European Medicines Agency

London, 19 September 2008
EMEA/CHMP/CPWP/319258/2008

WORK PLAN FOR CELL-BASED PRODUCTS WORKING PARTY (CPWP)

FOR 2009

CHAIRPERSON: Dr. Paula Salmikangas

STATUS: September 2008

1. MEETINGS SCHEDULED FOR 2009

- 29-30 January 2009
- 26-27 March 2009
- 9-10 July 2009
- 9-10 September 2009
- 5-6 November 2009

2. MULTIDISCIPLINARY PRODUCT RELATED ISSUES (such as support to Marketing Authorisation Assessment, Scientific Advice, Protocol Assistance).

- Contributions to CAT (expected numbers of involvement in dossiers[1]) for Scientific Advice, Protocol Assistance, Product Assessment (new applications, re-registration procedures[2]), Post-Authorisation issue (pharmacovigilance issue related to a product or a class of product) and Certification[3]:

	2009
Scientific advice & Protocol assistance	10
Product assessment	
• Pre-authorisation	3
• Post-authorisation	0
Certification procedure	10

- Contribution to CAT in procedure for the scientific classification of advanced therapy medicinal products[4]:

	2009
Classification procedure	12

[1] These figures may have to be adjusted taking into account the activities of the new Committee on Advanced Therapies (CAT) in 2009. Some of the product-related discussions could take place in the CAT instead of the Working Party

[2] Re-registration of Advanced Therapy products legally on the market, in accordance with art 29 of Regulation (EC) No 1394/2007

[3] Certification of Quality and/or non-clinical data, in accordance with art 18 of Regulation (EC) No 1394/2007

[4] Scientific recommendation on whether a product falls, on scientific grounds, within the definition of an advanced therapy medicinal product, in accordance with art 17 of Regulation (EC) No 1394/2007.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

- Preparation of advice to CHMP or CAT on specific issues related to Cell based medicinal products.

3. GUIDANCE DOCUMENTS

Guideline on Xenogeneic cell-based medical products

Action: Finalisation of Revision of the Points to consider on Xenogeneic cell therapy medical products (CPMP/1199/02) in collaboration with BWP.

Comments: Implementation of the comments on the draft guideline, which is published for external consultation in 4Q 2008.

Refection paper on stem cell products

Action: CPWP will initiate work on the preparation of a reflection paper on the non-clinical and clinical aspects of cell-based products containing stem cells

Comments:

Guideline on the application of the risk analysis approach for cell-based medicinal products in the pre- and post authorisation phase

Action: Preparation of a draft guideline in collaboration with BWP and PhVWP

Comments: The Guideline on Cell-based medicinal products (EMEA/CHMP/410869/2006) introduces a risk analysis approach for the development of cell-based products. This will provide further guidance on how to perform and present this risk analysis for initial marketing authorisation application. This guideline will complement the EMEA Guideline on Post-authorisation follow-up of safety and efficacy, and risk management of advanced therapy medicinal products (EMEA/14995/2008).
Development of a concept paper for external consultation in 2Q 2009

Guideline on clinical aspects specific to regenerative medicines

Action: Preparation of a draft guideline.

Comments: This guideline will include recommendation of for surgical trials and structural endpoints

Question and Answer document on pharmaceutical, non-clinical and clinical development of cell-based medicinal products

Action: This Q&A document will be developed in close collaboration with the BWP

Comments: To include (non-exclusive list): further clarification on the requirements for Combined advanced therapy medicinal products ; requirements for the change in starting material for an allogeneic cell-based product

4. EU REGULATORY ACTIVITIES

1. Specific activities

Guideline on scientific requirements for Certification of Quality and Non-clinical data for Advanced Therapy Medicinal products.

Action: Joint with BWP and GTWP

Comments: This guideline will address the requirements for an application for Certification of an ATMP.

On request of EMEA / CAT, CPWP will be involved in further EU Regulatory activities in relation to cell-based medicinal products

2. Contribution to legislative activities of the European Commission, upon request

3. Exchange and dissemination in the CHMP network of new information on cell-based medicinal products

5. OTHER ACTIVITIES AND ACTIVITIES WITH THIRD PARTIES

1. Liaison with Drug Regulatory Authorities Outside the EU on Safety and Efficacy aspects of cell based medicinal products

- Liaison with FDA
- Liaison with WHO
- Liaison with EDQM / European Pharmacopoeia

2. Meetings with Interested Parties

E.g. Learned Societies, Public health Stake Holders (Public health professionals, Patients' organisations), Pharmaceutical Industry Representatives (EuropaBio, EBE), Device industry Representatives (Eucomed), SMEs and Academia.

3. Briefing sessions with sponsors.

Involvement in training sessions of sponsors/applicants/manufacturers of cell therapy and tissue engineered products.

4. Contribution to conferences on Advanced Therapy products

5. Meetings with the competent authorities for Tissues and Cells and with the competent authorities for Medical Devices