17 June 2026
EMA/CAT/194496/2026
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 11-13 May 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 diilonsclosed. 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 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

The Chairperson opened the meeting by welcoming all participants. The meeting was held in person with some members connected 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 taken at this meeting were made in the presence of a quorum of members. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified. The members of the EEA-EFTA States agreed with the recommendation of the CAT, unless otherwise specified.

The EMA Secretariat announced the names of the Committee members who delegated their vote via proxy and the Committee members who received such proxy.

1.2. Adoption of agenda

The CAT agenda for 11-13 May 2026 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes for 15-17 April 2026 meeting were adopted.

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

2.2.1. Autologous melanoma-derived tumour infiltrating lymphocytes, ex vivo- expanded - EMA/H/C/006563/0000

Treatment of adult patients with advanced melanoma

Scope: Oral Explanation

Action: for discussion

The rapporteurs presented the assessment of the responses to the list of outstanding issues. Feedback from the BWP discussion was provided.

During the oral explanation, the applicant presented their arguments for the approval of their product. The draft opinion will be adopted at the June CAT meeting.

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

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. Aucatzyl - Obecabtagene autoleucel - Orphan - EMA/VR/0000335388

Autolus GmbH

Rapporteur: Tineke van den Hoorn

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.2. Hemgenix - Etranacogene dezaparvovec - Orphan - EMA/VR/0000315755

CSL Behring GmbH

Rapporteur: Silke Dorner

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.3. Libmeldy - Atidarsagene autotemcel - Orphan - EMA/VR/0000334917

Orchard Therapeutics (Netherlands) B.V.

Rapporteur: Emmely de Vries; PRAC Rapporteur: Dirk Mentzer

Scope: Clinical, Request for supplementary information

A grouped application consisting of:

C.12: Submission of the final report from study 201222 listed as a category 3 study in the RMP. This is a Phase I/II clinical trial of haematopoietic stem cell gene therapy for the treatment of metachromatic leukodystrophy (MLD).

C.12: Submission of the final report from study CUP 207394 listed as a category 3 study in the RMP. This is a gene therapy protocol using autologous haematopoietic stem cells for a patient with metachromatic leukodystrophy (MLD).

C.12: Submission of the final report from studies CUP 206258 and HE 205029 listed as category 3 studies in the RMP. These are Expanded Access Programs (EAP) for hematopoietic stem cell gene therapy OTL-200 in subjects with early-onset metachromatic leukodystrophy (MLD).

The RMP version 4.1 has also been submitted.

Action: for adoption

The request for supplementary information 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, opinion

Action: for adoption

The opinion was adopted.

2.11.5. Yescarta - Axicabtagene ciloleucel - Orphan - EMA/VR/0000313321

Kite Pharma EU B.V.

Rapporteur: Attila Sebe

Scope: Quality & Clinical, opinion

Action: for adoption

The opinion was adopted.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Zemcelpro - Dorocubicel / Allogeneic umbilical cord-derived CD34- cells, non-expanded - Orphan - EMA/R/0000333327

Cordex Biologics International Limited

Rapporteur: Emmely de Vries; PRAC Rapporteur: Mari Thorn

Scope: Renewal - 1 year

Action: for adoption

The renewal opinion was adopted.

2.13.2. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/PAM/0000335677

Janssen Cilag International

Rapporteur: Attila Sebe

Scope: PAM

Action: for adoption

The outcome of the assessment was agreed.

2.13.3. Hemgenix - Etranacogene dezaparvovec - Orphan - EMA/PAM/0000301642

CSL Behring GmbH

Rapporteur: Silke Dorner

Scope: PAM

Action: for adoption

The outcome of the assessment was agreed.

2.13.4. Waskyra - Etuvetidigene autotemcel - Orphan - EMA/PAM/0000334844

Fondazione Telethon Ets

Rapporteur: Violaine Closson Carella; PRAC Rapporteur: Jo Robays

Scope: PAM, PRAC led procedure

Action: for adoption

The outcome of the PRAC assessment was presented and agreed.

2.13.5. Zolgensma - Onasemnogene abeparvovec - Orphan - EMA/PAM/0000335675

Novartis Europharm Limited

Rapporteur: Emmely de Vries

Scope: PAM

Action: for adoption

The outcome of the assessment was agreed.

2.13.6. AUCATZYL - Obecabtagene autoleucel - Orphan – EMA/PASS/0000300590

Autolus GmbH

PRAC Rapporteur: Karin Erneholm

Scope: PASS protocol, PRAC led procedure

Action: for information

The outcome of the PRAC assessment was presented and agreed.

2.13.7. Ebvallo – Tabelecleucel - Orphan - EMA/S/0000326533

Pierre Fabre Medicament

Rapporteur: Attila Sebe

Scope: Annual reassessment

Action: for adoption

The request for supplementary information was adopted.

2.13.8. Waskyra - Etuvetidigene autotemcel – Orphan – EMEA/H/C/006525

Fondazione Telethon Ets

Rapporteur: Violaine Closson Carella

Scope: Feedback from the MAH on the parallel submission in EU and US

Action: for information

The information 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:	18.05.2026
-EMA Coordinator's draft report:	29.05.2026
-CAT Coordinator's comments:	03.06.2026
-Revised scientific recommendation:	12.06.2026
-CAT's discussion of scientific recommendation:	19.06.2026

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Virus-specific T lymphocytes enriched from peripheral blood

Treatment of virus reactivation in immunocompromised patients

Scope: ATMP scientific recommendation

Action: for nomination of CAT coordinator

The CAT coordinator was appointed.

4.1.2. 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 nomination of CAT coordinator

The CAT coordinator was appointed.

4.1.3. 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 nomination of CAT coordinator

The CAT coordinator was appointed.

4.2. Day 30 ATMP scientific recommendation

4.2.1. Autologous venous graft

Reconstruction of the extrahepatic bile duct following circumferential resection during hepatobiliary surgery for malignant biliary tumours, including perihilar cholangiocarcinoma and other tumours involving the biliary confluence

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 29.05.2026

4.2.2. Human type I collagen, lyophilised

For intradermal injection into the facial dermis to correct dynamic wrinkles (crow's feet)

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 29.05.2026

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

Treatment of refractory olfactory dysfunction

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 29.05.2026

4.2.4. Allogeneic human umbilical cord-derived mesenchymal stromal cells

Treatment of congenital diaphragmatic hernia

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 29.05.2026

4.2.5. Adeno-associated virus serotype rh.74 viral vector encoding the human B-cell Lymphoma 2 (BCL-2)-associated athanogene 3 (BAG3) gene (AAVrh.74-BAG3)

Treatment of BAG3-associated dilated cardiomyopathy (DCM)

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 29.05.2026

4.2.6. Replication-competent, plaque-purified, attenuated mumps virus variant

Treatment of breast cancer

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 29.05.2026

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

No items

4.4. Follow-up and guidance

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

COVID-19 prophylaxis

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

Action: for adoption

CAT discussed the classification report, reflecting the comments received from the European Commission. Based on the primary mode of action of the product (to mount an immune response to COVID-19, i.e. vaccine function), CAT considered that the exclusion of vaccines against infectious disease from the gene therapy medicinal product definition applies for this product. The product therefore does not fulfil the definition of an advanced therapy medicinal product as provided in Article 2(1) of Regulation (EC) 1394/2007. A disclaimer was included in the report that this classification applies solely to the product as described in the present application and is without prejudice to the classification of other products combining vaccine and gene therapy functions. The updated classification report was adopted.

4.4.2. Autologous adipose-derived stromal vascular fraction

Treatment of acute spinal cord injury

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

Action: for adoption

CAT discussed the classification report, reflecting the comments received from the European Commission. The product does fulfil the definition of a tissue engineered product as provided in Article 2(1) of Regulation (EC) 1394/2007. The updated classification report was adopted.

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: 04-07.05.2026
- Appointment of CAT Peer Reviewers: 11-13.05.2026

- SAWP first reports:	01.06.2026
- CAT Peer Reviewer comments (NC & C):	05.06.2026
- CAT Peer Reviewer comments (Q):	10.06.2026
- Discussion at SAWP:	08-11.06.2026
- Discussion at CAT and feedback to SAWP:	17-19.06.2026

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

No items

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:	
Procedure start:	04-07.05.2026
SAWP recommendation:	11.06.2026
CAT recommendation:	19.06.2026
CHMP adoption of report and final recommendation:	25.06.2026

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

Joseph DeCourcey gave a proxy to Emmely de Vries to vote on behalf of Ireland during the entire meeting.

Alessia Pochesci gave a proxy to Claire Beuneu to vote on behalf of Luxembourg during the entire meeting.

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

Scope: Feedback and lessons learnt from the meeting

CAT: Rafaella Pontou

Action: for information

The feedback from the SRLM was noted.

7.1.4. CAT Strategic Review & Learning meeting (SRLM) under the Irish presidency

Scope: Preparation for the meeting

CAT: Joseph deCourcey

Action: for information

The SRLM date was noted (11-13 November 2026). Discussion of the agenda will take place at the June CAT meeting.

7.1.5. CXMP Meeting Dates - Face to Face Schedule 2027

Scope: CAT members to be informed of 2027 plenary meetings taking place in person and online only

Action: for consultation

The schedule of the face-to-face CAT meetings in 2027 was agreed.

7.2. Coordination with EMA Scientific Committees

No items

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

7.3.1. Work plan for the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP)

Scope: PCWP/HCPWP Work Plan 2025–2028

Action: for information

The PCWP/HCPWP Work Plan 2025–2028 was noted.

7.4. Cooperation with the EU regulatory network

No items

7.5. Cooperation with international regulators

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

CAT: Ilona Reischl-Kok

Scope: Feedback from the ATMP cluster of 23.04.2026

Action: for information

The feedback from the previous ATMP cluster was noted. CAT members were asked to identify topics for inclusion on the agenda of the next ATMP cluster meeting (25.06.2026).

7.6. CAT work plan

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

CAT: Kieran Breen, Kerstin Sollerbrant Melefors, Donatella Capone

Scope: Outcome of the discussion at the SRLM in Cyprus

Action: for information

The topic was postponed until the next CAT meeting.

7.7. Planning and reporting

7.7.1. 3-year outlook report for the human scientific committees

Scope: 3-year outlook report for the human scientific committees

Action: for information

The 3-year outlook report was noted.

7.8. Others

7.8.1. Committee meeting minutes search agent

Scope: New EMA AI searching tool for committee meeting minutes

Action: for information

CAT noted the presentation of the Committee meeting minutes search agent.

CAT asked to investigate if this AI search tool or the Scientific Explorer (for scientific advice) could be used to search in ATMP classification reports.

7.8.2. Revamp

Scope: Update on the start of the new product information (PI) review process for initial MAA and extension applications

Action: for information

The updated process for PI checking was presented.

8. Any other business

No items

9. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 11-13 May 2026 CAT meeting, which was held in-person.

An asterisk (*) after the role, in the second column, signals that the member/alternate attended remotely. Additional experts participated in (part of) the meeting remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics for which restrictions apply
Ilona Reischl-Kok	Chair	Austria	No interests declared	
Silke Dorner	Member	Austria	No interests declared	
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	
Radka Nejezchlebová	Alternate	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	
Heli Suila	Member	Finland	No restrictions applicable to this meeting	
Violaine Closson Carella	Member	France	No interests declared	
Gabriela Ullio Gamboa*	Alternate	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	
Angeliki Rompoti*	Alternate	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	
Una Riekstina	Member	Latvia	No restrictions applicable to this meeting	

Vilma Petrikaite	Member (CHMP member)	Lithuania	No restrictions applicable to this meeting	
Alessia Pochesci*	Member	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 Kjeken	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	
Liviu Nitulescu*	Alternate	Romania	No restrictions applicable to this meeting	
Margareta Fogelová	Member	Slovakia	No interests declared	
Denisa Partelova*	Alternate	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 discussion, final deliberations and voting on:	Scientific Advice
Charlotte Anderberg*	Alternate	Sweden	No interests declared	
Julio Delgado Gonzalez*	Member	Clinicians' Representative	No restrictions applicable to this meeting	
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	

Olga Kolaj-Robin*	Observer/ Alternate	EDQM	No restrictions applicable to this meeting	
Torbjörn Callréus	Expert	Malta	No interests declared	
Maëva Robin	Expert	France	No interests declared	
Ramzi Mraidi	Expert	France	No restrictions applicable to this meeting	
Housam Eidi	Expert	France	No interests declared	
Solène Maitenaz	Expert	France	No interests declared	
Caroline Richard	Expert	France	No restrictions applicable to this meeting	
Agnès Mambole-Dema	Expert	France	No interests declared	
Simona Teodosiu	Expert	France	No interests declared	
Marianne Delville	Expert	France	No restrictions applicable to this meeting	
Paolo Petracci	Expert	France	No interests declared	
Dagmar Pospíšilová	Expert	Czechia	No interests declared	
Barbora Vokatá	Expert	Czechia	No restrictions applicable to this meeting	
Anna Mari Lone	Expert	Norway	No restrictions applicable to this meeting	
Fabrice Eroukhmanoff	Expert	Norway	No interests declared	
Lena Eroukmanhoff	Expert	Norway	No interests declared	
Eva Skovlund	Expert	Norway	No restrictions applicable to this meeting	
Eva Kristine Klemsdal	Expert	Norway	No interests declared	
Aina Øvrebust	Expert	Norway	No interests declared	
Annemarie den Harder	Expert	Netherlands	No restrictions applicable to this meeting	
Jolien de Groot	Expert	Netherlands	No interests declared	
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.				

Date of next CAT meeting:

17-19 June 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

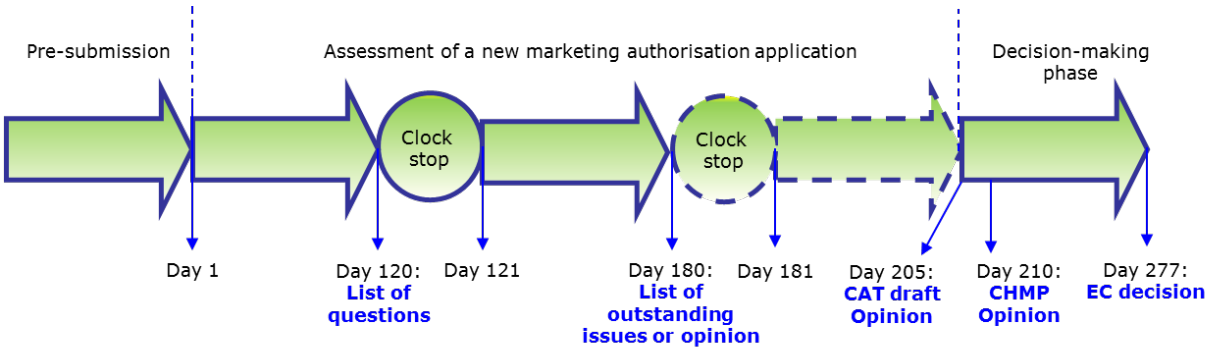
Evaluation of ATMPs (section 2)

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/