EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Monthly Report

Committee for Advanced Therapies (CAT)

December 2011 meeting

The CAT Monthly Report includes statistical data on CAT scientific recommendations 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 33rd meeting on 8th – 9th December 2011.

Scientific recommendation on advanced therapy product classification

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

The following product was classified as somatic cell therapy medicinal product:

- Autologous CD4+ T cells targeted to cells presenting class II restricted epitopes, intended for the treatment of autoimmune diseases with MHC restricted specific immunity e.g. multiple sclerosis, type I diabetes or graft rejection.

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 adopted two draft scientific recommendations on classification on advanced therapy medicinal products. This procedure will be finalised after consultation with the European Commission within 60 days (active review time).

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

European Medicines Agency - ATMP classification - ATMP classification

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

Organisational matters

The main topics addressed during the December 2011 CAT meeting related to:

- CAT adopted the final programme of the CAT Workshop with Stakeholders, which will take place on 12 January 2012. The aim of the workshop is to communicate the outcome of CAT-Interested parties Focus Groups meetings held in 2011. Discussions will focus on non-clinical develoment for ATMPs, better system to navigate ATMP scientific guidance documents, incentives for Academia, hospitals and charities. Registration is available via : CAT-Stakeholders workshop 12-01-2012

- Feedback from the CAT informal meeting, organised jointly by the Dutch Medicines Evaluation Board and the Dutch Health Care Inspectorate, which took place in Utrecht on 21st-22nd November 2011, on the implementation of the 'Hospital Exemption'.

- Feedback from the discussions at the EMA/CAT – Notified Body Collaboration Group teleconference meeting of 21st November 2011.

CAT Working Parties

- CAT adopted the Work programmes of the GTWP and CPWP for 2012.

- CAT adopted the Reflection paper on modifications of gene therapy medical product design during its development (EMA/CAT/GTWP/44236/2009).

- CAT adopted the Guideline on the application of the risk-based approach of ATMPs (EMA/CAT/CPWP/686637/2011). This guideline, which was developed jointly by the CPWP and GTWP, is released for external consultation until end of April 2012.

General scientific issues

- CAT adopted the Work Plan for 2012 of the Patient and Consumers Working Party (PCWP).

- CAT discussed with representatives from the European Directorate for the Quality of Medicines & Healthcare (EDQM) the proposal to elaborate an European Pharmacopoeia monograph on *Raw materials fro the production of cellular and gene transfer products*.

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	2	6
Positive draft Opinion	1	0	1[i]	2
Negative draft Opinion	1[*]	0	1	2
Withdrawals	1	1	0	2

* Application subsequently withdrawn
[i] Re-examination opinion (Glybera)

Scientific recommendation on advanced therapy classification				
	2009	**2010**	**2011**	**Total**
Submitted	22	19	12	53
Adopted	12	27	12	51

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	8	40

* Comments from CAT submitted to SAWP

Contribution to Paediatric Investigation Plans (PIP) for ATMPs				
	2009	**2010**	**2011**	**Total**
Submitted*	3	1	4	8

* Comments from CAT submitted to PDCO

Upcoming meetings following the December 2011 CAT meeting

The 34th meeting of the CAT will be held at the Agency on 11th – 13th January 2012.

The CAT Workshop with Stakeholders will be held at the Agency on 12th January 2012.

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)

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