10 October 2018
EMA/CAT/868466/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for Advanced Therapies (CAT)

Minutes for the meeting on 12-14 September 2018

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

Health and safety information

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

Disclaimers

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

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

Note on access to documents

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

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1. Introduction

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

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

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

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

1.2. Adoption of agenda

The CAT agenda for 12-14 September 2018 meeting was adopted

1.3. Adoption of the minutes

The CAT minutes for 18-20 July 2018 meeting were adopted

1.4. August 2018 Written Procedure

The CAT minutes for the August 2018 Written Procedure were adopted

2. Evaluation of ATMPs

2.1. Opinions

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

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

Scope: Opinion

Action: for adoption

List of Outstanding Issues adopted on 20.07.2018, 25.05.2018. List of Questions adopted on 08.12.2017.

CAT adopted the draft opinion and the CAT assessment report.

2.2. Oral explanations

2.2.1. 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: Oral Explanation held on 12.09.2018

Action: for adoption

List of Outstanding Issues adopted on 25.05.2018. List of Questions adopted on 08.09.2017.

The CAT Rapporteurs presented their assessment of the responses to the list of outstanding issues. The BWP report was presented.

The applicant addressed the issues from the List of outstanding issues during the oral explanation.

The Rapporteurs updated their assessment report in the light of the CAT discussions and outcome. The second list of outstanding issues was adopted.

The response timetable will be agreed with the applicant. The response timetable will be included in the CAT minutes.

2.3. Day 180 list of outstanding issues

No items

2.4. Day 120 list of questions

No items

2.5. Day 80 assessment reports

No items

2.6. Update on ongoing initial applications

No items

2.7. New applications

2.7.1. Autologous CD34+ cells transduced with a lentiviral vector encoding the human βA-T87Q-globin gene (LentiGlobin-BB305) – Orphan – EMA/H/C/0003691

Bluebird bio France; Indicated for the treatment of transfusion-dependent beta-thalassaemia (also referred to as beta-thalassaemia major).

Scope: timetable for accelerated assessment

Action: for adoption

The information was noted.

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/0024

Amgen Europe B.V.

Rapporteur: Olli Tenhunen, CHMP Coordinator: Tuomo Lapveteläinen, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Opinion. Quality.

Action: for adoption

The opinion was adopted.

2.12. Other Post-Authorisation Activities

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

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

Rapporteur: Rune Kjeken, Co-Rapporteur: Christiane Niederlaender, Peer Reviewer: Dariusz Sladowski, CHMP Coordinators: Bjørg Bolstad and Greg Markey, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: quality

Action: for information

The Rapporteurs and the EMA secretariat 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

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Allogeneic EBV-specific cytotoxic T cells – H0005168

Intended for the treatment of refractory / relapsed EBV-associated post-transplant lymphoproliferative disease (PTDL)

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 bone marrow derived mesenchymal stem cells – H0005176

Intended for the treatment of ischemic stroke

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. Autologous bone marrow derived mesenchymal stem cells – H0005177

Intended for the regeneration of cartilage, ligamentum and bone and muscle defects

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

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

4.1.4. Codon-optimised human cystic fibrosis transmembrane conductance regulator messenger ribonucleic acid complexed with lipid-based nanoparticles – H0005161

Intended for the treatment of cystic fibrosis

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. Adeno-associated virus (AAV) vector containing a human CLN2 (hCLN2) expression cassette encoding for the soluble lysosomal enzyme TPP1 – H0005160

Intended for the treatment of late-infantile neuronal ceroid lipofuscinosis Type 2 (CLN2) disease

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. Genetically modified AAV9 expressing shRNA as well as a codon-optimised shRNA-insensitive wildtype PABPN1 - H0005142

Intended for the treatment of oculopharyngeal muscular dystrophy

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 28 September 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. Organ donor derived haematopoietic stem cells and defined dose of donor-derived immune cells - H0005143

Intended for the treatment of solid organ 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 28 September 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. Stromal vascular fraction - H0005151

Intended for the regeneration of epithelial fibrosis as a result of vulvar lichen sclerosis

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 28 September 2018.

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

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

No items

4.4. Finalisation of procedure

4.4.1. Adeno-associated viral vector serotype 2 containing a gene encoding the channelrhodopsin-2 protein - H0005112

Treatment of retinitis pigmentosa

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

Action: for information

The information was noted.

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

Action: for information

The information was noted.

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

Action: for information

The information was noted.

4.4.4. 5´capped single stranded messenger RNA encoding tumour specific neoantigens - H0005111

Intended for the treatment of locally advanced or metastatic tumors

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

Action: for information

The information was noted.

5. Scientific Advice

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

5.1. New requests – appointment of CAT Rapporteurs

5.2. CAT reports

5.3. List of Issues

5.4. Finalisation of SA procedures

6. Pre-Authorisation Activities

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

6.1. Paediatric investigation plans

No items

6.2. ITF briefing meetings in the field of ATMPs

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

6.3.2. Month 1 – Discussion of eligibility

6.3.3. Month 2 – Recommendation of eligibility

6.3.4. Ongoing support

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. Regulatory Science Engagement Plan to 2025

Scope: presentation of EMA's regulatory science engagement plan

Action: for discussion

The plan was presented jointly to CAT and COMP. This presentation was to make the Committees aware of the work in progress. Updates will be provided when the Plan is further developed.

7.1.2. Abolishment of physical signatures for divergent positions for centrally authorised products (CAPs)

Scope: The divergent position members will be approached to confirm the agreed final wording for the divergent position.

Action: for information

Note: this proposal has already been presented to the PRAC and CHMP

CAT agreed with the proposal.

7.2. Coordination with EMA Scientific Committees

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

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

Action: for information

The information was noted.

7.2.2. Scientific Coordination Board (SciCoBo) – meeting of 10 September 2018

CAT: Martina Schüßler-Lenz

Scope: feedback on the outcome of the SciCoBo meeting that took place on 10 September 2018

Action: for information

A short feedback was provided by the CAT chair.

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

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

Scope: updated guideline following comments from BWP/CAT

Action: for discussion

Further to the discussion in the July CAT meeting and comments from CAT members and the European Commission representative, the sections of the guideline regarding sterilisation of ATMPs were revised. CAT agreed with the revised text.

7.3.2. Working Party with Patients' and Consumers' Organisations (PCWP) and Working Party with Healthcare Professionals' Organisations (HCPWP)

Scope:
PCWP: draft agenda PCWP meeting 25 Sep 2018
PCWP/HCPWP: draft agenda joint PCWP/HCPWP meeting 25 Sep 2018
HCPWP: draft agenda HCPWP meeting 26 Sep 2018

Action: for information

The information was noted.

7.4. Cooperation within the EU regulatory network

7.4.1. ATMP training curriculum

CAT Curriculum Committee: Claire Beuneu (non-clinical); Lisbeth Barkholt (clinical)

Scope: guidance document on the organisation of the ATMP trainings

Action: for information

The practical guidance on the organisation of the trainings/ presentations in the context of CAT training curriculum was presented to the Committee.

Michelino Lipucci Di Paola was nominated as additional member of the Curriculum Committee together with Claire Beuneu (non-clinical area), Lisbeth Barkholt (clinical area) and Ilona Reischl.

7.4.2. European Commission - draft guidelines on good clinical practice for advanced therapy medicinal products

Scope: public consultation on draft guidelines on GCP for ATMPs.

Action: for information

Note: the European Commission - DG Health and Food Safety has launched an online targeted public consultation on the draft guidelines on good clinical practice for advanced medicinal products addressed particularly to small and medium-sized enterprises (SMEs), academia, hospitals and patient organisations. Comments are invited to be sent by 31 October 2018 to sante-pharmaceuticals-B5@ec.europa.eu.

https://ec.europa.eu/health/human-use/consultations/2018_gcp_atmp_en

CAT noted the information.

7.5. Cooperation with international regulators

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

CAT: Martina Schüßler-Lenz

Scope: draft agenda

Action: for discussion

During the ATMP cluster teleconference, topics of common interest were discussed or presented.

7.5.2. International pharmaceutical regulators forum (IPRF) - gene therapy working group (GTWG): publication of the reflection paper on expectations for biodistribution assessment for gene therapy products

Scope: reflection paper can be found in the IPRF website: https://www.i-p-r-f.org/index.php/en/news/gene-therapy-working-group-reflection-paper/ .

Action: for information

Note: this reflection paper was discussed and agreed at the February 2018 CAT meeting.

The information was noted.

7.6. CAT work plan

7.6.1. CAT meeting with Interested Parties, September 2018, EMA, London

EMA: Martina Schüßler-Lenz

Scope: meeting with interested parties to take place on 13 September 2018, at 15:15hrs

Action: for discussion

The meeting was attended by over 30 participants representing the CAT Interested Parties. Discussion on the following topics took place: guidelines under development, comparability for ATMPs, ATMP action plan, GMO assessment of ATMPs in clinical trials and GCP for ATMPs.

7.6.2. CAT 2019 work plan

CAT: Martina Schüßler-Lenz

Scope: updated CAT work plan 2019 (following July 2018 CAT discussion)

Action: for adoption

Additional CAT members volunteered for the different topics in the CAT work plan for 2019. With these additions, the CAT work plan was adopted.

7.6.3. Genome editing – scientific considerations

Scope: report from the ad hoc expert meeting of 18 October 2017

Action: for information

Note: the report will be published on the EMA website shortly.
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2018/07/event_detail_001672.jsp&mid=WC0b01ac058004d5c3

The information was noted.

7.6.4. Genome editing – regulatory considerations

Scope: Reflection on regulatory aspects of medicinal product based on or produced using genome editing technologies

Action: for discussion of next steps

A virtual drafting group will be organised to continue the reflection.

7.7. Planning and reporting

7.7.1. Planning estimates of forthcoming ATMP MAAs

Scope: Q3/2018 update of the business pipeline report for the human scientific committees

Action: for information

The information was noted.

7.8. Others

7.8.1. Global consultation on the review and update of the Changsha Communique on Xenotranplantation, 12 – 14 December 2018, Changsha, China

CAT: Martina Schüßler-Lenz

Scope: nomination of Ralf Tönjes (PEI-DE) as CAT representative at the Global consultation meeting

Action: for agreement

CAT nominated Ralf Tönjes as CAT representative at the Global Consultation meeting.

8. Any other business

8.1. International Conference of Drug Regulatory Authorities (ICDRA), 04 September 2018, Dublin, Ireland

CAT: Martina Schüßler-Lenz

Scope: Pre-ICDRA, workshop 8: 'Regulation of advanced therapies', 04 September 2018, Ireland. Summary of discussion and draft recommendation

Action: for information

A short feedback was provided by the CAT chair.

8.2. Telematics - Concept paper on strategy 2020-2025

Action: For discussion

The Telematics Concept paper was presented. Any comments from CAT members on the document are welcomed.

Date of next CAT meeting:
10-12/10/2018

9. Explanatory notes

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

Abbreviations / Acronyms

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

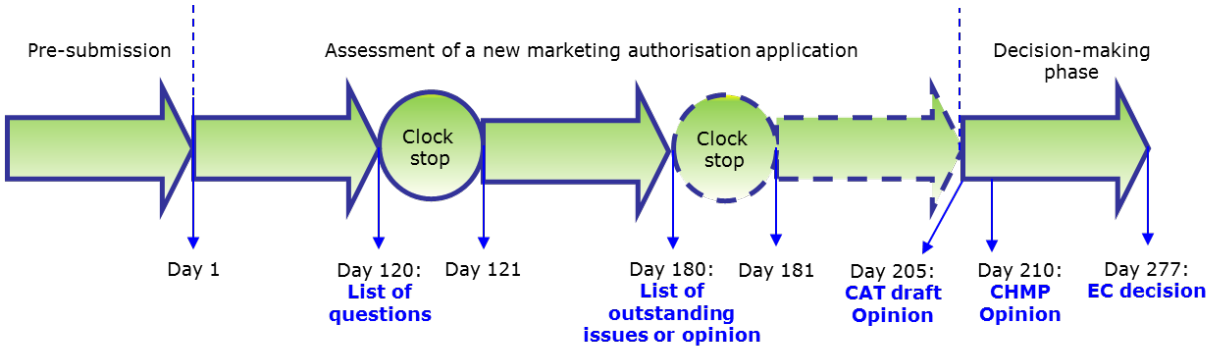
Evaluation of ATMPs (section 2)

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 12-14 September 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
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	N/A
Nenad Medic	Alternate	Croatia	No interests declared	N/A
Marina Ieridi	Member	Cyprus	No interests declared	N/A
Ivana Haunerova	Member	Czech Republic	No interests declared	N/A
Anne Pastoft	Alternate	Denmark	No interests declared	N/A
Toivo Maimets	Member	Estonia	No interests declared	N/A
Pille Saalik	Alternate	Estonia	No interests declared	N/A
Heli Suila	Member	Finland	No interests declared	N/A
Violaine Closson	Member	France	No interests declared	N/A
Jan Mueller-Berghaus	Member	Germany	No interests declared	N/A
Egbert Flory	Alternate	Germany	No interests declared	N/A
Asterios Tsiftsoglou	Member	Greece	No interests declared	N/A
Katalin Lengyel	Member	Hungary	No interests declared	N/A
Maura O'Donovan	Member	Ireland	No interests declared	N/A
Paolo Gasparini	Member	Italy	No interests declared	N/A
Giulio Pompilio	Alternate	Italy	No interests declared	N/A
Liga Saulite	Alternate	Latvia	No interests declared	N/A
Romaldas Mačiulaitis	Member	Lithuania	No interests declared	N/A
Guy Berchem	Member (to CHMP representative)	Luxembourg	No restrictions applicable to this meeting	N/A
Anthony Samuel	Alternate (to CHMP representative)	Malta	No interests declared	N/A
Johannes Hendrikus Ovelgönne	Member	Netherlands	No interests declared	N/A
Rune Kjeken	Alternate	Norway	No restrictions applicable to this meeting	N/A
Margarida Menezes-Ferreira	Alternate (to CHMP representative)	Portugal	No interests declared	N/A
Simona Badoi	Member	Romania	No interests declared	N/A
Lukas Slovak	Member	Slovakia	No interests declared	N/A

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Metoda Lipnik-Stangelj	Member	Slovenia	No interests declared	N/A
Sol Ruiz	Member (CHMP co-opted member)	Spain	No interests declared	N/A
Marcos Timón	Alternate, replacing CHMP member	Spain	No interests declared	N/A
Lisbeth Barkholt	Member	Sweden	No interests declared	N/A
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 restrictions applicable to this meeting	N/A
Kieran Breen	Member	Patients' Representative	No restrictions applicable to this meeting	N/A
Michelino Lipucci di Paola	Alternate	Patients' Representative	No restrictions applicable to this meeting	N/A
Maria Driessens	Member	Patients' Representative	No restrictions applicable to this meeting	N/A
Erik Briers	Alternate	Patients' Representative	No restrictions applicable to this meeting	N/A
Christos Sotirelis	Expert – In person*	Patients' Representative	No interests declared	N/A
Barbara Bonamassa	Expert – In person*	Italy	No interests declared	N/A
Giuseppa Pistritto	Expert – In person*	Italy	No interests declared	N/A
Tiina Palomäki	Expert – In person*	Finland	No interests declared	N/A
Wiebke Hoppensack	Expert – Via telephone*	Germany	No interests declared	N/A
Anke Zobywalski	Expert – Via telephone*	Germany	No interests declared	N/A
Susanne Poley-Ochmann	Expert – Via telephone*	Germany	No interests declared	N/A
Maren Hammann	Expert – Via telephone*	Germany	No interests declared	N/A
Juliane Rau	Expert – Via telephone*	Germany	No interests declared	N/A
Simona Stankevičiūtė	Expert – Via telephone*	Lithuania	No interests declared	N/A
Andreea Barbu	Expert – Via	Sweden	Indirect interests	N/A

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
	telephone*		declared	
Robert James Hemmings	Expert – Via telephone*	United Kingdom	No interests declared	N/A
Paula Boudewina van Hennik	Expert – Via telephone*	The Netherlands	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.