09 September 2020
EMA/CAT/476108/2020
Human Medicines Division

Committee for Advanced Therapies (CAT)

Agenda for the meeting on 09-11 September 2020

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

09 September 2020, 13:00 – 19:00 – virtual meeting

10 September 2020, 09:00 – 19:00 – virtual meeting

11 September 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. 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 09-11 September 2020. See September 2020 CAT minutes (to be published post October 2020 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 09-11 September 2020 meeting

1.3. Adoption of the minutes

CAT minutes for 15-17 July 2020 meeting

1.4. Adoption of the August 2020 Written Procedure

CAT minutes of 12-14 August 2020

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. 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

Accelerated assessment

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

Scope: List of outstanding issues

Action: for adoption

List of Questions adopted on 20.05.2020.

2.3.2. 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

Accelerated assessment

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

Scope: List of outstanding issues

Action: for adoption

List of Questions adopted on 20.03.2020.

2.3.3. Valoctocogene roxaparvovec - Orphan - EMEA/H/C/004749

Accelerated assessment

BioMarin International Limited; treatment of haemophilia A

Scope: List of outstanding issues

Action: for adoption

List of Questions adopted on 24.04.2020.

2.4. Day 120 list of questions

2.4.1. Idecabtagene vicleucel - Orphan - EMEA/H/C/004662

Accelerated assessment

Celgene Europe BV; treatment of multiple myeloma

Scope: Day 120 list of questions

Action: for adoption

2.5. Day 80 assessment reports

No items

2.6. Update on ongoing initial applications

2.6.1. Lisocabtagene maraleucel (liso-cel) – Orphan – EMEA/H/C/004731

Accelerated assessment

Celgene Europe BV; intended for the treatment of relapsed / refractory aggressive large B-cell Non-Hodgkin's Lymphoma (NHL)Scope: update **Action:** for information

2.7. New applications

2.7.1. Autologous human chondrocytes in vitro expanded – EMA/H/C/004598

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 - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

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

AveXis EU Limited

Rapporteur: Hans Ovelgönne

Scope: Quality

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/R/0039

Amgen Europe B.V.

Rapporteur: Olli Tenhunen, Co-Rapporteur: Rune Kjeken, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: 5-year Renewal of Marketing Authorisation. Opinion

Action: for adoption

Request for Supplementary Information adopted on 20.05.2020.

2.13.2. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/ANX/002

AveXis EU Limited

Rapporteur: Hans Ovelgönne, CHMP Coordinator: Johann Lodewijk Hillege

Scope: Rapporteur's Assessment Report
From initial MAA:
Non-interventional post-authorisation efficacy study (PAES) - Study no. AVXS-101-RG-001: In order to further characterise and contextualise the outcomes of patients with a diagnosis of SMA, including long-term safety and efficacy of Zolgensma, the MAH should conduct and submit the results of a prospective observational registry AVXS-101-RG-001 according to an

agreed protocol.
PAES PROTCOL

[future due date(s):
Interim reports to be submitted with annual renewal.
Final study report: 2038]

Action: for adoption

2.13.3. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/REC/010

AveXis EU Limited

Rapporteur: Hans Ovelgönne, CHMP Coordinator: Johann Lodewijk Hillege

Scope: Rapporteur's Assessment Report - quality

Action: for adoption

2.13.4. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/REC/011

AveXis EU Limited

Rapporteur: Hans Ovelgönne, CHMP Coordinator: Johann Lodewijk Hillege

Scope: Rapporteur's Assessment Report - quality

Action: for adoption

2.13.5. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/REC/012

AveXis EU Limited

Rapporteur: Hans Ovelgönne, CHMP Coordinator: Johann Lodewijk Hillege

Scope: Rapporteur's Assessment Report – quality

Action: for adoption

2.13.6. Zynteglo - betibeglogene autotemcel - Orphan - EMEA/H/C/003691/REC/013

bluebird bio (Netherlands) B.V

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

Scope: Rapporteur's Assessment Report - quality

Action: for adoption

2.13.7. Kymriah – tisagenlecleucel- Orphan – EMA/H/C/004090

Novartis Europharm Limited

Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang

Scope: quality

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

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

4.1. New requests – Appointment of CAT Coordinator

4.1.1. 3D bio-printed bionic pancreas composed of islets of Langerhans and non-viable printable porcine-derived matrix plus porcine–derived decellularized blood vessel

Intended for the treatment of late-chronic pancreatitis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. 3D bio-printed bionic pancreas composed of insulin- and glucagon-releasing cells and non-viable printable porcine-derived matrix plus porcine–derived decellularized blood vessel

Intended for the treatment of brittle diabetes mellitus type I

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

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

Intended for the treatment of neuronal ceroid lipofuscinosis type 5

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

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

Intended for the treatment of neuronal ceroid lipofuscinosis type 7

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Allogeneic CRISPR/Cas9-mediated genetically modified CAR T-cells targeting CD70

Intended for the treatment or renal cell carcinoma and haematological malignancies

Scope: ATMP scientific recommendation

Action: for adoption

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

Intended for the treatment in haematopoietic stem cell transplantation

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Autologous human endometrial stem cells

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: ATMP scientific recommendation

Action: for adoption

4.2.5. 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)

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

Scope: ATMP scientific recommendation

Action: for adoption

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

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

Scope: ATMP scientific recommendation

Action: for adoption

4.2.7. Adeno-associated viral vector serotype 9 encoding human ATP7B

Intended for the treatment of Wilson disease

Scope: ATMP scientific recommendation

Action: for adoption

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

4.3.1. 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: responses from the applicant to the LoQs. Revised ATMP scientific recommendation

Action: for adoption

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

Intended for the treatment of diabetic foot syndrome

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

Action: for adoption

4.4. Finalisation of procedure

4.4.1. Recombinant adeno-associated viral vector (serotype 8) carrying an optimised gene for human cyclic nucleotide gated channel subunit alpha 3 (CNGA3) protein – H0005726

Intended for the treatment of achromatopsia caused by mutations in the CNGA3 gene

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

Action: for information

4.4.2. Autologous naïve regulatory T cells transduced with a lentiviral vector encoding for a Chimeric Antigen Receptor (CAR) to recognize the HLA-A*02 antigen - H0005713

Intended for the prevention of immune-mediated graft rejection in HLA-A*02 mismatched renal transplantation

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

Action: for information

4.4.3. Live-attenuated, genetically modified Mycobacterium bovis expressing the gene coding for listeriolysin from Listeria monocytogenes – H0005714

Intended for treatment of non-muscle invasive bladder cancer

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: 25.09.2020
-Start of the procedure at SAWP: 01.10.2020
-CAT report due by: 02.10.2020
-CAT recommendation: 09.10.2020

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: 03.09.2020
SAWP recommendation: 01.10.2020
CAT recommendation: 09.10.2020
CHMP adoption of report and final recommendation: 15.10.2020

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

Romania: Felicia Ciulu-Costinescu – membership mandate started on 6 August 2020
Romania: Simona Badoi – membership mandate ended on 5 August 2020
Czech Republic: Ondřej Palán – membership mandate ended on 2 September 2020

Action: for information

7.1.2. EMA's decision on the management of committees' meetings for the Q4 of 2020

CAT: Martina Schüssler-Lenz

Scope: plan for the running of CAT meetings in October, November and December 2020

Action: for information

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

CAT: Martina Schüßler-Lenz, Egbert Flory

Scope: topics for the SRLM agenda:
Morning session: CAT-PDCO-PRAC joint meeting
Afternoon session: CAT-only meeting

Action: for discussion

7.2. Coordination with EMA Scientific Committees

7.2.1. CAT-PDCO interaction

CAT: Martina Schüßler-Lenz

Scope: CAT participants to the brainstorming meeting to be held .

Action: for appointment

Note: following CAT members will, together with the CAT chair and vice-chair, attend the brainstorming meeting: Maja Sommerfelt, Claire Beuneu.

PDCO group:
-Koen Norga (PDCO Chair)
-Sabine Scherer (PDCO Vice Chair)

-Karen van Melderen (Non-clinical expert)
-Sylvie Benchetrit (Clinical expert)

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

7.3.1. Summary of product characteristics Advisory Group - draft ONCWP/SmPC AG Mock-up of SmPC section 4.8 for anticancer medicines

CAT/CHMP members: Bruno Sepodes, Jan Müller-Berghaus, John-Joseph Borg, Romaldas Mačiulaitis, Sol Ruiz

Scope: CHMP's request that the CAT be consulted and questioned the need for specific or separate guidance for ATMPs.

Action: for information

Note:
-a Eudralink package with the mock-up was sent to CAT members on 27 July 2020. Comments on the draft mock-up to be sent by 07 September 2020.
-CHMP at its ORGAM July 2020 meeting concluded that this topic comes back to their ORGAM agenda, once CHMP and CAT have had one month to comment.

7.3.2. Reactivation of EMA/Committees' working parties

CAT: Martina Schüßler-Lenz

Scope: reactivation of EMA Working Parties – CAT perspective

Action: for information

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

Scope:
-Meeting report PCWP HCPWP meeting 2 June 2020
-Meeting report PCWP HCPWP meeting on ICH 3 June 2020
-Meeting report PCWP HCPWP meeting 24 June 2020
-Draft Agenda Workshop on the application of the General Data Protection Regulation (GDPR) in the area of health and Secondary Use of Data for Medicines and Public Health Purposes – 23 September 2020
-Draft Workshop on benefit-risk of medicines used during pregnancy and breastfeeding – 22 September 2020

Action: for information

7.4. Cooperation within the EU regulatory network

No items

7.5. Cooperation with international regulators

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

CAT: Ilona Reischl

Scope: feedback from the teleconference that took place on 23 July 2020

Action: for information

Following CAT members and experts attended the ATMP cluster TC: Ilona Reischl, Carla Herberts, Lisbeth Barkholt, Rune Kjeken, Nana Kruse, Juliane Rau (PEI), Louise Bang-Lauritsen (DKMA), Kristine Moll Harboe (DKMA), Eskild Coding Jorgensen (DKMA).

7.6. CAT work plan

No items

7.7. Planning and reporting

7.7.1. Planning estimates of forthcoming ATMP MAAs

Scope: Q3/2020 update of the business pipeline report for the human scientific committees

Action: for information

7.8. Others

7.8.1. Presence of nitrosamine impurities in human medicinal products

CAT: Martina Schüßler-Lenz

Scope: outcome of CHMP referral and applicability to ATMPs

Action: for information

Note: a presentation on nitrosamine impurities in human medicinal products containing chemically synthetised active pharmaceutical ingredients was given at the February 2020 CAT meeting.

8. Any other business

No items

Date of next CAT meeting:

07-09/10/2020

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

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

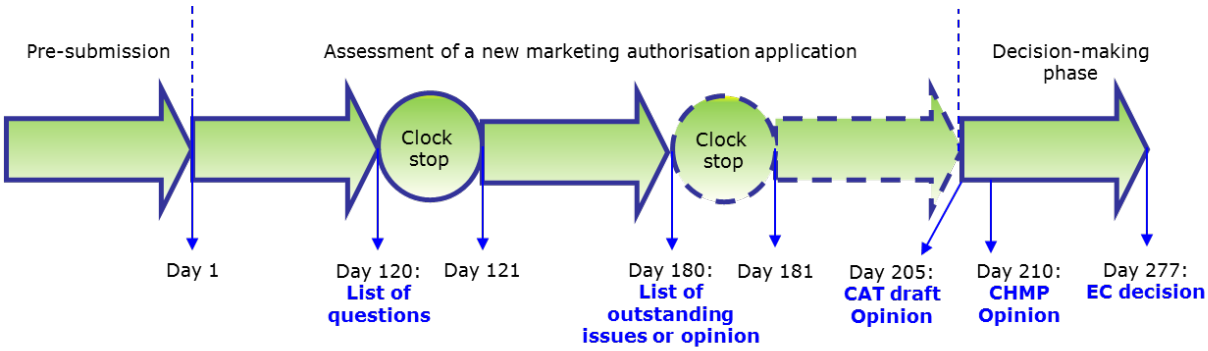
Evaluation of ATMPs (section 2)

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/