



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION



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**8th EGA Annual International Symposium on
Biosimilar Medicines**

**Greg Perry
Director General**

London 2-3 September 2010



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Outlines

- Snapshot of developments around the worlds since last symposium
- New Milestones and one major concern
- Developments in the Market Place
- Concluding messages

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Biosimilar Business Activities Increase



- New strategic alliances formed
- Further EU investment into facilities for production of state-of-the-art biopharmaceutical/biosimilar active substances
- New international agreements signed to form exclusive collaboration for developing, manufacturing, supplying and marketing of biosimilar medicines

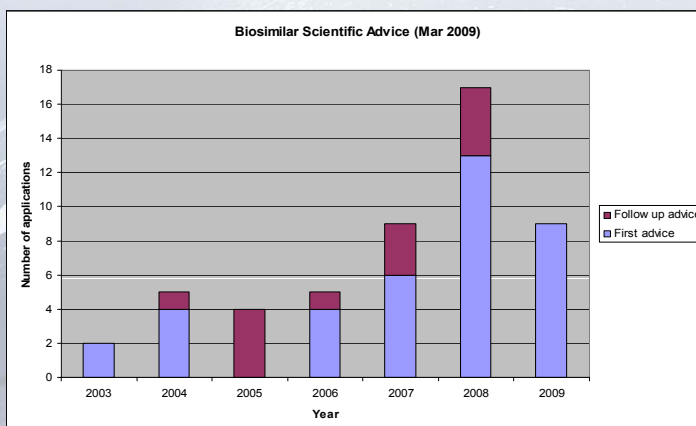
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EU 'Biosimilarity' Science Expands



- The EU continues to lead worldwide in developing and adopting guidelines
 - New Concept Papers released for comments and Guidelines finalised
 - We must address the importance of biosimilar monoclonal antibodies (mAbs) next if health care systems are to function long-term
 - The science for mAbs is already here today
 - Our industry is expecting a workable guideline

Increased Scientific Advice will Translate into New Submissions & Approvals



Source: T. Lönngren, EMA, 7th EGA symposium on biosimilar medicines

EU Continues to Inspire Rest of the World



- EU regulatory framework: excellent model for other parts of the world
- Need to reach a global agreement on criteria and guidelines in the interest of
 - patients and
 - better availability of high-quality medicines



Thorough Comparability Exercise IS Essential

- To demonstrate that the biosimilar product matches its reference product at the level of quality, safety and efficacy
- It provides confidence for patients and HCPs
- 2004 new EU Pharma legislation introduced legal basis for approval of similar biological products intended to compete with existing reference products

Final WHO Guideline Important Step towards Global Harmonisation



- WHO Guideline based on same scientific principles as in the EU
- First implementation workshop run by WHO in conjunction with Korean FDA
 - August 2010, Seoul
 - Active participation of EGA delegation



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Global Development Closer?

- EU, Japan, Canada, Australia, Turkey, Malaysia etc. now have a regulatory framework in place
- WHO guideline to be rolled out worldwide
 - Time for benchmarking exercise
 - Time for a consistent scientific global approach, key for true global development



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USA Finally on Board!



- Pathway for regulation and approval for biosimilars imbedded in health care law
- Biosimilar Implementation Committee (BIC) created by the US FDA
- Way is cleared for increased exchange between FDA and EMA
- Parallel scientific advice to be explored



Milestone: Approval of Generic Enoxaparin



- FDA approval of generic enoxaparin (generic version of Lovenox®)
 - Federal judge denied Sanofi's request for a preliminary injunction that would have forced the FDA to rescind approval of Sandoz generic enoxaparin

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Milestone: Biosimilar Filgrastim on Substitution List



- Biosimilar Tevagrastim® placed on substitution list in Norway
- Amgen has received a preliminary injunction (valid until end of Sept)

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Milestone: NICE Assessed First Biosimilar

- UK's National Institute for Health and Clinical Excellence (NICE) has assessed seven different somatropin products, including biosimilar Omnitrope®
 - first assessment of a biosimilar medicine by NICE
 - NICE declared 'no differences in clinical effectiveness'

Major Concern with Recent EC Handling of Duplicates in Centralised Procedure

- No duplicate Marketing Authorisation Applications accepted for companies of the same group
- Legal basis for EC interpretation of co-marketing?
- New handling
 - constitutes barrier to trade
 - will slow down market penetration of biosimilar medicines

Biosimilar Medicines: a Reality in Many EU Countries

- Biosimilars gaining significant market shares
- No reports on safety issues
- Support for wider use should be strengthened
 - Helps to secure access to essential biopharmaceuticals
 - Helps to contain sky-rocketing health care expenditure

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Ageing Europe

BARROSO
COMMISSION II



“Ageing is accelerating. Our working age population will be reduced by about 2 million by 2020 and the number of 60+ is increasing twice as fast as before 2007.”

Presentation of European Commission President J.M. Barroso to the Informal European Council, 11 February 2010

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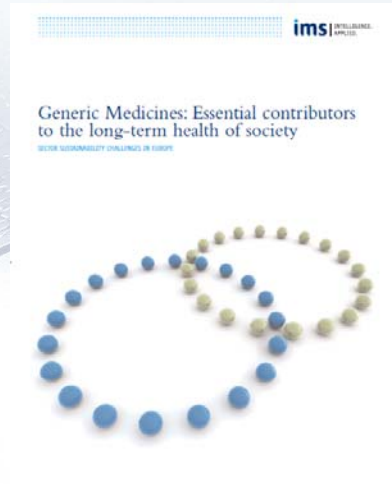
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IMS Sustainability Report

- ***‘Increased competition and market penetration of biosimilar medicines provide a major opportunity to control costs and availability of biopharmaceutical medicines’***

Alan Sheppard
IMS Health

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More Use of Biosimilar Medicines Requires

- Incentives for the demand side
- Consistent and rational approach towards interchangeability
- Increase of awareness and information



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Thank you

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