



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 March 2015
EMA/CAT/210624/2015
Procedure Management and Business Support Division

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

March 2015 meeting

The Committee for Advanced Therapies (CAT) held its 69th CAT meeting on 19 – 20 March 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 somatic cell therapy medicinal product:

- Allogeneic expanded adult human bone-marrow derived mesenchymal stem cells intended for the treatment of thromboangiitis obliterans (Buerger's disease).

CAT received three new ATMP classification requests 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](#)

Reflection paper on classification of ATMPs

The drafting groups have now reviewed all the comments that have been received during the public consultation on the [revision of the reflection paper on classification of ATMPs](#). The rewording of the section 2.2.3 on 'Substantial manipulation' and 'Different essential function' as proposed by the drafting groups was discussed and agreed by the CAT. The intention is to adopt the Reflection paper at the April or May CAT meeting.



Strategic Review and Learning meeting

The CAT discussed and agreed the agenda of the upcoming Strategic Review and Learning meeting (previously known as 'Presidency / Informal meeting') that will be held in Ljubljana (Slovenia) on 27-28 May 2015 under the auspices of the Latvian Presidency of the Council of the European Union. This meeting will be held, in part, jointly with the CHMP.

The agenda topics for the CAT session include discussions on: Guideline on investigational ATMPs in clinical trials; Question and Answer document on minimally manipulated cell-based medicinal products and the application of the Risk-Based Approach; Analysis of EudraCT database for clinical trials with ATMPs.

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	9	132
Adopted	12	27	12	14	23	29	5	124

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	20	226
Number of procedures	17	19	21	19	23	33	14	146

* 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 March 2015 CAT meeting

The 69th meeting of the CAT will be held on 16 – 17 April 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