04 November 2026
EMA/CAT/248979/2026 - Rev.1
Human Medicines Division

Committee for Advanced Therapies (CAT)

Agenda for the meeting on 04-06 November 2026

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

04 November 2026, 14:00 – 18:30

05 November 2026, 09:00 – 18:30

06 November 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 04-06 November 2026. See November 2026 CAT minutes (to be published post December 2026 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 04-06 November 2026 meeting

1.3. Adoption of the minutes

CAT minutes for 07-09 October 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

No items

2.4. Day 120 list of questions

2.4.1. Bilayer engineered collagen hydrogel containing living autologous keratinocytes and fibroblasts - Orphan - EMEA/H/C/006357

YES Pharmaceutical Development Services GmbH; Treatment of adults and children with partial deep dermal and full-thickness burns

Scope: Day 120 list of questions

Action: for adoption

2.5. Day 80 assessment reports

No items

2.6. Update on ongoing initial applications

No items

2.7. New applications

No items

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. Abecma - Idecabtagene vicleucel - Orphan - EMA/VR/0000370806

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken; Co-Rapporteur: Heli Suila

Scope: Clinical

C.12 Submission of the final report from study BB2121-MM-003 (KarMMa-3). This is a Phase 3, multicenter, randomized, open-label study to compare the efficacy and safety of ide-cel versus standard regimens in subjects with relapsed and refractory multiple myeloma (RRMM).

Action: for adoption

2.11.2. ADSTILADRIN - Nadofaragene firadenovec - EMA/VR/0000370372

Ferring Pharmaceuticals A/S

Rapporteur: Tineke van den Hoorn

Scope: Quality

Action: for adoption

2.11.3. Hemgenix - Etranacogene dezaparvovec - Orphan - EMA/VR/0000347644

CSL Behring GmbH

Rapporteur: Silke Dorner; PRAC Rapporteur: Bianca Mulder

Scope: Clinical

A grouped application consisting of:

Type II (C.9.c) to update the protocol and Statistical Analysis Plan (SAP) of Study CSL222_4001, listed as a Specific Obligation in the Annex II of the Product Information. CSL222_4001 is an observational, post-authorisation, long-term follow-up study designed to evaluate the effectiveness and safety of HEMGENIX in the commercial setting. The Annex II and the RMP (version 1.1) are updated accordingly.

Type IB (C.9.b) to request a one-year extension to the due date of Specific Obligation 3 (SOB3) under Annex II.E of the conditional marketing authorisation.

Action: for adoption

2.11.4. Libmeldy - Atidarsagene autotemcel – Orphan - EMA/VR/0000368167

Orchard Therapeutics (Netherlands) B.V.

Rapporteur: Emmely de Vries; PRAC Rapporteur: Dirk Mentzer

Scope: Clinical

Submission of the final report from study 205756, listed as a category 3 study in the RMP. This is a Phase II, single arm, open label, clinical study of cryopreserved autologous CD34+ cells transduced with lentiviral vector containing human ARSA cDNA (OTL-200), for the treatment of early-onset metachromatic leukodystrophy (MLD). The RMP version 4.2 has also been submitted.

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Abecma - Idecabtagene vicleucel - Orphan - EMA/PAM/0000365985

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken; PRAC Rapporteur: Jenny-Maria Jönsson

Scope: PAM

Action: for adoption

2.13.2. Tecartus - Brexucabtagene autoleucel - Orphan - EMA/PAM/0000371615

Kite Pharma EU B.V.

Rapporteur: Attila Sebe

Scope: PAM, request for supplementary information

Action: for adoption

2.13.3. Casgevy - Exagamglogene autotemcel - Orphan - EMA/R/0000365884

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Attila Sebe; PRAC Rapporteur: Bianca Mulder

Scope: Renewal – 1 year, request for supplementary information

Action: for adoption

2.13.4. Breyanzi - Lisocabtagene maraleucel - EMA/R/0000355073

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli; Co-Rapporteur: Claire Beuneu; PRAC Rapporteur: Dirk Mentzer

Scope: Renewal – 5 years

Action: for adoption

2.13.5. Vyjuvek - Beremagene geperpavec – Orphan - EMA/PASS/0000287685

Krystal Biotech Netherlands B.V.

PRAC Rapporteur: Liana Martirosyan

Scope: 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 DEB wounds in a real-life clinical setting (PRAC led procedure)

Action: for information

2.13.6. Carvykti - Ciltacabtagene autoleucel – Orphan – EMA/PASS/0000372428

Janssen Cilag International

PRAC Rapporteur: Jo Robays

Scope: PASS amendment [107o]: An observational PASS to evaluate the safety of multiple myeloma patients treated with ciltacabtagene autoleucel (PRAC led procedure)

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:	23.11.2026
-EMA Coordinator's draft report:	20.11.2026
-CAT Coordinator's comments:	25.11.2026
-Revised scientific recommendation:	27.11.2026
-CAT's discussion of scientific recommendation:	04.12.2026

4.1. New requests – Appointment of CAT coordinator

4.1.1. 3D-bioprinted structures composed of islets of Langerhans, endothelial cells and fibroblasts Chronic pancreatitis

Treatment of brittle diabetes mellitus type 1

Scope: ATMP scientific recommendation

Action: for appointment of CAT coordinator

4.1.2. Human autologous immune cells containing exogeneous mitochondrial DNA

Treatment of immune dysfunction associated with primary mitochondrial disease caused by

metabolic alterations

Scope: ATMP scientific recommendation

Action: for appointment of CAT coordinator

4.1.3. Allogeneic bone marrow derived mesenchymal stem cells (MSCs) and MSC-differentiated adipocytes

Treatment of chronic diabetic foot ulcers

Scope: ATMP scientific recommendation

Action: for appointment of CAT coordinator

4.2. Day 30 ATMP scientific recommendation

4.2.1. Sodium hyaluronate and purified, non-viable human type I collagen

Treatment to improve facial skin roughness and superficial fine lines

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Expanded autologous nasal chondrocytes and extracellular matrix

Treatment of patello femoral osteoarthritis

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Recombinant non-replicating adeno-associated virus serotype hu68 (AAVhu68) vector containing a codon-optimized complementary DNA (cDNA) encoding human frataxin (FXN)

Treatment of Friedreich's ataxia

CAT coordinator: John Joseph Borg

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Recombinant non-replicating adeno-associated virus serotype 8 (AAV8) vector containing the human calsequestrin 2 (CASQ2) gene

Treatment of catecholaminergic polymorphic ventricular tachycardia (CPVT)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.5. Autologous monocytes containing naturally occurring intracellular miRNA against BCL2

Treatment of cancer patients

Scope: ATMP scientific recommendation

Action: for adoption

4.2.6. Micronized adipose tissue

Intended for application in chronic deep anal fissures

Scope: ATMP scientific recommendation

Action: for adoption

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

No items

4.4. Finalisation of procedure

4.4.1. Primary human pancreatic islets of Langerhans loaded in a polyvinylidene fluoride (PVDF) membrane-based macroencapsulation device

Treatment of type 1 diabetes mellitus with recurrent severe hypoglycaemia and/or impaired awareness of hypoglycaemia; Preservation of endogenous insulin secretion following total pancreatectomy

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.2. 3D bio-printed bionic pancreas, composed of islets of Langerhans, a non-viable, printable porcine-derived hydrogel matrix, plus vascular prostheses and stents

Treatment of chronic pancreatitis; treatment of brittle diabetes mellitus type 1

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.3. Micronized autologous adipose tissue

Adjunctive local treatment of refractory gastrointestinal fistulas to support tissue repair and fistula closure

Scope: Comments from the applicant on the outcome of the classification (report adopted in October 2026)

Action: for discussion

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

Timetable:

- Start of procedure at SAWP:	23-26.11.2026
- Appointment of CAT Peer Reviewers:	02-04.12.2026
- SAWP first reports:	04.01.2027
- CAT Peer Reviewer comments (NC & C):	08.01.2027
- CAT Peer Reviewer comments (Q):	13.01.2027
- Discussion at SAWP:	11-14.01.2027
- Discussion at CAT and feedback to SAWP:	20-22.01.2027

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

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

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:	26-29.10.206
SAWP recommendation:	26.11.2026
CAT recommendation:	04.12.2026
CHMP adoption of report and final recommendation:	10.12.2026

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 Irish presidency

Scope: Preparation for the meeting

CAT: Ailise Carleton

Action: for information

7.2. Coordination with EMA Scientific Committees

No items

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

7.3.1. Q&As on individualised neoantigen therapies (BWP/QIG)

Scope: Presentation of the consolidated text

Rapporteur: Marcel Hoefnagel

Action: For adoption

7.3.2. Concept paper on guidance on the use of biomarkers of effect in risk assessment, jointly by EFSA, EMA and ECHA

Scope: Draft concept paper

CAT: Kieran Breen

Action: for information

7.4. Cooperation with the EU regulatory network

No items

7.5. Cooperation with international regulators

No items

7.6. CAT work plan

No items

7.7. Planning and reporting

No items

7.8. Others

No items

8. Any other business

No items

Date of next CAT meeting:

02-04 December 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

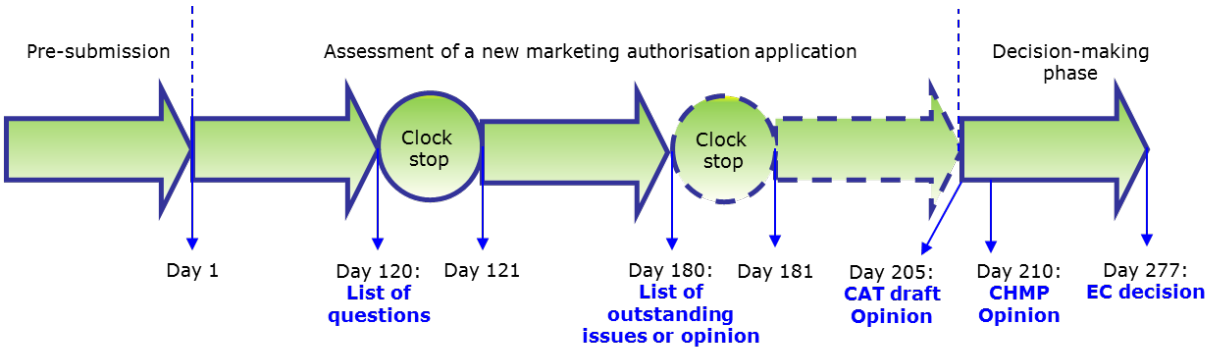
Evaluation of ATMPs (section 2)

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.

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/