16 March 2022
EMA/CAT/135722/2022
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 16-18 March 2022

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

16 March 2022, 14:00 – 18:30, room 01-D

17 March 2022, 09:00 – 18:30, room 01-D

18 March 2022, 09:00 – 13:00, room 01-D

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 16-18 March 2022. See 16-18 March 2022 CAT minutes (to be published post 11-13 April 2022 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 16-18 March 2022 meeting

1.3. Adoption of the minutes

CAT minutes for 16-17 February 2022 meeting

2. Evaluation of ATMPs

2.1. Opinions

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

Janssen-Cilag International NV; treatment of multiple myeloma

Scope: Opinion

Action: for adoption

List of Outstanding Issues adopted on 10.12.2021. List of Questions adopted on 10.09.2021.

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

2.3.1. Valoctocogene roxaparvovec - Orphan - EMEA/H/C/005830

BioMarin International Limited; treatment of severe haemophilia A

cope: Day 180 list of outstanding issues

Action: for adoption

List of Questions adopted on 05.11.2021.

2.4. Day 120 list of questions

2.4.1. Tabelecleucel - PRIME - Orphan - EMEA/H/C/004577

Accelerated assessment

Atara Biotherapeutics Ireland Limited; treatment of Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV^+ PTLD)

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. 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. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0048

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen

Scope: Clinical. Opinion.

Update of section 4.4 of the SmPC in order to add a new warning about the potential risk of hepatic hemorrhage with the transcutaneous intrahepatic route of administration of talimogene laherparepvec. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet.

Action: for adoption

2.11.2. Kymriah - tisagenlecleucel - PRIME - Orphan - EMEA/H/C/004090/II/0044

Novartis Europharm Limited

Rapporteur: Rune Kjeken, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: Quality and clinical. Opinion.

Extension of indication to include treatment of adult patients with follicular lymphoma (FL) after two or more lines of therapy who are refractory or relapsed during or within 6 months after completion of anti-CD20 antibody maintenance or relapsed after autologous haematopoietic stem cell transplantation (HSCT) for Kymriah. As a consequence, Sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC and corresponding sections in the Package Leaflet are updated accordingly. The RMP has been updated to version 4.0 to align with the indication extension. Lastly, the minor editorial corrections are made throughout the SmPC and package leaflet to align with the current QRD template version 10.2.

Action: for adoption

Request for Supplementary Information adopted on 10.12.2021.

2.11.3. Strimvelis - autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence - Orphan - EMEA/H/C/003854/II/0033

Orchard Therapeutics (Netherlands) BV

PRAC Rapporteur: Menno van der Elst

Scope: Clinical. Request for Supplementary Information.

Submission of the final report from study STRIM-001 "Evaluation of referring healthcare providers' and parents'/carers' understanding of specific risks associated with Strimvelis treatment" listed as a category 3 study in the RMP. The RMP version 6.1 has also been submitted.

Action: for adoption

2.11.4. 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 - PRIME - Orphan - EMEA/H/C/005102/II/0008/G

Kite Pharma EU B.V.

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

Scope: Quality and 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 RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template.

Action: for adoption

Request for Supplementary Information adopted on 10.09.2021.

2.11.5. 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 - PRIME - Orphan - EMEA/H/C/005102/II/0016

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality. Opinion.

Action: for adoption

Request for Supplementary Information adopted on 21.01.2022.

2.11.6. Yescarta - axicabtagene ciloleucel - PRIME - Orphan - EMEA/H/C/004480/II/0042

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, Co-Rapporteur: Claire Beuneu, PRAC Rapporteur: Anette Kirstine Stark

Scope: Clinical. Extension of a clock stop.

Extension of indication to include the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after three or more lines of systemic therapy. Consequently, sections 4.1, 4.8, 5.1 and 5.2 of the SmPC, Annex II (Section D) and Package Leaflet are proposed to be updated. As a consequence, the RMP (version 5.1) has been updated to align with the indication extension. In addition, the applicant has taken the opportunity to make minor editorial corrections throughout the SmPC and package leaflet to align with the current Quality Review of Documents (QRD) template.

Action: for adoption

Request for Supplementary Information adopted on 18.02.2022, 05.11.2021.

2.11.7. Zolgensma - onasemnogene abeparvovec - PRIME - Orphan - EMEA/H/C/004750/II/0020/G

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts

Scope: Quality. Opinion.

Action: for adoption

Request for Supplementary Information adopted on 10.12.2021.

2.11.8. Zolgensma - onasemnogene abeparvovec - PRIME - Orphan - EMEA/H/C/004750/II/0024

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts

Scope: Quality and clinical.

Submission of an evaluation of the finished product specifications, in accordance with the obligation in the Annex IID of the Product Information (ANX 004), to be undertaken when primary and key secondary endpoint data from additional patients with 2 copies of SMN2 are available (i.e. completion of CL-302 and CL-304 cohort 1). The Annex II is updated accordingly.

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Alofisel - darvadstrocel - Orphan - EMEA/H/C/004258/MEA/007

Takeda Pharma A/S

Rapporteur: Lisbeth Barkholt, CHMP Coordinator: Kristina Dunder

Scope: Relates to MEA 002:
Interim Study Result / Study ADMIRE CDII (Cx601-0303)
Title: To evaluate the long-term safety and efficacy of darvadstrocel including adverse events of special interest.
[Due date: Q4 2021]

Action: for adoption

2.13.2. Glybera – Alipogene tiparvovec – EMA/H/C/0002145/SOB/001.11

uniQure biopharma B.V.; treatment lipoprotein lipase deficiency (LPLD)

Rapporteur: Egbert Flory; CHMP Coordinator: Jan Mueller-Berghaus

Scope: Clinical. Annual safety update report. Long term surveillance programme/ disease registry to collect information on the epidemiology of the disease and the demographics, safety, and the effectiveness outcomes of patients treated with Glybera. The patients enrolled in clinical studies (CT-AMT-010 -10, CT-AMT 011-01, CT-AMT 011-02) should be followed up in the LPLD registry.

Action: for adoption

2.13.3. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/MEA/005

Amgen Europe B.V.

Rapporteur: Maija Tarkkanen, CHMP Coordinator: Johanna Lähteenvuo

Scope: Protocol Amendment (v.4) for Study 20130193 (category 3)
A post-marketing, prospective cohort study of patients treated with talimogene laherparepvec in clinical practice to characterize the risk of herpetic illness among patients, close contacts, and healthcare providers; and long term safety in treated patients.
Annual interim reports to be included in the PSUR and DSUR.

Action: for adoption

2.13.4. Zolgensma - onasemnogene abeparvovec - PRIME - Orphan - EMEA/H/C/004750/R/0021

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts, Co-Rapporteur: Egbert Flory, PRAC Rapporteur: Ulla Wändel Liminga

Scope: 1-year Renewal of Marketing Authorisation

Action: for adoption

Request for Supplementary Information adopted on 18.02.2022.

3. Certification of ATMPs

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

3.1. Opinion

No items

3.2. Day 60 Evaluation Reports

No items

3.3. New Applications

No items

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Autologous transduced CD8+ T cells expressing the Melanoma associated antigen 1-(MAGE-A1)-specific T cell receptor TCR 8001

Intended for the treatment of patients with MAGE-A1 expressing solid tumours

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. Suspension of VST cells. Dispersion for infusion

Intended for the treatment of adults and children with therapy-resistant viral infection after allogeneic hematopoietic stem cell transplantation

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Adipose-derived stem cells

Intended for the treatment of type 2 diabetes mellitus, Treatment of cardiac and pulmonary complications after Covid-19

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. Gingival fibroblast

Intended for the treatment of gonarthrosis

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Recombinant serotype 2 adeno-associated virus (AAV2) carrying a single-stranded expression cassette for human Interleukin 12 (IL-12)

Intended for the treatment of advanced solid tumours

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Leukocyte and platelet rich plasma, autologous

Intended for the treatment of critical limb ischemia

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Messenger RNA (mRNA) containing a bicistronic coding sequence that upon translation produces two independent proteins, ZF-DNMT and ZF-KRAB

Intended for the treatment of adult patients with intermediate (stage B) or advanced (stage C) MYC-associated hepatocellular carcinoma (HCC)

Scope: ATMP scientific recommendation

Action: for adoption

4.2.5. Stimulated anti-viral T-lymphocytes with specific anti-viral activity

Intended for the treatment of resistant viral infections in patients after allo-HSCT

Scope: ATMP scientific recommendation

Action: for adoption

4.2.6. Plasmid expressing variant of human interleukin-10

Intended for the treatment of osteoarthritis, neuropathic pain, amyotrophic lateral sclerosis

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

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:	07-10.03.2022
- Appointment of CAT Peer Reviewers:	16-18.03.2022
- SAWP first reports:	28.03.2022
- CAT Peer Reviewer comments:	01.04.2022
- Discussion at SAWP:	04-07.04.2022
- Discussion at CAT and feedback to SAWP:	13.04.2022

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	04-07.04.2022
- Appointment of CAT Peer Reviewers:	11-13.04.2022
- SAWP first reports:	25.04.2022
- CAT Peer Reviewer comments:	29.04.2022
- Discussion at SAWP:	02-05.2022
- Discussion at CAT and feedback to SAWP:	13.05.2022

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

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:	02.03.2022
Procedure start:	07-10.03.2022
SAWP recommendation:	07.04.2022
CAT recommendation:	13.04.2022
CHMP adoption of report and final recommendation:	22/04/2022

No items

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

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT membership

No items

7.1.2. CAT Strategic Review & Learning meeting (SRLM) under the French presidency, 3 March 2022 (virtual)

CAT: Violaine Closson-Carella, Martina Schuessler-Lenz

Scope: feedback from the discussion at the SRLM on 3 March 2022

Action: for discussion

7.1.3. CAT Strategic Review & Learning meeting (SRLM) under the Swedish presidency, Q2-Q3/2022

CAT: Lisbeth Barkholt, Martina Schuessler-Lenz

Scope: information about the upcoming SRLM in the Q2/Q3 of 2022

Action: for discussion

7.2. Coordination with EMA Scientific Committees

No items

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

7.3.1. Clarification on ATMP scientific advice and BWP interaction

Scope: to clarify the interactions with BWP on scientific advices and timing/role of CAT peer review

7.4. Cooperation with the EU regulatory network

7.5. Cooperation with international regulators

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

CAT: Martina Schuessler-Lenz

Scope: feedback from the teleconference that took place on 24 February 2022

Action: for information

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

CAT: Pille Säälik, Ivana Haunerova

Scope: Feedback from the international teleconference that took place on 10 March 2022

Action: for information

7.6. CAT work plan

No items

7.7. Planning and reporting

7.7.1. Planning estimates of forthcoming ATMP MAAs

Scope: Q1/2022 update of the business pipeline report for the human scientific committees

Action: for information

7.8. Others

7.8.1. Introducing DARWIN EU Coordination Centre and next steps for RWE

Action: for discussion

8. Any other business

No items

Date of next CAT meeting:

11-13/04/2022

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

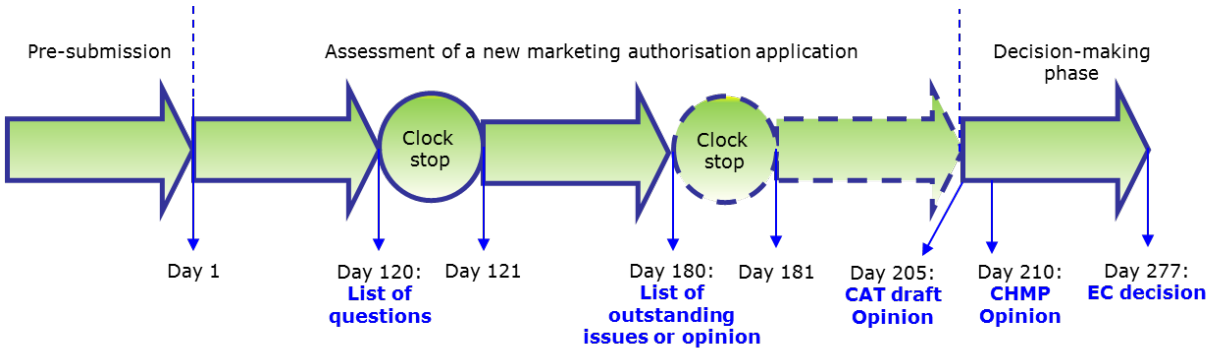
Evaluation of ATMPs (section 2)

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/