Introduction to nanotechnologies and medicinal products at the EMEA

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- **EMEA exposure at different steps of medicines development: early phase exposure with the Innovation Task Force allows for informal scientific dialogue and identification of emerging trends and issues**
  - **from “soft” to “hard” nanomedicines –**
  - **from naked nanoparticles to conjugated ones**
  - **convergence of technologies: pharmacological action + integration of physical methods to elicit effects – e.g. magneto-lysis, photo-immunolysis, photodynamic treatments**
  - **from drug-delivery to theranostics**
  - **risks associated not only to the substance but to the overall approach**
- **Evolution in the field is monitored on an ongoing basis via dialogue with sponsors and stakeholders**
- **Discussion on nanomedicine candidates within the EC/EMEA/FDA bilateral confidentiality agreements clusters**

The EMEA and nanotechnologies

- **Nanoscale materials are used in medicinal products (drug delivery systems, modified release formulations, carriers, diagnostics, structures in regenerative medicine, ect.).**

- **The challenges are similar to other emerging technologies in terms of:**
  - adequacy of existing guidelines
  - acceptability of new testing methods
  - availability of experts in the network.

- **An additional challenge is represented by the wide spectrum of nanotechnologies and the very diverse characteristics of resulting "nanomedicines".**

- **The think-tank group recommended that "the ongoing activities at the level of the EMEA and CHMP in support of the development of emerging therapies and technologies should be reinforced" and "There are particular challenges related to the introduction of these therapies [*including medicines based on nanotechnology etc*.] to the market".**

- **Initiatives are taken to better inform the EMEA, the experts network and the industry about what is known, needed, and expected for nanomedicines.**

Nanoproducts
DG SANCO Key Recommendations 2008

1. Developing trustworthy information on products containing nanomaterials that are on or near the market, and on how they are tested.
2. Meaningful public engagement on the basis of shared definitions of nanotechnologies.
3. Ongoing regulatory reviews to provide clear guidance to industry on how to interpret regulatory frameworks, and clear indications to the public about action being taken in cases where relevant risk data is limited or uncertain.

Activities 2009-2010

Scope

Scientific evaluation of nanopharmaceuticals

Objectives

- Assess current state of the use of nanotechnology in pharmaceuticals and identify areas of current interest
- Assess the adequacy of applicable scientific methods for Q/S/E/ERA/RMP and identify any gaps in current guidelines and practices
- Strengthen expertise available to the CHMP by setting up an ad-hoc specialized expert group
- Reinforce contribution to EC initiatives and the collaboration among CHMP and regulators of neighbouring frameworks (e.g. cosmetics, food, occupational medicine, environment etc.)

Tasks 2009 – 2010

- Identifying nanomedicines in the EMEA procedures and retrieve scientific information available internally as far as Q/S/E/ERA/RMP are concerned.
- Taking stock of requirements and methods already accepted for nanosize medicines (currently mostly liposomes, micelles, nanoparticles) in close interaction with working parties.
- Identifying scientific issues based on the review of current experience at the EMEA (e.g. scientific advice, centralized procedure, ITF briefings, etc.).
- Promoting further dialogue with sponsors to define level and areas of interest for the pharmaceutical industry, concerns and bottlenecks (involve working parties and experts in briefing meetings on nanomedicines).

Expert group work plan

1. Provide input for the relevant EMEA activities at EU and international level
2. Update about state of the art in the field of nanomedicines under development (e.g. new validated methods for characterization of nanopharmaceuticals, biodistribution, immunotoxicity, ERA)
3. Discuss potential impact of nanotechnology related methods on key guidelines identified with Working Parties in Q/S/ERA/E/RMP
4. Provide input to working parties for relevant guidelines
5. Organize training sessions (with working parties)
6. Advice on the EMEA workshop on nanomedicines planned for 2010

Deliverables 2009-2010

- Recommendations on the need of guidelines adaptation and on areas for further consideration
- Contribution to reflection paper/Q&A document on selected areas if needed (e.g. liposomes characterization principles)
- Public EMEA Nanomedicines Workshop on 26-27 April 2010 and publication of a report from the workshop
- Recommendations for an action plan on nanomedicines 2011-2013
- Update the nanopage on the EMEA's "Medicines and Emerging science" site