27 October 2022
EMA/CAT/836651/2022
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 03-04 November 2022

Chair: Martina Schuessler-Lenz; Vice-Chair: Ilona Reischl

03 November 2022, 09:00 – 18:30, room 01-D

04 November 2022, 09:00 – 13:00, room 01-D

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 02-04 November 2022. See November 2022 CAT minutes (to be published post December 2022 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 02-04 November 2022 meeting

1.3. Adoption of the minutes

CAT minutes for 05-07 October 2022 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. 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. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0002

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Quality.

Action: for adoption

2.11.2. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0031

Novartis Europharm Limited

Rapporteur: Carla Herberts

Scope: Quality.

Action: for adoption

Request for supplementary Information adopted on 09.09.2022.

2.11.3. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0033/G

Novartis Europharm Limited

Rapporteur: Carla Herberts, PRAC Rapporteur: Ulla Wändel Liminga

Scope: Clinical. Request for supplementary information

Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to introduce additional guidance on liver function laboratory tests and monitoring before and after infusion and update information based on new safety information on the topic of acute liver failure (ALF) following two reports of fatal ALF.

Update of sections 4.2 and 4.4 of the SmPC in order to provide additional guidance relevant to patient's overall health status prior to dosing and to strengthen the existing description and guidance on systemic immune response.
Update of the section 4.4 of the SmPC in order to indicate prompt attention to thrombotic microangiopathy (TMA) and to reflect the risk of life-threatening or fatal outcomes.
The Package Leaflet is updated accordingly. The RMP version 2.0 has also been submitted.
In addition, the MAH took the opportunity to update the Annex II.

Action: for adoption

2.11.4. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0034/G

Novartis Europharm Limited

Rapporteur: Carla Herberts

Scope: Quality.

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/013

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality.

Action: for adoption

2.13.2. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/REC/014

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality.

Action: for adoption

2.13.3. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/REC/015

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality.

Action: for adoption

2.13.4. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/REC/016

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality.

Action: for adoption

2.13.5. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/REC/017

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality.

Action: for adoption

2.13.6. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/REC/018

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality.

Action: for adoption

2.13.7. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/REC/019

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality.

Action: for adoption

2.13.8. Alofisel - darvadstrocel - Orphan - EMEA/H/C/004258/R/0036

Takeda Pharma A/S

Rapporteur: Lisbeth Barkholt, Co-Rapporteur: Isabel Vieira; PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: 5-year Renewal of Marketing Authorisation, opinion

Action: for adoption

Request for supplementary information adopted on 09.09.2022.

2.13.9. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/REC/013

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality.

Action: for adoption

2.13.10. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/REC/008

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Quality.

Action: for adoption

2.13.11. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/P46/011

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen

Scope: Paediatric studies submitted in accordance with Article 46 of Regulation (EC) No1901/2006, as amended. Clinical study report of Study No. 20110261: A Phase 1, Multi-centre, Open-label, Dose De-escalation Study to Evaluate the Safety and Efficacy of Talimogene Laherparepvec in Paediatric Subjects with Advanced Noncentral Nervous System Tumours that are amenable to direct injection.

Action: for adoption

2.13.12. Upstaza - eladocagene exuparvovec - Orphan - EMEA/H/C/005352/REC/003

PTC Therapeutics International Limited

Rapporteur: Maura O'Donovan

Scope: Quality.

Action: for adoption

2.13.13. Upstaza - eladocagene exuparvovec - Orphan - EMEA/H/C/005352/REC/004

PTC Therapeutics International Limited

Scope: Quality.

Action: for adoption

2.13.14. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/ANX/002.4

Kite Pharma EU B.V.

Scope: Second Annual Interim Report / No.: KT-EU-471-0117
Title: 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 (EU PAS Register no.: EUPAS32539).

Action: for adoption

2.14. Feedback from CHMP discussions on ATMP applications

2.14.1. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0053; EMEA/H/C/004090/II/0059

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Outcome of CHMP discussion

Action: for information

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

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Adult autologous regenerative cells

Indicated for regeneration, repair, or replacement of weakened or injured subcutaneous tissue

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. Autologous adipose-derived stromal vascular fraction cells (ADSVFCs)

Indicated for the treatment of haemophilic arthropathy

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Allogeneic Natural Killer cells armed with anti-EGFR monoclonal antibody

Indicated for the treatment of epidermal growth factor receptor (EGFR) positive cancers

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.4. Allogeneic natural killer cells armed with anti-HER2 monoclonal antibody

Indicated for the treatment of human epidermal growth factor receptor 2 (HER2) positive cancers

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.5. Ex-vivo expanded allogeneic neural crest-like stem cells

Indicated for the treatment of diabetic foot ulcer

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.6. Allogeneic wharton's jelly mesenchymal stem cells (WJ-MSCs)

Indicated for the treatment of stress incontinence

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.7. Autologous monocyte-derived dendritic cells electroporated with mRNAs encoding for immunostimulatory proteins caTLR4, CD40L and CD70 combined with one of the tumour-associated antigens (TAA) MAGE-C2, MAGE-A3, WT1 and NY-ESO-1

Indicated for the treatment of gastric cancer

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.8. Autologous human tumour infiltrating lymphocytes

Indicated for the treatment of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC)

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Allogeneic adipose-derived mesenchymal stem cells (ADMSCs)

Intended for the treatment of osteoarthritis of the knee and hip

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. Allogeneic adipose derived mesenchymal stem cells

Intended for the treatment of Crohn-related perianal fistula

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

Action: for adoption

4.4.2. Autologous adipose derived mesenchymal stem cells

Intended for the treatment of Crohn-related perianal fistula

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

Action: for adoption

4.4.3. Autologous anti-BCMA CAR-T cells

Intended for the treatment of multiple myeloma

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

Action: for adoption

4.4.4. Allogeneic latency-2 Epstein-Barr virus-targeted cytotoxic T lymphocytes

Intended for the treatment of multiple sclerosis

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

Action: for adoption

4.4.5. E1-deleted (replication defective) recombinant human adenovirus serotype 5 expressing TIMP3 (tissue inhibitor of metalloproteinases-3) under the control of the cytomegalovirus immediate early promoter

Intended for the treatment of coronary artery disease requiring artery bypass grafting (CABG)

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

Action: for adoption

4.4.6. Autologous CD34+ cells transfected with a lentiviral vector containing codon-optimised RPS19 gene

Intended for the treatment of transfusion-dependent, steroid-resistant paediatric patients with Diamond-Blackfan anaemia, who have a mutation in the RPS19 gene

Scope: The 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:	24-27.10.2022
- Appointment of CAT Peer Reviewers:	03-04.11.2022
- SAWP first reports:	21.11.2022
- CAT Peer Reviewer comments (NC/C):	25.11.2022
- CAT Peer Reviewer comments (Q):	30.11.2022
- Discussion at SAWP:	28.11.2022 – 01.12.2022
- Discussion at CAT and feedback to SAWP:	07-09.12.2022

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	28.11–01.12 2022
- Appointment of CAT Peer Reviewers:	07-09.12.2022
- SAWP first reports:	02.01.2023
- CAT Peer Reviewer comments (NC,C):	06.01.2023
- CAT Peer reviewer comments (Q):	11.01.2023
- Discussion at SAWP:	09-12.01.2023
- Discussion at CAT and feedback to SAWP:	18-20.01.2023

No items

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

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:	24-27.10.2022
SAWP recommendation:	01.12.2022
CAT recommendation:	09.12.2022
CHMP adoption of report and final recommendation:	15.12.2022

6.3.2. Month 1 – Discussion of eligibility

No items

6.3.3. Month 2 – Recommendation of eligibility

No items

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

No items

7.1.3. CAT Strategic Review & Learning meeting (SRLM) under the Czechia presidency, 17 – 18 November 2022 in Paris

CAT: Petr Soukup, Martina Schuessler-Lenz

Scope: final agenda content

Action: for discussion

7.1.4. CAT meeting dates 2023

Scope: Face-to-face CAT meetings in 2023

Action: for information

7.2. Coordination with EMA Scientific Committees

7.2.1. COMP project on Conditions for orphan designation in Inherited retinal diseases

Scope: conclusions of the COMP project

Action: for information

7.2.2. Focus group on submission predictability

Scope: invite nominations to participate in this focus group which aims to carry out analysis of the root causes of the delays and poor predictability in submissions of initial marketing authorisation applications; identify potential solutions to promote better submission planning by applicants, avoid delays and allow better resources planning at NCA level

Action: for discussion

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: Martina Schuessler-Lenz

Scope: Feedback from the teleconference of 20 October 2022

Action: for information

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

CAT: Pille Säälik, Ivana Haunerova

Scope: Feedback from the international teleconference that took place on 25 October 2022.

Action: for information

7.5.3. Real World Evidence (RWE) cluster teleconference with US-FDA and Health Canada

CAT: Jan Mueller-Berghaus, Marcos Timon

Scope: Feedback from the teleconference of 24 October 2022 (discussion on the authorisation of Carvykti)

Action: for information

7.6. CAT work plan

7.6.1. CAT Workplan for 2023

CAT: Martina Schüssler-Lenz

Scope: draft CAT workplan for 2023

Action: for discussion

7.7. Planning and reporting

No items

7.8. Others

7.8.1. Good Practice Guide for the use of the EU metadata catalogue and Data Quality Framework

Scope: Presentation of the following documents for public consultation: a. Good Practice Guide for the use of the EU metadata catalogue, and b. Data Quality Framework

Action: for information

7.8.2. European Society for Gene and cell therapy (ESGCT) annual meeting

CAT: Martina Schüssler-Lenz

Scope: Feedback from the CAT session at the ESGCT conference that took place in Edinburgh on 14 October 2022

Action: for discussion

7.8.3. Blood/tissue establishment in 3rd countries providing starting materials for ATMPs

CAT: Barbara Bonamassa

Scope: Inspection of leukapheresis centres in third countries

Action: for discussion

8. Any other business

No items

Date of next CAT meeting:

07-09/12/2022

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

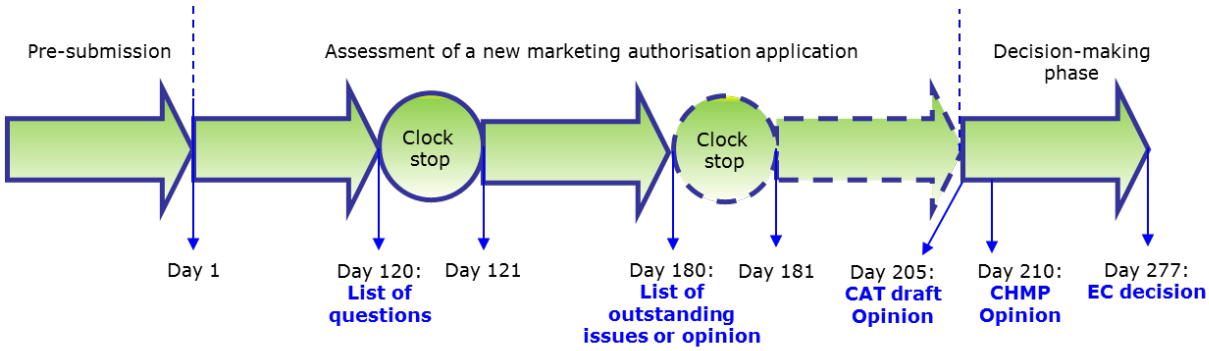
Evaluation of ATMPs (section 2)

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/