16th January 2014
EMA/CAT/30564/2014
Procedure Management and Business Support Division

Committee for Advanced Therapies (CAT)

Minutes of the 12th – 13th December 2013 meeting

Chair: Christian Schneider, Vice-chair: Paula Salmikangas

12 December 2013, 11:00hrs – 18:30hrs, room 2A
13 December 2013, 09:00hrs – 13:00hrs, room 2A

DECLARATION OF CONFLICT OF INTEREST

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 the restricted involvement of Committee members for the upcoming discussions, as will be found in the Annex I to the Minutes.

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

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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. Documents mentioned in the agenda cannot be released at present as they are currently in draft format or are classified as confidential. They will become public when adopted in their final form or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006). 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.

Announcements

- Christian Schneider informed the CAT that, due to new and additional responsibilities at the Danish Health and Medicines Authority, he will have to resign as CAT chair. This meeting was the last meeting chaired by Christian Schneider. CAT members congratulated him with his new position and thanked him for his excellent chairmanship over the last 5 years.
  The vice-chair, Paula Salmikangas, will chair the January 2014 meeting (which will be held virtually) and the election of a new CAT chair will take place in the beginning of the February 2014 CAT meeting.
- CAT welcomed Anna Cieślik, the alternate member of Poland, who attended the CAT for the first time.

1. PLENARY RELATED DOCUMENTS

1.1. AGENDA (EMA/CAT/737884/2013) and **TIMESCHEDULE** (EMA/CAT/737883/2013) for the CAT plenary to be held on 12th and 13th December 2013: **for adoption**	The agenda was adopted without amendments The secretariat informed the CAT about the publication of the CAT agenda on the EMA Website, after deletion of commercially confidential, personal and sensitive information.
1.2. TABLE OF DECISIONS CAT plenary held on 14th and 15th November 2013 (EMA/CAT/709024/2013): **for information**	Noted
1.3. MINUTES of the CAT plenary held on 14th and 15th November 2013 (EMA/CAT/721974/2013): **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 12th and 13th December 2013: **for information**	*Note: this listing will be incorporated as an annex to the minutes of this 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. NEW APPLICATIONS

No items on the agenda

2.8. PRE-SUBMISSION ISSUES

No items on the agenda

2.9. ONGOING EVALUATION PROCEDURES

No items on the agenda

2.10. PAEDIATRIC INVESTIGATION PLAN

No items on the agenda

2.11. GMP and GCP INSPECTIONS REQUESTS

No items on the agenda

2.12. VARIATIONS

2.12.1. Type II Variations

2.12.1.1. Glybera (EMEA/H/C/002145)
MAH: UniQure Biopharma B.V. Orphan

CAT Rapporteur: UK
CHMP Co-ordinator: Greg Markey

II/19 (quality)
Scope:
For adoption:
- Opinion

II/24 (quality)
Scope:
For adoption:
- Opinion

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:
- RSI

II/29 (quality)
Scope:
For adoption:
- Timetable

II/19 and II/24
CAT adopted the opinions for variations II/19 and II/24 by consensus

II/25
The Rapporteur's AR was discussed. CAT felt that additional information was necessary before adopting the opinion; the questions in the Request for supplementary information (RSI) were discussed. The revised RSI and the response timetable were adopted.

II/29
The review timetable for Variations II/29 was adopted.

2.12.2. Other Post-Authorisation Activities

2.12.2.1. 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:** ▪ Timetable	CAT Rapporteur: E. Flory (DE) CAT (Co-)Rapporteur: P. Salmikangas (FI) CHMP Co-ordinator: J. Müller-Berghaus (DE) CHMP Co-ordinator: O. Mäki-Ikola (FI) The review timetable was adopted.
2.12.2.2. 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:** ▪ Revised timetable	CAT Rapporteur: E. Flory (DE) CHMP Co-ordinator: J. Müller-Berghaus CAT agreed to align the review of this post-authorisation measure with the 5-year renewal. The revised timetable was adopted.
2.12.2.3. 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:** ▪ Revised timetable	CAT Rapporteur: E. Flory (DE) CHMP Co-ordinator: J. Müller-Berghaus CAT agreed to align the review of this post-authorisation measure with the 5-year renewal. The revised timetable was adopted.
2.12.2.4. Glybera (alipogene tiparvovec) (EMEA/H/C/2145) MAH: UniQure Biopharma B.V. Orphan **For adoption:** ▪ Extension of clock-stop for specific obligation for introduction of virus removal step in manufacturing process (ANX004)	CAT Rapporteur: UK (to be appointed) CHMP Coordinator: Greg Markey The delay in responding to this post authorisation measure is linked to operational aspects of the implementation of this change in the manufacturing process. CAT accepted the justification of the company and adopted the extension of clock-stop.

2.12.2.5. Glybera (alipogene tiparvovec) (EMEA/H/C/2145) MAH: UniQure Biopharma B.V. Orphan. Annual Reassessment **For adoption:** ▪ Timetable	CAT Rapporteur: UK (to be appointed) CHMP Co-ordinator: Greg Markey The timetable was adopted. Further to comments made, CAT will have to reflect on the need to request the submission of an updated RMP, as there is no new information to be included. CAT members to provide comments to the Rapporteur

3. CERTIFICATION

Disclosure of information related to ATMP certification cannot be released at the present time as these are deemed to contain commercially confidential information.

4. SCIENTIFIC RECOMMENDATION ON CLASSIFICATION OF ATMPs

4.1. [genetically modified serotype 5/3 adenovirus coding for granulocyte-macrophage colony-stimulating factor] Proposed indication: cancer **For discussion:** ▪ Comments received from EC dated 25.11.13. **For adoption:** ▪ Revised ATMP Classification report	*Scientific advice given in January 2011* See also 4.3. The revised classification report was adopted. This product is classified as a gene therapy medicinal product
4.2. [a suspension of allogeneic unrelated, buffy coat derived activated viable leukocytes]. Proposed indication: treatment of chronic lower extremity ulcers in adult diabetic patients **For information:** ▪ CAT's List of Questions **For discussion:** ▪ Applicant's responses to LoQs **For adoption:** ▪ ATMP Classification report	CAT discussed the responses provided by the applicant, justifying the substantial manipulation of the cells in this product. The CAT adopted by consensus the draft scientific recommendations prepared by the CAT Rapporteur. CAT secretariat to send the draft scientific recommendation to the Commission for comments until 8 January 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. [retinal pigment epithelium cells derived from human induced pluripotent stem cells]. Proposed indication: the treatment of retinal degenerative diseases associated with dystrophic or dysfunctional RPE cells **For discussion:** ▪ Comments received from EC dated 25.11.13. **For adoption:** ▪ Revised ATMP Classification report	See also 4.1. The revised classification report was adopted. This product is classified as a tissue engineered product.

4.4. [Cultured autologous skin substitute using acellular human donor dermis as matrix]. Proposed indication: wound healing **For adoption:** ▪ ATMP Classification report	The CAT adopted by consensus the draft scientific recommendations prepared by the CAT Rapporteur. CAT secretariat to send the draft scientific recommendation to the Commission for comments until 8 January 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. [a cell suspension of autologous skeletal myoblast]. Proposed indication: oculo-pharyngeal muscular dystrophy **For adoption:** ▪ ATMP Classification report	The CAT adopted by consensus the draft scientific recommendations prepared by the CAT Rapporteur. CAT secretariat to send the draft scientific recommendation to the Commission for comments until 8 January 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.
4.6. [Nuclear fraction separated from autologous bone marrow aspirate]. . Proposed indication: stage I-III of osteoarthrosis and osteochondral lesion **For adoption:** ▪ ATMP Classification report	CAT agreed on the following questions to be asked to the applicant before finalising this classification - Additional information should be provided on the mode of administration of product - The applicant should provide further justification on the homologous use in both proposed indications (osteoarthritis and osteocondral lesion).
4.7. [autologous *ex vivo* expanded leukocytes treated with 5-aza-2'-deoxycytidine]. Proposed indication: solid tumours. **For information:** ▪ Request received on 28th November 2013 **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from was appointed as CAT coordinator.
4.8. Reflection paper on classification of ATMPs: Proposal for revision of Sections 2.2.3. and 2.2.4.: **For information:** ▪ Oral feedback from the DGs	Section 2.2.3. Drafting Group: Section 2.2.4. Drafting Group: Work is ongoing in both drafting groups. A proposal will be put to the CAT in February 2014 for discussion
4.9. Revised ATMP Classification template**: for adoption**	The new template was adopted.

4.10. Classification procedure guideline: **for adoption**	The classification procedure guideline was updated to reflect the current way of working: it is no longer needed for the applicant to inform the CAT Secretariat (via an 'intent to submit' letter) in advance of the submission of the ATMP classification request. The revised classification procedure was adopted.
4.11. CAT consideration on classification : fat-extracted stem cells, for erectile dysfunction in men after prostectomy: **for discussion**	Most CAT members would consider this product as an ATMP on basis of non-homologous use. A general discussion took place on the classification of ATMPs made 'at-the-bedside' using CE-marked separation devices. It is noted that some of these CE-mark certificates make reference to a clinical use / indication of the cells prepared with these devices. This puts the NCA in difficult position to impose further regulatory oversight for such ATMPs (e.g. via clinical trials, hospital exemption or marketing authorisation). CAT suggested a further discussion with the Notified Bodies, e.g. via the EMA/CAT/Notified Bodies collaboration group. CAT members also discussed if cells/tissues that are excluded from the scope of Directive 2004/23/EC (i.e. tissues and cells used as an autologous graft within the same surgical procedure) are automatically excluded from the ATMP Regulation.

5. SCIENTIFIC ADVICE

Disclosure of information related to Scientific Advice cannot be released at the present time as these are deemed to contain commercially confidential information.

6. ORPHAN DRUG DESIGNATION

6.1. Committee for Orphan Medicinal Products (COMP) **For information:** ▪ Agenda for the meeting 10th–11th December 2013	COMP Secretariat Noted

7. OTHER TASKS OF THE CAT

7.1. ITF Briefing Meetings in the field of ATMPs

Disclosure of information related to ITF Briefing meetings cannot be released at the present time as these are deemed to contain commercially confidential information.

7.2. Other ITF Briefing Meetings of interest to CAT

No items on the agenda

7.3. International Co-operation

No items on the agenda

8. ELIGIBILITY AS ATMP AND RAPPORTEURSHIP

No items on the agenda

9. ORGANISATIONAL MATTERS

9.1. Regulatory and Procedural Guidance

No items on the agenda

9.2. CAT Meeting Organisation

9.2.1. CAT/PDCO joint informal meeting hosted by the Heads of the Italian and Slovenian agencies, held on 25th-26th November 2013 **For information:** ▪ Oral feedback on the meeting ▪	Feedback from the meeting was provided. The meeting was well balanced between scientific and regulatory issue. A meeting report is under preparation. A good interaction with PDCO colleagues took place. They indicated that the CAT input in PIPs for ATMPs is very much valued by the PDCO.
9.2.2. CAT Chair election **For information**: ▪ Timelines	**Timetable:** -Call for election with supporting documents to be sent out by CAT Secretariat: mid-Jan. 2014 -Deadline for receipt of candidatures: 12.02.14. -Election: first agenda item at the CAT February meeting: 13.02.14. The information was noted.

9.3. Co-ordination with Committees/WPs/SAGs/other groups

9.3.1. CHMP November 2013 ToD: for information	Noted

9.4. CAT interaction with Interested Parties

No items on the agenda

9.5. CAT Work Programme

9.5.1. Satellite CAT scientific workshop in the margins of the World Conference on Regenerative Medicine held in Leipzig (Germany) on 23-25 October 2013 **For information:** ▪ Feedback on the workshop	Postponed until the January 2014 CAT meeting.

10. CAT DGs / OTHER GROUPS

10.1. GTMP Guidelines

No items on the agenda

10.2. Guidelines for CTMP and TEP

10.2.1. CAT workshop on Cell based therapies for *Cardiac Repair scheduled* for 14-15 May 2014 **For information:** ▪ Draft agenda **For adoption:** ▪ Proposed experts	CAT discussed the proposed experts and provided some names of experts that can be invited if the first identified expert cannot attend the workshop. With this addition, the list of experts was adopted. Invitations will now be sent.

10.3. EMA / CAT-NB Collaboration Group

No items on the agenda

10.4. PCWP guidelines

10.4.1. PCWP draft work plan 2014: **for adoption**	Medical Information team Adopted

10.5. Healthcare Professionals WP

10.5.1. HCPWP draft work plan 2014: **for adoption**	Medical Information team Adopted

11. OTHER SCIENTIFIC GUIDELINES / ISSUES

11.1. Update on the future 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**	Feedback on the progress of the finalisation of this legislation was provided. It was mentioned that in the latest proposal, slightly longer evaluation timetimes for ATMPs are foreseen.

12. PHARMACOVIGILANCE

No items on the agenda

13. A.O.B.

Date of next CAT meeting:
Thursday 16th – Friday 17th January 2014

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.

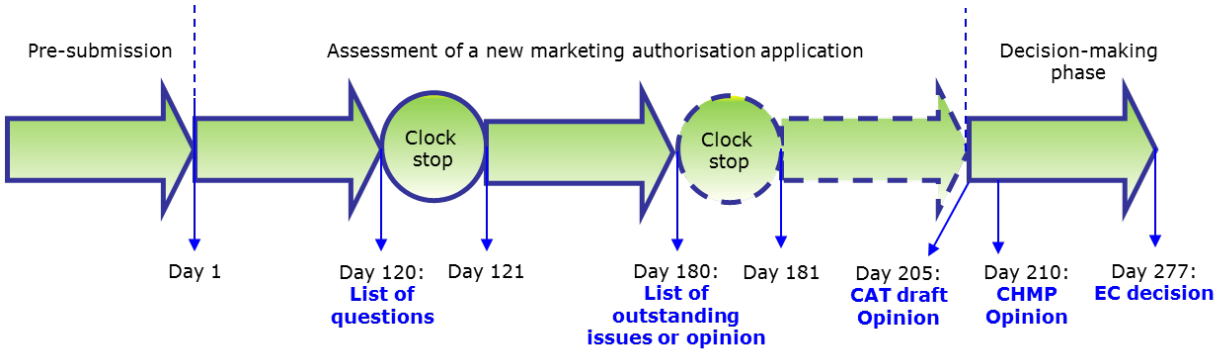
Evaluation of ATMPs (section 2)

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 the Paediatric Investigation Plans for ATMPs discussed by the Committee (*section 2.10*), any ATMP related inspection requests (*section 2.11*) and Post-authorisation activities (*section 2.12*)

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 2.9 (**Ongoing evaluation procedures**). Section 2.9 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 2.7*)

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.

Pre-submission (*section 2.8*)

In some cases the CAT may discuss an ATMPs 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.

Paediatric investigation Plans (*section 2.10*)

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.

Inspections Issues (*section 2.11*)

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.

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.

Orphan Drug Designation (section 6)

This section refers to the report from the Committee for Orphan Medicinal Products (COMP).

Other Tasks of the CAT (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 9)

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 Drafting groups / Other Groups (section 10)

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 Guidelines/issues (section 11)

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.

Pharmacovigilance (section 12)

Any non-product related Pharmacovigilance issue coming from the discussion of the PRAC will be listed here. PRAC issues related to ATMPs are included in section 2.12.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

List of participants: *including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 12-13 December 2013 meeting.*

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	
Lyubina Racheva Todorova	Bulgaria	Full involvement	
Christian Schneider	Chair	Full involvement	
Sinan B. Sarac	Denmark	Full involvement	
Toivo Maimets	Estonia	Full involvement	
Paula Salmikangas	Finland	Full involvement	
Nicolas Ferry	France	Full involvement	
Egbert Flory	Germany	Full involvement	
Zsuzsanna Buzás	Hungary	Full involvement	
Maura O'Donovan	Ireland	Full involvement	
Paolo Gasparini	Italy	Full involvement	
Jānis Ancāns	Latvia	Full involvement	
Hans Ovelgönne	Netherlands	Full involvement	
Marit Hystad	Norway	Full involvement	
Dariusz Śladowski	Poland	No involvement in discussion, final deliberation and voting; no rapporteur/coordinatorship	Scientific Advice ATMP classification
Simona Badoi	Romania	Full involvement	
Mikuláš Hrubiško	Slovakia	Full involvement	
Sol Ruiz	Spain	Full involvement	
Lennart Åkerblom	Sweden	Full involvement	
Michelino Lipucci di Paola	Eurodis	Full involvement	

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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
Kieran Breen	EPDA	Full involvement	
Bernd Gänsbacher	IEOT	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
Ivica Malnar	Croatia	Cannot act as rapporteur ; Involvement in discussions only	Scientific Advice
Tomáš Boráň	Czech Republic	Full involvement	
Olli Tenhunen	Finland	Full involvement	
Martina Schüssler-Lenz	Germany	Full involvement	
Anthony Samuel	Malta	Full involvement	
Rune Kjeken	Norway	Full involvement	
Anna Cieślik	Poland	Full involvement	
Margarida Menezes-Ferreira	Portugal	Full involvement	
Marcos Timón	Spain	Full involvement	
James McBlane	United Kingdom	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	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
* Experts were only evaluated against the product they have been invited to talk about.			
Guido Panté	Italy	Full involvement	
Louise Bisset	United Kingdom	Full involvement	