19 April 2023
EMA/CAT/151444/2023
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 19-21 April 2023

Chair: Ilona Reischl; Vice-Chair: Carla Herberts

19 April 2023, 14:00 – 18:30

20 April 2023, 09:00 – 18:30

21 April 2023, 09:00 – 13:00

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 19-21 April 2023. See 19-21 April 2023 CAT minutes (to be published post May 2023 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 19-21 April 2023 meeting

1.3. Adoption of the minutes

CAT minutes for 22-23 March 2023 meeting

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

2.2.1. Lenadogene nolparvovec - Orphan - EMEA/H/C/005047

GenSight Biologics S.A.; Treatment of vision loss due to Leber hereditary optic neuropathy (LHON)

Scope: Oral explanation

Action: for discussion

List of outstanding issues adopted on 09.12.2022. List of questions adopted on 19.02.2021.

2.3. Day 180 list of outstanding issues

No items

2.4. Day 120 list of questions

No items

2.5. Day 80 assessment reports

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

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

Scope: Day 80 assessment report

Action: for information

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

2.10.1.1. In vitro diagnostic medical device - EMEA/H/D/006255

Indicated as an aid in the selection of adult haemophilia A patients for whom valoctocogene roxaparvovec treatment is being considered

Scope: Opinion

Action: for adoption

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/0027

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken

Scope: Quality, Opinion

Action: for adoption

Request for supplementary information adopted on 24.03.2023.

2.11.2. Alofisel - darvadstrocel - Orphan - EMEA/H/C/004258/II/0045/G

Takeda Pharma A/S

Rapporteur: Lisbeth Barkholt

Scope: Quality, Opinion

Action: for adoption

2.11.3. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0059

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen

PRAC Rapporteur: Gabriele Maurer

Scope: Pharmacovigilance, Opinion (PRAC procedure)

Submission of an updated RMP version 10 in order to update and reclassify identified risk of 'disseminated herpetic infection' based on the cumulative assessment of literature review and MAH Global Safety Database, and to remove studies 20180062 and 20180099 from Planned and Ongoing Studies from the list of Pharmacovigilance Plan studies in Annex II.

Action: for adoption

Request for supplementary information adopted on 20.01.2023.

2.11.4. ROCTAVIAN - valoctocogene roxaparvovec - Orphan - EMEA/H/C/005830/II/0004/G

BioMarin International Limited

Rapporteur: Violaine Closson Carella

Scope: Quality, Opinion

Action: for adoption

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

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Concetta Quintarelli

Scope: Quality, Clock stop extension

Action: for adoption

2.11.6. Abecma – idecabtagene vicleucel – Orphan - EMEA/H/C/PSUSA/00010954/202209

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken, PRAC Rapporteur: Ulla Wändel Liminga

Scope: variation following PSUR assessment: Update of section 4.4 of the SmPC to add warning information on Parkinsonism and to mention it in the footnotes of the table in section 4.8 of the SmPC for the SOC "Nervous system disorders" (PRAC led procedure)

Action: for information

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/R/0029

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjeken, Co-Rapporteur: Heli Suila, PRAC Rapporteur: Ulla Wändel LimingaScope: 1 year Renewal of Marketing Authorisation, Opinion

Action: for adoption

2.13.2. CARVYKTI - ciltacabtagene autoleucel - Orphan - EMEA/H/C/005095/MEA/007.1

Janssen-Cilag International NV

Rapporteur: Jan Mueller-BerghausScope: Pharmacovigilance, Follow up MEA

Revised protocol of study No PCSONCA0014: Survey to evaluate the effectiveness of the ciltacabtagene autoleucel HCP Educational Program and the Product Handling Training.

The MAH is requested to consider a stratified randomisation approach in order to ensure that the acceptable number in each category of HCPs will complete the survey. A minimum number of participants should be proposed for physicians, nurses, pharmacists and wards on the one hand, and also for HCPs involved in prescribing vs handling of ciltacabtagene autoleucel in the selected countries. The estimations of effectiveness should also be performed separately, at least for HCPs involved in prescription, patient management and

product handling in order to be able to interpret effectiveness in a meaningful way, as criteria for success and even the weighting of the questions is different. [From Initial MAA]

Action: for adoption

2.13.3. Ebvallo - tabelecleucel - Orphan - EMEA/H/C/004577/REC/006

Pierre Fabre Medicament

Rapporteur: Egbert Flory

Scope: Quality, Opinion

Action: for adoption

2.13.4. ROCTAVIAN - valoctocogene roxaparvovec - Orphan - EMEA/H/C/005830/R/0003

BioMarin International Limited

Rapporteur: Violaine Closson Carella, Co-Rapporteur: Silke Dorner, PRAC Rapporteur: Menno van der Elst

Scope: 1 year Renewal of Marketing Authorisation, Request for supplementary information

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

3.2. Day 60 Evaluation Reports

3.3. New Applications

4. Scientific Recommendation on Classification of ATMPs

Timetable:

-Start of the procedure:	21.04.2023
-EMA Coordinator's draft report:	02.05.2023
-CAT Coordinator's comments:	05.05.2023
-Revised scientific recommendation:	10.05.2023
-CAT's discussion of scientific recommendation:	17.05.2023

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Living human adult allogeneic immunomodulatory progenitor (iMP) cells

Treatment of myocardial scarring

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. Allogeneic viable natural killer (NK) cells CD56+ CD3-

Treatment of patients with acute myeloid leukaemia (AML) who are in morphologic complete remission (CR) and for whom allogeneic haematopoietic stem cell transplantation (allo-HSCT) is not a suitable or preferred option

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Recombinant Adeno-associated virus serotype 9 vector containing the human-lysosome-associated membrane glycoprotein 2 isoform B transgene

Treatment of Danon disease

Scope: Appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Ixoberogene soroparvovec (Genetically engineered, replication-incompetent adeno-associated virus vector comprising the AAV.7m8 capsid proteins, carrying a version of complementary deoxyribonucleic acid for aflibercept)

Treatment of neovascular (wet) age-related macular degeneration

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Ex vivo fused allogeneic human myoblasts (MB-N) with autologous human myoblast (MB-ALS)

Treatment of amyotrophic lateral sclerosis (ALS)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Ex vivo fused allogeneic human myoblasts (MB-N) with autologous human bone marrow derived mesenchymal stem cells (MSC-ALS)

Treatment of amyotrophic lateral sclerosis (ALS)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Ex vivo fused allogeneic human mesenchymal stem cell (MSC-N) with autologous human myoblast (MB-ALS)

Treatment of amyotrophic lateral sclerosis (ALS)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.5. Ex vivo fused allogeneic human myoblasts (MB-N1) with allogeneic human myoblasts (MB-N2)

Treatment of amyotrophic lateral sclerosis (ALS)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.6. Helper-dependent adenovirus vector coding for interleukin-1 receptor antagonist

Treatment of osteoarthritis of the knee

Scope: ATMP scientific recommendation

Action: for adoption

4.2.7. Autologous CD34+ cells from mobilised peripheral blood

Treatment of amyotrophic lateral sclerosis (ALS)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.8. Biotinylated cultured reticulocytes, cultured from haematopoietic stem cells

Treatment of red cell suppletion (e.g. trauma/anaemia)

Scope: ATMP scientific recommendation

Action: for adoption

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

4.3.1. Autologous chondrocytes cultured in hyaluronan-derived scaffold

Repair of cartilage defects

Scope: ATMP scientific recommendation

Action: for discussion

4.4. Finalisation of procedure

4.4.1. Lyophilised supernatant of a pathogen inactivated and gamma sterilised platelet lysate

Treatment of topical treatment of skin ulcers

Scope: European Commission raised no comments. ATMP scientific recommendation

Action: for adoption

4.4.2. Autologous intestinal organoid derived from adult stem cells from intestinal epithelial tissue

Treatment of intractable ulcer

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:	11-14.04.2023
- Appointment of CAT Peer Reviewers:	19-21.04.2023
- SAWP first reports:	02.05.2023
- CAT Peer Reviewer comments (NC/C)	05.05.2023

- CAT Peer Reviewer comments (Q)	10.05.2023
- Discussion at SAWP:	08-10.2023
- Discussion at CAT and feedback to SAWP:	15-17.05.2023

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	13-16.03.2023
- Appointment of CAT Peer Reviewers:	22-24.03.2023
- SAWP first reports:	03.04.2023
- CAT Peer Reviewer comments (NC/C):	05.04.2023
- CAT Peer Reviewer comments (Q):	12.04.2023
- Discussion at SAWP:	11-14.04.2023
- Discussion at CAT and feedback to SAWP:	19-21.04.2023

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

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

5.4. Final Advice Letters for procedures finalised the previous month

6. Pre-Authorisation Activities

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

6.1. Paediatric investigation plans

No items

6.2. ITF briefing meetings in the field of ATMPs

No items

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:

Procedure start:	11-14.04.2023
SAWP recommendation:	12.05.2023
CAT recommendation:	17.05.2023
CHMP adoption of report and final recommendation:	25.05.2023

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

Action: for information

7.1.2. Vote by proxy

Action: for information

7.1.3. CAT Strategic Review & Learning meeting (SRLM) under the Sweden presidency, 4 and 5 May 2023, Upsala (Sweden)

CAT: Lisbeth Barkholt, Maria Lüttgen

Scope: Topics for discussion at the upcoming SRLM

Action: for discussion

7.1.4. New timeschedule layout

CAT: Ilona Reischl

Scope: New layout of the timeschedule to capture all relevant information in a single location

Action: for discussion

CAT members to provide any comments or suggestions for further improvement to CAT Secretariat

7.2. Coordination with EMA Scientific Committees

None

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

7.3.1. PRIME implementation of 5-year review recommendations – 2023 pilot features and guidance updates

Summary of new features and their impact on CAT Rapporteurs

Action: for information

7.3.2. Joint EU GCP inspectors-clinical assessors virtual workshop, 26th June

There will be a short presentation on the scope of the Joint EU GCP inspectors-clinical assessors virtual workshop organised by the subgroup of GCP inspectors and assessors working on embedding the outcome of GCP inspections into the benefit/risk assessment and modernisation of the inspection process. The presentation will also include a brief update on the deliverables of this subgroup.

Action: for information

7.3.3. Re-organisation of BWP

Scope: BWP 3-year work plan and call for nominations

Action: for discussion

7.4. Cooperation with the EU regulatory network

None

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 that was held on 13 April 2013

Action: for information

7.6. CAT work plan

7.6.1. Guideline of quality, non-clinical and clinical requirements for investigational ATMPs in clinical trials

CAT topic leads: Ilona Reischl, Rune Kjeken, Claire Beuneu, Alessandro Aiuti

Scope: Comments received during the external consultation; discussion on the scope and content of the guideline

Action: for discussion

7.7. Planning and reporting

None

7.8. Others

7.8.1. CAT stakeholder meeting 2023

CAT: Dariusz Sladowski, Ilona Reischl, Violaine Closson Carella, Carla Herberts

Scope: Topics proposed by the CAT stakeholders and plan of actions to prepare the agenda of the stakeholders meeting to take place on 16 May 2023

Action: for discussion

7.8.2. Euroscan – International HealthTechScan (i-HTS)

CAT: Ilona Reischl

Scope: Feedback from the presentation by the CAT chair on challenges in the field of ATMP in Europe at i-HTS Scientific meeting on ATMP4ALL – 'How to raise awareness, equal access and trust in complex therapies in Europe?'

Action: for information

7.8.3. European Health and Digital Executive Agency (HaDEA)

CAT: Ilona Reischl

Scope: Update on HaDEA activities

Action: for information

8. Any other business

8.1. New Expert Management Tool

Scope: Presentation on the new Expert Management Tool to maintain a list of experts involved in medicines-related activities to collect their declarations of interests (eDOIs) and CVs

Action: for information

Date of next CAT meeting:

15-17 May 2023

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

SME: Small and medium size enterprises

SmPC: Summary of Products Characteristics

TT: Timetable

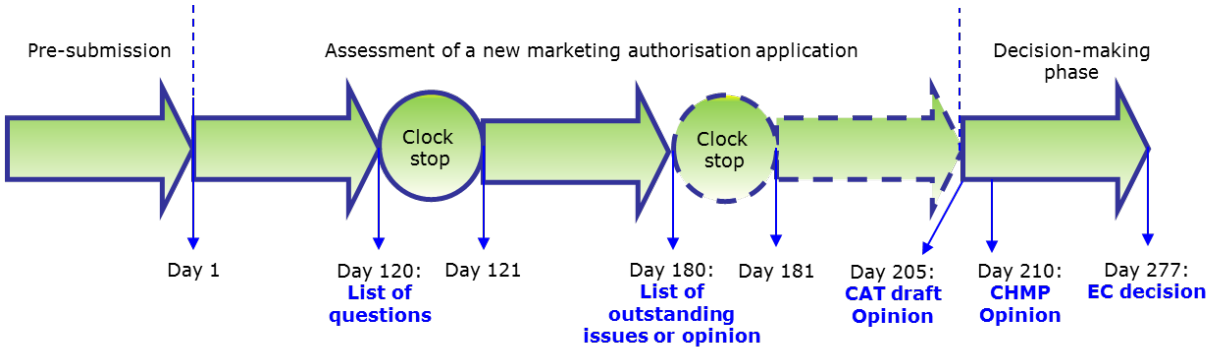
Evaluation of ATMPs (section 2)

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 and Post-authorisation activities.

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 (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.

Post-authorisation activities (section 2.11.-2.13.)

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.

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/