



London, 19th May 2009
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**COMMITTEE FOR ADVANCED THERAPIES (CAT)
MAY 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 fifth meeting on 14th-15th May 2009.

Organisational matters

The Committee addressed during the meeting topics related to:

- Public Consultation Paper on the Implementation of the Variations Regulation (EC) No. 1234/2008 Article 4(1) (a) and Article 4(1) (b);
- Discussion on the current EMEA Policy and Procedure on the handling of conflicts of interest of Committee members and experts;
- Discussion on the consultation of notified bodies in accordance with Article 9 of the Regulation (EC) No. 1394/2007;
- Overview of the pharmacovigilance system and the medical device vigilance system in the Community;
- Objectives of the ICH M5 project to develop harmonised electronic transmission standards that build on the regulatory and technical processes currently established in the three ICH regions and observer countries.

General scientific issues

The Committee discussed:

- Development of a 'Scientific guideline on the minimum quality and non-clinical data for certification of advanced therapy medicinal products';
- Outline of a reflection paper on requirements for chondrocyte-containing products;
- A draft 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;
- Comments on the ICH considerations concerning viral/vector shedding.

Product-related activities

Initial applications for marketing authorisation: Lists of Questions

The Committee adopted one List of Outstanding Issues 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	3	3
Ongoing	2	2
Adopted	0	0

Contribution to scientific advice procedures		
	2009	Total
Submitted*	7	7

* Comments from CAT submitted to SAWP

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 6th meeting of the CAT will be held at the EMEA on 18th-19th June 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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