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SCIENCE MEDICINES HEALTH

18 March 2026
EMA/CAT/70533/2026
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 18-20 February 2026

Chair: Ilona Reischl-Kok; Vice-Chair: Kieran Breen

Disclaimers

Some of the information contained in these minutes is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CAT meeting reports once the procedures are finalised.

Of note, these minutes are a working document primarily designed for CAT members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to ongoing procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).



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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

The Chairperson opened the meeting by welcoming all participants. The meeting was remotely.

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for concerned agenda topics.

Participants were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. Restrictions applicable to this meeting are captured in the List of participants included in the minutes.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

The CAT agenda for 18-20 February 2026 meeting was adopted with the addition of the following procedure in section 2.11: Hemgenix - Etranacogene dezaparvovec - EMA/VR/0000315755.

1.3. Adoption of the minutes

The CAT minutes for 21-23 January 2026 meeting were adopted.

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

2.3.1. Onasemnogene abeparvovec - Orphan - EMEA/H/C/006498

Novartis Europharm Limited; Treatment of 5q spinal muscular atrophy (SMA)

Scope: Day 180 list of outstanding issues

Action: for adoption

List of questions adopted on 12.09.2025.

The Rapporteurs presented the outcome of the assessment of the responses to the list of questions. The outstanding questions were discussed.

The list of outstanding issues was adopted.

2.4. Day 120 list of questions

No items

2.5. Day 80 assessment reports

2.5.1. Zopapogene imadenovec - Orphan - EMEA/H/C/006508

FGK Representative Service GmbH; Treatment of respiratory papillomatosis in adults

Scope: Day 80 assessment report

Action: for information

The information was noted.

2.6. Update on ongoing initial applications

No items

2.7. New applications

2.7.1. Rebisufligene etisparvovec – Orphan – PRIME – EMEA/H/C/005536

Ultragenyx Netherlands B.V.; Treatment of mucopolysaccharidosis type IIIA (MPS IIIA, Sanfilippo A syndrome)

Scope: Briefing note and Rapporteurs' recommendation on the request for accelerated assessment

Action: for adoption

The Rapporteur presented their recommendation on the request for accelerated assessment. CAT agreed not to grant accelerated assessment. The Rapporteur's briefing note and recommendation was adopted.

Post-meeting note: the applicant withdrew the request for accelerated assessment prior to adoption by CHMP at their February meeting.

2.8. Withdrawal of initial marketing authorisation application

No items

2.9. Re-examination of initial application procedures under Article 9(2) of Regulation No. 726/2004

No items

2.10. GMP and GCP inspections requests

No items

2.11. Type II variations and variations of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

2.11.1. Aucatzyl - Obecabtagene autoleucel – Orphan - EMA/VR/0000315083

Autolus GmbH

Rapporteur: Tineke van den Hoorn

Scope: Quality, opinion

Action: for adoption

The opinion was adopted

2.11.2. Breyanzi - Lisocabtagene maraleucel – Orphan - EMA/VR/0000313331

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, opinion

Action: for adoption

The opinion was adopted

2.11.3. CARVYKTI - Ciltacabtagene autoleucel – Orphan - EMA/VR/0000316059

Janssen Cilag International

Rapporteur: Attila Sebe

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.4. [Tecartus / Yescarta - Brexucabtagene autoleucel / Axicabtagene ciloleucel – Orphan - EMA/VR/0000309788](#)

Kite Pharma EU B.V.

Rapporteur: Attila Sebe

Scope: Quality, Request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.5. [Tecartus / Yescarta - Brexucabtagene autoleucel / Axicabtagene ciloleucel – Orphan - EMA/VR/0000309793](#)

Kite Pharma EU B.V.

Rapporteur: Attila Sebe

Scope: Quality, opinion

Action: for adoption

CAT concluded that this variation does not change the environmental risk assessment (ERA). The opinion was adopted.

2.11.6. [Tecartus / Yescarta - Brexucabtagene autoleucel / Axicabtagene ciloleucel – Orphan - EMA/VR/0000308229](#)

Kite Pharma EU B.V.

Rapporteur: Attila Sebe; PRAC Rapporteur: Karin Erneholm

Scope: Clinical, request for supplementary information

Update of sections 4.2, 4.4, 4.5, 4.7 and 6.4 of the SmPC in order to modify the pre- and post-infusion monitoring recommendations and requirements related to the risk of CRS (cytokine release syndrome) and ICANS (immune effector cell-associated neurotoxicity syndrome) based on data from clinical trials, post-marketing experience and literature. The Package Leaflet is updated accordingly. The RMP version 7.1 has also been submitted. In addition, Annex II has been updated accordingly. Furthermore, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4 and to implement editorial changes to the PI.

Action: for adoption

The request for supplementary information was adopted.

2.11.7. [Casgevry - Exagamglogene autotemcel - EMA/VR/0000314722](#)

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Attila Sebe

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.8. Vyjuvek - Beremagene geperpavec - EMA/VR/0000306575

Krystal Biotech Netherlands B.V.

Rapporteur: Joseph De Courcey

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.9. Hemgenix - Etranacogene dezaparvovec - EMA/VR/0000315755

CSL Behring GmbH

Rapporteur: Silke Dorner

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Upstaza - Eladocagene exuparvovec – Orphan - EMA/S/0000293355

PTC Therapeutics International Limited

Rapporteur: Joseph De Courcey; PRAC Rapporteur: Dirk Mentzer

Scope: Annual reassessment, opinion

Action: for adoption

The annual reassessment was adopted.

2.13.2. Strimvelis - Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence – Orphan - EMA/R/0000290462

Fondazione Telethon Ets

Rapporteur: Sol Ruiz, Co-Rapporteur: Attila Sebe, PRAC Rapporteur: Liana Martirosyan

Scope: Renewal - 5-year, opinion

Action: for adoption

The 5-year renewal with unlimited validity was adopted.

2.13.3. Aucatzyl - Obecabtagene autoleucel – Orphan - EMA/PAM/0000319863

Autolus GmbH

Rapporteur: Tineke van den Hoorn

Scope: PAM

Action: for adoption

The outcome of the assessment was agreed.

2.13.4. Casgevvy - Exagamglogene autotemcel – Orphan - EMA/PAM/0000316999

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Attila Sebe; PRAC Rapporteur: Bianca Mulder

Scope: PAM, PRAC led procedure

Action: for information

The outcome of the assessment was agreed.

2.13.5. Yescarta - Axicabtagene ciloleucel - EMA/PAM/0000316955

Kite Pharma EU B.V.

Rapporteur: Attila Sebe, PRAC Rapporteur: Karin Erneholm

Scope: PAM, PRAC led procedure

Action: for information

Feedback from the PRAC discussion was provided. The outcome of the assessment was agreed.

2.13.6. Zemcelpro - Dorocubicel / Allogeneic umbilical cord-derived CD34- cells, non-expanded - EMA/PAM/0000313184

Cordex Biologics International Limited

Rapporteur: Emmely de Vries

Scope: PAM, request for supplementary information

Action: for adoption

The request for supplementary information was agreed.

2.13.7. Vyjuvek - Beremagene geperpavec – EMA/PASS/0000287685

Applicant: Krystal Biotech Netherlands B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: PRAC-led procedure. PASS protocol [107n]: A prospective, non-interventional, multi-country study to confirm the long-term safety profile, including in paediatric patients less than 6 months of age, of B-VEC for the treatment of dystrophic epidermolysis bullosa (DEB) wounds in a real-life clinical setting.

Action: for information

Feedback from the PRAC discussion was provided. The outcome of the assessment was noted.

2.14. Companion diagnostics - initial consultation

No items

2.15. Companion diagnostics – Follow-up consultation

No items

3. Certification of ATMPs

Information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

3.1. Opinion

No items

3.2. Day 60 Evaluation Reports

No items

3.3. New Applications

No items

4. Scientific Recommendation on Classification of ATMPs

Timetable:

-Start of the procedure:	20.02.2026
-EMA Coordinator's draft report:	06.03.2026
-CAT Coordinator's comments:	11.03.2026
-Revised scientific recommendation:	13.03.2026
-CAT's discussion of scientific recommendation:	20.03.2026

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Live attenuated viral vector vaccine based on SARS-COV-2 backbone, expressing human interferon beta

COVID-19 prophylaxis

Scope: ATMP scientific recommendation

Action: for nomination of CAT coordinator

The CAT coordinator was appointed.

4.1.2. Messenger ribonucleic acid (mRNA) molecules encoding a cytosine-to-thymine transcription activator like effector base editor (TALEB) targeting APOC3 gene

Treatment of familial chylomicronemia syndrome (FCS) and severe hypertriglyceridemia (sHTG)

Scope: ATMP scientific recommendation

Action: for nomination of CAT coordinator

The CAT coordinator was appointed.

4.1.3. Allogeneic CAR-T lymphocytes targeting CEACAM6

Treatment of pancreatic ductal adenocarcinoma (PDAC) surgery-eligible patients

Scope: ATMP scientific recommendation

Action: for nomination of CAT coordinator

The CAT coordinator was appointed.

4.2. Day 30 ATMP scientific recommendation

4.2.1. Live attenuated *Listeria monocytogenes* bearing plasmids encoding the recombinant chimeric fusion protein of truncated nonhemolytic listerolysin O (tLLO) and a tumour associated antigen (TAA) comprised of two extracellular (EC1 and EC2) and one intracellular (IC1) fragments of the human Her2/neu protein

Treatment of pulmonary recurrence of resected osteosarcoma

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 06.03.2026.

4.2.2. Allogeneic Umbilical Cord-derived Mesenchymal Stem Cells

Treatment of lupus nephritis (LN) and systemic lupus erythematosus (SLE)

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 06.03.2026.

4.2.3. Autologous chimeric antigen receptor T cells against epidermal growth factor variant III (EGFRvIII) and messenger ribonucleic acid vaccine lipoplexes encoding EGFRvIII (intracerebroventricular administration)

Treatment of EGFRvIII-positive glioblastoma

Scope: ATMP scientific recommendation

Action: for discussion

CAT discussed the classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 06.03.2026.

4.2.4. Autologous chimeric antigen receptor T cells against epidermal growth factor variant III (EGFRvIII) and messenger ribonucleic acid vaccine lipoplexes encoding EGFRvIII (intravenous administration)

Treatment of EGFRvIII-positive glioblastoma

Scope: ATMP scientific recommendation

Action: for discussion

This product is the same as 4.2.3, only the route of administration is different.

CAT discussed the classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 06.03.2026.

4.2.5. Extracellular vesicles from Wharton Jelly hTERT- expressing Mesenchymal Stromal Cells (MSCs) loaded with the micro-RNA miR-140

Treatment of osteoarthritis

Scope: ATMP scientific recommendation

Action: for discussion

CAT discussed the classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 06.03.2026.

4.3. Day 60 revised scientific recommendation (following list of questions)

No items

4.4. Finalisation of procedure

4.4.1. Red blood cells derived from immortalised hematopoietic progenitors

Blood transfusion

Scope: ATMP scientific recommendation. European Commission raised no comments

Action: for adoption

The classification report was adopted. CAT concluded that based on the definition of what is a cell for classification purposes, the product does not fulfil the definition of an ATMP as provided in Article 2(1) of Regulation (EC) No 1394/2007, as the product does not contain cells or tissues, nor does it contain recombinant nucleic acids.

CAT noted the statement of the company that the extensive manufacturing process is (or will be) an industrial process; therefore, this product could fulfil the definition of a (biological) medicinal product. The applicant will be guided to one of the national competent authorities for the classification of their products as a medicinal product.

4.4.2. Platelets derived from immortalised hematopoietic progenitors

Platelet transfusion

Scope: ATMP scientific recommendation. European Commission raised no comments

Action: for adoption

The classification report was adopted. CAT concluded that based on the definition of what is a cell for classification purposes, the product does not fulfil the definition of an ATMP as provided in Article 2(1) of Regulation (EC) No 1394/2007, as the product does not contain cells or tissues, nor does it contain recombinant nucleic acids.

CAT noted the statement of the company that the extensive manufacturing process is (or will be) an industrial process; therefore, this product could fulfil the definition of a (biological) medicinal product. The applicant will be guided to one of the national competent authorities for the classification of their products as a medicinal product.

4.4.3. Allogeneic human induced pluripotent stem cell (hiPSC)-derived midbrain dopaminergic (mDA) neuronal progenitor cells

Treatment of Parkinson's disease

Scope: ATMP scientific recommendation. European Commission raised no comments

Action: for adoption

The classification report was adopted. The product does fulfil the definition of a tissue engineered product as provided in Article 2(1) of Regulation (EC) No 1394/2007.

4.5. Follow-up and guidance

No items

5. Scientific Advice

Information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

5.1. New requests - appointment of CAT Rapporteurs

5.1.1. Ongoing scientific advice procedures - Appointment of CAT Peer Reviewers

Timetable:

- Start of procedure at SAWP:	09-12.02.2026
- Appointment of CAT Peer Reviewers:	18-20.02.2026
- SAWP first reports:	02.03.2026
- CAT Peer Reviewer comments (NC & C):	06.03.2026
- CAT Peer Reviewer comments (Q):	11.03.2026
- Discussion at SAWP:	09-12.03.2026
- Discussion at CAT and feedback to SAWP:	18-20.03.2026

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	09-12.03.2026
- Appointment of CAT Peer Reviewers:	18-20.03.2026
- SAWP first reports:	31.03.2026
- CAT Peer Reviewer comments (NC & C):	06.04.2026
- CAT Peer Reviewer comments (Q):	08.04.2026
- Discussion at SAWP:	07-10.04.2026
- Discussion at CAT and feedback to SAWP:	15-17.04.2026

5.2. Procedures discussed at SAWP – 1st reports, D40 JRs, LoIs

5.3. Finalisation of D70 procedures – feedback from the discussion meeting

5.4. Final Advice Letters for procedures finalised the previous month

6. Pre-Authorisation Activities

Information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6.1. Paediatric investigation plans

No items

6.2. ITF briefing meetings in the field of ATMPs

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:	
Procedure start:	09-12.02.2026
SAWP recommendation:	12.03.2026
CAT recommendation:	20.03.2026
CHMP adoption of report and final recommendation:	26.03.2026

6.3.2. Month 1 – Discussion of eligibility

6.3.3. Month 2 – Recommendation of eligibility

6.3.4. Ongoing support

No items

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT membership

No items

7.1.2. Nominated proxy

No items

7.1.3. CAT Strategic Review & Learning meeting (SRLM) under the Cypriot presidency

Scope: Preparation for the meeting

CAT: Rafaella Pontou

Action: for information

Practical information on the upcoming SRLM was provided: the change of the meeting location (from Limasol to Paphos) was noted. The outline of the agenda was presented.

7.2. Coordination with EMA Scientific Committees

7.2.1. SAWP composition – re-examination exercise

Scope: Nomination of CAT members to SAWP

Action: for adoption

CAT nominated CAT members to SAWP

7.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

No items

7.4. Cooperation with the EU regulatory network

7.4.1. AI & Knowledge Mining - AI Roadmap and Scientific Explorer EPARs integration new release

Scope: Scientific Explorer - update

Action: for information and adoption

Information was provided on the AI based Scientific Explorer to search EMA-based documents.

7.4.2. Survey on horizon scanning topics

Scope: Feedback on horizon scanning topics to be prioritised is sought

Action: To complete the survey by Wednesday 4 March 2026

CAT members were asked to complete the survey: this will allow to prioritise the horizon scanning topics that are considered most relevant to be explored. It was suggested to look at topics with cross-legal framework involvement.

7.5. Cooperation with international regulators

No items

7.6. CAT work plan

7.6.1. Patient and Healthcare Professional involvement in assessment work

CAT: Kieran Breen

Scope: Including patient/HCP during the evaluation of MAAs: possibilities and practices in other committees

Action: for discussion

EMA informed the CAT of the possibilities for involving patients and healthcare professionals during the assessment of MAA for ATMPs. The experience in other committees was presented.

7.7. Planning and reporting

No items

7.8. Others

7.8.1. Meeting between CAT and competent authorities for organ transplantation

CAT: Ilona Reischl

Scope: Identification of members to attend this meeting

Action: for appointment

A meeting will take place between CAT/ATMP experts & experts from the organ authorities. The topics for exchange will be the interface between medicines / organ transplants and collaboration between the two authorities.

Following CAT members expressed interest to take part in the exchange: Ilona Reischl, Violaine Closson-Carella, Attila Sebe, Dariusz Sladowski, Marcos Timon, Rune Kjekken, Emmely de Vries/Tineke van den Hoorn.

8. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 18-20 February 2026 CAT meeting, which was held remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics for which restrictions apply
Ilona Reischl-Kok	Chair	Austria	No restrictions applicable to this meeting	
Andreas Maccani	Alternate	Austria	No restrictions applicable to this meeting	
Claire Beuneu	Member	Belgium	No interests declared	
Olga Kholmanskikh	Alternate	Belgium	No interests declared	

Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Azra Selimovic	Member	Croatia	No restrictions applicable to this meeting	
Rafaella Pontou	Member	Cyprus	No interests declared	
Isavella Kyriakidou	Alternate	Cyprus	No interests declared	
Eva Kolouchová	Member	Czechia	No interests declared	
Martin Oleksiewicz	Member	Denmark	No interests declared	
Johanne Juhl Korsbaek	Alternate	Denmark	No restrictions applicable to this meeting	
Toivo Maimets	Member	Estonia	No restrictions applicable to this meeting	
Pille Saalik	Alternate	Estonia	No interests declared	
Maija Tarkkanen	Alternate	Finland	No interests declared	
Violaine Closson Carella	Member	France	No interests declared	
Jan Mueller-Berghaus	Alternate	Germany	No interests declared	
Attila Sebe	Member	Germany	No interests declared	
Maria Gazouli	Member	Greece	No restrictions applicable to this meeting	
Viola Bardoczy	Member	Hungary	No restrictions applicable to this meeting	
Agnes Zotter	Alternate	Hungary	No restrictions applicable to this meeting	
Péter Zsolt Fekete	Member	Iceland	No interests declared	
Joseph De Courcey	Member	Ireland	No interests declared	
Richard Carroll	Alternate	Ireland	No interests declared	
Concetta Quintarelli	Member	Italy	No participation in discussion, final deliberations and voting on:	Scientific advice
Barbara Bonamassa	Alternate	Italy	No interests declared	
Liga Kunrade	Alternate	Latvia	No restrictions applicable to this meeting	
Vilma Perikaite	Member (CHMP member)	Lithuania	No restrictions applicable to this meeting	

Raimondas Benetis	Alternate (to CHMP representative)	Lithuania	No restrictions applicable to this meeting	
Alessia Pochesci	Member	Luxembourg	No restrictions applicable to this meeting	
Nancy De Bremaeker	Alternate	Luxembourg	No restrictions applicable to this meeting	
Emmely de Vries	Member	Netherlands	No interests declared	
Berendina Maria (Tineke) van den Hoorn	Alternate	Netherlands	No interests declared	
Rune Kjekken	Member	Norway	No interests declared	
Dariusz Sladowski	Member	Poland	No restrictions applicable to this meeting	
Maria Isabel Borba Vieira	Member	Portugal	No interests declared	
Denisa Marilena Margina	Member	Romania	No restrictions applicable to this meeting	
Denisa Partelova	Alternate	Slovakia	No interests declared	
Margareta Fogelová	Member	Slovakia	No interests declared	
Suzana Vidic	Member	Slovenia	No restrictions applicable to this meeting	
Sol Ruiz	Member (CHMP co- opted member)	Spain	No interests declared	
Marcos Timón	Alternate (to CHMP representative)	Spain	No interests declared	
Maria Luttgen	Member	Sweden	No participation in discussions, final deliberations and voting on:	Scientific advice
Charlotte Anderberg	Alternate	Sweden	No interests declared	
Julio Delgado Gonzalez	Member	Clinicians' Representative	No participation in discussion, final deliberations and voting on:	Scientific advice
Alessandra Renieri	Alternate	Clinicians' Representative	No restrictions applicable to this meeting	
Federica Chiara	Member	Patients' Representative	No restrictions applicable to this meeting	
Kieran Breen	Member (Vice- Chair)	Patients' Representative	No restrictions applicable to this meeting	

Donatella Capone	Alternate	Patients' Representative	No interests declared	
Catherine Milne	Observer	EDQM	No interests declared	
Gaelle De Meyer	Expert	Belgium	No restrictions applicable to this meeting	
Olive Smyth	Expert	Ireland	No interests declared	
Charlotte de Wolf	Expert	Netherlands	No interests declared	
Myra Langendonk	Expert	Netherlands	No restrictions applicable to this meeting	
Sara Ambrosino	Expert	Netherlands	No restrictions applicable to this meeting	
Melanie Ramberger	Expert	Austria	No interests declared	
Christian Gartner	Expert	Austria	No interests declared	
Torbjörn Callréus	Expert	Malta	No interests declared	
Nikolaus Zehetmayer	Expert	Austria	No interests declared	

Some representatives from the European Commission attended the meeting.

Representatives from the Swissmedic attended the meeting.

Meeting run with support from relevant EMA staff.

Experts' declared interests were evaluated against the agenda topics or activities they participated in.

9. Any other business

No items

Date of next CAT meeting:

18-20 March 2026

10. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

[Abbreviations in Committee CMD documents and in relation to EMA regulatory activities](#)

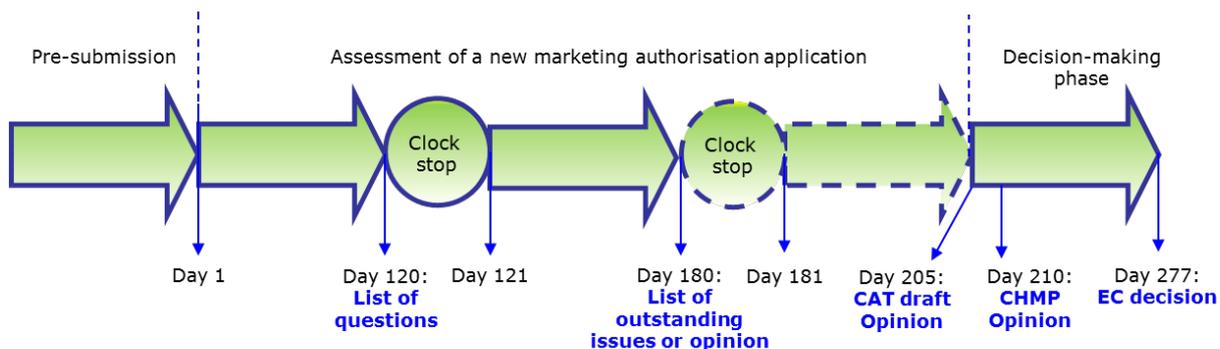
Evaluation of ATMPs (section 2)

This section lists applications for marketing authorisations of new Advanced Therapy Medicinal Products (ATMPs) that are to be discussed by the Committee. It also lists Post-authorisation activities (section 2.11-2.13) and any ATMP related inspection requests (section 2.14).

New applications (sections 2.1. to 2.9.)

Section 2.1 is for ATMPs nearing the end of the evaluation and for which the CAT is expected to adopt a draft **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CAT opinion is transmitted to the CHMP for final adoption. The CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU. More information on the evaluation of ATMPs can be found [here](#).

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CAT. The clock stop happens after day 120 and may also happen after day 180, when the CAT has adopted respectively a **Day 120 list of questions** (section 2.4) or a List of outstanding issues to be addressed by the company, which is listed in the agenda under sections 2.7 (**Ongoing evaluation procedures** (section 2.3). Section 2.6 also includes the CAT discussions at any other timepoint of the evaluation procedure of new applications.

Oral explanation (section 2.2.)

Prior to adoption of the CAT opinion, marketing authorisation applicants are normally invited to the CAT plenary meeting to address questions raised by the Committee.

Oral explanations normally relate to ongoing applications, but they can also relate to any other issue for which the CAT would like to discuss with company representatives in person.

New applications (section 2.7.)

In this section, information is included on upcoming marketing authorisation applications for ATMPs, as well as information on appointment of Rapporteurs for new ATMP applications.

Withdrawal of applications (section 2.8.)

This section includes information on marketing authorisation applications that are withdrawn by the applicant. Applicants may decide to withdraw applications at any stage during the assessment and a CAT opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 (section 2.9.)

This section lists applications for new marketing authorisation for ATMPs for which the applicant has requested a re-examination of the opinion previously issued by the CHMP. Similar to the initial evaluation of a marketing authorisation of an ATMP, CAT will adopt a draft re-examination opinion, which is transmitted to the CHMP for final adoption.

GMP and GCP Inspections Issues (section 2.10)

This section lists inspections that are undertaken for ATMPs. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Post-authorisation activities (section 2.11-2.13.)

Section 2.11 lists type II variations, including extension of indication applications and re-examination procedures for type II variations for which the applicant has requested re-examination of the opinion previously issued by the CHMP. Section 2.12 list extension application according to Annex I of Reg. 1234/2008 and section 2.13 includes all other post-authorisation activities concerning authorised ATMPs that are not covered elsewhere in the agenda such as post-authorisation measures, annual reassessments, 5-year renewals, supply shortages, qualify defects. Issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines, will also be included here.

Companion diagnostics (section 2.14. & 2.15.)

This section lists applications for initial and follow-on consultation of companion diagnostics.

Certification of ATMPs (section 3)

This section includes the scientific evaluation by the CAT of quality and non-clinical data that small and medium-sized enterprises have generated at any stage of the ATMP development process. More information on the ATMP certification procedure can be found [here](#).

Scientific Recommendation on Classification of ATMPs (Section 4)

This section includes the scientific recommendation by the CAT on whether medicines based on genes, cells or tissues meet the scientific criteria that define ATMPs. More information on the ATMP classification procedure, including the outcomes of finalised classifications, can be found [here](#).

Scientific Advice (section 5)

This section includes all scientific advice given to companies during the development of an ATMP. Information related to the number of ATMP related scientific advices discussed by CAT can be found in the CAT Monthly reports. Further information on SAWP can be found [here](#).

Pre-Authorisation (section 6)

Paediatric Investigation Plan (PIP)

This section includes the discussion of an ATMP before a formal application for marketing authorisation is submitted. These cases refer for example to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation: in case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

CAT contributes to the evaluation of a Paediatric Investigation Plan (PIPs) for ATMPs by the Paediatric Committee. These PIPs are included in this section of the Agenda.

ITF Briefing meeting in the field of ATMPs

This section refers to briefing meetings of the Innovation Task Force and International co-operations activities of the CAT.

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes of meetings with applicants developing ATMPs and of other ITF meetings of interest to the CAT are included in this section of the agenda. Further information on the ITF can be found [here](#).

Priority Medicines (PRIME)

This section includes the new requests for eligibility to PRIME for ATMPs under development, the discussions in CAT of these eligibility requests and the final recommendations for eligibility of ATMPs adopted by CHMP.

CAT will appoint one of its members as the CAT sponsor for each new ATMP eligibility request who will lead the CAT discussion based on the recommendation from the SAWP.

Organisational, regulatory and methodological matters (section 7)

This section includes topics related to regulatory and procedural guidance, CAT workplan, CAT meeting organisation (including CAT membership), planning and reporting, co-ordination with other committees, working parties and scientific advisory groups.

Furthermore, this section refers to the activities of the CAT drafting groups developing scientific guidelines for gene therapy medicinal products and for cell-based medicinal products, cooperation within the EU regulatory network and international regulators as well as direct interaction with interested

parties. It also includes topics of scientific interest for the Committee that are not directly related to the work of the CAT drafting groups or CAT associated working parties.

Any other business (section 8)

This section is populated with miscellaneous topics not suitable under the previous headings.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/