



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2018
EMA/CAT/262029/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

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

April 2018 meeting

The Committee for Advanced Therapies (CAT) held its 103rd CAT meeting on 18 – 20 April 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 6 scientific recommendations on the classification of advanced therapy medicinal products.

The following products were classified as a tissue engineered products:

- Allogeneic umbilical cord derived mesenchymal stem cells intended for the treatment of multiple sclerosis.
- Autologous bone marrow derived mesenchymal stem cells intended for the treatment of multiple sclerosis.
- Allogeneic human neural stem cells intended for the treatment of traumatic brain injuries and stroke.
- Autologous bone marrow derived mesenchymal stem cells intended for the treatment of articular cartilage damage and tendon injuries.
- Autologous bone marrow derived mesenchymal stem cells ex vivo fused with allogeneic human myoblasts intended for the treatment of Duchenne muscular dystrophy.

Organisational matters

- CAT discussed the public report from the expert meeting on genome editing that was held at the EMA on 18 October 2017. The report will be adopted via a written procedure and published on the EMA website.
- CAT will hold a meeting with its Interested Parties on Thursday 13 September 2018. The agenda will be developed in consultation with the CAT Interested Parties.



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	1	20
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											5

* Corresponding to 10 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	2	29

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	17	307
Adopted	12	27	12	16	23	29	31	87	49	12	298

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	1	11

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	21	293

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	4								42
Granted	8	6	1								15

Upcoming meetings following the April 2018 CAT meeting

- The 104th meeting of the CAT will be held on 23 – 25 May 2018.
- The Strategic Review and Learning meeting will be held on 7 – 9 May 2018 in Oslo, Norway.

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 \(CAT\)](#)

Thorsten Olski

Head of Scientific Committees Secretariat

Tel.: (+44-20) 3660 7684

AdvancedTherapies@ema.europa.eu