20 July 2018
EMA/CAT/724555/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for Advanced Therapies (CAT)

Minutes of meeting on 20-22 June 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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Table of contents

1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 22 or more members were present in the room). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

The CAT chair welcomed the new member from Slovakia, Lukas Slovak and the new alternate from Estonia, Pille Saalik.

1.2. Adoption of agenda

The CAT agenda for 20-22 June 2018 meeting was adopted

1.3. Adoption of the minutes

The CAT minutes for 23-25 May 2018 meeting were adopted

2. Evaluation of ATMPs

2.1. Opinions

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

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

Scope: Opinion

Action: for adoption

Note: List of Outstanding Issues adopted on 25.05.2018. List of Questions adopted on 16.03.2018.

The Rapporteur and CoRapporteur presented their position, taking into account the responses from the applicant to the LoOI .

During the Oral explanation, the applicant addressed the questions in the LoOI and responded to additional questions from the CAT members.

CAT adopted by majority the CAT draft opinion and the CAT assessment report. A divergent position was signed by the members who voted against.

2.1.2. Axicabtagene ciloleucel - Orphan - EMEA/H/C/004480

Kite Pharma EU B.V.; Intended for the treatment of B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL) and transformed follicular lymphoma (TFL)

Scope: Opinion

Action: for adoption

Note: List of Outstanding Issues adopted on 20.04.2018. List of Questions adopted on 08.12.2017.

The Rapporteur and CoRapporteur presented the assessment of the responses to the LoOI.

CAT adopted by consensus the draft CAT opinion and the CAT assessment report.

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

CO.DON AG

Rapporteur: Lisbeth Barkholt, CHMP Coordinators: Kristina Dunder

Scope: Safety and efficacy: Opinion

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

Note: requests for Supplementary Information adopted on 25.05.2018, 20.04.2018.

The opinion was adopted.

2.12. Other Post-Authorisation Activities

2.12.1. Strimvelis - autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - Orphan - EMEA/H/C/003854/REC/011

GlaxoSmithKline Trading Services Limited

Rapporteur: Christiane Niederlaender, CHMP Coordinator: Robert James Hemmings

Scope: post-authorisation measure from initial opinion/MA

Action: for adoption

CAT adopted the Rapporteur's assessment report. The post-authorisation measure is considered fulfilled.

2.12.2. Strimvelis - autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - Orphan - EMEA/H/C/003854/REC/012

GlaxoSmithKline Trading Services Limited

Rapporteur: Christiane Niederlaender, CHMP Coordinator: Robert James Hemmings

Scope: post-authorisation measure from initial opinion/MA

Action: for adoption

CAT adopted the Rapporteur's assessment report. The post-authorisation measure is considered fulfilled.

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

Intended for the treatment of retinitis pigmentosa

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

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

4.1.2. 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: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

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

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

Intended for the treatment of epithelial cancers and leukaemia

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

Nominations were received. The following CAT members was appointed as CAT coordinator

4.1.4. 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: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

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

4.1.5. 5´capped single stranded messenger RNA encoding tumor specific neoantigens - H0005111

Intended for the treatment of locally advanced or metastatic tumors

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

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

4.2. Day 30 ATMP scientific recommendation

4.2.1. 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: 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 6 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. *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: 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 6 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. *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: 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 6 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.

4.2.4. 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: 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 6 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. 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: 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 6 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)

4.3.1. Homogenate of antlerogenic stem cells - H0005050/0001

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

Scope: Responses from the applicant. Revised ATMP scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report which was updated to reflect the additional information provided by the applicant. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 6 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.

4.3.2. Homogenate of antlerogenic stem cells - H0005051/0001

Intended as support for the spinal cord injury in humans.

Scope: Responses from the applicant. Revised ATMP scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report which was updated to reflect the additional

information provided by the applicant. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 6 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.

4.4. Finalisation of procedure

4.4.1. Unpurified cell culture of human olfactory ensheathing cells (OECs) and human olfactory nerve fibroblasts (ONFs) - H0005049/0001

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

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

Action: for adoption

CAT adopted the revised classification report.

4.4.2. Donor-derived CD34+ hematopoietic stem cells with defined dose of donor derived CD3+ T-cells - H0005068/0001

Prevention of kidney graft loss in recipients of human leukocyte antigen-matched living donor kidney transplants

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

Action: for information

The information was noted.

4.4.3. CD34+ cells transduced with a lentiviral vector encoding the Fanconi anaemia complementation group A (FANCA) gene - Orphan - H0005064/0001

Treatment of Fanconi anaemia type A patients

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

Action: for information

The information was noted.

See also 5.2.3

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

Timetable:

-Final Briefing Package:	04.07.2018
-Start of the procedure at SAWP:	09-12.07.2018
-CAT report due by:	13.07.2018
-CAT recommendation:	20.07.2018

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

No item

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. CAT membership

Slovakia: Lukas Slovak - nominated as the new member from 26 May 2018

Action: for information

The information was noted.

7.1.2. Call for expression of interest from civil societies for the position of member of the committee for advanced therapies (CAT)

European Commission

Scope: European Commission's launch of a selection procedure to appoint the members and alternates representing patients' associations and clinicians in the Committee for Advanced Therapies. Deadline for submission of applications: 18 July 2018

Action: for information

European Commission's website link:
https://ec.europa.eu/health/documents/public_call/call_index_en#fragment0

Note:
-The mandate will run for three years from 1 July 2019
-the EC will appoint the new members after consultation with the European Parliament

The information was noted. Members and alternates currently representing patients' associations and clinicians in the CAT can re-apply.

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

CAT: Martina Schüßler-Lenz

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

Action: for adopted

The CAT Chair presented the report from the Strategic Review and Learning meeting (SRLM). The presentations will be included in MMD once received.

It was noted that no CAT SRLM will take place in the second half of 2018. Bulgaria is investigating to organise a CAT SRLM together with the Clinical Trial Facilitating Group (CTFG) in the first half of 2019.

7.2. Coordination with EMA Scientific Committees

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

Scope: Summary of Outcomes (SoO) for the May 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

The CAT chair provided feedback from the last SciCoBo meeting.

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

None

7.4. Cooperation within the EU regulatory network

7.4.1. ATMP training curriculum: assessor trainings on 'Review of quality, non-clinical and clinical aspects of advanced therapy medicinal product clinical trial application and marketing authorisation application' 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.

CAT reviewed the list of proposed trainings for 2018-2019 and agreed with the proposal to organise 30-60 mins trainings on the Wednesdays of the CAT week between 13.00-14.00 (before the start of the plenary meeting). CAT members willing to give a presentation (e.g. on a new guideline, or a talk prepared for an external conference) can inform the CAT secretariat. These presentations will be recorded for inclusion in the EU Network Training Centre System.

CAT members were 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. Nominations are awaited by 16 July 2018.

The ATMP curriculum will be adopted and the Curriculum Committee members will be appointed at the July CAT meeting.

7.4.2. Medical devices and in vitro diagnostic medical devices

CAT: Ilona Reischl

Scope:
- EU Network Awareness session on the new medical devices and in vitro diagnostic medical devices Regulations (2017/745 and 2017/746): Friday 22 June 2018, 12.30 – 14.00 Room 2-F
- Implementation of Art. 117 of the medical device Regulation: New requirement that medicinal products with an integral medical device component will require a notified body opinion or conformity assessment before the marketing authorisation can be granted: feedback from the discussions at the BWP interested parties meeting of 20 June 2018
- Feedback from the Pharmacogenomics Working Party workshop on predictive biomarker-based assay development in the context of drug development and lifecycle (workshop took place on 18 June 2018).

Action: for information

CAT noted the information. Awareness of the implementation of the medical device Regulation is important for the ATMP field.

7.5. Cooperation with international regulators

None

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 discussion

CAT discussed the proposed work plan topic. CAT suggested to include topics.

CAT proposed to organise a short breakout session in the margins of the July CAT .

A further discussion will be scheduled at the July CAT meeting.

7.7. Planning and reporting

7.7.1. Planning estimates of forthcoming advance therapy medicinal products applications

Scope: planning estimates of forthcoming initial ATMPs applications, type II variations and line extensions intended to be submitted within the next 34 months (period covered: March 2018-December 2020).

Action: for information

The information was noted.

7.8. Others

None

8. Any other business

No items

Date of next CAT meeting:

18-20 July 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

FDA: Food and Drug Administration

FL: Final Letter

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Genetically-modified organism

GMP: Good Manufacturing Practice

HTA: Health Technology Assessment Bodies

HSPC: Hematopoietic Stem and Progenitor Cells

ITF: Innovative Task Force

JR: Joint Report

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Application

MAH: Marketing Authorisation Holder

MNAT: Multinational Assessment Team

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

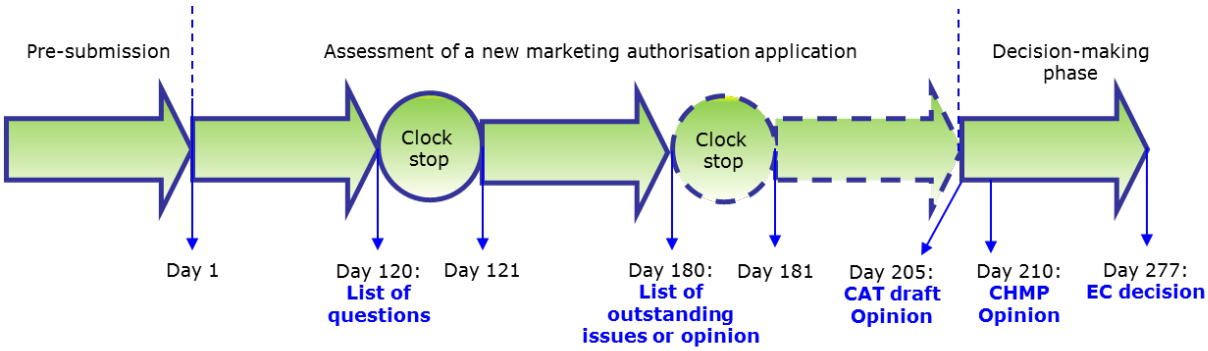
Evaluation of ATMPs (section 2)

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 20-22 June 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
Claire Beuneu	Member	Belgium	No interests declared	N/A
Belaïd Sekkali	Alternate	Belgium	No interests declared	N/A
Evelina Shumkova	Alternate	Bulgaria	No interests declared	N/A
Mirna Golemovic	Member	Croatia	No interests declared	N/A
Nenad Medic	Alternate	Croatia	No interests declared	N/A
Marina Ieridi	Member	Cyprus	No interests declared	N/A
Tomáš Boráň	Alternate	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
Pille Saalik	Alternate	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
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
Paolo Gasparini	Member	Italy	No interests declared	N/A
Giulio Pompilio	Alternate	Italy	No interests declared	N/A
Una Riekstina	Member	Latvia	No interests declared	N/A
Vitalis Briedis	Alternate (to CHMP representative)	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 Śladowski	Member	Poland	No restrictions applicable to this meeting	N/A

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Margarida Menezes-Ferreira	Alternate (to CHMP representative)	Portugal	No interests declared	N/A
Gianina-Nicoleta Andrei	Alternate	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
Willem Fibbe	Alternate	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
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
Frauke Naumann-Winter	Expert – Via telephone*	BfArM	No interests declared	N/A
Brigitte Keller-Stanislawski	Expert – Via telephone*	Germany	No interests declared	N/A
Marie-Pauline Evers	Expert – Via telephone*	The Netherlands	No interests declared	N/A
Jonas Bergh	Expert – Via telephone*	Sweden	No interests declared	N/A
Bjørg Bolstad	Expert – Via telephone*	Norway	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
Ingrid Wang	Expert – Via telephone*	Norway	No interests declared	N/A
Maria Kalland	Expert – Via telephone*	Norway	No interests declared	N/A
Ingebjørg Buajordet	Expert – Via telephone*	Norway	No interests declared	N/A
Anna Urbaniak	Expert – Via telephone*	Norway	No interests declared	N/A
Sylvie Benchetrit	Expert – Via telephone*	France	No interests declared	N/A
Doris Hovgaard	Expert – Via telephone*	Denmark	No interests declared	N/A
Olga Kholmanskikh	Expert – Via telephone*	Belgium	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.