06 September 2023
EMA/CAT/369627/2023
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 06-08 September 2023

Chair: Ilona Reischl; Vice-Chair: Kieran Breen

06 September 2023, 14:00 – 18:30

07 September 2023, 09:00 – 18:30

08 September 2023, 09:00 – 13:00

Disclaimers

Some of the information contained in this agenda 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, this agenda is a working document primarily designed for CAT members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda 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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CAT plenary session to be held 06-08 September 2023. See September 2023 CAT minutes (to be published post October 2023 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 06-08 September 2023 meeting

1.3. Adoption of the minutes

CAT minutes for 12-14 July 2023 and 09-11 August (by written procedure) meetings

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

2.3.1. Exagamglogene autotemcel - PRIME - Orphan - EMEA/H/C/005763

Vertex Pharmaceuticals (Ireland) Limited; Treatment of transfusion-dependent β-thalassemia and sickle cell disease

Scope: Day 180 list of outstanding issues

Action: for adoption

List of questions adopted on 17.05.2023.

2.4. Day 120 list of questions

2.4.1. Fidanacogene elaparvovec - PRIME - Orphan - EMEA/H/C/004774

Pfizer Europe MA EEIG; Indicated for the treatment of severe and moderately severe haemophilia B

Scope: Day 120 list of questions

Action: for adoption

2.5. Day 80 assessment reports

No items

2.6. Update on ongoing initial applications

No items

2.7. New applications

2.8. Withdrawal of initial marketing authorisation application

No items

2.9. Re-examination of initial application procedures under Article 9(2) of Regulation No. 726/2004

No items

2.10. Companion diagnostics

2.10.1. Initial consultation

No items

2.10.2. Follow-up consultation

No items

2.11. Type II variations and variations of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

2.11.1. Alofisel - darvadstrocel - Orphan - EMEA/H/C/004258/II/0044/G

Takeda Pharma A/S

Rapporteur: Maria Luttgen

Scope: Safety, Opinion

Grouped application comprising one type II variation and two type IB as follows:
- Update of section 4.8 of the SmPC in order to update the summary of the safety profile and to add anal abscess, proctalgia and anal fistula to the list of adverse drug reactions on post-marketing experience following the assessment of R/0036 based on a review of the MAH's Global Safety Database.
- Update of section 4.2 of the SmPC in order to add the term Perilesional as an EDQM term, following the assessment of R/0036.
- Update of sections 1, 2.2, 3, 4.2, 6.5 and 6.6 of the SmPC in order to replace the term "suspension for injection" for "dispersion for injection", following the assessment of R/0036. The Annex A, Package Leaflet and Labelling are updated in accordance.

Action: for adoption

Request for supplementary information adopted on 17.05.2023.

2.11.2. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0003

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, Opinion

Action: for adoption

Request for supplementary information adopted on 07.10.2022, 15.07.2022.

2.11.3. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0014

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli, PRAC Rapporteur: Gabriele Maurer

Scope: Clinical, Opinion

Update of section 5.1 of the SmPC in order to update efficacy information based on final results from studies 017001 and JCAR-017-BCM-001 listed as obligations in the Annex II. These studies aimed to further characterise the long-term efficacy and safety of Breyanzi in patients treated with relapsed or refractory DLBCL, PMBCL, FL3B after two or more lines of systemic therapy. Study 017001 is a phase 1, open-label, single-arm, multicohort, multicentre, seamless design trial, while study JCAR-017-BCM-001 is a phase 2, open-label, single-arm, multicohort, multicentre trial. The Annex II is updated accordingly. The RMP version 3.0 has also been submitted.

Action: for adoption

Request for supplementary information adopted on 24.03.2023.

2.11.4. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0021

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, Opinion

Action: for adoption

Request for supplementary information adopted on 14.07.2023.

2.11.5. Breyanzi - lisocabtagene maraleucel / lisocabtagene maraleucel - EMEA/H/C/004731/II/0026/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, Request for supplementary information

Action: for adoption

2.11.6. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/II/0021

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Jo Robays

Scope: Clinical, Request for supplementary information

Extension of indication to include treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 1 prior therapy, including an immunomodulatory agent (IMiD) and a protease inhibitor (PI), have demonstrated disease progression on or after the last therapy and are refractory to lenalidomide for CARVYKTI, based on interim results from study MMY3002 listed as a specific obligation (SOB/006) in the Annex II. This is an ongoing, Phase 3, randomised, open-label, multicentre study to determine whether treatment with cilta-cel provides an efficacy benefit compared to standard therapy in participants with relapsed and lenalidomide-refractory multiple myeloma. As a consequence, sections 4.1, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has also been submitted. In addition, the MAH took the opportunity to update Annex II of the product information (PI). As part of the application the MAH is requesting a 1-year extension of the market protection.

Action: for adoption

2.11.7. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0063

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen

Scope: Clinical, Opinion

Submission of the final report from study 20110261 listed as a category 3 study in the RMP. This is a Phase I, multi-centre, open-label, dose de-escalation study to evaluate the safety and efficacy of talimogene laherparepvec in paediatric subjects with advanced noncentral nervous system tumours that are amenable to direct injection.

Action: for adoption

2.11.8. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0064

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen, PRAC Rapporteur: Gabriele Maurer

Scope: Safety, Opinion

Submission of an updated RMP version 11.0 in order to remove the important potential risk of 'talimogene laherparepvec-mediated anti-GM-CSF antibody response', based on the accumulated scientific and clinical data.

Action: for adoption

2.11.9. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0072

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Quality

Action: for adoption

2.11.10. Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/II/0015

Orchard Therapeutics (Netherlands) B.V.

Rapporteur: Johannes Hendrikus Ovelgonne

Scope: Quality, Opinion

Action: for adoption

Request for supplementary information adopted on 16.06.2023.

2.11.11. Upstaza - eladocagene exuparvovec - Orphan - EMEA/H/C/005352/II/0013

PTC Therapeutics International Limited

Rapporteur: Maura O'Donovan

Scope: Quality, Request for supplementary information

Action: for adoption

2.11.12. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0040

Novartis Europharm Limited

Rapporteur: Johannes Hendrikus Ovelgonne, PRAC Rapporteur: Ulla Wändel Liminga

Scope: Safety, Opinion

Update of sections 4.4 and 5.1 of the SmPC in order to add a new warning and precaution capturing the theoretical risk of tumorigenicity as a result of vector integration and to include a new statement indicating random instances of vector integration are possible based on final results from studies 2220205 and 2220117, and literature. The Package Leaflet is updated accordingly. The RMP version 3 has also been submitted.

Action: for adoption

Request for supplementary information adopted on 14.07.2023.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/MEA/007.2

Janssen-Cilag International NV

Rapporteur: Jan Mueller-Berghaus

Scope: Pharmacovigilance, Opinion

From Initial MAA:
MAH Response to MEA 007.1 [Study no: PCSONCA0014] as adopted in April 2023:
The MAH should target a minimum enrolment of 30 healthcare professionals (HCPs) in each role (physicians, nurses, pharmacists) to allow valid statistical analysis. The MAH should make sure that there are least 30 HCPs in each role and continue to enrol centres until this target is achieved.
[Due dates
- First interim report: 31 Mar 2025
- Final study report due: 30 Sep 2026]

Action: for adoption

2.13.2. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/LEG/021

Novartis Europharm Limited

Rapporteur: Rune Kjeken

Scope: Pharmacovigilance, Request for supplementary information

From EMEA/H/C/PSUSA/00010702/202208:
MAH's responses to supplementary information.

List of issues relates to potential secondary malignancy cases including the case number NVS2022DE245136. (PSUR 07 (reporting period 13-Aug-2021 to 12-Aug-2022))

Action: for adoption

2.13.3. Upstaza - eladocagene exuparvovec - Orphan - EMEA/H/C/005352

PTC Therapeutics International Limited

Rapporteur: Maura O'Donovan

Scope: EMA updates on the interaction with iNTD, as a possible data source for Upstaza SOB PTC-AADC-MA-406

Action: for discussion

Note: this is an update on post-authorisation measure MEA/007 (discussed at the March 2023 CAT meeting, agenda point 2.13.7)

2.14. GMP and GCP inspections requests

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:	08.09.2023
-EMA Coordinator's draft report:	19.09.2023
-CAT Coordinator's comments:	27.09.2023
-Revised scientific recommendation:	29.09.2023
-CAT's discussion of scientific recommendation:	06.10.2023

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Devitalized cell-derived cartilaginous tissue

Bone substitute for maxillofacial and/or orthopaedic bone defects

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Allogeneic ex-vivo expanded pluripotent stem cell-derived cardiac ventricular progenitor cells

Intended for the treatment of chronic and acute heart disease

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Allogeneic ex-vivo expanded pluripotent stem cell-derived photoreceptor progenitor cells

Intended for the treatment of retinitis pigmentosa

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Allogeneic genetically modified human induced pluripotent stem cell-derived retinal pigment epithelial cells

Intended for the treatment of Stargardt indication

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Autologous cultured fibroblasts

Intended for the treatment of scars and wounds

Scope: ATMP scientific recommendation

Action: for adoption

4.2.5. Secretome (conditioned medium) from donor bone marrow mesenchymal stem cells (MSCs) containing cytokines, growth factors, proteins and extracellular vesicles

Intended for the treatment of paediatric respiratory diseases called childhood interstitial lung disease (ChILD)

Scope: ATMP scientific recommendation

Action: for adoption

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

4.5.1. Cells treated by extracorporeal photopheresis

CAT: Nancy De Bremaeker

Scope: Informal classification discussion on request of a member state

Action: for discussion

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:	28-31.08.2023
- Appointment of CAT Peer Reviewers:	06-08.09.2023
- SAWP first reports:	18.09.2023
- CAT Peer Reviewer comments (NC/C)	22.09.2023
- CAT Peer Reviewer comments (Q)	27.09.2023
- Discussion at SAWP:	25-28.09.2023
- Discussion at CAT and feedback to SAWP:	04-06.10.2023

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	25-28.09.2023
- Appointment of CAT Peer Reviewers:	04-06.10.2023
- SAWP first reports:	16.10.2023
- CAT Peer Reviewer comments (NC/C)	20.10.2023
- CAT Peer Reviewer comments (Q)	25.10.2023

- Discussion at SAWP:	23-23.10.2023
- Discussion at CAT and feedback to SAWP:	30-31.10.2023

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

No items

6. Pre-Authorisation Activities

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

6.1. Paediatric investigation plans

No items

6.2. ITF briefing meetings in the field of ATMPs

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:

Procedure start:	28-31.08.2023
SAWP recommendation:	28.09.2023
CAT recommendation:	06.10.2023
CHMP adoption of report and final recommendation:	12.10.2023

6.3.2. Month 1 – Discussion of eligibility

6.3.3. Month 2 – Recommendation of eligibility

No items

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

Action: for information

7.1.2. Vote by proxy

Action: for information

7.1.3. CAT Strategic Review & Learning meeting (SRLM) under the Spanish presidency, 25-27 October 2023 Madrid (Spain)

CAT: Sol Ruiz, Marcos Timon

Scope: Topics for discussion at the upcoming SRLM

Action: for discussion

7.1.4. CAT 15th anniversary

CAT: Ilona Reischl

Scope: CAT activities in 2024 related to its 15th anniversary

Action: for discussion

Note: the first meeting of CAT took place in January 2009

7.2. Coordination with EMA Scientific Committees

7.2.1. Update from the PCWP-HCPWP

Scope: Meeting summary of the PCWP-HCPWP that took place on 27 & 28 June 2023 and draft Agenda of the PCWP-HCPWP Joint meeting that will take place on 19 & 20 September 2023

Action: for information

7.2.2. CAT-COMP working group meeting

CAT: Ilona Reischl

Scope: Feedback from the CAT-COMP working group meeting that took place on 4 September 2023

Action: for information

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

7.3.1. Patient Experience Data (PED) project

Scope: PED community is to develop a reflection paper on the EU approach to collect and analyse PED and coordinate the actions agreed at the workshop in Sep 2022.

Action: for information

7.3.2. Streamlining of BWP operations

Scope: Discontinuation of systematic discussions of ATMP variations

Action: for discussion

7.4. Cooperation with the EU regulatory network

7.4.1. Support to member states for the assessment of ATMP Marketing Authorisation Applications

CAT: Ilona Reischl

Scope: General discussion on needs and start of survey on resources (ATMP assessors) available in the NCAs

Action: for discussion

7.5. Cooperation with international regulators

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

CAT: Ilona Reischl

Scope: Agenda of the teleconference that will take place on 28.09.2023

Action: for information

7.5.2. WHO considerations in developing a regulatory framework for human cells and tissues and for advanced therapy medicinal products

CAT: Ilona Reischl

Scope: Final Considerations document (adopted March 2023)

Action: for information

7.5.3. International Pharmaceutical Regulatory Programme (IPRP): Gene therapy and Cell therapy working groups

CAT: Pille Säälik

Scope: Merger of the gene therapy and cell therapy working groups

Action: for information

Note: Ivana Haunerova informed the CAT secretariat that is standing down as CAT representative for the cell therapy working group. Pille Säälik confirmed that she will continue as CAT representative for the (joined) IPRP gene and cell therapy working group.

7.5.4. FDA Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products

CAT: Ilona Reischl

Scope: Guidance of industry published on FDA website (August 2023)

Action: for information

7.6. CAT work plan

7.6.1. CAT work plan for 2024

CAT: Ilona Reischl

Scope: First reflection on work plan topics for 2024

Action: for discussion

7.6.2. CAT Stakeholder meeting of 16 May 2023

CAT: Ilona Reischl

Scope: Draft minutes of the CAT stakeholder meeting

Action: for adoption

7.7. Planning and reporting

7.7.1. Business Pipeline Report

Scope: Q3/2023 Update of the Business Pipeline report for the human scientific committees

Action: for information

7.8. Others

7.8.1. FDA Public workshop: Assessing genetic heterogeneity in the context of genome editing off-targets in gene therapy products

CAT: Ilona Reischl

Scope: Summary of the FDA public workshop that was held on 16 December 2022

Action: for information

7.8.2. CASSS China – 3rd CMC Strategy Forum for Biological Products (12-13 October 2023)

CAT: Ilona Reischl

Scope: Request for a speaker

Action: for information

8. Any other business

No item

Date of next CAT meeting:

04-06 October 2023

9. Explanatory notes

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

For a list of acronyms and abbreviations, see:

List of abbreviations used in EMA human medicines scientific committees and CMDh documents, and in relation to EMA's regulatory activities

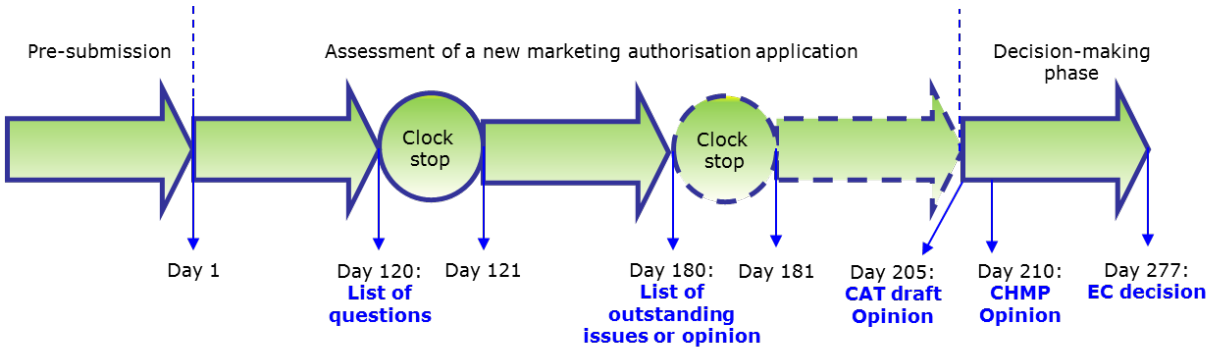
Evaluation of ATMPs (section 2)

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/