19 June 2024
EMA/CAT/248714/2024
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 22-24 May 2024

Chair: Ilona Reischl; Vice-Chair: Kieran Breen

Disclaimers

Some of the information contained in these minutes is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CAT meeting reports once the procedures are finalised.

Of note, these minutes are a working document primarily designed for CAT members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

The Chairperson opened the meeting by welcoming all participants. The meeting was held remotely.

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for concerned agenda topics.

Participants were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared. Restrictions applicable to this meeting are captured in the List of participants included in the minutes.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

The Chair welcomed the new member and alternates and thanked the departing members/alternates for their contributions to the Committee.

1.2. Adoption of agenda

The CAT agenda for 22-24 May 2024 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes for 17-20 April 2024 meeting were adopted.

2. Evaluation of ATMPs

2.1. Opinions

2.1.1. Fidanacogene elaparvovec - PRIME - EMEA/H/C/004774

Indicated for the treatment of severe and moderately severe haemophilia B

Scope: Opinion; third party intervention

Action: for adoption

List of outstanding issues adopted on 15.03.2024, list of questions adopted on 08.09.2023.

The CAT Rapporteur and CoRapporteur presented the assessment of the responses to the list of outstanding issues. Feedback was provided from the BWP discussion. The CAT draft opinion recommending the granting of a conditional marketing authorisation to (Fidanacogene elaparvovec) was adopted by majority: a divergent opinion, was attached to the opinion.

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

No items

2.4. Day 120 list of questions

No items

2.5. Day 80 assessment reports

No items

2.6. Update on ongoing initial applications

No items

2.7. New applications

2.8. Withdrawal of initial marketing authorisation application

No items

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

No items

2.10. Companion diagnostics

2.10.1. Initial consultation

No items

2.10.2. Follow-up consultation

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 - EMEA/H/C/004662/II/0047

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, request for supplementary information

Action: for adoption

The Rapporteur provided feedback from the BWP discussion on this variation. CAT agreed with the position of the BWP: the request for supplementary information was adopted.

2.11.2. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0036/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Safety, request for supplementary information

Grouped application comprising two variations as follows:
C.I.4 – Update of sections 4.4 and 4.8 of the SmPC in order to add immune effector cell-associated neurotoxicity syndrome (ICANS) as an adverse drug reaction (ADR) based on the cumulative review of MAH safety database and literature. The Package Leaflet is updated accordingly. In addition, the MAH took this opportunity to introduce editorial changes.
A.6 – To include the ATC Code L01XL08 in section 5.1 of the SmPC.

Action: for adoption

Request for supplementary information adopted on 16.02.2024.

The Rapporteur presented the assessment of the responses to the request of supplementary information. Not all issues are fully resolved . A second request for supplementary information was adopted.

2.11.3. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0027/G

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.4. Libmeldy - Atidarsagene autotemcel - Orphan - EMEA/H/C/005321/II/0025

Orchard Therapeutics (Netherlands) B.V.

Rapporteur: Emmely de Vries

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.5. Upstaza - Eladocagene exuparvovec - Orphan - EMEA/H/C/005352/II/0021

PTC Therapeutics International Limited

Rapporteur: Joseph DeCourcey

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.6. Tecartus; Yescarta - Axicabtagene ciloleucel; Brexucabtagene autoleucel - Orphan - EMEA/H/C/WS2500

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, request for supplementary information

Action: 2nd Request for supplementary information for adoption

Request for supplementary information adopted on 16.02.2024.

The second request for supplementary information was adopted.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/REC/021

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, opinion

Action: for adoption

The report was adopted.

2.13.2. Ebvallo - Tabelecleucel - Orphan - EMEA/H/C/004577/S/0008

Pierre Fabre Medicament

Rapporteur: Egbert Flory, PRAC Rapporteur: Amelia Cupelli

Scope: Annual re-assessment, opinion

Action: for adoption

The Rapporteur presented the annual reassessment. The opinion was adopted.

2.13.3. Luxturna - Voretigene neparvovec - Orphan - EMEA/H/C/004451/REC/007.1

Novartis Europharm Limited

Rapporteur: Sol Ruiz

Scope: Quality, opinion

Action: for adoption

The report was adopted.

2.13.4. ROCTAVIAN - Valoctocogene roxaparvovec - Orphan - EMEA/H/C/005830/R/0011

BioMarin International Limited

Rapporteur: Violaine Closson Carella, Co-Rapporteur: Silke Dorner, PRAC Rapporteur: Bianca Mulder

Scope: 1 year renewal of marketing authorisation, request for supplementary information

Action: for adoption

The Rapporteur presented the assessment of the second annual renewal of marketing authorisation of Roctavian. The benefit risk profile remains positive, but some clarifications are needed. The request for supplementary information was adopted.

2.13.5. Yescarta – axicabtagene ciloleucel – Orphan – EMA/H/C/004480/PSA/S/0102.4

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Protocol update for PASS study

Action: for information

EMA informed the CAT that PRAC adopted the update of the PASS protocol for study KT-EU-471-0117. The PASS study protocol was updated in line with the CAT request to consider additional data sources for the long-term safety and efficacy follow-up study based on EBMT data. The protocol is aligned to the PASS study for Tecartus.

CAT was reminded that for any extension of indication, the safety database should include all indications (no separate data collection for the different indications). CAT considered that this information should best be captured as a CAT learning.

2.14. GMP and GCP inspections requests

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:	24.05.2024
-EMA Coordinator's draft report:	07.06.2024
-CAT Coordinator's comments:	12.06.2024
-Revised scientific recommendation:	14.06.2024
-CAT's discussion of scientific recommendation:	21.06.2024

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Autologous antigen specific Cytotoxic T Lymphocytes

For treatment of cancer patients

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.2. Autologous dendritic cells against tumour peptides

For treatment of cancer patients

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.3. Autologous macrophages

For treatment of cancer patients

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.4. Autologous cytotoxic natural killer (NK) cells

For treatment of cancer patients

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.5. Autologous plasma cells producing antibodies against tumour antigen

For treatment of cancer patients

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.6. Autologous adipose-derived stromal vascular fraction cells

For chronic pain relief

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.7. Double stranded DNA targeting patient specific tumour neo-antigens

For treatment of non small cell lung cancer

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.8. Synthetic double-stranded RNA oligonucleotide conjugated to GalNAc aminosugar residues

For treatment of primary hyperoxaluria

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.2. Day 30 ATMP scientific recommendation

4.2.1. MicroRNA against BCL2 anti-apoptotic messenger RNA

For treatment of cancer 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 07.06.2024.

4.2.2. Allogeneic natural killer cells expanded in vitro and transfected to express modified Fas ligand

For treatment of haematological malignancies and glioblastoma

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 07.06.2024.

4.2.3. Stromal vascular fraction

For treatment of osteoarthritis

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 07.06.2024.

4.2.4. Implantable device 3D bioprinted with autologous microfat and hydrogel bioink

For treatment of breast reconstruction, soft tissue repair

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the classification report. CAT considered that the information provided was not sufficient to conclude on the ATMP classification: additional information is requested from the applicant. The classification will be finalised when the additional information is received.

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

4.3.1. Lymphocyte concentrate

For improvement of the pregnancy outcomes among women with unexplained repeated pregnancy loss and HLA sharing among partners

Scope: ATMP scientific recommendation

Action: for adoption

The CAT coordinator presented the additional information provided by the applicant. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 07.06.2024.

4.4. Finalisation of procedure

4.4.1. mRNA encoding ARCUS nuclease

For treatment of chronic hepatitis B (CHB) virus infection

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. Allogeneic human corneal endothelial cells (neltependocel) and a low molecular weight Rho kinase inhibitor (Y-27632)

For treatment of corneal oedema due to corneal endothelial dysfunction

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 tissue engineered 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:	13-16.05.2024
- Appointment of CAT Peer Reviewers:	22-24.05.2024
- SAWP first reports:	03.06.2024
- CAT Peer Reviewer comments (NC/C):	07.06.2024
- CAT Peer Reviewer comments (Q):	12.06.2024
- Discussion at SAWP:	10-12.06.2024
- Discussion at CAT and feedback to SAWP:	19-21.06.2024

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	10-13.06.2024
- Appointment of CAT Peer Reviewers:	19-21.06.2024
- SAWP first reports:	01.07.2024
- CAT Peer Reviewer comments (NC/C):	05.07.2024
- CAT Peer Reviewer comments (Q):	10.07.2024
- Discussion at SAWP:	08-11.07.2024
- Discussion at CAT and feedback to SAWP:	17-19.07.2024

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:	13-16.05.2024
SAWP recommendation:	13.06.2024
CAT recommendation:	21.06.2024
CHMP adoption of report and final recommendation:	27.06.2024

No items

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 Martin Oleksiewicz as the new member for Denmark.

The Chair thanked Anna Katalin Barane Gilicze, the member for Hungary, and Kristyna Rehorova Hradilkova, the alternate for Czechia, for their contributions to the work of the CAT.

7.1.2. Vote by proxy

No items

7.1.3. CAT Strategic Review & Learning meeting (SRLM) under the Belgian presidency – 15-17 May 2024

CAT: Claire Beuneu

Scope: Feedback from the SRLM

Action: for information

The Belgian CAT member provided a short overview of the discussion at the SRLM. The report of the meeting is under preparation.

7.2. Coordination with EMA Scientific Committees

7.2.1. Schedule of Face-to-Face (F2F) meetings for 2025

Scope: Proposed schedule of F2F meetings for 2025 was presented at the SciCoBo meeting on 6 May 2024

Action: for information

The F2F CAT meeting dates were noted.

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

7.3.1. SAWP/CTCG SA pilot

Scope: Feedback from the Consolidated advice pilots: ACT EU Priority Action 7

Action: for information

EMA presented the pilot for consolidated SAWP/CTCG scientific advice.

7.4. Cooperation with the EU regulatory network

No items

7.5. Cooperation with international regulators

7.5.1. WHO Conference in Muskat Oman, May 14-16th

CAT: Ilona Reischl

Scope: Feedback from the WHO conference

Action: for information

The CAT chair provided feedback from the discussion at the WHO training session for regulatory authorities from low and medium income countries that took place in Oman on 14-16 May 2024. The aim of the meeting was to support these countries to set up a regulatory framework for ATMPs.

7.6. CAT work plan

7.6.1. Workplan activity '1.2.3 - Interactions with Health Technology Assessment (HTA) bodies to optimise clinical evidence generation'

CAT: Ilona Reischl

Scope: Workshops on uncertainties

Action: for information

EMA presented the plan for workshops involving HTA bodies and Regulators (from CHMP, CAT and MWP) related to the management of uncertainties.

7.7. Others

7.7.1. Webinar on the "Regulation of Faecal Microbiota Transplants (FMT) and FMT-derived medicinal products in the EU"

Action: for information

CAT was informed of the agenda of the Webinar and were asked to register if they would like to attend.

7.7.2. Marketing Authorisation Applications (MAAs) 3-year forecast report (March 2024 to December 2026) and annexes

Action: For information

EMA presented the 3-year forecast report.

Olga Kholmanskikh was appointed as CAT representative in the focus group on submission predictability, replacing Ebru Karakoc Madsen.

8. Any other business

Date of next CAT meeting:

17-19 June 2024

9. List of participants

Including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 22-24 May 2024 meeting.

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	
Petra Sokol	Alternate	Croatia	No interests declared	
Rafaella Pontou	Member	Cyprus	No interests declared	
Isavella Kyriakidou	Alternate	Cyprus	No interests declared	
Petr Soukup	Member	Czechia	No interests declared	
Martin Oleksiewicz	Member	Denmark	No interests declared	
Bibi Fatima Syed Shah	Alternate	Denmark	No interests declared	
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	
Angeliki Rompoti	Alternate	Greece	No restrictions applicable to this meeting	
Viola Bardoczy	Alternate	Hungary	No restrictions applicable to this meeting	
Joseph De Courcey	Member	Ireland	No interests declared	
Concetta Quintarelli	Member	Italy	No interests declared	
Barbara Bonamassa	Alternate	Italy	No interests declared	
Una Riekstina	Member	Latvia	No interests declared	

Villma 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	
Anthony Samuel	Alternate (to CHMP representative)	Malta	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	Alternate (to CHMP representative)	Portugal	No interests declared	
Denisa Marilena Margina	Member	Romania	No interests declared	
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	Member	Slovenia	No interests declared	
Suzana Vidic	Alternate	Slovenia	No participation in final deliberations and voting on:	2.13.3 Luxturna REC/007.1
Sol Ruiz	Member (CHMP co-opted member)	Spain	No interests declared	
Marcos Timón	Alternate (to CHMP representative)	Spain	No interests declared	
Maria Luttgen	Member	Sweden	No participation in final deliberations and voting on:	4.1.8 Synthetic double-stranded RNA oligonucleotide conjugated to GalNAc aminosugar residues
Charlotte Anderberg	Alternate	Sweden	No interests declared	

Bernd Gansbacher	Alternate	Clinicians' Representative	No interests declared	
Alessandra Renieri	Alternate	Clinicians' Representative	No restrictions applicable to this meeting	
Kerstin Sollerbrant Melefors	Member	Patients' Representative	No interests declared	
Kieran Breen	Member (Vice-Chair)	Patients' Representative	No interests declared	
Catherine Milne	Observer/Alternate	EDQM	No interests declared	
Torjorn Callreus	Expert	Malta	No interests declared	
Juliane Rau	Expert	Germany	No interests declared	
Beate Mosl	Expert	Germany	No interests declared	
Clara Dingert	Expert	Germany	Indirect interests declared	
Verena Scheer	Expert	Germany	No interests declared	
Filip Josephson	Expert	Sweden	No interests declared	
Brigitte Mueller	Expert	Austria	No interests declared	
Philipp Janesch	Expert	Austria	No interests declared	
Odoardo Olimpieri	Expert	Italy	No interests declared	
Antonella Isgro	Expert	Italy	No interests declared	
Federico de Angelis	Expert	Italy	No interests declared	
Outi Mäki-Ikola	Expert	Finland	No restrictions applicable to this meeting	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

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

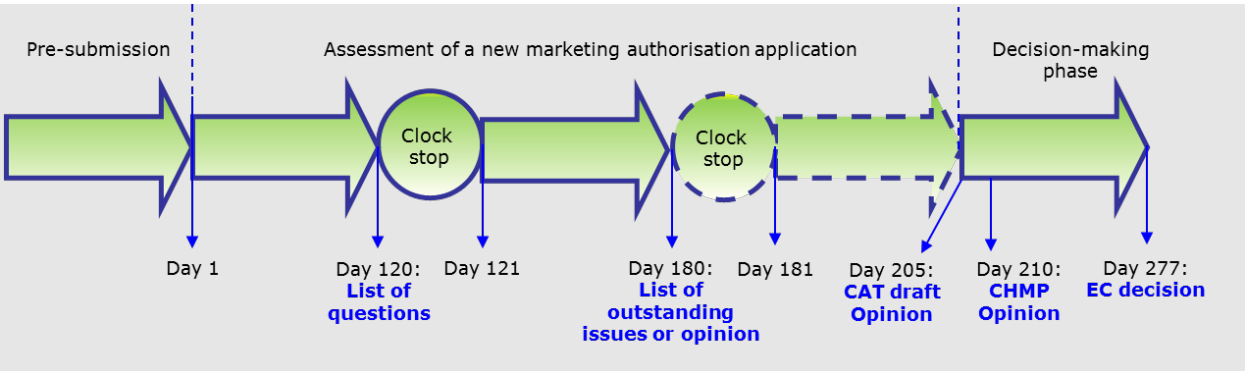
Evaluation of ATMPs (section 2)

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.

Companion diagnostics (section 2.10)

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

Post-authorisation activities (section 2.11-2.13.)

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

GMP and GCP Inspections Issues (section 2.14.)

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

Certification of ATMPs (section 3)

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

Scientific Recommendation on Classification of ATMPs (Section 4)

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

Scientific Advice (section 5)

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

Pre-Authorisation (section 6)

Paediatric Investigation Plan (PIP)

This section includes the discussion of an ATMP before a formal application for marketing authorisation

is submitted. These cases refer for example to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation: in case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

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

ITF Briefing meeting in the field of ATMPs

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

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

Priority Medicines (PRIME)

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

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

Organisational, regulatory and methodological matters (section 7)

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

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

Any other business (section 8)

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

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