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Patient Health Protection

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

February 2013 meeting

The Committee for Advanced Therapies (CAT) held its 46th CAT meeting on 14th – 15th February 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.

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:

- Allogeneic mesenchymal precursor cells, intended for the treatment of rheumatoid arthritis.

The following products were classified as not an ATMP:

- Adult autologous regenerative cells for subcutaneous administration, intended for the regeneration, repair or replacement of weakened or injured subcutaneous tissue.
- Adult autologous regenerative cells in autologous cell-enriched matrix for subcutaneous administration, intended for the regeneration, repair or replacement of weakened or injured subcutaneous tissue.

CAT received three 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:

European Medicines Agency - ATMP classification

Other Scientific issues

CAT discussed the prioritisation of the development of scientific guidelines for gene and cell-based medicinal products. The main activity for 2013 will be on: the *Reflection paper on clinical aspects*

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related to tissue engineered products (EMA/CAT/CPWP/573420/2009), the *Reflection paper on clinical risks from insertional mutagenesis*, and the revision of the *Note for Guidance on the Quality, Pre-clinical and Clinical aspects of gene transfer medicinal products* (CPMP/BWP/3088/99).

More information on the scientific guidelines for ATMPs can be found here:

European Medicines Agency - ATMP Scientific guidelines

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	4	79
Adopted	12	27	12	14	6	73

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	3	125

* 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 February 2013 CAT meeting

The 7th Informal CAT meeting 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.

The 47th meeting of the CAT will be held at the Agency on 14th – 15th March 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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