17 October 2014
EMA/CAT/737694/2014
Procedure Management and Business Support Division

Committee for Advanced Therapies (CAT)

Minutes of the 18 – 19 September 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/550904/2014) for the CAT plenary to be held on 18th and 19th September 2014: **for adoption**	Adopted without amendments
1.2. TABLE OF DECISIONS CAT plenary held on 17th and 18th July 2014 (EMA/CAT/440207/2014): **for information**	Noted
1.3. MINUTES of the CAT plenary held on 17th and 18th July 2014 (EMA/CAT/580044/2014): **for adoption**	Adopted without amendments
1.4. REPORT of the written procedure; August: **for information**	Noted

2. EVALUATION OF ATMPS

2.1. OPINION

No items on the agenda

2.2. ORAL EXPLANATION

No items on the agenda

2.3. LoOI

No items on the agenda

2.4. LIST OF QUESTIONS

No items on the agenda

2.5. DAY 80 ASSESSMENT REPORT

No items on the agenda

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

No items on the agenda

2.7. WITHDRAWAL OF APPLICATION

No items on the agenda

2.8. ONGOING EVALUATION PROCEDURES

2.8.1. (*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 adoption:** ▪ Timetable to response to LoQs	The response timetable was adopted.
2.8.2. (allogeneic human heterologous liver cells) (EMA/H/C/003750). Therapeutic indication: treatment of urea cycle disorders. **For discussion:** ▪ Letter from the applicant dated 27 August 2014, requesting an extension of the clock-stop to respond to the D120 LoQs ▪ Feasibility analysis by the Rapporteurs **For adoption:** ▪ Timetable to response to LoQs	CAT discussed the request for the company for an additional clock stop to respond to the list of questions related to module 3 and module 5. The feasibility analysis by the Rapporteurs was presented. CAT decided not to grant the clock stop extension. The applicant will be informed accordingly.

2.9. NEW APPLICATIONS

2.9.1. (talimogene laherparepvec) (EMA/H/C/H0002771). Therapeutic indication: treatment of adults with unresectable or metastatic melanoma. **For adoption:** ▪ Evaluation Timetable	The committee adopted the evaluation timetable pending satisfactory outcome of the validation.

2.10. GMP and GCP INSPECTIONS REQUESTS

2.10.1. (allogeneic human heterologous liver cells) (EMA/H/C/003750). Therapeutic indication: treatment of urea cycle disorders. **For discussion:**	

2.11. POST-AUTHORISATION

2.11.1. Type II Variations

2.11.1.1.	**Glybera** MAH: UniQure Biopharma B.V. (EMEA/H/C/002145/II/30) *Orphan* **II/30** **Scope:** update of the protocol of the CM efficacy and safety study requested in Annex II **For adoption:** ▪ Draft opinion or RSI	CAT Rapporteur: E. French (UK) CHMP Co-ordinator: G. Markey (UK) See also 2.11.1.2. The draft opinion was adopted by consensus.
2.11.1.2.	**Glybera** MAH: UniQure Biopharma B.V. (EMEA/H/C/002145/II/34) *Orphan* **II/34** **Scope:** submission of final study report AMT011-02 **For discussion:** ▪ Request by the MAA asking for a clock stop to answer to the RSI **For discussion:** ▪ Rapporteurs' AR **For adoption:** ▪ RSI	CAT Rapporteur: E. French (UK) CHMP Co-ordinator: G. Markey (UK) See also 2.11.1.1. CAT adopted the RSI for this variation. CAT agreed on a clock stop to respond to the questions.

2.11.2. Other PA Activities

2.11.2.1.	**MACI** [matrix-assisted autologous chondrocyte implantation]. MAH: Aastrom Biosciences DK ApS. (EMEA/H/A20/1409/C/002522/0004) **For discussion:** ▪ Notification from the European Commission, triggering a procedure under Article 20 **For adoption:** ▪ Draft CAT assessment report (Art. 20 procedure) ▪ Draft opinion recommending suspension	CAT Rapporteur: E. French (UK) CAT Co-Rapporteur: H. Ovelgönne (NL) CHMP Co-ordinators: G. Markey (UK) and J. Lodewijk Hillege (NL) See also 2.11.2.2. CAT adopted by consensus the draft opinion and assessment report for the article 20 procedure.
2.11.2.2.	**MACI** [matrix-assisted autologous chondrocyte implantation]. MAH: Aastrom Biosciences DK ApS. (EMA/H/C/002522/PSUV/0002) **Scope:** PSUR **For information:** ▪ PRAC PSUR AR (D60)	CAT Rapporteur: E. French (UK) CAT Co-Rapporteur: H. Ovelgönne (NL) PRAC Rapporteur: R. Suvarna (UK) See also 2.11.2.2. *PSUR adopted at PRAC in September 2014* Noted

2.11.2.3.	**PROVENGE** (autologous peripheral blood mononuclear cells activated with pap-gm-csf (sipuleucel-T)). MAH: Dendreon UK Ltd. (EMA/H/C/002513/PSUV/0001) (with RMP version 7.0) **Scope:** PSUR **For information:** ▪ PRAC PSUR AR (D60)	CAT Rapporteur: E. Flory (DE) CAT Co-Rapporteur: N. Ferry PRAC Rapporteur: B. Keller-Stanislawski (DE) *PSUR adopted at PRAC in September 2014* Noted
2.11.2.4.	**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 for specific obligation for introduction of virus removal step in manufacturing process (ANX004) **For adoption:** ▪ Timetable	CAT Rapporteur: UK CHMP Coordinator: Greg Markey *Note: upon agreement by CAT, the company will submit a variation to amend the Annex II to the opinion.* Discussion postponed until next month due to the late arrival of the request.

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.	[allogeneic peripheral blood mononuclear cells induced to an early apoptotic stage)]. Proposed indication: prevention of graft versus host disease. **For information:** ▪ ATMP Classification report	*The European Commission raised some minor comments that did not affect the scientific conclusion. The report was, therefore, amended and sent to the applicant.* Noted
4.2.	[allogeneic expanded CD34+HSC issue from cord blood unit allogeneic lymphoid cells CD34- issue from cord blood unit]. Proposed indication: malignant hemopathies. **For discussion:** ▪ Comments received by the Commission on 25 July 2014 **For adoption:** ▪ Revised ATMP Classification report following Commission's comments	The report was revised taking into account the comments from the Commission. CAT adopted by consensus the amended, revised ATMP classification report. This product is a classified as a Tissue engineered product.

4.3.	[AAV containing DNA encoding an RNAi targeting rhodopsin in combination with an AAV containing DNA encoding a rhodopsin gene]. Proposed indication: treatment of autosomal dominant rhodopsin-linked retinitis pigmentosa. **For information:** ▪ ATMP Classification report	*The European Commission raised some minor comments that did not affect the scientific conclusion. The report was, therefore, amended and sent to the applicant.* Noted
4.4.	[lyophilised genetically modified Lactococcus (L. lactis) strin sAGX0354]. Proposed indication: reduction of the signs and symptoms, and induction and maintenance of clinical remission in patients with moderately active ulcerative colitis (UC). **For adoption:** ▪ ATMP Classification report	CAT adopted by majority the amended, revised ATMP classification report. This product is a classified as a . A divergent position was signed by 6 CAT members. CAT secretariat to send the draft scientific recommendation to the Commission for comments until 2 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.
4.5.	[platelet generated from in-vitro derived megakaryocytes]. Proposed indication: treatment of thrombocytopenia in patients at risk of bleeding or with haemorrhagic events **For information:** ▪ Request for ATMP classification received 24.07.14. ▪ Additional information received on 05.09.14. **For discussion:** ▪ Start of procedure **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	CAT discussed the application. CAT conclude that this product is . The applicant will be informed accordingly. CAT will consider inclusion of its 'definition of a cell for the purpose of ATMP classification procedures' in the Reflection paper for ATMP classification (which is currently being revised).
4.6.	[oral/sublingual prophylactic vaccine that induces a mucosal immune response to prevent *Clostridium difficile* infection or relapse]. . Proposed indication: intended for vaccination against the infectious disease-causing bacterium *Clostridium difficile.* **For information:** ▪ Request for ATMP classification received 16.08.14. ▪ Draft letter to applicant .	EMA presented the considerations for this application: as the product does not contain genes, cells or tissues, CAT concluded that this is not an ATMP. The applicant will be informed accordingly.

4.7. [adeno-associated virus (AAV) vector carrying a gene for bacterial halorhodopsin]. Proposed indication: intended for the treatment of retinitis pigmentosa **For information:** ▪ Request for ATMP classification received 03.09.14. **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from: . The following CAT member was appointed as CAT co-ordinator: .
4.8. [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 information:** ▪ Request for ATMP classification received 02.09.14. **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from: . The following CAT member was appointed as CAT co-ordinator: .
4.9. [human embryonic stem cell derived retinal pigment epithelial cells]. Proposed indication: for the treatment of age-related macular degeneration and Stargardt's macular dystrophy. **For information:** ▪ Request for ATMP classification received 02.09.14. **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from: The following CAT member was appointed as CAT co-ordinator:
4.10. [autologous differentiated adipose cells isolated from adipose tissue]. Proposed indication: treatment of primary perianal fistula **For information:** ▪ Request for ATMP classification received 02.09.14. **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from: . The following CAT member was appointed as CAT co-ordinator:

4.11. [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 information:** ▪ Request for ATMP classification received 02.09.14. **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from: . The following CAT member was appointed as CAT co-ordinator:
4.12. [concentrate of autologous, uncultured, custom prepared bone marrow aspirate]. Proposed indication: field of regenerative medicine: bone damaged by disease (e.g. ostenecrosis), fracture or age-related loss of bone function. **For information:** ▪ Cover letter and classification report **For discussion:** ▪ Request from the applicant	The CAT classified this product as a tissue-engineered product in June 2014. CAT discussed the letter from the applicant. It was noted that the classification procedure, which is not binding, does not have the possibility for an appeal: the applicant will have to submit a new ATMP classification request. There was a scientific discussion on the arguments from the company that the use of bone marrow (BM) for bone repair should be considered as homologous use: publications show that BM-MSC are involved in bone repair. CAT indicated that other publications indicate that BM-MSC will not leave the BM in case of injury. Bone repair is rather mediated by cells of the bone periosteum. Administration of BM-MSC at the injury site is therefore considered to be non-homologous use of BM. This information will be included in the response letter 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.

CAT 0: new SAs - appointment of CAT Rapporteur

CAT 2: discussion of List of Issues

CAT 3: finalisation of SA procedures

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.

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	Postponed until the October CAT meeting
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 and proposal for reflection paper on questions to be asked for SA/PA for ATMPs **For discussion:** ▪ Oral feedback from the 1st meeting of the CAT Reflection Group of quality/manufacturing issues	CAT reflection groups: - Quality related issues: - Risk based approach: EMA provided feedback on the mapping of the guidelines and requirements for cell- and gene products. The final documents will be provided to CAT for the October meeting. Feedback was also provided from the first meeting of the CAT Reflection group on quality/manufacturing issues.
8.1.3. Final Procedural Advice on CAT/CHMP/PRAC Rapporteur Appointments: **for information**	Comments from PRAC have been incorporated. The information was noted.

8.2. CAT Meeting Organisation

8.2.1. CAT Membership **For information:** Hungary: ▪ Balázs Sarkadi – becomes member (from his former position of alternate) nominated on 15th August 2014 ▪ Krisztian Fodor – new alternate nominated on 15th August 2014	The information was 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 discussion:** ▪ Topics for the agenda for day two	Guido Pantè – AIFA CAT discussed the topics for the CAT only session on day 2. Following two main topics were identified: 1. Interface between tissues & cells and ATMPs; 2. Initial discussion of the comments received on the Reflection paper on ATMP classification.

8.3. Co-ordination with Committees/WPs/SAGs

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

8.4. CAT's Workplan

8.4.1.	CAT Workplan 2015: **for discussion**	Link to the EMA Work Programme 2014: http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2014/03/WC500163394.pdf Contributions received: *Note: a presentation was given in June 2014 on how the Committee workplan will be developed for the next years.* CAT identified following topics for the 2015-2016 workplan: - Training / webinar on ATMP classification to support NCAs - Assessor training for assessors and inspector (training to take place in 2016, preparatory work in 2015) - Understanding trends in R&D for ATMPs - Providing assistance to ATMP developers: organisation of a scientific training/meeting in association with a scientific society. EMA will on basis of this discussion prepare the CAT workplan for 2015-2016, for further discussion at the October CAT meeting.
8.4.2.	Joint CAT-DGTI workshop, Dresden (Germany), 11 September 2014. **For information:** ▪ Oral feedback ▪ Presentations	Organising committee: E. Flory, M. Hystad, I. Reischl, P. Salmikangas, P. Celis, T. Tonn (DGTI), H-D Volk (DGTI), P. Schlenke (DGTI) Oral feedback was provided from the CAT workshop in Dresden.

9. CAT's DGs / PCWP and HCPWP

9.1. DG on GTMP Guidelines

9.2. DG on CTMP and TEP Guidelines

9.2.1. Reflection Paper on clinical aspects related to tissue-engineered products (TEPs). **For information:** ▪ Overview of Guideline Consistency Group (GCG) comments **For adoption:** ▪ Revised RP ▪ Overview of comments	CAT adopted the Reflection Paper in March 2014 pending comments from the SWP and Guideline Consistency Group. Comments by the GCG have been incorporate in the revised RP. The Reflection paper was re-adopted by CAT and will now be published

9.3. PCWP and HCPWP

9.3.1. Joint meeting of the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals Working Party (HCPWP). To take place on 16th September 2014 **For information:** ▪ Agenda	The agenda was noted.

10.OTHER SCIENTIFIC TOPICS

10.1. European Commission's upcoming legislation on tissues and cells • Interest received from CAT members to attend the meeting at the Commission in Dec. '14: • Interest received from CAT to be interviewed by the Commission's contractant (Rathenau Institute, NL):	It was agreed that the following CAT members will attend the Commission meeting with the Competent Authorities for tissues and cells in the beginning of December 2014: .
10.2. 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/.	CAT members-EDQM WP members: 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

10.3.	Council of Europe – Guide to the Quality and Safety of Tissues and Cells for Human Application, second edition **For information:** ▪ Ongoing revision, and more specifically chapters 15, 21, 23 and 24 related to ATMPs	The Council of Europe is preparing a revision of the Tissues & Cells Guide. Chapters 15, 21, 23, and 24 are dealing with ATMP and are significantly extending the scope of chapter 20 ATMP, 1st edition TC guide. CAT will receive these draft chapters in advance of the October CAT meeting, and will have one month to comment. The need for a closer interaction and collaboration with EDQM was stressed.
10.4.	EMA/CAT/FDA/Health Canada bimonthly teleconference on ATMP cluster **For information:** ▪ Minutes of the June 2014 ATMP cluster teleconference **For adoption:** ▪ Agenda	The agenda was agreed. The next ATMP cluster telecon will take place on 13 November 2014. As CAT is meeting virtually in November, this telecon will be held, exceptionally, from 14.00 – 15.30 UK time.

11.A.O.B.

11.1.	Translational Regenerative Medicines Congress, Leipzig, 21-22 October 2014: **for information**	http://tools.emailsys.net/mailing/149/492927/0/cg0gss/index.html
11.2.	EMA's new building: 30, Churchill Place, Canary Wharf **For information:** ▪ Practical information affecting all delegates ▪ Induction at the start of the first meeting in the new building	
11.3.	Invitation of the GLP Inspector Working Group for CAT members to attend the upcoming meeting (8 October 2014) **For information**	GLP-IWG wants to discuss with CAT members the expectations of non-clinical studies for ATMP submissions. Post-meeting note: following CAT members are interested to join the GLP-IWG meeting: .

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.

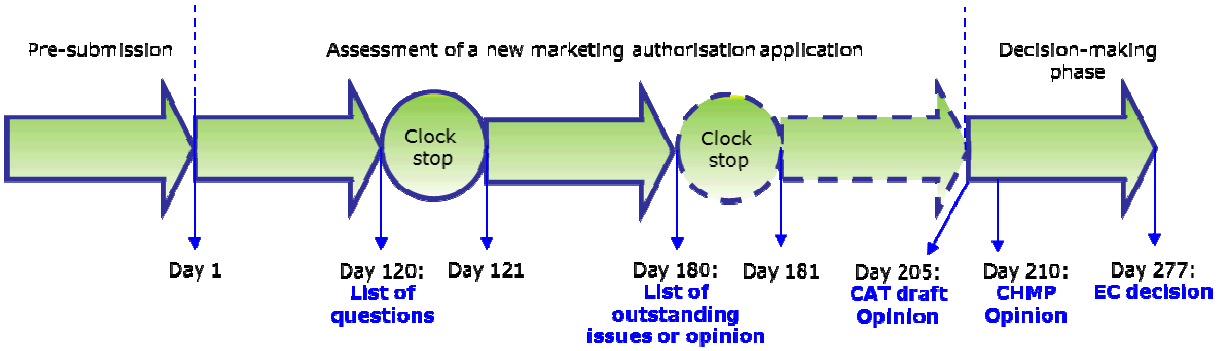
Evaluation of ATMPs (section 2)

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.

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 18-19 September 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			
Claire Beuneu	Belgium	22/5/2014	1	Full involvementr			
Rozalina Kulaksazova	Bulgaria	07/05/2014	1	Full involvement			
Sandra Tomljenovic	Croatia	30/08/2014	1	Full involvement			
Ivana Haunerova	Czech Republic	10/10/2013	1	Full involvement			
Toivo Maimets	Estonia	05/06/2014	1	Full involvement			
Sinan B. Sarac	Denmark	26/03/2014	3	No restrictions applicable to this meeting			Attended the 18th
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			Attended the 18th

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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
Balázs Sarkadi	Hungary	24/5/2014	1	Full involvement			
Paolo Gasparini	Italy	26/08/2014	1	Full involvement			
Una Riekstina	Latvia	04/11/2013	1	Full involvement			
Romaldas Mačiulaitis	Lithuania	02/06/2014	2	No restrictions applicable to this meeting			
Johannes 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			
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			
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			

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		
Belaïd Sekkali	Belgium	02/06/2014	1	Full involvement			
Ivica Malnar	Croatia	25/05/2014	3	No restrictions applicable to this meeting			
Tarmo Tiido	Estonia	27/05/2014	1	Full involvement			
Olli Tenhunen	Finland	14/02/2014	2	No restrictions applicable to this meeting			
Angeliki Roboti	Greece	22/07/2014	1	Full involvement			
Krisztián Fodor	Hungary	29/07/2014	1	Full involvement			
Guy Berchem	Luxembourg	26/03/2014	3	No restrictions applicable to this meeting			
Anthony Samuel	Malta	09/05/2014	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			
Marcos Timón	Spain	06/05/2014	1	Full involvement			
Björn Carlsson	Sweden	26/05/2014	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
Maura O'Donovan	Ireland	01/09/2014	1	Full involvement			

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

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

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

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	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
Karl-Heinz Buchheit	Conseil de l'Europe	10/04/2014	1	Full involvement			