



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management and Business Support Division

CAT monthly report of application procedures, guidelines and related documents on advanced therapies

December 2013 meeting

The Committee for Advanced Therapies (CAT) held its 55th CAT meeting on 12th – 13th December 2013.

The CAT Monthly Report includes statistical data on CAT scientific recommendations on Advanced Therapy Medicinal Product (ATMP) classification, certifications, initial evaluations, CAT contributions to Scientific Advice and Paediatric Investigation Plans, as well as variations, line extensions, renewals.

Resignation of Christian Schneider as Chair of the Committee

The Committee noted the resignation of Christian Schneider as CAT Chair from January 2014. Christian Schneider has taken up additional responsibilities at the Danish Health and Medicines Authority that make it impossible for him to continue his role as CAT Chair.

CAT members congratulated Christian Schneider with his new position and thanked him for his excellent chairmanship of the CAT.

Christian Schneider was elected as the first CAT chair in February 2009 and was re-elected for a second term in March 2012. Under his chairmanship, the CAT developed into a prominent player in the field of ATMPs, witnessed by its crucial role in the approval of ATMPs, in scientific advice for ATMPs and in ATMP classifications and certifications. CAT also established firm interactions with its Interested Parties and adopted its Work programme 2010-2015, to gain a better understanding of the environment in which CAT operates, further develop its stakeholders network and achieve European harmonisation via trainings and workshops, with as final aim to facilitate the development and authorisation of ATMPs in the EU. More information on the roles and responsibilities of the CAT and the CAT Work programme can be found [here](#).

CAT will elect a new Chairperson at the February 2014 CAT meeting.

Scientific recommendation on advanced therapy product classification

Further to consultation with the European Commission, the CAT finalised two scientific recommendations on the following classification of advanced therapy medicinal product (ATMP).

The following product was classified as a Tissue engineered product:



- Suspension of Retinal pigment epithelium cells derived from human induced pluripotent stem cells, intended for the treatment of retinal degenerative diseases associated with dystrophic or dysfunctional retinal pigment epithelium cells.

The following product was classified as a Gene Therapy Medicinal Product:

- Genetically modified adenovirus coding for human granulocyte-macrophage colony stimulating factor intended for the treatment of cancer.

CAT received one new ATMP classification request for which a scientific recommendation will be delivered within 60 days (active review time) after receipt of the final request.

Further information on the ATMP classification procedure can be found at:

[European Medicines Agency - ATMP classification](#)

Certification of quality and non-clinical data of ATMPs developed by small and medium-sized companies (SMEs)

CAT noted the start of two new applications for ATMP certification. CAT is a strong believer of the value of this ATMP specific procedure, which is the only procedure that allows for a scientific evaluation of data that the SME has generated at an early stage of the ATMP development.

CAT hopes that this positive trend in numbers of submissions for ATMP certifications will continue in 2014.

Further information on the ATMP certification can be found at:

[European Medicines Agency – ATMP Certification.](#)

CAT Workshop on Cell-based Therapies for Cardiac Repair

CAT discussed the organisation of a workshop on cell-based therapies for Cardiac Repair that will take place in the margins of the May 2014 CAT meeting. This will be a closed workshop between invited experts in the field and CAT members and experts, who will discuss manufacturing, non-clinical and clinical aspects (such as animal models, trial design, endpoints).

Publication of CAT agendas and minutes

From December 2013 onwards, the CAT agenda will be published on the EMA Website after redaction to remove certain commercially confidential information and personal data. The redacted CAT minutes of the December meeting will also be published, after its adoption by the CAT in January 2014. The public agenda and minutes can be found [here](#).

Overview of product-related activities

The Committee discussed ongoing evaluation procedures for ATMPs and other related procedures as summarised in the following tables:

Initial Evaluation of Marketing Authorisation Applications (MAA) for ATMP

	2009	2010	2011	2012	2013	Total
Submitted MAAs	3	1	2	3	2	11
Positive draft Opinion	1	0	1 ⁱ	1 ⁱ	2	5
						Corresponding to 4 ATMPs
Withdrawals	1	1	0	0	2	4
Ongoing MAAs						3

ⁱ Same product (Glybera)

Variations (Type II) for authorised ATMP

	2009	2010	2011	2012	2013	Total
Positive draft Opinion	0	0	1	1	9	11
Negative draft Opinion	0	0	0	0	0	0

Scientific recommendation on advanced therapy classification

	2009	2010	2011	2012	2013	Total
Submitted	22	19	12	17	20	95
Adopted	12	27	12	14	23	90

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs

	2009	2010	2011	2012	2013	Total
Submitted	1	0	0	1	3	5
Adopted	0	1	0	1	1	3

Scientific advice procedures on ATMPs

	2009	2010	2011	2012	2013	Total
Discussed*	25	30	36	31	36	158

* Most scientific advices for ATMPs are discussed by the CAT at 2 time points during the SA procedure

Paediatric Investigation Plans (PIP) for ATMPs

	2009	2010	2011	2012	2013	Total
Discussed*	4	7	6	9	7	33

* PIPs for ATMPs are discussed by the CAT once or twice during the procedure

Upcoming meetings following the December 2013 CAT meeting

The 56th meeting of the CAT will be held at the Agency on 16th – 17th January 2014.

NOTE:

1. This Monthly Report and other documents can be found on the internet at the following location:
[European Medicines Agency - Committee meeting reports - CAT: Committee meeting reports](#)
2. Specific information related to ATMPs and the activities of the CAT (role, responsibilities and composition) can be found at: [European Medicines Agency - CAT - Committee for Advanced Therapies \(CAT\)](#)

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