



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 June 2023  
EMA/CHMP/3137/01 Rev 2  
Human Medicines Division  
Veterinary Medicines Division

## Guidance document on voting in the framework of discussion and adoption of committee opinions

### Scope

This document provides guidance on the use of voting in the framework of discussion and adoption of opinions by the European Medicines Agency (EMA)'s scientific committees and by the Co-ordination groups for Mutual recognition and Decentralised procedures. Throughout this document, reference is made to 'opinion' in a generic way. It covers the range of deliverables adopted by the committees and the co-ordination groups as described in their rules of procedure<sup>1</sup>, including scientific opinions, recommendations, decisions, advice, agreements and positions. Also, the term 'committee' in this document encompasses the above-mentioned coordination groups, unless otherwise specified.

The rules of procedure of each of the committees contain a section on the adoption of these opinions. Such section outlines various considerations on voting, including quorum, consensus and majority vote, voting by proxy, expression of divergent positions.

### Background

This document is a revision of the "Guidance document on voting in the framework of the discussion and adoption of CHMP opinions" (CPMP/3137/01 Rev 1.1) which was adopted by the CHMP and published in June 2008.

This guidance document, which is **now extended to all committees**, provides additional clarification on the considerations laid down in the rules of procedure of each committee, taking into account the experience of use of voting in the different committees.

---

<sup>1</sup> Rules of procedure can be found on the [EMA website](#) or on the [Heads of Medicines \(HMA\) website](#); links are available at the end of this document.



## Voting principles

- A **quorum** is required for the adoption of an opinion. In the absence of a quorum, voting is rescheduled or a written procedure needs to be organised.
- Voting can take place in different contexts and at various stages of a procedure, e.g. finalisation of a scientific review, formal adoption of a committee opinion, etc. The **question(s)** put to a committee can be different depending on the nature of the matter discussed by the committee. Questions put to a committee must be unambiguous.
- The committee Chair works towards **achieving consensus** on the committee's opinion. In case of consensus, the Chair will simply ask the committee to confirm that all members are in agreement – i.e. no formal voting is necessary.
- At the time of adoption of an opinion, if consensus cannot be reached, a vote will be taken, and the opinion will be considered adopted if supported by an **absolute majority**<sup>2</sup>. When absolute majority is not reached at the final vote step, the vote outcome and corresponding committee opinion shall be deemed negative in relation to the matter at stake<sup>3,4</sup>. No further vote is to be taken.
- **Trend votes** are used in different contexts but also differently by committees depending on the type of procedures or issues being discussed. Whenever a divergence is identified in a committee, a trend vote can be used to confirm the committee orientation on the issue being discussed.
- At the time of adoption of an opinion at the end of the scientific evaluation procedure on an application, trend votes can be used, when it is clear that there is no consensus view, to determine that there is a clear majority one way or the other. When the outcome of such trend indicates that the opinion will be negative, such outcome is notified to the applicant, which may withdraw its application at this stage (where relevant). In absence of withdrawal, such trend vote at time of opinion's adoption is followed by a **final vote**, which is then the recorded vote.
- Members can cast a **positive** (in favour) **or negative** (against) **vote** only; it is not possible to abstain, with the caveat that members may be unable to participate in a vote due to a declared competing interest<sup>5</sup>. The result of the vote (number of positive and negative votes) is recorded in the meeting's minutes and/or in the opinion of the committee. Please refer to each committee's rules of procedure.
- Unless prevented to do so by a declared competing interest<sup>5</sup>, an **alternate** shall represent and vote for the nominated member in the absence of the member, i.e. when he/she is not in attendance at the meeting. This applies regardless of whether the vote is a trend or final.
- Members unable to participate in a meeting and where also the alternate is unable to participate, can nominate a **proxy**, which is then counted towards the vote.
- In case of adoption of an opinion by absolute majority, those members who did not agree with the absolute majority vote shall provide their **divergent position** in writing, clearly stating the reasons on which they are based, at the latest by the end of the meeting. The names of the

---

<sup>2</sup> In the COMP RoP, Art. 5 (2) stipulates that if a consensus cannot be reached, the scientific opinion will be adopted if supported by at least two thirds of the total number of Committee members eligible to vote.

<sup>3</sup> In the PRAC RoP, Art. 8 (5) stipulates that in the event of no absolute majority position in favour of the concerned recommendation/advice, the PRAC's recommendation/advice is deemed to be negative; Art. 8(6) stipulates that for referral procedures if the PRAC cannot achieve a majority vote in support of the questions(s) presented, the PRAC's recommendation will be to maintain the initial regulatory position.

<sup>4</sup> In the CVMP RoP, Art. 10 (9) stipulates that for Union interest referral procedures if the CVMP cannot achieve a majority vote in support of the question(s) presented, the Committee's opinion will be to maintain the initial regulatory position.

<sup>5</sup> Please see [EMA policy 0044 on handling of competing interests of scientific committees' members and experts](#)

members expressing the divergent positions shall be mentioned in the meeting's minutes and/or in the opinion of the committee. In case re-examination has been requested, the outcome of such re-examination has to be awaited<sup>6</sup> before publication of the names of individuals expressing divergent views on the opinion for which a re-examination has been requested can take place. Please refer to each committee's rules of procedure.

- EMA scientific committees' members should bear in mind the requirements of Article 61 (6) of Regulation (EC) No 726/2004 and Article 140 (9) of Regulation (EU) 2019/6 (*Member States shall refrain from giving committee members and experts any instruction which is incompatible with their own individual tasks or with the tasks and responsibilities of the Agency*)– when voting.

## Voting process

### *During the plenary meeting*

1. Voting can take place at any time during the meeting or during predefined timeslots, aiming to have the maximum attendance of committee members when voting.
2. The EMA Secretariat checks and records the presence of a **quorum** of members during the voting.
  - Quorum is defined as two thirds of the committee members eligible to vote, based on the composition of the committee at the given meeting. The number of members present is verified to ensure that the quorum is met. However, in situations of emergency<sup>7</sup> possibly coupled with the activation of the Agency's Business Continuity Plan, the quorum is reduced to absolute majority (except for COMP), as laid down in the respective committee's rules of procedure.
  - The members from EEA-EFTA States are excluded when calculating the quorum.
  - The quorum is not impacted by member(s)' competing interest<sup>5</sup> and inherent inability to participate in a vote.
  - Members unable to participate in a meeting and where also the alternate is unable to participate, can nominate a proxy, which is then counted towards the quorum.
3. Members, who are eligible to vote, take part in the adoption of an opinion.
  - The position of the members from EEA-EFTA States is not taken into consideration for the purpose of counting the votes for the adoption of an opinion. Where applicable, these positions shall be stated separately in the opinion and/or in the minutes of the committee and in case of divergent opinions appended to the committee's opinion.
  - A member, who received a proxy from a committee member unable to participate in a meeting, will vote twice.
  - A member with a competing interest<sup>5</sup> associated with a restriction leading to inability to take part in final deliberations and vote on a medicinal product is not permitted to take part in the adoption of the opinion of that product. In such circumstance, the alternate can vote if in attendance.
4. If consensus cannot be reached, a formal vote is taken, using a voting software/system that is suited to the meeting type (in-person, full committee remotely connected or hybrid setting). Each

---

<sup>6</sup> Please see [Principles for publication of agendas and minutes of EMA scientific committees](#).

<sup>7</sup> Apart from public health emergencies, situations of emergency are expected to be exceptional (e.g. ash cloud preventing air traffic over Europe, strike at airport in Amsterdam preventing airplanes to land).

committee's rules of procedure clarify circumstances when votes can be cast via e-mail. An adoption by **absolute majority** is defined as an adoption where favourable votes are cast by more than half of the committee members eligible to vote, based on the composition of the committee at the given meeting.

- For COMP, the majority equals the quorum, as Article 5 (6) of Regulation EC 141/2000 stipulates that, if consensus cannot be reached in the COMP, the opinion shall be adopted by a majority of two thirds of the members of the committee.

### ***Extraordinary meetings outside of the scheduled plenary meetings***

An extraordinary meeting may be convened outside of the scheduled committee meetings in order to take an urgent decision, with regard to, for example, pharmacovigilance, serious concerns on public or animal health or quality defects.

Such meetings should take place in the presence of a quorum<sup>8</sup>. Where a quorum is present, all rules described in the previous sections apply.

Where it has not been possible to obtain a quorum at the extraordinary meeting, either a new meeting is convened or the adoption of the opinion takes place via a written procedure with a short deadline, in line with the procedure outlined below.

### ***Written procedure***

Opinions to be adopted by written procedure are sent to all committee members and alternates, with all relevant annexes and appendices where applicable, and with any additional relevant documentation, with a clear deadline (at least 24 hours during working days).

Members are invited to only respond to express comments or objections. Comments or objections must be submitted within the defined deadline.

If comments lead to substantial changes to the opinion, the committee Chair in consultation with the Secretariat will decide to run a new written procedure. If only minor changes are implemented, no new written procedure is required.

An opinion submitted for adoption by a written procedure is considered adopted by consensus if no objections are received.

Any objections preventing adoption by consensus should be sent to the committee Chair, all committee members and alternates and the EMA Secretariat, with supporting justification. In case of objections (i.e. where consensus has not been achieved), the committee Chair will decide whether the written procedure should be suspended and the adoption of the opinion postponed to the next committee meeting.

Rules of procedures (RoP)

[CHMP RoP](#)

[CVMP RoP](#)

[PRAC RoP](#)

[CAT RoP](#)

[PDCO RoP](#)

[COMP RoP](#)

[HMPC RoP](#)

[CMDh RoP](#)

[CMDv RoP](#)

---

<sup>8</sup> The normal quorum defined as two thirds of the committee members eligible to vote applies, unless the extraordinary meeting is convened at a time when the Agency has declared being under a situation of emergency possibly coupled with the activation of its Business Continuity Plan.