7 October 2016
EMA/CAT/692224/2016
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 08-09 September 2016

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

08 September 2016, 09:00 – 14:00, virtual
09 September 2016, 09:00 – 13:00, virtual

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 CAT chair introduced the new CAT member (M Turner) and CAT alternate (E Briers) that were appointed by the European Commission on 5 July 2016 to represent the clinicians and patient organisations respectively.

1.2. Adoption of agenda

CAT agenda for the 8 - 9 September 2016 meeting was adopted.

1.3. Adoption of the minutes

CAT minutes of the 13 - 15 July 2016 meeting were adopted.

1.4. August Written Procedure

The report of the 2016 August written procedure was noted.

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 List of outstanding issues

No items

2.4. Day 120 Lists of questions

No items

2.5. Day 80 assessment reports

No items

2.6. Ongoing initial full application

Expanded human allogeneic mesenchymal adult stem cells extracted from adipose tissue; *Orphan*; EMA/H/C/0004258TiGenix S.A.U.; Treatment of complex perianal fistula(s)Scope: Request for extension of clock stop to respond to the list of questions.

Action: for adoption

Document: letter from the applicant dated 7 September 2016

CAT agreed with an extension of the clock stop. The new response timetable was adopted

2.7. New applications

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

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/56

UniQure Biopharma B.V.;
Rapporteur: Christiane Niederlaender; CHMP Coordinators: Greg Markey

Scope: quality

Action: for adoption of RSI

Document:
-RSI

CAT adopted the request of additional information.

2.12. Post-authorisation activities

No items

3. Certification of ATMPs

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

3.1. Opinions

No items

3.2. Day 60 evaluation reports

No items

3.3. Ongoing initial application

No items

3.4. New applications

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – appointment of CAT Co-ordinators

4.1.1. Autologous bone marrow-derived non-haematopoietic stem cells

Intended for the treatment of multiple sclerosis

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

Action: for nomination of CAT Coordinator

Document:
Request received

Note: CAT classified this product in October 2015 as somatic cell therapy product for the indications: treatment of patient with diabetes type I, diabetes type II and rheumatoid arthritis; and as *tissue engineered product* for the indications: treatment of patient after ischemic stroke and after myocardial infarction.

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

4.1.2. Anti-BCMA (B-cell Maturation Antigen) CAR T cells

Intended for the treatment of multiple myeloma and B cell lymphoma

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

Action: for nomination of CAT Coordinator

Document:
Request received

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

4.1.3. Wharton Jelly derived mesenchymal stem cells

Intended for the treatment of acute myocardial infarction, chronic ischemic heart failure and no-option critical limb ischemia

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

Action: for nomination of CAT Coordinator

Document:
Request received

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

4.1.4. Modified vaccinia virus Ankara encoding human mucin 1 and interleukin 2; H004658

Intended for the treatment of advanced non-squamous non-small cell lung cancer

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

Action: for nomination of CAT Coordinator

Document:
Request received

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

4.1.5. Autologous Human Adipose Mesenchymal Stromal Cells

Intended for the cardiac repair after myocardial infarction

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

Action: for nomination of CAT Coordinator

Document:
Request received

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

4.1.6. Autologous skin cell suspension

Intended for the treatment of burns, donor sites and other wounds

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

Action: for nomination of CAT Coordinator

Document:
Request received

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

4.1.7. Rilimogene galvacirepved and rilimogene glafolivec; H004657

Intended for the treatment of metastatic, castrate-resistant Prostate cancer

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

Action: for nomination of CAT Coordinator

Document:
Request received

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

4.2. Day 30 Co-ordinators' first reports

4.2.1. Genetically-modified *Lactobacillus reuteri* bacteria, with a plasmid containing the gene for human CXCL12-1a with an inducible promoter

Intended for wound healing of chronic ulcers in patients with diabetes

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.

4.2.2. Autologous cells of SVF and autologous adipose derived stem cells

Intended for the treatment of treatment of cutis laxa senilis

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.

4.2.3. Tumour selectively replicating oncolytic adenovirus expressing tumor necrosis factor alpha (TNFα) and interleukin 2 (IL2)

Intended for the treatment of metastatic melanoma and other solid tumors

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. Natural-killer [NK] group 2, member D autologous engineered T-cells

Intended for the treatment of various tumour types (solid and liquid)

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. DNA plasmid vectors encoding for Human Papilloma Virus (HPV) type 16 consensus E6 and E7 antigens and HPV type 18 consensus E6 and E7 antigens

Intended for the treatment of HPV-16 and 18 related high-grade squamous intraepithelial lesions (HSIL) of the cervix and vulva

Action: for adoption

Document:
ATMP classification report

CAT discussed the ATMP classification report. This product is developed to treat HSIL caused by HPV 16 or 18: CAT considered that the mechanism of action is broader than the elimination of an existing HPV infection alone. Therefore, the CAT concluded that this product should not be considered to be a vaccine against an infectious disease. This is in line with the guidance included in the CAT Reflection Paper on ATMP classification (EMA/CAT/600280/2010 rev. 1) and previous classifications of similar products.
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.

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

No items

4.4. Finalisation of procedures

4.4.1. REarranged during transfection (RET) activated human cord blood progenitor cells expanded *ex-vivo*; EMA/H0004545

Intended for the treatment of patients undergoing hematopoietic stem cell transplantation

Action: for information

Document:
ATMP classification report
The European Commission raised no comments

The information was noted.

4.4.2. Adeno-associated viral vector serotype 8 containing the human glucose-6-phosphatase gene; EMA/H0004544

Intended for the treatment of glycogen storage disease type Ia (GSDIa)

Action: for information

Document:
ATMP classification report

The European Commission raised no comments

The information was noted.

4.4.3. Recombinant adeno-associated virus 2 human aromatic L-amino acid decarboxylase gene; H0004546

Intended for the treatment of Parkinson's disease (PD)

Action: for Information

Document:
ATMP classification report

The European Commission raised no comments

The information was noted.

4.4.4. Heterologous human adult liver-derived progenitor cells (HHALPC)

Intended for the treatment of liver diseases

Action: for information

Document:
ATMP classification report

The European Commission raised no comments.

The information was noted.

4.5. Follow-ups and guidance

4.5.1. Autologous concentrated bone marrow

Intended for critical limb ischemia without surgical option

Scope: Feedback from the applicant on the CAT classification of July 2016

Action: for information

Document:
Feedback from the applicant

Note: the CAT adopted in July 2016 a classification as a tissue-engineered product.

The information was noted.

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. List of issues

5.4. Finalisation of Scientific Advice procedures

5.5. Follow-up of Scientific Advice procedures

No items

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

No items

6.2. ITF briefing meetings in the field of ATMPs

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

6.3.2. Month 1 – Discussion of eligibility

6.3.3. Month 2 – Recommendation for eligibility

6.3.4. Ongoing support

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. Strategic Review & Learning meeting

CAT Strategic Review & Learning meeting will take place in Dublin, Ireland on 24-25 October 2016

CAT resources: Maura O'Donovan

Scope: agreement on topics for the agenda

Action: for discussion

Document:
Draft agenda

Note: proposed topics so far: new medical device legislation, GMO issue including the wording for product information, use of real world data and registries.

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

CAT members were reminded to register for the meeting.

7.1.2. Recommendation on criteria for competence and expertise of CAT members and alternates

Action: for discussion

Documents:
-Briefing note on competence and expertise of CAT members and alternates
-Annex B: CAT-EMA recommendation on criteria for competence and expertise of new CAT members. This annex will be added to nomination invitation letters to the Members State when a new member or alternate is to be appointed
-CAT Areas of Expertise
-CAT Criteria for Expertise and Experience

This agenda item was postponed until the October CAT meeting.

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 July 2016 meeting

Action: for information

Documents:
-Summary of Outcomes

The information was noted.

7.2.2. Review of experience with the Early Background Summary

Postponed to October 2016

Action: for information

7.3. Co-ordination with EMA Working Parties/Working Groups/Drafting Groups

7.3.1. ATMP guideline on S&E follow-up and risk management

CAT resources: Maura O'Donovan, Tomáš Boráň

Scope: update on the revision

Action: for information

CAT noted the progress in the revision of this guideline.

7.3.2. Revision of the mandate of the Scientific Advice Working Party (SAWP)

Scope: the revision covers the interaction with the EMA's scientific committees, PRIME activities and rules of procedure for the appointment of SAWP members.

Action: for information

Document:
-Mandate, objectives and rules of procedure of the scientific advice working party (SAWP) (Doc ref: EMEA/CHMP/SAWP/69686/04 Rev 10) – revision

Note: the CHMP adopted the revised mandate at its July 2016 plenary.

The revised mandate was noted.

7.3.3. Guideline on quality, non-clinical and clinical aspects of gene therapy medicinal products

Scope: call for interest to involve additional members in the drafting group

Action: for discussion

Document:
-Overview of comments received during the external consultation

Note: The external consultation ended in July 2015

CAT was informed that 28 comments were received during the external consultation. CAT appointed following drafting group members to review the comments and finalise the revision

of this guideline:

Drafting group composition:
-Quality: M. Menezes-Ferreira, C. Niederlaender, S. Ruiz and P. Salmikangas
-Non-clinical: K. Breen, B. Sarkadi, M. Renner (tbc)
-Clinical: P. Gasparini, B. Klug, M. Hystad, O. Tenhunen (all tbc)

CAT agreed with the composition of the drafting groups. The 3 groups will review the comments received via Adobe Connect drafting group meetings.

7.3.4. Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement of animal testing) in regulatory testing of medicinal products

CAT resources: Tiina Palomäki

Scope: to address comments on the CAT table (pages 30 to 42).

Action: for discussion

Document:
-Reflection paper providing an overview of the current regulatory testing requirements for medicinal products for human use and opportunities for implementation of the 3Rs

Comments to be sent to by 16 September 2016

Note:
-18-19 October 2016: for adoption at the next JEG 3Rs meeting
-July 2016: CAT agreed to the document
-July 2016: CHMP and CVMP adopted the document by for a three-month consultation.
-May 2015: Tiina Palomäki presented to CAT the Annex table for cell and gene therapies.

CAT discussed the comments to the ATMP related entries in the tables in the reflection paper and agreed on the amendments proposed. The reflection paper, as amended, was adopted by CAT.

7.3.5. Working Party with Healthcare Professionals' Organisations (HCPWP)

Action: For information

Document tabled:
Minutes of the HCPWP meeting that took place on 15 June 2016

Noted.

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

Action: For information

Document tabled:
Minutes of the PCWP meeting that took place on 14 June 2016

Noted.

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

Action: For information

Documents tabled:
-Draft Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – 20 September 2016 (EMA/428004/2016

-Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – Workshop on social media – 19 September 2016 (EMA/825257/2015)
-Report of a joint EMA workshop with patient and healthcare professional representatives about communication on medicines - 8 March 2016 (EMA/194543/2016)
-Minutes of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting - 9 March 2016 (EMA/183905/2016)

Noted.

7.4. Co-operation within the EU regulatory network

7.4.1. EU Good Pharmacovigilance Practices (EU-GVP) – adoption of revised GVP modules in 2016-2017

Action: For information

Note: the EU Good Pharmacovigilance Practices (EU-GVP) has been updated on the EMA's GVP webpage (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp&mid=WC0b01ac058058f32c#section4)

Noted.

7.4.2. Analysis of European Clinical Trials Database (EudraCT)

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

Scope: manuscript for publication

Action: for information

Note: a virtual meeting will be organised before the October CAT meeting with all the authors for a possible discussion and finalisation at the October CAT 2016 meeting. A possible journal has been identified (Human Gene Therapy).

CAT noted to progress of the work.

7.5. Co-operation with international regulators

No items

7.6. CAT Work Plan

7.6.1. Guideline on requirements for investigational ATMPs

CAT drafting groups: Tiina Palomäki (Rapporteur), Ilona Reischl (Rapporteur), Metoda Lipnik-Stangelj, Margarida Menezes Ferreira, Maura O'Donovan, Simona Badoi, Tomáš Boráň, Christiane Niederlaender, Paolo Gasparini, Olli Tenhunen, Marit Hystad, Carla Herberts

Scope: initial draft of the guideline

Action: for discussion

Note: an outline of the structure of the guideline was provided in June 2016.

A drafting group meeting will be organised in advance of the October 2016 CAT meeting to progress the preparation of the draft guideline.

7.6.2. Questions and Answers on minimally manipulated ATMPs

CAT drafting group: Metoda Lipnik-Stangelj, Paula Salmikangas, Tiina Palomäki, Egbert Flory, Margarida Menezes Ferreira, Marit Hystad, Mikuláš Hrubiško

Scope: initial draft of the Q&A document

Action: for discussion

Note:
The Questions-and-Answers will describe the quality, non-clinical and clinical requirements for the marketing authorisation for a minimally manipulated ATMP (CD34+ cells for cardiac repair). In the answers, a practical explanation will be provided how to use the risk based approach to identify and justify deviations for the standard requirements for cell-based ATMPs as included in Annex I Part IV of Dir. 2001/83/EC.

A drafting group meeting will be organised in advance of the October 2016 CAT meeting to progress the preparation of the question and answer document.

7.6.3. CAT Workshop on cell-based cancer immunotherapies, EMA premises, 15-16 November 2016

CAT resources: Rune Kjeken, Björn Carlsson

Scope: attendance CAT member

Action: for information

Link to documents and registration

Note:
-CAT members interested to attend should complete the Registration Form
-CAT members are encourage to promote/disseminate this workshop in their NCAs

CAT members noted the information

7.7. Planning and reporting

7.7.1. ATMP Expert meeting, 27 May 2016

Action: for information

Documents:
-Regulators report and action plan

Link to the published stakeholders report: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/06/WC500208080.pdf

This topic is postponed.

7.7.2. Management Board data gathering exercise - CAT horizontal data collection

Scope: Update on progress. The project started in March 2014. The goal was to assemble evidence about the time spent on procedures at EMA and NCAs.

Action: For information

Topic postponed until the October 2016 CAT meeting

7.7.3. Planning estimates of Q3/2016 Advanced Therapies Medicinal Products (ATMP) MAAs

Action: for information

Topic postponed until the October 2016 CAT meeting

7.8. Others

7.8.1. Organisational adjustments to the EMA's Human Divisions to come into force on 1 September 2016

Action: for information

CAT noted the organisational changes to the EMA secretariat.

7.8.2. Cancer Drug Development Forum (CDDF)'s workshop on the 'Use of Real World Data to Optimise Oncology Drug Development and Access', London, 6-7 July 2016

CAT resources: Marit Hystad

Scope: session 5: 'Can Real World Data accelerate patient access to medicines'

Action: for information

Document:
Programme

Topic postponed until the October CAT meeting

8. Any other business

No items

Date of next CAT meeting:
Thursday 6 to Friday 7 October 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

CTFG: Clinical Trial Facilitation Group

DG: Drafting Group

EC: European Commission

FDA: Food and Drug Administration

FL: Final Letter

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Environmental Risk Assessment

GMP: Good Manufacturing Practice

HTA: Health Technology Assessment Bodies

HSCT: Hematopoietic stem cell transplant

HSPC: Hematopoietic Stem and Progenitor Cells

ITF: Innovative Task Force

JR: Joint Report

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Application

MAH: Marketing Authorisation Holder

MSC: Mesenchymal stem cells

PDCO: Paediatric Committee

PMDA: Pharmaceuticals and Medical Devices Agency (Japan)

PIP: Paediatric Investigation Plan

PL: Package leaflet

PRAC: Pharmacovigilance and Risk Assessment Committee #

PRIME: Priority Medicines

RMP: Risk Management Plan

RP: Reflection paper

RSI: Request for supplementary information

SA: Scientific Advice

SAG-O: Scientific Advisory Group Oncology

SAWP: Scientific Advice Working Party

SR: Summary Report

SWP: Safety Working Party

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

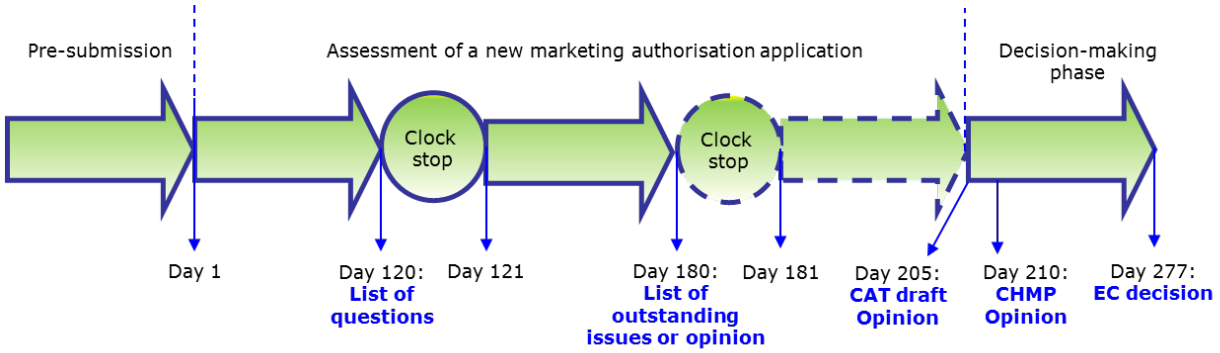
Evaluation of ATMPs (section 2)

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

New applications (sections 2.1. to 2.12.)

Section 2.1 is for ATMPs nearing the end of the evaluation and for which the CAT is expected to adopt a draft **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CAT opinion is transmitted to the CHMP for final adoption. The CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU. More information on the evaluation of ATMPs can be found here.

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CAT. The clock stop happens after day 120 and may also happen after day 180, when the CAT has adopted respectively a **Day 120 list of questions** (section 2.3) or a List of outstanding issues to be addressed by the company, which is listed in the agenda under sections 2.7 (**Ongoing evaluation procedures**). Section 2.7 also includes the CAT discussions at any other timepoint of the evaluation procedure of new applications.

Oral explanation (section 2.2.)

Prior to adoption of the CAT opinion, marketing authorisation applicants are normally invited to the CAT plenary meeting to address questions raised by the Committee.

Oral explanations normally relate to ongoing applications, but they can also relate to any other issue for which the CAT would like to discuss with company representatives in person.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 (section 2.6.)

This section lists applications for new marketing authorisation for ATMPs for which the applicant has requested a re-examination of the opinion previously issued by the CHMP. Similar to the initial evaluation of a marketing authorisation of an ATMP, CAT will adopt a draft re-examination opinion, which is transmitted to the CHMP for final adoption.

Withdrawal of applications (section 2.7.)

This section includes information on marketing authorisation applications that are withdrawn by the applicant. Applicants may decide to withdraw applications at any stage during the assessment and a CAT opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

New applications (section 2.9.)

In this section, information is included on upcoming marketing authorisation applications for ATMPs, as well as information on appointment of Rapporteurs for new ATMP applications.

GMP and GCP Inspections Issues (section 2.10.)

This section lists inspections that are undertaken for ATMPs. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Post-authorisation activities (section 2.12.)

This section lists type II variations, extension application according to Annex I of Reg. 1234/2008, re-examination procedures for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP and other issues concerning authorised medicines that are not covered elsewhere in the agenda such as annual reassessments, 5-year renewals, supply shortages, qualify defects. Issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines, will also be included here.

Certification of ATMPs (section 3)

This section includes the scientific evaluation by the CAT of quality and non-clinical data that small and medium-sized enterprises have generated at any stage of the ATMP development process. More information on the ATMP certification procedure can be found here.

Scientific Recommendation on Classification of ATMPs (Section 4)

This section includes the scientific recommendation by the CAT on whether medicines based on genes, cells or tissues meet the scientific criteria that define ATMPs. More information on the ATMP classification procedure, including the outcomes of finalised classifications, can be found here.

Scientific Advice (section 5)

This section includes all scientific advice given to companies during the development of an ATMP. Information related to the number of ATMP related scientific advices discussed by CAT can be found in the CAT Monthly reports. Further information on SAWP can be found here.

Pre-Authorisation (section 6)

Paediatric Investigation Plan (PIP)

This section includes the discussion of an ATMP before a formal application for marketing authorisation is submitted. These cases refer for example to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation: in case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

CAT contributes to the evaluation of a Paediatric Investigation Plan (PIPs) for ATMPs by the Paediatric Committee. These PIPs are included in this section of the Agenda.

ITF Briefing meeting in the field of ATMPs

This section refers to briefing meetings of the Innovation Task Force and International co-operations activities of the CAT

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes of meetings with applicants developing ATMPs and of other ITF meetings of interest to the CAT are included in this section of the agenda. Further information on the ITF can be found here.

Priority Medicines (PRIME)

This section includes the new requests for eligibility to PRIME for ATMPs under development, the discussions in CAT of these eligibility requests and the final recommendations for eligibility of ATMPs adopted by CHMP.

CAT will appoint one of its members as the CAT sponsor for each new ATMP eligibility request who will lead the CAT discussion based on the recommendation from the SAWP.

Organisational, regulatory and methodological matters (section 7)

This section includes topics related to regulatory and procedural guidance, CAT workplan, CAT meeting organisation (including CAT membership), planning and reporting, co-ordination with other committees, working parties and scientific advisory groups.

Furthermore, this section refers to the activities of the CAT drafting groups developing scientific guidelines for gene therapy medicinal products and for cell-based medicinal products, cooperation within the EU regulatory network and international regulators as well as direct interaction with interested parties. It also includes topics of scientific interest for the Committee that are not directly related to the work of the CAT drafting groups or CAT associated working parties.

Any other business (section 8)

This section is populated with miscellaneous topics not suitable under the previous headings.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/

10. List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 08-09 September 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	Austria	No interests declared	
Claire Beuneu	Member	Belgium	No interests declared	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Evelina Shumkova	Alternate	Bulgaria	No interests declared	
Mirna Golemovic	Member	Croatia	No interests declared	
Ivica Malnar	Alternate	Croatia	No interests declared	
Tomáš Boráň	Member	Czech Republic	No interests declared	
Ivana Haunerova	Alternate	Czech Republic	No interests declared	
Toivo Maimets	Member	Estonia	No interests declared	
Tarmo Tiido	Alternate	Estonia	No interests declared	
Tiina Palomäki	Member	Finland	No interests declared	
Violaine Closson	Member	France	No interests declared	
Martina Schüssler-Lenz	Member (Vice-Chair)	Germany	No interests declared	
Egbert Flory	Alternate	Germany	No interests declared	
Angeliki Roboti	Alternate	Greece	No interests declared	
Krisztian Fodor	Member	Hungary	No interests declared	
Maura O'Donovan	Member	Ireland	No interests declared	
Paolo Gasparini	Member	Italy	No interests declared	
Luca Sangiorgi	Alternate	Italy	No interests declared	
Una Riekstina	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member (CHMP member)	Lithuania	No restrictions applicable to this meeting	
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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Simona Badoi	Member	Romania	No interests declared	
Mikuláš Hrubiško	Member	Slovakia	No restrictions applicable to this meeting	
Ján Kyselovič	Alternate	Slovakia	No interests declared	
Metoda Lipnik-Stangelj	Member	Slovenia	No interests declared	
Sol Ruiz	Member (CHMP co-opted member)	Spain	No interests declared	
Marcos Timón	Alternate (to CHMP representative)	Spain	No interests declared	
Lennart Åkerblom	Member	Sweden	No interests declared	
Christiane Niederlaender	Member	United Kingdom	No interests declared	
James McBlane	Alternate	United Kingdom	No interests declared	
Marc Turner	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Kieran Breen	Member	Patients' Representative	No restrictions applicable to this meeting	
Michelino Lipucci di Paola	Alternate	Patients' Representative	No restrictions applicable to this meeting	
Mariëtte Driessens	Member	Patients' Representative	No restrictions applicable to this meeting	
Erik Briers	Alternate	Patients' Representative	No restrictions applicable to this meeting	
Wiebke Hoppensack	Expert – by telephone*	Germany	No restrictions applicable to this meeting	
Louise Bisset	Expert – by telephone*	United Kingdom	No interests declared	
Meeting run with support from relevant EMA staff				

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