23 March 2016
EMA/CAT/246676/2016
Procedure Management and Committees Support Division

Committee for Advanced Therapies (CAT)

Minutes for the meeting on 18-19 February 2016

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

18 February 2016, 09:00 – 18:30, room 03-E
19 February 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 the minutes 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, the minutes are a working document primarily designed for CAT members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes 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

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 22 or more members were present in the room). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

The list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CAT plenary session held on 18-19 February 2016 is available at the end of this set of minutes.

1.2. Adoption of agenda

The CAT agenda for 18-19 February 2016 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes of 21-22 January 2016 meeting were adopted.

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. 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-severe combined immunodeficiency (ADA-SCID) and for whom no suitable HLA-identical sibling bone marrow donor is available

Scope: Day 180 list of outstanding issues

Action: for adoption

Documents:
LoOIs
BWP report

Notes:
September 2015: D120 LoQs adopted
April 2015: CAT granted an accelerated assessment

The CAT Rapporteur and Co-Rapporteur presented the assessment of the responses to the list of questions for this product. CAT adopted the BWP report and the list of outstanding quality questions therein. The List of outstanding issues and the response timetable were adopted.

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

No items

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. Glybera - Alipogene tiparvovec; *Orphan*; EMEA/H/C/002145/SOB 002.4

UniQure Biopharma B.V.

Rapporteur: Christiane Niederlaender; CHMP Coordinators: Greg Markey

Scope: amendment to the protocol for the study to measure postprandial chylomicrons.

Action: for adoption

Documents:
Rapporteur's assessment report

CAT agreed with the conclusions of the assessment report. The amended protocol was accepted.

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

3.3. Ongoing initial application

3.4. New applications

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – appointment of CAT Co-ordinators

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

Intended for the treatment of type 1 diabetes mellitus

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

Action: for adoption

Document:
Request received 19th January 2016

Nominations were received. The CAT member was appointed as the CAT coordinator for this procedure.

4.1.2. 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

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

Action: for adoption

Document:
Request received 13th January 2016

Nominations were received. The CAT member was appointed as the CAT coordinator for this procedure.

4.1.3. Autologous stromal vascular fraction

Intended as an autologous lipofiller

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

Action: for adoption

Document:
Request received 4th February 2016

Nominations were received. The CAT member was appointed as the CAT coordinator for this procedure.

4.1.4. Autologous human bone marrow mononuclear cells

Intended for the treatment type 2 diabetes mellitus

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

Action: for adoption

Document:
Request received 11th February 2016

Nominations were received. The CAT member was appointed as the CAT coordinator for this procedure.

4.2. Day 30 Co-ordinators' first reports

4.2.1. Human burn eschar and debrided adipose tissue cells

Intended for the treatment of burns and non-healing wounds

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

Action: for adoption

Document:
ATMP classification report

CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification reports. CAT secretariat to send the draft scientific recommendation to the European Commission for comments
The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.2.2. 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:
-on acellular amniotic matrix
-on acellular dermal matrix

Action: for adoption

Document:
ATMP classification report

CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification reports. CAT secretariat to send the draft scientific recommendation to the European Commission for comments
The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.2.3. 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 adoption

Document:
ATMP classification report

CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments
The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.2.4. Irradiated, genetically modified, allogeneic pancreatic tumour cell lines

Intended for the treatment of pancreatic cancer

Action: for adoption

Document:
ATMP classification report

CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments
The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.2.5. 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 adoption

Document:
ATMP classification report

CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments
The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.2.6. Haematopoietic 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:
ATMP classification report

CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments
The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

Following CAT members agreed to be part of the ad-hoc group on gene editing: N. Ferry (chair), B. Sekkali, T. Maimets, T. Palomäki, M. Lipucci, P. ini, B. Niederlaender, E. Flory, M. Lipnik-Stangelj, R. Kjeken, A. Tsiftsoglou, M. Timón, R. Kjeken, M. Menezes-Ferreira, B. Gänsbacher. As a first task, this ad-hoc group will perform an analysis of how other products made by gene editing technologies could be classified using the current ATMP definitions.

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 March 2016

Intended for the treatment of cosmetic dermal filling

Scope: request from the applicant dated 10th February 2016 to a further one-month clock stop

Action: for information

A further clock stop of one month was granted.

4.3.2. 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:
Responses to the LoQs
Revised ATMP classification report

CAT discussed the ATMP revised classification report. CAT adopted by consensus the ATMP classification report for the indication: treatment of keloid scars. CAT secretariat to send the draft scientific recommendation to the European Commission for comments
The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.
CAT considered that the claim: treatment of aging skin is not a therapeutic indication; the company is advised to contact the relevant national authorities for the classification of their product for the treatment of aging skin.

4.4. Finalisation of procedures

4.4.1. 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 information

Document:
ATMP classification report

Note: the European Commission raised no comments

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

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

Action: for information

Document:
ATMP classification report

Note: the European Commission raised no comments

See also 5.4.1.

4.4.3. Human amniotic membrane mesenchymal stem cells

Intended for the treatment of burns and non-healing wounds

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

Action: for information

Document:
ATMP classification report

Note: the European Commission raised no comments

4.4.4. Human umbilical cord mesenchymal stem cells

Intended for the treatment of burns and non-healing wounds

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

Action: for information

Document:
ATMP classification report

Note: the European Commission raised no comments

4.4.5. 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 information

Document:
ATMP classification report

Note: the European Commission raised no comments

4.4.6. 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 information

Document:
ATMP classification report

Note: the European Commission raised no comments

4.4.7. 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 information

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)

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

Postponed until the March CAT meeting.

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

CAT resources: Paula Salmikangas, Martina Schüßler-Lenz, Marit Hystad

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.

Following CAT members were identified in January 2016 to contribute to the revision of this document: P. Salmikangas, M. Schüßler-Lenz and M. Hystad. CAT was informed of the members from CHMP that will also be involved in this revision: J. Müller-Berghaus, H. Hillege, I. Baotic and S. Sarac.
Feedback was provided from the discussions at the first teleconference with EMA, CAT and CHMP contributors.

7.1.3. Plenary meeting timing

CAT resources: Paula Salmikangas

Scope: request for 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 discussion

There was a general agreement by the CAT members with the proposal for new CAT plenary meeting times. The first meeting following this new timing will be the April CAT meeting.
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.

7.1.4. CAT template documents and procedures

CAT resources: Paula Salmikangas

Action: for discussion

The CAT chair highlighted some problems with the templates for ATMP reports, potentially translating in loss of time (late involvement of the CAT Rapporteur, e.g. in post-authorisation procedures) or confusion in the NCAs. EMA will looking into this and report back to CAT.

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 January 2016 meeting

Action: for information

Documents:
-Summary of Outcomes

The information was noted.

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

7.3.1. EMA/Cancer Drug Development Forum (CDDF) workshop on 4-5 February 2016 on cancer immunotherapy: 'Challenges for the approval of anti-cancer immunotherapeutic drugs'

CAT resources: Martina Schüßler-Lenz

Scope: Webinar on Challenges for the approval of anti-cancer immunotherapeutic drugs took place on 4-5 February 2016

Action: for information

A short feedback was provided from the workshop. It was noted that there is not a duplication of or interference with the content of the CAT workshop on cell-based cancer immunotherapies that will take place in the second half of this year.

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

EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – 17 September 2015

EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting - Session on communication and information on medicines – 08 March 2016

EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – 09 March 2016

Report on EMA's workshop on risk minimisation measures - Towards optimising risk minimisation measures – 16 Sept 2015

Action: For information

Document tabled:
Minutes of the PCWP/HCPWP joint meeting – 17 September 2015
Agenda of the PCWP/HCPWP joint meeting – Session on communication and information on medicines - 08 March 2016
Draft Agenda of the PCWP/HCPWP joint meeting – 09 March 2016
Report on EMA's workshop on risk minimisation measures – 16 September 2015

The information was noted.

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

EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting with all eligible organisations – 26 November 2015

Action: For information

Document tabled:
Minutes of the PCWP meeting - 26 November 2015

The information was noted.

7.4. Co-operation within the EU regulatory network

7.4.1. Good manufacturing practice (GMP) requirements for ATMPs

CAT drafting group members: Ivana Haunerova, Margarida Menezes-Ferreira, Guido Panté, Ilona Reischl, Paula Salmikangas, Belaid Sekkali, Marcos Timón, Christiane Niederlaender, Jurgen Scherer, M. Hoefnagel

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

Action: for information

A first virtual drafting group (DG) was held on 9 February 2016, in which the DG members from CAT and the GMDP inspectors groups discussed the sections on personnel and documentation. A next drafting group will take place on 23 February: the sections on premises and equipment will be discussed. Dariusz Śladowski will join the discussions.

It was agreed to put this topic on the agenda of the CAT when some information need to be conveyed from the DG discussions (not as a routine agenda item).

7.4.2. Orphan similarity for ATMPs

CAT drafting group: Martina 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'

Action: for discussion

Note: virtual meeting took place on 9th February 2016 and a drafting group meeting on 19 February in the morning.

Feedback was provided from the drafting group meetings. For (cell-based) ATMPs, it is felt that it will not be possible to work on basis of the Principal Molecular Structural Features (PMSF): for these complex products, the PMSF cannot be defined. For the determination of orphan similarity of two ATMPs, the proposal is to take into consideration the structural and functional characteristics that (could) have an impact on the biological activity of the product. An Adobe Connect Drafting group meeting will be organised in the week of 22 February to continue the discussion, especially for gene therapy products.

7.4.3. National requirements for post-licensure for medicinal products containing micro-organisms (GMO)

CAT resources: Ilona Reischl

Scope: National question on GMO issues for licensed medicinal products

Action: for discussion

http://www.epa.ie/pubs/legislation/geneticallymodifiedorganismsgmo/directive200941ec.html

Note: DIR/2009/41/EC article 3, 3) states that:

"This Directive shall not apply to the storage, culture, transport, destruction, disposal or use of GMMs which have been placed on the market in accordance with Directive 2001/18/EC or pursuant to other Community legislation which provides for a specific environmental risk

assessment similar to that laid down in that Directive, provided that the contained use is in accordance with the conditions, if any, of the consent for placing on the market."

It was confirmed that for authorised medicines, there could not be additional (national) requirements related to genetically modified organisms deliberate release (derogation from GMO directive). During the MA evaluation, the environmental risk assessment has also been taken care off. So consequently, there should be no reference in SmPC of authorised medicines to National requirements for biological safety with regards to GMOs.
The situation is different for clinical trials with GMOs (there is no similar derogation from the GMO directive, so national approval for deliberate release in the environment is necessary).

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 18th February from 14.00hrs – 15.00hrs

CAT resources: Paula Salmikangas

Action: for adoption

Document table:
Agenda

The ATMP cluster teleconference was postponed to Tuesday 22 March.

7.6. CAT Work Plan

No items

7.7. Planning and reporting

No items

7.8. Others

7.8.1. Seminar on 12th February 2016 in Budapest on adoptive T-cell immunotherapy

CAT resource: Mikuláš Hrubiško

Scope: oral feedback

Action: for information

A short feedback from this seminar was provided.

8. Any other business

Date of next CAT meeting:
Tuesday 22nd – Wednesday 23rd March 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: Genetically Modified Organisms

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

TT: Timetable

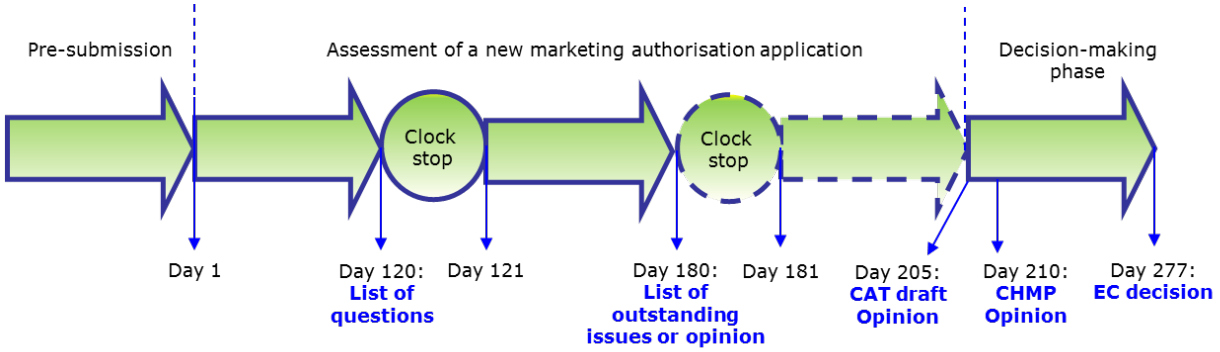
Evaluation of ATMPs (section 2)

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/

List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 18-19 February 2016 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Paula Salmikangas	Chair	Finland	No interests declared	
Ilona Reischl	Member – via TC	Austria	No interests declared	
Martin Brunner	Alternate	Austria	No restrictions applicable to this meeting	
Claire Beuneu	Member	Belgium	No interests declared	
Belaïd Sekkali	Alternate	Belgium	No interests declared	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Mirna Golemovic	Member	Croatia	No interests declared	
Ivana Haunerova	Alternate, replacing CAT member	Czech Republic	No interests declared	
Nanna Aaby Kruse	Member	Denmark	No restrictions applicable to this meeting	
vacant	Alternate	Denmark		
Toivo Maimets	Member	Estonia	No interests declared	
Tiina Palomäki	Member	Finland	No interests declared	
Nicolas Ferry	Member	France	No interests declared	
Violaine Closson	Alternate	France	No interests declared	
Martina Schüssler-Lenz	Member (Vice-Chair)	Germany	No interests declared	
Egbert Flory	Alternate	Germany	No interests declared	
Asterios Tsiftsoglou	Member	Greece	No interests declared	
Angeliki Roboti	Alternate	Greece	No interests declared	
Maura O'Donovan	Member	Ireland	No interests declared	
Anthony	Alternate (to	Malta	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Samuel	CHMP representative)			
Johannes Hendrikus Ovelgönne	Member	Netherlands	No interests declared	
Marit Hystad	Member	Norway	No interests declared	
Rune Kjeken	Alternate	Norway	No restrictions applicable to this meeting	
Dariusz Śladowski	Member	Poland	No restrictions applicable to this meeting	
Margarida Menezes-Ferreira	Alternate (to CHMP representative)	Portugal	No interests declared	
Simona Badoi	Member	Romania	No interests declared	
Mikuláš Hrubiško	Member	Slovakia	No restrictions applicable to this meeting	
Metoda Lipnik-Stangelj	Member	Slovenia	No interests declared	
Sol Ruiz	Member (CHMP co-opted member), via TC	Spain	No interests declared	
Marcos Timón	Alternate (to CHMP representative)	Spain	No interests declared	
Lennart Åkerblom	Member	Sweden	No interests declared	
Björn Carlsson	Alternate	Sweden	No interests declared	
Christiane Niederlaender	Member	United Kingdom	No interests declared	
James McBlane	Alternate, attended the 18th in person, 19th via TC	United Kingdom	No interests declared	
Bernd Gänsbacher	Member	Healthcare Professionals' Representative	No interests declared	
Michelino	Member	Patients'	No restrictions	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Lipucci di Paola		Representative	applicable to this meeting	
Kieran Breen	Member	Patients' Representative	No restrictions applicable to this meeting	
Guido Panté	Expert - in person*	Italy	No interests declared	
Sotirelis Chris	Expert - in person*	Italy	No interests declared	
Riaz Zuhrie	Expert - via telephone*	United Kingdom	No interests declared	
Marcel Kwa	Expert - via telephone*	Netherlands	No interests declared	
Heli Suila	Expert - via telephone*	Finland	No interests declared	
Fernando Méndez	Expert - via telephone*	Spain	No interests declared	
Nuria Prieto	Expert - via telephone*	Spain	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the agenda topics or activities they participated in.