21 June 2019
EMA/CAT/290589/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 22-24 May 2019

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. M Turner declared a potential conflict of interest for the product under agenda point 6.3.2. No further 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 22-24 May 2019 meeting was adopted with one addition: 7.6.1. Genome editing technologies for drug development, regulatory considerations.

1.3. Adoption of the minutes

The CAT minutes for 15-17 April 2019 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

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. Alofisel - darvadstrocel - Orphan - EMEA/H/C/004258/II/0006

Takeda Pharma A/S

Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Jan Mueller-Berghaus, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: submission of an updated RMP (version 7) in order to propose the replacement of the existing observational PASS (listed as category 3 study: 'a study to evaluate the long term safety of Alofisel (darvadstrocel (Cx601)) in patients treated and retreated (i.e. repeated dosing and immunogenicity) and to assess the effectiveness of Alofisel (darvadstrocel) in patients treated and retreated (i.e. repeated dosing) in routine clinical practice (for treatment of complex perianal fistulas in adult patients with non-active/mildly active luminal Crohn's disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy)' with two separate studies: 1) a long-term safety extension of the ADMIRE-CD II study: a phase 3 randomized, double-blind, parallel-group, placebo-controlled, multicentre study to assess efficacy and safety of darvadstrocel (Cx601), allogeneic expanded adipose-derived stem cells for complex perianal fistula(s) in Crohn's disease; and 2) a retreatment PASS. The European multi-database linkage study is added for the assessment of the potential risk of tumourgenicity. Opinion

Action: for adoption

CAT discussed the replacement of the original PASS by two separate studies. CAT agreed with the PRAC assessment that the proposed change to the RMP is acceptable.

CAT discussed the scientific reasoning behind the extension of the ADMIRE-CD II study and the European multi-database linkage study (registry study).

CAT adopted the opinion for this variation.

2.11.2. Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/II/0005/G

CO.DON AG

Rapporteur: Lisbeth Barkholt

Scope: safety: update of the product information to reflect the study results of the 36-month follow up data for trial cod 16 HS 13 and the final study report with 60-month follow-up data for trial cod 16 HS 14. Study cod 16 HS 13 is a prospective, randomised, open label, multicentre Phase-III clinical trial to compare the efficacy and safety of the treatment with the autologous chondrocyte transplantation product co.don chondrosphere (ACT3D-CS) with microfracture in subjects with cartilage defects of the knee with a defect size between 1 and 4 cm^2. Study cod 16 HS 14 is a prospective, randomised, open label, multicentre Phase-II clinical trial to investigate the efficacy and safety of the treatment of large defects (4-10 cm^2) with three different doses of the autologous chondrocyte transplantation product co.don chondrosphere (ACT3D-CS) in subjects with cartilage defects of the knee. Request for supplementary information (RSI)

Action: for adoption.

The Rapporteur presented their assessment.

CAT adopted the RSI for this variation.

2.11.3. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0007

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: quality. Request for supplementary information (RSI)

Action: for adoption

The Rapporteur presented their assessment. The RSI was revised taking into account of the comments received and the discussion in the CAT. The updated RSI was adopted.

2.11.4. Zalmoxis - nalotimagene carmaleucel - Orphan - EMEA/H/C/002801/II/0016

MolMed S.p.A

Rapporteur: Carla Herberts, Co-Rapporteur: Sol Ruiz, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: the MAH is proposing to terminate the study TK008 (specific obligation for the CMA) and replace it with study TK013. Request for supplementary information (RSI)

Action: for adoption

See also 2.12.3

To support the discussion, a short presentation was given by EMA Regulatory Affairs on conditional marketing authorisations.

The Rapporteur presented their assessment of the request from the MAH to replace study TK008 by study TK013 to fulfil the specific obligation of the CMA.

The RSI, updated following the CAT discussion, was adopted.

2.12. Other Post-Authorisation Activities

2.12.1. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/ANX/009

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: (from initial MAA) Study CCTL019H2301:Post-authorisation efficacy study (PAES): In order to further characterise the long-term efficacy and safety of Kymriah in relapsed/refractory diffuse large B-cell lymphoma (DLBCL), the applicant should submit the results of study CCTL019H2301 - open-label, Phase III study of Kymriah versus standard of care in adult patients with relapsed or refractory aggressive B-cell non-Hodgkin lymphoma. (Category 1). Request for supplementary information (RSI)

Action: for adoption

The Rapporteur presented the design of the PAES study CCTL019H2301 (Belinda study). Questions to the MAH have been raised in the RSI (points for clarification). Further to the discussion the RSI was revised. The revised RSI was adopted by CAT.

2.12.2. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090

Novartis Europharm Limited

Rapporteur: Rune Kjeken; CHMP Coordinator: Bjorg Bolstad

Scope: quality

Action: for discussion

Feedback was provided by the Rapporteur.

2.12.3. Zalmoxis - nalotimagene carmaleucel - Orphan - EMEA/H/C/002801/R/0015

MolMed S.p.A

Rapporteur: Carla Herberts, Co-Rapporteur: Sol Ruiz, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: annual renewal of marketing authorisation

Action: for adoption

Further to the discussion on the type II variation to replace study TK008 by study TK013 (see 2.11.4), CAT discussed the renewal of the application. The RSI (with other concerns) was adopted.

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

No items

3.3. New Applications

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – Appointment of CAT Coordinator

4.1.1. modified Vaccinia Ankara-Bavarian Nordic - Brachyury (MVA-BN-Brachyury) and recombinant fowlpox virus (FPV-Brachyury) encoding the human brachyury gene and three human costimulatory molecules known as TRICOM (triad of costimulatory molecules): B7.1, intercellular adhesion molecule-1 (ICAM-1), and leukocyte function-associated antigen-3 (LFA-3) – H0005394

Intended for the treatment of chordoma

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

Nominations were received. The CAT member was appointed as CAT-coordinator.

4.1.2. autologous $CD34^+$ cells – H0005399

Intended for the treatment of no-option critical limb ischemia

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

Nominations were received. The CAT member was appointed as CAT-coordinator.

4.1.3. uncapped, non-coding ribonucleic acid – H0005400

Intended for the treatment of adenoid cystic carcinoma, squamous cell carcinoma of the head and neck, melanoma and squamous cell carcinoma of the skin

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

Nominations were received. The CAT member was appointed as CAT-coordinator.

4.1.4. messenger ribonucleic acid (mRNA) coding for coiled-coil domain-containing protein 40 (CCDC40) protein – H0005395

Intended for the treatment of primary ciliary dyskinesia (PCD) caused by biallelic mutation in the CCDC40 gene

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

Nominations were received. The CAT member was appointed as CAT-coordinator.

4.1.5. autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor – H0005396

Intended for the treatment of various types of cancer

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

Nominations were received. The CAT member was appointed as CAT-coordinator.

4.2. Day 30 ATMP scientific recommendation

4.2.1. human embryonic stem cell-derived Müller cells – H0005356

Intended for the treatment of primary open angle glaucoma

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 7 June 2019.

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. allogeneic neonatal human cardiac progenitor cells – H0005357

Intended for the treatment of cardiac failure

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 7 June 2019.

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. allogeneic human enucleated red cell therapy expressing Anabaena variabilis (Av) phenylalanine ammonia lyase (AvPAL) – H0005355

Intended for the treatment of phenylketonuria (PKU)

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 7 June 2019.

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 adipose tissue/micronised adipose tissue - H0005338/0001

Intended for autologous skin wound healing

Scope: comments received by the European Commission. Revised ATMP scientific recommendation

Action: for adoption

The revised ATMP classification was adopted.

4.4.2. allogeneic haematopoietic stem and progenitor cells treated ex vivo with the protein transduction domain of the human immunodeficiency virus-1 (HIV-1) transactivation protein fused to MYC transcription factor - H0005340/0001

Intended for the treatment of acute myelogenous leukaemia (AML)

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

Action: for information

The information was noted.

4.4.3. allogeneic haematopoietic stem and progenitor cells treated ex vivo with the protein transduction domain of the human immunodeficiency virus-1 (HIV-1) transactivation protein fused to MYC transcription factor - H0005341/0001

Intended for the treatment of myelofibrosis (MF)

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

Action: for information

The information was noted.

4.4.4. autologous dendritic cell, electroporated with messenger ribonucleic acid (mRNA) encoding tumour antigen Wilms tumour r (WT)-1 – H0005240

Intended for the treatment of lung cancer

Scope: ATMP scientific recommendation

Action: for adoption

CAT agreed that the classification discussed and concluded in December 2018 should be considered as final.

The final report will be sent to the applicant.

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 Rapporteurs

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

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

6.3.4. Ongoing support

No items

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. Strategic Review & Learning meeting – joint CAT/Clinical trial facilitation group (CTFG), Bucharest, Romania, 13-14 June 2019

CAT resources: Simona Badoi

Scope: final agenda (version 9)

Action: for adoption

Note: a half day of this Strategic Review & Learning meeting (SRLM) will be held jointly with the CTFG.

CAT agreed to the topics on the agenda of the upcoming SRLM and appointed CAT members to take the lead for the different topics.

CAT members were reminded to register for the meeting not later than 3 June 2019.

7.1.2. Strategic Review & Learning meeting – joint CAT/COMP/PDCO, Helsinki, Finland, 20-21 November 2019

CAT resources: Heli Suila

Scope: initial announcement

Action: for information

The SRLM to take place on 20-21 November 2019 in Helsinki was announced. During this meeting, there is the possibility for joint meetings with COMP and PDCO. The development of the agenda will start at the July 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 April 2019 meeting

Action: for information

The information was noted.

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

7.3.1. Healthcare Professionals Working Party (HCPWP) and Patients and Consumers Working Party (PCWP) - Nomination of CAT representative(s)

Scope: invitation to nominate CAT representatives to these working parties for the period covering June 2019 to May 2022.

Action: for nomination

CAT appointed the following CAT representatives:

Erik Briers as member for PCWP and alternate for HCPWP and Bernd Gänsbacher as member of the HCPWP and alternate for PCWP.

7.4. Cooperation within the EU regulatory network

7.4.1. Notice to applicants

Scope: revised version of the text for the Notice to Applicants

Action: for information

The European Commission representative presented the proposed Notice to Applicant text.

7.4.2. European Commission - draft guidelines on good clinical practice (GCP) for advanced therapy medicinal products

Scope: adoption of GCP for ATMP Guidelines - consultation to CAT

Action: for discussion

Note: Article 4 of the ATMP Regulation mandates the Commission to draft GCP guidelines specific to ATMPs.

The European Commission representative presented the draft GCP guideline that is developed by a drafting group composed of members of the GCP inspectors working group and the CAT. This document will have to be read together with the ICH GCP guideline and only addresses the ATMP specific issues. CAT members can provide comments by 17 June 2019.

7.4.3. European Commission's Research and Innovation (R&I) Framework Programme

Scope: presentation on the future of the R&I programme in relation to ATMPs

Action: for information

The Commission Representation from DG Research & Innovation presented the ATMP specific proposals approved in last year's Horizon 2020 call and the proposals received for this year's Horizon Europe call on Regenerative medicines. There was a discussion on how CAT can support the work of DG Research & Innovation. Early scientific advice to academic developers is considered very important.

7.5. Cooperation with international regulators

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

The teleconference will take place

CAT: Martina Schüßler-Lenz

Scope: draft agenda

Action: for discussion

The agenda of the ATMP cluster teleconference, dedicated to comparability for ATMPs, was agreed.

7.5.2. International pharmaceutical regulators programme (IPRP) – cell therapy and gene therapy working groups

Scope: appointment of EU participants to cell therapy and gene therapy working group

Action: For information

CAT noted the appointment of EU participants to the 2 IPRP working groups.

7.5.3. Revision of Annex 2 of Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Manufacturing Practice Guide

Scope: Revision of the Annex 2 to the PIC/S GMP guide

Action: for information

EMA provided feedback on the revision of the Annex 2 to the PIC/S GMP guide.

7.6. CAT work plan

7.6.1. Genome editing technologies for drug development – regulatory considerations

Scope: Revised CAT considerations

Action: for adoption

The revised CAT regulatory considerations for medicinal product containing or consisting of genome editing components, taking into account comments received was presented and discussed. The proposal was adopted and will now be presented to CHMP.

7.7. Planning and reporting

None

7.8. Others

None

8. Any other business

8.1. Preparedness of the system and capacity increase

Action: for information

CAT noted the update.

Date of next CAT meeting:

19-21/06/2019

9. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

Abbreviations / Acronyms

AAV: Adeno-Associated Virus

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

GCG: Guideline Consistency Group

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Genetically-modified organism

GMP: Good Manufacturing Practice

GTMP: Gene Therapy Medicinal Product

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 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

SAs: Scientific Advices

SAG-O: Scientific Advisory Group Oncology

SAWP: Scientific Advice Working Party

TEP: Tissue Engineering Product

SR: Summary Report

SWP: Scientific Working Party

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

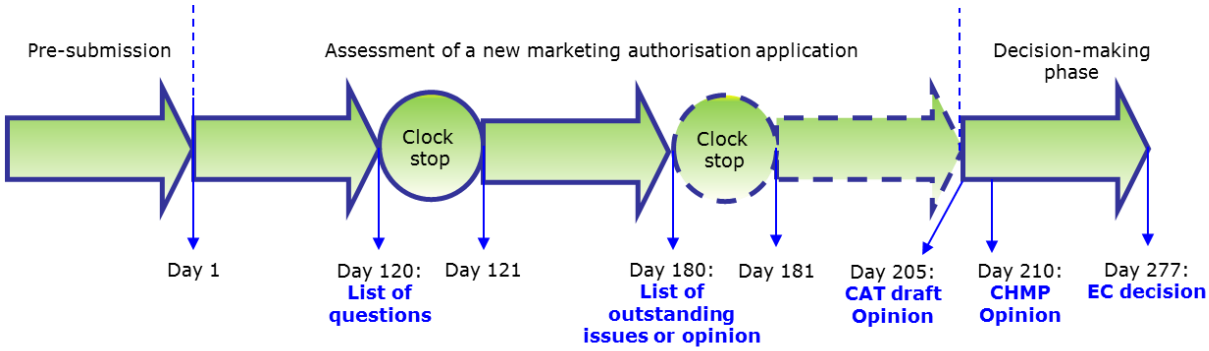
Evaluation of ATMPs (section 2)

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 22-24 May 2019 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	
Ilona Reischl	Member	Austria	No interests declared	
Corina Spreitzer	Alternate	Austria	No restrictions applicable to this meeting	
Claire Beuneu	Member	Belgium	No interests declared	
Belaïd Sekkali	Alternate	Belgium	No interests declared	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Evelina Shumkova	Alternate	Bulgaria	No interests declared	
Mirna Golemovic	Member	Croatia	No interests declared	
Petra Sokol	Alternate	Croatia	No interests declared	
Marina Ieridi	Member	Cyprus	No interests declared	
Maria Vassiliou	Alternate	Cyprus	No interests declared	
Ivana Haunerova	Member	Czech Republic	No interests declared	
Ondrej Palan	Alternate	Czech Republic	No interests declared	
Anne Pastoft	Member	Denmark	No interests declared	
Nanna Aaby Kruse	Alternate	Denmark	No restrictions applicable to this meeting	
Toivo Maimets	Member	Estonia	No interests declared	
Pille Saalik	Alternate	Estonia	No interests declared	
Heli Suila	Member	Finland	No interests declared	
Olli Tenhunen	Alternate	Finland	No interests declared	
Violaine Closson	Member	France	No interests declared	
vacant	Alternate	France		
Jan Mueller-Berghaus	Member (CHMP co-opted member)	Germany	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Egbert Flory	Alternate (to CHMP representative)	Germany	No interests declared	
Asterios Tsiftsoglou	Member	Greece	No interests declared	
Angeliki Roboti	Alternate	Greece	No interests declared	
Katalin Lengyel	Member	Hungary	No interests declared	
Balázs Sarkadi	Alternate	Hungary	No interests declared	
vacant	Member	Iceland		
vacant	Alternate	Iceland		
Maura O'Donovan	Member	Ireland	No interests declared	
Niamh Curran	Alternate	Ireland	No interests declared	
Paolo Gasparini	Member	Italy	No interests declared	
Giulio Pompilio	Alternate	Italy	No restrictions applicable to this meeting	
Una Riekstina	Member	Latvia	No interests declared	
Liga Saulite	Alternate	Latvia	No interests declared	
Romaldas Mačiulaitis	Member (CHMP member)	Lithuania	No restrictions applicable to this meeting	
Vitalis Briedis	Alternate (to CHMP representative)	Lithuania	No interests declared	
vacant	Member	Liechtenstein		
vacant	Alternate	Liechtenstein		
Guy Berchem	Member (to CHMP representative)	Luxembourg	No restrictions applicable to this meeting	
Anne-Cécile Vuillemin	Alternate	Luxembourg	No restrictions applicable to this meeting	
John J. Borg	Member (CHMP member)		No interests declared	
Anthony Samuel	Alternate (to CHMP representative)	Malta	No interests declared	
Carla Herberts	Member	Netherlands	No interests declared	
Johannes Hendrikus Ovelgonne	Alternate	Netherlands	No interests declared	
Rune Kjeken	Member	Norway	No restrictions applicable to this meeting	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Maja Sommerfelt Grønvold	Alternate	Norway	No interests declared	
Dariusz Śladowski	Member	Poland	No restrictions applicable to this meeting	
Anna Cieślik	Alternate	Poland	No interests declared	
Bruno Sepodes	Member (CHMP member)	Portugal	No interests declared	
Margarida Menezes-Ferreira	Alternate (to CHMP representative)	Portugal	No interests declared	
Gianina-Nicoleta Andrei	Alternate	Romania	No interests declared	
Simona Badoi	Member	Romania	No interests declared	
Lukas Slovak	Member	Slovakia	No interests declared	
vacant	Alternate	Slovakia		
Metoda Lipnik-Stangelj	Member	Slovenia	No interests declared	
Nevenka Trsinar Brodt	Alternate	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	
Lisbeth Barkholt	Member	Sweden	No interests declared	
Björn Carlsson	Alternate	Sweden	No interests declared	
Christiane Niederlaender	Member	United Kingdom	No interests declared	
John Johnston	Alternate	United Kingdom	No interests declared	
Marc Turner	Member	Healthcare Professionals' Representative	No participation in discussion, final deliberations and voting on:	6.3.2.2.
Francisco J Blanco	Alternate	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Bernd Gänsbacher	Member	Healthcare Professionals' Representative	No interests declared	
Willem Fibbe	Alternate	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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Mariëtte Driessens	Member	Patients' Representative	No restrictions applicable to this meeting	
Erik Briers	Alternate	Patients' Representative	No restrictions applicable to this meeting	
Karl-Heinz Buchheit	Observer	Conseil de l'Europe	No restrictions applicable to this meeting	
Catherine Milne	Observer/Alternate	European Directorate for the Quality of Medicine & Health Care(EDQM)	No restrictions applicable to this meeting	
Barbara Bonamassa	Expert - in person*	AIFA-IT	No restrictions applicable to this meeting	
Sonja Schonefeld	Expert - via telephone*	PEI-DE		
Brigitte Keller-Stanislawski	Expert - via telephone*	PEI-DE	No restrictions applicable to this meeting	
Markus Funk	Expert - via telephone*	PEI-DE	No restrictions applicable to this meeting	
Susanne Poley-Ochmann	Expert - via telephone*	PEI-DE	No restrictions applicable to this meeting	
Anke Zobywalski	Expert - via telephone*	PEI-DE	No restrictions applicable to this meeting	
Maren Hammann	Expert - via telephone*	PEI-DE	No restrictions applicable to this meeting	
Jolien de Groot	Expert - via telephone*	CBG-MEB-NL	No restrictions applicable to this meeting	
Paula van Hennik	Expert - via telephone*	CBG-MEB-NL	No restrictions applicable to this meeting	
Jorge Camarero Jiménez	Expert - via telephone*	AEMPS-ES	No restrictions applicable to this meeting	
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.