EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 January 2021
EMA/CAT/34179/2021
Human Medicines Division

Committee for Advanced Therapies (CAT)

Agenda for the meeting on 20-22 January 2021

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

20 January 2021, 14:00 – 18:30, virtual meeting

21 January 2021, 09:00 – 18:00, virtual meeting

22 January 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 20-22 January 2021. See January 2021 CAT minutes (to be published post-February 2021 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 20-22 January 2021 meeting

1.3. Adoption of the minutes

CAT minutes for 02-04 December 2020 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

2.4.1. 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: Day 120 list of questions

Action: for adoption

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

Accelerated assessment

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

Scope: Day 120 list of questions

Action: for adoption

2.5. Day 80 assessment reports

2.5.1. Lenadogene nolparvovec - Orphan - EMEA/H/C/005047

GenSight Biologics S.A.; treatment of vision loss due to Leber Hereditary Optic Neuropathy (LHON)

Scope: Day 80 assessment report

Action: for information

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

2.11. Type II variations and variations of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

2.11.1. Alofisel - darvadstrocel - Orphan - EMEA/H/C/004258/II/0021

Takeda Pharma A/S

Rapporteur: Lisbeth Barkholt

Scope: Quality

Action: for adoption

2.11.2. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0030

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Clinical

Update of section 5.1 of the SmPC to include the complete data set (updated overall survival analysis) of study CCTL019B2205J, a Phase II, single arm, multicenter study to determine the efficacy and safety of Kymriah in paediatric subjects with relapsed or refractory B-cell acute lymphoblastic leukemia (ALL). The clinical results have already been assesed in procedure EMA/H/C/004090/P46/011.
In addition, the final ATC code for tisagenlecleucel (L01XX71) has been added as an editorial change.

Action: for adoption

2.11.3. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0030

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/0031

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

2.11.5. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0033

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

2.11.6. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0007/G

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts

Scope: Quality

Action: for adoption

Request for Supplementary Information adopted on 06.11.2020.

2.11.7. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0009/G

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts

Scope: Quality

Action: for adoption

Request for Supplementary Information adopted on 04.12.2020.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Options paper on using the European Society for Blood & Marrow Transplantation (EBMT) as a data source for long-term safety and efficacy follow-up of EU patients receiving ATMPs

Scope: EMA update and discussion on possible ways forward and preferred option

Action: for discussion

2.13.2. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/ANX/003.3

Novartis Europharm Limited

Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

Scope: PhV
Non-interventional post-authorisation safety study (PASS):
In order to further characterise the safety - including long-term safety - of Kymriah, the applicant should conduct and submit a study based on data from disease registry CCTL019B2401 in ALL and diffuse large B-cell lymphoma (DLBCL) patients. (Cat. 1).

Submission and evaluation of EBMT safety data from the first semi-annual status report: 23-Apr-2020). Assessment of MAH responses, dated 26-Oct-2020, to the Rapporteurs' clarifications and additional data to be presented in the next reports.

Action: for adoption

2.13.3. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/ANX/006.1

Novartis Europharm Limited

Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

Scope: Clinical
Submission of the annual interim report for Study No. CCTL019B2401:
Post-authorisation efficacy study (PAES): In order to further evaluate the efficacy and safety of Kymriah in ALL patients below the age of 3 years, the applicant should conduct and submit a study based on data from a disease registry in ALL patients."

Action: for adoption

2.13.4. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/ANX/009.3

Novartis Europharm Limited

Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

Scope: Clinical
Submission of a revised protocol (protocol amendment 2) for Study No. CTL019H2301MAH (BELINDA) as a response to ANX-009.2 (adopted in August 2020) where the MAH was asked to address the following points:
1. To provide an additional analysis to time to remission (TTR) where the response time for patients who achieved either a confirmed complete or partial remission is determined.
2. One of the new updates in the protocol states the following «The crossover visit would also mark the end of the treatment and primary follow-up visit for patients in Arm B». It is unclear whether patients who are crossing over to the tisagenlecleucel arm also will be followed-up for

survival. However, this should be ensured.
The 1st study results will be provided by June 2021 in ANX-9.3.

Action: for adoption

2.13.5. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/ANX/002.1

Kite Pharma EU B.V.

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

Scope: PhV
PASS 107 - Non-Interventional Registry Study to further evaluate and characterise the identified risks, potential risks and missing information.
PASS Registry - Kite KT-EU-471-0117: first quarterly Safety Data Report
Action: for adoption

2.13.6. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/ANX/002.1

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege

Scope: Clinical & PhV
post-authorisation efficacy study - Study no. AVXS-101-RG-001 [ANX-002] as requested in September 2020.

Action: for adoption

2.13.7. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/R/0012

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts, Co-Rapporteur: Egbert Flory, PRAC Rapporteur: Ulla Wändel Liminga

Scope: 1 year Renewal of Marketing Authorisation. List of Questions.

Action: for adoption

2.13.8. Zynteglo - betibeglogene autotemcel - Orphan - EMEA/H/C/003691/R/0018

bluebird bio (Netherlands) B.V

Rapporteur: Carla Herberts, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: 1 year Renewal of Marketing Authorisation

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

No items

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:	22.01.2021
-Draft EMA Co-ordinator's report:	05.02.2021
-CAT Coordinator's comments:	10.02.2021
-Revised scientific recommendation:	12.02.2021
-Discussion of scientific recommendation by CAT:	19.02.2021

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Allogeneic human mesenchymal stem cells derived from Wharton's jelly , muscle and tendons disease

Intended for diseases of muscles and tendons

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. Allogeneic human mesenchymal stem cells derived from Wharton's jelly , anal fistula

Intended for the treatment of anal fistula

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Allogeneic human mesenchymal stem cells derived from Wharton's jelly , androgenic alopecia

Intended for the treatment of androgenic alopecia, unspecified

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.4. Allogeneic human mesenchymal stem cells derived from Wharton's jelly , diabetic foot syndrome

Intended for the treatment of diabetic foot syndrome (DFS)

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.5. Allogeneic human mesenchymal stem cells derived from Wharton's jelly , Parkinson's disease

Intended for the treatment of Parkinson's disease

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.6. Allogeneic human mesenchymal stem cells derived from Whartons jelly seeded on the dermal scaffold , skin ulcers

Intended for the treatment of skin ulcers

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.7. Autologous human mesenchymal stem cells derived from adipose tissue , anal fistula

Intended for the treatment of anal fistula

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.8. Autologous human mesenchymal stem cells derived from adipose tissue , androgenic alopecia

Intended for the treatment of androgenic alopecia, unspecified

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.9. Autologous human mesenchymal stem cells derived from adipose tissue (, muscle and tendons disease

Intended for diseases of muscles and tendons

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.10. Two mRNA active substances, encoding separately for Human Papilloma Virus type (HPV) 16 E6 and HPV16 E7 protein

Intended for the treatment of recurrent/metastatic HPV16-positive carcinoma

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.11. Human amniotic membrane, allogeneic, sterile, cryomilled and lyophilized

Intended for the treatment of symptoms of osteoarthritis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.12. Autologous dendritic cells activated against SARS-COV-2 peptides

Intended for the treatment of the prevention of SARS-COV-2 infection

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.13. Human umbilical cord MSC derived exosomes carrying recombinant hTERT mRNA and protein, hsa-miR-125b-5p, hsa-miR-125b-1-3p, AntimiR-21-5p

Intended for the treatment of Acute Respiratory Distress Syndrome and Chronic Obstructive Respiratory Disease

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.14. DNA plasmid encoding human transferring gene

Intended for the treatment of retinitis pigmentosa

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.15. Bacteriophage cocktail consisting of four CRISPR-armed phages

Intended for the treatment of prophylaxis of bloodstream E. coli infection in neutropenic patients with haematological malignancy

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Autologous bone marrow aspirate concentrate

Intended for the repair mechanism for bone repair in a variety of bony defects such as fractures, arthroplasty, bone cysts, osteonecrosis, or avascular necrosis

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. *In vitro* expanded autologous human articular chondrocytes

Intended for the repair of symptomatic, localised, full-thickness cartilage defects of the knee joint in patients with closed epiphyseal growth plates.

Scope: ATMP scientific recommendation

Action: for adoption

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

No items

4.4. Finalisation of procedure

4.4.1. Autologous anti-CD19 chimeric antigen receptor T cells

Intended for the treatment of B- cell malignancies

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

Action: for information

4.4.2. Autologous omental adipose tissue and biodegradable fibrin glue

Intended for the treatment of renal traumatic/disease conditions

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

Action: for information

4.4.3. Messenger ribonucleic acid (mRNA) encoding the human glucose debranching enzyme (GDE)

Intended for the treatment of glycogen storage disease III

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

Action: for information

4.4.4. *In vitro* transcribed messenger ribonucleic acid (mRNA) encoding human interleukin 2 (IL-2), linked to interfering RNA targeting vascular endothelial growth factor A (VEGF-A)

Intended for the treatment of solid tumours

Scope: the European Commission 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

5.2. CAT reports

5.3. List of Issues

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

No items

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:

Procedure start:	14.01.2021
SAWP recommendation:	11.02.2021
CAT recommendation:	19.02.2021
CHMP adoption of report and final recommendation:	25.02.2021

6.3.2. Month 1 – Discussion of eligibility

6.3.3. Month 2 – Recommendation of eligibility

6.3.4. Ongoing support

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT membership

Croatia – Mirna Golemović – membership mandate (member) ended on 01 January 2021

Greece – Maria Gazouli – membership mandate (member) started on 15 January 2021
Greece – Asterios Tsiftsoglou – membership mandate (member) ended on 14 January 2021

Romania – Felicia Costinescu membership mandate (member) ended on 01 January 2021

The Netherlands: Babs Fabriek – membership mandate (alternate) started on 01 January 2021
The Netherlands: Hans Ovelgönne - membership mandate (alternate) ended on 31 December 2020

Action: for information

7.2. Coordination with EMA Scientific Committees

No items

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

7.3.1. Scientific advice for ATMPs

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

Action: for information

This is a follow up from the presentation to CAT in June 2020.

7.4. Cooperation within the EU regulatory network

7.4.1. Inspection of manufacturers of viral vectors used as starting materials for genetically modified cells

CAT drafting group members: Heli Suila, Ivana Haunerova, Marcos Timón, Violaine Closson Carella

Scope: draft Q&A on principles for GMP

Action: for discussion

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

CAT: Ilona Reischl, Marcos Timón, Dariusz Śladowski, Violaine Closson-Carella and Lydie Meheus.

Scope: CAT position on the inception impact assessment on the revision of the BTC legislation

Action: for information

Note:
-Stefaan van der Spiegel (DG Santé, Unit B4 – Medical Products: Quality, Safety and Innovation) gave a presentation to CAT at the December meeting.
-the European Commission opened the inception impact assessment with deadline of 14 December 2020.
-Public consultation and targeted stakeholder consultation are opened for 12 weeks, from end of 2020/beginning of 2021 in order to inform the legislative impact assessment

7.4.3. Definition of gene therapy medicinal products

CAT: Martina Schüssler Lenz

Scope: letter dated 11 December 2020 from the European Commission – DG for Health and Food Safety, asking for CAT: 1) to reflect on the adequacy of the gene therapy medicinal product (GTMP) definition in the draft ICH S12 guideline and 2) to initiate a broader discussion on the need to revise the EU GTMP to align to the progress of science.

Action: for discussion

7.5. Cooperation with international regulators

None

7.6. CAT work plan

7.6.1. CAT work plan 2021

Scope: draft CAT work plan 2021

Action: for adoption

7.7. Planning and reporting

None

7.8. Others

7.8.1. Qualification of treatment centres for CAR T cells

CAT: Martina Schüssler Lenz

Scope: Letter dated 01.12.2020 from Universitätsklinikum Carl Gustav Carus (a German CAR T cell treatment center) which outlines issues with center qualification

Action: for discussion

7.8.2. Curriculum on Advanced Therapies Medicinal Products (ATMPs)

CAT: Ilona Reischl

Scope: plan of trainings for 2021

Action: for discussion

8. Any other business

8.1. New Executive Director at the EMA

Introduction of the new EMA Executive Director - Emer Cooke

Action: for information

8.2. Process for documenting of CAT experiences / CAT learning

CAT: Martina Schüssler Lenz, Niamh Curran, Carla Herberts, Heli Suila

Scope: Process for collecting and maintaining CAT learnings and presentation of CAT learnings:

Action: for discussion

Date of next CAT meeting: 17-19/02/2021

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: Scientific Working Party

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

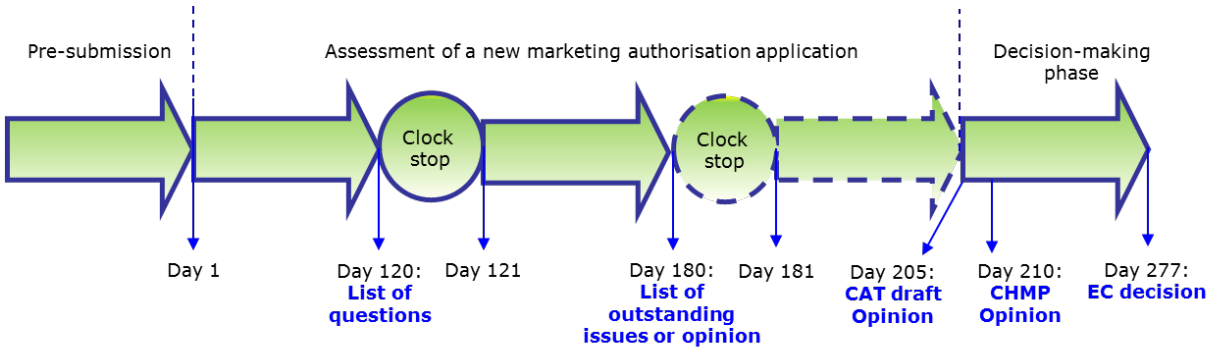
Evaluation of ATMPs (section 2)

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/