17 January 2024
EMA/CAT/20622/2024
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 17-19 January 2024

Chair: Ilona Reischl; Vice-Chair: Kieran Breen

17 January 2024, 14:00 – 18:30,

18 January 2024, 09:00 – 18:30,

19 January 2024, 09:00 – 13:00,

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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Table of contents

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 17-19 January 2024. See January 2024 CAT minutes (to be published post February 2024 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 17-19 January 2024 meeting

1.3. Adoption of the minutes

CAT minutes for 06-09 December 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. Autologous cartilage-derived articular chondrocytes, in-vitro expanded - EMEA/H/C/004594

TETEC Tissue Engineering Technologies AG; Repair of symptomatic, localised, full-thickness cartilage defects of the knee joint grade III or IV

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. Companion diagnostics

2.10.1. Initial consultation

No items

2.10.2. Follow-up consultation

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/0031

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken, Co-Rapporteur: Heli Suila, PRAC Rapporteur: Ulla Wändel Liminga

Scope: Clinical, opinion

Extension of indication to include treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD-38 antibody and have demonstrated disease progression on the last therapy for Abecma (idecabtagene vicleucel, ide-cel), based on results from study BB2121-MM-003 (MM-003, KarMMa-3). This is a Phase 3, multicentre, randomised, open-label study to compare the efficacy and safety of ide-cel

versus standard regimens in subjects with RRMM. As a consequence, sections 2.1, 2.2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 6.3, 6.4 and 6.6 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 3.0 of the RMP has also been submitted. Furthermore, the product information (PI) is brought in line with the Guideline on core SmPC, Labelling and Package Leaflet for advanced therapy medicinal products (ATMPs) containing genetically modified cells.

Action: for adoption

Request for supplementary information adopted on 16.06.2023 and 31.10.2023.

2.11.2. Alofisel - Darvadstrocel - Orphan - EMEA/H/C/004258/II/0047/G

Takeda Pharma A/S

Rapporteur: Maria Luttgen

Scope: Quality, opinion

Action: for adoption

2.11.3. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0023

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

Request for supplementary information adopted on 06.10.2023.

2.11.4. Upstaza - Eladocagene exuparvovec - Orphan - EMEA/H/C/005352/II/0013

PTC Therapeutics International Limited

Rapporteur: Joseph De Courcey

Scope: Quality, request for supplementary information

Action: for adoption

Request for supplementary information adopted on 08.09.2023.

2.11.5. Upstaza - Eladocagene exuparvovec - Orphan - EMEA/H/C/005352/II/0014/G

PTC Therapeutics International Limited

Rapporteur: : Joseph De Courcey

Scope: Clinical

Update of sections 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC in order to update information on safety and efficacy, based on final results from studies NTUH-AADC-010 and NTUH-AADC-011. NTUH-AADC-010 is an open-label, single arm, externally controlled trial to evaluate

safety, efficacy, pharmacodynamics and immunogenicity of AGIL-AADC in children from 18 months to less than 18 years of age with severe AADC deficiency, while NTUH-AADC-011 is an open-label, single arm, externally controlled trial to evaluate efficacy and safety of AGIL-AADC in children from 18 months to less than 6 years of age with severe AADC deficiency. In addition, sections 4.5, 4.9 and 6.6 of the SmPC are updated in order to provide better clarification and guidance for the medical practice. The Package Leaflet is updated accordingly. The MAH also took the opportunity to update the due date of the final report of study AADC-1602 in the Annex II, considering the 10-year follow up of the last patient in study AADC-011, and to introduce minor editorial changes to the product information.

Action: for adoption

Request for supplementary information adopted on 06.10.2023.

2.11.6. Tecartus; Yescarta - Axicabtagene ciloleucel; Brexucabtagene autoleucel - Orphan - EMEA/H/C/WS2607

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, request for supplementary information

Action: for adoption

2.11.7. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0021

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Jo Robays

Scope: Extension of indication, request for supplementary information

Extension of indication to include treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 1 prior therapy, including an immunomodulatory imide drug (IMiDs) and a proteasome inhibitors (PI), have demonstrated disease progression on or after the last therapy and are refractory to lenalidomide for CARVYKTI, based on interim results from study MMY3002 listed as a specific obligation (SOB/006) in the Annex II. This is an ongoing, phase 3, randomised, open-label, multicentre study to determine whether treatment with cilta-cel provides an efficacy benefit compared to standard therapy in participants with relapsed and lenalidomide-refractory multiple myeloma. As a consequence, sections 4.1, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update Annex II of the product information. As part of the application the MAH is requesting a 1-year extension of the market protection.

Action: for discussion (feedback on the ongoing procedure)

Request for supplementary information adopted on 08.09.2023.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Abecma - Idecabtagene vicleucel - Orphan - EMEA/H/C/004662/MEA/007

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Pharmacovigilance, opinion

From Initial MAA: Long-term follow-up study (GC-LTFU-001) to assess the risk of delayed adverse events (AEs) following exposure to GM T cells, to monitor for long-term persistence of GM T cells, including analysis of vector integration sites, as appropriate and to monitor for generation of replication competent retroviruses.
First Interim report (5 year) / Study GC-LTFU-001
Action: for adoption

2.13.2. Abecma - Idecabtagene vicleucel - Orphan - EMEA/H/C/004662/REC/016.1

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality

Action: for adoption

2.13.3. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/MEA/007

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Pharmacovigilance

From Initial MAA:
LTFU study (GC LTFU 001): Long-term follow-up of safety and efficacy for all paediatric and adult subjects exposed do a GM T cell therapy in Bristol-Myers Squibb sponsored, or Bristol Myers Squibb alliance partner sponsored, clinical trials in accordance with Health Authorities' guidance for long-term (up to 15 years) follow-up of subjects treated with gene therapy products (interim report 5 year)

Action: for adoption

2.13.4. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/REC/017

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, request for supplementary information

Action: for adoption

2.13.5. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/ANX/003.1

Janssen-Cilag International NV

Scope: Pharmacovigilance

Rapporteur: Jan Mueller-Berghaus

PASS STUDY First Interim Report / Study 68284528MMY4004
Title: An observational post-authorization safety study to evaluate the safety of multiple myeloma patients treated with ciltacabtagene autoleucel.

Action: for adoption

2.13.6. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/R/0025

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Marcos Timón, PRAC Rapporteur: Jo Robays

Scope: Renewal

1 year renewal of marketing authorisation

Action: for adoption

2.13.7. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/REC/013.1

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Clinical

MAH Response to REC 013 [Study MMY2003 Cohort A] Request for supplementary information as adopted in June 2023: safety and efficacy analysis of the subjects who received cilta-cel manufactured with Bern-LV in Study MMY2003 Cohort A.

Action: for adoption

2.13.8. Kymriah - Tisagenlecleucel - Orphan - EMEA/H/C/004090/ANX/009.7

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Pharmacovigilance

MAH's response to ANX 009.6 [Study CCTL019H2301:PAES]: Request for supplementary information as adopted in October 2023.

Action: for adoption

2.13.9. Kymriah - Tisagenlecleucel - Orphan - EMEA/H/C/004090/LEG/021.1

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Pharmacovigilance

MAH's response to LEG 021 [potential secondary malignancy cases including the case number NVS2022DE245136]. Request for supplementary information was adopted in September 2023.

Action: for adoption

2.13.10. Kymriah - Tisagenlecleucel - Orphan - EMEA/H/C/004090/P46/022

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Clinical

Paediatric studies submitted in accordance with Article 46 of Regulation (EC) No1901/2006, as amended. Final study report NO. CCTL019C2202: a phase II, single arm, multicentre open label trial to determine the safety and efficacy of tisagenlecleucel in paediatric patients with relapsed or refractory mature B-cell non-Hodgkin lymphoma (NHL) (BIANCA)

Action: for adoption

2.13.11. Luxturna - Voretigene neparvovec - Orphan - EMEA/H/C/004451/REC/012

Novartis Europharm Limited

Rapporteur: Sol Ruiz

Scope: Quality

Action: for adoption

2.13.12. ROCTAVIAN - Valoctocogene roxaparvovec - Orphan - EMEA/H/C/005830/SOB/006

BioMarin International Limited

Rapporteur: Violaine Closson Carella

Scope: Clinical, pharmacovigilance

Study 270-303 1-Year CSR: a phase 3b, single arm, open-label study to evaluate the efficacy and safety of BMN 270, an adeno-associated virus vector–mediated gene transfer of human factor VIII, with prophylactic corticosteroids in haemophilia A patients.

Action: for adoption

2.13.13. Abecma - idecabtagene vicleucel; Breyanzi - lisocabtagene maraleucel; Carvykti - ciltabtagene autoleucel; Kymriah - tisagenlecleucel; Tecartus - brexucabtagene autoleucel; Yescarta - axicabtagene ciloleucel

Bristol-Myers Squibb Pharma EEIG (Abecma, Breyanzi), Janssen-Cilag International NV (Carvykti), Novartis Europharm Limited (Kymriah), Kite Pharma EU B.V. (Tecartus, Yescarta)

CAT Rapporteurs: Rune Kjeken (Kymriah, Abecma), Jan Mueller-Berghaus (Carvykti, Tecartus, Yescarta), Concetta Quintarelli (Breyanzi)

PRAC Rapporteur (for the signal): Ulla Wändel Liminga

Scope: Feedback from PRAC discussion on signal of secondary malignancies of T-cell origin (EPITT 20040)

Action: for information

2.14. GMP and GCP inspections requests

No items

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:	19.01.2024
-EMA Coordinator's draft report:	02.02.2024
-CAT Coordinator's comments:	07.02.2024
-Revised scientific recommendation:	09.02.2024
-CAT's discussion of scientific recommendation:	16.02.2024

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Modified measles vaccine virus

For the treatment of solid cancer tumours

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Allogeneic expanded natural killer cells

For the treatment of acute myeloid leukaemia

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Autologous tissue generated in the human body (in vivo) through the foreign body reaction

For tissue augmentation

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Dendritic cells activated by lysate of circulating tumour cells

For the treatment of solid tumours in metastatic stage

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Autologous T Lymphocytes engineered with nanoparticles with curcumin incapsulated

For the treatment of melanoma

Scope: ATMP scientific recommendation

Action: for adoption

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

4.3.1. Spermatogonial stem cells, propagated *in vitro*

Male infertility due to gonadotoxic treatment

Scope: ATMP scientific recommendation

Action: for adoption

4.4. Finalisation of procedure

4.4.1. Allogeneic peripheral blood-derived HSPC, Treg cells and Tcon cells

Prevention of moderate to severe chronic graft-vs.-host disease and/or death in patients with acute leukaemias and in patients with myelodysplastic syndrome (MDS) undergoing HLA-matched allogeneic haematopoietic stem cell transplant (alloHCT)

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:	08-11.01-2024
- Appointment of CAT Peer Reviewers:	17-19.01.2024
- SAWP first reports:	29.01.2024
- CAT Peer Reviewer comments (NC/C):	02.02.2024
- CAT Peer Reviewer comments (Q):	07.02.2024
- Discussion at SAWP:	05-08-02.2024
- Discussion at CAT and feedback to SAWP:	14-16.02.2024

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	05-08.02.2024
- Appointment of CAT Peer Reviewers:	14-16.02.2024
- SAWP first reports:	26.02.2024
- CAT Peer Reviewer comments (NC/C):	01.03.2024
- CAT Peer Reviewer comments (Q):	06.02.2024
- Discussion at SAWP:	04-07.03.2024
- Discussion at CAT and feedback to SAWP:	13-15.03.2024

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

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

5.4. Final Advice Letters for procedures finalised the previous month

6. Pre-Authorisation Activities

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

6.1. Paediatric investigation plans

No items

6.2. ITF briefing meetings in the field of ATMPs

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:	
Procedure start:	08-11.01.2024
SAWP recommendation:	08.02.2024
CAT recommendation:	16.02.2024
CHMP adoption of report and final recommendation:	22.02.2024

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

Action: for information

7.1.2. Vote by proxy

Action: for information

7.1.3. CAT Strategic Review & Learning meeting (SRLM) under the Belgian presidency

CAT: Claire Beuneu

Scope: Date for the upcoming SRLM: 15-17 May 2024

Action: for information

7.2. Coordination with EMA Scientific Committees

7.2.1. BWP/CAT training on AAV based gene therapy

Scope: Discussion on upcoming training on AAV based gene therapy

Coordinator: Sean Barry, Ilona Reischl

Action: for information

7.2.2. Update on revamp project: available new templates, ongoing template revision and industry pilot

Scope: Provide update to the CAT members of the ongoing project and the achievements reached to this point

Action: for information

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

No items

7.6. CAT work plan

7.6.1. CAT work plan for 2024

CAT: Ilona Reischl

Scope: Draft CAT work plan for 2024

Action: for discussion

7.6.2. Update on real-world evidence (RWE) studies to support EMA scientific committees

Scope: Outcome of the SMA registry study

Action: for information

7.6.3. Reflection paper on the use of real-world data to generate real-world evidence in non-interventional studies

CAT: Ilona Reischl, Rozalina Kuloksozova

Scope: Comment from CAT on the draft Reflection Paper on real-world evidence

Action: for discussion

7.6.4. Guideline on quality, non-clinical and clinical requirements for investigational ATMPs in clinical trials

CAT: Ilona Reischl

Scope: Draft guideline, updated following the external consultation

Action: for discussion

7.7. Planning and reporting

No items

7.8. Others

No items

8. Any other business

8.1. Demo of the Scientific Explorer tool

Scope: AI/Knowledge Mining driven tool that EMA is developing to allow easy and accurate searching, finding, interrogating and accessing of scientific information to inform scientific decisions. The scope of the tool's first version are scientific advice letters.

Action: for information

Date of next CAT meeting:

14-16 February 2024

9. Explanatory notes

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

For a list of acronyms and abbreviations, see:

List of abbreviations used in EMA human medicines scientific committees and CMDh documents, and in relation to EMA's regulatory activities

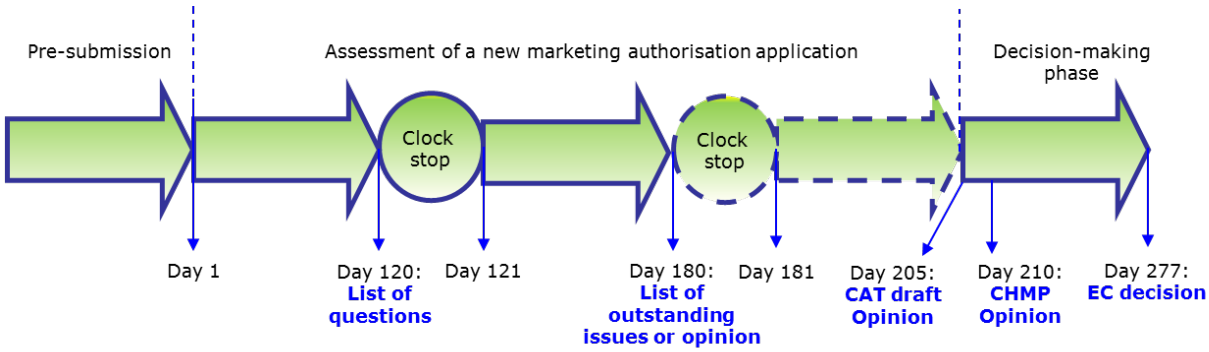
Evaluation of ATMPs (section 2)

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 Post-authorisation activities (section 2.11-2.13) and any ATMP related inspection requests (section 2.14).

New applications (sections 2.1. to 2.9.)

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 2.4) 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 2.3). Section 2.6 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.

New applications (section 2.7.)

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.

Withdrawal of applications (section 2.8.)

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.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 (section 2.9.)

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.

Companion diagnostics (section 2.10)

This section lists applications for initial and follow-on consultation of companion diagnostics.

Post-authorisation activities (section 2.11-2.13.)

Section 2.11 lists type II variations, including extension of indication applications and re-examination procedures for type II variations for which the applicant has requested re-examination of the opinion previously issued by the CHMP. Section 2.12 list extension application according to Annex I of Reg. 1234/2008 and section 2.13 includes all other post-authorisation activities concerning authorised ATMPs that are not covered elsewhere in the agenda such as post-authorisation measures, 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.

GMP and GCP Inspections Issues (section 2.14.)

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).

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/