18 February 2026
EMA/CAT/40771/2026
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 18-20 February 2026

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

18 February 2026, 14:00 – 18:30

19 February 2026, 09:00 – 18:30

20 February 2026, 09:00 – 13:00

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda 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, this agenda is a working document primarily designed for CAT members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda 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 on-going 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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CAT plenary session to be held 18-20 February 2026. See February 2026 CAT minutes (to be published post March 2026 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 18-20 February 2026 meeting

1.3. Adoption of the minutes

CAT minutes for 21-23 January 2026 meeting

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.

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

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

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

Action: for adoption

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

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality

Action: for adoption

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

Janssen Cilag International

Rapporteur: Attila Sebe

Scope: Quality

Action: for adoption

2.11.4. Tecartus / Yescarta - Brexucabtagene autoleucel / Axicabtagene ciloleucel – Orphan - EMA/VR/0000309788

Kite Pharma EU B.V.

Rapporteur: Attila Sebe

Scope: Quality

Action: for adoption

2.11.5. Yescarta - Axicabtagene ciloleucel – Orphan - EMA/VR/0000309793

Kite Pharma EU B.V.

Rapporteur: Attila Sebe

Scope: Quality

Action: for adoption

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

2.11.7. Casgevy - Exagamglogene autotemcel - EMA/VR/0000314722

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Attila Sebe

Scope: Quality, request for supplementary information

Action: for adoption

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

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

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

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

Autolus GmbH

Rapporteur: Tineke van den Hoorn

Scope: PAM

Action: for adoption

2.13.4. Casgevy - 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

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

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

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

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

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

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

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

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

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

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

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

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

4.4.2. Platelets derived from immortalised hematopoietic progenitors

Platelet transfusion

Scope: ATMP scientific recommendation. European Commission raised no comments

Action: for adoption

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

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

Action: for information

7.1.2. Nominated proxy

Action: for information

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

Scope: Preparation for the meeting

CAT: Rafaella Pontou

Action: for information

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

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

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

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

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

Background: a meeting is proposed 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

8. Any other business

No items

Date of next CAT meeting:

18-20 March 2026

9. 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

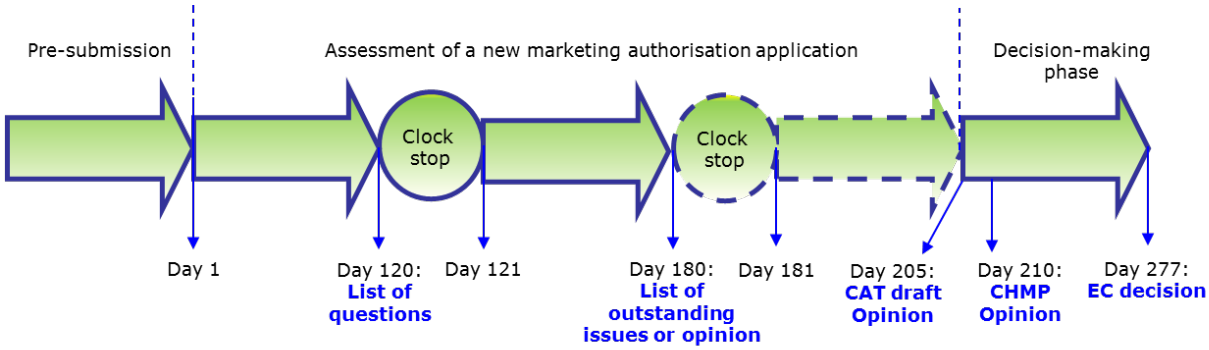
Evaluation of ATMPs (section 2)

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.

Companion diagnostics (section 2.10)

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

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.

GMP and GCP Inspections Issues (section 2.14.)

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).

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/