



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 November 2011
EMA/CAT/923034/2011

Monthly Report

Committee for Advanced Therapies (CAT)

November 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 32nd meeting on 10th–11th November 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 products (ATMPs).

The following products were classified as tissue-engineered products:

- Concentrate of autologous bone marrow mononuclear cells (MNC), intended for improvement of heart function and quality of life in patients with chronic ischaemic heart disease and after MI.
- CD 133+ Autologous bone marrow derived stem cells, intended for Improvement of heart function (LVEF) and quality of life in patients with chronic ischemic heart disease and after MI.

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).



CAT received two new ATMP classification requests 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 main topics addressed during the November 2011 CAT meeting related to:

- CAT-ESGTC Satellite Workshop on Advanced Therapy Medicinal Product: 'From promise to reality. Regulatory path for translation of research into commercial medicinal products'. More information on this conference, which took place on 27 October 2011, can be found at: [CAT-ESGCT Satellite Workshop 27 Oct 2011](#).
- CAT Workshop with Stakeholders which will take place on 12 January 2012. The aim of the workshop is to communicate the outcome of CAT-Interested parties Focus Groups meetings held in 2011. Discussions will focus on non-clinical development for ATMPs, better system to navigate ATMP scientific guidance documents, incentives for Academia, hospitals and charities. Registration is available via : (LINK)
- CAT training with inspectors and assessors to take place in April 2012
- Interaction / Co-operation with Notified Bodies. Teleconference meeting on 21st November 2011

- **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	2	6
Positive draft Opinion	1	0	1 ⁱ	2
Negative draft Opinion	1 [*]	0	1	2
Withdrawals	1	1	0	2

* Application subsequently withdrawn

ⁱ Re-examination opinion (Glybera)

Scientific recommendation on advanced therapy classification				
	2009	2010	2011	Total
Submitted	22	19	12	53
Adopted	12	27	11	50

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	7	39

* Comments from CAT submitted to SAWP

Contribution to Paediatric Investigation Plans (PIP) for ATMPs				
	2009	2010	2011	Total
Submitted*	3	1	4	8

* Comments from CAT submitted to PDCO

Upcoming meetings following the November 2011 CAT meeting

The 33rd meeting of the CAT will be held at the Agency on 8th – 9th December 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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