EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12th December 2012
EMA/CAT/798213/2012
Patient Health Protection

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

December 2012 meeting

The Committee for Advanced Therapies (CAT) held its 44th CAT meeting on 6th – 7th December 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

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

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

- Attenuated Salmonella typhi Ty21a strain carrying plasmid pVax10-VEGFR-2. The product is intended for the treatment of solid malignancies with or without metastases.

The following product was classified as a tissue engineered product:

- Autologous skeletal muscle-derived-cells. The product is intended for the repair of deficient external anal sphincter in patients suffering from faecal incontinence.

CAT received five 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

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CAT guidelines

- CAT adopted 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 will be published on the EMA website shortly:

  European Medicines Agency - Advanced Therapies - Scientific guidelines

Other Scientific issues

- CAT adopted 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 will be published on the EMA Website shortly:

  European Medicines Agency - ATMP classification - ATMP classification

- On 3th and 4th April 2013, the European Directorate for Quality of Medicines & HealthCare (EDQM) together with EMA will organise a meeting to discuss the quality requirements for the Raw Materials used in the manufacture of cell based and gene therapy products. A survey is being conducted to gather information from all stakeholders about their respective needs regarding the use and production of raw materials intended for the manufacture of ATMPs. CAT encourages the ATMP developers (companies, academia and hospitals) but also raw materials manufacturers to complete this survey. The deadline for responses is 21st December 2012. To participate to the survey, follow this link: https://www.surveymonkey.com/s/Raw_materials_for_cell_based_and_gene_therapy_products

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	75
Adopted	12	27	12	14	67

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	31	122

* 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 December 2012 CAT meeting

The 45th meeting of the CAT will be held at the Agency on 10th- 11th January 2013.

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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