



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 February 2022
EMA/CAT/47833/2022
Human Medicines Division

Committee for Advanced Therapies (CAT)

Minutes of the meeting on 19-21 January 2022

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

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 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 the restricted involvement of some Committee members, alternates and experts for concerned agenda topics. Participants 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. Restrictions applicable to this meeting are captured in the List of participants included in the minutes.

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](#). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

The Chair welcomed the new member(s) and alternate(s) and thanked the departing members/alternates for their contributions to the Committee. The Committee also expressed special thanks to the Representative of the European Commission, Rocio Salvador-Roldan, for her contributes to the CAT and the field of ATMPs in general over the last 9 years.

1.2. Adoption of agenda

The CAT agenda for 19-21 January 2022 meeting was adopted.

1.3. Adoption of the minutes

The CAT minutes for 08-11 December 2021 meeting were adopted.

2. Evaluation of ATMPs

2.1. Opinions

2.1.1. Lisocabtagene maraleucel / lisocabtagene maraleucel - PRIME - Orphan - EMEA/H/C/004731

Bristol-Myers Squibb Pharma EEIG; treatment of diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma (PMBCL) and follicular lymphoma grade 3B (FL3B)

Scope: Opinion

Action: for adoption

List of Outstanding Issues adopted on 08.10.2021, 16.04.2021. List of Questions adopted on 06.11.2020.

The Rapporteurs presented the outcome of the assessment of the responses to the second list of outstanding issues.

CAT adopted by draft opinion for Breyanzi.

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. 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: MAA's request (dated 10.01.2022) for a clock-stop extension

Action: for information

List of Questions adopted on 22.01.2021; list of outstanding issues adopted on 16.07.2021.

Note: the revised timetable was adopted via written procedure.

CAT discussed the request for clock stop extension. CAT granted additional clock stop to respond to the questions from the list of outstanding issued.

2.7. New applications

2.8. Withdrawal of initial marketing authorisation application

No items

2.9. Re-examination of initial application procedures under Article 9(2) of Regulation No. 726/2004

No items

2.10. GMP and GCP inspections requests

No items

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

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

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjekken

Scope: Quality. Opinion

Action: for adoption

Request for Supplementary Information adopted on 05.11.2021.

The draft opinion was adopted.

2.11.2. Abecma - idecabtagene vicleucel - PRIME - Orphan - EMEA/H/C/004662/II/0010

Bristol-Myers Squibb Pharma EEIG

Rapporteur: Rune Kjekken, PRAC Rapporteur: Annika Folin

Scope: Clinical. Opinion

Update of section 5.1 of the SmPC in order to update efficacy information based on 24 month follow up data from the pivotal study submitted during initial (BB2121-MM-001: A Phase 2, Multicenter Study to determine the Efficacy and Safety of bb2121 in Subjects with Relapsed and Refractory Multiple Myeloma) listed as a specific obligation in the Annex II and in the RMP; The annex II is updated with the proposed deletion of the relevant SOB. The RMP version 1.1 has also been submitted.

Action: for adoption

The draft opinion was adopted.

2.11.3. Luxturna - voretigene neparvovec - Orphan - EMEA/H/C/004451/II/0026/G

Novartis Europharm Limited

Rapporteur: Sol Ruiz

Scope: Quality. Request for Supplementary Information

Action: for adoption

The request for supplementary information was adopted.

2.11.4. Tecartus - autologous anti-CD19-transduced CD3+ cells - PRIME - Orphan - EMEA/H/C/005102/II/0016

Kite Pharma EU B.V.

Rapporteur: Jan Mueller-Berghaus

Scope: Quality. Request for Supplementary Information

Action: for adoption

The request for supplementary information was adopted.

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

Novartis Gene Therapies EU Limited

Rapporteur: Carla Herberts

Scope: Quality. Opinion

Action: for adoption

Request for Supplementary Information adopted on 05.11.2021.

The draft opinion was adopted.

2.12. Extension applications

No items

2.13. Other Post-Authorisation Activities

2.13.1. Kymriah - tisagenlecleucel - PRIME - Orphan - EMEA/H/C/004090/ANX/007.1

Novartis Europharm Limited

Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang

Scope: Statistical Analysis Plan (SAP) amendment 1 / (CCTL019B2401):

Sub-analysis to assess efficacy in patients with relapsed or refractory diffuse large B-cell lymphoma based on data from the Registry study to assess the long-term safety of patients with B lymphocyte malignancies treated with tisagenlecleucel.

Action: for adoption

CAT discussed the Rapporteur's report. The amendment of the protocol as proposed by the MAH was not agreed the MAH will have to provide additional information. The Rapporteur will amend the questions to the MAH in line with the CAT discussion.

2.13.2. Kymriah - tisagenlecleucel - PRIME - Orphan - EMEA/H/C/004090/P46/012.1

Novartis Europharm Limited

Rapporteur: Rune Kjekken, CHMP Coordinator: Ingrid Wang

Scope: Bioanalytical data reports and MAH's responses to P46 012 [Study no. CTL019B2001X, EudraCT no. 2016-001991-31] as adopted in June 2021.

Action: for adoption

The conclusion of the CAT Rapporteur was agreed.

2.13.3. Luxturna - voretigene neparvovec - Orphan - EMEA/H/C/004451/REC/008

Novartis Europharm Limited

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

Scope: From Letter of Recommendations: MAH's response to questions on Quality

Action: for adoption

The conclusion of the CAT Rapporteur was agreed.

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:	21.01.2022
-EMA Coordinator's draft report:	04.02.2022
-CAT Coordinator's comments:	09.02.2022
-Revised scientific recommendation:	11.02.2022
-CAT's discussion of scientific recommendation:	18.02.2022

4.1. New requests – Appointment of CAT Coordinator

No items

4.2. Day 30 ATMP scientific recommendation

4.2.1. Kidney progenitor cells isolated from the urine of preterm neonates

Intended for the kidney transplantation

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 4 February 2022.

4.2.2. Expanded mesenchymal stem cells (MSCs) cells isolated from umbilical cord Wharton jelly dilative cardiomyopathy (DCM)

Intended for the treatment of dilative cardiomyopathy (DCM)

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 4 February 2022.

4.2.3. [Recombinant serotype 9 adeno-associated virus \(rAAV9\) encoding a wild-type human MECP2 \(methyl cytosine binding protein 2\) transgene \(AAV9-hMECP2\)](#)

Intended for the treatment of Rett syndrome

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 4 February 2022.

4.2.4. [Recombinant adeno-associated virus \(rAAV\) containing human homology arms, expressing codon-optimised human phenylalanine hydroxylase \(hPAH\)](#)

Intended for the treatment of phenylalanine hydroxylase (PAH) deficiency

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 4 February 2022.

4.2.5. [Human embryonic stem cell \(hESC\)-derived midbrain dopaminergic \(mDA\) neuron cells](#)

Intended for the treatment of advanced Parkinson's disease

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 4 February 2022.

4.2.6. [Stem cells isolated from dental pulp, cultured](#)

Intended for the treatment of surgical bone defects

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 4 February 2022.

4.2.7. [Modulated immune cells](#)

Intended for solid organ transplantation / Treatment of autoimmune disease

Scope: ATMP scientific recommendation

Action: for adoption

CAT discussed the ATMP classification report. This is a resubmission of an application for classification for the same product that was classified in January 2020 as a non ATMP. The application provided additional scientific data for their product. CAT secretariat to send the

draft scientific recommendation to the European Commission for comments by 4 February 2022.

4.2.8. Autologous bone marrow concentrate

Intended for the treatment of bone fractures

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 4 February 2022.

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

No items

4.4. Finalisation of procedure

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

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

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

Action: for information

The information was noted. The finalised classification report will be sent to the applicant.

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

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

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

Action: for information

The information was noted. The finalised classification report will be sent to the applicant.

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

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

Scope: The European Commission raised minor comments. ATMP scientific recommendation

Action: for information

The information was noted. The finalised classification report will be sent to the applicant.

4.5. Follow-up and guidance

No items

5. Scientific Advice

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

5.1. New requests - appointment of CAT Rapporteurs

5.1.1. Ongoing scientific advice procedures - Appointment of CAT Peer Reviewers

Timetable:

- Start of procedure at SAWP:	10-13.01.2022
- Appointment of CAT Peer Reviewers:	19-21.01.2022
- SAWP first reports:	31.01.2022
- CAT Peer Reviewer comments:	04.02.2022
- Discussion at SAWP:	07-10.02.2022
- Discussion at CAT and feedback to SAWP:	18.02.2022

5.1.2. Scientific advice procedures starting at the next SAWP meeting

Timetable:

- Start of procedure at SAWP:	07-10.02.2022
- Appointment of CAT Peer Reviewers:	16-18.02.2022
- SAWP first reports:	28.02.2022
- CAT Peer Reviewer comments:	04.03.2022
- Discussion at SAWP:	07-10.03.2022
- Discussion at CAT and feedback to SAWP:	18.03.2022

5.2. Procedures discussed at SAWP – 1st reports, D40 JRs, LoIs

5.3. Finalisation of D70 procedures – feedback from the discussion meeting

5.4. Final Advice Letters for procedures finalised the previous month

6. Pre-Authorisation Activities

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

6.1. Paediatric investigation plans

No items

6.2. ITF briefing meetings in the field of ATMPs

6.3. Priority Medicines (PRIME) – Eligibility requests

6.3.1. Month 0 - Start of the procedure

Timetable for assessment:	
Procedure start:	10-13.01.2022
SAWP recommendation:	10/02/2020
CAT recommendation:	18/02/2022
CHMP adoption of report and final recommendation:	24/02/2022

No items

6.3.2. Month 1 – Discussion of eligibility

6.3.3. Month 2 – Recommendation of eligibility

6.3.4. Ongoing support

No items

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

7.1.1. CAT membership

Action: for information

The chair welcomed Jean-Michel Race as the new alternate member for France and thanked Alexandra Padova, the alternate member for Slovakia, for her contributions to the work of the CAT.

7.1.2. Vote by proxy

No items

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

CAT: Violaine Closson-Carella, Martina Schuessler-Lenz

Scope: Practical information and agenda content

Action: for discussion

The draft agenda of the upcoming CAT SRLM was presented.

7.2. Coordination with EMA Scientific Committees

7.2.1. 5-year review of PRIME experience

Scope: Presentation of the main findings and recommendations of the experience with the PRIME scheme since its launch in March 2016

Action: for information

CAT noted the presentation on the 5-year review of the PRIME experience. The proposals for improvement to the process were presented and agreed.

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

7.3.1. Call for nominations for Working Parties

CAT: Martina Schuessler-Lenz

Scope: Launch of call for nominations for the Oncology working parties

Action: for information

In the context of the new operational model of working parties that was agreed at the EMA management Board April 2021, the call for nominations for Oncology Working Party has been launched with the aim to have the Working Party new members and Chair and Vice-chair appointed during February CHMP PROM meeting. CAT members are asked to liaise within their agency for possible nominations. Calls for nominations for other working parties will follow in the next months. Especially for the non-clinical WP (NCWP), it would be advantageous that GTMP/ATMP experience would be included.

There was a question from CAT if members working in universities (nominate by the NCAs, or by the European Commission as patients' organisations and clinicians' representative in CAT) can be part of the Working Parties. EMA will get back to these members with a response to this question.

7.4. Cooperation with the EU regulatory network

No items

7.5. Cooperation with international regulators

No items

7.6. CAT work plan

7.6.1. CAT work plan 2022

CAT: Martina Schüssler-Lenz

Scope: final CAT work plan for 2022

Action: for adoption

The final version of the work plan for 2022 was presented. Additional CAT contributors to some of the work plan topics were added. With these additions, the CAT work plan 2022 was adopted.

7.6.2. Real World Data (RWD) in regulatory decision making of ATMPs

CAT: Martina Schuessler-Lenz

Scope: Technical specifications for an EMA funded study on spinal muscular atrophy (SMA)

Action: for information

EMA Secretariat provided feedback on the EMA-funded study on SMA. This presentation is related to the CAT work plan topic 2021 on "Real World Data in regulatory decision making of ATMPs" which will be pursued in the CAT 2022 work plan. The CAT working group`s proposal was to use SMA and existing disease registries as a case study, developed research questions for the EMA funded study and provided the background for the EMA funded study on SMA. Following CAT members will be part of the technical evaluation committee: Kieran Breen, Lisbeth Barkholt, Carla Herberts.

7.7. Planning and reporting

No items

7.8. Others

7.8.1. Lifecycle Regulatory Submissions Metadata project (LRSM)

Action: for information

The LRSM project was presented. Kieran Breen will take part in this exercise. Additional CAT members can volunteer. An update on the project will be provided later this year.

7.8.2. Speaker invitation to the International Society for Cellular Therapy (ISCT) 2022 Annual meeting

CAT: Martina Schuessler-Lenz

Scope: Opportunity to talk at the ISCT session (4 May 2022): "Shining a light on unlicensed CGTs: Where is the line between the right to care, ethics and patient safety?"

Action: identification of CAT speaker

Ilona Reischl agreed to contribute remotely to the ISCT annual meeting. Dariusz Sladowski will provide input in the presentation.

8. Any other business

No items

Date of next CAT meeting:

16-18/02/2022

9. Explanatory notes

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

Abbreviations / Acronyms

AAV: Adeno-Associated Virus

AR: Assessment Report

ATMP: Advanced Therapy Medicinal Product

BWP: Biologics Working Party

CAT: Committee for Advanced Therapies

CHMP: Committee for Medicinal Product for Human Use

COMP: Committee for Orphan Medicinal Products

CTFG: Clinical Trial Facilitation Group

DG: Drafting Group

EC: European Commission

EU NTC: European Union Network Training Centre

ERA: Environmental Risk Assessment

FDA: Food and Drug Administration

FL: Final Letter

GCG: Guideline Consistency Group

GCP: Good Clinical Practice

GLP: Good Laboratory Practice

GMO: Genetically-modified organism

GMP: Good Manufacturing Practice

GTMP: Gene Therapy Medicinal Product

HTA: Health Technology Assessment Bodies

HSPC: Hematopoietic Stem and Progenitor Cells

ITF: Innovative Task Force

JR: Joint Report

LoOI: List of outstanding issues

LoQ: List of questions

MA: Marketing Authorisation

MAA: Marketing Authorisation Application

MAH: Marketing Authorisation Holder

MNAT: Multinational assessment team

MSC: Mesenchymal stem cells

PDCO: Paediatric Committee

PMDA: Pharmaceuticals and Medical Devices Agency (Japan)

PIP: Paediatric Investigation Plan

PL: Package leaflet

PRAC: Pharmacovigilance and Risk Assessment Committee #

PRIME: Priority Medicines
 QRD: Quality review of documents
 RMP: Risk Management Plan
 RP: Reflection paper
 RSI: Request for supplementary information
 SAs: Scientific Advices
 SAG-O: Scientific Advisory Group Oncology
 SAWP: Scientific Advice Working Party
 SR: Summary Report
 SWP: Safety Working Party
 SME: Small and medium size enterprises
 SmPC: Summary of Products Characteristics
 TT: Timetable

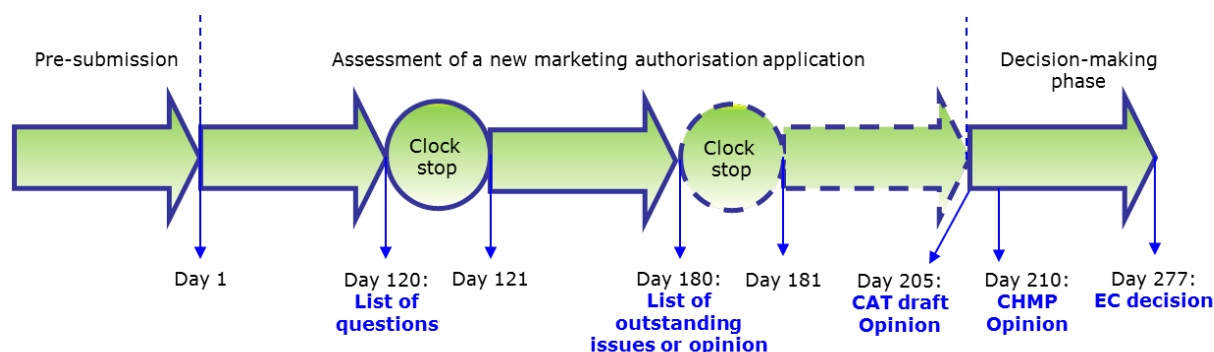
Evaluation of ATMPs (section 2)

This section lists applications for marketing authorisations of new Advanced Therapy Medicinal Products (ATMPs) that are to be discussed by the Committee. It also lists any ATMP related inspection requests (section 2.9) and Post-authorisation activities (section 2.10).

New applications (sections 2.1. to 2.12.)

Section 2.1 is for ATMPs nearing the end of the evaluation and for which the CAT is expected to adopt a draft **opinion** at this meeting on whether marketing authorisation should be granted. Once adopted, the CAT opinion is transmitted to the CHMP for final adoption. The CHMP opinion will be forwarded to the European Commission for a final legally binding decision valid throughout the EU. More information on the evaluation of ATMPs can be found [here](#).

The other items in the section are listed depending on the stage of the evaluation, which is shown graphically below:



The assessment of an application for a new medicine takes up to 210 'active' days. This active evaluation time is interrupted by at least one 'clock-stop' during which time the applicant prepares the answers to questions from the CAT. The clock stop happens after day 120 and may also happen after day 180, when the CAT has adopted respectively a **Day 120 list of questions** (section 2.3) or a List of outstanding issues to be addressed by the company, which is listed in the agenda under sections 2.7 (**Ongoing evaluation procedures**). Section 2.7 also includes the CAT discussions at any other timepoint of the evaluation procedure of new applications.

Oral explanation (section 2.2.)

Prior to adoption of the CAT opinion, marketing authorisation applicants are normally invited to the CAT plenary meeting to address questions raised by the Committee.

Oral explanations normally relate to ongoing applications, but they can also relate to any other issue for which the CAT would like to discuss with company representatives in person.

Re-examination procedures (new applications) under article 9(2) of regulation no 726/2004 (section 2.6.)

This section lists applications for new marketing authorisation for ATMPs for which the applicant has requested a re-examination of the opinion previously issued by the CHMP. Similar to the initial evaluation of a marketing authorisation of an ATMP, CAT will adopt a draft re-examination opinion, which is transmitted to the CHMP for final adoption.

Withdrawal of applications (section 2.7.)

This section includes information on marketing authorisation applications that are withdrawn by the applicant. Applicants may decide to withdraw applications at any stage during the assessment and a CAT opinion will therefore not be issued. Withdrawals are included in the agenda for information or discussion, as necessary.

New applications (section 2.9.)

In this section, information is included on upcoming marketing authorisation applications for ATMPs, as well as information on appointment of Rapporteurs for new ATMP applications.

GMP and GCP Inspections Issues (section 2.10.)

This section lists inspections that are undertaken for ATMPs. Inspections are carried out by regulatory agencies to ensure that marketing authorisation holders comply with their obligations. Inspection can relate to good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) or good pharmacovigilance practice (GVP).

Post-authorisation activities (section 2.12.)

This section lists type II variations, extension application according to Annex I of Reg. 1234/2008, re-examination procedures for type II variations (including extension of indication applications) for which the applicant has requested re-examination of the opinion previously issued by the CHMP and other issues concerning authorised medicines that are not covered elsewhere in the agenda such as annual reassessments, 5-year renewals, supply shortages, qualify defects. Issues that have been discussed at the previous meeting of the PRAC, the EMA's committee responsible for evaluating and monitoring safety issues for medicines, will also be included here.

Certification of ATMPs (section 3)

This section includes the scientific evaluation by the CAT of quality and non-clinical data that small and medium-sized enterprises have generated at any stage of the ATMP development process. More information on the ATMP certification procedure can be found [here](#).

Scientific Recommendation on Classification of ATMPs (Section 4)

This section includes the scientific recommendation by the CAT on whether medicines based on genes, cells or tissues meet the scientific criteria that define ATMPs. More information on the ATMP classification procedure, including the outcomes of finalised classifications, can be found [here](#).

Scientific Advice (section 5)

This section includes all scientific advice given to companies during the development of an ATMP. Information related to the number of ATMP related scientific advices discussed by CAT can be found in the CAT Monthly reports. Further information on SAWP can be found [here](#).

Pre-Authorisation (section 6)

Paediatric Investigation Plan (PIP)

This section includes the discussion of an ATMP before a formal application for marketing authorisation is submitted. These cases refer for example to requests for an accelerated assessment for medicines that are of major interest for public health or can be considered a therapeutic innovation: in case of an accelerated assessment the assessment timetable is reduced from 210 to 150 days.

CAT contributes to the evaluation of a Paediatric Investigation Plan (PIPs) for ATMPs by the Paediatric Committee. These PIPs are included in this section of the Agenda.

ITF Briefing meeting in the field of ATMPs

This section refers to briefing meetings of the Innovation Task Force and International co-operations activities of the CAT

The Innovation Task Force (ITF) is a body set up to encourage early dialogue with applicants developing innovative medicines. Minutes of meetings with applicants developing ATMPs and of other ITF meetings of interest to the CAT are included in this section of the agenda. Further information on the ITF can be found [here](#).

Priority Medicines (PRIME)

This section includes the new requests for eligibility to PRIME for ATMPs under development, the discussions in CAT of these eligibility requests and the final recommendations for eligibility of ATMPs adopted by CHMP.

CAT will appoint one of its members as the CAT sponsor for each new ATMP eligibility request who will lead the CAT discussion based on the recommendation from the SAWP.

Organisational, regulatory and methodological matters (section 7)

This section includes topics related to regulatory and procedural guidance, CAT workplan, CAT meeting organisation (including CAT membership), planning and reporting, co-ordination with other committees, working parties and scientific advisory groups.

Furthermore, this section refers to the activities of the CAT drafting groups developing scientific guidelines for gene therapy medicinal products and for cell-based medicinal products, cooperation within the EU regulatory network and international regulators as well as direct interaction with interested parties. It also includes topics of scientific interest for the Committee that are not directly related to the work of the CAT drafting groups or CAT associated working parties.

Any other business (section 8)

This section is populated with miscellaneous topics not suitable under the previous headings.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/

10. List of participants

Including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 19-21 January 2022 meeting.

<u>Name</u>	<u>Role</u>	<u>Member State or affiliation</u>	<u>Outcome restriction following evaluation of e-DoI</u>	<u>Topics on agenda for which restrictions apply</u>
Martina Schüssler-Lenz	Chair	Germany	No interests declared	
Ilona 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	
Evelina Shumkova	Alternate	Bulgaria	No interests declared	
Azra Selimovic	Member	Croatia	No interests declared	
Petra Sokol	Alternate	Croatia	No interests declared	
Rafaella Pontou	Member	Cyprus	No interests declared	
Isavella Kyriakidou	Alternate	Cyprus	No interests declared	
Tomas Boran	Member	Czechia	No interests declared	
Petr Soukup	Alternate	Czechia	No interests declared	
Ebru Karakoc Madsen	Alternate	Denmark	No restrictions applicable to this meeting	
Toivo Maimets	Member	Estonia	No interests declared	
Pille Saalik	Alternate	Estonia	No interests declared	
Heli Suila	Member	Finland	No interests declared	
Maija Tarkkanen	Alternate	Finland	No interests declared	
Violaine Closson	Member	France	No interests declared	
Jean-Michel Race	Alternate	France	No interests declared	
Jan Mueller-Berghaus	Member (CHMP co-opted member)	Germany	No interests declared	
Egbert Flory	Alternate (to CHMP representative)	Germany	No interests declared	

<u>Name</u>	<u>Role</u>	<u>Member State or affiliation</u>	<u>Outcome restriction following evaluation of e-DoI</u>	<u>Topics on agenda for which restrictions apply</u>
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	
Maura O'Donovan	Member	Ireland	No interests declared	
Niamh Curran	Alternate	Ireland	No restrictions applicable to this meeting	
Concetta Quintarelli	Member	Italy	No interests declared	
Barbara Bonamassa	Alternate	Italy	No restrictions applicable to this meeting	
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	
Vlasta Zavadova	Member	Liechtenstein	No interests declared	
Guy Berchem	Alternate	Luxembourg	Cannot act as rapporteur, other leading/co-ordinating role or peer reviewer for:	5.1.1.2.
Nancy De Bremaeker	Member	Luxembourg	No interests declared	
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 Kjeken	Member	Norway	No restrictions applicable to this meeting	

<u>Name</u>	<u>Role</u>	<u>Member State or affiliation</u>	<u>Outcome restriction following evaluation of e-DoI</u>	<u>Topics on agenda for which restrictions apply</u>
Maja Sommerfelt Grønvold	Alternate	Norway	No interests declared	
Dariusz Śladowski	Member	Poland	No restrictions applicable to this meeting	
Marcin Kolakowski	Alternate	Poland	No interests declared	
Bruno Sepodes	Member (CHMP member)	Portugal	No interests declared	
Maria Isabel Borba Vieira	Alternate (to CHMP representative)	Portugal	No interests declared	
Silviu Istrate	Member	Romania	No interests declared	
Alexandrina Preda	Alternate	Romania	No interests declared	
Lukas Slovak	Member	Slovakia	No interests declared	
Metoda Lipnik-Stangelj	Member	Slovenia	No interests declared	
Suzana Vidic	Alternate	Slovenia	No participation in final deliberations and voting on:	2.11.3., 2.11.5., 2.13.1., 2.13.2. & 2.13.3.
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 participation in final deliberations and voting on: Cannot act as rapporteur, other leading/co-ordinating role or peer reviewer for:	5.2.5. 5.1.1.2.
Bernd Gänzbacher	Member	Clinicians' Representative	No interests declared	
Frederic Bernard	Alternate	Clinicians' Representative	No interests declared	
Alessandro Aiuti	Member	Clinicians' Representative	No restrictions applicable to this meeting	

<u>Name</u>	<u>Role</u>	<u>Member State or affiliation</u>	<u>Outcome restriction following evaluation of e-DoI</u>	<u>Topics on agenda for which restrictions apply</u>
Alessandra Renieri	Alternate	Clinicians' Representative	No 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	
Catherine Milne	Observer/Alternate	EDQM	No interests declared	
Johannes Hendrikus Ovelgonne	Expert - via Webex*	CBG/MEB NL	No interests declared	
Olga Kholmanskikh	Expert - via Webex*	FAGG – AFMPS BE	No interests declared	
Filip Van Nuffel	Expert - via Webex*	FAGG – AFMPS BE	No interests declared	
Graziella Curtale	Expert - via Webex*	AIFA IT	No interests declared	
Filomena Nappi	Expert - via Webex*	AIFA IT	No interests declared	
Odoardo Olimpieri	Expert - via Webex*	AIFA IT	No interests declared	
Antonella Isgrò	Expert - via Webex*	AIFA IT	No interests declared	
Ralf Sanzenbacher	Expert - via Webex*	PEI DE	No interests declared	
Ivana Haureova	Expert - via Webex*	Czechia - SUKL	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				