EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 November 2014
EMA/CAT/737852/2014
Procedure Management and Business Support Division

Committee for Advanced Therapies (CAT)

Minutes of the 16 – 17 October 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/541592/2014) and **TIMESCHEDULE** (EMA/CAT/600212/2014 /2014) for the CAT plenary to be held on 16th and 17th October 2014: **for adoption**	Adopted with one addition under 2.11.2 (Other post-authorisation activities): ChondroCelect.
1.2. TABLE OF DECISIONS CAT plenary held on 18th and 19th September 2014 (EMA/CAT/577831/2014): **for information**	Noted
1.3. MINUTES of the CAT plenary held on 18th and 19th September 2014 (EMA/CAT/737694/2014): **for adoption**	Adopted with an editorial amendment on page 18.

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 OUSTANDING ISSUES

2.3.1. (formerly known as GPLSCD01) (*ex vivo* expanded autologous human corneal epithelial cells containing stem cells). (EMA/H/C/H0002450). Therapeutic indication: indicated for the treatment of patients with moderate-severe (superficial corneal neovascularisation in at least two quadrants) limbal stem cell deficiency, unilateral or bilateral with minimum 1-2 mm² of undamaged limbus, due to ocular burns. Strength: 790-3160 cells/mm^2. Pharmaceutical form: living tissue equivalent **For discussion:** ▪ BWP report **For adoption:** ▪ LoOIs	*CAT adopted in July 2013 the List of Questions;* *CAT adopted in September 2013 a clock stop extension* CAT adopted by consensus the list of outstanding issues with an amendment to question 11. *Post-meeting note: The letter form the MAA requesting a delay in the TT that was tabled in CAT-MMD is no longer valid as the applicant will respond in*

2.4. LIST OF QUESTIONS

No items on the agenda

2.5. DAY 80 ASSESSMENT REPORT

No items on the agenda

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

No items on the agenda

2.7. WITHDRAWAL OF APPLICATION

No items on the agenda

2.8. ONGOING EVALUATION PROCEDURES

2.8.1. (previously known as MM-TK) (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 discussion:** ▪ Letter from the applicant dated 30th September 2014, requesting a clock stop to response to the D120 LoQs **For adoption:** ▪ Timetable to response to LoQs	The revised response timetable was adopted.

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

No items on the agenda

2.11.2. Other PA Activities

2.11.2.1. Glybera (alipogene tiparvovec) (EMEA/H/C/2145) MAH: UniQure Biopharma B.V. *Orphan* **For discussion:** ▪ Letter by the MAH dated 17.09.14. requesting a further extension of the clock-stop to respond to the specific obligation for introduction of virus removal step in manufacturing process (ANX004)	CAT Rapporteur: E. French CHMP Coordinator: Greg Markey *Note: upon agreement by CAT, the company will submit a variation to amend the Annex II to the opinion.* CAT postponed the decision on the extended timeline for the introduction of the nanofiltration step until next month, awaiting following clarification from the MAH:

2.11.2.2.	**PROVENGE** (autologous peripheral blood mononuclear cells activated with pap-gm-csf (sipuleucel-T)). MAH: Dendreon UK Ltd. (EMA/H/C/002513/ANX/001) **Scope:** to establish and keep an observational EU-based registry of men with mCRPC (Therapy in Men with Metastatic Castrate-Resistant Prostate Cancer) to evaluate overall survival, the risk of ischemic stroke or myocardial infarction following treatment with Provenge and other identified and potential risks (observational study P13-1) **For information:** ▪ PASS Protocol PRAC AR	CAT Rapporteur: E. Flory CHMP Co-ordinators: J. Müller-Berghaus *Adopted at PRAC in October 2014* The PRAC AR was noted.
2.11.2.3.	**ChondroCelect** (characterised viable autologous cartilage cells expanded *ex vivo* expressing specific marker proteins) MAH: TiGenix N.V. (EMA/H/C/00878/MEA 16.2) **Scope:** Randomised control trial protocol TIG/ACT/04/2009 **For discussion:**	CAT Rapporteur: E. Flory CAT Co-Rapporteur: T. Palomäki CHMP Co-ordinator: J. Müller-Berghaus CAT was informed by the CAT Rapporteur.
2.11.2.4.	**ChondroCelect** (characterised viable autologous cartilage cells expanded *ex vivo* expressing specific marker proteins) MAH: TiGenix N.V. (EMA/H/C/00878/MEA 18.2) **Scope:** Non-interventional registry on the use of ChondroCelect to document the clinical effectiveness and safety outcome of treatment with ChondroCelect in real life in a patient population within the authorised indication **For discussion:**	CAT Rapporteur: E. Flory CAT Co-Rapporteur: T. Palomäki CHMP Co-ordinator: J. Müller-Berghaus See 2.11.2.3.

3. CERTIFICATION

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

4. SCIENTIFIC RECOMMENDATION ON CLASSIFICATION OF ATMPs

4.1. [lyophilised genetically modified Lactococcus (L. lactis) strin sAGX0354]. Proposed indication: intended for the reduction of the signs and symptoms, and induction and maintenance of clinical remission in patients with moderately active ulcerative colitis (UC). **For discussion:** ▪ Comments received by the Commission on 30 September 2014 **For adoption:** ▪ Revised ATMP Classification report	The CAT Classification report has been updated following the comments from the Commission. The revised report was adopted. This product is classified as a Gene Therapy Medicinal product (GTMP). The final report will be sent to the Applicant. There was a general discussion in the CAT on the definition of GTMP. More specifically, there was a discussion if transfer into human cells and subsequent expression are criteria to define a GTMP. This will have to be discussed further at the time when the legal definition of a GTMP will be updated. It was noted that the GTMP definitions is to be used as it currently stands: neither the incorporation of nucleic acids into human cells nor the risk level of the product are criteria for the classification of a product as a GTMP.
4.2. [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 information:** ▪ Letter to the application dated 23.09.14. **For discussion:** ▪ Request from the applicant dated 26.09.14. to re-discuss the classification **For adoption**: ▪ Appointment of CAT Co-ordinator ▪ Timetable	*Note: CAT discussed the application at its September 2014 meeting. CAT concluded that this product is.* CAT noted the request from the applicant requesting that CAT follows the procedures for ATMP classifications as published (which do not include the possibility to conclude on ATMP classification at the validation of the application). CAT agreed to start the CAT classification procedure. Nominations were received from . The following CAT member was appointed as CAT co-ordinator:

4.3. [adeno-associated virus (AAV) vector carrying a gene for bacterial halorhodopsin]. Proposed indication: intended for the treatment of retinitis pigmentosa. **For adoption:** ▪ ATMP Classification report	See also 7.2. CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. This product is a classified as a CAT secretariat to send the draft scientific recommendation to the Commission for comments until 30 October 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. [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 adoption:** ▪ ATMP Classification report	CAT discussed the ATMP classification report. CAT concluded that the following additional information should be provided by the applicant before concluding on the ATMP classification:
4.5. [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 adoption:** ▪ ATMP Classification report	CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. This product is a classified as a CAT secretariat to send the draft scientific recommendation to the Commission for comments until 30 October 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. [autologous differentiated adipose cells isolated from adipose tissue]. Proposed indication: intended for the treatment of primary perianal fistula **For adoption:** ▪ ATMP Classification report	CAT discussed the ATMP classification report. CAT concluded that the following additional information should be provided by the applicant before concluding on the ATMP classification:

4.7. [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 adoption:** ▪ ATMP Classification reports	CAT discussed the ATMP classification reports for the 4 proposed indications. CAT adopted by consensus the ATMP classification reports. This product is a classified as: CAT secretariat to send the draft scientific recommendation to the Commission for comments until 30 October 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.

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 discussion:** ▪ Registry to list possible/available CAT-related expertise/resources in each MS for MN-teams	CAT members provide input in the list of CAT-related expertise/resources in the MS of Multinational assessment teams. CAT members can provide further comments on the registry until 1 November 2014.

8.1.2. Application of ATMP Regulation **For information:** ▪ Feedback from EMA to the Commission's letter of 1st July 2014 requesting mapping of requirements of cell and gene therapies for MAs: mapping exercise **For discussion:** ▪ Aspects to consider' on questions to SAWP of ATMPs. Presentation by ▪ Oral feedback from the CAT reflection group on Risk Based Approach	CAT reflection groups: - Quality related issues: - Risk based approach: CAT members noted the feedback to the Commission (mapping exercise). CAT discussed the 'Aspects to consider on questions to SAWP of ATMPs'. The rationale and added value were discussed. It was agreed to review the document first (will be included in the CAT post-mail) and re-discuss the topic at the November CAT meeting. Feedback was provided from the discussions at the CAT reflection group on Risk based Approach. It was agreed that the next telecon would include the participants of both groups.
8.1.3. Review of the initial MAA process. Update on the consultation workshop with NCAs that took place in early September 2014: **for information**	CAT noted the initiative. Following CAT members will take part in the discussion on the 3 areas for improvement: - Peer review best practice guide: - Scope of the clarification meeting: - Document flow / AR templates:

8.2. CAT Meeting Organisation

8.2.1. CAT Membership **For information:** Czech Republic: ▪ Tomáš Boráň – becomes member (from his former position of alternate) nominated on 1st October 2014 ▪ Ivana Haunerova – becomes alternate (from her former position of member) nominated on 1st October 2014	Noted
8.2.2. CAT/CHMP/COMP joint informal meeting to be held in Rome on 28th – 30th October 2014 under the auspices of the Italian Presidency of the Council of the European Union **For information:** ▪ Agenda ▪ CAT final participation list	Noted

8.3. Co-ordination with Committees/WPs/SAGs

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

8.4. CAT's Workplan

8.4.1. CAT Workplan 2015-2016: **for discussion**	*Note: the draft workplan 2015-2016 was developed on basis of discussion at the September 2014 CAT meeting.* CAT agreed with the 4 WP activities and the timings proposed. Additional CAT participants were included for the topic on assessor training (WP activity 2) and Scientific workshop with learned society (WP activity 4).

8.5. Interested Parties to CAT

8.5.1. CAT meeting with interested parties (IP) during the December CAT meeting **For discussion:** ▪ Agenda topics	*This meeting will take place on Thursday 11 December from 15.00 – 18.00. The CAT plenary meeting would run on 11 December from 10.00 to 15.00 and on Friday from 9.00-15.00. All timings are provisional.* CAT agreed to hold this IP meeting during the December meeting. Topics for discussion: 1) classification reflection paper; 2) application of Risk based approach and 3) Topics proposed by IP.

9. CAT's DGs / PCWP and HCPWP

9.1. DG on GTMP Guidelines

No items on the agenda

9.2. DG on CTMP and TEP Guidelines

No items on the agenda

9.3. PCWP and HCPWP

No items on the agenda

10.OTHER SCIENTIFIC TOPICS

10.1. Meeting between CAT and Competent Authorities for tissues and cells: **for discussion**

For information:

- Minutes of the meeting between CAT and Competent Authorities for tissues and cells of 13 February 2012

In September, CAT appointed following CAT members to attend a meeting with the Competent Authorities for tissues and cells (CA T&C).

The Commission clarified that two meeting are proposed:

1) On 4 December, in the plenary meeting of the meeting of the CA T&C. Topic for discussion: Presentation of the CAT Reflection paper on classification.

2) On 5 December, as a joint meeting with approx. 7 participants from CAT and 7 participants from the CA T&C to discuss topics of common interest. Note that a similar meeting was held in February 2012 (the minutes of that meeting were tabled in CAT-MMD).

Further to discussion and clarifications from the Commission, it was agreed to postpone the 2nd meeting to a later date (first half of 2015) and to invite all interested members from the CAT and the CA for Tissue and Cells. During the meeting on the 4 December, there could be some discussion on topics for the larger meeting.

10.2.	Council of Europe – Guide to the Quality and Safety of Tissues and Cells for Human Application, second edition **For discussion:** ▪ Chapters 20, 21 and 22 related to ATMPs	*Note: the Council of Europe is preparing a revision of the Tissues & Cells Guide. Chapters 20, 21 and 22 are making reference to ATMP and are significantly extending the scope of chapter 20 ATMP, 1st edition TC guide.* CAT agreed to provide comments on these chapters by 14 November 2014. Following CAT members agreed to be involved: CAT secretariat will organise a telecon to agree on the tasks. The comments will be presented to the CAT in November before sending them to EDQM Post-meeting note: - EDQM will be asked for chapter 1 (introduction) and chapter 23 (adipose tissues) for review - Following colleagues will review chapter 1 and 20 - Following colleagues will review chapter 21 (Haematopoeitic stem cells): - Following colleagues will review chapter 22 (Other cells) and chapter 23 (when available):

10.3.	European Directorate for the Quality of Medicines & HealthCare (EDQM): General chapter 5.2.12 on raw materials used in the production of ATMPs **For information:** ▪ Publication in Pharmeuropa 26.4 (01 October 2014) of the general chapter 5.2.12 on raw materials used in the production of ATMPs. CAT comments can be sent to the following address: http://pharmeuropa.edqm.eu/home/.	Paula Salmikangas CAT members-EDQM WP members: P. Salmikangas, S. Ruiz, M. Menezes-Ferreira and L. Åkerblom, S. Saarela, L. Bisset and MT. Duffour Note: an EDQM/EMA meeting with ATMPs manufacturers and manufacturers of raw materials took place in April 2013. The EDQM WP have been working on the drafting of a general chapter of the raw materials using a *'family'* approach to define the quality requirements. The commenting period runs for 5 months from October (3 months public and 2 months for NPAs to collate responses). Information on how comments can be made on the EDQM website is provided in the following link: http://www.edqm.eu/site/how_to_commentpdf-en-31354-2.html The information was noted.
10.4.	The EMA's Executive Director – Guido Rasi's invitation to the CAT members to welcome the new building: 30, Churchill Place. Venue: The Promenade: -1 floor (one level below the ground floor) from 18:30hrs	
10.5.	Veterinary medicines: setting up of a trilateral meeting with the Center of Veterinary Medicines of FDA (US) and Health Canada as a Stem Cell Working Group Trilateral meeting **For appointment:** ▪ CAT member to participate in the trilateral TC on 17th October from 14:00 – 16:00hrs (room 9C): S. Ruiz and M. Timón	The topics proposed by FDA for discussion include: ▪ Questions on the recent GFI (Guidance for Industry) ▪ Update on FDA activity related to cellbased products ▪ Donor eligibility (FDA have a GFI underdevelopment) ▪ Good Tissue Practices (FDA have a GFI under development) ▪ Acceptable means of comparing potency and safety of new cell lines for a given product CAT members were invited to join this telecon.
11.A.O.B.		
11.1.	Quarterly report of panned MAAs with already appointed Rapporteurs: **for information**	The information was noted.

11.2.	11th Annual Phacilitates Cell & Gene Therapy Forum 2015, 26th-28th January 2015, Washington DC (USA) **For information:** ▪ will present the EU regulatory perspective (*tbc*)	will attend instead of
11.3.	Inauguration Meeting and the Affiliated International Conference of Cellular Therapy organized by the Taiwan Association of Cell Therapy (TACT) on 5th December 2014 in Taipei (Taiwan) **For information:** ▪ will present on the subject of cell therapy	

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.

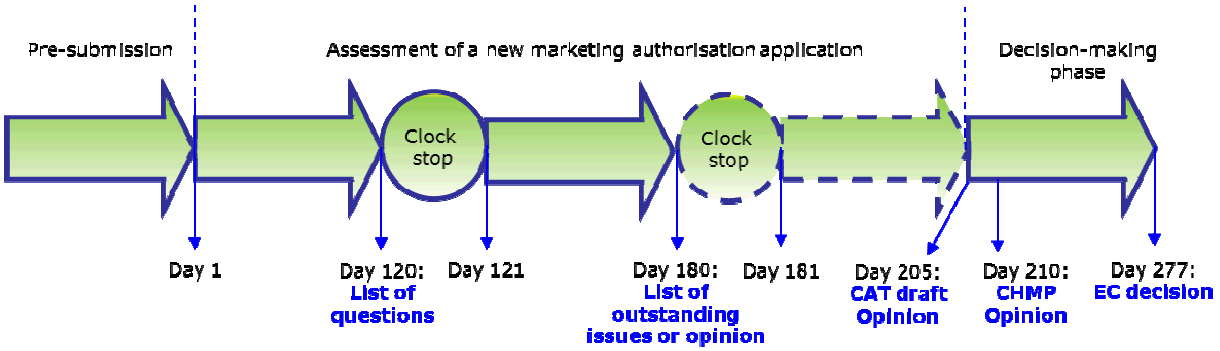
Evaluation of ATMPs (section 2)

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 2.6.*)

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.

List of participants: *including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 16-17 October 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			
Ivana Haunerova	Czech Republic	17/09/2014	1	Full involvement			
Sinan B. Sarac	Denmark	26/03/2014	3	No restrictions applicable to this meeting			Attended 16th
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			
Balázs Sarkadi	Hungary	24/5/2014	1	Full involvement			
Paolo Gasparini	Italy	26/08/2014	1	Full involvement			
Romaldas Mačiulaitis	Lithuania	02/06/2014	2	No restrictions applicable to this meeting			
Dariusz Śladowski	Poland	03/08/2014	3	No restrictions applicable to this meeting			
Mikuláš Hrubiško	Slovakia	11/06/2014	2	No restrictions applicable to this meeting			
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			Attended

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
							16th
Elaine French	UK	13/01/2014	1	Full involvement			
Bernd Gänsbacher	IEOT	10/07/2014	1	Full involvement			
Kieran Breen	EPDA	25/04/2014	2	Full involvement			
Michele Lipucci di Paola	EURORDIS	09/06/2014	2	Full involvement			
Pieter Doevendans	ESC	18/06/2014	2	Full involvement			

CAT Alternate	Country	Declaration of interest date	Risk level	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/ substance	Agenda points	Comments
Belaïd Sekkali	Belgium	02/06/2014	1	Full involvement			
Ivica Malnar	Croatia	25/05/2014	3	No restrictions applicable to this meeting			
Esteve Trias-Adroher	EATB	23/07/2014	1	Full involvement			Attended 16th
Olli Tenhunen	Finland	14/02/2014	2	No restrictions applicable to this meeting			
Krisztián Fodor	Hungary	29/07/2014	1	Full involvement			
Rune Kjeken	Norway	17/06/2014	2	No restrictions applicable to this meeting			
Margarida Menezes-Ferreira	Portugal	09/06/2014	1	Full involvement			

CAT members and alternates by phone	Country	Declaration of interest date	Risk level	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/ substance	Agenda point	Comments
Una Riekstina	Latvia	04/11/2013	1	Full involvement			

EUROPEAN COMMISSION	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/ substance
Rocío Salvador-Roldán		Full involvement	
Ioana Siska		Full involvement	Attended Friday 17.10.14

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			
Jana schweigertova	Slovakia		3	No restrictions applicable to this meeting			
Ann-Christin Bakker	Germany	17/12/2014	1	No restrictions applicable to this meeting		2.3.1.	Attended 16th

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.							

Observers By phone	Organisation	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
Marta Lopez-Fraga	Conseil de l'Europe	06/10/2014	1	Full involvement			