



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 January 2016
EMA/CAT/169534/2016
Procedure Management and Committees Support Division

Committee for Advanced Therapies (CAT)

Minutes for the meeting on 21-22 January 2016

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

21 January 2016, 09:00 – 18:30, room 03-E

22 January 2016, 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 the 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).



Table of contents

1.	Introduction	6
1.1.	Welcome and declarations of interest of members, alternates and experts	6
1.2.	Adoption of agenda.....	6
1.3.	Adoption of the minutes	6
2.	Evaluation of ATMPs	6
2.1.	Opinions	6
2.2.	Oral explanations	6
2.3.	Day 180 List of outstanding issues (LoOIs)	7
2.3.1.	Characterized viable haploidentical Herpes Simplex Virus Thymidine Kinase (HSV-Tk) and Human Low Affinity Nerve Growth Factor Receptor (Δ LNGFR) transfected donor lymphocytes; Orphan; EMA/H/C/002801	7
2.4.	Day 120 Lists of questions (LoQs)	7
2.5.	Day 80 assessment reports.....	7
2.6.	Ongoing initial full application	7
2.7.	New applications	7
2.8.	Withdrawal of initial marketing authorisation application	7
2.9.	Re-examination of initial application procedures under Article 9(2) of Regulation no. 726/2004	7
2.10.	GMP and GCP inspections requests	7
2.11.	Type II variations	8
2.11.1.	Glybera – Alipogene tiparovec; Orphan; EMA/H/C/002145/II/46/G	8
2.11.2.	Glybera - Alipogene tiparovec; Orphan; EMEA/H/C/002145/II/47	8
2.11.3.	Glybera - Alipogene tiparovec; Orphan; EMEA/H/C/002145/II/48	8
2.12.	Other post-authorisation activities	8
2.12.1.	Glybera - Alipogene tiparovec; Orphan; EMEA/H/C/002145/S/0051	8
2.12.2.	Glybera - Alipogene tiparovec; Orphan; EMEA/H/C/002145/SOB 002.3.....	9
3.	Certification of ATMPs	9
3.1.	New applications	9
3.2.	Day 60 evaluation reports	9
3.3.	Opinions	9
3.4.	Ongoing initial application	9
4.	Scientific Recommendation on Classification of ATMPs	9
4.1.	New requests – appointment of CAT Co-ordinators	9
4.1.1.	Human burn eschar and debrided adipose tissue cells	9
4.1.2.	Co-culture of keratinocytes and human burn eschar and debrided adipose tissue cells.....	10

4.1.3.	Recombinant non-replicative serotype 5 human adenovirus containing sequences coding for the core protein, polymerase protein and selected domains of the envelope protein of hepatitis B virus (Genotype D)	10
4.1.4.	Irradiated, whole-cell, allogeneic tumour immunotherapy	10
4.1.5.	Autologous Epstein-Barr virus specific T-cells derived from peripheral blood mononuclear cells, expanded <i>ex vivo</i>	10
4.1.6.	Hematopoietic stem and progenitor cells (HSPC) genetically modified with zinc finger nucleases (ZFNs) to disrupt the erythroid enhancer (ENH) of the gene encoding the human transcription factor BCL11A.....	11
4.2.	Day 30 Co-ordinators' first reports	11
	Adeno-associated viral vector serotype 2 containing the human <i>RPE65</i> gene.....	11
4.2.2.	<i>Ex vivo</i> expanded allogeneic human immuno-modulatory progenitor (iMP) cells.....	11
4.2.3.	Human amniotic membrane mesenchymal stem cells	12
4.2.4.	Human umbilical cord mesenchymal stem cells.....	12
4.2.5.	Co-culture of keratinocytes and human umbilical cord mesenchymal stem cells.....	12
4.2.6.	Co-culture of keratinocytes and human amniotic membrane mesenchymal stem cells	13
4.2.7.	Autologous cells of stromal vascular fraction (SVF) and autologous adipose derived stem cells	13
4.3.	Day 60 Co-ordinators' revised reports following List of Questions	13
4.3.1.	Autologous adipose-derived regenerative cells encapsulated in carboxymethylcellulose – Postponed to February 2016	13
4.3.2.	Fibroblasts and keratinocytes co-culture	13
4.4.	Finalisation of procedures	14
4.4.1.	Autologous cells of stromal vascular fraction (SVF) and autologous adipose derived stem cells	14
4.4.2.	Autologous bone marrow derived non-haematopoietic stem cells.....	14
4.4.3.	Autologous peripheral blood-derived total nucleated cells	14
4.4.4.	Human hepatoblastoma cells (HepG2) encapsulated in alginate, expanded in a fluidised bed bioreactor.....	14
4.4.5.	Adeno-associated virus serotype 8 vector encoding human ornithine transcarbamylase....	14
4.4.6.	Fibroblasts and keratinocytes co-culture	15
4.4.7.	Human acellular amniotic matrix	15
4.4.8.	Human acellular dermal matrix.....	15
4.4.9.	Allogeneic chondrocytes and irradiated genetically modified chondrocytes expressing human TGF- β 1.....	15
4.4.10.	Allograft tendon combined with suture ready to use	16
4.4.11.	Transgenic porcine acellular dermal matrix	16
4.5.	Follow-ups and guidance	16

5. Scientific Advice 16

5.1.	New requests – appointment of CAT Co-ordinators	16
 Error! Bookmark not defined.	

5.2.	CAT Rapporteurs' reports	16
5.3.	Lists of issues	16
5.4.	Finalisation of Scientific Advice procedures	16
6.	Pre-Authorisation Activities	16
6.1.	Paediatric investigation plans (PIP)	17
6.2.	ITF briefing meetings in the field of ATMPs	17
7.	Organisational, regulatory and methodological matters	17
7.1.	Mandate and organisation of the CAT	17
7.1.1.	CAT membership	17
7.1.2.	Strategic Review & Learning meeting	17
7.1.3.	Procedural advice on the evaluation of Advanced Therapy Medicinal Products (pre-authorisation, post-authorisation, re-examination); EMEA/630043/2008	17
7.2.	Coordination with EMA Scientific Committees	18
7.2.1.	Committee for Medicinal Products for Human Use (CHMP).....	18
7.3.	Coordination with EMA Working Parties/Working Groups/Drafting Groups	18
7.3.1.	Questions and Answers on minimally manipulated ATMPs	18
7.3.2.	Interaction between Scientific Advice Working Party (SAWP) and CAT (Committee for Advanced Therapies).....	18
7.3.3.	EMA/Cancer Drug Development Forum (CDDF) workshop on 4-5 February 2016 on cancer immunotherapy: 'Challenges for the approval of anti-cancer immunotherapeutic drugs' ...	19
7.3.4.	Type IB Variations	19
7.3.5.	Draft reflection on a proposal to enhance early dialogue to facilitate accelerated assessment of priority medicines (PRIME)	20
7.4.	Co-operation within the EU regulatory network	20
7.4.1.	Good manufacturing practice (GMP) requirements for ATMPs	20
7.4.2.	European Commission request for definition of: 'Principal Molecular Structural Features' ..	21
7.4.3.	Analysis of European Clinical Trials Database (EudraCT)	21
7.4.4.	Projects in Horizon 2020 related to ATMPs: new calls for proposals	21
7.5.	Co-operation with international regulators	22
7.5.1.	International Pharmaceutical Regulators Forum (IPRF) Gene therapy group	22
7.6.	CAT Work Plan	22
7.6.1.	CAT Work plan 2016	22
7.6.2.	CAT- International Society for Cellular Therapy (ISCT) Joint Workshop: 'Challenges and Opportunities for the Successful Development and Approval of Advanced Therapy Medicinal Products', Seville (Spain), 25 th September 2015	22
7.6.3.	ATMP assessor training 2016.....	22
7.7.	Planning and reporting	23
7.8.	Others	23

8.	Any other business	23
9.	Explanatory notes	24
	List of participants	28

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.

List of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CAT plenary session held on 21-22 January 2016.

1.2. Adoption of agenda

The CAT agenda for 21-22 January 2016 was adopted.

1.3. Adoption of the minutes

The CAT minutes of 10-11 December 2015 were adopted.

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 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 (Δ LNGFR) 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

Scope: second LoOIs and timetable

Action: for discussion

Documents:
Updated Rapporteurs report
PRAC AR on the RMP
PRAC advice
BWP report

Note:
Eight-month clock-stop agreed by CAT in April 2015
List of Outstanding Issues adopted on 20.03.15
BWP report was discussed in March 2015
List of Questions adopted on 16.01.15

The Rapporteur and CoRapporteur presented the assessment of the list of outstanding issues. The revised list of outstanding issues and the response timetable were adopted.

2.4. Day 120 Lists of questions (LoQs)

No items

2.5. Day 80 assessment reports

No items

2.6. Ongoing initial full application

No items

2.7. New applications

2.8. Withdrawal of initial marketing 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

2.11.1. Glybera – Alipogene tiparvovec; Orphan; EMA/H/C/002145/II/46/G

UniQure Biopharma B.V.

Rapporteur: Christiane Niederlaender; CHMP Coordinator: Greg Markey

Scope: quality:

Action: for adoption

Documents:

-Draft Opinion

-BWP report

CAT adopted a draft positive opinion for this quality variation.

2.11.2. Glybera - Alipogene tiparvovec; Orphan; EMEA/H/C/002145/II/47

UniQure biopharma B.V.

Rapporteur: Christiane Niederlaender; CHMP Coordinators: Greg Markey

Scope: quality:

Action: for adoption

Documents:

-Draft Opinion

-BWP report

CAT adopted a draft positive opinion for this quality variation.

2.11.3. Glybera - Alipogene tiparvovec; Orphan; EMEA/H/C/002145/II/48

UniQure biopharma B.V.

Rapporteur: Christiane Niederlaender; CHMP Coordinators: Greg Markey

Scope: quality:

Action: for adoption

Documents:

-Draft Opinion

-BWP report

CAT adopted a draft positive opinion for this quality variation.

2.12. Other post-authorisation activities

2.12.1. Glybera - Alipogene tiparvovec; Orphan; EMEA/H/C/002145/S/0051

UniQure Biopharma B.V.

Rapporteur: Christiane Niederlaender; CHMP Coordinators: Greg Markey

Scope: 3rd annual reassessment

Action: for adoption

Documents:

-Draft Opinion

CAT adopted a draft positive opinion for the third annual reassessment.

2.12.2. Glybera - Alipogene tiparvovec; Orphan; EMEA/H/C/002145/SOB 002.3

UniQure Biopharma B.V.

Rapporteur: Christiane Niederlaender; CHMP Coordinators: Greg Markey

Scope: Protocol for the study to measure postprandial chylomicrons.

Action: for adoption

Documents:

-RSI

CAT discussed the Rapporteurs assessment report of this specific obligation and adopted the request for additional information and the response timetable.

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

No items

3.2. Day 60 evaluation reports

No items

3.3. Opinions

No items

3.4. Ongoing initial application

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – appointment of CAT Co-ordinators

4.1.1. Human burn eschar and debrided adipose tissue cells

Intended for the treatment of burns and non-healing wounds

Different product formulations:

-hBEDATCs in suspension

-hBEDATCs as sheet

-hBEDATCs on acellular amniotic matrix

-hBEDATCs on acellular dermal matrix

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 2nd November 2015

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

4.1.2. Co-culture of keratinocytes and human burn eschar and debrided adipose tissue cells

Intended for the treatment of burns and non-healing wounds

Different product formulations:

-hBEDATCs on acellular amniotic matrix

-hBEDATCs on acellular dermal matrix

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 2nd November 2015

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

4.1.3. Recombinant non-replicative serotype 5 human adenovirus containing sequences coding for the core protein, polymerase protein and selected domains of the envelope protein of hepatitis B virus (Genotype D)

Intended for the treatment of chronic hepatitis B

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 1st December 2015

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

4.1.4. Irradiated, whole-cell, allogeneic tumour immunotherapy

Intended for the treatment of pancreatic cancer

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 21st December 2015

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

4.1.5. Autologous Epstein-Barr virus specific T-cells derived from peripheral blood mononuclear cells, expanded *ex vivo*

Intended for the treatment of Epstein-Barr Virus (EBV) positive malignancies

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 8th January 2016

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

4.1.6. Hematopoietic stem and progenitor cells (HSPC) genetically modified with zinc finger nucleases (ZFNs) to disrupt the erythroid enhancer (ENH) of the gene encoding the human transcription factor BCL11A

Intended for the treatment of β -thalassemia

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 8th January 2016

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

CAT also agreed to establish a group to look into gene editing technologies and its regulatory and scientific consequences for medicines / ATMPs. This group will analyse if the current ATMP / gene therapy definitions would capture all this type of technologies. They will also look into the current Guideline for Genetically Modified Cells and report to CAT on the need for (and content of) a revision of this Guideline. CAT members interested to join this group should inform the CAT secretariat in advance of the February CAT meeting.

4.2. Day 30 Co-ordinators' first reports

4.2.1. Adeno-associated viral vector serotype 2 containing the human *RPE65* gene

Intended for the treatment of inherited retinal degeneration due to autosomal recessive *RPE65* gene mutations

Document:

ATMP classification report

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

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.

4.2.2. *Ex vivo* expanded allogeneic human immuno-modulatory progenitor (iMP) cells

Intended for the treatment of incomplete revascularisation as an adjunct to CABG in patients with congenital coronary artery malformations

Action: for adoption

Document:

ATMP classification report

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

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.

4.2.3. Human amniotic membrane mesenchymal stem cells

Intended for the treatment of burns and non-healing wounds

Different product formulations:

- hAMMSCs in suspension
- hAMMSCs as sheet
- hAMMSCs seeded on acellular amniotic matrix
- hAMMSCs seeded on acellular dermal matrix

Action: for adoption

Document:

ATMP classification report

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

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.

4.2.4. Human umbilical cord mesenchymal stem cells

Intended for the treatment of burns and non-healing wounds

Different product formulations:

- hUSCs in suspension
- hUSCs as sheet
- hUSCs seeded on acellular amniotic matrix
- hUSCs seeded on acellular dermal matrix

Action: for adoption

Document:

ATMP classification report

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

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.

4.2.5. Co-culture of keratinocytes and human umbilical cord mesenchymal stem cells

Intended for the treatment of burns and non-healing wounds

Different product formulations:

- seeded on acellular amniotic matrix
- seeded on acellular dermal matrix

Action: for adoption

Document:

ATMP classification report

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

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.

4.2.6. Co-culture of keratinocytes and human amniotic membrane mesenchymal stem cells

Intended for the treatment of burns and non-healing wounds

Different product formulations:

- seeded on acellular amniotic matrix
- seeded on acellular dermal matrix

Action: for adoption

Document:

ATMP classification report

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

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.

4.2.7. Autologous cells of stromal vascular fraction (SVF) and autologous adipose derived stem cells

Intended for treatment of keloid scars and aging skin

Action: for adoption

Document:

ATMP classification report

CAT discussed the ATMP classification report. Questions were raised on the proposal from the applicant to define treatment of keloid scars and aging skin as medicinal indications. CAT requested some additional information from the applicant prior to concluding on this classification request.

4.3. Day 60 Co-ordinators' revised reports following List of Questions

4.3.1. Autologous adipose-derived regenerative cells encapsulated in carboxymethylcellulose – Postponed to February 2016

Intended for the treatment of cosmetic dermal filling

CAT agreed with the postponement until February 2016.

4.3.2. Fibroblasts and keratinocytes co-culture

Intended for the treatment of deep and extensive burns, chronic wounds, skin donor sites

Product formulation:

- seeded on transgenic porcine acellular dermal matrix

Action: for adoption

Document:

Revised ATMP classification report

Further to receipt of the additional information, the revised ATMP classification report was discussed. CAT adopted by consensus the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments

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 procedures

4.4.1. Autologous cells of stromal vascular fraction (SVF) and autologous adipose derived stem cells

Intended for the treatment of diabetic foot ulcer

Action: for information

Document:
ATMP classification report

Note: the European Commission raised no comments

4.4.2. Autologous bone marrow derived non-haematopoietic stem cells

Intended for the treatments of patients with rheumatoid arthritis; patients after ischemic stroke; patients after myocardial infarction; type I diabetes; type II diabetes

Action: for information

Documents:
ATMP classification report

Note: the European Commission raised no comments

4.4.3. Autologous peripheral blood-derived total nucleated cells

Intended for the treatment of critical limb ischemia

Action: for adoption

Documents:
Revised ATMP classification report

Note: comments received by the European Commission

CAT adopted the revised classification report.

4.4.4. Human hepatoblastoma cells (HepG2) encapsulated in alginate, expanded in a fluidised bed bioreactor

Intended for the treatment of acute liver failure

Action: for information

Document:
ATMP classification report

Note: the European Commission raised no comments

4.4.5. Adeno-associated virus serotype 8 vector encoding human ornithine transcarbamylase

Intended for the treatment of ornithine transcarbamylase tI

Action: for information

Document:
ATMP classification report

Note: the European Commission raised no comments

4.4.6. Fibroblasts and keratinocytes co-culture

Intended for the treatment of deep and extensive burns, chronic wounds, skin donor sites

Different product formulations:

- suspension of cell in platelet leukocyte rich gel
- in sheet
- seeded on acellular amniotic matrix
- seeded on acellular dermal matrix

Action: for adoption

Document:

Revised ATMP classification report

Note: the European Commission:

- raised no comments for a) suspension of cell in platelet leukocyte rich gel and b) in sheet
- raised comments for c) seeded on acellular amniotic matrix and d) seeded on acellular dermal matrix

CAT adopted the revised classification report for the Fibroblast and keratinocytes seeded on acellular amniotic matrix and seeded on acellular dermal matrix.

4.4.7. Human acellular amniotic matrix

Intended for the treatment of deep and extensive burns, chronic wounds, skin donor sites

Action: for information

Document:

ATMP classification report

Note: the European Commission raised no comments

4.4.8. Human acellular dermal matrix

Intended for the treatment of deep and extensive burns, chronic wounds, skin donor sites

Action: for information

Document:

ATMP classification report

Note: the European Commission raised no comments

4.4.9. Allogeneic chondrocytes and irradiated genetically modified chondrocytes expressing human TGF- β 1

Intended for the treatment of degenerative joint disease

Action: for adoption

Document:

Revised ATMP classification report

Note: comments received by the European Commission

CAT adopted the revised report.

4.4.10. Allograft tendon combined with suture ready to use

Intended for the treatment of anterior cruciate ligament reconstruction

Action: for adoption

Document:

Revised ATMP classification report

Note: comments received by the European Commission

CAT adopted the revised report.

4.4.11. Transgenic porcine acellular dermal matrix

Intended for the treatment of deep and extensive burns, chronic wounds, skin donor sites

Action: for adoption

Document:

ATMP classification report

Note: comments received by the European Commission

CAT adopted the revised report.

4.5. Follow-ups and guidance

No items

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 requests – appointment of CAT Co-ordinators

5.2. CAT Rapporteurs' reports

No items

5.3. Lists of issues

5.4. Finalisation of Scientific Advice 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 plans (PIP)

6.2. ITF briefing meetings in the field of ATMPs

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT membership

Croatia: Mirna Golemović - nomination as member

Croatia: Sandra Tomljenovic – termination of mandate for member

Action: for information

The information was noted. The CAT chair welcomed the new Croatian member and thanked Sandra Tomljenovic for her contributions to the CAT over the last years.

7.1.2. Strategic Review & Learning meeting

CAT-PDCO-CTFG joint Strategic Review & Learning meeting will take place in Utrecht, Netherlands on 1st-2nd June 2016 under the auspices of the Dutch Presidency of the Council of the European Union

CAT resources: Hans Ovelgönne

Scope: initial discussions to agree on topics for the agenda. The scientific focus will be on dose finding in the context of extrapolation to children

Action: for discussion

Note: CAT members are asked to send proposals for agenda topics

This meeting will include joint sessions with the PDCO and the Clinical Trial Facilitation Group (CTFG).

CAT noted the aim to discuss the topic of dose extrapolation with PDCO. An initial discussion on possible additional agenda topics took place: scientific advice for ATMP (streamlining interaction with SAWP); adaptive pathways (experience with ATMPs in the pilot scheme); GLP for ATMPs (interaction between CAT and CTFG). CAT members to send additional proposals for agenda item to CAT Secretariat. This will be further discussed during the March CAT meeting.

7.1.3. Procedural advice on the evaluation of Advanced Therapy Medicinal Products (pre-authorisation, post-authorisation, re-examination); EMEA/630043/2008

Scope: Update/revision of the document

Action: for discussion and appointment of CAT members to draft the revision

Note: CAT/CHMP adopted the document in March 2009. This guidance describes the procedure for evaluation of ATMPs for initial marketing authorisation and for post-authorisation procedures (e.g. variations, renewal, etc.) detailing the interactions, the roles and responsibilities of the committees involved in the assessment of ATMPs.

The proposal to update of the procedure for the evaluation of ATMPs was presented. CAT agreed with the proposed outline of this revision. Following CAT members agreed to assist with the revision of this important document: P Salmikangas, M Schübler-Lenz, M Hystad.

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 December 2015 meeting

Action: for information

Documents:
-Summary of Outcomes

The information was noted.

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

7.3.1. Questions and Answers on minimally manipulated ATMPs

CAT drafting group: Metoda Lipnik Stangelj, Paula Salmikangas, Tiina Palomäki, Egbert Flory, Margarida Menezes Ferreira, Pieter Doevendans, Mikuláš Hrubíško

Scope: to create a Q&A document following the discussion that took place at the CAT-CHMP joint Strategic Review & Learning meeting in May 2015

Action: feedback from drafting group meeting

Note:
CAT break-out meeting of the drafting group

Feedback was provided from the drafting group meeting. The proposal is to describe, via Questions and Answers format, the quality, non-clinical and clinical requirements for the marketing authorisation for a minimally manipulated ATMP (CD34+ cells for cardiac repair). In the answers, a practical explanation will be provided how to use the risk based approach to identify and justify deviations for the standard requirements for cell-based ATMPs as included in Annex I Part IV of Dir. 2001/83/EC.

A first outline will be prepared by P Salmikangas and the drafting group will meet virtually (Adobe Connect) to further develop a first draft, which should be ready by the March CAT meeting.

7.3.2. Interaction between Scientific Advice Working Party (SAWP) and CAT (Committee for Advanced Therapies)

Scope: further areas for improvement in the CAT-SAWP workflow

Action: for discussion

CAT discussed, in presence of a colleague from the SAWP secretariat, the experience of the last year with the CAT procedure to provide input into all scientific advices for ATMPs. CAT members acknowledged that the new procedure, in which CAT input is provided to SAWP before their first discussion takes place, is of more value for CAT than the previous procedure where CAT was commenting on the SAWP coordinators reports (post first discussion at the SAWP). Also more CAT members get experienced in dealing with ATMP scientific advices. It was indicated that the input from the CAT was greatly appreciated by the SAWP: the CAT issues are introduced during the SAWP plenary discussion on the ATMP (CAT Rapporteurs can join the SAWP discussions).

There was a discussion on following aspect:

- Timelines: the short timelines for the procedure, giving CAT Rapporteurs only 2 weeks to review the ATMP scientific advices.

- Quality questions: CAT agreed that BWP should remain responsible to address these questions: CAT, however, should have a look at the quality question with a view of possible impact on the non-clinical or clinical development. This feedback is provided to both the BWP and SAWP.

Ideally, CAT should also have the opportunity to review the BWP's responses to the quality questions before they are sent to SAWP, but that will not work out within the current timetable.

- In case of divergent views between SAWP and CAT, the procedure allows for the final outcome to be discussed at the CAT before the final scientific advice letter is adopted by CHMP. The SAWP colleagues and the CAT Rapporteur should actively use this possibility if needed. The participation of the CAT Rapporteur to the discussion meetings and SAWP meetings is a good tool to avoid divergences.

Following suggestions were made to improve the procedure:

- Include a (bullet point) conclusion in the CAT report to the SAWP, highlighting the main points to be flagged to the SAWP.

- The Rapporteurs sometimes do a very thorough exercise, providing responses to all questions. This is rather the job of the SAWP coordinator. CAT Rapporteurs should try to focus more on the ATMP specific questions (or part of the questions) and bring those points for discussion at the CAT meeting. The feedback to the SAWP can then also be more focussed on the ATMP issues.

- Better involvement /contribution of the CAT Rapporteur in the peer review of the final scientific advice letter

CAT agreed to revise the template of the CAT Report to SAWP. To guide the CAT Rapporteurs a set of criteria / key aspects for ATMPs will be developed that should be addressed in the report (instead of answering all questions). These criteria should cover the quality, non-clinical and clinical development. Following CAT members reflect on these guiding criteria: E Flory, H Ovelgönne, O Tenhunen, I Haunerova. It was suggested to have a discussion on these criteria during the upcoming Strategic Review and Learning meeting in the Netherlands (see agenda point 7.1.2).

7.3.3. EMA/Cancer Drug Development Forum (CDDF) workshop on 4-5 February 2016 on cancer immunotherapy: 'Challenges for the approval of anti-cancer immunotherapeutic drugs'

Scope: to discuss regulatory issues and the design of pivotal trials for the new immunotherapies together with a multi-stakeholder audience of regulators, industry representatives and academics.

Action: for information

Note: CAT colleague can follow by Webinar

An outline of the agenda was given. The meeting will be broadcasted on the EMA (public) website: there is no need to register for the broadcast.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2015/12/event_detail_001244.jsp&mid=WC0b01ac058004d5c3

M Schüßler-Lenz will debrief the CAT in February, especially on any issue that are relevant for ATMPs.

7.3.4. Type IB Variations

Scope: presentation on Type IB process

Action: for information

Note: CAT is receiving an increasing number of variations, especially Type IB. The presentation will clarify what is expected from the Rapporteurs in the new IB process of colour coding.

EMA colleagues presented the procedure for dealing with ATMPs and the criteria for involvement of the Rapporteur in the review of type IB variations.

7.3.5. Draft reflection on a proposal to enhance early dialogue to facilitate accelerated assessment of priority medicines (PRIME)

CAT resource: Paula Salmikangas

Scope: Update on the public consultation of the reflection paper. Discussion on operational aspects in view of CAT involvement in PRIME eligibility procedure and support for ATMPs

Action: for discussion

Reflection

paper: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/10/news_detail_002424.jsp&mid=WC0b01ac058004d5c1-

EMA provided an update on the PRIME procedure (comments received during the public consultation of the reflection paper and how they will be addressed).

There was discussion on the CAT involvement in the PRIME procedure and more specifically during the assessment of the eligibility of ATMPs to PRIME. It is important that national competent authorities are involved in (or at least aware of) the PRIME designation procedure. As indicated during the presentation, after discussion at SAWP, all outcomes for eligibility reviews will be ultimately adopted by the CHMP, after involvement of the CAT in case of ATMPs.

Further documents have been circulated to CAT for comments by 29 January: CAT members are asked to comment actively.

7.4. Co-operation within the EU regulatory network

7.4.1. Good manufacturing practice (GMP) requirements for ATMPs

CAT drafting group members: I. Haunerova, M. Menezes-Ferreira, G. Panté, I. Reischl, P. Salmikangas, B. Sekkali, M. Timón, C. Niederlaender, J. Scherer, M. Hoefnagel

Scope: discussion of the comments received during the external consultation and next steps: drafting group meeting on 20.01.16.

Action: for information

Documents:

Agenda

Minutes of the meeting that took place on 16.11.15.

Minutes of the meeting that took place on 30.11.15.

External comments

http://ec.europa.eu/health/files/advtherapies/2015_pc/publ_cons_doc_2015.pdf

A short feedback was given from the discussion at a meeting on Wednesday 20 January where both CAT and GMP inspectors drafting group members were present. A common way of working was agreed: both drafting groups will jointly discuss updated sections of the GMP guideline which take into account / reflect the comments received during the public consultation and the dates of telecons (Adobe Connect) have already been fixed (approx. every two weeks). The aim is to have a draft guideline ready before the summer: this document will go for a second, short external consultation before final adoption by the Commission by end of 2016.

7.4.2. European Commission request for definition of: 'Principal Molecular Structural Features'

CAT resources: Nicolas Ferry

Scope: revision of the Commission Regulation (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'

Action: for discussion

The proposal discussed at the BWP and QWP for a definition of Principle Molecular Structural Features (PMSF) was presented and discussed.

It was proposed to continue the discussion in a virtual drafting meeting (Adobe Connect or TC) to be organised before the February CAT meeting. Following CAT members will be involved: M Menezes-Ferreira, N Ferry, P Salmikangas, I Reischl, C Niederlaender, M Lipucci. This drafting group should also reflect on relevant examples to explain the specificities for ATMPs.

7.4.3. Analysis of European Clinical Trials Database (EudraCT)

CAT resources: Ivana Haunerova (Tomáš Boráň), Margarida Menezes-Ferreira, Ilona Reischl, Paula Salmikangas, Nicolas Ferry, Romaldas Mačiulaitis, Dariusz Śladowski, Michele Lipucci di Paola, Bernd Gänsbacher

Scope: feedback from the results of the analysis

Action: for information

Note:

-16 September 2015: CAT's first break-out meeting of the drafting group

-16 October CAT: presentation and discussion of the first results of the EudraCT analysis

I Haunerova presented the analysis performed by T Boran. A manuscript will now be prepared by the drafting group members: a breakout meeting will be organised in the margins of the February CAT meeting. A possible journal has been identified (Human Gene Therapy).

7.4.4. Projects in Horizon 2020 related to ATMPs: new calls for proposals

Resources: Charles Kessler and Arnd Hoeveler – EU's DG Research & Innovation

Scope: introduction of the EC's Horizon 2020 Work Programme for the years 2016 and 2017 in particular topics of relevant importance to

ATMPs: http://ec.europa.eu/research/participants/data/ref/h2020/wp/2016_2017/main/h2020-wp1617-health_en.pdf

Action: for information

Note: The European Commission's DG Research & Innovation presented to CAT in February 2015 the EU support/funding to ATMP research in the Framework programme 7 (2007-2013) and Horizon 2020.

Further to a presentation by the colleagues of DG Research of the ATMP-related research currently funded by Horizon 2020, CAT member indicated their experience with Horizon 2020 funded projects for ATMPs. It was mentioned that despite the requirement in the projects for involvement of regulatory authorities, these interactions are sometimes minimal. There was also an exchange of views on research priorities / topics that could be funded in future calls. DG Research colleagues invited CAT members to provide ideas for future projects. CAT

members can also become evaluators for projects (go to <http://ec.europa.eu/research/participants/portal>).

7.5. Co-operation with international regulators

7.5.1. International Pharmaceutical Regulators Forum (IPRF) Gene therapy group

CAT resource: Paula Salmikangas

Scope: Oral feedback from the teleconference that took place on 7 January 2016

Action: for information

Documents:
Draft agenda

This agenda item was postponed to the February CAT meeting.

7.6. CAT Work Plan

7.6.1. CAT Work plan 2016

CAT resources: Paula Salmikangas

Action: for adoption

The draft CAT work plan for 2016 was presented. Final amendments were made and CAT topic leaders and CAT participants were identified where needed. The CAT workplan was subsequently adopted.

CAT appointed the organising committee for the Workshop on cell-based cancer immunotherapy products (R Kjekken, B Carlsson, O Tenhunen, M Schüßler-Lenz, M Lipnik-Stangelj, P Salmikangas, M Hystad, D Śladowski, B Gänsbacher, P Celis). The topic leaders (R Kjekken and B Carlsson) will make a first agenda proposal.

7.6.2. CAT- International Society for Cellular Therapy (ISCT) Joint Workshop: 'Challenges and Opportunities for the Successful Development and Approval of Advanced Therapy Medicinal Products', Seville (Spain), 25th September 2015

CAT resources: Paula Salmikangas

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/06/new_s_detail_002357.jsp&mid=WC0b01ac058004d5c1

Action: for information

Documents:
Presentations

P. Salmikangas provide a short feedback from the CAT-ISCT workshop.

7.6.3. ATMP assessor training 2016

CAT resources: Margarida Menezes-Ferreira, Paula Salmikangas, Martina Schüßler-Lenz, Simona Badoi

Moderators: for Quality session: M. Menezes-Ferreira and I. Reischl; Clinical session: M. Schüßler-Lenz and S. Badoi.

Scope: appointment of CAT moderators for the non-clinical session

Action: for discussion

Note: the ATMP assessor training is included in the CAT work plans of 2015 and 2016. The proposal is to hold a 1.5 day assessor training on 23-24 June 2016 on: quality, non-clinical and clinical aspects of ATMPs (including combined ATMP), sessions on ERA review and RMP

B Carlsson and E Flory were appointed as moderators for the non-clinical session. The appointed moderators will develop an outline of the programme for this assessor training.

7.7. Planning and reporting

No items

7.8. Others

No items

8. Any other business

Date of next CAT meeting:
Thursday 18st – Friday 19nd February 2016

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
DG: Drafting Group
EC: European Commission
FL: Final Letter
GCP: Good Clinical Practice
GLP: Good Laboratory Practice
GMP: Good Manufacturing Practice
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
PDCO: Paediatric Committee
PIP: Paediatric Investigation Plan
PL: Package leaflet
PRAC: Pharmacovigilance and Risk Assessment Committee
RP: Reflection paper
RSI: Request for supplementary information
SA: Scientific Advice
SAG-O: Scientific Advisory Group Oncology
SAWP: Scientific Advice Working Party
SR: Summary Report
SWP: Scientific Working Party
SME: Small and medium size enterprises
SmPC: Summary of Products Characteristics
TT: Timetable

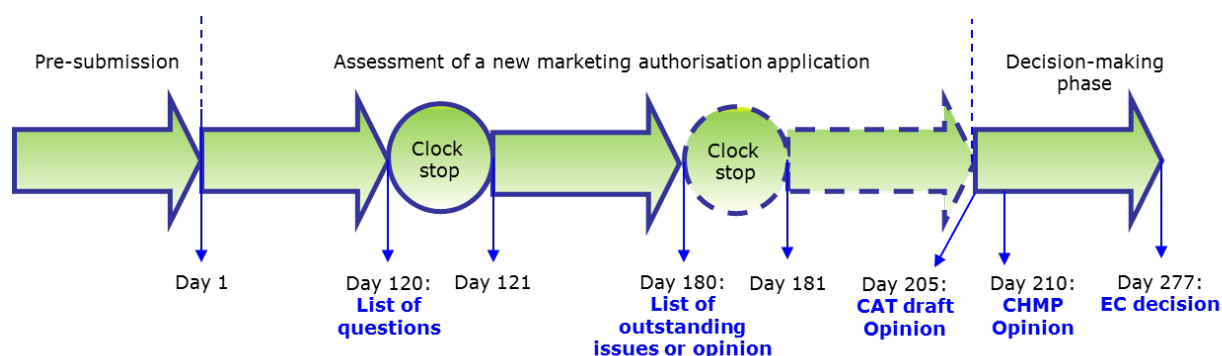
Evaluation of ATMPs (section 2)

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](#).

Organisational, regulatory and methodological matters (section 7)

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

Furthermore, this section refers to the activities of the CAT drafting groups developing scientific guidelines for gene therapy medicinal products and for cell-based medicinal products, cooperation within the EU regulatory network and international regulators as well as direct interaction with interested parties. It also includes topics of scientific interest for the Committee that are not directly related to the work of the CAT drafting groups or CAT associated working parties.

Any other business (section 8)

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

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

List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the <DD Month YYYY> meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Paula Salmikangas	Chair	Finland	No interests declared	
Ilona Reischl	Member	Austria	No interests declared	
Belaïd Sekkali	Alternate. Replacing CAT member	Belgium	No interests declared	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Evelina Shumkova	Alternate	Bulgaria	No interests declared	
Mirna Golemovic	Member	Croatia	No interests declared	
Ivica Malnar	Alternate	Croatia	No restrictions applicable to this meeting	
Ivana Haunerova	Alternate. Replacing CAT member	Czech Republic	No interests declared	
Nanna Aaby Kruse	Member	Denmark	No restrictions applicable to this meeting	
Toivo Maimets	Member	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	
Violaine Closson	Alternate	France	No interests declared	
Martina Schüssler-Lenz	Member (Vice-Chair)	Germany	No interests declared	
Egbert Flory	Alternate	Germany	No interests declared	
Angeliki	Alternate	Greece	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-Dol	Topics on agenda for which restrictions apply
Roboti				
Krisztian Fodor	Member	Hungary	No interests declared	
Maura O'Donovan	Member	Ireland	No interests declared	
Una Riekstina	Member	Latvia	No interests declared	
Guy Berchem	Alternate (to CHMP representative)	Luxembourg	No restrictions applicable to this meeting	
Johannes Hendrikus Ovelgönne	Member	Netherlands	No interests declared	
Marit Hystad	Member	Norway	No interests declared	
Rune Kjekken	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. 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 representative)	Spain	No interests declared	
Björn Carlsson	Alternate. Replacing CAT member	Sweden	No interests declared	
Christiane Niederlaender	Member	United Kingdom	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Pieter Doevendans	Member	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	
Guido Panté	Expert - in person*	Italy	No interests declared	
Carla Herberts	Expert - in person*	Netherlands	No interests declared	
Chris Sotirelis	Expert - in person*	United Kingdom	No interests declared	
Louise Bisset	Expert - via telephone*	UK	No interests declared	
Marcel Hoefnagel	Expert - via telephone*	Netherlands	No interests declared	
Paula van Hennik	Expert - via telephone*	Netherlands	No interests declared	

A representative from the European Commission attended the meeting

Meeting run with support from relevant EMA staff

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