



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Procedure Management and Committees Support Division

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

### December 2015 meeting

The Committee for Advanced Therapies (CAT) held its 77<sup>th</sup> CAT meeting on 10 – 11 December 2015.

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 four scientific recommendations on the classification of advanced therapy medicinal products.

The following products were classified as somatic cell therapy medicinal products:

- Allogeneic pro-inflammatory monocyte-derived dendritic cells intended for the treatment of metastatic renal cell carcinoma.
- Autologous cells of the stromal vascular fraction of adipose tissue intended for the treatment of pain associated with osteoarthritis.

The following product was classified as tissue engineered product:

- Autologous cells of the stromal vascular fraction of adipose tissue intended for the treatment of non-healing wounds and scared tissue.

The following product was classified as tissue engineered product, combined ATMP:

- Autologous adipose derived regenerative cells encapsulated in hyaluronic acid intended for the treatment on articular cartilage and bone defects.

CAT received 14 new ATMP classification requests for which a scientific recommendation will be delivered within 60 days (active review time).

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

[European Medicines Agency - ATMP classification](#)



## Organisational, regulatory and methodological matters

- CAT adopted their position regarding the application of Good Laboratory Practices (GLP) to ATMPs. The CAT position will be sent to the competent authorities in the member states responsible for clinical trials.
- CAT appointed sponsors for the revision of the Guideline on Safety and Efficacy follow-up – Risk management of ATMPs ([EMEA/149995/2008](#)).
- CAT received feedback from the recent activities by the International Pharmaceutical Regulators Forum ([IPRE](#)) Cell therapy and Gene therapy working groups.

## 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	Total
Submitted MAAs	3	1	2	3	2	2	1	14
Positive draft Opinion	1	0	1 <sup>ii</sup>	1 <sup>ii</sup>	2	1	1	7 Corresponding to 6 ATMPs
Negative draft opinions	1 <sup>i</sup>	0	1 <sup>ii</sup>	0	0	0	2 <sup>iii</sup>	4
Withdrawals	1	1 <sup>i</sup>	0	0	2	0	0	4
Ongoing MAAs								3

<sup>i</sup> Same product (Cerepro)

<sup>ii</sup> Same product (Glybera)

<sup>iii</sup> Same product (Heparesc)

Variations (Type II) for authorised ATMP								
	2009	2010	2011	2012	2013	2014	2015	Total
Positive draft Opinion	0	0	1	1	9	4	3	18

Scientific recommendation on advanced therapy classification								
	2009	2010	2011	2012	2013	2014	2015	Total
Submitted	22	19	12	22	20	28	61	184
Adopted	12	27	12	16	23	29	31	150

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

	2009	2010	2011	2012	2013	2014	2015	Total
Submitted	1	0	0	1	3	1	1	7
Adopted	0	1	0	1	1	2	1	6

### Scientific advice procedures on ATMPs

	2009	2010	2011	2012	2013	2014	2015	Total
Discussed*	25	30	36	31	36	48	58	269
Number of procedures	17	19	21	19	23	33	41	173

\* 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	2015	Total
Discussed*	4	7	6	9	7	7	3	43

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

## Upcoming meetings following the December 2015 CAT meeting

The 78<sup>th</sup> meeting of the CAT will be held on 21 – 22 January 2016.

#### 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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