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Procedure Management and Business Support Division

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

April 2014 meeting

The Committee for Advanced Therapies (CAT) held its 59th CAT meeting on 15th – 16th April 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.

ATMP Certification Procedure

At its April meeting, the CAT adopted two positive opinions on certification applications for ATMPs developed by micro, small and medium-sized enterprises (SMEs).

The ATMPs concerned by the certification are:

- Autologous oral mucosa cells seeded on a membrane, developed for the proposed therapeutic use: treatment of male urethral stricture. The certification for this product related to the quality and non-clinical data. CAT previously classified this product as a Tissue engineered product – combined ATMP.
- Autologous mesenchymal stem cells committed to the cardiovascular lineage, developed for the proposed therapeutic use: treatment of chronic advanced symptomatic heart failure secondary to ischemic cardiomyopathy. The certification for this product related to the quality data. CAT previously classified this product as a Tissue engineered product.

Further to the CAT opinions, the Agency issued the two certificates.

For more information on the ATMP certification procedure see here:

European Medicines Agency – ATMP Certification

Scientific recommendation on advanced therapy product classification

Further to consultation with the European Commission, the CAT finalised two scientific recommendations on the following classification of advanced therapy medicinal products (ATMP).

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The following product was classified as a tissue engineered product:

- Autologous bone marrow cell aspirate in autologous plasma, intended for the treatment of osteoarthrosis and osteochondral lesion.

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

- Allogeneic genetically modified Chimeric Antigen Receptor (CAR+) T-cells, intended for the treatment of acute lymphoblastic leukemia and chronic lymphocytic leukemia

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 Workshop on Cell-based therapies for Cardiac Repair

CAT finalised the agenda of the CAT Workshop on cell-based therapies for cardiac repair, which will take place on 14 and 15 May 2014. CAT members will discuss manufacturing technologies, non-clinical models and clinical aspects with invited experts. This is a closed workshop and will allow the CAT to be abreast of the evolution of scientific knowledge in this field.

The outcome of the workshop will be presented at the CAT-DGTI workshop on 11 September 2014 (see below). CAT will consider additional ways to make this information public (for example via a report, a scientific publication or a guidance document).

CAT – DGTI Workshop on ATMPs

CAT members discussed the programme of the joint CAT workshop with the German Society for Transfusion Medicine and Immunohematology (DGTI) in collaboration with the German Stem Cell Network (GSCN). The workshop will be place on 11 September 2014 in Dresden, Germany as a satellite symposium of the 47th DGTI Annual meeting.

The workshop invitation flyer can be found here.

Further information on this workshop will be published on the EMA Website shortly.

Report from the European Commission on the application of the ATMP Regulation

The report prepared by the European Commission on the application of the ATMP Regulation was published on the Commission's website on 1 April 2014.

Fee incentives for SMEs for post-authorisation activities.

New financial incentives to support micro, small and medium-sized enterprises developing medicines for human and veterinary use came into force on 1 April 2014. The new incentives apply to post-authorisation activities. Further information can be found here.

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	1*	12
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							4

[i] Same product (Glybera)
* Procedure started after the March CAT meeting.

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	6	101
Adopted	12	27	12	14	23	6	96

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	12	170

* 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	2	35

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

Upcoming meetings following the April 2014 CAT meeting

The 60th meeting of the CAT will be held at the Agency on 15th – 16th May 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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