14 September 2018
EMA/CAT/665989/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 18-20 July 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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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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 18-20 July 2018 meeting was adopted

1.3. Adoption of the minutes

The CAT minutes for 20-22 June 2018 meeting were adopted

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

2.2.1. 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: Opinion

Action: for adoption

List of Outstanding Issues adopted on 25.05.2018. List of Questions adopted on 08.12.2017.

The CAT Rapporteurs presented the assessment of the list of outstanding issues.

During the oral explanation, the applicant addressed the questions identified in the LoOI.

CAT adopted a second list of outstanding issues. The CAT opinion will be adopted at the September CAT meeting.

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

2.7.1. Autologous haematopoietic stem cells transduced with lentiviral vector encoding the human beta-A-T87Q-globin gene - Orphan - H0003691

bluebird bio GmbH; Treatment of adolescents and adults with transfusion-dependent β-thalassemia (TDT) who do not have a β0 mutation at both alleles of the β-globin (HBB) gene (i.e., patients with a non-β0/β0 genotype).Scope: Briefing note and Rapporteurs' recommendation on the request for accelerated assessment.

Action: for adoption

CAT adopted the Rapporteurs' recommendation to grant accelerated assessment.

2.7.2. Adeno-associated viral vector serotype 9 containing the human survival of motor neuron (SMN) gene - Orphan – PRIME - H0004750

AveXis EU Limited; Intended for the treatment of paediatric patients diagnosed with spinal muscular atrophy type 1

Scope: Briefing note and Rapporteurs' recommendation on the request for accelerated assessment.

Action: for adoption

CAT adopted the Rapporteurs' recommendation to grant accelerated assessment.

2.8. Withdrawal of initial marketing authorisation application

2.8.1. Axalimogene filolisbac - EMEA/H/C/004473

Treatment of cervical cancer

Scope: Letter from the applicant dated 10 July 2018 informing EMA about the withdrawal of the marketing authorisation application.

Action: for information

CAT noted this information.

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. 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/II/0009/G

MolMed S.p.A

Rapporteur: Johannes Hendrikus Ovelgonne, CHMP Coordinators: Paula Boudewina van Hennik

Scope: Opinion. Quality

Action: for adoption

Request for Supplementary Information adopted on 20.04.2018.

CAT adopted the opinion and assessment report.

2.12. Other Post-Authorisation Activities

No items

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

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

4.1. New requests – Appointment of CAT Coordinator

No items

4.2. Day 30 ATMP scientific recommendation

4.2.1. Adeno-associated viral vector serotype 2 containing a gene encoding the channelrhodopsin-2 protein – H0005122

Intended for the treatment of retinitis pigmentosa

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 31 July 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.

4.2.2. Autologous blood-derived endothelial and haematopoietic stem/progenitor cells – H0005110

Intended for the treatment of no-option patients with peripheral arterial disease (PAD) and critical limb ischemia (CLI)

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 31 July 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.

4.2.3. Non-viable allogeneic induced pluripotent stem cells – H0005108

Intended for the treatment of epithelial cancers and leukaemia

Scope: classification request withdrawn by the applicant

Action: for information

CAT noted the information.

4.2.4. Combination of four 5' capped single stranded messenger ribonucleic acids encoding one shared tumour-associated antigen - H0005109

Intended for the treatment of malignant melanoma

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 31 July 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.

4.2.5. 5´capped single stranded messenger RNA encoding tumour specific neoantigens - H0005111

Intended for the treatment of locally advanced or metastatic tumors

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 31 July 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. Homogenate of antlerogenic stem cells - H0005051/0001

Intended as support for the spinal cord injury in humans

Scope: the European Commission raised comments. Revised ATMP scientific recommendation

Action: for adoption

The classification report was updated to take into account the comments raised by the European Commission. The revised report was adopted.

4.4.2. Homogenate of antlerogenic stem cells - H0005050/0001

Intended for the treatment of recurrent corneal erosion syndrome (RCES)

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

Action: for information

The information was noted.

4.4.3. 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: the European Commission raised comments. Revised ATMP scientific recommendation

Action: for information

The revised report was noted.

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

Action: for information

The information was noted.

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

Action: for information

The information was noted.

4.4.6. Messenger ribonucleic acid, 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: the European Commission raised no comments . Final ATMP scientific recommendation

Action: for information

The information was noted.

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

Action: for information

The information was noted.

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)

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

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: confirmation of meeting dates

Action: for information

The date was noted. The agenda will be developed and discussed at future CAT meeting.

7.2. Coordination with EMA Scientific Committees

7.2.1. Committee for Medicinal Products for Human Use (CHMP)

Scope: Summary of Outcomes (SoO) for the July 2018 meeting

Action: for information

The information was noted.

7.2.2. Committee for Orphan Medicinal Products (COMP)

Scope: presentation on the interplay between orphan status and wording of therapeutic indications

Action: for information

CAT noted the presentation.

7.2.3. Scientific Coordination Board (SciCoBo) – meeting of 16 July 2018

CAT: Martina Schüßler-Lenz

Scope: feedback on the outcome of the SciCoBo meeting that took place on 16 July 2018

Action: for information

The CAT chair provided feedback from the last SciCoBo meeting. A presentation from EMA will be scheduled during the September 2018 CAT meeting on the 'Regulatory Science Strategy to 2025' for discussion and input from the CAT members.

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

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

CAT Rapporteur: Marcos Timón

Scope: revised draft agreed by guideline consistency group (GCG). Guideline for public consultation

Action: for adoption for public consultation

The CAT Rapporteur presented the guideline for public consultation. Drafting group members provided feedback on the change introduced following comments from the GCG. CAT adopted the guideline for public consultation for a period of 12 months.

7.3.2. Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container

Scope: presentation of the updated guideline following comments from BWP/CAT

Action: for discussion

Note: The draft guideline on sterilisation underwent a public consultation from April-October 2016. The guideline has been discussed extensively at QWP, GMDP Inspectors Working Group (IWP) and BWP.

The draft guideline was presented. CAT members are asked to provide comments in writing by 10 September 2018. Depending on the comments received, the guideline will be brought back to CAT in September 2018.

7.3.3. Training in GMP for ATMPs

Scope: training of GMP inspectors and ATMP assessors from national competent authorities will be organised on 27-28 September 2018

Action: for adoption

Note: The training is aimed at those who are active and competent in the inspection of ATMP facilities. Quality assessors who join the GMP inspectors during an inspection of the ATMP manufacturing site (or who could take up this role in the future) would also benefit from attendance.

CAT noted the information.

7.4. Cooperation within the EU regulatory network

7.4.1. ATMP training curriculum

Scope: ATMP curriculum and composition of the Curriculum Committee members

Action: for adoption and for nomination

Note: CAT will formally adopt the European Union network training centre (EU NTC) Training Curriculum for ATMP. CAT members will be asked to put forward candidatures to become a member of the Curriculum Committee, which will be composed of at least 3 members (one for Quality, Non-clinical and Clinical aspects each). This group will overview the training curriculum and the list of trainings for the next years.

CAT adopted the ATMP curriculum. Following members agreed to be part of the Curriculum Committee: Claire Beuneu (non-clinical) and Lisbeth Barkholt (clinical).

There was a short discussion on the format and timing of CAT training sessions.

7.5. Cooperation with international regulators

No items

7.6. CAT work plan

7.6.1. CAT 2019 work plan

CAT: Martina Schüßler-Lenz

Scope:
-Topics for the 2019 work plan.
-Feedback from the brainstorming meeting that took place on 18 July 2018

Action: for discussion

The draft CAT work plan for 2019 was updated taking into account the outcome of the brainstorming meeting and EMA Brexit preparedness's BCP.

The updated plan was discussed and agreed by CAT. It will be circulated to CAT members to confirm or indicate their involvement in the different work plan topics. Adoption is scheduled at the September 2018 CAT meeting.

7.6.2. Environmental assessment of gene therapy medicinal products

European Commission

Scope: outcome of the meeting between the European Commission and the GMO authorities that took place on 25 June 2018 regarding the assessment of human cells genetically modified.

Action: for information

The European Commission representative highlighted the different documents that have been developed on environmental assessment of GTMPs in clinical trials. All document are published on the Commission's
website: https://ec.europa.eu/health/human-use/advanced-therapies_en

7.7. Planning and reporting

7.7.1. Planning estimates of forthcoming marketing authorisation applications for advanced therapy medicinal products

Scope: MAAs with eligibility for Q2-2018

Action: for information

The information was noted.

7.8. Others

7.8.1. EMA implementation of the new medical device and *in* vitro diagnostic regulation

Action: for information

A presentation was given on the EMA implementation plan of the new medical device and in vitro diagnostics Regulation. CAT sponsor are sought to contribute to the following areas:

- Definitions of pharmacological, immunological, metabolic and medical diagnosis
- Substance Based medical devices
- Companion Diagnostics and
- Integral Drug Device Combinations

CAT members interested should inform the CAT secretariat or send email . There is an immediate need for sponsors for the Definitions (1st bullet point) . Regular updates to CAT on various workstreams is planned.

It was proposed to organise a breakout meeting at the September CAT meeting to discuss specifically the implications for combined ATMPs.

7.8.2. Relocation of EMA to The Netherlands

Scope: update on current state-of-play on EMA relocation

Action: for information

The state of play was presented by EMA.

8. Any other business

No items

Date of next CAT meeting:
12-14 September 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

CTFG: Clinical Trial Facilitation Group

DG: Drafting Group

EC: European Commission

ERA: Environmental Risk Assessment

EU NTC: European Union network training centre

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

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

SR: Summary Report

SWP: Scientific Working Party

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

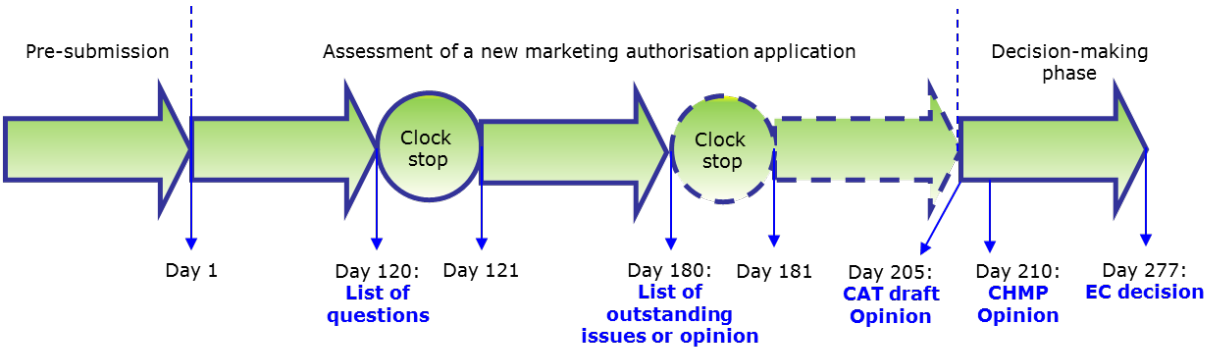
Evaluation of ATMPs (section 2)

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 18-20 July 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
Mirna Golemovic	Member	Croatia	No interests declared	N/A
Nenad Medic	Alternate	Croatia	No interests declared	N/A
Tomáš Boráň	Alternate	Czech Republic	No interests declared	N/A
Nanna Aaby Kruse	Member	Denmark	No interests declared	N/A
Pille Saalik	Alternate	Estonia	No interests declared	N/A
Heli Suila	Member	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
Angeliki Roboti	Alternate	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
Niamh Curran	Alternate	Ireland	No interests declared	N/A
Paolo Gasparini	Member	Italy	No interests declared	N/A
Una Riekstina	Member	Latvia	No interests declared	N/A
Romaldas Mačiulaitis	Member (CHMP member)	Lithuania	No interests declared	N/A
Guy Berchem	Member (to CHMP representative)	Luxembourg	No restrictions applicable to this meeting	N/A
Anthony Samuel	Alternate (to CHMP representative)	Malta	No interests declared	N/A
Johannes Hendrikus Ovelgonne	Member	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 Śladowski	Member	Poland	No restrictions applicable to this meeting	N/A
Margarida Menezes-Ferrei	Alternate (to CHMP	Portugal	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
ra	representative)			
Simona Badoi	Member	Romania	No interests declared	N/A
Lukas Slovak	Member	Slovakia	No interests declared	N/A
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
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
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
Barbara Bonamassa	Expert – In person*	Italy	No interests declared	N/A
Giuseppa Pistritto	Expert – In person*	Italy	No interests declared	N/A
Macarena Rodriguez Mendizabal	Expert – Via telephone*	Spain	No interests declared	N/A
Concha Prieto Yerro	Expert – Via telephone*	Spain	No interests declared	N/A
Gabriele Ruppert-Seipp	Expert – Via telephone*	Germany	No interests declared	N/A
Brigitte Keller-Stanislawski	Expert – Via telephone*	Germany	No interests declared	N/A
Juliane Rau	Expert – Via telephone*	Germany	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
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.