



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 February 2023
EMA/CAT/43624/2023
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 15-16 February 2023

Chair: Ilona Reischl; Vice-Chair: vacant

15 February 2023, 14:00 – 18:30, virtual meeting

16 February 2023, 09:00 – 18:30, virtual 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 ongoing 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 15-17 February 2023. See February 2023 CAT minutes (to be published post March 2023 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 15-17 February 2023 meeting

1.3. Adoption of the minutes

CAT minutes for 18-21 January 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

2.7.1. Exagamglogene autotemcel - PRIME - Orphan - EMEA/H/C/005763

Vertex Pharmaceuticals (Ireland) Limited; Treatment of transfusion-dependent β -thalassemia and sickle cell disease

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. GMP and GCP inspections requests

No items

2.11. Type II variations and variations of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

2.11.1. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0022/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjekken

Scope: Quality, Opinion

Action: for adoption

2.11.2. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0005

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli, PRAC Rapporteur: Gabriele Maurer

Scope: Clinical Pharmacology, Efficacy and Safety, Request for supplementary information

Extension of indication to include treatment of adult patients with Second-line (2L) Transplant Intended (TI) Large B-Cell Lymphoma (LBCL) for Beyanzi, based on interim analyses from pivotal study JCAR017-BCM-003; this is a global randomized multicentre Phase III Trial to compare the efficacy and safety of JCAR017 to standard of care in adult subjects with high-risk, transplant-eligible relapsed or refractory aggressive B-cell Non-

Hodgkin Lymphomas (TRANSFORM). As a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted.

Action: for adoption

Request for supplementary information adopted on 09.09.2022.

2.11.3. [Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0007/G](#)

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, Opinion

Action: for adoption

Request for supplementary information adopted on 09.12.2022.

2.11.4. [Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0009](#)

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, Opinion

Action: for adoption

Request for supplementary information adopted on 09.12.2022.

2.11.5. [Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0013/G](#)

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, Request for supplementary information

Action: for adoption

2.11.6. [Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/II/0011/G](#)

Orchard Therapeutics (Netherlands) B.V.

Rapporteur: Carla Herberts, PRAC Rapporteur: Gabriele Maurer

Scope: Clinical & Quality, Opinion

Update of sections 4.2, 4.4, 4.5, 4.8, and 5.1 of the SmPC in order to remove the option of using bone marrow (BM) as a cellular source for the manufacture of Libmeldy, as a result of an evolution of clinical practices and also to rationalise the manufacture of this highly

complex medicinal product; the Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to remove ANX/002 from the Annex II and to introduce minor editorial changes to the product information (PI). The RMP version 1.3 has also been submitted.

Action: for adoption

Request for supplementary information adopted on 09.12.2022.

2.11.7. Upstaza - eladocagene exuparvec - Orphan - EMEA/H/C/005352/II/0004/G

PTC Therapeutics International Limited

Rapporteur: Maura O'Donovan

Scope: Quality, Opinion

Action: for adoption

Request for supplementary information adopted on 09.12.2022.

2.11.8. Upstaza - eladocagene exuparvec - Orphan - EMEA/H/C/005352/II/0005/G

PTC Therapeutics International Limited

Rapporteur: Maura O'Donovan

Scope: Quality, Opinion

Action: for adoption

2.11.9. Tecartus - brexucabtagene autoleucel; Yescarta - axicabtagene ciloleucel; - Orphan - EMEA/H/C/WS2389/G

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 - idcabtagene vicleucel - Orphan - EMEA/H/C/004662/REC/012.1

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeklen

Scope: Quality

Action: for adoption

2.13.2. [Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/REC/013.1](#)

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjekken

Scope: Quality

Action: for adoption

2.13.3. [Carvykti - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/REC/011](#)

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

2.13.4. [Carvykti - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/REC/012](#)

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

2.13.5. [Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/R/0068](#)

Novartis Europharm Limited

Rapporteur: Rune Kjekken, Co-Rapporteur: Dariusz Sladowski, PRAC Rapporteur: Gabriele Maurer

Scope: 5-year Renewal of Marketing Authorisation, Opinion

Action: for adoption

2.13.6. [Roctavian - valoctocogene roxaparvovec - Orphan - EMEA/H/C/005830/MEA/003](#)

BioMarin International Limited

Rapporteur: Violaine Closson Carella

Scope: Pharmacovigilance

To inform the impact of BMN 270 on fertility, general toxicity, teratology, and germline transmission in females of childbearing potential and establish an adequate waiting period after BMN 270 infusion following which female patients can become pregnant.

Action: for adoption

2.13.7. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/R/0056

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Claire Beuneu, PRAC Rapporteur: Anette Kirstine Stark

Scope: 5-year Renewal of Marketing Authorisation, Request for supplementary information

Action: for adoption

2.13.8. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/REC/013

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Scope: Clinical, Request for supplementary information

Action: for adoption

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

4. Scientific Recommendation on Classification of ATMPs

Timetable:

-Start of the procedure:	22.02.2023
-EMA Coordinator's draft report:	03.03.2023
-CAT Coordinator's comments:	08.03.2023
-Revised scientific recommendation:	17.03.2023
-CAT's discussion of scientific recommendation:	24.03.2023

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Lyophilized supernatant of a pathogen inactivated and gamma sterilized platelet lysate

Treatment of topical treatment of skin ulcers

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. Autologous intestinal organoid derived from adult stem cells from intestinal epithelial tissue

Treatment of intractable ulcer

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Autologous chondrocytes cultured in hyaluronan-derived scaffold

Repair of cartilage defects

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Umbilical Cord Wharton Jelly-derived mesenchymal stem cells (MSCs) cells

Treatment of spinal cord injury; drug resistant epilepsy; hypoxia ischemia encephalopathy

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Bladder acellular matrix (BAM) based scaffold seeded with allogenic or autologous adipose-derived stromal cells

Treatment of urinary bladder wall augmentation in patients with small capacity high pressure urinary bladder

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Fibrin gel containing autologous leucocyte- and platelet-rich plasma, autologous thrombin, and ascorbic acid

Treatment of wounds

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Ex-vivo expanded allogeneic human corneal endothelial cells

Treatment of diseases of the corneal endothelium

Scope: ATMP scientific recommendation

Action: for adoption

4.2.5. Recombinant Adeno-Associated Viral Vector expressing a codon optimised human RPGR gene (rAAV2tYF-GRK1-RPGR)

Treatment of X-linked retinitis pigmentosa (XLRP) caused by mutations in the RPGR gene

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

4.4.1. Autologous platelet concentrate, consisting of a fibrin matrix enriched with platelets, leukocytes and of cytokines and growth factors

Treatment of patients with critical limb ischemia, in combination with mechanical lower limb revascularization (angioplasty)

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.2. Autologous adipose tissue derived progenitor cells in biodegradable chemically crosslinked hydrogel

Treatment of subacute spinal cord injury in adults with a complete lesion (ASIA A score)

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.3. Genetically engineered E. coli strain containing a plasmid expressing CRISPR-Cas against clbA, clbB and clbC

Prevention of disease progression in Familial Adenomatous Polyposis (FAP)

Scope: European Commission raised comments. Updated ATMP scientific recommendation

Action: for adoption

4.4.4. Mitochondria isolated from allogeneic umbilical-cord mesenchymal stem cells

Treatment of Polymyositis/Dermatomyositis

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.5. Macrophage-Drug Conjugate (MDC) composed of allogenic human monocyte-derived macrophages loaded with a protein-drug conjugate

Treatment of solid tumours

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.6. DNA plasmid vector encoding human insulin like growth factor binding protein 2

Treatment of newly diagnosed advanced ovarian cancer after debulking surgery

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.7. Autologous muscle precursor cells (MPCs)

Treatment of female stress urinary incontinence

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

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:	06-09.02.2023
- Appointment of CAT Peer Reviewers:	15-17.02.2023
- SAWP first reports:	06.03.2023
- CAT Peer Reviewer comments (NC/C):	10.03.2023
- CAT Peer Reviewer comments (Q):	15.03.2023
- Discussion at SAWP:	22-24.03.2023
- Discussion at CAT and feedback to SAWP:	19-21.04.2023

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	13-16.03.2023
- Appointment of CAT Peer Reviewers:	22-24.03.2023
- SAWP first reports:	03.04.2023
- CAT Peer Reviewer comments (NC/C):	05.04.2023
- CAT Peer Reviewer comments (Q):	12.04.2023
- Discussion at SAWP:	19-21.04.2023
- Discussion at CAT and feedback to SAWP:	15-17.05.2023

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:	06-09.02.2023
SAWP recommendation:	16.03.2023
CAT recommendation:	24.03.2023
CHMP adoption of report and final recommendation:	30.03.2023

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. Election of CAT Vice-chairperson

Action: for adoption

7.1.2. CAT membership

Action: for information

7.1.3. Vote by proxy

Action: for information

7.1.4. CAT Strategic Review & Learning meeting (SRLM) under the Sweden presidency, 4-5 May 2023, Upsala (Sweden)

CAT: Lisbeth Barkholt, Maria Lüttgen

Scope: Topics for discussion at the upcoming SRLM

Action: for discussion

7.1.1. CxMP meeting dates 2025/2026

Action: for information

7.2. Coordination with EMA Scientific Committees

7.2.1. CHMP Scientific Advice Working Party (SAWP): CAT-SAWP joint members

Scope: renomination or nomination of new joint CAT-SAWP members

Action: for discussion

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

7.3.1. PCWP-HCPWP annual meeting

Scope: Meeting summary from the PCWP-HCPWP annual meeting with all eligible organisations held on 15 November 2022 and agenda for the PCWP and HCPWP meeting to be held on 3 March 2023

Action: for information

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) - POSTPONED

CAT: Ilona G. Reischl

Scope: Agenda for the teleconference to be held on 23 February 2023.

Action: for information

Note: the ATMP cluster has been postponed. The next ATMP cluster will take place on 27 April 2023.

7.6. CAT work plan

7.6.1. Real World Evidence update, including DARWIN EU®

Scope: To update the CAT members on the progress and finalisation of year 1 studies, the prioritisation and selection of studies and data partners for year 2, the RWE experience report, and the new RWE MMD folder

Action: for information

7.6.2. Real World Evidence, Readers' Guidance

Scope: Template text for real world data / real world evidence in the Readers' Guidance

Action: for information

7.6.3. Update on collaboration with HTA-bodies

Action: for information

7.7. Planning and reporting

7.7.1. ITF end of the year report

Scope: ITF end of year report

Action: for information

7.8. Others

7.8.1. EIT EMAN Genome Editing Workshop

Scope: Nomination of 3 CAT members to attend this meeting as formal CAT representatives

Action: for discussion

7.8.2. Project on outcome measures in Epidermolysis Bullosa

Scope: Call for interest for kick-off meeting in April 2023

Action: for information.

8. Any other business

8.1.1. Oncology European Specialised Expert Community (ESEC)

Scope: Presentation and updates of their activities

Action: for information

8.2. EMA's reimbursement rules

Scope: Clarification of reimbursement rules for members and alternates following discussions at January's CAT meeting.

Action: for information

Date of next CAT meeting:

22-24 March 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
 SWP: Safety Working Party
 SME: Small and medium size enterprises
 SmPC: Summary of Products Characteristics
 TT: Timetable

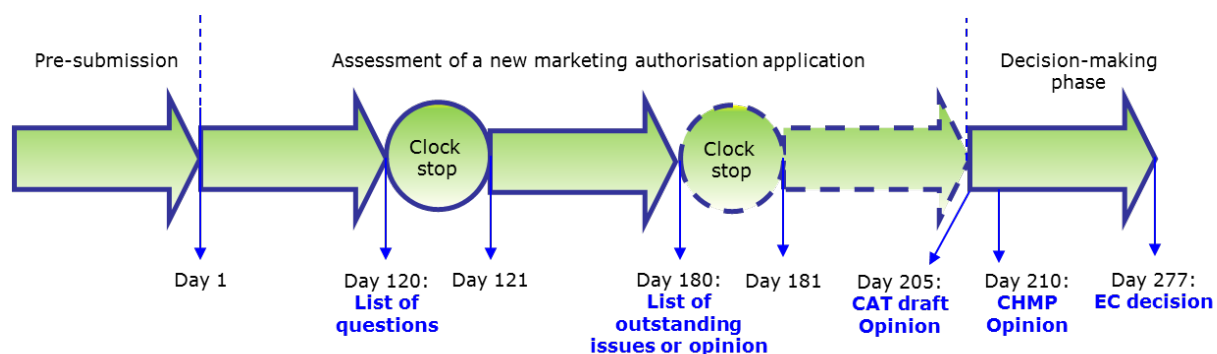
Evaluation of ATMPs (section 2)

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 any ATMP related inspection requests (section 2.9) and Post-authorisation activities (section 2.10).

New applications (sections 2.1. to 2.12.)

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 2.3) 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 2.7 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.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 (section 2.6.)

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.

Withdrawal of applications (section 2.7.)

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.

New applications (section 2.9.)

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.

GMP and GCP Inspections Issues (section 2.10.)

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

Post-authorisation activities (section 2.12.)

This section lists type II variations, extension application according to Annex I of Reg. 1234/2008, re-examination procedures for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP and other issues concerning authorised medicines that are not covered elsewhere in the agenda such as 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.

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/