



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

London, 21 September 2010
EMA/CAT/601590/2010

Monthly Report

Committee for Advanced Therapies (CAT) September 2010 meeting

The CAT Monthly Report includes statistical data on CAT scientific recommendation 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 19th meeting on 16th-17th September 2010.

Scientific recommendation on advanced therapy classification

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

The following products were classified as a tissue engineered products:

- Frozen, cultured allogeneic keratinocytes on a silicone dressing material, intended for the treatment of acute burn wounds.
- Autologous human keratinocytes, intended for the treatment of superficial, partial and full thickness burns.
- Allogeneic mesenchymal precursor cells, intended for the treatment of cardiovascular disease.
- Umbilical cord blood cells expanded ex vivo using allogeneic mesenchymal precursor cells, intended for treatment of diseases in haematology-oncology therapeutic area.

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 discussed 5 new ATMP classification procedures for which a scientific recommendation will be delivered within 60 days (active review time) after receipt of the final requests.

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:

- The 3rd informal CAT meeting to be held on 30 September – 1 October under the auspices of the Belgium Presidency of the EU.
- Implementation plans of some of the topics identified in the CAT Work programme 2010-2015.

Hearing with Interested Parties to the CAT

On 16th June 2010, CAT held a hearing with representatives of associations representing mainly Academia (ESGCT, EGBMT, EATRIS, CliniGene, TERMIS, Andalusian Initiative for Advanced Therapies, Spanish Association of Haematology and Haemotherapy, BCRT, ISCT). The CAT discussed topics identified by the stakeholders such as: cGMP and ATMP development, ATMP manufacturing process and QC tests, potency assay for ATMPs, Risk based approach, future CAT interactions with Interested Parties, CAT cooperation with other Regulatory agencies (e.g. FDA), implementation of the 'hospital exemption clause' at member state level, conduct of clinical trials for ATMPs.

Future hearings with other interested parties will be conducted in November-December 2010 in the margins of CAT Plenary meetings.

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	Total
Submitted	3	1	4
Positive draft Opinion	1	0	1
Negative draft Opinion	1 [#]	0	1
Withdrawals	1	1	2

[#] application subsequently withdrawn

Scientific recommendation on advanced therapy classification			
	2009	2010	Total
Submitted	22	16	38
Adopted	12	21	33

Contribution to scientific advice procedures			
	2009	2010	Total
Submitted*	17	12	29

* Comments from CAT submitted to SAWP

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

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

* Comments from CAT submitted to PDCO

UPCOMING MEETINGS FOLLOWING THE SEPTEMBER 2010 CAT MEETING

The 3rd informal CAT meeting will be held in Belgium on 30th September – 1st October 2010.

The 20th meeting of the CAT will be held at the Agency on 14th-15th October 2010.

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 \(CAT\)](#)
- 3.

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