



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 December 2021
EMA/CAT/685109/2021
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 08-10 December 2021

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

08 December 2021, 14:00 – 18:30, remote virtual meeting

09 December 2021, 09:00 – 18:30, remote virtual meeting

10 December 2021, 09:00 – 13:00, remote virtual meeting

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 08-10 December 2021. See December 2021 CAT minutes (to be published post January 2022 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 08-10 December 2021 meeting

1.3. Adoption of the minutes

CAT minutes for 03-06 November 2021 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. Ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095

Janssen-Cilag International NV; treatment of multiple myeloma

Scope: Day 180 list of outstanding issues

Action: for adoption

List of Questions adopted on 10.09.2021.

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

2.7.1. Tabelecleucel - Orphan - EMEA/H/C/004577

Accelerated assessment

Atara Biotherapeutics Ireland Limited; treatment of Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD)

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 - idcabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0005/G

Celgene Europe B.V.

Rapporteur: Rune Kjekken;

Scope: Quality. Opinion

Action: for adoption

2.11.2. Abecma - idcabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0009

Celgene Europe B.V.

Rapporteur: Rune Kjekken; PRAC Rapporteur: Annika Folin

Scope: Clinical. Opinion

Update of sections 4.2 and 4.4 of the SmPC, Annex IID and PIL in order to add statements for the use of Abecma exceptionally during shortage of tocilizumab following the "CAT recommendation for the use of CAR-T cell-based therapies in EU during shortages of tocilizumab"

Action: for adoption

2.11.3. [Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0044](#)

Novartis Europharm Limited

Rapporteur: Rune Kjekken; Rapporteur: Brigitte Keller-Stanislawski

Scope: Quality and clinical. Request for supplementary information

Extension of indication to include treatment of adult patients with follicular lymphoma (FL) after two or more lines of therapy who are refractory or relapsed during or within 6 months after completion of anti-CD20 antibody maintenance or relapsed after autologous haematopoietic stem cell transplantation (HSCT) for Kymriah. As a consequence, Sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC and corresponding sections in the Package Leaflet are updated accordingly. The RMP has been updated to version 4.0 to align with the indication extension. Lastly, the minor editorial corrections are made throughout the SmPC and package leaflet to align with the current QRD template version 10.2.

Action: for adoption

2.11.4. [Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0047](#)

Novartis Europharm Limited

Rapporteur: Rune Kjekken; PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Safety. Opinion

Update of sections 4.2 and 4.4 of the SmPC, Annex IID and PIL (information intended for healthcare professionals) in order to add statements for the use of Kymriah exceptionally during shortage of tocilizumab following the "CAT recommendation for the use of CAR-T cell-based therapies in EU during shortages of tocilizumab".

Action: for adoption

2.11.5. [Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/II/0004](#)

Orchard Therapeutics (Netherlands) BV

Rapporteur: Carla Herberts

Scope: Quality. Opinion

Action: for adoption

Request for Supplementary Information adopted on 08.10.2021.

2.11.6. [Tecartus - autologous peripheral blood t cells cd4 and cd8 selected and cd3 and cd28 activated transduced with retroviral vector expressing anti-cd19 cd28/cd3-zeta chimeric antigen receptor and cultured - Orphan - EMEA/H/C/005102/II/0012](#)

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality. Opinion

Action: for adoption

Request for Supplementary Information adopted on 08.10.2021.

2.11.7. [Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0020/G](#)

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts

Scope: Quality. Request for supplementary information

Action: for adoption

2.11.8. [Tecartus; Yescarta - axicabtagene ciloleucel; autologous peripheral blood t cells cd4 and cd8 selected and cd3 and cd28 activated transduced with retroviral vector expressing anti-cd19 cd28/cd3-zeta chimeric antigen receptor and cultured - Orphan - EMEA/H/C/WS2206](#)

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus; PRAC Rapporteur: Menno van der Elst

Scope: Safety. Opinion

Update of sections 4.2 and 4.4 of the SmPC and Annex IID in order to add statements for the use of Tecartus and Yescarta exceptionally during shortage of tocilizumab following the "CAT recommendation for the use of CAR-T cell-based therapies in EU during shortages of tocilizumab". The RMPs for both products are updated accordingly (version 1.2 for Tecartus and version 5.2 for Yescarta).

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. [Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/R/0024](#)

CO.DON AG

Rapporteur: Lisbeth Barkholt, Co-Rapporteur: Heli Suila; PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: 5-year Renewal of Marketing Authorisation

Action: for adoption

2.13.2. [Tecartus - autologous peripheral blood t cells cd4 and cd8 selected and cd3 and cd28 activated transduced with retroviral vector expressing anti-cd19 cd28/cd3-zeta chimeric antigen receptor and cultured - Orphan - EMEA/H/C/005102/MEA/005.1](#)

Kite Pharma EU B.V.

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

Scope: MAH Response to MEA-005 [Protocol, study no. KT-EU-472-5966] as adopted in July 2021: Prescriber Survey: Assess the prescribers' understanding of the risks of KTE-X19. Evaluate the effectiveness of risk minimization activities: HCP educational materials, and Patient Alert Card.

Action: for adoption

2.13.3. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/ANX/002.2

Kite Pharma EU B.V.

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

Scope: First annual interim report

Title: Long-term, non-interventional study of recipients of Yescarta for treatment of relapsed or refractory Diffuse Large B-cell Lymphoma and Primary Mediastinal B-cell Lymphoma. (EU PAS Register no.: EUPAS32539)

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:	20.12.2021
-EMA Coordinator's draft report:	07.01.2022
-CAT Coordinator's comments:	12.01.2022
-Revised scientific recommendation:	14.01.2022
-CAT's discussion of scientific recommendation:	21.01.2022

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Kidney progenitor cells isolated from the urine of preterm neonates

Intended for the kidney transplantation

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. Expanded mesenchymal stem cells (MSCs) cells isolated from umbilical cord Wharton jelly dilative cardiomyopathy (DCM)

Intended for the treatment of dilative cardiomyopathy (DCM)

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Recombinant serotype 9 adeno-associated virus (rAAV9) encoding a wild-type human MECP2 (methyl cytosine binding protein 2) transgene (AAV9-hMECP2)

Intended for the treatment of Rett syndrome

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.4. Recombinant adeno-associated virus (rAAV) containing human homology arms, expressing codon-optimised human phenylalanine hydroxylase (hPAH)

Intended for the treatment of phenylalanine hydroxylase (PAH) deficiency

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.5. Human embryonic stem cell (hESC)-derived midbrain dopaminergic (mDA) neuron cells

Intended for the treatment of advanced Parkinson's disease

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.6. Stem cells isolated from dental pulp, cultured

Intended for the treatment of surgical bone defects

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.7. Modulated immune cells

Intended for solid organ transplantation / Treatment of autoimmune disease

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.8. Autologous bone marrow concentrate

Intended for the treatment of bone fractures

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Non-replicating recombinant adeno-associated virus serotype 2 (rAAV2) encoding a soluble form of human CD59 (sCD59)

Intended for the treatment of geographic atrophy (via targeting the complement pathway)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. VTXM01 messenger RNA (mRNA) encoding for an adenine base editor (ABE) and VTXG01 guide RNA (gRNA) targeting the proprotein convertase subtilisin/kexin type 9 (PCSK9) serine protease gene

Intended for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) who require additional lowering of low-density lipoprotein cholesterol (LDL-C) despite maximally tolerated lipid-lowering therapy

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Autologous anti-CD19 chimeric antigen receptor T-cells

Intended for the treatment of CD19-expressing B-cell malignancies

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. CD 19 CAR T-cells transduced with lentiviral vector

Intended for the treatment of adults and children with B-cell non-Hodgkin's lymphoma and acute lymphoblastic leukemia.

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

Action: for information

4.4.2. Allogeneic adipose-derived mesenchymal stromal cells, ex-vivo expanded

Intended for the treatment of osteoarthritis, knee

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

Action: for information

4.4.3. Recombinant adeno-associated virus, serotype 2, containing human ND4 codon-optimised gene (rAAV2-ND4) - EMA/PRIME/21/039

Treatment of Leber's hereditary optic neuropathy (LHON) associated with ND4 G11778A mutation

Scope: ATMP scientific recommendation

Action: The European Commission raised no comments. for information

4.4.4. Allogeneic T-cell precursors, mobilised peripheral blood-derived, ex vivo cultured

Intended for the treatment of paediatric and adult patients undergoing partially human leucocyte antigen (HLA) compatible allogeneic haematopoietic stem cell transplantation to accelerate adaptive immunological reconstitution

Scope: Minor comments were made by the European Commission. Revised ATMP scientific recommendation

Action: for information

4.5. Follow-up and guidance

No items

5. Scientific Advice

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

5.1. New requests - appointment of CAT Rapporteurs

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

Timetable:

- Start of procedure at SAWP:	29.11 – 02.12.2021
- Appointment of CAT Peer Reviewers:	08-10.12.2021
- SAWP first reports:	03.01.2022
- CAT Peer Reviewer comments:	07.01.2022
- Discussion at SAWP:	10-13.01.2022
- Discussion at CAT and feedback to SAWP:	15.01.2022

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	10-13.01.2022
- Appointment of CAT Peer Reviewers:	19-21.01.2022
- SAWP first reports:	31.01.2022
- CAT Peer Reviewer comments:	04.02.2022
- Discussion at SAWP:	07-10.02.2022
- Discussion at CAT and feedback to SAWP:	18.02.2022

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

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:	
Procedure start:	02.12.2021
SAWP recommendation:	13.01.2022
CAT recommendation:	21.01.2022
CHMP adoption of report and final recommendation:	27.01.2022

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

No items

7.1.2. Vote by proxy

No items

7.2. Coordination with EMA Scientific Committees

7.2.1. Extension of indication of approved ATMPs: additional 1-year protection period

Scope: Presentation on the regulatory aspects

Action: for information

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

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

Scope: meeting summary of the PCWP/HCPWP joint meeting on the 21-22 September 2021

Action: for information

7.3.2. Working Party with Patients' and Consumers' Organisations (PCWP) and Working Party with Healthcare Professionals' Organisations (HCPWP)

Scope: Draft Agenda - Annual PCWP-HCPWP joint meeting with all Eligible Organisations on 24 November

Action: for information

7.4. Cooperation with the EU regulatory network

7.4.1. Revision of the Pharmaceutical legislation

CAT: Martina Schüssler-Lenz

Scope: Concept papers

Action: for discussion

7.4.2. Update on the Companion Diagnostics (CDx) consultation procedure

EMA guidance on CDx consultation and CHMP/CAT AR CDx template have been reviewed at the November meeting. Comments received are taken into account. Publication for external consultation is planned in January 2022.

Action: For adoption

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

CAT: Martina Schüssler-Lenz

Scope: CAT feedback to the European Commission

Action: for discussion

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: feedback from the teleconference that took place on 14 October 2021

Action: for information

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

CAT: Martina Schuessler-Lenz

Scope: Agenda of the teleconference that will take place on 16 December 2021

Action: for information

Note: the meeting has been cancelled

7.5.3. WHO consultation on cell and gene therapy products

CAT: Ilona Reischl

Action: for information

7.6. CAT work plan

7.6.1. Real World Data (RWD) in regulatory decision making of ATMPs

CAT: Martina Schuessler-Lenz

Scope: Feedback from the meeting with registry holders

Action: for information

7.6.2. CAT work plan 2022

CAT: Martina Schüssler-Lenz

Scope: draft work plan for 2022

Action: for discussion and identification of CAT contributors

7.7. Planning and reporting

7.7.1. Planning estimates of forthcoming ATMP MAAs

Scope: Q4/2021 update of the business pipeline report for the human scientific committees

Action: for information

7.8. Others

7.8.1. European Society of Gene and Cell Therapy (ESGCT)

CAT: Alessandro Aiuti

Scope: feedback from the meeting that took place on the 19-22 October 2021.

Action: for information

7.8.2. Lifecycle Regulatory Submissions Metadata project (LRSM)

Action: for information

7.8.3. Duration of follow-up of patients treated with AAV-based GTMPs

CAT: Martina Schüssler-Lenz

Scope: duration of follow-up of patients treated with AAV-based GTMPs

Action: for discussion

7.8.4. International Society for Extracellular Vesicles

Scope: Letter from the International Society for Extracellular Vesicles (ISEV) Task Force on Regulatory Affairs and Clinical Use of

EV-based Therapeutics

Action: for information

8. Any other business

8.1.1. CAT Learnings

CAT: Martina Schüssler-Lenz

Scope: CAT learnings on Insertional mutagenesis and germline transmission risk analysis in the context of genome editing

Action: for discussion

Note: see also 5.2.6:

Date of next CAT meeting:

19 – 21/01/2022

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

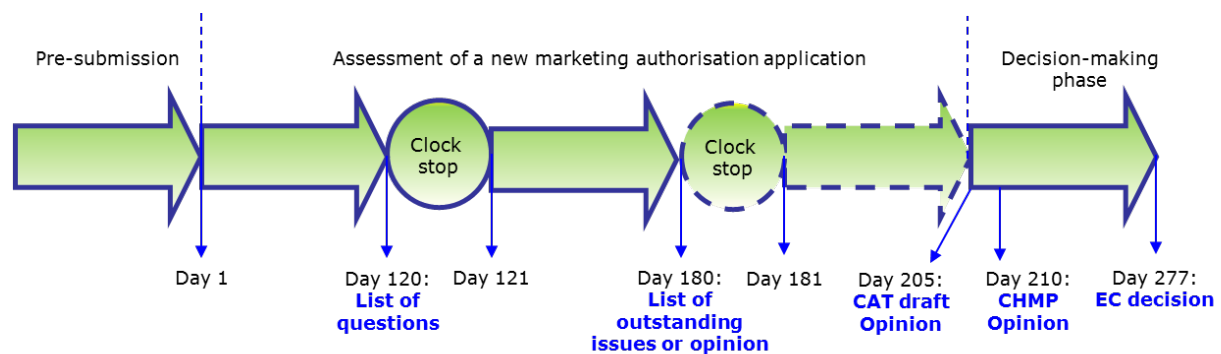
Evaluation of ATMPs (section 2)

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, quality 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/