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**COMMITTEE FOR ADVANCED THERAPIES (CAT)
SEPTEMBER 2009 MEETING
MONTHLY REPORT**

The CAT Monthly Report includes statistical data for the current year on CAT scientific recommendation on 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 eight meeting on 10th-11th September 2009.

Organisational matters

The Committee addressed during the meeting topics related to:

- Discussion on future steps to establish cooperation with notified bodies for issues related to the assessment of combined advanced therapy medicinal products;
- Discussion of the comments received during the external consultation of the procedural advice on the evaluation of Advanced Therapy medicinal products in accordance with article 8 of Regulation (EC) No 1394/2007 (EMEA/630043/2008)
- Discussion of the comments received during the external consultation of the procedural advice on the provision of scientific recommendation on classification of advanced therapy products in accordance with article 17 of Regulation (EC) No 1394/2007 (EMEA/99623/2009)
- Preparation of the first informal meeting of the CAT to be held under the Swedish presidency of the European Union;
- Draft EMEA transparency policy;
- Preparation of the first hearing with interested parties to CAT

General scientific issues

The Committee discussed:

- Reflection paper on requirements for chondrocyte-containing products for cartilage repair of the knee (EMEA/CAT/CPWP/288934/2009). The reflection paper was adopted for release for consultation until end of December 2009;
- Guideline on Follow-up of patients administered with gene therapy medicinal products; developed by the GTWP;
- Concept paper on the proposal for an ICH guideline on virus and gene therapy vector shedding and transmission;
- Reflection paper on stem cell containing products, developed by CPWP;
- Guideline on Xenogeneic cell-based medicinal products. The Committee discussed the comments received during the external consultation and the amendments introduced by the CPWP. The guideline was adopted by CAT.

First hearing with Interested Parties to the CAT

On 11th September 2009, CAT held its first hearing with interested parties to the CAT. In total 33 organisations registered to become interested parties to the CAT and 22 interested parties attended this first meeting.

The agenda included a presentation on the composition, role and activities of CAT, an outline of interactions between CAT and Interested Parties and an update on the current activities of CAT. In the subsequent question and answer session, CAT members provided feedback on issues raised. Some of the detailed questions will be taken forward outside of the meeting and/or will be communicated to the European Commission.

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 EMEA Website:

http://www.emea.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	Total
Submitted	3	3
Ongoing	1	1
Positive draft Opinion	1	1
Negative draft Opinion	0	0
Withdrawals	1	1

Scientific recommendation on advanced therapy classification		
	2009	Total
Submitted	8	8
Ongoing	5	5
Adopted*	3	3

* Two recommendations were adopted by CAT in August 2009 via a written procedure

Contribution to scientific advice procedures		
	2009	Total
Submitted*	12	12

* Comments from CAT submitted to SAWP

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs		
	2009	Total
Submitted	0	0

Contribution to Paediatric Investigation Plans (PIP) for ATMPs		
	2009	Total
Submitted*	2	2

* Comments from CAT submitted to PDCO

Note: the first contribution was provided at the July CAT.

UPCOMING MEETINGS FOLLOWING THE SEPTEMBER 2009 CAT MEETING

- The 9th meeting of the CAT will be held at the EMEA on 15th-16th October 2009.
- The 1st informal meeting of the CAT will be held on 1st-2nd October 2009 in Stockholm, Sweden.

NOTE:

1. This Monthly Report and other documents may be found on the internet at the following location: <http://www.emea.europa.eu>
2. Specific information related to ATMPs and the activities of the CAT (role, responsibilities and composition) can be found at:
http://www.emea.europa.eu/htms/human/advanced_therapies/intro.htm and
<http://www.emea.europa.eu/htms/general/contacts/CAT/CAT.html>

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