EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 June 2010
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Human Medicines Development and Evaluation

2-3 September 2010
European Medicines Agency
1st International Workshop on Nanomedicines

Agenda

Program Chairperson
Patrick Le Courtois

Program Committee
European Commission: Philippe Martin
European Medicines Agency: Tomas Salmonson, Jean-Louis Robert, Beatriz Silva Lima, Ruth Duncan, Rogério Gaspar, Marisa Papaluca Amati
MHLW/PMDA: Yoshikazu Hayashi
US FDA: Nakissa Sadrieh, Carlos Peña

Scope:

The proposed workshop will focus on key features of nanomedicines[1] and the emerging scientific knowledge in the field.

Objective:

Explore scientific aspects specific to nanomedicines and share experience at an international level, to anticipate future needs.

Outcome:

Report on identified issues and emerging science aspects, which may assist future developments in the field and may be relevant to future regulatory considerations.

[1] To ensure a comprehensive approach, the workshop will address products containing materials in the submicron range.

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1st International Workshop on Nanomedicines
Conference room 2A

Day 1
Starts on the 2nd of September at 9:00 am

09:00 – 09:30

Introduction

- Welcome address and objectives of the workshop
  Speaker: Patrick Le Courtois, Head of Unit, Human Medicines Development and Evaluation, European Medicines Agency

- European Commission perspective
  Speaker: Philippe Martin, Directorate General for Health and Consumers

09:30 – 10:30

Keynote lecture + Q&A session:

- Way to the future: key ongoing applications in nanosciences and how they apply to pharmaceuticals
  Promising and innovative applications today with outstanding preliminary clinical results; where we want to go and what are the milestones?
  Speaker: Rutledge Ellis-Behnke, Neuroscientist in the Brain and Cognitive Sciences Department at Massachusetts Institute of Technology and Associate Professor in the Department of Anatomy at the University of Hong Kong Faculty of Medicine

10:30 – 12:00

Session 1: Special aspects of nanomedicines
Nanosize does not necessarily imply novelty and experience has been gathered as nanomedicines have already been authorised under the existing regulatory frameworks. New methods have been developed to manufacture and characterise nanomedicines. The purpose of the session is to identify the most relevant characterisation methods indicative for safety and efficacy, the factors affecting the stability in vitro / in vivo of nanomedicines.

Development, Manufacturing & Characterisation

Chairperson: Jean-Louis Robert (European Medicines Agency Quality Working Party Chair)
European Medicines Agency: Evdokia Korakianiti (Quality of Medicines, Chemicals)

- Viewpoint by Mamoun Muhammed, Head of Functional Materials Division, and Nano Characterization Centre, Royal Institute of Technology, Stockholm

- Viewpoint by Simon Holland, GlaxoSmithKline, Director, Process Understanding & Control within GSK Pharmaceutical Development, Ware

- Viewpoint by Jan Möschwitzer, Abbott, Head of Early Pharmaceutical Development, Weesp, The Netherlands

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Q&A panel and conclusion by the Chair

12:00 – 13:00 Lunch break

13:00 – 15:00

Session 2: Special aspects of nanomedicines
The speakers will address new scientific knowledge on biological interactions of nanomedicines and existing and emerging toxicology approaches. Limits and possibility to extrapolate safety results from in vitro to in vivo will also be discussed.

Non-Clinical Assessment

Chairperson: Marc Pallardy (Director of Research, School of Pharmacy, University of Paris-Sud)
European Medicines Agency: Jean-Marc Vidal (Scientific Support & Projects Section)

- What about safety? How do we determine risk?
  Speaker: Wim de Jong, Toxicological pathologist at the Laboratory for Health Protection Research, National Institute for Public Health and the Environment, Bilthoven

- Immunology and immuno-toxicity of nanomedicines
  Speaker: Jacques Descotes, Professor and Head, Poison Center and Pharmacovigilance Department Lyon University Hospitals

- Nanomedicines interaction with biological systems
  Speaker: Kenneth Dawson, Professor of Physical Chemistry, University College of Dublin, School of Chemistry and Chemical Biology, Dublin

Q&A panel and conclusion by the Chair

15:00 – 15:30 Coffee break

15:30 – 17:30

Session 3: Nanomedicines on the market and in clinical development
The speakers will highlight scientific issues specifically relevant to the unique properties of each type of nanomedicine considered.

Chairperson: Eric Abadie (European Medicines Agency CHMP Chair)
European Medicines Agency: Mayeul Boucaumont (Scientific Support & Projects Section)

- Liposomal nanomedicines and innovative formulations
  Speaker: Daan Crommelin, Professor of Pharmaceutics, Utrecht University, and Scientific Director, Dutch Top Institute Pharma, Leiden

- Polymer conjugates
  Speaker: Ruth Duncan, Professor Emerita and Past Director Centre for Polymer Therapeutics Cardiff University

- Nanoparticles
  Speaker: Rogério Gaspar, Professor of Pharmaceutics, University of Lisbon

Q&A panel and conclusion by the Chair

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Day 2
Starts on 3rd of September at 9:00 am

09:00 – 11:00

Session 4: Emerging nanomedicines
The speakers will provide an overview of the challenges raised by the development of emerging nanomedicines in the light of existing frameworks and clinical development guidelines.

Chairperson: Paula Salmikangas (European Medicines Agency, Vice-Chair of the Committee for Advanced Therapies; Chair of the Working Party on Cell-based Product)
European Medicines Agency: Spiros Vamvakas (Head of Scientific Advice Section)

- Novel and innovative nanotechnology-based delivery systems
  Speaker: Alexander Kabanov, Parke-Davis Professor of Pharmaceutical Sciences and Director of the Center for Drug Delivery and Nanomedicine, University of Nebraska Medical Center

- Nanosystems in regenerative medicine
  Speaker: Jöns Hilborn, Professor of Polymer Chemistry and Research Coordinator on Polymer Chemistry, Uppsala University

- Theranostics nanoparticles (therapeutic and diagnostic)
  Speaker: Peter Dobson, Academic Director, Oxford University Begbroke Science Park

Q&A panel and conclusion by the Chair

11:00 – 11:30 Coffee break

11:30 – 13:30

Session 5: Nanomedicines and the application of Risk Management Principles
Nanomedicines and the application of Risk Management Principles Management of the risks to the patient and to the environment in the life cycle of medicinal products: What additional requirements for nanomedicines may be needed? How do we reconcile the risks from the interactions between medicines and "activating devices"? Risk Minimization: why and when? Risk communication?

Chairperson: Peter Arlett (European Medicines Agency Pharmacovigilance and Risk Assessment Sector)

Management of Risks to Patients

- Safety Specification - Identification and Methodology
  Speaker: Annalisa Rubino, Risk Management Section

- Pharmacovigilance and Risk Minimization Plans
  Speaker: Jan Petracek

Environmental Risk Assessment

- Specific Methodological Issues and Implications for Risk Assessment
  Speaker: Silvia Berkner, Risk assessor at the German Federal Environmental Agency

Q&A panel and conclusion by the Chair

13:30 – 14:30 Lunch break

14:30 – 16:00

Session 6: International outlook for Nanomedicines
An overview of the regulatory approaches and perspectives from different regulatory agencies viewpoint will be presented and discussed in this session.

Chairperson: Yoshikazu Hayashi (MHLW/PMDA Liaison Official at the European Medicines Agency)
European Medicines Agency: Emer Cooke (International liaison officer)

- Current initiatives in the US
  Carlos Peña, FDA

- Current initiatives in Japan
  Kumiko Sakai-Kato and Toru Kawanishi, National Institute of Health Sciences/MHLW

- Current initiatives in Canada
  Duc Vu, Health Canada

Q&A panel and conclusion by the Chair

16:00 – 16:15

Way forward:

- Marisa Papaluca, Head of Scientific Support and Projects, European Medicines Agency

16:15 – 16:45 Coffee

Closure of the meeting