European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 27th March 2009
EMEA/CAT/169206/2009

COMMITTEE FOR ADVANCED THERAPIES (CAT)
MARCH 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 third meeting on 12th-13th March 2009.

The Committee welcomed a delegation from Japan. Prof. Takao Hayakawa – Director of the Pharmaceutical Research Technology Institute at the Kinki University and Senior Advisor at the Pharmaceuticals and Medical Devices Agency and Dr Yoji Sato - Section Chief at the Division of Gene and Cellular Therapy Products at the national Institute of Health Sciences (NIHS) who attended the CAT meeting with a view to learning more about the European approach to advanced therapy medicinal products (ATMPs) and to exploring potential opportunities for co-operation between EC/EMEA and Japan in this area.

Organisational matters
The Committee adopted the following documents:

- CAT Rules of Procedure (EMEA/CAT/454446/2008) to be published in due course.

- Procedural Advice on the evaluation of Advanced Therapy Medicinal Products (ATMPs) (pre-authorisation, post-authorisation, re-examination) (EMEA/630043/2008) .
- Procedural Advice on Scientific Recommendation on Advanced Therapy Classification (EMEA/584508/2008)[1], including:
  - Request Form for Applicants
  - Report Template (EMEA/13650/2009)

These procedural advice documents 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 March 2009 CAT meeting related to:

- Implementation of legislation on ATMPs. The Committee was informed on the adoption of the implementing Regulation on Certification of ATMPs and of the revision of Annex I to Directive 2001/83/EC by the European Commission Standing Committee on Medicinal Products for Human Use at their meeting on 2nd March 2009.

[1] Already adopted at the February 2009 CAT plenary

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- Products legally on the Community market in accordance with national or Community legislation that need to comply with Regulation 1394/2007 by end of 2011/2012 (Article 29 of Regulation (EC) No 1394/2007[2]). CAT stressed the importance of early contacts with the Agency (see procedural announcement below).
- CAT members provided feedback on the implementation of the Article 28 (2) of Regulation (EC) No 1394/2007 ('hospital exemption' clause) at Member State level.

General scientific issues

The Committee discussed:

- Requirements for chondrocyte-containing products
- A proposal to strengthen collaboration with academia, including the publication of an overview article in a scientific journal on the role of the CAT and on challenges with ATMPs.
- Risk management plans and post-authorisation follow-up of ATMPs and the impact on evaluation procedures (pre /post activities).

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

Scientific recommendation on advanced therapy classification		
	2009	**Total**
Submitted	**0**	**0**

Contribution to scientific advice procedures		
	2009	**Total**
Submitted	5	5

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

[2] Regulation (EC) 1394/2007: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_2007_1394/reg_2007_1394_en.pdf

PROCEDURAL ANNOUNCEMENT

Article 29 of the Regulation on Advanced Therapies (Regulation (EC) 1394/2007): ATMPs legally on the Community market

Manufacturers, companies and hospitals having ATMPs legally on the Community market in accordance with national or Community legislation are recommended to contact the EMEA as soon as possible.

Such early interactions will facilitate discussions on the data package to be submitted for the marketing authorisation procedure according to Article 29 of the above mentioned Regulation and will also allow EMEA to complete their database on ATMPs already on the Community market.

Further information on this procedure can be found in the 'EMEA announcement to manufacturers, companies and hospitals having advanced therapy medicinal products legally on the Community market in accordance with national or Community legislation' (EMEA/326145/2008) which is available on the EMEA website at:
http://www.emea.europa.eu/pdfs/human/genetherapy/32614508en.pdf

UPCOMING MEETINGS FOLLOWING THE MARCH 2009 CAT MEETING

- The 4th meeting of the CAT will be held at the EMEA on 16th-17th April 2009.
- The 1st Workshop on ATMPs will be held at the EMEA on 3rd April 2009 (further information on this event is available at: http://www.emea.europa.eu/htms/human/advanced_therapies/regulation.htm).

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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