17 July 2024
EMA/CAT/328264/2024
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 17-19 July 2024

Chair: Ilona Reischl; Vice-Chair: Kieran Breen

17 July 2024, 14:00 – 18:30, Webex

18 July 2024, 09:00 – 18:30, Webex

19 July 2024, 09:00 – 13:00, Webex

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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

1. Introduction 5

1.1. Welcome and declarations of interest of members, alternates and experts 5

1.2. Adoption of agenda 5

1.3. Adoption of the minutes 5

2. Evaluation of ATMPs 5

2.1. Opinions 5

2.2. Oral explanations 5

2.3. Day 180 list of outstanding issues 5

2.4. Day 120 list of questions 5

2.4.1. Obecabtagene autoleucel - PRIME - Orphan - EMEA/H/C/005907 5

2.4.2. Mozafancogene autotemcel - PRIME - Orphan - EMEA/H/C/005537 6

2.5. Day 80 assessment reports 6

2.6. Update on ongoing initial applications 6

2.7. New applications 6

2.8. Withdrawal of initial marketing authorisation application 6

2.9. Re-examination of initial application procedures under Article 9(2) of Regulation No. 726/2004 6

2.10. Companion diagnostics 6

2.10.1. Initial consultation 6

2.10.2. Follow-up consultation 6

2.11. Type II variations and variations of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008 6

2.11.1. Abecma - Idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0047 6

2.11.2. Abecma - Idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0048 7

2.11.3. Alofisel - Darvadstrocel - Orphan - EMEA/H/C/004258/II/0051/G 7

2.11.4. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0037/G 7

2.11.5. Hemgenix - Etranacogene dezaparvovec - Orphan - EMEA/H/C/004827/II/0014/G 8

2.11.6. Imlygic - Talimogene laherparepvec - EMEA/H/C/002771/II/0067/G 8

2.11.7. Upstaza - Eladocagene exuparvovec - Orphan - EMEA/H/C/005352/II/0022/G 8

2.11.8. Yescarta - Axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0077 8

2.12. Extension applications 9

2.13. Other Post-Authorisation Activities 9

2.13.1. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/MEA/007.1 9

2.13.2. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/REC/016.1 9

2.13.3. Zolgensma - Onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/LEG/024 9

2.14. GMP and GCP inspections requests 10

3. Certification of ATMPs 10

3.1. Opinion 10

3.2. Day 60 Evaluation Reports 10

3.3. New Applications 10

4. Scientific Recommendation on Classification of ATMPs 10

4.1. New requests – Appointment of CAT Coordinator 10

4.2. Day 30 ATMP scientific recommendation 10

4.2.1. Autologous CD34 positive cells 10

4.2.2. Autologous antigenic tumor fragments isolated from patient's circulating cancer cells 10

4.2.3. Autologous antigenic tumor fragments isolated from patient's circulating cancer cells 11

4.2.4. Autologous antigenic tumor fragments isolated from patient's circulating cancer cells 11

4.2.5. Autologous antigenic tumor fragments isolated from patient's circulating cancer cells 11

4.3. Day 60 revised scientific recommendation (following list of questions) 11

4.3.1. Implantable device 3D bioprinted with autologous microfat and hydrogel bioink 11

4.4. Finalisation of procedure 11

4.4.1. Autologous adipose-derived stromal vascular fraction cells 11

4.4.2. Double stranded DNA targeting patient specific tumour neo-antigens 11

4.4.3. Spermatogonial stem cells, propagated in vitro 12

4.4.4. Autologous antigen specific Cytotoxic T Lymphocytes 12

4.4.5. Autologous dendritic cells against tumour peptides 12

4.4.6. Autologous macrophages 12

4.4.7. Autologous cytotoxic natural killer (NK) cells 12

4.4.8. Autologous plasma cells producing antibodies against tumour antigen 12

4.4.9. Synthetic double-stranded RNA oligonucleotide conjugated to GalNAc aminosugar residues13

4.5. Follow-up and guidance 13

5. Scientific Advice 13

5.1. New requests - appointment of CAT Rapporteurs 13

5.1.1. Ongoing scientific advice procedures - Appointment of CAT Peer Reviewers 13

5.1.2. Scientific advice procedures starting at the next SAWP meeting 13

5.2. Procedures discussed at SAWP – 1st reports, D40 JRs, LoIs 13

5.3. Finalisation of D70 procedures – feedback from the discussion meeting 13

5.4. Final Advice Letters for procedures finalised the previous month 14

6. Pre-Authorisation Activities 14

6.1. Paediatric investigation plans 14

6.2. ITF briefing meetings in the field of ATMPs 14

6.3. Priority Medicines (PRIME) – Eligibility requests 14
6.3.1. Month 0 - Start of the procedure 14
6.3.2. Month 1 – Discussion of eligibility 14
6.3.3. Month 2 – Recommendation of eligibility 14
6.3.4. Ongoing support 14

7. Organisational, regulatory and methodological matters 15
7.1. Mandate and organisation of the CAT 15
7.1.1. CAT membership 15
7.1.2. Vote by proxy 15
7.1.3. Update on CAT Timeschedule 15
7.1.4. Strategic Review and Learning meeting under the Hungarian Presidency of the European Union 15
7.2. Coordination with EMA Scientific Committees 15
7.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups 15
7.3.1. GVP Module XVI on risk minimisation measures and its Addendum II 15
7.3.2. Reflection paper on criteria to be considered for the evaluation of new active substance (NAS) status of biological substances 15
7.4. Cooperation with the EU regulatory network 16
7.5. Cooperation with international regulators 16
7.5.1. ATMP cluster teleconference with US-FDA, Health Canada and PMDA (Japan) 16
7.6. CAT work plan 16
7.6.1. CAT work plan 2025 16
7.6.2. Guideline on quality, non-clinical and clinical requirements for investigational ATMPs in clinical trials 16
7.7. Planning and reporting 16
7.8. Others 16

8. Any other business 17
8.1. Update to CxMPs on IRIS for Regulatory Procedures 17

9. Explanatory notes 18

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 17-19 July 2024. See July 2024 CAT minutes (to be published post September 2024 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 17-19 July 2024 meeting

1.3. Adoption of the minutes

CAT minutes for 19-22 June 2024 meeting

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. Obecabtagene autoleucel - PRIME - Orphan - EMEA/H/C/005907

Autolus GmbH; Treatment of patients with relapsed or refractory B cell precursor acute lymphoblastic leukaemia (ALL)

Scope: Day 120 list of questions

Action: for adoption

2.4.2. Mozafancogene autotemcel - PRIME - Orphan - EMEA/H/C/005537

Rocket Pharmaceuticals B.V.; Treatment of paediatric patients with Fanconi anaemia type A

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

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. 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. Abecma - Idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0047

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, request for supplementary information

Action: for adoption

Request for supplementary information adopted on 24.05.2024.

2.11.2. Abecma - Idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0048

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, request for supplementary information

Action: for adoption

Request for supplementary information adopted on 21.06.2024.

2.11.3. Alofisel - Darvadstrocel - Orphan - EMEA/H/C/004258/II/0051/G

Takeda Pharma A/S

Rapporteur: Maria Luttgen, PRAC Rapporteur: Gabriele Maurer

Scope: Efficacy, request for supplementary information

A grouped application comprised of 4 Type II Variations, as follows:

(C.I.4): Update of sections 4.8 and 5.1 of the SmPC in order to update the safety information, based on pooled safety data from the two phase 3 controlled studies (ADMIRE-CD & ADMIRE-CD II) and to update efficacy information based on final results from study ADMIRE-CD II, listed as an obligation in the Annex II. ADMIRE-CD II (Cx601-0303) is a Phase III randomised double blind, placebo controlled study to assess efficacy and safety of Cx601, adult allogeneic expanded adipose-derived stem cells (eASC) for the treatment of complex perianal fistula(s) in patients with Crohn's disease. The Annex II is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI, including to section 4.2 of the SmPC and to the Package Leaflet.

3 x (C.I.13): Submission of interim results from studies Darvadstrocel-3003 and Alofisel-5003 (INSPIRE) and final results from study Darvadstrocel-3002 to support the benefit-risk assessment of darvadstrocel based on all new available clinical data.

The RMP version 8.0 has also been submitted.

Action: for adoption

2.11.4. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/II/0037/G

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality

Action: for adoption

Request for supplementary information adopted on 21.06.2024, 15.03.2024.

2.11.5. Hemgenix - Etranacogene dezaparvovec - Orphan - EMEA/H/C/004827/II/0014/G

CSL Behring GmbH

Rapporteur: Silke Dorner

Scope: Quality, request for supplementary information

Action: for adoption

2.11.6. Imlygic - Talimogene laherparepvec - EMEA/H/C/002771/II/0067/G

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen

Scope: Clinical

A grouped application as follows:

Type II (C.I.4): Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update paediatric information based on the paediatric study 20110261, which was previously submitted in procedure II/0063. This is a phase 1, multicentre, open-label study of talimogene laherparepvec in paediatric subjects with advanced non-CNS tumours that were amenable to direct injection in the clinical setting. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial and formatting changes to the Product Information.

Type IA (A.6): To change the ATC Code of Antineoplastic cell and gene therapy from L01XX51 to L01XL02.

Action: for adoption

2.11.7. Upstaza - Eladocagene exuparvovec - Orphan - EMEA/H/C/005352/II/0022/G

PTC Therapeutics International Limited

Rapporteur: Joseph DeCourcey

Scope: Quality, opinion

Action: for adoption

2.11.8. Yescarta - Axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0077

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality, request for supplementary information

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/MEA/007.1

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Pharmacovigilance

MAH's response to MEA 007 [LTFU study (GC LTFU 001)] RSI as adopted in January 2024.

Long-term follow-up of safety and efficacy for all paediatric and adult subjects exposed do a GM T cell therapy in Bristol-Myers Squibb sponsored, or Bristol Myers Squibb alliance partner sponsored, clinical trials in accordance with Health Authorities' guidance for long-term (up to 15 years) follow-up of subjects treated with gene therapy products.

Action: for adoption

2.13.2. Breyanzi - Lisocabtagene maraleucel / Lisocabtagene maraleucel - EMEA/H/C/004731/REC/016.1

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality

Action: for adoption

2.13.3. Zolgensma - Onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/LEG/024

Novartis Europharm Limited

Rapporteur: Emmely de Vries

Scope: Non-clinical

From PSUSA-00010848-202305

Study reports for 2170026 & 222018:

- Study no. 2170026 (OAV101: Single Dose Intravenous or Intracerebroventricular Germline Transduction and Integration Study in Neonatal FVB/NCrl Mice with up to a 24-Week Evaluation Period).

- Study no. 2220183: AAV Vector expression in cynomolgus macaque gonadal tissue of scAAV9-CB-GFP and scAAV9-CB-mCherry 28 days after administration Molecular Localization Report.

Action: for adoption

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

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. Autologous CD34 positive cells

For regeneration purposes, to replace damaged tissue in blood and other tissues (adipogenic, osteogenic, chondrogenic, myogenic and angiogenic)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Autologous antigenic tumor fragments isolated from patient's circulating cancer cells

For treatment of cancer patients suffering from blood cancer

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Autologous antigenic tumor fragments isolated from patient's circulating cancer cells

For treatment of cancer patients suffering from cancer of epithelial origin

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Autologous antigenic tumor fragments isolated from patient's circulating cancer cells

For treatment of cancer patients suffering from melanoma

Scope: ATMP scientific recommendation

Action: for adoption

4.2.5. Autologous antigenic tumor fragments isolated from patient's circulating cancer cells

For treatment of cancer patients suffering from sarcoma

Scope: ATMP scientific recommendation

Action: for adoption

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

4.3.1. Implantable device 3D bioprinted with autologous microfat and hydrogel bioink

For treatment of breast reconstruction, soft tissue repair

Scope: ATMP scientific recommendation

Action: for adoption

4.4. Finalisation of procedure

4.4.1. Autologous adipose-derived stromal vascular fraction cells

For chronic pain relief

Scope: European Commission raised comments. ATMP scientific recommendation

Action: for adoption

4.4.2. Double stranded DNA targeting patient specific tumour neo-antigens

For treatment of non small cell lung cancer

Scope: European Commission raised comments. ATMP scientific recommendation

Action: for adoption

4.4.3. Spermatogonial stem cells, propagated in vitro

Male infertility due to gonadotoxic treatment

Scope: Feedback from the Commission. ATMP scientific recommendation

Action: for adoption

4.4.4. Autologous antigen specific Cytotoxic T Lymphocytes

For treatment of cancer patients

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.5. Autologous dendritic cells against tumour peptides

For treatment of cancer patients

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.6. Autologous macrophages

For treatment of cancer patients

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.7. Autologous cytotoxic natural killer (NK) cells

For treatment of cancer patients

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.8. Autologous plasma cells producing antibodies against tumour antigen

For treatment of cancer patients

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.9. Synthetic double-stranded RNA oligonucleotide conjugated to GalNAc aminosugar residues

For treatment of primary hyperoxaluria

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

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:	08-11.07.2024
- Appointment of CAT Peer Reviewers:	17-19.07.2024
- SAWP first reports:	26.08.2024
- CAT Peer Reviewer comments (NC/C):	30.08.2024
- CAT Peer Reviewer comments (Q):	04.09.2024
- Discussion at SAWP:	02-05.09.2024
- Discussion at CAT and feedback to SAWP:	11-13.09.2024

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	dd.mm.202y
- Appointment of CAT Peer Reviewers:	dd.mm.202y
- SAWP first reports:	dd.mm.202y
- CAT Peer Reviewer comments:	dd.mm.202y
- Discussion at SAWP:	dd.mm.202y
- Discussion at CAT and feedback to SAWP:	dd.mm.202y

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:	08-11.07.2024
SAWP recommendation:	05.09.2024
CAT recommendation:	13.09.2024
CHMP adoption of report and final recommendation:	19.09.2024

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. Update on CAT Timeschedule

Action: for information

7.1.4. Strategic Review and Learning meeting under the Hungarian Presidency of the European Union

CAT: Viola Bardoczy

Scope: Draft agenda

Action: for discussion

Note: Date for the SRLM under the Hungarian Presidency: 18-20 November 2024 (changed from date announced in the June CAT meeting)

7.2. Coordination with EMA Scientific Committees

No items

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

7.3.1. GVP Module XVI on risk minimisation measures and its Addendum II

Action: for information (presentation following written consultation of CAT concluded on 4 July 2024)

7.3.2. Reflection paper on criteria to be considered for the evaluation of new active substance (NAS) status of biological substances

Scope: Status update from drafting group

Action: for information

Following CAT members/experts are contributing to the drafting group discussions on the NAS status for ATMPs: M Timon, B Bonamassa, H Suila, I Reichl, J Scherer, M van de

Bovenkamp.

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 and PMDA (Japan)

CAT: Ilona Reischl

Scope: Feedback from the teleconference of 27.06.2024

Action: for information

7.6. CAT work plan

7.6.1. CAT work plan 2025

CAT: Ilona Reischl, Claire Beuneu, Rune Kjeken, Jan Mueller-Berghaus, Mencia de Lemus Belmonte, Maria Lüttgen, Olga Kholmanskikh, Dariusz Sladowski

Scope: Tour de table on progress of 2024 CAT workplan activities and discuss timelines and next steps for 2025 CAT workplan

Action: for information

7.6.2. Guideline on quality, non-clinical and clinical requirements for investigational ATMPs in clinical trials

CAT: Ilona Reischl

Scope: Status update: feedback from the quality and non-clinical drafting groups

Action: for information

7.7. Planning and reporting

No items

7.8. Others

No items

8. Any other business

8.1. Update to CxMPs on IRIS for Regulatory Procedures

Scope: To update the impacted committees on further procedures to be implemented in IRIS by the end of 2024 (PSURs, PAMs, Line extensions, Renewals, Annual Reassessments, PASS, Referrals)

Action: for information

Date of next CAT meeting:

13-16 August 2024 (written procedure)

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

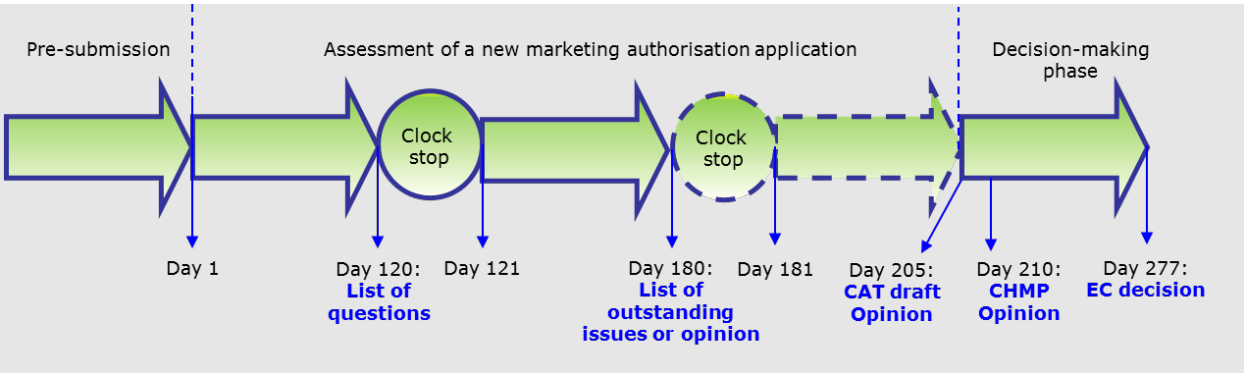
Evaluation of ATMPs (section 2)

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/