2007 EMEA-EFPIA INFO DAY

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PART II: The Innovative Medicines Initiative

EMEA Viewpoint on the Innovative Medicines Initiative -Stimulating research and innovation

by Marisa Papaluca-Amati
Deputy Head of Safety and Efficacy Sector
Pre-Authorisation Human Unit
European Medicines Agency

EUROPEAN COMMISSION

Community Research

The 7th European Commission Framework Programme for research in the EU 2007-2013

The Innovative Medicines Initiative/ Strategic Research Agenda

By European Commission/ DG Research and European Federation of Pharmaceutical Industries and Associations

European Commission/ DG Research supported by the EMEA/CHMP.

http://europa.eu.int/comm/research/fp6/pdf/innovative_medicines_sra_final_draft_en.pdf

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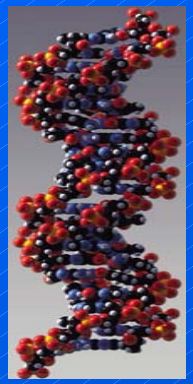
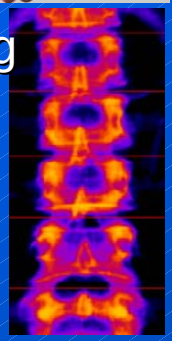
Science and technology advances present significant opportunities

'omics



Understanding human physiology



Imaging

IT

Public investment

Pre-competitive collaborative research

Industry investment

Better understanding of disease/drug mechanisms

More efficient drug discovery and development

Better medicines, faster

Delivery health benefits to citizens

The Innovative Medicines Initiative/ Strategic Research Agenda

Role of the EMEA

Partnership with the EC DG RTD

Brainstorming preparatory seminars in 2003-2004 to discuss perceived difficulties, needs and ways to better integrate pharmaceutical research and development in EU

Active support in contributing to the DG RTD public workshops on Knowledge management, Safety, Efficacy, Pharmacovigilance, Pharmacogenomics

Regular contacts and discussion on how the EMEA can best support the actual operations of IMI once launched

EMEA Initiatives

Intelligence gathering processes

"Scouting R&D"

- EMEA pipeline-project: looking at R&D: what and when

– Briefing meetings and informal dialogue with R&D: emerging knowledge and potential bottlenecks

- The Innovation Task Force
- Specialised Working Parties
- The CHMP Think-Tank

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Innovative Medicines Initiative –
To accelerate the development of safe and effective medicines
by joint public-private collaborations

=> **Research recommended** in the following areas:

-Improved predictivity of safety evaluation

-Improved predictivity of efficacy evaluation

-Improved knowledge management

-Improved education and training to develop the talent base needed for the EU biomedical environment.

Predictivity of safety evaluation

EMEA VIEWS/ ACTIONS

- **Non-clinical biomarkers**

  -Experience gathered in a number of areas including

  - **Collaboration with the Critical path Initiative**
  - **Pilot Genomic Biomarkers Qualification process mapping (jointly with FDA)**

- **New and alternative testing methods** supported:
  - **The EMEA and the ELSI initiative**
  - **Joint JRC/ECVAM/EMEA initiative**

- **Communication and education on safety matters:**
  - **The MIS establishment at the EMEA**
  - **EUDRA PHARM launch**
  - **Role of Working Party with Health Care Professionals Organisations**
  - **Role of Working Party with Patients organisations**

- **Pharmacovigilance aspects** (X Kurz)

Predictivity of efficacy evaluation
EMEA VIEWS/ ACTIONS

- Workshops on biomarkers in 2005 and in 2006: mapping progress
- Training of assessors on new statistical methods
- Workshop on adaptive/ flexible clinical trials designs
  -CHMP/EWP subgroup on adaptive designs
- Workshop on usefulness of Bayesian' methodology in clinical trials

EDUCATION AND TRAINING
EMEA VIEWS/ ACTIONS

- EMEA has long tradition in training of CHMP-members, assessors, internal staff, public, academia, etc

  ⇒ Collaboration in providing education and training highly supported

- **Special topics**: Adaptive/ flexible statistical designs, PK-modelling and simulation, advanced therapies, pharmacovigilance

Conclusions

- EMEA committed to support Pharmaceutical Innovation and the DG RTD SRA as of the beginning
  - EMEA is constantly networking with EC and with all resources available in the EU member states to prepare for new science and technologies to be integrated into the regulatory development and evaluation standards
  - Several relevant actions already being implemented as directly relevant to the EMEA remits
  - Discussions ongoing between EMEA/ EC on how to integrate the competences available
  - EMEA also likely to play a pivotal role in the global dimension part of the Agenda

http://www.emea.eu.int/pdfs/general/direct/directory/3416303enF.pdf

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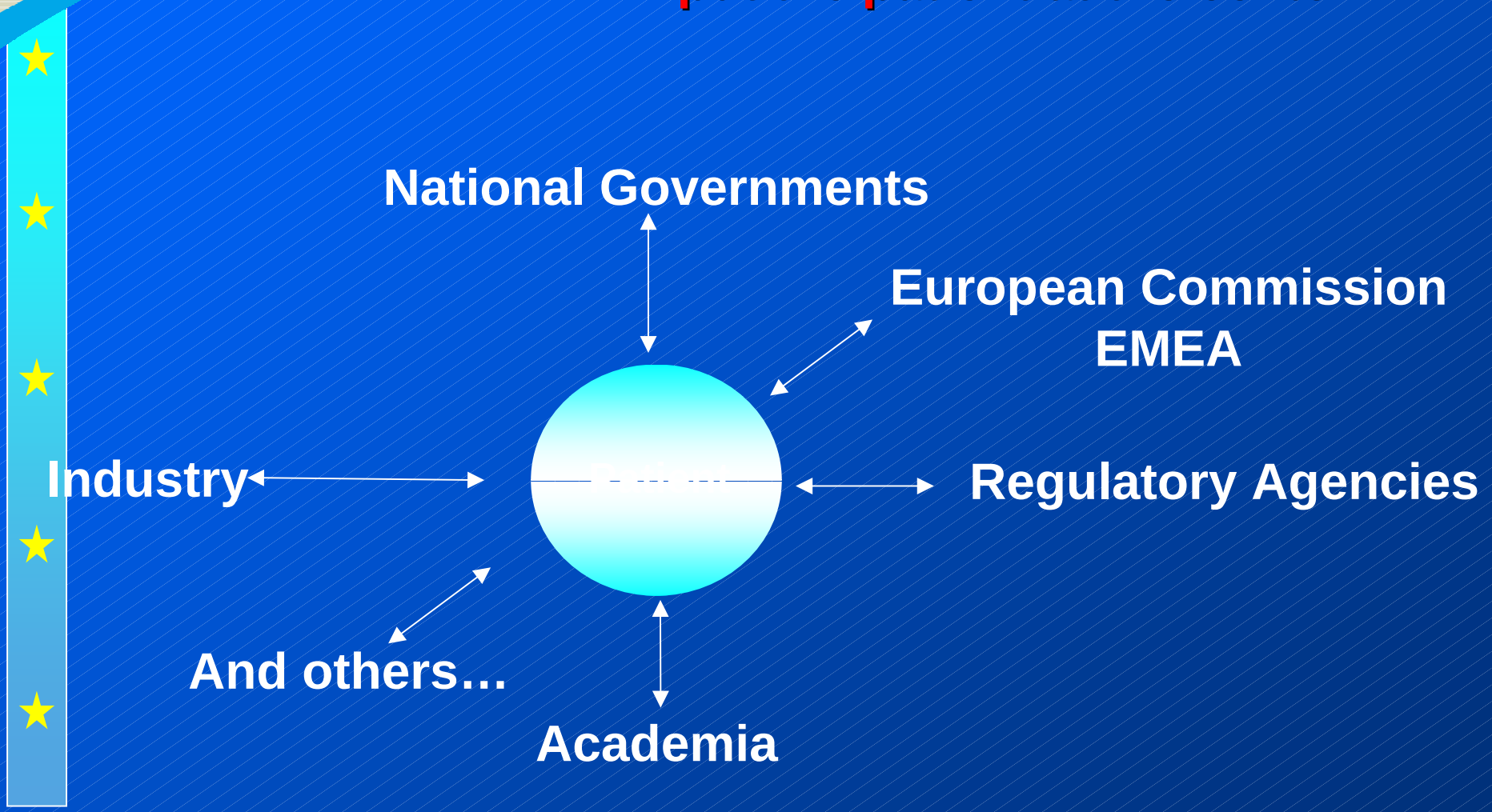
Foster a Collaborative Culture and put the patient at the center!



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