14 July 2017
EMA/CAT/581913/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for Advanced Therapies (CAT)

Minutes for the meeting on 15-16 June 2017

Chair: Martina Schüßler-Lenz; Vice-Chair: Ilona Reischl

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 these 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.

1.2. Adoption of agenda

The CAT agenda for 15-16 June 2017 meeting was adopted

1.3. Adoption of the minutes

The CAT minutes for 10-12 May 2017 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 list of questions

No items

2.5. Day 80 assessment reports

No items

2.6. Update on ongoing initial applications

No items

2.7. New applications

Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor – Orphan - EMA/H/C/0004480Kite Pharma UK Ltd; Intended for the treatment ofadult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL), and transformed follicular lymphoma (TFL) who are ineligible for autologous stem cell transplant (ASCT).

Scope: CAT conclusion on the evaluation of the request for accelerated assessment

Action: for adoption

2.8. Withdrawal of initial marking 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 - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

2.11.1. Holoclar – *Ex vivo* expanded autologous human corneal epithelial cells containing stem cells - EMEA/H/C/002450/II/0012/G

Chiesi Farmaceutici S.p.A.

Rapporteur: Egbert Flory; CHMP Coordinator: Jan Mueller-Berghaus

Scope: quality Draft opinion

Action: for adoption

CAT adopted the draft opinion for this variation.

2.12. Other Post-Authorisation Activities

2.12.1. Glybera - alipogene tiparvovec - Orphan - EMEA/H/C/002145/SOB/002.8

uniQure biopharma B.V.; Indicated for the long term correction of lipoprotein lipase

deficiency, to control or abolish symptoms and prevent complications in adult patients clinically diagnosed with lipoprotein lipase deficiency (LPLD)

Rapporteur: Christiane Niederlaender; Co-Rapporteur: Egbert Flory; CHMP Coordinators: Greg Markey, Jan Mueller-Berghaus

Scope: Rapporteur's report of the MAH's response to SOB-002.6 as adopted in February 2017

Action: for adoption

The Rapporteur's assessment report was adopted.

There was a discussion on how to collect long term patient safety follow-up data after the cessation of the Marketing Authorisation (October 2017). It will not be possible to impose new legal obligations on the company, but a statement (reminder) will be included in the assessment report of this Specific Obligation (SOB) for the company to continue submitting patient follow-up data until the closure of the registry (15 years after last patient inclusion).

2.12.2. Glybera - alipogene tiparvovec - Orphan - EMEA/H/C/002145/SOB/002.9

uniQure biopharma B.V. ; Indicated for the long term correction of lipoprotein lipase deficiency, to control or abolish symptoms and prevent complications in adult patients clinically diagnosed with lipoprotein lipase deficiency (LPLD)

Rapporteur: Christiane Niederlaender; Co-Rapporteur: Egbert Flory; CHMP Coordinators: Greg Markey, Jan Mueller-Berghaus

Scope: Rapporteur's report of the MAH's response to SOB-002.7 as adopted in February 2017

Action: for adoption

The Rapporteur's assessment report was adopted. See 2.12.1

2.12.3. Strimvelis - Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human adenosine deaminase (ADA) complementary deoxyribonucleic acid (cDNA) sequence - Orphan - EMEA/H/C/003854/PSUSA/10505/201611

GlaxoSmithKline Trading Services

Rapporteur: Christiane Niederlaender; Co-Rapporteur: Sol Ruíz; CHMP Coordinators: Robert H. Hemmings, Concepción Prieto Yerro; PRAC Rapporteur: Sabine Straus

Scope: Pharmacovigilance: evaluation of a post safety update single assessment (PSUSA) procedure

Action: for information

Note: PRAC issued a recommendation at its 6-9 June 2017 meeting

Feedback was provided from the discussion of the assessment of the first PSUR at the PRAC. For further background, see PRAC meeting minutes of June 2017.

3. Certification of ATMPs

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

3.1. Opinion

No items

3.2. Day 60 Evaluation Reports

3.3. New Applications

No items

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Autologous adipose derived mesenchymal stem cells - EMA/H0004813

Intended for the treatment of chronic wound

Scope: scientific recommendation

Action: for information

Note: start of procedure was postponed awaiting additional information from the applicant. The CAT Coordinator was already appointed in April 2017.

4.2. Day 30 ATMP scientific recommendation

4.2.1. Stromal vascular fraction cells for autologous use - EMA/H0004838

Intended for the relief of symptoms of osteoarthritis

Scope: scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. CAT adopted the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 30 June 2017.

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 human keratinocytes - EMA/H0004841

Intended for the treatment of burns and chronic, severe wounds

Scope: scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. CAT adopted the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 30 June 2017.

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. Autologous human chondrocytes - EMA/H0004840

Intended for the repair of single symptomatic cartilage defect of the knee or ankle

Scope: scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. CAT adopted the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 30 June 2017.

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. Allogeneic human umbilical cord blood-derived mesenchymal stem cells (hUCB-MSC) – EMA/H0004839

Intended for the treatment of atopic dermatitis

Scope: scientific recommendation

Action: for adoption

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 by 30 June 2017.

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 revised scientific recommendation (following list of questions)

No items

4.4. Finalisation of procedure

4.4.1. Autologous human adipose perivascular stromal cells genetically modified to secrete soluble tumour necrosis factor-related apoptosis-inducing ligand (sTRAIL) - EMA/H0004820

Intended for the treatment of TRAIL-sensitive cancers such as Ewing sarcoma and pancreatic ductal adenocarcinoma

Scope: minor comments received from the European Commission. Final ATMP scientific recommendation

Action: for information

Noted

4.4.2. Replication incompetent adenoviral serotype 5 vector encoding the human interleukin-12 p70 (hIL-12) transgene under the control of the activator ligand, veledimex - EMA/H0004805

Intended for the treatment of recurrent or progressive glioblastoma

Scope: no comments raised by the European Commission. Final ATMP scientific recommendation

Action: for information

Noted

4.4.3. Allogenic human mesenchymal stem cells - Mesenchymal stem cells isolated from umbilical cord - EMA/H0004815

Intended for the treatment of chronic obstructive pulmonary disease

Scope: minor comments received from the European Commission. Final ATMP scientific recommendation

Action: for information

Noted

4.4.4. Autologous adipose derived mesenchymal stem cells - EMA/H0004798

Intended for the treatment of autoimmune drug resistant epilepsy

Scope: minor editorial comments received from the European Commission. Final ATMP scientific recommendation

Action: for information

Noted

4.4.5. Cultured allogeneic Wharton jelly derived mesenchymal stem cells - EMA/H0004796

Intended for the treatment of amyotrophic lateral sclerosis (ALS)

Scope: minor editorial comments received from the European Commission. Final ATMP scientific recommendation

Action: for information

Noted

4.4.6. Cultured autologous adipose derived mesenchymal stem cells - EMA/H0004799

Intended for the treatment of autoimmune drug resistant epilepsy

Scope: minor editorial comments received from the European Commission. Final ATMP scientific recommendation

Action: for information

Noted

4.4.7. Cultured autologous adipose derived regenerative mesenchymal stem cells - EMA/H0004797

Intended for the treatment of autoimmune drug resistant epilepsy

Scope: minor editorial comments received from the European Commission. Final ATMP scientific recommendation

Action: for information

Noted

4.4.8. Cultured autologous Wharton jelly derived mesenchymal stem cells - EMA/H0004795

Intended for the treatment of amyotrophic lateral sclerosis (ALS)

Scope: revised ATMP classification report following comments by the European Commission

Action: for adoption

The changes introduced to the report were highlighted. CAT adopted the revised classification report.

4.4.9. Adenovirus-associated viral vector serotype 5 containing CRISPR Cas9 and guide ribonucleic acids (RNAs) targeting intron 26 of the centrosomal protein 290 gene (AAV5-GRK1-SauCas9-CEP290gRNA 323/64) - EMA/H0004818

Intended for the treatment of patients aged 3 years and older with Leber congenital amaurosis type 10 (LCA10) caused by a homozygous or compound heterozygous intron 26 mutation, c.2991+1655 A>G, in the CEP290 gene

Scope: no comments raised by the European Commission. Final ATMP scientific recommendation

Action: for information

Noted

4.4.10. Allogeneic unexpanded amniotic fluid derived cells suspended with dried and cryofractured amniotic tissue - EMA/H0004816

Intended for the treatment of chronic wound care

Scope: minor editorial comments received from the European Commission. Final ATMP scientific recommendation

Action: for information

Noted

4.4.11. Human autologous stromal vascular fraction (SVF) - EMA/H0004822

Intended for the treatment of articular cartilage and bone defects

Scope: revised ATMP classification report following comments by the European Commission

Action: for adoption

The changes introduced to the report were highlighted. CAT adopted the revised classification report.

4.4.12. Human autologous adipose-derived stromal/stem cells (ADSCs) - EMA/H0004823

Intended for the treatment of articular cartilage and bone defects

Scope: revised ATMP classification report following comments by the European Commission

Action: for adoption

The changes introduced to the report were highlighted. CAT adopted the revised classification report.

4.4.13. Bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts - EMA/H0004817

Intended for the treatment of partial deep dermal and full thickness burn wounds

Scope: no comments raised by the European Commission. Final ATMP scientific recommendation

Action: for information

See also 6.3.2.1.

Noted

4.4.14. Resorbable, viscoelastic matrix for use with autologous stromal vascular fraction (SVF) - EMA/H0004819

A resorbable matrix to be used for the delivery of autologous SVF adipose derived cells for the treatment of HIV-related facial lipoatrophy

Scope: minor editorial comments received from the European Commission. Final ATMP scientific recommendation

Action: for information

Noted

4.5. Follow-up and guidance

No items

5. Scientific Advice

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 Coordinators

5.2. CAT reports

5.3. List of Issues

5.4. Finalisation of SA procedures

6. Pre-Authorisation Activities

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 of eligibility

No items

6.3.4. Month 3 – Nomination of Rapporteurs

No items

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT membership

Scope: membership changes

Austria: Corina Spreitzer - nomination as member on 01 April 2017

Clinicians' representative: Willem Eduard Fibbe - nomination as alternate on 11 May 2017

Clinicians' representative: Francisco Blanco García - nomination as alternate on 11 May 2017

Action: for information

The CAT chair welcomed the new CAT members / alternates.

7.1.2. Strategic Review & Learning meeting – Malta, June 2017

Scope: feedback from the meeting that took place in Gozo, Malta on 1-2 June 2017 under the auspices of the Maltese Presidency of the Council of the European Union

Action: for information

Feedback from the meeting was postponed to the July CAT meeting.

7.1.3. Good manufacturing practice (GMP) requirements for ATMPs

Scope: discussion of the GMP for ATMP guideline following the joint inspectors-CAT drafting group of 26 April 2017

Action: for discussion

The version of the GMP for ATMP guideline, as discussed at the joint GMP-inspectors / CAT expert drafting group on 26 April 2017 with the changes proposed by the Inspectors Working

Group (IWG) on 30 May 2017, was presented. The CAT chair thanked the CAT drafting group members for their active collaboration and contributions over the last 2 years.

The CAT discussed the 2 main changes proposed by the IWG.

With these amendments, CAT endorsed the GMP for ATMP guideline.

The formal adoption of the guideline will take place at the European Commission (after consultation of the Pharmaceutical Committee). The European Commission will thereafter publish the guideline.

7.1.4. Advanced training on best use of EMA's technical tools for the committee's members

Scope: advanced training session at the July 2017 meeting on best use of technical applications for the committee's members. Send your queries or questions

Action: for information

The information was noted.

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 May 2017 meeting

Action: for information

The information was noted.

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

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

Scope: agenda of PCWP/HCPWP joint meeting to take place on 27-28 June 2017

Action: for information

The information was noted.

7.3.2. Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells

CAT topic leader: Marcos Timón; CAT members: Ilona Reischl, Paula Salmikangas, Christiane Niederlaender, Belaïd Sekkali, Margarida Menezes Ferreira, Tiina Palomäki, Guido Pantè, Matthias Renner, Brigitte Anliker, Nicoloas Anagnou

Scope: concept paper for the revision of the guideline

Action: for information

Adoption of this concept paper was postponed until July 2017 awaiting comments from the Guideline Consistency Group. CAT noted the dates of the drafting group meetings to start the development of the guideline .

7.4. Cooperation within the EU regulatory network

7.4.1. Orphan similarity for ATMPs

CAT drafting group: Simona Badoi, Violaine Closson-Carella, Michele Lipucci, Margarida Menezes-Ferreira, Christiane Niederlaender, Ilona Reischl, Paula Salmikangas

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'. Review of comments received from the public consultation.

Action: for discussion

Consultation document published by the European Commission
http://ec.europa.eu/health/sites/health/files/files/orphanmp/2016_07_pc_orphan/2016_07_consultation_paper.pdf

A CAT breakout meeting took place on 10 April 2017 during which the comments from the public consultation on the definition of orphan similarity for ATMPs were discussed.

The orphan similarity proposal (ATMP part) and the overview of comments as prepared following the CAT breakout meeting were briefly presented to CAT in the May 2017 CAT meeting, and the document was sent to the CAT members for adoption via written procedure.

Due to time constraint no full discussion took place in the May 2017 meeting and some observations were received by the CAT members during the written procedure. Therefore the documents were discussed in detail during the June 2017 CAT meeting. CAT agreed with the conclusion reached at the breakout meeting; one editorial change was proposed to the orphan similarity proposal. With that amendment, the orphan similarity proposal and the overview of comments document were agreed. The Commission will implement the editorial change.

7.5. Cooperation with international regulators

7.5.1. ATMP cluster teleconference with FDA, Health Canada and PMDA

Postponed to July 2017

CAT: Martina Schüßler-Lenz

Scope: draft agenda

Action: for adoption

7.6. CAT work plan

7.6.1. Expert meeting on adeno-associated viral vectors, 6 September 2017, EMA, London

CAT: Jan Mueller-Berghaus, Rune Kjeken

Scope: updated list of questions. For review and comments by CAT member by Wednesday 12 June 2017

Action: for adoption

Note: the list of questions was updated following the focus group in the margins of the Strategic & Review meeting that took place on 31 May – 2 June 2017.

The list of invited experts and the list of questions was presented. CAT proposed some changes to the questions. The list of questions was subsequently adopted. These will now be forwarded to the experts as an indication of the topics that the CAT would like to discuss with them during the meeting of 6 September 2017 (it is not the intention to discuss each individual question).
The organising committee will now develop the agenda for the expert meeting and bring that to the CAT in July 2017 for discussion and adoption.

7.7. Planning and reporting

7.7.1. Planning estimates of forthcoming ATMP MAAs

Scope: Q2/2017 update of the Business Pipeline report for the human scientific committees

Action: for information

The information was noted.

7.8. Others

7.8.1. Health and Environmental Sciences Institute (ILSI) annual meeting, May 2016

CAT: Carla Herberts

Scope: feedback from participating CAT member Carla Herberts on the initiation and subsequent activities of the ILSI-HESI emerging issue committee on Cell Therapy - TRAcking, Circulation, & Safety (CT-TRACS)

Action: for information

Postponed to July 2017

8. Any other business

No items

Date of next CAT meeting:

12-14 July 2017

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

ERA: Environmental Risk Assessment

FDA: Food and Drug Administration

FL: Final Letter

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Genetically-modified organism

GMP: Good Manufacturing Practice

HTA: Health Technology Assessment Bodies

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

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

SAs: Scientific Advices

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

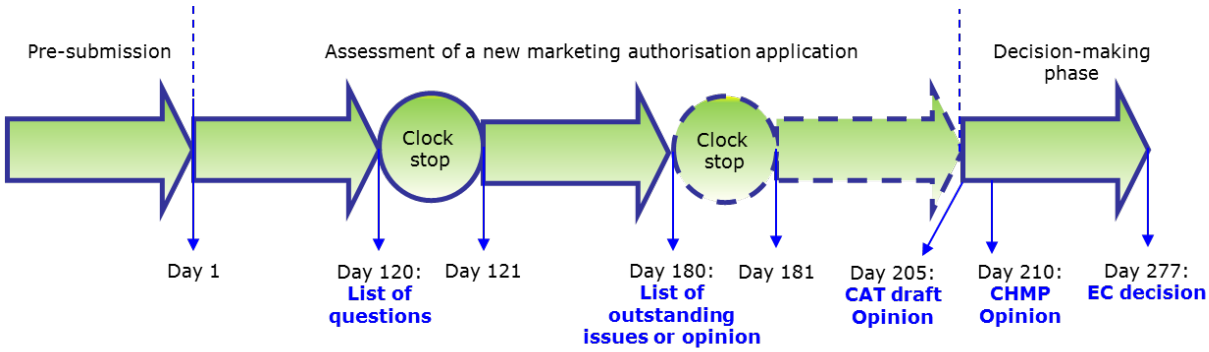
Evaluation of ATMPs (section 2)

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/

10. List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 15-16 June 2017 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Martina Schüssler-Lenz	Chair	Germany	No interests declared	
Corina Spreitzer	Alternate. Replacing member.	Austria	No restrictions applicable to this meeting	
Claire Beuneu	Member	Belgium	No interests declared	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Mirna Golemovic	Member	Croatia	No interests declared	
Marina Ieridi	Member	Cyprus	No interests declared	
Tomáš Boráň	Member	Czech Republic	No interests declared	
Nanna Aaby Kruse	Member	Denmark	No restrictions applicable to this meeting	
Anne Pastoft	Alternate	Denmark	No interests declared	
Toivo Maimets	Member	Estonia	No interests declared	
Paula Salmikangas	Member	Finland	No interests declared	
Olli Tenhunen	Alternate	Finland	No interests declared	
Violaine Closson	Member	France	No interests declared	
Jan Mueller-Berghaus	Member	Germany	No interests declared	
Egbert Flory	Alternate	Germany	No interests declared	
Angeliki Roboti	Alternate. Replacing member.	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	
Una Riekstina	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member (CHMP member)	Lithuania	No restrictions applicable to this meeting	
Guy Berchem	Alternate (to CHMP representative)	Luxembourg	No restrictions applicable to this meeting	
Anthony Samuel	Alternate (to CHMP representative)	Malta	No interests declared	
Johannes Hendrikus Ovelgönne	Member	Netherlands	No interests declared	
Carla Herberts	Alternate	Netherlands	No interests declared	
Helga Haugom Olsen	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-	Alternate (to	Portugal	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Ferreira	CHMP representative). Replacing member.			
Simona Badoi	Member	Romania	No interests declared	
Gianina-Nicoleta Andrei	Alternate	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	
Kieran Breen	Member	Patients' Representative	No restrictions applicable to this meeting	
Mariëtte Driessens	Member	Patients' Representative	No restrictions applicable to this meeting	
Guido Panté	Expert*	Italy	No restrictions applicable to this meeting	
Wiebke Hoppensack	Expert*	Germany	No restrictions applicable to this meeting	
A representative from the European Commission attended the meeting.				
Meeting run with relevant support from EMA staff				

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