07 December 2022
EMA/CAT/881712/2022
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 07-09 December 2022

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

07 December 2022, 14:00 – 18:30, room 01-D

08 December 2022, 09:00 – 18:30, room 01-D

09 December 2022, 09:00 – 13:00, room 01-D

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 07-09 December 2022. See December 2022 CAT minutes (to be published post January 2023 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 07-09 December 2022 meeting

1.3. Adoption of the minutes

CAT minutes for 03-04 November 2022 meeting

2. Evaluation of ATMPs

2.1. Opinions

2.1.1. Etranacogene dezaparvovec - PRIME - Orphan - EMEA/H/C/004827

CSL Behring GmbH; Treatment of adults with Haemophilia B

Scope: Opinion

Action: for adoption

List of outstanding issues adopted on 07.10.2022. List of questions adopted on 15.07.2022.

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

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

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

Scope: Day 180 list of outstanding issues

Action: for adoption

List of questions adopted on 19.02.2021.

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

2.8. 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/0019

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality; opinion

Action: for adoption

2.11.2. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0020

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune KjekenScope: Quality; opinioni

Action: for adoption

2.11.3. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0004

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta QuintarelliScope: Quality; opinion

Action: for adoption

Request for supplementary information adopted on 09.09.2022

2.11.4. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0007/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta QuintarelliScope: Quality; Request for supplementary information

Action: for adoption

2.11.5. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0009

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta QuintarelliScope: Quality; Request for supplementary information

Action: for adoption

2.11.6. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0003

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus, , PRAC Rapporteur: Jo RobaysScope: Clinical safety; opinion

Update of sections 4.4 and 4.8 of the SmPC in order to update the existing warnings on cytokine release syndrome (CRS), neurologic toxicities and grading of related events and to update the list of adverse drug reactions (ADRs) based on previously reviewed data from studies MMY2001 and MMY2003, and an additional internal characterisation of neurotoxicity risk; the Package Leaflet is updated accordingly. The RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the product information.

Action: for adoption

2.11.7. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0004/G

Janssen-Cilag International NV

Rapporteur: Jan Mueller-BerghausScope: Clinical safety; opinion

Grouped application comprising two type II variations as follows:
Update of section 4.4 of the SmPC in order to add a new warning on increased risk of severe/fatal Covid-19 infections following Covid-19 signal evaluation from the ongoing study 68284528MMY3002 (CARTITUDE-4) based on a cumulative review of all clinical trials, registries and literature.

Update of section 4.4 of the SmPC in order to add a new warning on risk of severe bleeding in the context of hemophagocytic lymphohistiocytosis syndrome (HLH) following a signal evaluation from the ongoing study 68284528MMY3002 (CARTITUDE-4) based on cumulative review of all clinical trials, registries and literature.

The Package Leaflet is updated accordingly.

The RMP version 2.2 has also been submitted.

Action: for adoption

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

Janssen-Cilag International NV

Rapporteur: Jan Mueller-BerghausScope: Quality, Request for supplementary information

Action: for adoption

2.11.9. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0056

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen, PRAC Rapporteur: Brigitte Keller-StanislawskiScope: Clinical safety

Submission of the final report from study 20120139 listed as a category 3 study in the RMP in order to fulfil MEA/004. This is a multicentre, observational registry study to evaluate the survival and long-term safety of subjects who previously received talimogene laherparepvec in Amgen or BioVEX sponsored clinical trials.

Action: for adoption

Request for supplementary information adopted on 09.09.2022.

2.11.10. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0050

Novartis Europharm Limited

Rapporteur: Rune KjekenScope: Quality; opinion

Action: for adoption

Request for supplementary information adopted on 13.04.2022.

2.11.11. Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/II/0011/G

Orchard Therapeutics (Netherlands) B.V.

Rapporteur: Carla Herberts, PRAC Rapporteur: Brigitte Keller-StanislawskiScope: Quality and Clinical safety; Request for supplementary information

Update of sections 4.2, 4.4, 4.5, 4.8 and 5.1 of the SmPC ; the Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to remove ANX/002 from the Annex II and to introduce minor editorial changes to the PI. The RMP version 1.3 has also been submitted.

Action: for adoption

2.11.12. Upstaza - eladocagene exuparvovec - Orphan - EMEA/H/C/005352/II/0004/G

PTC Therapeutics International Limited

Rapporteur: Maura O'DonovanScope: Quality; Request for supplementary information

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/MEA/007

Janssen-Cilag International NV

Rapporteur: Jan Mueller-BerghausScope: Pharmacovigilance

Survey to evaluate the effectiveness of the ciltacabtagene autoleucel HCP Educational Program and the Product Handling Training [From initial MAA]

Action: for adoption

2.13.2. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/REC/009

Janssen-Cilag International NV

Rapporteur: Jan Mueller-BerghausScope: Quality
Action: for adoption

2.13.3. Upstaza - eladocagene exuparvovec - Orphan - EMEA/H/C/005352/REC/005

PTC Therapeutics International Limited

Rapporteur: Maura O'DonovanScope: Quality

Action: for adoption

2.13.4. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/P46/020

Novartis Europharm Limited

Rapporteur: Carla Herberts

Scope: Clinical

Paediatric studies submitted in accordance with Article 46 of Regulation (EC) No1901/2006, as amended: FINAL STUDY REPORT, Study No. AVXS-101-CL-102 (COAV101A12102): Phase 1, Open-Label, Dose Comparison Study of AVXS-101 for Sitting but Non-Ambulatory Patients with Spinal Muscular Atrophy.

Action: for adoption

Request for supplementary information adopted on 09.09.2022

2.13.5. Implementation by the MAHs of CAR-Ts of the CAT-PRAC recommendation on using EBMT as a data source for imposed or requested studies for the long-term safety and efficacy follow-up for ATMPs

Scope: Feedback from the discussion with the Rapporteurs of CAR-Ts and feedback from the PRAC discussion

Action: for discussion

2.13.6. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/REC/020

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality

Action: for adoption

3. Certification of ATMPs

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

3.1. Opinion

No items

3.2. Day 60 Evaluation Reports

No items

3.3. New Applications

No items

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Autologous platelet concentrate, consisting of a fibrin matrix enriched with platelets, leukocytes and of cytokines and growth factors

Treatment of patients with critical limb ischemia, in combination with mechanical lower limb revascularization (angioplasty)

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. Autologous adipose tissue derived progenitor cells in biodegradable chemically crosslinked hydrogel

Subacute spinal cord injury in adults with a complete lesion (ASIA A score)

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Genetically engineered E. coli strain containing a plasmid expressing CRISPR-Cas against clbA, clbB and clbC

Prevention of disease progression in Familial Adenomatous Polyposis (FAP)

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.4. Mitochondria isolated from allogeneic umbilical-cord mesenchymal stem cells

Polymyositis/Dermatomyositis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.5. Macrophage-Drug Conjugate (MDC) composed of allogenic human monocyte-derived macrophages loaded with a protein-drug conjugate

Treatment of solid tumours

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.6. DNA plasmid vector encoding human insulin like growth factor binding protein 2

Treatment of newly diagnosed advanced ovarian cancer after debulking surgery

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.7. Autologous muscle precursor cells (MPCs)

Treatment of female stress urinary incontinence

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Adult autologous regenerative cells

Indicated for regeneration, repair, or replacement of weakened or injured subcutaneous tissue

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Autologous adipose-derived stromal vascular fraction cells (ADSVFCs)

Indicated for the treatment of haemophilic arthropathy

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Allogeneic Natural Killer cells armed with anti-EGFR monoclonal antibody

Indicated for the treatment of epidermal growth factor receptor (EGFR) positive cancers

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Allogeneic natural killer cells armed with anti-HER2 monoclonal antibody

Indicated for the treatment of human epidermal growth factor receptor 2 (HER2) positive cancers

Scope: ATMP scientific recommendation

Action: for adoption

4.2.5. Ex-vivo expanded allogeneic neural crest-like stem cells

Indicated for the treatment of diabetic foot ulcer

Scope: ATMP scientific recommendation

Action: for adoption

4.2.6. Allogeneic Wharton's jelly mesenchymal stem cells (WJ-MSCs)

Indicated for the treatment of stress incontinence

Scope: ATMP scientific recommendation

Action: for adoption

4.2.7. Autologous monocyte-derived dendritic cells electroporated with mRNAs encoding for immunostimulatory proteins caTLR4, CD40L and CD70 combined with one of the tumour-associated antigens (TAA) MAGE-C2, MAGE-A3, WT1 and NY-ESO-1

Indicated for the treatment of gastric cancer

Scope: ATMP scientific recommendation

Action: for adoption

4.2.8. Autologous human tumour infiltrating lymphocytes

Indicated for the treatment of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC)

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. Allogeneic adipose-derived mesenchymal stem cells (ADMSCs)

Intended for the treatment of osteoarthritis of the knee and hip

Scope: The 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:	28.11-01.12.2022
Appointment of CAT Peer Reviewers:	07-09.12.2022
SAWP first reports:	02.01.2023
CAT Peer Reviewer comments (NC/C):	06.01.2023
CAT Peer Reviewer comments (Q):	11.01.2023
Discussion at SAWP:	09-12.01.2023
Discussion at CAT and feedback to SAWP:	18-20.2023

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

Start of procedure at SAWP:	09-12.01.2023
Appointment of CAT Peer Reviewers:	18-20.01.2023
SAWP first reports:	30.01.2023
CAT Peer Reviewer comments (NC,C):	03.02.2023
CAT Peer reviewer comments (Q):	08.02.2023
Discussion at SAWP:	06-09.02.2023
Discussion at CAT and feedback to SAWP:	15-17.02.2023

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

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:	28/11-01/12/2022
SAWP recommendation:	12/01/2023
CAT recommendation:	20/01/2023
CHMP adoption of report and final recommendation:	26/01/2023

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

No items

7.1.2. Vote by proxy

No items

7.1.3. CAT Strategic Review & Learning meeting (SRLM) under the Czechia presidency, 17 – 18 November 2022 in Paris

CAT: Petr Soukup, Kristýna Řehořová Hradilková, Violaine Closson Carella, Martina Schuessler-Lenz

Scope: Feedback from the CAT SRLM

Action: for information

7.2. Coordination with EMA Scientific Committees

None

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

None

7.4. Cooperation with the EU regulatory network

None

7.5. Cooperation with international regulators

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

CAT: Martina Schuessler-Lenz

Scope: Agenda of the teleconference of 15 December 2022

Action: for information

7.5.2. International Pharmaceutical Regulators Programme (IPRP), gene and cell therapy working groups

CAT: Pille Säälik, Ivana Haunerova

Scope: Draft IPRP reflection paper: General Considerations for Materials Used in the Manufacture of Human Cell and Gene Therapy Products

Action: for discussion

7.6. CAT work plan

7.6.1. CAT Workplan for 2023

CAT: Martina Schüssler-Lenz

Scope: draft CAT workplan for 2023

Action: for discussion

7.7. Planning and reporting

7.7.1. Update of the Business Pipeline report – Q4-2022

Scope: Update of the business pipeline report for the human scientific committees

Action: for information

7.8. Others

7.8.1. Good Practice Guide for the use of the EU metadata catalogue and Data Quality Framework

Scope: Presentation of the following documents for public consultation: a. Good Practice Guide for the use of the EU metadata catalogue, and b. Data Quality Framework

Action: for information

7.8.2. Blood/tissue establishment in third countries providing starting materials for ATMPs

CAT: Barbara Bonamassa

Scope: CAT learning: inspection of leukapheresis centres in third countries

Action: for discussion

7.8.3. CAT Stakeholder meeting 2023

Scope: proposals for topics to be included in the agenda of the CAT stakeholder meeting that will be organised in the first half of 2023.

Action: for discussion

7.8.4. Feedback on the SMA study

CAT: Lisbeth Barkholt, Kieran Breen, Mencia de Lemus

Action: for information

7.8.5. Adeno-associated viral (AAV) vector toxicities: regulatory considerations

CAT: Carla Herberts, Egbert Flory

Scope: Revised discussion paper on insertional mutagenesis and follow-up for AAV gene therapy

Action: for adoption

7.8.6. Guideline on Clinical electronic Structured Harmonised Protocol (CeSHarP)

Scope: Introduction of the clinical protocol template and the technical specification

Action: for information

7.8.7. Reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation

CAT: Carla Herberts, Jan Mueller-Berghaus

Scope: presentation of the draft reflection paper

Action: for information

7.8.8. Methodology Working Party

MWP chair: Kit Roes; MWP member: Kristin Karlsson;

Scope: Presentation of the working of the Methodology Working Party and how it can support the CAT under the new working party model

Action: for information

8. Any other business

No items

Date of next CAT meeting:

18-20/01/2023

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

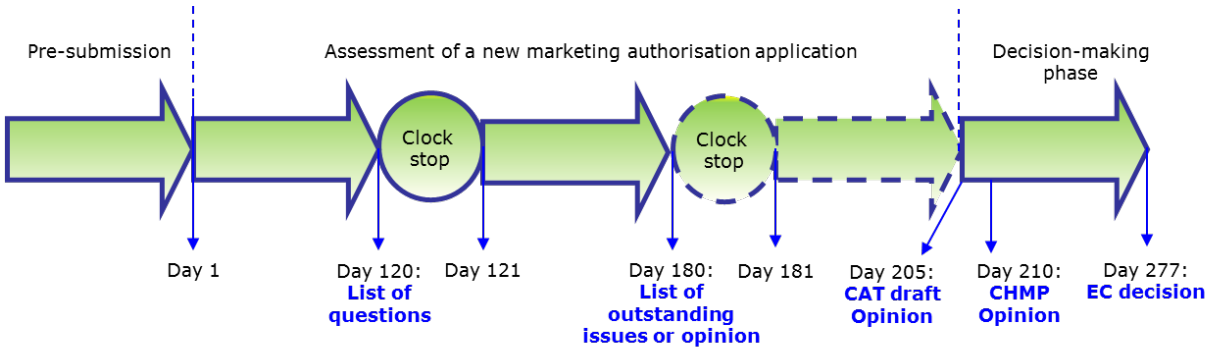
Evaluation of ATMPs (section 2)

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/