



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 January 2016
EMA/CAT/49183/2016
Procedure Management and Committees Support Division

Committee for Advanced Therapies (CAT) Agenda for the meeting on 21-22 January 2016

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

21 January 2016, 09:00 – 18:30, room 03-E

22 January 2016, 09:00 – 15:00, 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 21-22 January 2016. See January 2016 CAT minutes (to be published post February 2016 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 21-22 January 2016

1.3. Adoption of the minutes

CAT minutes of 10-11 December 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)

2.3.1. Characterized viable haploidentical Herpes Simplex Virus Thymidine Kinase (HSV-Tk) and Human Low Affinity Nerve Growth Factor Receptor (Δ LNGFR) transfected donor lymphocytes; *Orphan*; EMA/H/C/002801

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

Scope: second LoOIs and timetable

Action: for discussion

Documents:
Updated Rapporteurs report
PRAC AR on the RMP
PRAC advice
BWP report

Note:

Eight-month clock-stop agreed by CAT in April 2015
List of Outstanding Issues adopted on 20.03.15
BWP report was discussed in March 2015
List of Questions adopted on 16.01.15

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

2.11.1. Glybera – Alipogene tiparvovec; Orphan; EMA/H/C/002145/II/46-G

UniQure Biopharma B.V.

Rapporteur: Christiane Niederlaender; CHMP Coordinator: Greg Markey

Scope: quality:

Action: for adoption

Documents:

-Draft Opinion

-BWP report

2.11.2. Glybera - Alipogene tiparvovec; Orphan; EMEA/H/C/002145/II/47

UniQure biopharma B.V.

Rapporteur: Christiane Niederlaender; CHMP Coordinators: Greg Markey

Scope: quality:

Action: for adoption

Documents:

-Draft Opinion

-BWP report

2.11.3. Glybera - Alipogene tiparvovec; Orphan; EMEA/H/C/002145/II/48

UniQure biopharma B.V.

Rapporteur: Christiane Niederlaender; CHMP Coordinators: Greg Markey

Scope: quality:

Action: for adoption

Documents:

-Draft Opinion

-BWP report

2.12. Other post-authorisation activities

2.12.1. Glybera - Alipogene tiparvovec; Orphan; EMEA/H/C/002145/S/0051

UniQure Biopharma B.V.

Rapporteur: Christiane Niederlaender; CHMP Coordinators: Greg Markey

Scope: 3rd annual reassessment

Action: for adoption

Documents:

-Draft Opinion

2.12.2. Glybera - Alipogene tiparvovec; Orphan; EMEA/H/C/002145/SOB 002.3

UniQure Biopharma B.V.

Rapporteur: Christiane Niederlaender; CHMP Coordinators: Greg Markey

Scope: Protocol for the study to measure postprandial chylomicrons.

Action: for adoption

Documents:

-RSI

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

4.1.1. 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

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

Action: for adoption

Document:

Request received 2nd November 2015

4.1.2. 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

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

Action: for adoption

Document:

Request received 2nd November 2015

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

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

Action: for adoption

Document:

Request received 1st December 2015

Irradiated, whole-cell, allogeneic tumour immunotherapy Intended for the treatment of pancreatic cancer

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

Action: for adoption

Document:
Request received 21st December 2015

4.1.3. 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

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

Action: for adoption

Document:
Request received 8th January 2016

4.1.4. 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

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

Action: for adoption

Document:
Request received 8th January 2016

4.2. Day 30 Co-ordinators' first reports

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

Action: for adoption

Document:
ATMP classification report

4.2.1. *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

Action: for adoption

Document:
ATMP classification report

4.2.2. Human amniotic membrane mesenchymal stem cells

Intended for the treatment of burns and non-healing wounds

Different product formulations:

- hAMMSCs in suspension
- hAMMSCs as sheet
- hAMMSCs seeded on acellular amniotic matrix
- hAMMSCs seeded on acellular dermal matrix

Action: for adoption

Document:
ATMP classification report

4.2.3. 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

Action: for adoption

Document:
ATMP classification report

4.2.4. 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

Action: for adoption

Document:
ATMP classification report

4.2.5. 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

Action: for adoption

Document:
ATMP classification report

4.2.6. 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

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 – Postponed to February 2016

Intended for the treatment of cosmetic dermal filling

4.3.2. Fibroblasts and keratinocytes co-culture

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

Product formulation:

- seeded on transgenic porcine acellular dermal matrix

Action: for adoption

Document:

Revised ATMP classification report

4.4. Finalisation of procedures

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

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

Action: for information

Document:

ATMP classification report

Note: the European Commission raised no comments

4.4.2. 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 information

Documents:

ATMP classification report

Note: the European Commission raised no comments

4.4.3. Autologous peripheral blood-derived total nucleated cells

Intended for the treatment of critical limb ischemia

Action: for adoption

Documents:

Revised ATMP classification report

Note: comments received by the European Commission

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

Intended for the treatment of acute liver failure

Action: for information

Document:

ATMP classification report

Note: the European Commission raised no comments

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

Intended for the treatment of ornithine transcarbamylase tl

Action: for information

Document:

ATMP classification report

Note: the European Commission raised no comments

4.4.6. 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

Action: for adoption

Document:

Revised ATMP classification report

Note: the European Commission:

-raised no comments for a) suspension of cell in platelet leukocyte rich gel and b) in sheet

-raised comments for c) seeded on acellular amniotic matrix and d) seeded on acellular dermal matrix

4.4.7. Human acellular amniotic matrix

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

Action: for information

Document:

ATMP classification report

Note: the European Commission raised no comments

4.4.8. Human acellular dermal matrix

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

Action: for information

Document:

ATMP classification report

Note: the European Commission raised no comments

4.4.9. Allogeneic chondrocytes and irradiated genetically modified chondrocytes expressing human TGF- β 1

Intended for the treatment of degenerative joint disease

Action: for adoption

Document:

Revised ATMP classification report

Note: comments received by the European Commission

4.4.10. Allograft tendon combined with suture ready to use

Intended for the treatment of anterior cruciate ligament reconstruction

Action: for adoption

Document:

Revised ATMP classification report

Note: comments received by the European Commission

4.4.11. 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

Note: comments received by the European Commission

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

No items

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. CAT membership

Croatia: Mirna Golemović - nomination as member

Croatia: Sandra Tomljenovic – termination of mandate for member

Action: for information

7.1.2. 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 discussions 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

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

7.1.3. Procedural advice on the evaluation of Advanced Therapy Medicinal Products (pre-authorisation, post-authorisation, re-examination); EMEA/630043/2008

Scope: Update/revision of the document

Action: for discussion and appointment of CAT members to draft the revision

Note: CAT/CHMP adopted the document in March 2009. This guidance describes the procedure for evaluation of ATMPs for initial marketing authorisation and for post-authorisation procedures (e.g. variations, renewal, etc.) detailing the interactions, the roles and responsibilities of the committees involved in the assessment of ATMPs.

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 December 2015 meeting

Action: for information

Documents:

-Summary of Outcomes

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

7.3.1. Questions and Answers on minimally manipulated ATMPs

CAT drafting group: Metoda Lipnik Stangelj, Paula Salmikangas, Tiina Palomäki, Egbert Flory, Margarida Menezes Ferreira, Pieter Doevendans, Mikuláš Hrubíško

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:

CAT break-out meeting of the drafting group: meeting on 21st January 2016, from 18:30hrs to 19:30hrs, room 03-G

7.3.2. Interaction between Scientific Advice Working Party (SAWP) and CAT (Committee for Advanced Therapies)

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

Action: for discussion

7.3.3. EMA/Cancer Drug Development Forum (CDDF) workshop on 4-5 February 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

Note: CAT colleague can follow by Webinar

7.3.4. Type IB Variations

Scope: presentation on Type IB process

Action: for information

Note: CAT is receiving an increasing number of variations, especially Type IB. The presentation will clarify what is expected from the Rapporteurs in the new IB process of colour coding.

7.3.5. Draft reflection on a proposal to enhance early dialogue to facilitate accelerated assessment of priority medicines (PRIME)

CAT resource: Paula Salmikangas

Scope: Update on the public consultation of the reflection paper. Discussion on operational aspects in view of CAT involvement in PRIME eligibility procedure and support for ATMPs

Action: for discussion

Reflection

paper: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/10/news_detail_002424.jsp&mid=WCOb01ac058004d5c1-

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, C. Niederlaender, J. Scherer, M. Hoefnagel

Scope: discussion of the comments received during the external consultation and next steps

Action: for information

Documents:

Agenda

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'

CAT resources: Nicolas Ferry

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 discussion

Documents:

-European Commission's letter dated 25th November 2015

-Draft definition (with QWP/BWP's input already incorporated)

-BWP report

7.4.3. Analysis of European Clinical Trials Database (EudraCT)

CAT resources: Ivana Haunerova (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 results of the analysis

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

7.4.4. Projects in Horizon 2020 related to ATMPs: new calls for proposals

Resources: Charles Kessler and Arnd Hoeveler – EU's DG Research & Innovation

Scope: introduction of the EC's Horizon 2020 Work Programme for the years 2016 and 2017 in particular topics of relevant importance to

ATMPs: http://ec.europa.eu/research/participants/data/ref/h2020/wp/2016_2017/main/h2020-wp1617-health_en.pdf

Action: for information

Note: The European Commission's DG Research & Innovation presented to CAT in February 2015 the EU support/funding to ATMP research in the Framework programme 7 (2007-2013) and Horizon 2020.

7.5. Co-operation with international regulators

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

CAT resource: Paula Salmikangas

Scope: Oral feedback from the teleconference that took place on 7 January 2016

Action: for information

Documents:
Draft agenda

7.6. CAT Work Plan

7.6.1. CAT Work plan 2016

CAT resources: Paula Salmikangas

Action: for adoption

7.6.2. 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/new_s_detail_002357.jsp&mid=WC0b01ac058004d5c1

Action: for information

Documents:
Presentations

7.6.3. ATMP assessor training 2016

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

Moderators: for Quality session: M. Menezes-Ferreira and I. Reischl; Clinical session: M. Schüßler-Lenz and S. Badoi.

Scope: appointment of CAT moderators for the non-clinical session

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 23-24 June 2016 on: quality, non-clinical and clinical aspects of ATMPs (including combined ATMP), sessions on ERA review and RMP

7.7. Planning and reporting

No items

7.8. Others

No items

8. Any other business

Date of next CAT meeting:
Thursday 18st – Friday 19nd February 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
GMP: Good Manufacturing Practice
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
PDCO: Paediatric Committee
PIP: Paediatric Investigation Plan
PL: Package leaflet
PRAC: Pharmacovigilance and Risk Assessment Committee
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

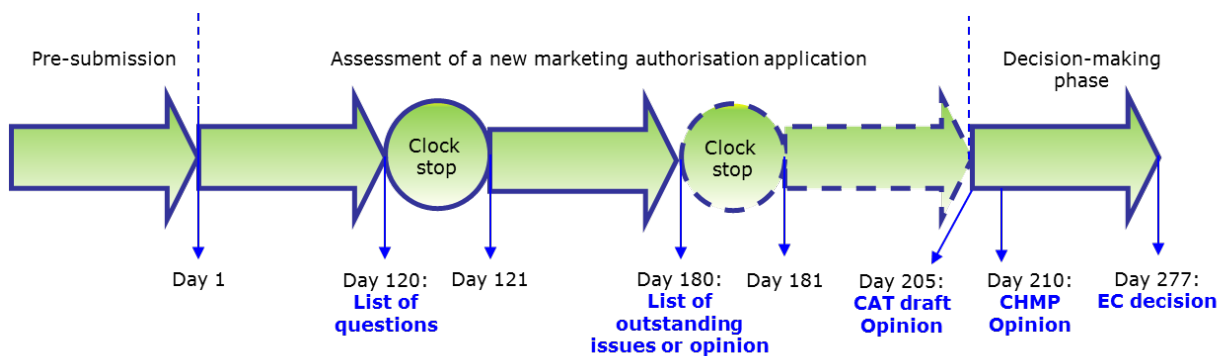
Evaluation of ATMPs (section 2)

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/