



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 September 2026
EMA/CAT/220878/2026
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 15-17 July 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 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).



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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. Attila Sebe declared a potential competing interest regarding a product in Scientific Advice. 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.

1.2. Adoption of agenda

The CAT agenda for 15-17 July 2026 meeting was adopted with the addition on an agenda point under 8. Any other business.

1.3. Adoption of the minutes

The CAT minutes for 17-19 June 2026 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

2.4.1. Zamtocabtagene autoleucel - PRIME - Orphan – OPEN - EMEA/H/C/005495

Miltenyi Biomedicine GmbH; Treatment of adults with large B-cell lymphoma

Scope: Day 120 list of questions

Action: for adoption

Colleagues from Swissmedic joined the discussion for this product (OPEN procedure).

The CAT Rapporteurs presented the outcome of the assessment of the marketing authorisation application (MAA) and the draft list of questions. Feedback was provided from the discussion in BWP.

The list of questions and the response timetable was adopted.

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/0000327431

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli, PRAC Rapporteur: Dirk Mentzer

Scope: Clinical, opinion

Submission of the final report from study CA082-1105 listed as a Specific Obligation in the Annex II of the Product Information. This is a non-interventional study submitted to summarize 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 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 rapporteur presented the assessment of the responses to the questions raised in the request for supplementary information. All issues are resolved. The opinion was adopted.

2.11.2. Breyanzi - Lisocabtagene maraleucel - Orphan - EMA/VR/0000347766

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, request for supplementary information

Action: for adoption

The request for supplementary information was adopted.

2.11.3. Hemgenix - Etranacogene dezaparvovec - Orphan - EMA/VR/0000347644

CSL Behring GmbH

Rapporteur: Silke Dorner, PRAC Rapporteur: Bianca Mulder

Scope: Clinical, request for supplementary information

A grouped application consisting of:

Type II (C.9.c) to update the protocol and Statistical Analysis Plan (SAP) of Study CSL222_4001, listed as a Specific Obligation in the Annex II of the Product Information. CSL222_4001 is an observational, post-authorisation, long-term follow-up study designed to evaluate the effectiveness and safety of HEMGENIX in the commercial setting. The Annex II and the RMP (version 1.1) are updated accordingly.

Type IB (C.9.b) to request a one-year extension to the due date of Specific Obligation 3 (SOB3) under Annex II.E of the conditional marketing authorisation.

Action: for adoption

The rapporteur provided feedback from the discussion in PRAC on the amendments made to the post authorisation study. Some questions have been raised. The request for supplementary information was adopted.

2.11.4. [Strimvelis - Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - Orphan - EMA/VR/0000347859](#)

Fondazione Telethon Ets

Rapporteur: Sol Ruiz, PRAC rapporteur: Liana Martirosyan

Scope: Quality & Clinical, request for supplementary information

Action: for adoption

The rapporteur presented the outcome of the assessment. Some questions were raised. The request for supplementary information was adopted.

2.11.5. [Vyjuvek - Beremagene geperpavec - Orphan - EMA/VR/0000306575](#)

Krystal Biotech Netherlands B.V.

Rapporteur: Richard Carroll

Scope: Quality, opinion

Action: for adoption

The opinion was adopted.

2.11.6. [Zolgensma - Onasemnogene abeparvovec - Orphan - EMA/VR/0000340942](#)

Novartis Europharm Limited

Rapporteur: Emmely de Vries

Scope: Clinical

Update of sections 4.6 and 5.3 of the SmPC in order to incorporate the findings from the fertility and early embryonic development (FEED) and embryo-foetal development (EFD) studies in mice.

Action: for adoption

The rapporteur presented the assessment of the responses to the questions raised in the request for supplementary information. The wording of the SmPC sections 4.6 and 5.3 is agreed. The opinion was adopted.

2.12. **Extension applications**

No items

2.13. Other Post-Authorisation Activities

2.13.1. Ebvallo – Tabelecleucel - Orphan - EMA/S/0000326533

Pierre Fabre Medicament

Rapporteur: Attila Sebe, PRAC rapporteur: Amelia Cupelli

Scope: Annual reassessment

Action: for adoption

The annual reassessment was adopted.

2.13.2. Libmeldy - Atidarsagene autotemcel - Orphan - EMA/PAM/0000348136

Orchard Therapeutics (Netherlands) B.V.

Rapporteur: Emmely de Vries

Scope: PAM

Action: for adoption

The outcome of the assessment of the quality PAM was agreed.

2.13.3. Waskyra - Etuvetidigene autotemcel - Orphan - EMA/PAM/0000339274

Fondazione Telethon Ets

Rapporteur: Violaine Closson-Carella

Scope: PAM

Action: for adoption

The outcome of the assessment of the quality PAM was agreed.

2.13.4. Yescarta - Axicabtagene ciloleucel - Orphan - EMA/PAM/0000319823

Kite Pharma EU B.V.

Rapporteur: Attila Sebe

Scope: PAM

Action: for adoption

The outcome of the assessment of the quality PAM was agreed.

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

Cordex Biologics International Limited

Rapporteur: Emmely de Vries

Scope: PAM

Action: for adoption

The outcome of the assessment of the PAM 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

4.1. New requests – Appointment of CAT Coordinator

No items

4.2. Day 30 ATMP scientific recommendation

4.2.1. Allogeneic umbilical cord-derived mesenchymal stem cells

Treatment of chronic kidney disease (CKD)

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 05.08.2026

4.2.2. Recombinant adeno-associated virus containing the human microdystrophin gene

Treatment of Duchenne muscular dystrophy (DMD)

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 05.08.2026

4.2.3. Recombinant adeno-associated virus vector containing a mini-dystrophin analog (mini-UDYS) transgene

Treatment of Duchenne muscular dystrophy (DMD)

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 05.08.2026

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

No items

4.4. Finalisation of procedure

4.4.1. Virus-specific T lymphocytes enriched from peripheral blood

Treatment of virus reactivation in immunocompromised patients

Scope: Comments received from the European Commission. ATMP scientific recommendation

Action: for adoption

The comments from the European Commission were presented. CAT considered that no changes to the report are needed. The classification report was adopted. The product prepared with the enrichment of the T-cells by exposure to viral peptide antigen mixtures (activation step) fulfils the definition of somatic cell therapy medicinal product as provided in Article 2(1) of Regulation (EC) 1394/2007.

4.4.2. Allogeneic peripheral blood-derived haematopoietic stem and progenitor cells (HSPCs), regulatory T cells (Tregs) and conventional T cells (Tcons)

For use in adult patients with haematologic malignancies to improve survival free of graft-versus-host disease in conjunction with an appropriate preparative regimen

Scope: ATMP scientific recommendation

Action: for adoption

The classification report was adopted. The product does not fulfil the definition of an advanced therapy medicinal product as provided in Article 2(1) of Regulation (EC) 1394/2007.

4.4.3. Adeno-associated virus serotype rh.74 vector containing the human Plakophilin-2a (PKP2) gene isoform (AAVrh.74-PKP2a)

Treatment of arrhythmogenic cardiomyopathy caused by pathogenic mutations in the PKP2 gene

Scope: ATMP scientific recommendation

Action: for adoption

The classification report was adopted. The product does fulfil the definition of a gene therapy medicinal product as provided in Article 2(1) of Regulation (EC) 1394/2007.

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 peer-reviewers

Timetable:

- Start of procedure at SAWP:	06-09.07.2026
- Appointment of CAT Peer Reviewers:	15-17.07.2026
- SAWP first reports:	24.08.2026
- CAT Peer Reviewer (NC & C) comments:	28.08.2026
- CAT Peer Reviewer (Q) comments:	02.09.2026
- Discussion at SAWP:	31.08-03.09.2026
- Discussion at CAT and feedback to SAWP:	07.09.2026

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

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: 06-09.07.2026

SAWP recommendation: 03.09.2026

CAT recommendation: 11.09.2026

CHMP adoption of report and final recommendation: 17.09.2026

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

Maria Gazouli gave a proxy to Rafaela Pontou to vote on behalf of Greece during the full meeting.

Suzana Vidic gave a proxy to Denisa Margina to vote on behalf of Slovenia during part of the meeting.

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

Scope: Preparation for the meeting

CAT: Richard Carroll

Action: for information

The data of the SLRM meeting was confirmed: 11-13 November 2026. The official invitation will be sent in two weeks.

There was an initial discussion on the agenda topics.

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

No items

7.5. Cooperation with international regulators

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

Scope: Feedback of the ATMP cluster of 25.06.2026

CAT: Ilona Reischl-Kok

Action: for information

A short feedback from the June ATMP cluster was provided.

CAT members were asked to provide suggestions for agenda items for the September ATMP cluster (25.09.2026) by the beginning of September.

7.6. CAT work plan

7.6.1. CAT workplan mid-year progress report

Scope: Mid-year progress report

CAT: Ilona Reischl-Kok

Action: for discussion

EMA presented the mid-year progress report: CAT discussed the activities to be taken

forward in the second half of 2026.

7.6.2. Update on Real World Evidence

Scope: Real-world evidence 4th report on the experience gained with regulator-led studies and presentation about the results for study Fitness-for-use of data sources relevant for real-world data studies on CAR-T cell therapy

Action: for information

The conclusions and key findings of the study 'Fitness-for-use of data sources relevant for real-world data studies on CAR-T cell therapy' were presented. The report will be circulated to CAT members.

7.7. Planning and reporting

7.8. Others

7.8.1. Updates on the revision of ATMP GMP guideline

Scope: Revision GMP guideline

Rapporteur: Jean Luc Golnez

Action: for discussion

A progress report on the revision of the ATMP GMP guideline was presented. The change to the 'principles of GMP' were discussed.

8. Any other business

8.1. EDQM update

Scope: Update to CAT on two upcoming events

EDQM: Olga Kolay-Robin

Action: for information

EDQM updated CAT on the following events: Microbiology on the Move (13-15.10.2026) and HTS (high-throughput sequencing) live webinar (3.09.2026).

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 July 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-Kok	Chair	Austria	No interests declared	
Silke Dorner	Member	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	
Isavella Kyriakidou	Alternate	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 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	
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	
Richard Carroll	Alternate	Ireland	No interests declared	

Concetta Quintarelli	Member	Italy	No restrictions applicable to this meeting	
Barbara Bonamassa	Alternate	Italy	No interests declared	
Una Riekstina	Alternate	Latvia	No restrictions applicable to this meeting	
Vilma Petrikaite	Member (CHMP member)	Lithuania	No restrictions applicable to this meeting	
Raimondas Benetis	Alternate (to CHMP representative)	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 Kjeklen	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 participation in discussion,	Scientific advice procedure

			final deliberations and voting on:	
Charlotte Anderberg	Alternate	Sweden	No interests declared	
Julio Delgado Gonzalez	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	
Olga Kolaj-Robin	Observer/Alternate	EDQM	No restrictions applicable to this meeting	
Torbjörn Callréus	Expert	Malta	No interests declared	
Dagmar Pospisilova	Expert	Czechia	No interests declared	
Jean-Luc Golnez	Expert	Belgium	No interests declared	
Johanna Lähteenvuo	Expert	Finland	No interests declared	
Hanna Kankkonen	Expert	Finland	No interests declared	
Kari Airene	Expert	Finland	No restrictions applicable to this meeting	
Pauliina Lehtolainen-Dalkilic	Expert	Finland	No interests declared	
Karri Penttilä	Expert	Finland	No interests declared	
Riitta Niittyvuopio	Expert	Finland	No interests declared	
Leena Luukkanen	Expert	Finland	No interests declared	
Lore Billiet	Expert	Belgium	No restrictions applicable to this meeting	
Carmen Susana Rojo	Expert	Spain	No interests declared	
Raquel Martín Palomeque	Expert	Spain	No interests declared	
Beatriz Gutiérrez Eugenio	Expert	Spain	No interests declared	
Teresa Llacer Delicado	Expert	Spain	No interests declared	
Carolina Prieto Fernandez	Expert	Spain	No interests declared	
Sandra Soto Revuelta	Expert	Spain	No interests declared	
Leire Aguado Elia	Expert	Spain	No interests declared	
Alba Juanes García	Expert	Spain	No interests declared	

David Ordoñez del Valle	Expert	Spain	No interests declared	
Representatives from 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:

12-14 August 2026 – *written procedure*

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

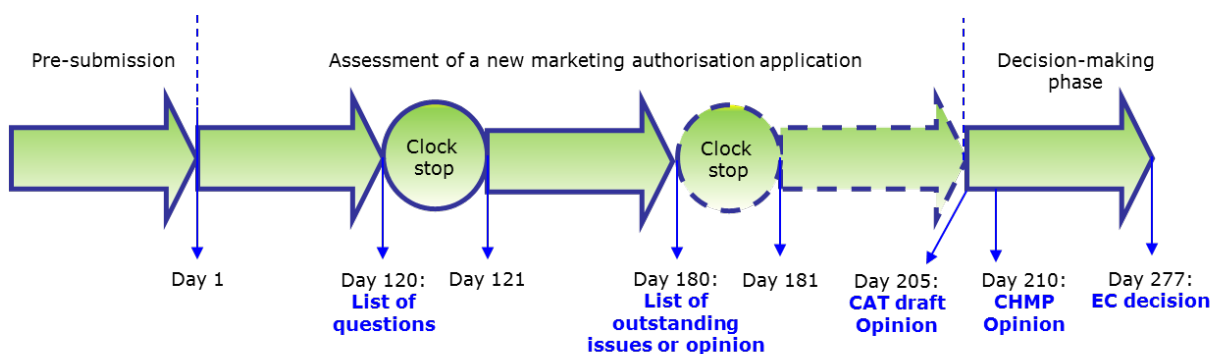
Evaluation of ATMPs (section 2)

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/