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Inspections, Human Medicines Pharmacovigilance and Committees Division

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

October 2016 meeting

The Committee for Advanced Therapies (CAT) held its 86th CAT meeting on 6 – 7 October 2016.

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 5 scientific recommendations on the classification of advanced therapy medicinal products.

The following products were classified as gene therapy medicinal products:

- Living, genetically modified *Lactobacillus reuteri* bacteria, with a plasmid containing the gene for human CXCL12-1a with an inducible promoter, intended for the treatment of chronic skin wounds in diabetic patients.
- Tumour selectively replicating oncolytic adenovirus expressing tumour necrosis factor alpha and interleukin 2, intended for the treatment of metastatic melanoma and other solid tumours.
- Autologous T-cells expressing a chimeric NKG2D receptor, intended for the treatment of various tumour types.
- A combination of two plasmids encoding for E6 and E7 antigens of human papilloma virus 16 and 18, intended for the treatment of HPV-16 and 18 related high-grade squamous intraepithelial lesions of the cervix and vulva.

The following product was classified as a tissue engineered product:

- Human autologous stromal vascular fraction cells and human autologous adipose-derived mesenchymal stem cells, intended for the treatment of treatment of cutis laxa senilis.

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CAT workshop on cell-based cancer immunotherapies

The CAT workshop on cell-based cancer immunotherapies that will take place at EMA on 15 – 16 November 2016 can be followed via live broadcast. No registration is required for the broadcast. To watch the broadcast, click on the 'Multimedia' tab on the event webpage.

Organisational matters

- CAT appointed CAT representatives in the Patients' and Consumers' Working Party (PCWP) and in the Health Care Professionals' Working Party (HCPWP).
- CAT discussed the agenda of the 'CAT Strategic Review & Learning meeting' that will take place in Dublin, Ireland on 24 – 25 October 2016 under the auspices of the Slovak Presidency of the Council of the European Union.

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**	**2014**	**2015**	**2016**	**Total**
Submitted MAAs	3	1	2	3	2	2	1	1	15
Positive draft Opinion	1	0	1[ii]	1[ii]	2	1	1	2	9 Corresponding to 8 ATMPs
Negative draft opinions	1[i]	0	1[ii]	0	0	0	2[*]	0	4
Withdrawals	1	1[i]	0	0	2	0	0	0	4
Ongoing MAAs									2

[i] Same product (Cerepro)
[ii] Same product (Glybera)
[*] CAT adopted two negative draft opinions for the same product (Heparesc)

Variations (Type II) for authorised ATMP									
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**Total**
Positive draft Opinion	0	0	1	1	9	4	3	6	24

Scientific recommendation on advanced therapy classification									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Submitted	22	19	12	22	20	28	61	53	237
Adopted	12	27	12	16	23	29	31	79	229

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Submitted	1	0	0	1	3	1	1	2	9
Adopted	0	1	0	1	1	2	1	1	7

Scientific advice procedure for ATMPs									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Discussed*	25	30	36	31	36	48	63	55	324
Number of procedures	17	19	21	19	23	33	39	40	211

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

Paediatric Investigation Plans (PIP) for ATMPs									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Discussed*	4	7	6	9	7	7	3	4	47

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

Prime Eligibility for ATMPs									
	2016								Total
Discussed	18								18
Granted	6								6

Upcoming meetings following the October 2016 CAT meeting

The CAT strategic review & learning meeting will be held in Dublin, Ireland on 24 – 25 October 2016

The 87th meeting of the CAT will be held on 3 – 4 November 2016.

NOTE:

1. This Monthly Report, the Agenda of this meeting, the Minutes of the previous CAT meeting 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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