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Procedure Management and Business Support Division

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

January 2014 meeting

The Committee for Advanced Therapies (CAT) held its 56th CAT meeting on 16th – 17th January 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 three scientific recommendations on the following classifications of advanced therapy medicinal products (ATMP).

The following product was classified as a somatic cell therapy product:

- Allogeneic unrelated, buffy coat derived activated viable leukocytes, intended for the treatment of chronic lower extremity ulcers in adult diabetic patients.

The following products were classified as a Tissue engineered products:

- Cultured autologous skin substitute using cellular human donor dermis as matrix, intended for wound healing.
- Cell suspension of autologous skeletal myoblasts, intended for the treatment of oculo-pharyngeal muscular dystrophy.

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

European Medicines Agency - ATMP classification

## Reflection paper on clinical aspects related to Tissue Engineered Products

The Rapporteur presented the final draft of this Reflection Paper, which was updated following receipt of external comments. This reflection paper is intended to provide specific guidance on clinical testing for tissue engineered products.

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Further to a discussion, CAT members were given one-month for reflection and provision of final comments. The reflection paper is scheduled for adoption at the February CAT meeting.

Further information on scientific guidelines for ATMPs can be found at:

European Medicines Agency – ATMP Scientific Guidelines

## 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 | 0 | 11 |
| Positive draft Opinion | 1 | 0 | 1[i] | 1[i] | 2 | 0 | 5<br>Corresponding to 4 ATMPs |
| Withdrawals | 1 | 1 | 0 | 0 | 2 | 0 | 4 |
| Ongoing MAAs | | | | | | | 3 |

[i] Same product (Glybera)

| Variations (Type II) for authorised ATMP | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **2009** | **2010** | **2011** | **2012** | **2013** | **2014** | **Total** |
| Positive draft Opinion | 0 | 0 | 1 | 1 | 9 | 1 | 12 |

| Scientific recommendation on advanced therapy classification | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **2009** | **2010** | **2011** | **2012** | **2013** | **2014** | **Total** |
| Submitted | 22 | 19 | 12 | 17 | 20 | 0 | 95 |
| Adopted | 12 | 27 | 12 | 14 | 23 | 3 | 93 |

| 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 | 0 | 3 |

| Scientific advice procedures on ATMPs | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **2009** | **2010** | **2011** | **2012** | **2013** | **2014** | **Total** |
| Discussed* | 25 | 30 | 36 | 31 | 36 | 3 | 161 |

* 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 | 0 | 33 |

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

## Upcoming meetings following the January 2014 CAT meeting

The 57th meeting of the CAT will be held at the Agency on 13th – 14th February 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)

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