



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION



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Biosimilar Medicines Towards Global Development and Monoclonal Antibodies

**7th EGA Annual Symposium on
Biosimilar Medicines**

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Outline

- Snapshot of EU Developments
- Snapshot of the Rest of the World
- Vision | Global Biosimilar Development Concept
- Marketplace | Successes and Challenges
- Concluding Messages

EU 'Biosimilar Thinking'



- Further consolidation of EU “biosimilar thinking” in 2008
- The EU continues to lead worldwide in the development of new guidelines
 - EMEA Biosimilar Monoclonal Antibodies (mAbs) workshop (2 July 2009)
 - Increasing complexity/challenge/investments

EU Framework is Operational and Delivering

■ Approved substances

- Somatropin
- Epoetin
- Filgrastim

■ 13 Marketing Authorisations based on 6 developments





Biosimilar EC Approvals

INN	Name	Company	Reference	CHMP opinion	EC Approval
Somatropin	Omnitrope	Sandoz	Genetropin (Pfizer)	Jan 2006	April 2006
Somatropin	Valtropin	Biopartners	Humatrope (Lilly)	Feb 2006	April 2006
Epoetin alfa	Binocrit	Sandoz	Eprex/Erypro (JnJ/Amgen)	June 2007	August 2007
Epoetin alfa	Epoetin alfa Hexal	Sandoz (Hexal)	Eprex/Erypro	June 2007	August 2007
Epoetin alfa	Abseamed	Medice	Eprex/Erypro	June 2007	August 2007
Epoetin zeta	Retacrit	Hospira	Eprex/Erypro	Oct 2007	Dec 2007
Epoetin zeta	Silapo	Stada	Eprex/Erypro	Oct 2007	Dec 2007
Filgrastim	TevaGrastim	Teva	Neupogen (Amgen)	Feb 2008	Sept 2008
Filgrastim	Ratiograstim	Ratiopharm	Neupogen	Feb 2008	Sept 2008
Filgrastim	Filgrastim ratiopharm	Ratiopharm	Neupogen	Feb 2008	Sept 2008
Filgrastim	Biograstim	CT Arzneimittel	Neupogen	Feb 2008	Sept 2008
Filgrastim	Filgrastim Hexal	Hexal	Neupogen	Nov 2008	Feb 2009
Filgrastim	Zarzio	Sandoz	Neupogen	Nov 2008	Feb 2009

Applications Rejected or Withdrawn

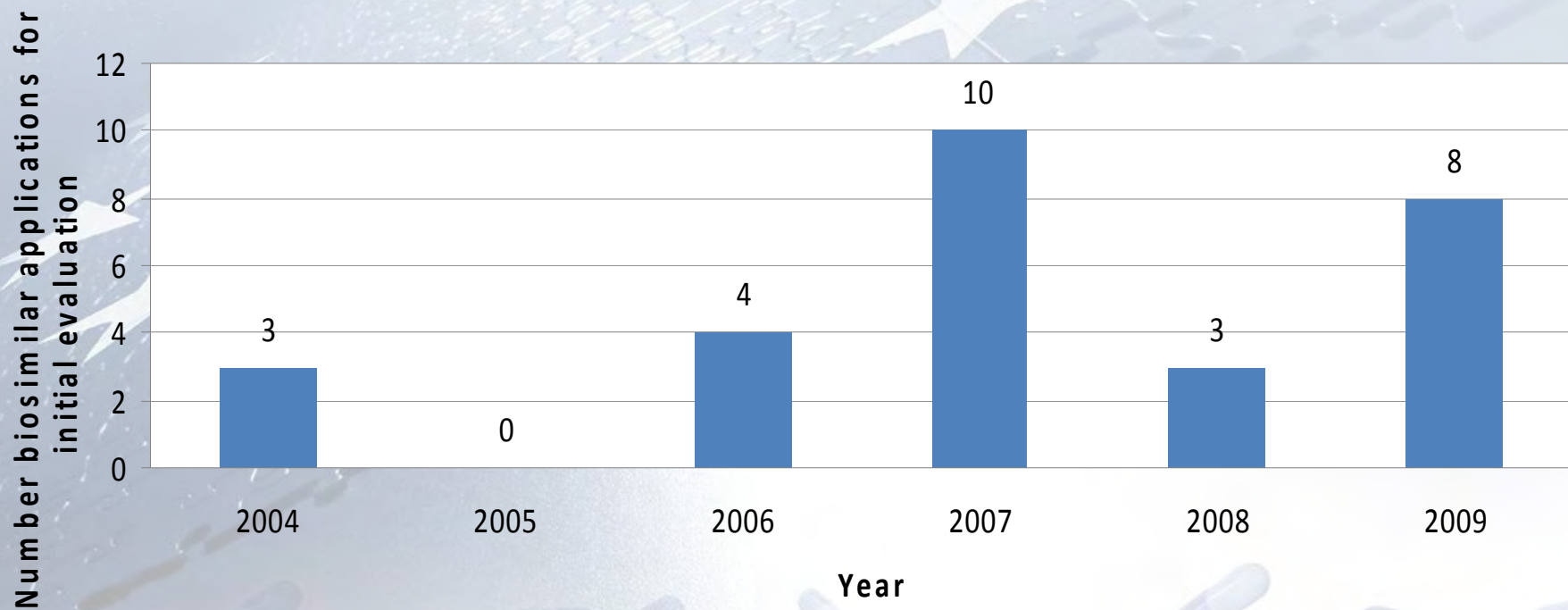
INN	Name	Reference	CHMP Opinion/ Withdrawal
Interferon alfa- 2a	Alpheon	Roferon-A (Roche)	June 2006
Human insulin	Insulin Human Rapid Marvel	Humulin (Lilly)	Withdrawn Jan 2008
Human insulin	Insulin Human Long Marvel	Humulin (Lilly)	Withdrawn Jan 2008
Human insulin	Insulin Human 30/70 Mix Marvel	Humulin (Lilly)	Withdrawn Jan 2008
Interferon beta- 1a	Biferonex	Avonex (Biogen)	Feb 2009

Proof of High Standards and Outstanding Level of Scientific Evaluation



- 6 developments successful
- 3 developments rejected or withdrawn
 - 67% success rate
 - 33% failure
- Confidence in our regulatory system

Positive Trend of Biosimilar Applications Continues



Source: EMA Annual Work Programmes

EU Inspiring Rest of World



- Guidelines finalised in Japan
- New round of consultation in Canada
- new bills on follow-on biologic legislation introduced to the US Congress
- WHO guideline, many other countries
 - Biosimilar medicines are entering an important period of development worldwide
 - Significant therapeutic impact for thousands of patients with serious, life-threatening, and chronic diseases

Vision: Global Biosimilar Development

- International developments: platform for further discussion of this concept
- Supported by ethical and scientific principles and economic considerations
- Biosimilar medicines on agenda of EMEA/FDA discussions
- Parallel scientific advice to be explored



Positive Developments in the Marketplace

- Extensive post-authorisation experience exists
 - eg, with first biosimilar Omnitrope[®]: more than 7,900 patient-years of exposure
- Interest and awareness are increasing
- Market inroads are made
- Germany (G-BA): same reference-price group for all somatotropins (including biosimilar medicines)
- MEB communicated disagreement with concerns of professionals about biosimilar growth hormone products in general

Ongoing Challenges

- Various supported publications still questioning biosimilar approvals
- PMDA International Symposium on Biologics in Tokyo (17 Feb)
 - Misrepresentation and misinterpretation of comparability data by JPMA, PhRMA, EBE/EFPIA speakers
- UK Parliamentary Summit on growth hormone in London (24 Feb) supported by Joint Industry WG on Growth Hormone (Ispen, Lilly, Merk Serono, Novo Nordisk, Pfizer)

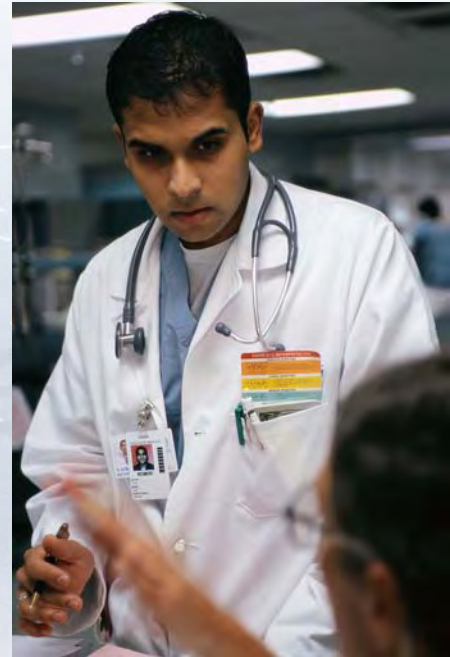
Denigration of Biosimilar Products Highlighted by the *Mutualité Française*

- *'In the context of its sector inquiry, the French Mutuality asks the European Commission to mention the denigration campaigns put in place by originator companies with the aim of maintaining an aura of suspicion around biosimilars. Indeed originator companies spread alarmist and often worrisome news regarding the difficulty of reproducing biotechnology derived products'.*

(Public submission sector inquiry-EGA internal translation)

Developing Market Pathways that Benefit Patients

- Key to developing biosimilar market pathway remains
 - building confidence among patients and healthcare professionals
 - building trust in the EMEA/CHMP scientific evaluation and pharmacovigilance system
 - increasing awareness and information
 - challenging misinformation, misinterpretations and misperceptions which is a shared responsibility



Conclusions





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Headroom for Competition

- Sustainability of pharmaceutical healthcare requires sustainability of a strong competitive and financially healthy EU generic and biosimilar industry
- The EU off-patent market must be based on the principle of “headroom for competition”

“Headroom for Competition” Requires...

- increased national and EU support for the ‘biosimilar thinking’
- development of a consistent global approach to regulating this new type of medicine
- discussions on global development programmes for biosimilar medicines
 - will improve availability, affordability and worldwide access
 - is in line with the European Commission December 2008 Communication on Safe, Innovative and Accessible Medicines: a Renewed Vision of the Pharmaceutical Sector



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Use of Biosimilar Medicines

■ Promoting the use of biosimilar medicines is vital

- to increasing patient access to medicinal care and
- to ensuring the sustainability of EU healthcare systems.





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Thank you

www.egagenerics.com

Greg Perry
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