



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13th November 2012
EMA/CAT/724123/2012
Patient Health Protection

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

November 2012 meeting

The Committee for Advanced Therapies (CAT) held its 43rd CAT meeting on 8th – 9th November 2012.

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.

In addition, the report includes a summary table of the draft opinions issued by the CAT in the current year and a list of adopted guidelines and other public documents.

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 - ATMP classification](#)

CAT guidelines

- CAT discussed the 'Guideline on the risk-based approach according to Annex I, part IV of Directive 2001/83/EC for ATMPs' (EMA/CAT/CPWP/686637/2011), which was revised taking into account the comments made during the public consultation. The final guideline is expected to be adopted by the CAT in December 2012.

Other Scientific issues

- CAT discussed the 'Reflection paper on classification of advanced therapy medicinal products' (EMA/CAT/600280/2010), which was revised taking into account the comments made during the public consultation. The aim of this reflection paper is to provide clarification on the grounds applied for the classification of ATMPs, communicate the current status of discussions on some borderline cases and on selected areas where scientific knowledge is fast evolving or experience is limited and provide further clarification on the background information to be



submitted by applicants. The final reflection paper is expected to be adopted in December 2012.

- A meeting of the CAT Focus Group (FG) on non-clinical development of ATMPs was held on 11th October. CAT Focus Groups are convened by CAT with representatives of Interested parties (IPs) to discuss specific topics and propose possible shared solutions to bottlenecks in the development of ATMPs. The CAT-IP FG on non-clinical development of ATMPs started operating in February 2011. A summary of the discussions held by the focus group will be available at: [European Medicines Agency - Interested Parties to the CAT](#)

Organisations which have not yet registered to become an interested party to the CAT can still do so by completing the form that can be found on the Agency's Website:

[European Medicines Agency - Interested Parties to the CAT](#)

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 MAA for ATMP					
	2009	2010	2011	2012	Total
Submitted	3	1	2	2	8
Positive draft Opinion	1	0	1 ⁱ	1 ⁱ	3
Negative draft Opinion	1*	0	1	0	2
Withdrawals	1	1	0	0	2

* Application subsequently withdrawn

ⁱ Re-examination opinion (Glybera)

Scientific recommendation on advanced therapy classification					
	2009	2010	2011	2012	Total
Submitted	22	19	12	17	70
Adopted	12	27	12	14	65

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

Scientific advice procedures on ATMPs					
	2009	2010	2011	2012	Total
Discussed*	25	30	36	29	120

* 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	Total
Discussed*	4	7	6	9	26
Written comments to PDCO	3	1	4	2	10

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

Upcoming meetings following the October 2012 CAT meeting

The 44th meeting of the CAT will be held at the Agency on 6th – 7th December 2012.

NOTE:

1. This Monthly Report 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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