13 July 2022
EMA/CAT/613798/2022
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 13-15 July 2022

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

13 July 2022, 14:00 – 18:30, room 01-D

14 July 2022, 09:00 – 18:30, room 01-D

15 July 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 13-15 July 2022. See 13-15 July CAT minutes (to be published post 07-09 September 2022 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 13-15 July 2022 meeting

1.3. Adoption of the minutes

CAT minutes for 15-17 June 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

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

Accelerated assessment

CSL Behring GmbH; treatment of adults with Haemophilia B

Scope: Day 120 list of questions

Action: for adoption

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. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0002

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality. Opinion

Action: for adoption

2.11.2. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0003

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality. Request for supplementary information

Action: for adoption

2.11.3. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0051

Amgen Europe B.V.

PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Pharmacovigilance

Submission of the final report from study 20180062: "Observational Research Study Report (ORSR)" listed as a category 3 study in the RMP. This is a multinational, non-interventional, cross-sectional survey study for the patients aged ≥ 18 years who have received Imlygic at least once in the 3 months prior to completing the survey to evaluate the effectiveness of the patient-directed additional risk minimisation measures. The primary objective of this study is to evaluate patients' knowledge levels of the key messages included in the Imlygic Patient Safety Brochure among patients who receive Imlygic.

Action: for adoption

Request for Supplementary Information adopted on 13.05.2022.

2.11.4. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0053

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen

Scope: Quality. Opinion

Action: for adoption

2.11.5. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0058

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality. Opinion

Action: for adoption

2.11.6. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0059

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Clinical. Request for supplementary information

Update of section 5.1 of the SmPC based on a subgroup analysis from CCTL019B2401 (B2401) disease registry listed as a PAES (ANX006) in the Annex II; this is a non-interventional study to evaluate the efficacy and safety of Kymriah in acute lymphoblastic leukemia (ALL) patients below the age of 3 years. In addition, the MAH took the opportunity to update Annex II.D of the SmPC to reflect the fulfilment of the PAES.

Action: for adoption

2.11.7. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0060

Novartis Europharm Limited

Rapporteur: Rune Kjeken, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Safety. Request for supplementary information

Update of section 4.2 of the SmPC in order to update the paediatric statement for the B-cell acute lymphocytic leukaemia (ALL) indication and section 4.4 to update the warning on 'prior treatment with anti-CD19 therapy' as well as sections 4.4 and 4.8 in order to update safety data to reflect the pool of the 3 studies B2202, B2205J and B2001X. The proposed changes are in line with the request of the CHMP following the assessment of P46/012. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to correct the complete response rate (CRR) 95% confidence interval (CI) on enrolled set for E2202 study presented in Table 8 in section 5.1 of the SmPC. The RMP version 5.0 has also been submitted.

Action: for adoption

2.11.8. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0061/G

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality. Request for supplementary information

Action: for adoption

2.11.9. Strimvelis - autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - Orphan - EMEA/H/C/003854/II/0033

Orchard Therapeutics (Netherlands) BV

Rapporteur: PRAC Rapporteur: Menno van der Elst

Scope: Safety. Opinion

Submission of the final report from study STRIM-001 "Evaluation of referring healthcare providers' and parents'/carers' understanding of specific risks associated with Strimvelis treatment" listed as a category 3 study in the RMP. The RMP version 6.1 has also been submitted.

Action: for adoption

Request for supplementary information adopted on 18.03.2022.

2.11.10. Tecartus - brexucabtagene autoleucel - Orphan - EMEA/H/C/005102/II/0008/G

Kite Pharma EU B.V.

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

Scope: Clinical and Safety. Opinion

Group of variations including an extension of indication to include treatment of adult patients with relapsed or refractory (r/r) B-cell acute lymphoblastic leukemia (B-ALL) for Tecartus and a type IB variation to change the drug product dose specification for the new indication. As a consequence, sections 2.2, 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet and Labelling are updated in accordance. Version 1.1 of the RMP has also been submitted. Furthermore, the product information (PI) is brought in line with the latest QRD template.

Action: for adoption

Request for supplementary information adopted on 18.03.2022, 10.09.2021.

2.11.11. Yescarta - axicabtagene ciloleucel - 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) 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

Request for supplementary information adopted on 13.05.2022 and 18.02.2022.

2.11.12. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0028/G

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts

Scope: Quality. Opinion

Action: for adoption

2.11.13. Tecartus; Yescarta – axicabtagene ciloleucel; brexucabtagene autoleucel – Orphan – EMEA/H/C/WS2247

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality. Request for supplementary information

Action: for adoption

Request for supplementary information adopted on 13.05.2022.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

No items

3. Certification of ATMPs

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

3.1. Opinion

No items

3.2. Day 60 Evaluation Reports

No items

3.3. New Applications

No items

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – Appointment of CAT Coordinator

No items

4.2. Day 30 ATMP scientific recommendation

4.2.1. Adeno-associated viral vector serotype 2 encoding glial cell line-derived neurotrophic factor

Intended for the treatment of Parkinson's disease (PD)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Ex-vivo expanded allogeneic human corneal epithelial cells containing P63 positively expressing cells

Intended for the treatment of persistent corneal epithelial defects

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Allogeneic adipose-derived mesenchymal stem cells

Intended for the treatment of arthritis and diabetes type I and II

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Acellular tubular graft composed of human collagen types I and III and other extracellular matrix proteins, including fibronectin and vitronectin

Intended for replacement or repair of injured blood vessels in cases of vascular trauma; for replacement or repair of diseased vessels as an arterial bypass conduit for peripheral arterial disease (PAD); and as an implanted vascular access conduit for haemodialysis in patients with end-stage renal disease (ESRD)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.5. A heterologous vaccine regimen composed of 2 components: replication incompetent gorilla adenovirus serotype 20 (GAd20) and modified vaccinia ankara (MVA) vectors encoding tumor-specific antigens mutant calreticulin (mutCALR) and Janus kinase 2 (mutJAK2)

Intended for the treatment of patients with myeloproliferative neoplasms (MPNs)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.6. Recombinant adeno-associated virus vector containing the human aspartoacylase complementary DNA (ASPA cDNA) with an optimized expression cassette and constitutive promoter

Intended for the treatment of Canavan disease

Scope: ATMP scientific recommendation

Action: for adoption

4.2.7. Adeno-associated virus serotype hu68 vector encoding human GLB1 gene

Intended for the treatment of GM1 gangliosidosis

Scope: ATMP scientific recommendation

Action: for adoption

4.2.8. Autologous human bone marrow derived mesenchymal stromal cells (MSCs)

Intended for the treatment of pathologies affecting the oesophageal tract in which total or partial organ replacement is required

Scope: ATMP scientific recommendation

Action: for adoption

4.2.9. Skin cell suspension obtained with the help of recombinant non-animal trypsin

Intended for skin regeneration after burns, skin trauma, invasive surgery

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. Wharton's Jelly Derived Mesenchymal Stem Cells – allogeneic

Intended for the treatment of other specified inflammatory spondylopathies (non-radiographic axial spondylarthritis, M46.8)

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

Action: for adoption

4.4.2. Autologous keratinocytes, fibroblasts

Intended for the treatment of partial deep dermal and full thickness burn wounds and reconstructive surgery

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

Action: for adoption

4.4.3. Dopaminergic neuronal microtissues containing A9 TH+ (tyrosine hydroxylase) dopaminergic mature neuron

Intended for the treatment of Parkinson's disease

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:	04-07.07.2022
- Appointment of CAT Peer Reviewers:	13-15.07.2022
- SAWP first reports:	22.08.2022
- CAT Peer Reviewer comments (NC,C):	26.08.2022
- CAT Peer reviewer comments (Q):	31.08.2022
- Discussion at SAWP:	29.08-01.09.2022
- Discussion at CAT and feedback to SAWP:	09.09.2022

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	29.08–01.09.2022
- Appointment of CAT Peer Reviewers:	07–09.09.2022
- SAWP first reports:	19.09.2022
- CAT Peer Reviewer comments (NC,C):	23.09.2022
- CAT Peer reviewer comments (Q):	28.09.2022
- Discussion at SAWP:	26–29.09.2022
- Discussion at CAT and feedback to SAWP:	07.10.2022

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

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

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

No items

7.1.3. CAT's August 2022 written procedure

Scope: August 2022: process and timelines

Action: for adoption

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

CAT: Petr Soukup, Martina Schuessler-Lenz

Scope: Practical information and proposal for agenda content

Action: for discussion

7.1.5. Publication of CAT regulatory outcomes on the EMA webpage

CAT: Martina Schüssler-Lenz

Scope: Presentation of improvements to communicate CAT outcomes on the EMA Website.

Action: for information

7.2. Coordination with EMA Scientific Committees

7.2.1. PRIME implementation of 5-year review recommendations

Scope: Presentation of the proposals for implementation of the recommendations arising from the first 5 years' experience with the scheme (see also prime-analysis-first-5-years-experience_en.pdf (europa.eu) as discussed and agreed by the PRIME oversight group.

Action: for adoption

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

7.3.1. Diffuse large B-cell lymphoma (DLBCL) indication wording and inclusion of high-grade B-cell lymphoma (HGBL)

Scope: key points from the discussion with haematologists that took place on the 31 May 2022

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 22 September 2022

Action: for information

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

Scope: PCWP-HCPWP minutes from the meeting on 1-2 June 2022

Action: for information

7.3.4. Reflection paper on criteria to be considered for the evaluation of new active substance (NAS) status of biological substances

Rapporteur: Martijn van der Plas

Action: For adoption

7.4. Cooperation with the EU regulatory network

No items

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 23 June 2022

Action: for information

7.6. CAT work plan

7.6.1. CAT workplan 2022

Scope: half-year review

Action: for discussion

7.6.2. ATMP Webinar: ATMP classification and MAA at CAT; Interface to GMO, medical devices and companion diagnostics – 15 July 2022

Scope: The goal of the module is to provide a general, high-level overview of the ATMP classification and ATMP-marketing authorisation procedures; to provide initial information and serve as a reference for further knowledge building.

7.7. Planning and reporting

No items

7.8. Others

7.8.1. DARWIN EU Coordination Centre

Scope: Follow up on real world evidence (RWE) and DARWIN EU® and the recently selected data partners and year 1 RWE studies.

Action: for discussion

7.8.2. European Society for Gene and cell therapy (ESGCT) annual meeting

CAT: Martina Schüssler-Lenz

Scope: Proposal of topics for the CAT regulatory session at the ESGCT annual meeting that will take place in Edinburgh on 14 October 2022

Action: for discussion

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

CAT: Carla Herberts, Egbert Flory

Scope: Discussion paper insertional mutagenesis and follow-up for AAV gene therapy

Action: for discussion

7.8.4. CAT Learnings on blood/tissue establishment providing starting materials for ATMPs

CAT: Barbara Bonamassa

BWP: Marja van de Bovenkamp

Scope: Blood/tissue establishment in 3rd countries providing starting materials for ATMPs

Action: for adoption

Note: Adoption postponed to September CAT meeting

7.8.5. CAT Learnings on SmPC section 2.1 for the AAV products

CAT: Niamh Curran

Scope: Harmonisation of section 2.1 of the SmPC for adeno-associated viral vector (AAV) based product

Action: for adoption

7.8.6. CAT-industry stakeholder meeting

CAT: Martina Schüssler-Lenz

Scope: Organisation of the next CAT stakeholder meeting at the end of 2022/beginning of 2023.

Action: for discussion

Note: the previous CAT stakeholder meeting was held on 26 October 2021. https://www.ema.europa.eu/en/events/committee-advanced-therapies-cat-meeting-interested-parties-0

7.8.7. Novel Therapies and Technologies Working Party

CAT: Daiusz Sladowski

Scope: feedback on the development of guidelines in the (veterinary) Novel Therapies and Technologies Working Party

Action: for information

8. Any other business

No items

Date of next CAT meeting:

07-09/09/2022

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

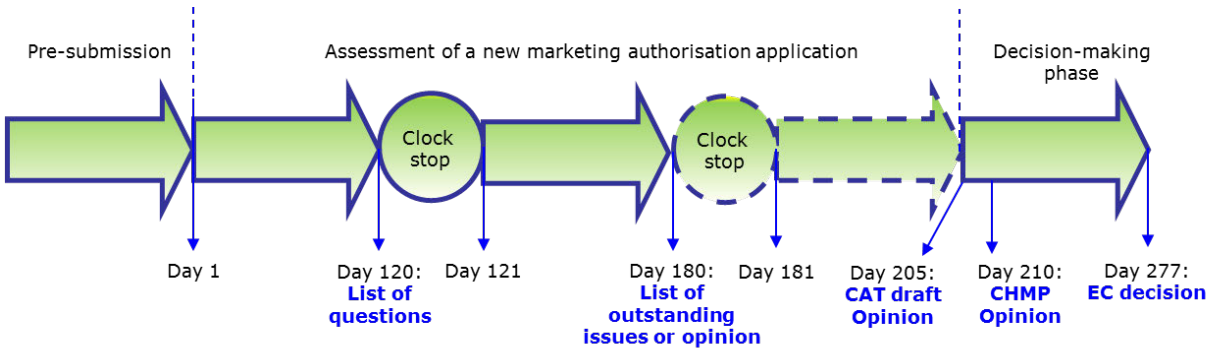
Evaluation of ATMPs (section 2)

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/