



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

January 2018 meeting

The Committee for Advanced Therapies (CAT) held its 100th CAT meeting on 17-19 January 2018.

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

The following product was classified as a tissue engineered product:

- Autologous CD34+ cells derived from bone marrow, intended for the improvement of neurological function in patients with non-lacunar acute ischemic stroke infarctions.

The following product was classified as a tissue engineered product, combined ATMP:

- Autologous adipose-derived stem cells seeded on a collagen matrix scaffold intended for the treatment of cancer-related lymphedema in breast cancer patients.

Organisational matters

- The CAT adopted the revision of the ATMP guideline on safety and efficacy follow-up and risk management. The document will be published for external consultation shortly.
- The CAT discussed various aspects related to the work of the International Pharmaceutical Regulators Forum (IPRF).
- The CAT adopted the report of the expert meeting on adeno-associated viral vector-based gene therapy medicinal products, held on 6 September 2017. A public report will now be prepared for publication on the EMA website.



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	Total
Submitted MAAs	3	1	2	3	2	2	1	1	4	0	19
Positive draft Opinion	1	0	1 ⁱⁱ	1 ⁱⁱ	2	1	1	2	2	0	11*
Negative draft opinions	1 ⁱ	0	1 ⁱⁱ	0	0	0	2 ⁱⁱⁱ	0	0	0	4
Withdrawals	1	1 ⁱ	0	0	2	0	0	0	0	0	4
Ongoing MAAs											4

* Corresponding to 9 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	Total
Positive Opinion	0	0	1	1	9	4	3	6	3	1	28

Scientific recommendation on advanced therapy classification											
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
Submitted	22	19	12	22	20	28	61	60	46	3	293
Adopted	12	27	12	16	23	29	31	87	49	2	288

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	Total
Submitted	1	0	0	1	3	1	1	2	2	0	11
Adopted	0	1	0	1	1	2	1	1	3	0	10

Scientific advice procedure for ATMPs											
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
Number of procedures	17	19	21	19	23	33	39	46	55	2	274

Paediatric Investigation Plans (PIP) for ATMPs											
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
Number of procedures	3	4	4	8	5	4	3	5	3	1	40

Prime Eligibility for ATMPs											
	2016	2017	2018								Total
Discussed	22	16	3								41
Granted	8	6	0								14

Upcoming meetings following the January 2018 CAT meeting

- The 101st meeting of the CAT will be held on 15 – 16 February 2018.

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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