



**COMMITTEE FOR ADVANCED THERAPIES (CAT)
JUNE 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 six meeting on 18th-19th June 2009.

Initial applications for marketing authorisation

The CAT adopted one draft positive opinion by majority on an initial marketing authorisation application (in accordance with Regulation (EC) No. 1394/2007). The draft opinion was transmitted to CHMP for adoption.

New medicinal products

ChondroCelect (Characterised viable autologous cartilage-forming cells expanded in vivo expressing specific marker proteins), from TiGenix NV, intended for the repair of single symptomatic cartilage defects of the femoral condyle of the knee (International Cartilage Repair Society [ICRS] grade III or IV) in adults.

Scientific recommendation on advanced therapy classification

The CAT adopted one scientific recommendation on the classification of an advanced therapy medicinal product (ATMP)

The product, composed of substantially modified human allogeneic fibroblasts and keratinocytes administered in conjunction with fibrin as structural component, intended for the treatment of chronic venous leg ulcers, was classified by CAT as an ATMP and in particular as a somatic cell therapy medicinal product.

The CAT delivered its scientific recommendations after consultation with the European Commission in 60 days after receipt of the request.

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

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

Organisational matters

The Committee agreed on the establishment of a list of interested parties to CAT with a view to fostering an active dialogue with industries, developers, academia, patients and clinicians and to exchange scientific views and further develop the regulatory framework for the authorisation of ATMPs.

A call for interest to become an interest party to the CAT is now published at:

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

The deadline for submitting the expression of interest is 31 July 2009

General scientific issues

The Committee adopted the following documents:

- 'Scientific guideline on the minimum quality and non-clinical data for certification of advanced therapy medicinal products' (EMEA/486831/2008)

This guideline addresses the scientific content of an application for certification of quality and non-clinical data for Small and Medium-Sized Enterprises (SMEs) developing ATMPs. In particular it defines the minimum data content for the certification dossier.

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

The Committee discussed:

- Outline of a reflection paper on requirements for chondrocyte-containing products to be further developed by working parties such as CPWP;
- Final version 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;

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	2	2
Positive draft Opinion	1	1
Negative draft Opinion	0	0
Withdrawals	0	0

Scientific recommendation on advanced therapy classification		
	2009	Total
Submitted	5	5
Ongoing	4	4
Adopted	1	1

Contribution to scientific advice procedures		
	2009	Total
Submitted*	9	9

* 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 7th meeting of the CAT will be held at the EMEA on 16th-17th July 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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