13 April 2021
EMA/CAT/212367/2021
Human Medicines Division

Committee for Advanced Therapies (CAT)

Agenda for the meeting on 14-16 April 2021

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

14 April 2021, 14:00 – 18:30, virtual meeting

15 April 2021, 09:00 – 18:30, virtual meeting

16 April 2021, 09:00 – 13:00, 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 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 14-16 April 2021. See April 2021 CAT minutes (to be published post-May 2021 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 14-16 April 2021 meeting

1.3. Adoption of the minutes

CAT minutes for 17-19 March 2021 meeting

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

2.3.1. Lisocabtagene maraleucel / lisocabtagene maraleucel - Orphan - EMEA/H/C/004731

Bristol-Myers Squibb Pharma EEIG; treatment of large B-cell lymphoma, diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma (PMBCL) and follicular lymphoma grade 3B (FL3B)

Scope: Day 180 list of outstanding issues

Action: for adoption

List of Questions adopted on 06.11.2020.

2.3.2. Elivaldogene autotemcel - Orphan - EMEA/H/C/003690

bluebird bio (Netherlands) B.V; treatment of ABCD1 genetic mutation and cerebral adrenoleukodystrophy

Scope: Opinion

Action: for adoption

List of Questions adopted on 22.01.2021.

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

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

Scope: Day 180 list of outstanding issues

Action: for adoption

List of Questions adopted on 20.05.2020.

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. Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/II/0021/G

CO.DON AG

Rapporteur: Lisbeth Barkholt

Scope: Quality

Action: for adoption

Request for Supplementary Information adopted on 19.02.2021.

2.11.2. Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/II/0022

CO.DON AG

Rapporteur: Lisbeth Barkholt

Scope: Clinical
Update of section 5.1 of the SmPC with the final results of study 'cod 16 HS 13', a 60-month follow up data assessing long-term efficacy and safety of Spherox.
Annex II has also been updated to reflect the completion of the study.

Action: for adoption

Request for Supplementary Information adopted on 19.03.2021.

2.11.3. Tecartus - autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured - Orphan - EMEA/H/C/005102/II/0001

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

2.11.4. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0028

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus; PRAC Rapporteur: Anette Kirstine Stark

Scope: Clinical
To update SmPC sections; 4.4 on CRS grading and neurologic adverse reactions; 4.8 on safety profile summary; 5.1 on follow up analysis; to update the safety information based on updates from study KTE-C19-101, entitled "A Phase 1/2 Multicenter Study Evaluating the Safety and Efficacy of KTE-C19 in Subjects with Refractory Aggressive Non-Hodgkin Lymphoma (ZUMA-1)", the pivotal study for Yescarta. The updates include the Phase 2 safety management ZUMA-1 Cohort 4, which was intended to assess the impact of earlier interventions (tocilizumab and/or corticosteroids, in addition to prophylactic levetiracetam) on the rate and severity of CRS and neurologic events; and data from a 36-month analysis from ZUMA-1 Cohorts 1 and 2.
The updated RMP version 3.1 has also been submitted.

Action: for adoption

Request for Supplementary Information adopted on 19.02.2021, 09.10.2020.

2.11.5. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0035

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

2.11.6. Zynteglo - betibeglogene autotemcel - Orphan - EMEA/H/C/003691/II/0022

bluebird bio (Netherlands) B.V

Rapporteur: Carla Herberts, CHMP Coordinator: Paula van Hennik

Scope: Quality. Request for RSI

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/009.4

Novartis Europharm Limited

Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

Scope: PhV
Study CCTL019H2301:
In order to further characterise the long-term efficacy and safety of Kymriah in relapsed/refractory diffuse large B-Cell lymphoma (DLBCL) the applicant should submit the results of study CCTL019H2301 - open-label, Phase III study of Kymriah versus standard of care in adult patients with relapsed or refractory aggressive B-cell non-Hodgkin

Action: for adoption

2.13.2. Committees discussion and outcome on milestones and performance indicators for the deadline for improvement for imposed PASS using the European Society for Blood and Marrow Transplantation (EBMT) as data source

Scope: debrief to the CAT on the communicating the March Outcome to MAH and EBMT, and notes from the teleconference with EBMT that took place on 22nd March 2121

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 ITF Coordinator

4.1.1. *Ex-vivo* expanded autologous cryopreserved Wharton's Jelly derived mesenchymal stem cells (CWJ-MSCs)

Intended for the treatment of Bronchopulmonary Dysplasia (BPD) for preterm infants

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. Allogeneic corneal endothelial cells in a confluent monolayer adhering to a cornea-shaped sheet of cross-linked collagen

Intended for the treatment of corneal dysfunction

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Proliferation arrested myelomonocytic leukemic cell line-derived cells with a mature dendritic cell phenotype for the treatment of acute myeloid leukaemia

Intended for the treatment of acute myeloid leukaemia

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.4. Allogeneic human Wharton's jelly derived mesenchymal stem cells (PBKM)

Intended for the treatment of idiopathic pulmonary fibrosis (IPF), pulmonary fibrosis after COVID-19

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Allogeneic, expanded, engineered E4ORF1+ human umbilical cord endothelial (CD31+) cells

Intended to treat organ vascular niche injuries caused by myeloablative, non-central nervous system penetrating high-dose chemotherapy (HDT) to prevent the development of severe regimen-related toxicities (SRRT) in patients diagnosed with aggressive systemic lymphoma

Scope: editorial comments received by the European Commission. ATMP Scientific recommendation

Action: for adoption

4.2.2. Oncolytic adenovirus

Intended for the treatment of histologically and radiologically confirmed progressive neuroendocrine neoplasm (NEN) of gastrointestinal, pancreatic or bronchial origin with multiple liver metastases (liver-dominant disease)

Scope: editorial comments received by the European Commission. ATMP Scientific recommendation

Action: for adoption

4.2.3. Autologous antigen presenting cells loaded with SARS-CoV-2 antigen

Vaccine against SARS-CoV-2

Scope: editorial comments received by the European Commission. ATMP Scientific recommendation

Action: for adoption

4.2.4. Autologous mesenchymal stem cells combined with a matrix pre-loaded with BMP2

Intended to treat femoral osteochondral lesion (grade III to IV)

Scope: editorial comments received by the European Commission. ATMP Scientific recommendation

Action: for adoption

4.2.5. DNA plasmid encoding several neoepitopes from the tumour of a patient, a live wild-type modified vaccinia strain Ankara (MVA) and a monoclonal antibody against Cytotoxic T-lymphocyte associated protein 4 (CTLA4)

Intended for the treatment of cancer

Scope: editorial comments received by the European Commission. ATMP Scientific recommendation

Action: for adoption

4.2.6. Autologous cultured chondrocytes

Intended for the treatment of filling of cartilage defects

Scope: editorial comments received by the European Commission. ATMP Scientific recommendation

Action: for adoption

4.2.7. Recombinant adeno-associated virus encoding for the human α-sarcoglycan-protein

Intended for the treatment of patients with a confirmed diagnosis of Limb-Girdle muscular dystrophy Type 2D/R3 (LGMD2D/R3)

Scope: editorial comments received by the European Commission. 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 antigen specific Cytotoxic T Lymphocytes

Intended for the treatment of cancer patients that are over expressing the specific antigen

Scope: awaiting comments by the European Commission. ATMP scientific recommendation

Action: for information

4.4.2. Autologous dendritic cells activated against tumour peptides

Intended for the treatment of cancer patients; *in vivo* immune stimulation against specific cancer overexpressing the tumour antigen

Scope: awaiting comments by the European Commission. ATMP scientific recommendation

Action: for information

4.4.3. Autologous M1-polarized macrophages

Intended for the treatment of cancer patients

Scope: awaiting comments by the European Commission. ATMP scientific recommendation

Action: for information

4.4.4. Autologous Cytotoxic Natural Killer (NK) cells

Intended for the treatment of cancer patients

Scope: awaiting comments by the European Commission. ATMP scientific recommendation

Action: for information

4.4.5. Autologous plasma cells producing monoclonal antibodies against specific tumor antigen, for treatment of cancer patients

Intended for the treatment of cancer patients

Scope: awaiting comments by the European Commission. ATMP scientific recommendation

Action: for information

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 the procedure at SAWP:	06-09.04.2021
-Appointment of CAT Peer-reviewers:	16.04.2021
-SAWP first reports:	26.04.2021
-CAT Peer-Reviewer's comments:	30.04.2021
-Discussion at SAWP:	03-06.05.2021
-Discussion at CAT and feedback to SAWP:	12.05.2021

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

-Start of procedure at SAWP:	03-06.05.2021
-Appointment of CAT Peer-Reviewers:	12.05.2021
-SAWP first reports:	31.05.2021
-CAT Peer-Reviewer's comments:	04.06.2021
-Discussion at SAWP:	07-10.06.2021
-Discussions at CAT and feedback to SAWP:	18.06.2021

5.2. CAT discussion

5.3. Finalisation of SA procedures

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:	09.04.2021
SAWP recommendation:	06.05.2021
CAT recommendation:	12.05.2021
CHMP adoption of report and final recommendation:	20.05.2021

6.3.2. Month 1 – Discussion of eligibility

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

Italy – Barbara Bonamassa – membership mandate (alternate) started on 20 March 2021
Italy – Giulio Pompilio – membership mandate (alternate) ended on 19 March 2021

Action: for information

7.1.2. Strategic Review & Learning meeting (SRLM) under the Portuguese presidency of the European Union - Lisbon, Portugal

CAT: Bruno Sepodes, Maria-Isabel Vieira

Scope: draft agenda of the joint CAT-CHMP meeting that is scheduled to take place at the SRLM on 27th May 2021

Action: for discussion

7.1.3. Overview of WebEx - new virtual meetings platform

Scope: training and dates of WebEx for CAT

Action: for information

7.2. Coordination with EMA Scientific Committees

7.2.1. CHMP learnings that impact CAT decisions

CAT: Jan Mueller-Berghaus, Romaldas Mačiulaitis, John-Joseph Borg, Bruno Sepodes, Sol Ruíz

Scope: CHMP learnings with relevance to CAT

Action: for information

The following proposal was agreed: the excel sheet with the new CHMP learnings will be presented during the CAT meeting and the CHMP-CAT double members will be asked to provide input, especially in relation to their relevance to CAT. This will be a pilot for the upcoming 6 months.

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

7.3.1. QWP/BWP Guideline on quality documentation for medicinal products when used in combination with a medical device

Rapporteur: Nicholas Lee (HPRA-IE)

Action: for adoption

7.3.2. Scientific Advisory Group (SAG) – renomination of the inter-committee SAG oncology (SAG-O) – request for nominations

Action: for information

7.4. Cooperation within the EU regulatory network

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

CAT-BTC group: Martina Schüßler-Lenz, Ilona Reischl, Violaine Closson-Carella, Marcos Timon, Maura O'Donovan, Egbert Flory, Claire Beuneu, Rune Kjeken, Silke Dorner

Scope: feedback from the teleconferences with the EC on 26 March and 9 April; provide information regarding the dates of the workshops on the context of the impact assessment of the revision of the BTC legislation

Action: for discussion

Note:
-The Commission is hosting different workshops on the revision of the BTC legislation. For some of them, EMA/CAT will be consulted.

7.4.2. Data standards strategy survey and virtual workshop to take place on 18 May 2021

Scope: contribution to a survey and call for expression of interest for three members of CAT (experts in the field of data standardisation/use, where possible) to actively join the workshop on 18.05.2021.

Action: for information

Note: EMA's Big Data Steering Group has launched an initiative to develop a *'Data Standards Strategy'* that will enable the Network more effectively to leverage data to deliver evidence in support of benefit-risk decision-making on the development, authorisation and use of medicines. Link to the online survey *(to be opened in Google Chrome)*: LINK. If you are interested to join the workshop, send your interest to DataStandardsStrategy@ema.europa.eu. Deadline to contribute to the survey or send your interest: 23.04.2021.

7.4.3. Pharmaceutical strategy for Europe

Scope: roadmap / inception impact assessment for the revision of the general pharmaceutical legislation

Action: for information

Note: The roadmap is open for feedback until 27 April 2021
https://ec.europa.eu/health/human-use/strategy_en

7.4.4. Verification of conditions of transport in cases foreseen under Section 11.17 of GMP for ATMPs

European Commission: Rocío Salvador Roldán

Scope: Question of interpretation of the guidelines of GMP for ATMPs

Action: for information

7.5. Cooperation with international regulators

No items

7.6. CAT work plan

No items

7.7. Planning and reporting

No items

7.8. Others

No items

8. Any other business

No items

Date of next CAT meeting:

10-12/05/2021

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

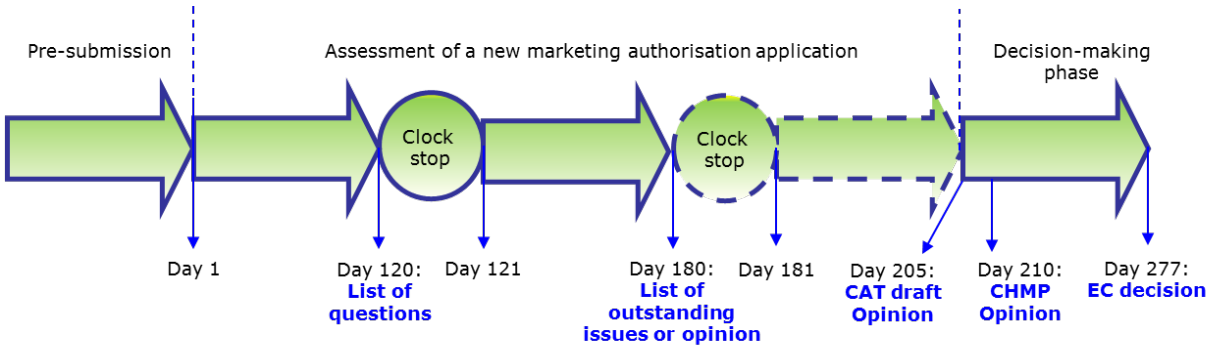
Evaluation of ATMPs (section 2)

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/