18 September 2015
EMA/CAT/484983/2015
Procedure Management and Committees Support Division

Committee for Advanced Therapies (CAT)

Adopted Minutes for the meeting on 16-17 July 2015

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

Disclaimers

Some of the information contained in this set of 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, this set of minutes is a working document primarily designed for CAT members and the work the Committee undertakes.

Further information with relevant explanatory notes can be found at the end of this document.

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CAT plenary session to be held 16-17 July 2015.

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

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

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

The CAT chair welcomed Christiane Niederlaender as the new member for the UK, replacing Elaine French. The CAT chair thanked Elaine French for her contributions to the work of the CAT over the last years.

1.2. Adoption of agenda

CAT agenda for 16-17 July 2015

The agenda was adopted.

1.3. Adoption of the minutes

CAT minutes for 18-19 June 2015

The minutes were adopted and will be published on the EMA website.

2. Evaluation of Advanced Therapies Medicinal Products (ATMPs)

2.1. Opinions

None

2.2. Oral explanations

None

2.3. D180 List of outstanding issues (LoOIs)

None

2.4. D120 Lists of questions (LoQs)

None

2.5. Day 80 assessment reports

None

2.6. Re-examination procedure (new applications) under Article 9(2) of Regulation No. 726/2004

2.6.1. Heparesc - allogeneic human heterologous liver cells; Orphan; EMA/H/C/003750

Cytonet GmbH & Co. KG.; treatment of urea cycle disorders

Action:
-for appointment of re-examination (Co-)Rapporteurs
-request for nominations for expert meeting following expertise: paediatrician and/or paediatric intensive care specialist with expertise in urea cycle disorders; paediatrician hepatologist with expertise in liver genetic diseases; surgeon with expertise in paediatric liver surgery; preclinical lab specialist with expertise in urea cycle disorders

Document(s) tabled:
Notification from the applicant dated 9th July 2015 requesting a re-examination and a SAG consultation

Note:
The CAT adopted in April 2015 a negative draft opinion.
The CHMP adopted in June 2015 a negative opinion.

CAT appointed Rapporteurs for the re-examination procedure:

Nominations for the expert meeting are awaited until 15 August 2015, taking into account the required expertise as mentioned above.

CAT noted the provisional re-examination evaluation timetable, which will be adopted via written procedure when finalised.

2.7. Withdrawal of initial full application

None

2.8. Ongoing initial full application

2.8.1. Talimogene laherparepvec; EMA/H/C/0002771

Intended for the treatment of adults with melanoma that is regionally or distantly metastaticKimmo Jaakkola

Scope: Feedback from CHMP discussion

Action: for information

Document tabled:
List of Questions to the Scientific Advisory Group-Oncology (SAG-O) (for information)

Note:

The CAT issued a classification as a gene therapy medicinal product in July 2012
The Scientific Advice Working Party (SAWP) gave advices in 2008 and 2013

The CAT rapporteur provided feedback from the discussion at the June CHMP meeting. CHMP agreed with the List of outstanding issues and the list of questions to the SAG-O but decided to add a further question.

CAT members can still propose expert for the SAG-O: experts with experience with oncolytic viruses would be beneficial. The list of additional experts for the SAG-O will be finalised in the next week and will then put to the CAT for adoption via written procedure.

2.9. New applications

2.9.1. Expanded adipose-derived stem cells of allogeneic origin; *Orphan*; EMA/H/C/0004258

TiGenix S.A.U.; treatment of complex perianal fistulas in adult patients

Action: for information

Note:
The CHMP granted at its June 2015 plenary eligibility as a centralised product under Art. 3(1) Indent 1a ATMP Regulation (EC) 126/2004

CAT noted this information.

2.10. GMP and GCP inspections requests

None

2.11. Type II variations

2.11.1. Glybera – alipogene tiparvovec; *Orphan*; EMA/H/C/002145/II/34

UniQure Biopharma B.V.; Scope: submission of final study report CT-AMT—011-02

Rapporteur: C. Niederlaender; CHMP Coordinator: G. Markey

Action: for adoption

Document(s) tabled:
Revised Assessment Report
Request for Supplementary Information

The CAT Rapporteur presented the revised assessment reports for Glybera variation II/34. CAT adopted the RSI, requesting changes to the SmPC and PL.

CAT adopted the response timetable.

2.11.2. Glybera – alipogene tiparvovec; *Orphan*; EMA/H/C/002145/II/37-G

UniQure Biopharma B.V.; Scope: PI update section 4.8 and 5.1 (five years FU of final CSR study 011.01) and FU of 011.3

Rapporteur: C. Niederlaender; CHMP Coordinators: G. Markey

Action: for adoption

Document(s) tabled:
Revised AR
RSI

The CAT Rapporteur presented the revised assessment reports for Glybera variation II/37-G. CAT adopted the RSI, requesting changes to the SmPC and PL.

CAT adopted the response timetable.

2.11.3. Glybera – alipogene tiparvovec; *Orphan*; EMA/H/C/002145/II/38

UniQure Biopharma B.V.; Scope: PI update section 5.1 (final CSR study 011.05) (FU of 011.03)

Rapporteur: C. Niederlaender; CHMP Coordinator: G. Markey

Action: for adoption

Document(s) tabled:
Revised AR
RSI

The CAT Rapporteur presented the revised assessment reports for Glybera variation II/38. CAT adopted the RSI, requesting changes to the SmPC and PL.

CAT adopted the response timetable.

2.12. Other post-authorisation activities

None

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. New applications

None

3.2. Day 60 evaluation reports

None

3.3. Opinions

None

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – appointment of CAT Co-ordinators

This procedure does not run in August. Next deadline for submission of requests: 30.07.15.

4.2. Day 30 Co-ordinators' first reports

4.2.1. Adeno-associated virus vector serotype rh10 encoding human factor IX

Intended for the treatment of patients with moderate/severe to severe factor IX deficiency, i.e. moderate/severe to severe haemophilia B

Action: for adoption

Document tabled:
Coordinator's Classification report

CAT discussed the coordinator's 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 Commission. The final report will be sent thereafter to the Applicant.

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

Intended to improve limb perfusion/restore blood flow to previously ischemic tissue, and improve the mobility and quality of life (QoL) of patients with peripheral artery disease (PAD) and critical limb ischemia (CLI)

Action: for adoption

Document tabled:
Coordinator's Classification report

CAT discussed the coordinator's 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 Commission. The final report will be sent thereafter to the Applicant.

4.3. Finalisation of procedures

4.3.1. Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor

Intended for the treatment of various types of cancer

Action: for information

Document tabled:
ATMP Classification report

Note:

The European Commission raised no comments.

4.3.2. Human monocytes-derived suppressive cells (HuMoSC), expanded ex vivo

Intended for the treatment of acute Graft-versus-Host Disease refractory to first-line treatment

Action: for information

Documents tabled:
Revised ATMP Classification report
Letter from the European Commission dated 29.06.15.

Note:
The European Commission requested a clarification and raised an editorial comment; these do not require re-adoption of the classification report.

The revised report was noted.

4.4. Follow-ups and guidance

None

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 scientific advices – appointment of CAT Rapporteur

5.2. CAT Rapporteurs' reports

5.3. Lists of issues

5.4. Finalisation of Scientific Advice procedures

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)

None

6.2. Innovation Task Force (ITF) briefing meetings in the field of ATMPs

None

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. Strategic Review & Learning meeting

CAT-CHMP joint Strategic Review & Learning meeting (formerly known as Informal meeting) took place in Ljubljana (Slovenia) on 27th-28th May 2015 under the auspices of the Latvian Presidency of the Council of the European Union

CAT resources: Metoda Lipnik-Stangelj, Una Riekstina

Scope: feedback from the meeting

Action: for discussion

See also

Feedback was provided from the meeting, as well as the actions arising (see agenda points 7.3.7., 7.4.2. and 7.4.4.). A questionnaire will be sent to CAT members (those that attended and those that did not) on the value of this type of meetings, the relevance of the agenda topics, the reasons for attending/non-attending etc. The will allow to improve future Strategic Review & Learning meetings.

7.1.2. CAT membership

UK: Christiane Niederlaender – new member nominated on 1st July 2015
UK: Elaine French – termination of mandate for member on 30th June 2015

Action: for information

The information was noted.

7.2. Coordination with EMA Scientific Committees

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

Summary of Outcomes (SoO) for the June 2015 meeting

Action: for information

The information was noted.

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

7.3.1. Good Laboratory Practice (GLP) requirements for non-clinical studies of Advanced Therapy Medicinal Products

Action: for discussion

Note:
The EMA Good Laboratory Practice (GLP) Inspectors Working Group (IWG) gave a presentation to CAT in June 2015 on GLP requirements for ATMPs.
Following CAT members agreed to prepare a document on CAT expectations and experience on GLP requirements for ATMPs: U. Riekstina, T. Palomäki, E. Flory, Netherlands (H.

Ovelgönne proposing for Carla Herberts to join the group), Portugal (M. Menezes-Ferreira proposing Isabelle Vieira).

The group will work via e-mail and will report back to the CAT in September 2015.

7.3.2. Scientific Co-ordination Board (SciCoBo) - meeting 26th June 2015

Action: for information

The CAT chair provided feedback from the SciCoBo discussions.

7.3.3. Post-authorisation efficacy studies (PAES) - Scientific guidance

Action: for discussion and comments

Note:

The aim of this draft is to provide scientific guidance for MAHs and NCAs on the general need for such studies including within the scope of Delegated Regulation (EU) No 357/2014, on general methodological considerations, on specific situations and on study conduct. Following its adoption by the EMA Scientific Committees the draft guidance will be released for public consultation (foreseen Q4 2015).

The draft guidance was presented. Written comments are expected from CAT members by the end of the deadline. The revised guideline will be presented to the committee before the launch of the external consultation.

7.3.4. EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP)

Scope: workshop on risk minimisation measures to take place on 16th September 2015
Scope: joint meeting to take place on 17th September 2015

Action: for information

The information was noted.

7.3.5. Pharmacovigilance: information systems and services

Update on projects which are currently being implemented to deliver the IT systems required by, or needed to support the business activities of, the new pharmacovigilance legislation.

Action: for information

A presentation was given to CAT on the information systems that are in place or will become operational.

7.3.6. Enhanced early dialogue to foster development and facilitate accelerated assessment

Scope: nomination of CAT members to review the document and prepare comments

Action: for discussion

Tabled document**:**
Concept document

Note:

-A group of CHMP sponsors and EMA representatives has been formed to elaborate a scheme to reinforce early dialogue and regulatory support to stimulate innovation, optimise development and enable accelerated assessment of new medicines addressing major public health needs in the current regulatory framework.
The outcome of the discussions and considerations of this group formed the basis of the proposal

The Committee was informed of development of a new scheme that is designed to facilitate the development and accelerated assessment of innovative medicines of major public health interest, in particular from the viewpoint of therapeutic innovation.

Questions were posed related to the identification of and criteria for candidate products, the link with accelerated assessment and conditional marketing approvals, the positioning of this procedure vis-a-vis the adaptive pathway pilot, the fee incentives, and how to measure the success of this procedure. CAT members can provide comments in writing to the CAT secretariat.

7.3.7. Questions and Answers on minimally manipulated ATMPs

Feedback from the discussion that took place at the CAT-CHMP joint Strategic Review & Learning meeting, Ljubljana (Slovenia), May 2015

Action: for appointment of drafting group members

See also 7.1.1.

CAT members agreed to take part in the development of this Questions & Answers document. M. Lipnik Stangelj (Rapporteur), P. Salmikangas (Rapp), T. Palomäki, E. Flory, M. Menezes Ferreira, M. Hrubisko, P. Doevendans. A kick-off meeting will take place on Wednesday 16 September, afternoon.

7.4. Co-operation within the EU regulatory network

7.4.1. Good Manufacturing Practice (GMP) requirements for ATMPs

CAT drafting group members: I. Haunerova, M. Menezes-Ferreira, G. Panté, I. Reischl, P. Salmikangas, B. Sekkali, M. Timón, Jürgen Scherer, Marcel Hoefnagel

Scope: feedback on the meeting held on 7th July with the GMP inspectors

Action: for information

Tabled document**:**
Draft guideline

Feedback was provided by the Drafting group members on the interactions with the GMP inspectors. The feedback provided by the CAT drafting group and the GMP inspectors will allow the European Commission to prepare a consultation document, that will be released for external consultation by the end of July 2015. Both groups will be involved in the latter part of 2015 and 2016 in the finalisation of the GMP document.

7.4.2. Drafting group for the guideline on requirements for Investigational ATMPs

CAT resources: Paula Salmikangas, Tiina Palomäki, Ilona Reischl

Scope: discussion on the survey targeting the clinical trial authorisation (CTA) assessors and to draft the guideline. For the guideline development, two drafting groups needed, one for gene therapy and another for cell-based therapies, each consisting experts for quality, nonclinical and clinical

Action: feedback from the discussion in the Strategic Review & Learning meeting – Ljubljana and appointment of DG members

CAT members interested to join the drafting of this guideline should inform the CAT Secretariat.

See also 7.1.1.

Following CAT members agreed to take part in the development of this guideline: T Palomäki (Rapporteur), I Reischl (Rapp), M Lipnik-Stangelj, M Menezes Ferreire, M O'Donovan, N Ferry, S Badoi, T Boran. A kick-off meeting will take place on Wednesday 16 September, afternoon. The survey to gather information from assessors of clinical trials on the guidance they apply when reviewing clinical trial applications will be further discussed at the September CAT meeting.

7.4.3. European Food Safety Authority (EFSA) - Draft guidance on uncertainty in scientific assessment

Scope: nomination of CAT members to review the document and prepare comments

Guidance on uncertainty in EFSA Scientific Assessment
http://www.efsa.europa.eu/en/consultations/call/150618.pdf
http://www.efsa.europa.eu/en/consultations/call/150618.htm

Action: for information

Note:

EFSA's Scientific Committee has developed this guidance document to offer a tool-box of methodologies – both quantitative and qualitative – for analysing scientific uncertainties in all its scientific assessments. EFSA invites input on this draft from other scientific advisory bodies as well as academic or applied experts in uncertainty analysis, particularly on the proposed methods contained in the tool box.

T. Boráň agreed to look into the document and provide comments by the deadline.

7.4.4. Analysis of European Clinical Trials Database (EudraCT)

CAT resources: Margarida Menezes-Ferreira, Ilona Reischl, Tomáš Boráň

Scope: Analysis of EudraCT for trials with ATMPs

Action: for discussion

See also 7.1.1.

Feedback was provided by T. Boráň and M. Menezes Ferreira on data on clinical trials with ATMPs, extracted from EudraCT. Further data cleaning will now the conducted. It was agreed to perform an initial analysis of the data in the margins of the September CAT meeting and to report back to the CAT at their September or October plenary meeting.

7.5. Co-operation with international regulators

7.5.1. International Pharmaceutical Regulators Forum (IPRF), New Orleans (USA), 13-16 May 2015

CAT resources: Nicolas Ferry

Scope: Feedback on IPRF Cell Therapy and Gene Therapy Groups

Scope: Feedback from the IPRF - Gene Therapy Working Group meeting (N. Ferry)

Action: for information

Postponed to the September CAT meeting

7.5.2. Therapeutics Goods Administration (TGA) – Department of Health, Australia Government. Consultation: regulation of autologous stem cell therapies

Scope: The TGA is considering whether the regulation applied to some autologous cells is appropriate.

https://www.tga.gov.au/consultation/consultation-regulation-autologous-stem-cell-therapies#documents

Action: for information

Document table:
Regulation of autologous stem cell therapies – discussion paper for consultation (version 1.0, Jan. 2015)

7.6. Contacts of the CAT with external parties and interaction with the Interested Parties to the Committee

None

7.7. CAT Work Plan

7.7.1. CAT Work Plan 2015

Scope: review of progress

Action: for discussion

CAT reviewed the progress of the CAT Work Plan (WP) projects for this year.

For the Webinar on ATMP classification, it was agreed to arrange that on Wednesday 11 November (afternoon). Preparatory discussions to take place in the margins of the September CAT meeting.

For the Assessor training (scheduled in 2016), it was proposed to arrange an adobe connect preparatory meeting in the beginning of October 2015 to discuss the topics for the agenda. Following CAT members to be involved: M. Menezes-Ferreira, P. Salmikangas, M. Schüßler-Lenz, S. Badoi, D. Sladowski.

7.7.2. CAT Work Plan 2016

Scope: identification of topics for next year

CAT resources: Paula Salmikangas

Action: for discussion

CAT proposed and discussed possible topics for inclusion in the CAT work plan for 2016**.** Further discussion and identification of projects, topic leaders and CAT participants for the different projects/topics will take place at the September CAT meeting.

7.7.3. CAT-ISCT Joint Workshop: *'Challenges and Opportunities for the Successful Development and Approval of Advanced Therapy Medicinal Products'*, Seville (Spain), Friday 25th September 2015, 14:15 – 18:45

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/06/news_detail_002357.jsp&mid=WC0b01ac058004d5c1

Action: for information

7.8. Planning and reporting

None

7.9. Others

8. Any other business

Date of next CAT meeting:
Thursday 17th – Friday 18th September 2015

9. Explanatory notes

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

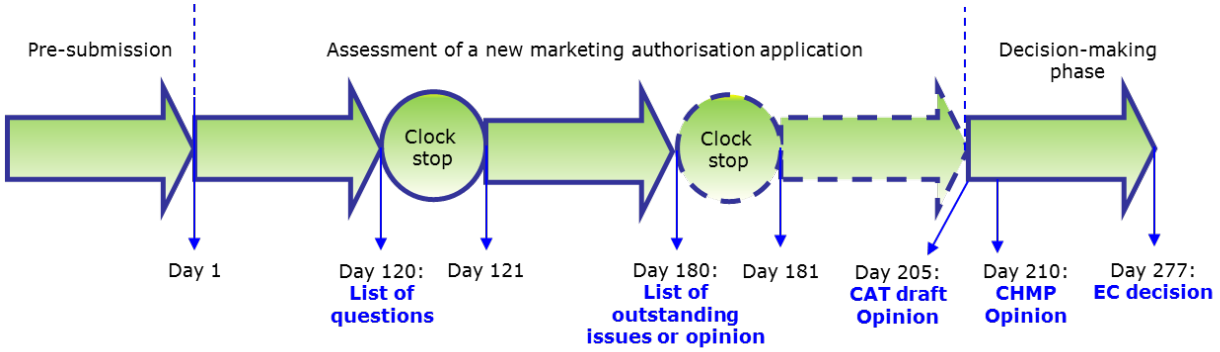
Evaluation of ATMPs (section 2)

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 17-18 July 2015 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	
Claire Beuneu	Member	Belgium	No interests declared	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Ivica Malnar	Alternate - replacing member	Croatia	No restrictions applicable to this meeting	
Tomáš Boráň	Member	Czech Republic	No interests declared	
Nanna Aaby Kruse	Alternate - replacing member	Denmark	No restrictions applicable to this meeting	
Tiina Palomäki	Member	Finland	No interests declared	
Olli Tenhunen	Alternate	Finland	No restrictions applicable to this meeting	
Nicolas Ferry	Member	France	No interests declared	
Martina Schüssler-Lenz	Member (Vice-Chair)	Germany	No interests declared	
Egbert Flory	Alternate	Germany	No interests declared	
Krisztian Fodor	Member	Hungary	No interests declared	
Maura O'Donovan	Member	Ireland	No interests declared	
Maeve Lally	Alternate	Ireland	No restrictions applicable to this meeting	
Paolo Gasparini	Member	Italy		
Una Riekstina	Member	Latvia	No interests declared	
Johannes Hendrikus Ovelgönne	Member	Netherlands	No interests declared	
Rune Kjeken	Alternate - replacing member	Norway	No restrictions applicable to this meeting	
Dariusz Śladowski	Member	Poland		

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Margarida Menezes-Ferreira	Alternate (to CHMP represenative)	Portugal	No interests declared	
Gianina-Nicoleta Andrei	Alternate	Romania	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 represenative)	Spain	No interests declared	
Lennart Åkerblom	Member	Sweden	No interests declared	
Christiane Niederlaender	Member	United Kingdom	No interests declared	
Pieter Doevendans	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Esteve Trias-Adroher	Alternate	Healthcare Professionals' Representative	No interests declared	
Ramadan Jashari	Alternate	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	
Wiebke Hoppe nsack	Expert	Germany	No restrictions applicable to this meeting	
John Johnston	Expert	United Kingdom	No interests declared	
Veronika Ganeva	Expert	United Kingdom	No restrictions applicable to this meeting	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the product(s) they have been invited to talk about.