20 March 2013
EMA/CAT/182530//2013
Patient Health Protection

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

March 2013 meeting

The Committee for Advanced Therapies (CAT) held its 47th CAT meeting on 14th – 15th March 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 CellSeed Europe Ltd. of their product OraNera (CAOMECS), a Cultured Autologous Oral Mucosal Epithelial Cell-Sheet, intended for the restoration of the ocular epithelial surface in patients with Limbal Stem Cell Deficiency (LSCD) without stromal involvement. 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European Medicines Agency - Withdrawn applications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 two scientific recommendations on the following classification of advanced therapy medicinal products (ATMPs).

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

- Epstein Barr virus (EBV) specific T Lymphocytes intended for the treatment of EBV-associated tumours.

The following product was classified a somatic cell therapy medicinal product, combined ATMP:

- Alginate encapsulated porcine pancreatic islet cells intended for the treatment of Type 1 (insulin-dependent) diabetes mellitus.

CAT received two new ATMP classification requests 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:

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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 MAA for ATMP	2009	2010	2011	2012	2013	Total
Submitted	3	1	2	3	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	2	4

* Application subsequently withdrawn
[i] Re-examination opinion (Glybera)

Scientific recommendation on advanced therapy classification	2009	2010	2011	2012	2013	Total
Submitted	22	19	12	17	6	81
Adopted	12	27	12	14	8	75

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	6	128

* 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	2	28

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

Upcoming meetings following the March 2013 CAT meeting

The 48th meeting of the CAT will be held at the Agency on 18th – 19th April 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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