Making Medicines Affordable

Biosimilar Medicines: Opportunities for Sustainable Healthcare

Opening Address

Greg Perry
Director General EGA

London 3-4 May 2007

Building on The Generic Medicines Legacy

1. Generic medicines account for almost 50% of sales in EU 27.
2. Generic medicines bring savings of €18-20 Billion pa in EU 27.
3. Major stimulus for innovation and budget management.
4. The generic industry is moving into added value products/incremental innovation.

The Future Role of Biosimilar Medicines

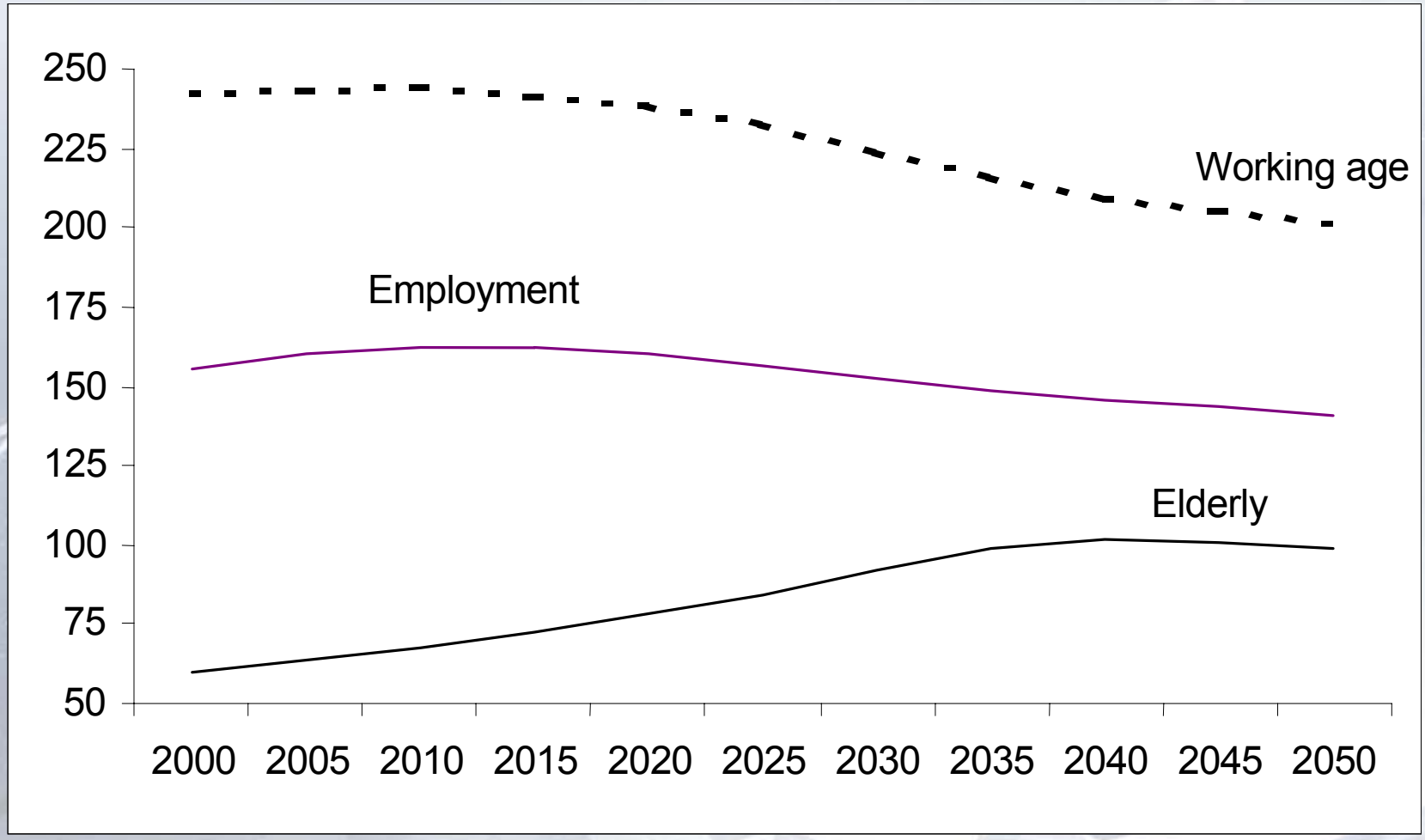
1. By 2010 Biopharmaceuticals will equal 25% of all Pharmaceutical sales and 50% of approvals but are expensive therapies.
2. Biosimilars will therefore need to become key component in future health care management policies.
3. 20% price reduction on 6 off-patent biopharmaceuticals could save the EU €1.6 Billion per year.
4. Biosimilars are "Economic Innovation".

Biosimilar Medicines Reality

" Biosimilars offer new opportunities both for the growth of our generic industry and for the control of our national health expenditure."

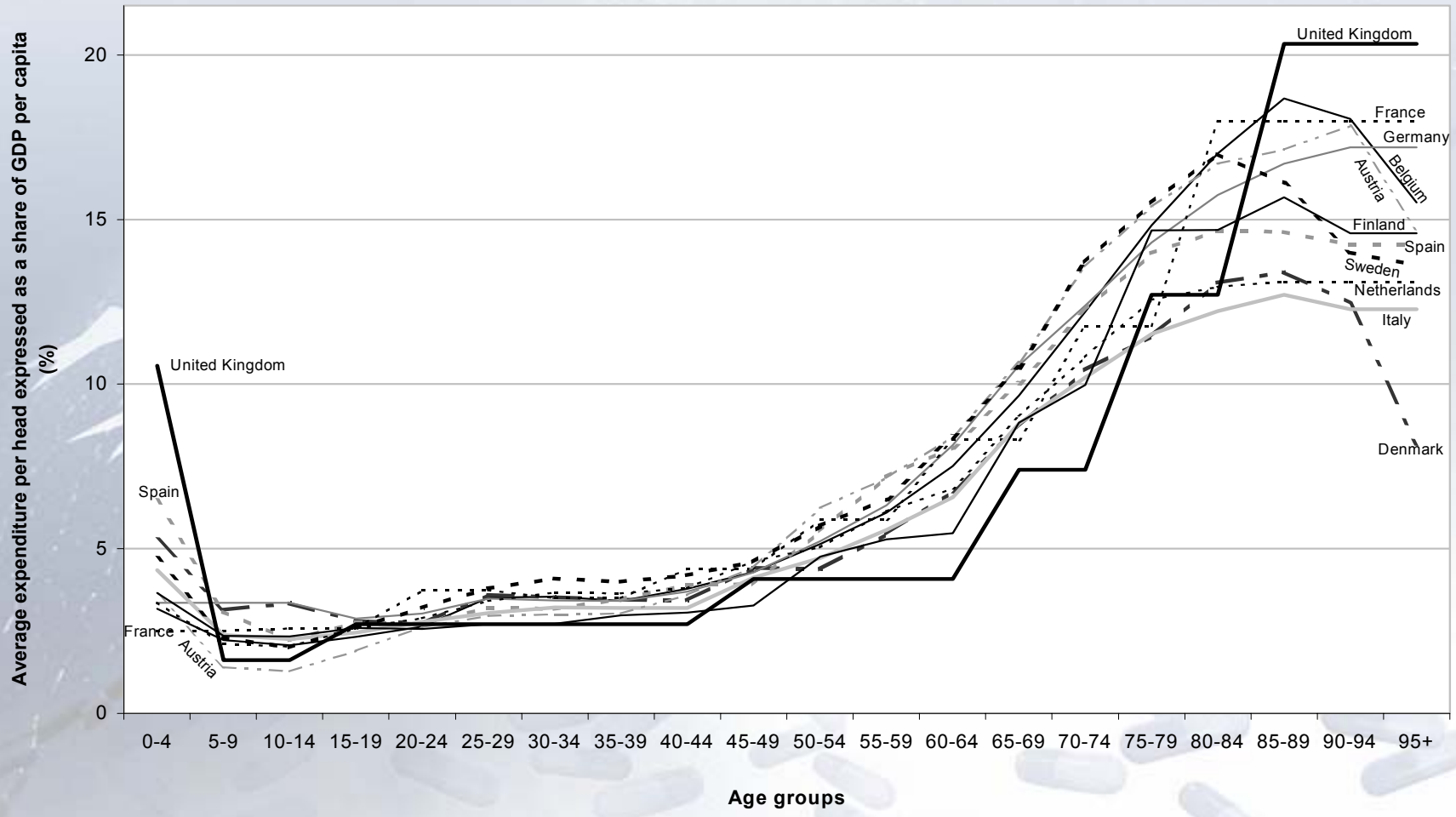
Günter Verheugen, Vice-President EU Commission (April 2006)

Europe's Ageing Population



Expenditure on Health Care In Relation to Age

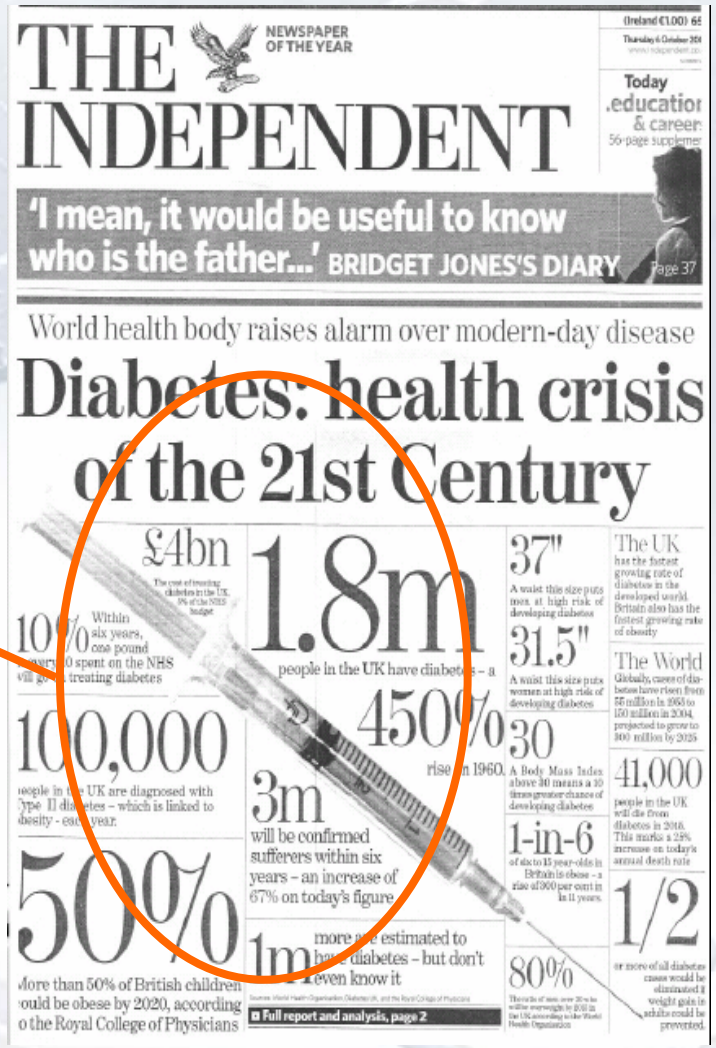
Source: Economic Policy Committee (2001) "Budgetary challenges posed by ageing populations



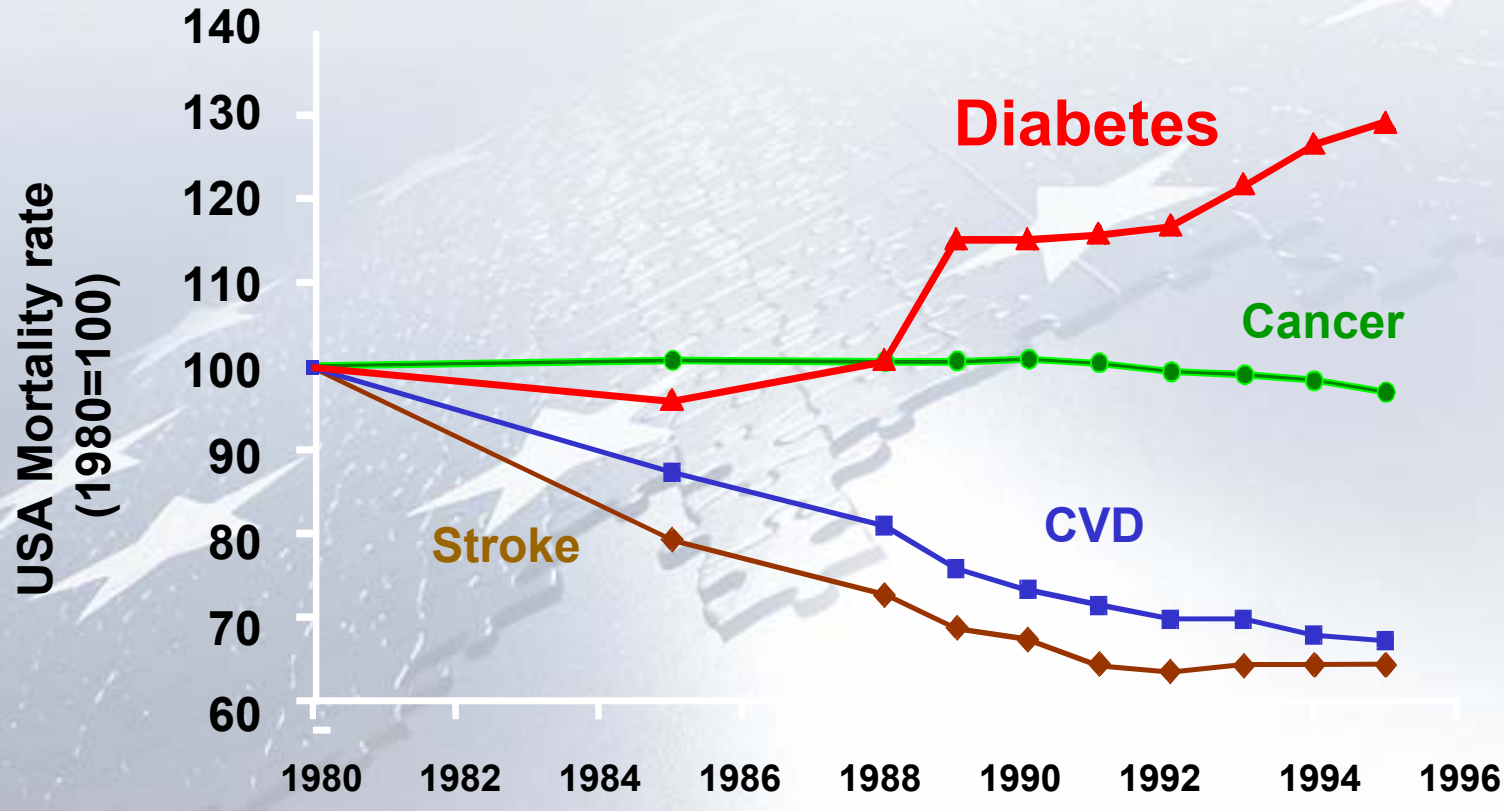
Diabetes: C21st Health Crisis

1. 194 million people globally suffer from diabetes mellitus (5 % of world population)
2. 4 Million deaths per year related to diabetes
3. Projected prevalence in 2025 (333 million I.e a 74% increase in 20 years!)

(WHO Report, 2002)



and Will Only Get Worse



Lancet, 2000

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

(The Independent, 2005)

Access Must Be Expanded

"Most people in most countries of the world who need life-saving insulin cannot obtain it."

(Australian organization "Insulin for Life")

Biosimilars In Progress

- **2006 EMEA approved the first two biosimilar medicines and began reviewing three more applications.**
- **Seven additional biosimilar medicine applications had been received by April 2007, with the expectation of a total of 12 applications in 2007.**

  (Source EMEA Annual Report)

Key Points Concerning Biosimilar Medicines

1. BSMs must demonstrate they are as safe and effective as the reference product (RP).
2. BSMs are rigorously evaluated for their similarity and comparability with the RP.
3. Companies must use latest analytical and clinical technologies - including some that may not have been available to assess the RP.
4. Specific post marketing monitoring assures continued safety and efficacy. (Includes a Risk Management Plan).

Competition Possible Despite High Safety Hurdles

1. EU regulators and policy makers have built a rigorous system with high demands but it is one that provides patients, doctors and pharmacists with medicines of secured BSM comparability of quality,safety and efficacy to the reference products currently marketed.
2. This system creates high expenditures for companies – R&D and manufacturing costs are at least 10 times that of generic medicines.
3. But savings and competition can still be achieved to benefit society.

Building a Market Pathway

- Now that the Science and the Regulatory Pathway is established in the EU, the debate is focusing on those issues related to building a “market pathway for Biosimilar Medicines”.
- Key to developing this market pathway is building confidence among patients and healthcare professionals.
- In opposition to BSMs we are seeing a re-run of the issues that accompanied the entry of generic medicines in the EU.

Key Elements for Ensuring The BSM Breakthrough.

1. Acknowledgement of interchangeability of BSMs among patients, physicians and pharmacists.
2. A scientific approach to INN naming should remain.
3. Pricing structures that help foster BSM market entry and competition.

EU Immediate Measures

In EU we must move forward to ensure health care benefits of BSMs

- The current INN debate must not create uncertainty and jeopardise the approval of the current wave of BSMs (15 products).
- Clarification should be made by the EC that the BSM INN is part of the EU regulatory process and not an WHO INN nomenclature issue.
- Support by the EU regulatory authorities of the interchangeability of BSMs.

Global Developments

- WHO should develop regulatory guidance for biosimilar products which would be a milestone in the history of BSMs / follow on biological products.
- EGA will be fully involved in this process at WHO.
- EGA will assist other bodies in other regions to develop appropriate pathways for BSMs.