



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

June 2012 meeting

The Committee for Advanced Therapies (CAT) held its 39th CAT meeting on 14th – 15th June 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.

Scientific recommendation on advanced therapy product classification

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

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

- Allogenic and autologous haptenised and irradiated cells and corresponding cell lysates derived from the tumour mass of patients diagnosed with Glioblastoma multiforme intended to for the treatment of Glioblastoma multiforme

The following product was classified as a tissue engineered product:

- Allogeneic human dermal fibroblasts intended for the treatment of dermal scars, hypertrophic scars and contractures

The following products were classified as not being ATMPs:

- Autologous, non-manipulated lipoaspirate containing adipocytes and stromal vascular fraction intended for cosmetic lipofilling in combination with fresh lipoaspirate
- Autologous cells of Stromal Vascular Fraction (SVF) of adipose tissue intended to act as a natural, autologous lipofiller



- Autologous collagen (AC) derived from human adipose tissue intended for cosmetic dermal filling

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](#)

Organisation matters

The 7th informal CAT meeting will be held on 24th – 25th September 2012 in Oslo, hosted by the Norwegian Medicines agency, in agreement with the Cyprus Presidency of the Council of the European Union. During the informal meeting, the CAT will discuss with invited representatives of the European Member States issues related to the implementation of the 'hospital exemption clause'.

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	11	64
Adopted	12	27	12	11	62

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

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs

Adopted	0	1	0	0	1
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Scientific advice procedures on ATMPs

	2009	2010	2011	2012	Total
Discussed*	25	30	36	20	111
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 June 2012 CAT meeting

The 40th meeting of the CAT will be held at the Agency on 12th – 13th July 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 \(CAT\)](#)

Tony Humphreys
Head of Regulatory, Procedural and Committee Support Sector
Tel.: (+44-20) 7418 8583
Fax: (+44-20) 7523 7051
AdvancedTherapies@ema.europa.eu