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Monthly Report

Committee for Advanced Therapies (CAT)
October 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 20th meeting on 14th-15th October 2010.

Scientific recommendation on advanced therapy classification

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

The following product was classified as a gene therapy medicinal product:

- Non-integrative vector including a gene coding for an anti-HSV-1 Meganuclease for the ex-vivo transduction of human cornea intended for prevention of infectious diseases in cornea grafted patients.

The following products were classified as somatic cell therapy medicinal products:

- Allogeneic human placenta-derived, culture-expanded, mesenchymal-like cell population intended for treatment of chronic inflammatory diseases such as Crohn's disease, multiple sclerosis, rheumatoid arthritis and the treatment of ischemic stroke.
- Allogeneic human aortic endothelial cells cultured in a porcine gelatin matrix intended for treatment of vascular injury (not combined ATMP).

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The following products were classified as tissue engineered products:

- Autologous bone marrow-derived progenitor cells intended for treatment of patients with failed left ventricular recovery despite successful reperfusion therapy post acute myocardial infarction, chronic ischemic heart disease, peripheral vascular diseases and Buerger's disease.
- Adult skeletal muscle derived cells intended for treatment of female stress urinary incontinence (not combined ATMP).

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

The CAT received 1 new ATMP classification procedure 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:

European Medicines Agency - ATMP classification - ATMP classification

Organisational matters

The Committee adopted the final procedural advice on the certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs (EMA/CAT/418458/2008) and the final scientific guideline on the minimum quality and non-clinical data for certification of ATMPs (EMA/CAT/486831/2008), together with the respective overviews of comments received during the public consultation. These documents will be published shortly on the public EMA website at:

European Medicines Agency - ATMP Certification

The Committee discussed during the meeting topics related to:

- The 4th informal CAT meeting to be held on 31 May – 1 June under the auspices of the Hungarian Presidency of the EU.
- Implementation plans for some of the objectives identified in the CAT Work programme 2010-2015.

General Scientific issues

- Feedback was provided to the CAT on the discussions that took place at the plenary meetings of the Gene Therapy Working Party (GTWP) and the Cell-based Products Working Party (CPWP) of 27th – 28th September 2010.
- CAT agreed the GTWP and CPWP Work Plans for 2011. These will be discussed by the EMA Working Party Coordination Group and adopted by CAT in November 2010.
- Feedback was provided to the CAT on the outcome of the meeting of the 'EMA/CAT and Notified Body for Medical Devices Coordination Group' (EMA/CAT-NB CG) held on 21st September 2010. A summary of the outcomes can be found in Annex 1. CAT also discussed the draft Mandate, Objectives and Rules of Procedure of this group, as well as their Work Programme for 2010-2011.
- CAT adopted the Work Programme for 2011 of the Patient and Consumers Working Party (PCWP).

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	17	39
Adopted	12	26	38

Contribution to scientific advice procedures			
	2009	**2010**	**Total**
Submitted*	17	13	30

* 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 SEPTEMBER 2010 CAT MEETING

The 21st meeting of the CAT will be held at the Agency on 11th-12th November 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.