27 May 2013
EMA/CAT/323934/2013
Patient Health Protection

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

May 2013 meeting

The Committee for Advanced Therapies (CAT) held its 49th CAT meeting on 23rd – 24th May 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 one scientific recommendation on the following classification of advanced therapy medicinal product (ATMP).

The following product was classified as a Tissue engineered product:

- Autologous expanded CD34+ stem cells intended for the treatment of patients with acute myocardial infarction.

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

Working Party with Patients' and Consumers' Organisations (PCWP) and Working Party with Healthcare Professionals' Organisations (HCPWP)

CAT adopted the revised mandate of the PCWP and the mandate of the newly established HCPWP.

Further information can be found at:

European Medicines Agency - Working Party with Patients' and Consumers' Organisations

European Medicines Agency - Working Party with Healthcare Professionals' Organisations

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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**	**Total**
Submitted MAAs	3	1	2	3	1	10
Positive draft Opinion	1	0	1[ii]	1[ii]	1	4 Corresponding to 3 ATMPs
Negative draft Opinion	1[i]	0	1[ii]	0	0	2 Corresponding to 0 ATMPs*
Withdrawals	1	1[i]	0	0	2	4
Ongoing MAAs						3

i Same product (Cerepro)
ii Same product (Glybera)
* MAAs subsequently withdrawn or re-examinated.

Scientific recommendation on advanced therapy classification						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Submitted	22	19	12	17	12	87
Adopted	12	27	12	14	13	80

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	1	3
Adopted	0	1	0	1	0	2

Scientific advice procedures on ATMPs						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Discussed*	25	30	36	31	11	133

* 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	4	30

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

Upcoming meetings following the May 2013 CAT meeting

The 50th meeting of the CAT will be held at the Agency on 20th – 21st June 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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