



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

May 2014 meeting

The Committee for Advanced Therapies (CAT) held its 60th CAT meeting on 15 – 16 May 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 three scientific recommendations on the following classification of advanced therapy medicinal products (ATMP).

The following product was classified as a tissue engineered product:

- Viable autologous adipose tissue-derived mesenchymal stem cells intended for the treatment of degenerative arthritis, osteoarthritis (OA), articular cartilage defects in the knee, ankle or hip joints.

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

- Autologous antigen-specific regulatory T lymphocytes intended for the treatment of inflammatory eyes diseases and inflammatory articular diseases.

The following product was classified as a tissue engineered product, combined ATMP:

- Tracheal scaffold seeded with autologous bone marrow derived mononuclear cells intended for the reconstruction of trachea subsequent to damage or stenosis due to cancer, injury or infection.

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](#)



CAT Workshop on Cell-based therapies for Cardiac Repair

The CAT Workshop on cell-based therapies for cardiac repair took place on 14 and 15 May 2014. CAT members discussed manufacturing technologies, non-clinical models and clinical aspects with invited experts.

The outcome of this closed workshop will be summarised in a CAT report, which will be published on the EMA website, and will be presented at the CAT-DGTI workshop on 11 September 2014. Information on the [CAT-DGTI workshop on Advanced Therapies](#) and information on registration can be found on the EMA website.

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	1	12
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							4

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	2	13

Scientific recommendation on advanced therapy classification							
	2009	2010	2011	2012	2013	2014	Total
Submitted	22	19	12	17	20	9	104
Adopted	12	27	12	14	23	9	99

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	18	176

* 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	2	35

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

Upcoming meetings following the May 2014 CAT meeting

The 61st meeting of the CAT will be held at the Agency on 19 – 20 June 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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