EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 September 2019
EMA/CAT/633465/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 17-19 July 2019

Chair: Martina Schüßler-Lenz; Vice-Chair: Ilona Reischl

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in these minutes is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CAT meeting reports once the procedures are finalised.

Of note, the minutes are a working document primarily designed for CAT members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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1. Introduction

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

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

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

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 22 or more members were present in the room. No new or additional interests or restrictions were declared.

The CAT chair welcomed the new alternate from France (Nathalie Morgensztejn), the new member and alternates representing the patient organisations (Kerstin Sollerbrant Melefors (member), Lydie Meheus (alternate), Roland Pochet (alternate)) and the new alternate representing the clinicians (Alessandra Renieri), who attended the CAT for the first time.

1.2. Adoption of agenda

The CAT agenda for 17-19 July 2019 meeting was adopted with two additions: agenda point 7.5.2; Genome editing (regulatory considerations) (Agenda point 7.6.1).

1.3. Adoption of the minutes

The CAT minutes for 19-21 June 2019 meeting were adopted.

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

No items

2.4. Day 120 list of questions

No items

2.5. Day 80 assessment reports

No items

2.6. Update on ongoing initial applications

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

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

Scope: ad-hoc expert group meeting to take place on 3 September 2019. Update on the draft list of experts.

Action: for information

List of Outstanding Issues adopted on 21.06.2019, 14.09.2018, 25.05.2018. List of Questions adopted on 08.09.2017.

CAT was informed of the experts identified so far for the ad-hoc expert group meeting. Additional experts can still be proposed: the list of experts will be adopted in August 2019 via a written procedure.

CAT noted the changes introduced to the List of questions to the experts further to discussion in the CHMP during their June 2019 meeting.

2.6.2. Onasemnogene abeparvovec - Orphan - EMEA/H/C/004750

AveXis Netherlands B.V.; treatment of spinal muscular atrophy (SMA)

Scope: scientific advisory group (SAG-Neurology) meeting to take place on 6 September 2019. Update on the draft list of experts

Action: for information

List of Outstanding Issues adopted on 21.06.2019. List of Questions adopted on 22.02.2019.

The list of experts in the field of SMA to join the SAG-Neurology meeting was presented. The declared conflicts of interest of some of the experts were reviewed in line with the policy. The list of experts will be adopted in August 2019 via a written procedure.

Additional questions to the experts will be circulated to CAT for adoption via written procedure.

2.7. New applications

2.8. Withdrawal of initial marking authorisation application

No items

2.9. Re-examination of initial application procedures under Article 9(2) of Regulation No. 726/2004

No items

2.10. GMP and GCP inspections requests

No items

2.11. Type II variations - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

2.11.1. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0034

Amgen Europe B.V.

Rapporteur: Olli Tenhunen, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Safety: to update the RMP for Imlygic to version 7.0 in order to add 2 category 3 studies (Studies 20180062 and 20180099), as well as an internal evaluation of managed distribution process metrics, to evaluate the effectiveness of additional risk minimization measures (aRMM). Request for Supplementary Information (RSI)

Action: for information

CAT noted the RSI adopted by PRAC.

2.11.2. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0011

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality. Request for Supplementary Information (RSI)

Action: for adoption

The RSI was adopted.

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

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality. Opinion

Action: for adoption

Request for Supplementary Information adopted on 24.05.2019.

The type II variation was adopted.

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

MolMed S.p.A

Rapporteur: Carla Herberts; PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: proposal to terminate the study TK008 (specific obligation for the Conditional MA) and replace it with study TK013: request by the MAH for an extension of the clock stop to respond to the RSI

Action: for adoption

Request for Supplementary Information adopted on 24.05.2019.

Further to the discussion, CAT agreed with the extension of the clock stop to respond to the RSI.

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

MolMed S.p.A

Rapporteur: Carla Herberts; PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: update on annual renewal

Action: for discussion

2.12. Other Post-Authorisation Activities

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

Novartis Europharm Limited

Rapporteur: Rune Kjeken; CHMP Coordinator: Bjorg Bolstad

Scope: Quality

Action: for discussion

2.12.2. Luxturna – voretigene neparvovec – Orphan - EMEA/H/C/004451

Novartis Europharm Ltd.

Rapporteur: Sol Ruiz, Co-Rapporteur: Jan Mueller-Berghaus

Scope: query on the scope of a future variation application

Action: for discussion

2.12.3. The CAT discussed the request by the MAH for Luxturna and the supporting information Chimeric antigen receptor T-cell (CAR-T cell) products

CAT: Martina Schüßler-Lenz

Scope: feedback

Action: for information

The CAT chair provided feedback.

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

4.1.1. Platelet-Rich Stroma (PRS) - combination of platelet-rich plasma and stromal vascular fraction – H0005430

Intended for wound healing as additional therapy to fistula surgery in patients with complex and therapy refractory perianal fistula

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

Following CAT member was appointed as CAT coordinator

4.2. Day 30 ATMP scientific recommendation

4.2.1. Autologous, *ex vivo* expanded, clonal neoantigen specific tumour infiltrating lymphocytes – H0005417

Intended for the treatment of solid tumours

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 2 August 2019.

The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.2.2. Autologous CD34+ cells transduced with lentiviral vector encoding human γ-globinG16D and short-hairpin RNA734 – H0005415

Intended for the treatment of moderate to severe Sickle Cell disease

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 2 August 2019.

The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.2.3. Autologous tumour-infiltrating lymphocytes (TIL) – H0005414

Intended for the treatment of solid tumours

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 2 August 2019.

The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.2.4. CD34+ haematopoietic stem/progenitor cells enriched with normal mitochondria derived from white blood cells from a related donor - H0005416

Intended for the treatment of non-inherited mtDNA deletion syndromes

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 2 August 2019.

The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.2.5. Purified recombinant adeno-associated viral vector serotype 2 (AAV2) encoding the complementary DNA (cDNA) of human Rab escort protein type 1 (REP1) – H0005418

Intended for the treatment of choroideremia (CHM)

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 2 August 2019.

The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.3. Day 60 revised scientific recommendation (following list of questions)

4.3.1. uncapped, non-coding ribonucleic acid – H0005400/0001

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

Scope: assessment of the responses from the applicant. Revised ATMP scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report prepared by the CAT coordinator and the second ATMP classification report Further to the discussion, CAT agreed, by majority. The divergent positions, by the following CAT members, were attached to the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 2 August 2019.

The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.4. Finalisation of procedure

4.4.1. Modified Vaccinia Ankara-Bavarian Nordic- Brachyury (MVA-BN-Brachyury) and recombinant fowlpox virus (FPV-Brachyury) encoding the human brachyury gene and three human costimulatory molecules known as TRICOM (triad of costimulatory molecules): B7.1, intercellular adhesion molecule-1 (ICAM-1), and leukocyte function-associated antigen-3 (LFA-3) – H0005394/0001

Intended for the treatment of chordomaScope: editorial comments from European Commission. Final ATMP scientific recommendation

Action: for information

The information was noted.

4.4.2. Autologous CD34^{+} cells – H0005399/0001

Intended for the treatment of no-option critical limb ischemia

Scope: editorial comments from European Commission. Final ATMP scientific recommendation

Action: for information

The information was noted.

4.4.3. Messenger ribonucleic acid (mRNA) coding for coiled-coil domain-containing protein 40 (CCDC40) protein – H0005395/0001

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

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

Action: for information

The information was noted.

4.4.4. Autologous peripheral blood T cells CD4 and CD8 selected, and CD3 and CD28 activated transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured - H0005396/0001

intended for the treatment of various types of cancer

Scope: editorial comments from European Commission. Final ATMP scientific recommendation

Action: for information

The information was noted.

4.5. Follow-up and guidance

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

Intended for the treatment of phenylketonuria (PKU)

Scope: request for clarification

Action: for discussion

The applicant provided additional clarification, for CAT to reconsider the outcome of the classification of their product. CAT discussed and carefully reflected upon these additional clarifications. Further to the discussion, CAT concluded that the classification of this product should not be re-opened. CAT secretariat will provide the position of the CAT to the applicant.

5. Scientific Advice

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

5.1. New requests – appointment of CAT Rapporteurs

5.2. CAT reports

5.3. List of Issues

5.4. Finalisation of SA procedures

6. Pre-Authorisation Activities

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

6.1. Paediatric investigation plans

6.2. ITF briefing meetings in the field of ATMPs

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

6.3.2. Month 1 – Discussion of eligibility

No items

6.3.3. Month 2 – Recommendation of eligibility

6.3.4. Ongoing support

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT membership

United Kingdom: John Johnston – becomes member (swap of roles) from 03 July 2019
United Kingdom: Louise Bisset – new alternate. Membership mandate from 03 July 2019
United Kingdom: Christiane Niederlaender – membership ended on 30 June 2019

Action: for information

The information was noted.

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

CAT: Simona Badoi

Scope: feedback from the SRLM meeting

Action: for discussion

NB: a half day of this SRLM was held jointly with the CTFG.

A short oral feedback was provided. The minutes of the meeting will be available shortly.

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 June 2019 meeting

Action: for information

The information was noted.

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

No items

7.4. Cooperation within the EU regulatory network

7.4.1. Questions and Answers on the exemption from EU batch release testing for imported ATMPs

Scope: Questions and answers document

Action: for discussion

The Questions and Answers (Q&A) document in collaboration with the European Commission's representative was presented and the comments received from members of the CAT, BWP and the Good Manufacturing and Distribution Practice Inspectors working group (GMP/GDP IWG) were discussed.

The Q&A will be updated in the light of the CAT discussion and adopted via written procedure.

7.4.2. Environmental risk assessment of medicinal products containing /consisting of genetically modified organisms through the centralised procedure

Scope: Revised procedure for consultation

Action: for discussion

Note: the revised consultation procedure of GMO competent authorities was developed during the drafting groups on 4, 8 and 12 July. Following CAT members were involved: Margarida Menezes Ferreira, Carla Herberts, Rune Kjeken, Violaine Closson Carella, Jan Mueller-Berghaus
The revised procedure for consultation of GMO authorities for GTMPs was presented. CAT welcomed the streamlined procedure. The new procedure was endorsed by CAT. As a next step, EMA will present the procedure at CHMP (for GMO that are not ATMPs, such as recombinant vaccines) and thereafter the GMO competent authorities will be informed.

CAT asked EMA to update the procedural guidance that is included in the *Guideline on environmental risk assessment for medicinal products consisting of/or containing genetically modified organisms (GMOs)* (EMEA/CHMP/BWP/473191/2006 – Corr).

7.4.3. Handling of competing interests within the EU network

Scope: training session on handling of competing interests held by delegates

Action: for information

CAT members were reminded of the handling of competing interest of Committee members and experts. CAT members can consult EMA in case of doubt. The information was noted.

7.5. Cooperation with international regulators

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

The teleconference will take place on Thursday 18 July 2019, 15:00 - 16.00hrs

CAT: Martina Schüssler-Lenz

Scope: draft agenda

Action: for discussion

The ATMP cluster TC was cancelled due to technical problems.

7.6. CAT work plan

7.6.1. Genome editing technologies for drug development – regulatory considerations

CAT: Martina Schüssler-Lenz

Scope: CAT position on regulatory considerations for Genome editing (GE) technologies

Action: for information

It was recapitulated that CAT started in 2018 (as part of its 2018 Work plan) to develop a regulatory framework for both in-vitro and in-vivo GE technologies. It was concluded not to pursue this exercise and deal with the classification of GE technologies as part of normal ATMP classification requests.

7.7. Planning and reporting

None

7.8. Others

7.8.1. CAT regulatory session at the 2019 Annual Congress of the European Society of Gene and Cell Therapy (ESGCT), 25 October 2019, Barcelona (Spain)

CAT: Martina Schüssler-Lenz

Scope: proposal for the contents of the CAT session

Action: for discussion

Link to the ESCGT annual congress: https://www.esgct.eu/Congress/Barcelona-2019.aspx

Topic postponed until the September CAT meeting.

8. Any other business

8.1. EMA's move to the permanent building

Scope: update

Action: For information

CAT noted the information on the move of EMA to the permanent building.

Date of next CAT meeting:

11-13/09/2019

9. Explanatory notes

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

Abbreviations / Acronyms

AAV: Adeno-Associated Virus

AR: Assessment Report

ATMP: Advanced Therapy Medicinal Product

BWP: Biologics Working Party

CAT: Committee for Advanced Therapies

CHMP: Committee for Medicinal Product for Human Use

COMP: Committee for Orphan Medicinal Products

CTFG: Clinical Trial Facilitation Group

DG: Drafting Group

EC: European Commission

ERA: Environmental Risk Assessment

FDA: Food and Drug Administration

FL: Final Letter

GCG: Guideline Consistency Group

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Genetically-modified organism

GMP: Good Manufacturing Practice

GTMP: Gene Therapy Medicinal Product

HTA: Health Technology Assessment Bodies

HSPC: Hematopoietic Stem and Progenitor Cells

ITF: Innovative Task Force

JR: Joint Report

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Application

MAH: Marketing Authorisation Holder

MSC: Mesenchymal stem cells

PDCO: Paediatric Committee

PMDA: Pharmaceuticals and Medical Devices Agency (Japan)

PIP: Paediatric Investigation Plan

PL: Package leaflet

PRAC: Pharmacovigilance and Risk Assessment Committee #

PRIME: Priority Medicines

RMP: Risk Management Plan

RP: Reflection paper

RSI: Request for supplementary information

SAs: Scientific Advices

SAG-O: Scientific Advisory Group Oncology

SAWP: Scientific Advice Working Party

SR: Summary Report

SWP: Scientific Working Party

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

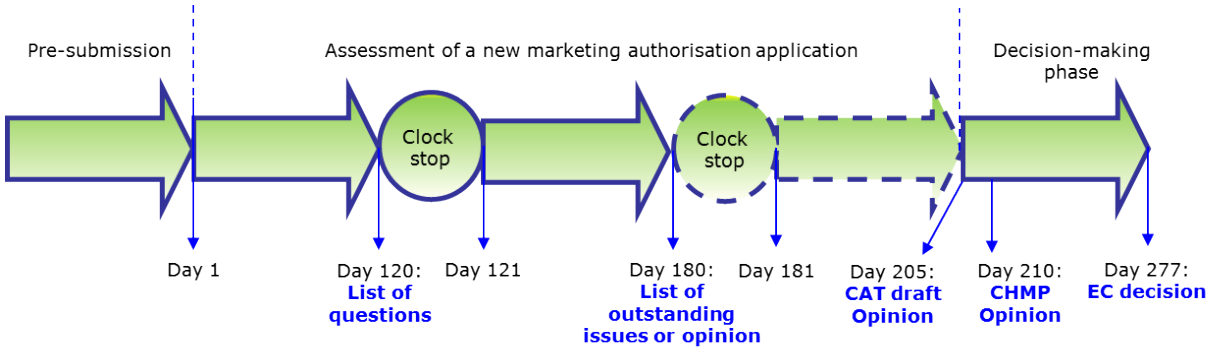
Evaluation of ATMPs (section 2)

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 17-19 July 2019 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Martina Schüssler-Lenz	Chair	Germany	No interests declared	
Ilona Reischl	Member	Austria	No interests declared	
Claire Beuneu	Member	Belgium	No interests declared	
Belaïd Sekkali	Alternate	Belgium	No interests declared	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Rafaella Pontou	Member	Cyprus	No interests declared	
Ivana Haunerova	Member	Czech Republic	No interests declared	
Anne Pastoft	Member	Denmark	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	
Angeliki Roboti	Alternate	Greece	No interests declared	
Katalin Lengyel	Member	Hungary	No interests declared	
Maura O'Donovan	Member	Ireland	No interests declared	
Niamh Curran	Alternate	Ireland	No restrictions applicable to this meeting	
Paolo Gasparini	Member	Italy	No interests declared	
Una Riekstina	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member (CHMP member)	Lithuania	No restrictions applicable to this meeting	
Guy Berchem	Member (to CHMP	Luxembourg	No restrictions applicable to this	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
	representative)		meeting	
Anthony Samuel	Alternate (to CHMP representative)	Malta	No interests declared	
Carla Herberts	Member	Netherlands	No interests declared	
Maja Sommerfelt Grønvold	Alternate	Norway	No restrictions applicable to this meeting	
Dariusz Śladowski	Member	Poland	No restrictions applicable to this meeting	
Margarida Menezes-Ferreira	Alternate (to CHMP representative)	Portugal	No interests declared	
Simona Badoi	Member	Romania	No interests declared	
Lukas Slovak	Member	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	
John Johnston	Member	United Kingdom	No interests declared	
Bernd Gänsbacher	Member	Healthcare Professionals' Representative	No interests declared	
Alessandra Renieri	Alternate	Healthcare Professionals' Representative	No interests declared	
Kerstin Sollerbrant	Member	Patients' 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	
Catherine Milne	Observer/Alternate	European Directorate for the Quality of Medicine & HealthCare(EDQM)	No interests declared	
Kristine Moltu	Expert - in person*	NOMA-NO	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Lotte Dahl	Expert - in person*	DKMA-DK	No interests declared	
Giuseppa Pistritto	Expert - in person*	AIFA-IT	No interests declared	
Therese Solstad Saunders	Expert - via telephone*		No interests declared	
Catherine Milne	Expert - in person*	EDQM		
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.