22 March 2016
EMA/CAT/164275/2016
Procedure Management and Committees Support Division

Committee for Advanced Therapies (CAT)

Agenda for the meeting on 22-23 March 2016

Chair: Paula Salmikangas - Vice-chair: Martina Schüßler-Lenz

22 March 2016, 09:00 – 18:30, room 02-A
23 March 2016, 09:15 – 17:00, room 02-A

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 on 22-23 March 2016. See March 2016 CAT minutes (to be published post April 2016 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 22-23 March 2016

1.3. Adoption of the minutes

CAT minutes of 18-19 February 2016

1.4. Technical information

2. Evaluation of ATMPs

2.1. Opinions

2.1.1. Autologous CD34+ cells transduced with retroviral vector containing the adenosine deaminase gene; *Orphan*; EMA/H/C/003854

GlaxoSmithKline Trading Services - UK; treatment of children aged 0-18 diagnosed with adenosine deaminase deficiency and for whom no suitable human leukocyte antigen-identical sibling bone marrow donor is available

Scope: Opinion

Action: for adoption

Documents:
Draft CAT AR
Draft Opinion
BWP report

Notes:
LoQs adopted: 18.09.2015
Accelerated assessment granted: 17.04.2015

2.2. Oral explanations

No items

2.3. Day 180 List of outstanding issues (LoOIs)

2.3.1. Characterised viable haploidentical herpes simplex virus thymidine kinase (HSV-Tk) and Human Low Affinity Nerve Growth Factor Receptor (ΔLNGFR) transfected donor lymphocytes; *Orphan*; EMA/H/C/002801

MolMed SpA; treatment of adjunctive treatment in haploidentical haematopoietic stem cell transplantation of adult patients with high-risk haematological malignancies

Scope: 3rd List of Outstanding Issues

Action: for adoption

Document:
-LoOIs
-BWP report

Revised Timetable *(tbc)*:
-CAT 3rd LoOI: 23.03.16 (CHMP 3rd LoOI: 01.04.16)
-Responses due: 01.04.16 (no-clock stop)
-Joint PRAC/CAT rapporteur AR: 06.04.16
-Comments: 08.04.16
-PRAC discussion: 11-14.04.16
-CAT oral explanation: 20.04.16
-CAT adoption of draft Opinion: 20.05.16.
-CHMP Opinion: May 2016

List of Outstanding Issues adopted on 20.03.2015. List of Questions adopted on 18.07.2014.

2.4. Day 120 Lists of questions (LoQs)

No items

2.5. Day 80 assessment reports

No items

2.6. Ongoing initial full application

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

No items

2.12. Other post-authorisation activities

2.12.1. ChondroCelect – Characterised viable autologous cartilage cells expanded *in vivo* expressing specific marker proteins; EMA/H/C/00878/MEA 020

TiGenix N.V.

Rapporteur: Egbert Flory; CHMP Coordinators: Jan Müller-Berghaus

Scope: MEA 020 Interim report/Study TGX001-2011. Area: clinical

Action: for adoption

Documents:
Draft Assessment Report

3. Certification of ATMPs

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

3.1. Opinions

No items

3.2. Day 60 evaluation reports

No items

3.3. Ongoing initial application

No items

3.4. New applications

No items

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – appointment of CAT Co-ordinators

4.1.1. Allogeneic bone marrow derived mesenchymal cells expanded *ex vivo* in synthetic media

Intended for the treatment of acute graft-versus-host disease grades III and IV resistant to first line treatment

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:
Request received 12th March 2016

4.1.2. Concentrate of autologous bone marrow-derived mononuclear cells (BM-MNC)

Intended for the improvement of heart function (left ventricular ejection fraction) and quality of life in patients with ischaemic post-acute myocardial infarction and in chronic heart disease

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:
Request received 9th March 2016

4.1.3. Live-attenuated, double-deleted *Listeria monocytogenes* expressing human mesothelin

Intended for the treatment of non-small cell lung cancer

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:
Request received 7th March 2016

4.1.4. Live-attenuated, double-deleted Listeria monocytogenes (Lm) expressing prostate antigens

Intended for the treatment of prostate cancer

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:
Request received 7th March 2016

4.1.5. Autologous cultured fibroblasts

Intended for the indications of:
-Facial skin regeneration;
-Reducing facial wrinkles;
-Treatment of deep lines in the skin;
-Tissue loss and to heal chronic non-closing injuries;
-Treatment of acne scars

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:
Request received 10th March 2016

4.1.6. Extracellular matrix from adipose tissue

Intended for the treatment of non-healing wounds

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption
Document:

Request received 12th March 2016

4.1.7. Adipose derived MSC

Intended for the treatment of non-healing wounds

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:
Request received 12th March 2016

4.1.8. Bone marrow derived MSC

Intended for the treatment of children's encephalopathy, children's epilepsy, children's spinal cord injury

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:
Request received 12th March 2016

4.1.9. Autologous cultured chondrocytes

Intended for the treatment of filling of cartilage loss in knee-joint

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:
Request received 12th March 2016

4.1.10. Autologous cultured fibroblasts

Intended for the treatment of filling of skin connective tissue loss

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:
Request received 12th March 2016

4.1.11. Autologous cultured keratinocytes

Intended for the treatment of non-healing wounds, burns, trophic ulcers

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 12th March 2016

4.1.12. Autologous cultured myoblasts

Intended for the treatment of faecal and urinary incontinence and of skeletal muscle injury

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:
Request received 12th March 2016

4.1.13. Autologous cultured melanocytes

Intended for the treatment of vitiligo

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:
Request received 12th March 2016

4.2. Day 30 Co-ordinators' first reports

4.2.1. Autologous *ex vivo* expanded polyclonal $CD4^+CD25^+CD127^{lo/-}FOXP3^+$ regulatory T cells

Intended for the treatment of type 1 diabetes mellitus

Action: for adoption

Document:
ATMP classification report

4.2.2. DNA plasmid encoding a recombinant fusion protein consisting of the extracellular domain of human TNFα p55 receptor linked to the human IgG1 Fc domain

Intended for the treatment of refractory chronic non-infectious uveitis

Action: for adoption

Document:
ATMP classification report

4.2.3. Autologous stromal vascular fraction

Intended as an autologous lipofiller

Action: for adoption

Document:
ATMP classification report

4.2.4. Autologous human bone marrow mononuclear cells

Intended for the treatment type 2 diabetes mellitus

Action: for adoption

Document:
ATMP classification report

4.3. Day 60 Co-ordinators' revised reports following List of Questions

4.3.1. Autologous adipose-derived regenerative cells encapsulated in carboxymethylcellulose

Intended for cosmetic dermal filling

Action: for adoption

Document:
ATMP classification report
Applicant responses to LoQs

Note: CAT adopted in January 2016 a two-month clock stop to allow the applicant time to respond to the LoQs.

4.4. Finalisation of procedures

4.4.1. Human burn eschar and debrided adipose tissue cells

Intended for the treatment of burns and non-healing wounds

Different product formulations:
-hBEDATCs in suspension
-hBEDATCs as sheet
-hBEDATCs on acellular amniotic matrix
-hBEDATCs on acellular dermal matrix

Action: for adoption

Document:
Revised ATMP classification report
Comments from the European Commission dated 3rd March 2016

4.4.2. Co-culture of keratinocytes and human burn eschar and debrided adipose tissue cells

Intended for the treatment of burns and non-healing wounds

Different product formulations:
-hBEDATCs on acellular amniotic matrix
-hBEDATCs on acellular dermal matrix

Action: for information

Document:
ATMP classification report

Note: The European Commission raised no comments

4.4.3. Recombinant non-replicative serotype 5 human adenovirus containing sequences coding for the core protein, polymerase protein and selected domains of the envelope protein of hepatitis B virus (Genotype D)

Intended for the treatment of chronic hepatitis B

Action: for information

Document:
ATMP classification report

Note: The European Commission raised no comments

4.4.4. Irradiated, whole-cell, allogeneic tumour immunotherapy

Intended for the treatment of pancreatic cancer

Action: for information

Document:
ATMP classification report

Note: The European Commission raised no comments

4.4.5. Autologous Epstein-Barr virus specific T-cells derived from peripheral blood mononuclear cells, expanded *ex vivo*

Intended for the treatment of Epstein-Barr Virus (EBV) positive malignancies

Action: for information

Document:
ATMP classification report

Note: The European Commission raised no comments

4.4.6. Hematopoietic stem and progenitor cells (HSPC) genetically modified with zinc finger nucleases (ZFNs) to disrupt the erythroid enhancer (ENH) of the gene encoding the human transcription factor BCL11A

Intended for the treatment of β-thalassemia

Action: for adoption

Documents:
Revised ATMP classification report
Comments from the European Commission dated 3rd March 2016

4.4.7. Autologous cells of stromal vascular fraction (SVF) and autologous adipose derived stem cells

Intended for treatment of keloid scars and aging skin

Action: for adoption

Documents:
Revised ATMP classification report
Comments from the European Commission dated 3rd March 2016

4.5. Follow-ups and guidance

No items

5. Scientific Advice

Disclosure of 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 Co-ordinators

5.2. CAT Rapporteurs' reports

5.3. Lists of issues

5.4. Finalisation of Scientific Advice procedures

6. Pre-Authorisation Activities

Disclosure of 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 (PIP)

6.2. ITF briefing meetings in the field of ATMPs

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. Strategic Review & Learning meeting

CAT-PDCO-CTFG joint Strategic Review & Learning meeting will take place in Utrecht, Netherlands on 1st-2nd June 2016 under the auspices of the Dutch Presidency of the Council of the European Union

CAT resources: Hans Ovelgönne

Scope: initial discussion to agree on topics for the agenda. The scientific focus will be on dose finding in the context of extrapolation to children

Action: for discussion

Document**:**
Draft agenda

Note**:** CAT members are asked to send proposals for agenda topics

7.1.2. Changes to the participation of alternate members in the meetings of the scientific committees (when there is no appointment member)

Action: for information

Document:
Principles for invitation to alternates to committees meetings.

7.1.3. New internal guidance on management of confidentiality and declarations of interests for observers participating in EMA scientific meetings

Action: for information

Note:
The Agency has developed internal guidance on observers participating in EMA scientific meetings, focusing on management of confidentiality and declarations of interests.

Observers from a non-EEA authority or organisation with no Confidentiality Arrangement in place with EMA require a personal Confidentiality undertaking only (no Declaration of Interests (DoI) /Curriculum vitae (CV)).

The following do not require a personal Confidentiality undertaking (no DoI/CV): Observers from European Institutions and European Union; Observers from non-EEA authorities or organisations with a Confidentiality Arrangement (CA) in place with EMA.

EEA National Competent Authorities (NCAs) staff members are considered as European experts: a DoI including a Confidentiality Undertaking and CV is required. *Exception: non-scientific administrative staff from NCAs attending EMA meetings on a one off / ad hoc basis: a personal CU is required, but no DoI/CV.*

7.1.4. New CAT plenaries dates and times – from April 2016

Scope: agreement by the EMA's Executive Director to the change in meeting times (from current timing of Thurs 09.00 – Fri 15.00 to new timing of Weds 14.00 - Fri 12.00, to accommodate CAT workload and needs)

Action: for information

Note: The CAT discussed and agreed on the new times at its plenary in February 2016. The main drivers for this change were: need for additional time for the discussion, updating and adoption of milestone documents (e.g. draft opinion on MAA); increase in workload (especially on pre-submission procedures and for guideline / CAT work topic development). It was clarified that the duration of the meeting will depend on the topics on the agenda (CAT meeting could finish earlier or could even take place virtually).
Within the new timing, ITF meetings could be organised either on Wednesdays before 14.00 or Fridays after 12.00.

7.2. Coordination with EMA Scientific Committees

7.2.1. Committee for Medicinal Products for Human Use (CHMP)

Scope: Summary of Outcomes (SoO) for the February 2016 meeting

Action: for information

Documents:
-Summary of Outcomes

7.2.2. Early access tools: initial marketing authorisation - revised accelerated assessment procedural timetables

Scope: amended guideline and timetables

Action: for information

Note: the CHMP adopted the new guideline at its February 2016 plenary meeting

7.2.3. Guideline on the scientific application and the practical arrangements necessary to implement Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004

Scope: CHMP guideline on conditional marketing authorisation

Action: for information

Note: the CHMP adopted the guideline at its February 2016 plenary meeting

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

7.3.1. CAT – CHMP (SWP) cluster on tumourigenicity studies for ATMPs

CAT resources: Tiina Palomäki, Hans Ovelgönne, Björn Carlsson, Egbert Flory; Carla Herberts and Isabelle Vieira; Scope: update on progress regarding drafting of the RP and discussion on how to best progress the topic

Action: for discussion

Documents:
-CAT-SWP cluster – Minutes of the 2nd teleconference that took place on 28th October 2015
-Draft proposal for reflection paper on non-clinical tumourigenicity studies for cell-based medicinal products

7.4. Co-operation within the EU regulatory network

7.4.1. Orphan similarity for ATMPs

CAT drafting group: Margarida Menezes-Ferreira, Nicolas Ferry, Paula Salmikangas, Ilona Reischl, Christiane Niederlaender, Michele Lipucci;

Scope: Reflection from the perspective of ATMPs on the concept of 'similar active substance' as referred to in Art 3(3)c of Reg (EC) No 847/2000 of April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concept 'similar medicinal product' and 'clinical superiority'

Scope: feedback from the breakout meeting of 23rd March 2016

Action: for discussion

7.5. Co-operation with international regulators

7.5.1. ATMP cluster teleconference with FDA / Health Canada / PMDA

The teleconference will take place during the plenary meeting on Tuesday 22th March from 14.00hrs – 15.00hrs

CAT resources: Paula Salmikangas

Action: for information

Document table:
Draft agenda

7.5.2. International Pharmaceutical Regulators Forum (IPRF) Gene therapy group

CAT resource: Paula Salmikangas

Scope: oral feedback from the teleconference that took place on 7th January and 9th March 2016

Action: for information

Documents:
Agenda

7.6. CAT Work Plan

7.6.1. CAT workshop for cell-based cancer immunotherapy products (15-16 November 2016)

CAT resources: Rune Kjeken, Björn Carlsson, Olli Tenhunen, Martina Schüßler-Lenz, Metoda Lipnik-Stangelj, Paula Salmikangas, Marit Hystad, Dariusz Sladowski, Bernd Gänsbacher

Scope: feedback from teleconference of 11th March 2016

Action: for information

7.6.2. CAT assessor training (23-24 June 2016)

Moderators: for Quality session: Margarida Menezes-Ferreira and Ilona Reischl; Clinical session: Martina Schüßler-Lenz and Simona Badoi; Non-clinical session: Björn Carlsson and Egbert Flory

Action: for information

Note: a breakdown meeting took place on Monday 21st March 2016

7.6.3. Guideline on requirements for investigational ATMPs

CAT drafting groups: Tiina Palomäki (Rapporteur), Ilona Reischl (Rapp), Metoda Lipnik-Stangelj, Margarida Menezes Ferreira, Maura O'Donovan, Nicolas Ferry, Simona Badoi, Tomas Boráň, Christiane Niederlaender

Scope: Feedback from the drafting group meeting

Action: for information

7.7. Planning and reporting

No items

7.8. Others

7.8.1. International Society for Cellular Therapy (ISCT) 2016 Annual Meeting, Singapore, 25-28 May 2016

Scope: request by ISCT for a CAT expert. Martina Schüßler-Lenz to speak on the quality and operations track session: *'Evolving regulatory regime for cell based therapies – faster/early access'*

Action: for adoption on participation

Note: the session will focus on regulatory pathways such as adaptive licensing or conditional licensing: Japan: Reg Med Law; EU: adaptive licensing pilot or PRIME; and US FDA: breakthrough are proposed to talk.

Programme: http://www.isct2016.com/wp-content/uploads/2016/03/ISCT-2016-Preliminary-Program_WEB.pdf

8. Any other business

8.1.1. EMA notification system

Scope: Test of the EMA emergency notification system – RapidReach
Action: for information

Date of next CAT meeting:
Wednesday 20th to Friday 22nd April 2016

9. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

Abbreviations / Acronyms

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

DG: Drafting Group

EC: European Commission

FL: Final Letter

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Environmental Risk Assessment

GMP: Good Manufacturing Practice

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 Applicant

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

SA: Scientific Advice

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

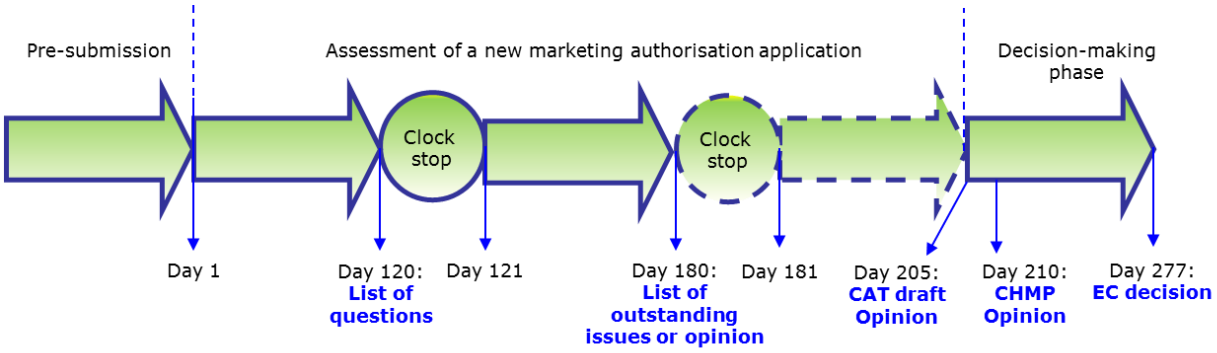
Evaluation of ATMPs (section 2)

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.

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/