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Monthly Report

Committee for Advanced Therapies (CAT)
June 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 17th meeting on 17th-18th June 2010.

CAT Working Parties

The Committee established two temporary working parties, the working party on cell-based products (CPWP) and gene therapy working party (GTWP), following the discontinuation of the two corresponding CHMP working parties. These working parties will provide recommendations to the CAT on all matters relating directly or indirectly to cell-based and gene therapy

The newly constituted CPWP and gene GTWP are multidisciplinary groups of experts that will focus their work mainly on the preparation, review and update of guidance documents in the respective scientific areas. In addition, they will inform the CAT on scientific issues, provide scientific reports on matters of public interest and emerging issues pertaining to cell and gene therapy medicinal products and tissue engineered products.

The mandate, objectives, rules of procedure and composition of the CPWP and GTWP will be published following the July 2010 meeting of the CAT.

Scientific recommendation on advanced therapy classification

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- The CAT started 6 new ATMP classification procedures for which a 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:

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

General scientific issues

The Committee adopted the following documents:

- Reflection paper on quality, non-clinical and clinical issues related to the development of recombinant adeno-associated viral vectors (rAAV) (EMA/CHMP/GTWP/587488/2007)

This reflection paper discusses quality, non-clinical and clinical issues that should be considered during the development of medicinal products derived from AAV, and to indicate requirements that might be expected the time of a market authorisation application (MAA).

The document, together with the overview of comments received during the consultation period, will be published in due course at:

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

- CHMP/CAT Position Statement on Creutzfeldt-Jakob disease and Advanced therapy medicinal products (EMA/CHMP/CAT/BWP/353632/2010)

This document contains considerations on the risk of transmitting CJD or vCJD agents through Advanced therapy medicinal products.

The document, to be released for public consultation until 30th September 2010 will be published in due course at:

http://www.ema.europa.eu/htms/human/humanguidelines/biologicals.htm under section 'CJD-related'.

Organisational matters

The Committee discussed during the meeting topics related to:

- Report from the International Conferences on Harmonisation (ICH) meeting of the Gene therapy discussion group/M6 Expert working groups held in Tallinn (Estonia) on 6th – 10th June 2010.
- Role of representatives of patients in EMA scientific committees.
- Draft reflection paper on 'Ethical and GCP aspects of clinical trials conducted in third countries for evaluation in marketing authorisation applications for medicines for human use, submitted to the EMA'.
- Procedural advice on the consultation of Notified Bodies in accordance with Article 9 of Regulation (EC) No. 1394/2007' (EMA/395054/2010). A summary of the outcomes of the Coordination group meeting of 2nd June 2010 can be found in Annex 1.

The Committee adopted meeting its Workplrogramme for 2010-2015, which will be published shortly.

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	14	26

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 JUNE 2010 CAT MEETING

The 18th meeting of the CAT will be held at the Agency on 15th-16th July 2010.

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

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Annex 1:

Summary of the outcomes of the EMA/CAT-Notified Body Coordination group meeting of 2nd June 2010

- The Coordination group met on 2nd of June 2010 under the chairmanship of Niall MacAleenan.

- The group revised and discussed the legal clarification document compiled by the European Medicines Agency (EMA) and identified issues for which written legal clarification will be requested from the European Commission.

- The group discussed the Procedural Advice on the consultation of Notified Bodies in accordance with Article 9 of Regulation (EC) No. 1394/2007. This document will finalised via a written consultation of the Coordination group members and will thereafter be transmitted to the Committee for Advanced Therapies (CAT) for discussion and adoption for release for external consultation.

- The group also discussed the assessment information / dossier requirements for combined ATMPs. This topic will be taken forward by a dedicated drafting group which includes representatives of CAT, NBOG, NBMED and EMA. The outcome of this drafting group will be discussed at the next Coordination group meeting, which will take place on 21st September 2010.