



GUIDANCE DOCUMENT ON VOTING IN THE FRAMEWORK OF DISCUSSION AND ADOPTION OF CHMP OPINIONS

Background

Scope: This procedure covers the discussion and adoption of opinions (i) during a CHMP meeting, (ii) outside of a CHMP meeting (extraordinary meeting) or (iii) by written procedure, including the checking of the trend amongst CHMP Members and the scope of the voting at the time of formal adoption.

This document is a revision of the “Guidance Document on Voting in the Framework of the Discussion and Adoption of CPMP Opinions,” which was adopted by the Committee in January 2002.

Extract from CHMP Rules of Procedure (EMEA/CHMP/111481/2004):

Alternates to nominated Committee members

Article 5, 2

Alternates shall represent and vote for the nominated member in the absence of the member, when he/she is not in attendance at the meeting.

Scientific opinions and recommendations

Article 8.

1. The quorum required for the adoption of scientific opinions or recommendations by the Committee shall be reached when two thirds of the total members of the Committee eligible to vote are present. The votes shall be positive or negative (unless the provision concerning the conflicts of interest is applied).

2. Whenever possible, scientific opinions or recommendations of the Committee shall be taken by consensus. If such a consensus cannot be reached, the scientific opinion or recommendation will be adopted if supported by an absolute majority of the members of the Committee (i.e. favourable votes by at least half of the total number of Committee members eligible to vote plus one).

3. The divergent positions of and the names of the members expressing the divergent positions shall be mentioned in the opinion of the Committee, and where relevant, the minutes of the Committee. Members having divergent positions shall provide them in writing, stating clearly the reasons on which they are based. They will be appended to the opinion. The reasons for the divergent opinions shall be publicly available together with the documentation made publicly available in relation to the evaluation of applications.

4. The members from the EEA-EFTA States may not vote but their positions 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 counted in reaching the Committee’s opinion.

5. In the event of no absolute majority position in favour of the granting, variation, suspension or withdrawal of a marketing authorisation, the Committee's opinion is deemed to be negative.

Procedure for urgent adoption of opinions

Article 9

1. In some instances, it may be necessary to take an urgent decision with regard to pharmacovigilance, serious concerns on public health or quality defects. This may be done by:

- Adoption of an opinion during the course of a scheduled meeting (using an accelerated timeframe if necessary), when the need for adoption of the urgent opinion /agreement on course of action has been identified during the course of the meeting (or within 48 hours before the meeting);
- The convening of an extraordinary meeting, if considered necessary and if feasible to organise within the necessary short timeframe. A separate full report of this meeting, formally recording the adoption of the opinion should be prepared;
- By written procedure in accordance with Article 10.

2. Where the action to be taken requires 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 a 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 EMEA Secretariat in discussion with the Committee Chairperson and Vice-Chairperson. The procedure for the adoption of such urgent opinions should be in line with the EMEA Crisis Management Plan.

Written procedure

Article 10

1. Draft opinions and recommendations can, after approval of the Chairperson, be submitted by the EMEA 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. Draft opinions or recommendations are addressed to members of the Committee, who may raise objections within a specified time period, to be established in agreement with the Chairperson. The Secretariat shall present a full report on the outcome of the written procedure at the following meeting of the Committee.

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

Principles:

- The Chairman works towards achieving consensus on the scientific opinions and recommendations of the Committee.
- At the time of finalisation of the scientific review: The trend amongst CHMP members should be **systematically checked**, once the CHMP has finalised its scientific review. Where the Committee is in consensus, the Chairman will ask the Committee to confirm that this is the case. Where such consensus has not been achieved, the trend (i.e. number expressing positive view and number expressing negative view) should be formally taken and recorded.
- The applicant/MAH should be informed of the trend amongst CHMP Members.

- At the time of adoption of the scientific opinion: Where the Committee is in consensus the Chairman will ask the Committee to confirm that this is the case. Where such consensus has not been achieved, a formal voting procedure should be initiated.

Checking of the Trend at CHMP meetings.

- Trend vote during Assessment procedure.

With a view towards achieving consensus, the Chairman can ask for a trend vote at various stages during the assessment procedure. Trend votes may be used to move the procedure forward – e.g. to determine the viewpoint of the committee with respect to proposed indications (inclusion/restriction etc), the need for an oral explanation etc. The checking of the trend, in these instances, is carried out to determine the informal position of Committee members, and is not reported to the Applicant /MAH. Such trends may be checked by a hand count.

- Following finalisation of scientific review.

Once the CHMP has finalised its scientific review, the Chairman should systematically check the trend amongst CHMP members. This may be carried out after an oral explanation, (and subsequent discussion to verify that all outstanding issues have been addressed), or - where no oral explanation is requested, - at the end of discussions on the assessment.

It should be noted that such checking of the trend can only be performed once all necessary information is available. If necessary, the trend can be checked separately in relation to different aspects of the application (e.g. different indications requested by the applicant).

The question(s) to be put to the Committee can be different depending on the nature of the matter discussed by the CHMP. In case of applications for marketing authorisation the question will be whether the Committee is in favour of recommending the granting of a marketing authorisation; whereas in case of referrals the recommendation put to the CHMP will depend on the issue, which has been raised in the referral to the CHMP. The question(s) put to the CHMP, as well as the trend, are recorded in the Minutes of the CHMP Meeting.

Where the Committee is in consensus, the Chairman will ask the Committee to confirm that this is the case. Where such consensus has not been achieved, the trend should be formally checked, using the electronic voting software.

The applicant/MAH should be systematically informed (by the Rapporteur, Co-Rapporteur and EMEA Product Team Leader) of the trend amongst CHMP Members, irrespective of whether there has been an oral explanation or not, and irrespective of whether a formal vote needs to take place.

Voting process.

Formal voting on the opinions of the Committee should take place during slots identified for the adoption of final documents, in order to guarantee the maximum attendance of CHMP Members.

The EMEA Secretariat should check and record the presence of a quorum of members during the voting slots.

CHMP Members will be requested to vote on the totality of the application as it has been presented to the CHMP at the time of the formal vote, i.e. after potential withdrawal of part(s) of the application submitted originally.

The recommendation put to the CHMP during the formal vote should be in accordance with the recommendation put to the Committee during the previous checking of the trend.

Where a trend vote has been recorded and notified to the applicant /MAH, it is not anticipated that the final formal vote will reflect a change in the opinion of the Committee, unless anything has changed substantially from the time of the trend vote to that of the final vote.

Where the Committee is in consensus, the Chairman will ask the Committee, during the identified voting slot, to confirm that this is the case. Where such consensus has not been achieved, a formal voting procedure, using the electronic voting software, should be used.

Members should bear in mind the requirements of Article 61, 6 of Regulation 726/2004 - *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 on any procedure.

The outcome of the voting, including the number of positive and negative votes in the event of a split opinion, as well as the names of any members expressing a divergent view, will be recorded in both the Minutes of the meeting and in the final opinion.

Note: The opinion procedure is only considered finalised when it is signed by the CHMP Chairman.

Voting procedure outside of the CHMP meeting.

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

Such meetings should ideally take place in the presence of a quorum of CHMP members (when two thirds of the total members of the Committee eligible to vote are present). Where a quorum is present, the rules as described in the previous sections apply.

Where it has not been possible to obtain a quorum at the meeting, the final opinion will be adopted via a written procedure, in line with the procedure outlined below.

Written procedure

Opinions to be adopted by written procedure should be forwarded to all CHMP members, with all relevant annexes and appendices, and with any additional relevant documentation, requesting comments within a defined deadline. Any objections should be forwarded to the CHMP Chairman and the EMEA Secretariat, with a copy to all CHMP Members, within the defined deadline.

The opinion will be considered adopted if supported by all members (consensus) or by an absolute majority of the members of the Committee (i.e. favourable votes by at least half of the total number of Committee members eligible to vote plus one). The absence of comments within the defined deadlines will be taken as agreement with the opinion.

In case of serious objections, (i.e. where consensus / majority position has not been achieved), the CHMP Chairman will decide whether the written procedure should be suspended and the adoption of the final Opinion postponed to the next CHMP meeting.