22 March 2023
EMA/CAT/86647/2023
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 22-23 March 2023

Chair: Ilona Reischl; Vice-Chair: Carla Herberts

22 March 2023, 14:00 – 18:30, room 1C

23 March 2023, 09:00 – 18:30, room 1C

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 regards 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 22-23 March 2023. See 22-23 March 2023 CAT minutes (to be published post April 2023 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 22-23 March 2023 meeting

1.3. Adoption of the minutes

CAT minutes for 15-18 February 2023 meeting

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

No items

2.4. Day 120 list of questions

No items

2.5. Day 80 assessment reports

No items

2.6. Update on ongoing initial applications

No items

2.7. New applications

2.7.1. In vitro diagnostic medical device - EMEA/H/D/006255

Indicated as an aid in the selection of adult haemophilia A patients for whom valoctocogene roxaparvovec treatment is being considered

Scope: Timetable for assessment

Action: for adoption

2.8. Withdrawal of initial marketing authorisation application

No items

2.9. Re-examination of initial application procedures under Article 9(2) of Regulation No. 726/2004

No items

2.10. 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. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0022/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, Opinion

Action: for adoption

Request for Supplementary Information adopted on 17.02.2023.

2.11.2. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0026

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, Opinion

Action: for adoption

2.11.3. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0027

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, Opinion

Action: for adoption

2.11.4. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0005

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli, PRAC Rapporteur: Gabriele Maurer

Scope: Clinical, Opinion

Extension of indication to include treatment of adult patients with second-line (2L) transplant intended (TI) large B-cell lymphoma (LBCL) for Breyanzi, based on interim analyses from pivotal study JCAR017-BCM-003; this is a global randomised multicentre phase III trial to compare the efficacy and safety of JCAR017 to standard of care in adult subjects with high-risk, transplant-eligible relapsed or refractory aggressive B-cell non-Hodgkin lymphomas (TRANSFORM); as a consequence, sections 4.1, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted.

Action: for adoption

Request for Supplementary Information adopted on 17.02.2023 and 09.09.2022.

2.11.5. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0014

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli, PRAC Rapporteur: Gabriele Maurer

Scope: Clinical, Request for supplementary information

Update of section 5.1 of the SmPC in order to update efficacy information based on final results from studies 017001 and JCAR-017-BCM-001 listed as obligations in the annex II. These studies aimed to further characterise the long-term efficacy and safety of Breyanzi in patients treated with relapsed or refractory diffuse large B cell lymphoma (DLBCL), primary mediastinal large B cell lymphoma (PMBCL), follicular lymphoma grade 3B (FL3B) after two or more lines of systemic therapy. Study 017001 is a phase 1, open-label, single-arm, multicohort, multicentre seamless design trial, while study JCAR-017-BCM-001 is a phase 2, open-label, single-arm, multicohort, multicentre trial. The annex II is updated accordingly. The RMP version 3.0 has also been submitted.

Action: for adoption

2.11.6. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0005

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, Opinion

Action: for adoption

Request for Supplementary Information adopted on 09.12.2022.

2.11.7. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0057

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, Request for supplementary information

Action: for adoption

Request for Supplementary Information adopted on 20.01.2023.

2.11.8. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0036/G

Novartis Europharm Limited

Rapporteur: Carla Herberts

Scope: Quality, Opinion

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/REC/014.1

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, Fulfilled

Action: for adoption

2.13.2. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/REC/011.1

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, Opinion

Action: for adoption

2.13.3. Glybera (EXP) - alipogene tiparvovec - EMEA/H/C/002145/SOB/001.12

uniQure biopharma B.V.

Rapporteur: Egbert Flory

Scope: Pharmacovigilance

Annual safety update report: 25 Oct 2021 – 24 Oct 2022. Long term surveillance programme/ disease registry to collect information on the epidemiology of the disease and the demographics, safety, and the effectiveness outcomes of patients treated with Glybera.

Action: for adoption

2.13.4. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/MEA/005.1

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen

Scope: Pharmacovigilance, Opinion

Submission of Protocol Amendment (amendment 5 and superseding amendment 5) of Study 20130193 (cat 3): A post-marketing, prospective cohort study of patients treated with talimogene laherparepvec in clinical practice to characterise the risk of herpetic illness among patients, close contacts, and healthcare providers; and long-term safety in treated patients.

Action: for adoption

2.13.5. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/ANX/003.10

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Pharmacovigilance

Sixth semi-annual report (EBMT data only). Study CCTL019B2401: 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 a disease registry in acute lymphoblastic Llukaemia (ALL) and diffuse large B-Cell lymphoma (DLBCL) patients.

Action: for adoption

2.13.6. Tecartus - brexucabtagene autoleucel - Orphan - EMEA/H/C/005102/ANX/011

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Clinical & Pharmacovigilance

Protocol of Study No. KTE-EU-474-6644: Long-term, non-interventional study of recipients of Tecartus for treatment of adult patients with relapsed or refractory acute lymphoblastic leukaemia (ALL) [From II-008-G]

Action: for adoption

2.13.7. Upstaza - eladocagene exuparvovec - Orphan - EMEA/H/C/005352/MEA/007

PTC Therapeutics International Limited

Rapporteur: Maura O'Donovan

Scope: Clinical

Feasibility assessment to determine the suitability of adding the registry of the International Working Group on Neurotransmitter Related Disorders (iNTD) as a secondary data source to the PTC-AADC-MA-406 registry [From initial MAA RMP]

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:	24.03.2023
- EMA Coordinator's draft report:	05.04.2023
- CAT Coordinator's comments:	12.04.2023
- Revised scientific recommendation:	14.04.2023
- CAT's discussion of scientific recommendation:	21.04.2023

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Ixoberogene soroparvovec (Genetically engineered, replication-incompetent adeno-associated virus vector comprising the AAV.7m8 capsid proteins, carrying a version of complementary deoxyribonucleic acid for aflibercept, under the control of a ubiquitous promoter)

Treatment of neovascular (wet) age-related macular degeneration

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. Ex vivo fused allogeneic human myoblasts (MB-N) with autologous human myoblast (MB-ALS)

Treatment of amyotrophic lateral sclerosis (ALS)

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Ex vivo fused allogeneic human myoblasts (MB-N) with autologous human bone marrow derived mesenchymal stem cells (MSC-ALS)

Treatment of amyotrophic lateral sclerosis (ALS)

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.4. Ex vivo fused allogeneic human mesenchymal stem cell (MSC-N) with autologous human myoblast (MB-ALS)

Treatment of amyotrophic lateral sclerosis (ALS)

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.5. Ex vivo fused allogeneic human myoblasts (MBN1) with allogeneic human myoblasts (MBN2)

Treatment of amyotrophic lateral sclerosis (ALS)

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.6. Helper-dependent adenovirus vector coding for interleukin-1 receptor antagonist

Treatment of osteoarthritis of the knee

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.7. Autologous CD34+ cells from mobilised peripheral blood

Treatment of amyotrophic lateral sclerosis (ALS)

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.8. Biotinylated cultured reticulocytes, cultured from haematopoietic stem cells

Treatment of red cell suppletion (e.g. trauma/anaemia)

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Lyophilised supernatant of a pathogen inactivated and gamma sterilised platelet lysate

Treatment of topical treatment of skin ulcers

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Autologous intestinal organoid derived from adult stem cells from intestinal epithelial tissue

Treatment of intractable ulcer

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Autologous chondrocytes cultured in hyaluronan-derived scaffold

Repair of cartilage defects

Scope: ATMP scientific recommendation

Action: for discussion

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

No items

4.4. Finalisation of procedure

4.4.1. Umbilical Cord Wharton Jelly-derived mesenchymal stem cells (MSCs) cells

Treatment of spinal cord injury; drug resistant epilepsy; hypoxia ischemia encephalopathy

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.2. Bladder acellular matrix (BAM) based scaffold seeded with allogenic or autologous adipose-derived stromal cells

Treatment of urinary bladder wall augmentation in patients with small capacity high pressure urinary bladder

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.3. Fibrin gel containing autologous leucocyte- and platelet-rich plasma, autologous thrombin, and ascorbic acid

Treatment of wounds

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.4. Ex-vivo expanded allogeneic human corneal endothelial cells

Treatment of diseases of the corneal endothelium

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.5. Recombinant Adeno-Associated Viral Vector expressing a codon optimised human RPGR gene (rAAV2tYF-GRK1-RPGR)

Treatment of X-linked retinitis pigmentosa (XLRP) caused by mutations in the RPGR gene

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.5. Follow-up and guidance

No items

5. Scientific Advice

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

5.1. New requests - appointment of CAT Rapporteurs

5.1.1. Ongoing scientific advice procedures - Appointment of CAT Peer Reviewers

Timetable:

- Start of procedure at SAWP:	13-16.03.2023
- Appointment of CAT Peer Reviewers:	22-24.03.2023
- SAWP first reports:	03.04.2023
- CAT Peer Reviewer comments (NC/C):	05.04.2023
- CAT Peer Reviewer comments (Q):	12.04.2023
- Discussion at SAWP:	11-14.04.2023
- Discussion at CAT and feedback to SAWP:	19-21.04.2023

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	06-09.02.2023
- Appointment of CAT Peer Reviewers:	15-17.02.2023
- SAWP first reports:	06.03.2023
- CAT Peer Reviewer comments (NC/C):	10.03.2023
- CAT Peer Reviewer comments (Q):	15.03.2023
- Discussion at SAWP:	22-24.03.2023
- Discussion at CAT and feedback to SAWP:	19-21.04.2023

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

5.3. Finalisation of D70 procedures – feedback from the discussion meeting

No items

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:	13-16.03.2023
SAWP recommendation:	14.04.2023
CAT recommendation:	21.04.2023
CHMP adoption of report and final recommendation:	26.04.2023

6.3.2. Month 1 – Discussion of eligibility

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

Action: for information

7.1.2. Vote by proxy

Action: for information

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

CAT: Lisbeth Barkholt, Maria Lüttgen

Scope: Topics for discussion at the upcoming SRLM

Action: for discussion

7.2. Coordination with EMA Scientific Committees

7.2.1. Companion Diagnostics

CAT: Ilona Reischl

Scope: Update from the Companion Diagnostics Expert group meeting (10 March 2023); IVD wording in the SmPC

Action: for information

7.2.2. CHMP AR template – Revamp Project

Presentation on the new CHMP AR template

Action: For discussion

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

No items

7.4. Cooperation with the EU regulatory network

No items

7.5. Cooperation with international regulators

7.5.1. International Pharmaceutical Regulators Programme (IPRP) – Gene therapy and cell therapy working group

CAT: Pille Säälik, Ivana Haunerova

Scope: Feedback from the international teleconference that took place on 7 March 2023

Action: for information

7.5.2. WHO approach towards the development of a global regulatory framework for cell and gene therapy products

CAT: Ilona Reischl

Scope: Final WHO paper

Action: for information

7.5.3. Strategic approach to international harmonization of cell and gene therapy products

Scope: Bio Reflection paper on ICH harmonisation of cell and gene therapy products

Action: for discussion

7.6. CAT work plan

No items

7.7. Planning and reporting

7.7.1. Update of the Business Pipeline report - Q1-2023

Action: for information

7.8. Others

7.8.1. CAT stakeholder meeting 2023

CAT: Dariusz Sladowski, Ilona Reischl, Kerstin Sollerbrandt

Scope: Topics proposed by the CAT stakeholders and plan of actions to prepare the agenda of the stakeholders meeting to take place on 16 May 2023

Action: for discussion

7.8.2. EMAN-EIT Expert workshop on Genome editing

CAT: Ilona Reischl, Kieran Breen, Sol Ruiz, Alessandro Aiuti, Alessandra Renieri

Scope: Oral feedback from the workshop held on 21 March 2023

Action: for information

7.8.3. Consensus of scientific principles and experimental approaches for the assessment of potential carcinogenicity of gene therapies

CAT: Carla Herberts

Scope: Feedback from a workshop held on 7-8 March 2023 on the development of a Consensus on the Scientific principles and experimental approaches for the assessment of potential carcinogenicity of gene therapies

Action: for information

7.8.4. ISCT Global Regulators Summit on the use of unproven cell and gene products – 30 May 2023 Paris, France

CAT: Ilona Reischl

Action: for information

8. Any other business

No items

Date of next CAT meeting:

19-21 April 2023

9. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

Abbreviations / Acronyms

AAV: Adeno-Associated Virus

AR: Assessment Report

ATMP: Advanced Therapy Medicinal Product

BWP: Biologics Working Party

CAT: Committee for Advanced Therapies

CHMP: Committee for Medicinal Product for Human Use

COMP: Committee for Orphan Medicinal Products

CTFG: Clinical Trial Facilitation Group

DG: Drafting Group

EC: European Commission

EU NTC: European Union Network Training Centre

ERA: Environmental Risk Assessment

FDA: Food and Drug Administration

FL: Final Letter

GCG: Guideline Consistency Group

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Genetically-modified organism

GMP: Good Manufacturing Practice

GTMP: Gene Therapy Medicinal Product

HTA: Health Technology Assessment Bodies

HSPC: Hematopoietic Stem and Progenitor Cells

ITF: Innovative Task Force

JR: Joint Report

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Application

MAH: Marketing Authorisation Holder

MNAT: Multinational assessment team

MSC: Mesenchymal stem cells

PDCO: Paediatric Committee

PMDA: Pharmaceuticals and Medical Devices Agency (Japan)

PIP: Paediatric Investigation Plan

PL: Package leaflet

PRAC: Pharmacovigilance and Risk Assessment Committee #

PRIME: Priority Medicines

QRD: Quality review of documents

RMP: Risk Management Plan

RP: Reflection paper

RSI: Request for supplementary information

SAs: Scientific Advices

SAG-O: Scientific Advisory Group Oncology

SAWP: Scientific Advice Working Party

SR: Summary Report

SWP: Safety Working Party

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

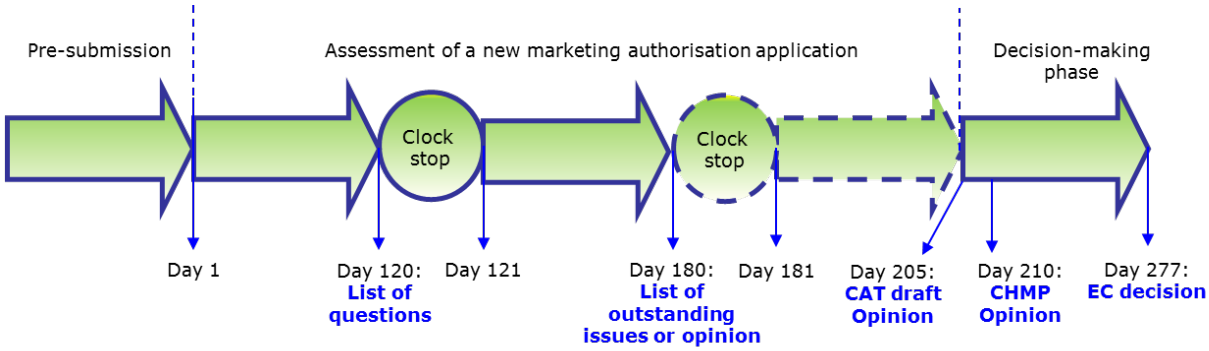
Evaluation of ATMPs (section 2)

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/