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**COMMITTEE FOR ADVANCED THERAPIES (CAT)
NOVEMBER 2009 MEETING
MONTHLY REPORT**

The CAT Monthly Report includes statistical data for the current year on CAT scientific recommendation on 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 10th meeting on 12th-13th November 2009.

Scientific recommendation on advanced therapy classification

The CAT adopted one scientific recommendation on the following classification of advanced therapy medicinal products (ATMPs):

- Fresh and freeze-dried thrombocytes isolated from autologous or allogeneic blood

These products, intended for wound healing in orthopaedic and dental surgery, were not considered by CAT as ATMPs. The CAT delivered this scientific recommendation after consultation with the European Commission in 60 days (active review time) after receipt of the final requests.

Further information on the ATMP classification procedure can be found at:

http://www.emea.europa.eu/htms/human/advanced_therapies/atmp_classification.htm

Organisational matters

Further to the end of the public consultation, the CAT adopted the following documents:

- Procedural Advice on Scientific Recommendation on Advanced Therapy Classification (EMEA/584508/2008).
- Overview of comments received during the consultation period (EMEA/CAT/558026/2008).

The ATMP classification is an optional procedure that can be used by Applicants to determine whether a given product based on genes, cells or tissues meets the scientific criteria which define ATMPs. The procedural advice document describes the procedure and gives guidance for the steps to be followed by Applicant and the EMEA for the ATMP classification. The CAT will deliver such scientific recommendations after consultation with the European Commission within 60 days after receipt of the request. This procedural advice document, the overview of comments and the respective revised application form will be available in due course on the EMEA web site at:

http://www.emea.europa.eu/htms/human/advanced_therapies/regulation.htm

The CAT also adopted the PCWP Work Plan 2010. That is now available at:

<http://www.emea.europa.eu/pdfs/human/pcwp/pcwpworkprogramme.pdf>

The Committee addressed during the meeting topics related to:

- Dossier requirements for new ATMP marketing authorisation applications (MAA): see procedural announcement below.

General scientific issues

The Committee discussed:

- 'Question and Answers' document on gene therapy, developed by GTWP;
- Concept Paper on the Revision of the Note for Guidance on the Quality, Pre-clinical and Clinical Aspects of Gene Transfer Medicinal Products, developed by GTWP;
- Concept paper on the development of a guideline on the application of the risk-based approach according to Annex I Part IV of Dir. 2001/83/EC applied to ATMPs, developed by CPWP/GTWP.

PROCEDURAL ANNOUNCEMENT

Submission of new MAA for ATMPs

Applicants who intend to submit a MAA for an ATMP are advised to check the dates for submission and the correct number of copies of MAA dossier to be sent to Rapporteur and Co-Rapporteur published at: http://www.emea.europa.eu/hums/human/advanced_therapies/MAAsubmission.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	Total
Submitted	3	3
Ongoing	1	1
Positive draft Opinion	1	1
Negative draft Opinion	0	0
Withdrawals	1	1

Scientific recommendation on advanced therapy classification		
	2009	Total
Submitted	20	20
Ongoing	12	12
Adopted	8	8

Contribution to scientific advice procedures		
	2009	Total
Submitted*	15	15

* Comments from CAT submitted to SAWP

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

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

* Comments from CAT submitted to PDCO

UPCOMING MEETINGS FOLLOWING THE NOVEMBER 2009 CAT MEETING

- The 11th meeting of the CAT will be held at the EMEA on 3rd-4th December 2009.

NOTE:

1. This Monthly Report and other documents may be found on the internet at the following location: <http://www.emea.europa.eu>
2. Specific information related to ATMPs and the activities of the CAT (role, responsibilities and composition) can be found at:
http://www.emea.europa.eu/htms/human/advanced_therapies/intro.htm and
<http://www.emea.europa.eu/htms/general/contacts/CAT/CAT.html>

Tony Humphreys
Head of Regulatory Affairs and Organisational Support Sector
Tel.: (44-20) 7418 8583
Fax: (44-20) 7523 7051
AdvancedTherapies@emea.europa.eu