



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 January 2015
EMA/CAT/45673/2015
Procedure Management and Business Support Division

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

January 2015 meeting

The Committee for Advanced Therapies (CAT) held its 67th CAT meeting on 15 – 16 January 2015.

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 tissue engineered product:

- Cultured autologous chondrocytes in fibrin based excipient of human origin intended for the treatment of non-arthritic cartilage defects of Outerbridge Classification Grade III or IV of the femoral condyle including the trochlea.

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](#)

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	2015	Total	
Submitted MAAs	3	1	2	3	2	2	0	13	
Positive draft Opinion	1	0	1 ⁱ	1 ⁱ	2	1	0	6 Corresponding to 5 ATMPs	
Withdrawals	1	1	0	0	2	0	0	4	
Ongoing MAAs									4

ⁱ Same product (Glybera)

Variations (Type II) for authorised ATMP								
	2009	2010	2011	2012	2013	2014	2015	Total
Positive draft Opinion	0	0	1	1	9	4	0	15

Scientific recommendation on advanced therapy classification								
	2009	2010	2011	2012	2013	2014	2015	Total
Submitted	22	19	12	17	20	28	1	124
Adopted	12	27	12	14	23	29	1	120

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs								
	2009	2010	2011	2012	2013	2014	2015	Total
Submitted	1	0	0	1	3	1	0	6
Adopted	0	1	0	1	1	2	0	5

Scientific advice procedures on ATMPs								
	2009	2010	2011	2012	2013	2014	2015	Total
Discussed*	25	30	36	31	36	48	4	210

* 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	2015	Total
Discussed*	4	7	6	9	7	7	0	40

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

Upcoming meetings following the January 2015 CAT meeting

The 68th meeting of the CAT will be held on 19 – 20 February 2015.

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 \(CAT\)](#)

Tony Humphreys
 Head of Scientific Committee Support
 Tel.: (+44-20) 3660 8583
 Fax: (+44-20) 3660 5520
AdvancedTherapies@ema.europa.eu