



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance and Committees Division

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

February 2017 meeting

The Committee for Advanced Therapies (CAT) held its 90th CAT meeting on 15 – 17 February 2017.

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 elected a new chair

The CAT elected Martina Schübler-Lenz as its new chair for a three-year mandate. She follows Paula Salmikangas, who had chaired the Committee since February 2014.

Martina Schübler-Lenz is a medical doctor, certified in internal medicine. She is currently the Deputy Head of the Advanced Therapy Medicinal Products Section at the Paul-Ehrlich Institute (PEI) in Langen, Germany, and has been vice-chair of the CAT since March 2014. Further information can be found [here](#).

CAT will elect a new vice-chairperson at the March 2017 CAT meeting.

Scientific recommendation on advanced therapy product classification

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

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

- Autologous tumour-infiltration lymphocytes intended for the treatment of metastatic melanoma.



Organisational matters

- CAT discussed with representatives of the European Pharmacopoeia alternative sterility testing methods for cell-based ATMPs.
- CAT discussed the revision of the ATMP guideline on safety and efficacy follow-up and risk management.
- CAT discussed the Question and Answer document on minimally manipulated ATMPs.
- CAT identified topics for discussion at the CAT Strategy Review and Learning meeting that will take place on 1 – 2 June 2017 in Malta under the auspices of the Maltese Presidency of the Council of the European Union.

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	2015	2016	2017	Total
Submitted MAAs	3	1	2	3	2	2	1	1	0	15
Positive draft Opinion	1	0	1 ⁱⁱ	1 ⁱⁱ	2	1	1	2	0	9*
Negative draft opinions	1 ⁱ	0	1 ⁱⁱ	0	0	0	2 ⁱⁱⁱ	0	0	4
Withdrawals	1	1 ⁱ	0	0	2	0	0	0	0	4
Ongoing MAAs										2

* Corresponding to 8 ATMPs

ⁱ Same product (Cerepro)

ⁱⁱ Same product (Glybera)

ⁱⁱⁱ CAT adopted two negative draft opinions for the same product (Heparesc)

Variations (Type II) for authorised ATMP										
	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Positive Opinion	0	0	1	1	9	4	3	6	0	24

Scientific recommendation on advanced therapy classification										
	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Submitted	22	19	12	22	20	28	61	60	8	252
Adopted	12	27	12	16	23	29	31	87	7	244

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

	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Submitted	1	0	0	1	3	1	1	2	0	9
Adopted	0	1	0	1	1	2	1	1	1	8

Scientific advice procedure for ATMPs

	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Discussed*	25	30	36	31	36	48	63	67	15	351
Number of procedures	17	19	21	19	23	33	39	46	12	229

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

Paediatric Investigation Plans (PIP) for ATMPs

	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Discussed*	4	7	6	9	7	7	3	4	2	49

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

Prime Eligibility for ATMPs

	2016	2017							Total
Discussed	22	5							27
Granted	8	2							10

Upcoming meetings following the February 2017 CAT meeting

The 91st meeting of the CAT will be held on 15 – 17 March 2017.

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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