



7 July 2011  
EMA/CAT/328232/2011 corr. <sup>1</sup>  
Committee for Advanced Therapies

## Monthly Report

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# Committee for Advanced Therapies (CAT)

## April 2011 meeting

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 as well as variations, line extensions, renewals.

In addition, the report includes a summary table of the draft opinions issued by the CAT in the current year and a list of adopted guidelines and other public documents.

The Committee for Advanced Therapies (CAT) held its 26<sup>th</sup> meeting on 7<sup>th</sup> April 2011.

### **Scientific recommendation on advanced therapy classification**

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

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

- Allogeneic human fibroblasts cultured onto a biodegradable matrix, intended for use of conditions in the therapeutic area of dermatology.

The CAT delivered its scientific recommendation after consultation with the European Commission within 60 days (active review time) after receipt of the final requests.

The CAT adopted one draft scientific recommendation on classification on advanced therapy medicinal product (ATMP). This procedure will be finalised after consultation with the European Commission within 60 days (active review time) after receipt of the final requests.

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<sup>1</sup> The document has been revised to correct statistical figures contained in the second table: 'Scientific recommendation on advanced therapy classification' (page 2)



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 - ATMP classification](#)

## Organisational matters

The Committee discussed during the meeting topics related to:

- 4th informal CAT meeting to be held on 31 May-1 June 2011 in Budapest under the auspices of the Hungarian Presidency of the EU
- Report from ATMP Assessors' training that took place on 5th-6th April 2011

## CAT Working Parties

The Committee adopted the agendas of the meetings of the Gene Therapy Working Party and the Cell-based Products Working Party that will take place on 5<sup>th</sup> – 6<sup>th</sup> May 2011.

In particular the Committee was informed on the progress on the development of the Guideline on risk-based approach.

## Overview of product-related activities

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

<b>Initial Evaluation of MAA for ATMP</b>				
	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>Total</b>
Submitted	3	1	0	4
Positive draft Opinion	1	0	0	1
Negative draft Opinion	1*	0	0	1
Withdrawals	1	1	0	2

\* Application subsequently withdrawn

<b>Scientific recommendation on advanced therapy classification</b>				
	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>Total</b>
Submitted	22	19	2	43
Adopted	12	27	3	42

<b>Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs</b>				
	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>Total</b>
Submitted	1	0	0	1
Adopted	0	1	0	1

<b>Contribution to scientific advice procedures</b>				
	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>Total</b>
Submitted*	17	15	2	34

\* Comments from CAT submitted to SAWP

<b>Contribution to Paediatric Investigation Plans (PIP) for ATMPs</b>				
	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>Total</b>
Submitted*	3	1	1	5

\* Comments from CAT submitted to PDCO

## **Upcoming meetings following the April 2011 CAT meeting**

The 27<sup>th</sup> meeting of the CAT will be held at the Agency on 12<sup>th</sup>-13<sup>th</sup> May 2011.

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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