9 September 2020
EMA/CAT/510852/2020
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 15-17 July 2020

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 this agenda 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, this agenda is a working document primarily designed for CAT members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda 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. 21 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

CAT agenda for 15-17 July 2020 meeting was adopted.

1.3. Adoption of the minutes

CAT minutes for 17-19 June 2020 meeting were adopted.

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

No items

2.4. Day 120 list of questions

No items

2.5. Day 80 assessment reports

No items

2.6. Update on ongoing initial applications

2.6.1. Eladocagene exuparvovec - Orphan - EMEA/H/C/005352

PTC Therapeutics International Limited; treatment of aromatic L-amino acid decarboxylase (AADC) deficiency

Scope: letter from the applicant dated 10 July 2020 requesting an extension of clock-stop to respond to the list of outstanding issues adopted in June 2019

Action: for adoption

CAT agreed with the extension of clock stop and adopted the revised evaluation timetable.

2.7. New applications

2.8. Withdrawal of initial marketing 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. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0025

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality.

Action: for adoption

The opinion was adopted.

2.12. Extension applications

No items

2.13. 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. Recombinant adeno-associated viral vector (serotype 8) carrying an optimised gene for human cyclic nucleotide gated channel subunit alpha 3 (CNGA3) protein – H0005726

intended for the treatment of achromatopsia caused by mutations in the CNGA3 gene

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 7 August 2020.

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. Irradiated allogeneic induced-pluripotent stem cells expressing pluripotent genes and cancer-specific embryonic neo-antigens – H0005108/0002

Intended for the treatment malignant solid tumours including all epithelial cancers in sub-group type harbouring a stemness mesenchymal-like signature and haematopoietic malignancies

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. Additional information and clarifications are needed before concluding on this classification. The applicant is asked to address the question agreed by CATThe list of issues was adopted by CAT and the procedure is stopped awaiting responses from the applicant.

4.2.3. Autologous naïve regulatory T cells transduced with a lentiviral vector encoding for a Chimeric Antigen Receptor (CAR) to recognize the HLA-A*02 antigen - H0005713

Intended for the prevention of immune-mediated graft rejection in HLA-A*02 mismatched renal transplantation

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 7 August 2020.

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. Live-attenuated, genetically modified Mycobacterium bovis expressing the gene coding for listeriolysin from Listeria monocytogenes – H0005714

Intended for treatment of non-muscle invasive bladder cancer

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 7 August 2020.

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. Autologous adipose-derived mesenchymal stem cell , diabetic foot syndrome - H0005699

Intended for the treatment of diabetic foot syndrome

Scope: awaiting responses from the applicant to the LoQs. Revised ATMP scientific recommendation

Action: for adoption

Postponed, awaiting responses from the applicant

4.4. Finalisation of procedure

4.4.1. Allogeneic CD34+-enhanced cell suspension derived from umbilical cord blood – H0005712

intended for the treatment of patients with inherited metabolic disorders [cerebral adrenoleukodystrophy, Hurler syndrome] where haematopoietic stem cell transplant is

indicated

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

Action: for information

The information was noted.

4.4.2. Aggregates of defined size of human embryonic stem cell derived insulin secreting pancreatic beta cells, encapsulated within an encapsulation device – H0005721

Intended for the treatment of type I diabetes mellitus

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

Action: for information

The information was noted.

4.4.3. Homogenate of antlerogenic stem cells – H0005710

Intended for the treatment of chronic obstructive pulmonary disease, bronchial asthma

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

Action: for information

The information was noted.

4.4.4. Autologous adipose-derived mesenchymal stem cells, cartilage lesions – H0005700

Intended for the treatment of cartilage lesions

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

Action: for information

The information was noted.

4.4.5. Wharton's jelly derived mesenchymal cells myelitis – H0005701

Intended for the treatment of myelitis

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

Action: for information

The information was noted.

4.4.6. Wharton's jelly derived mesenchymal cells meningitis – H0005693

Intended for the treatment of meningitis

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

Action: for information

The information was noted.

4.4.7. Wharton's jelly derived mesenchymal cells , meningomyelocele – H0005704

Intended for the treatment of meningomyelocele, myelomeningocele, spina bifida

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

Action: for information

The information was noted.

4.4.8. Wharton's jelly derived mesenchymal cells , cerebellum syndrome - H0005705

Intended for the treatment of cerebellum syndrome

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

Action: for information

The information was noted.

4.4.9. Wharton's jelly derived mesenchymal cells , encephalitis - H0005706

Intended for the treatment of encephalitis

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

Action: for information

The information was noted.

4.4.10. Wharton's jelly derived mesenchymal cells , Krabbe disease - H0005707

Intended for the treatment of Globoid cell leukodystrophy (Krabbe disease)

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

Action: for information

The information was noted.

4.4.11. Wharton's jelly derived mesenchymal cells , osteoarthritis – H0005708

Intended for the treatment of osteoarthritis

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

Action: for information

The information was noted.

4.4.12. Wharton's jelly derived mesenchymal cells , spinal and bulbar muscular atrophy – H0005709

Intended for the treatment of spinal and bulbar muscular atrophy

Scope: the European Commission raised no comments. 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

Next deadline for submission of Letters of Intent: 17 July 2020. New requests will be included in the agenda of the August 2020 CAT written procedure.

Timetable:

-Final Briefing Package:	28.08.2020
-Start of the procedure at SAWP:	03.09.2020
-CAT report due by:	04.09.2020
-CAT recommendation:	11.09.2020

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

Timetable for assessment:

Procedure start:	09.07.2020
SAWP recommendation:	03.09.2020
CAT recommendation:	11.09.2020
CHMP adoption of report and final recommendation:	17.09.2020

6.3.2. Month 1 – Discussion of eligibility

6.3.3. Month 2 – Recommendation of eligibility

No items

6.3.4. Ongoing support

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT's August 2020 written procedure

Scope: August 2020: process and timelines

Action: for adoption

The timelines and actions during the August CAT written procedure were agreed. Coordinators for new classifications and CAT Rapporteur for scientific advice procedures (additional to the 3 new procedures in section 5.1.) will be appointed via the written procedure.

7.1.2. Strategic Review & Learning (virtual) meeting (SRLM) under the German presidency, 22nd October 2020

CAT: Martina Schüßler-Lenz, Egbert Flory

Scope: topics for the SRLM agenda:
Morning session: CAT-PDCO-PRAC joint meeting
Afternoon session: CAT-only meeting

Action: for discussion

The draft programme for the joint session and the CAT only session was presented. The agenda topics were agreed.

7.2. Coordination with EMA Scientific Committees

7.2.1. CAT-PDCO interaction

CAT: Martina Schüßler-Lenz

Scope: improvement of CAT-PDCO interaction

Action: for discussion

CAT discussed the proposal on how to increase interactions and how to share the expertise (from PDCO for CAT discussions and vice versa). A brainstorming meeting will be held in September 2020 , involving the chair/vice chair from CAT and PDCO and 2 additional members from both Committees. A CAT member with non-clinical expertise and a CAT member with clinical expertise should join this brainstorming meeting. CAT members interested to join should inform the CAT secretariat .

7.2.2. CAT-COMP interaction

CAT, core members: Kieran Breen, Carla Herberts, Maura O'Donovan, Maja Sommerfelt, Martina Schüßler-Lenz

Scope: feedback from the CAT-COMP working group of 13 July 2020

Action: for information

A short feedback was provided from the discussion at the CAT-COMP working group meeting, which was held on 13 July 2020.

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 Rapporteurs: Marcos Timón, Tiina Palomäki, Martina Schüßler-Lenz

Scope: revision incorporating the comments received during the public consultation

Action: for discussion

The Rapporteurs presented the changes that were made to the guideline text based on the comments received during the public consultation. The non-clinical part was presented , on behalf of the non-clinical Rapporteur.

One remaining point in the non-clinical section will be addressed in parallel with the comments from the CAT members. On the clinical part, 2 questions were discussed: dose selection (in case of limited relevant non-clinical data) and the use of surrogate endpoints. It was agreed that the clinical experts will closely review these 2 issues.

A next version of the revised guideline, incorporating additional changes to the clinical part and with an updated section 8 (Environmental risk assessment), will be circulated to all CAT members. CAT and BWP members are asked to review the document and provide comments by 17 August 2020 .

7.3.2. White paper from Alliance of Regenerative Medicine (ARM): use of master files and certification schemes for ATMP manufacturing in Europe

BWP: Sol Ruíz

Scope: feedback from the BWP discussion that took place at its June 2020 meeting

Action: for information

CAT noted the feedback from the June 2020 BWP discussion. BWP expressed concerns regarding the extension of the EDQM certification scheme and the use of master files for reagents / starting materials for ATMPs. A response to ARM will be prepared.

7.4. Cooperation within the EU regulatory network

7.4.1. European Commission's initiative on GMO requirements for medicines used for treatment/prevention of COVID-19

Scope: oral feedback from the European Commission's representative

Action: for information

The European Commission representative informed CAT of the adoption by the European Parliament and the Council of the Regulation (EC) 2020/1043 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19).

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1043&from=EN

The Commission representative also informed CAT that work on the interplay with the GMO authorities will continue. Also, this interplay between the GMO and pharmaceutical legislation will be addressed in the context of the Pharmaceutical Strategy.

7.4.2. Regulatory status of RNA products in the context of vaccines against COVID-19

Scope: European Commission's feedback and possible implications for ATMPs

Action: for information

The Commission representative informed the CAT on the feedback the Commission provided on a question from EMA on the status of RNA vaccines that are prepared fully synthetically. The Commission supported EMA's interpretation that RNA derived products should be considered as biologicals, even if not derived from a biological source: therefore, such products using for vaccination against COVID-19 can be considered vaccines.

The consequences of this position for ATMP was discussed. The question is if this would extend the ATMP definition also to synthetic RNAs (such as small interfering RNAs) or synthetic DNA oligonucleotides. It was proposed to organise a short discussion meeting to discuss such examples at bring this topic back at the next CAT meeting. Following CAT members agreed to provide their thoughts / some examples in advanced of this discussion meeting.

7.4.3. Inspection of manufacturers of viral vectors used as starting materials for genetically modified cells

Scope: updates on the inspection of manufacturers of viral vectors used as starting materials for genetically modified cells

Action: for discussion

EMA provided feedback from the interactions between the inspectors working group (IWG) and the European Commission on this topic, and explained the next steps. See point 7.4.4.

7.4.4. Viral vectors used in the production of genetically modified cells - principles of GMP

CAT: Martina Schüssler-Lenz

Scope: call for a drafting group to define *'Principles of GMP'*

Action: for nomination

The CAT chair provided an overview of all the previous discussion on this topic. The next steps would be to draft a document on the principles of GMP, against which the manufacturers of viral vectors used in the production of genetically modified cells can be audited by the ATMP manufacturers. It was agreed to draft this document in collaboration with CAT-BWP-IWG. Because of the urgency, it was proposed that work could be done in parallel in IWG and BWP/CAT. A final version should be ready by November 2020. The following CAT members will be part of this drafting group.

Post meeting note:
Work is already ongoing at IWG: once the first draft is available BWP/CAT will be invited to provide input and the final version will be adopted by IWG, BWP and CAT.

7.4.5. Good Clinical Practice (GCP) – 2020 inspections strategy

Action: for information

CAT agreed with the 2020 GCP inspection strategy.

7.4.6. European Union Network-Pharmacovigilance Oversight Group (EU-POG)

Scope: nomination received from CAT member Maura O'Donovan to join the EU-POG.

Action: for agreement of nomination

Note: former CAT member was Corina Spreitzer who resigned in March 2020

CAT appointed Maura O'Donovan as CAT representative in EU-POG.

7.5. Cooperation with international regulators

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

CAT: Martina Schüssler-Lenz

Scope: agenda for the teleconference to take place on 23 July 2020

Action: for discussion

The agenda for the upcoming ATMP cluster was agreed.

7.6. CAT work plan

7.6.1. CAT work plan 2020

CAT: Martina Schüssler-Lenz

Scope: overview of status of the 2020 work plan topic

Action: for discussion

An update was provided on the status of the 2020 CAT work plan. There was discussion on activities related to the topic of registry studies and related to the topic on medical devices/in vitro diagnostics.

7.7. Planning and reporting

No items

7.8. Others

7.8.1. Fee waiver for Scientific Advice for academia developing orphan medicines

Action: for information

https://www.ema.europa.eu/en/news/academia-developing-medicines-rare-diseases-receive-free-ema-scientific-advice

The information was noted.

8. Any other business

8.1. DIA Europe, virtual meeting, 29 June-03 July 2020

CAT: Martina Schüssler-Lenz

Scope: feedback on the contribution as panellist in the session on 2nd July: *'Bringing down barriers for access for gene and cell therapies in Europe'*

Action: for information

Feedback was provided by the CAT chair. There was a short discussion on registry studies and the possibility of more interaction of CAT with patient organisation, HTAs, reimbursement bodies and registry holders.

8.2. 2nd Joint DIA-EUCOPE workshop on ATMPs, Innovative Gene and Cell Therapies in the EU, virtual meeting, 27-28 May 2020

CAT: Ilona Reischl

Scope: feedback on the workshop

Action: for information

https://www.diaglobal.org/en/conference-listing/meetings/2020/06/cell-and-gene-therapy-workshop

Feedback was provided by EMA and Ilona Reischl. It is noted that in the current virtual format of these conference, a lot more questions are posed to the Regulators. These questions would be a good basis to take into account when preparing or updating guidelines. It was suggested to prepare some responses to common questions in advance.

8.3. CASSS: Cell and Gene Therapy Products, virtual symposium, 8-10 June 2020

CAT: Ilona Reischl

Scope: feedback on the contribution as session chair: *'Accelerated development'*

Action: for information

Feedback was provided by Ilona Reischl. This was a quality-oriented conference.

Date of next CAT meeting:

09-11/09/2020

9. Explanatory notes

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

Abbreviations / Acronyms

AAV: Adeno-Associated Virus

AR: Assessment Report

ATMP: Advanced Therapy Medicinal Product

BWP: Biologics Working Party

CAT: Committee for Advanced Therapies

CHMP: Committee for Medicinal Product for Human Use

COMP: Committee for Orphan Medicinal Products

CTFG: Clinical Trial Facilitation Group

DG: Drafting Group

EC: European Commission

EU NTC: European Union Network Training Centre

ERA: Environmental Risk Assessment

FDA: Food and Drug Administration

FL: Final Letter

GCG: Guideline Consistency Group

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Genetically-modified organism

GMP: Good Manufacturing Practice

GTMP: Gene Therapy Medicinal Product

HTA: Health Technology Assessment Bodies

HSPC: Hematopoietic Stem and Progenitor Cells

ITF: Innovative Task Force

JR: Joint Report

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Application

MAH: Marketing Authorisation Holder

MSC: Mesenchymal stem cells

PDCO: Paediatric Committee

PMDA(Japan)

PIP: Paediatric Investigation Plan

PL: Package leaflet

PRAC: Pharmacovigilance and Risk Assessment Committee #

PRIME: Priority Medicines

RMP: Risk Management Plan

RP: Reflection paper

RSI: Request for supplementary information

SAs: Scientific Advices

SAG-O: Scientific Advisory Group Oncology

SAWP: Scientific Advice Working Party

SR: Summary Report

SWP: Scientific Working Party

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

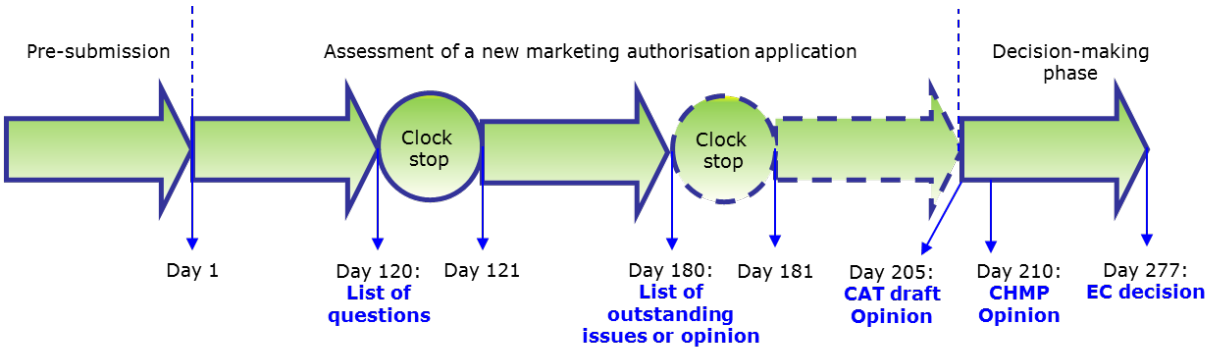
Evaluation of ATMPs (section 2)

This section lists applications for marketing authorisations of new Advanced Therapy Medicinal Products (ATMPs) that are to be discussed by the Committee. It also lists any ATMP related inspection requests (section 2.9) and Post-authorisation activities (section 2.10).

New applications (sections 2.1. to 2.12.)

Section 2.1 is for ATMPs nearing the end of the evaluation and for which the CAT is expected to adopt a draft **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CAT opinion is transmitted to the CHMP for final adoption. The CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU. More information on the evaluation of ATMPs can be found here.

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CAT. The clock stop happens after day 120 and may also happen after day 180, when the CAT has adopted respectively a **Day 120 list of questions** (section 2.3) or a List of outstanding issues to be addressed by the company, which is listed in the agenda under sections 2.7 (**Ongoing evaluation procedures**). Section 2.7 also includes the CAT discussions at any other timepoint of the evaluation procedure of new applications.

Oral explanation (section 2.2.)

Prior to adoption of the CAT opinion, marketing authorisation applicants are normally invited to the CAT plenary meeting to address questions raised by the Committee.

Oral explanations normally relate to ongoing applications, but they can also relate to any other issue for which the CAT would like to discuss with company representatives in person.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 (section 2.6.)

This section lists applications for new marketing authorisation for ATMPs for which the applicant has requested a re-examination of the opinion previously issued by the CHMP. Similar to the initial evaluation of a marketing authorisation of an ATMP, CAT will adopt a draft re-examination opinion, which is transmitted to the CHMP for final adoption.

Withdrawal of applications (section 2.7.)

This section includes information on marketing authorisation applications that are withdrawn by the applicant. Applicants may decide to withdraw applications at any stage during the assessment and a CAT opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

New applications (section 2.9.)

In this section, information is included on upcoming marketing authorisation applications for ATMPs, as well as information on appointment of Rapporteurs for new ATMP applications.

GMP and GCP Inspections Issues (section 2.10.)

This section lists inspections that are undertaken for ATMPs. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Post-authorisation activities (section 2.12.)

This section lists type II variations, extension application according to Annex I of Reg. 1234/2008, re-examination procedures for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP and other issues concerning authorised medicines that are not covered elsewhere in the agenda such as annual reassessments, 5-year renewals, supply shortages, qualify defects. Issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines, will also be included here.

Certification of ATMPs (section 3)

This section includes the scientific evaluation by the CAT of quality and non-clinical data that small and medium-sized enterprises have generated at any stage of the ATMP development process. More information on the ATMP certification procedure can be found here.

Scientific Recommendation on Classification of ATMPs (Section 4)

This section includes the scientific recommendation by the CAT on whether medicines based on genes, cells or tissues meet the scientific criteria that define ATMPs. More information on the ATMP classification procedure, including the outcomes of finalised classifications, can be found here.

Scientific Advice (section 5)

This section includes all scientific advice given to companies during the development of an ATMP. Information related to the number of ATMP related scientific advices discussed by CAT can be found in the CAT Monthly reports. Further information on SAWP can be found here.

Pre-Authorisation (section 6)

Paediatric Investigation Plan (PIP)

This section includes the discussion of an ATMP before a formal application for marketing authorisation

is submitted. These cases refer for example to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation: in case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

CAT contributes to the evaluation of a Paediatric Investigation Plan (PIPs) for ATMPs by the Paediatric Committee. These PIPs are included in this section of the Agenda.

ITF Briefing meeting in the field of ATMPs

This section refers to briefing meetings of the Innovation Task Force and International co-operations activities of the CAT

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes of meetings with applicants developing ATMPs and of other ITF meetings of interest to the CAT are included in this section of the agenda. Further information on the ITF can be found here.

Priority Medicines (PRIME)

This section includes the new requests for eligibility to PRIME for ATMPs under development, the discussions in CAT of these eligibility requests and the final recommendations for eligibility of ATMPs adopted by CHMP.

CAT will appoint one of its members as the CAT sponsor for each new ATMP eligibility request who will lead the CAT discussion based on the recommendation from the SAWP.

Organisational, regulatory and methodological matters (section 7)

This section includes topics related to regulatory and procedural guidance, CAT workplan, CAT meeting organisation (including CAT membership), planning and reporting, co-ordination with other committees, working parties and scientific advisory groups.

Furthermore, this section refers to the activities of the CAT drafting groups developing scientific guidelines for gene therapy medicinal products and for cell-based medicinal products, cooperation within the EU regulatory network and international regulators as well as direct interaction with interested parties. It also includes topics of scientific interest for the Committee that are not directly related to the work of the CAT drafting groups or CAT associated working parties.

Any other business (section 8)

This section is populated with miscellaneous topics not suitable under the previous headings.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/

10. List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 15-17 July 2020 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Martina Schüssler-Lenz	Chair	Germany	No interests declared	
Ilona Reischl	Member	Austria	No interests declared	
Claire Beuneu	Member	Belgium	No interests declared	
Belaïd Sekkali	Alternate	Belgium	No interests declared	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Petra Sokol	Alternate	Croatia	No interests declared	
Isavella Kyriakidou	Alternate	Cyprus	No interests declared	
Ivana Haunerova	Member	Czech Republic	No interests declared	
Anne Pastoft	Member	Denmark	No interests declared	
Toivo Maimets	Member	Estonia	No interests declared	
Pille Saalik	Alternate	Estonia	No interests declared	
Heli Suila	Member	Finland	No interests declared	
Violaine Closson	Member	France	No interests declared	
Nathalie Morgensztejn	Alternate	France	No interests declared	
Jan Mueller-Berghaus	Member (CHMP co-opted member)	Germany	No interests declared	
Egbert Flory	Alternate (to CHMP representative)	Germany	No interests declared	
Katalin Lengyel	Member	Hungary	No interests declared	
Maura O'Donovan	Member	Ireland	No interests declared	
Paolo Gasparini	Member	Italy	No interests declared	
Una Riekstina	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member (CHMP member)	Lithuania	No interests declared	
Vitalis Briedis	Alternate (to CHMP representative)	Lithuania	No interests declared	
John J. Borg	Member (CHMP member)		No interests declared	
Carla Herberts	Member	Netherlands	No interests declared	
Johannes Hendrikus Ovelgonne	Alternate	Netherlands	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Rune Kjeken	Member	Norway	No restrictions applicable to this meeting	
Dariusz Śladowski	Member	Poland	No restrictions applicable to this meeting	
Maria Isabel Borba Vieira	Alternate (to CHMP representative)	Portugal	No interests declared	
Simona Badoi	Member	Romania	No interests declared	
Lukas Slovak	Member	Slovakia	No interests declared	
Alexandra Padova	Alternate	Slovakia	No interests declared	
Metoda Lipnik-Stangelj	Member	Slovenia	No interests declared	
Sol Ruiz	Member (CHMP co-opted member)	Spain	No interests declared	
Marcos Timón	Alternate (to CHMP representative)	Spain	No interests declared	
Lisbeth Barkholt	Member	Sweden	No interests declared	
Bernd Gänsbacher	Member	Healthcare Professionals' Representative	No interests declared	
Alessandra Renieri	Alternate	Healthcare Professionals' Representative	No interests declared	
Lydie Meheus	Alternate	Patients' Representative	No interests declared	
Kieran Breen	Member	Patients' Representative	No restrictions applicable to this meeting	
Roland Pochet	Alternate	Patients' Representative	No interests declared	
Brigitte Anliker	Expert	PEI-DE	No restrictions applicable to this meeting	Brigitte Anliker
Juliane Rau	Expert	PEI-DE	No restrictions applicable to this meeting	Juliane Rau
Kirstine Moll Harboe	Expert	DKMA-DE	No interests declared	Kirstine Moll Harboe

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Eskild Colding Jørgensen	Expert	DKMA-DE	No restrictions applicable to this meeting	Eskild Colding Jørgensen
Ebru Karakoc Madsen	Expert	DKMA-DE	No restrictions applicable to this meeting	Ebru Karakoc Madsen
Louise F.S. Bang-Lauritsen	Expert	DKMA-DE	No interests declared	Louise F.S. Bang-Lauritsen
Barbara Bonamassa	Expert	AIFA-IT	No interests declared	
Wiebke Hoppensack	Expert	PEI-DE	No interests declared	
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.