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Monthly Report

Committee for Advanced Therapies (CAT)
February 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 24th meeting on 10th-11th February 2011.

Centralised Procedure: post authorisation activities
The CAT adopted the draft opinion on a type II variation submitted for ChondroCelect for a change to the manufacturing process of the active substance. The draft opinion has been subsequently adopted by the CHMP.

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 gene therapy medicinal product:

- Medicinal product composed of living, genetically modified Lactococcus lactis bacteria, containing the human Trefoil Factor 1 (hTFF1) gene, intended for the prevention and treatment of chemotherapy-Induced and/or radiotherapy-induced oral mucositis in patients with cancer of the head and the neck.

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

CAT received 1 new ATMP classification for which a scientific recommendation will be delivered within 60 days (active review time) after receipt of the final request.

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

European Medicines Agency - ATMP classification - ATMP classification

Organisational matters

The Committee adopted the following document:

- 'Procedural Advice on the consultation of Notified Bodies in accordance with art. 9 of Regulation (EC) No 1394/2007' (EMA/CAT/354785/2010)

This procedural advice, revised further to the comments received during the public consultation, and the respective 'Overview of comments' will be published in due course at:

European Medicines Agency - Advanced Therapies: Regulatory and Procedural Guidance

CAT Working Parties

The Committee adopted the draft Agendas of the meetings of the Gene Therapy Working Party and the Cell-based Products Working Party that will take place on 24th-25th February 2011.

Meeting of the first CAT-Interested Parties Focus Group

In relation to its work programme 2010-2015, the CAT started a new initiative to strengthening the dialogue with stakeholders on specific issues identified in 2010 at CAT general hearings. 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 meeting took place on 9th February 2011 and issues concerning non-clinical development of ATMPs were discussed. A summary of the discussions held can be found at: Interested Parties to the CAT

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	1	42
Adopted	12	27	2	41

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 FEBRUARY 2011 CAT MEETING

The 25th meeting of the CAT will be held at the Agency on 10th-11th March 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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