



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

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

May 2012 meeting

The Committee for Advanced Therapies (CAT) held its 38th CAT meeting on 15th – 16th May 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.

ATMP Certification

One new application for Certification of a tissue engineered product developed by an SME has been received by the European Medicines Agency. Within 90 days active review time, CAT will adopt an opinion on the quality data of this ATMP.

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

[European Medicines Agency - ATMP Certification](#)

CAT was also informed of the outcome of a survey on the ATMP Certification procedure, conducted by EMA amongst the SMEs developing ATMPs. CAT will reflect further on the relevance of the outcome and on any follow-up actions.

Scientific recommendation on advanced therapy product classification

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](#)



Other scientific issues

CAT noted the Reflection paper on ethical and GCP aspects of clinical trials conducted outside of the EU/EEA and submitted in marketing authorisation applications to EU/EEA Regulatory Authorities (EMA/121340/2011).

This document is published on the EMA website: [Reflection paper on ethical & GCP aspect of trials outside EU/EEA](#)

Organisation matters

The 5th informal CAT meeting 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)

Scientific recommendation on advanced therapy classification					
	2009	2010	2011	2012	Total
Submitted	22	19	12	10	63
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	1	2
Adopted	0	1	0	0	1

Scientific advice procedures on ATMPs					
	2009	2010	2011	2012	Total
Discussed*	25	30	36	16	107
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	4	21
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 May 2012 CAT meeting

The 39th meeting of the CAT will be held at the Agency on 14th – 15th June 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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