Biosimilar Medicines: Opportunities for Sustainable Healthcare

5th EGA Symposium on Biosimilars

4th May 2007

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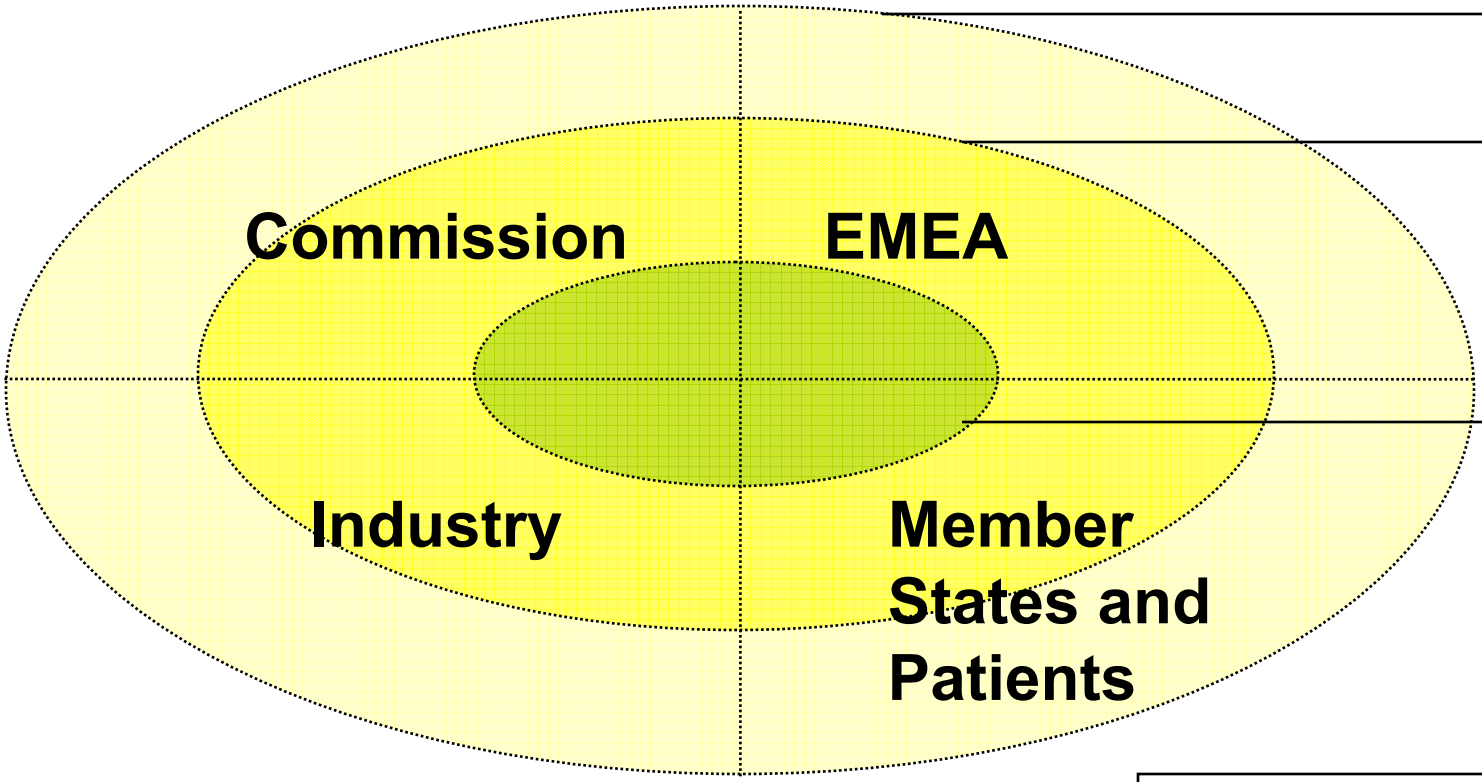
Sessions 1 - 6

- Market Overview
- International and EU Legal Developments
- INN naming of Biosimilar Medicines
- Science and Technology
- EU and International Regulatory Developments
- Stakeholder's Point of View on Market Entry of Biosimilar Medicines

Important Parameters for the EMEA



Legislation

Scientific Knowledge

New and Evolving Scientific Knowledge

EMEA SCIENCE DRIVEN

Idea stimulated by the book entitled "Consilience" – the unity of knowledge, by Edward O. Wilson ISBN 0-349-11112-X

Introduction and Background

- **Achievements**
  - » Implementation of legislation, guidelines
  - » 2 MAAs + Scientific Advice provided

- **Challenges for future**
  - » Evolution of scientific base
    - – Including manufacture and Process Analytical Technology
  - » Communication to stakeholders
  - » Harmonisation, technical / regulatory
  - » International Nonproprietary Name

INNs for Biologicals

- **INN: WHO policy**
  - » Highly valued – needs to keep pace with pharmaceutical practice / developments

- **Historical developments (science / regulatory)**
  - » INNs established > 50 years ago
  - » 1982 – insulin human
  - » Biotechnology – rapidly growing field
  - » Biosimilars have arrived

INNs for Biologicals

- **Purpose of INN**
  - » Classification / nomenclature
    - – Identification of pharmaceutical substances

- **WHO Guidance on INN – broad scope**
  - » Pharmacopoea, labelling, product information, advertising, drug regulation, basis for product names (generics)

INNs for Biologicals

- **Debate on "regulatory" element**
  - » eg Pharmacovigilance / Interchangeability / Substitution

- **What can be expected in future ?**
  - » Biologicals have inherent variability
  - » Analytical technology continually advancing, revealing greater molecular detail
  - » Where to "draw the line" for biologicals

- **INNs should have "high level" utility - identification**
  - » Up to Regulatory Authorities to assess Benefit / Risk

INNs for Biologicals

- **WHO discussions on-going**
  - » Informal consultation Sep-06 *
  - » Applicable to biologicals
  - » Meeting with industry Nov-06
  - » In depth review of policy
  - » Ad hoc meeting 23-24 Apr 07 (experts and industry)
    - – Report to INN Committee
  - » Review by INN Committee on-going

* http://www.who.int/medicines/services/inn/inn_bio/en/index.html

INNs for Biologicals

- **EU reflections fro consideration at WHO level:**
  - » AA sequence basis for INN
  - » Presence/absence of glycosylation compared to native protein
- **Further discussions necessary**

Communication

- **Biosimilars comparable to reference product**
  - » Based on Quality / Safety / Efficacy
  - » Post-marketing surveillance, as required

- **Health Care Professionals**
  - » Understanding of role of Regulators (EMEA)
  - » Product Information – satisfactory ?

Global Harmonisation

- **EU has lead role to play in biosimilars**
- **Regulatory pathways evolving**
  - » Need care with terminology, e.g. what does "interchangeable/substitution" mean: EU v USA
- **CTD Module 3 critical for biosimilars**
  - » Analytical advancement
  - » Principles of PAT

Biosimilar Future

- **Quality characterisation**
  - » Increased scope for biosimilars

- **EU Guidelines: add / amend depending on requirements / scientific advancement**
  - » Quality advances = reduced (non)clinical data ?

- **EU participation with other agencies**

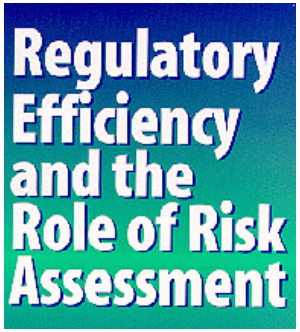
Process Analytical Technology

- **Some Reflections**

- Pharmaceutical development, based on science, has been a fundamental part of product development in the EU.
- New terms of PAT and Quality by design are compatible with this philosophy.
- Biological processes are carefully monitored by analytical tools. Complexity has always been present and much effort made to demonstrate consistency.

- New technologies being applied to gain better understanding and control of processes – scientific development is encouraged.
- Philosophy of risk is important in many areas of manufacture and use of medicinal products.

- **Regulators constantly need to adjust to new developments and adapt and facilitate these to the benefit of public health.**



- **ICH guidelines now incorporating more of a risk based approach – challenge for all : industry and regulators to develop strategies.**
- **Regulators recognise the global arena in which industry operates and the need for regulatory efficiency.**
- **Global harmonisation and Regulatory flexibility are often stated as goals, however, we must recognise some of the limitations of different region's regulatory structures and legislation**
- **Hope to gain a broad understanding of industry activities and how regulatory structures will be influenced and could be adapted in future.**

Thank you for your attention !

- **For your information:**

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