



**COMMITTEE FOR ADVANCED THERAPIES (CAT)
APRIL 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 will include 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 fourth meeting on 16th-17th April 2009.

The Committee welcomed Dr. Paolo Macchiarini from the Department of General Thoracic Surgery, Hospital Clinic, Barcelona who gave a lecture on his experience on trachea transplants using autologous stem cells.

Organisational matters

The Committee adopted the following documents:

- Procedural Advice on Certification of quality and non-clinical data for SMEs developing Advanced Therapy Medicinal Products (ATMPs) (EMEA/418458/2008)

This procedural advice document describes the procedure, timeline and administrative information related to the evaluation and certification of quality and non-clinical data for Small and Medium-Sized Enterprises (SMEs) developing ATMPs. The document will be available in due course on the EMEA web site at:

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

Other topics addressed during the April 2009 CAT meeting related to:

- Coordination with Patients' and Consumers' Working Party (PCWP): the CAT appointed a representative and alternate representative in the PCWP.
- Coordination with SAWP: the CAT proposed a CAT member as an additional member of the SAWP with a view to improving coordination on scientific advice/protocol assistance procedures concerning ATMPs.

General scientific issues

The Committee discussed:

- Development of 'Scientific guideline on the minimum quality and non-clinical data for certification of advanced therapy medicinal products'.
- Development of a reflection paper on requirements for chondrocyte-containing products.
- Draft of an article on the role of the CAT and on challenges with ATMPs, to be published in a scientific journal with a view to strengthening collaboration with academia.
- Scientific issues related to xenogeneic cells.
- Comments on ICH Consideration concerning oncolytic viruses.
- Definition of the term 'non-routine preparation' versus 'industrial manufacturing process' of ATMPs in the context of Article 28(2) of Regulation (EC) No. 1394/2007.

Product-related activities

Initial applications for marketing authorisation: Lists of Questions

The Committee adopted one List of Questions on an initial application (in accordance with Regulation (EC) No. 1394/2007).

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	3	3
Positive draft Opinion	0	0
Negative draft Opinion	0	0
Withdrawals	0	0

Scientific recommendation on advanced therapy classification		
	2009	Total
Submitted	1	1

Contribution to scientific advice procedures		
	2009	Total
Submitted	6	6

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

UPCOMING MEETINGS FOLLOWING THE APRIL 2009 CAT MEETING

- The 5th meeting of the CAT will be held at the EMEA on 14th-15th May 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>

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