03 December 2025
EMA/CAT/7940/2026
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 05-07 November 2025

Chair: Ilona Reischl; Vice-Chair: Kieran Breen

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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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 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 05-07 November 2025 meeting was adopted with one addition: 8.1. IRIS update.

1.3. Adoption of the minutes

The CAT minutes for 08-09 October 2025 meeting were adopted.

2. Evaluation of ATMPs

2.1. Opinions

2.1.1. Waskyra - Autologous CD34+ haematopoietic stem cells transduced ex vivo with a lentiviral vector encoding human Wiskott-Aldrich syndrome protein - Orphan - EMEA/H/C/006525

Fondazione Telethon Ets; Treatment of patients with Wiskott-Aldrich syndrome (WAS)

Scope: Opinion

Action: for adoption

List of outstanding issues adopted on 12.09.2025. List of questions adopted on 16.04.2025.

The Rapporteurs presented the outcome of the assessment of the responses to the list of outstanding issues. CAT adopted by consensus the draft opinion recommending the granting of a full marketing authorisation.

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

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: Oral explanation, opinion

Action: for adoption

The Rapporteur presented their assessment of the grounds for refusal (GfR).

In the oral explanation, the applicant addressed the three GfR and addressed the questions for the CAT members and experts.

Based on the outcome of the vote, CAT adopted by majority a negative draft opinion recommending denying of the marketing authorisation for Jelrix. 23 members considered that the benefit-risk of Jelrix in the indication sought was negative, 4 members (Jan Mueller Berghaus, Concetta Quintarelli, Isabel Vieira, Alessandra Renieri) considered that the benefit-risk was positive; these members signed a divergent opinion. Norway and Island joined the majority view.

2.10. GMP and GCP inspections requests

No items

2.11. Type II variations and variations of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

2.11.1. Abecma - Idecabtagene vicleucel - Orphan - EMA/VR/0000293201

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken, PRAC Rapporteur: Mari Thorn

Scope: Clinical, opinion

Update of sections 4.2, 4.4, and 4.7 of the SmPC in order to change the post-approval safety monitoring requirements after administration of Abecma; Annex II and the Package Leaflet are updated accordingly. The RMP version 5.0 has also been submitted.

Action: for adoption

The Rapporteur presented the outcome of the assessment. The opinion was adopted.

2.11.2. Kymriah - Tisagenlecleucel - Orphan - EMA/VR/0000282599

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.3. Kymriah - Tisagenlecleucel - Orphan - EMA/VR/0000290079

Novartis Europharm Limited

Rapporteur: Rune KjekenScope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.4. ROCTAVIAN - Valoctocogene roxaparvovec - Orphan - EMA/VR/0000294531

Biomarin International Limited

Rapporteur: Violaine Closson Carella, PRAC Rapporteur: Bianca Mulder

Scope: Clinical, opinion

Submission of an updated RMP version 1.6 in order to remove the biodistribution study investigating vertical transmission of the AAV5 vector in female mice listed as category 3 study in RMP.

Action: for adoption

The CAT rapporteur presented the outcome of the assessment and that PRAC agreed, based on the justification by the MAH, to remove the above mentioned biodistribution study from the RMP. The opinion was adopted.

2.11.5. Tecartus - Brexucabtagene autoleucel - Orphan - EMEA/H/C/005102/II/0051

Kite Pharma EU B.V.

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

Scope: Pharmacovigilance, opinion

Submission of the final study report for the non-interventional study KT-EU-472-5966 titled "Quantitative Testing of Health Care Professional Knowledge About Tecartus Risk Minimisation Measures'' listed as a category 3 study in the RMP.

Action: for adoption

Request for Supplementary Information adopted on 13.06.2025, 06.12.2024.

PRAC agreed with the outcome of the final study report of the PASS study. The opinion was adopted.

2.11.6. Yescarta, Tecartus - Axicabtagene ciloleucel, Brexucabtagene autoleucel - Orphan - EMA/VR/0000285857

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Clinical, opinion

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

Request for supplementary information adopted on 09.10.2025

The opinion was adopted.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Breyanzi - Lisocabtagene maraleucel - Orphan - EMA/PAM/0000292361

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: PAM

Action: for adoption

The outcome of the assessment was agreed.

2.13.2. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/PAM/0000291466

Janssen Cilag International

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

Scope: PAM, Pharmacovigilance

Action: for adoption

The outcome of the assessment was agreed.

2.13.3. ROCTAVIAN - Valoctocogene roxaparvovec - Orphan - EMA/PAM/0000292813

Biomarin International Limited

Rapporteur: Violaine Closson Carella; PRAC Rapporteur: Bianca Mulder

Scope: PAM, Pharmacovigilance

Action: for adoption

The outcome of the assessment was agreed.

2.13.4. Hemgenix - Etranacogene dezaparvovec - Orphan - EMA/R/0000288354

CSL Behring GmbH

Rapporteur: Silke Dorner, PRAC Rapporteur: Bianca Mulder

Scope: Renewal - 1 year

Action: for adoption

Request for supplementary information adopted on 09.10.2025

The renewal was adopted.

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

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. Attenuated Salmonella typhi strain Ty21a carrying plasmid pNECVAX-NEO1

Treatment of solid malignancies with or without metastases

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 21.11.2025.

4.2.2. 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

Action: for adoption

CAT discussed the classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 21.11.2025.

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. 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. 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. European Commission raised no comments

Action: for adoption

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

4.4.3. 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. 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.

4.5. 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:	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

5.1.2. Scientific advice procedures starting at the next SAWP meeting

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

5.2. 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 item

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:	
Procedure start:	27-30.10.2025
SAWP recommendation:	27.11.2025
CAT recommendation:	05-12.2025
CHMP adoption of report and final recommendation:	11.12.2025

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

No items

7.1.2. Vote by proxy

Peter Zsolt Fekete gave a proxy to Suzana Vidic to vote on behalf of Iceland for the whole meeting.

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

Scope: Feedback from the meeting

CAT: Martin Bronislaw Oleksiewicz

Action: for information

Feedback was provided from the discussions in the SRLM meeting under the Danish Presidency. CAT members thanked the organisers for an excellent and balanced meeting.

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

Scope: Preparation for the meeting

CAT: Rafaella Pontou

Action: for information

CAT provided suggestions for topics for discussion at the SRLM under the Cypriot presidency.

7.2. Coordination with EMA Scientific Committees

7.2.1. SAWP composition – re-examination exercise

Scope: SAWP secretariat would like to present details on the requirements, procedural aspects, application forms and timelines of the SAWP composition - re-examination exercise

Action: for information

EMA provided information on re-examination exercise of the SAWP composition. CAT is asked to (re)nominate the CAT representatives in SAWP.

CAT members interested to be nominated as joint CAT-SAWP members should inform CAT Secretariat in advance of the February 2026 CAT meeting.

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

Topic postponed until the next CAT meeting.

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

Short feedback was provided from the discussion in the ATMP cluster of 02.10.2025.

CAT members were informed that the planned ATMP cluster of 13.11.2025 will be postponed (new date to be communicated).

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

CAT: Pille Saalik

Scope: Identification of IPRP-CGTWG project topics

Action: for discussion

CAT discussed potential topics that could be taken forward at the level of IPRP.

7.6. CAT work plan

7.6.1. CAT work plan 2026

Scope: Work plan topics for 2026

CAT: Ilona Reischl

Action: for discussion

EMA presented the overview of the progress of the CAT work plan for 2025. CAT discussed the topics to be included in the CAT work plan for 2026.

7.7. Planning and reporting

No items

7.8. Others

7.8.1. 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

Short feedback was provided.

7.8.2. 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

Short feedback was provided.

7.8.3. Guideline on predictive biomarker assay development in the context of medicinal product lifecycle

CAT Resources: Jörg Engelbergs, Olga Kholmanskikh, Ilona Reischl

Scope: Presentation of the draft guideline

Action: for information

EMA presented the guideline on predictive biomarker assay development. The guideline covers the topic of companion diagnostics, highly relevant to ATMPs (e.g. co-development scenario). The guideline that is now undergoing internal consultation: CAT comments are awaited by 05.12.2025.

7.8.4. ATMP Support Pilot for academic developers of ATMPs

Scope: Report and learnings from the Academic support pilot

Action: for information

EMA presented the drafting findings and learning from the support pilot for academic developers of ATMPs.

8. Any other business

8.1.1. IRIS Update

Scope: The IRIS team will provide an update on the IRIS portal Implementation Roadmap.

Action: for information

The updated was noted.

Date of next CAT meeting:

3-5 December 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 5-7 November 2025 CAT meeting.

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	
Evelina Shumkova	Alternate	Bulgaria	No interests declared	
Azra Selimovic	Member	Croatia	No restrictions applicable to this meeting	
Rafaella Pontou	Member	Cyprus	No interests declared	
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	
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	

Egbert Flory	Alternate (to CHMP representative)	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	
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	
Raimondas Benetis	Alternate (to CHMP representative)	Lithuania	No restrictions applicable to this meeting	
Alessia Pochesci	Member	Luxembourg	No restrictions applicable to this meeting	
Nancy De Bremaeker	Alternate	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	
Denisa Partelova	Alternate	Slovakia	No interests declared	
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 participation in final deliberations and voting on:	Scientific advice procedure
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	
Federica Chiara	Member	Patients' Representative	No restrictions applicable to this meeting	
Kieran Breen	Member (Vice-Chair)	Patients' Representative	No restrictions applicable to this meeting	
Catherine Milne	Observer/Alternate	EDQM	No interests declared	
Torbjörn Callréus	Expert	Malta	No interests declared	
Andreaa Barbu	Expert	Sweden	No interests declared	
Nicolas Beix	Expert	France	No interests declared	
Solène Maitenaz	Expert	France	No interests declared	
Marie-Thérèse Duffour	Expert	France	No interests declared	
Nathalie Morgensztejn	Expert	France	No interests declared	
Paolo Petracci	Expert	France	No interests declared	
Simona Teodosiu	Expert	France	No interests declared	
Coralie Deligny	Expert	France	No interests declared	
Marianne Delville	Expert	France	No restrictions applicable to this meeting	
Juliane Rau	Expert	Germany	No interests declared	
Attila Sebe	Expert	Germany	No interests declared	
Macarena Gajardo Álvarez	Expert	Spain	No interests declared	
Leticia Labat de Hoz	Expert	Spain	No interests declared	
Jörg Engelbergs	Expert	Germany	No interests declared	

Nikolaus Zehetmayer	Expert	Austria	No interests declared	
Marja van den Bovenkamp	Expert	Netherlands	No interests declared	
Silke Schüle	Expert	Germany	No interests declared	
Odoardo Olimpieri	Expert	Italy	No interests declared	
Jayne Crowe	Expert	Ireland	No interests declared	
Sarah Brophy	Expert	Ireland	No restrictions applicable to this meeting	
Gavin McGauran	Expert	Ireland	No restrictions applicable to this meeting	
Ailise Carleton	Expert	Ireland	No interests declared	
František Dráfi	Expert	Slovakia	No restrictions applicable to this meeting	
Johanna Lähteenvuo	Expert	Finland	No interests declared	
Barbora Ladinová	Expert	Czechia	No interests declared	
Jan Oliver Karo	Expert	Germany	No interests declared	
Beáta Jákliné Ullrich	Expert	Hungary	No interests declared	
Benjamin Hoefner	Expert	Germany	No restrictions applicable to this meeting	
Thalia Marie Estrup Blicher	Expert	Denmark	No interests declared	
A representative from the European Commission attended the meeting. Observers from the Swissmedic attended the meeting. Observers from FDA 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

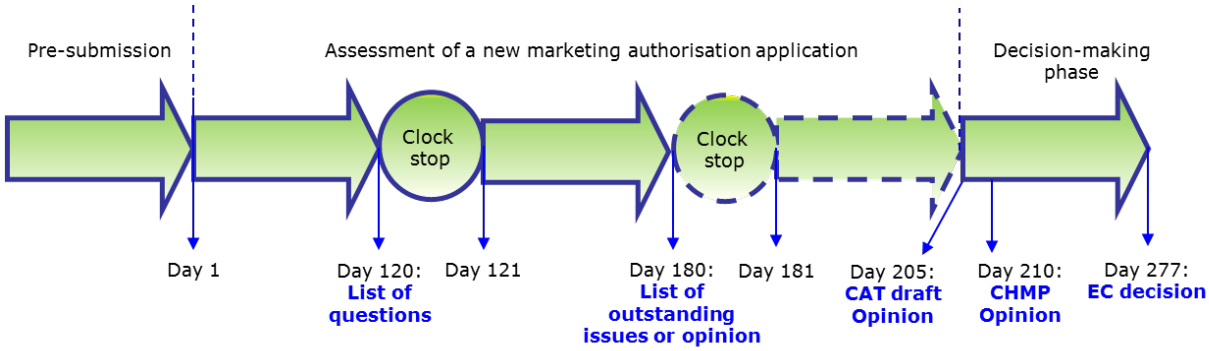
Evaluation of ATMPs (section 2)

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/