15 July 2026
EMA/CAT/194644/2026
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 17-19 June 2026

Chair: Ilona Reischl-Kok; 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. 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 taken at this meeting were made in the presence of a quorum of members. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified. The members of the EEA-EFTA States agreed with the recommendation of the CAT, unless otherwise specified.

The Chair thanked the departing member for his contributions to the Committee.

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

1.2. Adoption of agenda

The CAT agenda for 17-19 June 2026 meeting was adopted with the removal of procedure 2.13.2. Luxturna (procedure did not start).

1.3. Adoption of the minutes

The CAT minutes for 11-13 May 2026 meeting were adopted.

2. Evaluation of ATMPs

2.1. Opinions

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

Netherlands Cancer Institute; Treatment of melanoma

Scope: Opinion

Action: for adoption

Oral explanation on 11.05.2026. List of outstanding issues adopted on 20.03.2026. List of questions adopted on 18.07.2025.

The CAT Rapporteur presented the draft grounds for refusal (GfR), following the oral explanation held at the May CAT meeting. The revised GfR were agreed.

The CAT adopted by consensus the negative draft opinion recommending to refuse the marketing authorisation of Tacquell.

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

2.5.1. Zamtocabtagene autoleucel - PRIME - Orphan - EMEA/H/C/005495

Miltenyi Biomedicine GmbH; Treatment of adults with large B-cell lymphoma

Scope: Day 80 assessment report

Action: for information

The information was noted. CAT was also informed that this will be an 'OPEN' procedure.

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. Abecma - Idecabtagene vicleucel - Orphan - EMA/VR/0000327582

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.2. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/VR/0000316059

Janssen Cilag International

Rapporteur: Attila Sebe

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.3. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/VR/0000327548

Janssen Cilag International

Rapporteur: Attila Sebe

Scope: Quality, opinion

Action: for adoption

The opinion was adopted

2.11.4. Vyjuvek - Beremagene geperpavec - Orphan - EMA/VR/0000306575

Krystal Biotech Netherlands B.V.

Rapporteur: Joseph De Courcey

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.5. Waskyra - Etuvetidigene autotemcel - Orphan - EMA/VR/0000340506

Fondazione Telethon Ets

Rapporteur: Violaine Closson Carella

Scope: Clinical, request for supplementary information

Update of section 4.8 of the SmPC in order to revise and update the list of adverse reactions (ADRs). In addition, the MAH is taking the opportunity to introduce additional edits and formatting changes to the PI.

Action: for adoption

The request for supplementary information was adopted.

2.11.6. Zolgensma - Onasemnogene abeparvovec - Orphan - EMA/VR/0000340942

Novartis Europharm Limited

Rapporteur: Emmely de Vries

Scope: Clinical, request for supplementary information

Update of sections 4.6 and 5.3 of the SmPC in order to incorporate the findings from the fertility and early embryonic development (FEED) and embryo-foetal development (EFD) studies in mice.

Action: for adoption

The request for supplementary information was adopted.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/PAM/0000338559

Janssen Cilag International

Rapporteur: Attila Sebe; PRAC Rapporteur: Jo Robays

Scope: PAM, PASS

Action: for adoption

This is a PRAC led procedure related to the PASS Survey to evaluate the effectiveness of the

HCP Educational Program and the Product Handling Training. The outcome of the assessment was agreed.

2.13.2. Waskyra - Etuvetidigene autotemcel - Orphan - EMA/PAM/0000338735

Fondazione Telethon Ets

Rapporteur: Violaine Closson Carella

Scope: PAM

Action: for adoption

The outcome of the assessment of the quality PAM was agreed.

2.13.3. Waskyra - Etuvetidigene autotemcel - Orphan - EMA/PAM/0000338021

Fondazione Telethon Ets

Rapporteur: Violaine Closson Carella

Scope: PAM

Action: for adoption

The outcome of the assessment of the quality PAM was agreed.

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

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:	19.06.2026
-EMA Coordinator's draft report:	03.07.2026
-CAT Coordinator's comments:	08.07.2026
-Revised scientific recommendation:	10.07.2026
-CAT's discussion of scientific recommendation:	17.07.2026

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Allogeneic umbilical cord-derived mesenchymal stem cells

Treatment of chronic kidney disease (CKD)

Scope: ATMP scientific recommendation

Action: for nomination of CAT coordinator

The CAT coordinator was appointed.

4.1.2. Recombinant adeno-associated virus containing the human microdystrophin gene

Treatment of Duchenne muscular dystrophy (DMD)

Scope: ATMP scientific recommendation

Action: for nomination of CAT coordinator

The CAT coordinator was appointed.

4.1.3. Recombinant adeno-associated virus vector containing a mini-dystrophin analog (mini-UDYS) transgene

Treatment of Duchenne muscular dystrophy (DMD)

Scope: ATMP scientific recommendation

Action: for nomination of CAT coordinator

The CAT coordinator was appointed.

4.2. Day 30 ATMP scientific recommendation

4.2.1. Virus-specific T lymphocytes enriched from peripheral blood

Treatment of virus reactivation in immunocompromised patients

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 06.07.2026.

4.2.2. Allogeneic peripheral blood-derived haematopoietic stem and progenitor cells (HSPCs), regulatory T cells (Tregs) and conventional T cells (Tcons)

For use in adult patients with haematologic malignancies to improve survival free of graft-versus-host disease in conjunction with an appropriate preparative regimen

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 06.07.2026.

4.2.3. Adeno-associated virus serotype rh.74 vector containing the human Plakophilin-2a (PKP2) gene isoform (AAVrh.74-PKP2a)

Treatment of arrhythmogenic cardiomyopathy caused by pathogenic mutations in the PKP2 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 06.07.2026

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

No items

4.4. Follow-up and guidance

4.4.1. Autologous platelet-rich plasma (PRP) combined with mechanically processed autologous adipose tissue (nanofat) Treatment of refractory olfactory dysfunction

Scope: Comments received from the European Commission. ATMP scientific recommendation

Action: for adoption

The comments from the European Commission were presented. CAT agreed with the addition of a disclaimer in the report that the present classification is without prejudice of the regulatory status of autologous platelet rich plasma when used on its own. The classification report was adopted. The product fulfils the definition of tissue engineered product as provided in Article 2(1) of Regulation (EC) 1394/2007.

4.4.2. Allogeneic human umbilical cord-derived mesenchymal stromal cells

Treatment of congenital diaphragmatic hernia

Scope: Comments received from the European Commission ATMP scientific recommendation

The comments from the European Commission were presented. CAT agreed with the addition of a disclaimer in the report that the present classification is without prejudice of decellularised human scaffolds when used on their own or incorporated into products governed by other regulatory frameworks. The classification report was adopted. The product fulfils the definition of tissue engineered product and not a combined ATMP as provided in Article 2(1) of Regulation (EC) 1394/2007.

Action: for adoption

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 Peer Reviewers

Timetable:

- Start of procedure at SAWP:	08-11.06.2026
- Appointment of CAT Peer Reviewers:	17-19.06.2026
- SAWP first reports:	29.06.2026
- CAT Peer Reviewer (NC & C) comments:	03.07.2026
- CAT Peer Reviewer (Q) comments:	08.07.2026
- Discussion at SAWP:	06-09.07.2026
- Discussion at CAT and feedback to SAWP:	15-17.07.2026

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

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

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:	08-11.06.2026
SAWP recommendation:	09.07.2026
CAT recommendation:	17.07.2026
CHMP adoption of report and final recommendation:	23.07.2026

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

The chair thanked Joseph deCourcey, whose membership ended on 18.06.2026, for his contribution as member for Ireland.

7.1.2. Nominated proxy

Maija Tarkkanen gave a proxy to Andreas Maccani to vote on behalf of Finland during part of the meeting.

Eva Kolouchová gave a proxy to Margaréta Fogelová Czechia during part of the meeting

Isavella Kyriakidou gave a proxy to Maria Gazouli to vote on behalf of Cyprus during the full meeting

Joseph deCourcey gave a proxy to Emmely de Vries to vote on behalf of Ireland during part of the meeting (Wednesday 17 June 2026)[1]

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

Concetta Quintarelli gave a proxy vote to Attila Sebe to vote on behalf of Italy during part of the meeting (Wednesday 17 June 2026 and Thursday 18 June 2026)[2]

[1] This proxy vote was limited to 17.06.2026 following the end of membership of J deCourcey on 18.06.2026 (see 7.1.1.)
[2] This proxy vote was limited to 17-18.06.2026 as Atilla Sebe did not attend the CAT in person on 19.06.2026; for 19.06.2026 the proxy vote was given to Emmely de Vries

Concetta Quintarelli gave a proxy vote to Emmely de Vries to vote on behalf of Italy during part of the meeting (Friday 19 June 2026)

Attila Sebe gave a proxy to Johanne Julh Korsbaek to vote on behalf of Germany during part of the meeting.

Sol Ruiz gave a proxy to Julio Delgado to vote on behalf of Spain during the full meeting.

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

Scope: Preparation for the meeting

CAT: Joseph deCourcey

Action: for information

Topic postponed until the July CAT meeting.

7.1.4. Election of CAT Vice-Chairperson 2026

Action: for adoption

The mandate of the CAT Vice-Chair, Kieran Breen, will expire on 11 July 2026.

The election of the Vice-Chair took place on 18.06.2026 in accordance with the CAT rules of procedure.

The nominations received were presented to the Committee.

The CAT re-elected Kieran Breen as CAT Vice-chair for a second three-year mandate starting on start on 12.07.2026

The CAT and the Agency congratulated Kieran Breen on his election and wished him all the best in his continued role as Vice-Chair of the Committee.

7.1.5. Revised CAT Rules of Procedure

Scope: Revised CAT Rules of Procedure

Action: for information

The revised CAT Rules of Procedure were adopted by the Management Board and will enter in operation on 01.07.2026. The information was noted.

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. GMO assessment for ATMPs

CAT: Ilona Reischl-Kok

European Commission Representative

Scope: Current process for the consultation of GMO authorities during the marketing authorisation procedures and future process of ERA assessment for GMO containing ATMP in clinical trials

Action: for discussion

EMA presented the current process for consultation of GMO authorities during the marketing authorisation procedure. CAT members were asked to liaise with their GMO authorities.

A short exchange took place on the interdependencies in the new pharmaceutical legislation, the clinical trial regulation (including CTIS) and the biotech act in relation to the process of ERA assessment for GMO containing ATMP in clinical trials. Early interactions with all stakeholders will be needed to develop the future process.

7.4.2. Implementation of the new Pharmaceutical Legislation

CAT: Ilona Reischl-Kok

Scope: Governance & Network engagement model

Action: for information

The information was noted.

7.5. Cooperation with international regulators

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

CAT: Ilona Reischl-Kok

Scope: Agenda of the ATMP cluster of 25.06.2026

Action: for information

The agenda for the next ATMP cluster was noted.

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

CAT: Pille Saalik

Scope: Feedback from the IPRP meeting of 16.06.2026

Action: for discussion

Feedback was provided from the last IPRP meeting.

7.6. CAT work plan

7.6.1. Patient reported outcomes / patient preference studies in the ATMP development

Scope: Outcome of the discussion at the SRLM in Cyprus

CAT: Kieran Breen, Kerstin Sollerbrant Melefors, Donatella Capone, Federica Chiara

Action: for information

Kieran Breen presented the outcome of the SRLM discussions. The proposal is to develop a framework to take this work plan topic further: expand the CAT members working on this topic; interact with the Patient Experience Data (PED) Reflection paper group; to develop clear and realistically achievable PED objectives; to liaise with other committees/working parties (CHMP, SAWP, PCWP and HCPWP) to discuss pilot developments. CAT will be kept up to date on the progress.

Olga Kholmanskikh agreed to take part in this activity (she is already involved as members of the Oncology working party).

7.6.2. Joint Health Technology Assessment bodies (HTAb)-regulatory perspectives on understanding evidence challenges, managing uncertainties and exploring potential solutions

Scope: Outcome of a workshop series between HTA bodies and regulators

Action: for information

CAT noted the information on a planned webinar and workshop on this topic. This is an opportunity to continue the discussion with HTAb. A good representation from the regulatory network would be beneficial. More details will be provided to CAT when they become available.

7.6.3. CAT assessors training on GL for investigational ATMPs

Scope: Feedback from the CAT assessors training held on 17.06.2026

CAT: Ilona Reischl-Kok, Silke Dorner, Suzana Vidic, Olga Kholmanskikh

Action: for information

The assessors training took place on 17.06.2026 The recording of the training will be included in EU-NTC in the next couple of weeks.

7.7. Planning and reporting

7.7.1. Q2-2026 Business Pipeline report for the human scientific committees

Scope: Q2-2026 Business Pipeline report for the human scientific committees

Action: for information

The information was noted.

7.8. Others

7.8.1. International Society for Cell & Gene therapy (ISCT) annual meeting

Scope: Feedback from discussions at the International Regulators Summit (05.05.2026) and from the annual meeting (06-09.05.2026)

CAT: Pille Säälik, Kieran Breen

Action: for information

EMA and CAT members provided feedback from the ISCT Internation Regulators Summit and the ISCT annual meeting.

7.8.2. CASSS-Cell and Gene Therapy products (CGTP) symposium

Scope: Feedback from discussion at the CASSS-CGTP symposium (09-11.06.2026)

CAT: Barbara Bonamassa, Ilona Reischl-Kok

Action: for information

Feedback was provided from the CASS-CGTP symposium.

8. Any other business

8.1.1. Update on the transition to IRIS for initial marketing authorisation applications and pre-submission activities

Scope: Present the updated plan and anticipate upcoming engagement activities to support preparation for this transition

Action: for information

The information on the transition to IRIS for initial marketing authorisation applications and pre-submission activities was noted. The training opportunities and IRIS guidance & training resources (recorded presentations, guidance documents, FAQs etc) were highlighted

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 17-19 June 2026 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-Kok	Chair	Austria	No interests declared	
Silke Dorner*	Member	Austria	No interests declared	
Andreas Maccani	Alternate	Austria	No restrictions applicable to this meeting	
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	
Eva Kolouchová	Member	Czechia	No interests declared	
Martin Oleksiewicz	Member	Denmark	No interests declared	
Johanne Juhl Korsbaek	Alternate	Denmark	No restrictions applicable to this meeting	
Toivo Maimets	Member	Estonia	No restrictions applicable to this meeting	
Pille Saalik	Alternate	Estonia	No interests declared	
Maija Tarkkanen	Alternate	Finland	No interests declared	
Gabriela Ullio Gamboa	Alternate	France	No interests declared	
Attila Sebe	Member	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 deCourcey*	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	
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	
Margareta Fogelová	Member	Slovakia	No interests declared	
Denisa Partelova	Alternate	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 discussion, final deliberations and voting on:	Scientific advice
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	EDQM	No interests declared	
Torbjörn Callréus	Expert	Malta	No interests declared	
Barbora Vokata	Expert	Czechia	No restrictions applicable to this meeting	
Dagmar Pospisilova	Expert	Czechia	No interests declared	
Maëva Robin	Expert	France	No interests declared	
Housam Eidi	Expert	France	No interests declared	
Solène Maitenaz	Expert	France	No interests declared	
Caroline Richard	Expert	France	No restrictions applicable to this meeting	
Agnès Mambole-Dema	Expert	France	No interests declared	
Simona Teodosiu	Expert	France	No interests declared	
Ramzi Mraidi	Expert	France	No restrictions applicable to this meeting	
Nicolas Beix	Expert	France	No interests declared	
Charlotte M. T. de Wolf	Expert	Netherlands	No interests declared	
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.				

Date of next CAT meeting:

15-17 July 2026

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

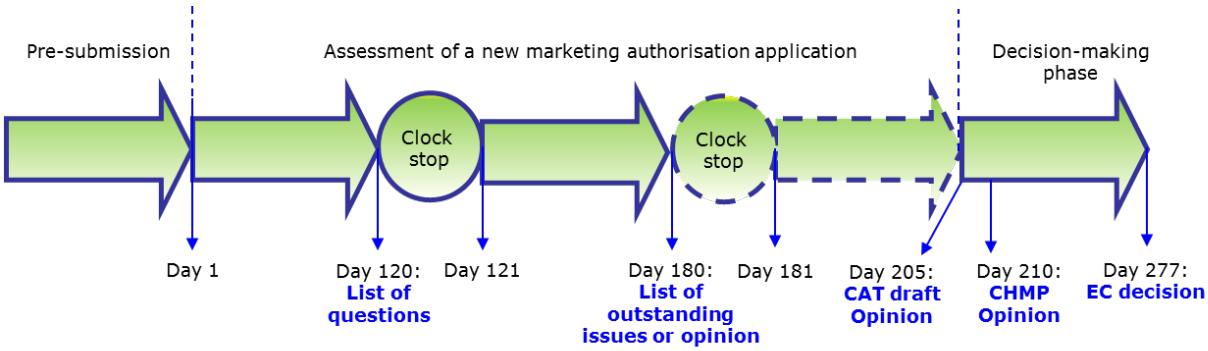
Evaluation of ATMPs (section 2)

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.

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/