London, 14 January 2011
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Monthly Report

Committee for Advanced Therapies (CAT)
January 2011 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 23rd meeting on 13th-14th January 2011.

Scientific recommendation on advanced therapy classification

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

The following product was classified as a tissue engineered product - not combined:

- Layer of autologous corneal epithelium containing stem cells intended for the treatment of extended corneal lesions.

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

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

European Medicines Agency - ATMP classification - ATMP classification

Organisational matters

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The Committee discussed during the meeting topics related to:

- Implementation plans for some of the objectives identified in the CAT Work programme 2010-2015.
- Eudra Clinical Trials Application Form v8.0

CAT Working Parties

The Committee conducted the election of the vice-chair of the Gene Therapy Working Party (GTWP): Sharon Longhurst was elected as Vice-chair of the GTWP.

The mandate, objectives, rules of procedure, composition and work programmes of the GTWP are available at: European Medicines Agency - Gene Therapy Working Party - Gene Therapy Working Party

General Scientific issues

The Committee adopted the following document:

- 'Reflection paper on stem cell based medicinal products' (EMA/CAT/571134/2009)

This reflection paper, revised further to comments received during the public consultation, covers specific quality, non-clinical and clinical aspects related to stem cells based medicinal products. 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

Hearing with Interested Parties to the CAT

On 13th January 2011, CAT held a hearing with representatives of associations representing mainly Patients' organisations, Charities, Trusts and other organisations supporting development of ATMPs (EPPOSI, Eurordis, Fondazione Telethon, German Society for Regenerative Medicine, Innovative Small Life Science Companies in Sweden, TOPRA, CIBER-BBN, Debra International, CIBERER, GENETHON).

The CAT discussed topics identified by the stakeholders such as: future CAT interactions with Interested Parties, implementation of the 'hospital exemption clause' at member state level, incentives for non-for profit developers, clarifications on ATMP classification and certification, cord blood banking for allogenic or autologous use.

In relation to its work programme 2010-2015, the CAT is starting a new initiative to strengthening the dialogue with stakeholders on specific issues identified in 2010 at CAT general hearings. From February 2011 the CAT will convene 'Focus Groups' (FG) with representatives of CAT and Interested parties (IPs) to discuss specific topics and propose possible shared solutions to bottlenecks in the development of ATMPs.

The first Focus Group will address issues concerning non-clinical development of ATMPs.

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**	**2011**	**Total**
Submitted	3	1	0	4
Positive draft Opinion	1	0	0	1
Negative draft Opinion	1*	0	0	1
Withdrawals	1	1	0	2

* Application subsequently withdrawn

Scientific recommendation on advanced therapy classification				
	2009	**2010**	**2011**	**Total**
Submitted	22	19	0	41
Adopted	12	27	1	40

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs				
	2009	**2010**	**2011**	**Total**
Submitted	1	0	0	1
Adopted	0	1	0	1

Contribution to scientific advice procedures				
	2009	**2010**	**2011**	**Total**
Submitted*	17	15	1	33

* Comments from CAT submitted to SAWP

Contribution to Paediatric Investigation Plans (PIP) for ATMPs				
	2009	**2010**	**2011**	**Total**
Submitted*	3	1	0	4

* Comments from CAT submitted to PDCO

UPCOMING MEETINGS FOLLOWING THE JANUARY 2011 CAT MEETING

The 24th meeting of the CAT will be held at the Agency on 10th-11th February 2011.

NOTE:

1. This Monthly Report and other documents can be found on the internet at the following location: European Medicines Agency - Committee meeting reports - CAT: Committee meeting reports
2. Specific information related to ATMPs and the activities of the CAT (role, responsibilities and composition) can be found at: European Medicines Agency - CAT - Committee for Advanced Therapies (CAT)

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