



7 July 2011
EMA/CAT/229545/2011 corr. ¹
Committee for Advanced Therapies

Monthly Report

Committee for Advanced Therapies (CAT)

March 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 25th meeting on 10th-11th March 2011.

Scientific recommendation on advanced therapy classification

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.

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:

- EudraLex Volume 4 GMP final version of Annex 2 'Manufacture of Biological Medicinal Substances and Products for Human Use'.

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



- 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
- ATMP Assessors' training to take place on 5th-6th April 2011
- Implementation of EMA Policy and Procedure on the Handling of Conflicts of Interests of Scientific Committees' Members and Experts (EMA/513078/2010)

CAT Working Parties

The Committee noted the minutes of the meetings of the Gene Therapy Working Party and the Cell-based Products Working Party that took place on 24th-25th February 2011.

In particular the Committee was informed on the following scientific issues:

- Insertional mutagenesis: feedback from GTWP meeting with experts on lessons learnt from design of vectors and relevance of models
- Mesenchymal stem cells and tumorigenicity: proposal to organise an expert meeting at the CPWP October 2011 meeting.

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 MAA for ATMP				
	2009	2010	2011	Total
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

Scientific recommendation on advanced therapy classification				
	2009	2010	2011	Total
Submitted	22	19	1	42
Adopted	12	27	2	41

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

Contribution to scientific advice procedures				
	2009	2010	2011	Total
Submitted*	17	15	1	33

* Comments from CAT submitted to SAWP

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

* Comments from CAT submitted to PDCO

Upcoming meetings following the March 2011 CAT meeting

The 26th meeting of the CAT will be held at the Agency on 7th-8th April 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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