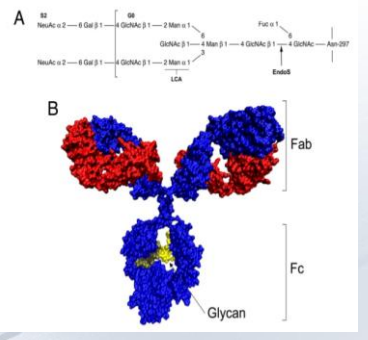
Making Medicines Affordable

OPENING ADDRESS
Biosimilar Medicines
11th EGA International Symposium
London,25 April, 2013

Gudbjorg Edda Eggertsdottir
President Iceland & Special Projects, Actavis
and President EGA

Making Medicines Affordable



Collin M. PNAS 2008

Biosimilar Monoclonal Antibodies
THE NEXT FRONTIER

Life in the Red Zone
Annual Deficit by Country

Life in the Red Zone

Euro-zone governments have increasingly broken their self-imposed limit of annual budget deficits of no more than 3% of gross domestic product.

Not yet in the euro zone | THE HIGH GROUND Surplus | WITHIN THE TARGET Deficit of 3.0% or less | BREAKING THE RULE Deficit of 3.1%–6.0% | DOUBLING THE LOAD Deficit of 6.1% of GDP or more

Limit under the Maastricht Treaty: Deficit of 3.0% of GDP

	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011 estimate
Euro area	-1.5	-0.1	-2.0	-2.7	-3.1	-2.9	-2.5	-1.4	-0.7	-2.1	-6.4	-6.2	-4.1
Austria	-2.3	-1.7	0	-0.7	-1.5	-4.4	-1.7	-1.5	-0.9	-0.9	-4.1	-4.4	-3.4
Belgium	-0.6	0	0.4	-0.1	-0.1	-0.3	-2.7	0.1	-0.3	-1.3	-5.8	-4.1	-3.6
Cyprus	-4.3	-2.3	-2.2	-4.4	-6.6	-4.1	-2.4	-1.2	3.5	0.9	-6.1	-5.3	-6.7
Estonia	-3.5	-0.2	-0.1	0.3	1.7	1.6	1.6	2.5	2.4	-2.9	-2.0	0.2	0.8
Finland	1.6	6.8	5.0	4.0	2.4	2.3	2.7	4.0	5.3	4.3	-2.5	-2.5	-1.0
France	-1.8	-1.5	-1.6	-3.3	-4.1	-3.6	-2.9	-2.3	-2.7	-3.3	-7.5	-7.1	-5.8
Germany	-1.6	1.1	-3.1	-3.8	-4.2	-3.8	-3.3	-1.6	0.2	-0.1	-3.2	-4.3	-1.3
Greece	-3.1	-3.7	-4.5	-4.8	-5.7	-7.6	-5.5	-5.7	-6.5	-9.8	-15.8	-10.6	-8.9
Ireland	2.7	4.7	0.9	-0.4	0.4	1.4	1.7	2.9	0.1	-7.3	-14.2	-31.3	-10.3
Italy	-2.0	-0.8	-3.1	-3.1	-3.6	-3.5	-4.4	-3.4	-1.6	-2.7	-5.4	-4.6	-4.0
Luxembourg	3.4	6.0	6.1	2.1	0.5	-1.1	0	1.4	3.7	3.0	-0.9	-1.1	-0.6
Malta	-7.7	-5.8	-6.4	-5.8	-9.2	-4.7	-2.9	-2.8	-2.4	-4.6	-3.7	-3.6	-3.0
Netherlands	0.4	2.0	-0.2	-2.1	-3.1	-1.7	-0.3	0.5	0.2	0.5	-5.6	-5.1	-4.3
Portugal	-2.7	-2.9	-4.3	-2.9	-3.0	-3.4	-5.9	-4.1	-3.1	-3.6	-10.1	-9.8	-5.8
Slovakia	-7.4	-12.3	-6.5	-8.2	-2.8	-2.4	-2.8	-3.2	-1.8	-2.1	-8.0	-7.7	-5.8
Slovenia	-3.0	-3.7	-4.0	-2.4	-2.7	-2.3	-1.5	-1.4	0	-1.9	-6.1	-5.8	-5.7
Spain	-1.2	-0.9	-0.5	-0.2	-0.3	-0.1	1.3	2.4	1.9	-4.5	-11.2	-9.3	-6.6

Note: Data include debt ratios for Greece, Slovenia, Cyprus, Malta, Slovakia and Estonia since 1999, even though they joined the euro zone later.

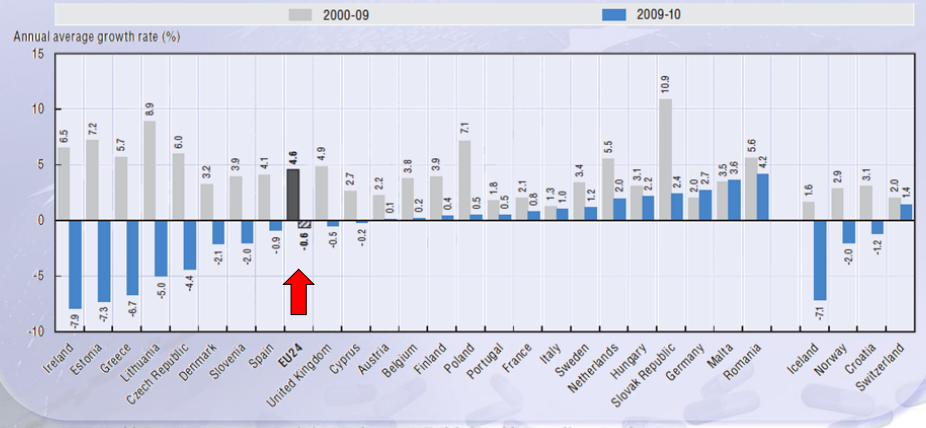
Source: European Commission

3

Source: European Commission

First Time Health Spending has Fallen in Europe since 1975

5.2.2. Annual average growth rate in health expenditure per capita, in real terms, 2000 to 2010 (or nearest year)

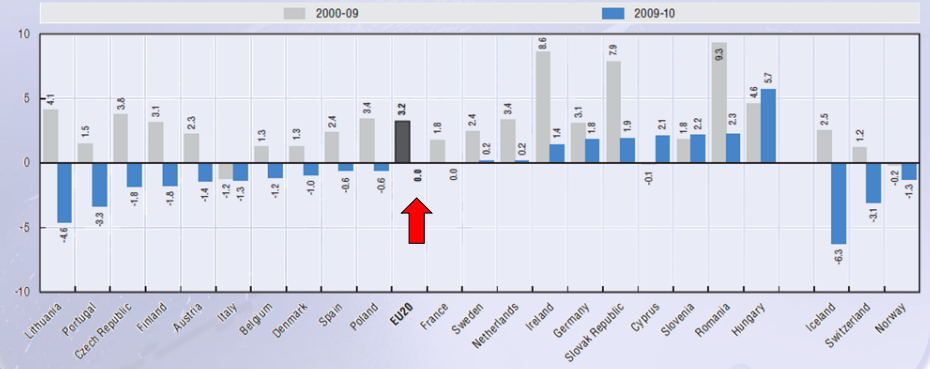


Source: OECD Health Data 2012; Eurostat Statistics Database; WHO Global Health Expenditure Database.

4

Pharmaceutical Expenditure Growth Rate Turned Negative in Several Countries in 2010

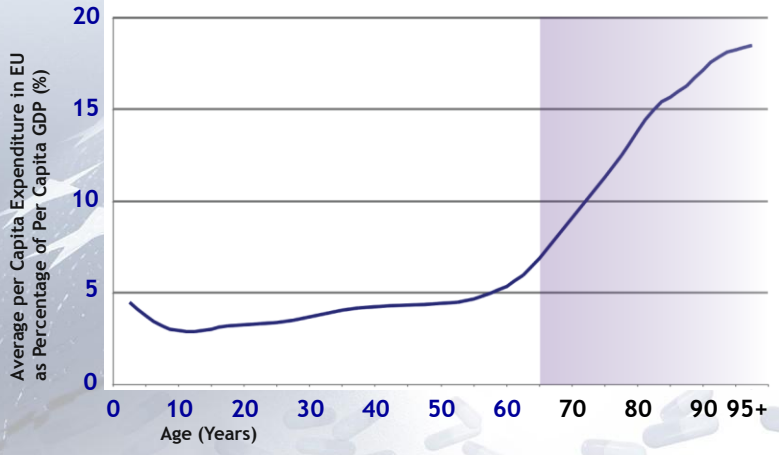
5.5.2. Average annual growth in pharmaceutical expenditure per capita, in real terms, 2000 to 2010 (or nearest year)



Source: OECD Health Data 2012; Eurostat Statistics Database.

Ageing Population will Drive Future Healthcare Costs across the EU

Healthcare Costs for Patients 65+ are Increasing Significantly



Biosimilars: Part of the Solution to Lowering Health Care Expenditure

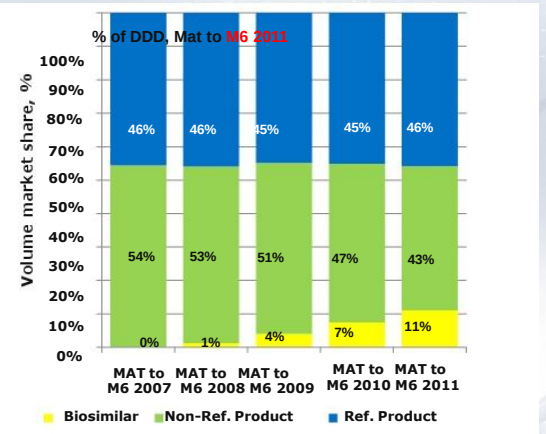
- Biosimilar medicines provide a unique opportunity to help manage the growing costs of biopharmaceutical medicines in Europe
- Market competition resulting from the introduction of even a small number of cost-effective biosimilars will save the EU several billion Euros annually
  - More patients can be treated within the same budget
  - Savings can be made in order to fund new 'high-cost' treatments

However

- Uptake of biosimilars has been inconsistent across member states
- Wide variation in funding and access pathways for biosimilars
- Most EU member states have been slow to take advantage of the opportunities offered by biosimilars

Biosimilars:11% Share of the Accessible European Market

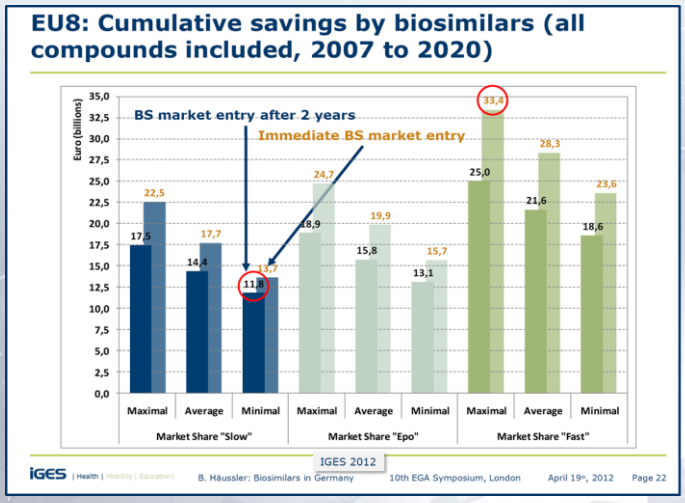
EU + NO, CH share of biosimilar accessible market by product type,



In the 12 month period, biosimilar products represent 19 million, of a total market estimate of 175 million DDD (11%)

Source: IMS MIDAS Q6 2011.

EU8: Cumulative Savings, 2007-2020: between €11.8 to 33.4 bn (IGES Study)



Source: EGA International Symposium London, April 19th, 2012 / Bertram Häussler IGES Institut, Berlin Germany

- EU8 = Germany, France, the UK, Italy, Spain, Sweden, Poland and Romania
- All compounds = Epoetin, Filgrastim, mAbs
- BS = biosimilar
- Market entry: immediate at IP expiry or 2 years later

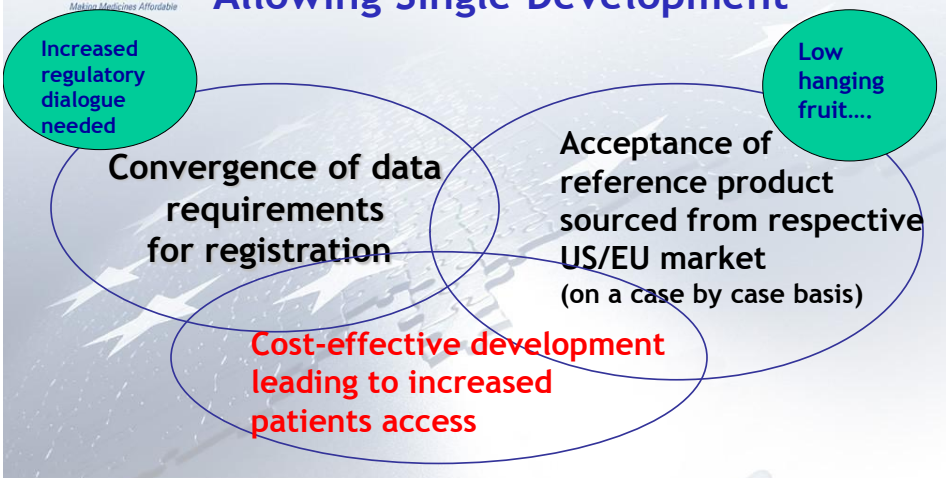
Safe and Effective Biosimilar mAbs will Come Soon

- More than 20 years of experience with therapeutic mAbs, well understood today
- EMA issued clear guidance for biosimilar mAbs, including analytical, bioanalytical, non-clinical and clinical aspects (in force since 1.12.12)
- Biosimilar mAbs are in the approval pipeline and in advanced clinical stages

Preparing the Right Environment for Biosimilar mAbs

1. EU/US Framework for single development to become a reality
2. Continued education of all stakeholders
3. All Member States to take action

1. EU/US Regulatory Framework Allowing Single Development

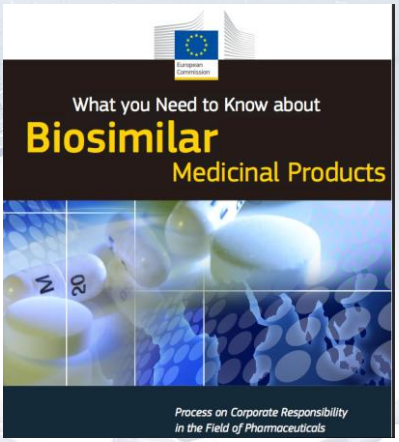


Due to current requirements for repetition of studies, total cost for launching a biosimilar in the EU and the US is $200-300M

12

2. Continued Education of All Stakeholders Needed

- Published on 22 April
- Will help tackle misinterpretation, misunderstanding and misinformation
- Biosimilars have proven to be safe and cost-effective alternatives for the past 7 years



3. Call to Member States to Boost Market Access for Biosimilars

- All Member States
  - to define the necessary conditions for uptake and patient access to biosimilars in their jurisdiction
  - to roll out the Tajani Project consensus information paper in local languages, in particular the Q&As for patients, doctors and payers
  - to organise conferences, workshops, lectures in hospitals

Biosimilars Market Access

Initiatives

Conference in Belgium

Emergence of biosimilar medicines

Which opportunities for patients and the Health insurance ?

Symposium

Belgian Federal Parliament, 22 November 2012

PROGRAMME

Conference in Spain

HTTP://WWW.YOUTUBE.COM/WATCH?FEATURE=PLAYER_EMBEDDED&V=NH8NEWBZIAE#!

Conference in Portugal

Infarmed Conference attended by 250 participants: hospital pharmacists, doctors, industry and hospital managers

Biosimilars Conference Next sessions

Os medicamentos Biossimilares
Presente e Futuro

- Market Access– 15th of May
- Pratical Utilisation– 9th of October
- Hurdles and way forward – 15th of November

Conclusion: Boosting Market Access for Biosimilars in the EU

- Establishing a strong and dynamic biosimilars industry in the EU is essential to increase competition and reduce healthcare expenditure on biopharmaceuticals over the long term
- To realise the economic benefits of biosimilar adoption, policy makers, payers, prescribers and manufacturers must work together to establish sustainable market access mechanisms
- Biosimilars should not be used only as a means of reducing the price of originator products
- Failure to support biosimilar market access in the short term may limit investment in future biosimilar development
- The advent of biosimilar mAbs provides another big opportunity to support the sustainability of the EU healthcare systems.


EGA
Making Medicines Affordable
Thank you
www.egagenerics.com