London, 20 July 2010
EMA/CAT/407854/2010

Monthly Report

Committee for Advanced Therapies (CAT)
July 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 18th meeting on 15th-16th July 2010.

CAT Working Parties

Further to the establishment of the Working Party on Cell-based Products (CPWP) and Gene Therapy Working Party (GTWP) and the appointment of its members at their June meeting, the Committee conducted the elections of the respective chairs and vice-chairs:

- For the Gene Therapy Working Party, Maria-Cristina Galli was elected as Chair. The position of Vice-chair remained vacant as no candidatures were received.
- For the Working Party on Cell-based Product, Paula Salmikangas was elected as Chair and Egbert Flory as Vice-chair.

CAT adopted the work programmes of the CPWP and GTWP for 2010. These work programmes were previously discussed by CAT and adopted by CHMP.

The mandate, objectives, rules of procedure, composition and work programmes of the CPWP and GTWP will be published shortly here:

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

Scientific recommendation on advanced therapy classification

Further to consultation with the European Commission, the CAT finalised three scientific recommendations on the following classifications of advanced therapy medicinal products (ATMPs).

The following products were classified as somatic cell therapy products:

- Autologous *ex-vivo* pulsed dendritic cells, intended for the treatment of ovarian cancer;
- Mixture of porcine beta cells and their accompanying endocrine cell populations embedded in an alginate matrix, intended for the treatment of diabetes.

The following product was classified as a somatic cell therapy medicinal product, combined:

- Hollow fibre cartridge populated with C3A cells, to be used with ancillary support equipment, intended for the treatment of acute or chronic hepatitis.

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

The CAT received 2 new ATMP classification procedures, which are scheduled to start on 13 August 2010. The scientific recommendation will be delivered 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

General scientific issues

The Committee was informed of the outcome of a Drafting group meeting, held on 14th July 2010, with experts from the CPWP, GTWP and BWP on the development of the 'Reflection paper on clinical aspects specific to tissue engineered product' and the 'Guideline on risk-based approach, and on the finalisation of 'Reflection paper on stem cell-based medicinal products'. Further discussion on these guidance documents will take place in the CPWP and GTWP meeting in September 2010.

Organisational matters

The Committee adopted the 'Procedural Advice on the consultation of Notified Bodies in accordance with art. 9 of Regulation (EC) No 1394/2007' (EMA/CAT/354785/2010). This document will be published in due course on the EMA website for comments until 29th October 2010 at:

European Medicines Agency - Guidance - Advanced therapies: Regulatory and procedural guidance

The Committee adopted the revised mandate, objectives and rules of procedure for the EMA human scientific committees' working party with patients' and consumers' organisations (PCWP) (EMA/369907/2010, rev. 1).

The Committee discussed during the meeting topics related to:

- The interaction with the Committee for Orphan Medicinal Products.
- The 3rd informal CAT meeting to be held on 30 September – 1 October under the auspices of the Belgium Presidency of the EU.
- Implementation plans of some of the topics identified in the CAT Roadmap to 2015.
- Guideline on quality, non-clinical and clinical aspects of live recombinant vectored vaccines (EMA/CHMP/141697/2010).

- WHO guiding principles for human cell, tissue and organ transplantation.
- Updated of the International Standardization of Identification of Medicinal Products (IDMP - ICH M5).

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	13	35
Adopted	12	17	29

Contribution to scientific advice procedures			
	2009	**2010**	**Total**
Submitted*	17	10	27

* 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	1	1

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

* Comments from CAT submitted to PDCO

UPCOMING MEETINGS FOLLOWING THE JULY 2010 CAT MEETING

The 19th meeting of the CAT will be held at the Agency on 16th-17th September 2010.

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)
3.

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