



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 March 2012
EMA/CAT/180791/2012
Patient Health Protection

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

March 2012 meeting

The Committee for Advanced Therapies (CAT) held its 36th CAT meeting on 8th-9th March 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.

Election of Chair and Vice-chair

CAT conducted the election of the Chair and Vice-Chair at the beginning of its 36th meeting, under the chairmanship of Tony Humphreys, Head of Regulatory, Procedural and Committee Support Sector.

CAT re-elected Dr Christian Schneider as its chair for a second three-year term.

During the election of the Committee's vice-chair, the CAT could not reach a majority on any of the three candidates. The vice-chair election was therefore postponed to the April CAT meeting.

After the election procedure, C. Schneider chaired the March CAT plenary meeting.

Scientific recommendation on advanced therapy product classification

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

The following product was classified as a somatic cell therapy medicinal product:

- A mixture of autologous dendritic cells (DCs) pulsed with a non-structural 3 (NS3) protein fragment of Hepatitis C Virus (HCV) and activated T-cells, intended for the treatment of patients with chronic HCV infection.

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 one new ATMP classification request 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 received feedback from the meetings of the Gene therapy and Cell-based Products Working Party, that took place on 23rd – 24th February 2012.

CAT discussed the 'Reflection paper on clinical aspects specific to tissue-engineered products' (EMA/13987/2012), which will soon be released for external consultation

Organisational matters

CAT discussed the scientific programme of the 5th informal CAT meeting that will be held on 24th-25th May 2012 in Copenhagen under the auspices of the Danish Presidency of the Council of the European Union. During the informal meeting, joint sessions of the CAT with the PDCO and COMP as well as CAT-only sessions are scheduled.

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)

For ATMPs currently under evaluation, consult the following document: 'Applications for new human medicinal products under evaluation by the Committee for Medicinal Products for Human Use – March 2012'

[\(EMA/152848/2012\)](#).

Scientific recommendation on advanced therapy classification					
	2009	2010	2011	2012	Total
Submitted	22	19	12	5	58
Adopted	12	27	12	3	54

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	9	100
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	1	18
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 March 2012 CAT meeting

The 37th meeting of the CAT will be held at the Agency on 11th – 13th April 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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