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SCIENCE MEDICINES HEALTH

06 December 2017  
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Inspections, Human Medicines Pharmacovigilance and Committees Division

## Committee for Advanced Therapies (CAT)

Agenda for the meeting on 06-08 December 2017

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

06 December 2017, 14:00 – 19:00, room 03-F

07 December 2017, 08:30 – 18:30, room 03-F

08 December 2017, 08:30 – 13:00, room 03-F

### 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 06-08 December 2017. See December 2017 CAT minutes (to be published post-January 2018 CAT meeting).

### 1.2. Adoption of agenda

CAT agenda for 06-08 December 2017 meeting

### 1.3. Adoption of the minutes

CAT minutes for 30-31 October 2017 meeting

### 1.4. Technical information

## 2. Evaluation of ATMPs

### 2.1. Opinions

#### 2.1.1. Expanded human allogeneic mesenchymal adult stem cells extracted from adipose tissue - Orphan - EMEA/H/C/004258

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Tigenix, S.A.U.; treatment of complex perianal fistula(s)

Scope: Oral explanation/Opinion

**Action:** for adoption

### 2.2. Oral explanations

No items

### 2.3. Day 180 list of outstanding issues

No items

### 2.4. Day 120 list of questions

#### 2.4.1. Voretigene neparvovec - Orphan - EMEA/H/C/004451

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Spark Therapeutics Ireland Ltd; treatment of patients with vision loss due to leber congenital amaurosis or retinitis pigmentosa inherited retinal dystrophy

Scope: Day 120 list of questions

**Action:** for adoption

#### 2.4.2. Axicabtagene ciloleucel - Orphan - EMEA/H/C/004480

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Kite Pharma EU B.V.; treatment of B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL) and transformed follicular lymphoma (TFL)

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

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

#### 2.7.1. Tisagenlecleucel-T - Orphan – H0004090

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Novartis Europharm Ltd.; Indicated for:

-the treatment of paediatric and young adult patients 3 to 25 years of age with relapsed or refractory B-cell acute lymphoblastic leukemia (ALL).

-the treatment of adult patients with relapsed or refractory diffuse large B cell lymphoma (DLBCL) who are ineligible for autologous stem cell transplant

Scope: timetable for accelerated assessment

**Action:** for adoption

### 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. MACI - matrix applied characterised autologous cultured chondrocytes - EMEA/H/C/002522/II/0014/G

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Vericel Denmark ApS

Rapporteur: Christiane Niederlaender, CHMP Coordinator: Greg Markey

Scope: Quality: RSI.

**Action:** for adoption

## 2.12. 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

### 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 dendritic cells pulsed with allogeneic tumour cell lysate - H0004949

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Intended for the treatment of malignant mesothelioma

Scope: appointment of CAT Coordinator and adoption of timetable

**Action:** for adoption

#### 4.1.2. Allogeneic mesenchymal stem cells suspended in cell supernatant - H0004952

---

Intended for the treatment of osteoarthritis

Scope: appointment of CAT Coordinator and adoption of timetable

**Action:** for adoption

## 4.2. Day 30 ATMP scientific recommendation

### 4.2.1. Autologous CD34<sup>+</sup> cells derived from bone marrow - H0004941

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Intended for the improvement of neurologic function in patients with non-lacunar acute ischemic stroke infarctions

Scope: scientific recommendation

**Action:** for adoption

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

### 4.3.1. Stromal vascular fraction (SVF) – H0004926

---

Intended to diminish cancer-related lymphedema in breast cancer patients

Scope: revised scientific recommendation

**Action:** for adoption

## 4.4. Finalisation of procedure

### 4.4.1. CD1c (BDCA1)+ myeloid dendritic cells (myDC) - H0004927

---

Intended for the treatment of patients with advanced, pretreated solid tumours with injectable metastases

Scope: comments received by the European Commission. Final revised ATMP scientific recommendation

**Action:** for adoption

### 4.4.2. Genetically modified epithelial cells (factor IX), encapsulated – H0004928

---

Intended for the treatment of haemophilia B

Scope: no comments received by the European Commission. Final ATMP scientific recommendation

**Action:** for information

## 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

Timetable:

-Final Briefing Package:	03.01.18
-Start of the procedure at SAWP:	08-11.01.18
-CAT report due by:	09.02.18
-CAT recommendation:	16.02.18

## 5.2. CAT reports

## 5.3. List of Issues

No items

## 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

Timetable for assessment:

Procedure start:	30.11.17.
SAWP recommendation:	11.01.18.
CAT recommendation:	19.01.18.
CHMP adoption of report and final recommendation:	25.01.18.

### 6.3.1. Month 1 – Discussion of eligibility

### 6.3.2. Month 2 – Recommendation of eligibility

### 6.3.4. Month 3 – Nomination of Rapporteurs

### 6.3.5. Ongoing support

No items

## 7. Organisational, regulatory and methodological matters

### 7.1. Mandate and organisation of the CAT

#### 7.1.1. Strategic Review & Learning meeting – Tallinn, Estonia, 15-17 November 2017

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Scope: CAT Strategic Review & Learning meeting (SRLM)

CAT: Martina Schübler-Lenz, Toivo Maimets

Scope: feedback from the meeting that took place on 15-17 November 2017

**Action:** for information

#### 7.1.2. CAT membership

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Scope: CHMP/CAT membership: new three-year mandate: Germany, Lithuania, Malta Portugal, Spain

**Action:** for nomination

### 7.2. Coordination with EMA Scientific Committees

#### 7.2.1. Committee for Medicinal Products for Human Use (CHMP)

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Scope: Summary of Outcomes (SoO) for the November 2017 meeting

**Action:** for information

#### 7.2.2. Procedural advice on the evaluation of advanced therapy medicinal products

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Scope: final updated procedural advice for ATMP

**Action:** for adoption

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

#### 7.3.1. Guideline on requirements for investigational ATMPs

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Drafting group: Ilona Reischl (Rapporteur), Tiina Palomäki (Rapporteur), Simona Badoi, Tomáš Boráň, Violaine Closson-Carella, Paolo Gasparini, Carla Herberts, Metoda Lipnik-Stangelj, Margarida Menezes Ferreira, Christiane Niederlaender, Maura O'Donovan, Olli Tenhunen, Guido Pantè, Marcel Hoefnagel

Scope: progress on the development of the guideline following a meeting to take place on 6<sup>th</sup> December 2017 to discuss the quality, non-clinical and clinical sections

**Action:** for information

#### 7.3.2. ATMP guideline on safety and efficacy follow-up and risk management

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Drafting group: Maura O'Donovan, Sol Ruiz, Tomas Boráň, Romaldas Mačiulaitis

**Action:** for adoption

Note: the guideline has been adopted by PRAC and reviewed by the Guideline Consistency Group

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

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Scope:

PCWP and HCPWP:

-Report on the information session on antimicrobial resistance – 19 September 2017

-Minutes of the PCWP-HCPWP meeting – 20 September 2017

-Agenda – training session for patients, consumers and healthcare professionals interested in EMA activities – 21 November 2017

PCWP:

-Agenda of the PCWP meeting with all eligible organisations - 22 November 2017

**Action:** for information

## 7.4. Cooperation within the EU regulatory network

### 7.4.1. Orphan similarity for ATMPs

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CAT drafting group: Simona Badoi, Violaine Closson-Carella, Michele Lipucci, Margarida Menezes-Ferreira, Christiane Niederlaender, Ilona Reischl

Scope: Reflection from the perspective of ATMPs on the concept of 'similar active substance' as referred to in Art 3(3)c of Reg (EC) No 847/2000 of April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concept 'similar medicinal product' and 'clinical superiority'. Review of additional comments received during the consultation on the draft regulation.

**Action:** for discussion

## 7.5. Cooperation with international regulators

No items

## 7.6. CAT work plan

### 7.6.1. CAT 2018 work plan

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CAT: Martina Schübler-Lenz

Scope: CAT 2018 work plan

**Action:** for adoption

### 7.6.2. Registry requirements for chimeric antigen receptor T (CAR-T) cells

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CAT: Martina Schübler-Lenz

Scope: feedback on the activities

**Action:** for information

Note: this will be a cross-committee activity, involving members/experts from CAT, SAWP, PRAC, CHMP and PDCO.

## 7.7. Planning and reporting

No items

## 7.8. Others

### 7.8.1. European Biopharmaceutical Enterprises (EBE), 2017 annual conference, 5 December 2017, London, UK

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CAT: Martina Schüssler-Lenz

Scope: feedback on the participation of EMA and CAT to the EBE's sixth annual regulatory conference: *'Realising the potential of advanced therapies for patients'*

**Action:** for information

## 8. Any other business

No items

Date of next CAT meeting:

17-19 January 2018

## 9. Explanatory notes

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

### Abbreviations / Acronyms

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

ERA: Environmental Risk Assessment

FDA: Food and Drug Administration

FL: Final Letter

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Genetically-modified organism

GMP: Good Manufacturing Practice

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 Applicant

MAH: Marketing Authorisation Holder

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

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  
 SB: Significant benefit  
 SR: Summary Report  
 SWP: Scientific Working Party  
 SME: Small and medium size enterprises  
 SmPC: Summary of Products Characteristics  
 TT: Timetable

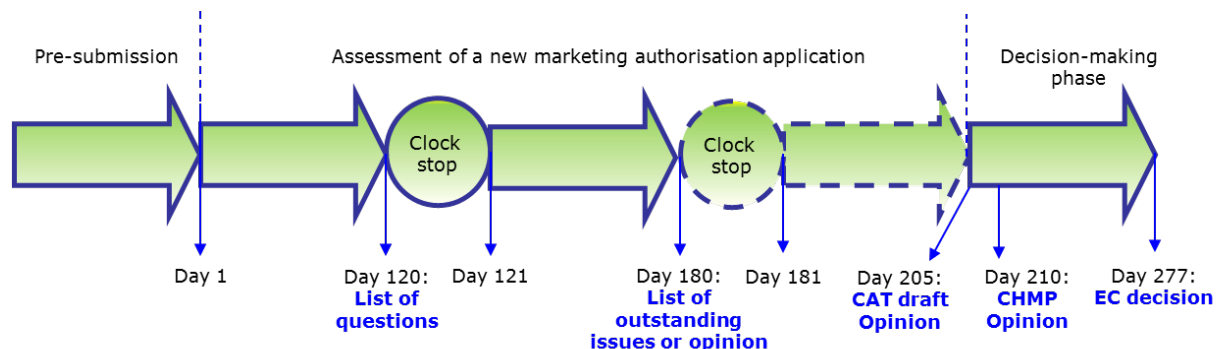
## Evaluation of ATMPs (section 2)

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/](http://www.ema.europa.eu/)