



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 October 2014  
EMA/CAT/654520/2014  
Procedure Management and Business Support Division

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

### October 2014 meeting

The Committee for Advanced Therapies (CAT) held its 64<sup>th</sup> CAT meeting on 16-17 October 2014.

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 one scientific recommendation on the following classification of advanced therapy medicinal products (ATMP).

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

- Medicinal product composed of living, genetically modified *Lactococcus lactis* bacteria, containing the gene for anti-human tumour necrosis factor-alpha protein intended for the reduction of signs and symptoms, and induction and maintenance of clinical remission in patients with moderately active ulcerative colitis.

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

[European Medicines Agency - ATMP classification](#)

### **Meeting with CAT-Interested Parties**

CAT decided to organise a meeting with its Interested Parties during the December CAT meeting. The agenda of this meeting will be developed in consultation with the Interested Parties: the Reflection Paper on ATMP Classification (currently under [revision](#)) and the application of the Risk Based Approach during ATMP development were already identified by CAT as topics for discussion.

Further information on the CAT Interested Parties can be found here:

[European Medicines Agency - 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 | Total                         |
| Submitted MAAs  | 3    | 1    | 2              | 3              | 2    | 2    | 13                            |
| Positive draft Opinion  | 1    | 0    | 1 <sup>i</sup> | 1 <sup>i</sup> | 2    | 0    | 5<br>Corresponding to 4 ATMPs |
| Withdrawals   | 1    | 1    | 0              | 0              | 2    | 0    | 4                             |
| Ongoing MAAs  |      |      |                |                |      |      | 5                             |

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

| Variations (Type II) for authorised ATMP |      |      |      |      |      |      |       |
|--|------|------|------|------|------|------|-------|
|  | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | Total |
| Positive draft Opinion                   | 0    | 0    | 1    | 1    | 9    | 4    | 15    |

| Scientific recommendation on advanced therapy classification |      |      |      |      |      |      |       |
|--|------|------|------|------|------|------|-------|
|  | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | Total |
| Submitted  | 22   | 19   | 12   | 17   | 20   | 24   | 119   |
| Adopted  | 12   | 27   | 12   | 14   | 23   | 20   | 110   |

| Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs |      |      |      |      |      |      |       |
|--|------|------|------|------|------|------|-------|
|  | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | Total |
| Submitted  | 1    | 0    | 0    | 1    | 3    | 0    | 5     |
| Adopted  | 0    | 1    | 0    | 1    | 1    | 2    | 5     |

| Scientific advice procedures on ATMPs |      |      |      |      |      |      |       |
|---------------------------------------|------|------|------|------|------|------|-------|
|                                       | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | Total |
| Discussed*                            | 25   | 30   | 36   | 31   | 36   | 37   | 195   |

\* 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 | Total |
| Discussed*                                     | 4    | 7    | 6    | 9    | 7    | 7    | 40    |

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

## Upcoming meetings following the October 2014 CAT meeting

The 9<sup>th</sup> Presidency meeting will be held on 29 – 30 October 2014 in Rome under the auspices of the Italian Presidency of the Council of the European Union. This meeting will be held jointly with the CHMP and COMP.

The 65<sup>th</sup> meeting of the CAT will be held on 13-14 November 2014.

### 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 \(CAT\)](#)

Tony Humphreys  
 Head of Scientific Committee Support  
 Tel.: (+44-20) 3660 8583  
 Fax: (+44-20) 3660 5520  
[AdvancedTherapies@ema.europa.eu](mailto:AdvancedTherapies@ema.europa.eu)