Committee for Advanced Therapies (CAT)
Minutes of the meeting on 16-17 February 2022

Chair: Martina Schuessler-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 are considered commercially confidential or sensitive and therefore not disclosed. Regarding 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, these 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 ongoing 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

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Introduction</td>
<td>6</td>
</tr>
<tr>
<td>1.1.</td>
<td>Welcome and declarations of interest of members, alternates and experts</td>
<td>6</td>
</tr>
<tr>
<td>1.2.</td>
<td>Adoption of agenda</td>
<td>6</td>
</tr>
<tr>
<td>1.3.</td>
<td>Adoption of the minutes</td>
<td>6</td>
</tr>
<tr>
<td>2.</td>
<td>Evaluation of ATMPs</td>
<td>6</td>
</tr>
<tr>
<td>2.1.</td>
<td>Opinions</td>
<td>6</td>
</tr>
<tr>
<td>2.2.</td>
<td>Oral explanations</td>
<td>6</td>
</tr>
<tr>
<td>2.3.</td>
<td>Day 180 list of outstanding issues</td>
<td>6</td>
</tr>
<tr>
<td>2.4.</td>
<td>Day 120 list of questions</td>
<td>7</td>
</tr>
<tr>
<td>2.5.</td>
<td>Day 80 assessment reports</td>
<td>7</td>
</tr>
<tr>
<td>2.5.1.</td>
<td>Tablecleucel - PRIME - Orphan - EMEA/H/C/004577</td>
<td>7</td>
</tr>
<tr>
<td>2.6.</td>
<td>Update on ongoing initial applications</td>
<td>7</td>
</tr>
<tr>
<td>2.7.</td>
<td>New applications</td>
<td>7</td>
</tr>
<tr>
<td>2.8.</td>
<td>Withdrawal of initial marketing authorisation application</td>
<td>7</td>
</tr>
<tr>
<td>2.9.</td>
<td>Re-examination of initial application procedures under Article 9(2) of Regulation No. 726/2004</td>
<td>7</td>
</tr>
<tr>
<td>2.10.</td>
<td>GMP and GCP inspections requests</td>
<td>7</td>
</tr>
<tr>
<td>2.11.</td>
<td>Type II variations and variations of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008</td>
<td>7</td>
</tr>
<tr>
<td>2.11.1.</td>
<td>Kymriah - tisagenlecleucel - PRIME - Orphan - EMEA/H/C/004090/II/0049/G</td>
<td>7</td>
</tr>
<tr>
<td>2.11.2.</td>
<td>Yescarta - axicabtagene ciloleucel - PRIME - Orphan - EMEA/H/C/004480/II/0040</td>
<td>8</td>
</tr>
<tr>
<td>2.11.3.</td>
<td>Yescarta - axicabtagene ciloleucel - PRIME - Orphan - EMEA/H/C/004480/II/0042</td>
<td>8</td>
</tr>
<tr>
<td>2.11.4.</td>
<td>Yescarta - axicabtagene ciloleucel - PRIME - Orphan - EMEA/H/C/004480/II/0046</td>
<td>8</td>
</tr>
<tr>
<td>2.11.5.</td>
<td>Tecartus; Yescarta - autologous anti-CD19-transduced CD3+ cells; axicabtagene ciloleucel - PRIME - Orphan - EMEA/H/C/WS2197</td>
<td>9</td>
</tr>
<tr>
<td>2.12.</td>
<td>Extension applications</td>
<td>9</td>
</tr>
<tr>
<td>2.13.</td>
<td>Other Post-Authorisation Activities</td>
<td>9</td>
</tr>
<tr>
<td>2.13.2.</td>
<td>Kymriah - tisagenlecleucel - PRIME - Orphan - EMEA/H/C/004090/REC/016</td>
<td>9</td>
</tr>
<tr>
<td>2.13.3.</td>
<td>Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/REC/007</td>
<td>9</td>
</tr>
<tr>
<td>2.13.4.</td>
<td>Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/R/0024</td>
<td>9</td>
</tr>
<tr>
<td>2.13.5.</td>
<td>Tecartus - autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured - PRIME - Orphan - EMEA/H/C/005102/ANX/002.2</td>
<td>10</td>
</tr>
<tr>
<td>2.13.7.</td>
<td>Zynteglo - betibeglogene autotemcel - PRIME - Orphan - EMEA/H/C/003691/SOB/003</td>
<td>10</td>
</tr>
<tr>
<td>2.13.8.</td>
<td>Zynteglo - betibeglogene autotemcel - PRIME - Orphan - EMEA/H/C/003691/SOB/004</td>
<td>11</td>
</tr>
</tbody>
</table>
2.13.9. Interactions with the European Society for Blood and Marrow Transplantation (EBMT) and marketing authorisation holders of CAR-Ts on the use of data from the EBMT registry for the imposed PASS

3. Certification of ATMPs

3.1. Opinion

3.2. Day 60 Evaluation Reports

3.3. New Applications

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Gingival fibroblast

4.1.2. (AAV2.hIL-12) Recombinant serotype 2 adeno-associated virus (AAV2) carrying a single-stranded expression cassette for human Interleukin 12 (IL-12)

4.1.3. Leukocyte and platelet rich plasma, autologous

4.1.4. Messenger RNA (mRNA) containing a bicistronic coding sequence that upon translation produces two independent proteins, ZF-DNMT and ZF-KRAB

4.1.5. Stimulated anti-viral T-lymphocytes with specific anti-viral activity

4.1.6. Plasmid expressing variant of human interleukin-10

4.2. Day 30 ATMP scientific recommendation

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

4.4. Finalisation of procedure

4.4.1. Kidney progenitor cells isolated from the urine of preterm neonates

4.4.2. Expanded mesenchymal stem cells (MSCs) cells isolated from umbilical cord Wharton jelly dilative cardiomyopathy (DCM)

4.4.3. Recombinant serotype 9 adeno-associated virus (rAAV9) encoding a wild-type human MECP2 (methyl cytosine binding protein 2) transgene (AAV9-hMECP2)

4.4.4. Recombinant adeno-associated virus (rAAV) containing human homology arms, expressing codon-optimised human phenylalanine hydroxylase (hPAH)

4.4.5. Human embryonic stem cell (hESC)-derived midbrain dopaminergic (mDA) neuron cells

4.4.6. Stem cells isolated from dental pulp, cultured

4.4.7. Modulated immune cells

4.4.8. Autologous bone marrow concentrate

4.5. Follow-up and guidance

5. Scientific Advice

5.1. New requests - appointment of CAT Rapporteurs

5.1.1. Ongoing scientific advice procedures - Appointment of CAT Peer Reviewers

5.1.2. Scientific advice procedures starting at the next SAWP meeting

5.2. Procedures discussed at SAWP – 1st reports, D40 JRs, LoIs

5.3. Finalisation of D70 procedures – feedback from the discussion meeting

5.4. Final Advice Letters for procedures finalised the previous month
**6. Pre-Authorisation Activities**

| 6.1. | Paediatric investigation plans | 15 |
| 6.2. | ITF briefing meetings in the field of ATMPs | 15 |
| 6.3. | Priority Medicines (PRIME) – Eligibility requests | 16 |
| 6.3.1. | Month 0 - Start of the procedure | 16 |
| 6.3.2. | Month 1 – Discussion of eligibility | 16 |
| 6.3.3. | Month 2 – Recommendation of eligibility | 16 |
| 6.3.4. | Ongoing support | 16 |

**7. Organisational, regulatory and methodological matters**

| 7.1. | Mandate and organisation of the CAT | 16 |
| 7.1.1. | CAT membership | 16 |
| 7.1.2. | Joint CAT-ChMP Strategic Review & Learning meeting (SRLM) under the Slovenian presidency, 21 October 2021 (virtual) | 16 |
| 7.1.3. | CAT Strategic Review & Learning meeting (SRLM) under the French presidency, 3 March 2022 (virtual) | 16 |
| 7.2. | Coordination with EMA Scientific Committees | 17 |
| 7.2.1. | Classification of Post-Authorisation Studies (CPAS) | 17 |
| 7.2.2. | CHMP learnings with relevance to CAT: Revision to the Appendix 3 of the anticancer guideline | 17 |
| 7.2.3. | CHMP learnings with relevance to CAT: Topics discussed at February CHMP PROM | 17 |
| 7.2.4. | Extension of indication of approved ATMPs: additional 1-year protection period | 17 |
| 7.3. | Coordination with EMA Working Parties/Working Groups/Drafting Groups | 18 |
| 7.3.1. | Working Party with Patients’ and Consumers’ Organisations (PCWP) and Working Party with Healthcare Professionals’ Organisations (HCPWP) | 18 |
| 7.3.2. | Working Party with Patients’ and Consumers’ Organisations (PCWP) and Working Party with Healthcare Professionals’ Organisations (HCPWP) | 18 |
| 7.3.3. | BWP/QWP/IWG Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME and certain marketing authorisation applications targeting an unmet medical need | 18 |
| 7.3.4. | EMA Working Parties Implementation Plan Review – (H+V) | 18 |
| 7.4. | Cooperation with the EU regulatory network | 19 |
| 7.4.1. | Accelerating Clinical Trials in the EU (ACT EU) | 19 |
| 7.5. | Cooperation with international regulators | 19 |
| 7.5.1. | Joint EMA-FDA Q&As on PRIME/Breakthrough applications (control strategy, process validation, stability, GMP) | 19 |
| 7.5.2. | ATMP cluster teleconference with US-FDA, Health Canada and PMDA (Japan) | 19 |
| 7.5.3. | WHO consultation on cell and gene therapy products | 19 |
| 7.6. | CAT work plan | 20 |
| 7.6.1. | ATMP training for 2022 | 20 |
| 7.6.2. | Implementation of the medical device and in-vitro diagnostics Regulations | 20 |
| 7.7. | Planning and reporting | 20 |
### 7.8. Others

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>8.</td>
<td>Any other business</td>
</tr>
<tr>
<td>9.</td>
<td>Explanatory notes</td>
</tr>
<tr>
<td>10.</td>
<td>List of participants</td>
</tr>
</tbody>
</table>

20

21

24
1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

The Chairperson opened the meeting by welcoming all participants. Due to the current coronavirus (COVID-19) outbreak, and the associated EMA Business Continuity Plan (BCP), the meeting was held remotely.

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. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

The Chair welcomed the new alternate from the Slovak Republic.

1.2. Adoption of agenda

The CAT agenda for 16-17 February 2022 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes for 19-21 January 2022 meeting 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

No items
2.4. **Day 120 list of questions**

No items

2.5. **Day 80 assessment reports**

2.5.1. **Tablecleucel - PRIME - Orphan - EMEA/H/C/004577**

**Accelerated assessment**

Atara Biotherapeutics Ireland Limited; treatment of Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV⁺ PTLD)

Scope: Day 80 assessment report

**Action:** for information

The information was noted.

2.6. **Update on ongoing initial applications**

No items

2.7. **New applications**

No items

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 and variations of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008**

2.11.1. **Kymriah - tisagenlecleucel - PRIME - Orphan - EMEA/H/C/004090/II/0049/G**

Novartis Europharm Limited

**Rapporteur:** Rune Kjeken

Scope: Quality. Opinion

**Action:** for adoption

The opinion was adopted.
2.11.2.  **Yescarta - axicabtagene ciloleucel - PRIME - Orphan - EMEA/H/C/004480/II/0040**

Kite Pharma EU B.V.
Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Anette Kirstine Stark
Scope: Clinical. Opinion

**Action:** for adoption

The opinion was adopted.

2.11.3.  **Yescarta - axicabtagene ciloleucel - PRIME - Orphan - EMEA/H/C/004480/II/0042**

Kite Pharma EU B.V.
Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Claire Beuneu, PRAC Rapporteur: Anette Kirstine Stark
Scope: Clinical. Request for Supplementary information.
Extension of indication to include the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after three or more lines of systemic therapy. Consequently, sections 4.1, 4.8, 5.1 and 5.2 of the SmPC, Annex II (Section D) and package leaflet are proposed to be updated. As a consequence, the RMP (version 5.1) has been updated to align with the indication extension. In addition, the applicant has taken the opportunity to make minor editorial corrections throughout the SmPC and package leaflet to align with the current Quality Review of Documents (QRD) template.

**Action:** for adoption

Request for Supplementary Information (RSI) adopted on 05.11.2021.

The Rapporteur presented the outcome of the assessment of the response to the RSI. The comments from the member states were discussed. A second RSI was adopted to allow the applicant to address the SmPC issues.

2.11.4.  **Yescarta - axicabtagene ciloleucel - PRIME - Orphan - EMEA/H/C/004480/II/0046**

Kite Pharma EU B.V.
Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Claire Beuneu, PRAC Rapporteur: Anette Kirstine Stark
Scope: Clinical. Request for supplementary information
Extension of indication to include treatment of adult patients with relapsed or refractory (r/r) diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) as second line treatment for Yescarta; as a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The package leaflet is updated in accordance. Version 5.3 of the RMP has also been submitted. In addition, the marketing authorisation holder (MAH) took the opportunity to update the product information with minor editorial changes.

**Action:** for adoption

The Rapporteur presented the outcome of the assessment. The request for supplementary information was adopted.
2.11.5. Tecartus; Yescarta - autologous anti-CD19-transduced CD3+ cells; axicabtagene ciloleucel - PRIME - Orphan - EMEA/H/C/WS2197

Kite Pharma EU B.V.
Scope: Quality. Opinion
**Action:** for adoption
The opinion was adopted.

2.12. **Extension applications**

No items

2.13. **Other Post-Authorisation Activities**


Novartis Europharm Limited
Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang
Scope: Quality.
**Action:** for adoption
The outcome of the post-authorisation measure was adopted.

2.13.2. Kymriah - tisagenlecleucel - PRIME - Orphan - EMEA/H/C/004090/REC/016

Novartis Europharm Limited
Rapporteur: Rune Kjeken, CHMP Coordinator: Ingrid Wang
Scope: Quality.
**Action:** for adoption
The outcome of the post-authorisation measure was adopted.

2.13.3. Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/REC/007

Orchard Therapeutics (Netherlands) BV
Rapporteur: Carla Herberchts, CHMP Coordinator: Johann Lodewijk Hillega
Scope: Quality
**Action:** for adoption
The outcome of the post-authorisation measure was adopted.

2.13.4. Spherox - spheroids of human autologous matrix-associated chondrocytes - EMEA/H/C/002736/R/0024

CO.DON AG
Rapporteur: Lisbeth Barkholt, Co-Rapporteur: Heli Suila, PRAC Rapporteur: Brigitte Keller-Stanislawski
Scope: 5-year Renewal of Marketing Authorisation
**Action:** for adoption
CAT adopted the renewal of the marketing authorisation. It was agreed that no further renewal of the marketing authorisation is required.

2.13.5. Tecartus - autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured - PRIME - Orphan - EMEA/H/C/005102/ANX/002.2

Kite Pharma EU B.V.
Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Scope: MAH Response to ANX-002.1 [Study No. KTE-EU-472-6036: Long-term, non-interventional study of recipients of Tecartus for treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)]

**Action:** for adoption

The protocol for the post-authorisation efficacy study (PAES) was agreed. The outcome of the post-authorisation measure was adopted.

2.13.6. Zolgensma - onasemnogene abeparvovec - PRIME - Orphan - EMEA/H/C/004750/R/0021

Novartis Gene Therapies EU Limited
Rapporteur: Carla Herberts, Co-Rapporteur: Egbert Flory, PRAC Rapporteur: Ulla Wändel Liminga

Scope: 1-year Renewal of Marketing Authorisation. Request for supplementary information

**Action:** for adoption

The Rapporteur presented the outcome of the evaluation of the second renewal of the marketing authorisation of Zolgensma. Provided that the MAH response satisfactorily to a number of minor questions, all specific obligations for this product are fulfilled. CAT agreed that at the time of the adoption of this renewal the marketing authorisation can be switched from conditional to full. The request for supplementary information was adopted.

2.13.7. Zynteglo - betibeglogene autotemcel - PRIME - Orphan - EMEA/H/C/003691/SOB/003

bluebird bio (Netherlands) B.V
Rapporteur: Carla Herberts, CHMP Coordinator: Paula Boudewina van Hennik

Scope: From Initial MAA:
Study HGB-207: in order to confirm the efficacy and safety of Zynteglo in patients 12 years and older with transfusion-dependent β thalassaemia (TDT) who do not have a β0/β0 genotype, the MAH should submit interim and final data.

**Action:** for adoption

The Rapporteur presented the outcome of the assessment of the specific obligations (SOBs) 03 and 04. The SOBs are considered fulfilled. CAT adopted the outcome of the assessment. CAT also noted the upcoming withdrawal by the MAH of the marketing authorisation of this product for commercial reasons.
2.13.8. **Zynteglo - betibeglogene autotemcel - PRIME - Orphan -**

*bluebird bio (Netherlands) B.V*

_Rapporteur: Carla Herberts, CHMP Coordinator: Paula Boudewina van Hennik_

_Scope: From Initial MAA:
Study HGB-212: in order to confirm the efficacy and safety of Zynteglo in patients 12 years and older with transfusion-dependent β thalassaemia (TDT) who do not have a β0/β0 genotype, the MAH should submit interim and final data from patients with a severe non β0/β0 genotype such as IVS I 110._

**Action:** for adoption

CAT adopted the outcome of the assessment.

See 2.13.8

2.13.9. **Interactions with the European Society for Blood and Marrow Transplantation (EBMT) and marketing authorisation holders of CAR-Ts on the use of data from the EBMT registry for the imposed PASS**

_Scope: feedback from the meeting on 26.01.2022_

**Action:** for discussion

EMA provided feedback from the discussion with EBMT and the MAHs of CAR-T products. A meeting will be set up with the CAT Rapporteurs of CAR-T products to discuss possible follow-up steps.

## 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**

No items

### 3.3. **New Applications**

No items
4. **Scientific Recommendation on Classification of ATMPs**

4.1. **New requests – Appointment of CAT Coordinator**

4.1.1. **Gingival fibroblast**

- Intended for the treatment of gonarthrosis
- Scope: appointment of CAT Coordinator and adoption of timetable
- **Action:** for adoption
- The CAT coordinator was appointed.

4.1.2. **(AAV2.hIL-12) Recombinant serotype 2 adeno-associated virus (AAV2) carrying a single-stranded expression cassette for human Interleukin 12 (IL-12)**

- Intended for the treatment of advanced solid tumours
- Scope: appointment of CAT Coordinator and adoption of timetable
- **Action:** for adoption
- The CAT coordinator was appointed.

4.1.3. **Leukocyte and platelet rich plasma, autologous**

- Intended for the treatment of critical limb ischemia
- Scope: appointment of CAT Coordinator and adoption of timetable
- **Action:** for adoption
- The CAT coordinator was appointed.

4.1.4. **Messenger RNA (mRNA) containing a bicistronic coding sequence that upon translation produces two independent proteins, ZF-DNMT and ZF-KRAB**

- Intended for the treatment of adult patients with intermediate (stage B) or advanced (stage C) MYC-associated hepatocellular carcinoma (HCC)
- Scope: appointment of CAT Coordinator and adoption of timetable
- **Action:** for adoption
- The CAT coordinator was appointed.

4.1.5. **Stimulated anti-viral T-lymphocytes with specific anti-viral activity**

- Intended for the treatment of resistant viral infections in patients after allo-HSCT
- Scope: appointment of CAT Coordinator and adoption of timetable
- **Action:** for adoption
- The CAT coordinator was appointed.
4.1.6. **Plasmid expressing variant of human interleukin-10**

Intended for the treatment of osteoarthritis, neuropathic pain, amyotrophic lateral sclerosis

**Scope:** appointment of CAT Coordinator and adoption of timetable

**Action:** for adoption

The CAT coordinator was appointed.

4.2. **Day 30 ATMP scientific recommendation**

No items

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

No items

4.4. **Finalisation of procedure**

4.4.1. **Kidney progenitor cells isolated from the urine of preterm neonates**

Intended for the kidney transplantation

**Scope:** The European Commission raised no comments. ATMP scientific recommendation

**Action:** for information

The information was noted. The finalised classification report will be sent to the applicant.

4.4.2. **Expanded mesenchymal stem cells (MSCs) cells isolated from umbilical cord Wharton jelly dilative cardiomyopathy (DCM)**

Intended for the treatment of dilative cardiomyopathy (DCM)

**Scope:** The European Commission raised no comments. ATMP scientific recommendation

**Action:** for information

The information was noted. The finalised classification report will be sent to the applicant.

4.4.3. **Recombinant serotype 9 adeno-associated virus (rAAV9) encoding a wild-type human MECP2 (methyl cytosine binding protein 2) transgene (AAV9-hMECP2)**

Intended for the treatment of Rett syndrome

**Scope:** Minor comments were made by the European Commission. Revised ATMP scientific recommendation

**Action:** for information

The information was noted. The finalised classification report will be sent to the applicant.
4.4.4. Recombinant adeno-associated virus (rAAV) containing human homology arms, expressing codon-optimised human phenylalanine hydroxylase (hPAH)

Intended for the treatment of phenylalanine hydroxylase (PAH) deficiency
Scope: The European Commission raised no comments. ATMP scientific recommendation

**Action:** for information

The information was noted. The finalised classification report will be sent to the applicant.

4.4.5. Human embryonic stem cell (hESC)-derived midbrain dopaminergic (mDA) neuron cells

Intended for the treatment of advanced Parkinson’s disease
Scope: The European Commission raised no comments. ATMP scientific recommendation

**Action:** for information

The information was noted. The finalised classification report will be sent to the applicant.

4.4.6. Stem cells isolated from dental pulp, cultured

Intended for the treatment of surgical bone defects
Scope: The European Commission raised no comments. ATMP scientific recommendation

**Action:** for information

The information was noted. The finalised classification report will be sent to the applicant.

4.4.7. Modulated immune cells

Intended for solid organ transplantation / Treatment of autoimmune disease
Scope: The European Commission raised no comments. Revised ATMP scientific recommendation

**Action:** for information

The information was noted. The finalised classification report will be sent to the applicant.

4.4.8. Autologous bone marrow concentrate

Intended for the treatment of bone fractures
Scope: Minor comments were made by the European Commission. Revised ATMP scientific recommendation

**Action:** for information

The information was noted. The finalised classification report will be sent to the applicant.

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**

5.1.1. **Ongoing scientific advice procedures - Appointment of CAT Peer Reviewers**

**Timetable:**
- Start of procedure at SAWP: 07-10.02.2022
- Appointment of CAT Peer Reviewers: 16-18.02.2022
- SAWP first reports: 28.02.2022
- CAT Peer Reviewer comments: 04.03.2022
- Discussion at SAWP: 07-10.03.2022
- Discussion at CAT and feedback to SAWP: 18.03.2022

5.1.2. **Scientific advice procedures starting at the next SAWP meeting**

**Timetable:**
- Start of procedure at SAWP: 07-10.03.2022
- Appointment of CAT Peer Reviewers: 16-18.03.2022
- SAWP first reports: 28.03.2022
- CAT Peer Reviewer comments: 01.04.2022
- Discussion at SAWP: 04-07.04.2022
- Discussion at CAT and feedback to SAWP: 13.04.2022

5.2. **Procedures discussed at SAWP – 1st reports, D40 JRs, LoIs**

5.3. **Finalisation of D70 procedures – feedback from the discussion meeting**

5.4. **Final Advice Letters for procedures finalised the previous month**

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**

No items

6.2. **ITF briefing meetings in the field of ATMPs**
6.3. **Priority Medicines (PRIME) – Eligibility requests**

6.3.1. **Month 0 - Start of the procedure**

Timetable for assessment:

- Procedure start: 07-10.02.2022
- SAWP recommendation: 10/03/2022
- CAT recommendation: 18/03/2022
- CHMP adoption of report and final recommendation: 24/03/2022

No items

6.3.2. **Month 1 – Discussion of eligibility**

No items

6.3.3. **Month 2 – Recommendation of eligibility**

6.3.4. **Ongoing support**

7. **Organisational, regulatory and methodological matters**

7.1. **Mandate and organisation of the CAT**

7.1.1. **CAT membership**

The Chair welcomed Katarina Vavrova as the new alternate member for Slovak Republic.

**Action:** for information

7.1.2. **Joint CAT-CHMP Strategic Review & Learning meeting (SRLM) under the Slovenian presidency, 21 October 2021 (virtual)**

CAT: Metoda Lipnik-Štangelj, Martina Schuessler-Lenz

Scope: Minutes of the meeting

**Action:** for information

CAT noted the minutes of the SRLM of 21 October 2021.

7.1.3. **CAT Strategic Review & Learning meeting (SRLM) under the French presidency, 3 March 2022 (virtual)**

CAT: Violaine Closson-Carella, Martina Schuessler-Lenz

Scope: Review and adoption of the agenda content
Action: for discussion

The final agenda of the upcoming SRLM was presented. CAT members were reminded to register for the meeting and to inform the organisers of any additional expert/assessor from the NCA that plans to attend the meeting.

7.2. Coordination with EMA Scientific Committees

7.2.1. Classification of Post-Authorisation Studies (CPAS)

Scope: Presentation of the mandate of the CPAS
Action: For discussion
CAT noted the presentation on the role and mandate of the CPAS.

7.2.2. CHMP learnings with relevance to CAT: Revision to the Appendix 3 of the anticancer guideline

Scope: Revision to the Appendix 3 of the anticancer guideline related to section 4.8 of the Summary Products Characteristics (SmPC) for the anticancer medicinal products.
Action: for discussion
EMA and the Rapporteur of the guideline, Sigrid Klaar, presented the revised Appendix 3. Guidance is provided in this document on how to present safety data in section 4.8 of the SmPC, especially safety data from related indications. It is part of the assessment to determine if the population in related indications are similar enough for the safety data to be presented in a single safety table in the SmPC.

7.2.3. CHMP learnings with relevance to CAT: Topics discussed at February CHMP PROM

CAT: Martina Schüssler-Lenz
Scope: Summary of topics of interest that were discussed at the last CHMP PROM meeting
Action: for information
Following topics are of relevance for CAT:
- Oncology working party: selection of candidates has taken place;
- Call for nominations for candidates for clinical working parties (with the exception of the oncology working party), non-clinical and methodology working parties: CAT members interested should contact their national authorities; CAT members representing the doctors and patient organisations can also be proposed by one of the national authorities;
- Classification of post-authorisation studies: presentation of mandate (see 7.2.1);
- Extrapolation: assessor guidance template;
- Proof of concept raw data pilot.
CAT asked for the last two topics to be presented at the March CAT meeting.

7.2.4. Extension of indication of approved ATMPs: additional 1-year protection period

Scope: Presentation on the regulatory aspects
Action: for information

---

1 The CHMP PROM is a meeting to discuss CHMP organisational matters and other topics in preparation for the CHMP Plenary meeting.
EMA presented the regulatory aspects related to the additional 1-year protection period when the indication of an approved ATMP is extended. As part of the assessment of a variation for extension of indication, clinical superiority have to be assessed.

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

7.3.1. **Working Party with Patients’ and Consumers’ Organisations (PCWP) and Working Party with Healthcare Professionals’ Organisations (HCPWP)**

Scope: Meeting summary of the PCWP/HCPWP joint meeting with all eligible organisations on the 24 November 2021  
**Action**: for information
The information was noted.

7.3.2. **Working Party with Patients’ and Consumers’ Organisations (PCWP) and Working Party with Healthcare Professionals’ Organisations (HCPWP)**

Scope: Draft agenda - PCWP-HCPWP joint meeting on 02-03 March 2022  
**Action**: for information
The information was noted.

7.3.3. **BWP/QWP/IWG Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME and certain marketing authorisation applications targeting an unmet medical need**

DG members: Mats Welin, Sean Barry, Marcel Hoefnagel, Tone Agasoster, Kristofer Olofsson, Jobst Limberg, Giampiero Lorenti  
**Action**: for adoption
EMA and Marcel Hoefnagel presented the final Toolbox and highlighted the main changes that were implemented following the external consultation: the scope has been extended to cover not only PRIME designated products but also other medicinal products targeting an unmet medical need.

The document is now presented to BWP, QWP, IWG and CAT: comments are awaited within the next 2 weeks. The Toolbox will be considered adopted if no major comments are received (minor comments will be reviewed and if needed implemented by the drafting group).

7.3.4. **EMA Working Parties Implementation Plan Review – (H+V)**

Scope: Information on creation of the Quality Innovation Group (QIG) within the Quality Domain  
**Action**: For discussion
EMA presented the creation of the QIG and how this group fits within the new working party organisation model. The QIG will specifically look at the translation of innovation, trying to find solutions for innovative developments, set priorities and develop strategies towards the needs of the network. A call for nomination will be initiated in April 2022.
7.4. **Cooperation with the EU regulatory network**

7.4.1. **Accelerating Clinical Trials in the EU (ACT EU)**

Scope: This business-change programme aims to strengthen the European environment for clinical trials and was recently endorsed at both HMA November 2021 and EMA Management Board December 2021 meetings, including the accompanying paper outlining the objectives and priority actions for the ACT EU.

**Action:** for information

EMA presented the topic. The main objective of ACT EU is to optimise the environment for clinical trials in the EU. The ACT-EU steering group will be looking for CAT experts to lead and participate in different actions.

CAT members mentioned the implementation of the clinical trial information system (CTIS) is causing problems with clinical trials of products containing or consisting of GMOs and also with the interoperability of trials with medicinal products and medical devices. It is clear that these issues have to be tackled in order to make EU attractive for clinical trials with ATMPs.

7.5. **Cooperation with international regulators**

7.5.1. **Joint EMA-FDA Q&As on PRIME/Breakthrough applications (control strategy, process validation, stability, GMP)**

DG members: Mats Welin, Sean Barry, Marcel Hoefnagel, Tone Agasoster, Kristofer Olofsson, Jobst Limberg, Giampiero Lorenti

Scope: Joint EMA-FDA Q&As on PRIME/Breakthrough applications

**Action:** for adoption

Marcel Hoefnagel presented the content of the Q&A related to: control strategy, process validation, stability and GMP considerations.

The document is now presented to BWP, QWP, IWG and CAT: comments are awaited within the next 2 weeks. The Q&A document will be considered adopted if no major comments are received (minor comments will be reviewed and if needed implemented by the drafting group).

7.5.2. **ATMP cluster teleconference with US-FDA, Health Canada and PMDA (Japan)**

CAT: Martina Schuessler-Lenz

Scope: Agenda of the teleconference that will take place on 24 February 2022

**Action:** for information

The agenda for the upcoming ATMP cluster was presented.

CAT members interested to join this ATMP cluster should inform CAT Secretariat.

7.5.3. **WHO consultation on cell and gene therapy products**

CAT: Ilona Reischl

Scope: Presentations from WHO consultation meeting that took place on 07-09 February 2022.

**Action:** for information
CAT noted the information

### 7.6. CAT work plan

#### 7.6.1. ATMP training for 2022

CAT: Ilona Reischl  
Scope: Identification of ATMP training for assessors and experts

**Action:** for discussion

The plan for training for the network (ATMP assessors in the NCAs and CAT members) was discussed. Friday (13.30 – 14.30) after the virtual CAT plenary meeting was identified as a suitable time. Following training topics will be developed first: guideline for genetically modified cells, Q&A for comparability, comprehensiveness criteria, marketing authorisation procedure for ATMPs. CAT secretariat will contact the CAT members to identify speakers.

#### 7.6.2. Implementation of the medical device and in-vitro diagnostics Regulations

CAT: Ilona Reischl  
Scope: Status update

**Action:** for discussion

A detailed update on this topic was provided.

### 7.7. Planning and reporting

No items

### 7.8. Others

No items

### 8. Any other business

No items

Date of next CAT meeting:  
16-18/03/2022
9. Explanatory notes

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

Abbreviations / Acronyms

AAV: Adeno-Associated Virus
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
EU NTC: European Union Network Training Centre
ERA: Environmental Risk Assessment
FDA: Food and Drug Administration
FL: Final Letter
GCG: Guideline Consistency Group
GCP: Good Clinical Practice
GLP: Good Laboratory Practice
GMO: Genetically-modified organism
GMP: Good Manufacturing Practice
GTMP: 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 Application
MAH: Marketing Authorisation Holder
MNAT: Multinational assessment team
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
#
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, quality 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/](http://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 16-17 February 2022 meeting.
<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Member State or affiliation</th>
<th>Outcome restriction following evaluation of e-DoI</th>
<th>Topics on agenda for which restrictions apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Martina Schüssler-Lenz</td>
<td>Chair</td>
<td>Germany</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Ilona Reischl</td>
<td>Member (Vice-Chair)</td>
<td>Austria</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Silke Dorner</td>
<td>Alternate</td>
<td>Austria</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Claire Beuneu</td>
<td>Member</td>
<td>Belgium</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Belaïd Sekkali</td>
<td>Alternate</td>
<td>Belgium</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Rozalina Kulaksazova</td>
<td>Member</td>
<td>Bulgaria</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Evelina Shumkova</td>
<td>Alternate</td>
<td>Bulgaria</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Azra Selimovic</td>
<td>Member</td>
<td>Croatia</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Petra Sokol</td>
<td>Alternate</td>
<td>Croatia</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Rafaella Pontou</td>
<td>Member</td>
<td>Cyprus</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Isavella Kyriakidou</td>
<td>Alternate</td>
<td>Cyprus</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Tomas Boran</td>
<td>Member</td>
<td>Czechia</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Petr Soukup</td>
<td>Alternate</td>
<td>Czechia</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Ebru Karakoc Madsen</td>
<td>Alternate</td>
<td>Denmark</td>
<td>No restrictions applicable to this meeting</td>
<td></td>
</tr>
<tr>
<td>Toivo Maimets</td>
<td>Member</td>
<td>Estonia</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Pille Saalik</td>
<td>Alternate</td>
<td>Estonia</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Heli Suila</td>
<td>Member</td>
<td>Finland</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Maija Tarkkanen</td>
<td>Alternate</td>
<td>Finland</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Violaine Closson</td>
<td>Member</td>
<td>France</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Jean-Michel Race</td>
<td>Alternate</td>
<td>France</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Jan Mueller-Berghaus</td>
<td>Member (CHMP co-opted member)</td>
<td>Germany</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Egbert Flory</td>
<td>Alternate (to CHMP representative)</td>
<td>Germany</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Maria Gazouli</td>
<td>Member</td>
<td>Greece</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Angeliki Rompoti</td>
<td>Alternate</td>
<td>Greece</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>Role</td>
<td>Member State or affiliation</td>
<td>Outcome restriction following evaluation of e-DoI</td>
<td>Topics on agenda for which restrictions apply</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------------------</td>
<td>-----------------------------</td>
<td>--------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Katalin Lengyel</td>
<td>Member</td>
<td>Hungary</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Balázs Sarkadi</td>
<td>Alternate</td>
<td>Hungary</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Maura O'Donovan</td>
<td>Member</td>
<td>Ireland</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Niamh Curran</td>
<td>Alternate</td>
<td>Ireland</td>
<td>No restrictions applicable to this meeting</td>
<td></td>
</tr>
<tr>
<td>Concetta Quintarelli</td>
<td>Member</td>
<td>Italy</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Barbara Bonamassa</td>
<td>Alternate</td>
<td>Italy</td>
<td>No restrictions applicable to this meeting</td>
<td></td>
</tr>
<tr>
<td>Una Riekstina</td>
<td>Member</td>
<td>Latvia</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Romaldas Mačiulaitis</td>
<td>Member (CHMP member)</td>
<td>Lithuania</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Raimondas Benetis</td>
<td>Alternate (to CHMP representative)</td>
<td>Lithuania</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Vlasta Zavadova</td>
<td>Member</td>
<td>Liechtenstein</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Guy Berchem</td>
<td>Alternate</td>
<td>Luxembourg</td>
<td>Cannot act as rapporteur, other leading/co-ordinating role or peer reviewer for:</td>
<td>5.1.1.4.</td>
</tr>
<tr>
<td>Nancy De Bremaeker</td>
<td>Member</td>
<td>Luxembourg</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>John J. Borg</td>
<td>Member (CHMP member)</td>
<td>Malta</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Anthony Samuel</td>
<td>Alternate (to CHMP representative)</td>
<td>Malta</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Carla Herberts</td>
<td>Member</td>
<td>Netherlands</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Babs Fabriek</td>
<td>Alternate</td>
<td>Netherlands</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Rune Kjeken</td>
<td>Member</td>
<td>Norway</td>
<td>No restrictions applicable to this meeting</td>
<td></td>
</tr>
<tr>
<td>Maja Sommerfelt Grønvold</td>
<td>Alternate</td>
<td>Norway</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>Role</td>
<td>Member State or affiliation</td>
<td>Outcome restriction following evaluation of e-DoI</td>
<td>Topics on agenda for which restrictions apply</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------------------------------</td>
<td>-----------------------------</td>
<td>--------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Dariusz Śladowski</td>
<td>Member</td>
<td>Poland</td>
<td>No restrictions applicable to this meeting</td>
<td></td>
</tr>
<tr>
<td>Marcin Kolakowski</td>
<td>Alternate</td>
<td>Poland</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Bruno Sepodes</td>
<td>Member (CHMP member)</td>
<td>Portugal</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Maria Isabel Borba Vieira</td>
<td>Alternate (to CHMP representative)</td>
<td>Portugal</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Silviu Istrate</td>
<td>Member</td>
<td>Romania</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Alexandrina Preda</td>
<td>Alternate</td>
<td>Romania</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Lukas Slovak</td>
<td>Member</td>
<td>Slovakia</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Katarina Vavrová</td>
<td>Alternate</td>
<td>Slovakia</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Metoda Lipnik-Stangelj</td>
<td>Member</td>
<td>Slovenia</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Suzana Vidic</td>
<td>Alternate</td>
<td>Slovenia</td>
<td>No participation in final deliberations and voting on:</td>
<td>2.11.1., 2.13.1., 2.13.2. &amp; 2.13.6.</td>
</tr>
<tr>
<td>Sol Ruiz</td>
<td>Member (CHMP co-opted member)</td>
<td>Spain</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Marcos Timón</td>
<td>Alternate (to CHMP representative)</td>
<td>Spain</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Lisbeth Barkholt</td>
<td>Member</td>
<td>Sweden</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Maria Luttgen</td>
<td>Alternate</td>
<td>Sweden</td>
<td>Cannot act as rapporteur, other leading/co-ordinating role or peer reviewer for:</td>
<td>5.1.1.4.</td>
</tr>
<tr>
<td>Bernd Gänbsbacher</td>
<td>Member</td>
<td>Clinicians' Representative</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Frederic Bernard</td>
<td>Alternate</td>
<td>Clinicians' Representative</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>Role</td>
<td>Member State or affiliation</td>
<td>Outcome restriction following evaluation of e-DoI</td>
<td>Topics on agenda for which restrictions apply</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------</td>
<td>----------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Alessandro Aiuti</td>
<td>Member</td>
<td>Clinicians' Representative</td>
<td>No participation in discussions, final deliberations and voting on:</td>
<td>2.13.3.</td>
</tr>
<tr>
<td>Alessandra Renieri</td>
<td>Alternate</td>
<td>Clinicians' Representative</td>
<td>No restrictions applicable to this meeting</td>
<td></td>
</tr>
<tr>
<td>Kerstin Sollerbrant</td>
<td>Member</td>
<td>Patients' Representative</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Lydie Meheus</td>
<td>Alternate</td>
<td>Patients' Representative</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Kieran Breen</td>
<td>Member</td>
<td>Patients' Representative</td>
<td>No restrictions applicable to this meeting</td>
<td></td>
</tr>
<tr>
<td>Roland Pochet</td>
<td>Alternate</td>
<td>Patients' Representative</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Catherine Milne</td>
<td>Observer/Alternate</td>
<td>EDQM</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Sofie Peirs Peirs</td>
<td>Expert - via Webex</td>
<td>FAGG AFMPS (BE)</td>
<td>No restrictions applicable to this meeting</td>
<td></td>
</tr>
<tr>
<td>Marcel H.N. Hoefnagel</td>
<td>Expert - via Webex</td>
<td>CBG/MEB (NL)</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Sigrid Klaar</td>
<td>Expert - via Webex</td>
<td>MPA (SE)</td>
<td>No restrictions applicable to this meeting</td>
<td></td>
</tr>
<tr>
<td>Matthias Renner</td>
<td>Expert - via Webex</td>
<td>PEI</td>
<td>No restrictions applicable to this meeting</td>
<td></td>
</tr>
<tr>
<td>Attila Sebe</td>
<td>Expert - via Webex</td>
<td>PEI</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Beate Mosl</td>
<td>Expert - via Webex</td>
<td>PEI</td>
<td>No restrictions applicable to this meeting</td>
<td></td>
</tr>
<tr>
<td>Olga Kolomanskikh</td>
<td>Expert - via Webex</td>
<td>FAGG AFMPS (BE)</td>
<td>No interests declared</td>
<td></td>
</tr>
<tr>
<td>Filip Van Nuffel</td>
<td>Expert - via Webex</td>
<td>FAGG AFMPS (BE)</td>
<td>No interests declared</td>
<td></td>
</tr>
</tbody>
</table>

A representative from the European Commission attended the meeting

Meeting run with support from relevant EMA staff