



# **WHO - Theme C: Innovation**

**Are there new ideas to stimulate innovation and promote access,  
and to improve the process of R&D, for therapeutics?**

**EMA PERSPECTIVE**

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# Overview of Presentation

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- **Background - EMEA and the future**
- **Objective – to stimulate innovation and promote access and to improve the process of R&D, for therapeutics**
- **Concluding remarks**



# EMEA and the future

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- **Environmental changes**
  - » Legislation changes
  - » Institutional changes: enlargement, new Commission and EP
  - » Economic and social changes: globalisation, active participation EU citizens, transparency and communication requirements
  - » EMEA Road Map 2010
  - » Scientific changes: new technologies, availability of medicines, unmet medical needs



# Challenges for the EMEA

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- Reinforce partnership amongst EU Authorities
- Greater collaboration with non-EU authorities, academia, learned societies
- Reinforce the scientific advice process and scientific support to committees
- Ensuring timely access to medicines
- Stimulate research and innovation in the pharmaceutical, biotech and healthcare industry
- Incentives for SMEs
- Improve the pharmacovigilance system

# Opportunities

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- **Orphan medicinal products**
- **Conditional approvals**
- **Accelerated review**
- **Shortening decision making process**
- **Compassionate use**
- **Opinions on medicines not to be marketed in the EU**
- **Provision of scientific, and regulatory, advice**
- **Guidelines**
- **Dialogue and debate**

# Factors affecting submissions

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- **A number of factors identified, which may explain the downturn of applications (Charles River Associates – report)**
  - » Increased cost of R & D
  - » Number of trials to support registration appears to have gone up
  - » Price regulation
  - » Growing importance of generics – decrease in R & D incentive
  - » Mergers in the early 1990s – rationalisation of R & D and negative effect

# Observations

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- **Charles River Associates - report**
  - » Need to focus on longer term issues regarding new technologies
  - » Improve discussions between regulators and the industry during development to facilitate registration
  - » Products languishing in Phase II – applied science has not kept pace with basic research
  - » Improved links needed between basic research in public sector and industry

# European Technology Platform

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- **Agreement that the environment for drug development and innovation must be improved**
  - » Contribute to technology platform by developing Strategic Research Agenda
  - » Safety – improve predictive toxicology and risk assessment areas
  - » Efficacy – focus on predictive pharmacology, biomarker identification and validation, patient recruitment and risk assessment
  - » Knowledge management – integration and use of large corpus of data
  - » Training and education – addressing gaps in expertise

# Reflections

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- **Better collaboration –**
  - » stakeholders need to work together in a more optimal manner, by integration of efforts and sharing data
- **Integration of scientific understanding**
  - » bridging gaps between scientists of different disciplines to promote synergy

## Looking ahead (1/4)

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- **Both authorities and innovators have a role to play:**
  - » At what stage can the authorities (e.g. EMEA) facilitate the development and marketing authorisation of innovative medicines?
  - » What can the innovators (Academia / Industry - SME & Big pharma) do to speed up the market access of innovative medicines?

# Looking ahead

## – Authorities' role (2/4)

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- **Scientific Innovation: a moving target**
  - » Keeping up to date with scientific progress and its potential benefit for public health
  - » Knowledge management: how to handle the corpus of scientific knowledge and how to find and keep the experts needed for scientific review
  - » Flexibility needed to integrate the scientific outcome different disciplines and improve benefit /risk assessment



# Looking ahead

## – Authorities' role (3/4)

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- **Regulatory challenges: rules cannot stand still**
  - » Regulatory requirements must reflect scientific progress, not define scientific pathways
  - » Authorities should not become complacent about using established methodologies
  - » New ways of ensuring compliance in a changing environment (pre- and post-licensing)
  - » Greater regulatory transparency, with more complex risk communication issues
  - » International cooperation to establish common rules that take into account different interests

# Looking ahead

## – Innovators' role (4/4)

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- **Academic (basic) research is urgently needed on new tools for demonstrating safety and efficacy of innovative medicines, for example:**
  - » New animal or computer-based predictive models
  - » New biomarkers and surrogate markers for safety and efficacy
  - » Alternative methodologies or combination of methodologies to monitor and predict quality, safety and efficacy
  - » New clinical evaluation techniques
  - » Improvement of existing methodologies, e.g. characterisation of biotech molecules

## Concluding remarks (1/2)

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- **Authorities and innovators should communicate at a very early timepoint:**
  - » Create greater awareness with EMEA on pipeline products
  - » Discuss and anticipate hurdles in development:
    - Scientific issues and advice procedure
    - Regulatory problems
  - » This will allow EMEA to:
    - gain insight in hurdles to product development
    - prioritise their activities (e.g. guideline development)
    - design procedures for successful assessment in the interest of public health and innovation

## Concluding remarks (2/2)

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- **Prospective issues to be addressed:**
  - » Safety – improve predictive toxicology and risk assessment areas
  - » Efficacy – focus on predictive pharmacology, biomarker identification and validation, patient recruitment and risk assessment
  - » Knowledge management – integration and use of large corpus of data
  - » Training and education – addressing gaps in expertise
  - » Only via a combined effort of all actors will it be possible to facilitate the development and early market access of innovative medicinal products!