14 May 2025
EMA/CAT/186753/2025
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 14-16 April 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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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 Chair welcome the new member and alternate.

1.2. Adoption of agenda

The CAT agenda for 14-16 April 2025 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes for 19-21 March 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. Delandistrogene moxeparvovec - Orphan - EMEA/H/C/005293

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

Scope: Day 180 list of outstanding issues

Action: for adoption

List of questions adopted on 11.10.2024.

The Rapporteur presented the outcome of the assessment of the responses to the list of questions. Feedback was provided from the discussion in the BWP. CAT discussed the request for clock stop extension.

The list of outstanding issues and the response timetable was adopted.

2.4. Day 120 list of questions

2.4.1. 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 120 list of questions

Action: for adoption

The Rapporteurs presented the outcome of the assessment. Feedback was provided from the discussion in the BWP.

The list of questions was adopted.

2.4.2. 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: Day 120 list of questions

Action: for adoption

The Rapporteurs presented the outcome of the assessment of the responses to the list of questions. Feedback was provided from the discussion in the BWP.

The list of questions was adopted.

2.5. Day 80 assessment reports

No items

2.6. Update on ongoing initial applications

No items

2.7. New applications

No items

2.8. Withdrawal of initial marketing authorisation application

No items

2.9. Re-examination of initial application procedures under Article 9(2) of Regulation No. 726/2004

No items

2.10. GMP and GCP inspections requests

No items

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

2.11.1. Breyanzi - Lisocabtagene maraleucel - EMEA/H/C/004731/II/0055/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, opinion

Action: for adoption

Request for supplementary information adopted on 21.02.2025.

The opinion was adopted.

2.11.2. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0034

Janssen-Cilag International NV

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

Scope: Safety, opinion

Submission of an updated RMP version 5.2 in order to add a new important identified risk of "Secondary malignancy of T-cell origin", to change the important potential risk of "Second primary malignancies" to "Second primary malignancy except secondary malignancy of T-cell origin", and to include an additional pharmacovigilance activity for testing of secondary malignancies of T-cell origin, following the PRAC recommendation for the Secondary

malignancy of T-cell origin signal (EPITT no: 20040).

Action: for adoption

Request for supplementary information adopted on 24.01.2025.

The opinion was adopted.

2.11.3. Abecma - Idecabtagene vicleucel - EMA/VR/0000249089

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary was adopted.

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

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, request of supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.5. Kymriah - Tisagenlecleucel - EMA/VR/0000249024

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.6. Abecma - Idecabtagene vicleucel - EMA/VR/0000248772

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.7. Kymriah - Tisagenlecleucel - EMA/VR/0000248534

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Clinical; opinion

Submission of the interim report from study CCTL019H2301 / BELINDA, including final overall survival results, listed as an obligation in the Annex II of the Product Information. This is an open label, phase III PAES of Kymriah versus standard of care in adult patients with relapsed or refractory aggressive B cell non-Hodgkin lymphoma. The Annex II is updated accordingly.

Action: for adoption

The rapporteur presented the outcome of the assessment: the applicant has submitted the final overall survival (OS) results from the Belinda study. These data confirm the conclusion of the variation II/53 that was finalised in October 2022 and did not raise new issues or concerns. CAT considered that the Annex II condition is fulfilled with the submission of the final OS study results.

The opinion was adopted.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Ebvallo - Tabelecleucel - EMA/PAM/0000249629

Pierre Fabre Medicament

Rapporteur: Egbert Flory

Scope: PAM

Action: for adoption

The Rapporteur’s assessment report was adopted.

2.13.2. Hemgenix - Etranacogene dezaparvovec - EMA/PAM/0000248926

CSL Behring GmbH

Rapporteur: Silke Dorner

Scope: PAM

Action: for adoption

The Rapporteur’s assessment report was adopted.

2.13.3. Imlygic - Talimogene laherparepvec - EMA/PAM/000247962

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen

Scope: PAM

Action: for adoption

The Rapporteur's assessment report was adopted.

2.13.4. BEQVEZ - Fidanacogene elaparvovec - EMA/R/0000247045

Pfizer Europe MA EEIG

Rapporteur: Jan Mueller-Berghaus

Scope: Renewal 1 year; opinion

Action: for adoption

The opinion 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

No items

4. Scientific Recommendation on Classification of ATMPs

Timetable:

-Start of the procedure:	16.04.2025
-EMA Coordinator's draft report:	27.04.2025
-CAT Coordinator's comments:	05.05.2025
-Revised scientific recommendation:	08.05.2025
-CAT's discussion of scientific recommendation:	16.05.2025

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Human oocyte cytoplasma

For use in case of low human egg quality in in vitro fertilisation (IVF)

Scope: Appointment of CAT coordinator

Action: for adoption

The CAT coordinator was appointed.

4.1.2. Selected autologous Tumour-Infiltrating Lymphocytes (TILs) isolated from tumour tissue, lymph node metastases, or peripheral blood, expanded, activated

Treatment of advanced or metastatic solid tumours

Scope: Appointment of CAT coordinator

Action: for adoption

The CAT coordinator was appointed.

4.1.3. Autologous T cells ex vivo transduced with LVV encoding a CAR that recognises BCMA

Treatment of relapsed or refractory form of plasmocytic myeloma (RRMM)

Scope: Appointment of CAT coordinator

Action: for adoption

The CAT coordinator was appointed.

4.2. Day 30 ATMP scientific recommendation

4.2.1. Allogeneic T cells genetically modified ex vivo using CRISPR/Cas9 to express an anti-CD19 chimeric antigen receptor

Treatment of frontotemporal dementia (FTD) in adults who have a mutation in the GRN or chromosome 9 open reading frame 72 (C9orf72) genes

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 05.05.2025.

4.2.2. Induced pluripotent stem cell (iPSC)-derived photoreceptor precursor cells

Treatment of primary photoreceptor disease

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 05.05.2025.

4.2.3. Messenger mRNA encoding the human Dynein Axonemal Intermediate Chain 1 (DNAI1) protein

Treatment of primary ciliary dyskinesia caused by mutations in the DNAI1 gene

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 05.05.2025.

4.2.4. Messenger mRNA encoding the cystic fibrosis transmembrane conductance regulator (CFTCR) protein

Treatment of cystic fibrosis

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 05.05.2025.

4.2.5. Allogeneic genetically modified T-cells expressing two chimeric antigen receptors (CARs) targeting the human CD19 and CD70 proteins

Treatment of autoimmune diseases

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 05.05.2025.

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

4.3.1. Autologous tumour-derived dendritic cells

Prevention of relapse and metastasis of non-small cell lung carcinoma (NSCLC)

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the revised classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 05.05.2025.

4.4. Finalisation of procedure

4.4.1. mRNA transfected macrophages cultured from autologous monocytes

Treatment of end stage liver disease

Scope: European Commission raised no comments. ATMP scientific recommendation

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. Genetically modified porcine heart

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

Scope: European Commission raised comments. ATMP scientific recommendation

Action: for adoption

CAT noted the comments from the European Commission. The adoption of the report was postponed awaiting further legal input.

4.4.3. Genetically modified Escherichia coli bacteria engineered to carry genes to metabolize tryptophan and genes to use an exogenously administered sugar source

Treatment of type 2 diabetes

Scope: European Commission raised no comments. ATMP scientific recommendation

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.

4.4.4. mRNAs encoding modified C. acnes protein

Treatment of acne

Scope: European Commission raised comments. ATMP scientific recommendation

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.

4.4.5. Adeno-associated virus (AAV) serotype 1 (AAV1) vector containing the human granulin precursor (GRN) cDNA encoding progranulin (PGRN)

Treatment of frontotemporal dementia (FTD) in adults who have a mutation in the GRN or chromosome 9 open reading frame 72 (C9orf72) genes

Scope: European Commission raised no comments. ATMP scientific recommendation

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:	07-10.04.2025
- Appointment of CAT Peer Reviewers:	14-16.04.2025
- SAWP first reports:	28.04.2025
- CAT Peer Reviewer comments (NC & C):	02.05.2025
- CAT Peer Reviewer comments (Q):	07.05.2025
- Discussion at SAWP:	05-08.05.2025
- Discussion at CAT and feedback to SAWP:	14-16.05.2025

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	05-08.05.2025
- Appointment of CAT Peer Reviewers:	14-16.05.2025
- SAWP first reports:	26.05.2025
- CAT Peer Reviewer comments (NC & C):	30.05.2025
- CAT Peer Reviewer comments (Q):	04.06.2025
- Discussion at SAWP:	02-05.06.2025
- Discussion at CAT and feedback to SAWP:	11-13.06.2025

5.2. Procedures discussed at SAWP – 1st reports, D40 JRs, LoIs

5.3. Finalisation of D70 procedures – feedback from the discussion meeting

5.4. Final Advice Letters for procedures finalised the previous month

6. Pre-Authorisation Activities

Information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6.1. Paediatric investigation plans

No items

6.2. ITF briefing meetings in the field of ATMPs

No items

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:	
Procedure start:	07-10.04.2025
SAWP recommendation:	08.05.2025
CAT recommendation:	16.05.2025
CHMP adoption of report and final recommendation:	22.05.2025

6.3.2. Month 1 – Discussion of eligibility

No items

6.3.3. Month 2 – Recommendation of eligibility

6.3.4. Ongoing support

No items

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT membership

The Chair announced that Viola Bardoczy is the new member for Hungary and welcomed Agnes Zotter as the new alternate for Hungary.

7.1.2. Vote by proxy

No items

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

CAT: Dariusz Sladowski

Scope: Agenda

Action: for information

The final agenda was presented and practical information was provided.

7.2. Coordination with EMA Scientific Committees

No items

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

7.3.1. BWP/CAT Learning on Claims for New Active Substance (NAS) status for ATMPs

Rapporteur/Coordinator: Sean Barry, Ilona Reischl

Scope: To present a draft learning on assessment of NAS claims for ATMPs

Action: for discussion

Ilona Reischl presented the draft learning. CAT members are asked to provide comments by 02.05.2025. Finalisation of this learning is expected to take place at the May CAT meeting.

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: Agenda topics for the teleconference of 24.04.2025

Action: for information

CAT was informed that this meeting is cancelled as no urgent agenda points were identified. The next ATMP cluster will take place in June 2025.

7.6. CAT work plan

No items

7.7. Planning and reporting

7.7.1. Business Pipeline Report – 3-year Outlook Report

Scope: 3-year Outlook Report for the human scientific committees

Action: for information

CAT noted the information on the 3-year outlook report.

7.8. Others

No items

8. Any other business

No items

9. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 14-16 April 2025 CAT meeting, which was held in-person.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Ilona Reischl	Chair	Austria	No interests declared	

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	
Isavella Kyriakidou	Alternate	Cyprus	No interests declared	
Eva Kolouchová	Member	Czechia	No interests declared	
Radka Nejezchlebová	Alternate	Czechia	No interests declared	
Martin Oleksiewicz	Member	Denmark	No interests declared	
Johanne Juhl Korsbaek	Alternate	Denmark	No restrictions applicable to this meeting	
Toivo Maimets	Member	Estonia	No interests declared	
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 interests declared	
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 interests declared	
Viola Bardoczy	Alternate	Hungary	No restrictions applicable to this meeting	
Péter Zsolt Fekete	Member	Iceland	No interests declared	
Joseph De Courcey	Member	Ireland	No interests declared	
Richard Carroll	Alternate	Ireland	No interests declared	
Concetta Quintarelli	Member	Italy	No restrictions applicable to this meeting	

Barbara Bonamassa	Alternate	Italy	No interests declared	
Liga Kunrade	Alternate	Latvia	No restrictions applicable to this meeting	
Vilma Perikaite	Member (CHMP member)	Lithuania	No interests declared	
Raimondas Benetis	Alternate (to CHMP representative)	Lithuania	No interests declared	
Alessia Pochesci	Member	Luxembourg	No restrictions applicable to this meeting	
Nancy De Bremaeker	Alternate	Luxembourg	No interests declared	
Emmely de Vries	Member	Netherlands	No interests declared	
Berendina Maria (Tineke) van den Hoorn	Alternate	Netherlands	No interests declared	
Rune Kjeken	Member	Norway	No restrictions applicable to this meeting	
Ole Henrik Myrdal	Alternate	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	
Katarina Kollarova	Member	Slovakia	No interests declared	
Margareta Fogelová	Alternate	Slovakia	No interests declared	
Metoda Lipnik-Stangelj	Alternate	Slovenia	No interests declared	
Sol Ruiz	Member (CHMP co-opted member)	Spain	No interests declared	
Marcos Timón	Alternate (to CHMP representative)	Spain	No interests declared	
Maria Luttgen	Member	Sweden	No participation in discussion, final deliberations and voting on:	2.3.1 - Delandistrogene moxeparvovec - Orphan - EMEA/H/C/005293
Charlotte Anderberg	Alternate	Sweden	No interests declared	

Bernd Gansbacher	Alternate	Clinicians' Representative	No interests declared	
Kerstin Sollerbrant Melefors	Member	Patients' Representative	No interests declared	
Kieran Breen	Member (Vice-Chair)	Patients' Representative	No restrictions applicable to this meeting	
Federica Chiara	Alternate	Patients' Representative	No restrictions applicable to this meeting	
Torbjörn Callréus	Expert	Malta	No interests declared	
Paolo Petracci	Expert	France	No interests declared	
Solène Maitenaz	Expert	France	No participation in discussion, final deliberations and voting on:	4.4.4. mRNAs encoding modified C. acnes protein
Gabriela Ullio Gamboa	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	
Nathalie Morgensztejn	Expert	France	No interests declared	
Carolina Prieto Fernandez	Expert	Spain	No interests declared	
Macarena Gajardo Alvarez	Expert	Spain	No interests declared	
Beatriz Gutierrez Eugenio	Expert	Spain	No interests declared	
Teresa Llacer Delicado	Expert	Spain	No interests declared	
Sandra Soto	Expert	Spain	No interests declared	
Laura Rodriguez Garcia	Expert	Spain	No interests declared	
Juan Fernando Martinez Leal	Expert	Spain	No restrictions applicable to this meeting	
Esther Rincon Gila	Expert	Spain	No interests declared	
Gloria Palomo	Expert	Spain	No interests declared	
Jayne Crowe	Expert	Ireland	No interests declared	
Sarah Brophy	Expert	Ireland	No participation in discussion, final deliberations and voting on:	2.13.4 Beqvez
Caoimhin Concannon	Expert	Ireland	No interests declared	

Monika Jarzabek	Expert	Expert	No restrictions applicable to this meeting	
Charlotte de Wolf	Expert	Netherlands	No interests declared	
Wouter Hoogenboom	Expert	Netherlands	No interests declared	
Christian Gartner	Expert	Austria	No interests declared	
Melanie Ramberger	Expert	Austria	No interests declared	
Brigitte Müller	Expert	Austria	No interests declared	
Tobias Fellinger	Expert	Austria	No restrictions applicable to this meeting	
Christoph Mück	Expert	Austria	No interests declared	
Elisabeth Fürst	Expert	Austria	No interests declared	
Filip Josephson	Expert	Sweden	No interests declared	
Daiana Vasilcanu	Expert	Sweden	No interests declared	
Ingrid Wang	Expert	Norway	No interests declared	
Kathrin Bayanga	Expert	Germany	No interests declared	
Representatives from the FDA attended the meeting. Representatives from the European Commission attended the meeting.				
Meeting run with support from relevant EMA staff. Experts' declared interests were evaluated against the agenda topics or activities they participated in.				

Date of next CAT meeting:

14-16 May 2025

10. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

For a list of acronyms and abbreviations, see:

List of abbreviations used in EMA human medicines scientific committees and CMDh documents, and in relation to EMA's regulatory activities

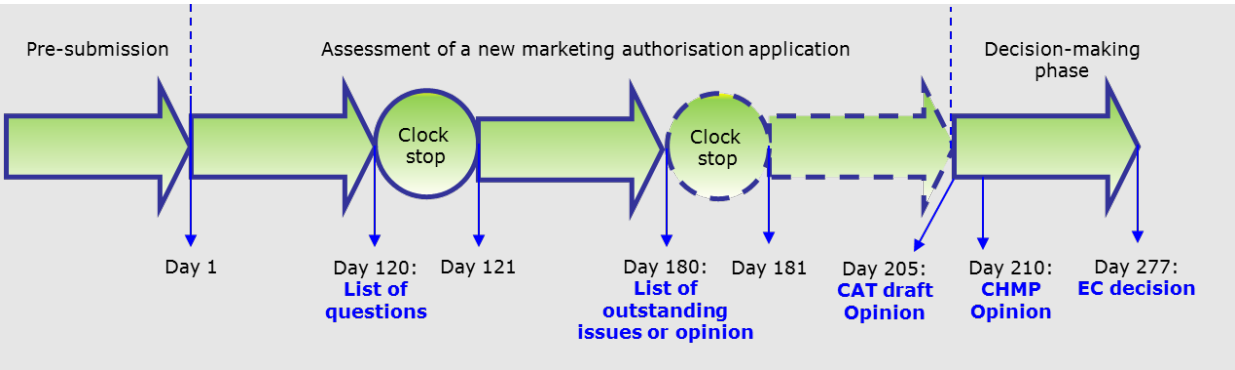
Evaluation of ATMPs (section 2)

This section lists applications for marketing authorisations of new Advanced Therapy Medicinal Products (ATMPs) that are to be discussed by the Committee. It also lists Post-authorisation activities (section 2.11-2.13) and any ATMP related inspection requests (section 2.14).

New applications (sections 2.1. to 2.9.)

Section 2.1 is for ATMPs nearing the end of the evaluation and for which the CAT is expected to adopt a draft **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CAT opinion is transmitted to the CHMP for final adoption. The CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU. More information on the evaluation of ATMPs can be found here.

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CAT. The clock stop happens after day 120 and may also happen after day 180, when the CAT has adopted respectively a **Day 120 list of questions** (section 2.4) or a List of outstanding issues to be addressed by the company, which is listed in the agenda under sections 2.7 (**Ongoing evaluation procedures** (section 2.3). Section 2.6 also includes the CAT discussions at any other timepoint of the evaluation procedure of new applications.

Oral explanation (section 2.2.)

Prior to adoption of the CAT opinion, marketing authorisation applicants are normally invited to the CAT plenary meeting to address questions raised by the Committee.

Oral explanations normally relate to ongoing applications, but they can also relate to any other issue for which the CAT would like to discuss with company representatives in person.

New applications (section 2.7.)

In this section, information is included on upcoming marketing authorisation applications for ATMPs, as well as information on appointment of Rapporteurs for new ATMP applications.

Withdrawal of applications (section 2.8.)

This section includes information on marketing authorisation applications that are withdrawn by the applicant. Applicants may decide to withdraw applications at any stage during the assessment and a CAT opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 (section 2.9.)

This section lists applications for new marketing authorisation for ATMPs for which the applicant has requested a re-examination of the opinion previously issued by the CHMP. Similar to the initial evaluation of a marketing authorisation of an ATMP, CAT will adopt a draft re-examination opinion, which is transmitted to the CHMP for final adoption.

GMP and GCP Inspections Issues (section 2.10.)

This section lists inspections that are undertaken for ATMPs. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Post-authorisation activities (section 2.11-2.13.)

Section 2.11 lists type II variations, including extension of indication applications and re-examination procedures for type II variations for which the applicant has requested re-examination of the opinion previously issued by the CHMP. Section 2.12 list extension application according to Annex I of Reg. 1234/2008 and section 2.13 includes all other post-authorisation activities concerning authorised ATMPs that are not covered elsewhere in the agenda such as post-authorisation measures, annual reassessments, 5-year renewals, supply shortages, qualify defects. Issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines, will also be included here.

Companion diagnostics (section 2.14-2.15)

This section lists applications for initial and follow-on consultation of companion diagnostics.

Certification of ATMPs (section 3)

This section includes the scientific evaluation by the CAT of quality and non-clinical data that small and medium-sized enterprises have generated at any stage of the ATMP development process. More information on the ATMP certification procedure can be found here.

Scientific Recommendation on Classification of ATMPs (Section 4)

This section includes the scientific recommendation by the CAT on whether medicines based on genes, cells or tissues meet the scientific criteria that define ATMPs. More information on the ATMP classification procedure, including the outcomes of finalised classifications, can be found here.

Scientific Advice (section 5)

This section includes all scientific advice given to companies during the development of an ATMP. Information related to the number of ATMP related scientific advices discussed by CAT can be found in the CAT Monthly reports. Further information on SAWP can be found here.

Pre-Authorisation (section 6)

Paediatric Investigation Plan (PIP)

This section includes the discussion of an ATMP before a formal application for marketing authorisation is submitted. These cases refer for example to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation: in case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

CAT contributes to the evaluation of a Paediatric Investigation Plan (PIPs) for ATMPs by the Paediatric Committee. These PIPs are included in this section of the Agenda.

ITF Briefing meeting in the field of ATMPs

This section refers to briefing meetings of the Innovation Task Force and International co-operations activities of the CAT

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes of meetings with applicants developing ATMPs and of other ITF meetings of interest to the CAT are included in this section of the agenda. Further information on the ITF can be found here.

Priority Medicines (PRIME)

This section includes the new requests for eligibility to PRIME for ATMPs under development, the discussions in CAT of these eligibility requests and the final recommendations for eligibility of ATMPs adopted by CHMP.

CAT will appoint one of its members as the CAT sponsor for each new ATMP eligibility request who will lead the CAT discussion based on the recommendation from the SAWP.

Organisational, regulatory and methodological matters (section 7)

This section includes topics related to regulatory and procedural guidance, CAT workplan, CAT meeting organisation (including CAT membership), planning and reporting, co-ordination with other committees, working parties and scientific advisory groups.

Furthermore, this section refers to the activities of the CAT drafting groups developing scientific guidelines for gene therapy medicinal products and for cell-based medicinal products, cooperation within the EU regulatory network and international regulators as well as direct interaction with interested parties. It also includes topics of scientific interest for the Committee that are not directly related to the work of the CAT drafting groups or CAT associated working parties.

Any other business (section 8)

This section is populated with miscellaneous topics not suitable under the previous headings.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/