



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

February 2014 meeting

The Committee for Advanced Therapies (CAT) held its 57th CAT meeting on 13th – 14th February 2014.

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.

CAT elects a new chair

Further to the resignation of Christian Schneider as CAT chair (see CAT monthly report of December 2013), CAT elected a new chair. Paula Salmikangas was elected as the CAT chair for a three-year mandate.

Paula Salmikangas is a senior researcher at the Finnish Medicines Agency and was the CAT vice-chair since the start of the CAT in 2009. Further information can be found [here](#).

CAT will elect a new vice-chairperson at the March 2014 CAT meeting.

Scientific recommendation on advanced therapy product classification

Further to consultation with the European Commission, the CAT finalised one scientific recommendation on the following classification of advanced therapy medicinal products (ATMP).

The following product was classified as a somatic cell therapy product:

- Autologous lymphoid effector cells, intended for the treatment of solid cancers.

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

[European Medicines Agency - ATMP classification](#)

CAT input in International harmonisation activities

CAT discussed its interaction with and input in the activities of the Regulators Forum Cell Therapy discussion group and the Regulators Forum Gene Therapy discussion group.



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	2014	Total
Submitted MAAs	3	1	2	3	2	0	11
Positive draft Opinion	1	0	1 ⁱ	1 ⁱ	2	0	5 Corresponding to 4 ATMPs
Withdrawals	1	1	0	0	2	0	4
Ongoing MAAs							3

ⁱ Same product (Glybera)

Variations (Type II) for authorised ATMP							
	2009	2010	2011	2012	2013	2014	Total
Positive draft Opinion	0	0	1	1	9	1	12

Scientific recommendation on advanced therapy classification							
	2009	2010	2011	2012	2013	2014	Total
Submitted	22	19	12	17	20	2	97
Adopted	12	27	12	14	23	4	94

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs							
	2009	2010	2011	2012	2013	2014	Total
Submitted	1	0	0	1	3	0	5
Adopted	0	1	0	1	1	0	3

Scientific advice procedures on ATMPs							
	2009	2010	2011	2012	2013	2014	Total
Discussed*	25	30	36	31	36	5	163

* 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	2014	Total
Discussed*	4	7	6	9	7	0	33

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

Upcoming meetings following the February 2014 CAT meeting

The 58th meeting of the CAT will be held at the Agency on 13th – 14th March 2014.

NOTE:

1. This Monthly Report, the Agenda of this meeting, the Minutes of the previous CAT meeting 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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