10 December 2015
EMA/CAT/841770/2015
Procedure Management and Committees Support Division

Committee for Advanced Therapies (CAT)

Agenda for the meeting on 10-11 December 2015

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

10 December 2015, 09:00 – 18:30, room 03-E
11 December 2015, 09:00 – 14:00, room 03-E

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 10-11 December 2015. See December 2015 CAT minutes (to be published post January 2016 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 10-11 December 2015

1.3. Adoption of the minutes

CAT minutes of 12-13 November 2015

1.4. Technical information

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 List of outstanding issues (LoOIs)

No items

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 16.5., 18.5.

TiGenix N.V.

Rapporteur: Egbert Flory; Co-rapporteur: Tiina Palomäki; CHMP Coordinator: Jan Müller-Berghaus

Scope 16.5.: randomised control trial protocol TIG/ACT/04/2009
Scope 18.5.: non-interventional registry of ChondroCelect, study TGX001-2011 & randomised controlled study in small lesions using microfracture as comparator

Action: for adoption

Document:
pRAR

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. New applications

No items

3.2. Day 60 evaluation reports

No items

3.3. Opinions

No items

3.4. Ongoing initial application

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – appointment of CAT Co-ordinators

Adeno-associated viral vector serotype 2 containing the human *RPE65* gene Intended for the treatment of inherited retinal degeneration due to autosomal recessive *RPE65* gene mutations

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

Action: for adoption

Document:
Request received 26th November 2015

4.1.1. *Ex vivo* expanded allogeneic human immuno-modulatory progenitor (iMP) cells

Intended for the treatment of incomplete revascularisation as an adjunct to CABG in patients with congenital coronary artery malformations

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

Action: for adoption

Document:
Request received 26th November 2015

4.1.2. Human amniotic membrane mesenchymal stem cells

Intended for the treatment of burns and non-healing wounds

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

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

Action: for adoption

Document:
Request received 2th November 2015

4.1.3. Human umbilical cord mesenchymal stem cells

Intended for the treatment of burns and non-healing wounds

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

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

Action: for adoption

Document:

Request received 2th November 2015

4.1.4. Co-culture of keratinocytes and human umbilical cord mesenchymal stem cells

Intended for the treatment of burns and non-healing wounds

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

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

Action: for adoption

Document:
Request received 2th November 2015

4.1.5. Co-culture of keratinocytes and human amniotic membrane mesenchymal stem cells

Intended for the treatment of burns and non-healing wounds

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

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

Action: for adoption

Document:
Request received 2th November 2015

4.2. Day 30 Co-ordinators' first reports

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

Intended for the treatment of treatment of (1) diabetic foot ulcer and (2) keloid scars and aging skin

Action: for adoption

Document:
ATMP classification report

4.2.2. Autologous adipose-derived regenerative cells encapsulated in carboxymethylcellulose

Intended for the treatment of cosmetic dermal filling

Action: for adoption

Document:
ATMP classification report

4.2.3. Human hepatoblastoma cells (HepG2) encapsulated in alginate, expanded in a fluidised bed bioreactor

Intended for the treatment of acute liver failure

Action: for adoption

Document:
ATMP classification report

4.2.4. Adeno-associated virus serotype 8 vector encoding human ornithine transcarbamylase

Intended for the treatment of ornithine transcarbamylase tl

Action: for adoption

Document:
ATMP classification report

4.2.5. Fibroblasts and keratinocytes co-culture

Intended for the treatment of deep and extensive burns, chronic wounds, skin donor sites

Different product formulations:
-suspension of cell in platelet leukocyte rich gel
-in sheet
-seeded on acellular amniotic matrix
-seeded on acellular dermal matrix
-seeded on transgenic porcine acellular dermal matrix

Action: for adoption

Document:
ATMP classification report

4.2.6. Human acellular amniotic matrix

Intended for the treatment of deep and extensive burns, chronic wounds, skin donor sites

Action: for adoption

Document:
ATMP classification report

4.2.7. Human acellular dermal matrix

Intended for the treatment of deep and extensive burns, chronic wounds, skin donor sites

Action: for adoption

Document:
ATMP classification report

4.2.8. Allogeneic chondrocytes and irradiated genetically modified chondrocytes expressing human TGF-β1

Intended for the treatment of degenerative joint disease

Action: for adoption

Document:
ATMP classification report

4.2.9. Allograft tendon combined with suture ready to use

Intended for the treatment of anterior cruciate ligament reconstruction

Action: for adoption

Document:
ATMP classification report
List of Questions to applicant

4.2.10. Transgenic porcine acellular dermal matrix

Intended for the treatment of deep and extensive burns, chronic wounds, skin donor sites

Action: for adoption

Document:
ATMP classification report

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

4.3.1. Autologous bone marrow derived non-haematopoietic stem cells

Intended for the treatments of patients with rheumatoid arthritis; patients after ischemic stroke; patients after myocardial infarction; type I diabetes; type II diabetes

Action: for adoption

Documents:
Revised ATMP classification report
Applicant's response to the LoQs

4.3.2. Autologous peripheral blood-derived total nucleated cells

Intended for the treatment of critical limb ischemia

Action: for adoption

Documents:
Revised ATMP classification report
Applicant's response to the LoQs

4.4. Finalisation of procedures

4.4.1. Autologous adipose derived regenerative cells encapsulated in hyaluronic acid

Intended for the treatment of articular cartilage and bone defects

Action: for information

Document:
ATMP classification report

Note:
The European Commission raised no comments

4.4.2. Autologous cells of stromal vascular fraction (SVF) of adipose tissue

Intended for (1) cosmetic lipofiling; (2) treatment for non-healing wounds and scared tissue; (3) treatment of osteoarthritis in the knee

Action: for information

Document:
ATMP classification report

Note:
The European Commission raised no comments

4.4.3. Allogeneic pro-inflammatory monocyte-derived dendritic cells

Intended for the treatment of metastatic renal cell carcinoma (mRCC)

Action: for adoption

Document:
ATMP classification report

Note:
The European Commission raised no comments

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)

No items

6.2. ITF briefing meetings in the field of ATMPs

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

No items

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 November 2015 meeting
Scope: Workplan for 2016

Action: for information
Documents:
-Summary of Outcomes
-Workplan

Note: the CHMP will adopt their workplan in December 2015

7.2.2. Experience with 'Early Background Summaries'

Scope: upcoming survey to gather feedback from rapporteurs and assessors on the experience with the Early Background Summaries that were introduced in 2014

Action: for information

7.2.3. Guideline on Good Pharmacovigilance Practices (GVP). Module V: Risk Management Plan (RMP), rev. 1.5.

Scope: First major revision of the guideline

Action: for discussion

Note:
-an e-mail with the module was sent to CAT member on 18.11.15. with deadline for comments 2nd December 2015
-the section on ATMP specific guidance is to be found in rows 529 to 590

7.2.4. Guideline on Safety and Efficacy – RMP for ATMPs

Scope: Update and follow up on the guideline

Action: for information

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500006326.pdf

Note:
EMA has set up a task force to re-visit the document and are looking for CAT volunteers.

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

7.3.1. Good Laboratory Practice (GLP) requirements of non-clinical studies for ATMPs

CAT drafting group: Una Riekstina, Tiina Palomäki, Egbert Flory, Ilona Reischl, Carla Herberts (NL), Isabel Vieira (PT)

Scope: Application of GLP principles on ATMPs

Action: for adoption

Document:
CAT's position

Note:
June 2015: presentation by the EMA GLP Inspections Working Party (IWP) on GLP requirements for ATMPs
July 2015: CAT agreed on the composition of a drafting group to draft a document summarising experiences and expectation in relation to the GLP requirements of non-clinical studies of ATMP
26 October 2015: teleconference of the drafting group to develop a draft CAT position
13 November 2015: discussion at CAT with one-month for comments to 8th December 2015

7.3.2. Questions and Answers on minimally manipulated ATMPs

CAT drafting group: M. Lipnik Stangelj (Rapp), P. Salmikangas (Rapp), T. Palomäki, E. Flory, M. Menezes Ferreira, P. Doevendans, M. Hrubiško

Scope: to create a Q&A document following the discussion that took place at the CAT-CHMP joint Strategic Review & Learning meeting in May 2015

Action: feedback from drafting group meeting

Note:
-16 September 2015: CAT break-out meeting of the drafting group

7.3.3. Interaction between SAWP and CAT

Scope: further areas for improvement in the CAT-SAWP workflow

Action: for discussion

7.3.4. Scientific Co-ordination Board (SciCoBo) - meeting 3rd December 2015

CAT resources: Paula Salmikangas

Action: for information

Document:
Agenda

7.3.5. EMA/Cancer Drug Development Forum (CDDF) workshop in 2016 on cancer immunotherapy: 'Challenges for the approval of anti-cancer immunotherapeutic drugs'

Scope: to discuss regulatory issues and the design of pivotal trials for the new immunotherapies together with a multi-stakeholder audience of regulators, industry representatives and academics.

Action: for information

7.4. Co-operation within the EU regulatory network

7.4.1. Good manufacturing practice (GMP) requirements for ATMPs

CAT drafting group members: I. Haunerova, M. Menezes-Ferreira, G. Panté, I. Reischl, P. Salmikangas, B. Sekkali, M. Timón, Jürgen Scherer, Marcel Hoefnagel, C Niederlaender

Scope: Comments received during the external consultation and next steps

Action: for information

Documents:
Minutes of the meeting that took place on 16.11.15.
Minutes of the meeting that took place on 30.11.15.
External comments
http://ec.europa.eu/health/files/advtherapies/2015_pc/publ_cons_doc_2015.pdf

7.4.2. European Commission request for definition of: 'Principal Molecular Structural Features'

Scope: revision of the Commission Regulation (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'

Action: for information

Document:
European Commission's letter dated 25th November 2015

7.4.3. Analysis of European Clinical Trials Database (EudraCT)

CAT resources: Tomáš Boráň, Margarida Menezes-Ferreira, Ilona Reischl, Paula Salmikangas, Nicolas Ferry, Romaldas Mačiulaitis, Dariusz Śladowski, Michele Lipucci di Paola, Bernd Gänsbacher

Scope: feedback from the breakout meeting of 9 December 2015

Action: for information

Note:
-16 September 2015: CAT's first break-out meeting of the drafting group
-16 October CAT: presentation and discussion of the first results of the EudraCT analysis

7.5. Co-operation with international regulators

7.5.1. ATMP cluster teleconference with FDA and Health Canada

The teleconference will take place during the plenary meeting on Thursday 10th December from 14.00hrs – 15.00hrs

CAT resources: Paula Salmikangas

Action: for adoption

Document table:
Agenda

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

CAT resource: Paula Salmikangas

Scope: Oral feedback from the teleconference of 7 December 2015 and request for CAT involvement in the topic 6: 'Nature and duration of patient follow-up after receiving a cell therapy product'.

Action: for discussion

Document:
Agenda

Note: Documents circulated for the IPRF meetings are available in MMD (General / International Activities / Regulators Forum cell therapy group)

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

CAT resource: Paula Salmikangas

Scope: Next international teleconference will take place on 7 January 2016

Action: for information

Documents:
Draft agenda

7.6. CAT Work Plan

7.6.1. CAT- International Society for Cellular Therapy (ISCT) Joint Workshop: 'Challenges and Opportunities for the Successful Development and Approval of Advanced Therapy Medicinal Products', Seville (Spain), 25th September 2015

CAT resources: Paula Salmikangas

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/06/news_detail_002357.jsp&mid=WC0b01ac058004d5c1

Action: for information

Documents:
Presentations

7.6.2. ATMP assessor training 2016

CAT resources: Margarida Menezes-Ferreira, Paula Salmikangas, Martina Schüßler-Lenz, Simona Badoi

Scope: outline of the programme and appointment of CAT moderators and presenters

Action: for discussion

Note: The ATMP assessor training is included in the CAT work plans of 2015 and 2016. The proposal is to hold a 1.5 day assessor training on quality, non-clinical and clinical aspects of ATMPs. This will include also presentations on the ERA and the RMP. The date for the training: week of 20 June 2016 (*tbc*)

7.6.3. Webinar on ATMP classification

Date: 11 December 2015, 13.00-14.00
Presenters: Nicolas Ferry, Belaïd Sekkali, Paula Salmikangas, Patrick Celis

Scope: this Webinar is addressed to the national authorities (NCAs) who are conducting ATMP classifications in their member state

Action: for information

Interested assessors should send an e-mail by 9th December 2015.

Note:
CAT members are asked to promote this Webinar at their Agency
CAT members can attend the Webinar in person

7.7. Planning and reporting

No items

7.8. Others

7.8.1. Talk on: 'The value of involving patients and healthcare professionals in medicines regulation', Promenade lounge (-1 floor), 10th December 2015, 13:00-14:00hrs.

Speakers invited: David Haerry - Co-Chair of the PCWP; Gonzalo Calvo - Co-Chair of the HCPWP; Bruno Sepodes - chair of the COMP and Isabelle Moulon head of EMA's Patients and Healthcare Professionals Department

Scope: panel discussion and open floor debate

Action: for information

Note:
The debate is part of a series of events that have been planned to celebrate this year's 20th anniversary of the European Medicines Agency. The talk will be video recorded and later published on the EMA website to reach a wider audience.

CAT members are encouraged to attend this panel discussion in the margins of the December 2015 CAT meeting.

7.8.2. Biomedical Excellence for Safer Transfusion Collaborative (BEST), UK. – letter addressed to the CAT Chair on interference of drugs with blood group testing before transfusion

CAT resources: Paula Salmikangas

Action: for information

Document:
Letter from BEST dated 11 November 2015

7.8.3. Pharmaceuticals and Medical Devices Agency (PMDA) and The Japanese Society for Regenerative Medicine (JSRM): International Regulatory Forum of Human Cell Therapy and Gene therapy Products, 16th March 2016, Osaka, Japan

CAT resources: Paula Salmikangas

Action: for information

Document:
Programme

8. Any other business

Date of next CAT meeting:
Thursday 21st – Friday 22nd January 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

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMP: Good Manufacturing Practice

GVP: Good Pharmacovigilance Practice

ITF: Innovative Task Force

LoOI: List of outstanding issues

LoQ: List of questions

PDCO: Paediatric Committee

PIP: Paediatric Investigation Plan

PL: Package leaflet

PRAC: Pharmacovigilance and Risk Assessment Committee

RSI: Request for supplementary information

SA: Scientific Advice

SAG-O: Scientific Advisory Group Oncology

SAWP: Scientific Advice Working Party

SMEs: Small and Medium-size Enterprises

SmPC: Summary of Products Characteristics

Evaluation of ATMPs (section 2)

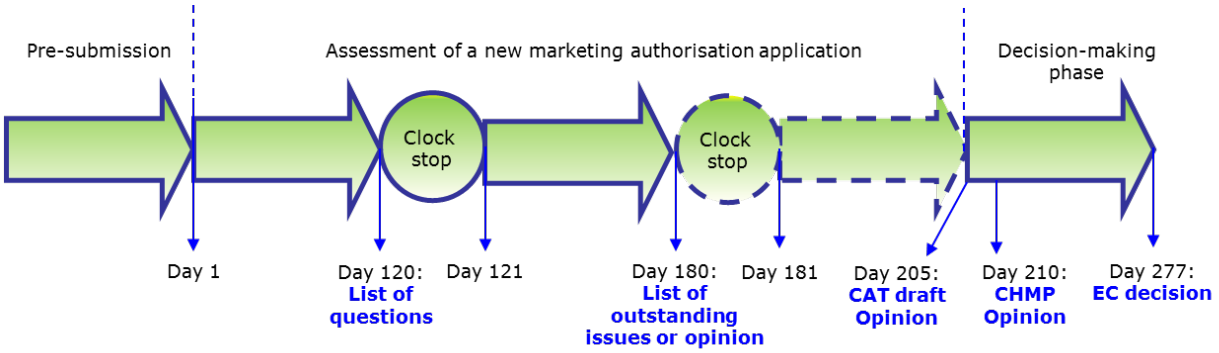
This section lists applications for marketing authorisations of new Advanced Therapy Medicinal Products (ATMPs) that are to be discussed by the Committee. It also lists any ATMP related inspection requests (*section 2.9*) and Post-authorisation activities (*section 2.10*).

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/