8 September 2016
EMA/CAT/493509/2016
Procedure Management and Committees Support Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 13-15 July 2016

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

13 July 2016, 14:00 – 18:30, room 03-E
14 July 2016, 09:00 – 18:30, room 03-E
15 July 2016, 09:00 – 12:00, 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 CAT chair introduced the new and re-appointed CAT members and alternates that were appointed by the European Commission on 5 July 2016 to represent the doctors and patient organisations.

1.2. Adoption of agenda

The CAT agenda for the 13 - 15 July 2016 meeting was adopted. Agenda point 7.7.1 was postponed to a later meeting.

1.3. Adoption of the minutes

The CAT minutes of the 16 - 17 June 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

No items

2.4. Day 120 Lists of questions

2.4.1. Expanded human allogeneic mesenchymal adult stem cells extracted from adipose tissue; *Orphan*; EMA/H/C/0004258

TiGenix S.A.U.; Treatment of complex perianal fistula(s)Scope: Day 120 list of questions (LoQ)

Action: for adoption

The Rapporteurs presented the initial assessment of the MAA. Feedback was provided from outcome of the BWP discussion of the quality part of the application. CAT adopted the revised list of questions.

2.5. Day 80 assessment reports

No items

2.6. Ongoing initial full application

No items

2.7. New applications

2.8. Withdrawal of initial marketing authorisation application

No items

2.9. Re-examination of initial application procedures under Article 9(2) of Regulation no. 726/2004

No items

2.10. GMP and GCP inspections requests

No items

2.11. Type II variations

No items

2.12. Other post-authorisation activities

2.12.1. ChondroCelect - Characterised viable autologous cartilage cells expanded *ex vivo* expressing specific marker proteins; EMEA/H/C/000878

MAH: TiGenix NV; Treatment of repair of single symptomatic cartilaginous defects

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

Action: for discussion

Document tabled:
MAH's Letter of withdrawal dated 05.07.16.

CAT noted the withdrawal letter and the statement from Tigenix that the withdrawal is for commercial reasons. No more information is available.

3. Certification of ATMPs

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

3.1. Opinions

No items

3.2. Day 60 evaluation reports

No items

3.3. Ongoing initial application

No items

3.4. New applications

No items

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – appointment of CAT Co-ordinators

Next deadline for submission of new requests for ATMP classification: 28.07.16. Additional new requests will appear in the CAT Written Procedure of August 2016 (for appointment of CAT co-ordinators)

4.1.1. 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

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. RET activated human cord blood progenitor cells expanded *ex-vivo*; EMA/H0004545

Intended for the treatment of patients undergoing hematopoietic stem cell transplantion

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

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

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.

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

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

Intended for the treatment of fibro-inflammatory liver diseases

Action: for adoption

Document:
Revised ATMP classification report
Applicant's responses to LoQ

CAT discussed the ATMP revised classification report. Based on the feedback to questions, CAT considered that the indication should be restricted to fibro-inflammatory liver disease.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.

It was proposed to include in the cover letter to the applicant a recommendation to resubmit a request for classification for HepaStem for the indication 'treatment of inborn errors of liver metabolism' (classification as somatic cell therapy medicinal product in 2011).

4.4. Finalisation of procedures

4.4.1. Live attenuated *Listeria monocytogenes* transfected with plasmids encoding HPV-16E7 protein fused to a truncated fragment of the *Lm* protein listeriolysin O

Intended for the treatment of cervical cancer

Action: for information

Document:
ATMP classification report

The European Commission raised no comments

4.4.2. Autologous expanded human fibroblasts

Intended for the treatment of scar of different aetiology as post- traumatic, post-surgical or outcomes of acne scars

Action: for adoption

Document:
Revised ATMP classification report

Comments received from the European Commission

The revised ATMP classification report was adopted.

4.4.3. Autologous concentrated bone marrow

Intended for critical limb ischemia without surgical option

Action: for information

Document:
ATMP classification report

The European Commission raised no comments

4.4.4. Hepatitis B virus DNA vaccine delivered via electroporation

Intended for the treatment of chronic hepatitis B virus infection

Action: for adoption

Document:
Revised ATMP classification report

Comments received from the European Commission

The revised ATMP classification report was adopted.

4.4.5. Collagenase from *Clostridium histolyticum*; H0004547

Intended to be used for *ex-vivo* dissociation of adipose tissue

Action: for information

Document:
ATMP classification report

The European Commission raised no comments

4.5. Follow-ups and guidance

4.5.1. Informal classification discussion on request of a National Competent Authority

Procedure to treat cartilage defects. Background: distributor intends to market the equipment for the 'single-step' procedure to treat cartilage defects. Harvest of cartilage cells from the hip by biopsy and mesenchymal stem cells from a bone marrow aspirate are prepared in the surgery suite. After 1hr they are added on a matrix and re-implanted. **Action:** for discussion

Document**:** presentation

Following the presentation, CAT discussed the available information and would consider that the product produced using this manufacturing equipment is an ATMP. As a consequence the medicines legislation will have to be applied and before use of this product in patients, a clinical trial, hospital exemption or marketing authorisation have to be approved. The exclusion from the Tissue and Cell legislation using the 'single surgical procedure' clause does not excludes this type of products from the ATMP legislation. It was mentioned that the GMP for ATMP guidance (see agenda point 7.1.3) does address the requirement for ATMP production using a (closed system) manufacturing equipment.

4.5.2. ATMP classification – revised template for the background document for applicants

Scope: improved revised template

Action: for information

Document:
-revised template
-revised template (annotated)

The updated template for the background document for applicants of ATMP classification was presented. Any comments on the template can be sent to the CAT secretariat by 1 August 2016.

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

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

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. Appointment members and alternates of the Committee for Advanced Therapies to represent clinicians and patients' associations

Scope: Commission decision dated 5 July 2016 (ref. C/2016 4160) on the new appointment of civil societies to CAT for a mandate of three years, from 1 July 2016 to 30 June 2019

Patients' organisations representatives:
-Member: Mariëtte H.E. Driessens representing the Patients Network for Medical Research and Health (EGAN)
-Alternate Erik Briers representing EUROPA UOMO – The European Prostate Cancer Coalition

-Member: Kieran Breen representing the European Parkinson's Disease Association
-Alternate: Michele Lipucci de Paola representing EURORDIS

Clinicians' representatives:
-Member: Bernd Gänsbacher
-Member: Marc Turner

Action: for information

Note: the CAT Secretariat will organise an induction meeting for the new cohort of civil societies in the week of the next face-to-face CAT meeting (5-8 October 2016)

The information was noted. CAT welcomed back the members and alternates that were already representing the clinicians and patients' organisations previously. The new member and alternate will be invited for the next plenary CAT meeting and an introduction training will be organised for them.

7.1.2. 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: initial discussion to agree 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.

The updated draft agenda was presented. CAT proposed to remove the GMP topic (not possible to discuss at that timepoint as the comments received during the external consultation will not have been reviewed yet). Following topics was proposed: 1) Information on standard practices and regulations in the field of transfusion and transplantation; information on the European Group for Blood and Marrow Transplantation (EMBT) registry. 2) Guidelines in the field of gene therapy medicinal products.

7.1.3. 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, Marcel Hoefnagel

Action: for information

Documents:
-Letter dated 29 June 2016 from Robert Vanhoorde – DG for Health and Food Safety to CAT Chair and EMA (Compliance and Inspections Dept.) detailing next consultation steps following the drafting of the guideline
-European Commissions consultation document on good manufacturing practice for advanced therapy medicinal products

The draft GMP for ATMPs guideline is published for public consultation until 20 September and competent authorities are also asked to provide comments. The comments received will be discussed in drafting group meetings (composed of members/experts of the CAT and GMP Inspectors working group): this work will restart in October with the aim to have the document adopted before the end of 2016.

Feedback was also provided on the Good Laboratory Practice (GLP) for ATMPs: a CAT document was agreed in December 2015 and this pragmatic approach has now been discussed with the competent authorities for clinical trials. If no objections are raised by them, the CAT position will be published by them as a Question and Answer document.

7.1.4. Survey to committee members on the service provided by the Scientific Committees Service

Action: for information

The deadline for completion is 29 July 2016.

Note:
The purpose of the survey is to gather feedback on the service provided by the Committee Secretariats, as well as capturing information on the needs and expectations of those involved in Committee activities. The survey can, also, be completed by colleagues involved in supporting the work of members outside of the meeting and/or participation in person or by teleconference in committee and other associated meetings.

The Scientific Committees Service will share the outcome of the survey with the various committees and will also inform of any planned improvements or communication with respect to the support provided, further to analysis of the survey results.

CAT members were reminded to complete the survey by 29 July 2016.

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 June 2016 meeting

Action: for information

Documents:
-Summary of Outcomes

Noted

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

7.3.1. ATMP guideline on safety and efficacy follow-up and risk management

Scope: update on the revision

Action: for information

Topic postponed to the next CAT meeting.

CAT noted that in this guideline, some reflections will need to be included on registries (e.g. regulatory aspects when requiring registries in to collect post authorisation data, criteria for registries to ensure that good data can be extracted from them).

7.3.2. 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

Scope: report on actions taken

Action: for information

Documents:
-Review and update of EMA guidelines to implement best practice with regard to 3Rs - report on actions taken
-Background note on EMA guidelines to implement best practice with regard to 3Rs in regulatory testing of medicinal products

-Guideline on 'Potency testing of cell-based immunotherapy medicinal for the treatment of cancer': minor additions added in line with the 3R principles

Note:
-The document will be adopted by CHMP and CVMP in July 2016 for a three-month consultation.
-Agreement from CAT was sought on the part concerning guidelines for ATMPs. The final annex table contains information from all non-clinical guidelines. In May 2015 Tiina Palomäki presented to CAT the Annex table for cell and gene therapies.

The document entitled 'Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal

products – report on actions taken' was presented. CAT proposed one editorial amendment on page 4. With this change the document was agreed.
CAT noted the revised Guideline on 'Potency testing of cell-based immunotherapy medicinal for the treatment of cancer' (addition of a paragraph reflection the 3R principle).

7.4. Co-operation within the EU regulatory network

No items

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 teleconferences that took place on 14th June 2016

Action: for information

Feedback was given from the discussions at the last IPRF teleconference. On the topic on Biodistribution studies for GTMP, following CAT members agreed to look into the tabled document which will form the basis of a future consideration / reflection paper (deadline for comments: 15 August 2016).

7.6. CAT Work Plan

7.6.1. Guideline on requirements for investigational ATMPs

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

Feedback was provided on the progress of development of this guideline. A first draft will be presented to CAT in September or October with the aim to finalise the draft guideline for external consultation by the end of 2016.

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, 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.

Feedback was provided on the progress of development of this Q&A. A draft will be presented to CAT in September or October with the aim to finalise the document by the end of 2016.

7.6.3. CAT workplan 2016

Scope: mid-year reporting

Action: for discussion

Document:
Workplan

The finalised, ongoing and pending workplan topics were presented and discussed. On the first topic (Guideline for investigational ATMPs), CAT indicated that the survey of ATMP assessors will not be undertaken as CTFG will be directly involved. For the CAT contribution to innovation medicines initiative-medicines adaptive pathways to patients, EMA secretariat will investigate the status of this project. For the topic on extrapolation, Hans Ovelgönne agreed to contribute (development of CAT point of view regarding the applicability for ATMPs of the extrapolation criteria defined by PDCO). The expert meeting on libraries for haplo cell banks will be postponed until 2017.

7.6.4. CAT Workshop on cell-based cancer immunotherapies, 15-16 November 2016

CAT resource: Rune Kjeken, Björn Carlsson;

Scope: draft programme

Action: for discussion

The draft programme was presented. CAT members were encouraged to attend this workshop (for training purposes). The workshop will be announced on the EMA webpage in the beginning of August.

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

Topic postponed until the September or October 2016 CAT meeting.

7.8. Others

7.8.1. Gene therapy for Wiskott-Aldrich syndrome (WAS): long term efficacy and safety findings

CAT resource: Martina Schüßler-Lenz

Scope: finding of leukaemia cases in patients treated with retroviral vector containing the gene for WAS protein

Action: for information

Feedback provided on the long term outcome of this trial.

8. Any other business

No items

Date of next CAT meeting:
Thursday 8th to Friday 9th September 2016 (virtual with Adobe Connect)

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

CVMP: Committee for Medicinal Products for Veterinary Use

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

HSPC: Hematopoietic Stem and Progenitor Cells

ITF: Innovative Task Force

JR: Joint Report

LoI: List of Issues

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Applicant

MAH: Marketing Authorisation Holder

MSC: Mesenchymal stem cells

PDCO: Paediatric Committee

PMDA: Pharmaceuticals and Medical Devices Agency (Japan)

PIP: Paediatric Investigation Plan

PL: Package leaflet

PRAC: Pharmacovigilance and Risk Assessment Committee #

PRIME: Priority Medicines

RMP: Risk Management Plan

RP: Reflection paper

RSI: Request for supplementary information

SA: Scientific Advice

SAG-O: Scientific Advisory Group Oncology

SAWP: Scientific Advice Working Party

SR: Summary Report

SWP: Scientific Working Party

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

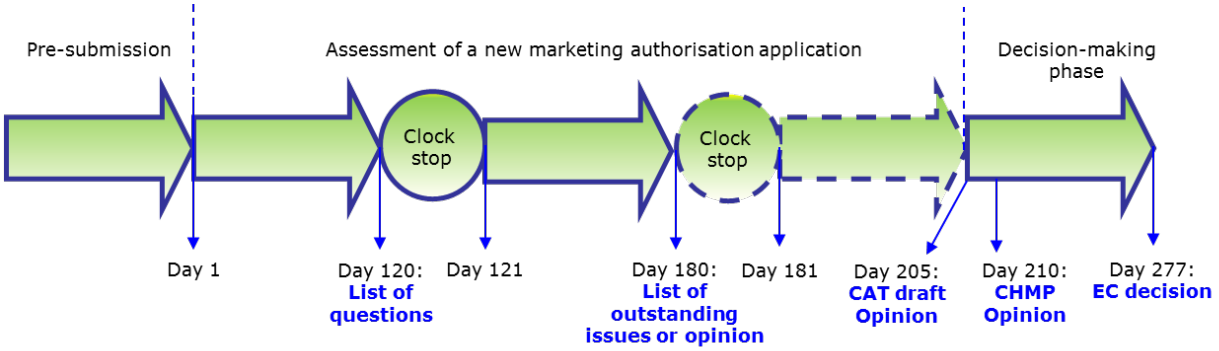
Evaluation of ATMPs (section 2)

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

New applications (sections 2.1. to 2.12.)

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

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



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

Oral explanation (section 2.2.)

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

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

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

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

Withdrawal of applications (section 2.7.)

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

New applications (section 2.9.)

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

GMP and GCP Inspections Issues (section 2.10.)

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

Post-authorisation activities (section 2.12.)

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

Certification of ATMPs (section 3)

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

Scientific Recommendation on Classification of ATMPs (Section 4)

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

Scientific Advice (section 5)

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

Pre-Authorisation (section 6)

Paediatric Investigation Plan (PIP)

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

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

ITF Briefing meeting in the field of ATMPs

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

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

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/

List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 13-15 July 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	
Ivica Malnar	Alternate	Croatia	No interests declared	
Tomáš Boráň	Member	Czech Republic	No interests declared	
Ivana Haunerova	Alternate	Czech Republic	No interests declared	
Nanna Aaby Kruse	Member	Denmark	No restrictions applicable to this meeting	
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	
Una Riekstina	Member	Latvia	No interests declared	
Guy Berchem	Alternate (to CHMP representative)	Luxembourg	No restrictions applicable to this meeting	
Johannes Hendrikus Ovelgönne	Member	Netherlands	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)	Spain	No interests declared	
Marcos Timón	Alternate (to CHMP	Spain	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
	representative)			
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	United Kingdom	No interests declared	
Bernd Gänsbacher	Member	Healthcare Professionals' Representative	No interests declared	
Kieran Breen	Member	Patients' Representative	No restrictions applicable to this meeting	
Michelino Lipucci di Paola	Alternate	Patients' Representative	No restrictions applicable to this meeting	
Guido Pantè	Expert	AIFA	No interests declared	
Christos Sotirelis	Expert	UK Thalassaemia Society	No interests declared	
Åsa Sullivan	Expert - via telephone*	Sweden	No interests declared	
Monique Wakelkamp	Expert - via telephone*	Sweden	No restrictions applicable to this meeting	
Wiebke Hoppensack	Expert - via telephone*	Germany		
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.