18 February 2026
EMA/CAT/48944/2026
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 21-23 January 2026

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

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

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

Of note, 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 in person with some members connected 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. Attila Sebe declared a potential competing interest regarding a product in PRIME. 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 opinions, recommendations, decisions 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 Chair welcomed the new member and alternates and thanked the departing members/alternates for their contribution to the Committee.

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

The Chair announced the start of the Cypriot presidency of the Council of the European Union (EU).

1.2. Adoption of agenda

The CAT agenda for 21-23 January 2026 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes for 03-05 December 2025 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

No items

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. Breyanzi - Lisocabtagene maraleucel – Orphan - EMA/VR/0000258227

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.2. Breyanzi - Lisocabtagene maraleucel – Orphan - EMA/VR/0000313331

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.3. CARVYKTI - Ciltacabtagene autoleucel - Orphan - EMA/VR/0000290398

Janssen Cilag International

Rapporteur: Attila Sebe

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.4. Yescarta - Axicabtagene ciloleucel – Orphan - EMA/VR/0000313321

Kite Pharma EU B.V.

Rapporteur: Attila Sebe

Scope: Quality, request for supplementary information

Action: for adoption

The Rapporteur presented the assessment of this variation. The request for supplementary information was adopted.

2.11.5. Hemgenix - Etranacogene dezaparvovec - EMA/VR/0000308793

CSL Behring GmbH

Rapporteur: Silke Dorner

Scope: Clinical, opinion

Update of sections 4.4, 4.8, 5.1, 5.2, and 6.6 of the SmPC concerning clinical pharmacology, efficacy and safety based on final results from study AMT 061-02 / CSL222_3001 listed as a specific obligation in the Annex II; this is a phase III, open-label, single-dose, multi-center multinational trial investigating a serotype 5 adeno-associated viral vector containing the Padua variant of a codon-optimized human factor IX gene (AAV5-hFIXco-Padua, AMT-061) administered to adult subjects with severe or moderately severe haemophilia B; the Package Leaflet is updated accordingly. In addition, the MAH took the

opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI.

Action: for adoption

The Rapporteur presented the assessment of this variation. Relevant sections of the SmPC and Annex II have been updated. The opinion was adopted.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. CARVYKTI - Ciltacabtagene autoleucel – Orphan - EMA/PAM/0000286337

Janssen Cilag International

Rapporteur: Attila Sebe, PRAC Rapporteur: Jo Robays

Scope: PAM, opinion

Action: for adoption

The outcome of the assessment was agreed.

2.13.2. CARVYKTI - Ciltacabtagene autoleucel – Orphan - EMA/PAM/0000308135

Janssen Cilag International

Rapporteur: Attila Sebe

Scope: PAM

Action: for adoption

The outcome of the assessment was agreed.

2.13.3. Hemgenix - Etranacogene dezaparvovec – Orphan - EMA/PAM/0000248926

CSL Behring GmbH

Rapporteur: Silke Dorner, PRAC Rapporteur: Bianca Mulder

Scope: PAM, opinion

Action: for adoption

The outcome of the assessment was agreed.

2.13.4. Zemcelpro - Dorocubicel / Allogeneic umbilical cord-derived CD34- cells, non-expanded – Orphan - EMA/PAM/0000308204

Cordex Biologics International Limited

Rapporteur: Emmely de Vries

Scope: PAM, request for supplementary information

Action: for adoption

The outcome of the assessment and the request for supplementary information were noted.

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

3.3. New Applications

No items

4. Scientific Recommendation on Classification of ATMPs

Timetable:

-Start of the procedure:	23.01.2026
-EMA Coordinator's draft report:	06.02.2026
-CAT Coordinator's comments:	11.02.2026
-Revised scientific recommendation:	13.02.2026
-CAT's discussion of scientific recommendation:	20.02.2026

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Live attenuated Listeria monocytogenes bearing plasmids encoding the recombinant chimeric fusion protein of truncated nonhemolytic listerolysin O (tLLO) and a tumour

associated antigen (TAA) comprised of two extracellular (EC1 and EC2) and one intracellular (IC1) fragments of the human Her2/neu protein

Treatment of pulmonary recurrence of resected osteosarcoma

Scope: for nomination of CAT coordinator

Action: for adoption

The CAT coordinator was appointed.

4.1.2. Allogeneic Umbilical Cord-derived Mesenchymal Stem Cells

Treatment of lupus nephritis (LN) and systemic lupus erythematosus (SLE)

Scope: for nomination of CAT coordinator

Action: for adoption

The CAT coordinator was appointed.

4.1.3. Autologous chimeric antigen receptor T cells against epidermal growth factor variant III (EGFRvIII) and messenger ribonucleic acid vaccine lipoplexes encoding EGFRvIII (intracerebroventricular administration)

Treatment of EGFRvIII-positive glioblastoma

Scope: for nomination of CAT coordinator

Action: for adoption

The CAT coordinator was appointed.

4.1.4. Autologous chimeric antigen receptor T cells against epidermal growth factor variant III (EGFRvIII) and messenger ribonucleic acid vaccine lipoplexes encoding EGFRvIII (intravenous administration)

Treatment of EGFRvIII-positive glioblastoma

Scope: for nomination of CAT coordinator

Action: for adoption

The CAT coordinator was appointed.

4.1.5. Extracellular vesicles from Wharton Jelly hTERT- expressing Mesenchymal Stromal Cells (MSCs) loaded with the micro-RNA miR-140

Treatment of osteoarthritis

Scope: for nomination of CAT coordinator

Action: for adoption

The CAT coordinator was appointed.

4.2. Day 30 ATMP scientific recommendation

4.2.1. Red blood cells derived from immortalised hematopoietic progenitors

Blood transfusion

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 06.02.2026.

4.2.2. Platelets derived from immortalised hematopoietic progenitors

Platelet transfusion

Scope: ATMP scientific recommendation

Action: for adoption

See also 4.2.1

CAT discussed the classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 06.02.2026.

4.2.3. Allogeneic human induced pluripotent stem cell (hiPSC)-derived midbrain dopaminergic (mDA) neuronal progenitor cells

Treatment of Parkinson's disease

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 06.02.2026.

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

No items

4.4. Finalisation of procedure

No items

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:	12-15.01.2025
- Appointment of CAT Peer Reviewers:	21-23.01.2025
- SAWP first reports:	02.02.2026
- CAT Peer Reviewer comments (NC & C):	06.02.2026
- CAT Peer Reviewer comments (Q):	11.02.2023
- Discussion at SAWP:	09-12.02.2026
- Discussion at CAT and feedback to SAWP:	18-20.02.2026

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	09-12.02.2026
- Appointment of CAT Peer Reviewers:	18-20.02.2026
- SAWP first reports:	02.03.2026
- CAT Peer Reviewer comments (NC & C):	06.03.2026
- CAT Peer Reviewer comments (Q):	11.03.2026
- Discussion at SAWP:	09-12.03.2026
- Discussion at CAT and feedback to SAWP:	18-20.03.2026

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

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

No items

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

No items

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:	
Procedure start:	12-15.01.2026
SAWP recommendation:	12.02.2026
CAT recommendation:	20.02.2026
CHMP adoption of report and final recommendation:	26.02.2026

6.3.2. Month 1 – Discussion of eligibility

6.3.3. 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

The chair welcomed Andreas Maccani as the new alternate for Austria and Attila Sebe as the new member for Germany.

The Chair announced that Jan Mueller Berghaus is the new alternate for Germany.

The Chair thanked Corina Spreitzer, Egbert Flory and Ole Henrik Myrdal for their contribution as alternate for Austria, Germany and Norway respectively.

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

Scope: Preparation for the meeting

CAT: Rafaella Pontou

Action: for information

The draft agenda for the meeting was presented.

7.1.3. Election of CAT Chair person 2026

Action: for adoption

The mandate of the CAT Chair, Ilona Reischl-Kok, will expire on 14 February 2026.

The election of the new chair took place in accordance with the CAT rules of procedure.

The nomination received was presented to the Committee.

The CAT elected Ilona Reischl-Kok as CAT Chair for a second three-year mandate starting on 15 February 2026.

The CAT and the Agency congratulated Ilona Reischl-Kok on her election and wished her all the best in her continued role as Chair of the Committee.

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. Webinar on the use of platform technologies in the non-clinical and clinical domains

Scope: Agenda & information on the upcoming webinar on 02.03.2026, 9:30 – 12:30

Action: for information

The programme for the upcoming webinar was presented. This is an open workshop (broadcasted, not recorded); there is no need for registration.

7.4.2. Mandate of Novel therapies European Specialised Expert Communities

Setting up a novel therapies & technologies European Specialised Expert Communities (ESEC) in the veterinary domain

Action: for information

The Novel Therapies ESEC was presented. The ESEC will kick-off in June 2026.

Human experts can join this ESEC: a call for Nominations will be launched in February 2026. CAT members are automatically included.

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 29.01.2026

Action: for information

The upcoming ATMP cluster meeting is postponed to a later date.

7.6. CAT work plan

7.6.1. CAT Workplan 2026

Scope: Work plan topics for 2026

CAT: Ilona Reischl

Action: for adoption

The CAT workplan for 2026 was presented. The workplan was adopted pending confirmation of the list of contributors by the CAT members.

The workplans of all Committees will be published on the EMA website in the beginning of February 2026.

7.7. Planning and reporting

7.7.1. Q4-2025 Business Pipeline report for the human scientific committees

Scope: Q4-2025 Business Pipeline report for the human scientific committees

Action: for information

CAT noted the information.

7.8. Others

7.8.1. Progression updates and expansion of the scope for the revision of the ATMP GMP guideline

Scope: Proposal for voiding the site of physical import of ATMPs in relation to the general requirements for import of medicinal product from third countries into the EU directly to the clinical site rather than to the importation site.

Rapporteur: Jean Luc Golnez

Action: for adoption

The Rapporteur presented a progress report to CAT: some of the comments raised during the public consultation of the concept paper on the revision of the ATMP GMP guideline were highlighted. The proposal for a waiver of the site of physical importation was discussed. CAT to provide comments by 4 February 2026.

7.8.2. Questions and answers on the use of out-of-specification batches of authorised cell/tissue-based advanced therapy medicinal products (EMA/CAT/224381/2019)

Scope: Proposal to amend the Q&A with the revised process for notification of out-of-specification (OOS) ATMPs

Action: for discussion

The changes proposed to the Q&A were presented. The changes were in principle agreed. CAT to provide comments by 30 January 2026: if there are no major comments, the Q&A will be considered adopted.

7.8.3. REVAMP update

Scope: Overview of upcoming updates, including for the review of the product information.

Action: for information

EMA presented the template for extension application, the removal of the executive summary and the new process for review of the product information during the initial evaluation procedure.

8. Any other business

No items

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 21-23 January 2026 CAT meeting, which was held in-person.

An asterisk (*) after the role, in the second column, signals that the member/alternate attended remotely. Additional experts participated in (part of) the meeting remotely.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of DoI	Topics for which restrictions apply
Ilona Reischl-Kok	Chair	Austria	No restrictions applicable to this meeting	
Silke Dorner	Member	Austria	No interests declared	
Andreas Maccani*	Alternate	Austria	No interests declared	
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	
Eva Kolouchová*	Member	Czechia	No interests declared	
Radka Nejezchlebová*	Alternate	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 interests declared	
Violaine Closson Carella	Member	France	No interests declared	
Attila Sebe	Member	Germany	No participation in discussion, final deliberations and voting on:	PRIME
Jan Mueller-Berghaus*	Alternate	Germany	No interests declared	
Maria Gazouli	Member	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 Recommendation on Classification of ATMPs
Barbara Bonamassa	Alternate	Italy	No interests declared	
Una Riekstina	Member	Latvia	No restrictions applicable to this meeting	
Liga Kunrade*	Alternate	Latvia	No restrictions applicable to this meeting	

Vilma Perikaite	Member (CHMP member)	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 interests declared	
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	
Marcin Kolakowski	Alternate	Poland	No interests declared	
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	
Denisa Partelova*	Alternate	Slovakia	No interests declared	
Margareta Fogelová	Member	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 participation in discussions, final deliberations and voting on:	Scientific advice
Charlotte Anderberg*	Alternate	Sweden	No restrictions applicable to this meeting	
Julio Delgado Gonzalez	Member	Clinicians' Representative	No participation in discussion, final deliberations and voting on: [products from:	Scientific advice

Alessandra Renieri	Member	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	
Catherine Milne	Observer	EDQM	No interests declared	
Olga Kolaj-Robin	Observer/ Alternate	EDQM	No participation in discussions, final deliberations and voting on:	Scientific advice
Torbjörn Callréus	Expert	Malta	No interests declared	
Jean-Luc Golnez	Expert		No interests declared	
Lynette Mikula	Expert	Austria	No interests declared	
Elisabeth Wischnitzki	Expert	Austria	No interests declared	
Martin Walter	Expert	Austria	No interests declared	
Melanie Ramberger	Expert	Austria	No interests declared	
Nikolaus Zehetmayer	Expert	Austria	No interests declared	
Tobias Fellinger	Expert	Austria	No restrictions applicable to this meeting	
Nathalie Morgensztejn	Expert	France	No interests declared	
Sylvie Benchetrit	Expert	France	No interests declared	
Some 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:

18-20 February 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

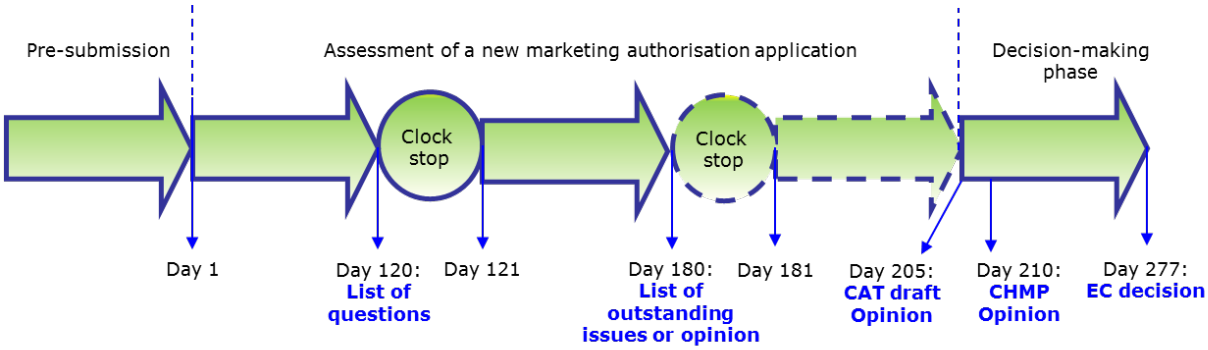
Evaluation of ATMPs (section 2)

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.

Companion diagnostics (section 2.10)

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

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.

GMP and GCP Inspections Issues (section 2.14.)

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).

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/