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Monthly Report

Committee for Advanced Therapies (CAT)
December 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 22nd meeting on 9th-10th December 2010.

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 gene therapy medicinal product:

- Lentiviral vector expressing the naturally occurring human anti-angiogenic proteins endostatin and angiostatin intended for treatment of age-related macular degeneration.

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 received one new ATMP classification procedure 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

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Organisational matters

The Committee discussed during the meeting topics related to:

- Implementation plans for some of the objectives identified in the CAT Work programme 2010-2015.
- New Pharmacovigilance Legislation as adopted by the European Parliament at its plenary on 22 September 2010
- EMA Policy and Procedure on the Handling of Conflicts of Interests of Scientific Committees' Members and Experts (EMA/513078/2010)

General Scientific issues

- Feedback was provided to the CAT on the discussions that took place at the plenary meetings of the Gene Therapy Working Party (GTWP) on 25th – 26th November 2010and the Cell-based Products Working Party (CPWP) on 22nd – 23rd November 2010.

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	19	41
Adopted	12	27	39

Contribution to scientific advice procedures			
	2009	**2010**	**Total**
Submitted*	17	15	32

* 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 DECEMBER 2010 CAT MEETING

The 23rd meeting of the CAT will be held at the Agency on 13th-14th January 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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Annex 1:

Summary of the outcomes of the EMA/CAT-Notified Body Coordination group meeting of 24th November 2010

The collaboration group members held their 24th November 2010 meeting by teleconference, during which the review of the external comments received on the draft "Procedural advice on the consultation of Notified Bodies in accordance with Article 9 of Regulation (EC) No. 1394/2007" have been reviewed. The details and updated guidance is expected to be presented at the January 2011 CAT plenary meeting for discussion.

"The EMA/CAT and Medical Devices' Notified Body (EMA/CAT-NB) Collaboration Group Mandate, objectives and work program as adopted by the CAT collaboration group and CAT in September 2010 is now published together with the composition of the group on EMA website at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CAT/people_listing_000086.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac058029021c