



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 May 2011
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Monthly Report

Committee for Advanced Therapies (CAT)

May 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 27th meeting on 12th–13th May 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 somatic cell therapy medicinal product:

- Heterologous human adult liver-derived progenitor cells, intended for the treatment of inborn errors of liver metabolism

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.

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.

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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

CAT Working Parties

The Committee heard a report from the meetings of the Gene Therapy Working Party and the Cell-based Products Working Party that will take place on 5th – 6th May 2011.

Meeting of the second CAT-Interested Parties Focus Group

The second Focus Group meeting took place on 12th May 2011 to discuss possible means to improve the system by which developers can navigate the maze of ATMPs guidance documents. A summary of the discussions held will be published at: [Interested Parties to the CAT](#)

In relation to its work programme 2010-2015, the CAT started this new initiative in February 2011 to strengthening the dialogue with stakeholders on specific issues identified in 2010 at CAT general hearings. The CAT will continue to convene 'Focus Groups' (FG) with representatives of CAT and Interested parties (IPs) to discuss specific topics and propose possible shared solutions to bottlenecks in the development of ATMPs.

Organisations which have not yet registered to become an interested party to the CAT can still do so by completing the form that can be found on the Agency's Website:

http://www.ema.europa.eu/htms/human/advanced_therapies/interested_parties.htm

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	3	44
Adopted	12	27	4	43

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	3	35

* 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 April 2011 CAT meeting

The 28th meeting of the CAT will be held at the Agency on 16th-17th June 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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