11 May 2022
EMA/CAT/231456/2022
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 11-13 May 2022

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

11 May 2022, 14:00 – 18:30, room 01-D

12 May 2022, 09:00 – 18:30, room 01-D

13 May 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 11-13 May 2022. See 11-13 May 2022 CAT minutes (to be published post 15-17 June 2022 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 11-13 May 2022 meeting

1.3. Adoption of the minutes

CAT minutes for 11-13 April 2022 meeting

2. Evaluation of ATMPs

2.1. Opinions

2.1.1. Eladocagene exuparvovec - Orphan - EMEA/H/C/005352

PTC Therapeutics International Limited; treatment of aromatic L-amino aciddecarboxylase (AADC) deficiency

Scope: Opinion

Action: for adoption

Oral explanation on 11.04.2022. List of Outstanding Issues adopted on 05.11.2021, 16.04.2021. List of Questions adopted on 20.05.2020.

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

No items

2.8. Withdrawal of initial marketing authorisation application

2.8.1. Autologous glioma tumor cells, inactivated / autologous glioma tumor cell lysates, inactivated / allogeneic glioma tumor cells, inactivated / allogeneic glioma tumor cell lysates, inactivated - Orphan - EMEA/H/C/003693

Epitopoietic Research Corporation-Belgium (E.R.C.); treatment of glioma

Scope: withdrawal of marketing authorisation application.

Action: for information

Oral explanation on 11.04.2022. List of Outstanding Issues adopted on 16.07.2021. List of Questions adopted on 22.01.2021.

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. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0050

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen

Scope: Quality. Opinion.

Action: for adoption

2.11.2. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0051

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Pharmacovigilance. Request for Supplementary Information

Submission of the final report from study 20180062; "Observational Research Study Report (ORSR)" listed as a category 3 study in the RMP. This is a multinational, non-interventional, cross-sectional survey study for the Patients aged ≥ 18 years who have received Imlygic at least once in the 3 months prior to completing the survey to evaluate the effectiveness of the patient-directed additional risk minimisation measures (aRMM). The primary objective of this study is to evaluate patients' knowledge levels of the key messages included in the IMLYGIC Patient Safety Brochure among patients who receive Imlygic.

Action: for adoption

2.11.3. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0052/G

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen

Scope: Quality. Request for Supplementary Information.

Action: for adoption

2.11.4. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0053

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Clinical. Request for Supplementary Information

Submission of the final report from study CCTL019H2301 (BELINDA) listed as an obligation in the Annex II of the Product Information. This is a randomized open-label parallel-group multicentre phase III trial to evaluate the efficacy and safety of tisagenlecleucel in adult patients with relapsed or refractory B-cell aggressive non-Hodgkin lymphoma (NHL) after failure of rituximab and anthracycline containing first-line immune-chemotherapy. Annex II is updated accordingly.

Action: for adoption

2.11.5. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0046

Kite Pharma EU B.V.

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

Scope: Clinical. Request for Supplementary Information

Extension of indication to include treatment of adult patients with relapsed or refractory (r/r) diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) for

Yescarta; as a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.3 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the product information with minor editorial changes.

Action: for adoption

Request for Supplementary Information adopted on 18.02.2022.

2.11.6. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0020/G

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts

Scope: Quality. Opinion

Action: for adoption

Request for Supplementary Information adopted on 18.03.2022, 10.12.2021.

2.11.7. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0024

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts

Scope: Quality and clinical. Opinion

Submission of an evaluation of the finished product specifications, in accordance with the obligation in the Annex IID of the Product Information (ANX 004), to be undertaken when primary and key secondary endpoint data from additional patients with 2 copies of survival motor neuron 2 (SMN2) are available (i.e. completion of CL-302 and CL-304 cohort 1). Annex II is updated accordingly.

Action: for adoption

Request for Supplementary Information adopted on 18.03.2022.

2.11.8. Yescarta - axicabtagene ciloleucel; Tecartus - brexucabtagene autoleucel - Orphan - EMEA/H/C/WS2247

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. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/ANX/007.2

Novartis Europharm Limited

Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

Scope: Statistical Analysis Plan (SAP) amendment 1 / (CCTL019B2401) - The MAH is requested to respond to the request for supplementary information adopted with the outcome of ANX-7.1

Action: for adoption

2.13.2. Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/ANX/002.2

Orchard Therapeutics (Netherlands) BV

Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege

Scope: MAH Response to ANX-002.1 [LongTERM-MLD study protocol] as adopted in November 2021: In order to further characterise the long-term efficacy and safety of Libmeldy in children with late infantile or early juvenile forms of metachromatic leukodystrophy (MLD), the MAH shall conduct and submit the results of a prospective study based on data from a registry, according to an agreed protocol.

Action: for adoption

2.13.3. Tecartus - brexucabtagene autoleucel - Orphan - EMEA/H/C/005102/MEA/005.2

Kite Pharma EU B.V.

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

Scope: MAH response to MEA 005.1 [Protocol, study no. KT-EU-472-5966] as adopted in December 2021 - Prescriber Survey: Assess the prescribers' understanding of the risks of KTE-X19. Evaluate the effectiveness of risk minimization activities: HCP educational materials, and Patient Alert Card.

Action: for information

2.13.4. CAT recommendation to MAHs of CAR-T cell-based therapies with regards to long-term safety and efficacy follow-up studies using European Society for Blood and Marrow Transplantation (EBMT) as a data source

Scope: CAT/PRAC recommendations

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. Wharton's Jelly Derived Mesenchymal Stem Cells – allogeneic

Intended for the treatment of other specified inflammatory spondylopathies (non-radiographic axial spondyloarthritis, M46.8)

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. Autologus keratinocytes, fibroblasts

Intended for the treatment of partial deep dermal and full thickness burn wounds and reconstructive surgery

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Dopaminergic neuronal microtissues containing A9 TH+ (Tyrosine hydroxylase) dopaminergic mature neuron

Intended for the treatment of Parkinson's disease

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Ex-vivo expanded autologous Wharton's Jelly derived mesenchymal stem cells (WJ-MSCs)

Intended for the treatment of autism spectrum disorder

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Autologous adipose tissue-derived stromal cell fraction devoid of mature adipocytes

Intended for the treatment of temporomandibular disorders

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Cultured human adipose derived stromal cells

Intended for the treatment of stress urinary incontinence in men after radical prostatectomy

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Human autologous tumour and hypoxia educated macrophages

Intended for the treatment of spinal cord injury

Scope: ATMP scientific recommendation

Action: for adoption

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

4.3.1. Leukocyte and platelet rich plasma, autologous - postponed

Intended for the treatment of critical limb ischemia

Scope: ATMP scientific recommendation

Action: for adoption

4.4. Finalisation of procedure

4.4.1. Autologous transduced CD8+ T cells expressing the Melanoma associated antigen 1-(MAGE-A1)-specific T cell receptor TCR 8001

Intended for the treatment of patients with MAGE-A1 expressing solid tumours

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

Action: for adoption

4.4.2. Suspension of VST cells

Intended for the treatment of adults and children with therapy-resistant viral infection after allogeneic hematopoietic stem cell transplantation

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

Action: for adoption

4.4.3. Adipose-derived stem cells

Intended for the treatment of type 2 diabetes mellitus, Treatment of cardiac and pulmonary complications after Covid-19

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:	02-05.05.2022
- Appointment of CAT Peer Reviewers:	11-13.05.2022
- SAWP first reports:	30.05.2022
- CAT Peer Reviewer comments (NC/C):	03.06.2022
- CAT Peer Reviewer comments (Q):	08.06.2022
- Discussion at SAWP:	07-10.06.2022
- Discussion at CAT and feedback to SAWP:	16.06.2022

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	07-10.06.2022
- Appointment of CAT Peer Reviewers:	15-17.06.2022
- SAWP first reports:	27.06.2022
- CAT Peer Reviewer comments (NC, C):	01.07.2022
- CAT Peer reviewer comments (Q):	06.07.2022
- Discussion at SAWP:	04-07.07.2022
- Discussion at CAT and feedback to SAWP:	14.07.2022

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

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

No items

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:

Procedure start:	02-05.2022
SAWP recommendation:	10.05.2022
CAT recommendation:	17.06.2022
CHMP adoption of report and final recommendation:	23.06.2022

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

No items

7.1.2. Vote by proxy

No items

7.2. Coordination with EMA Scientific Committees

7.2.1. COMP expert meeting on orphan conditions in inherited retinal diseases

Action: for discussion

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

7.3.1. Procedure on ATMP scientific advice and BWP interaction

Scope: procedure for interactions with BWP on scientific advice and timing/role of CAT peer review

Action: for adoption

Note: comments received from B Bonamassa, Kristyna Rehorova Hradilkova

7.3.2. Routine GCP inspections selection – proposal to lift restrictions on the applications to be considered

Action: for information

7.3.3. Embedding the outcome of GCP inspections into the benefit/risk assessment and modernisation of the inspection process

GCP WG: Jayne Crowe

Scope: Bringing to attention the GCP survey for assessors for the purpose of benchmarking awareness of GCP guidance within the regulatory network.

Action: for information

7.4. Cooperation with the EU regulatory network

7.4.1. Revision of the EU pharmaceutical legislation (Directive 2001/83/EC and Regulation (EC) No 726/2004)

Action: for information

7.4.2. Revision of the EU legislation on blood, tissues and cells (BTC)

CAT: Martina Schüssler-Lenz

Scope: Update from the European Commission representative on the status of the BTC proposal

Action: for discussion

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: Agenda of the teleconference that will take place on 24 May 2022

Action: for information

7.5.2. Introduction of the new EMA/FDA and EMA/ MHLW/PMDA liaisons

Action: for information

7.5.3. EDQM Stakeholder consultation 5th edition Tissue and Cells Guide

CAT: Ilona Reischl

Scope: Consultation for the 5th edition of the Guide to the quality and safety of tissues and cells for human application

Action: for appointment of CAT members to review the draft

Note: link to download the DRAFT document of the 5th edition of the Guide in .pdf version (document reference PA/PH/TO (22)16) https://act.edqm.eu/s/6BC6pt2WmqAPfJZ

Comments should be submitted using the form referenced FORM05/TC/OC.

7.6. CAT work plan

No items

7.7. Planning and reporting

7.7.1. Marketing authorisation applications: 3-year forecast report

Scope: Update of the business pipeline report for the human scientific committees

Action: for information

7.8. Others

7.8.1. Consensus meeting on carcinogenicity of gene therapies

CAT: Martina Schüssler-Lenz

Scope: Invitation of participate as observer in a consensus meeting about assessment of potential carcinogenicity of gene therapies on the 11-14 October 2022 in Edinburgh.

Action: for information

7.8.2. GTMPs for haemophilia, consistency in assays for factor activity

CAT: Martina Schüssler-Lenz

Scope: to address the question on how factor activities are assessed after gene therapy treatment and whether recommendations proposed by the developer in terms of treatment monitoring are consistent with EMA requirements, also with regards to the SmPC.

Action: for information

7.8.3. Adeno-associated viral (AAV) vector toxicities: regulatory considerations

CAT: Carla Herberts, Egbert Flory

Action: for discussion

7.8.4. Launch of call for nominations to Quality Innovation Group

Scope: This group will aim to support the translation of innovative approaches to the design, manufacture and quality control of medicines for the benefit of patients. The group will be composed of 6 core members able to cover wide ranging aspects associated with innovation in chemical and biological APIs, finished products, ATMPs, manufacturing facilities and GMP compliance.

Action: for discussion

8. Any other business

Date of next CAT meeting:

15-17/06/2022

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

EDQM: The European Directorate for the Quality of Medicines & HealthCare

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

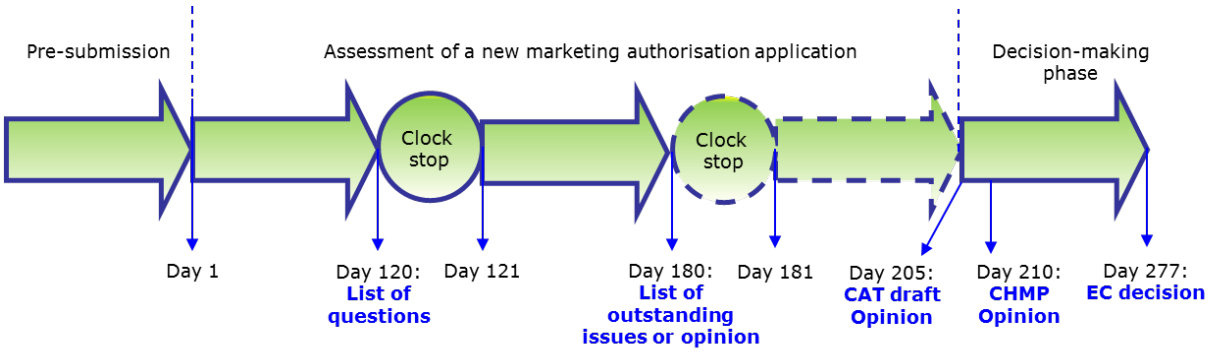
Evaluation of ATMPs (section 2)

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/