



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management and Business Support Division

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

November 2014 meeting

The Committee for Advanced Therapies (CAT) held its 65th CAT meeting on 13 – 14 November 2014.

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

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

The following product was classified as a gene therapy medicinal product:

- Adeno-associated virus (AAV) vector carrying a gene for bacterial halorhodopsin intended for the treatment of Retinitis Pigmentosa.

The following products were classified as somatic cell therapy products:

- Living human mesenchymal stem cells derived from Wharton's jelly tissue of umbilical cord intended for the treatment of Acute and chronic Graft-versus-Host-Disease.
- Living human mesenchymal stem cells derived from Wharton's jelly tissue of umbilical cord intended for the treatment of Amyotrophic lateral sclerosis.

The following products were classified as tissue engineered products:

- Human embryonic stem cell derived retinal pigment epithelial cells intended for the treatment of age-related macular degeneration and Stargardt's macular dystrophy.
- Living human mesenchymal stem cells derived from Wharton's jelly tissue of umbilical cord intended for the treatment of Cerebral Palsy.
- Living human mesenchymal stem cells derived from Wharton's jelly tissue of umbilical cord intended for the treatment of cartilage lesions.



CAT received one new ATMP classification request for which a scientific recommendation will be delivered within 60 days (active review time) after the receipt of the final request.

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

[European Medicines Agency - ATMP classification](#)

Meeting with CAT-Interested Parties

CAT is organising a meeting with its Interested Parties on Thursday 11 December 2014 (from 15.00 to 18.00). The agenda of this meeting will be developed in consultation with the Interested Parties: the Reflection Paper on ATMP Classification (currently under [revision](#)) and the application of the Risk Based Approach during ATMP development were already identified by CAT as topics for discussion.

Interested parties who have not received the e-mail invitation and would like to attend this meeting should inform the CAT secretariat (AdvancedTherapies@ema.europa.eu) by 1 December 2014.

Further information on the CAT Interested Parties can be found here:

[European Medicines Agency - CAT Interested Parties](#)

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	2014	Total
Submitted MAAs	3	1	2	3	2	2	13
Positive draft Opinion	1	0	1 ⁱ	1 ⁱ	2	0	5
							Corresponding to 4 ATMPs
Withdrawals	1	1	0	0	2	0	4
Ongoing MAAs							5

ⁱ Same product (Glybera)

Variations (Type II) for authorised ATMP							
	2009	2010	2011	2012	2013	2014	Total
Positive draft Opinion	0	0	1	1	9	4	15

Scientific recommendation on advanced therapy classification							
	2009	2010	2011	2012	2013	2014	Total
Submitted	22	19	12	17	20	25	120

Scientific recommendation on advanced therapy classification

Adopted	12	27	12	14	23	26	116
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Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs

	2009	2010	2011	2012	2013	2014	Total
Submitted	1	0	0	1	3	0	5
Adopted	0	1	0	1	1	2	5

Scientific advice procedures on ATMPs

	2009	2010	2011	2012	2013	2014	Total
Discussed*	25	30	36	31	36	41	199

* 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	2014	Total
Discussed*	4	7	6	9	7	7	40

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

Upcoming meetings following the November 2014 CAT meeting

The 66th meeting of the CAT will be held on 11-12 December 2014.

NOTE:

1. This Monthly Report, the Agenda of this meeting, the Minutes of the previous CAT meeting 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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