19 January 2018
EMA/CAT/92967/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 06-08 December 2017

Chair: Martina Schüßler-Lenz; Vice-Chair: Ilona Reischl

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

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 22 or more members were present in the room). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

The CAT chair welcomed Vitalis Briedis (CAT alternate from Lithuania) who attended CAT for the first time.

1.2. Adoption of agenda

The CAT agenda for 06-08 December 2017 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes for 30-31 October 2017 meeting were adopted.

2. Evaluation of ATMPs

2.1. Opinions

2.1.1. Expanded human allogeneic mesenchymal adult stem cells extracted from adipose tissue - Orphan - EMEA/H/C/004258

Tigenix, S.A.U.; treatment of complex perianal fistula(s)

Scope: Oral explanation/Opinion

Action: for adoption

The CAT Rapporteurs presented their assessment of the responses from the applicant to the latest list of outstanding issues.

Regarding the outstanding clinical issues, satisfactory responses were provided. The CAT Rapporteurs proposed to include the ongoing phase 3 trial (randomised control trial conducted mainly in the US) as an Annex II conditions and the post-authorisation safety

study (PASS) in the RMP.

CAT agreed with the BWP report that all pending quality issues can be resolved post-authorisation (Quality recommendations included in the CAT assessment report).

The draft CAT opinion was adopted by majority: 28 members voted in favour, 2 members vote against. Norway voted in favour. The divergent position was signed by Hans Ovelgönne, NL and Christiane Niederlaender, UK.

The CAT assessment report was adopted and transmitted to the CHMP.

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

No items

2.4. Day 120 list of questions

2.4.1. Voretigene neparvovec - Orphan - EMEA/H/C/004451

Spark Therapeutics Ireland Ltd; treatment of patients with vision loss due to Leber congenital amaurosis or retinitis pigmentosa inherited retinal dystrophy

Scope: Day 120 list of questions

Action: for adoption

The CAT Rapporteurs presented the draft list of questions.

Regarding the quality part of the dossier, CAT agreed with the BWP report for this product.

The Rapporteurs presented the clinical development . CAT discussed the clinical questions.

Further to the discussion, CAT adopted a revised list of questions.

2.4.2. Axicabtagene ciloleucel - Orphan - EMEA/H/C/004480

Kite Pharma EU B.V.; treatment of diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL) and transformed follicular lymphoma (TFL)

Scope: Day 120 list of questions

Action: for adoption

The CAT Rapporteurs presented the draft list of questions.

CAT discussed and agreed with the BWP report on the quality questions raised.

Further to the discussion CAT adopted the list of questions.

2.5. Day 80 assessment reports

No items

2.6. Update on ongoing initial applications

No items

2.7. New applications

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

2.7.1. Tisagenlecleucel-T - Orphan – H0004090

Novartis Europharm Ltd.; Indicated for:
-the treatment of paediatric and young adult patients 3 to 25 years of age with relapsed or refractory B-cell acute lymphoblastic leukemia (ALL).
-the treatment of adult patients with relapsed or refractory diffuse large B cell lymphoma (DLBCL) who are ineligible for autologous stem cell transplant

Scope: evaluation timetable

Action: for adoption

The evaluation timetable was adopted.

2.8. Withdrawal of initial marking authorisation application

No items

2.9. Re-examination of initial application procedures under Article 9(2) of Regulation No. 726/2004

No items

2.10. GMP and GCP inspections requests

No items

2.11. Type II variations including variations of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

2.11.1. MACI - matrix applied characterised autologous cultured chondrocytes - EMEA/H/C/002522/II/0014/G

Vericel Denmark ApS

Rapporteur: Christiane Niederlaender, CHMP Coordinator: Greg Markey

Scope: Quality: RSI.

Action: for adoption

The Rapporteurs presented their assessment report. CAT adopted the RSI. It was proposed that this variation should also be brought to the attention of the BWP.

2.12. Other Post-Authorisation Activities

No items

3. Certification of ATMPs

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

3.1. Opinion

No items

3.2. Day 60 Evaluation Reports

3.3. New Applications

No items

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Autologous dendritic cells pulsed with allogeneic tumour cell lysate - H0004949

Intended for the treatment of malignant mesothelioma

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

Nominations were received. The CAT member was appointed as CAT coordinator

4.1.2. Allogeneic mesenchymal stem cells suspended in cell supernatant - H0004952

Intended for the treatment of osteoarthritis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

Nominations were received. The CAT member was appointed as CAT coordinator

4.2. Day 30 ATMP scientific recommendation

4.2.1. Autologous $CD34^+$ cells derived from bone marrow - H0004941

Intended for the improvement of neurologic function in patients with non-lacunar acute ischemic stroke infarctions

Scope: scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. CAT adopted the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 3 January 2018.

The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.3. Day 60 revised scientific recommendation (following list of questions)

4.3.1. Stromal vascular fraction (SVF) – H0004926

Intended to diminish cancer-related lymphedema in breast cancer patients

Scope: revised scientific recommendation

Action: for adoption

CAT discussed the revised ATMP classification report, which was updated incorporating the additional information provided by the applicant . CAT adopted the ATMP classification report. . CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 3 January 2018.

The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.4. Finalisation of procedure

4.4.1. CD1c (BDCA1)+ myeloid dendritic cells (myDC) - H0004927

Intended for the treatment of patients with advanced, pretreated solid tumours with injectable metastases

Scope: comments received by the European Commission. Final revised ATMP scientific recommendation

Action: for adoption

The revised ATMP classification report was adopted.

4.4.2. Genetically modified epithelial cells (factor IX), encapsulated – H0004928

Intended for the treatment of haemophilia B

Scope: no comments received by the European Commission. Final ATMP scientific recommendation

Action: for information

The information was noted.

4.5. Follow-up and guidance

No items

5. Scientific Advice

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

5.1. New requests – appointment of CAT Rapporteurs

5.2. CAT reports

5.3. List of Issues

5.4. Finalisation of SA procedures

6. Pre-Authorisation Activities

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 plans

6.2. ITF briefing meetings in the field of ATMPs

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 1 – Discussion of eligibility

6.3.2. Month 2 – Recommendation of eligibility

6.3.4 Month 3 – Nomination of Rapporteurs

6.3.5 Ongoing support

No items

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. Strategic Review & Learning meeting – Tallinn, Estonia, 15-17 November 2017

Scope: CAT Strategic Review & Learning meeting (SRLM)

CAT: Martina Schüßler-Lenz, Toivo Maimets

Scope: feedback from the meeting that took place on 15-17 November 2017

Action: for information

The CAT chair reported from the discussions at the SRLM in Tallinn. In particular feedback was provided from the discussion on the topic on genome editing. The topic on development of an ATMP training curriculum will be put on the agenda of the January 2018 CAT meeting for a further in-depth discussion.

A report of the meeting is under preparation.

7.1.2. CAT membership

Scope: CHMP/CAT membership: new three-year mandate for representatives from Germany, Lithuania, Malta, Portugal, Spain

Action: for nomination

CAT noted the new 3-year mandate for the joint CHMP/CAT members.

As per the legal requirement, the CHMP co-opted members were asked to nominate their alternates: Jan Mueller-Berghaus nominated Egbert Flory and Sol Ruiz nominated Marcos Timon.

The nomination of the alternates to the other joint CHMP/CAT members will be done by the respective national authorities.

Luxembourg (which previously held one of the joint memberships) will be asked to nominate a CAT member and alternate.

7.2. Coordination with EMA Scientific Committees

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

Scope: Summary of Outcomes (SoO) for the November 2017 meeting

Action: for information

The information was noted.

7.2.2. Procedural advice on the evaluation of advanced therapy medicinal products

Scope: final updated procedural advice for ATMP

Action: for adoption

The final document was presented.

CAT adopted the Procedure advice on the evaluation of ATMPs.

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

7.3.1. Guideline on requirements for investigational ATMPs

Drafting group: Ilona Reischl (Rapporteur), Tiina Palomäki (Rapporteur), Simona Badoi, Tomáš Boráň, Violaine Closson-Carella, Paolo Gasparini, Carla Herberts, Metoda Lipnik-Stangelj, Margarida Menezes Ferreira, Christiane Niederlaender, Maura O'Donovan, Olli Tenhunen, Guido Pantè, Marcel Hoefnagel

Scope: progress on the development of the guideline following a meeting to take place on 6th December 2017 to discuss the quality, non-clinical and clinical sections

Action: for information

Feedback was provided from the discussions in the drafting group (DG) of 6th December 2017. Further Adobe Connect DGs will be organised to discuss the different parts of the guideline.

Additional support to the drafting group was requested, especially on the quality, non-clinical and clinical aspects of gene therapy investigational medicinal products. Kieran Breen and Heli Suila will join respectively the non-clinical and the quality DG.

7.3.2. ATMP guideline on safety and efficacy follow-up and risk management

Drafting group: Maura O'Donovan, Sol Ruiz, Tomas Boráň, Romaldas Mačiulaitis

Action: for adoption

Note: the guideline has been adopted by PRAC and reviewed by the Guideline Consistency Group

The revised guideline which included additional comments from CAT members was presented. A discussion took place.

The drafting group members will review the changes introduced in the document and reflect on the comments made by the CAT members. Simona Badoi and Violaine Closson will join the drafting group. It was agreed that the document will be adopted at the January 2018 CAT and CHMP meetings for publication for external consultation.

It was agreed that after publication for external consultation, work will start to tailor the RMP template to the ATMP specificities (similar to what has been done for biosimilars).

7.3.3. Working Party with Patients' and Consumers' Organisations (PCWP) and Working Party with Healthcare Professionals' Organisations (HCPWP)

Scope:
PCWP and HCPWP:
-Report on the information session on antimicrobial resistance – 19 September 2017
-Minutes of the PCWP-HCPWP meeting – 20 September 2017
-Agenda – training session for patients, consumers and healthcare professionals interested in EMA activities – 21 November 2017

PCWP:
-Agenda of the PCWP meeting with all eligible organisations - 22 November 2017

Action: for information

The information was noted.

7.4. Cooperation within the EU regulatory network

7.4.1. Orphan similarity for ATMPs

CAT drafting group: Simona Badoi, Violaine Closson-Carella, Michele Lipucci, Margarida Menezes-Ferreira, Christiane Niederlaender, Ilona Reischl

Scope: Reflection from the perspective of ATMPs on the concept of 'similar active substance' as referred to in Art 3(3)c of Reg (EC) No 847/2000 of April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concept 'similar medicinal product' and 'clinical superiority'. Review of additional comments received during the consultation on the draft regulation.

Action: for discussion

CAT discussed the additional comments received during the consultation of the draft regulation. CAT noted that most of the comments were already made during the previous public consultation and discussed by CAT in April/June 2017.

7.5. Cooperation with international regulators

No items

7.6. CAT work plan

7.6.1. CAT 2018 work plan

CAT: Martina Schüßler-Lenz

Scope: CAT 2018 work plan

Action: for adoption

The last changes (to the work plan topic on ATMP comparability) were presented. The CAT adopted their work plan for 2018.

7.6.2. Registry requirements for chimeric antigen receptor T (CAR-T) cells

CAT: Martina Schüßler-Lenz

Scope: feedback on the activitiesorganisation of the workshop with all stakeholders (9 February 2018, tbc)

Action: for information

Note: this will be a cross-committee activity, involving members/experts from CAT, SAWP, PRAC, CHMP and PDCO.

The CAT chair provided feedback on the organisation of a workshop with all stakeholders (i.e. registry holders (European Group for Blood and Marrow Transplantation and Center for International Blood and Marrow Transplant Research), CAR-T developers (Novartis, Kite Pharma, Celgene/Juno, Cellectis), participants from CAT, CHMP, PDCO, PRAC and SAWP and representatives from patients, health care professionals and HTA/payers). The workshop is likely to take place on 9 February 2018 and the programme is currently under development.

7.7. Planning and reporting

No items

7.8. Others

7.8.1. European Biopharmaceutical Enterprises (EBE), 2017 annual conference, 5 December 2017, London, UK

CAT: Martina Schüssler-Lenz

Scope: feedback on the participation of EMA and CAT to the EBE's sixth annual regulatory conference: *'Realising the potential of advanced therapies for patients'*

Action: for information

A short oral feedback from the meeting was provided by the CAT chair.

8. Any other business

No items

Date of next CAT meeting:

17-19 January 2018

9. Explanatory notes

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

Abbreviations / Acronyms

AR: Assessment Report

ATMP: Advanced Therapy Medicinal Product

BWP: Biologics Working Party

CAT: Committee for Advanced Therapies

CHMP: Committee for Medicinal Product for Human Use

COMP: Committee for Orphan Medicinal Products

CTFG: Clinical Trial Facilitation Group

DG: Drafting Group

EC: European Commission

ERA: Environmental Risk Assessment

FDA: Food and Drug Administration

FL: Final Letter

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Genetically-modified organism

GMP: Good Manufacturing Practice

GMTM: Gene Therapy Medicinal Product

HTA: Health Technology Assessment Bodies

HSPC: Hematopoietic Stem and Progenitor Cells

ITF: Innovative Task Force

JR: Joint Report

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Applicant

MAH: Marketing Authorisation Holder

MSC: Mesenchymal stem cells

PDCO: Paediatric Committee

PMDA: Pharmaceuticals and Medical Devices Agency (Japan)

PIP: Paediatric Investigation Plan

PL: Package leaflet

PRAC: Pharmacovigilance and Risk Assessment Committee #

PRIME: Priority Medicines

RMP: Risk Management Plan

RP: Reflection paper

RSI: Request for supplementary information

SAs: Scientific Advices

SAG-O: Scientific Advisory Group Oncology

SAWP: Scientific Advice Working Party

SB: Significant benefit

SR: Summary Report

SWP: Scientific Working Party

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

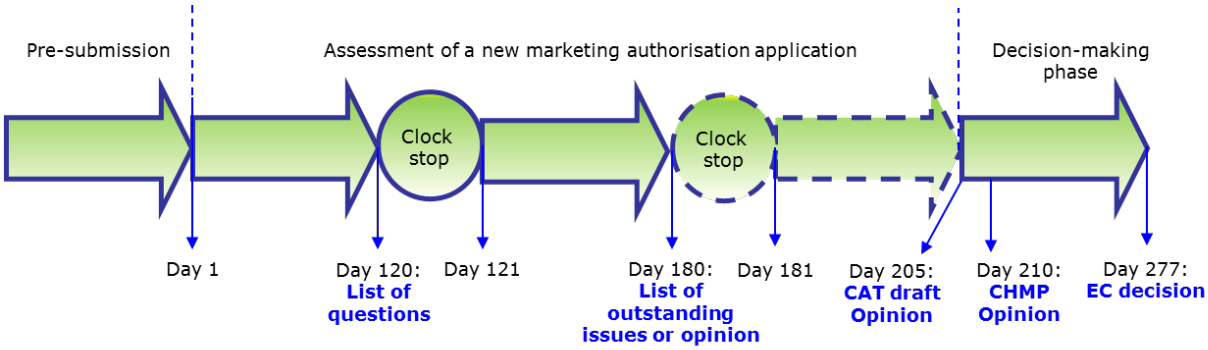
Evaluation of ATMPs (section 2)

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.

Priority Medicines (PRIME)

This section includes the new requests for eligibility to PRIME for ATMPs under development, the discussions in CAT of these eligibility requests and the final recommendations for eligibility of ATMPs adopted by CHMP.

CAT will appoint one of its members as the CAT sponsor for each new ATMP eligibility request who will lead the CAT discussion based on the recommendation from the SAWP.

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/

10. List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 6-8 December 2017 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Martina Schüssler-Lenz	Chair	Germany	No interests declared	N/A
Ilona Reischl	Member	Austria	No interests declared	N/A
Claire Beuneu	Member	Belgium	No interests declared	N/A
Belaïd Sekkali	Alternate	Belgium	No interests declared	N/A
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	N/A
Mirna Golemovic	Member	Croatia	No interests declared	N/A
Marina Ieridi	Member	Cyprus	No interests declared	N/A
Ivana Haunerova	Member	Czech Republic	No interests declared	N/A
Tomáš Boráň	Alternate	Czech Republic	No interests declared	N/A
Anne Pastoft	Alternate	Denmark	No interests declared	N/A
Toivo Maimets	Member	Estonia	No interests declared	N/A
Heli Suila	Member	Finland	No interests declared	N/A
Violaine Closson	Member	France	No interests declared	N/A
Jan Mueller-Berghaus	Member	Germany	No interests declared	N/A
Egbert Flory	Alternate – via telephone	Germany	No interests declared	N/A
Asterios Tsiftsoglou	Member	Greece	No interests declared	N/A
Balázs Sarkadi	Alternate	Hungary	No interests declared	N/A
Maura O'Donovan	Member	Ireland	No interests declared	N/A
Paolo Gasparini	Member	Italy	No interests declared	N/A
Una Riekstina	Member	Latvia	No interests declared	N/A
Vitalis Briedis	Alternate	Lithuania	No interests declared	N/A
Guy Berchem	Alternate (to CHMP representative)	Luxembourg	No restrictions applicable to this meeting	N/A
Anthony Samuel	Alternate (to CHMP representative)	Malta	No interests declared	N/A
Johannes Hendrikus Ovelgönne	Member	Netherlands	No interests declared	N/A
Carla Herberts	Alternate	Netherlands	No interests declared	N/A
Helga Haugom Olsen	Member	Norway	No interests declared	N/A
Rune Kjeken	Alternate	Norway	No restrictions applicable to this meeting	N/A
Dariusz Śladowski	Member	Poland	No restrictions applicable to this meeting	N/A

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Margarida Menezes-Ferreira	Alternate (to CHMP representative)	Portugal	No interests declared	N/A
Simona Badoi	Member	Romania	No interests declared	N/A
Ján Kyselovič	Alternate	Slovakia	No interests declared	N/A
Metoda Lipnik-Stangelj	Member	Slovenia	No interests declared	N/A
Sol Ruiz	Member (CHMP co-opted member)	Spain	No interests declared	N/A
Marcos Timón	Alternate, replacing CHMP member	Spain	No interests declared	N/A
Lennart Åkerblom	Member	Sweden	No interests declared	N/A
Björn Carlsson	Alternate	Sweden	No interests declared	N/A
Christiane Niederlaender	Member	United Kingdom	No interests declared	N/A
James McBlane	Alternate	United Kingdom	No interests declared	N/A
Bernd Gansbacher	Member	Healthcare Professionals' Representative	No interests declared	N/A
Kieran Breen	Member	Patients' Representative	No restrictions applicable to this meeting	N/A
Michelino Lipucci di Paola	Alternate	Patients' Representative	No restrictions applicable to this meeting	N/A
Mariëtte Driessens	Member	Patients' Representative	No restrictions applicable to this meeting	N/A
Erik Briers	Alternate	Patients' Representative	No restrictions applicable to this meeting	N/A
Guido Panté	Expert – in person*	Italy	No interests declared	N/A
Lisbeth Barkholt	Expert – in person*	Sweden	No interests declared	N/A
Christos Sotirelis	Expert – in person*	Patients' Representative	No interests declared	N/A
Jack Price	Expert – in person*	United Kingdom	Direct interests declared	N/A
Michael Udell	Expert – in person*	United Kingdom	No interests declared	N/A
John Johnston	Expert – in person*	United Kingdom	No interests declared	N/A
Janet Glassford	Expert – in person*	United Kingdom	No interests declared	N/A
Koenraad Norga	Expert – via telephone*	Belgium	Indirect interests declared	N/A
Olga Kholmanskikh	Expert – via telephone*	Belgium	No interests declared	N/A
Tineke van den Hoorn	Expert – via telephone*	The Netherlands	No interests declared	N/A
Marcel Hoefnagel	Expert – via telephone*	The Netherlands	No interests declared	N/A

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Marja van de Bovenkamp	Expert – via telephone*	The Netherlands	No interests declared	N/A
Fátima Ventura	Expert – via telephone*	Portugal	Indirect interests declared	N/A
Katrin Féchir	Expert – via telephone*	Germany	No interests declared	N/A
Ann-Christin Bakker	Expert – via telephone*	Germany	No interests declared	N/A
Silke Schuele	Expert – via telephone*	Germany	No interests declared	N/A
Jürgen Scherer	Expert – via telephone*	Germany	No interests declared	N/A
Mathias Renner	Expert – via telephone*	Germany	Direct interests declared	N/A
Brigitte Anliker	Expert – via telephone*	Germany	Indirect interests declared	N/A
Benjamin Hofner	Expert – via telephone*	Germany	Indirect interests declared	N/A
Kerstin Wickström	Expert – via telephone*	Sweden	Indirect interests declared	N/A
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the agenda topics or activities they participated in.