15 May 2020
EMA/CAT/268957/2020
Human Medicines Division

Committee for Advanced Therapies (CAT)

Agenda for the meeting on 18-20 May 2020

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

18 May 2020, 14:00 – 18:30, virtual meeting

19 May 2020, 09:00 – 18:30, virtual meeting

20 May 2020, 09:00 – 12:00, 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 18-20 May 2020. See May 2020 CAT minutes (to be published post-June 2020 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 18-20 May 2020 meeting

1.3. Adoption of the minutes

CAT minutes for 22-24 April 2020 meeting

1.4. Technical information

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

2.4.1. 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

Accelerated assessment

Kite Pharma EU B.V.; treatment of adult patients with relapsed or refractory Mantle cell lymphoma (MCL).

Scope: Day 120 list of questions

Action: for adoption

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

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

Scope: Day 120 list of questions

Action: for adoption

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

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 - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

2.11.1. Alofisel - darvadstrocel - Orphan - EMEA/H/C/004258/II/0016/G

Takeda Pharma A/S

Rapporteur: Lisbeth Barkholt

Scope: quality: Opinion

Action: for adoption

2.11.2. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0021/G

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: quality: Opinion

Action: for adoption

2.11.3. Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/II/0015

CO.DON AG

Scope: safety: Opinion
Update of section 4.8 and 5.1 of the SmPC following the 48-month follow up data for trial cod 16 HS 13, a study assessing the long-term efficacy and safety of Spherox.

Action: for adoption

Request for Supplementary Information adopted on 24.04.2020.

2.11.4. Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/II/0016

CO.DON AG

Rapporteur: Lisbeth Barkholt, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: safety: Opinion
Update of the RMP to bring it in line with GVP Module V Rev. 2 template.
The educational materials described in Annex II have been updated accordingly.

Action: for adoption

Note: this is an update of the RMP, which has been agreed by PRAC. No discussion in CAT is expected.

2.11.5. 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/II/0026

Orchard Therapeutics (Netherlands) BV

Rapporteur: Sol Ruiz, PRAC Rapporteur: Menno van der Elst

Scope: safety: Opinion
Submission of an updated RMP version 2.0 in order to introduce changes to the design of the post-authorisation study STRIM-002 to reflect a change in the proposed RIS analysis methodology from SLiM-PCR to S-EPTS/LM-PCR and shifting the timelines.

Action: for adoption

2.11.6. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0021

Kite Pharma EU B.V.

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

Scope: safety: Opinion
Submission of a variation to allow clinicians to administer Yescarta to seriously ill patients with relapsed/refractory non-Hodgkin lymphoma while having on site an adequate supply of tocilizumab (i.e. to ensure that 1 dose of tocilizumab per patient is available at the treating centres to manage CRS, in addition, treatment centres should have access to an additional dose within 8 hours of each previous dose). The PL and RMP have been updated accordingly.

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/R/0039

Amgen Europe B.V.

Rapporteur: Olli Tenhunen, Co-Rapporteur: Violaine Closson Carella, CHMP Coordinator: Paula Van Hennink, Alexandre Moreau, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: 5-year Renewal of Marketing Authorisation. RSI

Action: for adoption

2.13.2. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/REC/008

Kite Pharma EU B.V.

Scope: quality

Action: for adoption

3. Certification of ATMPs

Information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

3.1. Opinion

3.2. Day 60 Evaluation Reports

No items

3.3. New Applications

No items

4. Scientific Recommendation on Classification of ATMPs

Timetable:

-Start of the procedure:	20.05.2020
-Draft CAT co-ordinator's report:	04.06.2020
-ITF peer-review comments:	10.06.2020
-Revised scientific recommendation:	12.06.2020
-Adoption of scientific recommendation by CAT:	19.06.2020

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Allogeneic CD34+-enhanced cell suspension derived from umbilical cord blood

Intended for the treatment of patients with inherited metabolic disorders [cerebral adrenoleukodystrophy, Hurler syndrome] where haematopoietic stem cell transplant is indicated

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. Homogenate of antlerogenic stem cells

Intended for the treatment of chronic obstructive pulmonary disease, bronchial asthma

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Aggregates of defined size of human embryonic stem cell derived insulin secreting pancreatic beta cells, encapsulated within an encapsulation device

Intended for the treatment of type I diabetes mellitus

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.4. Autologous adipose-derived mesenchymal stem cells, cartilage lesions

Intended for the treatment of cartilage lesions

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.5. Wharton's jelly derived mesenchymal cells myelitis

Intended for the treatment of myelitis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.6. Wharton's jelly derived mesenchymal cells meningitis

Intended for the treatment of meningitis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.7. Wharton's jelly derived mesenchymal cells, meningomyelocele

Intended for the treatment of meningomyelocele, myelomeningocele, spina bifida

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.8. Wharton's jelly derived mesenchymal cells, cerebellum disease

Intended for the treatment of cerebellum disease

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.9. Wharton's jelly derived mesenchymal cells, encephalitis

Intended for the treatment of encephalitis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.10. Wharton's jelly derived mesenchymal cells , Krabbe disease

Intended for the treatment of Globoid cell leukodystrophy (Krabbe disease)

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.11. Wharton's jelly derived mesenchymal cells, osteoarthritis

Intended for the treatment of osteoarthritis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.12. Wharton's jelly derived mesenchymal cells, spinal and bulbar muscular atrophy

Intended for the treatment of spinal and bulbar muscular atrophy

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Recombinant adeno-associated viral vector (serotype 8) carrying an optimised gene for human cyclic nucleotide gated channel subunit beta 3 (CNGB3) protein

Intended for the treatment of achromatopsia caused by mutations in the CNGB3 gene

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Genetically modified Lactococcus lactis strain , engineered to secrete human pro-insulin and human IL-10

Intended for the treatment of clinical recent-onset Type 1 diabetes mellitus

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Autologous CD34+ cells transduced with a lentiviral vector encoding a modified γ-globin gene

Intended for the treatment of sickle cell disease (SCD) and β -thalassemia

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Human autologous hematopoietic stem cells transduced with a lentiviral vector containing codon-optimized cDNA encoding for functional human alpha galactosidase

Intended for the treatment of Fabry disease

Scope: ATMP scientific recommendation

Action: for adoption

4.2.5. Human autologous hematopoietic stem cells transduced with a lentiviral vector containing codon-optimized cDNA encoding for functional human glucocerebrosidase

Intended for the treatment of Gaucher disease

Scope: ATMP scientific recommendation

Action: for adoption

4.2.6. Wharton's jelly derived mesenchymal cells

Intended for the treatment of patients with COVID-19 infections

Scope: ATMP scientific recommendation

Action: for adoption

4.2.7. Wharton's jelly derived mesenchymal stem cells

Intended for the treatment of patients with COVID-19 infections

Scope: ATMP scientific recommendation

Action: for adoption

4.2.8. Wharton's jelly derived mesenchymal stem cell, Optic atrophy

Intended for the treatment of optic atrophy

Scope: ATMP scientific recommendation

Action: for adoption

4.2.9. Wharton's jelly derived mesenchymal stem cell, IFAP syndrome

Intended for the treatment of patients with Ichthyosis follicularis with alopecia and photophobia (IFAP) syndrome

Scope: ATMP scientific recommendation

Action: for adoption

4.2.10. Wharton's jelly derived mesenchymal stem cell, Bone marrow transplant rejection

Intended for the treatment of bone marrow transplant rejection

Scope: ATMP scientific recommendation

Action: for adoption

4.2.11. Wharton's jelly derived mesenchymal stem cell, Secondary graft failure

Intended for the treatment of secondary bone marrow transplant failure/ secondary graft failure

Scope: ATMP scientific recommendation

Action: for adoption

4.2.12. Wharton's jelly derived mesenchymal stem cell, Progressive supranuclear palsy

Intended for the treatment of progressive supranuclear palsy

Scope: ATMP scientific recommendation

Action: for adoption

4.2.13. Wharton's jelly derived mesenchymal stem cell, Multiple system atrophy

Intended for the treatment of multiple system atrophy

Scope: ATMP scientific recommendation

Action: for adoption

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

4.3.1. Autologous adipose-derived mesenchymal stem cell, diabetic foot syndrome

Postponed intended for the treatment of diabetic foot syndrome

Scope: awaiting responses from the applicant to the LoQs. Revised ATMP scientific recommendation

Action: for adoption

4.4. Finalisation of procedure

4.4.1. Recombinant chimeric vesicular stomatitis virus carrying the envelope glycoprotein (GP) of the visceral non-neurotropic strain of the lymphocytic choriomeningitis virus – H0005624

Intended for the treatment of solid tumours, including non-small cell lung carcinoma.

Scope: Comments received by the European Commission. Final ATMP scientific recommendation

Action: for adoption

Request for List of Questions adopted on 20.03.2020.

4.4.2. Gene-activated matrix based on octacalcium phosphate and a plasmid carrying VEGF-A gene – H0005629

Intended to various bone healing indications (sinus lift, non-unions, spinal fusion, etc.)

Scope: Comments received by the European Commission. Final ATMP scientific recommendation

Action: for adoption

4.4.3. Leuco platelet enriched plasma – H0005630

Intended for the treatment of ulcers, chronic wounds

Scope: Comments received by the European Commission. Final ATMP scientific recommendation

Action: for adoption

4.4.4. Recombinant adeno-associated viral vector rh74 containing the human beta-sarcoglycan gene – H0005631

Intended for the treatment of limb-girdle muscular dystrophy type 2E

Scope: the European Commission has raised no comments. ATMP scientific recommendation

Action: for information

4.4.5. Wharton's jelly derived mesenchymal stem cell, drug resistant epilepsy

Intended for the treatment of drug resistant epilepsy

Scope: the European Commission has raised no comments. ATMP scientific recommendation

Action: for information

4.4.6. Wharton's jelly derived mesenchymal stem cell, Behcet disease

Intended for the treatment of Behcet disease

Scope: the European Commission has raised no comments. ATMP scientific recommendation

Action: for information

4.4.7. Wharton's jelly derived mesenchymal stem cell, choroideremia

Intended for the treatment of choroideremia

Scope: the European Commission has raised no comments. ATMP scientific recommendation

Action: for information

4.4.8. Wharton's jelly derived mesenchymal stem cell, foetal alcohol syndrome

Intended for the treatment of foetal alcohol syndrome

Scope: the European Commission has raised no comments. ATMP scientific recommendation

Action: for information

4.4.9. Wharton's jelly derived mesenchymal stem cell, frontotemporal dementia

Intended for the treatment of frontotemporal dementia

Scope: the European Commission has raised no comments. ATMP scientific recommendation

Action: for information

4.4.10. Wharton's jelly derived mesenchymal stem cell, progressive bulbar palsy

Intended for the treatment of progressive bulbar palsy

Scope: the European Commission has raised no comments. ATMP scientific recommendation

Action: for information

4.4.11. Wharton's jelly derived mesenchymal stem cell, vitelliform macular degeneration

Intended for the treatment of vitelliform macular degeneration (Best disease)

Scope: the European Commission has raised no comments. 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

Timetable:
-Final Briefing Package: 05.06.2020
-Start of the procedure at SAWP: 11.06.2020
-CAT report due by: 14.06.2020
-CAT recommendation: 19.06.2020

5.2. CAT reports

5.3. List of Issues

No items

5.4. 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

No items

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

Romania: Simona Badoi – membership mandate started on 07 May 2020

Action: for information

7.1.2. Procedure on voting remotely with Adobe Connect

Scope: improved procedure on the voting exercise procedure, management and recording

Action: for information

7.2. Coordination with EMA Scientific Committees

7.2.1. Committee for Medicinal Products for Human Use (CHMP)

Scope: Summary of Outcomes (SoO) for the 28-30 April 2020 meeting

Action: for information

7.2.2. Scientific Coordinator Board (SciCoBo) – meeting of 7 May 2020

CAT: Martina Schüßler-Lenz

Scope: feedback on the outcome of the SciCoBo meeting that will take place on 7 May 2020

Action: for information

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

7.3.1. GMP/GCP inspections for ATMPs

Scope:
- GMP/GCP inspections during the COVID-19 pandemic
- MRA for ATMPs

Action: for discussion

7.3.2. Scientific advice for ATMPs

Scope: new procedure for providing CAT input to SAWP on scientific advices for ATMPs

Action: for information

Note: CAT members can provided comments on the proposed new procedure by 12 June 2020 (comments to: CATsecretariat@ema.europa.eu). A formal discussion will be scheduled for the June CAT meeting.

7.3.3. Working Party with Patients' and Consumers' Organisations (PCWP) and Working Party with Healthcare Professionals' Organisations (HCPWP)

Scope: meeting Summary from the PCWP/HCPWP joint meeting, held on 3-4 March 2020

Action: for information

7.4. Cooperation within the EU regulatory network

None

7.5. Cooperation with international regulators

7.5.1. ATMP cluster teleconference with FDA-USA, Health Canada and PMDA-Japan

CAT: Martina Schüssler-Lenz, Carla Herberts, Ilona Reischl, Pille Saalik

Scope: feedback on the teleconference that took place on 30 April 2020

Action: for information

7.6. CAT work plan

None

7.7. Planning and reporting

None

7.8. Others

7.8.1. EMA initiative to support the development of medicines against Covid-19

Scope: EMA initiative to support the development of medicines against Covid-19

Action: for information

8. Any other business

8.1. Participation of CAT members/alternates as speakers or panellist to international conferences

Scope: criteria for participation to international conferences

Action: for discussion

8.2. American Society of Gene & Cell Therapy (ASGCT)'s annual meeting, 11th May 2020, Boston MS (USA)

Scope: feedback from Jan Mueller-Berghaus who presented at the ASGCT pre-meeting workshop: 'Commercialization I Workshop'

Action: for information

Date of next CAT meeting:

17-19 June 2020

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

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

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: Scientific Working Party

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

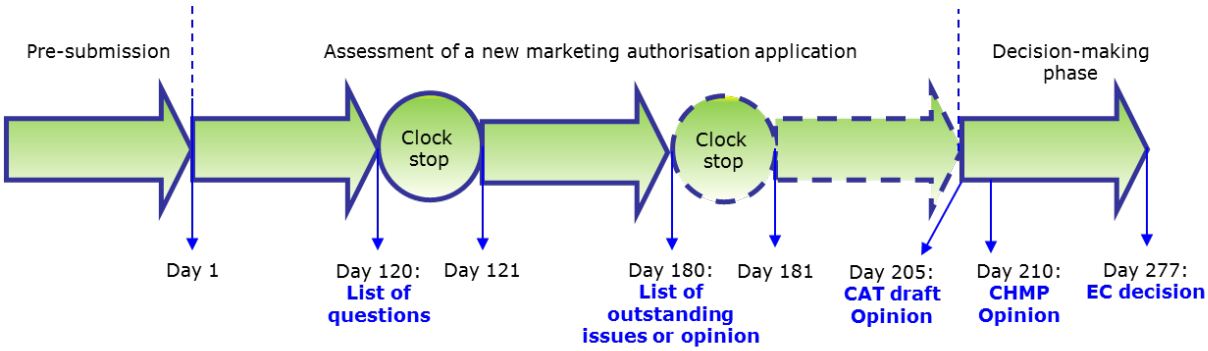
Evaluation of ATMPs (section 2)

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/