



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

June 2014 meeting

The Committee for Advanced Therapies (CAT) held its 61st CAT meeting on 19-20 June 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 one scientific recommendation on the following classification of advanced therapy medicinal products (ATMP).

The following product was classified as a tissue engineered product:

- Concentrate of autologous, uncultured, custom prepared bone marrow aspirate, intended for the treatment of bone damaged by disease (e.g. osteonecrosis), fracture or age-related loss of bone function.

CAT received four 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 Reflection paper on classification of ATMPs

CAT adopted the revision of the reflection paper on classification of ATMPs. The reflection paper was updated to reflect the current thinking of the CAT on substantial manipulation, non-homologous use and the demarcation between gene therapy medical products and vaccines against infectious disease. The reflection paper will be published shortly for public consultation. The deadline for comments is 31 October 2014.

The reflection paper can be found at the ATMP classification webpage (go to the bottom of the page):

[European Medicines Agency - ATMP classification](#)

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Organisation matters

CAT discussed the scientific programme of the 9th informal CAT meeting that will be held on 29-30 October 2014 in Rome under the auspices of the Italian Presidency of the Council of the European Union. During the informal meeting, joint sessions with the CHMP and the COMP are 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	2014	Total
Submitted MAAs	3	1	2	3	2	1	12
Positive draft Opinion	1	0	1 ¹	1 ¹	2	0	5
Withdrawals	1	1	0	0	2	0	4
Ongoing MAAs							4

¹ Same product (Glybera)

Variations (Type II) for authorised ATMP							
	2009	2010	2011	2012	2013	2014	Total
Positive draft Opinion	0	0	1	1	9	3	14

Scientific recommendation on advanced therapy classification							
	2009	2010	2011	2012	2013	2014	Total
Submitted	22	19	12	17	20	13	108
Adopted	12	27	12	14	23	10	100

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	22	180

* 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 June 2014 CAT meeting

The 62nd meeting of the CAT will be held at the Agency on 17-18 July 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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