11 April 2026
EMA/CAT/128640/2026
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 15-17 April 2026

Chair: Ilona Reischl-Kok; Vice-Chair: Kieran Breen

Disclaimers

Some of the information contained in these minutes is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CAT meeting reports once the procedures are finalised.

Of note, 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 on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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1. Introduction

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

The Chairperson opened the meeting by welcoming all participants. 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 on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for concerned agenda topics.

Participants were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. Restrictions applicable to this meeting are captured in the List of participants included in the minutes.

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. 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 members of the EEA-EFTA States agreed with the recommendation of the CAT, unless otherwise specified.

The EMA Secretariat announced the names of the Committee members who delegated their vote via proxy and the Committee members who received such proxy.

1.2. Adoption of agenda

The CAT agenda for 15-17 April 2026 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes for 18-20 March 2026 meeting were adopted.

2. Evaluation of ATMPs

2.1. Opinions

2.1.1. Itvisma (previously known as Zamzura) - Onasemnogene abeparvovec - Orphan - EMEA/H/C/006498

Novartis Europharm Limited; Treatment of 5q spinal muscular atrophy (SMA)

Scope: Opinion

Action: for adoption

List of outstanding issues adopted on 20.02.2026. List of questions adopted on 12.09.2025.

The rapporteurs presented the outcome of the assessment of the list of outstanding issues. CAT was informed that all the outstanding issues were resolved.

CAT adopted the positive opinion recommending granting of a marketing authorisation to Itvisma.

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

No items

2.6. Update on ongoing initial applications

2.6.1. Zopapogene Imadenovec - Orphan - EMEA/H/C/006508

FGK Representative Service GmbH; Treatment of respiratory papillomatosis in adults

Scope: List of questions

Action: for adoption

The rapporteur presented the list of questions. The revised list of questions was adopted.

2.7. New applications

2.7.1. Lunsotogene parvec - Orphan - H0006802

Regeneron Ireland DAC; Treatment of patients with biallelic OTOF variant-associated hearing loss

Scope: Accelerated assessment, opinion

Action: for discussion

The rapporteur presented the outcome of the assessment of the request for accelerated assessment. CAT agreed with the conclusion of the rapporteurs.

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. Abecma - Idecabtagene vicleucel - Orphan - EMA/VR/0000327582

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.2. Breyanzi - Lisocabtagene maraleucel - EMA/VR/0000327431

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli, PRAC-Rapporteur: Dirk Mentzer

Scope: Clinical, request for supplementary information

Submission of the final report from study CA082-1105 listed as a condition in the Annex II of the Product Information. This is a non-interventional study submitted to summarise the consistency of Breyanzi product batch quality data measured at the time of release and clinical outcomes in patients treated with Breyanzi in the post-marketing setting for relapsed/refractory large B-cell lymphoma (R/R LBCL) within the approved indications and dose range per the EU PI. The Annex II and the RMP version 10.0 are updated accordingly. In addition, the MAH took the opportunity to make a minor editorial update by removing some grey shading from Annex III.

Action: for adoption

The rapporteurs presented the outcome of the assessment The request for supplementary information was adopted.

2.11.3. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/VR/0000327548

Janssen Cilag International

Rapporteur: Attila Sebe

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.4. Kymriah - Tisagenlecleucel - Orphan - EMA/VR/0000302038

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.5. Tecartus / Yescarta - Brexucabtagene autoleucel / Axicabtagene ciloleucel - Orphan - EMA/VR/0000308229

Kite Pharma EU B.V.

Rapporteur: Attila Sebe, PRAC Rapporteur: Karin Erneholm

Scope: Clinical, opinion

Update of sections 4.2, 4.4, 4.5. 4.7 and 6.4 of the SmPC in order to modify the pre- and post-infusion monitoring recommendations and requirements related to the risk of CRS (cytokine release syndrome) and ICANS (immune effector cell-associated neurotoxicity syndrome) based on data from clinical trials, post-marketing experience and literature. The Package Leaflet is updated accordingly. The RMP version 7.1 has also been submitted. In addition, Annex II has been updated accordingly. Furthermore, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4 and to implement editorial changes to the PI.

Action: for adoption

The rapporteurs presented the outcome of the assessment. The opinion was adopted.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Casgevy - Exagamglogene autotemcel - Orphan - EMA/PAM/0000328242

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Attila Sebe

Scope: PAM

Action: for adoption

The outcome of the assessment was agreed.

2.13.2. Casgevy - Exagamglogene autotemcel - Orphan - EMA/PAM/0000328232

Vertex Pharmaceuticals (Ireland) Limited

Rapporteur: Attila Sebe

Scope: PAM

Action: for adoption

The outcome of the assessment was agreed.

2.13.3. Ebvallo - Tabelecleucel - Orphan - EMA/PAM/0000326954

Pierre Fabre Medicament

Rapporteur: Attila Sebe

Scope: PAM

Action: for adoption

The outcome of the assessment was agreed.

2.14. Companion diagnostics - initial consultation

No items

2.15. Companion diagnostics – Follow-up consultation

No items

3. Certification of ATMPs

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

3.1. Opinion

No items

3.2. Day 60 Evaluation Reports

No items

3.3. New Applications

No items

4. Scientific Recommendation on Classification of ATMPs

Timetable:

-Start of the procedure:	20.04.2026
-EMA Coordinator's draft report:	30.04.2026
-CAT Coordinator's comments:	06.05.2026
-Revised scientific recommendation:	08.05.2026
-CAT's discussion of scientific recommendation:	13.05.2026

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Autologous venous graft

Reconstruction of the extrahepatic bile duct following circumferential resection during hepatobiliary surgery for malignant biliary tumours, including perihilar cholangiocarcinoma and other tumours involving the biliary confluence

Scope: ATMP scientific recommendation

Action: for nomination of CAT Coordinator

The CAT Coordinator was appointed.

4.1.2. Human type I collagen, lyophilised

For intradermal injection into the facial dermis to correct dynamic wrinkles (crow's feet)

Scope: ATMP scientific recommendation

Action: for nomination of CAT Coordinator

The CAT Coordinator was appointed.

4.1.3. Autologous platelet-rich plasma (PRP) combined with mechanically processed autologous adipose tissue (nanofat)

Treatment of refractory olfactory dysfunction

Scope: ATMP scientific recommendation

Action: for nomination of CAT Coordinator

The CAT Coordinator was appointed.

4.1.4. Allogeneic human umbilical cord-derived mesenchymal stromal cells

Treatment of congenital diaphragmatic hernia

Scope: ATMP scientific recommendation

Action: for nomination of CAT Coordinator

The CAT Coordinator was appointed.

4.1.5. Adeno-associated virus serotype rh.74 viral vector encoding the human B-cell Lymphoma 2 (BCL-2)-associated athanogene 3 (BAG3) gene (AAVrh.74-BAG3)

Treatment of BAG3-associated dilated cardiomyopathy (DCM)

Scope: ATMP scientific recommendation

Action: for nomination of CAT Coordinator

The CAT Coordinator was appointed.

4.1.6. Replication-competent, plaque-purified, attenuated mumps virus variant

Treatment of breast cancer

Scope: ATMP scientific recommendation

Action: for nomination of CAT Coordinator

The CAT Coordinator was appointed.

4.2. Day 30 ATMP scientific recommendation

4.2.1. Recombinant chicken annexin V labelled inactivated autologous tumour cells

Treatment of solid tumours, especially renal cell carcinoma and breast cancer

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 04.05.2026.

4.2.2. Adenovirus type 5 vector expressing human granulocyte-macrophage colony-stimulating factor

Treatment of bladder cancer

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 04.05.2026.

4.2.3. Autologous adipose-derived stromal vascular fraction

Treatment of acute spinal cord injury

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 04.05.2026.

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

No items

4.4. Follow-up and guidance

4.4.1. Live attenuated viral vector vaccine based on SARS-COV-2 backbone, expressing human interferon beta

COVID-19 prophylaxis

Scope: ATMP scientific recommendation

Action: for adoption

The adoption of the classification report was postponed until the May CAT meeting awaiting further legal clarifications.

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:	07-10.04.2026
- Appointment of CAT Peer Reviewers:	15-17.04.2026
- SAWP first reports:	27.04.2026
- CAT Peer Reviewer comments (NC & C):	30.04.2026
- CAT Peer Reviewer comments (Q):	06.05.2026

- Discussion at SAWP: 04-07.05.2026
- Discussion at CAT and feedback to SAWP: 11-13.05.2026

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

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

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

6.2.1. Overview of ITF meetings in 2025

Scope: Update

Action: for information

The overview was noted.

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:

Procedure start:	07-10.04.2026
SAWP recommendation:	07.05.2026
CAT recommendation:	13.05.2026
CHMP adoption of report and final recommendation:	21.05.2026

6.3.2. Month 1 – Discussion of eligibility

6.3.3. Month 2 – Recommendation of eligibility

6.3.4. Ongoing support

No items

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT membership

No items

7.1.2. Nominated proxy

Martin Oleksiewicz gave a proxy to Emmely de Vries to vote on behalf of Denmark during part of the meeting.

7.1.3. CAT Strategic Review & Learning meeting (SRLM) under the Cypriot presidency

Scope: Preparation for the meeting

CAT: Rafaella Pontou

Action: for information

The final agenda and some practical information were presented.

7.1.4. CAT Strategic Review & Learning meeting (SRLM) under the Irish presidency

Scope: Preparation for the meeting

CAT: Joseph deCourcey

Action: for information

The date of the SRLM meeting on the Irish presidency was noted: the meeting will take place on 11-13 November 2026 in Dublin.

7.1.5. Revised CAT Rules of Procedure

Scope: Working arrangements

Action: for adoption

EMA presented the changes made to the CAT Rules of Procedure (RoP). The revised RoP was adopted.

7.2. Coordination with EMA Scientific Committees

No items

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

No items

7.4. Cooperation with the EU regulatory network

7.4.1. EDQM update for CAT April 2026

CAT: Olga Kolaj-Robin

Scope: Adoption of the revised chapter 5.1.6 Alternative methods for control of microbiological quality and news on the certified review of microbiological methods per the European Pharmacopoeia

Action: for information

The information from EDQM was noted.

7.5. Cooperation with international regulators

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

CAT: Ilona Reischl

Scope: Agenda of the ATMP cluster of 23.04.2025

Action: for information

The information was noted.

7.6. CAT work plan

No items

7.7. Planning and reporting

No items

7.8. Others

No items

8. Any other business

8.1. New reimbursement rules of expenses for delegates attending meetings

Scope: Update on reimbursement rules for delegates

Action: for information

The main changes were presented.

1. Entitlement of business class for flights from and above 5 hours instead of current 4 hours.

   Within Europe the current rules only allow business class for the journey between the Netherlands and Cyprus (i.e. duration over 4 hours). With the new rules, this will no longer be the case as they require minimum flight duration of 5 hours.

2. Recommendation to travel by train for journeys under 550 km.

   By analogy with the Missions rules, train travel is encouraged for journeys up to 550 km per segment, and for longer distances where efficient alternatives exist (e.g., overnight, or high-speed trains). This measure is in line with the EU Green Deal and the Communication to the Commission Greening the Commission.

3. Extension of the travel allowances to train and car journeys

   Should the meeting schedule prevent the delegate from travelling by plane and train to or from the place of the meeting on the actual day of the meeting, currently a single travel allowance (TA) is paid; for travel by plane of 4 hours or more a double travel allowance (DTA) is paid. No DTA is paid for journeys by train or car.
   The Agency is now extending TA to journeys where delegates travel by car and DTA to journeys by train and by car when the journey duration is equal or longer than 5 hours.

4. Reduction of payment of double daily subsistence allowances (DDSA)

   The payment of the double daily subsistence allowance to patients and healthcare professionals is now replaced by a remuneration according to Executive Decision EMA/394602/2025. However, members of scientific committees and Management Board representing patients and healthcare professionals (HCPs) are still entitled to a DDSA. This covers committee members who participate in scientific committee meetings including strategic review and learning meetings (SRLM), provided that they are not currently acting as COMP/PDCO rapporteur or participating as Management Board members in Management Board meetings.

9. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 15-17 April 2026 CAT meeting, which was held remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics for which restrictions apply
Ilona Reischl	Chair	Austria	No interests declared	
Silke Dorner	Member	Austria	No interests declared	
Andreas Maccani	Alternate	Austria	No restrictions applicable to this meeting	
Claire Beuneu	Member	Belgium	No interests declared	
Olga Kholmanskikh	Alternate	Belgium	No interests declared	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Azra Selimovic	Member	Croatia	No restrictions applicable to this meeting	
Rafaella Pontou	Member	Cyprus	No interests declared	
Isavella Kyriakidou	Alternate	Cyprus	No interests declared	
Eva Kolouchová	Member	Czechia	No interests declared	
Martin Oleksiewicz	Member	Denmark	No interests declared	
Johanne Juhl Korsbaek	Alternate	Denmark	No restrictions applicable to this meeting	
Toivo Maimets	Member	Estonia	No restrictions applicable to this meeting	
Pille Saalik	Alternate	Estonia	No interests declared	
Heli Suila	Member	Finland	No restrictions applicable to this meeting	
Violaine Closson Carella	Member	France	No interests declared	
Gabriela Ullio Gamboa	Alternate	France	No interests declared	
Jan Mueller-Berghaus	Alternate	Germany	No interests declared	
Attila Sebe	Member	Germany	No interests declared	

Maria Gazouli	Member	Greece	No restrictions applicable to this meeting	
Angeliki Rompoti	Alternate	Greece	No restrictions applicable to this meeting	
Viola Bardoczy	Member	Hungary	No restrictions applicable to this meeting	
Agnes Zotter	Alternate	Hungary	No restrictions applicable to this meeting	
Péter Zsolt Fekete	Member	Iceland	No interests declared	
Joseph De Courcey	Member	Ireland	No interests declared	
Richard Carroll	Alternate	Ireland	No interests declared	
Concetta Quintarelli	Member	Italy	No participation in discussion, final deliberations and voting on:	Scientific Advice
Barbara Bonamassa	Alternate	Italy	No interests declared	
Liga Kunrade	Alternate	Latvia	No restrictions applicable to this meeting	
Vilma Perikaite	Member (CHMP member)	Lithuania	No restrictions applicable to this meeting	
Raimondas Benetis	Alternate (to CHMP represent ative)	Lithuania	No restrictions applicable to this meeting	
Alessia Pochesci	Member	Luxembourg	No restrictions applicable to this meeting	
Nancy De Bremaeker	Alternate	Luxembourg	No restrictions applicable to this meeting	
John J. Borg	Member (CHMP member)	Malta	No restrictions applicable to this meeting	
Emmely de Vries	Member	Netherlands	No interests declared	
Berendina Maria (Tineke) van den Hoorn	Alternate	Netherlands	No interests declared	
Rune Kjeken	Member	Norway	No interests declared	
Dariusz Sladowski	Member	Poland	No restrictions applicable to this meeting	

Maria Isabel Borba Vieira	Member	Portugal	No interests declared	
Denisa Marilena Margina	Member	Romania	No restrictions applicable to this meeting	
Liviu Nitulescu	Alternate	Romania	No restrictions applicable to this meeting	
Margareta Fogelová	Member	Slovakia	No interests declared	
Denisa Partelova	Alternate	Slovakia	No interests declared	
Suzana Vidic	Member	Slovenia	No restrictions applicable to this meeting	
Sol Ruiz	Member (CHMP co-opted member)	Spain	No interests declared	
Marcos Timón	Alternate (to CHMP representative)	Spain	No interests declared	
Maria Luttgen	Member	Sweden	No restrictions applicable to this meeting	
Charlotte Anderberg	Alternate	Sweden	No interests declared	
Julio Delgado Gonzalez	Member	Clinicians' Representative	No restrictions applicable to this meeting	
Alessandra Renieri	Alternate	Clinicians' Representative	No restrictions applicable to this meeting	
Federica Chiara	Member	Patients' Representative	No restrictions applicable to this meeting	
Kieran Breen	Member (Vice-Chair)	Patients' Representative	No restrictions applicable to this meeting	
Donatella Capone	Alternate	Patients' Representative	No interests declared	
Olga Kolaj-Robin	Observer/ Alternate	EDQM	No restrictions applicable to this meeting	
Torbjörn Callréus	Expert	Malta	No interests declared	
Rou-Afza Gunput	Expert	Netherlands	No interests declared	
Myra Langendonk	Expert	Netherlands	No restrictions applicable to this meeting	
Sara Ambrosino	Expert	Netherlands	No restrictions applicable to this meeting	

Kinga Nowicka-Matus	Expert	Denmark	No restrictions applicable to this meeting	
Jenny (Zhiyi) You	Expert	Denmark	No interests declared	
Kristina Bech Jensen	Expert	Denmark	No interests declared	
Christian Gartner	Expert	Austria	No interests declared	
Odoardo Olimpieri	Expert	Italy	No interests declared	
Antonella Isgro	Expert	Italy	No interests declared	
Representatives from the European Commission attended the meeting. Representatives from the Swissmedic attended the meeting				
Meeting run with support from relevant EMA staff. Experts' declared interests were evaluated against the agenda topics or activities they participated in.				

Date of next CAT meeting:

11-13 May 2026

10. Explanatory notes

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

Abbreviations in Committee CMD documents and in relation to EMA regulatory activities

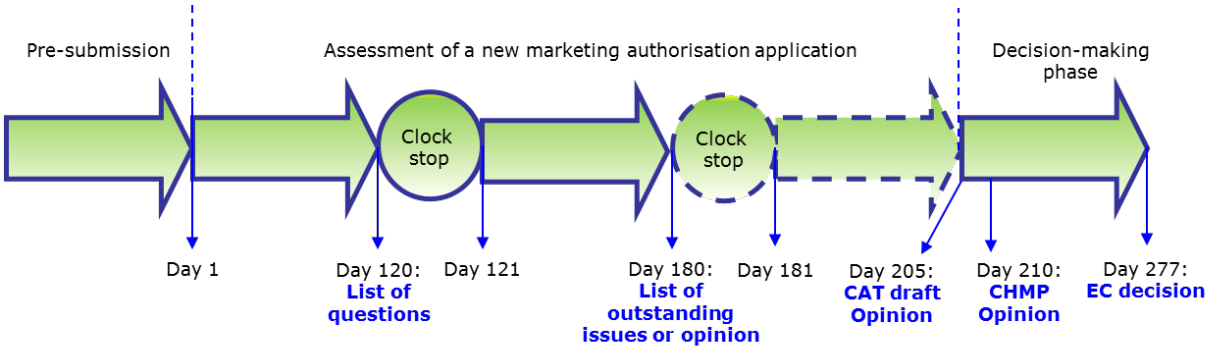
Evaluation of ATMPs (section 2)

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 Post-authorisation activities (section 2.11-2.13) and any ATMP related inspection requests (section 2.14).

New applications (sections 2.1. to 2.9.)

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

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



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CAT. The clock stop happens after day 120 and may also happen after day 180, when the CAT has adopted respectively a **Day 120 list of questions** (section 2.4) 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 2.3). Section 2.6 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.

New applications (section 2.7.)

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.

Withdrawal of applications (section 2.8.)

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.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 (section 2.9.)

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.

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 2.11-2.13.)

Section 2.11 lists type II variations, including extension of indication applications and re-examination procedures for type II variations for which the applicant has requested re-examination of the opinion previously issued by the CHMP. Section 2.12 list extension application according to Annex I of Reg. 1234/2008 and section 2.13 includes all other post-authorisation activities concerning authorised ATMPs that are not covered elsewhere in the agenda such as post-authorisation measures, 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.

Companion diagnostics (section 2.14. & 2.15.)

This section lists applications for initial and follow-on consultation of companion diagnostics.

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/