26 February 2016
EMA/158306/2016
Procedure Management and Committees Support Division

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

February 2016 meeting

The Committee for Advanced Therapies (CAT) held its 79th CAT meeting on 18-19 February 2016.

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

The following product was classified as gene therapy medicinal product:

- Adeno-associated serotype 2 virus vector containing the human RPE65 gene for the treatment of Treatment of inherited retinal degeneration due to autosomal recessive RPE65 gene mutations

The following products were classified as tissue engineered products:

- Human adult allogenic mesodermal progenitor cells intended for the treatment of incomplete revascularisation as an adjunct to coronary artery bypass operation in patients with congenital coronary artery malformations
- Human amniotic membrane mesenchymal stem cells as a suspension, intended for the treatment of burns and non-healing wounds.
- Human amniotic membrane mesenchymal stem cells as a sheet, intended for the treatment of burns and non-healing wounds.
- Human amniotic membrane mesenchymal stem cells seeded on acellular amniotic matrix, intended for the treatment of burns and non-healing wounds.
- Human amniotic membrane mesenchymal stem cells seeded on acellular dermal matrix, intended for the treatment of burns and non-healing wounds.

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- Human umbilical cord mesenchymal stem cells as a suspension, intended for the treatment of burns and non-healing wounds.
- Human umbilical cord mesenchymal stem cells as a sheet, intended for the treatment of burns and non-healing wounds.
- Human umbilical cord mesenchymal stem cells seeded on acellular amniotic matrix, intended for the treatment of burns and non-healing wounds.
- Human umbilical cord mesenchymal stem cells seeded on acellular dermal matrix, intended for the treatment of burns and non-healing wounds.
- Co-culture of keratinocytes and human amniotic membrane mesenchymal stem cells seeded on acellular amniotic matrix, intended for the treatment of burns and non-healing wounds.
- Co-culture of keratinocytes and human amniotic membrane mesenchymal stem cells seeded on acellular dermal matrix, intended for the treatment of burns and non-healing wounds.
- Co-culture of keratinocytes and human umbilical cord mesenchymal stem cells seeded on acellular amniotic matrix, intended for the treatment of burns and non-healing wounds.
- Co-culture of keratinocytes and human umbilical cord mesenchymal stem cells seeded on acellular dermal matrix, intended for the treatment of burns and non-healing wounds.

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

- Co-culture of fibroblasts and keratinocytes seeded on transgenic porcine acellular dermal matrix for the treatment of deep and extensive burns, chronic wound and skin donor sides.

CAT received 4 new ATMP classification requests for which a scientific recommendation will be delivered within 60 days (active review time).

Further information on the ATMP classification procedure can be found at:

European Medicines Agency - ATMP classification

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	Total
Submitted MAAs	3	1	2	3	2	2	1	0	14
Positive draft Opinion	1	0	1[ii]	1[ii]	2	1	1	0	7 Corresponding to 6 ATMPs
Negative draft opinions	1[i]	0	1[ii]	0	0	0	2[*]	0	4
Withdrawals	1	1[i]	0	0	2	0	0	0	4
Ongoing MAAs									3

[i] Same product (Cerepro)
[ii] Same product (Glybera)
[*] 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	Total
Positive draft Opinion	0	0	1	1	9	4	3	3	21

Scientific recommendation on advanced therapy classification									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Submitted	22	19	12	22	20	28	61	15	199
Adopted	12	27	12	16	23	29	31	33	183

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Submitted	1	0	0	1	3	1	1	1	8
Adopted	0	1	0	1	1	2	1	0	6

Scientific advice procedure for ATMPs									
	2009	2010	2011	2012	2013	2014	2015	2016	Total
Discussed*	25	30	36	31	36	48	63	8	277

Scientific advice procedure for ATMPs									
Number of procedures	17	19	21	19	23	33	39	14	185

* Most scientific advices for ATMPs are discussed by the CAT at 2 time points during the SA procedure

Paediatric Investigation Plans (PIP) for ATMPs									
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**Total**
Discussed*	4	7	6	9	7	7	3	1	44

* PIPs for ATMPs are discussed by the CAT once or twice during the procedure

Upcoming meetings following the February 2016 CAT meeting

The 80th meeting of the CAT will be held on 22 – 23 March 2016.

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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