EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Monthly Report

Committee for Advanced Therapies (CAT)
April 2010 meeting

The CAT Monthly Report includes statistical data on CAT scientific recommendation on Advanced Therapy Medicinal Product (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 15th meeting on 15th-16th April 2010.

Public statement 'Concerns over unregulated medicinal products containing stem cells'

The Agency and the CAT have issued a public statement highlighting that access to medicinal products containing stem cells should only be under certain controlled conditions. The public statement is available at http://www.ema.europa.eu/pdfs/human/cat/76346309en.pdf

Scientific recommendation on advanced therapy classification

Further to consultation with European Commission, the CAT finalised one scientific recommendation on the following classification of advanced therapy medicinal products (ATMPs).

The following medicine was classified as gene therapy medicinal product:

- Product consisting of a DNA plasmid encoding for the human fibroblast growth factor type 1 (FGF 1), intended for the treatment of Critical limb ischemia.

The CAT delivered its scientific recommendation after consultation with the European Commission within 60 days (active review time) after receipt of the final requests.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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

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

General scientific issues

The Committee adopted the following document:

- Reflection paper on requirements for chondrocyte-containing products for cartilage repair of the knee (EMEA/CAT/CPWP/288934/2009)

This reflection paper, revised further to comments received during the public consultation, covers specific quality, non-clinical and clinical aspects related to medicinal products containing in vitro cultured autologous chondrocytes intended for the repair of cartilage lesions of the knee.

The document and the respective 'overview of comments' will be published in due course at:

http://www.ema.europa.eu/htms/human/humanguidelines/multidiscipline.htm#celltherapy

Organisational matters

The Committee discussed during the meeting topics related to:

- Agenda of the CAT informal meeting to be held under the Spanish presidency of the European Union on 5th May 2010.
- Draft CAT Work programme 2010-2015;
- EMA contribution to the European Commission's guideline on traceability requirements for ATMP.
- Training on recent implementation plans regarding the revised SmPC. Within such context, a EudraSmPC webpage for use by National Competent Authorities and the Agency was launched on 22nd March 2010 (http://eudrasmpc.eudra.org/)

Hearing with Interested Parties to the CAT

Based on the review of the responses to a questionnaire sent to all its interested parties, the CAT decided to hold separate meetings dedicated to specific needs of the various interested parties (large associations representing industry; SMEs; Academia, hospitals and research groups).

On 15th April 2010, CAT held a hearing with representatives of large industry associations (EuropaBio, EBE, Eucomed, BHA, BIA). The agenda included a presentation on the current activities of CAT and a question and answer session on access/use of regulatory procedures, scientific guidelines on categories of products, other specific topics suggested by participants . In order to allow for an in-depth discussion of all the topics on the agenda, the hearing will be continued during the next CAT meeting on 11-12 May 2010.

Future hearings with other interested parties will be conducted between June and September 2010 in the margins of CAT Plenary meetings.

Organisations which have not yet registered to become an interested party to the CAT can still do so by completing the form that can be found on the Agency's Website:

http://www.ema.europa.eu/htms/human/advanced_therapies/interested_parties.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	**2010**	**Total**
Submitted	3	1	4
Positive draft Opinion	1	0	1
Negative draft Opinion	1[#]	0	1
Withdrawals	1	1	2

[#] application subsequently withdrawn

Scientific recommendation on advanced therapy classification			
	2009	**2010**	**Total**
Submitted	22	4	26
Adopted	12	14	26

Contribution to scientific advice procedures			
	2009	**2010**	**Total**
Submitted*	17	7	24

* Comments from CAT submitted to SAWP

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs			
	2009	**2010**	**Total**
Submitted	1	0	1
Adopted	0	0	0

Contribution to Paediatric Investigation Plans (PIP) for ATMPs			
	2009	**2010**	**Total**
Submitted*	3	0	3

* Comments from CAT submitted to PDCO

UPCOMING MEETINGS FOLLOWING THE APRIL 2010 CAT MEETING

The 16th meeting of the CAT will be held at the Agency on 11th-12th May 2010.

The European Medicines Agency's Workshop on stem cell based therapies will be held at the Agency on 10th May 2010. More information can be found at:
http://www.ema.europa.eu/pdfs/conferenceflyers/EMA_Stemcell_Workshop.pdf

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

Tony Humphreys
Head of Regulatory, Procedural and Committee Support Sector
Tel.: (44-20) 7418 8583
Fax: (44-20) 7523 7051
AdvancedTherapies@ema.europa.eu