



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Advanced Therapies

Committee for Advanced Therapies (CAT)

Rules of Procedure

Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on Advanced Therapy Medicinal Products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 lays down specific rules concerning the authorisation, supervision and pharmacovigilance of Advanced Therapy Medicinal Products and set up a Committee for Advanced Therapies (CAT or the Committee).

Since the CAT is part of the European Medicines Agency, the Integrated Quality Management System, endorsed by the Agency Management Board on 11 March 2004, applies to this Committee;

Having regard to Article 61(8) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

Having regard to Parliament and Council Directive 2001/83/EC, as amended, on the Community Code relating to medicinal products for human use;

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 EMA;

Having regard to Article 48(3), (4), (7) and (8) of Regulation (EU) 2017/746 in conjunction with Section 5.2 of Annex IX and Section 3 (point (k)) and 5.5 of Annex X relating to the consultation procedure initiated by a notified body on the suitability of a companion diagnostic in relation to the ATMP concerned.

Having consulted the Commission and the Management Board of the Agency on the basis of Article 61(8) of Regulation (EC) No 726/2004;

The Committee adopts the following rules of procedure:

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Composition

Article 1

1. The Committee consists of:

(a) five members or co-opted members of the Committee for Medicinal Products for Human Use (CHMP) coming from five Member States, with alternates either proposed by their respective Member State or, in the case of co-opted members of the CHMP, identified by the latter on the advice of the corresponding co-opted member. These five members with their alternates shall be appointed by the CHMP;

(b) one member and one alternate appointed by each EU Member State whose national competent authority is not represented among the members and alternates appointed by the CHMP;

(c) One member and one alternate appointed by their respective Member States from the EEA-EFTA;

(d) two members and two alternates appointed by the European Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent clinicians;

(e) two members and two alternates appointed by the European Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent patients' associations.

(f) A chair, which shall be elected in line with Article 3.

2. All members of the CAT shall be chosen for their scientific qualification or experience in respect of Advanced Therapy Medicinal Products (ATMP). For the purposes of the appointment of the members and alternates by the CHMP and the Member States, the Member States shall cooperate, under the coordination of the Executive Director of the Agency, in order to ensure that the final composition of the CAT appropriately and in a balanced way covers the scientific areas relevant to advanced therapies, including medical devices, tissue engineering, gene therapy, cell therapy, biotechnology, surgery, pharmacovigilance, risk management and ethics.

At least two members and two alternates of the CAT shall have scientific expertise in medical devices.

3. The members of the CAT shall be appointed for a renewable period of three years. At meetings of the CAT, they may be accompanied by experts.

4. The names and scientific qualifications of the members shall be made public by the Agency, in particular on the Agency's website.

Responsibilities of Chair and Vice-Chair

Article 2

1. The chair, and in their absence the vice-chair, is responsible for the efficient conduct of the business of the CAT and shall in particular:

- plan the work of the CAT meetings together with the European Medicines Agency (EMA) Secretariat;
- monitor, together with the EMA Secretariat, that the rules of procedure are respected;

- ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the CAT;
 - decide when a vote is necessary;
 - ensure, together with the CAT and the EMA Secretariat, the regulatory and scientific consistency of the draft opinions prepared by the CAT for final approval by the CHMP (hereafter called "draft opinion");
 - ensure that scientific grounds are adequately reflected in such draft opinions;
 - ensure, together with the CAT and the EMA Secretariat, the regulatory and scientific consistency of any scientific recommendations;
 - ensure, together with the CAT and the EMA Secretariat, the regulatory and scientific consistency of the CAT opinion for certification;
 - ensure, together with the CAT and the EMA Secretariat, the regulatory and scientific consistency of the CAT scientific recommendation on advanced therapy classification;
 - ensure, together with the CAT and the EMA Secretariat, the regulatory and scientific consistency of the CAT scientific reports;
 - co-ordinate together with the EMA secretariat the work of the CAT with that of the other committees of the Agency and in particular the CHMP and others such as COMP, PDCO and PRAC.
2. The vice-chair deputises for the chair when the latter is unable to chair either all or part of the CAT meeting. On such occasions, the chair seeks the agreement of the vice-chair as early as possible, prior to the meeting and the EMA Secretariat shall be informed immediately.
 3. If the vice-chair takes the chair, their place and vote is assigned to their alternate.

Election of Chair and Vice-Chair

Article 3

1. The chair and vice-chair 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 chair may be elected for a second mandate if a nomination for a renewed term is submitted before the end of their first mandate.
2. Nominations for chair and vice-chair should be submitted in writing to the EMA secretariat no later than the start of the Committee's meeting at which the election is 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 chair and the vice-chair 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 shall withdraw, 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, they need favourable votes from more than half of the total number of CAT members eligible to vote, to be elected chair or vice-chair, 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 CAT following the same procedure as stated in paragraphs 2 to 4 of the present Article.

5. Once a chair has been elected, the chair shall lose their vote as member from the start of the mandate as chair. If a member is elected as chair, the Member State or, as appropriate, the CHMP or the European Commission who appointed them, will appoint a new member of the CAT.
6. In the event of resignation of the chair, the vice-chair shall take the chair until a new election is convened.
7. The members and alternates from the EEA-EFTA States may not vote nor be elected chair or vice-Chair of the Committee.

Alternates to nominated Committee members

Article 4

1. Each alternate of the CAT shall be appointed for a renewable period of three years.
2. Alternates shall represent and vote for the nominated member in the absence of the member, when they are not in attendance at the meeting. They may act as (co)-rapporteurs at any time. At the request of the member, the alternate may respond on behalf of the member in case of written procedures or any request for urgent advice from members between meetings.
3. Alternates may not be elected as chair or vice-chair of the Committee but may vote for the election of the chair or vice-chair in the absence of the member.

CAT Rapporteur, Co-Rapporteur and Assessment Team

Article 5

1. For any scientific evaluation of an ATMP, CHMP shall appoint under consultation of the CAT and the CHMP chair two evaluation teams, including, respectively, a CAT rapporteur and a CAT co-rapporteur from amongst the members or alternates of the CAT, together with the assessment team members. Such appointment shall be made on the basis of objective criteria, which allows the use of the best available expertise in the EU on the relevant scientific area of advanced therapies. The Committee may also appoint (a) peer reviewer(s) from amongst the members or alternates.

For such appointment, the two chairs of the CHMP and CAT discuss the appointment before their proposal is made to the CHMP. The assessment team identified when expressing interest for the rapporteurship of an ATMP must include a CHMP Member as CHMP Co-ordinator.

2. The CAT rapporteur, and when appropriate, CAT co-rapporteur chooses the experts who will form their assessment team. They also propose a CHMP Co-ordinator from the CHMP members/alternates (including the co-opted members). They notify their choice to the EMA prior to the start of the procedure. Members of the Committee 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.
3. The role of the CAT rapporteur and CAT co-rapporteur together with the appointed assessment team members is/are to perform the scientific evaluation of ATMPs, to prepare an assessment

report and to circulate it to the CAT and CHMP members according to the timetable agreed for the evaluation procedure and taking into account the timeframe laid down in the relevant legislation. There should be adequate and sufficient interaction and communication between the two committees, CAT and CHMP, via the assessment team members.

4. For the evaluation of new marketing authorisations, Type II variation applications involving a new indication and renewals, the rapporteur is supported by the co-rapporteur.
5. For the consultation procedure initiated by a notified body on the suitability of a companion diagnostic in relation to the ATMP concerned, the CAT rapporteur for the ATMP concerned shall act as the CAT rapporteur. The CHMP Co-ordinator will be closely involved. No co-rapporteur appointment is foreseen.
6. Whenever meetings between CAT rapporteur or CAT co-rapporteur with applicants or marketing authorisation holders (MAH) take place, minutes of all contacts shall be made available to all the assessment team members and to the EMA Secretariat. Contacts by other members and alternates with applicants and MAHs are not considered appropriate and should be avoided during assessment procedures. Should such contacts take place, these shall be reported to the CAT (co)-rapporteurs and to the EMA Secretariat.
7. The provision of services by the (co)-rapporteurs or experts shall be governed by a written contract between the Agency and the person concerned, or where appropriate between the Agency and their employer. The person concerned, or their employer, shall be remunerated in accordance with a scale of fees to be included in the financial arrangements established by the Management Board.
8. The CAT may 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 case, the assessment report(s) prepared by the CAT rapporteur and co-rapporteur, where appropriate, shall be forwarded to the group for advice in accordance with the procedure to be agreed by the CAT. The CAT may consult the relevant working party and/or relevant experts from the European expert list, as appropriate.
9. The quality of the assessment report should be determined and judged by the CAT.
10. CAT (co)-rapporteurs may establish contacts on an advisory basis, with representatives of patient organisations and health-care professionals' associations relevant to the indication of the medicinal product concerned or to the intended purpose of the medical device concerned. Any such contacts should be organised in liaison with the EMA Secretariat with the prior agreement of the CAT. The rapporteur should provide a report on the outcome of such contacts to the CAT.

Draft opinions, opinions and recommendations

Article 6

1. The quorum required for the adoption of the draft opinions, recommendations/advice by the CAT shall be reached when two thirds of the total members of the CAT eligible to vote are present, either directly or by nominated proxy. A member of the CAT, or their alternate, may represent only one other member, when this member and their alternate is unable to participate in a meeting. The member that is being represented shall inform the Committee Secretariat in advance. Pending appointments of members made by the European Commission shall not be taken into account for the purpose of determining the quorum. The votes shall be in favour or against (unless a member is unable to participate due to a declared conflict of interest).

2. Whenever possible, opinions, scientific recommendation/advice of the CAT shall be taken by consensus. If such a consensus cannot be reached, the draft opinion, scientific recommendation/advice will be adopted if supported by an absolute majority of the members of the CAT (i.e. favourable votes by more than half of the total number of CAT members eligible to vote).
3. The names of the members expressing divergent positions shall be mentioned in the draft opinion, recommendation/advice of the CAT and in the minutes of the CAT. Members having divergent positions shall provide them in writing, stating clearly the reasons on which they are based. The reasons for the divergent positions shall be publicly available together with the documentation made publicly available in relation to the CAT's opinions, recommendation/advice.
4. If scientific divergences remain, the chair may ask the members for a "trend vote" on the outcome of a procedure. If a "trend vote" takes place, the applicant is informed of the trend at CAT level at the end of the scientific discussion ahead of any formal vote to conclude the CAT evaluation process.
5. 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 separately in the draft opinion, where relevant, in the minutes of the CAT and in case of divergent opinions appended to the draft opinion, opinions and recommendations. Their position is not taken into consideration for the purpose of counting the votes for the adoption of the draft opinion, opinions and recommendations.
6. In the event of no absolute majority position in favour of the concerned draft opinion, scientific recommendation/advice, the CAT's draft opinion, scientific recommendation/advice is deemed to be negative.

CAT adoption of the draft opinion for final approval by the CHMP

Article 7

1. The CAT is responsible for preparing a draft opinion on the quality, safety and efficacy of each ATMP for final approval by the CHMP. This draft opinion is issued on any scientific assessment of ATMPs necessary to draw up the scientific opinions by the CHMP relating to granting, variation, suspension or revocation of an authorisation to place an ATMPs on the market in accordance with Regulation (EC) No 1394/2007 and pharmacovigilance. At the request of the Executive Director of the Agency or the European Commission, an opinion is also drawn up on any scientific matter on ATMPs.
2. The CAT is also responsible for preparing a draft scientific opinion on the suitability of a companion diagnostic in relation to the ATMP concerned. The draft scientific opinion will be prepared for final approval by the CHMP in the framework of the consultation procedure initiated by a notified body in accordance with Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices.
3. The divergent positions and the names of the members expressing the divergent positions shall be mentioned in the draft opinion of the CAT and where relevant, the minutes of the CAT. Members having divergent positions shall provide them in writing, stating clearly the reasons on which they are based. The divergent positions are appended to the draft opinion.

4. 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 draft opinion, where relevant, in the minutes of the CAT and in case of divergent opinions appended to the draft opinion. Their position is not taken into consideration for the purpose of counting the votes for the adoption of the draft opinion.

Procedure for urgent draft opinions

Article 8

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 a draft opinion during the course of a scheduled CAT meeting (using an accelerated timeframe if necessary), when the need for adoption of the urgent draft opinion/agreement on course of action has been identified during the course of the CAT meeting;
 - Exceptionally, an extraordinary meeting could be held, if considered necessary and if feasible to organise within the short timeframe. This meeting should take place in the presence of a quorum allowing the CAT to adopt a draft opinion i.e. when at least two thirds of the members are available to participate. This extraordinary meeting might be organised jointly with the CHMP. A separate full report of this meeting, formally recording the adoption of the draft opinion should be prepared;
 - Written procedure in accordance with Article 9.
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, in collaboration with the CHMP, which is the ultimate Committee adopting the final action to be taken based on the draft opinion prepared by the CAT.
3. The decision on the need for the adoption of an urgent opinion outside of a scheduled CAT or CHMP meetings is taken by the EMA Secretariat in discussion with the committee's chairs and vice-chairs. The procedure for the adoption of such urgent draft opinions should be in line with the EMA incident management arrangements.

Written procedure

Article 9

1. The preliminary version of the following documents can, after approval of the chair, be submitted by the EMA Secretariat to the CAT for adoption by written procedure, without impeding the legal timeframes of the evaluation:
 - The draft opinions prepared by the CAT for final approval by the CHMP;
 - The CAT opinion for certification;
 - The CAT scientific recommendation on advanced therapy classification;
 - Any CAT scientific recommendation;
 - The CAT scientific reports.

However, such written procedures should be restricted to measures required to be taken between scheduled meetings.

2. CAT members may raise objections to the preliminary version of the above documents within a specified time period, to be established in agreement with the chair. The Secretariat shall present a full report on the outcome of the written procedure at the following meeting of the CAT/CHMP, as appropriate.
3. In the case of serious objections, the chair decides whether the written procedure should be suspended and the adoption of the draft opinion, CAT opinion for certification, CAT scientific recommendation on advanced therapy classification, CAT scientific recommendation or CAT report postponed to the next meeting of the CAT.

Re-examination of CHMP opinions

Article 10

1. For the implementation of the procedures for the re-examination of CHMP opinions as mentioned in Article 8(1) of Regulation (EC) No 1394/2007, different CAT (co)-rapporteurs from the one appointed for the initial CAT/CHMP evaluation are appointed to assess the grounds for the re-examination of opinions. This re-examination procedure shall use the best endeavour to ensure a new examination, independent from the first CHMP opinion.
2. The CAT, on basis of the assessment reports from the new appointed CAT (co)-rapporteurs, is responsible for preparing and adopting the draft opinion for final approval by the CHMP.
3. The re-examination may deal only with the points of the opinion initially identified by the applicant/MAH and is based only on the scientific data available when the CHMP adopted the initial CHMP opinion. The applicant/MAH may request that the CHMP consult a scientific advisory group/Ad Hoc Expert group in connection with the re-examination. In this case, the CAT shall request the advice of additional available expertise.
4. The applicant/MAH is given the right to an oral explanation in front of the CAT before it adopts its draft opinion.

Certification of quality and non-clinical data

Article 11

Article 18 of Regulation (EC) No 1394/2007 provides that small and medium-sized enterprises developing an ATMP may submit to the EMA all relevant quality and, where available, non-clinical data required in accordance with modules 3 and 4 of Annex I to Directive 2001/83/EC (as amended) on the Community code relating to medicinal products for human use, for scientific evaluation and certification.

This procedure is detailed in the "EMA procedural advice on certification of quality and non-clinical data for small and medium enterprises developing advanced therapy medicinal products".

Scientific recommendation on ATMPs classification

Article 12

Within 60 calendar days following receipt of a valid request for scientific recommendation classification, the EMA shall deliver its recommendation after consultation with the European Commission. The EMA shall also publish summaries of the recommendation, after deletion of all information of commercial confidential nature according to Article 17(1) and 17(2) of Regulation (EC) No 1394/2007.

This procedure and the involvement of the CAT is detailed in the "EMA procedural advice on provision of scientific recommendation on advanced therapy medicinal products classification in accordance with Article 17 of Regulation (EC) No 1394/2007".

Other tasks of the CAT

Article 13

1. The CAT contributes to the EMA scientific advice following relevant procedures established between the CAT and the SAWP.
2. The CAT is involved in any procedure regarding the provision of advice for undertakings on the conduct of efficacy follow-up, pharmacovigilance and risk management system of ATMPs.
3. At the request of the CHMP, the CAT may advise on any medicinal product which may require, for the evaluation of its quality, safety or efficacy, expertise in ATMPs.
4. At the request of other committees (e.g. PDCO, COMP, PRAC), the CAT can be consulted on any relevant procedures which may require specific expertise on ATMPs.
5. The CAT assists scientifically in the elaboration of any documents related to the fulfilment of the objectives of Regulation (EC) No 1394/2007. A scientific report from the CAT is prepared.
6. At the European Commission's request, the CAT provides scientific expertise and advice for any Community initiative related to the development of innovative medicines and therapies, which requires expertise on ATMPs. A scientific report from the CAT is prepared.
7. On request of the CHMP, the CAT can be asked to assist in the tasks identified in the work programmes of the CHMP Working parties.

Organisation of meetings

Article 14

1. The CAT shall in principle meet on a monthly basis with the exception of the month of August during which no meeting is convened unless explicitly required. The CAT may hold in-person meetings at EMA or virtual meetings. In the event of virtual meetings, members participate through a remote connection. The meeting shall be convened by the Executive Director or their representative after consultation with the chair.
2. The dates of meetings are decided on an annual basis in consultation with the CAT. In exceptional circumstances and on motivated grounds agreed with the chair an extraordinary meeting may be convened at short notice.
3. The meetings are held and minuted in English.

4. The draft agenda for every meeting shall be circulated, together with the relating documents, by the EMA Secretariat, in consultation with the chair, at least 14 calendar days before the meeting. This draft agenda shall enable the CAT to perform its duties as defined in Article 23 of Regulation (EC) No 1394/2007.
5. When a member or alternate of the Committee is unable to participate to a meeting, part of meeting, or discussion topic due to conflict of interest, they must inform the EMA Secretariat in advance in writing. Such declaration is recorded in the minutes of the respective meeting in accordance with the EMA policy on competing interests.
6. In order to cope with situations of emergency, possibly coupled with the activation of the Agency's Business Continuity Plan in compliance with internal guidelines, the following rules shall apply:
 - 6.1. 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 draft opinions, scientific opinions or recommendations/advices by the CAT shall be reached when an absolute majority of the members of the CAT is present (i.e. more than half of the total number of CAT members eligible to vote), either directly (in person or remotely) or by nominated proxy. The votes shall be in favour or against (unless the provision concerning the conflicts of interest is applied). The members from the EEA-EFTA States may participate to the meeting either directly or by nominated proxy given to another EEA-EFTA member.
 - 6.2 Whenever possible, draft opinions, scientific opinions or recommendations/advices of the CAT shall be taken by consensus. If such a consensus cannot be reached, the draft opinion, scientific opinion or recommendation/advice will be adopted if supported by an absolute majority of the members of the CAT (i.e. favourable votes by more than half of the total number of CAT 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 draft opinion, where relevant, in the minutes of the CAT and in case of divergent opinions appended to the CAT's draft opinion, scientific opinion or recommendation/advice. Their position is not taken into consideration for the purpose of counting the votes for the adoption of the draft opinion, opinions and recommendations/advices.
 - 6.3. Members connected remotely can cast their votes remotely. In case a CAT member/alternate temporarily faces difficulties to connect remotely, it is acceptable that their 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 product/procedure for which the vote is being cast and the matter that is being voted upon, as well as the vote cast (against or in favour). For transparency reasons, the vote cast by email shall be brought immediately to the attention of the chair and other members/alternates of the Committee.

Oral Explanations – Meeting(s) with Applicant or Marketing Authorisation Holders

Article 15

1. The CAT may invite an applicant or the MAH, for a meeting to provide oral explanations in person or remotely in connection with an evaluation procedure on its own initiative, or following a request of the applicant/MAH. Oral explanations may also be provided by the applicant or MAH to working parties or scientific advisory groups when the CAT has delegated tasks associated with the scientific evaluation to a working party or a scientific advisory group or together with the CHMP.

2. The CAT may also invite on its own initiative or may consider a request of any other relevant third party for a meeting in person or remotely in connection with an evaluation procedure.
3. Oral explanation/meetings shall be indicated clearly in the draft agenda of the meeting.
4. The CAT, working party or scientific advisory group as appropriate shall not draw any conclusions during these presentations in the presence of the company representatives or the third parties.

Coordination with relevant notified bodies for the assessment of the medical device or active implantable medical device part of a combined ATMP

Article 16

1. The CAT may decide to consult relevant notified bodies on any question relating to the assessment of the medical device or active implantable medical device part of a combined ATMP.
2. The CAT shall recognize the results of the assessment by a notified body of the medical device or active implantable medical device part of a combined ATMP. However, the CAT can request from the relevant notified body to transmit, within 1 month, any information related to the results of the assessment of the medical device or active implantable medical device part of a combined ATMP.
3. In those cases where the application for authorisation of a combined ATMP does not include the results of the assessment by a notified body, the CAT, advised by its experts for medical devices, can decide that involvement of a notified body is not necessary.
4. The EMA Secretariat ensures that there is appropriate coordination and communication/exchange of information between the CAT, CHMP and the Notified Bodies. Such interaction should be established in line with timelines described in the legislation.

Consultation of Working parties and Scientific Advisory Groups

Article 17

1. Whenever considered appropriate, the CAT may consult the CHMP working parties/Scientific Advisory Groups on any scientific issue related to their specific fields of expertise or set up and consult CAT temporary/standing working parties. The CAT may also delegate certain tasks associated with the scientific evaluation of applications, or drafting of guidelines to the relevant CHMP standing or CAT temporary/standing working parties. The tasks identified by the CAT should be included in the work programme of each temporary/standing working party to be adopted by the CAT.
2. The CAT may establish possible consultation procedures with standing working parties and Scientific Advisory Groups.
3. Temporary ad hoc specialised advisory groups and working parties, as required, may also be established when work of a temporary nature is required such as preparation of proposals on a specific scientific topic, preparation of responses to specific questions raised by CAT, drafting of new guidelines or revision of existing ones in relation to specific scientific fields.

4. The CAT working parties may identify and propose topics for consideration by the CAT. Any proposal for a guideline, providing adequate justification, shall be transmitted to the CAT for endorsement and shall be preceded by a concept paper to be endorsed by the CAT and CHMP.
5. The recommendation from the working parties from CHMP or other committees shall be transmitted to the CAT for information/adoption.
6. Agenda, table of conclusions and minutes of the meetings of the CAT working parties should be circulated to the CAT.
7. The CAT shall put in place measures to ensure that there is coordination of work and exchange of information between the CHMP and CAT and any relevant EMA committee, as appropriate, the CAT/CHMP working parties and vice-versa.
8. The CAT shall review the mandate and objectives of each CAT Working Parties/temporary working party either at the end of the period for which they have been created or after three years, whichever comes first.
9. The work programmes of each temporary working party shall be reviewed at least annually and are made publicly available.

Drafting Groups

Article 18

When further consideration is required in order to prepare proposals on specific topics, the Committee may convene drafting groups constituted by members or alternates of the Committee, and additional experts, as appropriate.

Participation of experts in meetings

Article 19

1. When necessary, the Committee and its working parties may avail themselves of the services of experts in specific scientific or technical fields. Such experts shall have proven experience in the assessment of medicinal products or in their field of expertise and must 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 or recommendations 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.
4. With a view to facilitate international cooperation and exchanges of scientific views with other regulatory authorities under the OPEN framework, the Committee may avail itself of the views of experts from international organisations and/or non-EEA regulatory authorities which are performing in parallel an evaluation of the same medicinal product under discussion at the Committee. In these cases, the following applies:

4.1. Such experts are appointed by the EMA at its discretion upon a proposal from the entity to which they are affiliated. Only experts from international organisations or non-EEA regulatory authorities with whom working arrangements have been concluded, may be appointed.

4.2. The experts must fulfil all the requirements and obligations set forth in Articles 20 and 21 of these rules of procedure.

4.3. The experts may be requested to present the state of play of the scientific evaluation of the benefit/risk of the relevant medicinal product performed in parallel by the non-EEA entity to which they are respectively affiliated. They may be invited to support the Committee in queries or recommendations regarding the products concerned, local epidemiology or disease expertise. However, the assessment reports should reflect the view of the CAT only.

4.4. These experts cannot participate in the decision-making process of the Committee at any stage of the procedure.

Guarantees of independence

Article 20

1. The names of the members and alternates of the CAT shall be made public. When each appointment is published, the professional qualifications of each member and alternate shall be specified.
2. The members and alternates of the CAT and experts shall not have any direct interests, financial or otherwise, in the pharmaceutical industry, medical device industry or biotechnology sector 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 interests. All indirect interests which could relate to the pharmaceutical industry, medical device industry or biotechnology sector shall be entered in a register held by the Agency which is accessible to the public. In addition, the declarations of interest of the members and alternates of the Committee shall be made available on the Agency's website.
3. Members and alternates of the CAT and experts attending these meetings shall declare at the beginning of each meeting any interests, which may be prejudicial to their independence with respect to the points of the agenda. This will be made available to the public.
4. The specific provisions for handling declarations of interests and confidentiality undertakings as *inter alia* defined in the EMA Policy 0044 on the Handling of Competing Interests of Scientific Committees' Members and Experts, adopted by the Managements Board, are applicable to members and alternates of the CAT and experts participating in the scientific activities of the Agency.
5. The members and alternates of the CAT shall not accept from the Member States any instructions incompatible with the tasks incumbent upon them within the Agency. It is essential for these tasks to remain strictly scientific in nature. Each national competent authority shall monitor the level and independence of the evaluation carried out and facilitates the activities of nominated members and experts. Member States shall refrain from giving CAT members and experts any instruction which is incompatible with their own individual tasks or with the tasks and responsibilities of the Agency.
6. Any incomplete and/or incorrect declaration of interests as well as any disclosure of confidential information will be handled according to the European Medicines Agency breach of trust procedure

for competing interests of and disclosure of confidential information by scientific committees' members and experts.

Code of conduct

Article 21

Members and alternates of the Committee and of its working parties and experts participating in EMA's activities shall abide by the principles set out in the EMA Code of Conduct.

EMA Secretariat

Article 22

1. Under the authority of the Executive Director, the EMA Secretariat shall provide regulatory, legal, technical, scientific and administrative support to the CAT with a view to assist in the performance of Committees's duties as set out in Regulation (EC) No 1394/2007. This includes but is not limited to the following:
 - Organise meetings of the CAT ensuring timely circulation of meeting documents;
 - Prepare the minutes of the meetings of the CAT in consultation with the chair;
 - Prepare and co-ordinate the work of the Committee in consultation with the chair;
 - Provide technical and scientific support to (co)-rapporteurs and other members of the Committee;
 - Provide legal and regulatory support to the Committee;
 - Carry out the validation of the applications submitted to the Agency;
 - Prepare the assessment reports on the basis of CAT's (co)-rapporteur(s)' assessment reports;
 - Ensure draft assessment report is adopted by the CAT prior to transmission to the CHMP;
 - Prepare draft opinions for transmission and final approval by CHMP;
 - Ensure scientific and regulatory consistency of the draft opinions;
 - Ensure that the periods laid down by Community legislation for the adoption of the draft opinions and its corresponding final CHMP opinions and for the decisions are complied with;
 - Communicate to applicants/MAHs or any other interested parties the relevant opinions or recommendations of the CAT;
 - Prepare opinions for Certification and Certificates;
 - Contribute to scientific recommendations on advanced therapy classification and make their summaries publicly available;
 - Prepare and communicate relevant public information related to the activities of the CAT, such as Press Releases, public statements, Q&A documents, scientific recommendation on advanced therapy classification taking into account aspect of confidentiality and EMA transparency policy.
 - Ensure adequate co-ordination of the work carried out or exchange of information between this Committee and the CHMP, COMP, PDCO, SAWP, PRAC and other CHMP WPs/SAGs, where appropriate;

- Organise, when necessary, joint meetings with the CHMP, COMP, PDCO, PRAC and/or other EMA committees, as required;
 - Communicate the views of the Committee in international fora.
2. The Executive Director of the Agency, members of the EMA Secretariat, and representatives of the European Commission, may attend all meetings of the Committee, its working parties and scientific advisory groups.

Contacts with Interested Parties

Article 23

1. The Committee may establish contacts, on an advisory basis, with parties concerned with the advanced therapy medicinal products, in particular patient organisations and healthcare professionals' associations. The CAT may agree to invite representatives of such interested parties to address a plenary meeting.
2. Concept papers, draft guidelines and general regulatory developments are subject to public consultation of all interested parties (industry, healthcare professionals, patients/consumers or other).
3. When considered appropriate by the CAT, oral presentations 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 under specific conditions to be agreed by the CAT.
4. In any case, the CAT 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 CAT members 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 CAT chair and circulation by the EMA secretariat.

Observers

Article 24

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 regulations applicable to medicinal products 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 beforehand by the European Commission.
2. 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 CAT. Participation shall be agreed with the EMA Executive Director and with the chair in advance of the meeting.
3. The observers shall be bound by the rules of confidentiality mentioned in Article 20.

General Provisions

Article 25

For tasks incumbent on the Agency, other than those of evaluation, the Committee may propose that the Agency has recourse to (co)-rapporteurs within the meaning of Article 6 paragraph 1 or to experts within the meaning of Article 18 and Article 19.

Article 26

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

Article 27

The members and alternates of the CAT 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.

Article 28

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 CAT members eligible to vote).

Article 29

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

Adopted by the Committee on 13 March 2009.

Date of entry into force: April 2009 CAT meeting.

Revised by the Committee on 13 February 2014.

Revised by the Committee on 19 March 2020.

Revised by the Committee on 10 September 2021.

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Revised by the Committee on 17 April 2026.

Date of entry into force on 1 July 2026.