



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

December 2016 meeting

The Committee for Advanced Therapies (CAT) held its 88th CAT meeting on 8 – 9 December 2016.

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.

Scientific recommendation on advanced therapy product classification

Further to consultation with the European Commission, the CAT finalised 1 scientific recommendation on the classification of advanced therapy medicinal products.

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

- Bone marrow derived mesenchymal cells, intended for the treatment of acute graft versus host disease.

CAT workshop on cell-based cancer immunotherapies

The presentations and the video-recording of the CAT workshop on cell-based cancer immunotherapies that took place at EMA on 15 – 16 November 2016 can be found on the [event webpage](#).

Organisational matters

- CAT discussed their Work Plan for 2017. The plan will be adopted by CAT in January 2017.
- CAT provided input in the Action plan developed by EMA following the ATMP multi-stakeholders [workshop](#) that took place on 27 May 2016.
- CAT discussed the revision of the ATMP guideline on safety and efficacy follow-up and risk management.
- CAT was informed of the revised Policy on handling competing interests for scientific committees' members and experts.



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	Total
Submitted MAAs	3	1	2	3	2	2	1	1	15
Positive draft Opinion	1	0	1 ⁱⁱ	1 ⁱⁱ	2	1	1	2	9
									Corresponding to 8 ATMPs
Negative draft opinions	1 ⁱ	0	1 ⁱⁱ	0	0	0	2 [*]	0	4
Withdrawals	1	1 ⁱ	0	0	2	0	0	0	4
Ongoing MAAs									2

ⁱ Same product (Cerepro)

ⁱⁱ Same product (Glybera)

* 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	Total
Positive draft Opinion	0	0	1	1	9	4	3	6	24

Scientific recommendation on advanced therapy classification									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Submitted	22	19	12	22	20	28	61	60	244
Adopted	12	27	12	16	23	29	31	87	237

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Submitted	1	0	0	1	3	1	1	2	9
Adopted	0	1	0	1	1	2	1	1	7

Scientific advice procedure for ATMPs									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Discussed*	25	30	36	31	36	48	63	67	336
Number of procedures	17	19	21	19	23	33	39	48	219

* 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	Total
Discussed*	4	7	6	9	7	7	3	4	47

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

Prime Eligibility for ATMPs									
	2016								Total
Discussed	22								22
Granted	7								7

Upcoming meetings following the December 2016 CAT meeting

The 89th meeting of the CAT will be held on 18 – 20 January 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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