07 October 2020
EMA/CAT/531222/2020
Human Medicines Division

Committee for Advanced Therapies (CAT)

Agenda for the meeting on 07-09 October 2020

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

07 October 2020, 14:00 – 18:30, virtual meeting

08 October 2020, 09:00 – 18:00, virtual meeting

09 October 2020, 09:00 – 13:00, virtual meeting

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. Regarding 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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

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 October 2020. See October 2020 CAT minutes (to be published post-November 2020 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 07-09 October 2020 meeting

1.3. Adoption of the minutes

CAT minutes for 09-11 September 2020 meeting

2. Evaluation of ATMPs

2.1. Opinions

2.1.1. 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

Kite Pharma EU B.V.; treatment of adult patients with relapsed or refractory Mantle cell lymphoma (MCL)

Scope: Opinion

Action: for adoption

List of Outstanding Issues adopted on 11.09.2020. List of Questions adopted on 20.05.2020.

2.2. Oral explanations

2.2.1. Autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding the human arylsulfatase A gene - Orphan - EMEA/H/C/005321

Orchard Therapeutics (Netherlands) BV; treatment of metachromatic leukodystrophy (MLD)

Scope: oral explanation

Action: oral explanation to be held on Wednesday, 07 October 2020 at 14:05hrs

List of Outstanding Issues adopted on 11.09.2020. List of Questions adopted on 20.03.2020.

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. Lisocabtagene maraleucel - Orphan - EMEA/H/C/004731

Accelerated assessment

Celgene Europe BV; treatment of large B-cell lymphoma, diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma (PMBCL) and follicular lymphoma grade 3B (FL3B)

Scope: Day 80 assessment report

Action: for information

2.6. Update on ongoing initial applications

No items

2.7. New applications

2.7.1. Autologous glioma tumour cells, inactivated / autologous glioma tumour cell lysates, inactivated / allogeneic glioma tumour cells, inactivated / allogeneic glioma tumour cell lysates, inactivated - Orphan - EMEA/H/C/003693

Epitopoietic Research Corporation-Belgium (E.R.C.); treatment of glioma

Scope: Timetable for assessment

Action: for adoption

2.7.2. Elivaldogene autotemcel - Orphan - EMEA/H/C/003690

Accelerated assessment

bluebird bio (Netherlands) B.V; treatment of patients less than 18 years of age with an *ABCD1* genetic mutation and early cerebral adrenoleukodystrophy

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

2.10.1. Good manufacturing practice (GMP) - forthcoming inspections for ATMPs

Scope: forthcoming inspections

Action: for information

Note: these requests were adopted by CHMP at its September 2020 meeting

2.11. Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

2.11.1. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0026/G

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality.

Action: for adoption

2.11.2. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0027

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality.

Action: for adoption

2.11.3. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0028

Kite Pharma EU B.V.

Rapporteur: Jan Müller-Berghaus, PRAC Rapporteur: Anette Kristine Stark

Scope: Clinical. To update SmPC sections; 4.4 on CRS grading and neurologic adverse reactions; 4.8 on safety profile summary; 5.1 on follow up analysis; to update the safety information based on updates from study KTE-C19-101, entitled "A Phase 1/2 Multicentre Study Evaluating the Safety and Efficacy of KTE-C19 in Subjects with Refractory Aggressive Non-Hodgkin Lymphoma (ZUMA-1)", the pivotal study for Yescarta. The updates include the Phase 2 safety management ZUMA-1 Cohort 4, which was intended to assess the impact of earlier interventions (tocilizumab and/or corticosteroids, in addition to prophylactic levetiracetam) on the rate and severity of CRS and neurologic events; and data from a 36-month analysis from ZUMA-1 Cohorts 1 and 2. The updated RMP version 3.1 has also been submitted. Request for supplementary information (RSI).

Action: for adoption

2.11.4. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0003/G

AveXis EU Limited

Rapporteur: Hans Ovelgönne

Scope: Quality. Opinion

Action: for adoption

Request for Supplementary Information adopted on 11.09.2020.

2.11.5. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0006

AveXis EU Limited

Rapporteur: Hans Ovelgönne

Scope: Quality. Request for supplementary information (RSI)

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Holoclar - ex vivo expanded autologous human corneal epithelial cells containing stem cells - Orphan - EMEA/H/C/002450/R/0032

Holostem Terapie Avanzate s.r.l.

Rapporteur: Egbert Flory, Co-Rapporteur: Paolo Gasparini, PRAC Rapporteur: Rhea Fitzgerald

Scope: 1 year Renewal of Marketing Authorisation

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 CD34+ cells transduced with a lentiviral vector encoding human cystinosin

Intended for the treatment of cystinosis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. Autologous tumour-infiltrating lymphocytes

Intended for the treatment of advance melanoma

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Delolimogene mupadenorepvec (oncolytic adenovirus expressing two immunostimulatory transgenes (TMZ-CD40L and 4-1BBL))

Intended for the treatment of cancer

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.4. Allogeneic cord tissue-derived mesenchymal stromal cells

Intended for the treatment of inflammatory and immunological diseases (acute graft-versus-host disease, systemic lupus erythematosus, systemic sclerosis, acute respiratory distress syndrome)

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. 3D bio-printed bionic pancreas composed of islets of Langerhans and non-viable printable porcine-derived matrix plus porcine–derived decellularised blood vessel

Intended for the treatment of late-chronic pancreatitis

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. 3D bio-printed bionic pancreas composed of insulin- and glucagon-releasing cells and non-viable printable porcine-derived matrix plus porcine–derived decellularised blood vessel

Intended for the treatment of brittle diabetes mellitus type I

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Recombinant serotype 9 adeno-associated virus (rAAV9) encoding a codon-optimised human neuronal ceroid lipofuscinosis-5 (CLN5) transgene

Intended for the treatment of neuronal ceroid lipofuscinosis type 5

Scope: ATMP scientific recommendation

Action: for adoption

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

4.3.1. Autologous adipose-derived mesenchymal stem cell , diabetic foot syndrome - H0005699

Intended for the treatment of diabetic foot syndrome

Scope: Responses from the applicant to the LoQs. Revised ATMP scientific recommendation

Action: for adoption

4.4. Finalisation of procedure

4.4.1. Allogeneic CRISPR/Cas9-mediated genetically modified chimeric antigen receptor (CAR) T-cells targeting CD70 - H0005771

Intended for the treatment or renal cell carcinoma and haematological malignancies

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

Action: for information

4.4.2. Umbilical cord derived CD34+ cells expanded and umbilical cord derived non-expanded CD34- cells - H0005772

Intended for the treatment in haematopoietic stem cell transplantation

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

Action: for information

4.4.3. Autologous human endometrial stem cells - H0005773

Intended for the treatment of stem cell therapy for ovarian insufficiency includes diminished ovarian reserve (DOR), premature ovarian failure (POF), primary ovarian insufficiency (POI) and poor ovarian response (POR)

Scope: the European Commission raised minor comments. ATMP scientific recommendation

Action: for information

4.4.4. Irradiated allogeneic induced-pluripotent stem cells expressing pluripotent genes and cancer-specific embryonic neo-antigens – H0005108/0002

Intended for the treatment malignant solid tumours including all epithelial cancers in sub-group type harbouring a stemness mesenchymal-like signature and haematopoietic malignancies

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

Action: for information

List of Issues adopted on 17.07.2020.

4.4.5. Autologous human T cells genetically modified ex vivo with a lentiviral vector encoding a chimeric antigen receptor (CAR) directed against G protein-coupled receptor family C group 5 member D (GPRC5D) - H0005774

Intended for the treatment of patients with relapsed or refractory multiple myeloma

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

Action: for information

4.4.6. Recombinant serotype 9 adeno-associated virus (rAAV9) encoding a codon-optimised human neuronal ceroid lipofuscinosis-7 (CLN7) transgene - H0005770

Intended for the treatment of neuronal ceroid lipofuscinosis type 7

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

Action: for information

4.4.7. Autologous regulatory T lymphocytes (Treg), with the marker profile of CD3+, CD4+, CD25high, CD127-, FoxP3+ - H0004575/0002

Intended for the treatment and prevention of progression of, multiple sclerosis (MS) [relapsing remitting (RRMS), primary progressing (PPMS), secondary progressing (SPMS)]

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

Action: for information

4.4.8. Adeno-associated viral vector serotype 9 encoding human ATP7B - H0005775

Intended for the treatment of Wilson disease

Scope: the European Commission raised no comments. 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

Timetable:
-Final Briefing Package: 23.10.2020
-Start of the procedure at SAWP: 29.10.2020
-CAT report due by: 29.10.2020

-CAT recommendation: 06.11.2020

5.2. CAT reports

5.3. List of Issues

5.4. Finalisation of SA procedures

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: 01.10.2020
SAWP recommendation: 29.10.2020
CAT recommendation: 06.11.2020
CHMP adoption of report and final recommendation: 12.11.2020

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

Czech Republic: Tomáš Boráň – membership mandate started on 01 October 2020

Action: for information

7.1.2. Strategic Review & Learning (virtual) meeting (SRLM) under the German presidency, 22 October 2020

CAT: Martina Schüßler-Lenz, Egbert Flory

Scope: final agenda

Action: for discussion

Note: to further develop the agenda for the joint meeting, a teleconference (Adobe Connect) with all interested CAT members took place .

7.1.3. CAT meeting dates for the period 2022-2024

Action: for adoption

7.2. Coordination with EMA Scientific Committees

7.2.1. CAT-PDCO interaction

CAT: Martina Schüßler-Lenz, Ilona Reischl, Maja Sommerfelt, Claire Beuneu
PDCO: Koen Norga (PDCO Chair), Sabine Scherer (PDCO Vice Chair), Karen van Melderen (Non-clinical expert), Sylvie Benchetrit (Clinical expert)

Scope: feedback from the inaugural brainstorming meeting that took place on 17 September 2020

Action: for information

7.2.2. New Readers Guidance template

Scope: introduction to the new template

Action: for information

7.2.3. Scientific Coordination Board (SciCoBo) – meeting of 21 September 2020

CAT: Martina Schüßler-Lenz

Scope: feedback on the outcome of the SciCoBo meeting that took place on 21 September 2020

Action: for information

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

7.3.1. Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells

CAT Rapporteurs: Martina Schüßler-Lenz, Marcos Timón, Tiina Palomäki

Scope: Guideline

Action: for adoption

Note: comments from the public consultations have been incorporated.

7.3.2. Biostatistics Working Party (BSWP) – new guideline on single arm trials

CAT: Martina Schüssler-Lenz

Scope: CAT representative to take part in the development of the guideline on single arm trials

Action: for appointment

7.3.3. Draft BWP/QWP/IWG toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME marketing authorisation applications

Scope: scientific and regulatory approaches for consideration by Applicants to facilitate the development and preparation of robust quality data packages for PRIME products.

Action: for information

Background:
Experience to date has shown that applicants face challenges to complete quality and manufacturing development and data requirements during development of medicines for early access (PRIME). In order to address this, a workshop[1] with industry took place to discuss quality and GMP deficiencies in PRIME products and possible scientific and regulatory approaches which could be used to facilitate development and preparation of robust quality data packages, to enable timely access to medicines for patients whilst providing assurance that patient safety, efficacy and product quality are not compromised.

As a follow-up action, the toolbox guidance was prepared. The toolbox considers which flexibility could be accepted to defer data to the post-approval phase considering the available data and the benefit/risk of the product.

7.3.4. Workshop on guideline on registry-based studies

Scope: announcement of a workshop scheduled on Monday, 19 October 2020 from 12:30-17:00 (CET) where the guideline will be presented and where stakeholders will have the opportunity to ask questions for clarification

Action: nomination of CAT member to join the workshop

Note:
-the draft Guideline on registry-based studies has been published for consultation until 31 December 2020: LINK
-an e-mail was sent out on 25.09.20. to all committees inviting participation in the workshop

[1] See meeting report:
https://www.ema.europa.eu/en/documents/report/report-workshop-stakeholders-support-quality-development-early-access-approaches-ie-prime_en.pdf

7.4. Cooperation within the EU regulatory network

7.4.1. Provision on non-conforming batches of ATMPs

Scope: feedback from the IWG discussion on provision on non-conforming ATMPs batches

Action: for discussion

7.5. Cooperation with international regulators

7.5.1. ATMP cluster teleconference with FDA-USA, Health Canada and PMDA-Japan

CAT: Martina Schüssler-Lenz, Ilona Reischl, Violaine Closson-Carella, Rocío Salvador-Roldán

Scope: feedback from the teleconference that took place on 17 September 2020

Action: for information

7.6. CAT work plan

None

7.7. Planning and reporting

None

7.8. Others

None

8. Any other business

8.1. Clinical presentation of aromatic l-amino acid decarboxylase (AADC) deficiency

CAT: Martina Schüßler-Lenz

Scope: presentation by Prof. Thomas Opladen, Centre for Paediatric and Adolescent Medicine, Heidelberg University Hospital (Germany)

Action: for information

Date of next CAT meeting:

04-06/11/2020

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

IWG: Inspectors Working Group

JR: Joint Report

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Application

MAH: Marketing Authorisation Holder

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

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: Scientific Working Party

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

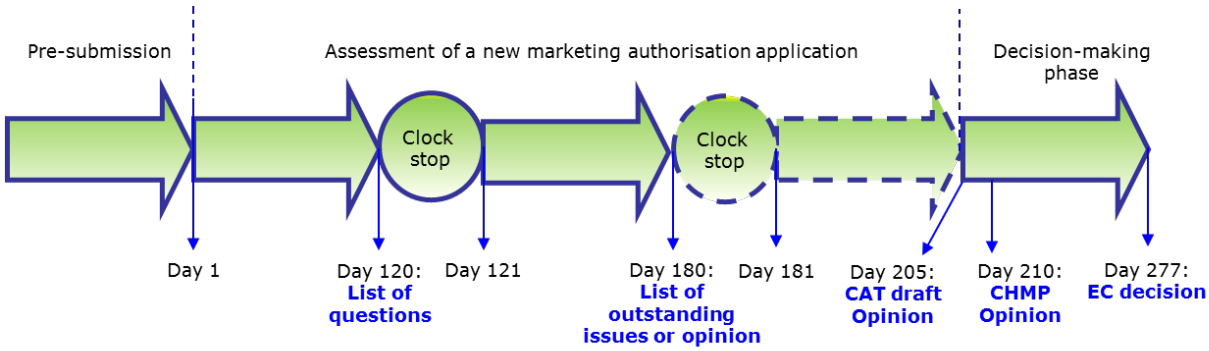
Evaluation of ATMPs (section 2)

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/