15 June 2023
EMA/CAT/240971/2023
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 15 June 2023

Chair: Ilona Reischl

15 June 2023, 09:00 – 18:00

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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

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 14-15 June 2023. See June 2023 CAT minutes (to be published post July 2023 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 14-15 June 2023 meeting

1.3. Adoption of the minutes

CAT minutes for 15-18 May 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. fidanacogene elaparvovec - PRIME - Orphan - EMEA/H/C/004774

Pfizer Europe MA EEIG; Indicated for the treatment of severe and moderately severe haemophilia B

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/0031

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken, Co-Rapporteur: Heli Suila, PRAC Rapporteur: Ulla Wändel Liminga

Scope: Clinical

Extension of indication to include treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD-38 antibody and have demonstrated disease progression on the last therapy for Abecma (idecabtagene vicleucel, ide-cel), based on results from study BB2121-MM-003 (MM-003, KarMMa-3). This is a Phase 3, multicentre, randomised, open-label study to compare the efficacy and safety of ide-cel

versus standard regimens in subjects with RRMM. As a consequence, sections 2.1, 2.2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3, 6.4 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 3.0 of the RMP has also been submitted. Furthermore, the PI is brought in line with the Guideline on core SmPC, Labelling and Package Leaflet for advanced therapy medicinal products (ATMPs) containing genetically modified cells.

Action: for adoption

2.11.2. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0032/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality

Action: for adoption

Request for supplementary information adopted on 17.05.2023.

2.11.3. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0034

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, Request for supplementary information

Action: for adoption

2.11.4. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0013/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality

Action: for adoption

Request for supplementary information adopted on 17.02.2023.

2.11.5. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0018/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality

Action: for adoption

2.11.6. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0019

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality

Action: for adoption

2.11.7. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0016

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

2.11.8. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0062/G

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen

Scope: Quality, opinion

Action: for adoption

Request for supplementary information adopted on 17.05.2023.

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

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality

Action: for adoption

Request for supplementary information adopted on 17.05.2023.

2.11.10. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0070/G

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality

Action: for adoption

2.11.11. Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/II/0015

Orchard Therapeutics (Netherlands) B.V.

Rapporteur: Carla Herberts

Scope: Quality, request for supplementary information

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/REC/013

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

2.13.2. Hemgenix - etranacogene dezaparvovec - Orphan - EMEA/H/C/004827/REC/005

CSL Behring GmbH

Rapporteur: Silke Dorner

Scope: Quality, fullfilled

Action: for adoption

2.13.3. ROCTAVIAN - valoctocogene roxaparvovec - Orphan - EMEA/H/C/005830/ANX/002.1

BioMarin International Limited

Rapporteur: Violaine Closson Carella

Scope: Clinical

MAH response to ANX 002 [Study protocol 270-601 as adopted in January 2023]:

To fulfil the request of PAM, the MAH opted for a prospective longitudinal study that is observational. Most of the concerns raised in this report are related to the observational nature of the study with regard to the examinations and tests required to achieve the objectives of the study.

Action: for adoption

2.13.4. ROCTAVIAN - valoctocogene roxaparvovec - Orphan - EMEA/H/C/005830/ANX/004.1

BioMarin International Limited

Rapporteur: Violaine Closson Carella

Scope: Clinial

MAH response to ANX 004 [Study protocol Study 270-801] as adopted in January 2023:

This study is being undertaken to better characterise the long-term safety and effectiveness of Roctavian in patients in a real-world setting using periodic data extractions from registries databases to further substantiate the risk-benefit of Roctavian and to provide information on the long-term impact of treatment with Roctavian for approximately 15 years (risk of malignancy on the safety side and uncertainties on the durability on the efficacy side). This protocol is not the final version as the MAH plans to develop registry specific protocol to be added as appendices 2, 3, and 4 of the study protocol.

Action: for adoption

2.13.5. ROCTAVIAN - valoctocogene roxaparvovec - Orphan - EMEA/H/C/005830/MEA/005

BioMarin International Limited

Rapporteur: Violaine Closson Carella

Scope: Pharmacovigilance

Survey of haematologists to assess the effectiveness of the additional risk minimisation measures (aRMMs) for Roctavian (valoctocogene roxaparvovec) (Version 1.0).

Action: for adoption

2.13.6. Strimvelis - autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - Orphan - EMEA/H/C/003854/ANX/004.4

Orchard Therapeutics (Netherlands) B.V.

Rapporteur: Sol Ruiz

Scope: Clinical and Pharmacovigilance

Third interim patient registry / STRIM-0003. Title: Adenosine deaminase severe combined immunodeficiency (ADA-SCID) registry for patients treated with Strimvelis™ (or GSK2696273) gene therapy: long-term prospective, non-interventional follow-up of safety and effectiveness. [Interim reports submitted every 2 years.]

Action: for adoption

2.13.7. Upstaza - eladocagene exuparvovec - Orphan - EMEA/H/C/005352/REC/009

PTC Therapeutics International Limited

Rapporteur: Maura O'Donovan

Scope: Quality, fullfilled

Action: for adoption

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

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. 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: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. 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: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

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

Treatment of metastatic solid cancers

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

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

Treatment of heart failure

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

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

Treatment of recurrent respiratory papillomatosis

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.6. TERT Ribonucleoprotein

Treatment of cancer

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

No items

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

No items

4.4. Finalisation of procedure

4.4.1. Living human adult allogeneic immunomodulatory progenitor (iMP) cells

Treatment of myocardial scarring

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.2. Allogeneic viable natural killer (NK) cells CD56+ CD3-

Treatment of patients with acute myeloid leukaemia (AML) who are in morphologic complete remission and for whom allogeneic haematopoietic stem cell transplantation (allo-HSCT) is not a suitable or preferred option

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.3. Recombinant Adeno-associated virus serotype 9 vector containing the human-lysosome-associated membrane glycoprotein 2 isoform B transgene

Treatment of Danon disease

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:	05–08.06.2023
- Appointment of CAT Peer Reviewers:	14-16.06.2023
- SAWP first reports:	26.06.2023
- CAT Peer Reviewer comments (NC/C)	30.06.2023
- CAT Peer Reviewer comments (Q)	05.07.2023
- Discussion at SAWP:	03–06.07.2023
- Discussion at CAT and feedback to SAWP:	12-14.07.2023

5.1.2. Scientific advice procedures starting at the next SAWP meeting

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

5.2. 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:	31/05/2023
EMA scientific officer draft report sent to SAWP reviewer:	16/06/2023
Report circulated to SAWP:	26/06/2023
SAWP recommendation:	06/07/2023
CAT recommendation (for ATMP):	14/07/2023
CHMP adoption of report and final recommendation:	20/07/2023

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. 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, Madrid (Spain)

CAT: Sol Ruiz, Marcos Timon

Scope: Topics for discussion at the upcoming SRLM

Action: for discussion

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

CAT: Maria Lüttgen, Lisbeth Barkholt

Scope: Presentations

Action: for information

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: Agenda of the teleconference that will take place on 22 June 2023

Action: for information

7.6. CAT work plan

7.6.1. Report on experience with RWE studies to support EMA scientific committees

Scope: Presentation on the main findings of the report on the experience with real world evidence (RWE) studies to support regulatory decision making

Action: for information

7.6.2. European Rare Disease Registries: a collaborative effort to assess the quality and suitability of registries to describe the natural history of disease and treatment landscape of spinal muscular atrophy

CAT: Kieran Breen, Mencia de Lemus, Lisbeth Barkholt

Scope: Acceptance of an abstract for the spinal muscular dystrophy (SMA) study at ICPE 2023; the objective of this study is the conduct of a fit-for-purpose (FFP) assessment of European SMA registries from the TREAT-NMD network and assess their suitability to participate in the first ever EMA-funded registry study in collaboration with CAT

Action: for information

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

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

Scope: Alignment of the quality, non-clinical and clinical parts of the guideline (concepts, terminology and abbreviations) for investigational ATMPs in clinical trials

Action: for discussion

7.7. Planning and reporting

7.7.1. Business Pipeline Report – 3 year Forecast report

Scope: Q2/2023 update of the business pipeline report for the human scientific committees

Action: for information

7.8. Others

7.8.1. International Society for Gene and Cell therapy (ISCT) Paris 2023

CAT: Ilona Reischl

Scope: Feedback from the ISCT Global Regulators feedback on the use of unproven cell and gene products (30.05.2023) and from the ISCT 2023 Annual Meeting (31.05.2023 - 03.06.2023)

Action: for information

8. Any other business

8.1. Accessibility of PRIME reports in IRIS

Scope: Update to the committee on the accessibility of PRIME reports in IRIS

Action: for information

Date of next CAT meeting:

12-14 July 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

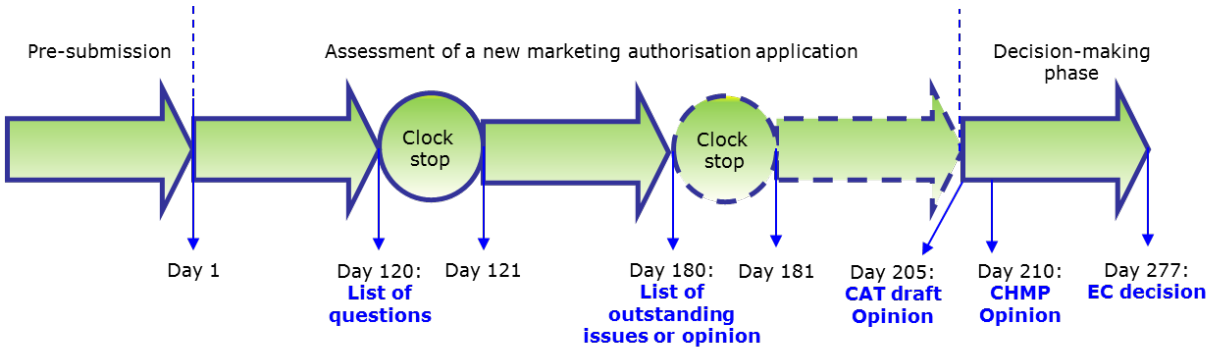
Evaluation of ATMPs (section 2)

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/