16 June 2016
EMA/CAT/472337/2016
Procedure Management and Committees Support Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 18-20 May 2016

Chair: Paula Salmikangas - Vice-chair: Martina Schüßler-Lenz

18 May 2016, 14:00 – 18:00, room 03-E
19 May 2016, 09:00 – 18:00, room 03-E
20 May 2016, 09:00 – 12:00, room 03-E

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 the 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 18 - 20 May 2016 was adopted.

1.3. Adoption of the minutes

The CAT minutes of 20 - 21 April 2016 were adopted.

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

2.2.1. Characterised viable haploidentical Herpes Simplex virus thymidine kinase (HSV-Tk) and human low affinity nerve growth factor receptor (ΔLNGFR) transfected donor lymphocytes; *Orphan*; EMA/H/C/002801

MolMed SpA; treatment of adjunctive treatment in haploidentical haematopoietic stem cell transplantation of adult patients with high-risk haematological malignancies

Scope: Oral explanation

Action: Oral explanation to be held on 18.05.2016 at 15:00hrs

Documents:

-Updated Rapporteurs report
-PRAC AR on the RMP on the responses to the 3rd LoOIs
-BWP report

3rd List of Outstanding Issues adopted on 23.03.16. Eight-month clock-stop agreed on 17.04.15. 2nd List of Outstanding Issues adopted on 22.01.16. 1st List of Outstanding Issues adopted on 20.03.15. List of Questions adopted on 18.07.14.

The CAT rapporteurs presented the assessment of the responses to the third list of outstanding issues.
At the oral explanation, CAT questioned the company .
After the oral explanation, CAT discussed the outstanding points.

CAT discussed the wording of the indication .
CAT discussed with the PRAC rapporteur the proposed Post authorisation safety study (PASS).
At the June CAT meeting, CAT will review the commitments of the marketing authorisation and the final product information before the adoption of the draft opinion for Zalmoxis.

2.3. Day 180 List of outstanding issues

No items

2.4. Day 120 Lists of questions

No items

2.5. Day 80 assessment reports

No items

2.6. Ongoing initial full application

No items

2.7. New applications

No items

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

2.11.1. ChondroCelect - Characterised viable autologous cartilage cells expanded *ex vivo* expressing specific marker proteins; EMEA/H/C/000878/II/0018/G

MAH: TiGenix NV

Rapporteur: Egbert Flory; Co-rapporteur: Tiina Palomäki; CHMP Coordinator: Jan Müller-Berghaus

Scope: submission of a revised RMP version 10 in order to add information resulting from the assessment of MEA16 and MEA18 in relation to the confirmatory randomized controlled trial in small lesions. Two potential risks 'transmission of infective agents' and 'allergic/hypersensitivity reaction' (from the recommendation of PSUSA/273/201504) are also added together with updated information in the RMP.

Action: adopted without plenary discussion

Document:
Opinion

The opinion was adopted.

2.12. Other post-authorisation activities

No items

3. Certification of ATMPs

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

3.1. Opinions

No items

3.2. Day 60 evaluation reports

No items

3.3. Ongoing initial application

No items

3.4. New applications

No items

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – appointment of CAT Co-ordinators

4.1.1. Live attenuated *Listeria monocytogenes* transfected with plasmids encoding HPV-16E7 protein fused to a truncated fragment of the *Lm* protein listeriolysin O

Intended for the treatment of cervical cancer

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for nomination of CAT Coordinator

Document:
Request received

Nominations were received. The CAT member was appointed as the CAT coordinator for this procedure.

4.1.2. Heterologous human adult liver-derived progenitor cells (HHALPC)

Intended for the treatment of liver diseases

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for nomination of CAT Coordinator

Document:
Request received

Note: In May 2011, CAT classified the same product for the indication 'treatment of inborn errors of liver metabolism' as a somatic cell therapy product

Nominations were received. The CAT member was appointed as the CAT coordinator for this procedure.

4.1.3. Autologous expanded human fibroblasts

Intended for the treatment of scar of different aetiology as post- traumatic, post-surgical or outcomes of acne scars

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for nomination of CAT Coordinator

Document:
Request received

Nominations were received. The CAT member was appointed as the CAT coordinator for this procedure.

4.1.4. Autologous concentrated bone marrow

Intended for critical limb ischemia without surgical option

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for nomination of CAT Coordinator

Document:

Request received

Nominations were received. The CAT member was appointed as the CAT coordinator for this procedure.

4.2. Day 30 Co-ordinators' first reports

4.2.1. Hepatitis B virus DNA vaccine delivered via electroporation

Intended for the treatment of chronic hepatitis B virus infection

Action: for adoption

Document:
ATMP classification report

CAT discussed the draft classification report. CAT decided to request some additional information from the applicant before concluding on this classification request.

4.2.2. Adeno-associated viral vector containing the ChrimsonR-td tomato gene

Intended for the treatment of retinitis pigmentosa

Action: for adoption

Document:
ATMP classification report

CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments
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 regulatory T lymphocytes $CD3^+CD4^+CD25^+CD127^-FoxP3^+$

Intended for the treatment of, and prevention of progression of, recently diagnosed paediatric type I diabetes mellitus

Action: for adoption

Document:
ATMP classification report

CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments
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. Allogeneic Epstein-Barr virus cytotoxic T lymphocytes

Intended for the treatment of Epstein-Barr virus-associated post-transplant lymphoproliferative disorder

Action: for adoption

Document:
ATMP classification report

CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments.
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 Co-ordinators' revised reports following List of Questions

4.3.1. Bone marrow derived mesenchymal stem cells

Intended for the treatment of children's encephalopathy, children's epilepsy, children's spinal cord injury

Action: for adoption

Document:
Revised ATMP classification report
Applicant's responses to LoQ

The CAT coordinator presented the responses provided by the applicant. CAT agreed with the conclusion of the CAT coordinator. The ATMP classification report will be finalised and send to the CAT members for adoption via written procedure.

CAT secretariat to send the draft scientific recommendation to the European Commission for comments.
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 procedures

4.4.1. Allogeneic bone marrow derived mesenchymal cells expanded *ex vivo* in synthetic media

Intended for the treatment of acute graft-versus-host disease grades III and IV resistant to first line treatment

Action: for adoption

Document:
Revised ATMP classification report

Comments received from the European Commission

The revised ATMP classification report was adopted.

4.4.2. Concentrate of autologous bone marrow-derived mononuclear cells (BM-MNC)

Intended for the improvement of heart function (left ventricular ejection fraction) and quality of life in patients with ischaemic post-acute myocardial infarction and in chronic heart disease

Action: for adoption

Document:
Revised ATMP classification report

Comments received from the European Commission

The revised ATMP classification report was adopted.

4.4.3. Live-attenuated, double-deleted *Listeria monocytogenes* (*Lm*) expressing human mesothelin

Intended for the treatment of non-small cell lung cancer

Action: for adoption

Document:
Revised ATMP classification report

Comments received from the European Commission

The revised ATMP classification report was adopted.

4.4.4. Live-attenuated, double-deleted *Listeria monocytogenes (Lm)* expressing prostate antigens

Intended for the treatment of prostate cancer

Action: for adoption

Document:
Revised ATMP classification report

Comments received from the European Commission

The revised ATMP classification report was adopted.

4.4.5. Autologous cultured fibroblasts

Intended for the indications of:
-Facial skin regeneration;
-Reducing facial wrinkles;
-Treatment of deep lines in the skin;
-Tissue loss and to heal chronic non-closing injuries;
-Treatment of acne scars

Action: for adoption

Document:
Revised ATMP classification report

Comments received from the European Commission

The revised ATMP classification report was adopted.

4.4.6. Extracellular matrix from adipose tissue

Intended for the treatment of non-healing wounds

Action: for adoption

Document:
Revised ATMP classification report

Comments from the European Commission

The revised ATMP classification report was adopted.

4.4.7. Adipose derived MSC

Intended for the treatment of non-healing wounds

Action: for adoption

Document:
Revised ATMP classification report

Comments from the European Commission
The revised ATMP classification report was adopted.

4.4.8. Autologous cultured chondrocytes

Intended for the treatment of filling of cartilage loss in knee-joint

Action: for adoption

Document:
Revised ATMP classification report

Comments received from the European Commission

The revised ATMP classification report was adopted.

4.4.9. Autologous cultured fibroblasts

Intended for the treatment of filling of skin connective tissue loss

Action: for adoption

Document:
Revised ATMP classification report

Comments received from the European Commission

The revised ATMP classification report was adopted.

4.4.10. Autologous cultured keratinocytes

Intended for the treatment of non-healing wounds, burns, trophic ulcers

Action: for adoption

Document:
Revised ATMP classification report

Comments from the European Commission

The revised ATMP classification will be adopted via a written procedure (alignment with the changes introduced in the classification report of Autologous cultured chondrocytes, see 4.4.8).

Post-meeting note: the report was adopted via a written procedure.

4.4.11. Autologous cultured myoblasts

Intended for the treatment of faecal and urinary incontinence and of skeletal muscle injury

Action: for adoption

Document:
Revised ATMP classification report

Comments received from the European Commission

The revised ATMP classification report was adopted.

4.4.12. Autologous cultured melanocytes

Intended for the treatment of vitiligo

Action: for adoption

Document:
Revised ATMP classification report

Comments received from the European Commission

The revised ATMP classification will be adopted via a written procedure (alignment with the changes introduced in the classification report of Autologous cultured chondrocytes, see 4.4.8).

Post-meeting note: the report was adopted via a written procedure.

4.5. Follow-ups and guidance

4.5.1. Update to the legal disclaimer for ATMP classification reports

Action: for information

CAT agreed with the new legal disclaimer for the ATMP classification reports. The new disclaimer will read as follows: "The present scientific recommendation refers exclusively to the case as presented to the Agency without prejudice to future evaluations by the Agency. It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant."

5. Scientific Advice

Disclosure of 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 Co-ordinators

5.2. CAT Rapporteurs' reports

5.3. Lists of issues

5.4. Finalisation of Scientific Advice procedures

5.5. Follow-up of Scientific Advice procedures

No items

6. Pre-Authorisation Activities

Disclosure of 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 (PIP)

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

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. Strategic Review & Learning meeting

CAT-PDCO-CTFG joint Strategic Review & Learning meeting will take place in Utrecht, Netherlands on 1st-2nd June 2016 under the auspices of the Dutch Presidency of the Council of the European Union

CAT resources: Hans Ovelgönne

Scope: discussion/agreement on topics for the agenda (mainly for the CAT-only session)

Action: for discussion

Document**:**
Final draft of the agenda (CAT only session)

Note**:** CAT members are asked to send proposals for agenda topics

The Agenda of CAT only session was discussed. It was agreed to foresee more time for the topic on genome editing and also to take the opportunity to discuss the future revision of the guideline on genetically modified cells.

For the session with the CTFG, CAT will present an outline of the guideline under development on requirements for investigational ATMPs (see agenda point 7.6.1).

7.1.2. Good manufacturing practice (GMP) requirements for ATMPs

CAT drafting group members: Ivana Haunerova, Margarida Menezes-Ferreira, Guido Panté, Ilona Reischl, Paula Salmikangas, Belaid Sekkali, Marcos Timón, Christiane Niederlaender, Jurgen Scherer, M. Hoefnagel

Scope: feedback from the discussions in the drafting groups and next steps

Action: for information

The Commission representative provided feedback on the progress of the development of the GMP requirement for ATMPs. A large part of the document has already been discussed by the drafting group (composed of member of the CAT and the GMP inspectors working party). The document will be published for a second public consultation over the summer, with the aim to finalise it by end of 2016.

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 April 2016 meeting

Action: for information

Documents:
-Summary of Outcomes

The information was noted.

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

No items

7.4. Co-operation within the EU regulatory network

No items

7.5. Co-operation with international regulators

7.5.1. International Pharmaceutical Regulators Forum (IPRF) Gene therapy group

CAT resource: Paula Salmikangas

Scope: oral feedback from the teleconferences that took place on 7th January and 9th March 2016

Action: for information

Documents:
Agenda
Minutes

The role, composition and main topics discussed and under discussion at the IPRF gene and cell therapy groups was presented. Following CAT member will take part to the IPRF gene therapy group teleconferences and discussions: Björn Carlsson (replacing Nicolas Ferry).

Maura O'Donovan will take part in the IPRF cell therapy group telecons and discussions.

7.6. CAT Work Plan

7.6.1. Guideline on requirements for investigational ATMPs

CAT drafting groups: Tiina Palomäki (Rapporteur), Ilona Reischl (Rapp), Metoda Lipnik-Stangelj, Margarida Menezes Ferreira, Maura O'Donovan, Simona Badoi, Tomas Boráň, Christiane Niederlaender

Scope: Feedback from the drafting group meeting of 18th May 2016

Action: for information

Feedback on the progress of the development of this guideline was given. Adobe Connect drafting group meetings (separate for the Quality, Non-clinical and Clinical parts) will be organised in June/July 2016. Further feedback will be provided at the July CAT meeting.

7.7. Planning and reporting

No items

7.8. Others

No items

8. Any other business

No items

Date of next CAT meeting:
Thursday 16th to Friday 17th June 2016

9. Explanatory notes

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

Abbreviations / Acronyms

AR: Assessment Report

ATMP: Advanced Therapy Medicinal Product

BWP: Biologics Working Party

CAT: Committee for Advanced Therapies

CHMP: Committee for Medicinal Product for Human Use

COMP: Committee for Orphan Medicinal Products

DG: Drafting Group

EC: European Commission

FDA: Food and Drug Administration

FL: Final Letter

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Environmental Risk Assessment

GMP: Good Manufacturing Practice

HTA: Health Technology Assessment Bodies

HSPC: Hematopoietic Stem and Progenitor Cells

ITF: Innovative Task Force

JR: Joint Report

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Applicant

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

SA: Scientific Advice

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

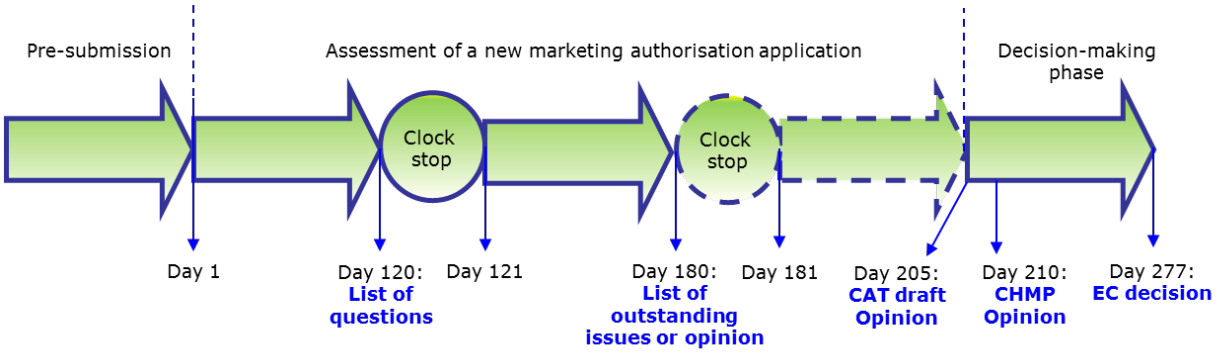
Evaluation of ATMPs (section 2)

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.

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/

List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 18-20 May 2016 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Paula Salmikangas	Chair	Finland	No interests declared	
Ilona Reischl	Member	Austria	No interests declared	
Evelina Shumkova	Alternate	Bulgaria	No interests declared	
Mirna Golemovic	Member	Croatia	No interests declared	
Ivica Malnar	Alternate	Croatia	No interests declared	
Tomáš Boráň	Member	Czech Republic	No interests declared	
Ivana Haunerova	Alternate	Czech Republic	No interests declared	
Nanna Aaby Kruse	Member	Denmark	No restrictions applicable to this meeting	
Toivo Maimets	Member	Estonia	No interests declared	
Tiina Palomäki	Member	Finland	No interests declared	
Violaine Closson	Alternate	France	No interests declared	
Egbert Flory	Alternate	Germany	No interests declared	
Asterios Tsiftsoglou	Member	Greece	No interests declared	
Krisztian Fodor	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 restrictions applicable to this meeting	
Guy Berchem	Alternate (to CHMP representative)	Luxembourg	No restrictions applicable to this meeting	
Anthony Samuel	Alternate (to CHMP representative)	Malta	No interests declared	
Johannes Hendrikus Ovelgönne	Member	Netherlands	No interests declared	
Rune Kjeken	Alternate	Norway	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
			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	
Mikuláš Hrubiško	Member	Slovakia	No restrictions applicable to this meeting	
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	
Lennart Åkerblom	Member	Sweden	No interests declared	
Björn Carlsson	Alternate	Sweden	No interests declared	
Christiane Niederlaender	Member	United Kingdom	No interests declared	
Pieter Doevendans	Member	Healthcare Professionals' Representative	No interests declared	
Esteve Trias-Adroher	Alternate	Healthcare Professionals' Representative	No interests declared	
Bernd Gänsbacher	Member	Healthcare Professionals' Representative	No interests declared	
Michelino Lipucci di Paola	Member	Patients' Representative	No restrictions applicable to this meeting	
Kieran Breen	Member	Patients' Representative	No restrictions applicable to this meeting	
Karri Penttila	Expert - in person*	Finland	No interests declared	
Violeta Stoyanova-Beninska	Expert - in person*	Netherlands	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Frauke Naumann-Winter	Expert - in person*	Germany	No interests declared	
Armando Magrelli	Expert - in person*	Italy	No interests declared	
Carla Herberts	Expert - via telephone*	Netherlands	No interests declared	
Sabine Straus	Expert - via telephone*	Netherlands	No interests declared	
Brigitte Keller-Stanislawski	Expert - via telephone*	Germany	No interests declared	
Ferran Torres	Expert - via telephone*	Spain	No restrictions applicable to this meeting	
Markus Funk	Expert - via telephone*	Germany	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.