London, 30 November 2010
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Monthly Report

Committee for Advanced Therapies (CAT)
November 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 21st meeting on 11th-12th November 2010.

Scientific recommendation on advanced therapy classification

The CAT received one new ATMP classification procedure 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 welcomed the publication the **CAT work programme to 2015** on the EMA website at: CAT Work Programme 2010-2015 (EMA/CAT/235374/2010). With its five-year work programme, the CAT aims to contribute to an environment that encourages the development of ATMPs. Recognising that the traditional regulatory framework for medicines does not currently fully address the needs of companies and organisations that develop these medicines, the work

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programme sets out a proactive approach for the CAT, in which training and early dialogue with relevant stakeholders play a central role.

In the context of the work programme, the CAT will also look at the current regulatory framework and at how it can be made more accessible for small and medium-sized enterprises, academia, patient groups, hospitals, charity foundations and trusts developing ATMPs. The actions proposed tie in with the Agency's Road Map to 2015 that has identified new and emerging science as an important driver for progress and change in the healthcare field. The CAT has already started work on some of the actions proposed in the work programme. The Committee will provide regular update reports as the work progresses.

The Committee discussed during the meeting topics related to:

- The 3rd informal CAT meeting which took place on 30th September – 1st October 2010 under the auspices of the Belgian Presidency of the EU.
- Implementation plans for some of the objectives identified in the CAT Work programme 2010-2015.

General Scientific issues

- CAT adopted the Work Plan for 2011 of the Gene Therapy Working Party (GTWP) and the Cell-based Products Working Party (CPWP). The Work Plans for 2011 will be published on the EMA Website: Gene Therapy Working Party (GTWP) ; Cell-based Products Working Party (CPWP). CAT also adopted the agendas of the meetings of GTWP and CPWP of 25-26 November 2010.
- CAT adopted the Mandate, Objectives and Rules of Procedure of the 'EMA/CAT and Notified Body for Medical Devices Collaboration Group' (EMA/CAT-NB CG) as well as their Work Programme for 2011. These documents will be published on the EMA Website 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	18	40
Adopted	12	26	38

Contribution to scientific advice procedures			
	2009	**2010**	**Total**
Submitted*	17	14	31

* 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 NOVEMBER 2010 CAT MEETING

The 22nd meeting of the CAT will be held at the Agency on 9th-10th December 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)

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Annex 1:

Summary of the outcomes of the EMA/CAT-Notified Body Coordination group meeting of 21st September 2010

- The coordination group with representatives from the European Medicines Agency, Committee for Advanced Therapies (CAT), European Commission (Medical device unit), Notified Body Operation Group (NBOG) and the Notified Body Medical Devices EU Coordination group (NBMED) met on 21st September 2010.
- The above mentioned coordination group is chaired by Niall MacAleenan from the Irish Medicine Board Medical Devices Competent Authority and co-chaired by Marie-Helene Pinheiro from the EMA. The Mandate, Objectives, Rules of Procedures of the EMA/CAT/NB Coordination Group (EMA/327938/2010 rev. 2) together with its Work Programme for 2010-2011 (EMA/328081/2010) were adopted by the Group and transmitted to the CAT for discussion and adoption. Thereafter, both documents will be published on the EMA website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000473.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac05801fe159
- Furthermore the following was discussed:
    - Preliminary scopes and action plans for defining combined ATMPs data requirements and post-authorisation activities including variations, PSURs review and pharmacovigilance.
    - Combined ATMPs classifications process.

Further to the CAT adoption in July 2010 of the **"Procedural Advice on the consultation of Notified Bodies in accordance with Article 9 of Regulation (EC) No. 1394/2007" (EMA/354785/2010)** the document was published for consultation with **deadline for comments by 29th October 2010**. The document can be found on the EMA Website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500095323&murl=menus/document_library/document_library.jsp&mid=WC0b01ac058009a3dc

The next Coordination group meeting will take place at the Agency on 24th November 2010 where comments on the above mentioned Procedural Advice will be reviewed and discussed.