22 April 2015
EMA/CAT/268414/2015
Procedure Management and Business Support Division

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

April 2015 meeting

The Committee for Advanced Therapies (CAT) held its 70th CAT meeting on 16 – 17 April 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 five scientific recommendations on the following classification of advanced therapy medicinal products (ATMP).

The following products were classified as somatic cell therapy medicinal product:

- Allogeneic *ex vivo* expanded human umbilical tissue-derived cells, intended for the improvement of visual acuity in patients with vision loss from geographic atrophy secondary to age-related macular degeneration.
- Autologous dendritic cells loaded with autologous irradiated tumour stem cells intended for the treatment of melanoma.

The following products were classified as tissue engineered product:

- Autologous mononuclear cells derived from human cord blood intended for the treatment of Paediatric brain damage, hypoxic-ischaemic encephalopathy, and cerebral palsy.
- Allogeneic adult stem cell population, prepared from human skeletal muscle, supposed to display myogenic differentiation abilities, intended for the treatment of Duchenne Muscular Dystrophy.
- Allogeneic *ex vivo* expanded placental mesenchymal-like adherent stromal cells, intended for the treatment of peripheral arterial occlusive disease.

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

European Medicines Agency - ATMP classification

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ATMP certification finalised

The CAT adopted a positive opinion on the certification application for an ATMP developed by a micro-, small- and medium-size enterprise. The concerned ATMP is composed of hapto-identical donor lymphocytes depleted of alloreactive T-cells. This is an orphan medicinal product intended for the prevention or reduction of transplant-related mortality (caused by graft-versus-host disease and/or infections) following haplo-identical haemotopoetic stem cell transplantation. The certification of this product is related to quality and non-clinical data.

Following the CAT opinion, the Agency issued the ATMP certificate.

For more information on the ATMP certification procedure, see here:

European Medicines Agency – ATMP certification

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	10	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	25	231
Number of procedures	17	19	21	19	23	33	16	148

* 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 March 2015 CAT meeting

The 71st meeting of the CAT will be held on 12 – 13 May 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)

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