22 June 2018
EMA/CAT/354919/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for Advanced Therapies (CAT)

Minutes for the meeting on 23-25 May 2018

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 23-25 May 2018 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes for 18-20 April 2018 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

2.3.1. Viable T-cells - Orphan - EMEA/H/C/002397

Kiadis Pharma Netherlands B.V.; adjunctive treatment in haematopoietic stem cell transplantation (HSCT) for a malignant disease

Scope: Day 180 list of outstanding issues

Action: for adoption

List of questions adopted on 08.09.2017.

The Rapporteurs presented their assessment of the responses to the list of questions. CAT discussed the BWP report.

The list of outstanding questions was adopted.

2.3.2. The response timetable was agreed.

Voretigene neparvovec - Orphan - EMEA/H/C/004451

Spark Therapeutics Ireland Ltd; treatment of patients with vision loss due to Leber congenital amaurosis or retinitis pigmentosa inherited retinal dystrophy

Scope: Day 180 list of outstanding issues

Action: for adoption

List of questions adopted on 08.12.2017.

The Rapporteurs presented their assessment of the responses to the list of questions. CAT discussed the BWP report.

The list of outstanding issues was adopted. CAT agreed with the response timetable.

2.3.3. Tisagenlecleucel - Orphan - EMEA/H/C/004090

Accelerated assessment

Novartis Europharm Limited; treatment of B cell acute lymphoblastic leukaemia (ALL) and diffuse large B cell lymphoma (DLBCL)

Scope: Day 150 list of outstanding issues

Action: for adoption

List of questions adopted on 16.03.2018.

The Rapporteurs presented their assessment of the responses to the list of questions. CAT discussed the BWP report.

The accelerated timetable was reverted to a normal timetable. The response timetable was agreed.

The LoOI was adopted.

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. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0020

Amgen Europe B.V.

Rapporteur: Olli Tenhunen, CHMP Coordinator: Tuomo Lapveteläinen

Scope: Safety: Opinion

Update of section 4.8 of the SmPC in order to add the new adverse drug reaction 'hypersensitivity' with a frequency 'unknown'. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement a minor editorial change in section 3 of the SmPC in order to clarify that the current description of the liquid applies to both strengths, and minor changes in section 4.4 of the SmPC and the Package Leaflet regarding sorbitol and sodium subsequent to the revised Annex to the EC guideline on excipients in the labelling (EMA/CHMP/302620/2017).

Action: for adoption

The CAT adopted the opinion.

2.11.2. Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/II/0002/G

CO.DON AG

Rapporteur: Lisbeth Barkholt; CHMP Coordinator: Kristina Dunder

Scope: Safety and efficacy: RSI

Update of sections 4.2, 4.7, 4.8 and 5.1, of the SmPC in order to revise the wording and to update the safety and efficacy information based on the interim results from studies 16 HS 13 (24-month follow-up data) and 16 HS 14 (48-month follow-up data); the package leaflet is updated accordingly

Action: for adoption

The CAT adopted the second request for supplementary information.

2.12. Other Post-Authorisation Activities

2.12.1. Zalmoxis - allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2) - Orphan - EMEA/H/C/002801/R/0010

MolMed SpA

Rapporteur: Johannes Hendrikus Ovelgonne, CHMP Coordinators: Paula Boudewina van Hennik, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: 1 year renewal of conditional marketing authorisation

Action: for adoption

CAT adopted the opinion for the 1-year renewal of the marketing authorisation. The due date for the specific obligation has not changed.

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

No items

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Autologous human T cells genetically expressing a chimeric antigen receptor (CAR) for B-cell maturation antigen (BCMA) – H0005095

Intended for the treatment of relapsed or refractory multiple myeloma

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. *Ex vivo* fused allogenic human myoblast (MB^{N}) with autologous human myoblast (MB^{DMD}) forming MB^{N}/MB^{DMD} dystrophin expressing chimeric cells – H0005097

Intended for the treatment of Duchenne muscular dystrophy

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. *Ex vivo* fused allogenic human myoblast (MB^{N1}) with allogenic human myoblast (MB^{N2}) forming MB^{N1}/MB^{N2} dystrophin expressing chimeric cells – H0005098

Intended for the treatment of Duchenne muscular dystrophy

Scope: appointment of CAT Ccordinator 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), codon optimised human, complexed with lipid-based nanoparticles, encoding for the human ornithine transcarbamylase deficiency - H0005081

Intended for the treatment of ornithine transcarbamylase deficiency

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. Recombinant adeno-associated viral vector capsid containing the human iduronate-2-sulfatase (hIDS) gene expression cassette - H0005096

Intended for the treatment of mucopolysaccharidosis type II (Hunter syndrome)

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. Homogenate of antlerogenic stem cells - H0005050

Intended for the treatment of recurrent corneal erosion syndrome

Scope: scientific recommendation

Action: for adoption

The CAT discussed the ATMP classification report. CAT decided that additional information is needed from the applicant before concluding on this classification's request.

4.2.2. Homogenate of antlerogenic stem cells - H0005051

Intended for therapeutic support in spinal cord injury Scope: scientific recommendation

Action: for adoption

The CAT discussed the ATMP classification report. CAT decided that additional information is needed from the applicant before concluding on this classification request.

4.2.3. Mixture of cultured human olfactory ensheathing cells and olfactory nerve fibroblasts - H0005049

Intended for the treatment of complete spinal cord injury in human patients

Scope: scientific recommendation

Action: for adoption

The AT discussed the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 8 June 2018.

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. CD34+ cells transduced with a lentiviral vector containing the Fanconi anemia complementation group A (FANCA) gene - H0005064

Intended for the treatment of Fanconi anemia type A patients

Scope: scientific recommendation

Action: for adoption

The CAT discussed the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 8 June 2018.

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.

See also 5.1.1.

4.2.5. Allogeneic CD34+ haematopoietic stem cells and allogeneic CD3+ T-cells - H0005068

Intended for prevention of kidney transplant rejection

Scope: scientific recommendation

Action: for adoption

The CAT discussed the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 8 June 2018.

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. Allogeneic foetal neural stem cells (ALS) - H0005022

Intended for the treatment of amyotrophic lateral sclerosis (ALS)

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

Action: for information

The information was noted.

4.4.2. Allogeneic foetal neural stem cells (SCI) - H0005023

Intended for the treatment of spinal cord injury (SCI)

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

Action: for information

The information was noted.

4.4.3. Fat graft - H0005024

Intended for lipofilling of anal fistula

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

Action: for information

The information was noted.

4.4.4. Exosomes carrying recombinant cystic fibrosis transmembrane conductance regulator (CFTR) mRNA and microRNA-17 – H0005021

OmniSpirant Limited; Intended for the treatment of cystic fibrosis

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

Action: for information

The information was noted.

4.5. Follow-up and guidance

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

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

6.3.4. Month 3 – Nomination of Rapporteurs

6.3.5. Ongoing support

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT membership

Croatia: Nenad Medić -nominated as the new member from 16 May 2018
Croatia: Ivica Malnar -membership ended on 15 May 2018
Slovakia: Jan Kyselovic - membership ended on 30 April 2018

Action: for information

The information was noted. The CAT thanked Ivica Malnar and Jan Kyselovic for their support to the CAT over the last years.

7.1.2. Strategic Review & Learning meeting - Joint CHMP/PDCO/CAT, Oslo, Norway, 07-09 May 2018

Postponed to June 2018

CAT resources: Martina Schüßler-Lenz

Scope: feedback from the meeting that took place on 07-09 May 2018

Action: for adoption

Note: Strategic Review & Learning meeting partnered with CAT/CHMP/PDCO.

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 2018 meeting

Action: for information

The information was noted.

7.2.2. Scientific Coordination Board (SciCoBo) - meeting of 03 May 2018

CAT: Martina Schüßler-Lenz

Scope: feedback on the outcome of the SciCoBo meeting on 3 May 2018

Action: for information

Postponed until the June meeting 2018.

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

7.3.1. Guideline on quality of water for pharmaceutical use

CAT: Margarida Menezes-Ferreira; QWP Rapporteur/Coordinator: Eugenia Cogliandro

Scope: CAT's input to the guideline

Action: for discussion

Note: the revision of the guideline aims at harmonisation with US and Japanese pharmacopeias. The guideline is currently being revised by QWP (with input from BWP and GMDP IWG). It is planned to be adopted by QWP/CHMP/CVMP and released for public consultation in June 2018. The background to the revision is outlined in this Concept paper (EMA/CHMP/CVMP/QWP/BWP/428135/2016).

The comments from the CAT members on the guideline were discussed. One change was proposed. With this amendment, the CAT comments were agreed.

7.4. Cooperation within the EU regulatory network

7.4.1. Guidelines on good clinical practice for advanced therapy medicinal products

CAT drafting group: Simona Badoi, Maura O'Donovan, Kieran Breen

Scope: draft GCP for ATMP guidelines

Action: for discussion

The European Commission's representative presented the draft GCP for ATMP guidelines prepared by a drafting group composed of CAT members and members of the GCP inspections working group.

CAT members can provide comments on the draft guidelines directly to the European Commission.

The draft guidelines will thereafter be published by the European Commission for a public consultation of 3 to 4 months. Additional CAT members can join the drafting group to review the comments from the public consultation.

7.4.2. ATMP training curriculum: assessor trainings on *'Review of Quality, Non-Clinical and Clinical aspects of ATMP CTA and MAA'* jointly with the Clinical Trial Facilitation Group (CTFG)

Scope: call for expression of interest from CAT and CTFG members to present relevant case studies to cover review of quality, non-clinical and clinical aspects of ATMP clinical trial applications.

Action: for discussion

Note: an e-mail calling for volunteers to present their case studies was sent to CAT members on 10 May 2018.

Postponed to the June 2018 CAT meeting.

7.4.3. Orphan similarity for ATMPs

CAT drafting group: Margarida Menezes-Ferreira, Christiane Niederlaender, Violaine Closson Carella, Simona Badoi, Guido Pantè.

Scope: Questions and Answers (Q&A) document

Action: for information

Note: amendments were introduced in response to question 3 and agreed by written procedure on 11 May 2018.

The Q&A will be published by the European Commission and will accompany the revised legislation on orphan similarity.

The information was noted.

7.4.4. Pharmacogenomics Working Party (PgWP)

Scope: EMA multi-stakeholder workshop on predictive biomarker-based assay development in the context of drug development and lifecycle (EMA/136048/2018) - scheduled on 18 June 2018

Action: for information

The agenda of the multi-stakeholder meeting was presented. The aim of the meeting is to discuss the comment received on the concept paper on companion diagnostics prepared by the PgWP. CAT members are interested to join the workshop

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

During the ATMP cluster teleconference, CAT received a feedback form the ATMP cluster review (survey conducted in 2017) and discussed with the international participants regulatory and scientific issues related to automated production and decentralised manufacture of ATMPs.

7.6. CAT work plan

7.6.1. CAT 2019 work plan

CAT: Martina Schüßler-Lenz

Scope: initial discussions of topics for the 2019 work plan

Action: for discussions

Postponed to the June CAT meeting 2018.

7.6.2. Environmental assessment of gene therapy medicinal products

Scope: presentation on outcome of discussions with GMO authorities regarding the assessment of gene therapy medicinal products.

Action: for discussion

The European Commission representative provided feedback from the discussions that took place with a group of experts regarding the GMO classification for certain type of gene therapy medicinal products. CAT members were part of the group of experts.
The outcome of the discussion of the group of experts was supported by CAT.

A meeting with the GMO authorities and the Competent Authorities for medicines will take place at the European Commission on 25 June 2018.

7.7. Planning and reporting

7.7.1. European Commission and European Medicines Agency Action Plan on ATMPs

CAT: Martina Schüßler-Lenz

Scope: status update of the European Commission and European Medicines Agency Action Plan on ATMPs

Action: for information

The information was noted.

7.8. Others

None

8. Any other business

No items

Date of the next CAT meeting:
20-22 June 2018

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

CTA: Clinical Trial Authorisation

CTFG: Clinical Trial Facilitation Group

CVMP: Committee for Medicinal Products for Veterinary Use

QWP: Quality Working Party

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

GMDP IWG: Good Manufacturing Practice/Good Distribution Practice Inspectors Working Group

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

QWP: Quality Working Party

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Application

MAH: Marketing Authorisation Holder

MSC: Mesenchymal stem cells

OE: Oral Explanation

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: Scientific Advisory Group

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

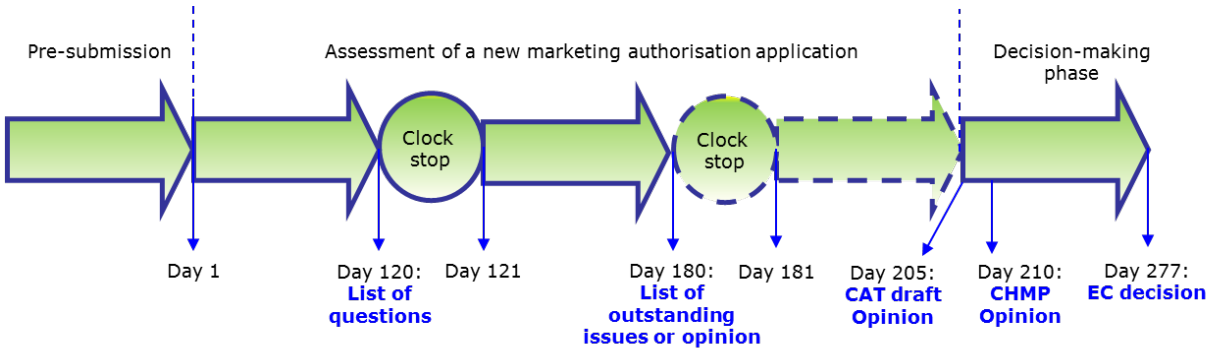
Evaluation of ATMPs (section 2)

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 23-25 May 2018 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	N/A
Ilona Reischl	Member	Austria	No interests declared	N/A
Corina Spreitzer	Alternate	Austria	No interests declared	N/A
Claire Beuneu	Member	Belgium	No interests declared	N/A
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	N/A
Nenad Medic	Alternate	Croatia	No interests declared	N/A
Marina Ieridi	Member	Cyprus	No interests declared	N/A
Ivana Haunerova	Member	Czech Republic	No interests declared	N/A
Anne Pastoft	Alternate	Denmark	No interests declared	N/A
Toivo Maimets	Member	Estonia	No interests declared	N/A
Heli Suila	Member	Finland	No interests declared	N/A
Olli Tenhunen	Alternate	Finland	No interests declared	N/A
Violaine Closson	Member	France	No interests declared	N/A
Jan Mueller-Berghaus	Member	Germany	No interests declared	N/A
Egbert Flory	Alternate	Germany	No interests declared	N/A
Asterios Tsiftsoglou	Member	Greece	No interests declared	N/A
Katalin Lengyel	Member	Hungary	No interests declared	N/A
Maura O' Donovan	Member	Ireland	No interests declared	N/A
Giulio Pompilio	Alternate	Italy	No interests declared	N/A
Una Riekstina	Member	Latvia	No interests declared	N/A
Romaldas Maiulaitis	Member	Lithuania	No interests declared	N/A
Anthony Samuel	Alternate (to CHMP representative)	Malta	No interests declared	N/A
Johannes Hendrikus Ovelgonne	Member	Netherlands	No interests declared	N/A
Carla Herberts	Alternate	Netherlands	No interests declared	N/A
Helga Haugom Olsen	Member	Norway	No interests declared	N/A
Rune Kjeken	Alternate	Norway	No restrictions applicable to this meeting	N/A
Dariusz ladowski	Member	Poland	No restrictions applicable to this meeting	N/A
Margarida Menezes-Ferreira	Alternate (to CHMP representative)	Portugal	No interests declared	N/A
Simona Badoi	Member	Romania	No interests declared	N/A

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Metoda Lipnik-Stangelj	Member	Slovenia	No interests declared	N/A
Sol Ruiz	Member (CHMP co-opted member)	Spain	No interests declared	N/A
Marcos Timón	Alternate, replacing CHMP member	Spain	No interests declared	N/A
Lisbeth Barkholt	Member	Sweden	No interests declared	N/A
Björn Carlsson	Alternate	Sweden	No interests declared	N/A
Christiane Niederlaender	Member	United Kingdom	No interests declared	N/A
James McBlane	Alternate	United Kingdom	No interests declared	N/A
Marc Turner	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	N/A
Bernd Gänsbacher	Member	Healthcare Professionals' Representative	No interests declared	N/A
Kieran Breen	Member	Patients' Representative	No restrictions applicable to this meeting	N/A
Michelino Lipucci di Paola	Alternate	Patients' Representative	No restrictions applicable to this meeting	N/A
Maria Driessens	Member	Patients' Representative	No restrictions applicable to this meeting	N/A
Erik Briers	Alternate	Patients' Representative	No restrictions applicable to this meeting	N/A
Christos Sotirelis	Expert – In person*	Patients' Representative	No interests declared	N/A
John Johnston	Expert – In person*	United Kingdom	No interests declared	N/A
Wiebke Hoppensack	Expert – Via telephone*	Germany	No interests declared	N/A
Brigitte Keller-Stanislawski	Expert – Via telephone*	Germany	No interests declared	N/A
Alexander Mergel	Expert – Via telephone*	Germany	No interests declared	N/A
Gabriele Ruppert-Seipp	Expert – Via telephone*	Germany	No interests declared	N/A
Susanne Poley-Ochmann	Expert – Via telephone*	Germany	No interests declared	N/A
Anke Zobywalski	Expert – Via telephone*	Germany	No interests declared	N/A
Andreea Barbu	Expert – Via telephone*	Sweden	No interests declared	N/A
Marcel S.G. Kwa	Expert – Via telephone*	The Netherlands	No interests declared	N/A
Evelien Minten	Expert – Via	The Netherlands	No interests declared	N/A

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
	telephone*			
Filip Josephson	Expert – Via telephone*	Sweden	No interests declared	N/A
Khadija Rantell	Expert – Via telephone*	United Kingdom	No interests declared	N/A
Janet Glassford	Expert – Via telephone*	United Kingdom	No interests declared	N/A
Michael Udell	Expert – Via telephone*	United Kingdom	No interests declared	N/A
Simona Stankeviciute	Expert – Via telephone*	Lithuania	No interests declared	N/A
Macarena Rodriguez	Expert – Via telephone*	Spain	No interests declared	N/A
Bjørg Bolstad	Expert – Via telephone*	Norway	No interests declared	N/A
Maria Kalland	Expert – Via telephone*	Norway	No interests declared	N/A
Anna Urbaniak	Expert – Via telephone*	Norway	No interests declared	N/A
Sonja Schonefeld	Expert – Via telephone*	Germany	No interests declared	N/A
Ingrid Wang	Expert – Via telephone*	Norway	No interests declared	N/A
Frauke Naumann-Winter	Expert – Via telephone*	Germany	No interests declared	N/A
Eugenia Cogliandro	Expert – Via telephone*	Italy	No interests declared	N/A
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.