



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 November 2013
EMA/CAT/574533/2013
Patient Health Protection

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

November 2013 meeting

The Committee for Advanced Therapies (CAT) held its 54th CAT meeting on 14th – 15th November 2013.

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.

Scientific recommendation on advanced therapy product classification

CAT received three 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](#)

EMA/CAT-TRM Leipzig collaborative workshop - advanced-therapy medicinal products: from bench to bedside. Regulatory path for translation of research to commercial medicinal products

On 23 October 2013, EMA/CAT in cooperation with the Translational Centre for Regenerative Medicines (TRM) Leipzig held a very successful collaborative workshop. During this workshop participants from industry, academia and regulators discussed how to progress forward the development of advanced therapy medicinal products.

More information will soon be published [here](#).

Publication of CAT agendas and minutes

From December 2013 onwards, the CAT agenda will be published on the EMA Website after redaction to remove certain confidential information and personal data. The redacted CAT minutes of the December meeting will also be published, after its adoption by the CAT in January 2014.

This is in line with the Agency's plan to publish the agenda and minutes of its Scientific Committees. More information can be found in the [EMA Press release of 18 July 2013](#).



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 Marketing Authorisation Applications (MAA) for ATMP						
	2009	2010	2011	2012	2013	Total
Submitted MAAs	3	1	2	3	1	10
Positive draft Opinion	1	0	1 ⁱ	1 ⁱ	2	5
						Corresponding to 4 ATMPs
Withdrawals	1	1	0	0	2	4
Ongoing MAAs						2

ⁱ Same product (Glybera)

Variations (Type II) for authorised ATMP						
	2009	2010	2011	2012	2013	Total
Positive draft Opinion	0	0	1	1	7	9
Negative draft Opinion	0	0	0	0	0	0

Scientific recommendation on advanced therapy classification						
	2009	2010	2011	2012	2013	Total
Submitted	22	19	12	17	19	94
Adopted	12	27	12	14	21	88

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs						
	2009	2010	2011	2012	2013	Total
Submitted	1	0	0	1	1	3
Adopted	0	1	0	1	1	3

Scientific advice procedures on ATMPs						
	2009	2010	2011	2012	2013	Total
Discussed*	25	30	36	31	31	153

* 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	2013	Total
Discussed*	4	7	6	9	7	33

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

Upcoming meetings following the November 2013 CAT meeting

The 55th meeting of the CAT will be held at the Agency on 12th – 13th December 2013.

The 8th informal CAT meeting, organised jointly by the Italian and Slovenian Agency, will be held in Trieste (Italy) on 25th – 26th November 2013.

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 Scientific Committee Support
Tel.: (+44-20) 7418 8583
Fax: (+44-20) 7523 7051
AdvancedTherapies@ema.europa.eu