22 May 2015
EMA/CAT/335502/2015
Procedure Management and Business Support Division

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

May 2015 meeting

The Committee for Advanced Therapies (CAT) held its 71st CAT meeting on 12 – 13 May 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.

Provenge: CAT notes the withdrawal of the marketing authorisation

The marketing authorisation holder of Provenge (Sipuleucel-T) informed the European Medicines Agency of their request to withdrawn the marketing authorisation for Provenge in the EU. In their letter, they indicate that their decision is based on commercial reasons. See here for more information.

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 products were classified as somatic cell therapy medicinal product:

- Irradiated plasmacytoid dendritic cell line loaded with peptides from tumour antigens intended for the treatment of metastatic stages of cancer.
- Autologous human gamma-delta T lymphocytes activated *in vitro* by cytokines and a monoclonal antibody intended for the treatment of chronic lymphocytic leukaemia and acute lymphoblastic leukaemia.

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

- Autologous expanded viable chondrocytes combined with a three dimensional matrix, intended for the treatment of articular cartilage defects on the knee.

CAT received two new ATMP classification requests for which a scientific recommendation will be delivered within 60 days (active review time).

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

European Medicines Agency - ATMP classification

CAT adopts the revision of the Reflection Paper on ATMP classification

CAT finalised the revision of the Reflection Paper on ATMP classification. The reflection paper, which was updated in the light of the experience gained by the CAT on ATMP classification, was published for external consultation in June 2014. CAT received extensive comments from 60 organisations or individuals, which were all reviewed by the CAT and incorporated in the final document where possible.

The reflection paper will soon be available on the EMA website (go to the bottom of the page):

European Medicines Agency - ATMP classification

Guideline on quality, non-clinical and clinical aspects of gene therapy medicinal products

The draft Guideline on quality, non-clinical and clinical aspects of gene therapy medicinal product has now been published for comments until end of August 2015. See here for more information:

European Medicines Agency - Press release: Facilitating the development of gene therapies.

CAT contributes to the work of the Joint Expert Group on the Application of the 3Rs in regulatory testing of ATMPs

The EMA Joint Expert Group (JEG) on the application of the 3Rs (replacement, reduction and refinement) is reviewing the EU guidelines to collect relevant information on recommendations concerning testing strategies that would reduce animal use in the regulatory testing of medicines. CAT contributes to the work of the EMA JEG 3Rs by providing input on the requirements for gene- and cell-based medicinal products and highlighting the possibilities for implementation of the 3Rs.

For more information, see here:

European Medicines Agency – Expert Group on the Application of the 3Rs in Regulatory testing of medicinal products

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	11	132
Adopted	12	27	12	14	23	29	13	129

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	1	6

Scientific advice procedures on ATMPs								
	2009	2010	2011	2012	2013	2014	2015	Total
Discussed*	25	30	36	31	36	48	30	236
Number of procedures	17	19	21	19	23	33	22	154

* 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	1	41

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

Upcoming meetings following the May 2015 CAT meeting

The 72nd meeting of the CAT will be held on 18 – 19 June 2015.

The CHMP-CAT Joint Strategic Review and Learning meeting (formally known as Presidency meeting) 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.

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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