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SCIENCE MEDICINES HEALTH

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Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 20-22 January 2021

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

Disclaimers

Some of the information contained in these minutes are considered commercially confidential or sensitive and therefore not disclosed. Regarding 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, these minutes are a working document primarily designed for CAT members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes 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 ongoing 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

The Chairperson opened the meeting by welcoming all participants. Due to the current coronavirus (COVID-19) outbreak, and the associated EMA Business Continuity Plan (BCP), the meeting was held remotely.

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

The CAT chair welcomed Maria Gazouli, the new member for Greece, and Babs Fabriek, the new alternate for the Netherlands. The CAT chair also thanked Mirna Golemović and Felicia Costinescu, whose mandates ended on 1 January 2021 and Asterios Tsiftoglou, whose mandate ended on 14 January 2021, for their contributions to the CAT over the last years.

1.2. Adoption of agenda

The CAT agenda for 20-22 January 2021 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes for 02-04 December 2020 meeting were adopted.

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

2.4.1. Autologous glioma tumor cells, inactivated / autologous glioma tumor cell lysates, inactivated / allogeneic glioma tumor cells, inactivated / allogeneic glioma tumor cell lysates, inactivated - Orphan - EMEA/H/C/003693

Epitopoietic Research Corporation-Belgium (E.R.C.); treatment of glioma

Scope: Day 120 list of questions

Action: for adoption

The Rapporteurs presented the assessment of the marketing authorisation application.

CAT adopted the list of question and the response timetable.

2.4.2. Elivaldogene autotemcel - Orphan - EMEA/H/C/003690

Accelerated assessment

bluebird bio (Netherlands) B.V; treatment of ABCD1 genetic mutation and cerebral adrenoleukodystrophy

Scope: Day 120 list of questions

Action: for adoption

The Rapporteurs presented the assessment of the marketing authorisation application.

CAT adopted the list of questions. The accelerated assessment was maintained. The evaluation timetable was adopted.

2.5. Day 80 assessment reports

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

GenSight Biologics S.A.; treatment of vision loss due to Leber Hereditary Optic Neuropathy (LHON)

Scope: Day 80 assessment report

Action: for information

The list of questions will be discussed at the February CAT meeting. No further information was provided.

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

2.11. Type II variations and variations of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

2.11.1. Alofisel - darvadstrocel - Orphan - EMEA/H/C/004258/II/0021

Takeda Pharma A/S

Rapporteur: Lisbeth Barkholt

Scope: Quality

Action: for adoption

CAT adopted the opinion for this variation.

2.11.2. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/II/0030

Novartis Europharm Limited

Rapporteur: Rune Kjekken

Scope: Clinical

Update of section 5.1 of the SmPC to include the complete data set (updated overall survival analysis) of study CCTL019B2205J, a Phase II, single arm, multicentre study to determine the efficacy and safety of Kymriah in paediatric subjects with relapsed or refractory B-cell acute lymphoblastic leukaemia (ALL). The clinical results have already been assessed in procedure EMA/H/C/004090/P46/011.

In addition, the final ATC code for tisagenlecleucel (L01XX71) has been added as an editorial change.

Action: for adoption

CAT adopted a request for supplementary information for this variation.

2.11.3. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0030

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

CAT adopted a request for supplementary information for this variation.

2.11.4. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0031

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

CAT adopted a request for supplementary information for this variation.

2.11.5. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/II/0033

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality

Action: for adoption

CAT adopted the opinion for this variation.

2.11.6. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0007/G

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts

Scope: Quality

Action: for adoption

Request for Supplementary Information adopted on 06.11.2020.

CAT adopted the opinion for this variation.

2.11.7. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0008

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts

Scope: PhV

Update of sections 4.4 (special warnings and precautions for use), 4.8 (Undesirable Effects) of the SmPC and corresponding sections in the Package Leaflet to add a new safety signal of 'thrombotic microangiopathy'

Action: for adoption

Request for Supplementary Information adopted on 4.12.2020

This procedure is ongoing and scheduled to finalise at the February CAT.

2.11.8. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/II/0009/G

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts

Scope: Quality

Action: for adoption

Request for Supplementary Information adopted on 04.12.2020.

CAT adopted the opinion for this variation.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Options paper on using the European Society for Blood & Marrow Transplantation (EBMT) as a data source for long-term safety and efficacy follow-up of EU patients receiving ATMPs

Scope: EMA update and discussion on possible ways forward and preferred option

Action: for discussion

EMA presented to options paper. CAT members were asked to send their input (indication of their preferred option) by 4 February 2021. This will be further discussed in the February PRAC and CAT meetings.

2.13.2. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/ANX/003.3

Novartis Europharm Limited

Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang

Scope: PhV

Non-interventional post-authorisation safety study (PASS):

In order to further characterise the safety - including long-term safety - of Kymriah, the applicant should conduct and submit a study based on data from disease registry CCTL019B2401 in acute lymphoblastic leukaemia (ALL) and diffuse large B-cell lymphoma (DLBCL) patients. (Cat. 1).

Submission and evaluation of European Society for Blood & Marrow Transplantation (EBMT) safety data from the first semi-annual status report: 23-Apr-2020). Assessment of MAH responses, dated 26-Oct-2020, to the Rapporteurs' clarifications and additional data to be presented in the next reports.

Action: for adoption

CAT adopted the Rapporteurs assessment report.

2.13.3. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/ANX/006.1

Novartis Europharm Limited

Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang

Scope: Clinical

Submission of the annual interim report for Study No. CCTL019B2401:

Post-authorisation efficacy study (PAES): In order to further evaluate the efficacy and safety of Kymriah in acute lymphoblastic leukaemia (ALL) patients below the age of 3 years, the applicant should conduct and submit a study based on data from a disease registry in ALL patients.

Action: for adoption

CAT adopted the Rapporteurs assessment report.

2.13.4. Kymriah - tisagenlecleucel - Orphan - EMEA/H/C/004090/ANX/009.3

Novartis Europharm Limited

Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang

Scope: Clinical

Submission of a revised protocol (protocol amendment 2) for Study No. CTL019H2301MAH (BELINDA) as a response to ANX-009.2 (adopted in August 2020) where the MAH was asked to address the following points:

1. To provide an additional analysis to time to remission (TTR) where the response time for patients who achieved either a confirmed complete or partial remission is determined.
 2. One of the new updates in the protocol states the following «The crossover visit would also mark the end of the treatment and primary follow-up visit for patients in Arm B». It is unclear whether patients who are crossing over to the tisagenlecleucel arm also will be followed-up for survival. However, this should be ensured.
- The 1st study results will be provided by June 2021 in ANX-9.3.

Action: for adoption

CAT adopted the Rapporteurs assessment report.

2.13.5. Yescarta - axicabtagene ciloleucel - Orphan - EMEA/H/C/004480/ANX/002.1

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus, CHMP Coordinator: Jan Mueller-Berghaus

Scope: Pharmacovigilance

PASS 107 - Non-Interventional Registry Study to further evaluate and characterise the identified risks, potential risks and missing information: first quarterly Safety Data Report

Action: for adoption

CAT adopted the Rapporteurs assessment report.

2.13.6. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/ANX/002.1

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts, CHMP Coordinator: Johann Lodewijk Hillege

Scope: Clinical & Pharmacovigilance

Post-authorisation efficacy study - Study no. AVXS-101-RG-001 [ANX-002] as requested in September 2020.

Action: for adoption

CAT adopted the Rapporteurs assessment report (PAES protocol).

2.13.7. Zolgensma - onasemnogene abeparvovec - Orphan - EMEA/H/C/004750/R/0012

Novartis Gene Therapies EU Limited

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

Scope: 1-year Renewal of Marketing Authorisation. List of Questions.

Action: for adoption

The Rapporteur presented the assessment of the data submitted for this first renewal. Questions have been raised.

The list of questions was adopted. The renewal opinion is expected in March 2021.

2.13.8. Zynteglo - betibeglogene autotemcel - Orphan - EMEA/H/C/003691/R/0018

bluebird bio (Netherlands) B.V

Rapporteur: Carla Herberts, PRAC Rapporteur: Brigitte Keller-Stanislawski

Scope: 1-year Renewal of Marketing Authorisation

Action: for adoption

The Rapporteur presented the assessment of the dossier for the second renewal. Some questions have been raised and amendments to the product information will be implemented.

The list of questions was adopted. The renewal opinion is expected in February 2021.

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:	22.01.2021
-Draft EMA Co-ordinator's report:	05.02.2021
-CAT Coordinator's comments:	10.02.2021
-Revised scientific recommendation:	12.02.2021
-Discussion of scientific recommendation by CAT:	19.02.2021

4.1. New requests – Appointment of CAT Coordinator

4.1.1. Allogeneic human mesenchymal stem cells derived from Wharton's jelly, muscle and tendons disease

Intended for diseases of muscles and tendons

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.2. Allogeneic human mesenchymal stem cells derived from Wharton's jelly, anal fistula

Intended for the treatment of anal fistula

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.3. Allogeneic human mesenchymal stem cells derived from Wharton's jelly, androgenic alopecia

Intended for the treatment of androgenic alopecia, unspecified

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.4. Allogeneic human mesenchymal stem cells derived from Wharton's jelly, diabetic foot syndrome

Intended for the treatment of diabetic foot syndrome (DFS)

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.5. Allogeneic human mesenchymal stem cells derived from Wharton's jelly, Parkinson's disease

Intended for the treatment of Parkinson's disease

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.6. Allogeneic human mesenchymal stem cells derived from Whartons jelly seeded on the dermal scaffold, skin ulcers

Intended for the treatment of skin ulcers

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.7. Autologous human mesenchymal stem cells derived from adipose tissue, anal fistula

Intended for the treatment of anal fistula

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.8. Autologous human mesenchymal stem cells derived from adipose tissue, androgenic alopecia

Intended for the treatment of androgenic alopecia, unspecified

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.9. Autologous human mesenchymal stem cells derived from adipose tissue muscle and tendons disease

Intended for diseases of muscles and tendons

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.10. Two mRNA active substances, encoding separately for Human Papilloma Virus type (HPV) 16 E6 and HPV16 E7 protein

Intended for the treatment of recurrent/metastatic HPV16-positive carcinoma

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.11. Human amniotic membrane, allogeneic, sterile, cryomilled and lyophilized

Intended for the treatment of symptoms of osteoarthritis

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.12. Autologous dendritic cells activated against SARS-COV-2 peptides

Intended for the prevention of SARS-COV-2 infection

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.13. Human umbilical cord MSC derived exosomes carrying recombinant hTERT mRNA and protein, hsa-miR-125b-5p, hsa-miR-125b-1-3p, AntimiR-21-5p

Intended for the treatment of Acute Respiratory Distress Syndrome and Chronic Obstructive Respiratory Disease

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.14. DNA plasmid encoding human transferring gene

Intended for the treatment of retinitis pigmentosa

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.1.15. Bacteriophage cocktail consisting of four CRISPR-armed phages

Intended for the treatment of prophylaxis of bloodstream E. coli infection in neutropenic patients with haematological malignancy

Scope: appointment of CAT Coordinator and adoption of timetable

Action: for adoption

The CAT coordinator was appointed.

4.2. **Day 30 ATMP scientific recommendation**

4.2.1. Autologous bone marrow aspirate concentrate

Intended for the repair mechanism for bone repair in a variety of bony defects such as fractures, arthroplasty, bone cysts, osteonecrosis, or avascular necrosis

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 5 February 2021.

4.2.2. In vitro expanded autologous human articular chondrocytes

Intended for the repair of symptomatic, localised, full-thickness cartilage defects of the knee joint in patients with closed epiphyseal growth plates.

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments by 5 February 2021.

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

No items

4.4. **Finalisation of procedure**

4.4.1. Autologous anti-CD19 chimeric antigen receptor T cells

Intended for the treatment of B- cell malignancies

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

Action: for information

The information was noted.

4.4.2. Autologous omental adipose tissue and biodegradable fibrin glue

Intended for the treatment of renal traumatic/disease conditions

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

Action: for information

The information was noted.

4.4.3. Messenger ribonucleic acid (mRNA) encoding the human glucose debranching enzyme (GDE)

Intended for the treatment of glycogen storage disease III

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

Action: for information

The information was noted.

4.4.4. *In vitro* transcribed messenger ribonucleic acid (mRNA) encoding human interleukin 2 (IL-2), linked to interfering RNA targeting vascular endothelial growth factor A (VEGF-A)

Intended for the treatment of solid tumours

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

Action: for information

The information was noted.

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

5.2. 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

No items

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:

Procedure start:	14.01.2021
SAWP recommendation:	11.02.2021
CAT recommendation:	19.02.2021
CHMP adoption of report and final recommendation:	25.02.2021

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

Croatia – Mirna Golemović – membership mandate (member) ended on 01 January 2021
Greece – Maria Gazouli – membership mandate (member) started on 15 January 2021
Greece – Asterios Tsiftoglou – membership mandate (member) ended on 14 January 2021
Romania – Felicia Costinescu membership mandate (member) ended on 01 January 2021
The Netherlands: Babs Fabriek – membership mandate (alternate) started on 01 January 2021
The Netherlands: Hans Ovelgönne - membership mandate (alternate) ended on 31 December 2020

Action: for information

The changes in membership were noted. The CAT chair welcomed the new member / alternate.

7.1.2. Strategic Review & Learning meeting (SRLM) -Lisbon, Portugal, 27 May 2021

CAT: Bruno Sepodes, Maria-Isabel Vieira

Scope: save the date for the joint meeting CHMP/CAT, 27 May 2021, 09:00 – 16:30hrs (CET)

Action: for information

The information was noted.

7.2. Coordination with EMA Scientific Committees

No items

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

7.3.1. Scientific advice for ATMPs

Scope: new procedure for providing CAT input to SAWP on scientific advices for ATMPs

Action: for information

This is a follow up from the presentation to CAT in June 2020.

EMA presented the new procedure that will be implemented from February onwards. Some practical aspects were addressed.

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

CAT: Martina Schüssler-Lenz

Scope: Amendment to Annex I (Clinical requirements for CAR-Ts) following comments provided by Oncology Working Party

Action: for adoption

CAT was informed that the revision of the Guideline on quality, non-clinical and clinical aspects on medicinal products containing genetically modified cells was published on the EMA website in December 2020. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-quality-non-clinical-clinical-aspects-medicinal-products-containing-genetically-modified_en-0.pdf

As mentioned during the December 2020 CAT meeting, additional comments were received from the Oncology working party (OncWP). These have been discussed by the clinical drafting group, together with the chair and secretariat of the OncWP.

The changes to the Annex I of the Guideline (section on CAR-Ts) were presented and discussed at CAT. CAT agreed with the changes, which clarify the requirements for the clinical development of CAR-Ts in haemato-oncology indications. The updated guideline was adopted. This will be published shortly on the EMA website.

7.4. Cooperation within the EU regulatory network

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

CAT drafting group members: Heli Suila, Ivana Haunerova, Marcos Timón, Violaine Closson Carella

Scope: draft Q&A on principles for GMP

Action: for discussion

Detailed feedback was provided from the discussions in the drafting group (including members / experts from CAT, BWP, Inspectors working group). The draft document was presented.

Following to the presentation, further comments were made: scope of the document (should it be extended beyond starting materials (SM) use in the manufacture of genetically modified cells, such as plasmid SM for the manufacture of gene therapy vectors for in vivo use), documents to be shared by the SM manufacture with the ATMP manufacturer, definition of SM.

The drafting group will address all comments received and finalise Q&A. The final Q&A will be brought back to CAT.

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

CAT: Ilona Reischl, Marcos Timón, Dariusz Śladowski, Violaine Closson-Carella and Lydie Meheus.

Scope: CAT position on the inception impact assessment on the revision of the BTC legislation

Action: for information

Note:

Stefaan van der Spiegel (DG Santé, Unit B4 – Medical Products: Quality, Safety and Innovation) gave a presentation to CAT at the December meeting.

The European Commission opened the inception impact assessment with deadline of 14 December 2020.

Public consultation and targeted stakeholder consultation are opened for 12 weeks, from end of 2020/beginning of 2021 in order to inform the legislative impact assessment

Feedback was provided on what happened after the December CAT meeting.

The public consultation and targeted consultation on the revision of the BTC legislation was launched by the European Commission on 21 January 2021, closing on 15 April 2021.

<https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12734-Revision-of-the-Union-legislation-on-blood-tissues-and-cells/public-consultation>

CAT members were encouraged to respond to this consultation from their national competent authority.

7.4.3. Definition of gene therapy medicinal products

CAT: Martina Schüssler Lenz

Scope: letter dated 11 December 2020 from the European Commission – DG for Health and Food Safety, asking for CAT: 1) to reflect on the adequacy of the gene therapy medicinal product (GTMP) definition in the draft ICH S12 guideline and 2) to initiate a broader discussion on the need to revise the EU GTMP to align to the progress of science.

Action: for discussion

The following ad-hoc drafting group was established to work on this topic: Belaïd Sekkali, Egbert Flory, Marcos Timon, Violaine Closson Carella, Ilona Reischl, Toivo Maimets, Rune Kjekken, Claire Beuneu and Rocio Salvador Roldan.

A discussion took place on the differences between the definition in the glossary of the draft S12 guideline and the EU GTMP definition: inclusion of genome editing technologies; exclusion of direct effect of recombinant nucleic acids on the therapeutic effect (only genetic material active in transcriptional/translations ways); unclarity if vaccines against infectious diseases are included.

The EU Rapporteurs of the ICH S12 guideline (Rune Kjekken, Claire Beuneu) clarified that two international telecons will take place until end of February, during which the comments on the ICH Gene therapy definition need to be brought up. It was agreed to work on the EU

reflection on the adequacy of the ICH gene therapy definition in the ad-hoc drafting group and report back at the February CAT meeting.
If the time does not allow for an adoption of the groups position in the February CAT meeting, an adoption via written procedure will be conducted.

7.5. Cooperation with international regulators

None

7.6. CAT work plan

7.6.1. CAT work plan 2021

Scope: draft CAT work plan 2021

Action: for adoption

The draft workplan was discussed, and additional CAT topic leaders / CAT contributors were appointed. On the ICH 12S work plan topic, reflection on the GTMP definition (see 7.4.3) will be added.

CAT discussed the extension of the topic of the use of Real World Data to both pre- and post-authorisation regulatory activities. This extension was agreed, and the CAT work plan 2021 will be updated accordingly.

The updated CAT work plan 2021 will be sent to all CAT members, for adoption via written procedure.

7.7. Planning and reporting

None

7.8. Others

7.8.1. Qualification of treatment centres for CAR T cells

CAT: Martina Schüssler Lenz

Scope: letter dated 01.12.2020 from Universitätsklinikum Carl Gustav Carus (a German CAR T cell treatment center) which outlines issues with center qualification

Action: for discussion

CAT discussed the letter highlighting the burden and financial cost linked to the qualification of CAR-T treatment centres. The issue was acknowledged. However, a solution cannot be offered: the centre qualification is linked to the Risk Management Plan to ensure the safety of the patients treated with CAR-Ts. A GMP certification of the treatment centres, or a JACIE accreditation will not cover all aspects linked the qualification of CAR-T treatment centres.

A response letter from CAT will be prepared.

7.8.2. Curriculum on Advanced Therapies Medicinal Products (ATMPs)

CAT: Ilona Reischl

Scope: plan of trainings for 2021

Action: for discussion

The ATMP Curriculum was presented. Further to the discussion, CAT members were asked to identify the priorities for training (quality, non-clinical, clinical, post-authorisation activities, methodology) and indicate the most appropriate timing (in the margins of CAT, or outside of the CAT week). In this exercise, CAT members should consider the prioritisation that is currently included in the CAT curriculum and should reflect on the training needs of themselves and of the ATMP assessors / colleagues in their Agencies. Anyone volunteering to give presentations can also inform the CAT Secretariat.

8. Any other business

8.1. New Executive Director at the EMA

Introduction of the new EMA Executive Director - Emer Cooke

Action: for information

The CAT welcomed Emer Cooke as new EMA Executive Director.

8.2. Process for documenting of CAT experiences / CAT learning

CAT: Martina Schüssler Lenz, Niamh Curran, Carla Herbets, Heli Suila

Scope: Process for collecting and maintaining CAT learnings and presentation of CAT learnings: '

Action: for discussion

The process of documentation CAT learnings was presented and agreed.

CAT members were asked to review the three CAT learnings that are currently in the excel sheet and provide comments. This will allow to agree on these learnings at the February CAT meeting.

Date of next CAT meeting: 17-19/02/2021

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 #

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

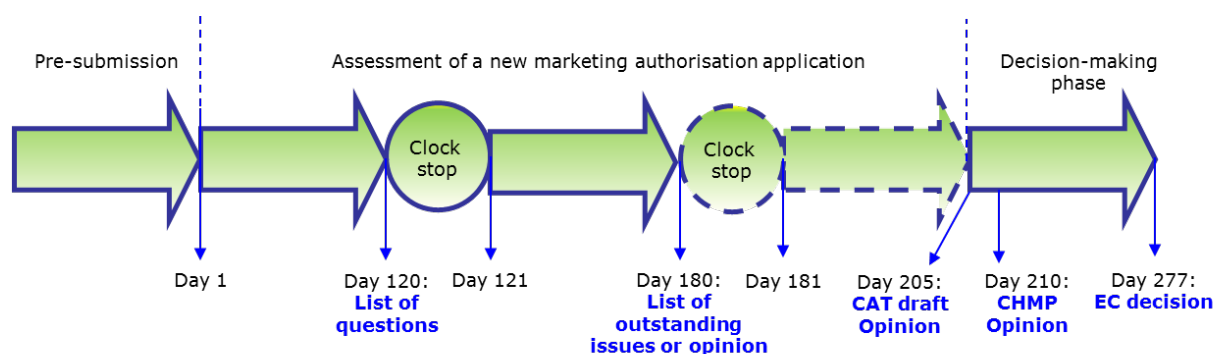
Evaluation of ATMPs (section 2)

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/

10. List of participants

Including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 20-22 January 2021 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Martina Schüssler-Lenz	Chair	Germany	No interests declared	
Iлона Reischl	Member (Vice-Chair)	Austria	No interests declared	
Silke Dorner	Alternate	Austria	No interests declared	
Claire Beuneu	Member	Belgium	No interests declared	
Belaïd Sekkali	Alternate	Belgium	No interests declared	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Petra Sokol	Alternate	Croatia	No interests declared	
Isavella Kyriakidou	Alternate	Cyprus	No interests declared	
Ivana Haunerova	Member	Czechia	No interests declared	
Tomas Boran	Alternate	Czechia	No interests declared	
Anne Pastoft	Member	Denmark	No interests declared	
Toivo Maimets	Member	Estonia	No interests declared	
Pille Saalik	Alternate	Estonia	No interests declared	
Heli Suila	Member	Finland	No interests declared	
Olli Tenhunen	Alternate	Finland	No interests declared	
Violaine Closson	Member	France	No interests declared	
Jan Mueller-Berghaus	Member (CHMP co-opted member)	Germany	No interests declared	
Maria Gazouli	Member	Greece	No interests declared	
Angeliki Rompoti	Alternate	Greece	No interests declared	
Katalin Lengyel	Member	Hungary	No interests declared	
Balázs Sarkadi	Alternate	Hungary	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Maura O'Donovan	Member	Ireland	No interests declared	
Niamh Curran	Alternate	Ireland	No restrictions applicable to this meeting	
Paolo Gasparini	Member	Italy	No interests declared	
Una Riekstina	Member	Latvia	No interests declared	
Romaldas Mačiulaitis	Member (CHMP member)	Lithuania	No interests declared	
Raimondas Benetis	Alternate (to CHMP representative)	Lithuania	No interests declared	
Guy Berchem	Member	Luxembourg	No restrictions applicable to this meeting	
John J. Borg	Member (CHMP member)	Malta	No interests declared	
Anthony Samuel	Alternate (to CHMP representative)	Malta	No interests declared	
Carla Herberts	Member	Netherlands	No interests declared	
Babs Fabriek	Alternate	Netherlands	No interests declared	
Rune Kjekken	Member	Norway	No restrictions applicable to this meeting	
Maja Sommerfelt Grønvold	Alternate	Norway	No restrictions applicable to this meeting	
Dariusz Śladowski	Member	Poland	No restrictions applicable to this meeting	
Bruno Sepodes	Member (CHMP member)	Portugal	No interests declared	
Maria Isabel Borba Vieira	Alternate (to CHMP representative)	Portugal	No interests declared	
Lukáš Slovak	Member	Slovakia	No interests declared	
Alexandra Padova	Alternate	Slovakia	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Metoda Lipnik-Stangelj	Member	Slovenia	No interests declared	
Sol Ruiz	Member (CHMP co-opted member)	Spain	No interests declared	
Marcos Timón	Alternate (to CHMP representative)	Spain	No interests declared	
Lisbeth Barkholt	Member	Sweden	No interests declared	
Maria Luttgen	Alternate	Sweden	No restrictions applicable to this meeting	
Bernd Gänsbacher	Member	Healthcare Professionals' Representative	No interests declared	
Alessandro Aiuti	Member	Healthcare Professionals' Representative	Restrictions applicable to this meeting	
Kerstin Sollerbrant	Member	Patients' Representative	No interests declared	
Lydie Meheus	Alternate	Patients' Representative	No interests declared	
Kieran Breen	Member	Patients' Representative	No restrictions applicable to this meeting	
Roland Pochet	Alternate	Patients' Representative	No interests declared	
Blanca García Ochoa	Expert	AEMPS.ES	No interests declared	
Susana Rojo	Expert	AEMPS.ES	No interests declared	
Miguel Angel Ortíz Rosales	Expert	AEMPS.ES	No restrictions applicable to this meeting	
María Isabel García Gallego	Expert	AEMPS.ES	No interests declared	
Milena Peraita Ezcurra	Expert	AEMPS.ES	No interests declared	
Marja van de Bovenkamp	Expert	CBG-MEB.NL	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Monique van Raamsdonk	Expert	CBG-MEB.NL	No interests declared	
Miki Hew	Expert	CBG-MEB.NL	No interests declared	
Serena Marchetti	Expert	CBG-MEB.NL	No restrictions applicable to this meeting	
Kirstine Moll Harboe	Expert	CHMP Co-Rapporteur, DKMA.DK	No interests declared	
Ebru Gulsun Karadok Madsen	Expert	DKMA.DK	No restrictions applicable to this meeting	
Elisabeth Penninga	Expert	DKMA.DK	No interests declared	
Annette-Malene Barfoed-Israelson	Expert	DKMA.DK	No restrictions applicable to this meeting	
Gabriele Ruppert Seipp	Expert	PEI.DE	No interests declared	
Andreea Barbu	Expert	MPA.SE	No restrictions applicable to this meeting	
Monique Wakelkamp	Expert	MPA.SE	No restrictions applicable to this meeting	
Markus Funk	Expert	PEI.DE	No interests declared	
Christoph Liebold	Expert	REG.OFR.Bayer. DE	No restrictions applicable to this meeting	
Matthias Renner	Expert	PEI.DE	No restrictions applicable to this meeting	
Kristine Moltu	Expert	NOMA.NO	No interests declared	
Christophe Genisset	Expert	ANSM.SANTE.FR	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the agenda topics or activities they participated in.