



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 October 2017
EMA/CAT/674185/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

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

October 2017 meeting

The Committee for Advanced Therapies (CAT) held its 97th CAT meeting on 4 – 6 October 2017.

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 product was classified as a gene therapy medicinal product:

- Messenger RNA encoding immunostimulatory proteins and tumour associated antigens, intended for the treatment of melanoma.

The following products were classified as tissue engineered products:

- Allogeneic human glial-restricted precursor cells, intended for the treatment of amyotrophic lateral sclerosis.
- Allogeneic human glial-restricted precursor cells, intended for the treatment of spinal cord injuries.

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

- Culture viable chondrocytes in a 3-dimensional hydrogel, intended for the treatment of articular cartilage defects of the knee.

The following product was not classified as an ATMP:

- Nuclease-resistant, synthetic double-stranded, small interfering ribonucleic acid designed to temporarily inhibit the expression of collagen-specific chaperone, heat shock protein 47, intended for the treatment of hepatic fibrosis.



Organisational matters

- CAT discussed the activities for inclusion in the 2018 CAT work plan.
- CAT discussed and agreed the programme of the CAT Strategic Review and Learning meeting that will take place on 16 – 17 November 2017 in Estonia under the auspices of the Estonian 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	2017	Total
Submitted MAAs	3	1	2	3	2	2	1	1	3	18
Positive draft Opinion	1	0	1 ⁱⁱ	1 ⁱⁱ	2	1	1	2	1	10*
Negative draft opinions	1 ⁱ	0	1 ⁱⁱ	0	0	0	2 ⁱⁱⁱ	0	0	4
Withdrawals	1	1 ⁱ	0	0	2	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	Total
Positive Opinion	0	0	1	1	9	4	3	6	3	27

Scientific recommendation on advanced therapy classification										
	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Submitted	22	19	12	22	20	28	61	60	43	287
Adopted	12	27	12	16	23	29	31	87	40	277

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs

	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Submitted	1	0	0	1	3	1	1	2	1	10
Adopted	0	1	0	1	1	2	1	1	3	10

Scientific advice procedure for ATMPs

	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Number of procedures	17	19	21	19	23	33	39	46	44	261

Paediatric Investigation Plans (PIP) for ATMPs

	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Number of procedures	3	4	4	8	5	4	3	5	3	39

Prime Eligibility for ATMPs

	2016	2017								Total
Discussed	22	14								36
Granted	8	5								13

Upcoming meetings following the October 2017 CAT meeting

The 98th meeting of the CAT will be held on 30 - 31 October 2017.

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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