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# **BIOSIMILAR MEDICINES**

**Helsinki - 31 October 2008**

Suzette Kox

EGA Senior Director Scientific Affairs





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**Good afternoon**

**Hyvää iltapäivää**

# Outlines

- EGA
- Definition
- EU Legal and Regulatory Framework
- EU Approvals
- Post Marketing Issues
- Health economic considerations
- Summary of key messages

# EGA - Representing the Generic & Biosimilar Medicines Industry

- Established in 1993
- Pan European
- Representing over 600 companies
  - employing over 100.000 people in Europe
  - Major EU healthcare provider
- Plays an important consultative role in EU healthcare policy-making
- Discussion partner for WHO, WTO, WIPO



# Generic Medicines: Ensuring Budget Savings and Access

- Generic medicines account for nearly half of packs sold in the EU and 18% of pharmaceutical sales
- Generic medicines bring savings of €20 Billion pa in the EU 27
- Generic medicines cover a full spectrum of pharmaceutical needs



# Biosimilar Medicines Europe's New Opportunity

- *“Biosimilars offer new opportunities both for the growth of our generic industry and for the control of our national health expenditure.”*

Günter Verheugen,  
Vice-President EU  
Commission - April 2006



# Overview on Biopharmaceuticals (Biologicals)

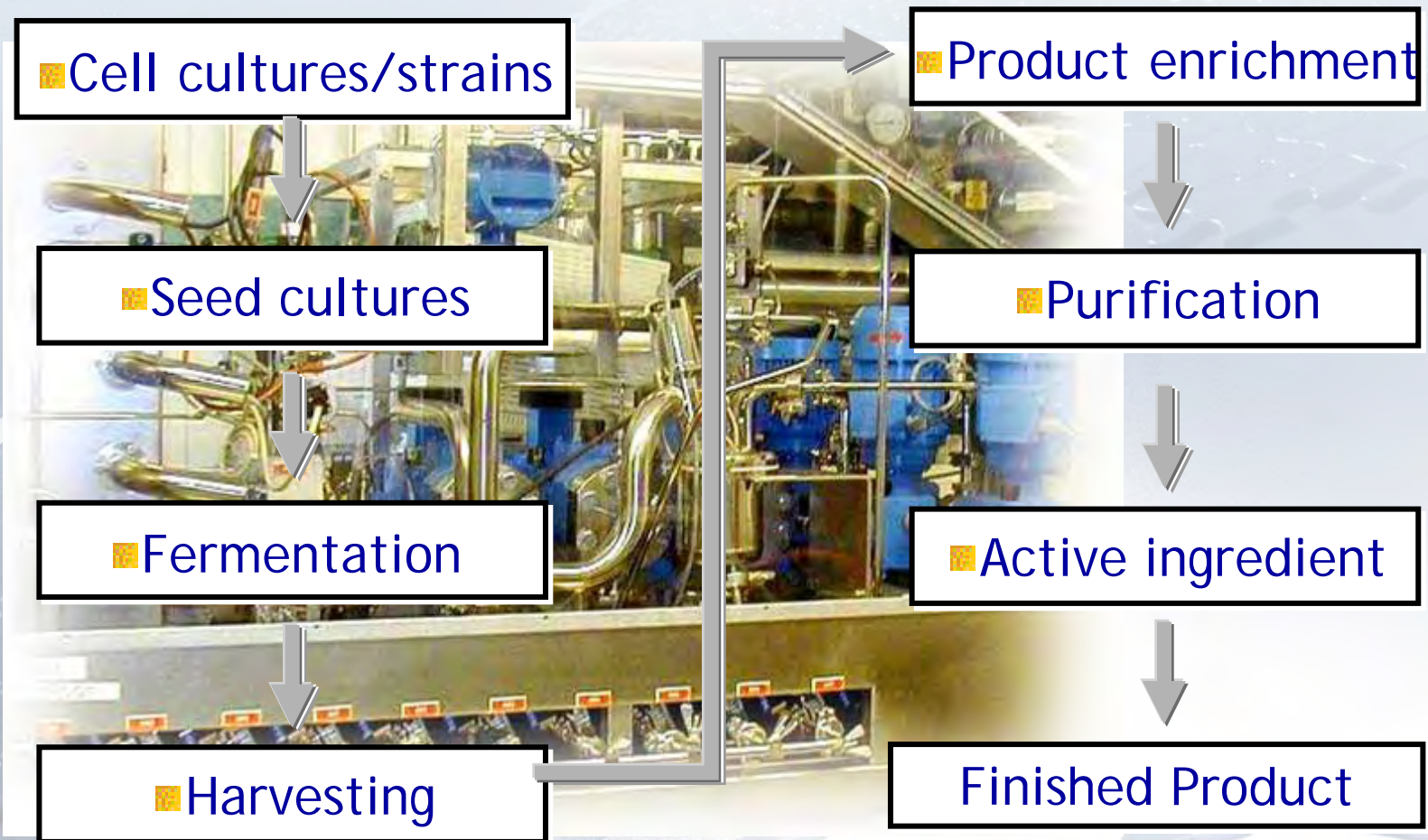
## Biopharmaceuticals

made by or derived from  
living organisms using  
biotechnology

**Originator  
biopharmaceuticals**  
used as reference medicinal  
products for the development of  
biosimilar medicines

**Biosimilar medicines**  
can now be made available by  
manufacturers other than the  
originator companies when the  
relevant patents have expired

## Quality Standards in Manufacture Apply Equally to All Biopharmaceuticals Including Biosimilars



# European Medicines Agency (EMA) Definition

- A biosimilar medicine is a medicine which is similar to a biological medicine that has already been authorised (the 'biological reference medicine')

EMA Q&A



# Conventional Pharmaceuticals versus Biopharmaceuticals

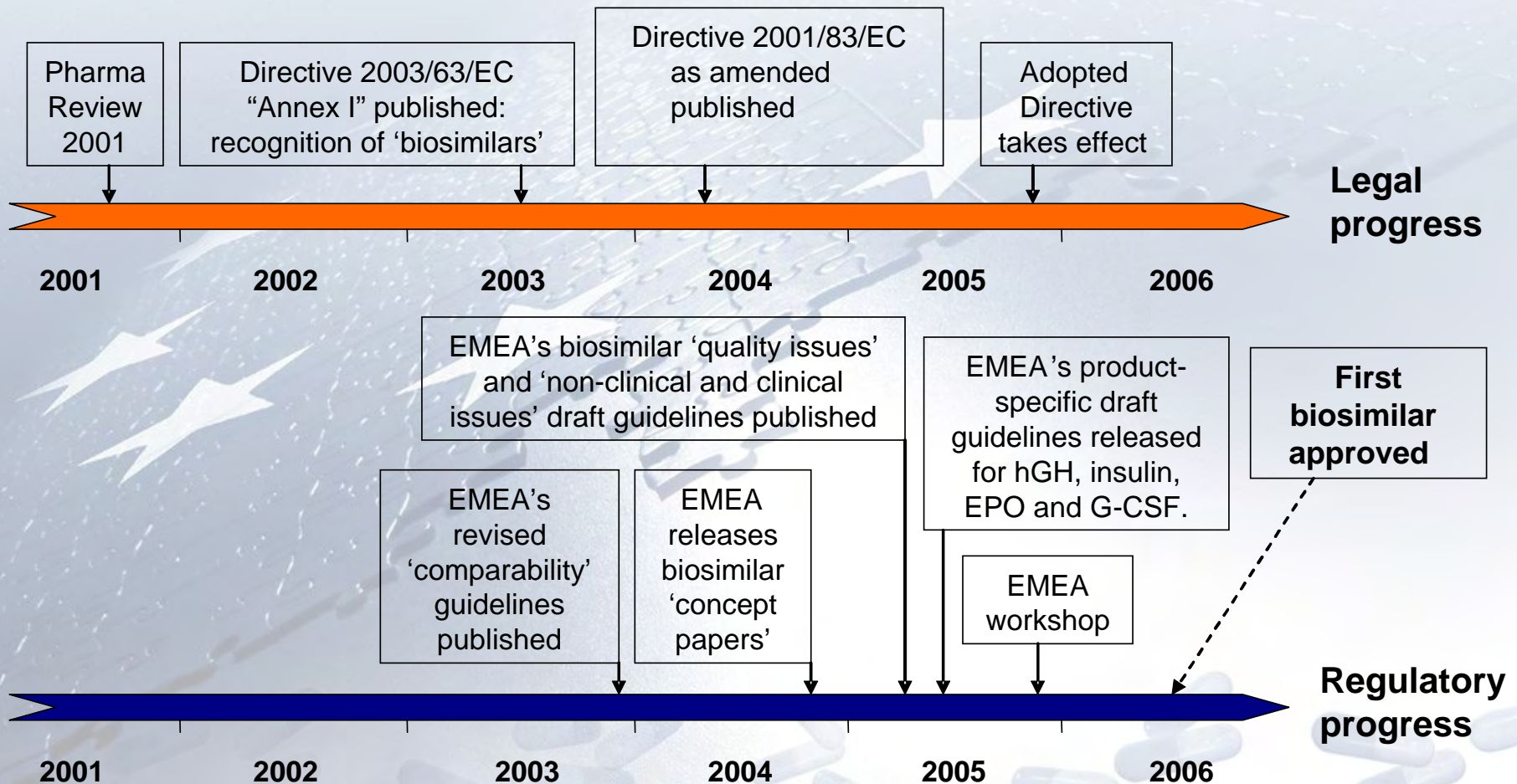
- Conventional Pharmaceuticals are generally small, relatively simple molecules made from natural or synthetic chemicals
- Biopharmaceuticals are complex protein molecules manufactured by recombinant DNA technology (insertion of gene into the host cell to produce the protein)

# Biosimilar Medicines EU Leadership

- EU is leading the world in creating a specific legal framework and a regulatory pathway for biosimilar medicines

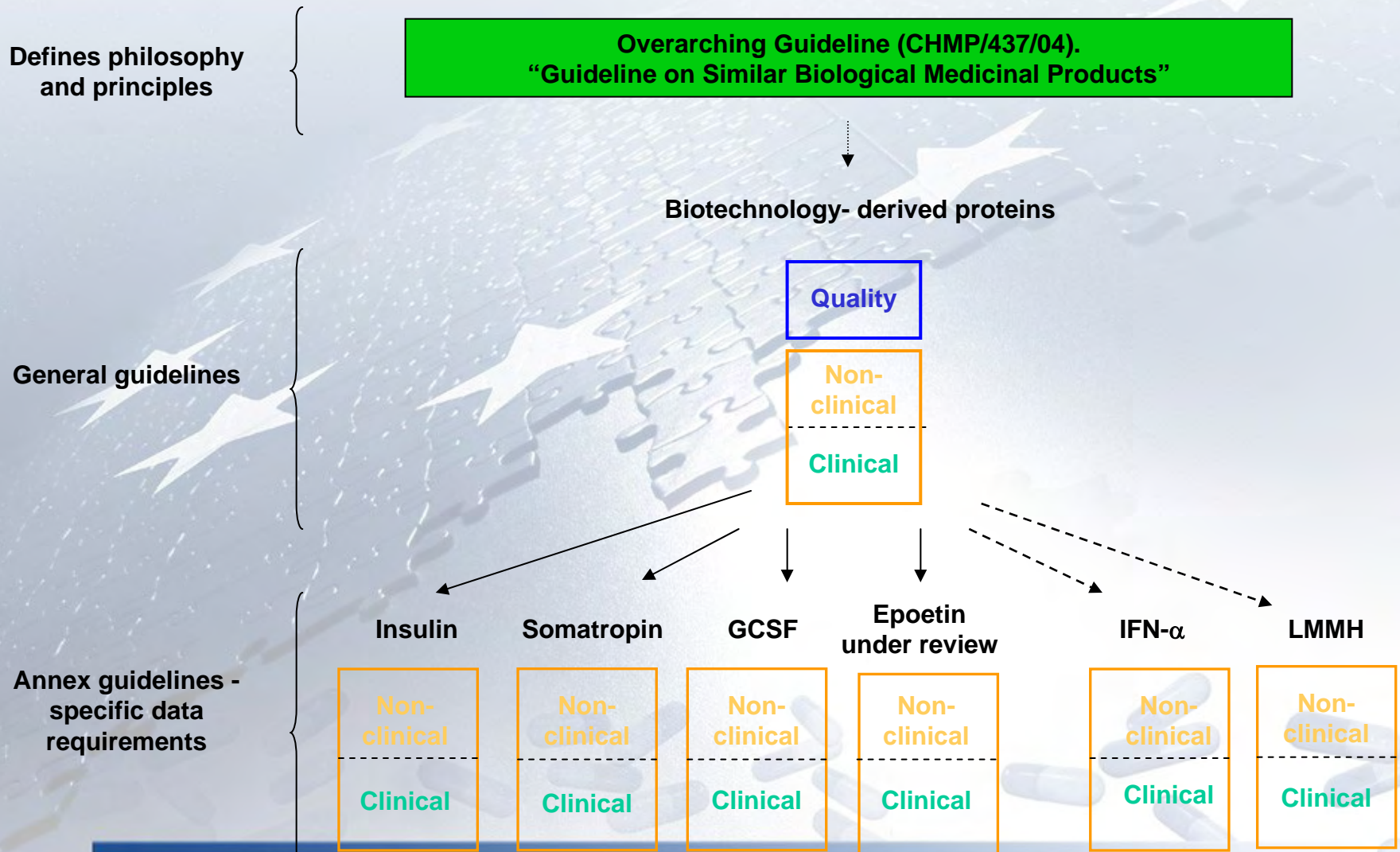


# Legal & Regulatory Pathway Carefully Developed Over Time



# Current EU Biosimilar Guidelines

<http://www.emea.europa.eu/htms/human/humanguidelines/multidiscipline.htm>



Source: P. Richardson EMEA-EGA 6th symposium on biosimilar medicines



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# EU Legal & Regulatory Framework

## Legal basis

The legal basis is provided in EU Directive 2001/83/EC, as amended, in Article 10, Paragraph 4, published in EU Directive 2004/27/EC (31 March 2004 )

The requirements are set forth in EU Directive 2003/63/EC, Annex, Part II, Point 4, for “Similar Biological Medicinal Products”

**Biosimilars  
have a  
solid legal  
& scientific  
footing in  
Europe**

## Scientific guidelines

EMA/CHMP issued a set of guidelines for biosimilars which address general, quality-relevant and preclinical/clinical requirements for specific products (e.g. Somatropin, Epoetin, Filgrastim, Insulin)

All general ICH and EMA, guidelines on the quality and safety (including immunogenicity) of biological products apply to all biopharmaceuticals including biosimilar medicines

# EU Framework Combines

## ■ Legal certainty

- Clear legal basis
- Abbreviated data package

----->key for  
investments

## ■ Flexibility

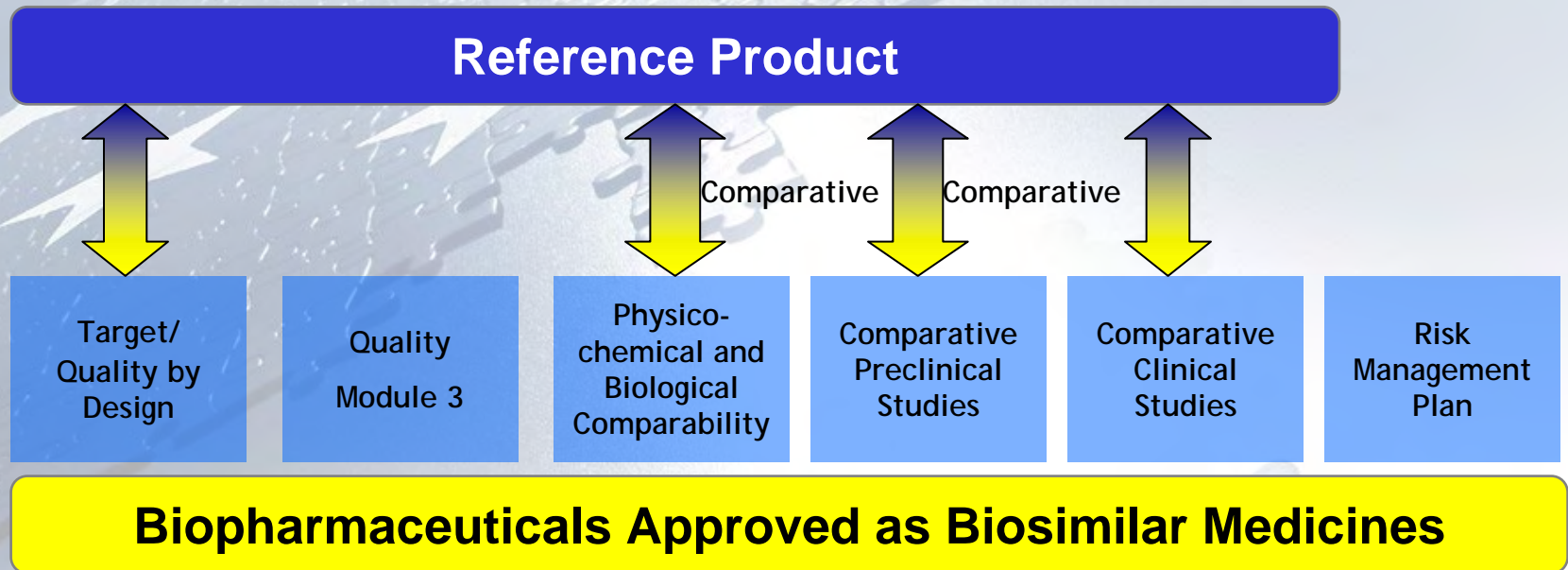
- Case by case approach
- General and product specific guidelines

-----> adjustments of data requirements (science, technology, experience)

# Biosimilar Medicines Approved on the basis of a **Comprehensive Comparability Exercise**

The development of a biosimilar medicine requires a complete independent product and process development

**PLUS** comparative testing at all stages of in order to obtain approval by the European authorities (EMA, CHMP, EC)

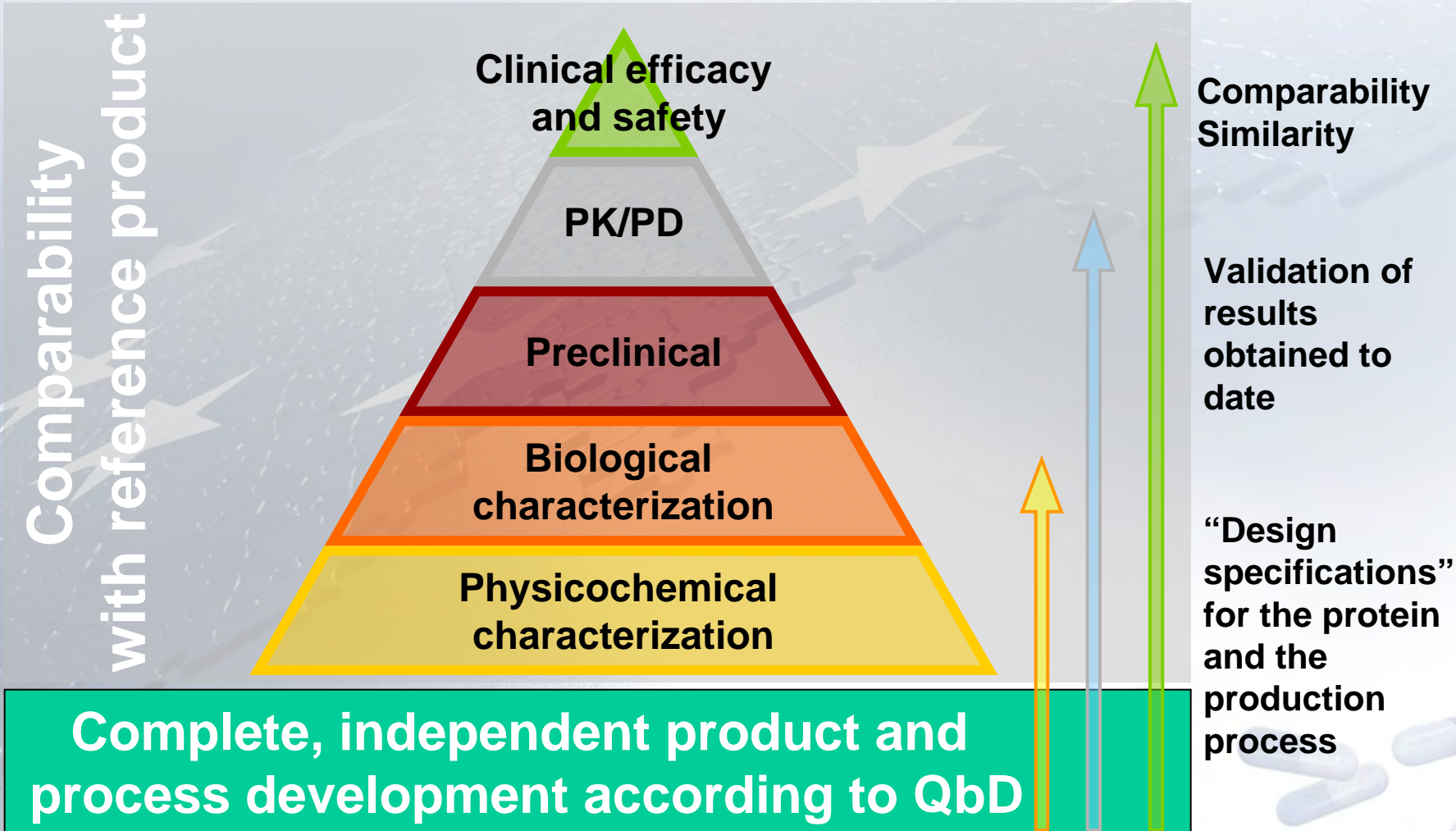




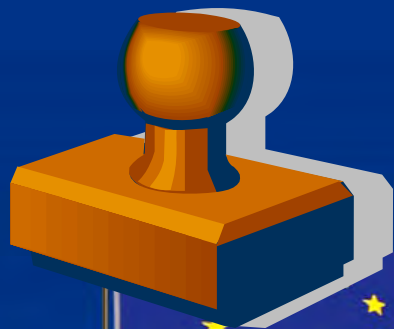
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# "The Comparability Exercise"

Comparability with the reference product must be ensured at all levels.



# European Commission Approval



# Biosimilar Approvals Area of Growth

## ■ 3 active substances

- Human Growth Hormone (GH deficiency)
- Epoetin (anemia associated with chronic kidney failure)
- Filgrastim (neutropenia in cancer patients)

## ■ 15 Marketing Authorisation (MA) applications leading to 11 MAs held by 9 MA Holders

# Pharmacovigilance

- Same for all biopharmaceuticals including biosimilar medicines
  - Mandatory Risk Assessment Plan (RMP)
    - Published in European Public Assessment Report (EPAR)
  - Includes:
    - Spontaneous reporting of adverse Drug reactions (ADRs) from patients and professionals
    - Preparation of Period safety Update Reports (PSURs)
    - Post-Authorisation Safety Studies (PASS)

# Traceability of ALL Biopharmaceuticals

All biological products need to be monitored

- An adverse reaction report **for any biological drug** must include
  - full name of the biological product
  - batch number
- Where information is missing, Member States/Company must ensure that reports are followed up for completion

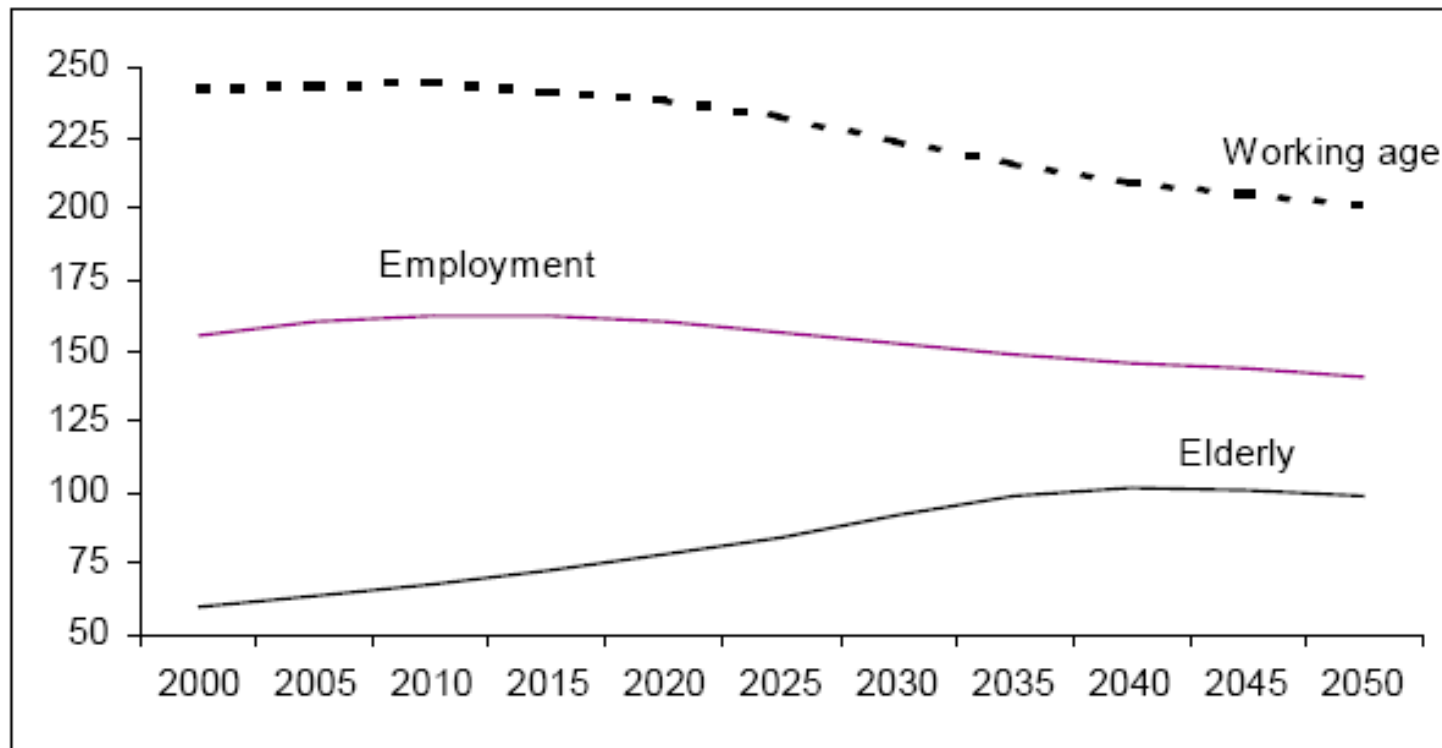


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# Health Economic Considerations

# A steadily aging population being treated with ever more sophisticated and expensive biopharmaceuticals is driving pharmaceutical costs to unprecedented levels

**Graph 2.1** Projected size the EU working-age and elderly population (millions)



**Note:** Working age population refers to persons aged 15 to 64.

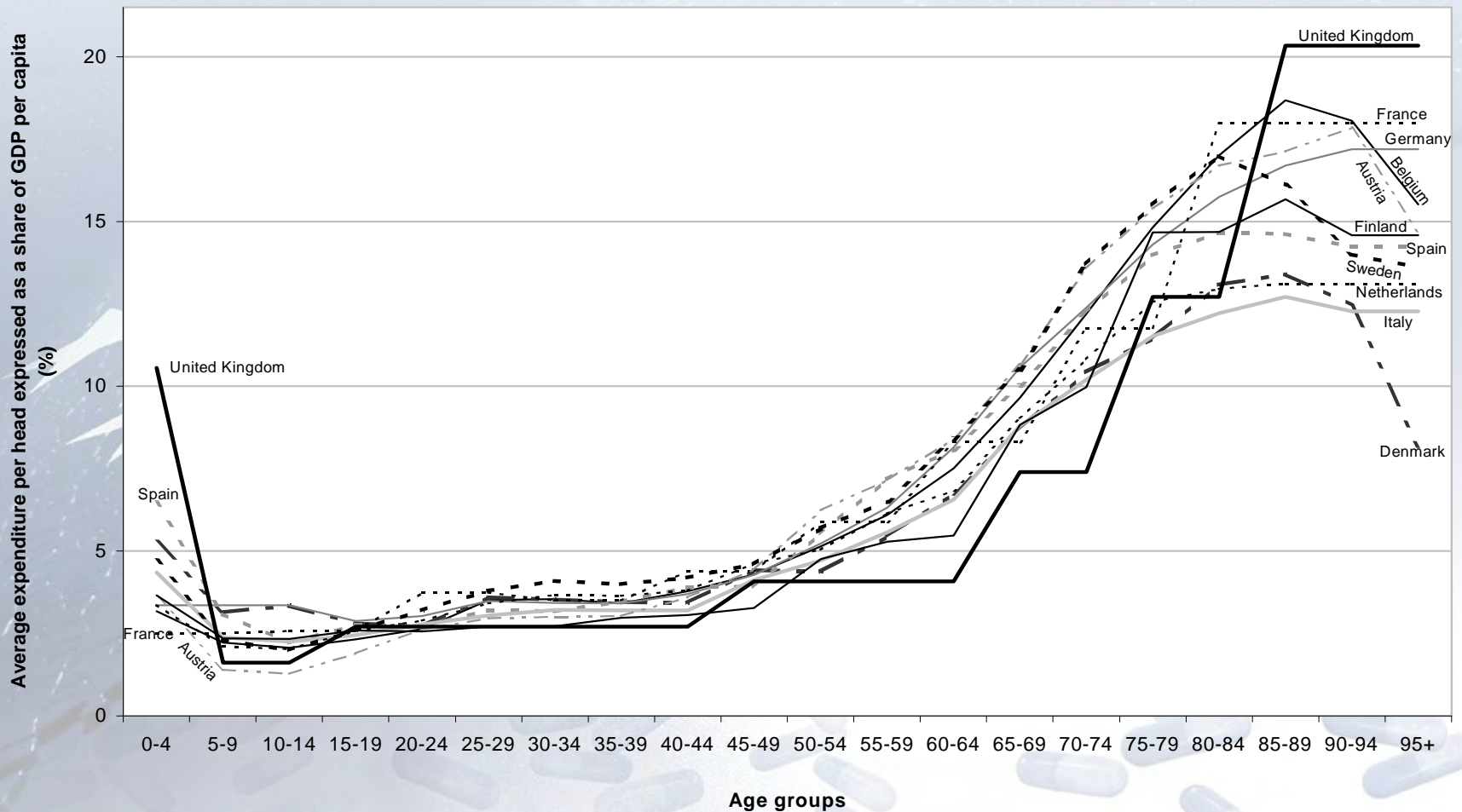
Elderly population refers to persons aged 65 and above

Source: EU Economic Policy Committee

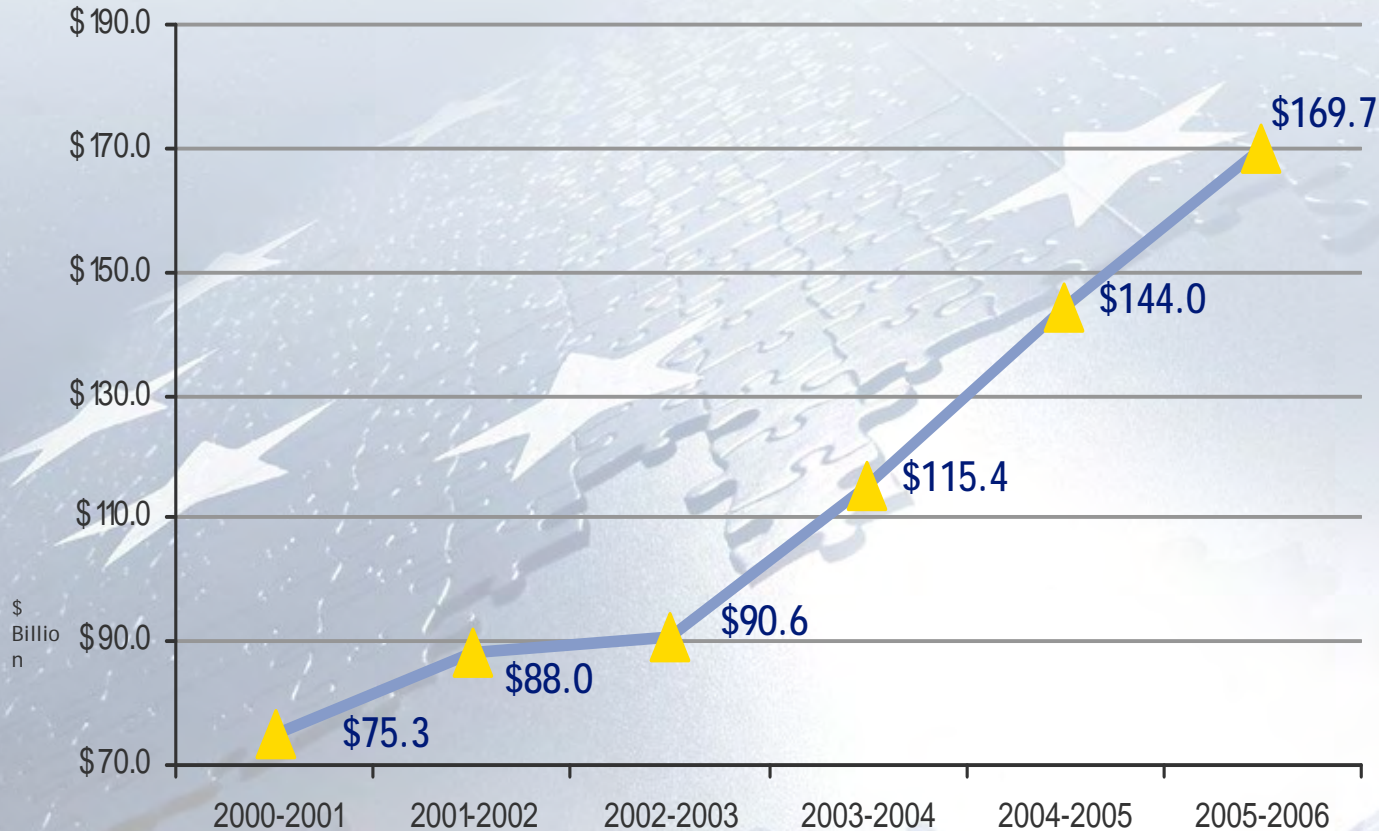
**Source:** Eurostat and projections of the EPC working group on ageing populations.

# Expenditure on Health Care in Relation to Age

Source: Economic Policy Committee (2001) "Budgetary challenges posed by ageing populations"



# Pharmaceutical Spending Europe 2000-2005

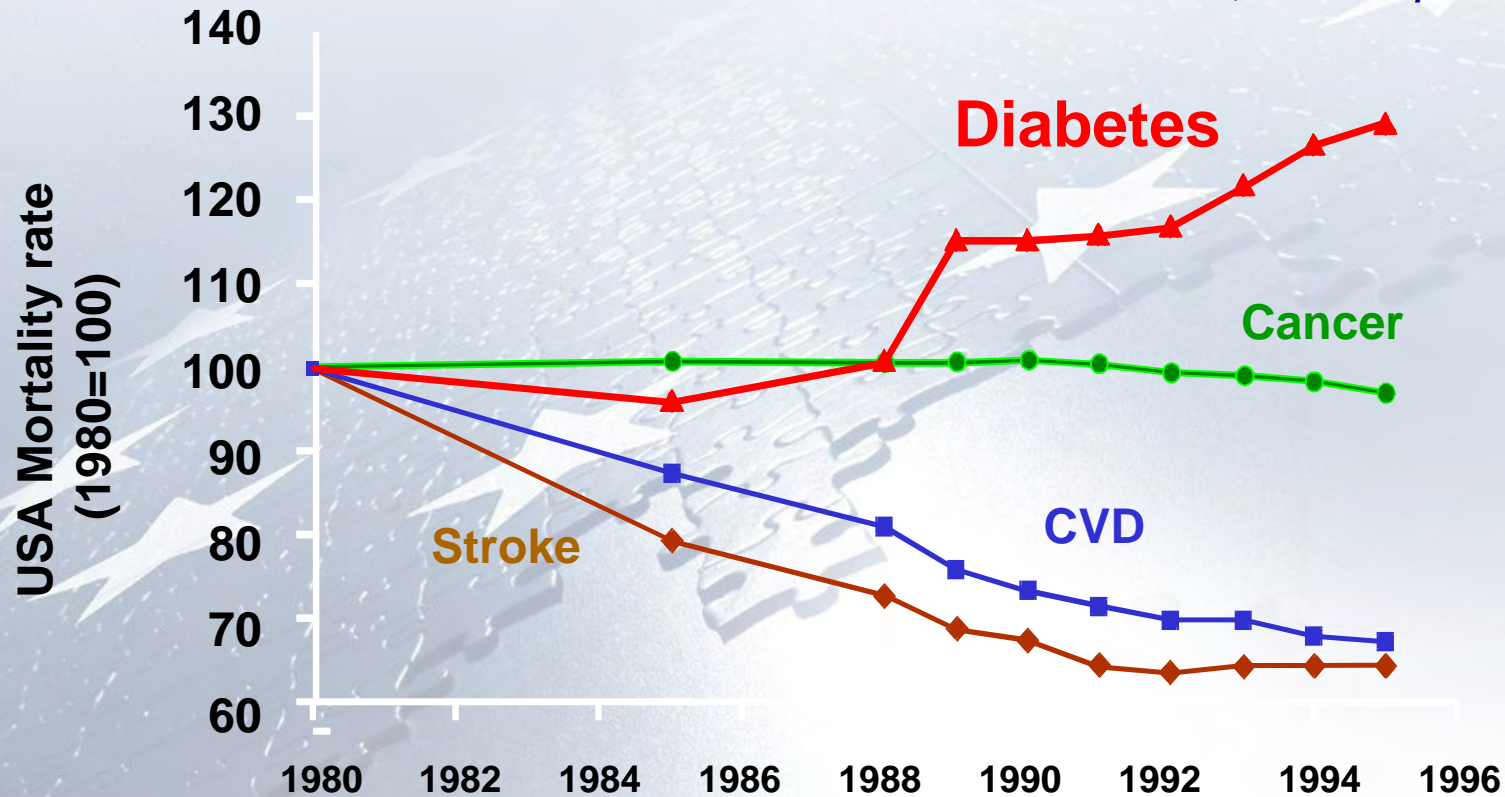


IMS Health Global Pharmaceutical Report 2005

More than  
**125% growth**  
in European pharmaceutical  
sales from  
2000 to 2005.

# "Diabetes could bring first cut in life expectancy for 200 years"

*(The Independent, 2005)*



*Lancet, 2000*

# Improved Affordability of Healthcare

- 20% price reduction of 5 biopharmaceuticals off patent, or imminently off patent, would save the EU over € 1.6 billion pa

*Oldham T. Strategies for entering the biosimilar market Nov 2006*



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# Market Competition

- Market competition from biosimilar medicines will drive the biotechnology industry to do what it does best - discover new medicines that enhance, sustain, and save lives



# Summary of Key Messages (1)

- Biosimilars are successors to biological medicinal products for which patent protection no longer applies
- They are comparable with the European reference product in terms of quality, efficacy and safety
- They are to be used in the same indications for which the reference product is approved

## Summary of Key Messages (2)

- They are assessed by the EMEA and approved by the European Commission like any other biotech product
- All biopharmaceuticals, including biosimilars, should be considered in the same way in terms of pharmacovigilance, traceability, risk management plan, pricing and reimbursement

# Last Message from the European Commission

..... *'we are confident that if a product goes through all the steps and meets all the requirements and gets at the end an approval through a Commission Decision, it means that this product is as safe and efficacious as any other product authorised by the European Commission in the EU'.*

■ N. Rossignol at 6th EGA symposium on biosimilar medicines 2008



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# *Kiitos*

*Professor Dr. Pekka Kurki*

- *Head of Department, Marketing Authorisation (NAM/Lääkelaitos)*
- *'Founding Father' of the 'Biosimilar Philosophy'*
- *First Chair of the Biosimilar Working Party (EMEA)*

*Thank you!*  
*Kiitos!*