THE 2006 SYMPOSIUM APEC NETWORK

“Global Development”

“EMEA’s Views on Global Development”

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Royal Park Hotel, Tokyo, Japan
13 October 2006

CONTENT

- Challenges
- Pipeline
- EMEA Roadmap 2010
- EU initiatives
- International cooperation
- Medical needs
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CHALLENGES

- New science and new therapies
- Need to improve research and development
- Globalisation
- Medical needs
- Adaptation of regulatory requirements

CHALLENGES

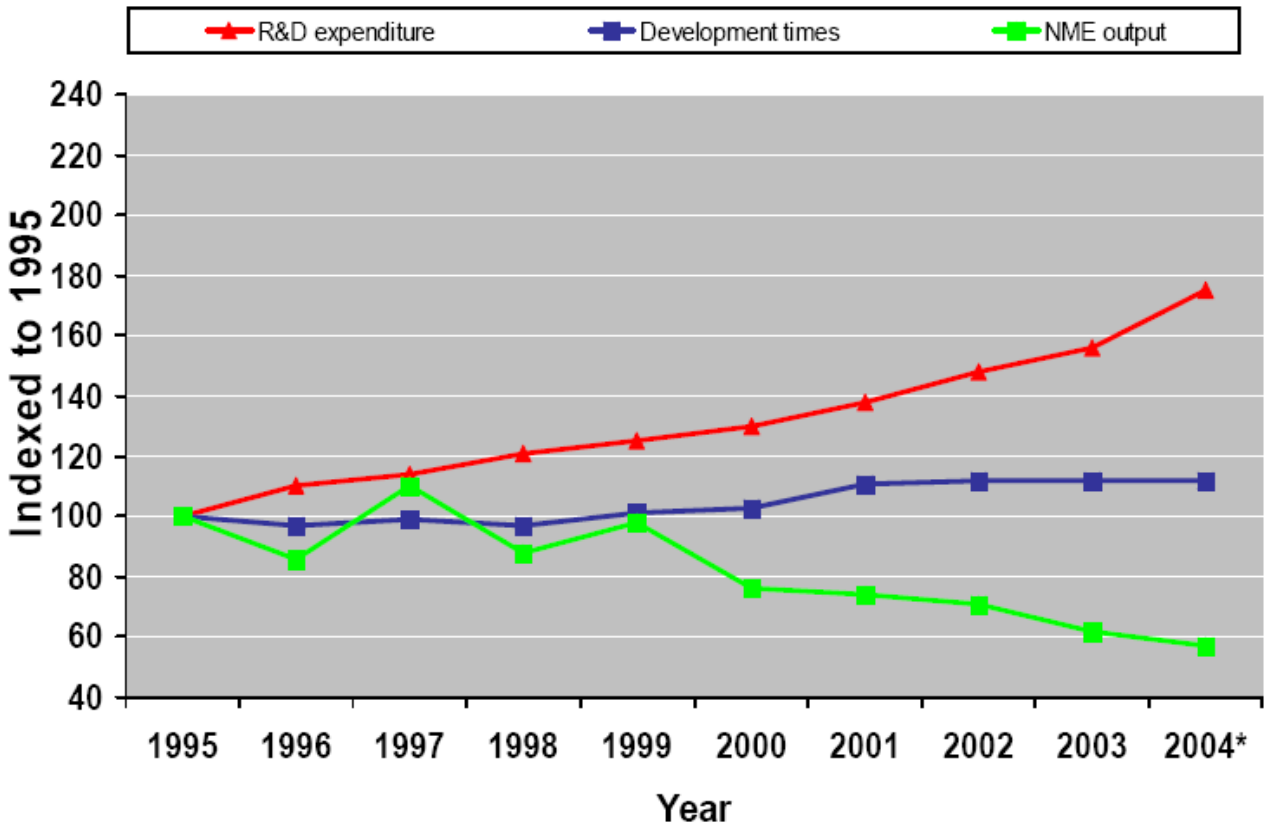


Figure 3 : Global R&D Expenditure, Development Times and NMEs 1995–2004[3]

THE PIPELINE

- What about applications in the coming years?
- Centralised procedure the entry in to EU
  - New medicines
  - Bio similar medicinal products
  - “Generics and OTC “
  - Article 58 (medicines for developing countries)
- Pipeline forecast
  - Survey of R&D pipeline

GENERICS: growth (CAGR = 20%-30%)

BIOSIMILARS: significant variation

SMEs: mild growth (CAGR = 5%-10%)

ORPHANS: constant

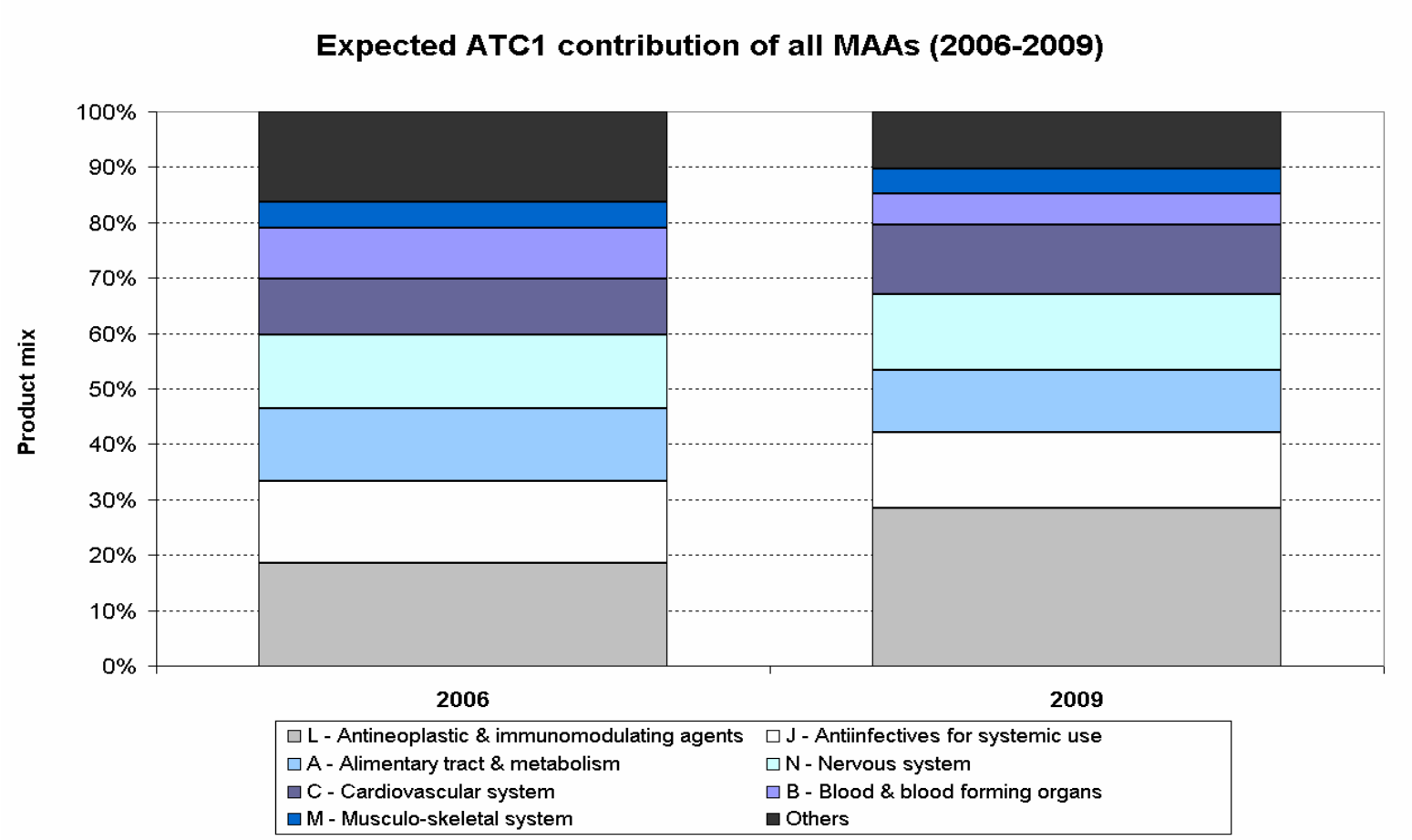
BIOLOGIC NMP: mild growth (CAGR = 5%-10%)

CHEMICAL NMP: slight variation

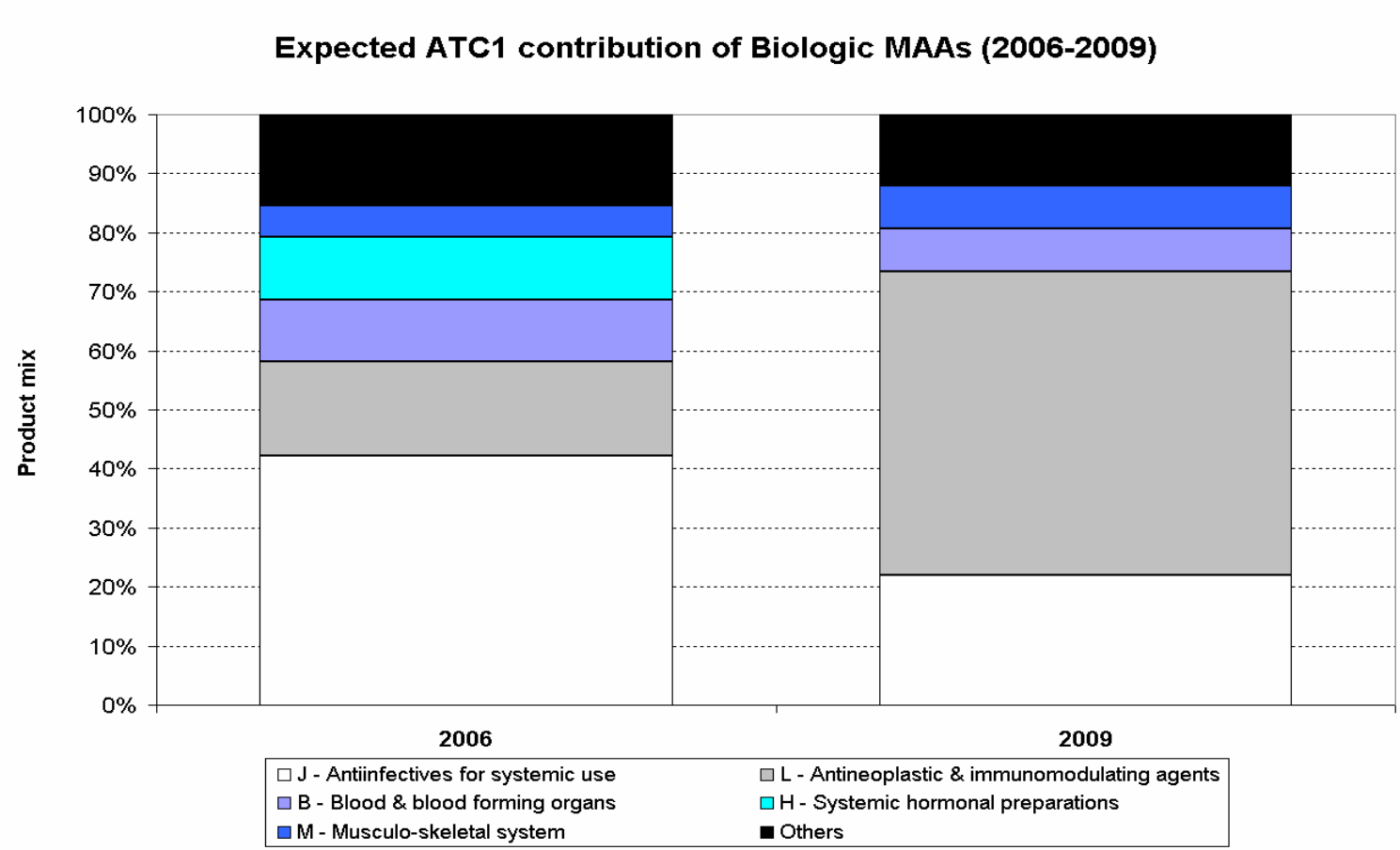
2006	2007	2008	2009	2010
• First generic submissions through centralised process	• First significant impact of generic applications	• Potential change in product mix to include more oncology products	• Possible first submission of new technology products	
• Increasing use of Scientific Advise process by industry	• Influx of PIP submissions due to new Paediatric Regulation	• Extension of Mandatory Scope e.g. antivirals, autoimmune products	• Possible first submission of disease modifiers	
• Increasing number of new technologies in scientific advice e.g. DNA-based therapies, cell-based therapies, nanotechnology	• Increased submissions of Fixed Dose Combinations	• Continued submission of flu vaccines (pandemic, inter-pandemic, seasonal)		

CAGR = Compound annual growth rate

EXPECTED SUBMISSIONS



EXPECTED SUBMISSIONS



EMEA ROADMAP 2010

- Safety of medicinal products
- Rapid access for new medicinal products and Support to innovation
- Transparency/communication and provision of information
- Management of the EU regulatory network

SAFETY

- Challenges
  - Balance rapid access/safety
  - Better public information on risks and benefit
- Actions
  - EU risk management strategy
  - Eudravigilance
- New legislation in the EU
  - Risk management plans
  - Studies in targeted population
  - Permanent follow up benefit/risk balance
  - Financial penalties

ACCESS TO NEW MEDICINAL PRODUCTS

- The new legislation
  - Conditional marketing authorisation
  - Exceptional circumstances
  - Accelerated evaluation
  - Compassionate use
  - 30 days to decision
  - Data protection

EMEA SUPPORT INNOVATION AND R&D

- New procedure scientific advice/protocol assistance by 1 July 2006
- Scientific advisory groups
- New procedure for issuing of guidelines
- Support small and medium size enterprises
- Consolidation of benefit-risk evaluation

EMEA SUPPORT INNOVATION AND R&D

- EMEA task force for new technologies
  - EMEA entry point for novel technologies
  - EMEA website for new technologies

- EMEA/CHMP think tank group
  - To consider innovative methods of drug development and assess potential hurdles encountered by pharmaceutical industry

EU COMMISSION INITIATIVES

- Paediatric Regulation
- Advanced Therapies Regulation
- Full implementation of the clinical trials directive
- Pharmaceutical forum (following G10)
  - Patient information
  - Therapeutic added value
  - Pricing
- 7th Research framework program 2007-2014 of the EC

EU INITIATIVES

- European Technology Platform (IMI)
  - Part of the 7th Research framework program
  - Promote development innovative therapies
  - Partners: EU Commission, Academia, Patients Associations, EU Industry (including SMEs), Regulatory Authorities
  - Objectives: to make development process cheaper, faster, predictable

EU INITIATIVES

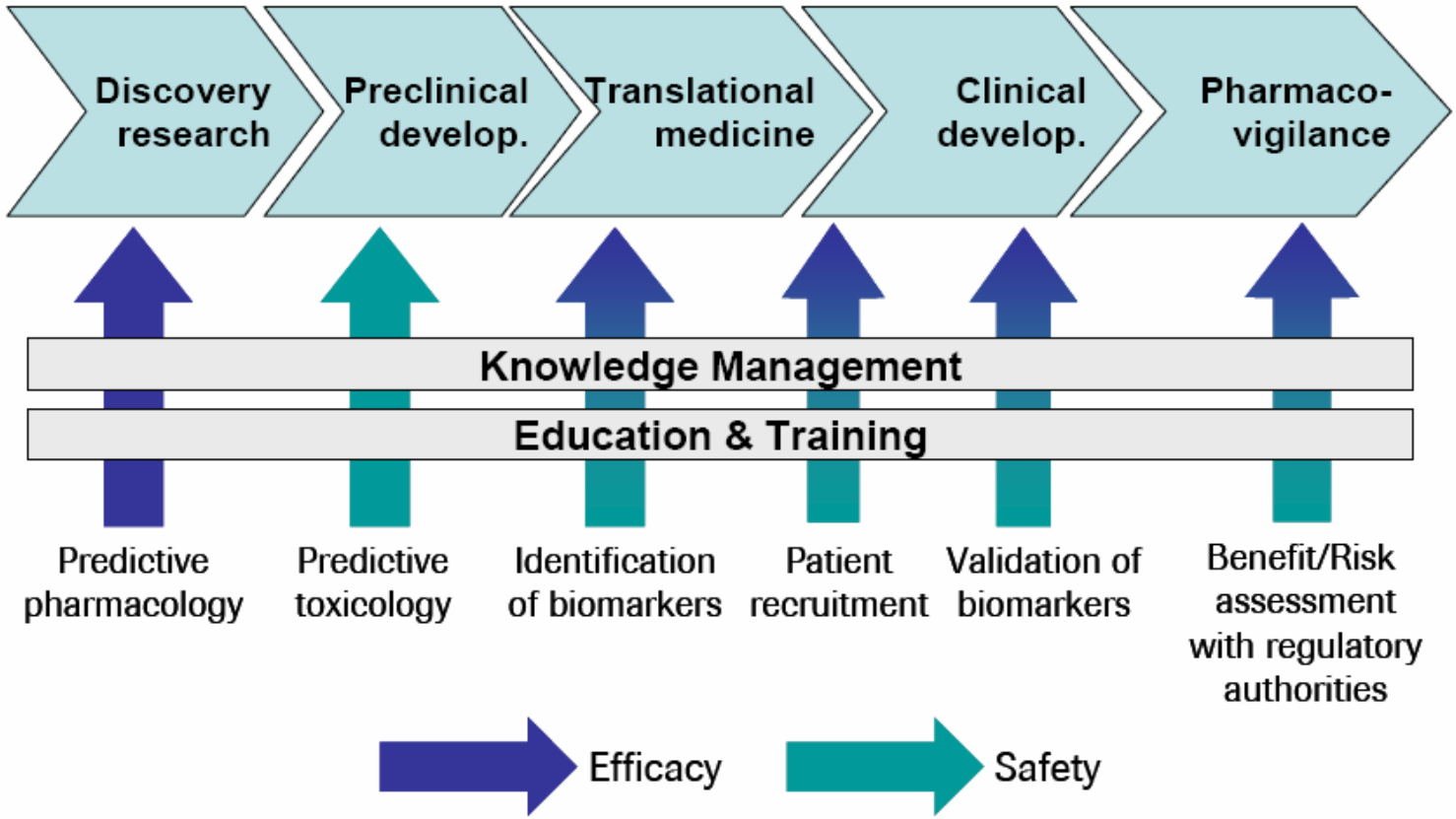
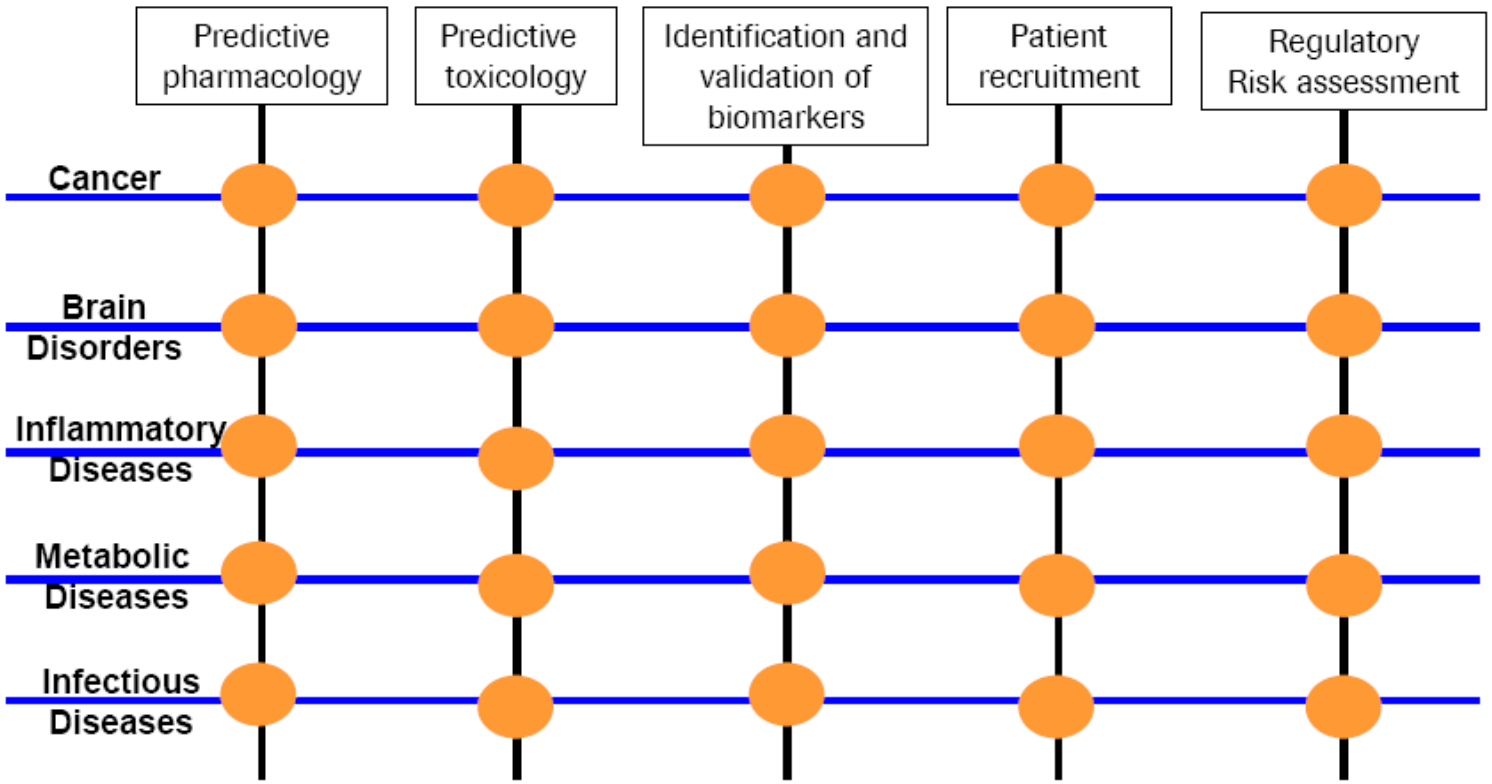


Figure 2 : Key Bottlenecks in the Pharmaceutical R&D Process

EU INITIATIVES



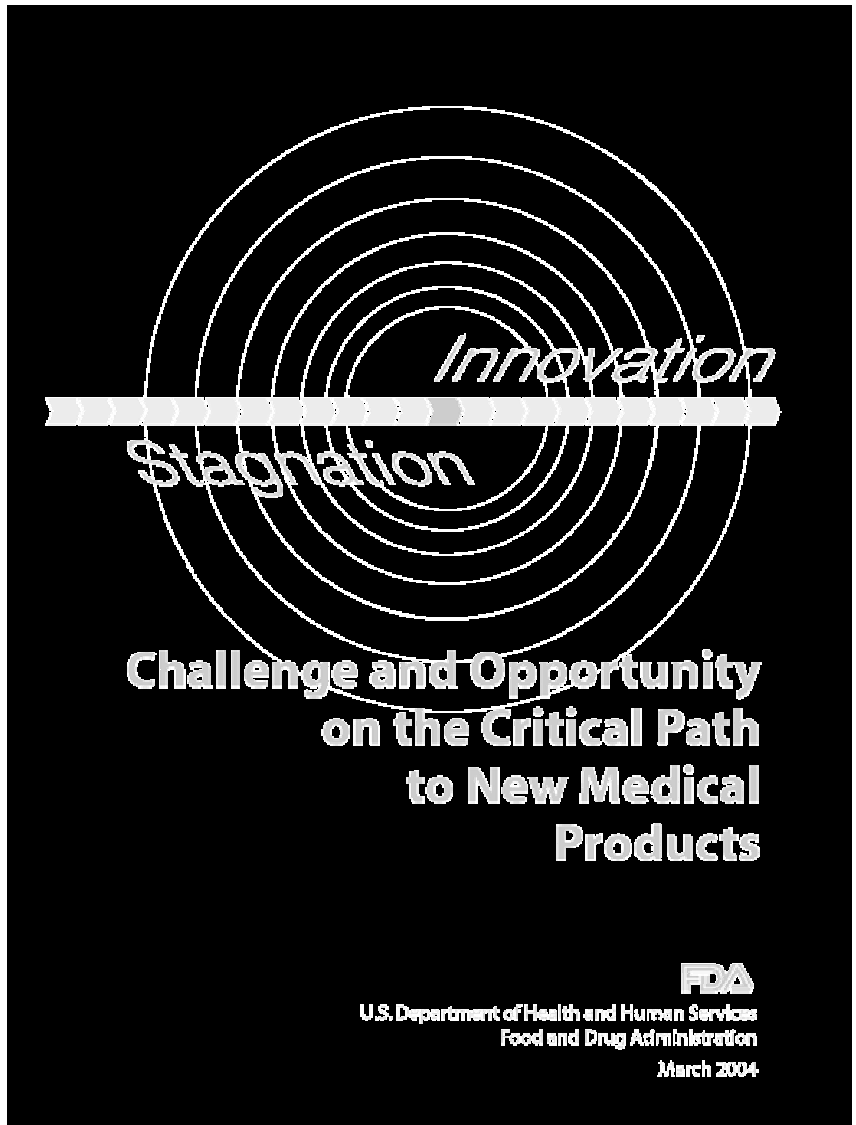
INTERNATIONAL COOPERATION

- International conference on harmonisation (ICH)
- International exchanges (Workshops, Conferences, EMEA visits, exchange of staff)
- With Japan EC/EMEA/MHLW confidentiality arrangement planned for 2007

EC/EMEA/FDA CONFIDENTIALITY ARRANGEMENT

- Implementation plan regularly updated
- Parallel scientific advice
- Voluntary advice on pharmacogenomics
- Exchange of information on inspections
- Exchange on on-going procedures
- Regular teleconferences on oncology, Pandemic Influenza
- Exchange on on-going guidelines

FDA's Critical Path Initiative



MEDICAL NEEDS

- Already addressed
  - Orphan medicinal products
  - Paediatric medicinal products
  - Medicinal products for neglected diseases (Article 58/EMEA procedure)
  - Advanced therapies
  - Influenza pandemic

MEDICAL NEEDS

- Still to be addressed
  - WHO report on priority medicines
  - Antibiotic resistance
  - Elderly population

CONCLUSION

- New science and technologies are a driver for change in the drug development process and regulatory requirement
- Also other drivers like high costs for new medicines, failure rate and unmet medical needs
- EMEA and its scientific committees do respond to a rapidly changing environment and adopt regulatory requirements as needed
- **Drug development is global**
- **Regulatory cooperation is needed**