21 July 2011
EMA/CAT/576474/2011

Monthly Report

Committee for Advanced Therapies (CAT)

July 2011 meeting

The CAT Monthly Report includes statistical data on CAT scientific recommendations 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 29th meeting on 14th–15th July 2011.

Centralised procedure

Re-examination procedure under Article 9(2) of Regulation (EC) No. 726/2004

The Agency has been formally requested by Amsterdam Molecular Therapies B.V. [Applicant for Glybera [Alipogene tiparvovec)] to re-examine the negative opinion adopted during the meeting of the Committee for Medicinal Products for Human Use (CHMP) on 20th – 23rd June 2011, recommending that an initial marketing authorisation for this product was refused.

The applicant did not agree with the adopted opinion. The CAT will be responsible for preparation of the draft opinion on this re-examination procedure according to Article 8(1) of Regulation (EC) No. 1394/2007 which will then be transmitted to the CHMP for final adoption.

Glybera is intended for the treatment of adult patients diagnosed with lipoprotein lipase deficiency demonstrating hyperchylomicronemia or having a history of acute pancreatitis.

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).

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The following product was classified as a Tissue Engineered Product, non-combined:

- Suspension of allogeneic bone-marrow derived osteoblastic cells, intended for the treatment of non-union, delayed union or other fractures. .

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

The CAT adopted two draft scientific recommendations on classification on advanced therapy medicinal product (ATMP). This procedure will be finalised after consultation with the European Commission within 60 days (active review time).

CAT requested additional information from the applicant for one scientific recommendation on classification on ATMP. Once this information has been received, the classification procedure will restart in accordance with the deadlines set out in the Procedural advice on the provision of scientific recommendation on classification of Advanced Therapy Medicinal Products in accordance with Article 17 of Regulation (EC) no 1394/2007.

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

European Medicines Agency - ATMP classification - ATMP classification

Organisational matters

The main topics addressed during the July 2011 CAT meeting related to:

- CAT-ESGTC Satellite Workshop on Advanced Therapy Medicinal Product: 'From promise to reality. Regulatory path for translation of research into commercial medicinal products'. More information on this conference, which will take place on 27 October 2011, can be found at: ESGCT-CAT Workshop on ATMPs - 27 October 2011
- The revised policy on handling of conflicts of interest of scientific committee members and experts (EMA/513078/2010), which will enter into operation at the end of September 2011.
- Nomination of Cristina Pintus (Italy) as member of the EMA/CAT-Notified Body Collaboration Group

General scientific issues

The Committee discussed during the July 2011 CAT meeting the draft Reflection paper on changes during development of gene therapy medicinal products (EMA/CAT/GTWP/44236/2011).

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	1	5
Positive draft Opinion	1	0	0	1
Negative draft Opinion	1*	0	1	2
Withdrawals	1	1	0	2

* Application subsequently withdrawn

Scientific recommendation on advanced therapy classification				
	2009	**2010**	**2011**	**Total**
Submitted	22	19	7	48
Adopted	12	27	6	45

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	4	36

* Comments from CAT submitted to SAWP

Contribution to Paediatric Investigation Plans (PIP) for ATMPs				
	2009	**2010**	**2011**	**Total**
Submitted*	3	1	1	5

* Comments from CAT submitted to PDCO

Upcoming meetings following the July 2011 CAT meeting

The 30th meeting of the CAT will be held at the Agency on 15th – 16th September 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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