03 November 2021
EMA/CAT/618998/2021
Human Medicines Division

Committee for Advanced Therapies (CAT)

Draft agenda for the meeting on 03-05 November 2021

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

03 November 2021, 14:00 – 18:30, remote virtual meeting

04 November 2021, 09:00 – 18:30, remote virtual meeting

05 November 2021, 09:00 – 13:00, remote virtual meeting

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 03-05 November 2021. See November 2021 CAT minutes (to be published post December 2021 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 03-05 November 2021 meeting

1.3. Adoption of the minutes

CAT minutes for 06-08 October 2021 meeting

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

2.2.1. Eladocagene exuparvovec - Orphan - EMEA/H/C/005352

PTC Therapeutics International Limited; treatment of aromatic L-amino acid decarboxylase (AADC) deficiency

Scope: adoption of the list of outstanding issues

Action: for adoption

List of outstanding issues adopted on 16 April 2021

2.3. Day 180 list of outstanding issues

No items

2.4. Day 120 list of questions

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

Accelerated assessment

BioMarin International Limited; treatment of severe haemophilia 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

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

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

Scope: MAA's request for additional 9 months clock stop extension

Action: for adoption

D120 List of Questions adopted in February 2021

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. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0001/G

Celgene Europe B.V.

Rapporteur: Rune Kjeken

Scope: Quality. Opinion

Action: for adoption

2.11.2. Abecma - idecabtagene vicleucel - Orphan - EMEA/H/C/004662/II/0002

Celgene Europe B.V.

Rapporteur: Rune Kjeken

Scope: Quality. Request for Supplementary Information

Action: for adoption

2.11.3. Imlygic - talimogene laherparepvec - EMEA/H/C/002771/II/0047/G

Amgen Europe B.V.

Rapporteur: Heli Suila

Scope: Quality. Opinion

Action: for adoption

2.11.4. Yescarta - axicabtagene ciloleucel - 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. Request for Supplementary Information

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

2.11.5. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0019/G

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts

Scope: Quality. Request for Supplementary Information

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/ANX/002.1

Orchard Therapeutics (Netherlands) BV

Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege

Scope: Revised Protocol / LongTERM-MLD Study
In order to further characterise the long-term efficacy and safety of Libmeldy in children with late infantile or early juvenile forms of MLD, the MAH shall conduct and submit the results of a prospective study based on data from a registry, according to an agreed protocol.

Action: for adoption

2.13.2. Libmeldy - atidarsagene autotemcel - Orphan - EMEA/H/C/005321/REC/006

Orchard Therapeutics (Netherlands) BV

Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege

Scope: The applicant is recommended to confirm the linearity of the transgene (ARSA) activity assay independently of VCN. The ARSA activity of transduced cells will be diluted with non-transduced cells to demonstrate linearity. (recommendation #7)

Action: for adoption

2.13.3. Luxturna - voretigene neparvovec - Orphan - EMEA/H/C/004451/REC/007

Novartis Europharm Limited

Rapporteur: Sol Ruiz, CHMP Coordinator: Maria Concepcion Prieto Yerro

Scope: Medical Safety Risk and Impact assessment submitted as follow-up to the 'Communication concerning Novartis ophthalmic products associated with the Field Safety Notice issued by Becton Dickinson (BD, MPS-18-1209).

Action: for adoption

2.13.4. Withdrawal of the marketing authorisations for Zynteglo and Skysona

Bluebird bio.

Rapporteur (Zynteglo): Carla Herberts, CoRapporteur (Zynteglo): Violaine Closson-Carella, Rapporteur (Skysona): Lisbeth Barkholt, CoRapporteur (Skysona): Denmark

Scope: bluebird bio has decided to withdraw the MAs for Zynteglo and Skysona and also the PRIME bb-1111. The reason is commercial due to not being able to reach agreements on reimbursement.

Action: for information

Note: formal requests for the withdrawal of Skysona and Zynteglo will be submitted in late October and mid December 2021 respectively.

3. Certification of ATMPs

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

3.1. Opinion

No items

3.2. Day 60 Evaluation Reports

No items

3.3. New Applications

No items

4. Scientific Recommendation on Classification of ATMPs

Timetable:

-Start of the procedure:	22.11.2021
-EMA Coordinator's draft report:	19.11.2021
-CAT Coordinator's comments:	24.11.2021
-Revised scientific recommendation:	03.12.2021
-CAT's discussion of scientific recommendation:	10.12.2021

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Non-replicating recombinant adeno-associated virus serotype 2 (rAAV2) encoding a soluble form of human CD59 (sCD59)

Intended for the treatment of geographic atrophy (via targeting the complement pathway)

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.2. VTXM01 messenger RNA (mRNA) encoding for an adenine base editor (ABE) and VTXG01 guide RNA (gRNA) targeting the proprotein convertase subtilisin/kexin type 9 (PCSK9) serine protease gene

Intended for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) who require additional lowering of low-density lipoprotein cholesterol (LDL-C) despite maximally tolerated lipid-lowering therapy

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.1.3. Autologous anti-CD19 chimeric antigen receptor T-cells

Intended for the treatment of CD19-expressing B-cell malignancies

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

4.2. Day 30 ATMP scientific recommendation

4.2.1. CD 19 CAR T-cells transduced with lentiviral vector

Intended for the treatment of adults and children with B-cell non-Hodgkin's lymphoma and acute lymphoblastic leukemia. CD 19 CAR-T cell therapy will be used as first salvage in patients with primary refractory disease or in first relapse, after one line of systemic therapy, and with the presence of least one pre-defined high-risk feature

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Allogeneic adipose-derived mesenchymal stromal cells, ex-vivo expanded

Intended for the treatment of osteoarthritis, knee

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Recombinant adeno-associated virus, serotype 2, containing human ND4 codon-optimised gene (rAAV2-ND4) - EMA/PRIME/21/039

Treatment of Leber's hereditary optic neuropathy (LHON) associated with ND4 G11778A mutation

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Allogeneic T-cell precursors, mobilised peripheral blood-derived, ex vivo cultured

Intended for the treatment of paediatric and adult patients undergoing partially human leucocyte antigen (HLA) compatible allogeneic haematopoietic stem cell transplantation to accelerate adaptive immunological reconstitution

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

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

Intended for the treatment of multiple sclerosis

Scope: The European Commission raised no comments. ATMP scientific recommendation

Action: for information

4.5. Follow-up and guidance

4.5.1. Revision of the procedural advice on ATMP classification

Scope: Revision of the procedural advice to align to current practices

Action: for adoption

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:	25-28.10.2021
- Appointment of CAT Peer Reviewers:	03-05.11.2021
- SAWP first reports:	22.11.2021
- CAT Peer Reviewer comments:	26.11.2021
- Discussion at SAWP:	29.11-02.12.2021
- Discussion at CAT and feedback to SAWP:	10.12.2021

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	29.11–02.12.2021
- Appointment of CAT Peer Reviewers:	08-10.12.2021
- SAWP first reports:	03.01.2022
- CAT Peer Reviewer comments:	07.01.2022
- Discussion at SAWP:	10-13.01.2022
- Discussion at CAT and feedback to SAWP:	15.01.2022

5.2. Procedures discussed at SAWP – 1st reports, 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

6. Pre-Authorisation Activities

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

6.1. Paediatric investigation plans

No items

6.2. ITF briefing meetings in the field of ATMPs

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:

Procedure start:	28.10.2021
SAWP recommendation:	02/12/2021
CAT recommendation:	10/12/2021
CHMP adoption of report and final recommendation:	16/12/2021

6.3.2. Month 1 – Discussion of eligibility

6.3.3. Month 2 – Recommendation of eligibility

6.3.4. Ongoing support

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

No items

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: feedback from the meeting

Action: for information

7.1.4. Joint CAT-CHMP Strategic Review & Learning (virtual) meeting (SRLM) under the Portuguese presidency, 27 May 2021, Lisbon (Portugal)

CAT: Bruno Sepodes, Maria Isabel Vieira

Scope: minutes of the joint CAT-CHMP session

Action: for information

7.2. Coordination with EMA Scientific Committees

7.2.1. CHMP learning with relevance to CAT

CAT: Romaldas Maciulaitis

Scope: Topics from the October CHMP PROM with relevance to CAT decisions: (1) Structured guidance on reflection of use of extrapolation - development of an assessor's guidance template; (2) ICH E8(R1) step 5 - General considerations for clinical studies

Action: for information

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

7.3.1. Scientific advice for ATMPs

Scope: Review of the new procedure for SA for ATMPs that was implemented in February 2021

Action: for discussion

7.3.2. Call for interest for nomination of CAT members to join the subgroup "GCP inspection outcomes in support of B/R evaluation"

Scope: to review current inspections procedures to enhance Inspector assessor information flow and understanding

Survey to better understand the expectations of assessors regarding Integrated Inspection Reports to be launched.

Interested members should contact EMA responsible colleagues by 12 November 2021

Action: for information

7.3.3. Call for interest for nomination of CAT members to join Advisory Group on Raw Data on Lifecycle Regulatory Submissions Raw Data

Scope: Call for interest for nomination of CHMP members to join Advisory Group on Raw Data in order to assist the design of the future proof-of-concept raw data pilot (estimated to kick-off on April 2022).

EMA's Lifecycle Regulatory Submissions Raw Data project is focusing on utilising raw data to generate evidence for better and more efficient regulatory decision making.

This project is part of the Data Analytics Programme also known as the Agency's vehicle for evolving to data-driven medicines regulation and constitutes one of the priority recommendations of the EMA-HMA Big Data Taskforce.

Interested members should contact EMA responsible colleagues by 10 November 2021.

Action: for information

7.3.4. Guideline on registry-based studies

Action: for information

Note: The guideline on registry-based studies has now been published. This new guideline is based on a discussion paper on methodological and operational aspects for use in patient registries for regulatory purposes, which was available for a public consultation that generated almost 1,000 comments from 68 stakeholder organisations. Experience gained from CHMP qualification opinions on two networks of registries and input collected during five workshops on specific patient registries organised by the Agency helped shape the final guidance.

LINK to the News Item – LINK to the Guideline

7.4. Cooperation with the EU regulatory network

7.4.1. Update on the Companion Diagnostics (CDx) consultation procedure

Scope: To provide an update on interactions of CHMP-CAT-EMA experts with Notified Bodies (NBs) to develop the NB consultation procedure on CDx suitability with EMA. EMA guidance on CDx consultation and CHMP AR CDx consultation have been reviewed. Comments to be provided by 17th November 2021

Action: for discussion

7.4.2. Pharma legislation revision - Core definition concept paper

CAT: Ilona Reischl

Scope: Gene Therapy definition; Interplay between vaccines and ATMP; Tailored medicines and platform MA; Industrial process.

Action: for discussion

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

CAT: Martina Schüssler-Lenz

Scope: Feedback from discussions with the European Commission

Action: for information

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 14 October 2021

Action: for information

7.6. CAT work plan

7.6.1. CAT work plan 2022

CAT: Martina Schuessler-Lenz

Scope: identification of work plan topics for 2022

Action: for discussion

7.7. Planning and reporting

None

7.8. Others

7.8.1. CAT stakeholder meeting on 26 October 2021

CAT: Martina Schuessler-Lenz

Scope: feedback from the meeting

Action: for discussion

7.8.2. European Society of Gene and Cell Therapy (ESGCT)

CAT: Alessandro Aiuti

Scope: feedback from the meeting that took place on the 19-22 October 2021

Action: for information

8. Any other business

Date of next CAT meeting:

08-10/12/2021

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 #

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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

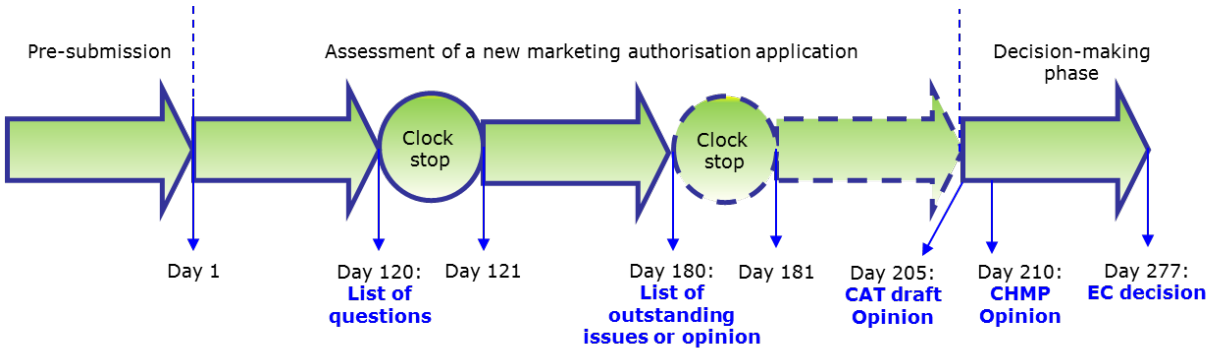
Evaluation of ATMPs (section 2)

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.

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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.

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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/