EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 March 2015
EMA/CAT/199284/2015
Procedure Management and Business Support Division

Committee for Advanced Therapies (CAT)

Minutes for the meeting on 19–20 February 2015

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 19-20 February 2015.	See Annex to the Draft 1 of February 2015 minutes (to be published post March 2015 CAT meeting) M Hrubisko informed that CAT that he has been supplying the starting material (cord blood) for a product similar to 4.5.
1.2. Adoption of agenda of the meeting of 19-20 February 2015	Adopted
1.3. Adoption of the minutes of the previous CAT meeting on 15-16 January 2015	Adopted. *CAT members were informed that the Table of Decisions was replaced by Draft 0 of the minutes.*

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 MAH: UniQure Biopharma B.V. (EMEA/H/C/002145/II/34) *Orphan* **II/34** **Scope:** submission of final study report AMT011-02 **For information:** **For adoption:** ▪ Revised timetable	CAT Rapporteur: E. French CHMP Co-ordinator: G. Markey See also 2.11.2.1. CAT adopted the revised timetable.

2.11.2. Other PA Activities

2.11.2.1. Glybera (EMEA/H/C/002145/S/0039), (alipogene tiparvovec), MAH: UniQure Biopharma B.V. *Orphan*. Second Annual Reassessment **For information:** ▪ Updated Rapporteur's assessment report **For adoption:** ▪ Draft Opinion	CAT Rapporteur: E. French CHMP Co-ordinator: G. Markey PRAC Rapporteur: J. Williams CAT adopted by consensus the Draft Opinion of the 2nd Annual assessment of Glybera. Minor changes are introduced in Annex II to update the status of the quality specific obligation (update of the deadline for providing the information on virus safety).
2.11.2.2. ChondroCelect (characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins) MAH: TiGenix N.V. (EMA/H/C/00878/MEA 16.3 and 18.3) **Scope:** Randomised control trial protocol TIG/ACT/04/2009 **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 information:** **For adoption:** ▪ Revised timetable	CAT Rapporteur: E. Flory CAT Co-Rapporteur: T. Palomäki CHMP Co-ordinator: J. Müller-Berghaus **Revised timetable:** CAT adopted the revised timetable. CAT requested to align the assessment of PAM 16.3 and 18.3 with the outcome of the .

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. [adipose-derived mesenchymal stem cells]. Proposed indication: intended for the treatment of autoimmune diseases. **For information**: ▪ ATMP Classification report	*The European Commission raised no comments*
4.2. [Tumour-infiltrating lymphocytes derived from metastatic melanoma]. Proposed indication: intended for the treatment of metastatic melanoma **For information**: ▪ ATMP Classification report	*The European Commission raised no comments*
4.3. [human extracellular matrix on a absorbable polymer matrix]. Proposed indication: intended for the surgical/ interventional treatment of congenital heart malformations **For discussion:** ▪ Comments received from the Commission dated 6th February 2015 **For adoption**: ▪ Revised ATMP Classification report	The revised report, taking into account the comments from the Commission, was adopted.
4.4. [adult human bone-marrow derived, *ex-vivo* expanded, pooled allogeneic mesenchymal stromal cells]. Proposed indication: intended for thromboangiitis obliterans (Buerger's disease) **For adoption:** ▪ ATMP Classification report	CAT discussed the ATMP classification report. In view of the claimed mode of action and the disease characteristics, CAT considered that the product is rather working Amendments were made to the report. CAT adopted by consensus the revised ATMP classification report. This product is a classified as a . CAT secretariat to send the draft scientific recommendation to the Commission for comments until 6 March 2015. 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. [autologous mononuclear cells derived from human cord blood]. Proposed indication: intended for paediatric brain damage, hypoxic-ischaemic encephalopathy, and cerebral palsy **For information:** ▪ Request received on 06.02.15. **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from . The following CAT member was appointed as CAT co-ordinator:

4.6. [suspension of allogeneic human adult stern cells, isolated from skeletal muscle]. Proposed indication: intended for the treatment of Duchenne Muscular Dystrophy (DMD) **For information:** ▪ Request received on 04.02.15. **For adoption:** **Appointment of CAT Co-ordinator** ▪ Timetable	Nominations were received from . The following CAT member was appointed as CAT co-ordinator:
4.7. [allogeneic *ex-vivo* expanded placental adherent stromal cells] Proposed indication: intended for Peripheral Arterial Occlusive Disease (PAOD). **For information:** ▪ Request received on 04.02.15. **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 somatic cells therapy medicinal product derived from the isolation and *ex vivo* expansion of human Umbilical Tissue-Derived Cells]. Proposed indication: improvement of visual acuity in patients with vision loss from geographic atrophy secondary to age-related macular degeneration. **For information:** ▪ Request received on 04.02.15. **For adoption:** **Appointment of CAT Co-ordinator** ▪ Timetable	Nominations were received from . The following CAT member was appointed as CAT co-ordinator:
4.9. [autologous dendritic cells loaded with autologous irradiated tumour stem cells suspended in a cryopreservation medium]. . Proposed indication: intended for the treatment of melanoma. **For information:** ▪ Request received on 02.02.15. **For adoption:** **Appointment of CAT Co-ordinator** ▪ Timetable	Nominations were received from . The following CAT member was appointed as CAT co-ordinator:
4.10. Reflection Paper on Classification of ATMPs **For discussion:** ▪ Update on the activities of the Drafting groups	Following CAT members will take part in the review of the comments received: - Drafting group on substantial manipulation: - Drafting group on non-homologous use CAT discussed the proposed rewording of the sections on substantial manipulation and non-homologous use (not the same essential function). The drafting groups will now finalise the wording taking into account the CAT comments.

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)

6.1.1. The PDCO requests the CAT's view on the acceptable levels of DMSO for children (to be consistent with future procedures) and whether they could provide recommendations on the maximum acceptable DMSO levels for the paediatric population: **for discussion**	– Paediatric Medicines Dept. provided feedback from his own clinical experience. Reference was made to the following article: M.A. Cox, J Kastrup, M. Hrubiško. *Historical perspectives and the future of adverse reactions associated with haematopoietic stem cells cryopreserved with dimethyl sulfoxide.* Cell Tissue Bank (2012) 13: 203-215. In short, the plasma volume of the child needs to be calculated and the DMSO concentration after administration needs to be less than 1% of this volume (e.g. if the plasma volume is 800 ml, the child should not receive more than 80 ml of stem cells with 10% DMSO). CAT agreed that under certain circumstances it could be harmful for stem cells' efficacy to introduce a washing step prior to the Stem cell transfusion to reduce the concentration of DMSO.

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. Application of ATMP Regulation **For discussion:** ▪ Report from the joint telecon of the CAT reflection groups on quality-related issues and risk based approach ▪ Next steps	CAT reflection groups: - Quality related issues: - Risk based approach: CAT agreed to initiate work on a Q&A on requirements for minimally manipulated cells. Risk based approach (RBA) will be incorporated in the Q&A (using minimally manipulated cells as a case study / example to explain the use of RBA). Following CAT members will work in this Q&A:
8.1.2. Development of GMP requirements for investigational ATMPs **For discussion** ▪ Outcome of the DG meeting of 18.02.15.	CAT drafting group members: A short feedback was provided from the work of the Drafting group. Further telecon DG's will be scheduled. will join the GMDP-Inspectors Group meeting on 4 March (via telephone) for this topic.

8.1.3.	Joint SAWP/CAT/CHMP manuscript: *'Challenges related to development of Advanced Therapy Medicinal Products – an EMA/CAT/SAWP survey from past marketing authorization and scientific processes'* **For information:** ▪ Update of members of the Drafting Group and Reference Group	CAT noted the preparation of an article on this topic. Members from CAT, CHMP and SAWP take part to this exercise.
8.1.4.	Benefit-risk project. New template for assessment reports: **for information**	presented the B/R Project: - Structure of the B/R in the assessment report and the use of Effects table. - PROTECT Project - B/R methodology steering group. Following CAT members are already part of this steering groupIt was agreed to organise a training on B/R in the margins of the May or June CAT meeting.

8.2. CAT Meeting Organisation

8.2.1.	CAT-CHMP joint Strategic Operations Review & Learning meeting to be held in Ljubljana (Slovenia) on 26th-28th May 2015 under the auspices of the Latvian Presidency of the Council of the European Union **For information:** ▪ Practical information **For discussion:** ▪ Topics for the agenda	Note: EMA has renamed the formerly known *'informal'* meetings to *'Strategic Operations Review & Learning'* meeting. This new name accurately illustrates the true purpose of such meetings as a key part of the work of the Committees. The CAT chair and the CAT secretariat provided feedback on the discussions with CHMP chair and CHMP secretariat on topics for the joint meeting. For the joint session, following topics were proposed: - data generation pre- and post-marketing and difficulties therein (previous examples of ATMPs and other MPs for ultra-rare diseases); - patient involvement in decision making. CAT was asked to send proposals for agenda topics for the CAT only session to the CAT secretariat. Discussion on the Q&A for minimally manipulated ATMPs (see 8.1.1), the guideline for investigational ATMPs for clinical trials (see 9.2.1) and the analysis of clinical trials for ATMPs (WP 2015 project; see 8.4.2) were already proposed.
8.2.2.	CAT/CHMP/COMP joint informal meeting that took place in Rome in October 2014 under the auspices of the Italian Presidency of the Council of the European Union **For information:** ▪ Minutes of the joint session **For discussion / adoption:** ▪ Minutes of the CAT break-out session	The minutes of the joint session were noted. The minutes of the CAT break-out session were adopted via a written procedure.

8.2.3.	MMD. Training session to take place at the CAT March meeting. Send any questions/query/issues in advanced to CATSecretariat@ema.europa.eu: **for information**	CAT members were asked to provide questions, issues or specific topics for re-training on MMD to the CAT secretariat.
8.2.4.	Cross-Committee Task Force on Patient Registries. CAT members are requested to volunteer to join this task force **For information:** ▪ Description of the project and composition of this task force	presented the status of the project on Patient registries. The Task force will finalise a strategy paper, identify/develop tools and make a proposal for a pilot phase to develop and test an EU collaborative framework for patient registries that would facilitate the collection and analysis of high quality data to inform regulatory decisions and the benefit-risk profile of medicinal products. indicated his willingness to take part to the work of this steering group. See also 8.3.2.
8.2.5.	CAT Membership: Hungary: switch of roles of member and alternate: Krisztian Fodor becomes the member and Balázs Sarkadi becomes the alternate as of 19th February 2015	Noted

8.3. Co-ordination with Committees / WPs / SAGs

8.3.1.	CHMP January 2015 ToD: **for information**	Noted
8.3.2.	Oral feedback from the Scientific Co-ordination Board (SciCoBo) meeting of 29th January 2015 **For information:** ▪ Minutes of meeting 13.10.14. ▪ Report of meeting on 29.01.15.	See also 8.2.4. and 8.4.2. The CAT chair provided feedback from the discussions at the SciCoBo meeting.
8.3.3.	Question from Safety Working Party to CAT: non-clinical tumourigenicity studies for ATMPs: **for discussion**	It was agreed to organise some initial brainstorming via e-mail followed by a small telecon with members from CAT and SAWP. The outcome of this discussion will be brought to the CAT during one of its next meetings. Following CAT members agreed to take part in this discussion:

8.4. CAT's Workplan

8.4.1. Joint CAT/ISCT workshop/satellite meeting to take place in the margins of the European Meeting of the ISCT to be held on 25 September 2015, Seville (Spain): '*What should and can we do to make cellular therapies that bring value to patients available to these patients as soon as possible?'* **For information:** ▪ Feedback from the first Programme Committee teleconference **For discussion:** ▪ Topics for the agenda ▪ E-mail from ISCT dated 13th February 2015 proposing topics for the CAT/ISCT workshop	This relates to Topic 4 in the CAT Workplan 2015-2016: *'Provide assistance to ATMP developers via the organisation of a scientific workshop in collaboration with a scientific society'*. Programme Committee members: Feedback was given from the first telecon of the programme committee that took place on 21st January 2015. The proposal form ISCT was discussed. CAT proposed following agenda items: - Requirements for clinical trials from the perspective of a marketing authorisation - A general presentation of the clinical trial regulation - A general presentation of the EMA support to ATMP developers and the new regulatory pathways to facilitate development of innovative medicines.
8.4.2. CAT workplan 2015-2016: **for adoption**	See also 8.3.2. Further to presentation and discussion at the Scientific Coordination Board meeting of 29 January 2015, the CAT is asked to adopt their workplan 2015-2016. The workplan was adopted. There was a short discussion on how to organise the work on the work plan topic related to the analysis of clinical trial data from 2010-2014. A telecon will be organised with the appointed CAT members. will take part in this exercise.

8.5. Interested Parties to CAT

No items on the agenda

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 adoption:** ▪ Guideline for external consultation	The guideline was adopted for external consultation via a written procedure. The external consultation will be initiated after adoption by CHMP at their Orgam meeting and will run until end of July 2015.

9.2. DG on CTMP and TEP Guidelines

9.2.1.	Guideline on investigational ATMPs in clinical trails **For information:** ▪ Letter from Commission dated 26th January 2015 **For appointment:** ▪ Drafting group members	Postponed to March CAT meeting. CAT members interested to join this drafting group should inform the CAT secretariat by 6 March 2015.

9.3. PCWP and HCPWP

9.3.1.	Nomination of CAT members to join the HCPWP. **For information:** ▪ Job description	Olli Tenhunen stepped down in January 2015. Bernd Gänsbacher agreed to join the HCPWP.
9.3.2.	Draft Agenda EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting 4 March 2015: **for information**	Noted
9.3.3.	Draft Agenda EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting: information session on Biosimilars 5 March 2015: **for information**	Noted
9.3.4.	Minutes of the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting with all eligible organisations held in November 2014: **for information**	Noted

10. Other Scientific Topics

10.1.	EMA/CAT/FDA/Health Canada bimonthly teleconference on ATMP cluster. **For information:** ▪ Minutes of the November 2014 TC **For adoption:** ▪ Agenda	Thursday 19th February 2015 18:30hrs – 19:30hrs, room 02-C The agenda was adopted.
10.2.	Council of Europe – Guide to the Quality and Safety of Tissues and Cells for Human Application, second edition **For information:** ▪ Letter from EDQM to CAT chair dated 11th December 2014 ▪ Draft Guide, published for external consultation ▪ Communication from CAT chair to EDQM (dated 30 January 2015)	CAT provided comments on 18 November 2014 to EDQM/Council of Europe. The external consultation on the guideline expired on 31.01.15. The documents were noted

10.3. Draft INN naming scheme for cell therapy products **For agreement:** ▪ Letter from EMA to WHO (including feedback from CAT and BWP) **For information**: ▪ INN scheme ▪ Comments by CAT and BWP	Note: the draft has been developed by the WHO INN secretariat in collaboration with the INN expert group. CAT agreed with the content of the letter to WHO
10.4. European Union Clinical Trial Regulation. Public consultation on application of transparency rules. Stakeholders to submit their comments by 18th February 2015: **for information**	The clinical trial regulation was adopted on 20 December 2013. An advanced e-mail informing of the public consultation deadline was sent out to CAT members on 29.01.15 The information was noted.
10.5. Projects in Horizon 2020 related to ATMPs: current and future calls: **for information**	The colleagues from DG Research & Innovation presented the EU support/funding to ATMP research in the Framework programme 7 (2007-2013) and Horizon 2020. CAT agreed with the need to fund translational research, but has the impression that not many of the funded project result in ATMPs going into later stage clinical trials. Funding of Phase 2 and Phase 3 trials was discussed. CAT indicated that a strong regulatory aspect should be built into each project that is funded. The need for interactions between DG Research & Innovation and the CAT was acknowledged. CAT to identify and provide topics for future research projects to the Commission for their consideration for future calls.
10.6. International Pharmaceutical Regulators Forum (IPRF) – Gene Therapy Working Group. In-person meeting in the margins of the ASGCT Annual Meeting (New Orleans, Louisiana, U.S.A., 13-16 May 2015). **For agreement:** ▪	CAT agreed with the participation of to the IPRF in-person meeting and ASGCT meeting on behalf of EMA/CAT.
10.7. Joint meeting between CAT and Competent Authorities for tissues and cells / medicines **For information:** ▪ Joint meeting to take place on 23rd April 2015 (*tbc*) ▪ Letter from the CAT Chair dated 23rd January 2015 to DG Santé, Tissue and Cells Unit	The correspondence and the possible date for the joint meeting were noted.

10.8.	Invitation to write scientific/regulatory articles for four scientific publications: **For discussion and agreement:** Requests from: 1. *Current Gene Therapy* (September 2014) 2. *BioMed Research International* (January 2015) for the special issue on MSC-based mesenchymal Regenerative Medicines 3. *Cell and Gene Therapy Insights* (February 2015 4. *Current Tissue Engineering* (February 2015)	*Current Gene Therapy*. In September 2014, following CAT members agree to contribute to the writing of an article: Following CAT members agreed to take part in the preparation of an article on stem cells (likely to be submitted to Cell and Gene Therapy insights): . Other CAT members should indicate their interest.
10.9.	Similarity of orphan ATMPs **For discussion:** ▪ Question from on the consequence of the Holoclar approval for their ATMP development ▪ E-mails on similarity of two GTMPs	CAT indicated that discussion should take place jointly at COMP, CAT and BWP. Following CAT members agreed to take part to this discussion:

11. Any Other Business

No items on the agenda

Date of next CAT meeting:
Thursday 19th – Friday 20th March 2015

Explanatory notes

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

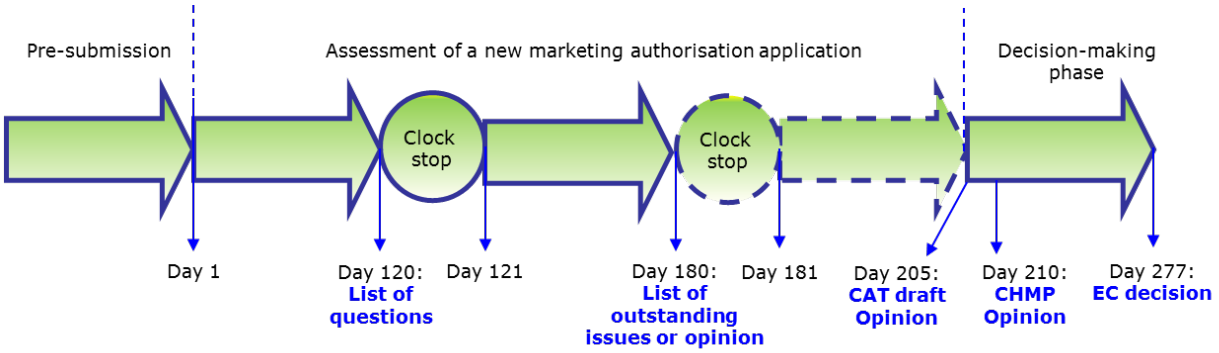
Evaluation of ATMPs (section 2)

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/

List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 19-20 February 2015 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Paula Salmikangas	Chair	Finland	No interests declared	
Martin Brunner	Alternate (replacing member)	Austria	No restrictions applicable to this meeting	
Belaïd Sekkali	Alternate (replacing member)	Belgium	No interests declared	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Sandra Tomljenovic	Member	Croatia	No interests declared	
Tomáš Boráň	Member	Czech Republic	No interests declared	
Sinan B. Sarac	Member by teleconference	Denmark	No interests declared	By telephone for Glybera
Tarmo Tiido	Alternate (replacing member)	Estonia	No interests declared	
Tiina Palomäki	Member	Finland	No interests declared	
Olli Tenhunen	Alternate	Finland	No restrictions applicable to this meeting	
Nicolas Ferry	Member	France	No interests declared	
Martina Schüssler-Lenz	Member (Vice-Chair)	Germany	No interests declared	
Egbert Flory	Alternate	Germany	No interests declared	
Asterios Tsiftsoglou	Member	Greece	No interests declared	
Balázs Sarkadi	Alternate (replacing member)	Hungary	No interests declared	
Maeve Lally	Alternate (replacing member)	Ireland	No restrictions applicable to this meeting	
Una Riekstina	Member	Latvia	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Romaldas Mačiulaitis	Member (CHMP member)	Lithuania	No restrictions applicable to this meeting	
Anthony Samuel	Alternate (to CHMP represenative)	Malta	No interests declared	
Johannes Hendrikus Ovelgönne	Member	Netherlands	No interests declared	
Rune Kjeken	Alternate (replacing member)	Norway	No restrictions applicable to this meeting	
Dariusz Śladowski	Member	Poland	No restrictions applicable to this meeting	
Margarida Menezes-Ferreira	Alternate (to CHMP represenative)	Portugal	No interests declared	
Simona Badoi	Member	Romania	No interests declared	
Mikuláš Hrubiško	Member	Slovakia	No restrictions applicable to this meeting	
Metoda Lipnik-Stangelj	Member	Slovenia	No interests declared	
Sol Ruiz	Member (CHMP co-opted member)	Spain	No interests declared	
Marcos Timón	Alternate (to CHMP represenative)	Spain	No interests declared	
Lennart Åkerblom	Member	Sweden	No interests declared	
Björn Carlsson	Alternate	Sweden	No interests declared	
Elaine French	Member	United Kingdom	No interests declared	
Pieter Doevendans	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Bernd Gänsbacher	Member	Healthcare Professionals' Representative	No interests declared	
Michelino Lipucci di	Member	Patients' Representative	No restrictions applicable to this	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Paola			meeting	
Kieran Breen	Member	Patients' Representative	No restrictions applicable to this meeting	
Guido Panté	Expert - in person*	Italy	No interests declared	
Christos Sotirelis	Expert - in person*	Italy	No interests declared	
Anke Zobywalski	Expert - via telephone*	Germany	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the product(s) they have been invited to talk about.