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SCIENCE MEDICINES HEALTH

13 July 2020
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Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for Advanced Therapies (CAT)

Agenda for the meeting on 15-17 July 2020

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

15 July 2020, 14:00 – 18:30, virtual meeting

16 July 2020, 09:00 – 13:30, virtual meeting

17 July 2020, 09:00 – 13:00, 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 15-17 July 2020. See July 2020 CAT minutes (to be published post-September 2020 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 15-17 July 2020 meeting

1.3. Adoption of the minutes

CAT minutes for 17-19 June 2020 meeting

2. Evaluation of ATMPs

2.1. Opinions

No items

2.2. Oral explanations

No items

2.3. Day 180 list of outstanding issues

No items

2.4. Day 120 list of questions

No items

2.5. Day 80 assessment reports

No items

2.6. Update on ongoing initial applications

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

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

Scope: letter from the applicant dated 10 July 2020 requesting an extension of clock stop

to respond to the list of outstanding issues adopted in June 2019

Action: for adoption

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 - variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

2.11.1. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0025

Novartis Europharm Limited

Rapporteur: Rune Kjekken

Scope: Quality.

Action: for adoption

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

No items

3. Certification of ATMPs

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

3.1. Opinion

No items

3.2. Day 60 Evaluation Reports

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

No items

4.2. Day 30 ATMP scientific recommendation

4.2.1. Recombinant adeno-associated viral vector (serotype 8) carrying an optimised gene for human cyclic nucleotide gated channel subunit alpha 3 (CNGA3) protein – H0005726

Intended for the treatment of achromatopsia caused by mutations in the CNGA3 gene

Scope: ATMP scientific recommendation

Action: for adoption

4.2.2. Irradiated allogeneic induced-pluripotent stem cells expressing pluripotent genes and cancer-specific embryonic neo-antigens – H0005108/0002

Intended for the treatment malignant solid tumours including all epithelial cancers in sub-group type harbouring a stemness mesenchymal-like signature and haematopoietic malignancies

Scope: ATMP scientific recommendation

Action: for adoption

4.2.3. Autologous naïve regulatory T cells transduced with a lentiviral vector encoding for a Chimeric Antigen Receptor (CAR) to recognize the HLA-A*02 antigen - H0005713

Intended for the prevention of immune-mediated graft rejection in HLA-A*02 mismatched renal transplantation

Scope: ATMP scientific recommendation

Action: for adoption

4.2.4. Live-attenuated, genetically modified Mycobacterium bovis expressing the gene coding for listeriolysin from Listeria monocytogenes – H0005714

Intended for treatment of non-muscle invasive bladder cancer

Scope: ATMP scientific recommendation

Action: for adoption

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

4.3.1. Autologous adipose-derived mesenchymal stem cell , diabetic foot syndrome - H0005699

Intended for the treatment of diabetic foot syndrome

Scope: awaiting responses from the applicant to the LoQs. Revised ATMP scientific recommendation

Action: for adoption

4.4. Finalisation of procedure

4.4.1. Allogeneic CD34+-enhanced cell suspension derived from umbilical cord blood – H0005712

Intended for the treatment of patients with inherited metabolic disorders [cerebral adrenoleukodystrophy, Hurler syndrome] where haematopoietic stem cell transplant is indicated

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

Action: for information

4.4.2. Aggregates of defined size of human embryonic stem cell derived insulin secreting pancreatic beta cells, encapsulated within an encapsulation device – H0005721

Intended for the treatment of type I diabetes mellitus

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

Action: for information

4.4.3. Homogenate of antlerogenic stem cells – H0005710

Intended for the treatment of chronic obstructive pulmonary disease, bronchial asthma

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

Action: for information

4.4.4. Autologous adipose-derived mesenchymal stem cells, cartilage lesions – H0005700

Intended for the treatment of cartilage lesions

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

Action: for information

4.4.5. Wharton's jelly derived mesenchymal cells, myelitis – H0005701

Intended for the treatment of myelitis

Scope: the European Commission raised no comments. ATMP scientific recommendation
Action: for information

4.4.6. Wharton's jelly derived mesenchymal cells, meningitis – H0005693

Intended for the treatment of meningitis
Scope: the European Commission raised no comments. ATMP scientific recommendation
Action: for information

4.4.7. Wharton's jelly derived mesenchymal cells, meningomyelocele – H0005704

Intended for the treatment of meningomyelocele, myelomeningocele, spina bifida
Scope: the European Commission raised no comments. ATMP scientific recommendation
Action: for information

4.4.8. Wharton's jelly derived mesenchymal cells, cerebellum syndrome - H0005705

Intended for the treatment of cerebellum syndrome
Scope: the European Commission raised no comments. ATMP scientific recommendation
Action: for information

4.4.9. Wharton's jelly derived mesenchymal cells, encephalitis - H0005706

Intended for the treatment of encephalitis
Scope: the European Commission raised no comments. ATMP scientific recommendation
Action: for information

4.4.10. Wharton's jelly derived mesenchymal cells, Krabbe disease - H0005707

Intended for the treatment of Globoid cell leukodystrophy (Krabbe disease)
Scope: the European Commission raised no comments. ATMP scientific recommendation
Action: for information

4.4.11. Wharton's jelly derived mesenchymal cells, osteoarthritis – H0005708

Intended for the treatment of osteoarthritis
Scope: the European Commission raised no comments. ATMP scientific recommendation
Action: for information

4.4.12. Wharton's jelly derived mesenchymal cells, spinal and bulbar muscular atrophy – H0005709

Intended for the treatment of spinal and bulbar muscular atrophy
Scope: the European Commission raised no comments. ATMP scientific recommendation
Action: for information

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

Next deadline for submission of Letters of Intent: 17 July 2020. New requests will be included in draft 1 of the September 2020 CAT meeting.

Timetable:

-Appointment of peer reviewers:	11.09.2020
-SAWP coordinators' reports:	21.09.2020
-Peer review comments on SAWP coordinators' reports:	25.09.2020
-CAT discussion:	7-9.10.2020

5.2. CAT reports

5.3. List of Issues

5.4. Finalisation of SA procedures

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:	09.07.2020
SAWP recommendation:	03.09.2020
CAT recommendation:	11.09.2020
CHMP adoption of report and final recommendation:	17.09.2020

6.3.2. Month 1 – Discussion of eligibility

6.3.3. Month 2 – Recommendation of eligibility

No items

6.3.4. Ongoing support

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT's August 2020 written procedure

Scope: August 2020: process and timelines

Action: for adoption

7.1.2. Strategic Review & Learning (virtual) meeting (SRLM) under the German presidency, 22nd October 2020

CAT: Martina Schübler-Lenz, Egbert Flory

Scope: topics for the SRLM agenda:

Morning session: CAT-PDCO-PRAC joint meeting

Afternoon session: CAT-only meeting

Action: for discussion

7.2. Coordination with EMA Scientific Committees

7.2.1. CAT-PDCO interaction

CAT: Martina Schübler-Lenz

Scope: improvement of CAT-PDCO interaction

Action: for discussion

7.2.2. CAT-COMP interaction

CAT, core members: Kieran Breen, Carla Herberts, Maura O'Donovan, Maja Sommerfelt, Martina Schübler-Lenz

Scope: feedback from the CAT-COMP working group of 13 July 2020

Action: for information

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

7.3.1. Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells

CAT Rapporteurs: Marcos Timón, Tiina Palomäki, Martina Schübler-Lenz

Scope: revision incorporating the comments received during the public consultation

Action: for discussion

Note: the non-clinical part will be presented by Brigitte Anliker, on behalf of the non-clinical drafting group

7.3.2. White paper from Alliance of Regenerative Medicine: Use of Master Files and certification schemes for ATMP Manufacturing in Europe

BWP: Sol Ruíz

Scope: feedback from the BWP discussion that took place at its June 2020 meeting

Action: for information

7.4. Cooperation within the EU regulatory network

7.4.1. European Commission's initiative on GMO requirements for medicines used for treatment/prevention of COVID-19

Scope: oral feedback from the European Commission's representative

Action: for information

The European Commission representative presented to CAT at its June 2020 meeting the draft Regulation on the application of certain aspect of the GMO legislation to medicinal product against COVID-19. The explanatory memorandum of the Commission Proposal also includes the Commission's interpretation on the interplay between the GMO and medicinal product legislation in case of medicines used under compassionate use authorisation.

7.4.2. Regulatory status of RNA products in the context of vaccines against COVID-19

Scope: European Commission's feedback and possible implications for ATMPs

Action: for information

7.4.3. Inspection of manufacturers of viral vectors used as starting materials for genetically modified cells

Scope: updates on the inspection of manufacturers of viral vectors used as starting materials for genetically modified cells

Action: for discussion

7.4.4. Viral vectors used in the production of genetically modified cells - principles of GMP

CAT: Martina Schüssler-Lenz

Scope: call for a drafting group to define '*Principles of GMP*'

Action: for nomination

7.4.5. Good Clinical Practice (GCP) – 2020 inspections strategy

Action: for information

7.4.6. European Union Network-Pharmacovigilance Oversight Group (EU-POG)

Scope: nomination received from CAT member Maura O'Donovan to join the EU-POG.

Action: for adoption

Note: former CAT member was Corina Spreitzer who resigned in March 2020

7.5. Cooperation with international regulators

7.5.1. ATMP cluster teleconference with FDA-USA, Health Canada and PMDA-Japan

CAT: Martina Schüssler-Lenz

Scope: agenda for the teleconference to take place on 23 July 2020

Action: for discussion

7.6. CAT work plan

7.6.1. CAT work plan 2020

CAT: Martina Schüssler-Lenz

Scope: overview of status of the 2020 work plan topic

Action: for discussion

7.7. Planning and reporting

No items

7.8. Others

7.8.1. Fee waiver for Scientific Advice for academia developing orphan medicines

Action: for information

<https://www.ema.europa.eu/en/news/academia-developing-medicines-rare-diseases-receive-free-ema-scientific-advice>

8. Any other business

8.1. DIA Europe, virtual meeting, 29 June-03 July 2020

CAT: Martina Schüssler-Lenz

Scope: feedback on the contribution as panellist in the session on 2nd July: '*Bringing down barriers for access for gene and cell therapies in Europe*'

Action: for information

8.2. 2nd Joint DIA-EUCOPE workshop on ATMPs, Innovative Gene and Cell Therapies in the EU, virtual meeting, 27-28 May 2020

CAT: Ilona Reischl

Scope: feedback on the workshop

Action: for information

<https://www.diaglobal.org/en/conference-listing/meetings/2020/06/cell-and-gene-therapy-workshop>

8.3. CASSS: Cell and Gene Therapy Products, virtual symposium, 8-10 June 2020

CAT: Ilona Reischl

Scope: feedback on the contribution as session chair: '*Accelerated development*'

Action: for information

Date of next CAT meeting:

09-11/09/2020

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

MSC: Mesenchymal stem cells

PDCO: Paediatric Committee

PMDA(Japan)

PIP: Paediatric Investigation Plan

PL: Package leaflet

PRAC: Pharmacovigilance and Risk Assessment Committee #

PRIME: Priority Medicines

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: Scientific Working Party
 SME: Small and medium size enterprises
 SmPC: Summary of Products Characteristics
 TT: Timetable

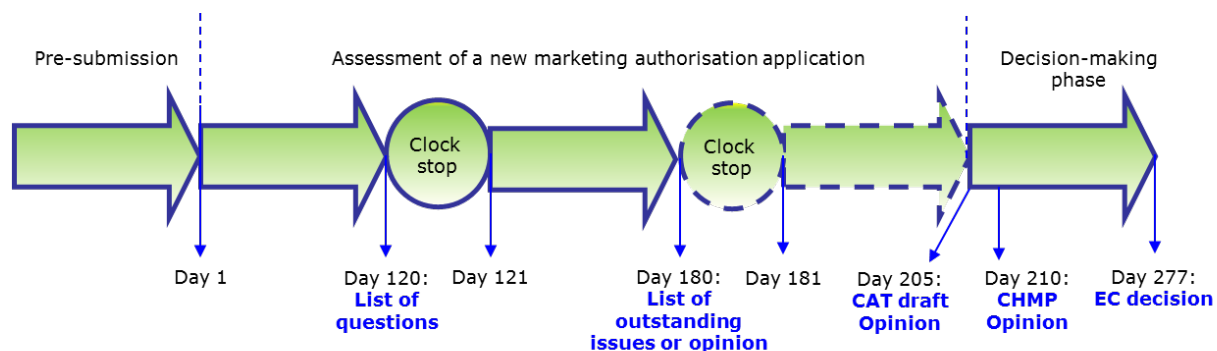
Evaluation of ATMPs (section 2)

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/