



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Procedure Management and Committees Support Division

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

### July 2016 meeting

The Committee for Advanced Therapies (CAT) held its 84<sup>th</sup> CAT meeting on 13 – 15 July 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 5 scientific recommendations on the classification of advanced therapy medicinal products.

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

- Live attenuated *Listeria monocytogenes* transfected with plasmids encoding HPV-16E7 protein fused to a truncated fragment of the Lm protein Listeriolysin O, intended for treatment of cervical cancer.

The following products were classified as tissue engineered products:

- Autologous fibroblasts expanded *in vitro*, intended for the treatment of the scars of different aetiology (such as post-traumatic, post-surgical or outcomes of acne scars).
- Autologous concentrated bone marrow, intended for critical limb ischemia without surgical option.

The following products were classified as non ATMPs:

- Hepatitis B virus DNA vaccine, intended for the treatment of chronic hepatitis B virus infection.
- Collagenase from *Clostridium histolyticum*, intended to be used for *ex-vivo* dissociation of adipose tissue.



## Organisational, regulatory and methodological matters

- CAT welcomed the new and re-appointed members and alternates of the CAT to represent clinicians and patients' associations.
- The European Commission's consultation document on Good Manufacturing Practices (GMP) for ATMPs has been published on the Commission's website for public consultation until 26 September. External stakeholders and National Competent Authorities are encouraged to provide comments. For more information, see [here](#).

## CAT workshop on cell-based cancer immunotherapies

The draft programme of the CAT workshop on cell-based cancer immunotherapies which will take place on 15 – 16 November 2016 was presented. This public workshop will be announced on the EMA website in the beginning of August 2016.

## 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	1	15
Positive draft Opinion	1	0	1 <sup>ii</sup>	1 <sup>ii</sup>	2	1	1	2	9 Corresponding to 8 ATMPs
Negative draft opinions	1 <sup>i</sup>	0	1 <sup>ii</sup>	0	0	0	2 <sup>*</sup>	0	4
Withdrawals	1	1 <sup>i</sup>	0	0	2	0	0	0	4
Ongoing MAAs									2

<sup>i</sup> Same product (Cerepro)

<sup>ii</sup> Same product (Glybera)

<sup>\*</sup> 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	4	22

### Scientific recommendation on advanced therapy classification

	2009	2010	2011	2012	2013	2014	2015	2016	Total
Submitted	22	19	12	22	20	28	61	40	224
Adopted	12	27	12	16	23	29	31	70	220

### 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	1	7

### Scientific advice procedure for ATMPs

	2009	2010	2011	2012	2013	2014	2015	2016	Total
Discussed*	25	30	36	31	36	48	63	43	312
Number of procedures	17	19	21	19	23	33	39	31	202

\* 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	4	47

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

### Prime Eligibility for ATMPs

	2016								Total
Discussed	9								9

## Upcoming meetings following the July 2016 CAT meeting

The 85<sup>th</sup> meeting of the CAT will be held on 8 – 9 September 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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