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Patient Health Protection

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

September 2012 meeting

The Committee for Advanced Therapies (CAT) held its 41st CAT meeting on 13rd – 14th September 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.

Centralised procedure

- CAT concluded on a type II variation for an ATMP

During its September meeting, CAT adopted a positive draft opinion on a Type II variation to add a new manufacturing site including batch release for ChondroCelect drug product and to update the Product Informaton in line with the new QRD template version 8.0.

The draft opinion and CAT assessment report have been sent to the CHMP for adoption.

Scientific recommendation on advanced therapy product classification

Further to consultation with the European Commission, the CAT finalised one scientific recommendation on the following classification of advanced therapy medicinal products (ATMPs).

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

- Recombinant Herpes Simplex Virus type 1 (HSV-1) containing the gene encoding human granulocyte macrophage colony-stimulating factor (GM-CSF) intended for the treatment of adults with unresectable or metastatic melanoma.

In August 2012, 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.

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

European Medicines Agency - ATMP classification - ATMP classification

Organisation matters

- Streamlining of CAT activities: as part of an overall project to improve efficiency and optimise the use of the expertise available, the current work of the Gene Therapy Working Party (GTWP) and Cell-based Products Working Party (CPWP) will be taken over by the CAT. CAT now takes the lead responsibility for the development of guidelines and the organisation of workshops. Please see here for more information (link to press release).

  CAT decided to set up small *ad-hoc* drafting groups, composed of members from the CAT, former working parties and additional experts to complement expertise amongst the CAT members, to finalise the guidance documents that are already under development and to develop new guidelines.

- An informal CAT meeting will be held on 24th – 25th September 2012 in Oslo. During the informal meeting, CAT members and representatives from the National competent authorities will discuss issues related to the implementation of the *Hospital exemption* clause for ATMPs.

Other Scientific issues

CAT agreed to organise following scientific expert symposiums:

- Reducing the number of laboratory animals used in tissue engineering research (to take place in October or December 2012, pending availability of experts)
- Application of cell-based therapies for Myocardial infarction (scheduled for the second half of 2013)

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	14	67
Adopted	12	27	12	13	64

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	0	1

Scientific advice procedures on ATMPs					
	2009	**2010**	**2011**	**2012**	**Total**
Discussed*	25	30	36	26	117
Written comments to SAWP	17	15	8	1	41

* 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	4	21
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 September 2012 CAT meeting

The 42nd meeting of the CAT will be held at the Agency on 11th – 12th October 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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