13 April 2015
EMA/CAT/267023/2015
Procedure Management and Business Support Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 19-20 March 2015

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

19 March 2015, 09:00 – 18:30, room 03-E

20 March 2015, 09:00 – 15:00, room 03-E

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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Table of contents

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 March 2015.

No additional declarations of interest were made by the members.

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

1.2. Adoption of agenda

CAT agenda for 19-20 March 2015

Adopted

1.3. Adoption of the minutes

CAT minutes for 19-20 February 2015

Adopted

1.4. Technical information

2. Evaluation of ATMPs

2.1. Opinions

None

2.2. Oral Explanations

2.3. D180 List of Outstanding Issues (LoOIs)

2.3.1. - Characterized viable haploidentical Herpes Simplex Virus Thymidine Kinase (HSV-Tk) and Human Low Affinity Nerve Growth Factor Receptor (ΔLNGFR) transfected donor lymphocytes; *Orphan*; EMA/H/C/002801

MolMed SpA; treatment of adjunctive treatment in haploidentical haematopoietic stem cell transplantation of adult patients with high-risk haematological malignancies

Action: for adoption

Documents tabled:
Overview of comments by the Environmental CA on GMO aspects
LoOIs
BWP report
Request from the applicant for an extension of the clock stop to respond to the list of outstanding issues.

The Rapporteur presented the Day 150 response AR and highlighted to main open issues with this application. CAT discussed the clinical assessment.
The list of outstanding issues was adopted with an amendment. CAT will discuss the request of extension of the clock stop at the April CAT meeting: the Rapporteurs were asked to perform a feasibility analysis.

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

Action: for discussion

Document tabled:
Letter received from applicant dated 12th March 2015 requesting clock-stop of the Oral Explanation to the CAT April meeting.
BWP report

Notes:
Oral report by the Rapporteurs on the outcome of the assessment of the LoOIs and questions to be addressed at the OE.

CAT agreed with the postponement of the OE via a written procedure.

The Rapporteurs presented the outcome of the assessment of the responses to the list of outstanding issues. The outstanding questions for the oral explanation were highlighted.

CAT identified one additional quality other concern, which the applicant is asked to address during the oral explanation.

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.

Action: for discussion

Document tabled:
Applicant's submission of 13th March requesting an accelerated assessment procedure.

Notes:
Intended submission date: 05.05.15.

CAT was in principle in favour of granting an accelerated review for this product. The final decision will be taken at the next CAT meeting.

A presentation was given to CAT on accelerated review (in the EU) and Priority review (in US)

2.10. GMP and GCP Inspections Requests

None

2.11. Type II Variations

None

2.12. Other Post-Authorisation Activities

2.12.1. Glybera – alipogene tiparvovec; *Orphan*; EMA/H/C/002145/S/0039

UniQure Biopharma B.V.;

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

Action: for information

Document tabled:
CM study: FDA /IND and CM study protocol and potential impact on current approved protocol

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. 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:
Request received on 26th February 2015

Notes:
Appointment of CAT Co-ordinator
Timetable

Procedure timetable**:**

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

4.1.2. autologous chondrocyte transplantation system

intended for the treatment of articular cartilage defect of the knee

ITF Coordinator:

Action: for adoption
Document tabled:
Request received on 27th February 2015

Notes:
Appointment of CAT Co-ordinator
Timetable

Procedure timetable

Nominations were received

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

4.1.3. 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.

ITF Coordinator:

Action: for adoption

Document tabled:
Request received on 27th February 2015

Notes:
Appointment of CAT Co-ordinator
Timetable

Procedure timetable

See also 5.2.3.

Nominations were received
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 mononuclear cells derived from human cord blood

intended for the treatment of paediatric brain damage, hypoxic-ischaemic encephalopathy, and cerebral palsy

Action: for adoption

Document tabled:
Co-ordinator's draft 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 until 7 April 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.

4.2.2. suspension of allogeneic human adult stern cells, isolated from skeletal muscle

intended for the treatment of Duchenne Muscular

Action: for adoption

Document tabled:
Co-ordinator's draft 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 until 7 April 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.

4.2.3. allogeneic *ex-vivo* expanded placental adherent stromal cells

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

Action: for adoption

Documents tabled
Co-ordinator's draft report

CAT discussed the ATMP classification report. Amendments were made to the report. CAT adopted by consensus the revised ATMP classification report.
CAT secretariat to send the draft scientific recommendation to the Commission for comments until 7 April 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.

4.2.4. allogeneic somatic cells therapy medicinal product derived from the isolation and *ex vivo* expansion of human Umbilical Tissue-Derived Cells

intended improvement of visual acuity in patients with vision loss from geographic atrophy secondary to age-related macular degeneration

Action: for adoption

Document tabled:
Co-ordinator's draft 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 until 7 April 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.

4.2.5. autologous dendritic cells loaded with autologous irradiated tumour stem cells suspended in a cryopreservation medium

intended for the treatment of melanoma.

Action: for adoption

Document tabled:
Co-ordinator's draft 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 until 7 April 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.

4.3. Finalisation of Procedure

4.3.1. adult human bone-marrow derived, *ex vivo* expanded, pooled allogeneic mesenchymal stromal cells

intended for the treatment of thromboangiitis obliterans (Buerger's disease)

Action: for information

Document tabled:
Co-ordinator's adopted report

Note:
The commission made some observations that did not require an amendment to the report

4.4. Follow-up and Guidance

4.4.1. Reflection Paper on Classification of ATMPs

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

Action: for discussion
Oral updates of DGs
Draft Revised reflection paper after the DG meeting of 19 March 2015.

Notes:
DG members to meet on Thursday 19th March in room 03-L from 18:30-19:30hrs

The outcome of the drafting group meeting of 19 March was presented and discussed. CAT agreed with the revised sections on substantial manipulation and different essential function (non-homologous use) in the draft reflection paper.
The DG members will now reflect on the comments received during the external consultation on other parts of the reflection paper and present the final revision at the April CAT meeting for discussion and adoption.

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' Reports

5.3. List of Issues

5.3.1.

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. Product Information process for initial MA

The process has been revised for the review of the Product Information for initial Marketing Authorisation in the centralised procedure

EMA resources: - Labelling Review and Standards Office

Action: for information

CAT noted the information. The new procedure will be used for all centralised applications starting after April 2015. A training session (webinar) will take place on 31 March 2015: the Rapporteurs (or their assessors) of the upcoming ATMP MAA (see 2.9.1) might want to attend this training.

7.1.2. 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:
Draft agenda

Notes:
Information on reimbursement of members/alternates nominated by the European Commission (Civil Societies)

CAT agreed with proposed agenda items, and identified CAT sponsors for the CHMP-CAT and the CAT agenda items:

- Patient engagement:

- Approval on basis of unconventional data (e.g. patient files, registries): (to reflect the experience with Glybera)

- Guideline on investigational products:

- Q&A on minimally manipulated ATMPs:

- Analysis of EudraCT data:

(The identified CAT sponsors for the joint session were asked to confirm).

CAT members representing the doctors and patient organisations are asked to confirm if they plan to attend this meeting by 31 March 2015.

7.1.3. Harmonisation of committees' agenda and minutes

Implementation of the new agenda template and on the development of Service Level Agreements (SLAs) for the minutes.

Action: for information

CAT noted the information and provided some initial comments on the new agenda layout.

7.1.4. CAT membership

Italy: Paolo Gasparini's membership expired on 1st February 2015

Poland: Dariusz Śladowski's membership expired on 28th February 2015

France: Sophia Lucas terminated her alternate membership on 9th Mach 2015

Action: for information

The information was noted.

~~7.1.5. MMD~~. Postponed to April

~~Training session on MMD. Send any questions/query/issues in advanced to CATSecretariat@ema.europa.eu~~

~~CAT resources:~~

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

~~Document(s) tabled:~~
~~Questions and queries~~

7.2. Coordination with EMA Scientific Committees

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

Table of Decisions for the February 2015 meeting

Action: for information

The information was noted.

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

7.3.1. Guideline on investigational ATMPs in clinical trials

CAT members interested to join this drafting group should inform the CAT secretariat in advance of the March meeting. A teleconference call will be organised in advance of the April CAT meeting to initiate the work of the DG.

CAT resources: Paula Salmikangas

Nominations received:

Action: for adoption

Documents tabled:
Letter from Commission dated 26th January 2015

Notes:
Appointment of drafting group members

Following CAT members will take part in the drafting of this guideline: .

A first brainstorming discussion on this new guideline will take place at the Strategic Review and Learning meeting in Ljubljana (see 7.1.2). The guideline will address the quality and non-clinical requirements for early clinical trials with ATMPs.

7.3.2. Framework of interaction with patients and consumers and their organisations

The framework has been revised.

EMA resources: – Patients and Healthcare Professionals Dept.

Action: for information

CAT noted the information

7.3.3. GMP requirements for investigational ATMPs

CAT drafting group members: **Action:** for discussion

Notes:
Feedback on the outcome of the DG meeting of 18.03.15.

Information was provided from the DG meetings. The work is ongoing, but takes more time than originally expected due to the many source documents to review. Aim is to identify those aspects where flexibility (with regard to the GMP requirements) would be appropriate for ATMP in clinical trials, and where not. The chapters on premises, equipment and quality control will be finalised first, so that these can be shared with the other CAT members and the GMP/GDP inspectors working group (IWG). Meetings with GMP inspectors will take place over the period mid-April – beginning of June. The Commission will perform a public consultation of the document afterwards.

The Commission representative recalled that the Commission services had requested input from both the CAT and the IWG in connection with the GMPs for investigational ATMPs as well as for marketed ATMPs. The expectation was that both the CAT and the GMP/GDP IWG would provide input to the Commission services on both projects.

The chair of GMP/GDP IWG reported that work will start once a report from the UK's Regenerative Medicines Expert Group is available. It was mentioned that GMP/GDP IWG believes that any GMP issues for ATMPs are likely to be the same as for investigational ATMPs so GMP/GDP is keen to see CAT's proposals as soon as possible.

Post-meeting note: the UK RMEG report has now become available.

https://www.gov.uk/government/publications/regenerative-medicine-a-uk-pathway

7.4. Cooperation within the EU regulatory network

7.4.1. National Competent Authorities

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

CAT resources: Paula Salmikangas

Action: for discussion

Document tabled:
Agenda

Notes:
Appointment of CAT members to attend the meeting

The list of CAT members attending the meeting, either on behalf of their NCA or on behalf of CAT was noted. A preparatory meeting with the CAT speakers will be organised in the margins of the April CAT meeting.

7.4.2. EU Network Training Centre

The EU Network Training Centre is a joint initiative of the EMA and HMA. The EU NTC has recently launched its new interim platform, a website containing the first catalogue of trainings accessible to the entire Network: http://euntc.eudra.org/index.html

EMA resources: – EU Network Training Centre

Action: for information

The presentation was noted.

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

7.7.1. Work plan 2015-2016

Objective 1: organise a webinar for the NCAs on ATMP classification. The aim is to explain on basis of practical examples the principles described in the Reflection Paper on ATMP classification. It is proposed to organise a one-hour webinar in the margins of the June CAT meeting.
Objective 2: Analysis of EudraCT for ATMP trials between 2011 and 2014.

EMA resources:

Action: for discussion

In view of the heavy workload of the Committee, it was agreed to postpone the webinar on ATMP classification until September 2015. The webinar will be included in the EU Network Training centre (see 7.4.2).

A discussion on the Analysis of EudraCT for ATMP trials will take place at the Strategic Review and Learning meeting in Ljubljana (see 7.1.2).

7.8. Planning and reporting

None

7.9. Others

7.9.1. Publicly Available Specification (PAS) 157: 2015. Evaluation of materials of biological origin in the production of cell-based medicinal products - Guide

Action: for information

Document tabled:
Guide
The information was noted.

8. Any other business

None

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

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.

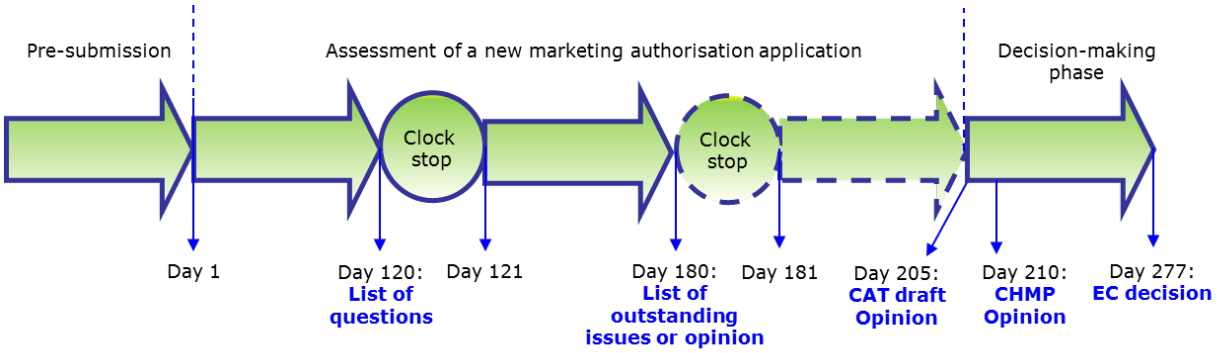
Evaluation of ATMPs (section 2)

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 19-20 March 2015 Month 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	
Ivica Malnar	Alternate (replacing CAT member)	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	Denmark	No interests declared	
Tarmo Tiido	Alternate (replacing CAT member)	Estonia	No interests declared	
Tiina Palomäki	Member	Finland	No interests declared	
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	
Romaldas Mačiulaitis	Member (CHMP member)	Lithuania	No restrictions applicable to this meeting	
Guy Berchem	Alternate (to CHMP represenative)	Luxembourg	No restrictions applicable to this meeting	
Johannes Hendrikus	Member	Netherlands	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Ovelgönne				
Marit Hystad	Member	Norway	No interests declared	
Margarida Menezes-Ferreira	Alternate (to CHMP represenative)	Portugal	No interests declared	
Simona Badoi	Member	Romania	No interests declared	
Ján Kyselovič	Alternate (replacing CAT member)	Slovakia	No interests declared	
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	
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	
Richard McFarland	Observer	FDA	No restrictions applicable to this meeting	
Guido Panté	Expert - in person*	Italy	No interests declared	
Christos	Expert - in		No restrictions	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Sotirelis	person*		applicable to this meeting	
Marcel Hoefnagel	Expert - in person*		No interests declared	
Wiebke Hop pensack	Expert - via telephone*	Germany	No restrictions applicable to this meeting	
Paula van Hennik	Expert - via telephone*	Netherlands	No interests declared	
Jan Müller-Berghaus	Expert - via telephone*	Germany	No interests declared	
Jorge Camarero	Expert - via telephone*	Spain	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.