17 January 2013
EMA/CAT/25123/2013
Patient Health Protection

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

January 2013 meeting

The Committee for Advanced Therapies (CAT) held its 45th CAT meeting on 10th – 11th January 2013.

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.

Withdrawal of an application for an ATMP

CAT noted the withdrawal of the marketing authorisation application by Anika Therapeutics S.r.l of their product Hyalograft C autograft, which is composed of characterised viable autologous chondrocytes expanded in vitro, seeded and cultured on a hyaluronan-based scaffold, intended to be used for the surgical repair of symptomatic cartilage defects of the femoral condyle (medial, lateral) or trochlea, caused by acute or repetitive trauma in adults. Further information will be published here:

European Medicines Agency - Withdrawn applications

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 (ATMPs).

The following product was classified as a somatic cell therapy medicinal product:

- Autologous mesenchymal stromal cells secreting neurotrophic factors, intended for the treatment of amylotrophic lateral sclerosis.

The following product was classified as a tissue engineered product:

- Tissue like combination of osteogenic cells and demineralised bone matrix, intended for the treatment of bone defects.

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

- Concentrate of autologous bone marrow seeded on a matrix consisting of cross-linked bovine Type-1 collagen, coated with hydroxyapatite, intended to increase new bone formation in critical areas of atrophic bone non-union.

CAT received one new ATMP classification request 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

Organisation Matters

CAT discussed the scientific programme of the 7th informal CAT meeting that will be held on 28th February – 1st March 2013 in Dublin under the auspices of the Irish Presidency of the Council of the European Union. During the informal meeting, a joint session of the CAT with Committee for Orphan Medicinal Product (COMP) is scheduled.

Other Scientific issues

CAT noted the outcome of the EMA Survey on ATMP certification for SMEs, and recommended the publication of the report of the survey on the EMA Website. The objective of this survey was to obtain feedback directly from SMEs developing ATMPs and their stakeholders as to why the certification procedure is not more widely utilised by applicants and to obtain suggestions on how to improve the procedure to make it a more attractive incentive. The report of the survey will be published here:

European Medicines Agency - ATMP Certification procedure

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 MAA for ATMP						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Submitted	3	1	2	3 [ii]	0	9
Positive draft Opinion	1	0	1[i]	1[i]	0	3
Negative draft Opinion	1[*]	0	1	0	0	2
Withdrawals	1	1	0	0	1	3

* Application subsequently withdrawn
[i] Re-examination opinion (Glybera)
[ii] One additional MAA was validated after the December 2012 CAT meeting and therefore not reported in the previous CAT monthly report

Scientific recommendation on advanced therapy classification						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Submitted	22	19	12	17	1	76
Adopted	12	27	12	14	3	70

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

Scientific advice procedures on ATMPs						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Discussed*	25	30	36	31	2	124

* 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**	**Total**
Discussed*	4	7	6	9	1	27

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

Upcoming meetings following the January 2013 CAT meeting

The 46th meeting of the CAT will be held at the Agency on 14th – 15th February 2013.

NOTE:

1. This Monthly Report 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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