5 November 2025
EMA/CAT/383728/2025
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes for the meeting on 08-09 October 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).

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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 joining 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 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 08-09 October 2025 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes for 10-12 September 2025 meeting were adopted.

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

No items

2.4. Day 120 list of questions

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

2.9.1. 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: List of questions

Action: for discussion

Negative opinion adopted on 18.07.2025.

The re-examination Rapporteur and Co-Rapporteur presented the assessment of the Ground for Refusal (GfR). Feedback was provided from the BWP discussion.

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. Breyanzi - Lisocabtagene maraleucel – Orphan - EMA/VR/0000264124

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Clinical, opinion

A grouped application consisting of:

C.I.4: Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study JCAR017-BCM-003; this is a global randomised multicentre phase 3 trial to compare the efficacy and safety of JCAR017 to standard of care in adult subjects with high-risk, transplant-eligible relapsed or refractory aggressive B-cell Non-Hodgkin lymphomas (TRANSFORM). In addition, final study reports for studies 017006 and JCAR017-BCM-001 Cohort 2 are submitted to support the main scope.

C.I.4: Update of section 4.8 of the SmPC in order to update information for the safety and immunogenicity based on pooled final data form the three follow up studies: (TRANSFORM BCM-003, PILOT 17006 and TRANSCEND WORLD, cohort 2 BCM-001). In addition, the MAH took the opportunity to remove the dose verification worksheet statement from the Labelling.

Action: for adoption

The Rapporteur presented the assessment of the response to the request for supplementary information. The opinion was adopted.

2.11.2. Breyanzi - Lisocabtagene maraleucel – Orphan - EMA/VR/0000258227

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

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, opinion

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 outcome of the assessment. The revised post-treatment safety information in the SmPC was agreed. The opinion was adopted.

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

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli, Co-Rapporteur: Claire Beuneu, PRAC rapporteur: Gabriele Maurer

Scope: Quality & Clinical, opinion

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.

Action: for adoption

The Rapporteur presented the assessment of the response to the request for supplementary information. CAT agreed that based on the submitted information, the benefit risk of Breyanzi in the adult patients with relapsed or refractory MCL is positive. The opinion was adopted

2.11.5. CARVYKTI - Ciltacabtagene autoleucel – Orphan - EMA/VR/0000290398

Janssen Cilag International

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.6. Kymriah – Tisagenlecleucel – Orphan - EMA/VR/0000284307

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.7. Kymriah – Tisagenlecleucel – Orphan - EMA/VR/0000290079

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.8. Vyjuvek - Beremagene geperpavec – Orphan - EMA/VR/0000284864

Krystal Biotech Netherlands B.V.

Rapporteur: Joseph De Courcey

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.9. Yescarta, Tecartus - Axicabtagene ciloleucel; Brexucabtagene autoleucel – Orphan - EMA/VR/0000285857

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Clinical, request for supplementary information

Update of section 4.4 of the SmPC in order to add a reference statement to current institutional / national guidelines for the monitoring and management of cytokine release syndrome (CRS) neurologic events and immune effector cell-associated neurotoxicity syndrome (ICANS). In addition, the MAH took the opportunity to introduce clarification and administrative updates to the PI, including Annex II.

Action: for adoption

The Rapporteur presented the outcome of the assessment. The request for supplementary information was adopted.

2.11.10. Zolgensma - Onasemnogene abeparvovec – Orphan - EMA/VR/0000271863

Novartis Europharm Limited

Rapporteur: Emmely de Vries

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. CARVYKTI - Ciltacabtagene autoleucel – Orphan - EMA/PAM/0000286337

Janssen Cilag International

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Jo Robays

Scope: PAM, PRAC led procedure

Action: for adoption

The outcome of the assessment was agreed.

2.13.2. Casgevy - Exagamglogene autotemcel – Orphan - EMA/PAM/0000266941

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Jan Mueller-Berghaus

Scope: PAM, request supplementary information

Action: for adoption

The outcome of the assessment was agreed.

2.13.3. Casgevy - Exagamglogene autotemcel – Orphan - EMA/PAM/0000266944

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Jan Mueller-Berghaus

Scope: PAM, fulfilled

Action: for adoption

The outcome of the assessment was agreed.

2.13.4. Casgevy - Exagamglogene autotemcel – Orphan - EMA/PAM/0000266949

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur Jan Mueller-Berghaus

Scope: PAM, fulfilled

Action: for adoption

The outcome of the assessment was agreed.

2.13.5. Kymriah – Tisagenlecleucel – Orphan - EMA/PAM/0000258545

Novartis Europharm Limited

Rapporteur: Rune Kjeken, PRAC Rapporteur: Gabriele Maurer

Scope: PAM, PRAC led procedure

Action: for adoption

The outcome of the assessment was agreed.

2.13.6. Casgevy - Exagamglogene autotemcel – Orphan - EMA/R/0000290395

Vertex Pharmaceuticals (Ireland) Limited

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

Scope: Renewal - 1 year, request for supplementary information

Action: for adoption

The Rapporteur presented the outcome of the assessment. The request for supplementary information was adopted.

2.13.7. Hemgenix - Etranacogene dezaparvovec – Orphan - EMA/R/0000288354

CSL Behring GmbH

Rapporteur: Silke Dorner, PRAC Co-Rapporteur: Bianca Mulder

Scope: Renewal - 1 year, request for supplementary information

Action: for adoption

The Rapporteur presented the outcome of the assessment. The request for supplementary information was adopted.

2.13.8. Carvykti

Jansen Cilag International

Rapporteur: Jan Mueller-Berghaus

Scope: Overview

Action: for information

The Rapporteur presented the information from the MAH

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: Withdrawal of consultation procedure

Action: for information

The information was noted.

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

4. Scientific Recommendation on Classification of ATMPs

Timetable:

-Start of the procedure:	10.10.2025
-EMA Coordinator's draft report:	24.10.2025
-CAT Coordinator's comments:	29.10.2025
-Revised scientific recommendation:	31.10.2025
-CAT's discussion of scientific recommendation:	07.11.2025

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Attenuated Salmonella typhi strain Ty21a carrying plasmid pNECVAX-NEO1

Treatment of solid malignancies with or without metastases

Scope: for nomination of CAT coordinator

Action: for adoption

The CAT coordinator was appointed.

4.1.2. iPSC-derived Retinal Pigment Epithelium (RPE) cells on a synthetic polymer membrane

Restoring vision in advanced (late-stage) retinitis pigmentosa (RP)

Scope: for nomination of CAT coordinator

Action: for adoption

The CAT coordinator was appointed.

4.2. Day 30 ATMP scientific recommendation

4.2.1. CD4+CD25+CD127-MOG-CAR+ T regulatory cells

Treatment and prevention of progression of Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease, Amyotrophic Lateral Sclerosis (ALS), Primary Progressive Multiple Sclerosis

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 24.10.2025.

4.2.2. Non-replicating recombinant adeno-associated viral vector serotype hu68 (AAVhu68), containing a codon-optimized human survival motor neuron 1 (SMN1) gene

Treatment of Spinal Muscular Atrophy (SMA)

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 24.10.2025.

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

No items

4.4. Finalisation of procedure

4.4.1. Lentiviral vector encoding for short hairpin RNA (shRNA) sequences down-regulating human leukocyte antigen (HLA) class I and HLA class II by targeting key messenger RNAs (mRNAs)

Ex vivo genetic modification of lung grafts prior to transplantation in patients

Scope: ATMP scientific recommendation.

Action: for adoption

The finalisation of this classification procedure was postponed awaiting input from the European Commission

4.4.2. Viable, allogeneic, in vitro expanded human corneal keratocytes on an adhesive scaffold matrix

Treatment of deep or perforating corneal defects

Scope: ATMP scientific recommendation. European Commission raised no comments

Action: for adoption

The classification report was adopted. The product does fulfil the definition of a tissue engineered product and a combined ATMP as provided in Article 2(1) of Regulation (EC) No. 1394/2007.

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:	29.09–02.10.2025
- Appointment of CAT Peer Reviewers:	08-10.10.2025
- SAWP first reports:	20.10.2025
- CAT Peer Reviewer comments (NC & C):	24.10.2025
- CAT Peer Reviewer comments (Q):	29.10.2025
- Discussion at SAWP:	27-30.10.2025
- Discussion at CAT and feedback to SAWP:	05-07.11.2025

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	27-30.10.2025
- Appointment of CAT Peer Reviewers:	05-07.11.2025
- SAWP first reports:	17.11.2025
- CAT Peer Reviewer comments (NC & C):	21.11.2025
- CAT Peer Reviewer comments (Q):	26.11.2025
- Discussion at SAWP:	24-27.11.2025
- Discussion at CAT and feedback to SAWP:	03-05.12.2025

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:	29.09.-02.10.2025
SAWP recommendation:	30.10.2025
CAT recommendation:	07.11.2025
CHMP adoption of report and final recommendation:	13.11.2025

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

None

7.1.2. Vote by proxy

Maria Gazouli gave a proxy to Rafaella Pontou to vote on behalf of Greece for the entire meeting.

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

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

Scope: Preparation for the meeting

CAT: Martin Bronislaw Oleksiewicz

Action: for information

The final programme of the upcoming SRLM and some practical information were presented.

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

Scope: Preparation for the meeting

CAT: Rafaella Pontou

Action: for information

Some practical information was presented. CAT members were asked to propose topics for discussion at the Cypriot SRLM in advance of the November CAT meeting.

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

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

Scope: Feedback from the ATMP cluster of 02.10.2025

Action: for information

Topic postponed until the next CAT meeting.

7.6. CAT work plan

7.6.1. CAT workshop on gene editing

Scope: Feedback up from the workshop

Action: for information

Topic postponed. Detailed feedback from the workshop will be provided during the Danish SRLM.

7.7. Planning and reporting

No items

7.8. Others

7.8.1. Code of conduct of the European Medicines Agency – provisions for members and experts of scientific committees

Action: for information

CAT noted the information that was presented by EMA.

7.8.2. Update on PRIME Pilot Features: Analysis and Surveys

Scope: Status update outlining some of the main findings from the PRIME Pilot, and the plan for finalisation of the report and recommendations

Action: for information

EMA presented the analysis of the implementation of the new PRIME features (roadmap & development tracker; submission readiness meeting; expedited scientific advice).

7.8.3. WHO Consultation on Regulatory Aspects of Xenotransplantation

Scope: Feedback from the WHO meeting that took place on 29.09.2025

CAT: Ilona Reischl

Action: for information

Topic postponed until the next CAT meeting.

7.8.4. WHO Implementation Workshop: WHO Considerations in developing a regulatory framework for human cells and tissues and for advanced therapy medicinal products

Scope: Feedback from the WHO meeting that took place on 24-26.09.2025 in Brazzaville, Congo

CAT: Ilona Reischl

Action: for information

Topic postponed until the next CAT meeting.

8. Any other business

No items

Date of next CAT meeting:

05-07 November 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 8-9 October 2025 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	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	
Rafaella Pontou	Member	Cyprus	No interests declared	
Eva Kolouchová	Member	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	
Jean-Michel Race*	Alternate	France	No restrictions applicable to this meeting	
Jan Mueller-Berghaus	Member (CHMP co-opted member)	Germany	No interests declared	
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	
Concetta Quintarelli	Member	Italy	No restrictions applicable to this meeting	
Liga Kunrade	Alternate	Latvia	No restrictions applicable to this meeting	
Vilma Perikaite	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	
Rune Kjeken	Member	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	
Margareta Fogelová	Member	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 restrictions applicable to this meeting	
Charlotte Anderberg*	Alternate	Sweden	No interests declared	
Julio Delgado Gonzalez	Member	Clinicians' Representative	No restrictions applicable to this meeting	
Alessandra Renieri	Member	Clinicians' 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	
Torbjörn Callréus	Expert	Malta	No interests declared	
Walter Johannes Beiersdorf	Expert	Austria	No restrictions applicable to this meeting	
Odoardo Olimpieri	Expert	Italy	No interests declared	
Antonella Isgrò	Expert	Italy	No interests declared	
Federico De Angelis	Expert	Italy	No interests declared	
Anna Vikerfors	SAWP	Sweden	No interests declared	
Taina Mattila	SAWP	Netherlands	No interests declared	
Attila Sebe	Expert	Germany	No interests declared	

Sean Barry	Expert	Ireland	No restrictions applicable to this meeting	
Leticia Labat	Expert	Spain	No interests declared	
Macarena Gajardo	Expert	Spain	No interests declared	
Patricia Ruiz	Expert	Spain	No interests declared	
Silke Schüle	Expert	Germany	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

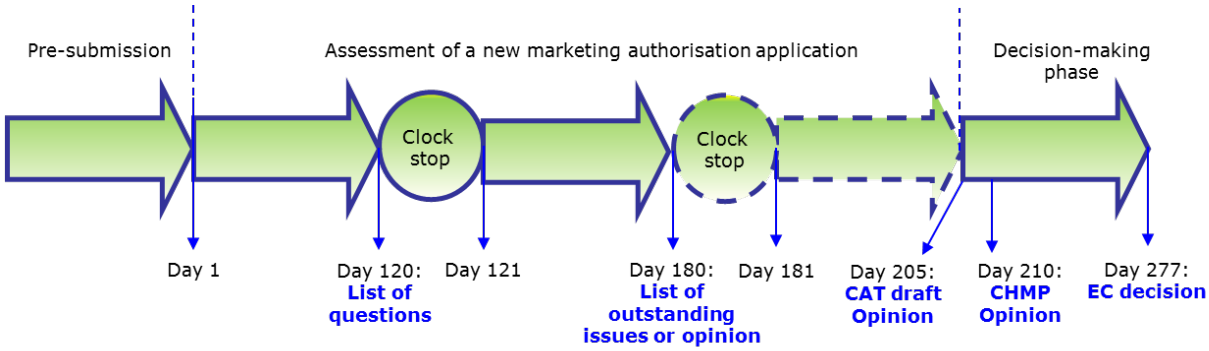
Evaluation of ATMPs (section 2)

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/