2 December 2014
EMA/CAT/786798/2014
Procedure Management and Business Support Division

Committee for Advanced Therapies (CAT)

Minutes for the meeting on 13–14 November 2014

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. 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 13 - 14 November 2014.	See attached List of Participants
1.2. Adoption of agenda of the meeting of 13-14 November 2014	Adopted
1.3. Adoption of the minutes of the previous CAT meeting on 18-19 October 2014	Adopted with a correction in agenda point 8.2.1.
1.4. Table of Decisions of the previous CAT meeting on 18-19 October	Noted

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 Outstanding Issues

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 Application)+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

No items on the agenda

2.9. New Applications

No items on the agenda

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** (alipogene tiparvovec) (EMEA/H/C/2145) MAH: UniQure Biopharma B.V. *Orphan* **II/37-G** **Scope:** Update of sections 4.8 and 5.1 of the SmPC in order to reflect the complete data generated with studies CT-AMT-010-01 and CT-AMT-011-01. Inclusion of the final clinical study report (CSR) for CT-AMT-010-01. This CSR includes patient follow-up up to 5 years. Inclusion of the final clinical study report (CSR) for CT-AMT-011-01. This CSR includes patient follow-up up to 5 years. The Package Leaflet is updated accordingly. **For adoption:** ▪ Request for Supplementary Information ▪ Timetable	CAT Rapporteur: E. French CHMP Coordinator: G. Markey The Rapporteur indicated that not only the content of the submitted report but also the layout has changed, which made the assessment very difficult (not easy to see what is new and what is reworded/reformatted). CAT highlighted the need for a telecon between the MAH, the Rapporteur and EMA. The request for supplementary information and the response timetable were adopted.
2.11.1.2.	**Glybera** (alipogene tiparvovec) (EMEA/H/C/2145) MAH: UniQure Biopharma B.V. *Orphan* **II/38** **Scope:** Update of section 5.1 of the SPC based on the final clinical study report for Study CT-AMT-011-05, a retrospective clinical records review study undertaken to generate further long-term follow-up data on the incidence and severity of acute pancreatitis episodes in subjects with lipoprotein lipase deficiency and who had previously participated in clinical studies with alipogene tiparvovec or AMT-10. **For adoption:** ▪ Request for Supplementary Information ▪ Timetable	CAT Rapporteur: E. French CHMP Coordinator: G. Markey CAT discussed the questions proposed by the Rapporteur in the RSI. More specifically, following points were addressed by CAT: CAT proposed to upgrade one question to a major objection. The Request for supplementary information will be adopted via a written procedure. The response timetable was adopted. Post-meeting note: the RSI was adopted via a written procedure on 18 November 2014. The above mentioned question was reworded by the Rapporteur and reclassified as an 'Other concern'.

2.11.2. Other PA Activities

2.11.2.1. **Glybera** (alipogene tiparvovec) (EMEA/H/C/2145/Anx 004) MAH: UniQure Biopharma B.V. *Orphan* **For discussion:** ▪ Letter from the MAH dated 17.09.14. requesting a further extension of the clock-stop for specific obligation for introduction of virus removal step in manufacturing process (ANX004) ▪ Letter from the MAH dated 04.11.14. in response to the CAT's question on nanofiltration	CAT Rapporteur: E. French CHMP Coordinator: G. Markey Note: upon agreement by CAT, the company will submit a variation to amend the Annex II to the opinion. CAT agreed to extend the timeline for the introduction of the nanofiltration. It was clarified that the Phase IV study can start independently from the introduction of the nanofiltration step. CAT requested for an interim report to be submitted on the pilot scale experiments .
2.11.2.2. **Glybera** (alipogene tiparvovec) (EMEA/H/C/2145/PSUV/36) MAH: UniQure Biopharma B.V. *Orphan* **Scope:** PSUR **For information:** ▪ PRAC PSUR AR	CAT Rapporteur: E. French CHMP Coordinator: G. Markey *PSUR adopted at PRAC in November 2014* *PRAC Recommendation: maintenance* The PRAC AR and recommendation were noted.

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.

4. Scientific Recommendation on Classification of ATMPs

4.1. [platelet generated from in-vitro derived megakaryocytes]. Proposed indication: intended for the treatment of thrombocytopenia in patients at risk of bleeding or with haemorrhagic events **For adoption**: ▪ ATMP Classification report	CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. This product is classified as a . CAT secretariat to send the draft scientific recommendation to the Commission for comments until 28 November 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. [adeno-associated virus (AAV) vector carrying a gene for bacterial halorhodopsin]. Proposed indication: intended for the treatment of retinitis pigmentosa. **For information:** ▪ ATMP Classification report	*The European Commission raised no comments*

4.3. [allogeneic cord blood cells, *ex vivo* modulated with 16,16 dimethyl prostaglandin E2 (dmPGE2/ FT1050)]. Proposed indication: intended for the treatment of patients undergoing allogeneic hematopoietic reconstitution after high dose conditioning therapy for haematologic malignancies and certain rare genetic disorders. *Orphan* **For discussion:** ▪ Response to the LoQ received on 29th October 2014 **For adoption:** ▪ Revised ATMP Classification report	CAT discussed the responses from the applicant and the revised ATMP classification report. CAT adopted the ATMP classification report by majority (17 positive out of 23 votes). The Norwegian member was in agreement with the CAT recommendation. A divergent opinion was signed by 6 CAT members (S Ruiz, L Akerblom, T Palomäki, S Badoi, M Menezes-Ferreira, E Trias-Adroher).This product is classified as a CAT secretariat to send the draft scientific recommendation to the Commission for comments until 28 November 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. [human embryonic stem cell derived retinal pigment epithelial cells]. Proposed indication: intended for the treatment of age-related macular degeneration and Stargardt's macular dystrophy. **For information:** ▪ ATMP Classification report	*The European Commission raised no comments*
4.5. [autologous differentiated adipose cells isolated from adipose tissue]. Proposed indication: intended for the treatment of primary perianal fistula **For discussion:** ▪ Response to the LoQ received on 4th November 2014 **For adoption:** ▪ Revised ATMP Classification report	CAT discussed the responses from the applicant and the revised ATMP classification report. The report was updated following the discussion. CAT adopted by consensus the ATMP classification report. This product is classified as a . CAT secretariat to send the draft scientific recommendation to the Commission for comments until 28 November 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. [living human mesenchymal stem cells derived from Wharton's jelly tissue of umbilical cord].**Proposed indications:** 1. Acute and chronic Graft-versus-Host-Disease (aGvHD and cGvHD); 2. Cartilage lessions; 3. Cerebral palsy; 4. Amyotrophic lateral sclerosis (ALS) **For discussion** ▪ Comments raised by the Commission on 29th October 2014 **For adoption:** ▪ Revised ATMP Classification report	*Comments raised by the European Commission on two of the four therapeutic indications:* -acute and chronic GvHD; -cerebral palsy CAT adopted the revised classification reports for the two indications mentioned above.

4.7. [solid flexible implant with chondrocytes fixed in biodegradable human origin fibrin based excipient]. Proposed indication: intended for the treatment of focal non-arthrotic cartilage defects of Outerbridge Grade III or IV of the femoral condyle including the trochlea **For discussion:** ▪ Request for ATMP Classification received on 30.10.14. **For adoption**: ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from . The following CAT member was appointed as CAT co-ordinator:
4.8. Reflection Paper on Classification of ATMPs: overview of comments received during external consultation: **for discussion**	Appointment of drafting group(s) to review the comments CAT members interested to take in the drafting groups (one on substantial manipulation, one of non-homologous use) should inform the CAT secretariat by Friday 21 November. All comments received during the external consultation are tabled in MMD/CAT/ATMP classif. Reports/Reflection Paper revision. Drafting group members should perform a first review of the comments received. A telecon will be organised in advanced of the December CAT meeting.

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)

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. Multinational Assessment Teams for initial marketing authorisation applications. **For information:** ▪ Updated registry to list possible/available CAT-related expertise/resources in each MS for MN-teams	No additional comments received to the list of CAT-related expertise/resources in the MS of Multinational assessment teams. The updated resource list was noted.

8.1.2.	Application of ATMP Regulation **For discussion:** ▪ Oral feedback from the joint telecon of the CAT reflection groups on quality related issues and risk based approach ▪ 'Aspects to consider on questions to SAWP of ATMPs'	CAT reflection groups: - Quality related issues: - Risk based approach: Feedback from the CAT reflection group telecon was postponed until the December CAT meeting. CAT members noted the timetable for providing comments to the document *'Aspects to consider on questions to SAWP on ATMPs'*: -Comments by CAT: Friday 5th December 2014 -Discussion at CAT: 11-12 December 2014
8.1.3.	Changes to the MAA process **For information** ▪ Presentation	Feedback was provided on the following issues: - Scope of the clarification meeting (see 8.1.4). The deadline for comments was noted. - Peer review process: the document will be circulated to the CAT next week for comments. - Presubmission meetings at the EMA. Additionally, the Committee members were informed that for new MAAs, EMA will provided to the Rapporteurs an Early Background Summary (including reference to precedent cases, relevant guidelines etc) around 10 days after the start of the MAA procedure. CAT members were also reminded that the EMA Procedural Manager is the first point of contact for all questions (from Rapporteurs, from applicants).
8.1.4.	Draft Guidance on meetings with applicants on responses to questions received from EMA Scientific Committees during the evaluation within the centralised procedure **For information:** ▪ draft guidance document	Committees drafting group members: **Timetable:** Comment by committees: 05.12.14

8.2. CAT Meeting Organisation

8.2.1.	CAT/CHMP/COMP joint informal meeting took place in Rome on 28th – 30th October 2014 under the auspices of the Italian Presidency of the Council of the European Union **For information:** ▪ Oral debriefing	Postponed until the December CAT meeting

8.2.2.	CAT Membership **For information:** Cyprus: ▪ Maria Vasiliou terminated her alternate membership on 24.10.14. ▪ Ioannis Kkolos – new alternate member nominated on 25.10.14.	Noted
8.2.3.	CAT Dates for 2015: **for information**	External website: CAT meeting dates Noted.

8.3. Co-ordination with Committees/WPs/SAGs

8.3.1.	CHMP October 2014 ToD: **for information**	Noted
8.3.2.	COMP November 2014 agenda: **for information**	Noted

8.4. CAT's Workplan

8.4.1.	CAT Workplan 2015-2016: **for adoption**	The CAT workprogramme 2015-2016 was adopted.

8.5. Interested Parties to CAT

8.5.1.	CAT meeting with Interested Parties during the December CAT meeting **For discussion:** ▪ Agenda topics	*This meeting will take place on Thursday 11th December from 15.00 – 18.00 (the CAT plenary meeting will run on 11th December from 09.00 to 15.00 and on Friday from 9.00-15.00. All timings are provisional.* CAT indicated the need for sufficient time for an open dialogue with the interested parties. agreed to present the agenda topic on the application of the risk based approach will be asked if he can present the topic on the revision of the CAT reflection paper on classification.

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 information**	Feedback was provided by the drafting group members on the changes introduced to the Quality, Non-clinical and Clinical parts of the guideline since the version commented by CAT in July 2014. The guideline is scheduled for adoption (for external consultation) in December 2014(pending agreement from the Guideline Consistency Group).

9.2. DG on CTMP and TEP Guidelines

No items on the agenda

9.3. PCWP and HCPWP

9.3.1.	Draft Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP): **for endorsement**	The workplan was endorsed by CAT
9.3.2.	Draft Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP): **for endorsement**	The workplan was endorsed by CAT

10. Other Scientific Topics

10.1.	Council of Europe – Guide to the Quality and Safety of Tissues and Cells for Human Application, second edition **For discussion:** ▪ Comments on Chapters 1, 20, 21 and 22 related to ATMPs	*Note: the Council of Europe is preparing a revision of the Tissues & Cells Guide. Chapters 1, 20, 21 and 22 are making reference to ATMP and are significantly extending the scope of chapter 20 ATMP, 1st edition TC guide.* CAT drafting members made comments by 14th November 2014 CAT members were asked to review the comments made by the drafting group members on chapters 1, 20, 21 and 22 and provide their final feedback by Monday 17 November 12.00 UK time. The comments will thereafter be forwarded to EDQM. Post-meeting note: the CAT comments on chapters 1, 20, 21 and 22 were finalised including comments for CAT members and forwarded to EDQM on 18 November.

10.2. Draft INN naming scheme for cell therapy products: **for discussion**	Note: the draft has been developed by the WHO INN secretariat in collaboration with the INN expert group. CAT members commented that the draft WHO proposal was not clear. Also, to be useful for the EU, tissue engineered products and more specifically combined ATMPs (where the active substance can contain a matrix or medical device) should be included. Written comments from CAT are expected by 1 December 2014.
10.3. EMA/CAT/FDA/Health Canada bimonthly teleconference on ATMP cluster **For information:** ▪ Minutes of the September 2014 ATMP cluster teleconference **For adoption:** ▪ Agenda	The agenda was adopted
10.4. '*Development pathways for advanced therapy medicinal products*': workshop organised by Emerging Biopharmaceutical Enterprises (EBE) in collaboration with EMA and Italian Embassy's Scientific Office in London – 15 December 2014 **For information:** ▪ Programme	CAT members interested to attend this workshop should inform the CAT Secretariat by 28 November 2014. Registration and agenda
10.5. Joint meeting between CAT and Competent Authorities for tissues and cells to take place in Brussels in the 1Q of 2015, to discuss topics of common interest. **For discussion:** ▪ Brainstorming for topics	Note that a similar meeting was held in February 2012. CAT confirmed that following member will attend the two meetings on 4 December (1. Meeting with the CA for tissues and cells ; 2. Preparation for a larger meeting between CAT and CAT for tissues and cells in the beginning of 2015).

11. Any Other Business

Date of next CAT meeting:
Thursday 11th – Friday 12th December 2014

Explanatory notes

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

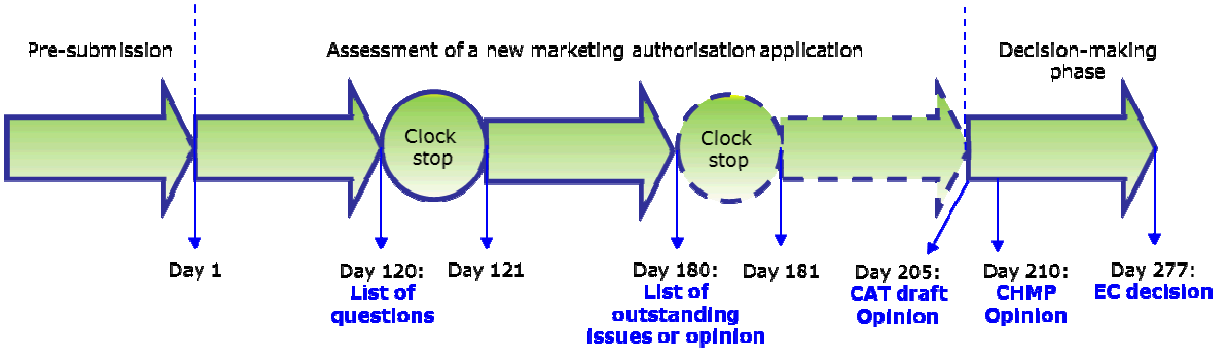
Evaluation of ATMPs (section 2)

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 2.9*)

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 2.6.*)

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.

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 2.11.*)

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.

More detailed information on the adobe terms can be found on the EMA website: www.ema.europa.eu/

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 13-14 November 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 G. Reischl	Austria	11/04/2014	1	Full involvement			Attended Thursday 13th
Sandra Tomljenovic	Croatia	08/08/2014	1	Full involvement			
Sinan B. Sarac	Denmark	26/03/2014	3	No restrictions applicable to this meeting			Attended Friday 14th
Toivo Maimets	Estonia	05/06/2014	1	Full involvement			
Tiina Palomäki	Finland	05/08/2014	1	Full involvement			
Nicolas Ferry	France	22/07/2014	1	Full involvement			
Martina Schüssler-Lenz	Germany	30/04/2014	1	Full involvement			
Maura O'Donovan	Ireland	01/09/2014	1	Full involvement			
Paolo Gasparini	Italy	26/08/2014	1	Full involvement			
Una Riekstina	Latvia			Full involvement			Attended Friday 14th

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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
Romaldas Mačiulaitis	Lithuania	02/06/2014	2	No restrictions applicable to this meeting			Attended Thursday 13th
Hans H. Ovelgönne	Netherlands	02/06/2014	1	Full involvement			
Marit Hystad	Norway	21/05/2014	1	Full involvement			
Dariusz Śladowski	Poland	03/08/2014	3	No restrictions applicable to this meeting			
Simona Badoi	Romania	02/07/2014	1	Full involvement			
Metoda Lipnik-Stangelj	Slovenia	20/06/2014	1	Full involvement			
Lennart Åkerblom	Sweden	02/06/2014	1	Full involvement			
Sol Ruíz	Spain	02/06/2014	1	Full involvement			
Elaine French	UK	13/01/2014	1	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	Agenda points	Comments
					Product/ substance		
Martin Brunner	Austria	26/06/2014	3	No restrictions applicable to this meeting			Attended Thursday 13th
Belaïd Sekkali	Belgium	02/06/2014	1	Full involvement			
Evelina Shumkova	Bulgaria	19/02/2014	1	Full involvement			
Ivica Malnar	Croatia	25/05/2014	3	No participation in final deliberations and voting on products from. Cannot act as Rapporteur for products from.		5.3	
Ivana Haunerova	Czech Republic	17/09/2014	1	Full involvement			
Tarmo Tiido	Estonia	27/05/2014	1	Full involvement			
Sophie Lucas	France	16/09/2014	1	Full involvement			Attended Thursday 13th
Egbert Flory	Germany	13/06/2014	1	Full involvement			
Krisztián Fodor	Hungary	29/07/2014	1	Full involvement			
Maeve Lally	Ireland	24/03/2014	2	No restrictions applicable to this meeting			
Guy Berchem	Luxembourg	26/05/2014	3	No restrictions applicable to this meeting			Attended Thursday 13th
Rune Kjeken	Norway	17/06/2014	2	No restrictions applicable to this meeting			Attended Friday 14th
Margarida Menezes-Ferreira	Portugal	09/06/2014	1	Full involvement			
Gianina-Nicoleta Andrei	Romania	06/06/2014	1	Full involvement			
Marcos Timón	Spain	05/05/2014	1	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
Esteve Trias-Adroher	EATB	23/07/2014	1	Full involvement			Attended Thursday 13th
Mariëtte Driessens	EGAN	28/01/2014	1	Full involvement			
Ramadan Jashari	EATB	29/06/2014	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

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 applicable to this meeting			Attended Thursday 13th

CAT Expert 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
* Experts were only evaluated against the product they have been invited to talk about.							
Bettina Klug	Germany	08/07/2014	1	Full involvement		9.1.1. GL on the quality, non-clinical and clinical aspects of GTMPs	
Dominique Masset	France	03/06/2014	1	Full involvement		9.1.1. GL on the quality, non-clinical and clinical aspects of GTMPs	