21 January 2026
EMA/CAT/29045/2026
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 03-05 December 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 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 03-05 December 2025 meeting was adopted

1.3. Adoption of the minutes

The CAT minutes for 05-07 November 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

2.3.1. Nadofaragene firadenovec - EMEA/H/C/005856

Treatment of adult patients with high-grade (HG), Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC).

Scope: Day 180 list of outstanding issues

Action: for adoption

List of questions adopted on 16.04.2025.

The Rapporteurs presented the assessment of the responses to the list of questions. Feedback was provided from the BWP discussion. The proposed list of outstanding issues was discussed and adopted by CAT.

CAT discussed the request for a clock stop extension to respond to the list of outstanding issues.

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

2.8. Withdrawal of initial marketing authorisation application

2.8.1. 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: Withdrawal of the marketing authorisation application

Action: for information

The information was noted.

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. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/VR/0000302440

Janssen Cilag International

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.2. Ebvallo - Tabelecleucel - Orphan - EMA/VR/0000284818

Pierre Fabre Medicament

Rapporteur: Egbert Flory

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.3. Kymriah - Tisagenlecleucel - Orphan - EMA/VR/0000302038

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.4. Yescarta - Axicabtagene ciloleucel - Orphan - EMA/VR/0000301490

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Karin Erneholm

Scope: Clinical, opinion

Submission of the final report from study KTE-C19-105 (ZUMA-5) to fulfil additional pharmacovigilance activities (Category 3) requirements listed in RMP. This is a phase 2 multicenter study of axicabtagene ciloleucel in subjects with relapsed/refractory indolent non-Hodgkin lymphoma. The RMP version 11.3 was also submitted.

Action: for adoption

The Rapporteur presented the outcome of the assessment. There are no changes to the product information. The opinion was adopted.

2.11.5. Yescarta - Axicabtagene ciloleucel - Orphan - EMA/VR/0000280312

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Aucatzyl - Obecabtagene autoleucel - Orphan - EMA/PAM/0000301546

Autolus GmbH

Rapporteur: Tineke van den Hoorn, PRAC Rapporteur: Karin Erneholm

Scope: PAM, opinion

Action: for adoption

The outcome of the assessment was agreed.

2.13.2. Aucatzyl - Obecabtagene autoleucel - Orphan - EMA/PASS/0000300590

Autolus GmbH

Rapporteur: Tineke van den Hoorn, PRAC Rapporteur: Karin Erneholm

Scope: Imposed PASS protocol

Action: for information

The outcome of the assessment was noted.

2.13.3. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/PAM/0000301551

Janssen Cilag International

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

Scope: PAM, PRAC led

Action: for adoption

This PAM was related to the submission of the interval safety report for study MMY4004 (PASS study). The outcome of the assessment was agreed.

2.13.4. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/PAM/0000304040

Janssen Cilag International

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

Scope: PAM

Action: for adoption

This PAM was related to the submission of the interval safety report for study MMY4009 (PASS study). The outcome of the assessment was agreed.

2.13.5. Hemgenix - Etranacogene dezaparvovec - Orphan - EMA/PAM/0000302041

CSL Behring GmbH

Rapporteur: Silke Dorner

Scope: PAM, opinion

Action: for adoption

The outcome of the assessment was agreed.

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

Kite Pharma EU B.V.

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

Scope: PAM, PRAC led

Action: for adoption

The outcome of the assessment was agreed.

2.13.7. Casgevy - Exagamglogene autotemcel - Orphan - EMA/R/0000290395

Vertex Pharmaceuticals (Ireland) Limited

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

Scope: Renewal - 1 year, opinion

Action: for adoption

The Rapporteur presented the outcome of the assessment. The opinion on the 1-year renewal was adopted.

2.13.8. Strimvelis - Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - Orphan - EMA/R/0000290462

Fondazione Telethon Ets

Rapporteur: Sol Ruiz, Co-Rapporteur: Egbert Flory, PRAC Rapporteur: Liana Martirosyan

Scope: Renewal - 5 year

Action: for adoption

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

2.13.9. Upstaza - Eladocagene exuparvovec - Orphan - EMA/S/0000293355

PTC Therapeutics International Limited

Rapporteur: Joseph De Courcey, PRAC Rapporteur: Dirk Mentzer

Scope: Annual reassessment

Action: for adoption

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

2.13.10. Reporting of out of specification of ATMP

Scope: Proposal for a new approach

Action: for adoption

EMA presented the new proposal: the MAH will be asked to notify the supervisory authority (SA) of the batch release site with every out of specification (OOS) administration and provide a 6-monthly periodic overview report to EMA. The latter will be recorded by EMA as a quality defect and will be sent to the Rapporteur and the SA. The proposal was agreed by CAT. The *Questions and answers on the use of out-of-specification batches of authorised cell/tissue-based advanced therapy medicinal products* (EMA/CAT/224381/2019) will be revised accordingly.

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:	22.12.2025
-EMA Coordinator's draft report:	16.12.2025
-CAT Coordinator's comments:	19.12.2025
-Revised scientific recommendation:	14.01.2026
-CAT's discussion of scientific recommendation:	16.01.2026

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Red blood cells derived from immortalised hematopoietic progenitors

Blood transfusion

Scope: for nomination of CAT coordinator

Action: for adoption

The CAT coordinator was appointed.

4.1.2. Platelets derived from immortalised hematopoietic progenitors

Platelet transfusion

Scope: for nomination of CAT coordinator

Action: for adoption

The CAT coordinator was appointed.

4.1.3. Allogeneic human induced pluripotent stem cell (hiPSC)-derived midbrain dopaminergic (mDA) neuronal progenitor cells

Treatment of Parkinson's disease

Scope: for nomination of CAT coordinator

Action: for adoption

The CAT coordinator was appointed.

4.2. Day 30 ATMP scientific recommendation

No items

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

No items

4.4. Finalisation of procedure

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

Treatment of solid malignancies with or without metastases

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 gene therapy medicinal product as provided in Article 2(1) of Regulation (EC) No 1394/2007.

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

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

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:	24-27.11.2025
- Appointment of CAT Peer Reviewers:	03-05.12.2025
- SAWP first reports:	05.01.2026
- CAT Peer Reviewer comments (NC & C):	09.01.2026
- CAT Peer Reviewer comments (Q):	14.01.2026
- Discussion at SAWP:	12-15.01.2026
- Discussion at CAT and feedback to SAWP:	21-23.01.2026

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	12-15.01.2025
- Appointment of CAT Peer Reviewers:	21-23.01.2025
- SAWP first reports:	02.02.2026
- CAT Peer Reviewer comments (NC & C):	06.02.2026
- CAT Peer Reviewer comments (Q):	11.02.2026
- Discussion at SAWP:	09-12.02.2026
- Discussion at CAT and feedback to SAWP:	18-20.02.2026

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

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:	
Procedure start:	24-27.11.2025
SAWP recommendation:	15.01.2026
CAT recommendation:	23.01.2026
CHMP adoption of report and final recommendation:	29.01.2026

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. Vote by proxy

Alessia Pochesi gave a proxy to Claire Beuneu to vote on behalf of Luxembourg for the whole meeting.

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

Scope: Preparation for the meeting

CAT: Rafaella Pontou

Action: for information

Agenda topics for the upcoming SRLM were discussed.

7.1.4. CAT Chair and Vice-Chair elections 2026

Scope: Informing the committee on timings and rules of procedures

Action: for information

EMA provided information on the rules of procedure and timing pertinent to the upcoming election of the CAT chair during the January CAT meeting. A call for expression of interest for Chair will be sent to all members.

7.2. Coordination with EMA Scientific Committees

No items

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

No items

7.4. Cooperation with the EU regulatory network

7.4.1. EU Life Science Strategy and Biotech Act

European Commission

Scope: Update to the Committee

Action: for information

The Commission Representative gave a high-level overview of the measures proposed in the EU Life Science Strategy and Biotech Act to bridge the competitiveness gaps between EU and rest of the world. More details will be provided in the January 2026 CAT meeting when the EU Life Science Strategy and Biotech Act is published.

7.5. Cooperation with international regulators

7.5.1. ICH Cell and Gene Therapy discussion group

Scope: Update

CAT: Jan Muller-Berghaus

Action: for information

EMA informed CAT of the outcome of the discussion in the ICH Management Board meeting in Singapore in November 2025. The activities of the ICH Cell and Gene Therapy discussion group are closed, and the relevant expertise of this group will be transferred to the guideline drafting group that will develop the Annex to ICH Q5 on comparability for ATMPs.

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

CAT: Ilona Reischl

Scope: Agenda of the ATMP cluster of 29.01.2025

Action: for information

The ATMP cluster teleconference was postponed.

7.5.3. Individualized Therapies on the Rare Disease Innovation, Science and Exploration (RISE) workshop, FDA

CAT: Ilona Reischl

Scope: Brief summary of the meeting (20.11.2025)

Action: for information

The information was noted. The presentations and recording are available online.

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

CAT: Pille Säälik

Scope: Feedback from the IPRP meeting of 13.11.2025

Action: for discussion

Pille Säälik provided a summary for the discussions at the last IPRP meeting. The topics proposed by EMA for the IPRP Roadmap were mentioned.

CAT was informed that a drafting group meeting will be convened at the end of January 2026 to finalise the IPRP Roadmap (to avoid duplication with the ICH gene and cell therapy priority list). Pille Säälik and EMA will participate to this meeting.

7.6. CAT work plan

7.6.1. CAT Workplan 2026

Scope: Work plan topics for 2026

CAT: Ilona Reischl

Action: for discussion

CAT discussed the CAT work plan topics and the proposed deliverables. The CAT comments will be incorporated in the next version of the work plan. CAT members are asked to inform CAT secretariat of their interest to contribute to one or more of the work plan topics; for topics continuing from the 2025 work plan, the involved members are asked to confirm their involvement. Adoption of the work plan is scheduled at the January 2026 CAT meeting.

7.6.2. Good Pharmacovigilance Practice (GVP) Module V update

Scope: Launch for Committee consultation of the draft revision 3.0 of GVP Module V – Risk Management Systems, and draft revision 3.0 of EU RMP template, both incorporating recommendation for ATMP risk management.

CAT: Kerstin Elisabeth Sollerbrant Melefors, Concetta Quintarelli

Action: for information

EMA presented the main changes in the revision of the GVP Module V and of EU RMP template. The Committee consultation will run from 10 December 2025 until 24 January 2026; PRAC and CHMP will be consulted at the same time. After the Committee consultation, the draft will be published for public consultation.

7.7. Planning and reporting

No items

7.8. Others

7.8.1. EMA Lunchtime Talk: Where do we stand in our fight against AMR?

Scope: Agenda of the lunchtime talk organised for CVMP and CAT members on Wednesday 3 December at 13.00

Action: for information

Proposed Agenda:

13.00 - 13.20 - Presentation from Kristina Nadrah, Slovenian CHMP member and specialist in infectious diseases

13.20 - 13.40 - Presentation from Jaap Wagenaar, Professor at the University of Utrecht, main topics of his research are on antimicrobial resistance and on Campylobacter

13.40 - 14.00 - Question time

The information was noted

8. Any other business

No items

Date of next CAT meeting:

21-23 January 2026

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 3-5 December 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	
Isavella Kyriakidou	Alternate	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 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	
Egbert Flory	Alternate (to CHMP representative)	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 restrictions applicable to this meeting	
Barbara Bonamassa	Alternate	Italy	No interests declared	
Una Riekstina	Member	Latvia	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	
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	
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	
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 final deliberations and voting on:	
Charlotte Anderberg*	Alternate	Sweden	No interests declared	
Julio Delgado Gonzalez	Member	Clinicians' Representative	No participation in final deliberations and voting on:	
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	
Torbjörn Callréus	Expert	Malta	No interests declared	
Carolina Prieto Fernandez	Expert	Spain	No interests declared	
Macarena Gajardo Álvarez	Expert	Spain	No interests declared	
Laura Rodríguez García	Expert	Spain	No interests declared	
Esther Rincón Gila	Expert	Spain	No interests declared	
Juan Fernando Martínez Leal	Expert	Spain	No restrictions applicable to this meeting	
Teresa LLacer Delicado	Expert	Spain	No interests declared	
Juan Ignacio Bedoya Ponte	Expert	Spain	No restrictions applicable to this meeting	
Attila Sebe	Expert	Germany	No interests declared	
Mark van Bussel	Expert	Netherlands	No interests declared	
Martijn van Gils	Expert	Netherlands	No interests declared	
Charlotte de Wolf	Expert	Netherlands	No interests declared	
Jolien de Groot	Expert	Netherlands	No interests declared	

Olive Smyth	Expert	Ireland	No interests declared	
Some 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.				

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

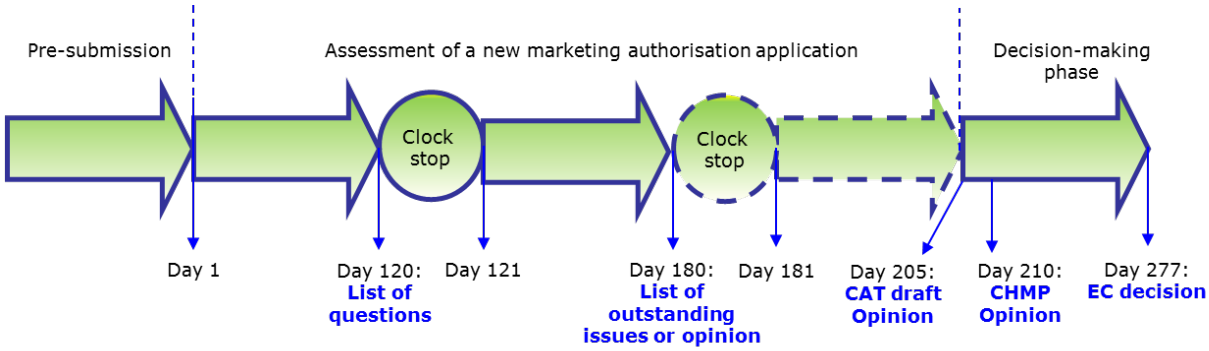
Evaluation of ATMPs (section 2)

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/