19 March 2025
EMA/CAT/97209/2025
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 19-21 March 2025

Chair: Ilona Reischl; Vice-Chair: Kieran Breen

19 March 2025, 14:00 – 18:30, room 2C

20 March 2025, 09:00 – 18:30, room 2C

21 March 2025, 09:00 – 13:00, room 2C

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 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 19-21 March 2025. See March 2025 CAT minutes (to be published post April 2025 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 19-21 March 2025 meeting

1.3. Adoption of the minutes

CAT minutes for 19-22 February 2025 meeting

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

2.3.1. Obecabtagene autoleucel - PRIME - Orphan - EMEA/H/C/005907

Autolus GmbH; Treatment of patients with relapsed or refractory B cell precursor acute lymphoblastic leukaemia (ALL)

Scope: Day 180 list of outstanding issues

Action: for adoption

List of questions adopted on 19.07.2024.

2.3.2. Autologous cartilage-derived articular chondrocytes, in-vitro expanded - EMEA/H/C/004594

Repair of symptomatic, localised, full-thickness cartilage defects of the knee joint grade III or IV

Scope: Day 180 list of outstanding issues

Action: for adoption

List of questions adopted on 19.04.2024.

2.3.3. Dorocubicel / Allogeneic umbilical cord-derived CD34- cells, non-expanded - PRIME - Orphan - EMEA/H/C/005772

Cordex Biologics International Limited; Treatment of adult patients with haematological malignancies

Scope: Day 180 list of outstanding issues

Action: for adoption

List of questions adopted on 11.10.2024.

2.4. Day 120 list of questions

No items

2.5. Day 80 assessment reports

2.5.1. Nadofaragene firadenovec - EMEA/H/C/005856

Treatment of adult patients with high-grade (HG), Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC)

Scope: Day 80 assessment report

Action: for information

2.5.2. Autologous CD34+ haematopoietic stem cells transduced ex vivo with a lentiviral vector encoding human Wiskott-Aldrich syndrome protein - Orphan - EMEA/H/C/006525

Fondazione Telethon Ets; Treatment of patients with Wiskott-Aldrich Syndrome (WAS)

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

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/0058/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, opinion

Action: for adoption

Request for supplementary information adopted on 21.02.2025.

2.11.2. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0036

Janssen-Cilag International NV

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

Scope: Clinical, opinion

Update of sections 4.8, and 5.1 of the SmPC in order to update the list of adverse drug reactions (ADRs), and update clinical efficacy and safety information based on second interim analysis from study 68284528MMY3002 (CARTITUDE-4); this is a phase 3 randomized study comparing ciltacabtagene autoleucel, a chimeric antigen receptor T cell (CAR-T) therapy directed against BCMA, versus Pomalidomide, Bortezomib and Dexamethasone (PVd) or Daratumumab, Pomalidomide and Dexamethasone (DPd) in subjects with relapsed and lenalidomide-refractory multiple myeloma; The RMP version 5.3 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.

Action: for adoption

Request for supplementary information adopted on 21.02.2025.

2.11.3. Kymriah - Tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0092

Novartis Europharm Limited

Rapporteur: Rune Kjeken, PRAC Rapporteur: Gabriele MaurerScope: Safety, opinion

Update of section 4.2 of the SmPC in order to update the 'monitoring after infusion' recommendations, based on existing clinical trial data as well as literature references reporting real word experience. The Package Leaflet is updated accordingly. The RMP version 8.0 has also been submitted. In addition, the MAH took the opportunity to introduce a minor change to the HCP educational programme in the Annex II in order to enhance readability.

Action: for adoption

Request for supplementary information adopted on 24.01.2025.

2.11.4. Luxturna - Voretigene neparvovec - Orphan - EMEA/H/C/004451/II/0054/G

Novartis Europharm Limited

Rapporteur: Sol Ruiz

Scope: Quality, opinion

Action: for adoption

2.11.5. Tecartus; Yescarta - Axicabtagene ciloleucel; Brexucabtagene autoleucel - Orphan - EMEA/H/C/WS2821/G

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, opinion

Action: for adoption

2.11.6. Ebvallo - Tabelecleucel - EMA/VR/0000245074

Pierre Fabre Medicament

Rapporteur: Egbert Flory

Scope: Quality

Action: for adoption

2.11.7. Tecartus, Yescarta - Brexucabtagene autoleucel, Axicabtagene ciloleucel - EMA/VR/0000242383

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, opinion

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Casgevy - Exagamglogene autotemcel - Orphan - EMEA/H/C/005763/MEA/011.1

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Jan Mueller-Berghaus

Scope: Clinical & Pharmacovigilance (PRAC-led procedure)

From initial MAA

Revised Protocol Version 2.0 for PASS no. VX24-290-102

Title: Healthcare Professional Survey (HCP) to Assess the Effectiveness of the Additional Risk Minimization Measures (aRMM) for Casgevy® (exagamglogene autotemcel)

Action: for information (PRAC-led procedure)

2.13.2. Imlygic - Talimogene laherparepvec - EMEA/H/C/002771/MEA/005.3

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen

Scope: 6th Interim Report for PASS 20130193 (PRAC-led procedure)

A post-marketing, prospective cohort study of patients treated with talimogene laherparepvec in clinical practice to characterize the risk of herpetic illness among patients, close contacts, and healthcare providers; and long term safety in treated patients.

Annual interim reports to be included in the PSUR and DSUR.

Action: for information

2.13.3. Tecartus - Brexucabtagene autoleucel - Orphan - EMEA/H/C/005102/ANX/002.6

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Response to MEA 002.5 (PRAC-led procedure):

Revised Protocol #5 for Study KTE-EU-472-6036
Title: Long-term, non-interventional study of recipients of Tecartus (brexucabtagene autoleucel) for treatment of adult patients with relapsed or refractory Mantle Cell Lymphoma (MCL).

Action: for information

2.13.4. Tecartus - Brexucabtagene autoleucel - EMA/PAM/0000245367

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: ANX/0101/1 Clinical and Pharmacovigilance

Action: for adoption

2.14. Companion diagnostics - initial consultation

No items

2.15. Companion diagnostics – Follow-up consultation

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

3.3. New Applications

No items

4. Scientific Recommendation on Classification of ATMPs

Timetable:

-Start of the procedure:	21.03.2025
-EMA Coordinator's draft report:	01.04.2025
-CAT Coordinator's comments:	09.04.2025
-Revised scientific recommendation:	09.04.2025
-CAT's discussion of scientific recommendation:	16.04.2025

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Allogeneic T cells genetically modified ex vivo using CRISPR/Cas9 to express an anti-CD19 chimeric antigen receptor

Treatment of frontotemporal dementia (FTD) in adults who have a mutation in the GRN or chromosome 9 open reading frame 72 (C9orf72) genes

Scope: Appointment of CAT coordinator

Action: for adoption

4.1.2. Induced pluripotent stem cell (iPSC)-derived photoreceptor precursor cells

Treatment of primary photoreceptor disease

Scope: Appointment of CAT coordinator

Action: for adoption

4.1.3. Messenger mRNA encoding the human Dynein Axonemal Intermediate Chain 1 (DNAI1) protein

Treatment of primary ciliary dyskinesia caused by mutations in the DNAI1 gene

Scope: Appointment of CAT coordinator

Action: for adoption

4.1.4. Messenger mRNA encoding the cystic fibrosis transmembrane conductance regulator (CFTCR) protein

Treatment of cystic fibrosis

Scope: Appointment of CAT coordinator

Action: for adoption

4.1.5. Allogeneic genetically modified T-cells expressing two chimeric antigen receptors (CARs) targeting the human CD19 and CD70 proteins

Treatment of autoimmune diseases

Scope: Appointment of CAT coordinator

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. mRNA transfected macrophages cultured from autologous monocytes

Treatment of end stage liver disease

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Genetically modified porcine heart

Intended for cardiac xenotransplantation to human patients with end-stage heart failure

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Genetically modified Escherichia coli bacteria engineered to carry genes to metabolize tryptophan and genes to use an exogenously administered sugar source

Treatment of type II diabetes

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. mRNAs encoding modified C.acnes protein

Treatment of acne

Scope: ATMP scientific recommendation

Action: for adoption

4.2.5. Autologous tumour-derived dendritic cells

Prevention of relapse and metastasis of non-small cell lung carcinoma (NSCLC)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.6. adeno-associated virus (AAV) serotype 1 (AAV1) vector containing the human granulin precursor (GRN) cDNA encoding progranulin (PGRN)

Treatment of frontotemporal dementia (FTD) in adults who have a mutation in the GRN or chromosome 9 open reading frame 72 (C9orf72) genes

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

No items

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:	10-13.03.2025
- Appointment of CAT Peer Reviewers:	19-21.03.2025
- SAWP first reports:	31.03.2025
- CAT Peer Reviewer comments (NC/C):	04.04.2025
- CAT Peer Reviewer comments (Q):	09.04.2025
- Discussion at SAWP:	07-10.04.2025
- Discussion at CAT and feedback to SAWP:	14-16.04.2025

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	dd.mm.202y
- Appointment of CAT Peer Reviewers:	dd.mm.202y
- SAWP first reports:	dd.mm.202y
- CAT Peer Reviewer comments (NC/C):	dd.mm.202y
- CAT Peer Reviewer comments (Q):	dd.mm.202y
- Discussion at SAWP:	dd.mm.202y
- Discussion at CAT and feedback to SAWP:	dd.mm.202y

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

No items

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:

Procedure start:	10-13.03.2025
SAWP recommendation:	13.03.2025
CAT recommendation:	21.03.2025
CHMP adoption of report and final recommendation:	25.04.2025

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 Polish presidency

CAT: Dariusz Sladowski

Scope: Preparation for the meeting

Action: for discussion

7.1.4. Onboarding Programme for CAT members and alternates

CAT: Ilona Reischl

Scope: Onboarding Programme, revision 1

Action: for adoption

7.1.5. Revision of EMA policy 0044 on handling of competing interests

Scope: The main changes in the revision of policy 044, the updated declaration of interests form and the next steps for experts will be presented

Action: for information

7.2. Coordination with EMA Scientific Committees

7.2.1. CDx expert group - - IVD/CDx information

Scope: IVD/CDx information in assessment report and in the MAA ()

Action: for endorsement

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

7.3.1. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)

7.3.1.1. Updates to Rules of Procedure and mandates for PCWP and HCPWP

Scope: Updates to Rules of Procedure and mandates for PCWP and HCPWP

Action: for adoption

7.3.1.2. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP) - Agenda and minutes

Scope:

- Meeting summary of the PCWP/HCPWP and all eligible organisations meeting held on 20 November 2024
- Draft Agenda of the PCWP-HCPWP meeting to be held on 1-2 April 2025

Action: for information

7.4. Cooperation with the EU regulatory network

7.4.1. Revisions made to the Reflection Paper on RWE

Scope: Present the main changes introduced to the reflection paper on Use of RWD in NIS to generate RWE for regulatory purposes after the public consultation

Action: for information

7.4.2. Engineered living materials (ELMs)

Scope: Presentation of the Horizon scanning report on ELMs

Action: for discussion

Note: comments from CAT by 28.03.2025, especially on the recommendation section

7.5. Cooperation with international regulators

7.5.1. ATMP cluster teleconference with US-FDA, Health Canada, PMDA (Japan) and SwissMedic

CAT: Ilona Reischl

Scope: Feedback from the teleconference on 27.02.2025

Action: for information

7.5.2. US-FDA-EMA collaboration on gene therapies for (ultra) rare diseases (CoGenT)

Scope: Update on the CoGenT pilot

Action: for information

7.5.3. ICH E22 - General Considerations for Patient Preference Studies (PPS)

Scope: Presentation of the outline of the ICH E22 guideline

Action: for discussion

Note: CAT comments are awaited by 31.03.2025

7.6. CAT work plan

7.6.1. Guideline on requirements for investigational ATMPs in clinical trials

CAT: Ilona Reischl

Scope: Organisation of training/webinar on the guideline: plan of actions

Action: for discussion

7.6.2. Publication of clinical trials in EU

CAT: Ilona Reischl

Scope: Confirmation of list of authors and call for CAT members to identify scientific publications where there is reference to the number of ATMP clinical trials in EU

Action: for discussion

7.7. Planning and reporting

No items

7.8. Others

7.8.1. Draft Reflection Paper on Patient Experience Data

Scope: Presentation of the draft reflection paper.

Action: for information

Note: A drafting group composed of members from EMA committees (CHMP, COMP, PDCO, PRAC and CAT) and selected WPs (SAWP, ONCWP, PCWP, HCPWP) has drafted a reflection paper on Patient Experience Data. The RP provides a framework for discussion and clarifies in particular areas where scientific knowledge is fast evolving or regulatory experience is limited. The Reflection Paper is complementary to the ICH guidance work and is not intended to be a methodological guidance.

The Drafting Group is circulating the draft for internal consultation to the relevant committees and WPs. CAT comments are awaited by 31.03.2025.

Public consultation is foreseen in Q3 2025.

7.8.2. Unauthorised Dendritic cell therapies

Scope: EMA- HMA statement: 'Unregulated advanced therapy medicinal products pose serious risks to health'

Action: for information

8. Any other business

8.1. Health & Safety Video

Scope: To remind delegates of Health and Safety procedures in the EMA building

Action: for information

Date of next CAT meeting:

14-16 April 2025

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

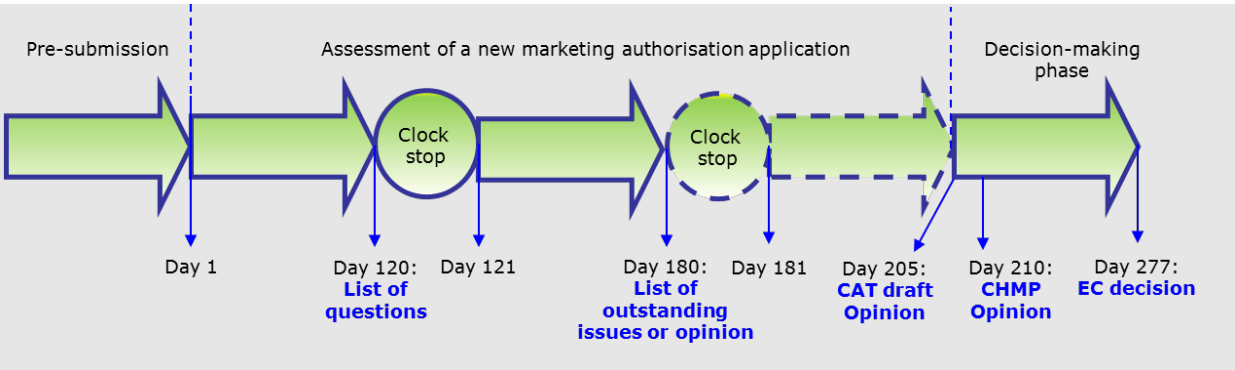
Evaluation of ATMPs (section 2)

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.

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 2.11-2.13.)

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.

Companion diagnostics (section 2.14-2.15)

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

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/