16 April 2014
EMA/CAT/252280/2014
Procedure Management and Business Support Division

Committee for Advanced Therapies (CAT)

Minutes of the 13 – 14 March 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/58386/2014) and **TIMESCHEDULE** (EMA/CAT/58385/2014) for the CAT plenary to be held on 13th and 14th March 2014: **for adoption**	Adopted
1.2. TABLE OF DECISIONS CAT plenary held on 13th and 14th January 2014 (EMA/CAT/792076/2013): **for information**	Noted
1.3. MINUTES of the CAT plenary held on 13th and 14th January 2014 (EMA/CAT/51170/2013): **for adoption**	Adopted without amendments
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 13th – 14th March 2014: **for information**	*See March 2014 minutes (to be published post April 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. LIST OF QUESTIONS

No items on the agenda

2.4. DAY 80 ASSESSMENT REPORT

No items on the agenda

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

No items on the agenda

2.6. WITHDRAWAL OF APPLICATION

No items on the agenda

2.7. ONGOING EVALUATION PROCEDURES

No items on the agenda

2.8. NEW APPLICATIONS

2.8.1. (talimogene laherparepvec) (EMA/H/C/H0002771). Therapeutic indication: treatment of adults with unresectable or metastatic melanoma. **For information:** ▪ Nominations received for Rapporteurship: ▪ Nominations received for Co-rapporteurship: ▪ Nominations received for Peer reviewers: ▪ Overview of Rapporteurs for ATMP-MAAs and Coordinators for ATMP certification and classification over the period 2009-2013	CAT noted the nominations for Rapporteur / Peer reviewer for this new MAA. The procedure for appointment of Rapporteurs and peer reviewer was explained. An overview of Rapporteurs for ATMP-MAAs and Coordinators for ATMP certification and classification over the period 2009-2013 was provided for information. Post-meeting note: following teams were appointed for this procedure: - CAT Rapporteur: - CAT CoRapporteur: - CHMP Coordinators: - CAT Peer reviewer: - CHMP Peer reviewer:
2.8.2. (Characterized viable haploidentical Herpes Simplex Virus Thymidine Kinase (HSV-Tk) and Human Low Affinity Nerve Growth Factor Receptor (ΔLNGFR) transfected donor lymphocytes) (EMEA/H/C/002801).Therapeutic indication: adjunctive treatment in haploidentical haematopoietic stem cell transplantation of adult patients with high-risk haematological malignancies. **For information:** ▪ Review timetable	The review timetable was noted (pending validation of the marketing authorisation application).

2.9. GMP and GCP INSPECTIONS REQUESTS

No items on the agenda

2.10. POST-AUTHORISATION

2.10.1. Type II Variations

2.10.1.1. Glybera (EMEA/H/C/002145) MAH: UniQure Biopharma B.V. *Orphan* **II/25** **Scope:** update of section 5.1. to allow for standard genetic testing to be used as an alternative to CE marking testing **For adoption:** ▪ CAT assessment report ▪ Draft opinion	CAT Rapporteur: E. French (UK) CHMP Co-ordinator: G. Markey (UK) CAT discussed the assessment report of the responses from the MAH to the request for supplementary information of December 2013. CAT agreed with the Rapporteur's conclusion: the update of the section 5.1 of the SmPC on the genetic testing to be performed for the diagnosis of LPLD patients is therefore acceptable. CAT adopted by consensus the CAT assessment report and draft opinion of the variation

2.10.2. Other PA Activities

2.10.2.1. ChondroCelect (characterised viable autologous cartilage cells expanded *ex vivo* expressing specific marker proteins) (EMA/H/C/00878). MAH: TiGenix N.V. **Scope:** Five-year renewal **For adoption:** ▪ Draft opinion	CAT Rapporteur: E. Flory (DE) CHMP Co-ordinator: J. Müller-Berghaus (DE) The Rapporteur presented the assessment of the quality, non-clinical and clinical issues. CAT agreed that the renewal is approvable provided that satisfactory responses to the questions (other concerns) are provided. CAT recommends changes to the SmPC sections 4.2, 4.3, 4.5 and 5.3 and agrees that one additional 5-year renewal on basis of pharmacovigilance grounds is required (too limited number of patients treated so far). CAT adopted the request for supplementary information for the 5 Year renewal. The response timetable was agreed.

2.10.2.2. ChondroCelect (characterised viable autologous cartilage cells expanded *ex vivo* expressing specific marker proteins) MAH: TiGenix N.V. (EMA/H/C/00878/016) **Scope:** Randomised control trial protocol TIG/ACT/04/2009 **For adoption:** ▪ Draft AR on MAH's responses to the RSI	CAT Rapporteur: E. Flory (DE) CHMP Co-ordinator: J. Müller-Berghaus (DE) CAT adopted a further request for supplementary information, which will be sent to the MAH. The response timetable was agreed. CAT considered the need to consult experts / orthopaedic surgeons on general aspects related to cartilage repair by chondrocyte products, such as: the (change of) treatment of cartilage defects, the current standard of care for small / large lesions, definition of treatment failure and new primary or secondary endpoints. CAT discussed the questions, which will be sent to clinicians' organisations for their scientific input. The Co-rapporteur (Olli Tenhunen) will take the lead for this request and circulate an updated document for comments to the CAT in the coming week. The document and questions will be adopted at the April CAT meeting.
2.10.2.3. ChondroCelect (characterised viable autologous cartilage cells expanded *ex vivo* expressing specific marker proteins) MAH: TiGenix N.V. (EMA/H/C/00878/018) **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 adoption:** ▪ Draft AR on MAH's responses to the RSI	CAT Rapporteur: E. Flory (DE) CHMP Co-ordinator: J. Müller-Berghaus (DE) See 2.10.2.2.

2.10.2.4.	**PROVENGE** (autologous peripheral blood mononuclear cells activated with pap-gm-csf (sipuleucel-T)). MAH: Dendreon UK Ltd. (EMA/H/C/002513) **Scope MEA 009:** re-evaluate the CD54 up-regulation acceptance criterion, based on quality and clinical data from patient batches manufactured in Europe, when sufficient data is available. **For adoption:** ▪ Rapporteur's AR circulated on 17.02.2014	CAT Rapporteur: E. Flory (DE) CHMP Co-ordinators: J. Müller-Berghaus (DE) CAT adopted the request for supplementary information.

3. CERTIFICATION

Disclosure of information related to ATMP certification 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.	[Nuclear fraction separated from autologous bone marrow aspirate]. Proposed indication: stage I-III of osteoarthrosis and osteochondral lesion **For discussion:** ▪ Response to the second list of issues received 10th February 2014 **For adoption:** ▪ ATMP Classification report	The draft classification report, which was amended taking into account the additional information received from the applicant and the comments from CAT members, was discussed. CAT took note of the discussion in the drafting group on homologous/non-homologous use (see agenda 4.6). CAT considered that the mechanism of action of this product is The CAT adopted by consensus the draft scientific recommendations. This product is classified as a. CAT secretariat to send the draft scientific recommendation to the Commission for comments until 31 March 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.

4.2. [allogeneic genetically engineered TCR-/CD52-/RQR8+/CD19 CAR+ T cells]. Proposed indication: CD19+ B-cell lymphomas **For adoption:** ▪ ATMP Classification report	CAT discussed the mechanism of action of this product, i.e. if related directly to the gene expression of the CD19 receptor, or if linked mainly to the intrinsic characteristics of the T-cells. CAT noted the art. 2.5 of the ATMP regulation stating that if a product falls within the definition of a somatic cell therapy product and a gene therapy product, it shall be considered a gene therapy product. The CAT adopted by majority the draft scientific recommendations prepared by the CAT Co-ordinator. Three CAT members signed a divergent position, which will be attached to the CAT recommendation. CAT secretariat to send the draft scientific recommendation to the Commission for comments until 31 March 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. [characterised viable autologous stem cells expanded in vitro]. Proposed indication: treatment of degenerative arthritis, osteoarthritis (OA), articular cartilage defects in the knee, ankle or hip joints. **For adoption:** ▪ ATMP Classification report	CAT adopted a list of issues. Responses are requested by 1 April 2014 and the ATMP classification report will revised by the CAT co-ordinator by 7 April 2014.
4.4. [autologous collagen type II-specific regulatory Treg lymphocyte expanded population]. Proposed indication: treatment of inflammatory eyes diseases and inflammatory articular diseases **For information:** ▪ Request received on 21st February 2014 **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from: The following CAT member was appointed as the CAT co-ordinator:

4.5. [polyethylene terephthalate (PET) scaffold seeded with autologous bone marrow derived mononuclear cell]. Proposed indication: reconstruction of trachea subsequent to damage or stenosis due to cancer, injury or infection. **For information:** ▪ Request received on 27th February 2014 **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	An ITF Briefing meeting took place in November 2013 Nominations were received from: The following CAT member was appointed as the CAT co-ordinator:
4.6. Reflection paper on classification of ATMPs. **For discussion and adoption:** ▪ Revision of section 2.2.3.: 'reflections on homologous/non-homologous use'	Meeting scheduled for 13th March 18.30 - 19:30, room 3C Feedback was provided from the discussion in the drafting group meeting. The proposal is to consider the same essential function as follows: CAT agreed with this approach to classify non-substantially manipulated cell products and provided some comments and observation on the proposed wording, for consideration by the drafting group. The Reflection paper will now be revised by the drafting group members and included in the agenda of the April CAT meeting for discussion. After adoption, the revised reflection paper will be release for a short external consultation round.

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. Second update on CAT and SAWP improved interaction	Note: first update given in February 2014 In the presentation, the new interaction procedure between CAT and SAWP was explained, as well a description of the role and responsibilities of the CAT Rapporteur(s) appointed for a scientific advice procedure. The model for interaction with BWP on quality questions need to be further considered/developed. It was noted that this was a pilot phase and that the procedure will be finalised on basis of the experience that will be gained.

6. PRE-AUTHORISATION ACTIVITIES

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. Article 57(p) of Regulation (EC) No. 726/2004 EC Scientific opinion request. Follow-up request from the European Commission – DG SANCO (B2 Unit) under Article 57(p) of Regulation (EC) No. 726/2004 **For discussion:**	Previously discussed in January 2013. CAT members provided input on this request from the EC
8.1.2. Legislation on tissues and cells: legislative proposals on importation of tissues and cells and on coding system for each donation: **for discussion**	An initial discussion took place. It was agreed to have a further discussion at the April CAT meeting.

8.2. CAT Meeting Organisation

8.2.1. Election of Vice-Chairperson to CAT. **For discussion**: Nominations received:	Martina Schüßler-Lenz was elected as CAT vice-chair for a period of 3 years.
8.2.2. CAT Membership **For information:** ▪ Latvia: Jānis Ancāns – stood down from his member role on 27th February 2014	Noted
8.2.3. 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 discussion:** ▪ Topics for the agenda	CAT supported the proposals for scientific presentations for Day 1 as suggested by the Italian Agency. CAT had an initial discussion on topics for the joint CAT/CHMP/COMP sessions on Day 2.
8.2.4. CAT/PDCO joint informal meeting hosted by the Heads of the Italian and Slovenian NCAs in November 2013 **For adoption:** ▪ Draft minutes	Postponed until April CAT meeting
8.2.5. CAT-MMD architecture: upgrade: **for information**	Postponed until April CAT meeting

8.3. Co-ordination with Committees/WPs/SAGs

8.3.1. Creation of the Inter-Committee Scientific Advisory Group (IC-SAG) for Oncology (which will replace the former SAG Oncology): **Call for nomination for core members:** ▪	Nominations to be sent to by 31.03.14. *Note: core members **cannot** be members or alternates of any committee but rather external **clinical experts** to be proposed for nomination by committee members. They should be experts in the fields of clinical oncology, haematological oncology, paediatric oncology, or biostatistics. There is no limit to the number of nominations, the proposal will go to all the committees, to the Scientific Coordination Board and for final appointment by the CHMP*
8.3.1. CHMP February 2014 ToD: for information	Noted
8.3.1. COMP March 2014 agenda: for information	Noted

8.4. CAT's Work Programme

8.4.1. Objectives 2014-2015 **For agreement on objectives for 2014:** ▪ Oral feedback on a proposal for a joint CAT-DGTI workshop (11 September 2014) ▪ Appointment of Organising/programme committee members for: 1) Joint CAT-DGTI workshop 2) Assessor training 3) Interested parties meeting ▪ Discussion of scientific topics identified for horizon scanning ▪ Appointment of CAT member(s) to analysis and review of existing guidelines	CAT appointed following members to take part in the organising committee for a joint CAT-DGTI workshop: . Discussion on the other topics on the CAT work programme was postponed until April CAT meeting.

9. CAT's DGs / PCWP and HCPWP

9.1. DG on GTMP Guidelines

9.2. DG on CTMP and TEP Guidelines

9.2.1. Reflection paper on clinical aspects related to TEPs **For adoption:** ▪ Reflection paper ▪ List of Comments	CAT adopted the Reflection paper, pending the feedback from the Safety working party. If SWP comments are received, then the reflection paper will be put to CAT in April for re-adoption.

9.2.2.	CAT workshop on Cell based therapies for Cardiac Repair scheduled for 14th-15th May 2014 **For information:** ▪ List of participants **For discussion:** ▪ Draft agenda **For nomination:** ▪ Proposed moderators for each session	Moderators for the different sessions were appointed. In preparation of the workshop, an analysis will be performed of the scientific advices for the cell-based product in this indication. agreed to join the clinical group. A preparatory meeting will be scheduled in the margins of the April CAT meeting. CAT members will be able to join the workshop, which starts the day before the May plenary CAT meeting, but no reimbursement is foreseen. EMA will investigate if experts/staff members in the NCAs can join the workshop via an audio or video link.

10.OTHER SCIENTIFIC TOPICS

10.1.	CAT international interactions – overview. **For action:** ▪ Call for candidatures for CAT members to take part in Regulators Forum Gene Therapy Discussion Group (RFGTDG) and Regulators Forum Cell Therapy Discussion Group (RFCTDG)	Following CAT members were appointed as core-members: - for RFGTDG: - for RFCTDG: Other CAT members can join the international telecon for specific agenda topics.
10.2.	European Clinical Trials Framework. Regulation of the EP and the Council on clinical trials on medicinal products for human use and transparency initiatives **For information:** ▪ Presentation on the published document	The clinical trial Regulation was adopted by the EU in December 2013. Presentation postponed until the April CAT meeting.
10.3.	DIA annual meeting in June 2014, San Diego, USA. Request for a CAT speaker to give a talk on the approval of regenerative medicines in the EU and support to developers by EMA/CAT **For information:** ▪ Dariusz Śladowski will represent the CAT in this meeting	

10.4.	Joint MHRA and BIA Innovation Conference on 19th June 2014 in Central London. Request for a CAT speaker to give a talk on ATMPs: scientific and regulatory considerations **For appointment of speaker from CAT**	Interest received from: Post-meeting note: Elaine French will be asked to represent the CAT in this meeting.
10.5.	Criteria for selection of CAT members as representative to scientific meetings and publications: **for discussion**	The general principles as stated in the EMA *Policy on scientific publications and representation for European Medicines Agency's scientific committees and their members* (EMA/231477/2005 rev. 1) apply. CAT agreed on additional parameters that will be taken into account for representation at scientific meetings and publications. These include the experience of the member in the scientific and regulatory framework for ATMPs. The wish is to spread the participation in meetings /publications evenly amongst CAT members. Reference was made to discussions in the September 2013 CAT meeting regarding publication and authorship of guidelines, reflection papers and associated articles.
11.A.O.B.		
11.1.	Multinational assessment teams: for discussion	The concept of multinational teams has already been tried out (pilot) successfully for a couple of centralised MAA (non ATMPs) for the Co-Rapporteurship. It can now be extended for ATMP MAAs.
11.2.	Project 2014: move to 30, Churchill Place, Canary Wharf **For information:** ▪ Update presentation	

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.

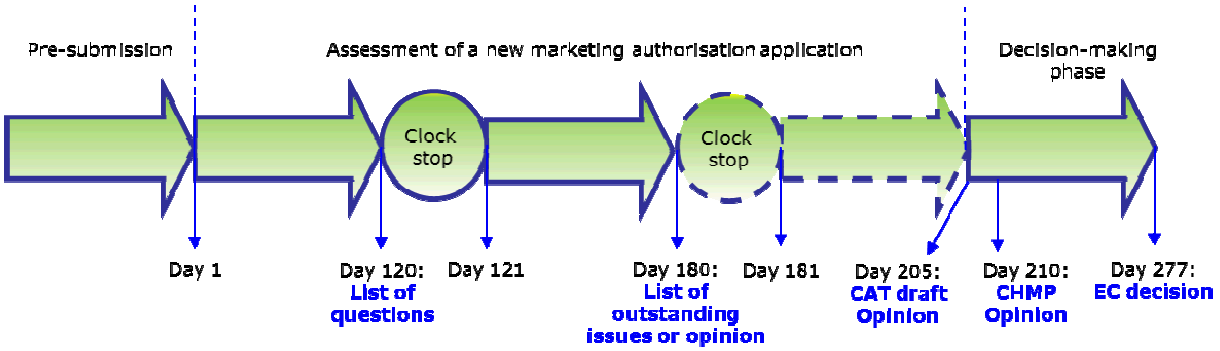
Evaluation of ATMPs (section 2)

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 13-14 March 2014 meeeting.***

CAT Member	*Country*	*Outcome restriction following evaluation of e-DoI for the meeting*	*Topics on the current Committee Agenda for which restriction applies* *Product/ substance*
Ilona G. Reischl	Austria	Full involvement	
Claire Beuneu	Belgium	Full involvement	
Sandra Tomljenovic	Croatia	Full involvement	
Sinan B. Sarac	Denmark	No restrictions	
Toivo Maimets	Estonia	Full involvement	
Paula Salmikangas	Finland	Full involvement	
Nicolas Ferry	France	Full involvement	
Martina Schüssler-Lenz	Germany	Full involvement	
Asterios Tsiftsoglou	Greece	Full involvement	
Zsuzsanna Buzás	Hungary	Full involvement	
Paolo Gasparini	Italy	Full involvement	
Romaldas Mačiulaitis	Lithuania	No restrictions	
Johannes H. Ovelgönne	Netherlands	Full involvement	
Marit Hystad	Norway	Full involvement	
Dariusz Śladowski	Poland	No restrictions	
Mikuláš Hrubiško	Slovakia	No restrictions	
Metoda Lipnik-Stangelj	Slovenia	Full involvement	
Sol Ruíz	Spain	Full involvement	
Elaine French	United Kingdom	Full involvement	
Bernd Gänsbacher	IEOT	Full involvement	
Kieran Breen	EPDA	No restrictions	
Michelino Lipucci di Paola	EURODIS	No restrictions	

CAT Alternate	*Country*	*Outcome restriction following evaluation of e-DoI for the meeting*	*Topics on the current Committee Agenda for which restriction applies* *Product/ substance*
Evelina Shumkova	Bulgaria	Full involvement	
Ivica Malnar	Croatia	No restrictions	
Tomáš Boráň	Czech Republic	Full involvement	

CAT Alternate	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/ substance
Olli Tenhunen	Finland	No restrictions	
Egbert Flory	Germany	Full involvement	
Meave Lally	Ireland	No restrictions	
Guy Berchem	Luxembourg	Involvement in discussion only	
Rune Kjeken	Norway	Involvement in discussion only	
Margarida Menezes-Ferreira	Portugal	Full involvement	
Marcos Timón	Spain	Full involvement	
Björn Carlsson	Sweden	Full involvement	
Esteve Trias-Adroher	EATB	Full involvement	

CAT members and alternates by phone	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/ substance
Maura O'Donovan	Ireland	Full involvement	telephone

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	European Commission	Full involvement	

CAT Expert *	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/ substance
Guido Panté	Italy	No restrictions	

CAT Expert by phone*	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/ substance
Lisbeth Barkholt	Sweden	Full involvement	
Outi Maki-Ikola	Finland	No restrictions	
Elisabeth Baker	United Kingdom	No restrictions	
Jürgen Scherer	Germany	Full involvement	

Observer	*Organisation*	*Outcome restriction following evaluation of e-DoI for the meeting*	*Topics on the current Committee Agenda for which restriction applies Product/ substance*
Karl-Heinz Buchheit	Conseil de l'Europe	Full involvement	