



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 March 2014
EMA/CAT/161687/2014
Procedure Management and Business Support Division

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

March 2014 meeting

The Committee for Advanced Therapies (CAT) held its 58th CAT meeting on 13th – 14th March 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.

CAT elects a new vice-chair

Further to the election of Paula Salmikangas as CAT chair in February 2014, CAT elected during its March meeting a new vice-chair. Martina Schübler-Lenz was elected as the CAT vice-chair for a three-year mandate.

Martina Schübler-Lenz is the deputy head of the Section Advanced Therapies and senior clinical assessor at the Paul-Ehrlich Institute (Germany). She was CAT alternate member since the start of the CAT in 2009 until January 2014, and is CAT member since February 2014.

Scientific recommendation on advanced therapy product classification

CAT received two new ATMP classification requests for which a scientific recommendation will be delivered within 60 days (active review time) after receipt of the final request.

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

[European Medicines Agency - ATMP classification](#)

CAT initiated a new procedure to provide input in scientific Advice requests for ATMPs

This month, CAT started with a new procedure to provide input to the Scientific Advice Working Party (SAWP). In the new procedure, a CAT Rapporteur is appointed for each scientific advice for ATMPs. The CAT Rapporteur will review the briefing document and questions from the company and will prepare preliminary comments for the plenary CAT discussion. The review by the CAT Rapporteur is done in parallel with the review done by the Coordinators appointed by the SAWP.



This new procedure will allow for the CAT feedback to be provided to the SAWP before its first discussion. By doing so, the role of the CAT in all scientific advices for ATMPs will be strengthened. The new procedure will be further streamlined based on the experience gained over the next months.

CAT Work Programme Objectives

During the February 2014 CAT meeting, CAT members discussed the objectives for 2014 originating from the CAT Work programme. One of the proposals that will now be further explored is the organisation of a joint CAT workshop with the German Society for Transfusion Medicine and Immunehematology (DGTI) during the DGTI annual conference in September 2014. Further information on this workshop will be published on the EMA Website in due course.

In [October 2011](#) and [October 2013](#), CAT organised joined workshops with scientific societies: the aim of these workshops is to outreach to the ATMP developers, especially those in academia, hospitals and small companies.

Further information on the CAT Work Programme 2010-2015 can be found at:

[CAT Work programme 2010-2015](#)

Reflection paper on clinical aspects related to Tissue Engineered Products

The CAT adopted the Reflection Paper on clinical aspects related to Tissue Engineered Products. This reflection paper is intended to provide specific guidance on clinical testing for tissue engineered products. The Reflection paper will be published shortly.

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 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	2	13

Scientific recommendation on advanced therapy classification

	2009	2010	2011	2012	2013	2014	Total
Submitted	22	19	12	17	20	4	99
Adopted	12	27	12	14	23	4	94

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	7	165

* 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 March 2014 CAT meeting

The 59th meeting of the CAT will be held at the Agency on 15th – 16th April 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) 7418 8583
Fax: (+44-20) 7523 7051
AdvancedTherapies@ema.europa.eu