



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Patient Health Protection

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

### February 2012 meeting

The Committee for Advanced Therapies (CAT) held its 35<sup>th</sup> CAT meeting on 9<sup>th</sup>-10<sup>th</sup> February 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.

### **CAT Workshop with Stakeholders**

On Thursday 12<sup>th</sup> January 2012, CAT held a workshop entitled: 'Focus Groups, a model for fruitful interactions between CAT and its Interested Parties'. The one-day workshop was organised by the CAT as part of the Committee's effort to strengthen the dialogue with all of its stakeholders. During its February meeting, CAT discussed the input from the stakeholders on:

- Non-clinical development of Advanced Therapy Medicinal Products (ATMPs);
- A better system to navigate scientific guidance documents on gene therapy and cell-based medicinal products;
- Incentives for Academic, hospitals and trusts developing ATMPs.

All presentations given during the workshop and the lists of questions from participants can now be found at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/events/2011/11/event\\_detail\\_000545.jsp&mid=WC0b01ac058004d5c3](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2011/11/event_detail_000545.jsp&mid=WC0b01ac058004d5c3)

The draft Workshop Report was discussed by CAT and will be published after adoption on the EMA Website.



## Scientific recommendation on advanced therapy product classification

CAT received three 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 Working Parties

CAT adopted the agenda of the meetings of the Gene therapy and Cell-based Products Working Party, that will take place on 23rd – 24th February 2012.

## General scientific issues

The Framework for interaction between the Agency and Health Care Professionals was presented to CAT. More information on this Framework and on the Criteria to be fulfilled by healthcare professionals' organisations involved in EMA activities can be found here: [Healthcare professionals](#)

## 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	1	7
Positive draft Opinion	1	0	1 <sup>i</sup>	0	2
Negative draft Opinion	1*	0	1	0	2
Withdrawals	1	1	0	0	2

\* Application subsequently withdrawn

<sup>i</sup> Re-examination opinion (Glybera)

Scientific recommendation on advanced therapy classification					
	2009	2010	2011	2012	Total
Submitted	22	19	12	4	57
Adopted	12	27	12	2	53

### Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs

	2009	2010	2011	2012	Total
Submitted	1	0	0	0	1
Adopted	0	1	0	0	1

### Scientific advice procedures on ATMPs

	2009	2010	2011	2012	Total
Discussed*	25	30	36	4	97
Written comments to SAWP	17	15	8	1	42

\* 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	1	18
Written comments to PDCO	3	1	4	0	8

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

## Upcoming meetings following the February 2012 CAT meeting

The 36<sup>th</sup> meeting of the CAT will be held at the Agency on 8<sup>th</sup> – 9<sup>th</sup> March 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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