



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# **Workshop on Nanomedicines Session 3: Nanomedicines on the market and in clinical development**

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Introduction

E Abadie, Committee for the Medicinal Product for Human use (CHMP) chair  
Session Chair

An agency of the European Union





# EMA involvement in Nanomedicines

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CHMP Reflection Paper on Nanotechnology-based medicinal products for Human Use (June 2006)

- Evaluation of any application to place a nanomedicinal product on the market:  
utilizing established principles of **benefit/risk analysis**, rather than solely on the basis of the technology per se (including Risk Management Plan and Environmental Risk Assessment).
- Acknowledgement of the need for additional specialised expertise: Ad-hoc expert group created in 2009.



# Benefits for patients

## Addressing clinical needs:

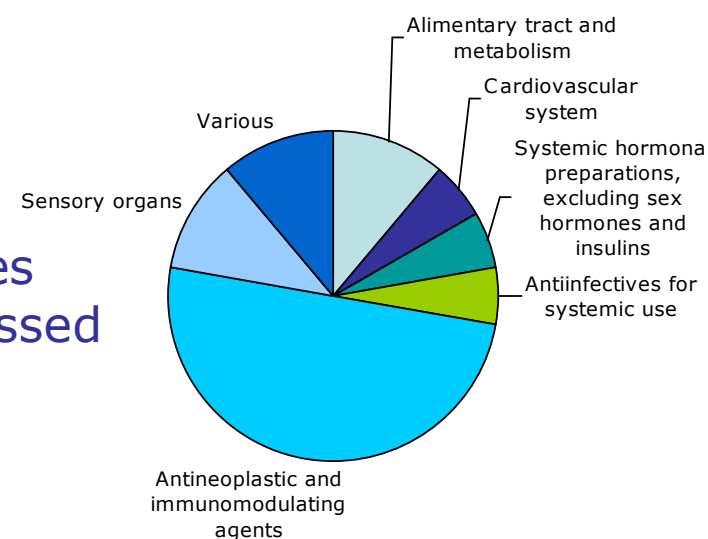
- Orphan Designations: Benefiting to rare diseases

Over 10 nanomedicines designated

- Marketing Authorization Applications  
(centralized procedure)

10 liposomal formulations, nanoparticles  
and over 8 polymers / conjugates assessed

Mainly anti-infectives, anti-neoplastic  
& immuno-modulating agents

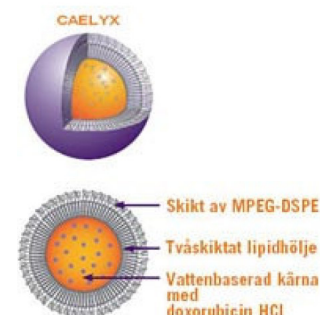




# Experience in the Centralised Procedure 1/2

## 1. Liposomes:

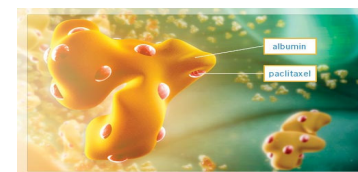
- **Caelyx** (*metastatic breast cancer, AIDS related Kaposi's syndrome, ...*) doxorubicin in sterically stabilised (Stealth®) pegylated liposomes
- **Mepact** (*high-grade resectable non-metastatic osteosarcoma*) mifamurtide in multilamellar liposomes



Source:  
[http://caelyx.se/Global/caelyx/caelyx\\_ge\\_nomskarning.jpg](http://caelyx.se/Global/caelyx/caelyx_ge_nomskarning.jpg)

## 2. Nanoparticles:

- **Abraxane** (*metastatic breast cancer*) paclitaxel albumin bound spherical nanoparticles
- **Rapamune** (*organ rejection in renal transplant*) sirolimus particles in nanocrystal colloidal dispersion



Source:  
[www.abraxane.com/professional/moa.aspx](http://www.abraxane.com/professional/moa.aspx)

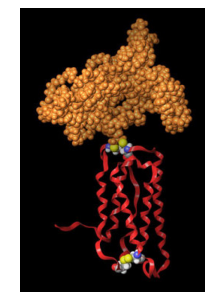


## Experience in the Centralised Procedure 2/2

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### 3. Polymers/conjugates

- **PegIntron** (*chronic hepatitis C*) pegylated derivative of IntronA
- **Somavert** (*acromegaly*) pegylated recombinant analogue of the human growth hormone

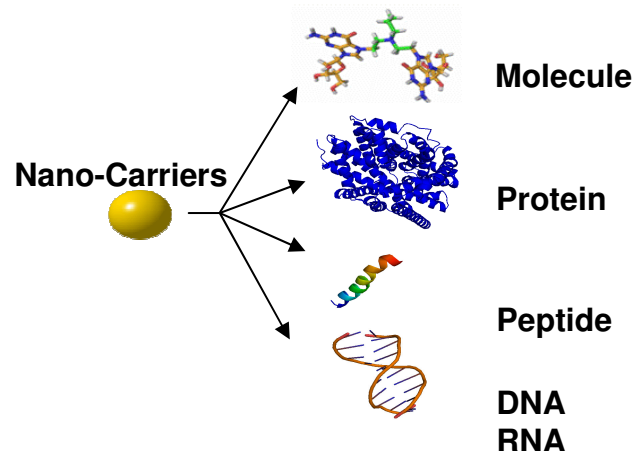


Source:  
<http://www.biojobblog.com/tags/pegintron/>

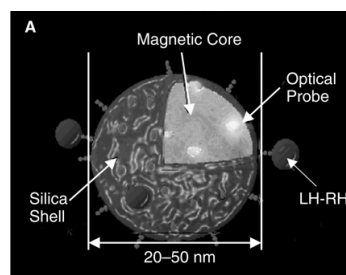


# Examples of emerging nanomedicines

- Further developments of nano delivery systems



- Converging technologies: Nanoshells for cancer magnetolysis





# Some challenges with nanomedicines

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## ➤ Scientific challenges

- ✓ Applicability and relevance of current methods
- ✓ Interactions with biological systems
- ✓ Impact on immune system
- ✓ Impact of intracellular or interstitial persistence

## ➤ Regulatory challenges

- ✓ Comparability of existing nano-formulations
- ✓ Tools for characterisation of risks
- ✓ Classification of converging technologies

## ➤ Ethical issues:

- ✓ Informed choice of the patients vs. benefit/risk based labeling



# Workshop: Objectives of Session 3

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## **Session 3:** Nanomedicines on the market and in clinical development

- ✓ Experience from approved nanomedicines and review key factors for design of emerging applications
- ✓ Review of progress in technologies in each class
- ✓ Discussion on specific challenges and opportunities





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**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

