17 July 2015
EMA/CAT/512537/2015
Procedure Management and Committees Support Division

Committee for Advanced Therapies (CAT)

Minutes for the meeting on 18-19 June 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 these minutes 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, the minutes are a working document primarily designed for CAT members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes 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 18-19 June 2015. See June 2015 CAT minutes (to be published post July 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 18-19 June 2015

Adopted with one addition in 2.12. Glybera – change of Annex II conditions

1.3. Adoption of the minutes

CAT minutes for 12-13 May 2015.

The minutes were adopted with one amendment to section 2.11.1: Provenge.

1.4. Technical information

2. Evaluation of ATMPs

2.1. Opinions

None

2.2. Oral explanations

None

2.3. D180 List of Outstanding Issues (LoOIs)

2.3.1. (talimogene laherparepvec); EMA/H/C/002771

Treatment of adults with melanoma that is regionally or distantly metastatic

Action: for adoption

Documents tabled:
LoOIs
Draft questions to SAG
PP on GMO ERA consultation
BWP report

Note:

The SAWP gave SA in 2008 and 2013
The CAT issued a classification as a gene therapy medicinal product in July 2012

The Rapporteurs presented the D180 assessment report. CAT discussed the draft list of outstanding issues and the questions to the Scientific Advisory Group Oncology (SAG-O). The revised list of outstanding issues and the revised questions to the SAG-O was adopted.

A call for additional experts for the SAG-O is requested, in particular experts with experience in the treatment of patients with immunotherapy and/or anti-cancer immune therapy with oncolytic viruses. Please send nominations by 17 July.

A presentation was given, on request of the CAT, of the procedure for consultation of EU Environmental Agencies during the marketing authorisation application of a GMO-containing medicinal product (see 7.4.4).

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

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

Scope: Oral feedback from the discussion that took place at CHMP in April 2015

Action: for information

Note:

2.8.2. 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.

Scope: to discuss the feasibility analysis and reach an agreement on whether a further clock stop can be granted

Action: for discussion

2.9. New Applications

None

2.10. GMP and GCP Inspections Requests

None

2.11. Type II Variations

None

2.12. Other Post-Authorisation Activities

2.12.1. ChondroCelect – Characterised viable autologous cartilage cells expanded in vivo expressing specific marker proteins; EMA/H/C/00878/MEA 16.3 and 18.3

TiGenix N.V.;

Scope 16.3: randomised control trial protocol TIG/ACT/04/2009

Scope 18.3: 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

Rapporteur: Egbert Flory; Co-rapporteur: Tiina Palomäki; CHMP Coordinators: Jan Müller-Berghaus

Action: for adoption

Document tabled:
Assessment reports of the PAMs

The Rapporteur presented at assessment of the PAM 16.3 and 18.3. CAT adopted the list of issues and the response timetable.

2.12.2. 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 Rapporteur: Brigitte Keller-Stanislawski, PRAC Co-Rapporteur: Isabelle Robine

Scope: withdrawal of the MA: EPAR - summary for public

Action: for information

Notes:
Valeant reached a business decision to discontinue the commercial availability of Provenge in Europe and to withdraw the Marketing Authorization (letter dated 21.04.15.).

CAT noted the revised EPAR for Provenge.

2.12.3. Glybera - alipogene tiparvovec; *Orphan*; EMA/H/C/002145

UniQure Biopharma B.V.;

Rapporteur: E. French; CHMP Coordinators: G. Markey

Scope: Change to Annex II – introduction of additional virus removal step.

Action: for adoption

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. Adeno-associated virus vector serotype rh10 encoding human factor IX

Intended for the treatment of patients with moderate/severe to severe factor IX deficiency, i.e. moderate/severe to severe haemophilia B

Action: for adoption

Document tabled:
Request received on 29th May 2015

Notes:
Appointment of CAT Co-ordinator

Timetable:

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

4.1.2. Concentrate of autologous bone marrow-derived mononuclear cells (BM-MNC)

Intended to improve limb perfusion/restore blood flow to previously ischemic tissue, and improve the mobility and quality of life (QoL) of patients with peripheral artery disease (PAD) and critical limb ischemia (CLI).

Action: for adoption

Document tabled:
Request received on 4th June 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

4.2.1. 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:
Co-ordinator's Classification report

CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report.
CAT secretariat to send the draft scientific recommendation to the Commission for comments .
The CAT recommendation will be considered final if no comments are received from the Commission. The final report will be sent thereafter to the Applicant.

4.2.2. 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:
Co-ordinator's Classification report

CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report.
CAT secretariat to send the draft scientific recommendation to the Commission for comments .
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.

4.3. Finalisation of Procedure

None

4.4. Follow-up and Guidance

4.4.1. Informal classification discussion from the Danish Health and Medicines Authority

Action: for discussion

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. CAT Rapporteurs' Report

5.3. List of Issues

5.4. 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)

None

6.2. ITF Briefing Meetings in the field of ATMPs

None

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) took place in Ljubljana (Slovenia) on 27th-28th May 2015 under the auspices of the Latvian Presidency of the Council of the European Union

Scope: feedback from the meeting

Action: for discussion

Postponed until the July CAT meeting

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

Scope: how to use the search functionality in MMD

Action: for discussion

CAT received this additional training on the search functionality in MMD.

7.2. Coordination with EMA Scientific Committees

7.2.1. Committee for Medicinal Products for Veterinary Use (CVMP): Ad Hoc Group on Veterinary Novel Therapies (ADVENT)

Scope: oral feedback on the work of the Advent Group

Action: for information

Feedback was provided on the activities of the CVMP's Advent group on novel veterinary medicines. The CAT representative in the group informed the CAT on his role in the group and the contributions from the CAT on a document on cell-based therapies – stem cells for veterinary use (Problem statement and questions: tumourigenicity of stem cells).

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

Summary of Outcomes (SoO) for the May 2015 meeting

Action: for information

The information was noted.

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

7.3.1. Draft update of CHMP guidelines concerning tools for early access to medicines: release for consultation

Scope: Revised guideline on Accelerated Assessment
Scope: Conditional Marketing Authorisation

Action: for information

Note: both guidelines will be adopted by the CHMP at their July 2015 meeting.

7.3.2. Training on the structure of the Benefit-risk in the assessment report

The new template for assessment report was presented at the CAT in February 2015

Action: for information

Training was provided to CAT on structured frameworks to describe the effects and information for the benefit risk balance (which may include quantitative methods), on the structure of the Benefit-Risk part of the Assessment Report and on the general principles and use of the 'Effects Table'.

7.3.3. Good Laboratory Practice (GLP) requirements of non-clinical studies for ATMPs

The upcoming clinical trial regulation requires that all non-clinical testing is performed under GLP

Action: for discussion

A presentation was given on previous interactions of CAT representatives with the EMA GLP IWG (Oct. 2014) on GLP requirements for ATMPs, encouraging collaboration between CAT assessors and GLP inspectors, e.g. by using the dedicated CAT contact points within the GLP Working Group. During the discussion, it was underlined that GLP is a legal requirement for pivotal non-clinical data in both MAAs and CTAs, yet that the application of GLP may be challenging for ATMP studies, hence the need for pragmatism. For some ATMPs (e.g. cell-based ATMPs) it is not so clear what would be the pivotal safety studies for which GLP is required, and what are the constraints of applying GLP. This requires further discussion. It remains a judgement call which safety data is pivotal for the risk assessment.

CAT agreed to collect their experience with GLP requirement for ATMPs and any issues they are aware of. The GLP inspectors were also asked to inform the CAT of any GLP related questions or issues they encountered with ATMPs. CAT could also give some reflection on what constitute a pivotal safety study for ATMPs. CAT also noted the suggestion for text providing clarification of GLP for inclusion of the GTMP guideline. This will be taken in consideration when the GTMP guideline is finalised.

The GLP topic will be discussed further at the July CAT meeting.

~~7.3.4.~~ Postponed to July 2015. ~~CAT involvement in scientific advice procedures for ATMPs:~~

~~**Action**: for discussion~~

7.3.5. Human Scientific Committees' Patients and Consumers Working Party (PCWP) and Healthcare Professionals' Organisations (HCPWP)

Scope: meeting taking place on 3-4 June 2015

Action: for information

Documents tabled:
PCWP agenda of 3rd June 2015
PCWP-HCPWP agenda of 4th June 2015
HCPWP agenda of 4th June 2015

The information was noted.

7.3.6. BWP position on similarity criteria for AAV vectors and gene therapy medicinal products in the context of the orphan legislation

CAT members should review the BWP position

7.4. Cooperation within the EU regulatory network

7.4.1. EU Medicines Agencies Network Strategy to 2020: *'Working Together to Improve Health'* – consultation phase

The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) have released the 'EU Medicines Agencies Network Strategy to 2020', a draft common strategy to 2020 for the European medicines agencies network, for a three-month public consultation. Stakeholders are invited to send their comments before 30 June 2015.

Action: for information

Link to Network Strategy:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/03/WC500185138.pdf

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/03/news_detail_002301.jsp&mid=WC0b01ac058004d5c1

The key strategic priorities described in the 'EU Medicines Agency Network Strategy to 2020' were presented. CAT members can provide comments by the deadline of 30 June 2015.

The CAT chair mentioned that she and some other CAT members already reviewed the Network strategy and provided input. It was mentioned that CAT activities can also be communicated for inclusion the multi-annual EMA workplan.

7.4.2. GMP requirements for ATMPs

Scope: feedback on the meetings held on 28th May, 4th and 17th June

Action: for discussion

Feedback was provided on the development of the GMP requirement for ATMPs (and investigational ATMPs), and more specifically on the discussions between the CAT drafting group and the GMP inspectors at the meetings/telecons of 28 May, 4 June and 17 June. The very valuable input from the inspectors was acknowledged and is essential to improve the document. There will be further teleconference drafting groups with the inspectors in the next weeks before the document is published by the Commission for public consultation. The final draft will be included in the July CAT agenda.

7.4.3. Drafting group for the guideline on requirements for Investigational Medicinal Products (IMPs)

Scope: discuss the survey targeting the CTA assessors.

Action: for discussion

Postponed until July CAT meeting.

CAT members interested to join the drafting of this guideline should inform the CAT secretariat by 6 July 2015.

7.4.4. Consultation of the EU Environmental Agencies during the evaluation of medicinal products containing Genetically Modified Organisms (GMO): presentation of the procedure

Action: for information

Document tabled:
Presentation

A presentation was given of the procedure for consultation of EU Environmental Agencies during the marketing authorisation application of a GMO-containing medicinal product.

7.5. Co-operation with International Regulators

7.5.1. ATMP cluster teleconference with FDA and Health Canada

The teleconference will take place during the plenary meeting on Thursday 18th June from 14.00hrs – 15.00hrs

Action: for adoption

Document table:
Agenda

The agenda was agreed. The ATMP cluster telecon took place in the presence of all CAT members.

7.5.2. International Pharmaceutical Regulators Forum (IPRF), New Orleans (USA), 13-16 May 2015

Scope: Feedback on IPRF Cell Therapy and Gene Therapy Groups
Scope: Feedback from the IPRF - Gene Therapy Working Group meeting

Action: for information

Postponed until the July CAT meeting

7.5.3. Therapeutics Goods Administration – Department of Health, Australia Government. Consultation: regulation of autologous stem cell therapies

Scope: The TGA is considering whether the regulation applied to some autologous cells is appropriate.

https://www.tga.gov.au/consultation/consultation-regulation-autologous-stem-cell-therapies#documents

Action: for information

Document table:
Regulation of autologous stem cell therapies – discussion paper for consultation (version 1.0, Jan. 2015)

Postponed to the July CAT meeting.

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

None

7.7. CAT Work Plan

7.7.1. CAT Work Plan 2016 drafting process

Action: for information

A presentation was given on the process of drafting of the CAT work plan 2016. This will be based on CAT work plan of 2015 and the cross-committee projects that have been identified.

The draft CAT work plan 2016 and the review of the progress of the current work plan will be presented / discussed at the July or September CAT meeting.

7.8. Planning and reporting

None

7.9. Others

7.9.1. EMA Cross-Committee Task Force on Patient Registries

Feedback from the CAT representative on the second meeting of the Task Force that took place in June 2015.

Action: for information

Note:
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.

Postponed until the July CAT meeting.

CAT agreed with the nomination of the Luca Sangiorgi (Italian CAT alternate) to this Task Force.

8. Any other business

8.1.1. Biennial on-line survey on the quality of the services and support provided by the Agency

In addition to the EMA's meeting services, the survey will also cover participation in virtual meetings and videoconferences. The survey was sent out on 10th June 2015 to the MB, all scientific committees and several working parties

Action: for information

Document table:
Survey

The survey was noted.

Date of next CAT meeting:
Thursday 16th – Friday 17th July 2015

9. Explanatory notes

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

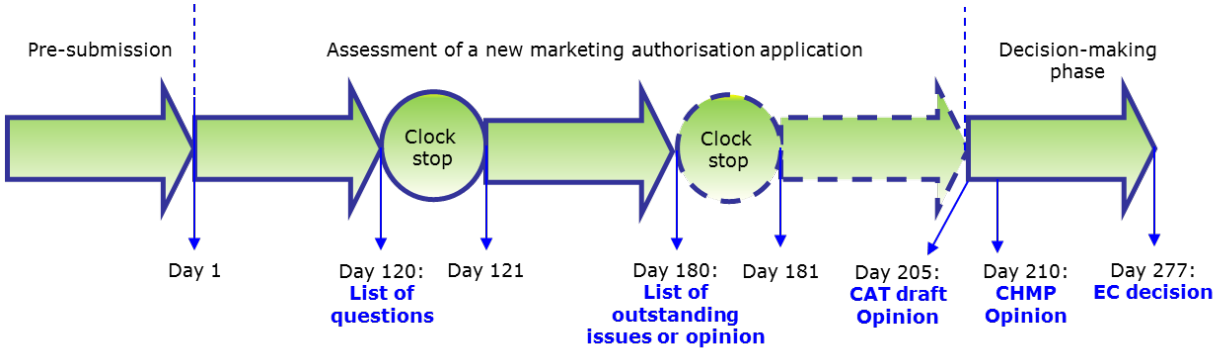
Evaluation of ATMPs (section 2)

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 2.12.)

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 18-19 June 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	Austria	No restrictions applicable to this meeting	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Ivica Malnar	Alternate	Croatia	No restrictions applicable to this meeting	
Anna Paphitou	Member	Cyprus	No interests declared	
Tomáš Boráň	Member	Czech Republic	No interests declared	
Sinan B. Sarac	Member – via telephone	Denmark	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	
Angeliki Roboti	Alternate	Greece	No interests declared	
Krisztian Fodor	Member	Hungary	No interests declared	
Maeve Lally	Alternate	Ireland	No restrictions applicable to this meeting	
Luca Sangiorgi	Alternate	Italy	No interests declared	
Una Riekstina	Member	Latvia	No interests declared	
Guy Berchem	Alternate (to CHMP represenative)	Luxembourg	No restrictions applicable to this meeting	
John J. Borg	Member (CHMP member) – via telephone	Malta	No interests declared	
Johannes Hendrikus Ovelgönne	Member	Netherlands	No interests declared	
Marit Hystad	Member	Norway	No interests declared	
Dariusz Śladowski	Member	Poland		
Margarida Menezes-Ferreira	Alternate (to CHMP represenative)	Portugal	No interests declared	
Simona Badoi	Member	Romania	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Mikuláš Hrubiško	Member	Slovakia	No restrictions applicable to this meeting	
Metoda Lipnik-Stangelj	Member	Slovenia	No interests declared	
Marcos Timón	Alternate (to CHMP represenative)	Spain	No interests declared	
Björn Carlsson	Alternate	Sweden	No interests declared	
Elaine French	Member	United Kingdom	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	
Guido Panté	Expert - in person*	Italy	No interests declared	
Christiane Niederlaender	Expert - in person*	United Kingdom	No interests declared	
Karri Penttilä	Expert - in person*	Finland	No interests declared	
Chris Sotirelis	Expert - in person*	Healthcare Professionals' Representative	No interests declared	
Violaine Closson-Carella	Expert - in person*	France	No interests declared	
Ingrid Wang	Expert - in person*	Norway	No restrictions applicable to this meeting	
Wiebke Hoppensack	Expert - via telephone*	Germany	No restrictions applicable to this meeting	
Taina Methuen	Expert - via telephone*	Finland	No interests declared	
Outi Mäki-Ikola	Expert - via telephone*	Finland	No restrictions applicable to this meeting	
Pernille Sterling	Expert - via telephone*	Denmark	No restrictions applicable to this meeting	
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.