08 September 2021
EMA/CAT/468912/2021
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 08-10 September 2021

Chair: Martina Schuessler-Lenz; Vice-Chair: Ilona Reischl

08 September 2021, 14:00 – 18:00, room 01-C

09 September 2021, 09:00 – 18:00, room 01-A

10 September 2021, 09:00 – 13:00, room 01-C

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 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 08-10 September 2021. See 08-10 September 2021 CAT minutes (to be published post 06-08 October 2021 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 08-10 September 2021 meeting

1.3. Adoption of the minutes

CAT minutes for 14-17 July 2021 meeting

CAT minutes of the 11-13 August 2021 written procedure

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. Ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095

Accelerated assessment

Janssen-Cilag International NV; treatment of multiple myeloma

Scope: Day 120 list of questions

Action: for adoption

2.5. Day 80 assessment reports

No items

2.6. Update on ongoing initial applications

2.6.1. Autologous glioma tumor cells, inactivated / autologous glioma tumor cell lysates, inactivated / allogeneic glioma tumor cells, inactivated / allogeneic glioma tumor cell lysates, inactivated - Orphan - EMEA/H/C/003693

Epitopoietic Research Corporation-Belgium (E.R.C.); treatment of glioma

Scope: MAA's request (dated 27.08.2021) for a clock-stop extension

Action: for information

List of Questions adopted on 22.01.2021.

Note: revised timetable via written procedure, adopted.

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. 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. Alofisel - darvadstrocel - Orphan - EMEA/H/C/004258/II/0027

Takeda Pharma A/S

CAT Rapporteur: Lisbeth Barkholt

Scope: Quality. Opinion

Action: for adoption

2.11.2. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0044

Amgen Europe B.V.

CAT Rapporteur: Heli Suila, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: PhV. Opinion

Submission of the final report from study 20180099 listed as a category 3 study in the risk management plan (RMP). This is a cross-sectional survey to evaluate physician knowledge of safety messages included in the physician education booklet (PEB) for Imlygic.

Action: for adoption

Request for Supplementary Information adopted on 16.07.2021, 12.05.2021.

2.11.3. Tecartus - autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured - Orphan - EMEA/H/C/005102/II/0008/G

Kite Pharma EU B.V.

CAT Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Menno van der Elst

Scope: Clinical. Request for supplementary information

Group of variations including an extension of indication to include treatment of adult patients with relapsed or refractory (r/r) B-cell acute lymphoblastic leukemia (B-ALL) for Tecartus and a type IB variation to change the Drug Product Dose specification for the new indication. As a consequence, sections 2.2, 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The package leaflet and labelling are updated in accordance. Version 1.1 of the risk management plan (RMP) has also been submitted. Furthermore, the product information (PI) is brought in line with the latest quality review document (QRD) template.

Action: for adoption

2.11.4. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0040t

Kite Pharma EU B.V.

CAT Rapporteur: Jan Mueller-Berghaus, PRAC Rapporteur: Anette Kirstine Stark

Scope: PhV. Request for supplementary information

Submission of the final study report for the non-interventional study KT-EU-471-0116 (quantitative testing of healthcare provider knowledge about Yescarta (axicabtagene ciloleucel) risk minimisation measures) in fulfilment of an additional pharmacovigilance activity (Category 3) listed in the EU risk management plan (RMP) for Yescarta.

Action: for adoption

2.11.5. Zynteglo - betibeglogene autotemcel - Orphan - EMEA/H/C/003691/II/0025

bluebird bio (Netherlands) B.V

CAT Rapporteur: Carla Herberts

Scope: Quality. Opinion

Action: for adoption

2.11.6. Tecartus; Yescarta - axicabtagene ciloleucel; autologous anti-CD19-transduced CD3+ cells - Orphan - EMEA/H/C/WS2071

Kite Pharma EU B.V.

CAT Rapporteur: Jan Mueller-Berghaus

Scope: Quality. Request for supplementary information

Opinion

Action: for adoption

Request for Supplementary Information adopted on 16.07.2021.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/ANX/003

Orchard Therapeutics (Netherlands) BV

Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege

Scope: Progress report
Measures proposed to reduce the overall time from patient screening to treatment.

Action: for adoption

2.13.2. Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/REC/004

Orchard Therapeutics (Netherlands) BV

Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege

Scope: Quality, Progress report

Action: for adoption

2.13.3. Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/REC/005

Orchard Therapeutics (Netherlands) BV

Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege

Scope: Quality

Action: for adoption

2.13.4. Tecartus - autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured - Orphan - EMEA/H/C/005102/R/0010

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Rune Kjeken, PRAC Rapporteur: Menno van der Elst

Scope: 1-year Renewal of Marketing Authorisation. Opinion

Action: for adoption

2.13.5. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/REC/011

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

2.13.6. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/REC/012

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

2.13.7. Tecartus - autologous anti-CD19-transduced CD3+ cells - Orphan - EMEA/H/C/005102/REC/008

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

2.13.8. Skysona – Elivaldogene autotemcel - Orphan – EMEA/H/C/003690

bluebird bio (Netherlands) B.V.; treatment of early cerebral adrenoleukodystrophy

Rapporteur: Lisbeth Barkholt, Co-rapporteur: Anne Pastoft
Scope: New safety findings

Action: for information

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

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

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Autologous red blood cells chemically coupled with 12 antigenic peptides

Intended for the treatment of multiple sclerosis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Point-of-care skin cell isolation kit

Intended for skin regeneration after burns, skin trauma, invasive surgery

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Optimised DNA encoding the sequence of interest COL7A1

Intended for the treatment of dystrophic epidermolysis bullosa (DEB)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Adipose derived Mesenchymal Stem/Stromal Cells

Intended for the treatment of amyotropthic lateral sclerosis

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Recombinant adeno-associated virus serotype HSC 15 (rAAVHSC15) expressing human iduronate-2-sulfatase (hIDS)

Intended for the treatment of mucopolysaccharidosis type II (known as Hunter syndrome)

Scope: ATMP scientific recommendation

Action: for adoption

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

4.3.1. Extracellular matrix and non-viable osteogenic cells derived from human adipose-derived stem cells, associated with hydroxyapatite/beta-tricalcium phosphate (HA/βTCP) particles

Intended to stimulate bone regeneration in pathological hypoxic and/or necrotic bone conditions

Scope: ATMP scientific recommendation

Action: for adoption

4.3.2. Isolated CD31+ cells

Intended for the treatment of erectile dysfunction

Scope: ATMP scientific recommendation

Action: for adoption

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:	30.08-02.09.2021
- Appointment of CAT Peer Reviewers:	08-10.09.2021
- SAWP first reports:	20.09.2021
- CAT Peer Reviewer comments:	24.09.2021
- Discussion at SAWP:	27-30.09.2021
- Discussion at CAT and feedback to SAWP:	08.10.2021

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	27-30.09.2021
- Appointment of CAT Peer Reviewers:	06-08.10.2021
- SAWP first reports:	18.10.2021
- CAT Peer Reviewer comments:	22.10.2021
- Discussion at SAWP:	25-28.10.2021
- Discussion at CAT and feedback to SAWP:	05.11.2021

5.2. Procedures discussed at SAWP – 1st report and D40 JRs, LoOIs

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

No items

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:

Procedure start:	02.09.2021
SAWP recommendation:	30.09.2021
CAT recommendation:	08.10.2021
CHMP adoption of report and final recommendation:	14.10.2021

6.3.2. Month 1 – Discussion of eligibility

No items

6.3.3. Month 2 – Recommendation of eligibility

No items

6.3.4. Ongoing support

No items

6.3.4.1. Resamirigene bilparovec – PRIME - ATMP – H0004719

Prime Rapporteur: Anne Pastoft

Scope: notification of serious adverse event in ASPIRO trial

Action: for information

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. Joint CAT-CHMP Strategic Review & Learning (virtual) meeting (SRLM) under the Slovenian presidency, 20-21 October 2021, Ljubljana (Slovenia)

CAT: Metoda Lipnik-Štangelj, Martina Schuessler-Lenz

Scope: Practical information and agenda content

Action: for discussion

7.1.4. Pilot – Relaunch of face to face Scientific Committee meetings

Action: for discussion

7.1.5. CAT rules of procedure - revision

Action: For adoption

7.2. Coordination with EMA Scientific Committees

7.2.1. Scientific Coordination Board (SciCoBo) – meeting of 03 September 2021

CAT: Martina Schuessler-Lenz

Scope: feedback on the discussions in the SciCoBo meeting

Action: for discussion

7.2.2. Evaluation and grading of neurotoxicities for CAR-T cells ATMPs – a proposal for using ICANS

Scope: ICANS in CAR-T post-autorisation reports

Action: for agreement

Note: During its July meeting, CAT agreed in principle to use ICANS for the reporting of neurotoxicity for CAR-Ts. The proposal was also discussed in PRAC. Formal endorsement by CAT and PRAC will take place in September.

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

7.3.1. Final guideline on registry-based studies

Action: for information

Note: Update on the guideline after public consultation

7.3.2. Working Party with Patients' and Consumers' Organisations (PCWP) and Working Party with Healthcare Professionals' Organisations (HCPWP)

Scope: draft agenda of the PCWP/HCPWP joint meeting on the 21-22 September 2021

Action: for information

7.4. Cooperation with the EU regulatory network

7.4.1. Revision of the EU legislation on blood, tissues and cells (BTC)

CAT: Martina Schüssler-Lenz

Action: for discussion

Scope: exchange with the European Commission representative

7.5. Cooperation with international regulators

7.5.1. WHO consultation on cell and gene therapy products

CAT: Ilona Reischl

Action: for information

Note: CAT members are asked to provide comments to Ilona Reischl cc. CAT secretariat by Tuesday 7 September

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

CAT: Martina Schuessler-Lenz

Scope: Feedback from the teleconference that took place on 22 July 2021

Action: for information

7.5.3. International Pharmaceutical Regulators Programme (IPRP) – Gene therapy and cell therapy working group

CAT: Pille Säälik

Scope: Agenda of the international teleconference that took place on 22 July 2021

Action: for Information

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

CAT: Martina Schuessler-Lenz

Scope: Topic for the agenda of the teleconference that will take place on 16 September 2021

Action: for discussion

7.6. CAT work plan

7.6.1. Real World Data (RWD) in regulatory decision making of ATMPs

CAT: Martina Schuessler-Lenz

Scope: Feedback from the second meeting

Action: for information

7.7. Planning and reporting

7.7.1. Planning estimates of forthcoming ATMP MAAs

Scope: Q3/2021 update of the business pipeline report for the human scientific committees

Action: for information

7.8. Others

7.8.1. CAT stakeholder meeting on 26 October 2021

CAT: Martina Schuessler-Lenz

Scope: revision of agenda topics

Action: for discussion

Note: One of the topics is linked to the CAT work plan: Real World Data (RWD) in regulatory decision making of ATMPs.

8. Any other business

No items

Date of next CAT meeting:

06-08/10/2021

9. Explanatory notes

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

Abbreviations / Acronyms

AAV: Adeno-Associated Virus

AR: Assessment Report

ATMP: Advanced Therapy Medicinal Product

BWP: Biologics Working Party

CAT: Committee for Advanced Therapies

CHMP: Committee for Medicinal Product for Human Use

COMP: Committee for Orphan Medicinal Products

CTFG: Clinical Trial Facilitation Group

DG: Drafting Group

EC: European Commission

EU NTC: European Union Network Training Centre

ERA: Environmental Risk Assessment

FDA: Food and Drug Administration

FL: Final Letter

GCG: Guideline Consistency Group

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Genetically-modified organism

GMP: Good Manufacturing Practice

GTMP: Gene Therapy Medicinal Product

HTA: Health Technology Assessment Bodies

HSPC: Hematopoietic Stem and Progenitor Cells

ITF: Innovative Task Force

JR: Joint Report

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Application

MAH: Marketing Authorisation Holder

MNAT: Multinational assessment team

MSC: Mesenchymal stem cells

PDCO: Paediatric Committee

PMDA: Pharmaceuticals and Medical Devices Agency (Japan)

PIP: Paediatric Investigation Plan

PL: Package leaflet

PRAC: Pharmacovigilance and Risk Assessment Committee #

PRIME: Priority Medicines

QRD: Quality review of documents

RMP: Risk Management Plan

RP: Reflection paper

RSI: Request for supplementary information

SAs: Scientific Advices

SAG-O: Scientific Advisory Group Oncology

SAWP: Scientific Advice Working Party

SR: Summary Report

SWP: Safety Working Party

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

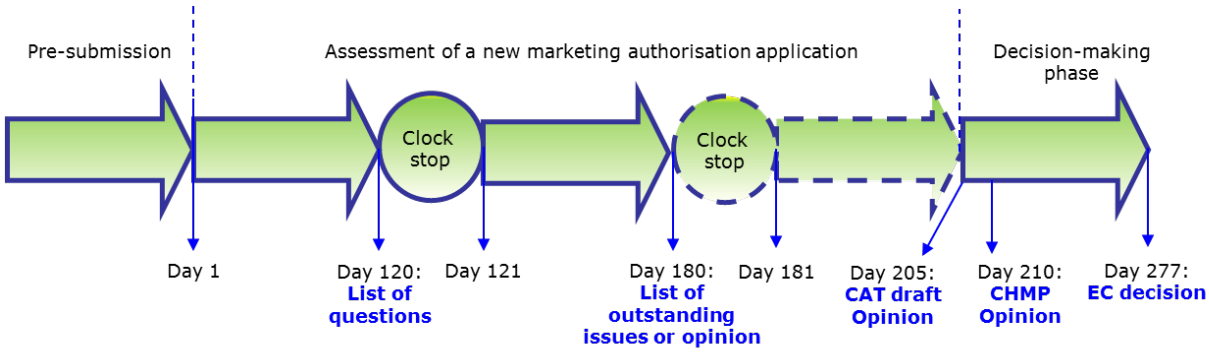
Evaluation of ATMPs (section 2)

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 any ATMP related inspection requests (section 2.9) and Post-authorisation activities (section 2.10).

New applications (sections 2.1. to 2.12.)

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 2.3) 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 2.7 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.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 (section 2.6.)

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.

Withdrawal of applications (section 2.7.)

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.

New applications (section 2.9.)

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.

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 2.12.)

This section lists type II variations, extension application according to Annex I of Reg. 1234/2008, re-examination procedures for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP and other issues concerning authorised medicines that are not covered elsewhere in the agenda such as 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.

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/