10 September 2025
EMA/CAT/315554/2025
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 16-18 July 2025

Chair: Ilona Reischl; Vice-Chair: Kieran Breen

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

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

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to 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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

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. No new or additional interests or restrictions were declared. Restrictions applicable to this meeting are captured in the List of participants included in the minutes.

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

The Chair welcomed the new and renewed members and alternates representing the clinicians and patients' organisations and thanked the departing members and alternates for their contributions to the Committee.

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

The Chair announced the start of the Danish presidency of the Council of the European Union (EU).

1.2. Adoption of agenda

The CAT agenda for 16-18 July 2025 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes for 11-13 June 2025 meeting were adopted.

2. Evaluation of ATMPs

2.1. Opinions

2.1.1. AMTAGVI - Lifileucel - EMEA/H/C/004741

Iovance Biotherapeutics B.V.; Treatment of unresectable or metastatic melanoma

Scope: Opinion

Action: for adoption

List of outstanding issues adopted on 16.05.2025. List of questions adopted on 06.12.2024.

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

CAT discussed the ground for refusal.

CAT adopted by consensus a negative opinion recommending denying granting a marketing authorisation for Amtagvi.

2.1.2. Elevidys - Delandistrogene moxeparvovec - Orphan - EMEA/H/C/005293

Roche Registration GmbH; Treatment of ambulatory patients aged 3 to 7 years old with Duchenne muscular dystrophy

Scope: Opinion

Action: for adoption

List of outstanding issues adopted on 16.04.2025. List of questions adopted on 11.10.2024.

Following the oral explanation and the trend vote at the June 2025 CAT meeting; CAT discussed the ground for refusal

CAT adopted by consensus a negative opinion recommending denying granting a marketing authorisation.

2.1.3. JELRIX - Autologous cartilage-derived articular chondrocytes, in-vitro expanded - EMEA/H/C/004594

TETEC Tissue Engineering Technologies AG; Repair of symptomatic, localised, full-thickness cartilage defects of the knee joint grade III or IV

Scope: Opinion

Action: for adoption

List of outstanding issues adopted on 21.03.2025. List of questions adopted on 19.04.2024.

Following the oral explanation and the trend vote at the June 2025 CAT meeting; CAT discussed the ground for refusal.

A final vote was taken. CAT adopted by majority a negative opinion recommending denying

granting a marketing authorisation for Jelrix.

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

Treatment of melanoma

Scope: Day 120 list of questions

Action: for adoption

The Rapporteurs presented the outcome of the assessment. Feedback was provided from the BWP discussion. The revised list of questions was adopted.

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. Yescarta, Tecartus - Axicabtagene ciloleucel, Brexucabtagene autoleucel - Orphan - EMA/VR/0000255932

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

The opinion was adopted.

2.11.2. Hemgenix - Etranacogene dezaparvovec - Orphan - EMA/VR/0000270071

CSL Behring GmbH

Rapporteur: Silke Dorner

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.3. Breyanzi - Lisocabtagene maraleucel - Orphan - EMA/VR/0000272242

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli, PRAC rapporteur: Gabriele Maurer

Scope: Clinical, request for supplementary information

Update of sections 4.2, 4.4, 4.7 and 4.8 of the SmPC in order to update the post-treatment safety monitoring information based on clinical trials and real-world data. The Package leaflet section is updated in accordance. Version 8.0 of the RMP has also been submitted. In addition, the MAH the opportunity to update Annex II.

Action: for adoption

The Rapporteur presented the assessment of the proposed changes. Some clarifications are needed before concluding. The request for supplementary information was adopted.

2.11.4. Breyanzi - Lisocabtagene maraleucel - Orphan - EMA/VR/0000249056

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.5. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/VR/0000264446

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Clinical, opinion

Update of section 4.4 of the SmPC in order to amend an existing warning on secondary malignancies including of T-cell origin to limit the testing only to secondary malignancy of T-cell origin based on the data from clinical studies and literature.

Action: for adoption

Request for supplementary information adopted on 13.06.2025

The Rapporteur presented the assessment of the responses to the request for supplementary information. The wording of the section 4.4 was discussed. The opinion was adopted.

2.11.6. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/VR/0000272240

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.7. Abecma - Idecabtagene vicleucel - Orphan - EMA/VR/0000249089

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.8. Ebvallo - Tabelecleucel - Orphan - EMA/VR/0000267364

Pierre Fabre Medicament

Rapporteur: Egbert Flory

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.9. Casgevy - Exagamglogene autotemcel - Orphan - EMA/VR/0000258214

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Jan Mueller-Berghaus

Scope: Clinical, opinion

Update of section 5.3 of the SmPC in order to update non-clinical information and remove existing wording on off-target editing based on (1) Results of in silico analysis to nominate genetic variants and (2) Interim study report presenting results from genotyping of subjects and off-target editing in drug product from subjects in clinical Studies 111 and 121. In addition, the MAH took the opportunity to make editorial changes to the PI.

Action: for adoption

Request for supplementary information adopted on 16.05.2025

The Rapporteur presented the assessment of the responses to the request for supplementary information. Information on off-target events are included in sections 4.4 and 5.3 of the SmPC. Changes were proposed to simplify the proposed text of section 5.3. The opinion was adopted.

2.11.10. Breyanzi - Lisocabtagene maraleucel – Orphan - EMA/VR/0000265024

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli; Co-Rapporteur: Claire Beuneu; PRAC Rapporteur: Gabriele Maurer

Scope: Clinical, request for supplementary information

A grouped application comprised of two Type II variations, as follows:

Type II (C.I.6): Extension of indication to include the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor for BREYANZI, based on results from the pivotal Study 017001 MCL Cohort (TRANSCEND-NHL-001); this is a Phase 1, Multicenter, Open-Label Study of JCAR017, CD19-targeted Chimeric Antigen Receptor (CAR) T Cells, for Relapsed and Refractory (R/R) B-cell Non-Hodgkin Lymphoma (NHL). As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package leaflet is updated in accordance. Version 7.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to update the list of local representatives in the Package Leaflet.

Type II (B.II.d.1.e): Quality.

Action: for adoption

The Rapporteur presented the assessment of the extension of indication and of the quality variation. The request of supplementary information was adopted.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Tecartus - Brexucabtagene autoleucel - Orphan - EMA/PAM/0000267756

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, PRAC rapporteur: Bianca Mulder

Scope: PAM, Clinical and Pharmacovigilance, request for supplementary information

Action: for adoption

The outcome of the assessment was agreed.

2.13.2. Casgevy - Exagamglogene autotemcel - Orphan - EMA/PAM/0000268688

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Jan Mueller-Berghaus, PRAC rapporteur: Bianca Mulder

Scope: PAM, Pharmacovigilance

Action: for adoption

The outcome of the assessment was agreed.

2.13.3. ROCTAVIAN - Valoctocogene roxaparvovec - Orphan - EMA/R/0000250212

BioMarin International Limited

Rapporteur: Violaine Closson Carella, PRAC rapporteur: Bianca Mulder

Scope: Renewal 1 year, opinion

Action: for adoption

The 1-year renewal was adopted.

2.13.4. Breyanzi - Lisocabtagene maraleucel – Orphan - EMA/PASS/0000269320

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Updated PASS protocol v3.0 for JCAR017-BCM-005, an imposed category 1 mandatory additional pharmacovigilance activity: Non-interventional, post-authorisation safety study (PASS) of patients treated with commercially available liso-cel (lisocabtagene maraleucel) for large B-cell lymphomas; changes consequential to EMEA/H/C/004731/II/0043/G: updates in the objectives wording (for readability), eligibility criteria, and background to add therapeutic context for follicular lymphoma patients. PRAC-only Article 107o of Directive 2001/83/EC procedure, no CAT step

Action: for information

The outcome of the assessment was agreed.

2.14. Companion diagnostics - initial consultation

2.14.1. In vitro diagnostic medical device - EMEA/H/D/006768

Qualitative determination of antibodies to adeno-associated virus serotype 74 (AAVrh74) in human serum and/or plasma

Scope: List of questions

Action: For adoption

The Rapporteur presented the outcome of the assessment. The draft list of questions was discussed. This in vitro diagnostic is to be used in the context of the product Elevidys (see 2.1.2). The revised list of questions was adopted.

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

4.1. New requests – Appointment of CAT Coordinator

No items

4.2. Day 30 ATMP scientific recommendation

4.2.1. Allogeneic human midbrain dopaminergic neuron (mDA) progenitor cells derived from human pluripotent stem cells

Treatment of Parkinson's disease

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 01.08.2025.

4.2.2. Cell-free extracellular matrix derived from decellularized porcine skin tissue and cell-free concentrated secretome from human adipose-derived stromal cells

Treatment of perianal fistulas.

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 01.08.2025.

4.2.3. Bone-marrow and/or adipose tissue derived mesenchymal stem cells, embedded into a 3d non-woven polymer matrix

Treatment of critical limb ischemia

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 01.08.2025.

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

No items

4.4. Finalisation of procedure

4.4.1. Replication defective SV40 vector encoding for human proinsulin

Treatment of type 1 diabetes

Scope: ATMP scientific recommendation. European Commission raised no comments.

Action: for adoption

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

4.4.2. Anitocabtagene autoleucel

Treatment of patients with multiple myeloma

Scope: ATMP scientific recommendation. European Commission raised no comments.

Action: for adoption

The classification report was adopted. The product does fulfil the definitions of a gene therapy medicinal product and a somatic cell therapy medicinal product and is therefore classified as a gene therapy medicinal product as provided in Article 2(5) of Regulation (EC) No. 1394/2007.

4.4.3. Genetically modified porcine heart

Intended for cardiac xenotransplantation to human patients with end-stage heart failure

Scope: ATMP scientific recommendation. European Commission feedback.

Action: for adoption

CAT was informed of the feedback from the European Commission on the classification of genetically modified porcine heart. CAT considered that from a public health perspective, it is essential that this product is regulated (as an ATMP). The classification report was adopted: CAT concluded that the engineered cells that constitute the genetically modified porcine heart fall within the definition of a tissue engineered product as provided in Article 2(1) of Regulation (EC) No 1394/2007. This recommendation is without prejudice to any future changes in the EU legislative frameworks for EU healthcare products.

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:	07-10.07.2025
- Appointment of CAT Peer Reviewers:	16-18.07.2025
- SAWP first reports:	25.08.2025
- CAT Peer Reviewer comments (NC & C):	29.08.2025

- CAT Peer Reviewer comments (Q):	03.09.2025
- Discussion at SAWP:	01-04.09.2025
- Discussion at CAT and feedback to SAWP:	10-12.09.2025

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	01-04.09.2025
- Appointment of CAT Peer Reviewers:	10-12.09.2025
- SAWP first reports:	22.09.2025
- CAT Peer Reviewer comments (NC & C):	26.09.2025
- CAT Peer Reviewer comments (Q):	01.10.2025
- Discussion at SAWP:	29.09-02.10.2025
- Discussion at CAT and feedback to SAWP:	08-10.10.2025

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

No items

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:

Procedure start:	07-10.07.2025
SAWP recommendation:	04.09.2025
CAT recommendation:	12.09.2025
CHMP adoption of report and final recommendation:	18.09.2025

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

The Chair welcomed the new and renewed members and alternates representing the clinicians:

- Julio Delgado Gonzalez (member), Bernd Gansbacher (alternate)

- Michal Konstacky (member), Alessandra Renieri (alternate)

The Chair welcomed the new and renewed members and alternates representing the patients' organisations:

- Kieran Breen (member), Donatella Capone (alternate)

- Federica Chiara (member), Kerstin Sollerbrant (alternate)

The Chair announced that Margareta Fogelova has swapped roles and she is the new member for Slovakia instead of the alternate.

7.1.2. Vote by proxy

Maija Tarkkanen gave a proxy to Silke Dorner to vote on behalf of Finland on Thursday afternoon and Friday.

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

Jan Mueller-Berghaus gave a proxy to Rune Kjeken to vote on behalf of Germany during the entire meeting.

7.1.3. CAT Dates (online & face-to-face) 2026

Scope: CAT Plenary 2026 dates

Action: for information

The information was noted.

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

CAT: Martin Bronislaw Oleksiewicz

Scope: Preparation for the meeting

Action: for information

The agenda for the CAT session at the upcoming SRLM was presented and practical was provided.

The date of the SRLM under the Cypriot presidency was communicated .

7.1.5. EMA Committee reform

CAT: Ilona Reischl

Scope: Feedback from the co-creation meeting with all Committee Chairs (24.06.2025) on the novel committee structures

Action: for information

The CAT chair provided high-level feedback from the first discussion amongst all the Committee Chairs on the new committee structures. She mentioned that she was able to bring forward the comments that were made by CAT members during the June CAT meeting.

7.2. Coordination with EMA Scientific Committees

7.2.1. Guideline on good pharmacovigilance practices (GVP) Module XVI Addendum I – Risk minimisation measures for medicinal products with embryo-fetal risks

Action: for information

The guideline was presented. CAT members made some observations. EMA will discuss these comments with the guideline drafting group members.

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

7.3.1. Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) new three-year mandate

Scope: Invitation from the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) to nominate new three-year candidates (June 2025-May 2028)

Action: for information

Kerstin Sollerbrant was appointed as CAT representatives in the PCWP and Julio Delgado as CAT representative in the HCPWP.

7.3.2. Revised Guideline on clinical investigation of medicinal products for the treatment of peripheral arterial occlusive disease of the lower extremities for comments

Scope: Revised guideline, comments on chapter 10 awaited

Action: for information

The guideline was presented. CAT members were reminded of the deadline to provide comments.

7.4. Cooperation with the EU regulatory network

7.4.1. RWE activities including projects on Duchenne Muscular Dystrophy (DMD)

Scope: To inform CAT about a project that has been launched to assess the fitness-for-purpose of real-world data (RWD) sources on Duchenne Muscular Dystrophy to support regulatory decision-making

Action: for information

EMA presented the project to assess the fitness-for-purpose of RWD sources on Duchenne Muscular Dystrophy (DMD): objectives and deliverables were highlighted. A multi-stakeholder workshop is planned at the end of 2026 to present the outcome of the project. CAT noted that development landscape for DMD is changing: it is important also to look at novel endpoints, also for registries.

EMA also informed CAT of the Patient registry multi-stakeholder workshop on Alzheimer's disease that will take place on 15.12.2025.

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: Feedback from the teleconference of 26.06.2025

Action: for information

A short feedback was provided from the discussion during the June ATMP cluster TC.

7.5.2. ICH Cell and Gene discussion Group update and call for review

CAT: Jan Müller-Berghaus

Scope: To introduce the CGDG's recommendation paper and invite CAT to provide comments on the paper

Action: for information

Jan Mueller-Berghaus presented the ICH Cell and Gene discussion Group (CGDG) recommendation paper. CAT members were asked to review the paper and provide

comments.

7.6. CAT work plan

7.6.1. CAT Workshop on Gene Editing

Scope: Update on the CAT Workshop (16.09.2025)

Action: for information

EMA provided some practical information on the upcoming CAT workshop. CAT members and colleagues within their agencies are invited to join the remote workshop.

7.7. Planning and reporting

No items

7.8. Others

No items

8. Any other business

8.1.1. Committee specific areas of expertise in the EMT

Action: for information

The information was noted.

8.1.2. General chapter on gene therapies

EDQM: Catherine Milne

Scope: publication of the General chapter on gene therapies in the European Pharmacopoeia

Action: for information

CAT members were informed that the general chapter is published for comments by 30.09.2025. This chapter also includes mRNA-based gene therapy products.

Date of next CAT meeting:

12-14 August 2025 – written procedure

10-12 September 2025

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 16-18 July 2025 CAT meeting.

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

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Ilona Reischl	Chair	Austria	No restrictions applicable to this meeting	
Silke Dorner	Member	Austria	No interests declared	
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	
Isavella Kyriakidou	Alternate	Cyprus	No interests declared	
Eva Kolouchová	Member	Czechia	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	
Maija Tarkkanen	Alternate	Finland	No interests declared	
Violaine Closson Carella	Member	France	No interests declared	
Jean-Michel Race*	Alternate	France	No restrictions applicable to this meeting	
Jan Mueller-Berghaus*	Member (CHMP co-opted member)	Germany	No interests declared	

Maria Gazouli	Member	Greece	No restrictions applicable to this meeting	
Viola Bardoczy	Member	Hungary	No restrictions applicable to this meeting	
Agnes Zotter*	Alternate	Hungary	No restrictions applicable to this meeting	
Péter Zsolt Fekete*	Member	Iceland	No interests declared	
Joseph De Courcey	Member	Ireland	No interests declared	
Richard Carroll*	Alternate	Ireland	No interests declared	
Concetta Quintarelli*	Member	Italy	No restrictions applicable to this meeting	
Barbara Bonamassa	Alternate	Italy	No interests declared	
Liga Kunrade	Alternate	Latvia	No restrictions applicable to this meeting	
Vilma Perikaite*	Member (CHMP member)	Lithuania	No restrictions applicable to this meeting	
Raimondas Benetis	Alternate (to CHMP representative)	Lithuania	No restrictions applicable to this meeting	
Alessia Pochesci*	Member	Luxembourg	No restrictions applicable to this meeting	
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	
Ole Henrik Myrdal	Alternate	Norway	No interests declared	
Dariusz Sladowski	Member	Poland	No restrictions applicable to this meeting	
Marcin Kolakowski	Alternate	Poland	No interests declared	
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	

Metoda Lipnik-Stangelj	Alternate	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:	2.1.2. Elevidys 2.14.1. Elecsys Anti-AAVrh74
Charlotte Anderberg	Alternate	Sweden	No interests declared	
Julio Delgado Gonzalez	Member	Clinicians' Representative	No restrictions applicable to this meeting	
Bernd Gansbacher*	Alternate	Clinicians' Representative	No interests declared	
Alessandra Renieri	Alternate	Clinicians' Representative	No restrictions applicable to this meeting	
Kerstin Sollerbrant Melefors*	Alternate	Patients' Representative	No restrictions applicable to this meeting	
Kieran Breen	Member (Vice-Chair)	Patients' Representative	No restrictions applicable to this meeting	
Donatella Capone	Alternate	Patients' Representative	No interests declared	
Catherine Milne	Observer/Alternate	EDQM	No interests declared	
Torbjörn Callréus	Expert	Malta	No interests declared	
Boje Kvorning Pires Ehmsen	Expert	Denmark	No interests declared	
Christian Gartner	Expert	Austria	No interests declared	
Melanie Ramberger	Expert	Austria	No interests declared	
Brigitte Müller	Expert	Austria	No interests declared	
Filip Josephson	Expert	Sweden	No interests declared	
Maëva Robin	Expert	France	No interests declared	
Marie-Thérèse Duffour	Expert	France	No interests declared	
Sawssen El-Ouisi	Expert	France	No interests declared	
Agnès Mambole-Dema	Expert	France	No interests declared	
Solène Maitenaz	Expert	France	No restrictions applicable to this meeting	

Housam Eidi	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	
Ramzi Mraidi	Expert	France	No restrictions applicable to this meeting	
Jenny-Maria Jönsson	Expert	Sweden	No restrictions applicable to this meeting	
Daiana Vasilcanu	Expert	Sweden	No interests declared	
Annemarie den Harder	Expert	Netherlands	No restrictions applicable to this meeting	
Nancy Breekveldt-Postma	Expert	Netherlands	No interests declared	
Anna Mari Lone	Expert	Norway	No restrictions applicable to this meeting	
Fabrice Eroukhmanoff	Expert	Norway	No interests declared	
Aina Jannicke Øvrebust	Expert	Norway	No interests declared	
Eva Skovlund	Expert	Norway	No restrictions applicable to this meeting	
Andreaa Barbu	Expert	Sweden	No interests declared	
A representative 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.				

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

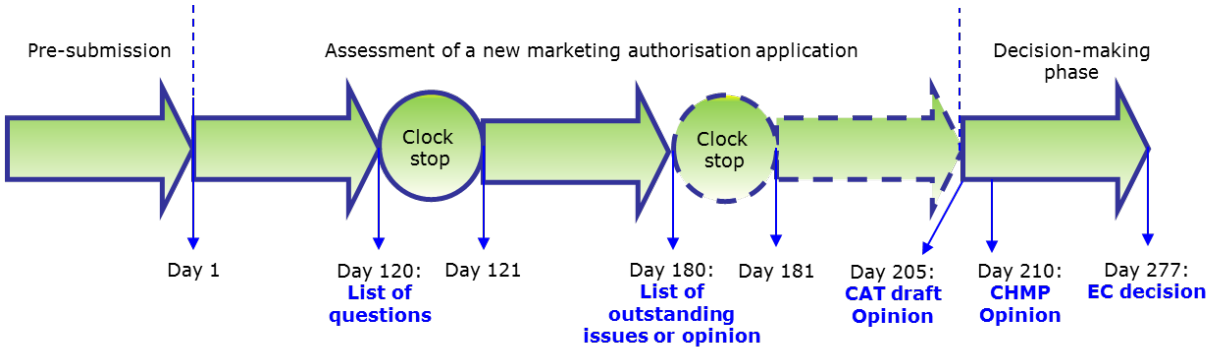
Evaluation of ATMPs (section 2)

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.

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/