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Inspections, Human Medicines Pharmacovigilance and Committees Division

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

June 2019 meeting

The Committee for Advanced Therapies (CAT) held its 116th meeting on 19 – 21 June 2019.

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

The following product was classified as a tissue engineered product:

- Allogeneic neonatal human cardiac progenitor cells, intended for the treatment of cardiac failure.

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

- Human embryonic stem-cell derived Müller cells, intended for the treatment of primary open angle glaucoma.

The following product was classified as non-ATMP:

- Allogeneic human enucleated red cells expressing Anabaena variabilis phenylalanine ammonia lyase, intended for the treatment of phenylketonuria.

Organisational matters

- The Questions and Answers on the use of out-of-specification batches of authorised cell/tissue-based ATMPs, developed by CAT in collaboration with the GMP Inspectors Group and Biologics Working Party, was published on the EMA Website.

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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**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
Submitted MAAs	3	1	2	3	2	2	1	1	4	3	0	22
Positive draft Opinion	1	0	1[ii]	1[ii]	2	1	1	2	2	3	1	15*
Negative draft opinions	1[i]	0	1[ii]	0	0	0	2[iii]	0	0	0	0	4
Withdrawals	1	1[i]	0	0	2	0	0	0	0	1	0	5
Ongoing MAAs												2

*** Corresponding to 14 ATMPs**
[i] Same product (Cerepro)
[ii] Same product (Glybera)
[iii] 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**	**2017**	**2018**	**2019**	**Total**
Positive opinion	0	0	1	1	9	4	3	6	3	8	6	41

Scientific recommendation on advanced therapy classification												
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
Submitted	22	19	12	22	20	28	61	60	46	55	27	372
Adopted	12	27	12	16	23	29	31	87	49	43	33	362

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs												
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
Submitted	1	0	0	1	3	1	1	2	2	1	0	12
Adopted	0	1	0	1	1	2	1	1	3	1	1	12

Scientific advice procedure for ATMPs												
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
Number of procedures	17	19	21	19	23	33	39	46	55	53	33	358

Paediatric Investigation Plans (PIP) for ATMPs												
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
Number of procedures	3	4	4	8	5	4	3	5	3	3	2	44

Prime Eligibility for ATMPs									
	2016	**2017**	**2018**	**2019**					**Total**
Discussed	22	16	14	7					59
Granted	8	6	6	4					24

Upcoming meetings following the June 2019 CAT meeting

- The 117th meeting of the CAT will be held on 17 – 19 July 2019.

NOTE:

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

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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