



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2023
EMA/CAT/329617/2023
Human Medicines Division

Committee for Advanced Therapies (CAT)

Agenda for the meeting on 12-14 July 2023

Chair: Ilona Reischl; Vice-Chair: vacant

12 July 2023, 14:00 – 18:30, room 01C

13 July 2023, 09:00 – 18:30, room 01C

14 July 2023, 09:00 – 13:00, room 01C

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 this agenda 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, this agenda is a working document primarily designed for CAT members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda 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).



Table of contents

1.	Introduction	5
1.1.	Welcome and declarations of interest of members, alternates and experts.....	5
1.2.	Adoption of agenda	5
1.3.	Adoption of the minutes	5
2.	Evaluation of ATMPs	5
2.1.	Opinions	5
2.2.	Oral explanations	5
2.3.	Day 180 list of outstanding issues	5
2.4.	Day 120 list of questions	5
2.5.	Day 80 assessment reports	5
2.6.	Update on ongoing initial applications.....	5
2.7.	New applications	6
2.8.	Withdrawal of initial marketing authorisation application	6
2.9.	Re-examination of initial application procedures under Article 9(2) of Regulation No. 726/2004	6
2.10.	Companion diagnostics.....	6
2.10.1.	Initial consultation	6
2.10.2.	Follow-up consultation.....	6
2.11.	Type II variations and variations of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008	6
2.11.1.	Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0034	6
2.11.2.	Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0021	6
2.11.3.	CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0018	7
2.11.4.	CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0019	7
2.11.5.	Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0069	7
2.11.6.	Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/II/0017	7
2.11.7.	Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0040.....	7
2.12.	Extension applications.....	8
2.13.	Other Post-Authorisation Activities	8
2.13.1.	Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/REC/014	8
2.13.2.	ROCTAVIAN - valoctocogene roxaparvovec - Orphan - EMEA/H/C/005830/MEA/003.1.....	8
2.13.3.	Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/REC/013.1.....	8
2.13.4.	Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/PSA/S/0102.2.....	8
2.14.	GMP and GCP inspections requests.....	9

3.	Certification of ATMPs	9
3.1.	Opinion	9
3.2.	Day 60 Evaluation Reports.....	9
3.3.	New Applications	9
4.	Scientific Recommendation on Classification of ATMPs	9
4.1.	New requests – Appointment of CAT Coordinator	9
4.2.	Day 30 ATMP scientific recommendation	10
4.2.1.	Neonatal human dermal fibroblast (nHDF) cell-produced living extracellular vascular tissue	10
4.2.2.	Bovine collagen membrane seeded with allogeneic mesenchymal stem cells derived from adipose tissue (ADSC)	10
4.2.3.	Lymphocytic Choriomeningitis Virus (LCMV) reassortant strain exerting efficient anti-tumoral activity	10
4.2.4.	Human Cardiomyocytes (CM), Human Stromal Cells (StC)	10
4.2.5.	Doruxapapogenum ralaplasmidum (pGX3024), DNA plasmid encoding E6 and E7 proteins of HPV6 and HPV11	10
4.2.6.	TERT Ribonucleoprotein	10
4.3.	Day 60 revised scientific recommendation (following list of questions)	11
4.4.	Finalisation of procedure	11
4.5.	Follow-up and guidance.....	11
5.	Scientific Advice	11
5.1.	New requests - appointment of CAT Rapporteurs	11
5.1.1.	Ongoing scientific advice procedures - Appointment of CAT Peer Reviewers	11
5.1.2.	Scientific advice procedures starting at the next SAWP meeting	11
5.2.	Procedures discussed at SAWP – 1st reports, D40 JRs, LoIs	12
5.3.	Finalisation of D70 procedures – feedback from the discussion meeting.....	12
5.4.	Final Advice Letters for procedures finalised the previous month.....	12
6.	Pre-Authorisation Activities	12
6.1.	Paediatric investigation plans.....	12
6.2.	ITF briefing meetings in the field of ATMPs	12
6.3.	Priority Medicines (PRIME) – Eligibility requests.....	12
6.3.1.	Month 0 - Start of the procedure	12
6.3.2.	Month 1 – Discussion of eligibility	12
6.3.3.	Month 2 – Recommendation of eligibility.....	12
6.3.4.	Ongoing support.....	12
7.	Organisational, regulatory and methodological matters	13
7.1.	Mandate and organisation of the CAT	13
7.1.1.	CAT membership	13

7.1.2.	Vote by proxy	13
7.1.3.	Election of CAT Vice-chairperson.....	13
7.1.4.	CAT Strategic Review & Learning meeting (SRLM) under the Spanish presidency, 25-27 October 2023 Madrid (Spain)	13
7.1.5.	Meeting schedule for 2024.....	13
7.1.6.	Feedback from the SciCoBo meeting of 23 June 2023.....	13
7.1.7.	CAT members' participation in drafting group, work plan and other cross-committee activities	13
7.1.8.	CAT Strategic Review & Learning meeting (SRLM) under the Swedish Presidency, 4 - 5 May 2023, Uppsala (Sweden)	13
7.1.9.	CAT members participation and voting	14
7.2.	Coordination with EMA Scientific Committees.....	14
7.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	14
7.4.	Cooperation with the EU regulatory network.....	14
7.5.	Cooperation with international regulators.....	14
7.5.1.	ATMP cluster teleconference with US-FDA, Health Canada and PMDA (Japan).....	14
7.5.2.	ATMP cluster teleconference with US-FDA, Health Canada and PMDA (Japan).....	14
7.6.	CAT work plan	14
7.6.1.	CAT workplan 2023.....	14
7.6.2.	Guideline of quality, non-clinical and clinical requirements for investigational ATMPs in clinical trials	14
7.7.	Planning and reporting	15
7.7.1.	EMA-FDA Q&A on PRIME/Breakthrough Therapies.....	15
7.7.2.	Quality Innovation Group (QIG).....	15
7.8.	Others	15
7.8.1.	Webinar – EU Network awareness session on Companion Diagnostics (CDx)	15
7.8.2.	Academic ATMP Pilot	16
7.8.3.	CASSS Cell and Gene Therapy Products symposium.....	16
7.8.4.	10th Industry Stakeholder platform on Research and Development support.....	16
8.	Any other business	16
9.	Explanatory notes	17

1. Introduction

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CAT plenary session to be held 12-14 July 2023. See July 2023 CAT minutes (to be published post September 2023 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 12-14 July 2023 meeting

1.3. Adoption of the minutes

CAT minutes for 14-17 June 2023 meeting

2. Evaluation of ATMPs

2.1. Opinions

No items

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/0034

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeklen

Scope: Quality, Opinion

Action: for adoption

Request for supplementary information adopted on 16.06.2023.

2.11.2. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0021

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, Request for supplementary information

Action: for adoption

2.11.3. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0018

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, Request for supplementary information

Action: for adoption

2.11.4. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0019

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, opinion

Action: for adoption

2.11.5. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0069

Novartis Europharm Limited

Rapporteur: Rune Kjekken

Scope: Quality, opinion

Action: for adoption

Request for supplementary information adopted on 15.06.2023, 17.05.2023.

2.11.6. Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/II/0017

Orchard Therapeutics (Netherlands) B.V.

Rapporteur: Netherlands

Scope: Quality, Opinion

Action: for adoption

2.11.7. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0040

Novartis Europharm Limited

Rapporteur: Netherlands

Scope: Safety, Request for supplementary information

Update of sections 4.4 and 5.1 of the SmPC in order to add a new warning and precaution capturing the theoretical risk of tumorigenicity as a result of vector integration and to include a new statement indicating random instances of vector integration are possible; based on final results from studies 2220205 and 2220117, and literature. The Package Leaflet is updated accordingly. The RMP version 3 has also been submitted.

Action: for adoption

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/014

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality

Action: for adoption

2.13.2. ROCTAVIAN - valoctocogene roxaparvovec - Orphan - EMEA/H/C/005830/MEA/003.1

BioMarin International Limited

Rapporteur: Violaine Closson Carella

Scope: Safety

MAH's response to MEA 003 [Impact of BMN 270 on fertility, general toxicity, teratology, and germline transmission in females of childbearing potential] as adopted in February 2023.

Action: for adoption

2.13.3. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/REC/013.1

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Clinical

MAH's Response to REC 013 [Study KT-US-482-0147 (ZUMA-26): to study and analyse the impact of tumour CD19 expression on response to treatment using a quantitative flow cytometry method. A phase II open label, multicentre study exploring the efficacy of axicabtagene ciloleucel and its association with the CD19 expression profile in large B-cell lymphoma in subjects whose disease has relapsed 12 or more months after first-line chemoimmunotherapy] as adopted in February 2023

Action: for adoption

2.13.4. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/PSA/S/0102.2

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus; PRAC Rapporteur: Marie Louise Schougaard Christiansen

Scope: Substantial amendment to a protocol for a long-term, non-interventional study of recipients of Yescarta for treatment of relapsed or refractory Diffuse Large B-cell Lymphoma and Primary Mediastinal B-cell Lymphoma [MAH's further response to PSA/S/0102]: feedback from the PRAC discussion

Action: for information

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

Deadline for submission of new requests: 27.07.2023. New requests will appear in the agenda of the August 2023 CAT meeting.

Timetable:

-Start of the procedure:	11.08.2023
-EMA Coordinator's draft report:	22.08.2023
-CAT Coordinator's comments:	30.08.2023
-Revised scientific recommendation:	01.09.2023
-CAT's discussion of scientific recommendation:	08.09.2023

4.1. New requests – Appointment of CAT Coordinator

No items

4.2. Day 30 ATMP scientific recommendation

4.2.1. Neonatal human dermal fibroblast (nHDF) cell-produced living extracellular vascular tissue

For regeneration, repair, or replacement of damaged blood vessels in patients with end-stage renal disease (ESRD), needing arterial bypass and with vascular trauma

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Bovine collagen membrane seeded with allogeneic mesenchymal stem cells derived from adipose tissue (ADSC)

Treatment of patients who are undergoing a surgical procedure of coronary artery bypass grafting and have ischemic left ventricular dysfunction

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Lymphocytic Choriomeningitis Virus (LCMV) reassortant strain exerting efficient anti-tumoral activity

Treatment of metastatic solid cancers

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Human Cardiomyocytes (CM), Human Stromal Cells (StC)

Treatment of heart failure

Scope: ATMP scientific recommendation

Action: for adoption

4.2.5. Doruxapapogenum ralaplasmidum (pGX3024), DNA plasmid encoding E6 and E7 proteins of HPV6 and HPV11

Treatment of recurrent respiratory papillomatosis

Scope: ATMP scientific recommendation

Action: for adoption

4.2.6. TERT Ribonucleoprotein

Treatment of cancer

Scope: ATMP scientific recommendation

Action: for adoption

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

No items

4.4. Finalisation of procedure

No items

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:	03-06.07.2023
- Appointment of CAT Peer Reviewers:	12-14.07.2023
- SAWP first reports:	21.08.2023
- CAT Peer Reviewer comments (NC/C)	25.08.2023
- CAT Peer Reviewer comments (Q)	30.08.2023
- Discussion at SAWP:	28-31.08.2023
- Discussion at CAT and feedback to SAWP:	06-08.09.2023

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	28-31.08.2023
- Appointment of CAT Peer Reviewers:	06-08.09.2023
- SAWP first reports:	18.09.2023
- CAT Peer Reviewer comments (NC/C)	22.09.2023
- CAT Peer Reviewer comments (Q)	27.09.2023
- Discussion at SAWP:	25-28.09.2023
- Discussion at CAT and feedback to SAWP:	04-06.10.2023

- 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:	03-06.07.2023
SAWP recommendation:	31.08.2023
CAT recommendation:	08.09.2023
CHMP adoption of report and final recommendation:	14.09.2023

6.3.2. Month 1 – Discussion of eligibility

6.3.3. Month 2 – Recommendation of eligibility

No items

6.3.4. Ongoing support

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT membership

Action: for information

7.1.2. Vote by proxy

Action: for information

7.1.3. Election of CAT Vice-chairperson

Action: for information

7.1.4. CAT Strategic Review & Learning meeting (SRLM) under the Spanish presidency, 25-27 October 2023 Madrid (Spain)

CAT: Sol Ruiz, Marcos Timon

Scope: Topics for discussion at the upcoming SRLM

Action: for discussion

7.1.5. Meeting schedule for 2024

Scope: Information on the dates of face to face and online only meetings for 2024

Action: for information

7.1.6. Feedback from the SciCoBo meeting of 23 June 2023

CAT: Ilona Reischl

Scope: Feedback from the SciCoBo meeting of 23.06.2023

Action: for information

7.1.7. CAT members' participation in drafting group, work plan and other cross-committee activities

Scope: Nomination of CAT members replacing Carla Herberts

Action: for discussion

7.1.8. CAT Strategic Review & Learning meeting (SRLM) under the Swedish Presidency, 4 - 5 May 2023, Uppsala (Sweden)

CAT: Maria Lüttgen

Scope: Minutes of the CAT-COMP SRLM

Action: for information

7.1.9. CAT members participation and voting

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

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

CAT: Ilona Reischl

Scope: Update on the teleconference that took place on 22.06.2023

Action: for information

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

CAT: Ilona Reischl

Scope: Agenda of the teleconference that took place on 14.09.2023

Action: for information

7.6. CAT work plan

7.6.1. CAT workplan 2023

Scope: half-year review

Action: for discussion

7.6.2. Guideline of quality, non-clinical and clinical requirements for investigational ATMPs in clinical trials

CAT topic leads: Ilona Reischl, Rune Kjekken, Claire Beuneu, Alessandro Aiuti

Scope: Feedback from drafting group meeting

Action: for discussion

A drafting group meeting, open to all CAT members, will take place on 13.07.2023 (afternoon). The aim is to discuss and align the quality, non-clinical and clinical parts of the guideline taking into account the comments received.

7.7. Planning and reporting

7.7.1. EMA-FDA Q&A on PRIME/Breakthrough Therapies

QIG chair: Marcel Hoefnagel

Scope: Final EMA-FDA Q&A on PRIME/Breakthrough Therapies

Action: for adoption

7.7.2. Quality Innovation Group (QIG)

QIG chair: Marcel Hoefnagel

Scope: Update from the chair of the Quality Innovation Group (QIG)

Action: for information

7.8. Others

7.8.1. Webinar – EU Network awareness session on Companion Diagnostics (CDx)

Scope: CDx Awareness session – 14 July, 11.00-13.00

Action: for information

The session, organised by EMA, welcomes the participation of Jörg Engelbergs and Hilke Zander (PEI), Ilona Reischl (AGES MEA), Olga Kholmanskikh Van Criecken (FAMHP), Ingrid Wang and Alben Mihailova (Statens legemiddelverk)

Topics:

- case studies relating to companion diagnostics (CDx), including both co-developed and follow-on cases within the context of the consultation procedure by the Notified Bodies with the medicines regulators;
- lessons learned from analytical/clinical performance to form an opinion on the suitability of CDx.

Note: Interested CAT member can join this Awareness session in person. Registration is required (Deadline for registration: 13 July 2023)

7.8.2. Academic ATMP Pilot

Scope: Status overview of the pilot and draft Executive Director Decision on Fee reduction for Academic ATMP Pilot

Action: for discussion

7.8.3. CASSS Cell and Gene Therapy Products symposium

CAT: Ilona Reischl

Scope: Feedback from the CASSS symposium held in Bethesda (USA) on 27-29.06.2023

Action: for information

7.8.4. 10th Industry Stakeholder platform on Research and Development support

CAT: Ilona Reischl

Scope: Feedback from the meeting topic on scientific advice for medicinal product developments comprising of drug-device combinations and drug-companion diagnostic combinations

Action: for information

8. Any other business

No items

Date of next CAT meeting:

06-08 September 2023

9. Explanatory notes

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

Abbreviations / Acronyms

AAV: Adeno-Associated Virus
AR: Assessment Report
ATMP: Advanced Therapy Medicinal Product
BWP: Biologics Working Party
CAT: Committee for Advanced Therapies
CHMP: Committee for Medicinal Product for Human Use
COMP: Committee for Orphan Medicinal Products
CTFG: Clinical Trial Facilitation Group
DG: Drafting Group
EC: European Commission
EU NTC: European Union Network Training Centre
ERA: Environmental Risk Assessment
FDA: Food and Drug Administration
FL: Final Letter
GCG: Guideline Consistency Group
GCP: Good Clinical Practice
GLP: Good Laboratory Practice
GMO: Genetically-modified organism
GMP: Good Manufacturing Practice
GTMP: Gene Therapy Medicinal Product
HTA: Health Technology Assessment Bodies
HSPC: Hematopoietic Stem and Progenitor Cells
ITF: Innovative Task Force
JR: Joint Report
LoOI: List of outstanding issues
LoQ: List of questions
MA: Marketing Authorisation
MAA: Marketing Authorisation Application
MAH: Marketing Authorisation Holder
MNAT: Multinational assessment team
MSC: Mesenchymal stem cells
PDCO: Paediatric Committee
PMDA: Pharmaceuticals and Medical Devices Agency (Japan)
PIP: Paediatric Investigation Plan
PL: Package leaflet
PRAC: Pharmacovigilance and Risk Assessment Committee #

PRIME: Priority Medicines
 QRD: Quality review of documents
 RMP: Risk Management Plan
 RP: Reflection paper
 RSI: Request for supplementary information
 SAs: Scientific Advices
 SAG-O: Scientific Advisory Group Oncology
 SAWP: Scientific Advice Working Party
 SR: Summary Report
 SME: Small and medium size enterprises
 SmPC: Summary of Products Characteristics
 TT: Timetable

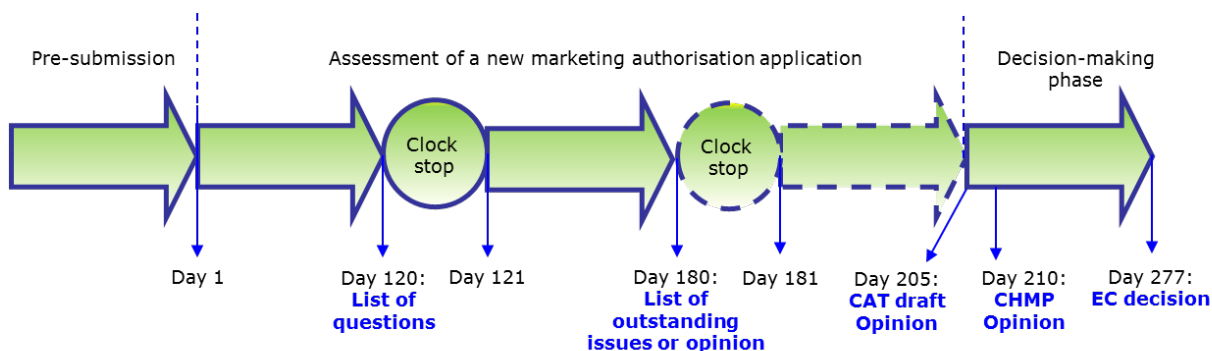
Evaluation of ATMPs (section 2)

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/