EUROPEAN COMMISSION

Directorate-General for Health & Consumers

2nd Annual nano
BRUSSELS, 2nd-3rd October 2008
SAFETY FOR SUCCESS DIALOGUE

Medicines Breakout Group

Chair: Professor Ruth Duncan,
Centre for Polymer Therapeutics, Welsh School of Pharmacy, Cardiff University

Co-Chair: Dr. Hermann Stamm
European Commission Joint Research Centre, Institute for Health and Consumer Protection (Ispra)

Brussels, Friday, 3 October 2008

Needs - improve communication/dialogue Aspect 1.

- **Communication scientists/experts to general public**
  - Duty to explain developments of "Nanotechnology" in Medicine in a timely way
  - **Different perspectives**
    - Benefit-risks in communication, and of non-communication
    - What to communicate? Technical details-mechanisms of action?
    - How to communicate uncertainties
    - Building trust while sharing risk-benefit
    - Information should not be withheld - early access to information - it should be an interactive process

Needs - improve communication/dialogue Aspect 2.

- **Communication of Scientist to Scientist -Expert to Expert**
  - Definition of status and emerging needs
  - Improve communication across all constituent disciplines -including technical expertise and policy making agencies, regulatory agencies and society….
    ……expert to Healthcare Professionals
- **Communication between the medical doctor and the patient**

Who should do what, where, and when to improve communication/dialogue? Aspect 1.

- **Communication to the General Public**
  - **examples of good practice**
- **Regulatory Agencies**
  - Website information - Readability - lay language
    - Possibility to interact/feedback to the information provider
  - Follow-up by the Agency on feedback from public
  - Involving patient organisations in decision making bodies
- **Scientists and Experts**
  - Nanodialogues/Nanojuries
  - Enabling feedback in policy-making

Who should do what, where, and when to improve communication/dialogue? Aspect 2.

- ***Communication across Scientific Disciplines/ Experts -best practice***
- EC -Safety for Success……..
- Member State Government Policy setting Strategic Advisory Teams
- Other eg.
  - ESF Research Conferences, Summer Schools Workshops
  - Use existing communication lines, nano-specific information

Needs to improve the implementation of the existing legislation ?

- **Current regulation**
  - Medicine and medical device area already well regulated
    - No need to re-invent the wheel
    - How to deal with borderlines/nano issues?
    - How to deal with fast/emerging nano scientific developments
      - Medicinal products – medical devices
      - New knowledge to be integrated on case by case basis
- **Integration of different regulatory areas**
  - Exchanging best practice
  - Exchanging best technical practice

Who should do what, where, and when - means to improve impl. of existing reg.?

- **Regulatory Agencies**
  - Ongoing review of regulatory practice
  - Ensure uniformity of best practice
- **Involvement of patient representatives**
  - Workshops with patient/healthcare provider organisations
  - Involvement of patients prior to product approval
  - Encourage website interaction/feedback