



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2015
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Procedure Management and Committees Support Division

Committee for Advanced Therapies (CAT) Minutes of the meeting on 12-13 November 2015

Chair: Paula Salmikangas - Vice-chair: Martina Schübler-Lenz

12 November 2015, 09:00 – 13:30, virtual

13 November 2015, 09:00 – 13:30, virtual

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 set of minutes 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 and start of referrals will also be available.

Of note, this set of minutes is a working document primarily designed for CAT members and the work the Committee undertakes.

Further information with relevant explanatory notes can be found at the end of this document.

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 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

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 (i.e. 22 or more members were present in the room). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

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 12-13 November 2015. See November 2015 CAT minutes (to be published post December 2015 CAT meeting).

1.2. Adoption of agenda

CAT agenda for 12-13 November 2015

Adopted without amendments

1.3. Adoption of the minutes

CAT minutes of 15-16 October 2015

Adopted without amendments

2. Evaluation of ATMPs

2.1. Opinions

None

2.2. Oral explanations

None

2.3. Day 180 List of outstanding issues (LoOIs)

None

2.4. Day 120 Lists of questions (LoQs)

None

2.5. Day 80 assessment reports

None

2.6. Re-examination procedure (new applications) under Article 9(2) of Regulation No. 726/2004

None

2.7. Withdrawal of initial full application

None

2.8. Ongoing initial full application

2.8.1. Characterised viable haploidentical herpes simplex virus thymidine kinase (HSV-Tk) and Human Low Affinity Nerve Growth Factor Receptor (Δ LNGFR) transfected donor lymphocytes; *Orphan*; EMA/H/C/002801

MolMed SpA; adjunctive treatment in haploidentical haematopoietic stem cell transplantation of adult patients with high-risk haematological malignancies

Action: for adoption of the revised timetable

CAT adopted the revised timetable. A general comments was made on the short review timelines at the end of the procedure and the challenges for the Rapporteurs to review new data submitted by the applicants.

2.9. New applications

None

2.10. GMP and GCP inspections requests

None

2.11. Type II variations

None

2.12. Other post-authorisation activities

2.12.1. Glybera - Alipogene tiparvovec; Orphan; EMEA/H/C/002145/S/0051

UniQure biopharma B.V.

Rapporteur: Christiane Niederlaender; CHMP Coordinators: Greg Markey

Scope: 3rd annual reassessment

Action: timetable for adoption

CAT adopted the evaluation timetable for the 3rd annual reassessment.

2.12.2. ChondroCelect – Characterised viable autologous cartilage cells expanded *in vivo* expressing specific marker proteins; EMA/H/C/00878/MEA 16.4., 18.4

TiGenix N.V.

Rapporteur: Egbert Flory; Co-rapporteur: Tiina Palomäki; CHMP Coordinator: Jan Müller-Berghaus

Scope 16.4: Randomised control trial protocol TIG/ACT/04/2009

Scope 18.4: Non-interventional registry of ChondroCelect, study TGX001-2011 & randomised controlled study in small lesions using microfracture as comparator

Action: timetable for adoption

CAT adopted the timetable.

3. Certification of ATMPs

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

3.1. New applications

3.2. Day 60 evaluation reports

3.3. Opinions

None

4. Scientific Recommendation on Classification of ATMPs

4.1. New requests – appointment of CAT Co-ordinators

4.1.1. Autologous cells of serial vector format and autologous adipose derived stem cells

Intended for the treatment of treatment of (1) diabetic foot ulcer and (2) keloid scars and aging skin

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 29th October 2015

Nominations were received. The CAT member was appointed as CAT coordinator for this procedure.

4.1.2. Autologous adipose-derived regenerative cells encapsulated in carboxymethylcellulose

Intended for the treatment of cosmetic dermal filling

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 29th October 2015

Nominations were received. The CAT member was appointed as CAT coordinator for this procedure.

4.1.3. Human hepatoblastoma cells (HepG2) encapsulated in alginate, expanded in a fluidised bed bioreactor

Intended for the treatment of acute liver failure

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 23rd October 2015

Nominations were received. The CAT member was appointed as CAT coordinator for this procedure.

4.1.4. Adeno-associated virus serotype 8 vector encoding human ornithine transcarbamylase

Intended for the treatment of ornithine transcarbamylase

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 29th October 2015

Nominations were received. The CAT member was appointed as CAT coordinator for this procedure.

4.1.5. Fibroblasts and keratinocytes co-culture

Intended for the treatment of deep and extensive burns, chronic wounds, skin donor sites

Different product formulations:

- suspension of cell in platelet leukocyte rich gel
- in sheet
- seeded on acellular amniotic matrix
- seeded on acellular dermal matrix
- seeded on transgenic porcine acellular dermal matrix

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 2nd November 2015

Nominations were received. The CAT member was appointed as CAT coordinator for this procedure.

4.1.6. Human acellular amniotic matrix

Intended for the treatment of deep and extensive burns, chronic wounds, skin donor sites

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 2nd November 2015

Nominations were received. The CAT member was appointed as CAT coordinator for this procedure.

4.1.7. Human acellular dermal matrix

Intended for the treatment of deep and extensive burns, chronic wounds, skin donor sites

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 2nd November 2015

Nominations were received. The CAT member was appointed as CAT coordinator for this procedure.

4.1.8. Allogeneic chondrocytes and irradiated genetically modified chondrocytes expressing human TGF- β 1

Intended for the treatment of degenerative joint disease

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 16th October 2015

Nominations were received. The CAT member was appointed as CAT coordinator for this procedure.

4.1.9. Allograft tendon combined with suture ready to use

Intended for the treatment of anterior cruciate ligament reconstruction

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 28th October 2015

Nominations were received. The CAT member was appointed as CAT coordinator for this procedure.

4.1.10. Transgenic porcine acellular dermal matrix

Intended for the treatment of deep and extensive burns, chronic wounds, skin donor sites

Scope: appointment of CAT Co-ordinator and adoption of timetable

Action: for adoption

Document:

Request received 2nd November 2015

Nominations were received. The CAT member was appointed as CAT coordinator for this procedure.

4.2. Day 30 Co-ordinators' first reports

4.2.1. Autologous adipose derived regenerative cells encapsulated in hyaluronic acid

Intended for the treatment of articular cartilage and bone defects

Action: for adoption

Document:

ATMP classification report

CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments .

The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.2.2. Autologous bone marrow derived non-haematopoietic stem cells

Intended for the treatments of patients with rheumatoid arthritis; patients after ischemic stroke; patients after myocardial infarction; type I diabetes; type II diabetes

Action: for adoption

Document:

ATMP classification report

CAT discussed the ATMP classification report and decided to request some additional information from the applicant prior to concluding on this classification request.

4.2.3. Autologous peripheral blood-derived total nucleated cells

Intended for the treatment of critical limb ischemia

Action: for adoption

Document:
ATMP classification report

CAT discussed the ATMP classification report and decided to request some additional information from the applicant prior to concluding on this classification request.

4.2.4. Allogeneic pro-inflammatory monocyte-derived dendritic cells

Intended for the treatment of metastatic renal cell carcinoma (mRCC)

Action: for adoption

Document:
ATMP classification report

CAT discussed the ATMP classification report. CAT adopted by consensus the ATMP classification report. CAT secretariat to send the draft scientific recommendation to the European Commission for comments .

The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.3. Day 60 Co-ordinators' revised reports following List of Questions

4.3.1. Autologous cells of stromal vascular fraction (SVF) of adipose tissue

Intended for (1) cosmetic lipofiling; (2) treatment for non-healing wounds and scared tissue; (3) pain associated with joint osteoarthritis

Action: for adoption

Document:
Revised ATMP classification report
Response to the LoQs received 28th October 2015

Further to the receipt of the additional information, the revised ATMP classification report as discussed. The classification report was updated after the discussion. For the first indication (cosmetic lipofiling), as there is no therapeutic indication, the company is advised to contact the relevant national authorities for the classification of this product. CAT adopted the revised classification report by consensus.

CAT secretariat to send the draft scientific recommendation to the European Commission for comments.

The CAT recommendation will be considered final if no comments are received from the European Commission. The final report will be sent thereafter to the applicant.

4.4. Finalisation of procedures

4.4.1. Decellularised trachea seeded with autologous expanded mesenchymal stem cells

Intended for the treatment of reconstruction of trachea subsequent to damage or stenosis due to cancer, injury, infection or congenital deformities

Action: for information

Document:
ATMP classification report

Note:
The European Commission raised no comments

4.4.2. Autologous bone marrow - adipose tissue or allogeneic umbilical cord derived human mesenchymal stem cells

Intended for the treatment of amyotrophic lateral sclerosis

Action: for information

Document:
ATMP classification report

Note:
The European Commission raised some comments for clarification, which do not impact on the outcome of the classification. These comments were incorporated in the report.

4.4.3. Allogeneic mesenchymal precursor cells

Intended for the treatment of chronic lumbar back pain

Action: for information

Document:
ATMP classification report

Note:
The European Commission raised no comments

4.4.4. *In vitro* expanded autologous articular chondrocytes

Intended for the treatment of articular cartilage defect

Action: for information

Document:
ATMP classification report

Note:
The European Commission raised no comments

4.4.5. hESC-derived hepatocyte like cells

Intended for the treatment of inborn errors of liver metabolism diseases and liver acute failure

Action: for information

Document:
ATMP classification report

Note:
The European Commission raised no comments

4.4.6. Allogeneic hematopoietic progenitor cells (HPC–CD34+) accompanied by facilitating cells (FC– CD8+/αβTCR-) and αβ T cells, prepared from mobilized peripheral blood mononuclear cells

Intended for the prophylaxis of organ rejection in adult patients receiving living donor kidney transplantation

Action: for information

Document:
ATMP classification report

Note:
The European Commission raised no comments

4.5. Follow-ups and guidance

None

5. Scientific Advice

Disclosure of 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 Co-ordinators

5.2. CAT Rapporteurs' reports

5.3. Lists of issues

None

5.4. Finalisation of Scientific Advice procedures

6. Pre-Authorisation Activities

Disclosure of 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 (PIP)

6.2. ITF briefing meetings in the field of ATMPs

7. Organisational, regulatory and methodological matters

7.1. Mandate and organisation of the CAT

None

7.2. Coordination with EMA Scientific Committees

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

Summary of Outcomes (SoO) for the October 2015 meeting

Action: for information

The information was noted.

7.2.2. CAT – CHMP (Safety Working Party) cluster on tumourigenicity studies for ATMPs

CAT resources: Tiina Palomäki, Hans Ovelgönne, Björn Carlsson, Egbert Flory Scope: potential creation of a reflection paper

Action: for discussion

Document:

CAT – CHMP (SWP) Project plan

Note: first step in the exercise is to gather examples of non-clinical study evaluation in the context of clinical trials application.

The background and the proposal to draft a reflection paper was presented. The exercise relate to cell-based ATMPs only. CAT noted that this is an important topic and agreed with the proposal to develop a reflection paper. CAT recommended not only to look at the non-clinical parts of MAA and scientific advices: some relevant aspect might also be addressed in quality development.

Following additional CAT experts will join this drafting group: Carla Herberts and Isabelle Vieira.

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

7.3.1. Good Laboratory Practice (GLP) requirements of non-clinical studies for ATMPs

CAT drafting group: Una Riekstina, Tiina Palomäki, Egbert Flory, Ilona Reischl, Carla Herberts, Isabel Vieira

Scope: Application of GLP principles on ATMPs

Action: for adoption

Document:
CAT's position

Note:

June 2015: presentation by the EMA GLP Inspections Working Party (IWP) on GLP requirements for ATMPs

July 2015: CAT agreed on the composition of a drafting group to draft a document summarising experiences and expectation in relation to the GLP requirements of non-clinical studies of ATMP

26 October 2015: teleconference of the DG drafting group to develop a draft CAT position

CAT discussed the proposal developed by the CAT drafting group. The aim of the proposal is to describe a feasible framework for non-clinical studies for ATMPs. After agreement by CAT, the CAT position will be forwarded to the colleagues at the European Commission responsible for the development of the rules for clinical trials..

CAT members provided some input and comments. It was agreed that CAT members can provide additional comments in writing (comment to be sent to CAT Secretariat by 4 December at the latest). The document will be adopted at the December CAT meeting.

7.3.2. [CHMP draft guideline on conditional marketing authorisation \(CMA\)](#)

Scope: public consultation comments and corresponding amendments to the CHMP guideline on the scientific application and the practical arrangements necessary to implement European Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004

Action: for discussion

Documents:
CHMP guideline
Overview of comments

Note:

CAT was consulted on this update of the guideline in June 2015

An overview was provided of the comments received and the proposed amendments to the Guideline on CMA. CAT highlighted that the role of the CAT should be better reflected i.e. the need for CAT to agree on the CMA, as they are reviewing the MAA for ATMPs and adopting the Draft opinion.

7.3.3. [CHMP draft guideline on the scientific application and the practical arrangements necessary to implement the procedure for accelerated assessment pursuant to article 14\(9\) of regulation \(EC\) No 726/2004](#)

Scope: update on public consultation comments

Action: for appointment of CAT sponsors

Documents:
CHMP guideline
Note:

-The guideline will be revised by the end 2015
-Input of CAT on specific timetable

The draft guideline was presented. There was a discussion on the feasibility of a reduction of the time for Rapporteurs' assessment report from 80 to 60 days for ATMPs: it was mentioned that aspects like European Research Area (ERA) consultation (for gene therapy medicinal product) and involvement of notified bodies (for combined ATMPs) will make the shortened initial evaluation phase very challenging. CAT members agreed to act as CAT sponsor to assist the EMA and CHMP to finalise the draft guideline: Marit Hystad and Tomas Boran.

7.3.4. Adaptive pathway approach

CAT resources: Hans Ovelgönne;

Scope: presentation of the procedure and experience with ATMPs under discussion in the Adaptive Pathway pilot

Action: for information

Further information can be found

here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000601.jsp&mid=WC0b01ac05807d58ce

A presentation on the Adaptive Pathways (APs) initiative was given. CAT discussed one of the ATMPs that were recently discussed in the AP pilot. It was suggested that more CAT members should get involved in the AP project.

7.3.5. Draft reflection on a proposal to enhance early dialogue to facilitate accelerated assessment of priority medicines (PRIME)

CAT resource: Paula Salmikangas

Scope: Reflection paper on enhanced early dialogue

Action: for discussion

Reflection

paper: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/10/news_detail_002424.jsp&mid=WC0b01ac058004d5c1-

Note:

The CHMP adopted the reflection paper at its October 2015 meeting and it has now been released for a two-month public consultation, prior to a targeted launch in Q1 2016

The PRIME scheme was presented at July CAT meeting, and the comments made during that meeting were taken into consideration in the reflection paper that was published after the October CHMP.

CAT members were invited to provide any additional written comments and observations on the published reflection paper. Further discussion will take place on operational aspects in view of CAT involvement in PRIME eligibility procedure and support for ATMPs.

7.3.6. EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP)

Scope: Work plan 2016 for the PCWP

Scope: Work plan 2016 for the HCPWP

Scope: draft Agenda - training session for patients and consumers interested in EMA activities – 25 November 2015

Scope: draft Agenda - PCWP meeting with all eligible organisations – 26 November 2015

Action: for adoption

Documents:

Work plans

Agendas

CAT adopted the workplans and agendas of the PCWP and HCPWP.

7.4. Co-operation within the EU regulatory network

None

7.5. Co-operation with international regulators

None

7.6. CAT Work Plan

7.6.1. CAT- International Society for Cellular Therapy (ISCT) Joint Workshop: 'Challenges and Opportunities for the Successful Development and Approval of Advanced Therapy Medicinal Products', Seville (Spain), 25th September 2015

CAT resources: Paula Salmikangas

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/06/new_s_detail_002357.jsp&mid=WC0b01ac058004d5c1

Action: for information

Documents:
Presentations

Postponed until the December CAT meeting

7.6.2. CAT Workplan for 2015: Webinar on ATMP classification

Date: 11 December 2015, 13.00-14.00

Presenters: Nicolas Ferry, Belaid Sekkali, Paula Salmikangas

This Webinar is addressed to the National authorities who are conducting ATMP classifications in their member state

CAT members can attend the Webinar in person

Action: for information

CAT members were asked to promote this webinar at their national agencies.

7.7. Planning and reporting

7.7.1. EMA's Management Board - extension to phase II

Scope: involvement of CAT members and assessment teams

Action: for information

A presentation was given on the data generated on the time spent by the NCA and EMA staff for the scientific advice procedure. It was mentioned that a similar data gathering exercise will be conducted in 2016 for fee generating and for non-fee generating procedures.

7.8. Others

7.8.1. EMA website: upgrade of the ATMPs page

Action: for information

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_00294.jsp&mid=WC0b01ac05800241e0

Note: the improvement of this web page results from a request from EC to clarify and map the requirements for ATMPs in order to help ATMP developers who are often SMEs.

The updated ATMP webpage were presented. The aim of this update is to make the navigating to the various documents and subpages clearer for ATMP developers. CAT members identified a couple of issue that should be considered: it was mentioned that the ATMP webpages are not static and that any comments received (from CAT or from outside CAT) will be taken into consideration.

8. Any other business

Date of next CAT meeting:
Thursday 10th – Friday 11th December 2015

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
DG: Drafting Group
EC: European Commission
FL: Final Letter
GCP: Good Clinical Practice
GLP: Good Laboratory Practice
GMP: Good Manufacturing Practice
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
PDCO: Paediatric Committee
PIP: Paediatric Investigation Plan
PL: Package leaflet
PRAC: Pharmacovigilance and Risk Assessment Committee
RP: Reflection paper
RSI: Request for supplementary information
SA: Scientific Advice
SAG-O: Scientific Advisory Group Oncology
SAWP: Scientific Advice Working Party
SWP: Scientific Working Party
SME: Small and medium size enterprises
SmPC: Summary of Products Characteristics
TT: Timetable

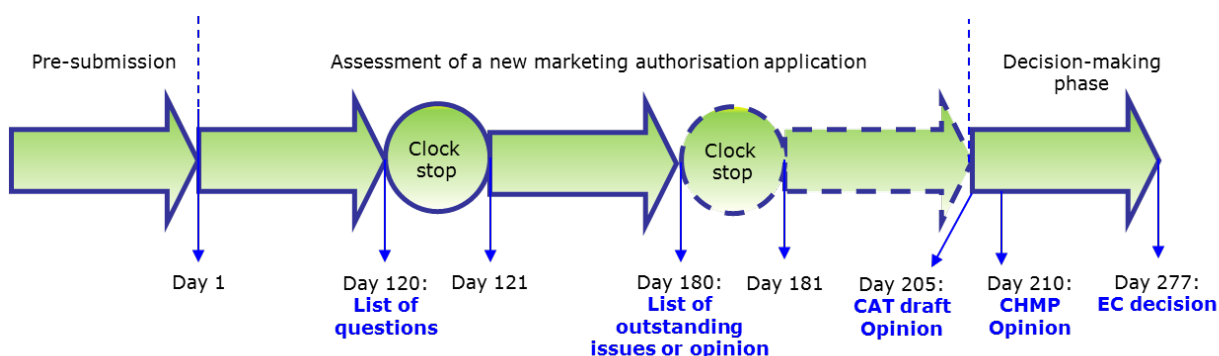
Evaluation of ATMPs (section 2)

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](#).

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/

List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the <DD Month YYYY> meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Paula Salmikangas	Chair	Finland	No interests declared	
Ilona Reischl	Member	Austria	No interests declared	
Belaïd Sekkali	Alternate	Belgium	No interests declared	
Rozalina Kulaksazova	Member	Bulgaria	No interests declared	
Evelina Shumkova	Alternate	Bulgaria	No interests declared	
Ivica Malnar	Alternate	Croatia	No restrictions applicable to this meeting	
Tomáš Boráň	Member	Czech Republic	No interests declared	
Nanna Aaby Kruse	Member	Denmark	No restrictions applicable to this meeting	
Toivo Maimets	Member	Estonia	No interests declared	
Tarmo Tiido	Alternate	Estonia	No interests declared	
Tiina Palomäki	Member	Finland	No interests declared	
Olli Tenhunen	Alternate	Finland	No restrictions applicable to this meeting	
Nicolas Ferry	Member	France	No interests declared	
Violaine Closson	Alternate	France	No interests declared	
Martina Schüssler-Lenz	Member (Vice-Chair)	Germany	No interests declared	
Egbert Flory	Alternate	Germany	No interests declared	
Krisztian Fodor	Member	Hungary	No interests declared	
Maura O'Donovan	Member	Ireland	No interests declared	
Maeve Lally	Alternate	Ireland	No restrictions applicable to this meeting	
Paolo Gasparini	Member	Italy	No interests declared	
Una Riekstina	Member	Latvia	No interests declared	
Guy Berchem	Alternate (to CHMP representative)	Luxembourg	No restrictions applicable to this meeting	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Anthony Samuel	Alternate (to CHMP representative)	Malta	No interests declared	
Johannes Hendrikus Ovelgönne	Member	Netherlands	No interests declared	
Marit Hystad	Member	Norway	No interests declared	
Dariusz Śladowski	Member	Poland	No restrictions applicable to this meeting	
Anna Cieślik	Alternate	Poland	No interests declared	
Margarida Menezes-Ferreira	Alternate (to CHMP representative)	Portugal	No interests declared	
Gianina-Nicoleta Andrei	Alternate	Romania	No interests declared	
Simona Badoi	Member	Romania	No interests declared	
Mikuláš Hrubíško	Member	Slovakia	No restrictions applicable to this meeting	
Ján Kyselovič	Alternate	Slovakia	No interests declared	
Metoda Lipnik-Stangelj	Member	Slovenia	No interests declared	
Marcos Timón	Alternate (to CHMP representative)	Spain	No interests declared	
Lennart Åkerblom	Member	Sweden	No interests declared	
Christiane Niederlaender	Member	United Kingdom	No interests declared	
James McBlane	Alternate	United Kingdom	No interests declared	
Esteve Trias-Adroher	Alternate	Healthcare Professionals' Representative	No interests declared	
Kieran Breen	Member	Patients' Representative	No restrictions applicable to this meeting	
Mariëtte Driessens	Alternate	Patients' Representative	No restrictions applicable to this meeting	
Wiebke Hoppen sack	Expert - via telephone*	Germany	No restrictions applicable to this meeting	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Guido Panté	Expert - via telephone*	Italy	No interests declared	
Carla Herberts	Expert - via telephone*	Netherlands	No interests declared	
Isabel Vieira	Expert - via telephone*	Portugal	No interests declared	
Paulina Lehtolainen-Dalkilic	Expert - via telephone*	Finland	No interests declared	
Heli Suila	Expert - via telephone*	Finland	No interests declared	
Fatima Ventura	Expert - via telephone*	Portugal	No restrictions applicable to this meeting	
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.