European Medicines Agency

Network of Excellence - 6th Framework Programme
European Commission (DG Research)

EMEA/INFARMED/EXPERTISSUES
JOINT WORKSHOP ON
CELL BASED MEDICINAL PRODUCTS

18-19 October 2007
Lisbon

Background

New legislation on advanced therapy medicinal products is currently being developed. This legislation will provide a framework for the authorisation of gene therapy, cell therapy and tissue engineered products as medicinal products in the European Union.

The European Medicines Agency (EMEA: http://www.emea.europa.eu), more specifically the Working Party on Cell-based products (CPWP) and the Biologics Working Party (BWP) have developed a guideline on quality, non-clinical and clinical development of cell-based medicinal products (cell therapy medicinal products and tissue engineered products) (http://www.emea.europa.eu/pdfs/human/cpwp/41086906en.pdf). This guideline is currently published for external consultation.

An open workshop will be organised on 18-19 October 2007 to discuss with all concerned stakeholders (regulators, industry, academia) scientific aspects and requirements for the authorisation of cell-based medicinal products. It is the intention to focus the discussion on the draft guideline on cell-based medicinal products and the comments received during the external consultation. The outcome of the discussion will facilitate the finalisation of the guideline by CPWP and BWP.

The workshop is scheduled for a 1.5 day meeting. Adjacent to this workshop a 0.5 day satellite meeting is organised by EXPERTISSUES (www.expertissues.org) on tissue engeneering. Other European research networks participate in the programme of the workshop (EUROSTEMCELLS and DC-THERA).

Who should attend?

This workshop will focus mainly of scientific aspects in relation to development and marketing authorisation applications for cell therapy medicinal products and tissue engineered products. The workshop is directed to professionals working in the Regulatory affairs department of companies developing cell-based products, for cell-biologist working in academia and start-up companies and also for attendees from European Regulatory Authorities, who will be evaluating clinical trials and marketing authorisation applications for these advanced therapy products.

Registration

- Pré-Registration: June 1 to June 29 2007
- Appreciation and confirmation of the registrations by the organization: July 2 to July 13
- Final Registration and Payment: July 16 to August 31
- The number of registrations for this Workshop is subject to the room capacity (250 participants).
- The registration fee includes 4 coffee-breaks, 2 lunches, 1 gala dinner, a panoramic tour of Lisbon and transfer from the hotels to INFARMED and vice-versa.

Fees

- Academy: € 200; National Regulatory Authorities: € 400; Industry: € 800

Programme and Registration form

Go to: http://www.infarmed.pt

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