



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 February 2022
EMA/CAT/58286/2022
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 16-17 February 2022

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

16 February 2022, 14:00 – 18:00, remote virtual meeting

17 February 2022, 09:00 – 18:00, 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 ongoing 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 16-17 February 2022. See 16-17 February 2022 CAT minutes (to be published post 16-18 March 2022 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 16-17 February 2022 meeting

1.3. Adoption of the minutes

CAT minutes for 19-21 January 2022 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

2.5.1. Tabelecleucel - PRIME - Orphan - EMEA/H/C/004577

Accelerated assessment

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

Scope: Day 80 assessment report

Action: for information

2.6. Update on ongoing initial applications

No items

2.7. New applications

No items

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. Kymriah - tisagenlecleucel - PRIME - Orphan - EMEA/H/C/004090/II/0049/G

Novartis Europharm Limited

Rapporteur: Rune Kjeklen

Scope: Quality. Opinion

Action: for adoption

2.11.2. Yescarta - axicabtagene ciloleucel - PRIME - Orphan - EMEA/H/C/004480/II/0040

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Anette Kirstine Stark

Scope: Clinical. Opinion

Submission of the final study report for the non-interventional study KT-EU-471-0116 (Quantitative Testing of Healthcare Provider Knowledge about Yescarta (axicabtagene ciloleucel) Risk Minimisation Measures) in fulfilment of an additional pharmacovigilance activity (Category 3) listed in the EU Risk Management Plan for Yescarta.

Action: for adoption

Request for Supplementary Information adopted on 10.09.2021.

2.11.3. Yescarta - axicabtagene ciloleucel - PRIME - Orphan - EMEA/H/C/004480/II/0042

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Claire Beuneu, PRAC Rapporteur: Anette Kirstine Stark

Scope: Clinical. Opinion

Extension of indication to include the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after three or more lines of systemic therapy. Consequently, sections 4.1, 4.8, 5.1 and 5.2 of the SmPC, Annex II (Section D) and package leaflet are proposed to be updated. As a consequence, the RMP (version 5.1) has been updated to align with the indication extension. In addition, the applicant has taken the opportunity to make minor editorial corrections throughout the SmPC and package leaflet to align with the current Quality Review of Documents (QRD) template.

Action: for adoption

Request for Supplementary Information adopted on 05.11.2021.

2.11.4. [Yescarta - axicabtagene ciloleucel - PRIME - Orphan - EMEA/H/C/004480/II/0046](#)

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Claire Beuneu, PRAC Rapporteur: Anette Kirstine Stark

Scope: Clinical. Request for supplementary information

Extension of indication to include treatment of adult patients with relapsed or refractory (r/r) diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) as second line treatment for Yescarta; as a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated in accordance. Version 5.3 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to update the product information with minor editorial changes.

Action: for adoption

2.11.5. [Tecartus; Yescarta - autologous anti-CD19-transduced CD3+ cells; axicabtagene ciloleucel - PRIME - Orphan - EMEA/H/C/WS2197](#)

Kite Pharma EU B.V.

Scope: Quality. Opinion

Action: for adoption

2.12. **Extension applications**

No items

2.13. **Other Post-Authorisation Activities**

2.13.1. [Kymriah - tisagenlecleucel - PRIME - Orphan - EMEA/H/C/004090/REC/015](#)

Novartis Europharm Limited

Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang

Scope: Quality

Action: for adoption

2.13.2. [Kymriah - tisagenlecleucel - PRIME - Orphan - EMEA/H/C/004090/REC/016](#)

Novartis Europharm Limited

Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang

Scope: Quality

Action: for adoption

2.13.3. Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/REC/007

Orchard Therapeutics (Netherlands) BV

Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege

Scope: Quality

Action: for adoption

2.13.4. 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

Request for Supplementary Information adopted on 10.12.2021.

2.13.5. 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 - PRIME - Orphan - EMEA/H/C/005102/ANX/002.2

Kite Pharma EU B.V.

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

Scope: MAH Response to ANX-002.1 [Study No. KTE-EU-472-6036: Long-term, non-interventional study of recipients of Tecartus for treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)].

Action: for adoption

2.13.6. Zolgensma - onasemnogene abeparvovec - PRIME - Orphan - EMEA/H/C/004750/R/0021

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts, Co-Rapporteur: Egbert Flory, PRAC Rapporteur: Ulla Wändel Liminga

Scope: 1-year Renewal of Marketing Authorisation

Action: for adoption

2.13.7. Zynteglo - betibeglogene autotemcel - PRIME - Orphan - EMEA/H/C/003691/SOB/003

bluebird bio (Netherlands) B.V

Rapporteur: Carla Herberts, CHMP Coordinator: Paula Boudewina van Hennik

Scope: From Initial MAA:

Study HGB-207: in order to confirm the efficacy and safety of Zynteglo in patients 12 years and older with transfusion-dependent β thalassaemia (TDT) who do not have a $\beta 0/\beta 0$ genotype, the MAH should submit interim and final data.

Action: for adoption

2.13.8. Zynteglo - betibeglogene autotemcel - PRIME - Orphan - EMEA/H/C/003691/SOB/004

bluebird bio (Netherlands) B.V

Rapporteur: Carla Herberts, CHMP Coordinator: Paula Boudewina van Hennik

Scope: From Initial MAA:

Study HGB-212: in order to confirm the efficacy and safety of Zynteglo in patients 12 years and older with transfusion-dependent β thalassaemia (TDT) who do not have a $\beta 0/\beta 0$ genotype, the MAH should submit interim and final data from patients with a severe non $\beta 0/\beta 0$ genotype such as IVS I 110.

Action: for adoption

2.13.9. Interactions with the European Society for Blood and Marrow Transplantation (EBMT) and marketing authorisation holders of CAR-Ts on the use of data from the EBMT registry for the imposed PASS

Scope: feedback from the meeting on 26.01.2022

Action: for discussion

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. Gingival fibroblast

Intended for the treatment of gonarthrosis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. (AAV2.hIL-12) Recombinant serotype 2 adeno-associated virus (AAV2) carrying a single-stranded expression cassette for human Interleukin 12 (IL-12)

Intended for the treatment of advanced solid tumours

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Leukocyte and platelet rich plasma, autologous

Intended for the treatment of critical limb ischemia

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.4. Messenger RNA (mRNA) containing a bicistronic coding sequence that upon translation produces two independent proteins, ZF-DNMT and ZF-KRAB

Intended for the treatment of adult patients with intermediate (stage B) or advanced (stage C) MYC-associated hepatocellular carcinoma (HCC)

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.5. Stimulated anti-viral T-lymphocytes with specific anti-viral activity

Intended for the treatment of resistant viral infections in patients after allo-HSCT

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.6. Plasmid expressing variant of human interleukin-10

Intended for the treatment of osteoarthritis, neuropathic pain, amyotrophic lateral sclerosis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

No items

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

No items

4.4. Finalisation of procedure

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

Intended for the kidney transplantation

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

Action: for adoption

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

Intended for the treatment of dilative cardiomyopathy (DCM)

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

Action: for adoption

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

Action: for adoption

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

Action: for adoption

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

Intended for the treatment of advanced Parkinson's disease

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

Action: for adoption

4.4.6. Stem cells isolated from dental pulp, cultured

Intended for the treatment of surgical bone defects

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

Action: for adoption

4.4.7. Modulated immune cells

Intended for solid organ transplantation / Treatment of autoimmune disease

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

Action: for adoption

4.4.8. Autologous bone marrow concentrate

Intended for the treatment of bone fractures

Scope: Minor comments were made by the European Commission. Revised 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:	07-10.02.2022
- Appointment of CAT Peer Reviewers:	16-18.02.2022
- SAWP first reports:	28.02.2022
- CAT Peer Reviewer comments:	04.03.2022
- Discussion at SAWP:	07-10.03.2022
- Discussion at CAT and feedback to SAWP:	18.03.2022

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	07-10.03.2022
- Appointment of CAT Peer Reviewers:	16-18.03.2022
- SAWP first reports:	28.03.2022
- CAT Peer Reviewer comments:	01.04.2022
- Discussion at SAWP:	04-07.04.2022
- Discussion at CAT and feedback to SAWP:	13.04.2022

- 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:	07-10.02.2022
SAWP recommendation:	10/03/2022
CAT recommendation:	18/03/2022
CHMP adoption of report and final recommendation:	24/03/2022

No items

6.3.2. Month 1 – Discussion of eligibility

no items

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

Action: for information

7.1.2. Joint CAT-CHMP Strategic Review & Learning meeting (SRLM) under the Slovenian presidency, 21 October 2021 (virtual)

CAT: Metoda Lipnik-Štangelj, Martina Schuessler-Lenz

Scope: Minutes of the meeting

Action: for information

7.1.3. CAT Strategic Review & Learning meeting (SRLM) under the French presidency, 3 March 2022 (virtual)

CAT: Violaine Closson-Carella, Martina Schuessler-Lenz

Scope: Review and adoption of the agenda content

Action: for discussion

7.2. Coordination with EMA Scientific Committees

7.2.1. Classification of Post-Authorisation Studies (CPAS)

Scope: Presentation of the mandate of the CPAS

Action: For discussion

7.2.2. CHMP learnings with relevance to CAT

Scope: Revision to the Appendix 3 of the anticancer guideline related to section 4.8 of the Summary Products Characteristics (SmPC) for the anticancer medicinal products.

Action: for discussion

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 with all eligible organisations on the 24 November 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 - PCWP-HCPWP joint meeting on 02-03 March 2022

Action: for information

7.3.3. BWP/QWP/IWG Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME and certain marketing authorisation applications targeting an unmet medical need

DG members: Mats Welin, Sean Barry, Marcel Hoefnagel, Tone Agasoster, Kristofer Olofsson, Jobst Limberg, Giampiero Lorenti

Action: for adoption

7.3.4. EMA Working Parties Implementation Plan Review – (H+V)

Scope: Information on creation of the Quality Innovation Group (QIG) within the Quality Domain

Action: for discussion

7.4. Cooperation with the EU regulatory network

7.4.1. Accelerating Clinical Trials in the EU (ACT EU)

Scope: This business-change programme aims to strengthen the European environment for clinical trials and was recently endorsed at both HMA November 2021 and EMA Management Board December 2021 meetings, including the accompanying paper outlining the objectives and priority actions for the ACT EU.

Action: for information

7.5. Cooperation with international regulators

7.5.1. Joint EMA-FDA Q&As on PRIME/Breakthrough applications (control strategy, process validation, stability, GMP)

DG members: Mats Welin, Sean Barry, Marcel Hoefnagel, Tone Agasoster, Kristofer Olofsson, Jobst Limberg, Giampiero Lorenti

Scope: Joint EMA-FDA Q&As on PRIME/Breakthrough applications

Action: for adoption

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 24 February 2022

Action: for information

7.5.3. WHO consultation on cell and gene therapy products

CAT: Ilona Reischl

Scope: Presentations from WHO consultation meeting that took place on 07-09 February 2022.

Action: for information

7.6. CAT work plan

7.6.1. ATMP training for 2022

CAT: Ilona Reischl

Scope: Identification of ATMP training for assessors and experts

Action: for discussion

7.6.2. Implementation of the medical device and in-vitro diagnostics Regulations

CAT: Ilona Reischl

Scope: Status update

Action: for discussion

7.7. Planning and reporting

No items

7.8. Others

No items

8. Any other business

No items

Date of next CAT meeting:

16-18/03/2022

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

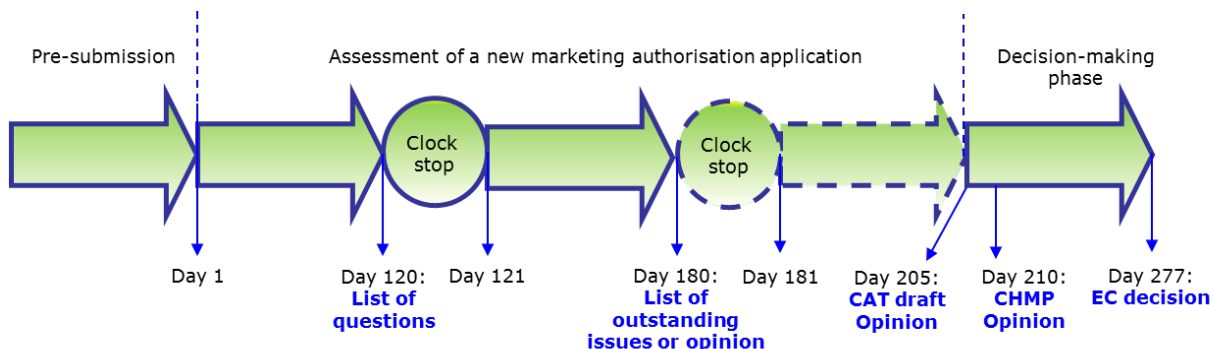
Evaluation of ATMPs (section 2)

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, 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/