



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance and Committees Division

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

May 2019 meeting

The Committee for Advanced Therapies (CAT) held its 115th meeting on 22 – 24 May 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 4 scientific recommendations on the classification of advanced therapy medicinal products.

The following product was classified as a gene therapy medicinal product:

- Autologous dendritic cells, electroporated with messenger ribonucleic acid encoding tumour antigen Wilms tumour-1, intended for the treatment of lung cancer.

The following products were classified as somatic cell therapy medicinal products:

- Allogeneic haematopoietic stem and progenitor cells treated *ex vivo* with the protein transduction domain of the human immunodeficiency virus-1 transactivation protein fused to MYC transcription factor, intended for the treatment of acute myelogenous leukaemia.
- Allogeneic haematopoietic stem and progenitor cells treated *ex vivo* with the protein transduction domain of the human immunodeficiency virus-1 transactivation protein fused to MYC transcription factor, intended for the treatment of myelofibrosis.

The following product was classified as non-ATMP:

- Autologous adipose tissue/micronised adipose tissue, intended for autologous skin wound healing.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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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	5	40

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	22	367
Adopted	12	27	12	16	23	29	31	87	49	43	30	359

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	29	354

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	1	43

Prime Eligibility for ATMPs												
	2016	2017	2018	2019								Total
Discussed	22	16	14	6								58
Granted	8	6	6	3								23

Upcoming meetings following the May 2019 CAT meeting

- The Strategic Review and Learning meeting, organised under the auspices of the Romanian presidency of the European Union, will take place in Bucharest (Romania) on 13 - 14 June 2019.
- The 116th meeting of the CAT will be held on 19 – 21 June 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 \(CAT\)](#)

Thorsten Olski

Head of Scientific Committees Secretariat
Tel.: (+44-20) 3660 7684
AdvancedTherapies@ema.europa.eu