15 April 2026
EMA/CAT/96509/2026
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 18-20 March 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).

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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 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 welcomed the new alternate and thanked the departing alternate for their contribution 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 18-20 March 2026 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes for 18-20 February 2026 meeting were adopted.

2. Evaluation of ATMPs

2.1. Opinions

2.1.1. ADSTILADRIN - Nadofaragene firadenovec - EMEA/H/C/005856

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

Scope: Oral explanation and opinion

Action: for adoption

List of outstanding issues adopted on 05.12.2025. List of questions adopted on 16.04.2025.

The Rapporteurs presented the outcome of the assessment of the list of outstanding issues. CAT was informed of the outcome of the discussion in the BWP.

The oral explanation was cancelled. CAT adopted the positive opinion recommending granting of a conditional marketing authorisation. The specific obligation was agreed.

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

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

Treatment of melanoma

Scope: Day 180 list of outstanding issues

Action: for adoption

List of questions adopted on 18.07.2025.

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

The list of outstanding issues was adopted.

2.4. Day 120 list of questions

2.4.1. Zopapogene Imadenovec - Orphan - EMEA/H/C/006508

FGK Representative Service GmbH; Treatment of respiratory papillomatosis in adults

Scope: Day 120 list of questions

Action: for adoption

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

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. Aucatzyl - Obecabtagene autoleucel - Orphan - EMA/VR/0000322591

Autolus GmbH

Rapporteur: Tineke van den Hoorn

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Aucatzyl - Obecabtagene autoleucel - Orphan - EMA/R/0000319964

Autolus GmbH

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

Scope: Renewal 1-year

Action: for adoption

The 1-year renewal was adopted.

2.13.2. Kymriah - Tisagenlecleucel - Orphan - EMA/PAM/0000258545

Novartis Europharm Limited

Rapporteur: Rune Kjeken, PRAC Rapporteur: Dirk Mentzer

Scope: PAM, PRAC lead procedure

Action: for information

The outcome of the assessment was agreed.

2.13.3. Roctavian - Valoctogene Roxaparvovec – EMEA/H/C/005830

BioMarin International Limited

Rapporteur: Violaine Closson-Carella, Co-Rapporteur: Silke Dorner

Scope: Withdrawal of the marketing authorisation

Action: for information

The MAH informed EMA of their intention to withdraw the MA for Roctavian. The information was noted.

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:	20.03.2026
-EMA Coordinator's draft report:	01.04.2026
-CAT Coordinator's comments:	08.04.2026
-Revised scientific recommendation:	10.04.2026
-CAT's discussion of scientific recommendation:	17.04.2026

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Recombinant chicken annexin V labelled inactivated autologous tumour cells

Treatment of solid tumours, especially renal cell carcinoma and breast cancer

Scope: ATMP scientific recommendation

Action: for nomination of CAT coordinator

The CAT coordinator was appointed.

4.1.2. Adenovirus type 5 vector expressing human granulocyte-macrophage colony-stimulating factor

Treatment of bladder cancer

Scope: ATMP scientific recommendation

Action: for nomination of CAT coordinator

The CAT coordinator was appointed.

4.1.3. Autologous adipose-derived stromal vascular fraction

Treatment of acute spinal cord injury

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. Live attenuated viral vector vaccine based on SARS-COV-2 backbone, expressing human interferon beta

COVID-19 prophylaxis

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 07.04.2026.

4.2.2. Messenger ribonucleic acid (mRNA) molecules encoding a cytosine-to-thymine transcription activator like effector base editor (TALEB) targeting APOC3 gene

Treatment of familial chylomicronaemia syndrome (FCS) and severe hypertriglyceridemia (sHTG)

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 07.04.2026.

4.2.3. Allogeneic CAR-T lymphocytes targeting CEACAM6

Treatment of pancreatic ductal adenocarcinoma (PDAC) surgery-eligible 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 07.04.2026.

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

No items

4.4. Finalisation of procedure

4.4.1. Live attenuated Listeria monocytogenes bearing plasmids encoding the recombinant chimeric fusion protein of truncated nonhemolytic listerolysin O (tLLO) and a tumour associated antigen (TAA) comprised of two extracellular (EC1 and EC2) and one intracellular (IC1) fragments of the human Her2/neu protein

Treatment of pulmonary recurrence of resected osteosarcoma

Scope: ATMP scientific recommendation. European Commission raised no comments.

Action: for adoption

The classification report was adopted. The product does fulfil the definition of gene therapy medicinal product as provided in Article 2(1) of Regulation (EC) No 1394/2007.

4.4.2. Allogeneic umbilical cord-derived Mesenchymal stem cells

Treatment of lupus nephritis (LN) and systemic lupus erythematosus (SLE)

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

4.4.3. Autologous chimeric antigen receptor T cells against epidermal growth factor variant III (EGFRvIII) and messenger ribonucleic acid vaccine lipoplexes encoding EGFRvIII (intracerebroventricular administration)

Treatment of EGFRvIII-positive glioblastoma

Scope: ATMP scientific recommendation. European Commission raised no comments.

Action: for adoption

The classification report was adopted. The CAR-T component does fulfil the definitions of a somatic cell therapy medicinal product and a gene therapy medicinal product and is therefore considered a gene therapy medicinal product as provided in Article 2(5) of Regulation (EC) 1394/2007. The mRNA component 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. Autologous chimeric antigen receptor T cells against epidermal growth factor variant III (EGFRvIII) and messenger ribonucleic acid vaccine lipoplexes encoding EGFRvIII (intravenous administration)

Treatment of EGFRvIII-positive glioblastoma

Scope: ATMP scientific recommendation. European Commission raised no comments.

Action: for adoption

The classification report was adopted. The CAR-T component does fulfil the definitions of a somatic cell therapy medicinal product and a gene therapy medicinal product and is therefore considered a gene therapy medicinal product as provided in Article 2(5) of Regulation (EC) 1394/2007. The mRNA component 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. Extracellular vesicles from Wharton Jelly hTERT- expressing Mesenchymal Stromal Cells (MSCs) loaded with the micro-RNA miR-140

Treatment of osteoarthritis

Scope: ATMP scientific recommendation. European Commission raised no comments.

Action: for adoption

The classification report was adopted. The product does not fulfil the definition of an advanced 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:	09-12.03.2026
- Appointment of CAT Peer Reviewers:	18-20.03.2026
- SAWP first reports:	31.03.2026
- CAT Peer Reviewer comments (NC & C):	06.04.2026
- CAT Peer Reviewer comments (Q):	08.04.2026
- Discussion at SAWP:	07-10.04.2026
- Discussion at CAT and feedback to SAWP:	15-17.04.2026

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	07-10.04.2026
- Appointment of CAT Peer Reviewers:	15-17.04.2026
- SAWP first reports:	27.04.2026
- CAT Peer Reviewer comments (NC & C):	30.04.2026
- CAT Peer Reviewer comments (Q):	06.05.2026
- Discussion at SAWP:	04-07.05.2026
- Discussion at CAT and feedback to SAWP:	11-13.05.2026

No items

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

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

5.4. Final Advice Letters for procedures finalised the previous month

6. Pre-Authorisation Activities

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

6.1. Paediatric investigation plans

No items

6.2. ITF briefing meetings in the field of ATMPs

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:

Procedure start:	09-12.03.2026
SAWP recommendation:	10.04.2026
CAT recommendation:	17.04.2026
CHMP adoption of report and final recommendation:	23.04.2026

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 welcomed Gabriela Ullio-Gamboa as the new alternate for France and thanked Jean-Michel Race for his contribution as alternate for France.

Action: for information

7.1.2. Nominated proxy

Maria Gazouli gave a proxy to Isabella Kyriakidou to vote on behalf of Greece during the entire meeting.

Eva Kolouchova gave a proxy to Margareta Fogelova to vote on behalf of Czechia during the entire meeting.

Péter Zsolt Fekete gave a proxy to Suzana Vidic to vote on behalf of Iceland during the entire meeting.

Action: for information

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

Scope: Preparation for the meeting

CAT: Rafaella Pontou

Action: for information

The final agenda of the upcoming SRLM and some practical information was presented.

7.1.4. Welcoming email to new members

Action: for information

CAT secretariat presented the welcome email to new members.

7.2. Coordination with EMA Scientific Committees

No items

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

No items

7.4. Cooperation with the EU regulatory network

No items

7.5. Cooperation with international regulators

No items

7.6. CAT work plan

No items

7.7. Planning and reporting

7.7.1. Revamp Project - report from the pilot project (pre-completion of reports by applicants)

Scope: The Revamp Project, which has been focussing for the last 4 years on revamping the assessment report templates, carried out a pilot whereby applicants were asked to complete

the factual parts of the D80 AR templates. 11 companies participated in the pilot and one of the products was an ATMP. Now that the pilot has concluded, the Revamp team would like to bring to the committees the findings and the recommendations from the Revamp Steering Group

Action: for information

EMA presented the report of the Revamp project and the recommendations arising from the pilot.

7.8. Others

7.8.1. Exploring ATMP feasibility assessment for surveillance capacity development

Scope: Surveillance

EDQM: Christina Goengrich, Katarina Bacevic

Action: for discussion

EDQM presented the ATMP feasibility assessment, to build knowledge on ATMP testing (beginning with in vivo gene therapies), increase preparedness and capacity of Official Medicines Control Laboraratorie (OMCLs)(in case testing of ATMPs by OMCL is required, e.g. defective medicines) and allow OMCLs to gain hands-on experience, and evaluate the feasibility of testing ATMPs under near-real conditions; it was emphasised that the goal is not to include ATMPs in the current CAP sampling & testing programme or to deprive patients of access to the medicinal products.

Following the discussion, the feasibility assessment project as proposed by EDQM was not endorsed by a majority of CAT members.

The outcome was noted by EDQM representatives. In view of the above position, an EMA-EDQM collaboration will not be set up.

7.8.2. ATMP-FDA-EMA CMC (AFEC) meeting

CAT: Ilona Reischl

Scope: Feedback from the AFEC meeting of 12.03.2026

Action: for information

A short feedback was provided to CAT.

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 18-20 March 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	Chair	Austria	No restrictions applicable to this meeting	
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	
Isavella Kyriakidou	Alternate	Cyprus	No interests declared	
Eva Kolouchová*	Member	Czechia	No interests declared	
Martin Oleksiewicz	Member	Denmark	No interests declared	
Johanne Juhl Korsbaek	Alternate	Denmark	No restrictions applicable to this meeting	
Toivo Maimets	Member	Estonia	No restrictions applicable to this meeting	
Pille Saalik	Alternate	Estonia	No interests declared	
Heli Suila	Member	Finland	No restrictions applicable to this meeting	
Violaine Closson Carella	Member	France	No interests declared	
Jan Mueller-Berghaus*	Alternate	Germany	No interests declared	
Attila Sebe	Member	Germany	No interests declared	
Viola Bardoczy	Member	Hungary	No restrictions applicable to this meeting	

Agnes Zotter*	Alternate	Hungary	No restrictions applicable to this meeting	
Péter Zsolt Fekete*	Member	Iceland	No interests declared	
Joseph De Courcey	Member	Ireland	No interests declared	
Richard Carroll*	Alternate	Ireland	No interests declared	
Concetta Quintarelli	Member	Italy	No participation in discussion, final deliberations and voting on:	Scientific advice procedure
Barbara Bonamassa*	Alternate	Italy	No interests declared	
Liga Kunrade	Alternate	Latvia	No restrictions applicable to this meeting	
Vilma Perikaite*	Member (CHMP member)	Lithuania	No restrictions applicable to this meeting	
Raimondas Benetis	Alternate (to CHMP representative)	Lithuania	No restrictions applicable to this meeting	
Alessia Pochesci	Member	Luxembourg	No restrictions applicable to this meeting	
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 restrictions applicable to this meeting	
Charlotte Anderberg	Alternate	Sweden	No interests declared	
Julio Delgado Gonzalez	Member	Clinicians' Representative	No restrictions applicable to this meeting	
Alessandra Renieri*	Alternate	Clinicians' Representative	No restrictions applicable to this meeting	
Federica Chiara	Member	Patients' Representative	No restrictions applicable to this meeting	
Kerstin Sollerbrant Melefors*	Alternate	Patients' Representative	No restrictions applicable to this meeting	
Kieran Breen	Member (Vice-Chair)	Patients' Representative	No restrictions applicable to this meeting	
Catherine Milne	Observer	EDQM	No interests declared	
Christina Goengrich	Observer	EDQM		
Katarina Bacevic	Observer	EDQM		
Torbjörn Callréus	Expert	Malta	No interests declared	
Sonia Klinger	Expert	Denmark	No interests declared	
Violeta Georgieva Tsonkova	Expert	Denmark	No interests declared	
Britta Hjerrild	Expert	Denmark	No restrictions applicable to this meeting	
Kinga Nowicka-Matus	Expert	Denmark	No restrictions applicable to this meeting	
Carolina Prieto Fernandez	Expert	Spain	No interests declared	
Macarena Gajardo Álvarez	Expert	Spain	No interests declared	
Laura Rodríguez García	Expert	Spain	No interests declared	
Esther Rincón Gila	Expert	Spain	No interests declared	
Teresa LLacer Delicado	Expert	Spain	No interests declared	
Juan Ignacio Bedoya Ponte	Expert	Spain	No restrictions applicable to this meeting	
Maëva Robin	Expert	France	No interests declared	
Solène Maitenaz	Expert	France	No interests declared	

Agnès Mambole-Dema	Expert	France	No interests declared	
Simona Teodosiu	Expert	France	No interests declared	
Marianne Delville	Expert	France	No restrictions applicable to this meeting	
Paolo Petracci	Expert	France	No interests declared	
Martijn van Gils	Expert	Netherlands	No interests declared	
Mark van Bussel	Expert	Netherlands	No interests declared	
Christophe Focke	Expert	Belgium	No restrictions applicable to this meeting	
Ingrid Bourges	Expert	Belgium	No restrictions applicable to this meeting	
Violette Dirix	Expert	Belgium	No restrictions applicable to this meeting	
Anna Mari Lone	Expert	Norway	No restrictions applicable to this meeting	
Fabrice Eroukhmanoff	Expert	Norway	No interests declared	
Eva Skovlund	Expert	Norway	No restrictions applicable to this meeting	
Greger Abrahamsen	Expert	Norway	No interests declared	
Eva Kristine Klemsdal	Expert	Norway	No restrictions applicable to this meeting	
Anne Torrez Flores	Expert	Netherlands	No interests declared	
Helena Back	Expert	Sweden	No interests declared	
Hannah Wootz	Expert	Sweden	No interests declared	
Filip Josephson	Expert	Sweden	No interests declared	
Bianca Mulder	Expert	Netherlands	No interests declared	
Odoardo Olimpieri	Expert	Italy	No interests declared	
Aina Jannicke Øvrebust	Expert	Norway	No interests declared	
Some representatives from the European Commission attended the meeting. Representatives from the Swissmedic attended the meeting				
Meeting run with support from relevant EMA staff. Experts' declared interests were evaluated against the agenda topics or activities they participated in.				

Date of next CAT meeting:

15-17 April 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

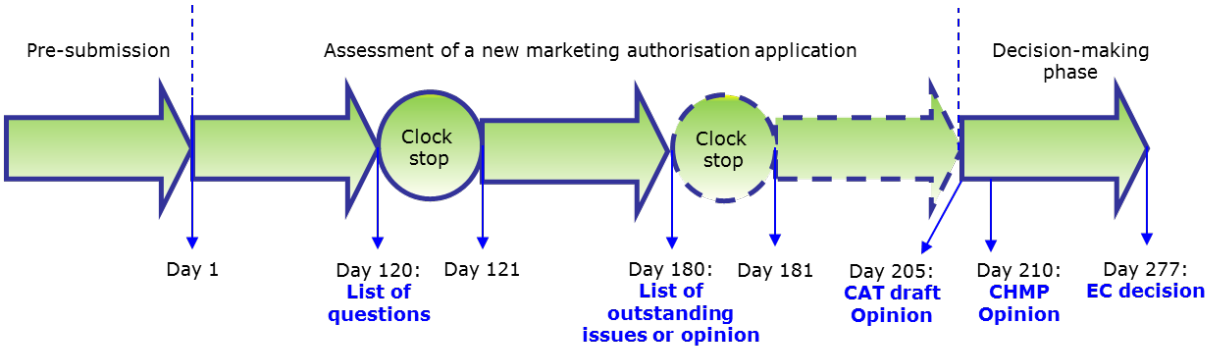
Evaluation of ATMPs (section 2)

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/