17 June 2026
EMA/CAT/139022/2026
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 17-19 June 2026

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

17 June 2026, 14:00 – 18:30

18 June 2026, 09:00 – 18:30

19 June 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 17-19 June 2026. See June 2026 CAT minutes (to be published post July 2026 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 17-19 June 2026 meeting

1.3. Adoption of the minutes

CAT minutes for 11-13 May 2026 meeting

2. Evaluation of ATMPs

2.1. Opinions

2.1.1. Autologous melanoma-derived tumour infiltrating lymphocytes, ex vivo-expanded - EMEA/H/C/006563

Treatment of melanoma

Scope: Opinion

Action: for adoption

Oral explanation on 11.05.2026. List of outstanding issues adopted on 20.03.2026. List of questions adopted on 18.07.2025.

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

No items

2.4. Day 120 list of questions

No items

2.5. Day 80 assessment reports

2.5.1. Zamtocabtagene autoleucel - PRIME - Orphan - EMEA/H/C/005495

Miltenyi Biomedicine GmbH; Treatment of adults with large B-cell lymphoma

Scope: Day 80 assessment report

Action: for information

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/0000327582

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, opinion

Action: for adoption

2.11.2. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/VR/0000316059

Janssen Cilag International

Rapporteur: Attila Sebe

Scope: Quality

Action: for adoption

2.11.3. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/VR/0000327548

Janssen Cilag International

Rapporteur: Attila Sebe

Scope: Quality

Action: for adoption

2.11.4. Vyjuvek - Beremagene geperpavec - Orphan - EMA/VR/0000306575

Krystal Biotech Netherlands B.V.

Rapporteur: Joseph De Courcey

Scope: Quality, request for supplementary information

Action: for adoption

2.11.5. Waskyra - Etuvetidigene autotemcel - Orphan - EMA/VR/0000340506

Fondazione Telethon Ets

Rapporteur: Violaine Closson Carella

Scope: Clinical, request for supplementary information

Update of section 4.8 of the SmPC in order to revise and update the list of adverse reactions (ADRs). In addition, the MAH is taking the opportunity to introduce additional edits and formatting changes to the PI.

Action: for adoption

2.11.6. Zolgensma - Onasemnogene abeparvovec - Orphan - EMA/VR/0000340942

Novartis Europharm Limited

Rapporteur: Emmely de Vries

Scope: Clinical

Update of sections 4.6 and 5.3 of the SmPC in order to incorporate the findings from the fertility and early embryonic development (FEED) and embryo-foetal development (EFD) studies in mice.

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/PAM/0000338559

Janssen Cilag International

Rapporteur: Attila Sebe; PRAC Rapporteur: Jo Robays

Scope: PAM, PASS

Action: for adoption

2.13.2. Luxturna - Voretigene neparvovec - Orphan - EMA/PAM/0000339319

Novartis Europharm Limited

Rapporteur: Sol Ruiz; PRAC Rapporteur: Dirk Mentzer

Scope: PAM, PASS

Action: for adoption

2.13.3. Waskyra - Etuvetidigene autotemcel - Orphan - EMA/PAM/0000338735

Fondazione Telethon Ets

Rapporteur: Violaine Closson Carella

Scope: PAM

Action: for adoption

2.13.4. Waskyra - Etuvetidigene autotemcel - Orphan - EMA/PAM/0000338021

Fondazione Telethon Ets

Rapporteur: Violaine Closson Carella

Scope: PAM

Action: for adoption

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

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:	19.06.2026
-EMA Coordinator's draft report:	03.07.2026
-CAT Coordinator's comments:	08.07.2026
-Revised scientific recommendation:	10.07.2026
-CAT's discussion of scientific recommendation:	17.07.2026

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Allogeneic umbilical cord-derived mesenchymal stem cells

Treatment of chronic kidney disease (CKD)

Scope: ATMP scientific recommendation

Action: for nomination of CAT coordinator

4.1.2. Recombinant adeno-associated virus containing the human microdystrophin gene

Treatment of Duchenne muscular dystrophy (DMD)

Scope: ATMP scientific recommendation

Action: for nomination of CAT coordinator

4.1.3. Recombinant adeno-associated virus vector containing a mini-dystrophin analog (mini-UDYS) transgene

Treatment of Duchenne muscular dystrophy (DMD)

Scope: ATMP scientific recommendation

Action: for nomination of CAT coordinator

4.2. Day 30 ATMP scientific recommendation

4.2.1. Virus-specific T lymphocytes enriched from peripheral blood

Treatment of virus reactivation in immunocompromised patients

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Allogeneic peripheral blood-derived haematopoietic stem and progenitor cells (HSPCs), regulatory T cells (Tregs) and conventional T cells (Tcons)

For use in adult patients with haematologic malignancies to improve survival free of graft-versus-host disease in conjunction with an appropriate preparative regimen

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Adeno-associated virus serotype rh.74 vector containing the human Plakophilin-2a (PKP2) gene isoform (AAVrh.74-PKP2a)

Treatment of arrhythmogenic cardiomyopathy caused by pathogenic mutations in the PKP2 gene

Scope: ATMP scientific recommendation

Action: for adoption

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

No items

4.4. Follow-up and guidance

4.4.1. Autologous platelet-rich plasma (PRP) combined with mechanically processed autologous adipose tissue (nanofat)

Treatment of refractory olfactory dysfunction

Scope: Comments received from the European Commission. ATMP scientific recommendation

Action: for adoption

4.4.2. Allogeneic human umbilical cord-derived mesenchymal stromal cells

Treatment of congenital diaphragmatic hernia

Scope: Comments received from the European Commission ATMP scientific recommendation

Action: for adoption

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 Peer Reviewers

Timetable:

- Start of procedure at SAWP:	08-11.06.2026
- Appointment of CAT Peer Reviewers:	17-19.06.2026
- SAWP first reports:	29.06.2026
- CAT Peer Reviewer (NC & C) comments:	03.07.2026
- CAT Peer Reviewer (Q) comments:	08.07.2026
- Discussion at SAWP:	06-09.07.2026
- Discussion at CAT and feedback to SAWP:	15-17.07.2026

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:	08-11.06.2026
SAWP recommendation:	09.07.2026

CAT recommendation:	17.07.2026
CHMP adoption of report and final recommendation:	23.07.2026

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: Joseph deCourcey

Action: for information

7.1.4. Election of CAT Vice-Chairperson 2026

Action: for adoption

7.1.5. Revised CAT Rules of Procedure

Scope: Revised CAT Rules of Procedure

Action: for information

Note: The revised CAT Rules of procedure were adopted by the Management Board and will enter in operation on 1 July 2026.

7.2. Coordination with EMA Scientific Committees

No items

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

No items

7.4. Cooperation with the EU regulatory network

7.4.1. GMO assessment for ATMPs

CAT: Ilona Reischl

European Commission representative

Scope: Current process for the consultation of GMO authorities during the marketing authorisation procedures and future process of ERA assessment for GMO containing ATMP in clinical trials

Action: for discussion

7.4.2. Implementation of the new Pharmaceutical Legislation

CAT: Ilona Reischl

Scope: Governance & Network engagement model

Action: for information

7.5. Cooperation with international regulators

7.5.1. ATMP cluster teleconference with US-FDA, Health Canada, PMDA (Japan) and Swissmedic

CAT: Ilona Reischl

Scope: Agenda of the ATMP cluster of 25.06.2026

Action: for information

7.5.2. IPRP (International Pharmaceutical Regulators Programme) cell and gene therapy working group

CAT: Pille Saalik

Scope: Feedback from the IPRP meeting of 16.06.2026

Action: for discussion

7.6. CAT work plan

7.6.1. Patient reported outcomes / patient preference studies in the ATMP development

Scope: Outcome of the discussion at the SRLM in Cyprus

CAT: Kieran Breen, Kerstin Sollerbrant Melefors, Donatella Capone, Federica Chiara

Action: for information

7.6.2. Joint Health Technology Assessment bodies (HTAb)-regulatory perspectives on understanding evidence challenges, managing uncertainties and exploring potential solutions

Scope: Outcome of a workshop series between HTA bodies and regulators

Action: for information

7.6.3. CAT assessors training on GL for investigational ATMPs

Scope: Feedback from the CAT assessors training held on 17.06.2026

CAT: Ilona Reischl-Kok, Silke Dorner, Suzana Vidic, Olga Kholmanskikh

Action: for information

7.7. Planning and reporting

7.7.1. Q2-2026 Business Pipeline report for the human scientific committees

Scope: Q2-2026 Business Pipeline report for the human scientific committees

Action: for information

7.8. Others

7.8.1. International Society for Cell & Gene therapy (ISCT) annual meeting

Scope: Feedback from discussions at the International Regulators Summit (5 May 2026) and from the annual meeting (6-9 May 2026)

CAT: Pille Säälik, Kieran Breen

Action: for information

7.8.2. CASSS-Cell and Gene Therapy products (CGTP) symposium

Scope: Feedback from discussion at the CASSS-CGTP symposium (9-11 June 2026)

CAT: Barbara Bonamassa, Ilona Reischl-Kok

Action: for information

8. Any other business

8.1.1. Update on the transition to IRIS for initial marketing authorisation applications and pre-submission activities

Scope: Present the updated plan and anticipate upcoming engagement activities to support preparation for this transition

Action: for information

Date of next CAT meeting:

15-17 July 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

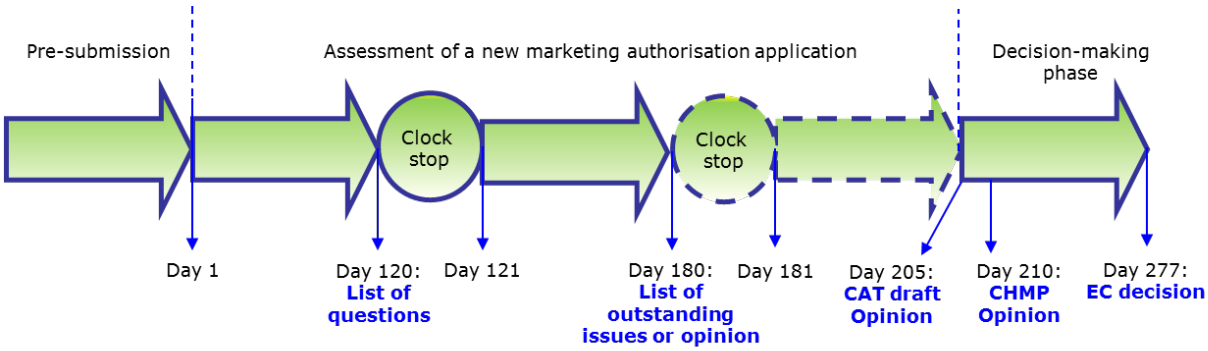
Evaluation of ATMPs (section 2)

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/