



20 September 2011
EMA/CAT/770104/2011

Monthly Report

Committee for Advanced Therapies (CAT)

September 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 30th meeting on 15th–16th September 2011.

Scientific recommendation on advanced therapy classification

Further to consultation with the European Commission, the CAT finalised two scientific recommendations on the following classification of advanced therapy medicinal products (ATMPs).

The following product was classified as a Tissue Engineered Product, non-combined:

- [Autologous mesenchymal stem cells \(MSC\)](#), intended for the treatment of chronic heart failure symptoms by improvement in exercise capacity of NYHA class II and III chronic heart failure patients receiving standard therapy

The following product was not classified as an ATMP:

- [Human islets of Langerhans](#), intended for: Post pancreatectomy for benign pancreatic pathologies (autologous); Treatment of severe forms of type 1 diabetes (Allogeneic).

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).

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 September 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 will take place on 27 October 2011, can be found at: [CAT-ESGCT Satellite Workshop 27 Oct 2011](#). Registration is available via the ESGCT at: [ESGCT](#).
- Update on the implementation of the revised policy on handling of conflicts of interest of scientific committee members and experts (EMA/513078/2010), which will enter into operation at the end of September 2011.
- Invitation to CAT to participate in the informal meeting organised jointly by the Dutch Medicines Evaluation Board and the Dutch Health Care Inspectorate, to take place in Utrecht on 21-22 November 2011, to discuss implementation of the 'hospital exemption'.

Meeting of the third CAT-Interested Parties Focus Group

The third Focus Group meeting took place on 15th September 2011 to discuss incentives for Academia, hospitals, charities for the development of ATMPs. 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 on the Agency's Website the questionnaire: ['Eligibility to become an interested party to CAT'](#)

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	1	5
Positive draft Opinion	1	0	0	1
Negative draft Opinion	1*	0	1	2
Withdrawals	1	1	0	2

* Application subsequently withdrawn

Scientific recommendation on advanced therapy classification				
	2009	2010	2011	Total
Submitted	22	19	9	50
Adopted	12	27	8	47

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	5	37

* 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 September 2011 CAT meeting

The 31st meeting of the CAT will be held at the Agency on 13th – 14th October 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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