18 October 2013
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Patient Health Protection

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

October 2013 meeting

The Committee for Advanced Therapies (CAT) held its 53rd CAT meeting on 17th – 18th October 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:

- *Ex-vivo* expanded autologous human corneal epithelium containing stem cells on human amniotic membrane for the treatment of limbal stem cell deficiency (ophthalmology).

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

Organisation Matters

CAT nominated Mr Kieran Breen as the CAT representative in the Patients' and Consumers' Working Party (PCWP), and Mr Olli Tenhunen as the CAT representative in the Healthcare Professionals' Working Party (HCPWP).

CAT discussed the scientific programme of the 8th informal CAT meeting that will be held on 25th – 26th November 2013 in Trieste (Italy), organised jointly by the Italian and Slovenian Agency. During the informal meeting, a joint session of the CAT with Paediatric Committee (PDCO) is scheduled.

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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[i]	1[i]	2	5 Corresponding to 4 ATMPs
Withdrawals	1	1	0	0	2	4
Ongoing MAAs						2

[i] Same product (Glybera)

Variations (Type II) for authorised ATMP						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Positive draft Opinion	0	0	1	1	6	8
Negative draft Opinion	0	0	0	0	0	0

Scientific recommendation on advanced therapy classification						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Submitted	22	19	12	17	16	91
Adopted	12	27	12	14	21	88

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	1	3

Scientific advice procedures on ATMPs						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Discussed*	25	30	36	31	19	144

* 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	31

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

Upcoming meetings following the October 2013 CAT meeting

The 54th meeting of the CAT will be held at the Agency on 14th – 15th November 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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