18 June 2015
EMA/CAT/331519/2015
Procedure Management and Business Support Division

Committee for Advanced Therapies (CAT)

Minutes for the meeting on 12-13 May 2015

Chair: Paula Salmikangas - Vice-chair: Martina Schüßler-Lenz

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CAT meeting reports once the procedures are finalised.

Of note, this agenda is a working document primarily designed for CAT members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of 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 12-13 May 2015. See May 2015 CAT minutes (to be published post June 2015 CAT meeting).

No additional declarations of interest were made by the participants.

The discussions, deliberations and voting took place in the presence of 22 CAT members (quorum reached)

1.2. Adoption of agenda

CAT agenda for 12-13 May 2015

Adopted with two additions under AOB (Workshop of the WHS on stem cell research; Training of CAT members).

1.3. Adoption of the minutes

CAT minutes for 16-17 April 2015

Adopted with one amendment to section 2.2.1.

1.4. Technical information

2. Evaluation of ATMPs

2.1. Opinions

2.1.1. Allogeneic human heterologous liver cells; *Orphan*; EMA/H/C/003750

Cytonet GmbH & Co. KG.; treatment of urea cycle disorders

Action: for adoption

Documents tabled:

Draft CAT AR

Draft Opinion

Note:

OE took place on 16th April 2015

2.2. Oral Explanations

None

2.3. D180 List of Outstanding Issues (LoOIs)

None

2.4. D120 List of Questions (LoQs)

None

2.5. Day 80 Assessment Report

None

2.6. Re-Examination Procedure (new applications) under Article 9(2) of Regulation No. 726/2004

None

2.7. Withdrawal of Initial Full Application

None

2.8. Ongoing Initial Full Application

2.8.1. Human autologous spheroids of matrix– associated chondrocytes for transplantation EMA/H/C/0002736

Treatment is eligible for single as well as multiple adjacent defects. Cartilage defects of the knee, hip, elbow, shoulder and ankle joints were treated successfully. In a few cases, defect sizes between 11 and 23 cm^2 were treated successfully. The product is indicated for adults and adolescents with a closed epiphyseal growth platecancer.

Action: for information

2.8.2. Talimogene laherparepvec; EMA/H/C/H0002771

Indicated for the treatment of adults with melanoma that is regionally or distantly metastatic

Action: for information

Notes:

-CAT issued a classification as a gene therapy medicinal product in July 2012

-CAT adopted the List of Questions in January 2015

The Rapporteur informed the CAT of the discussions that took place at a recent FDA Advisory Committee meeting.

2.9. New Applications

2.9.1. Autologous CD34+ cells transduced with retroviral vector containing the adenosine deaminase gen; *Orphan*; EMA/H/C/003854

GlaxoSmithKline Trading Services- UK; indicated for the treatment of children aged 0-18 diagnosed with ADA-SCID and for whom no suitable HLA-identical sibling bone marrow donor is available.

Notes:
CAT granted an accelerated assessment in April 2015

A presentation will be scheduled at the June CAT meeting on the procedure of GMO consultation.

2.10. GMP and GCP Inspections Requests

None

2.11. Type II Variations

None

2.12. Other Post-Authorisation Activities

2.12.1. Provenge - autologous Peripheral Blood Mononuclear Cells Activated With Pap-Gm-Csf (Sipuleucel-T)); EMA/H/C/002513

Dendreon UK LTD; Treatment of metastatic castrate resistant (hormone refractory) prostate cancer.Rapporteur: Egbert Flory; Co-rapporteur: Nicolas Ferry; CHMP Coordinators: Jan Mueller-Berghaus, Pierre Demolis; PRAC Coordinators: Brigitte Keller-Stanislawski, PRAC Co-Rapporteur: Arnaud Batz

Action: for discussion

Document tabled:
Letter from the MAH dated 21.04.15. withdrawing their MA

Notes:
After acquiring Dendreon and world-wide rights to Provenge, Valeant Pharmaceuticals performed a comprehensive review of Dendreon's portfolio, which included a careful examination of the viability of the European operations. Through this review, Valeant reached a business decision to discontinue the commercial availability of Provenge in Europe and to withdraw the Marketing Authorization.

CAT noted the information provided by the MAH. On request of the CAT, the MAH provided information on the status of the product in the USA.

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.

3.1. New Applications

None

3.2. Day 60 Evaluation Reports

None

3.3. Opinion

None

4. Scientific Recommendation on Classification of ATMPs

4.1. New Requests – Appointment of CAT Co-ordinators

4.1.1. Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor

Intended for the treatment of various types of cancer

Action: for adoption

Document tabled:

Request received on 28th April 2015

Notes:
Appointment of CAT Co-ordinator
See also 5.2.1. and 5.2.2.

Timetable:
The following CAT member was appointed as the CAT coordinator for this procedure: .

4.1.2. Human monocytes-derived suppressive cells (HuMoSC), expanded ex vivo

Intended for the treatment of acute Graft-versus-Host Disease refractory to first-line treatment

Action: for adoption

Document tabled:
Request received on 28th April 2015

Notes:
Appointment of CAT Co-ordinator

Timetable:

The following CAT member was appointed as the CAT coordinator for this procedure.

4.2. Day 30 Co-ordinators' First Reports

None

4.3. Finalisation of Procedure

4.3.1. Cell-based product made of a plasmacytoid dendritic cell line loaded with peptides from tumour antigens and irradiated

Intended for the treatment of metastatic stages of cancer

Action: for adoption

Document tabled:

Revised CAT Classification report

Comments by the European Commission dated 29th April 2015

CAT adopted the revised Classification Report.

4.3.2. Autologous chondrocyte transplantation system

Intended for the treatment of articular cartilage defect of the knee

Action: for adoption

Document tabled:

Revised CAT Classification report

Comments by the European Commission dated 29th April 2015

CAT adopted the revised Classification Report.

4.3.3. Autologous human peripheral blood Vδ1+ T lymphocytes activated in vitro by cytokine and monoclonal antibody treatment

Intended for the treatment of Chronic Lymphocytic Leukaemia, Acute Lymphoblastic Leukaemia.

Action: for information

Document tabled:
The European Commission raised no comments

4.4. Follow-up and Guidance

4.4.1. Allogeneic ex-vivo expanded placental adherent stromal cells

Intended for the treatment of Peripheral Arterial Occlusive Disease (PAOD)

Action: for discussion in view of the update of the reflection paper on classification

Documents tabled:
E-mail from the applicant dated 4th May 2015
Response from EMA to the applicant dated 6th May 2015

Note:
CAT classified it as Tissue Engineered Product (TEP) in March 2015
See also 5.2.3.

CAT agreed to include a statement in the reflection paper on classification that a product consisting of engineered cells that induces regeneration, repair or replacement in the native tissue e.g. via secretion of paracrine factors (by the engineered cells/tissue), also fulfils the definition of a TEP.

4.4.2. Informal classification query from the National Transplant Bureau (Lithuania)

National Transplant Bureau (the competent authority on tissue, cell and organ donation and transplantation) asks for interpretation of treatment, which may belong to advanced therapies.

Action: for discussion

Documents tabled:
E-mails from the NTB (Lithuania) dated 7th May 2015

On basis of the limited information provided, CAT cannot come to a conclusion. The National Transplant Bureau (Lithuania) is asked to submit an ATMP classification request with the necessary information for CAT to come to a conclusion.

4.4.3. Reflection Paper on Classification of ATMPs

DG on substantial manipulation:
DG on non-homologous use:
EMA resources:

Action: for adoption

Documents tabled:
Reflection Paper
Overview of comments

The final draft of the Reflection Paper on classification was presented and discussed. Some additional changes were made (see 4.4.1 and a further clarification that the paper gives examples of classifications, not generic classifications for some types of products). The reflection paper, together with the overview of comments, will be sent to the CAT members for final comments/agreement until Friday 22 May 2015. Thereafter, the reflection paper and

overview of comments will be published on the EMA Website. agreed to review of Overview of comments document.

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.

5.1. New SAs – Appointment of CAT Rapporteur

5.2. List of Issues

5.3. 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.

6.1. Paediatric Investigation Plan (PIP)

6.2. ITF Briefing Meetings in the field of ATMPs

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. Strategic Review & Learning meeting

CAT-CHMP joint Strategic Review & Learning meeting (formerly known Informal meeting) to be held in Ljubljana (Slovenia) on 27th-28th May 2015 under the auspices of the Latvian Presidency of the Council of the European Union

CAT resources: Metoda Lipnik-Stangelj, Una Riekstina

Action: for discussion

Documents tabled:
Final agenda

The final agenda was discussed. For the CAT only session, the following CAT members will join the discussion on the analysis of EudraCT and the Guideline on Investigational ATMPs via telephone: .
There was a short feedback on the preparatory work done to extract the number of trials with ATMPs from the EudraCT database.

7.1.2. CAT membership

Poland: Dariusz Śladowski re-nomination as member started on 28th April 2015.

Action: for information

The information was noted.

7.1.3. Training on Meeting Management Documents application (CAT-MMD)

Send any questions/query/issues in advanced to CATSecretariat@ema.europa.eu

CAT resources:

Action: for discussion

Document(s) tabled:
Questions

Training was provided on the 'Deep export' possibility of MMD. At the next CAT, a short training on the Search function will be organised.

7.2. Coordination with EMA Scientific Committees

7.2.1. Committee for Medicinal Products for Human Use (CHMP)

Table of Decisions for the April 2015 meeting

Action: for information

Noted.

7.2.2. EU Good Pharmacovigilance Practices (GVP)

Public consultation of GVP Module XVI Addendum I on educational materials. This has been developed within the governance structure for the implementation and maintenance in relation to the pharmacovigilance legislation and lead mainly by Portugal and other Member States, as it provides guidance on the submission and approval of educational materials for implementation at national level.

Action: for public consultation until 30 June

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp&mid=WC0b01ac058058f32c#section4

A short presentation was given to CAT on the set of Pharmacovigilance guidelines that have been developed and are under development.
CAT members can provide comments on the GVP Module XVI Addendum I on education materials.

7.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

7.3.1. GCP guideline specific to ATMPs: need for revision

Action: for discussion

CAT members interested to join:

Notes:
Call of expression of interest

In 2009, a GCP guideline for ATMPs was developed. This guideline, which was published on the Commission's website was never finalised, awaiting more experience with ATMP trials. The Guideline will now be revisited and finalised. Following CAT members will contribute to this revision.

7.3.2. Scientific Co-ordination Board (SciCoBo): meeting of 30th March 2015

CAT resources: Paula Salmikangas

Action: for information

Documents tabled:

Minutes
Summary of meeting
Various meeting presentations

P Salmikangas provided feedback from the discussions at the SciCoBo.
There was a follow-on discussion on Adaptive pathways for ATMPs, CAT involvement in the scientific advice procedure and interaction with the CVMP on MSC tumourigenicity for veterinary cell-based medicinal products.

7.4. Cooperation within the EU regulatory network

7.4.1. GMP requirements for investigational ATMPs

CAT drafting group members:
Action: for discussion

Notes:
Feedback on the outcome of the DG meetings' discussions which will take place on 5 and 12 May 2015

Feedback was given to the CAT on the progress of the development of the guideline on GMP for (investigational) ATMPs: the drafting has almost been completed and as a next step, 2 telecons and one face-to-face meeting between the DG members and the GMP inspectors are scheduled before the June CAT meeting.
The draft GMP guideline for ATMP will be included in MMD: CAT member are invited to review the document and provide comments.

7.4.2. National Competent Authorities: tissues and cells / medicines

Joint meeting between CAT and NCAs responsible for tissues and cells / medicines took place on 23rd April 2015 at the European Commission

Action: for information

Document tabled:
Agenda

The presentations of the joint meeting will be included in MMD.
P Salmikangas provided detailed feedback from the Joint meeting. This was not an easy meeting, as the T&C authorities and the CAT/Pharma authorities were not in the position to come to consensus / conclusions on most of agenda items.
CAT considered that further meetings to build confidence between the two sectors would be helpful: in the preparation of a next meeting, it is important to have a slim agenda to allow sufficient discussion and to define and agree in advance what would be scope / expected outcome of the meeting.
It was agreed to provide feedback to the EC on next steps (future meetings, topics for discussion) after the minutes of this meeting are available.

Feedback was also provided on the revision of the Medical Device legislation. CAT members were alerted that the draft legislation includes the combination of medical device with non-viable human cells or tissues or their derivatives (whereby the non-viable cell/tissue part is ancillary to the device). An open issue for discussion/agreement at the next meeting of the Council (in June) is who should be consulted for the ancillary non-viable human cells/tissues or their derivatives (Pharma authorities/EMA or the Tissue and Cell authorities). CAT members can contribute to the discussions via their national authorities: the views from their national authorities should be transmitted to their delegates at the Council meeting.

7.4.3. Review of 3Rs (replacement, reduction and refinement) recommendations in the guidelines for cell based and gene therapy products

JEG 3Rs (joint Expert Group on the Application of the 3Rs in Regulatory Testing of Medicinal Products) reviewed the EMA guidelines with regard to application of 3Rs approaches in regulatory testing. As part of this exercise, an Annex table has been prepared related to the

non-clinical testing requirement included in the guidelines for cell based and gene therapy products. The aim of this table is to review and collect the relevant information and to make recommendations to reduce *in vivo* animal testing.

Action: for discussion

Note:
Agreement from CAT is sought on the part concerning guidelines for ATMPs. The final annex table will contain information from all non-clinical guidelines; relevant working parties will be consulted.

T Palomäki presented this exercise and the Annex table for cell and gene therapies. CAT members were asked to review the table and provide their input (especially for the column E) by Friday 22 May.

7.4.4. Pharmacovigilance: Information systems and services. Postponed to July

~~Update on projects which are currently being implemented to deliver the IT systems required by, or needed to support the business activities of, the new pharmacovigilance legislation.~~

~~CAT resources:~~

~~**Action:** for information~~

7.5. Cooperation with International Regulators

None

7.6. Contacts of the CAT with external parties and interaction with Interested Parties

None

7.7. CAT work plan

None

7.8. Planning and reporting

7.8.1. Planning estimates of forthcoming Advanced Therapies Medicinal Products (ATMP) MAAs for the period March. 2015 - Dec. 2017

The planning estimates for the next 2.5 years were presented.

7.9. Others

7.9.1. Talk on: *'Orphan medicines – an unaffordable good?'* 12th May 2015, 12:30-13:30hrs, Room 3E

This event will be a panel discussion and open floor debate.
Speakers: Bruno Sepodes, chair of COMP; Paula Salmikangas, chair of CAT; Yann le Cam, CEO of Eurordis; and Ad Schurmann, Head of the Reimbursement Department at the Dutch Health Care Insurance Board

Action: for information

Note:
Delegates are invited to join the discussion and open floor debate organised by the Communications Department. This discussion is part of the EMA's 20th anniversary monthly event series entitled: *'Debating Science, Medicines, Health'*.

7.9.2. EMA Cross-Committee Task Force on Patient Registries

Feedback from the CAT representative on the first meeting of the Task Force that took place on 30th March 2015.

Action: for information

Note:
K. Breen provided feedback from the meeting of the Task Force. CAT highlighted some regulatory issues: there is no legal definition of registries. They will have to be considered as non-interventional studies. The group might want to discuss these regulatory constraints with the Clinical Trial Facilitation Group (CTFG).

K. Breen will provide feedback from the next meeting of the Task Force at the June CAT meeting.

7.9.3. Article on regulatory/scientific issues related to stem cell containing medicinal products, to be published in the journal: Cell and Gene Therapy Insights.

Following members indicated their interest to participate in the drafting:

Action: for discussion

Authors to confirm their active participation to the drafting of this article.
Rapporteurs of Holoclar (E. Flory, P. Gasparini) to agree to contribute.

It was mentioned that the some concepts that were formulated in a manuscript that was prepared after the Workshop on Stem cells (2010) was never published will be incorporated in this article.

8. Any other business

8.1.1. Parental Drug Association: 2015 Europe Conference, Advanced Therapy Medicinal Products, 2-3 June, Amsterdam (The Netherlands)

Action: for information

8.1.2. Workshop of the World Health Summit on Stem Cell Reserach

An invitation was received to nominate a CAT representative to the Workshop that will be held on 12 October 2015.

CAT agreed for Egbert Flory to represent the CAT.

8.1.3. Training on ATMPs using the EU Training Network Centre

I. Reischl informed the CAT on her experience with a national training that was made available to other NCAs via the EU Training Network Centre. Over 50 external participants attended the training. In view of this success, CAT should reflect on organising additional training: the need to present some case studies was highlighted. It was mentioned that a training on ATMP classifications will be organised after the summer break.

Explanatory notes

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

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

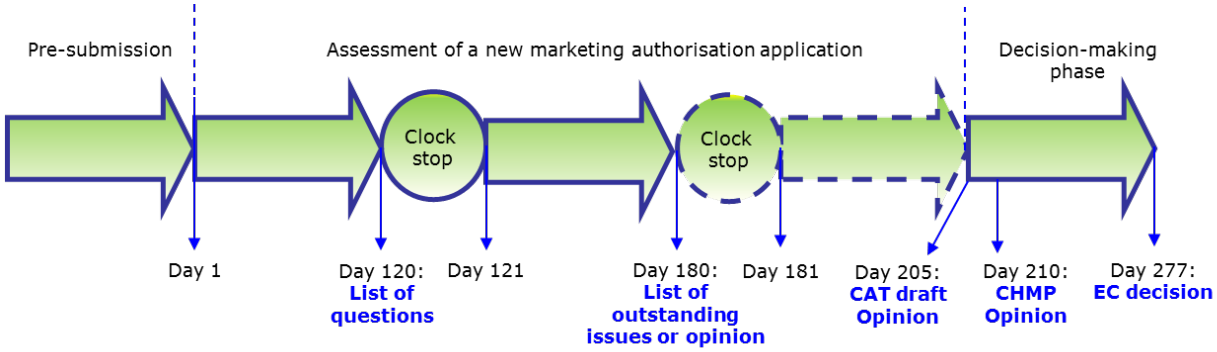
Evaluation of ATMPs (section 2)

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 2.12.)

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.

GMP and GCP 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 2.12.)

This section lists type II variations, extension application according to Annex I of Reg. 1234/2008, re-examination procedures for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP and other issues concerning authorised medicines that are not covered elsewhere in the agenda such as annual reassessments, 5-year renewals, supply shortages, qualify defects. Issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines, will also be included here.

Certification of ATMPs (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)

Paediatric Investigation Plan (PIP)

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

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, regulatory and methodological matters (section 7)

This section includes topics related to regulatory and procedural guidance, CAT workplan, CAT meeting organisation (including CAT membership), planning and reporting, co-ordination with other committees, working parties and scientific advisory groups.

Furthermore, 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, cooperation within the EU regulatory network and international regulators as well as direct interaction with interested parties. It also 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.

Any other business (section 8)

This section is populated with miscellaneous topics not suitable under the previous headings.

More detailed information on the above 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 <DD Month YYYY> 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	
Ilona Reischl	Member	Austria	No interests declared	
Belaïd Sekkali	Alternate	Belgium	No interests declared	
Evelina Shumkova	Alternate	Bulgaria	No interests declared	
Sandra Tomljenovic	Member	Croatia	No interests declared	
Tomáš Boráň	Member	Czech Republic	No interests declared	
Nanna Aaby Kruse	Alternate	Denmark	No restrictions applicable to this meeting	
Toivo Maimets	Member	Estonia	No interests declared	
Tarmo Tiido	Alternate	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	
Krisztian Fodor	Member	Hungary	No interests declared	
Maura O'Donovan	Member	Ireland	No interests declared	
Paolo Gasparini	Member	Italy		
Una Riekstina	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member (CHMP member)	Lithuania	No restrictions applicable to this meeting	
Johannes Hendrikus Ovelgönne	Member	Netherlands	No interests declared	
Marit Hystad	Member	Norway	No interests declared	
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	
Ján Kyselovič	Alternate	Slovakia	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
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	
Elaine French	Member	United Kingdom	No interests declared	
Esteve Trias-Adroher	Alternate	Healthcare Professionals' Representative	No interests declared	
Bernd Gänsbacher	Member	Healthcare Professionals' Representative	No interests declared	
Michelino Lipucci di Paola	Member	Patients' Representative	No restrictions applicable to this meeting	
Kieran Breen	Member	Patients' Representative	No restrictions applicable to this meeting	
Christiane Niederlaender	Expert - in person*	Spain	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.