EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2015
EMA/CAT/37348/2015
Procedure Management and Business Support Division

Committee for Advanced Therapies (CAT)

Minutes for the meeting on 15–16 January 2015

Chair: Martina Schüßler-Lenz (replacing the CAT chair at this meeting)

Declaration on conflict of interest

In accordance with the Agency's revised Policy and Procedure on the handling of conflicts of interests, participants in this meeting were asked to declare any conflict of interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). No additional conflicts of interest were declared.
Discussions, deliberations and voting took place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of meeting. The discussion, deliberations and voting took place in the presence of 22 CAT members (quorum reached).

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regards to therapeutic indications listed against products, it must be noted that these may not reflect the full wording proposed by the applicant and may also vary during the course of the review. The procedures discussed at CAT are on-going and therefore certain aspects are considered confidential. Additional details on some of the procedures (for example the ATMP classification procedure) will be published in the CAT monthly report. For orphan medicinal products the product name and the applicant are published to be consistent with already publicly available information. Of note, this agenda is a working document primarily designed for CAT members and the work the Committee undertakes. Further information with relevant explanatory notes can be found at the end of this document.

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present following a request for access to documents under Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts.	
PRE-MEETING LIST of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CAT plenary session to be held 15-16 January 2015.	See Annex List of Participants. No new conflicts of interest were declared related to products on the agenda.
1.2. Adoption of agenda of the meeting of 15-16 January 2015	Adopted with the addition of one topic under 8.2 on the CHMP/CAT presidency meeting in May 2015.
1.3. Adoption of the minutes of the previous CAT meeting on 11-12 December 2014	*Adopted*
1.4. Table of Decisions of the previous CAT meeting on 11-12 December	*Noted*

2. Evaluation of ATMPs

2.1. Opinion

No items on the agenda

2.2. Oral Explanation

No items on the agenda

2.3. List of Outstanding Issues

No items on the agenda

2.4. List of Questions

2.4.1. (talimogene laherparepvec) (EMA/H/C/H0002771). Therapeutic indication: treatment of adults with melanoma that is regionally or distantly metastatic **For discussion:** ▪ Proposal to convene a SAG meeting (oncology) ▪ Proposed questions to SAG ▪ Request for nomination of expert to attend the SAG ▪ BWP report **For adoption:** ▪ Draft list of questions ▪ Response timetable	*The CAT issued a classification as a gene therapy medicinal product in July 2012* CAT discussed the draft list of questions. CAT agreed with the conclusions of the BWP report. Amendments were made to the questions. CAT adopted the revised list of questions and the response timetable. It was noted that the company used the Risk based concept to justify the data package provided (mainly for the non-clinical part). CAT members requested the EMA to give a short presentation in one of the next CAT meetings on the procedure for ERA review during a MAA.

2.5. Day 80 Assessment Report

No items on the agenda

2.6. Re-Examination Procedure (New Application)+Under Article 9(2) of Regulation No. 726/2004

No items on the agenda

2.7. Withdrawal of Application

No items on the agenda

2.8. Ongoing Evaluation Procedures

No items on the agenda

2.9. New Applications

No items on the agenda

2.10. GMP and GCP Inspections Requests

No items on the agenda

2.11. Post-Authorisation

2.11.1. Type II Variations

To be completed

2.11.2. Other PA Activities

2.11.2.1.	**Glybera** (EMEA/H/C/002145/S/0039), (alipogene tiparvovec), MAH: uniQure biopharma B.V. *Orphan*. Second Annual Reassessment **For adoption:** ▪ Draft Opinion/ RSI	CAT Rapporteur: E. French CHMP Co-ordinator: G. Markey PRAC Rapporteur: J. Williams CAT agreed with the questions raised by the PRAC. CAT adopted a request for supplementary information for this procedure. The adoption of the annual reassessment is planned for EMA provided an overview to the CAT of the ongoing procedures for Glybera.

3. Certification of ATMPs

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

4. Scientific Recommendation on Classification of ATMPs

4.1. [solid flexible implant with chondrocytes fixed in biodegradable human origin fibrin based excipient]. Proposed indication: intended for the treatment of focal non-arthrotic cartilage defects of Outerbridge Grade III or IV of the femoral condyle including the trochlea **For information**: ▪ ATMP Classification report	*The European Commission raised no comments*
4.2. [adipose-derived mesenchymal stem cells]. Proposed indication: intended for the treatment of autoimmune diseases. **For adoption**: ▪ ATMP Classification report	CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. This product is classified as a. CAT secretariat to send the draft scientific recommendation to the Commission for comments until 30 January 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. [Tumour-infiltrating lymphocytes derived from metastatic melanoma]. Proposed indication: intended for the treatment of metastatic melanoma **For adoption**: ▪ ATMP Classification report	CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. This product is classified as a. CAT secretariat to send the draft scientific recommendation to the Commission for comments until 30 January 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.
4.4. [human extracellular matrix on a absorbable polymer matrix]. Proposed indication: intended for the surgical/ interventional treatment of congenital heart malformations **For adoption**: ▪ ATMP Classification report	CAT discussed the ATMP classification report. CAT classified by consensus this product as. The classification report will be updated accordingly. CAT secretariat to send the draft scientific recommendation to the Commission for comments until 30 January 2015. The CAT recommendation will be considered final if no comments are received from the Commission. The final report will be sent thereafter to the Applicant.

4.5. [adult human bone-marrow derived, *ex-vivo* expanded, pooled allogeneic mesenchymal stromal cells]. Proposed indication: intended for thromboangiitis obliterans (Buerger's disease) **For information:** ▪ Request received on 22.12.14. **For adoption:** ▪ Appointment of CAT Co-ordinator ▪ Timetable	Nominations were received from . The following CAT member was appointed as CAT co-ordinator:
4.6. Reflection Paper on Classification of ATMPs **For information:** ▪ Update on the activities of the Drafting groups	Following CAT members will take part in the review of the comments received: - Drafting group on substantial manipulation: - Drafting group on non-homologous use CAT was informed that the drafting groups are reviewing the comments received during the external consultation.

5. Scientific Advice

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6. Pre-Authorisation Activities

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6.1. Paediatric Investigation Plan (PIP)

7. ITF Briefing Meetings in the field of ATMPs

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

8. Organisational Matters

8.1. Regulatory and Procedural Guidance

8.1.1. Application of ATMP Regulation **For discussion:** ▪ Oral feedback from the joint Telecon of the CAT reflection groups on quality-related issues and risk based approach ▪ Next steps	CAT reflection groups: - Quality related issues: - Risk based approach: Postponed to the next CAT meeting

8.1.2.	Development of GMP requirements for investigational ATMPs **For discussion** ▪ First draft or oral feedback from DG	CAT drafting group members: The Commission representative provided clarification of the scope of this request. An official letter requesting CAT to develop GMP requirements for investigational ATMPs will be sent shortly; CAT will consult the GMP inspectors group (to ensure consistency with the GMP requirements for marketed ATMPs). Feedback was provided from the first drafting group (DG) telecom and the DG that took place on Thursday 15 January. The DG proposed to work first on GMP requirement for early clinical trials (First in Human, Phase I/II). Different levels of complexity could be envisaged for different types of ATMPs. Following CAT member will review the draft proposal from the drafting group with the aim to consider possible consequences at hospital level. It was agreed that following quality experts would be asked to join the drafting group
8.1.3.	Draft Guidance on meetings with applicants on responses to questions received from EMA Scientific Committees during the evaluation within the centralised procedure **For re-adoption:** ▪ Revised guidance document	Committees drafting group members: The revised guidance was adopted.

8.2. CAT Meeting Organisation

8.2.1.	CAT/CHMP/COMP joint informal meeting that took place in Rome in October 2014 under the auspices of the Italian Presidency of the Council of the European Union **For information:** ▪ Minutes	*Postponed to February 2015*
8.2.2.	Revised Declaration of Interest form. Submission before end of January 2015: **for action**	Note: Reference is made to the EMA's Chief Policy Adviser's presentation in June 2014 on the revised policy on Conflict of Interest. CAT members were urged to complete and submit their revised eDOI.
8.2.3.	CAT membership **For information:** ▪ IT – Luca Sangiorgi – new alternate nominated on 30th December 2014	Noted
8.2.4.	Training to CAT members on the electronic voting equipment: for information	AudioVisual Team A short hands-on training was provided on the electronic voting equipment.

8.2.5.	CAT/CHMP joint Presidency meeting to take place in Ljubjana (Slovenia) in May 2015. **For information**	informed the CAT of the upcoming joint CAT/CHMP Presidency meeting that will be organised by the Slovenia Agency in Ljubjana between 26 – 28 May 2015. CAT asked for sufficient time for discussion with CHMP of topic of common interest. CAT members identified some topic for the joint session with the CHMP: benefit-risk project, adaptive licencing, use of patient data/registries for authorisation.

8.3. Co-ordination with Committees/WPs/SAGs

8.3.1.	CHMP December 2014 ToD: **for information**	noted

8.4. CAT's Workplan

8.4.1.	Joint CAT/ISCT workshop/satellite meeting to take place in the margins of the European Meeting of the ISCT to be held on 24-26 September 2015, Seville (Spain): '*What should and can we do to make cellular therapies that bring value to patients available to these patients as soon as possible?'* **For information:** ▪ Draft Workplan 2015-2016 **For agreement:** ▪ Appointment of CAT participants for the programme committee **For discussion:** ▪ Topics for the agenda	This relates to Topic 4 in the CAT Workplan 2015-2016: 'Provide assistance to ATMP developers via the organisation of a scientific workshop in collaboration with a scientific society'. Proposed timing for the first telecon of the programme Committee: - Monday 26.01 at 17.00 or 18.00 CET (16.00 or 17.00 UK time) - Wednesday 28.01 at 16.00 CET (15.00 UK time) CAT appointed following members to the programme committee: Following possible agenda topics were identified by CAT: - Regulatory frameworks EU/US/Japan - Requirement for investigational ATMPs - New pathways to facilitate product approval (different types of authorisations, adaptive licensing pilot etc) - Training for academic developers on regulatory framework and on the technical requirements (guidelines) for ATMPs.

8.5. Interested Parties to CAT

8.5.1.	CAT meeting with Interested Parties **For adoption:** ▪ Report of the meeting of 11th December 2014	CAT members were asked to provide comments by Friday 23 January 2014. The report will thereafter be considered adopted and will be published on the EMA website.

9. CAT's DGs / PCWP and HCPWP

9.1. DG on GTMP Guidelines

9.1.1. Guideline on the quality, non-clinical and clinical aspects of gene therapy medicinal products **For discussion:** ▪ Comments by the Guideline Consistency Group (GCG)	CAT discussed the outstanding comments from the GCG. CAT members considered that the level of detail of the guideline is reasonable and should be maintained. For the section on special population, agreed to look into this question and the proposed answer . It was proposed that the CAT vice-chair will call the GCG member to discuss and explain.

9.2. DG on CTMP and TEP Guidelines

No items on the agenda

9.3. PCWP and HCPWP

10. Other Scientific Topics

10.1. Council of Europe – Guide to the Quality and Safety of Tissues and Cells for Human Application, second edition **For information:** ▪ Letter from EDQM to CAT chair dated 11th December 2014 ▪ Draft Guide, published for external consultation ▪ Form to provide comments to the Tissue and Cell Guide, 2nd edition	CAT has provided comments to EDQM/Council of Europe on 18 November 2014. The Draft Guide has now been published for external consultation until 31 January 2015. CAT noted that most of their comments were not included in the draft Guide. It was also noted that this document is undergoing a targeted consultation only: it was not sent to the NCA for medicines, or to the ATMP developers. It was agreed that the CAT chair will write to EDQM . CAT members were asked to comment directly to EDQM (on behalf of their NCA).
10.2. Draft INN naming scheme for cell therapy products **For discussion** : ▪ INN scheme ▪ Comments by CAT and BWP	Note: the draft has been developed by the WHO INN secretariat in collaboration with the INN expert group. CAT confirmed it previous view, indicating that they consider the development of the INN name for cell therapies not useful. WHO will be asked for the rationale for developing an INN naming for cell therapy products. This proposal is further hampered by the different definitions of cell therapies in the world. A letter will be sent to WHO which will summarise the reasons why CAT is in disagreement with the current proposal. will review the draft letter that will be prepared by EMA. If WHO decides to further develop this INN naming scheme, EMA/CAT will provide input as the current proposal is insufficient for the name of cell-based ATMPs in the EU.

10.3.	European Directorate for the Quality of Medicines & HealthCare (EDQM). Meeting of the Advisory Group of the Official Control Authority Batch Release (OCABR) Network for Human Biologicals which took place in October 2014, Strasbourg. **For information:** ▪ Letter to the CAT from the OCABR dated 19th November 2014 on the outcome of their discussion on *'Batch release requirements for human blood and plasma derived excipients used in ATMPs'* ▪ Annex IIf	The letter from EDQM was presented. It was highlighted that CAT will have to decide if an official batch release of human blood or plasma derived excipient in an ATMP is required: this needs to be included in the opinion of the ATMP.
10.4.	Public Consultation on the preliminary opinion on Synthetic Biology II. Risk assessment methodologies and safety aspects: **for comments**	http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_consultation_26_en.htm CAT members were asked to review the preliminary opinion for any consequences for ATMPs. Provide comments to CAT secretariat by 2 February 2015 .
10.5.	International Pharmaceutical Regulators Forum (IPRF) – Gene Therapy Working Group. In-person meeting in the margins of the ASGCT Annual Meeting (New Orleans, Louisiana, U.S.A., 13-16 May 2015). **For discussion:** ▪ CAT participation	CAT members (with expertise in the field of GTMP) who are interested to represent EU/CAT at this meeting should inform the CAT secretariat by 2 February 2015.
10.6.	Joint meeting between Competent Authorities for tissues and cells / medicines and CAT, to take place in first half of 2015 **For discussion:** ▪ Draft agenda	CAT discussed the draft agenda and highlighted following issues: - There should be sufficient time for discussion for each of the agenda items: it is proposed to limit the number of presentations and to restrict the time of the presentations. - Need title of the talks to know what will be discussed / to judge if the agenda is balanced - The draft agenda should also be sent to the national authorities (for medicines) that were present, for their comments and input. Minutes of the meeting would be welcome. In addition, specific comments were made on the different agenda section. These will be sent to DG Sante, Tissue and Cell unit for discussion / incorporation in the agenda.

11. Any Other Business

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

Explanatory notes

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

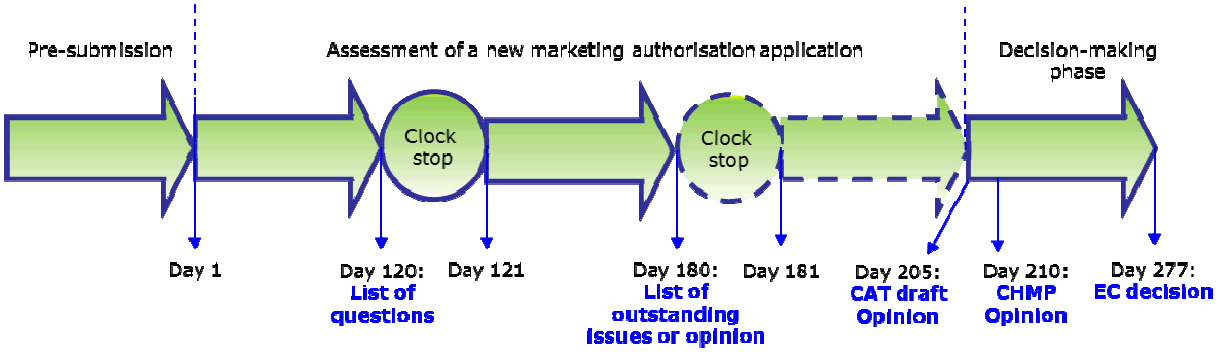
Evaluation of ATMPs (section 2)

This section lists applications for marketing authorisations of new Advanced Therapy Medicinal Products (ATMPs) that are to be discussed by the Committee. It also lists any ATMP related inspection requests (*section 2.9*) and Post-authorisation activities (*section 2.10*).

New applications (*sections 2.1 to 2.9*)

Section 2.1 is for ATMPs nearing the end of the evaluation and for which the CAT is expected to adopt a draft **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CAT opinion is transmitted to the CHMP for final adoption. The CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU. More information on the evaluation of ATMPs can be found here.

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CAT. The clock stop happens after day 120 and may also happen after day 180, when the CAT has adopted respectively a **Day 120 list of questions** (section 2.3) or a List of outstanding issues to be addressed by the company, which is listed in the agenda under sections 2.7 (**Ongoing evaluation procedures**). Section 2.7 also includes the CAT discussions at any other timepoint of the evaluation procedure of new applications.

Oral explanation (*section 2.2*)

Prior to adoption of the CAT opinion, marketing authorisation applicants are normally invited to the CAT plenary meeting to address questions raised by the Committee.

Oral explanations normally relate to ongoing applications, but they can also relate to any other issue for which the CAT would like to discuss with company representatives in person.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 (*section 2.6.*)

This section lists applications for new marketing authorisation for ATMPs for which the applicant has requested a re-examination of the opinion previously issued by the CHMP. Similar to the initial

evaluation of a marketing authorisation of an ATMP, CAT will adopt a draft re-examination opinion, which is transmitted to the CHMP for final adoption.

Withdrawal of applications (*section 2.7.*)

This section includes information on marketing authorisation applications that are withdrawn by the applicant. Applicants may decide to withdraw applications at any stage during the assessment and a CAT opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

New applications (*section 2.9.*)

In this section, information is included on upcoming marketing authorisation applications for ATMPs, as well as information on appointment of Rapporteurs for new ATMP applications.

Inspections Issues (*section 2.10.*)

This section lists inspections that are undertaken for ATMPs. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Post-authorisation activities (*section 2.11.*)

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

ATMP Certification (section 3)

This section includes the scientific evaluation by the CAT of quality and non-clinical data that small and medium-sized enterprises have generated at any stage of the ATMP development process. More information on the ATMP certification procedure can be found here.

Scientific Recommendation on Classification of ATMPs (Section 4)

This section includes the scientific recommendation by the CAT on whether medicines based on genes, cells or tissues meet the scientific criteria that define ATMPs. More information on the ATMP classification procedure, including the outcomes of finalised classifications, can be found here.

Scientific Advice (section 5)

This section includes all scientific advice given to companies during the development of an ATMP. Information related to the number of ATMP related scientific advices discussed by CAT can be found in the CAT Monthly reports. Further information on SAWP can be found here.

Pre-Authorisation (section 6)

This section includes the discussion of an ATMP before a formal application for marketing authorisation is submitted. These cases refer for example to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation: in case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

CAT contributes to the evaluation of a Paediatric Investigation Plan (PIPs) for ATMPs by the Paediatric Committee. These PIPs are included in this section of the Agenda.

ITF Briefing meeting in the field of ATMPs (Section 7)

This section refers to briefing meetings of the Innovation Task Force and International co-operations activities of the CAT

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes of meetings with applicants developing ATMPs and of other ITF meetings of interest to the CAT are included in this section of the agenda. Further information on the ITF can be found here.

Organisational matters (section 8)

This section includes topics related to Regulatory and Procedural Guidance, CAT meeting organisation (including CAT membership) and Co-ordination with other Committees, Working Parties, Scientific Advisory Groups and other groups.

CAT's DGs / PCWP and HCPWP (section 9)

This section refers to the activities of the CAT drafting groups developing Scientific Guidelines for gene therapy medicinal products and for cell-based medicinal products, the EMA/CAT-Notified Body Collaboration Group, the Patient and Consumer Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP).

Other Scientific Topics (section 10)

This section includes topics of scientific interest for the Committee that are not directly related to the work of the CAT drafting groups or CAT associated working parties.

More detailed information on the adobe terms can be found on the EMA website: www.ema.europa.eu/

List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 15-16 January 2015 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Martin Brunner	Alternate	Austria	No restrictions applicable to this meeting	
Belaïd Sekkali	Alternate	Belgium	No interests declared	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Evelina Shumkova	Alternate	Bulgaria	No interests declared	
Ivica Malnar	Alternate	Croatia	No participation in final deliberations and voting on products from GlaxoSmithKline	5.4.3
Anna Paphitou	Member	Cyprus	No interests declared	
Tomáš Boráň	Member	Czech Republic	No interests declared	
Sinan B. Sarac	Member	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	(acted as Chair)
Angeliki Roboti	Alternate	Greece	No interests declared	
Krisztian Fodor	Alternate	Hungary	No interests declared	
Maura O'Donovan	Member	Ireland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Una Riekstina	Member	Latvia	No interests declared	
Guy Berchem	Alternate (to CHMP representative)	Luxembourg	No restrictions applicable to this meeting	
Anthony Samuel	Alternate (to CHMP representative)	Malta	Full involvement	
Johannes Hendrikus Ovelgönne	Member	Netherlands	No interests declared	
Marit Hystad	Member	Norway	No interests declared	
Rune Kjeken	Alternate	Norway	No restrictions applicable to this meeting	
Dariusz Śladowski	Member	Poland	No restrictions applicable to this meeting	
Margarida Menezes-Ferreira	Alternate (to CHMP representative)	Portugal	No interests declared	
Simona Badoi	Member	Romania	No interests declared	
Ján Kyselovič	Alternate	Slovakia	No interests declared	
Metoda Lipnik-Stangelj	Member	Slovenia	No interests declared	
Sol Ruiz	Member (CHMP co-opted member)	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	
James McBlane	Alternate	United Kingdom	No interests declared	
Bernd Gänsbacher	Member	Healthcare Professionals' Representative	No interests declared	
Michelino	Member	Patients'	No restrictions	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Lipucci di Paola		Representative	applicable to the meeting	
Kieran Breen	Member	Patients' Representative	No restrictions applicable to the meeting	
Marcos Timón	Expert - in person*	Spain	No interests declared	
Guido Panté	Expert - in person*	Italy	No interests declared	
Niklas Ekman	Expert - in person*	Finland	No interests declared	
Ingrid Wang	Expert - in person*	Norway	No interests declared	
Madli Pintson	Expert - in person*	Estonia	No interests declared	
Svein Rune Andersen	Expert - via telephone*	Norway	No interests declared	
Anne Dybwad	Expert - via telephone*	Norway	No interests declared	
Therese Solstad Sauders	Expert - via telephone*	Norway	No interests declared	
Bjørn Bremnes	Expert - via telephone*	Norway	No interests declared	
Mona Opsata	Expert - via telephone*	Norway	No restrictions applicable to the meeting	
Anja Schiel	Expert - via telephone*	Norway	No interests declared	
Eirik Grønevik	Expert - via telephone*	Norway	No interests declared	
Christian Syvertsen	Expert - via telephone*	Norway	No interests declared	
Venke Skibeli	Expert - via telephone*	Norway	No interests declared	
Paulii Lehtolainen-Dalkilic	Expert - via telephone*	Finland	No interests declared	
Paivi Ruokoniemi	Expert - via telephone*	Finland	No interests declared	
André Elferink	Expert - via telephone*	The Netherlands	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
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.