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Patient Health Protection

CAT monthly report of application procedures, guidelines and related documents on advanced therapies

April 2012 meeting

The Committee for Advanced Therapies (CAT) held its 37th CAT meeting on 11th and 13th April 2012. A training for assessors and inspectors took place on 12th April 2012.

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 and Paediatric Investigation Plans, 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.

Marketing authorisation applications

Further to the request of the European Commission, for the CHMP to review the benefit risk of Glybera in a restricted patient population, the CHMP consulted the CAT and the CAT Chair presented the outcome of the CAT discussion to the CHMP.

Further information can be found in the CHMP meeting highlights of the April 2012 meeting: CHMP: Committee meeting reports

Scientific recommendation on advanced therapy product classification

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

The following product was classified as a tissue engineered product, combined:

- Cell layer of autologous oral mucosa cells on a collagen membrane, intended for the use in urethroplasty.

The following product was classified as a tissue engineered product:

- Suspension of non-substantially manipulated autologous CD34+ cells formulated in

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solution for intramyocardial delivery, intended for improvement of heart function in patients with refractory angina and chronic myocardial ischemia.

The following product was classified as not being an ATMP:

- Suspension of oncolytic adenovirus, intended for the treatment of colorectal cancer.

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

CAT received four new ATMP classification requests 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

CAT Working Parties

CAT discussed and adopted the 'Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells' (EMA/CAT/GTWP/671639/2008), which will soon be published on the EMA website.

Other scientific issues

CAT discussed and adopted the draft 'Reflection paper on classification of advanced therapy medicinal products' (EMA/CAT/600280/2010). The aim of this reflection paper is to provide clarification on the grounds applied for the classification of ATMPs, communicate the current status of discussions on some borderline cases and on selected areas where scientific knowledge is fast evolving or experience is limited and provide further clarification on the background information to be submitted by applicants.

The reflection paper will be soon be published for 3-months public consultation at:

European Medicines Agency - Advanced therapies - ATMP classification

Organisational matters

CAT was informed of the revised EMA Policy on the handling of conflict of interests of scientific committee members and experts and of the EMA breach-of-trust procedure on conflicts of interests for scientific committee members and experts. Both documents are available on the EMA Website at:

Handling conflicts of interest

Training of Assessors and Inspectors

The CAT hosted a one-day training for ATMP assessors and inspectors with a particular focus on specific aspects relevant to the GMP for ATMPs. The primary objective of this training was to increase awareness and knowledge on the criteria for assessment of ATMPs. The programme was designed to train assessors, inspectors, experts and interested CAT members on the scientific regulatory issues involved in the authorisation of ATMPs with emphasis on the impact of the inspection findings on the data presented by the Applicant.

This training was part of the activity planned under the CAT Work Programme 2010-2015 to fulfil the objectives to provide training for all stakeholders and reinforce dialogue and interactions with inspectors (GMP, GLP, GCP).

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**	**2012**	**Total**
Submitted	3	1	2	1	7
Positive draft Opinion	1	0	1[i]	0	2
Negative draft Opinion	1[*]	0	1	0	2
Withdrawals	1	1	0	0	2

* Application subsequently withdrawn
[i] Re-examination opinion (Glybera)

Scientific recommendation on advanced therapy classification					
	2009	**2010**	**2011**	**2012**	**Total**
Submitted	22	19	12	9	62
Adopted	12	27	12	6	57

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs					
	2009	**2010**	**2011**	**2012**	**Total**
Submitted	1	0	0	0	1
Adopted	0	1	0	0	1

Scientific advice procedures on ATMPs					
	2009	**2010**	**2011**	**2012**	**Total**
Discussed*	25	30	36	11	102
Written comments to SAWP	17	15	8	1	41

* Most scientific advices for ATMPs are discussed by the CAT at 2 time points during the SA procedure

Paediatric Investigation Plans (PIP) for ATMPs					
	2009	**2010**	**2011**	**2012**	**Total**
Discussed*	4	7	6	3	20
Written comments to PDCO	3	1	4	0	8

* PIPs for ATMPs are discussed by the CAT once or twice during the procedure

Upcoming meetings following the April 2012 CAT meeting

The 38th meeting of the CAT will be held at the Agency on 15th – 16th May 2012.

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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