EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 July 2014
EMA/CAT/449117/2014
Procedure Management and Business Support Division

Committee for Advanced Therapies (CAT)

Minutes of the 19 – 20 June 2014 meeting

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

Declaration on conflict of interest

In accordance with the Agency's revised Policy and Procedure on the handling of conflicts of interests, participants in this meeting were asked to declare any conflict of interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). No additional conflicts of interest were declared.
Discussions, deliberations and voting took place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of meeting. The discussion, deliberations and voting took place in the presence of 22 CAT members (quorum reached).

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regards to therapeutic indications listed against products, it must be noted that these may not reflect the full wording proposed by the applicant and may also vary during the course of the review. The procedures discussed at CAT are on-going and therefore certain aspects are considered confidential. Additional details on some of the procedures (for example the ATMP classification procedure) will be published in the CAT monthly report. For orphan medicinal products the product name and the applicant are published to be consistent with already publicly available information. Of note, this agenda 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 agenda/minutes cannot be released at present following a request for access to documents under 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. PLENARY RELATED DOCUMENTS

1.1. AGENDA (EMA/CAT/318496/2014) and **TIMESCHEDULE** (EMA/CAT/337347/2014) for the CAT plenary to be held on 19th and 20th June 2014: **for adoption**	Adopted
1.2. TABLE OF DECISIONS CAT plenary held on 15th and 16th May 2014 (EMA/CAT/301148/2014): **for information**	Noted
1.3. MINUTES of the CAT plenary held on 15th and 16th May 2014 (EMA/CAT/333504/2014): **for adoption**	Adopted
1.4. 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 of 19th – 20th June 2014: **for information**	*See June minutes (to be published post July 2014 CAT meeting)*

2. EVALUATION OF ATMPS

2.1. OPINION

No items on the agenda

2.2. ORAL EXPLANATION

No items on the agenda

2.3. LoOI

No items on the agenda

2.4. LIST OF QUESTIONS

No items on the agenda

2.5. DAY 80 ASSESSMENT REPORT

No items on the agenda

2.6. RE-EXAMINATION PROCEDURE (NEW APPLICATIONS)+UNDER ARTICLE 9(2) OF REGULATION No 726/2004

No items on the agenda

2.7. WITHDRAWAL OF APPLICATION

No items on the agenda

2.8. ONGOING EVALUATION PROCEDURES

2.8.1. (allogeneic human heterologous liver cells) (EMA/H/C/003750). Therapeutic indication: Treatment of urea cycle disorders. **For discussion:** ▪ Request from the applicant of 26th May 2014, requesting a three-month extension of the clock stop to respond to the D120 LoQs **For adoption:** ▪ Revised timetable to response to LoQs	CAT agreed with the extension of clock stop by 3 months. The revised response timetable was adopted.

2.9. NEW APPLICATIONS

2.9.1. (autologous CD34+ cells transduced with retroviral vector containing the adenosine deaminase gen), (EMA/H/C/H0003854).
Therapeutic indication: treatment of severe combined immunodeficiency due to adenosine deaminase deficiency. Indicated for the treatment of children aged 0-18 diagnosed with ADA-SCID and for whom no suitable HLA-identical sibling bone marrow donor is available. *Orphan*

For information:

- Nominations received for Rapporteurship:
- Nominations received for Co-rapporteurship:
- Nominations received for Peer reviewers:

2.10. GMP and GCP INSPECTIONS REQUESTS

No items on the agenda

2.11. POST-AUTHORISATION

2.11.1. Type II Variations

2.11.1.1. Glybera MAH: UniQure Biopharma B.V. (EMEA/H/C/002145/II/30)
Orphan
II/30
Scope: update of the protocol of the CM efficacy and safety study requested in Annex II

For discussion:

- Oral explanation by the MAH

For adoption

- Request for supplementary information

CAT Rapporteur: E. French (UK)
CHMP Co-ordinator: G. Markey (UK)

See also 2.11.2.1.

Oral explanation was held on Friday 20 June 2014

CAT noted the information provided by the MAH during the oral explanation on.

CAT adopted the second Request for Supplementary information for variation II/30 and the response timetable.

2.11.1.2. Glybera (EMEA/H/C/002145/II/33
MAH: UniQure Biopharma B.V.
Orphan
II/33
Scope: Quality.

For discussion/adoption:

- Draft opinion /RSI

CAT Rapporteur: E. French (UK)
CHMP Co-ordinator: G. Markey (UK)

CAT adopted the Request for Supplementary Information and the response timetable.

2.11.1.3. Glybera (EMEA/H/C/002145/II/05 MAH: UniQure Biopharma B.V. Orphan **II/05** *Scope*: ***Quality.*** **For adoption – no discussion required:** ▪ Draft opinion ▪ CAT draft AR	CAT Rapporteur: E. French (UK) CHMP Co-ordinator: G. Markey (UK) CAT adopted by consensus the draft opinion and CAT assessment report

2.11.2. Other PA Activities

2.11.2.1. Glybera (EMEA/H/C/002145) MAH: UniQure Biopharma B.V. *Orphan* **For discussion:**	CAT Rapporteur: E. French (UK) CHMP Co-ordinator: G. Markey (UK) See also 2.11.1.1. CAT noted the explanations given by the MAH on the course of actions taken
2.11.2.2. ChondroCelect (characterised viable autologous cartilage cells expanded *ex vivo* expressing specific marker proteins) (EMA/H/C/00878/R/09). MAH: TiGenix N.V. **Scope:** Five-year renewal **For adoption:** ▪ Draft opinion ▪ CAT draft AR	CAT Rapporteur: E. Flory (DE) CHMP Co-ordinator: J. Müller-Berghaus (DE) CAT adopted by consensus the Draft opinion and CAT draft AR for the 5-year renewal of ChondroCelect.
2.11.2.3. ChondroCelect (characterised viable autologous cartilage cells expanded *ex vivo* expressing specific marker proteins) MAH: TiGenix N.V. (EMA/H/C/00878/MEA 16.2) **Scope:** Randomised control trial protocol TIG/ACT/04/2009 **For information:** ▪ Reflection paper on chondrocyte products **For discussion:** ▪ Overview of comments received to the LoQs from the experts consultation (Healthcare Professional Organisations) **For adoption:** ▪ Draft AR of responses to the RSI	CAT Rapporteur: E. Flory (DE) CAT Co-Rapporteur: T. Palomäki CHMP Co-ordinator: J. Müller-Berghaus (DE) http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/05/WC500090887.pdf CAT discussed the draft AR of responses to the RSI. The finalisation of post-authorisation measure 16 and 18 was put hold awaiting the feedback from . CAT decided that for the moment no further information from the MAH is needed. CAT discussed the feedback provided by the Healthcare Professional Organisations. CAT thanks the organisations for their input. There is no need for further input from them. CAT proposes to open a bilateral dialogue with ICRS . See also 2.11.2.4.

2.11.2.4.	**ChondroCelect** (characterised viable autologous cartilage cells expanded *ex vivo* expressing specific marker proteins) MAH: TiGenix N.V. (EMA/H/C/00878/MEA 18.2) **Scope:** Non-interventional registry on the use of ChondroCelect to document the clinical effectiveness and safety outcome of treatment with ChondroCelect in real life in a patient population within the authorised indication **For discussion:** ▪ Overview of comments received to the LoQs from the experts consultation (Healthcare Professional Organisations) **For adoption:** ▪ Draft AR of responses to the RSI	CAT Rapporteur: E. Flory (DE) CAT Co-Rapporteur: T. Palomäki CHMP Co-ordinator: J. Müller-Berghaus (DE) See 2.11.2.3.
2.11.2.5.	**PROVENGE** (autologous peripheral blood mononuclear cells activated with pap-gm-csf (sipuleucel-T)). MAH: Dendreon UK Ltd. (EMA/H/C/002513/MEA 005) **Scope:** Interventional PASS Protocol P13-2, Phase 2 study of coagulation parameters in men with metastatic castrate-resistant prostate cancer who receive Sipuleucel-T] including statistical analysis plan **For adoption:** ▪ Timetable	CAT Rapporteur: E. Flory (DE) CHMP Co-ordinators: J. Müller-Berghaus (DE) The timetable was adopted.
2.11.2.6.	**MACI** [matrix-assisted autologous chondrocyte implantation]. MAH: Genzyme Europe BV. (EMA/H/C/002522) **For discussion:**	CAT Rapporteur: E. French (UK) CAT Co-Rapporteur: H. Ovelgönne (NL) CHMP Co-ordinators: G. Markey (UK) and J. Lodewijk Hillege (NL)

3. CERTIFICATION

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

4. SCIENTIFIC RECOMMENDATION ON CLASSIFICATION OF ATMPs

4.1. [concentrate of autologous, uncultured, custom prepared bone marrow aspirate]. Proposed indication: field of regenerative medicine: bone damaged by disease (e.g. ostenecrosis), fracture or age-related loss of bone function. **For discussion:** ▪ Comments received from the European Commission on 6 June 2014 **For adoption:** ▪ Revised ATMP Classification report	CAT noted the comments raised by the European commission and discussed the revised ATMP classification report. CAT proposed to delete one paragraph in the report. CAT adopted by consensus the amended, revised ATMP classification report. This product is a classified as a Tissue engineered product. The final report will be sent to the Applicant.
4.2. [an antiinfectious naked DNA vaccine encoding mutationinactivated E7-E6 fusion protein from Human Papillomavirus 16 linked to the human chemokine hMIP-1α via a dimerization module derived from human IgG3.]. Proposed indication: to prevent and treat HPV16 induced pre-malignancies and malignancies. **For discussion:** ▪ Response to the LoQ received on 3rd June 2014 **For adoption:** ▪ Revised ATMP Classification report	CAT discussed the revised ATMP classification report. CAT proposed to delete one paragraph in the report. CAT adopted by consensus the amended, revised ATMP classification report. This product is a classified as a CAT secretariat to send the draft scientific recommendation to the Commission for comments until 4 July 2014 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. [active substance (NTC8685-eRNA41H-Ubi-hTERT) is a double-stranded naked DNA plasmid of 7120 bp encoding an inactive human telomerase reverse transcriptase protein fused to ubiquitin (Ubi-hTERT)]. Proposed indication: immunotherapy (therapeutic DNA vaccination) for the treatment of various malignancies and the prevention of tumour relapse. **For adoption:** ▪ ATMP Classification report	CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. This product is a classified as a CAT secretariat to send the draft scientific recommendation to the Commission for comments until 4 July 2014 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.

4.4.	[an oncolytic virus derived from type 1 herpes simplex virus (HSV-1) by deletion of two genes (ribonucleotid reductase RR/ICP6, and gamma34.5) and re-insertion of one copy of gamma34.5 gene under expression control of b-myb transcription factor inserted upstream]. Proposed indication: treatment of advanced pancreatic cancer and / or unresectable hepatocellular carcinoma **For adoption:** ▪ ATMP Classification report	CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. This product is a classified as a CAT secretariat to send the draft scientific recommendation to the Commission for comments until 4 July 2014 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.
4.5.	[allogeneic peripheral blood mononuclear cells induced to an early apoptotic stage)]. Proposed indication: prevention of graft versus host disease. **For adoption:** ▪ ATMP Classification report	CAT agreed on the following question to be asked to the applicant before finalisation of the ATMP classification request
4.6.	[allogeneic expanded CD34+HSC issue from cord blood unit allogeneic lymphoid cells CD34- issue from cord blood unit]. Proposed indication: malignant hemopathies. **For information:** ▪ Request received on 27 May 2014 **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from: . The following CAT member was appointed as CAT co-ordinator
4.7.	[Autologous dendritic cells pulsed with tumour antigen-derived synthetic peptides]. Limited, USA. Proposed indication: treatment of glioblastoma **For information:** ▪ Request received on 27 May 2014 **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from: . The following CAT member was appointed as CAT co-ordinator

4.8. [AAV containing DNA encoding an RNAi targeting rhodopsin in combination with an AAV containing DNA encoding a rhodopsin gene]. Proposed indication: treatment of autosomal dominant rhodopsin-linked retinitis pigmentosa **For information:** ▪ Request received on 5 June 2014 **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from: . The following CAT member was appointed as CAT co-ordinator
4.9. [autologous bone marrow-derived progenitor cells in a suspension form for infusion]. Proposed indication: intended for chronic heart disease **For information:** ▪ Request received on 6 June 2014 **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from: . The following CAT member was appointed as CAT co-ordinator
4.10. [lysate of tumor cells associated to hydroxylapatite particles]. Proposed indication: intended for a therapeutic vaccine **For information:** ▪ Request received on 10 June 2014	
4.11. Reflection paper on classification of ATMPs: **for adoption for external consultation**	CAT adopted the revised reflection paper on classification of ATMPs. The reflection paper will be published on the EMA website for external comments until 31 October 2014.

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.

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 Plan (PIP)

No items on the agenda

7. ITF BRIEFING MEETINGS IN THE FIELD 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.

8. ORGANISATIONAL MATTERS

8.1. Regulatory and Procedural Guidance

8.1.1. Presentation on the Conflict of Interest revised policy: **for information**	Postponed until the July CAT meeting.
8.1.2. Multinational Assessment Teams for initial marketing authorisation applications. **For discussion:** ▪ Registry to list possible/available CAT-related expertise/resources in each MS for MN-teams	Postponed until the July CAT meeting.
8.1.3. Report from the European Commission to the European Parliament and the Council on the application of the ATMP Regulation: **for information**	Following CAT members expressed interest to take part in CAT reflection groups: - Quality related issues: - Risk based approach: Postponed until the July CAT meeting.

8.2. CAT Meeting Organisation

8.2.1. CAT Membership **For information:** ▪ Finland: Tiina Palomäki – new member nominated on 14th May 2014	Noted
8.2.2. CAT/CHMP/COMP joint informal meeting to be held in Rome on 28th – 30th October 2014 under the auspices of the Italian Presidency of the Council of the European Union **For information:** ▪ Feedback on topics for the agenda	CAT noted the revised agenda. CAT members to reflect on the topics proposed for the breakout session on 30 October 2014.

8.3. Co-ordination with Committees/WPs/SAGs

8.3.1. CHMP May 2014 ToD: **for information**	Noted
8.3.2. COMP June 2014 agenda: **for information**	Noted

8.4. CAT's Workplan

8.4.1. CAT Workplan 2015 **For discussion:** ▪ List of proposed topics	Link to the EMA Work Programme 2014: http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2014/03/WC500163394.pdf A presentation was given on how the Committee workplan for the next years will be developed. In order to facilitate the discussion during the July CAT meeting, CAT members were asked to provide items for the CAT work plan 2015 in advance of the July CAT meeting. An e-mail will be send to all CAT members: CAT input is requested by 11 July 2014.

9. CAT's DGs / PCWP and HCPWP

9.1. DG on GTMP Guidelines

9.1.1. Guideline on the quality, non-clinical and clinical aspects of gene therapy medicinal products **For discussion:** ▪ Comments received from Finland	CAT agreed to set up a drafting group to review the quality part of the guideline (to be held in the afternoon of Wednesday 16 July, at the end of the BWP): CAT proposed to invite for this drafting group. A drafting group on the non-clinical part will be organised on Thursday 17 July from 9.00 to 11.00: CAT proposed to invite . The clinical part will be finalised via a written procedure. Additional CAT members interested to take part in these drafting groups should inform and the CAT secretariat by 2 July 2014.

9.2. DG on CTMP and TEP Guidelines

No items on the agenda

10.OTHER SCIENTIFIC TOPICS

10.1. Regulation Forum Gene Therapy discussion Group (RFGTDG) **For information:** ▪ Agenda of the international telecon which took place in April 2014 ▪ Agenda of the international telecon to take place on 23 June 2014	Feedback from the two meetings will be given at the July CAT meeting.
10.2. EMA/CAT/FDA/Health Canada bimonthly teleconference on ATMP cluster **For adoption:** ▪ Agenda	CAT discussed and adopted the agenda.

11.A.O.B.

11.1. Project 2014: move to 30, Churchill Place, Canary Wharf **For information:** ▪ Last presentation ▪ Visit by the committee to the new building organised for Thursday 17th July at 7pm (after the CAT meeting)	The information was noted.

Explanatory notes

The notes below give a brief explanation of the main sections and headings in the CAT agenda and should be read in conjunction with the agenda or the minutes.

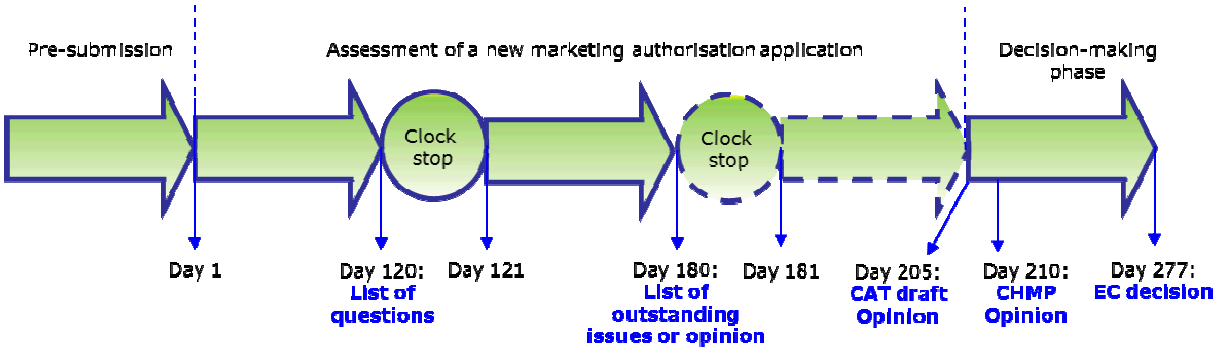
Evaluation of ATMPs (section 2)

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 2.9*)

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 2.5*)

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 2.6*)

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 2.8*)

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.

Inspections Issues (*section 2.9*)

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 2.10*)

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.

ATMP Certification (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)

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 (Section 7)

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 matters (section 8)

This section includes topics related to Regulatory and Procedural Guidance, CAT meeting organisation (including CAT membership) and Co-ordination with other Committees, Working Parties, Scientific Advisory Groups and other groups.

CAT's DGs / PCWP and HCPWP (section 9)

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, the EMA/CAT-Notified Body Collaboration Group, the Patient and Consumer Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP).

Other Scientific Topics (section 10)

This section 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.

List of participants: ***including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 19-20 June 2014 meeeting.***

CAT Member	Country	Declaration of interest date	Risk level	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/ substance	Agenda point	Comments
Paula Salmikangas	CAT chair	07/05/2014	1	Full involvement			
Ilona Reischl	Austria	11/04/2014	1	Full involvement			
Claire Beuneu	Belgium	14/06/2013	1	Full involvement			
Ivana Haunerova	Czech Republic	10/10/2014	1	Full involvement			
Tiina Palomäki	Finland	05/08/2014	1	Full involvement			
Nicolas Ferry	France	21/08/2013	1	Full involvement			
Martina Schüssler-Lenz	Germany	30/04/2014	1	Full involvement			
Paolo Gasparini	Italy	18/09/2013	1	Full involvement			
Una Riekstina	Latvia		1	Full involvement			
Johannes H. Ovelgönne	Netherlands	21/06/2013	1	Full involvement			
Marit Hystad	Norway	13/06/2013	1	Full involvement			
Dariusz Śladowski	Poland	06/08/2013	3	No restrictions			
Simona Badoi	Romania	01/08/2013	1	Full involvement			
Mikuláš Hrubiško	Slovakia	03/07/2013	2	No restrictions			
Metoda Lipnik-Stangelj	Slovenia	21/06/2013	1	Full involvement			
Sol Ruíz	Spain	11/06/2013	1	Full involvement			Attended Friday 20th
Elaine French	UK	13/01/2014	1	Full involvement			
Bernd Gänsbacher	IEOT	01/08/2013	1	Full involvement			
Kieran Breen	EPDA	25/04/2014	2	Full involvement			Attended Thursday 19th

CAT Member	Country	Declaration of interest date	Risk level	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/ substance	Agenda point	Comments
Michele Lipucci di Paola	EURORDIS	09/06/2014	2	Full involvement			

CAT Alternate	Country	Declaration of interest date	Risk level	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/ substance	Agenda points	Comments
Belaïd Sekkali	Belgium	02/06/2014	1	Full involvement			
Rozalina Kulaksazova	Bulgaria	07/05/2014	1	Full involvement			
Ivica Malnar	Croatia	25/05/2014	3	No participation in final deliberations and voting on products from GlaxoSmithKline. Cannot act as Rapporteur for products from GlaxoSmithKline.		2.9.1, 5.5	
Tarmo Tiido	Estonia	27/05/2014	1	Full involvement			
Egbert Flory	Germany	12/07/2013	1	Full involvement			
Margarida Menezes-Ferreira	Portugal	21/06/2013	1	Full involvement			
Marcos Timón	Spain	06/05/2014	1	Full involvement			
Björn Carlsson	Sweden	24/06/13	1	Full involvement			
Esteve Trias-Adroher	EATB	23/07/2014	1	Full involvement			

CAT members and alternates by phone	Country	Declaration of interest date	Risk level	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/ substance	Agenda point	Comments
Sinan B. Sarac	Denmark	26/03/2014	3	Full involvement			
Olli Tenhunen	Finland	14/02/2014	2	Full involvement			
Maura O'Donovan	Ireland	30/09/2014	1	Full involvement			
Romaldas Mačiulaitis	Lithuania	02/06/2014	1	Full involvement			
Lennart Åkerblom	Sweden	02/06/2014	1	Full involvement			

EUROPEAN COMMISSION	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/ substance
Rocío Salvador-Roldán		Full involvement	

CAT Expert *	Country	Declaration of interest date	Risk level	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/ substance	Agenda point	Comments
* Experts were only evaluated against the product they have been invited to talk about.							
Guido Panté	Italy	22/01/2014	3	No restrictions			