States on the questions which are referred to them, the members of the Committee shall ensure that there is appropriate coordination between the tasks of the Agency and the work of national competent authorities including the consultative bodies concerned with the marketing authorisation, and the Committee may consult national competent authorities and consultative bodies regarding specific scientific expertise.

Working parties

Article 18

1. In addition to the Scientific Advice Working Party and the Pharmacovigilance Working Party the Committee may establish other standing working parties.
2. Temporary working parties may also be established when work of a temporary or ad hoc nature is required such as preparation of proposals on a specific scientific topic, preparation of responses to specific questions raised by the Committee, drafting of new guidelines or revision of existing ones in relation to specific scientific fields.
3. Working parties are composed of experts selected from the European experts list according to their specific expertise.
4. The document establishing the mandate and objectives of each working party shall include its composition and meeting frequency and in the case of temporary working parties, also the duration of their activity. The Committee shall review the mandate and objectives of each standing working party at least every three years. Those of the temporary working parties should be reviewed either at the end of the period for which they have been created or after three years, whichever comes first. Where amendments are introduced in the mandate, of any working party, the Committee shall consider if the composition of the working party should be re-visited in order to ensure that scientific experience is available to execute the respective mandate.
   The work programmes of each working party shall be reviewed at least annually and will be made publicly available.
5. Whenever considered appropriate the Committee shall consult its working parties on any scientific issue related to their specific fields of expertise. The Committee may also delegate certain tasks associated with the scientific evaluation of applications or drafting of guidelines to the relevant working parties. The tasks identified by the Committee should be included in the work programme of each working party to be adopted by the Committee.
6. The working parties may identify and propose topics for consideration by the working party. Any proposal for a guideline, providing adequate justification, shall be transmitted to the Committee for endorsement and shall be preceded by a concept paper to be endorsed by the Committee.
7. The recommendation from the working parties shall be transmitted to the Committee for adoption.
8. The chairperson of a working party shall be elected by the members of the Committee for a term of three years, which may be renewed once. A Committee member preferably, an alternate or a member of the working party may be elected by the Committee to fulfil this responsibility. The

chairperson will be invited to attend plenary Committee meetings to report on the activities on the working party and ensure liaison with the work of the Committee.

9. A vice-chairperson may be elected by the Committee if the working party considers it appropriate.
10. Nominations should be submitted in writing to the EMA secretariat no later than the start of the Committee meeting at which election of working party (vice-) chairpersons is to take place.
11. Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.
12. The election of the chairperson and the vice-chairperson, where appropriate, shall follow the same procedure as that for the election of the chairperson of Committee as stated in Article 3, paragraphs 1 to 4, of these Rules of Procedure.
13. Agenda and minutes of the meetings of the working parties should be circulated to the Committee. Activity reports are presented by the chairperson or vice-chairperson of the working party or by the EMA secretariat at the following Committee meeting.
14. The Committee shall put in place measures to ensure that there is coordination of work and exchange of information between the standing and temporary working parties.

Scientific advisory groups

Article 19

1. Scientific advisory groups may be established to provide advice to the Committee in connection with the evaluation of specific types of veterinary medicinal products.
2. The group shall consist of a core panel of members. The group may also include additional experts who may be called upon depending on the required expertise by the Committee or the core panel. The Committee shall appoint the members of the group on the basis of nominations from Committee members or the EMA from the European experts list.
3. The scientific advisory group shall appoint a chairperson for the group, who may either be a member of the group, a member of the Committee or an alternate, for endorsement by the Committee. A vice-chairperson may also be appointed if the group considers it appropriate.
4. The Committee shall establish the mandate and objectives of each scientific advisory group and the duration of their activity shall be determined and reviewed when appropriate by the Committee.
5. When considered appropriate the Committee may delegate certain tasks associated with drawing up scientific opinions regarding the evaluation of veterinary medicinal products to the appropriate scientific advisory group.
6. When a scientific advisory group is consulted to provide advice to the Committee in relation to the evaluation of a specific product, the opinion of the group further to the consideration of the draft assessment report(s) prepared by the rapporteur and co-rapporteur, where appropriate shall be forwarded to the chairperson of the Committee according the timetable established in order to ensure that the legal deadlines for evaluation of applications are met.
7. Agenda and minutes of the meetings of the scientific advisory groups shall be circulated to the Committee. Activity reports are presented by the chairperson or vice-chairperson of the scientific advisory groups or by the EMA secretariat at a subsequent Committee meeting.

Drafting groups

Article 20

When further consideration is required in order to prepare proposals on specific topics the Committee or the working parties may convene drafting groups constituted by members or alternates of the Committee, members of the working parties or experts involved in the assessment of an application, as appropriate.

Participation of experts in meetings

Article 21

1. When necessary, the Committee, its working parties and scientific advisory groups may avail themselves of the services of experts in specific scientific or technical fields. Such experts shall have proven experience in the assessment of (veterinary) medicinal products or in their field of expertise and be included in the European experts list.
2. Specialised experts included in the European experts list may be invited to support the Committee in queries, opinions or advices regarding quality, safety or efficacy issues for centrally authorised veterinary medicinal products further to a proposal from the rapporteur, co-rapporteur(s), any member of the Committee or the Agency and with the agreement of the Committee in accordance with the procedure established by the Committee.
3. In addition, members of the Committee may be accompanied by the experts mentioned in paragraph 1 (at their own expense). The names of these experts shall be notified to the EMA secretariat before the meeting which they are due to attend.

Guarantees of independence

Article 22

1. The names of the members and alternates of the Committee shall be made public. When each appointment is published, the professional qualifications of each member and alternate shall be specified.
2. The members of the Committee and alternates, members of working parties, scientific advisory groups and experts mentioned in various articles of the present Rules of Procedure, shall not have any direct interests in the pharmaceutical industry, which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner and shall make an annual declaration of their financial or other interests in the pharmaceutical industry and update such declaration when changes in interests arise. The Declarations of Interest of the members and alternates of the Committee shall be made available on the Agency's website.
3. Members of the Committee and alternates, members of working parties and scientific advisory groups (and experts attending these meetings) shall declare at the beginning of each meeting any specific interests, which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be recorded in the minutes of the meeting.
4. The specific provisions for handling declaration of interests and confidentiality undertakings as defined in the EMA policy on the handling of competing interests of scientific committees' members

and experts, are applicable to members of the Committee, working parties, scientific advisory groups and experts participating in the scientific activities of the Agency.

5. Any incomplete and/or incorrect declarations of interests will be handled according to the Agency's breach of trust procedure on declarations of interests for scientific committees' members and experts.

6. The members of the Committee, and experts, in line with the direction given to Member States by Article 140(9) of Regulation (EU) 2019/6, shall not accept any instructions from the Member States that is incompatible with their own individual tasks, or with the tasks and responsibilities of the Agency. Each national competent authority shall monitor the level and independence of the evaluation carried out and facilitate the activities of nominated members, alternates and experts.

Code of conduct

Article 23

Members of the Committee, working parties, scientific advisory groups and experts participating in the EMA's activities shall abide by the principles set out in the EMA Code of Conduct.

Call for expression of interest

Article 24

The performance of scientific services for which there are several potential providers may result in a call for an expression of interest, if the scientific and technical context allows, and if it is compatible with the tasks of the Agency, in particular the need to provide a high level of public and animal health protection.

EMA secretariat

Article 25

1. Under the authority of the Executive Director, the EMA secretariat shall provide technical, scientific and administrative support to the Committee, its working parties and scientific advisory groups with a view to the performance of its duties as defined in Article 57 of Regulation (EC) No 726/2004 as amended and in Article 139(7) of Regulation (EU) 2019/6. This includes, but is not limited to, the following:

    - Provide technical and scientific support to rapporteurs, and other members of the Committee, working parties and scientific advisory groups;
    - Provide legal and regulatory support to the Committee, working parties and scientific advisory groups;
    - Prepare the Committee's assessment reports on the basis of rapporteur's and co-rapporteurs assessment reports or critique, as appropriate;
    - Prepare and communicate relevant public information related to the activities of the Committee such as news highlights, public statements, questions and answers documents and opinions after consultation of the Committee, where appropriate;

- Prepare and coordinate the work of the Committee, its working parties, scientific advisory groups and ad hoc expert groups in consultation with their chairpersons;
- Ensure that the periods laid down by Union legislation for the adoption of the opinions are complied with;
- Organise meetings of the Committee, working parties and scientific advisory groups ensuring timely circulation of meeting documents;
- Carry out the administrative validation of the applications submitted to the Agency;
- Facilitate the necessary contacts between the Committee, the rapporteur and co-rapporteur, where appropriate, and the applicant or person responsible for the placing on the market of the product;
- Ensure adequate coordination of the work carried out within this Committee, its working parties and scientific advisory groups and between them;
- Ensure scientific and regulatory consistency and quality of the opinions and advices of the Committee in co-operation with the chairperson or vice-chairperson, as appropriate;
- Ensure appropriate coordination between the Committee and other committees of the Agency referred to in Article 56 of Regulation (EC) No 726/2004 and the coordination group for mutual recognition and decentralised procedures for veterinary medicinal products;
- Prepare the minutes of the meetings of the Committee, its working parties and, scientific advisory groups in consultation with the chairpersons;
- Communicate to applicants the relevant opinions and advices of the Committee;
- Communicate to interested parties relevant advices of the Committee;
- Communicate the views of the Committee in international fora;
- Contribute to the joint reporting with the European Food Safety Authority and European Centre for Disease Prevention and Control on the sales and use of antimicrobials in human and veterinary medicine as well as on the situation as regards antimicrobial resistance in the Union based on contributions received by Member States, taking into account the reporting requirements and periodicity in Article 57 of Regulation (EC) No 726/2004 as amended.

2. The Executive Director of the Agency or her/his representative, members of the EMA secretariat and representatives of the Commission, may attend all meetings of the Committee, its working parties and scientific advisory groups.

Contacts with interested parties

Article 26

1. The Committee and its working parties and scientific advisory groups will establish contacts, on an advisory basis, with parties concerned with the use of veterinary medicinal products, in particular animal owner organisations and veterinarians or other healthcare professionals' associations. The Committee may agree to invite representatives of such interested parties to address a plenary meeting.
2. Concept papers and draft guidelines will be subject to public consultation of all interested parties (for example: industry, health care professionals, animal owners or other).

3. When considered appropriate by the Committee, oral explanations by interested parties can be made during working party or scientific advisory group meetings in earlier stages of development of guidelines. The working parties may also meet with interested parties to discuss general matters or specific scientific issues with the agreement of the Committee and under specific conditions to be agreed by the Committee.
4. In any case, the Committee, working parties or scientific advisory groups shall neither conduct any deliberations nor reach any formal decisions in the presence of members of interested parties.
5. Before any consultation session, interested party representatives and Committee members will communicate to the EMA secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the Committee's chairperson and circulation by the EMA secretariat.

Observers

Article 27

1. At the initiative of the European Commission and in agreement with the Management Board, the Committee may admit representatives of international organisations with interests in the harmonisation of technical requirements applicable to veterinary medicinal products to participate as observers at the Committee and working parties' meetings or meetings arranged for this purpose to discuss topics of common interest. The conditions for participation shall be determined in advance by the European Commission.
2. At the initiative of the Management Board, in agreement with the European Commission, the Committee may admit representatives of the industry, animal owners, veterinarians or other healthcare professionals to participate as observers in certain aspects of the Committee's and working parties' work. The conditions for participation shall be determined in advance by the Management Board, in agreement with the Commission.
3. For the purposes of regulatory cooperation, and particularly within the framework of mutual recognition agreements, visiting experts or other representatives from non-EEA regulatory authorities may also participate as observers to the Committee and its working parties. Participation shall be agreed with the respective chairperson in advance of the meeting.
4. The observers shall be bound by the rules of confidentiality.

General Provisions

Article 28

For tasks incumbent on the Agency, other than those of evaluation, the Committee may propose that the Agency has recourse to rapporteurs within the meaning of Article 7 paragraph 1 or to experts within the meaning of Article 21.

Article 29

The Committee may if, they consider it appropriate, seek guidance on important questions of a general scientific or ethical nature.

Article 30

1. The Members of the Committee, working parties and scientific advisory groups 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 professional secrecy.
2. When participating in European, international or other fora on behalf of the Committee, members shall ensure that the views expressed are those of the Committee. They shall follow the EMA policy on scientific publication and representation of EMA scientific committees and their members.
3. When participating in European, international or other fora not specifically on behalf of the Committee, members shall make clear that the views expressed are their own views and not those of the Committee.

Article 31

The decision to adopt or to amend these rules of procedure shall be taken by an absolute majority of the Members of the Committee (i.e. favourable votes by more than half of the total number of Committee members eligible to vote).

Article 32

The rules of procedure or any amendment to them shall enter into force after receiving a favourable opinion from the Commission and the EMA Management Board and will be made publicly available.

Adopted by the Committee on 14 July 2004

Agreed by the Commission on 30 September 2004

Agreed by the Management Board on 30 September 2004

Date of entry into force: 12 October 2004

Revision adopted by the Committee on 15 February 2007

Revision agreed by the Commission on 8 March 2007

Revision agreed by the Management Board on 8 March 2007

Date of entry into force: 16 March 2007

Revision agreed by the Commission on 18 March 2020

Revision agreed by the Management Board on 19 March 2020

Revision adopted by the Committee on 23 April 2020

Date of entry into force: 23 April 2020

Revision adopted by the Committee on 8 September 2021

Revision agreed by the Commission on 29 September 2021

Revision agreed by the Management Board on 7 October 2021

Date of entry into force: 18 October 2021

Revision adopted by the Committee on 8 September 2021

Revision agreed by the Commission on 19 November 2021

Revision agreed by the Management Board on 16 December 2021

Date of entry into force: 28 January 2022