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SCIENCE MEDICINES HEALTH

19 June 2024
EMA/CAT/283543/2024
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 19-21 June 2024

Chair: Ilona Reischl; Vice-Chair: Kieran Breen

19 June 2024, 14:00 – 18:30, room 1C

20 June 2024, 09:00 – 18:30, room 1C

21 June 2024, 09:00 – 13:00, room 1C

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).



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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 19-21 June 2024. See June 2024 CAT minutes (to be published post July 2024 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 19-21 June 2024 meeting

1.3. Adoption of the minutes

CAT minutes for 22-25 May 2024 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

2.5.1. Obecabtagene autoleucel - PRIME - Orphan - EMEA/H/C/005907

Aulus GmbH; Treatment of patients with relapsed or refractory B cell precursor acute lymphoblastic leukaemia (ALL)

Scope: Day 80 assessment report

Action: for information

2.5.2. Mozafancogene autotemcel - PRIME - Orphan - EMEA/H/C/005537

Rocket Pharmaceuticals B.V.; Treatment of paediatric patients with Fanconi Anaemia Type A

Scope: Day 80 assessment report

Action: for information

2.6. **Update on ongoing initial applications**

No items

2.7. **New applications**

2.7.1. DorocubiceL / Allogeneic umbilical cord-derived CD34+ cells, non-expanded - PRIME - Orphan - EMEA/H/C/005772

Accelerated assessment

Cordex Biologics International Limited; Treatment of adult patients with haematological malignancies

Scope: Timetable for assessment

Action: for adoption

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/0048

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeklen

Scope: Quality, request for supplementary information

Action: for adoption

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

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 24.05.2024, 16.02.2024.

2.11.3. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0037/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, request for supplementary information

Action: for adoption

Request for supplementary information adopted on 15.03.2024.

2.11.4. Casgevy - Exagamglogene autotemcel - Orphan - EMEA/H/C/005763/II/0003/G

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, request for supplementary information

Action: for adoption

2.11.5. [Imlygic - Talimogene laherparepvec - EMEA/H/C/002771/II/0066/G](#)

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen

Scope: Clinical, opinion

A grouped application consisting of two Type II variations, as follows:

C.I.13: Submission of the final report from Study 5 (added in EMEA-001251-PIP01-11-M04) titled "Exposure-Response analysis of Talimogene Laherparepvec for adult subjects with melanoma from Study 20120324 and comparison to pediatric subjects' data from Study 20110261 in support of a pediatric investigational plan"

C.I.13: Submission of the final report from Study 6 (added in EMEA-001251-PIP01-11-M04) titled "Efficacy Analysis of the Young Adult Melanoma Subgroup (from 18 to less than 36 years of age) From 4 Talimogene Laherparepvec Monotherapy Studies Using Bayesian Extrapolation With Data Collected From the Older Adult Melanoma Subgroup (from 36 years of age and older) to Support Extrapolation of Efficacy From Adult Patient With Advanced Melanoma to Adolescent Patients With Advanced Melanoma".

Action: for adoption

2.11.6. [Yescarta - Axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0075/G](#)

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus; PRAC Rapporteur: Karin Erneholm

Scope: Clinical, request for supplementary information

Grouped application comprising two type II variations as follows:

C.I.13 - Submission of the final report from study KTE-C19-101 (ZUMA-1) listed as a category 3 study in the RMP. This is a Phase 1/2 Multicenter Study Evaluating The Safety And Efficacy Of Kte-C19 In Subjects With Refractory Aggressive Non-Hodgkin Lymphoma.

C.I.13 - Submission of the final report from study KTE-C19-106 (ZUMA-6) listed as a category 3 study in the RMP. This is a Phase 1-2 Multi-Center Study Evaluating The Safety And Efficacy Of Kte-C19 In Combination With Atezolizumab In Subjects With Refractory Diffuse Large B-Cell Lymphoma (Dlbcl).

The RMP version 9.2 has also been submitted.

Action: for adoption

2.11.7. [Tecartus; Yescarta - Axicabtagene ciloleucel; Brexucabtagene autoleucel - Orphan - EMEA/H/C/WS2689](#)

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, request for supplementary information

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Abecma - Idecabtagene vicleucel - Orphan - EMEA/H/C/004662/REC/021

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjekken

Scope: Quality, opinion

Action: for adoption

2.13.2. Abecma - Idecabtagene vicleucel - Orphan - EMEA/H/C/004662/REC/022

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjekken

Scope: Clinical

From II/0031:

Recommendation #19: The MAH should submit, within a time period of two months, a draft protocol and SAP for a prospective observational study assessing whether potentially suboptimal bridging therapy in high-risk patients observed in the KarMMa-3 study may be alleviated in a real-world setting. This draft should then be discussed with CAT/CHMP, so that a decision can be made on whether such a prospective study should be initiated, in its initial or amended form.

Action: for adoption

2.13.3. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/ANX/003.2

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Pharmacovigilance

MAH Response to ANX 003.1 [PASS Study 68284528MMY4004] RSI as adopted in January 2024.

Title: An Observational Post-authorization Safety Study to Evaluate the Safety of Multiple Myeloma Patients Treated with Ciltacabtagene Autoleucel.

Action: for adoption

2.13.4. Hemgenix - Etranacogene dezaparvovec - Orphan - EMEA/H/C/004827/REC/003.1

CSL Behring GmbH

Rapporteur: Silke Dorner

Scope: Quality

Action: for adoption

2.13.5. Luxturna - Voretigene neparvovec - Orphan - EMEA/H/C/004451/ANX/011.1

Novartis Europharm Limited

Rapporteur: Sol Ruiz

Scope: Pharmacovigilance

Fourth interim analysis for PASS CLTW888A12401 (PERCEIVE): A Post-Authorization, Multicenter, Multinational, Longitudinal, Observational Safety Registry Study for Patients Treated with Voretigene Neparvovec.

The objective of this post-authorization observational study is to collect long-term safety information (i.e. for 5 years after treatment) associated with voretigene neparvovec (vector and/or transgene), its subretinal injection procedure, the concomitant use of corticosteroids, or a combination of these procedures and products.

Action: for adoption

2.13.6. 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

Action: for adoption

Request for supplementary information adopted on 24.05.2024.

2.13.7. Tecartus - Brexucabtagene autoleucel - Orphan - EMEA/H/C/005102/ANX/011.2

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Clinical & Pharmacovigilance, request for supplementary information

REVISED PROTOCOL combining STUDY No. KTE-EU-472-6036 & KT-EU-474-6644

Joint protocol combining studies KTE-EU-472-6036 & KT-EU-474-6644 as follows:
KT-EU-472-6036: Long-term, non-interventional study of recipients of Tecartus for treatment of adult patients with relapsed or refractory (r/r) mantle cell lymphoma (MCL) or adult patients with r/r B-cell precursor acute lymphoblastic leukemia (ALL).

[From Initial MAA (ANX 002): Study No. KTE-EU-472-6036: Long-term, non-interventional study of recipients of Tecartus for treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

From II-008-G (ANX 011): KT-EU-474-6644: Long-term, non-interventional study of the treatment by Tecartus of adult patients with relapsed or refractory (r/r) B-cell precursor acute lymphoblastic leukemia (ALL).]

Action: for adoption

2.13.8. Zolgensma - Onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/P46/023

Novartis Europharm Limited

Rapporteur: Emmely de Vries

Scope: Clinical

Paediatric studies submitted in accordance with Article 46 of Regulation (EC) No1901/2006, as amended.

Clinical study report - Study No. COAV101A1IC01 (OFELIA): Phase IV Open-label, single-arm, single-dose, multicentre study to evaluate the safety, tolerability and efficacy of gene replacement therapy with intravenous OAV101(AVXS101) in paediatric patients from Latin America with spinal muscular atrophy (SMA).

Action: for adoption

Request for supplementary information adopted on 15.03.2024.

2.13.9. Axicabtagene ciloleucel - YESCARTA (CAP) - EMEA/H/C/004480/SDA/015.1; Brexucabtagene autoleucel - TECARTUS (CAP) - EMEA/H/C/005102/SDA/013.1; Ciltacabtagene autoleucel - CARVYKTI (CAP) - EMEA/H/C/005095/SDA/016.1; Idcabtagene vicleucel - ABECMA (CAP) - EMEA/H/C/004662/SDA/020.1; Lisocabtagene maraleucel - BREYANZI (CAP) - EMEA/H/C/004731/SDA/019.1; Tisagenlecleucel - KYMRIAH (CAP) - EMEA/H/C/004090/SDA/024.1;

Bristol-Myers Squibb Pharma EEIG (Abecma, Breyanzi), Kite Pharma EU B.V. (Tecartus, Yescarta), Janssen-Cilag International NV (Carvykti), Novartis Europharm Limited (Kymriah)

CAT Rapporteurs: Rune Kjekken (Kymriah, Abecma), Jan Mueller-Berghaus (Carvykti, Tecartus, Yescarta), Concetta Quintarelli (Breyanzi)

PRAC Rapporteur: Ulla Wändel Liminga

Scope: PRAC recommendation on signal of secondary malignancies of T-cell origin (EPITT 20040)

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

Timetable:

-Start of the procedure:	21.06.2024
-EMA Coordinator's draft report:	05.07.2024
-CAT Coordinator's comments:	10.07.2024
-Revised scientific recommendation:	12.07.2024
-CAT's discussion of scientific recommendation:	19-07.2024

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Autologous CD34 positive cells

For regeneration purposes, to replace damaged tissue in blood and other tissues (adipogenic, osteogenic, chondrogenic, myogenic and angiogenic)

CAT Coordinator: Kieran Breen / Federica Chiara

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. Autologous antigenic tumor fragments isolated from patient's circulating cancer cells

For treatment of cancer patients suffering from blood cancer

CAT Coordinator: Emmely de Vries

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Autologous antigenic tumor fragments isolated from patient's circulating cancer cells

For treatment of cancer patients suffering from cancer of epithelial origin

CAT Coordinator: Emmely de Vries

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.4. Autologous antigenic tumor fragments isolated from patient's circulating cancer cells

For treatment of cancer patients suffering from melanoma

CAT Coordinator: Emmely de Vries

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.5. Autologous antigenic tumor fragments isolated from patient's circulating cancer cells

For treatment of cancer patients suffering from sarcoma

CAT Coordinator: Emmely de Vries

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Autologous antigen specific Cytotoxic T Lymphocytes

For treatment of cancer patients

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Autologous dendritic cells against tumour peptides

For treatment of cancer patients

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Autologous macrophages

For treatment of cancer patients

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Autologous cytotoxic natural killer (NK) cells

For treatment of cancer patients

Scope: ATMP scientific recommendation

Action: for adoption

4.2.5. Autologous plasma cells producing antibodies against tumour antigen

For treatment of cancer patients

Scope: ATMP scientific recommendation

Action: for adoption

4.2.6. Autologous adipose-derived stromal vascular fraction cells

For chronic pain relief

Scope: ATMP scientific recommendation

Action: for adoption

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

For treatment of non small cell lung cancer

Scope: ATMP scientific recommendation

Action: for adoption

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

For treatment of primary hyperoxaluria

Scope: ATMP scientific recommendation

Action: for adoption

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

4.4. Finalisation of procedure

4.4.1. MicroRNA against BCL2 anti-apoptotic messenger RNA

For treatment of cancer patients

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

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

For treatment of haematological malignancies and glioblastoma

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.3. Stromal vascular fraction

For treatment of osteoarthritis

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.5. Follow-up and guidance

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:	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

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	08-11.07.2024
- Appointment of CAT Peer Reviewers:	17-19.07.2024
- SAWP first reports:	26.08.2024
- CAT Peer Reviewer comments (NC/C):	30.08.2024
- CAT Peer Reviewer comments (Q):	04.09.2024
- Discussion at SAWP:	02-05.09.2024
- Discussion at CAT and feedback to SAWP:	11-13.09.2024

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

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

No items

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

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:	10-13.06.2024
SAWP recommendation:	11.07.2024
CAT recommendation:	19.07.2024
CHMP adoption of report and final recommendation:	25.07.2024

6.3.2. Month 1 – Discussion of eligibility

No items

6.3.3. Month 2 – Recommendation of eligibility

6.3.4. Ongoing support

No items

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT membership

Action: for information

7.1.2. Vote by proxy

Action: for information

7.1.3. Impact of Hopveus judgment on EMA scientific meetings

Action: for information

7.2. Coordination with EMA Scientific Committees

7.2.1. Joint resolution regarding scientific committee conduct

Action: for action

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

7.3.1. Update to the main changes for the single-arm trials reflection paper following public consultation

CAT: Jan Mueller-Berghaus

Action: for information

7.4. Cooperation with the EU regulatory network

7.4.1. CAT/RWE Quarterly Update

Scope: To present the RWE/DARWIN quarterly update

Action: for information

7.5. Cooperation with international regulators

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

CAT: Ilona Reischl

Scope: Agenda of the teleconference of 27.06.2024

Action: for discussion

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

CAT: Pille Säälük

Scope: Feedback from the in-person IPRP meeting of 29.05.2024

Action: for information

7.6. CAT work plan

7.6.1. Guideline on quality, non-clinical and clinical requirements for investigational ATMPs in clinical trials

CAT: Ilona Reischl

Scope: Overview of comments from the second public consultation

Action: for discussion

Note: A discussion of the general comments will take place during the plenary meeting, followed by quality and non-clinical drafting group meetings on Thursday 20 June 2024 .

7.7. Planning and reporting

No items

7.8. Others

7.8.1. International Society for cell and gene therapy (ISCT) Annual meeting

CAT: Pille Säälük

Scope: Feedback from the 2nd Annual Global Regulators Summit (28.05.2024) and the ISCT Annual meeting (29.05.2024-01.06.2024)

Action: for information

7.8.2. CASSS Cell and Gene Therapy Products meeting

CAT: Ilona Reischl

Scope: Feedback from the CASSS Cell and Gene Therapy Products meeting (11-13.06.2024)

Action: for information

7.8.3. EU Regulation on standards of quality and safety for substances of human origin intended for human application

Scope: Conference, 24 June 2024

Action: for information

Note: the conference will be web-streamed

7.8.4. Social media guidance for chairs and members of Committees

Scope: Presentation from EMA Press Office

Action: for information

8. Any other business

No items

Date of next CAT meeting:

17-19 July 2024

9. 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](#)

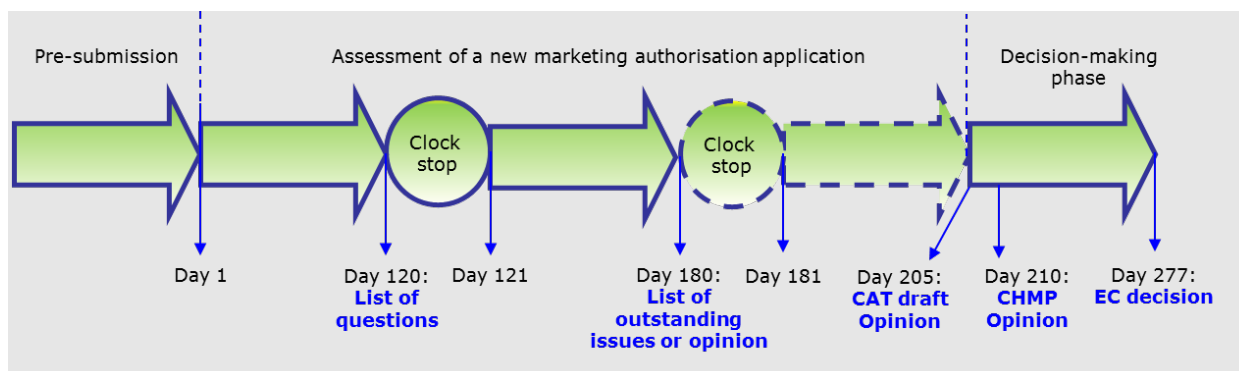
Evaluation of ATMPs (section 2)

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/