



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

September 2013 meeting

The Committee for Advanced Therapies (CAT) held its 52nd CAT meeting on 12th – 13th September 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.

ATMP Certification Procedure

Further to the CAT opinion the Agency issued the third certification on the quality and non-clinical data of an ATMP product developed by an SME. This is the first time that the certification procedure is applied for also for the evaluation of the non-clinical data package of an ATMP.

The ATMP concerned by the certification is a suspension of autologous expanded smooth muscle derived cells, developed for the proposed therapeutic use: treatment of stress urinary incontinence. This product was previously classified by the CAT as a Tissue Engineered Product and received an ATMP certification for its quality data in October 2012.

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

[European Medicines Agency - ATMP certification](#)

Scientific recommendation on advanced therapy product classification

In August 2013, 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](#)



Organisation Matters

CAT adopted the final minutes of the 7th informal CAT meeting that will be held on 28th February – 1st March 2013 in Dublin under the auspices of the Irish Presidency of the Council of the European Union.

CAT discussed the scientific programme of the 8th informal CAT meeting that will be held on 25th – 26th November 2013 in Trieste (Italy), organised jointly by the Italian and Slovenian Agency. During the informal meeting, a joint session of the CAT with Paediatric Committee (PDCO) is 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 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	6	8
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	13	88
Adopted	12	27	12	14	20	87

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	19	141

* 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	4	31

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

Upcoming meetings following the September 2013 CAT meeting

The 53rd meeting of the CAT will be held at the Agency on 17th – 18th October 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 \(CAT\)](#)

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