



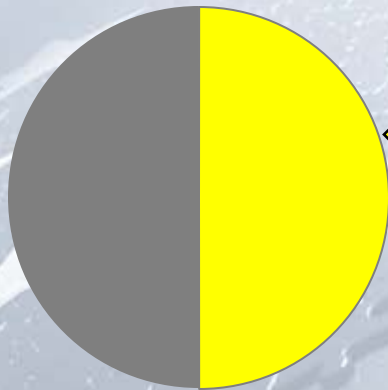
Making Medicines Affordable

Sustaining EU Healthcare Systems Through Sustainable Generic Competition

Greg Perry
EGA Director General
Brussels, 28 April 2009

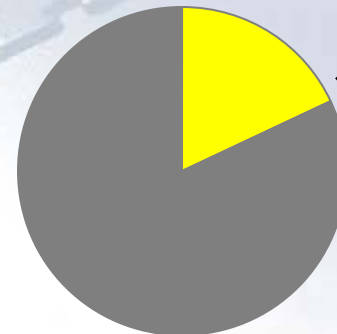
Generic Medicines- Key to Healthcare Sustainability

Volume dispensed
medicines in EU27



50% generic
medicines

Pharmaceutical
expenditure in
EU27



18% generic
medicines

Generic medicines in EU27 represent
€25 Billion savings every year

Affordable Generic Medicines Cover a Full Spectrum of Pharmaceutical Treatments

- Cancer
- Viral Infections
- Diabetes
- Bacterial Infections
- Depression
- Osteoporosis
- High Cholesterol
- Epilepsy
- High blood pressure
- Rheumatism
- Asthma
- Pain Relief
- Gastro-intestinal disorders
- Inflammation

Generic Medicines - A Highly Competitive Industry



- Over 1000 companies in 34 European countries
- 130,000 EU jobs in R&D, production and sales
- 10-30 companies competing on one product
- Investments in incremental innovation



Generic Medicines: Healthcare Provision and Innovation

“Generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers, while liberating budgets for financing new innovative medicines.”

Pharma Forum
Progress Report June 2007



Pharmaceutical
FORUM



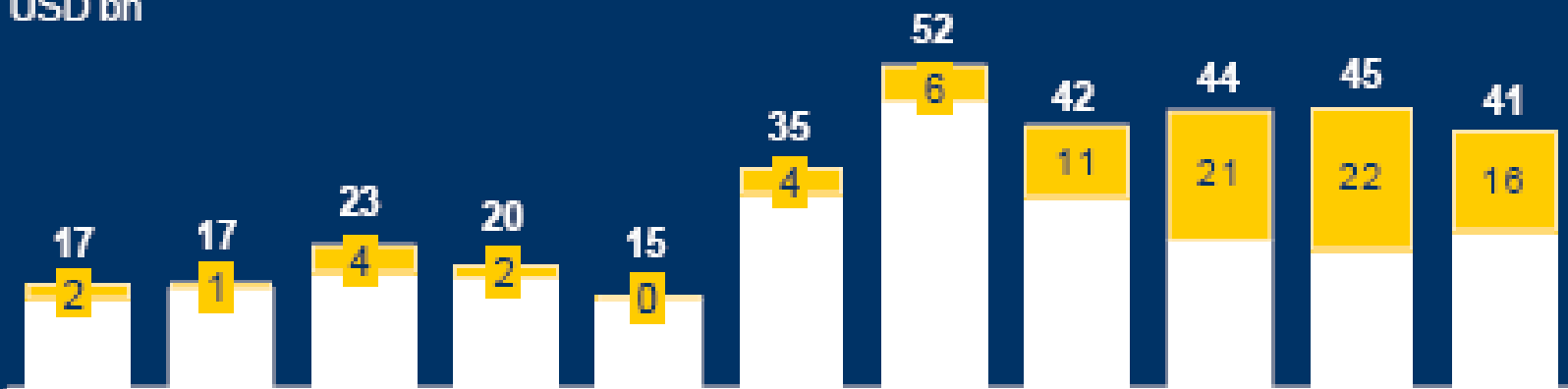
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Patent Expiries: Opportunities for Affordability and Access

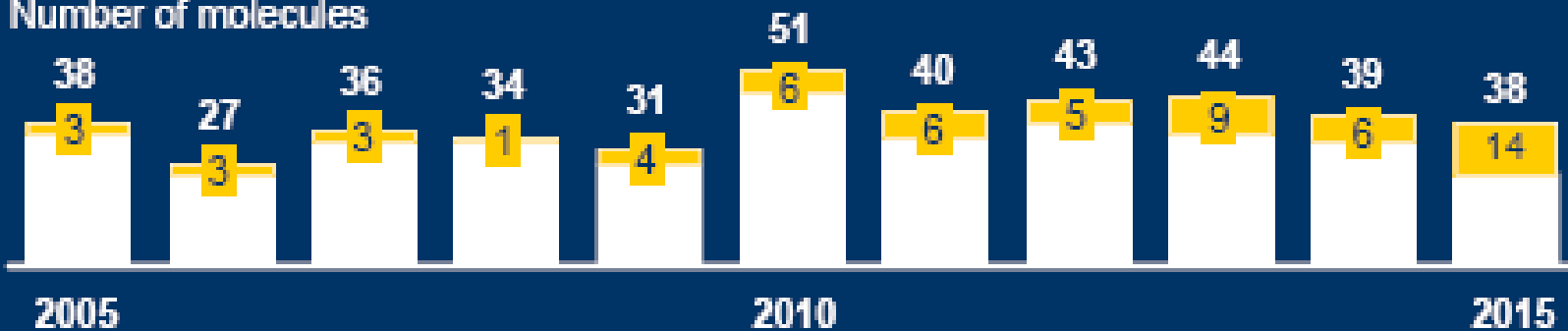
US patent expiries¹ 2005-15

■ Biotech products
■ Conventional products

Worldwide sales of expiring products in year of US patent expiry
USD bn



Molecules coming off-patent²
Number of molecules



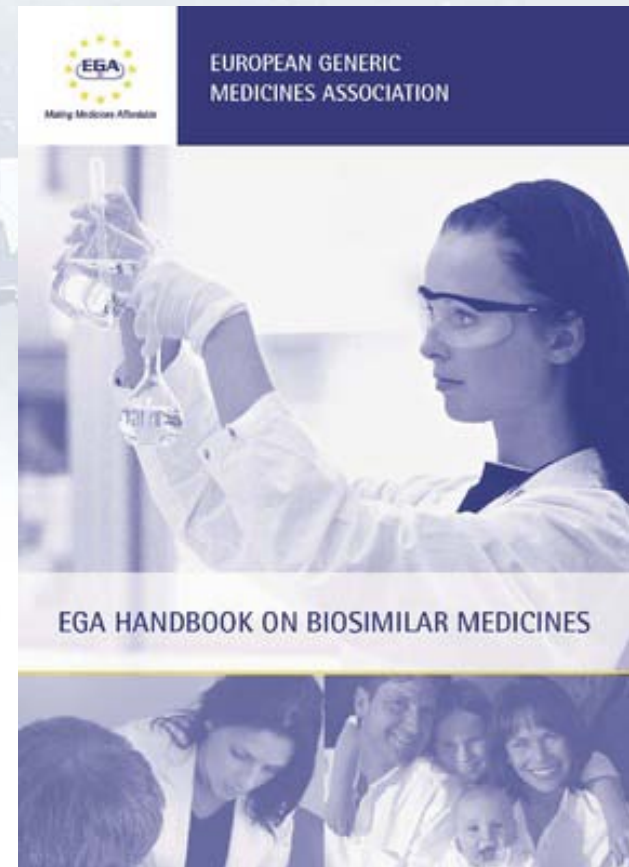
¹ Nominal patent expiries not corrected for supplementary patents, litigation probability

² Only molecules with associated sales were counted, a combination of two molecules is considered to be a separate molecule

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)



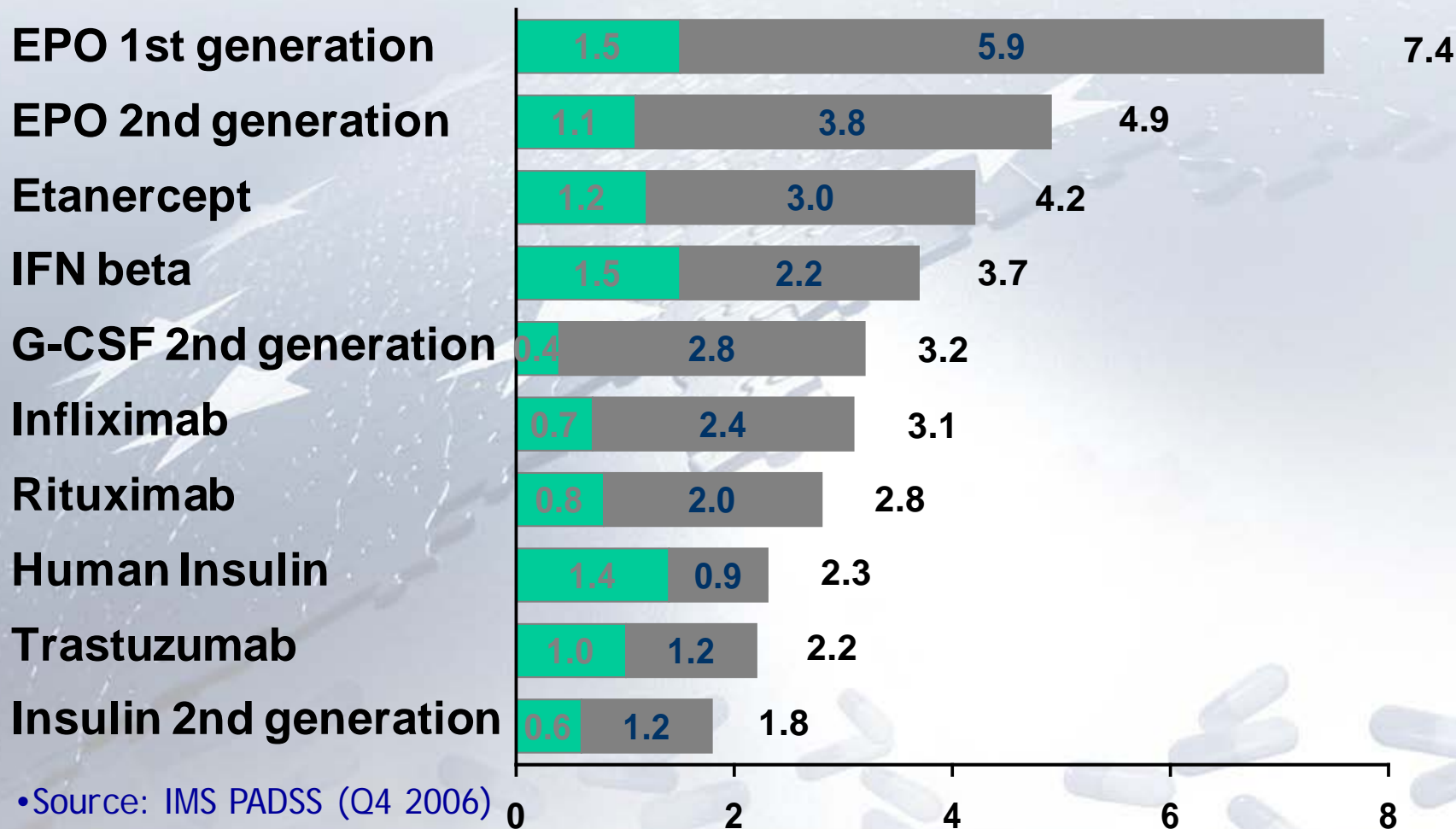


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High Biosimilar Potential for Healthcare Sustainability

Top 10 Biopharmaceuticals, in bn USD (2006)

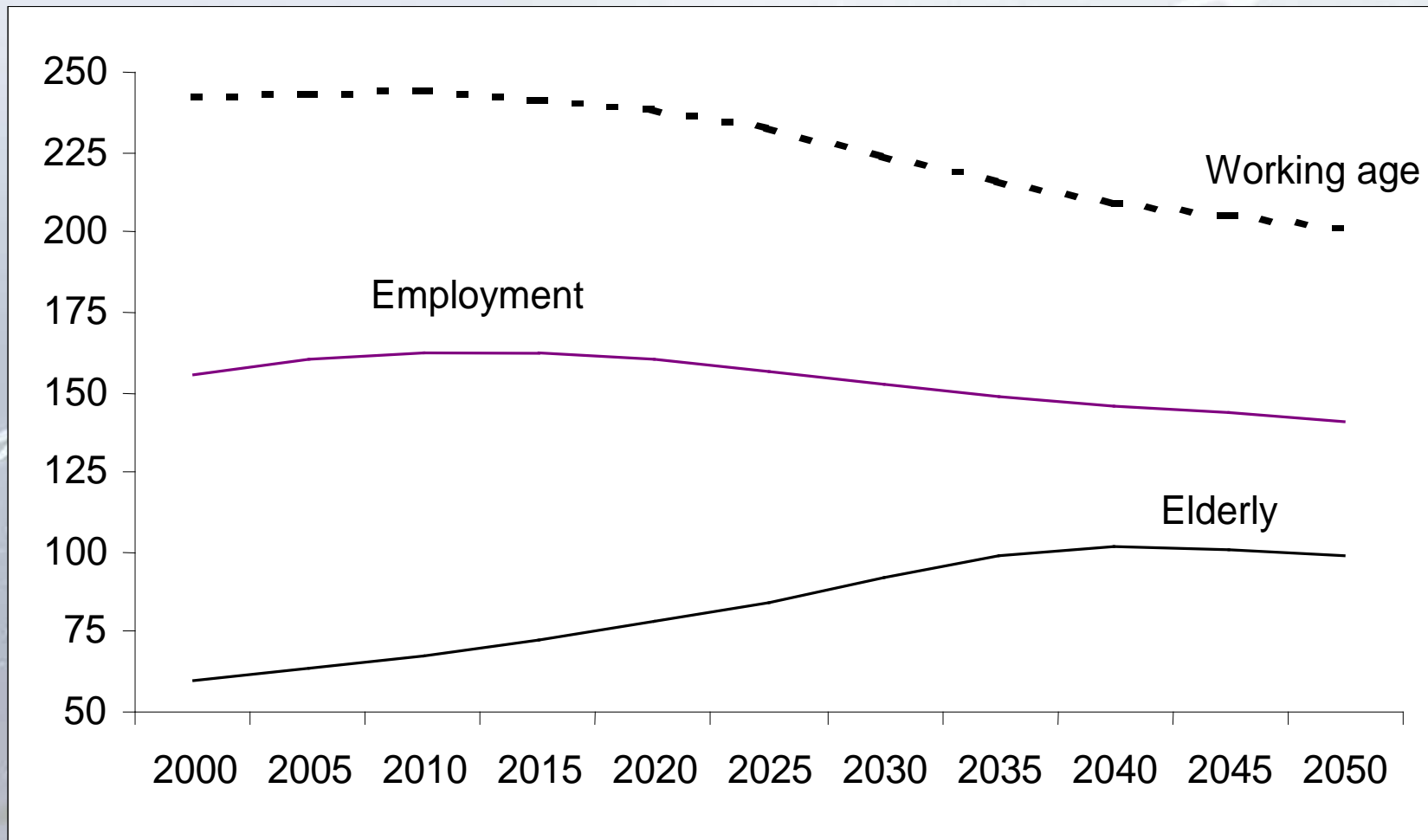
■ EU
■ US



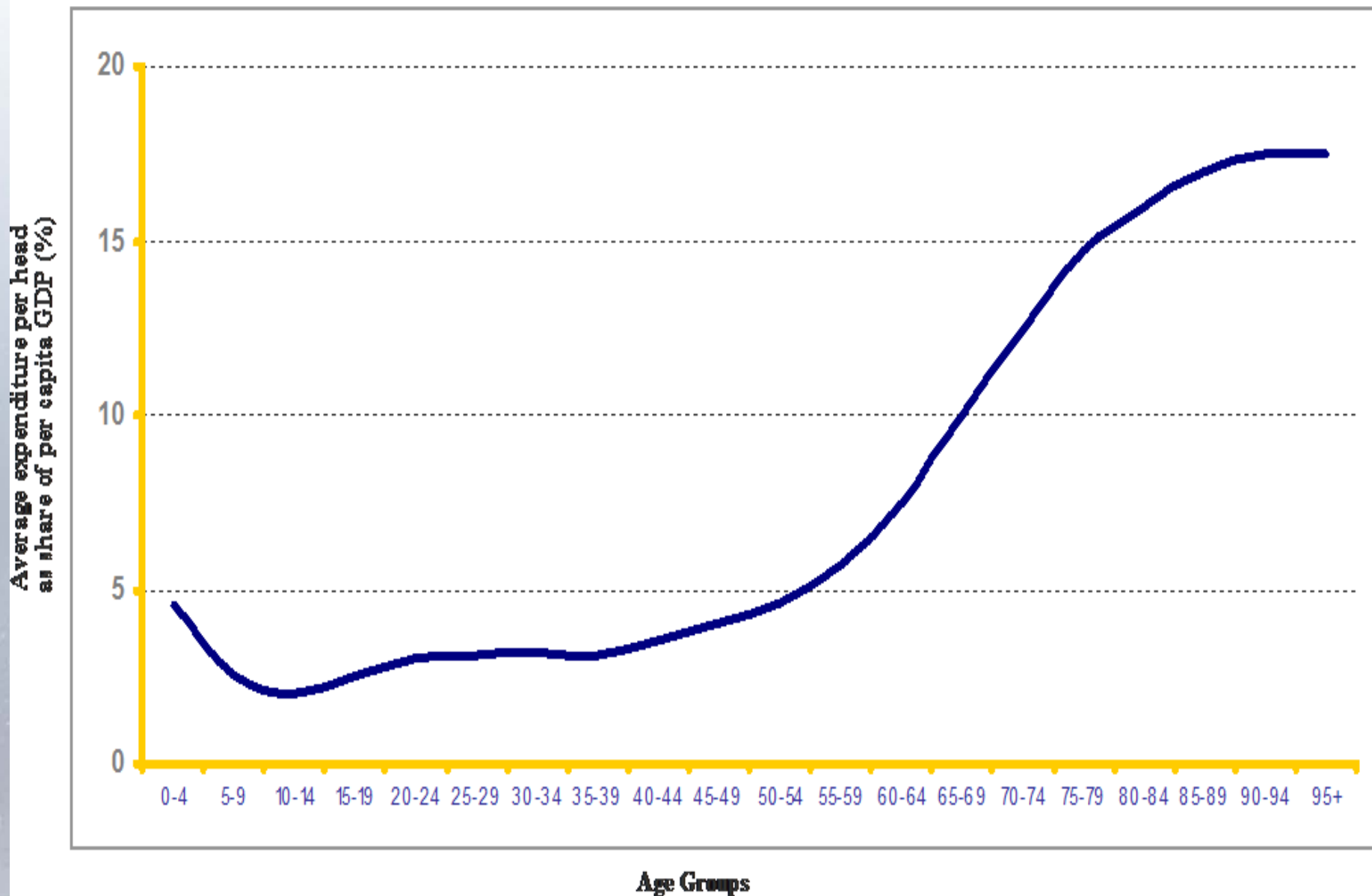
•Source: IMS PADSS (Q4 2006)



Europe's Ageing Population



Average EU Healthcare Expenditure Per Head by Age Group



Diabetes: 21st Century Health Crisis

- 194 million people suffer from diabetes mellitus (5 % world population)
- 4 Million deaths per year related to diabetes
- “Diabetes could bring first cut in life expectancy for 200 years” (*The Independent, 2005*)
- Projected prevalence in 2025 (333 million i.e a 74% increase in 20 years!)



NEWSPAPER OF THE YEAR

THE INDEPENDENT

(Ireland €1.00) 65
Thursday 6 October 2005
Today
education & career
56-page supplement

'I mean, it would be useful to know who is the father...' BRIDGET JONES'S DIARY Page 37

World health body raises alarm over modern-day disease

Diabetes: health crisis of the 21st Century

£4bn The cost of treating diabetes in the UK, 1% of the NHS budget

1.8m people in the UK have diabetes - a 450% rise since 1960.

3m will be confirmed sufferers within six years - an increase of 67% on today's figure

100,000 people in the UK are diagnosed with Type II diabetes - which is linked to obesity - each year.

50% more than 50% of British children could be obese by 2020, according to the Royal College of Physicians

37" A waist this size puts men at high risk of developing diabetes

31.5" A waist this size puts women at high risk of developing diabetes

30 A Body Mass Index above 30 means a 30 times greater chance of developing diabetes

41,000 people in the UK will die from diabetes in 2016. This marks a 12% increase on today's annual death rate

1-in-6 of 15-year-olds in Britain is obese - a rise of 900 per cent in 11 years.

1/2 or more of all diabetes cases would be eliminated if weight gain in adults could be prevented.

80% The risk of men over 20 who are overweight is 80% in the UK according to the World Health Organisation

Full report and analysis, page 2

Lost Opportunities for Healthcare Sustainability

Generic medicines Market Share 2006 (volume)



Major Potential Growth

Getting the Right Environment for Generic Competition

Three Foundation Stones:

- Efficient Regulatory System
- ▪ Intellectual Property Balance
- ▪ National Measures Promoting Generic Medicines





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Balanced IP Systems





Pharma Properties Eligible For Patenting

1980s (5 properties)

- Primary uses
- Processes and intermediates
- Bulk forms
- Simple formulations
- Composition of matter

1990s (18 properties)

- Primary uses
- Processes and intermediates
- Bulk forms
- Simple formulations
- Composition of matter
- Expansive numbers of uses
- Methods of treatment
- Mechanism of action
- Packaging
- Delivery profiles
- Dosing regimen
- Dosing range
- Dosing route
- Combinations
- Screening Methods
- Chemistry Methods
- Biological Target
- Field of use

Source: "Evolution of IPR & Pharmaceutical discovery and Development", Eric Larson, Sr Director, Groton Site Head, Pfizer Global Research & Development.

Viewed on 9/11/2005 at:
http://www7.nationalacademies.org/step/Larson_ppt.ppt

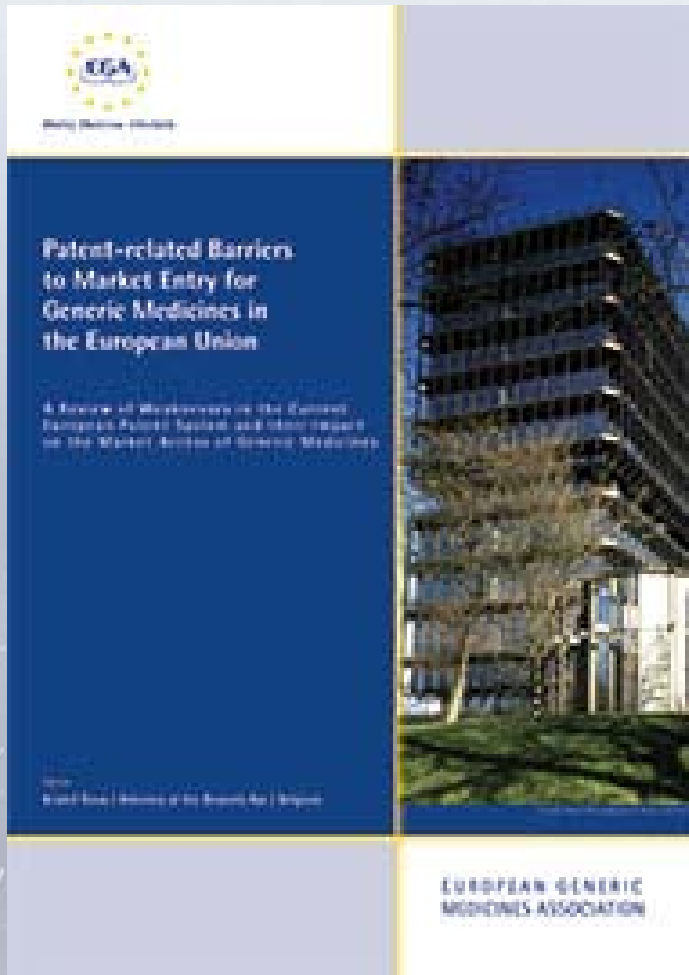


Increasing IP Protection: Example Europe

- 1992 SPC regulation granting up to 25 year patent life.
- 1992-94 introduction of Product Patents for pharmaceuticals in CEE and South Europe.
- Mid 1990s increasing secondary patents
- 1994 introduction of TRIPS.
- 2004 data exclusivity increased to 8-11 yrs.
- By 2007 over 8500 Patent extensions granted through SPC Regulation

Despite increased IP the rate of “innovation is declining”

EGA IP Barriers to Innovation and Competition



- “Patents have a key role in incentives & rewarding crucial pharmaceutical research & development”
- Misuse of the patent system however will
 - a) restrict access/affordability and
 - b) discourage real innovation.

Also Generic Access is not Being Optimised

- EGA in a study prepared for Pharma Forum observed that of the top 35 off-patent molecules in some cases the first generic medicine only entered the market up to 20 months after the patent expired.
 - Causes are
 - a) lack of government measures to promote generic medicines
 - b) uncertainties created by patent system and consequential patent strategies
-



- Improve quality: of patent applications
- Need to raise bar for patent granting
- Need to counterbalance pressure to grant patents

- Increase in patent litigation
- Lack of unitary system
- Abusive Litigation

- Concerns with patents & competition
- Patent clusters
- Use of defensive patent strategies

EGA	✓	✓	✓
EC pharma inquiry	✓	✓	✓
European Parliament report (STOA)	✓	✓	✓



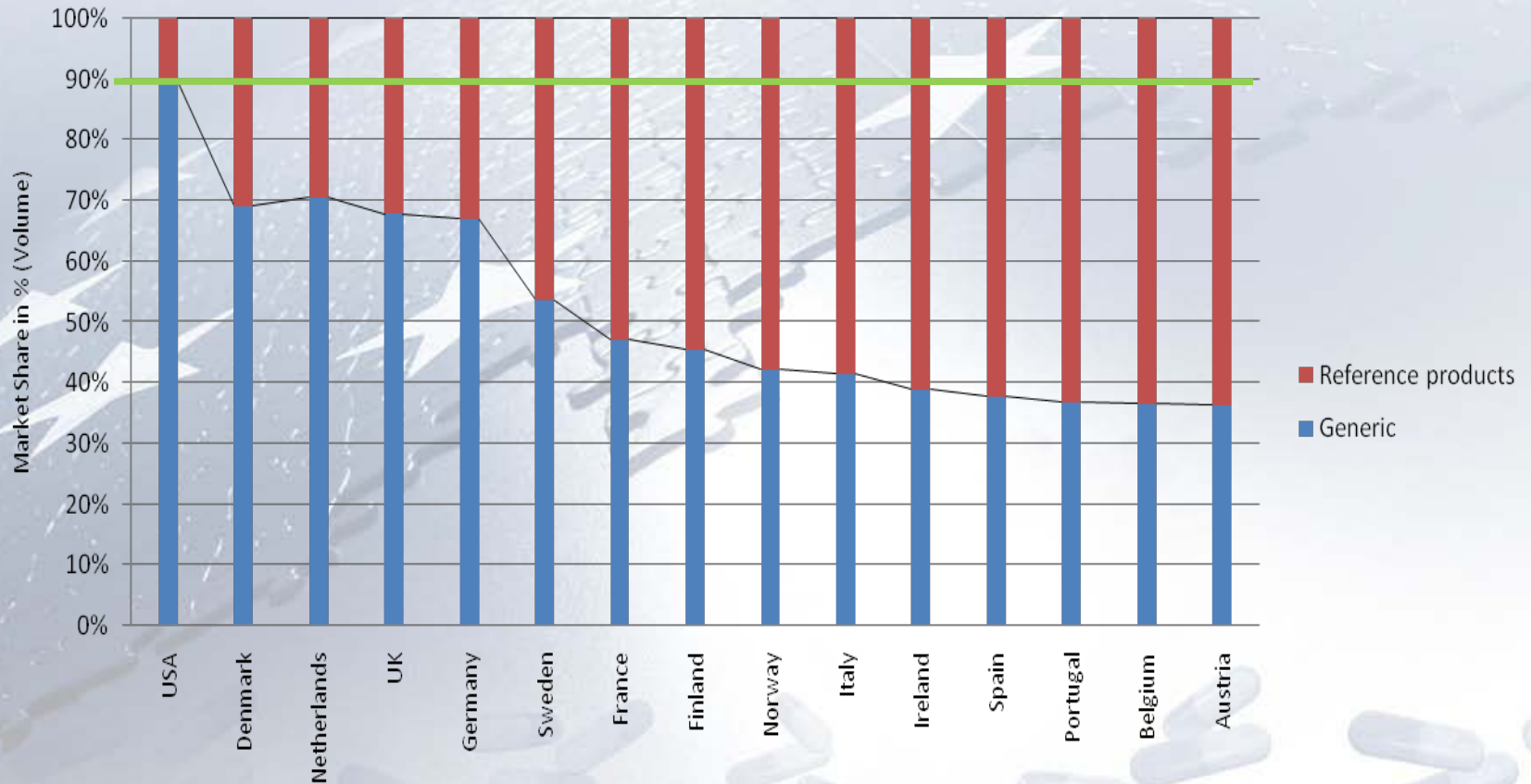
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Market Issues



Resistance to Generic Medicine Competition in Off Patent Sector

UNPROTECTED MARKET SEGMENTATION (VOLUME)





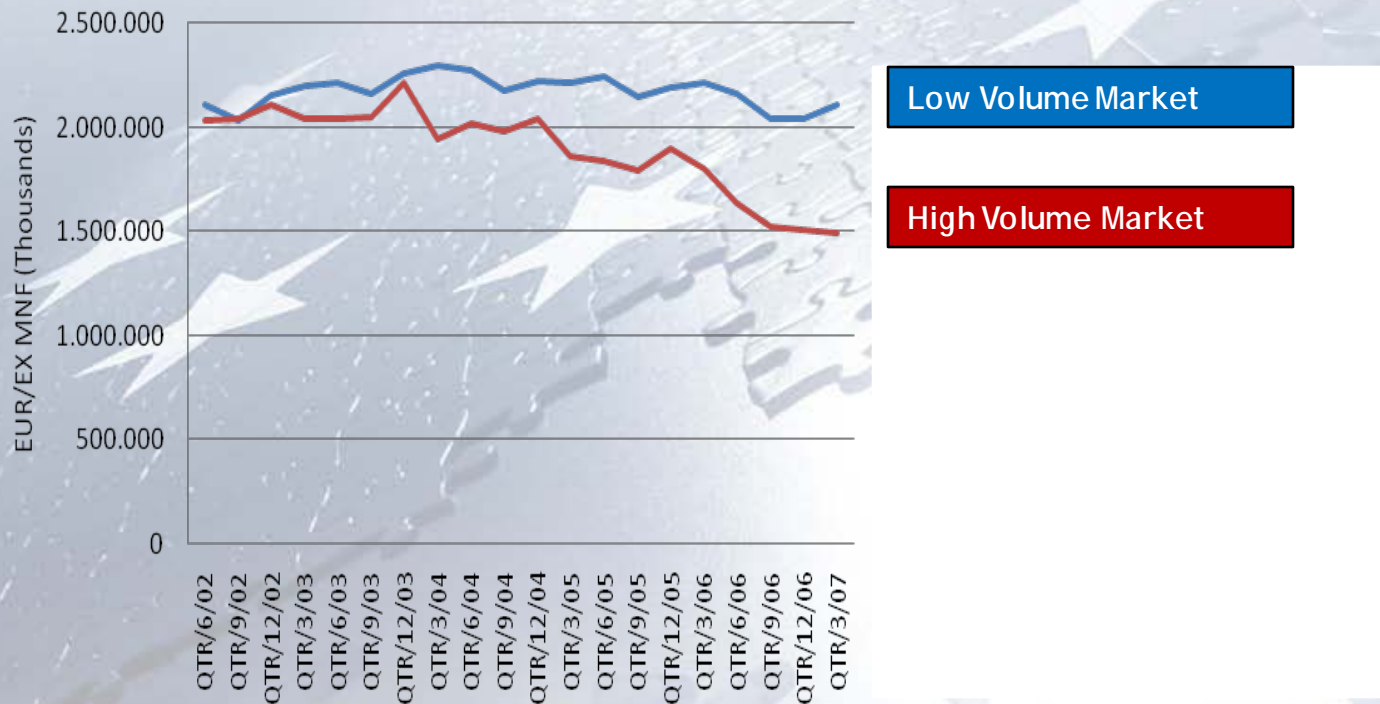
Importance of Volume for Generic Medicines Competition

“The ability of the (European) generic medicines industry to deliver competitive prices can only be achieved and sustained if its assured a high volume of the pharmaceutical market. High volume is dependent on demand side measures”

Simoens Report- 2006

Generic Medicines Industry able to Deliver Competitive Prices when High Volume is Assured

Total Value of the Basket of 35 molecules (Total Market)

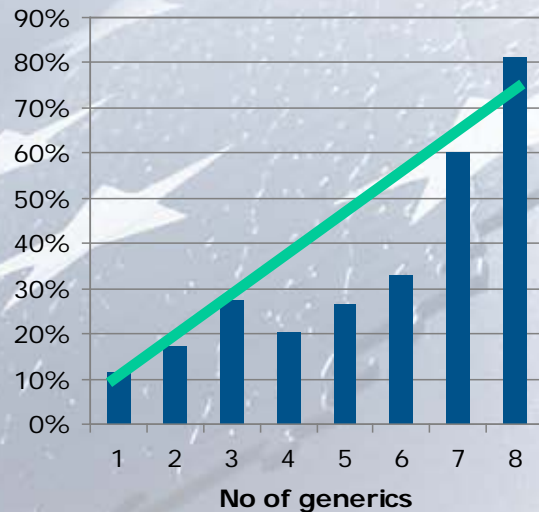


Source: IMS MIDAS
DATABASE Q3 2007

“Generic drug prices decrease substantially as more manufacturers enter the market.”

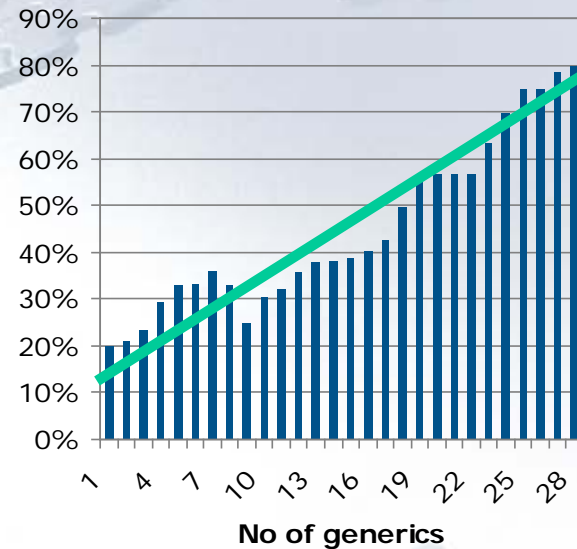
Source: London School of Economics, Panos Kanavos

Average generic price discount



Sweden

Average generic price discount



Germany

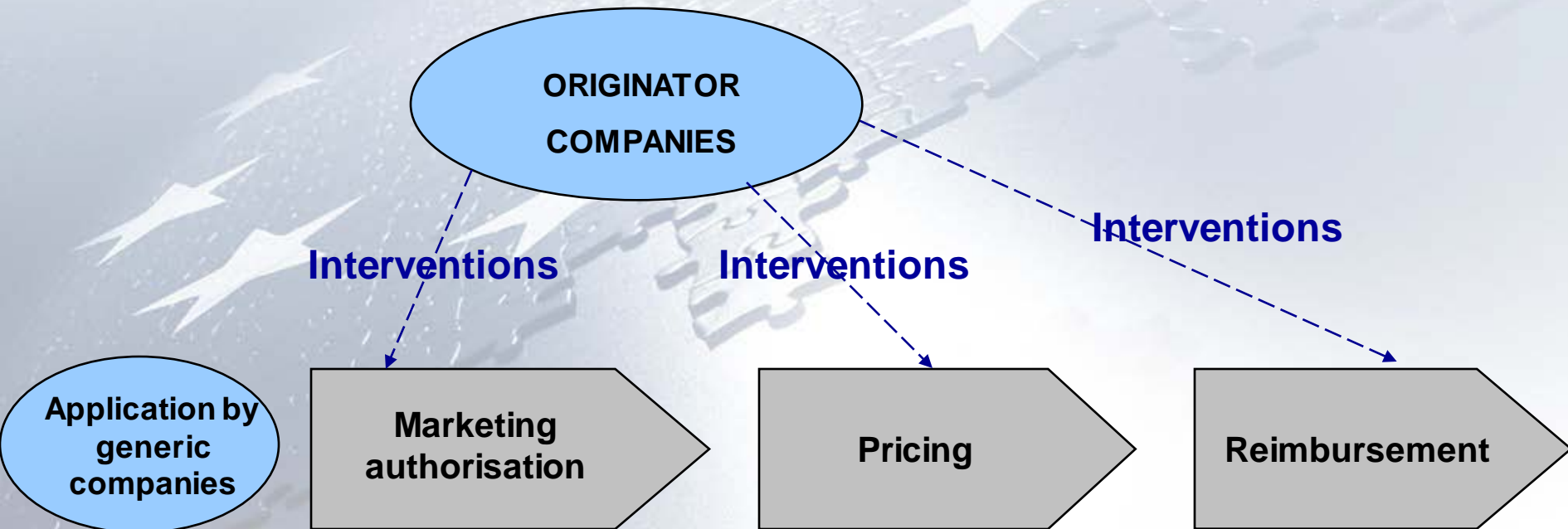
Limits to Sustainable Generic Competition in the EU

- **European average ex-factory generic medicines prices are lower/comparable to USA despite:**
 - lower volume share
 - higher 'operating costs'
 - more IP hurdles and lack of a single market
 - **Industry sustainability threatened by:**
 - Increasing regulatory requirements
 - Lowering prices/tendering
 - Lack of volume and limited generic policies
-

Market Environment for Generic Medicines: USA v EU

Market Environment for Generic medicines	USA	EU
Generic Medicines as % of Total Pharmaceutical Market Volume	63%	42%
Basic Product Patent	Yes 20 years	Yes 20 years
Data Exclusivity Blocks market authorisation procedures for generics	5 years	8+2+(1) years
Patent Extensions Supplementary Protection Certificates, etc.	Yes 14 years Maximum	Yes 15 years
Bolar Provision Right to perform generic R&D before patent expiration	Yes	Yes (but no correctly implemented in all member states)
Immediate Generic Competition Upon patent expiration	Yes	No (due to Price & Reimbursement procedures in many member states)
Fees for Generic Registrations	No	Yes (between 80.000 - 120.000 Euros)
Free Price Competition	Yes	No (not in most member states)
Harmonized Regulatory and IP Requirements	Yes	No

Pharma Sector Inquiry



Source: Prelim report Sector Inquiry, November 2008



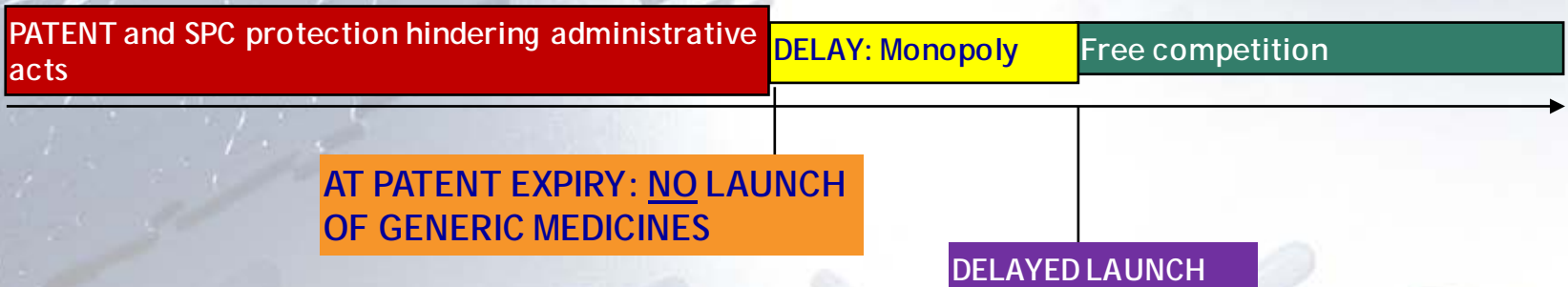
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Impact of Patent Linkage

1. No patent linkage



2. Patent linkage

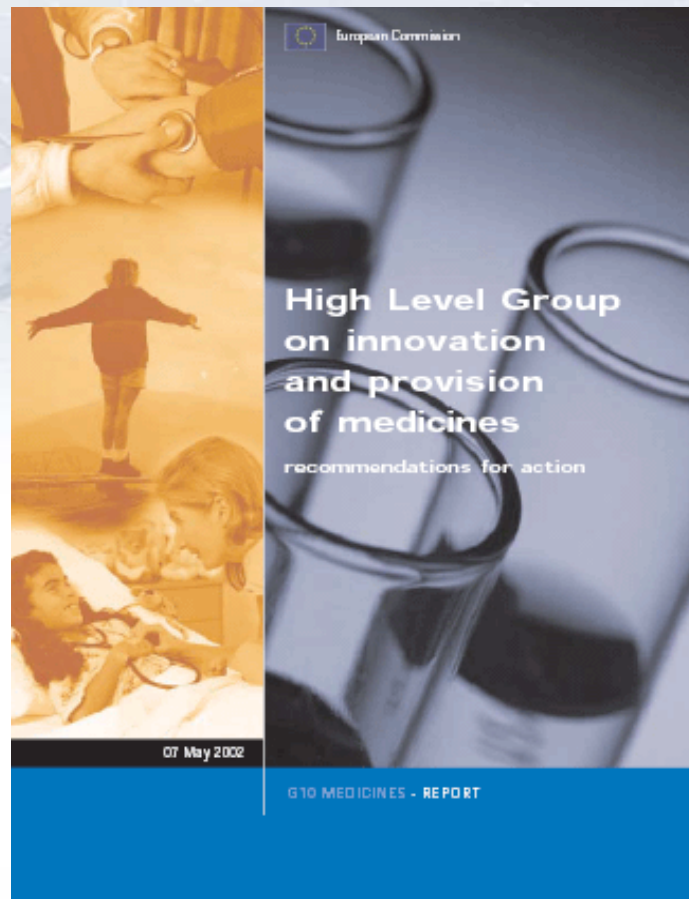


Tendering is Changing Market Dynamics

- Tendering is leading to short-term gains with the risk of long-term losses
 - Unbalanced competition and creation of new monopolies, while endangering the availability of medicines for patients
 - Companies that have not been awarded products cannot keep stock for longer periods of time, giving no other option than to discontinue these products
 - Smaller/niche products cannot be developed smaller regional companies as they cannot afford the risk of such investment and into coming into the market
-

G10 High Level Group - 2004

- *Member States - facilitated by the Commission - should explore ways of increasing generic penetration in individual markets (including generic prescribing and dispensing). Particular attention should be given to improved market mechanisms in full respect of public health considerations.*





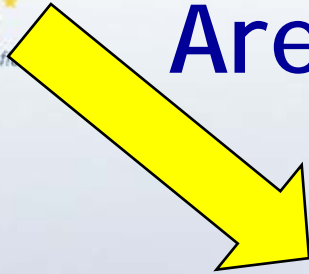
Pharma Forum Progress Report June 2007

“Promoting generic medicines requires a good combination of demand-side as well as supply-side mechanisms.”

Pharma Forum
Progress Report June 2007

Pharmaceutical
FORUM

Incentives for Demand Side Are Needed



	LOW VOLUME MARKETS					HIGH VOLUME MARKETS				
	AT	BE	IT	FR	ES	DK	DE	NL	SE	UK
Pharmacists	X	√	X	√	X	√	√	√	√	√
Physicians	X	X	X	X	X	X	√	√	√	√
Patients	X	X	X	X	√	√	√	√	√	X

Source: EGA Market Review 2007

In high volume markets, more coherent generic medicines policies foresee incentives for the demand side



Measures for Sustainable Generic Competition (EGA)

1. Ensure that pharmacists are not financially discouraged from dispensing generics
 2. Encourage prescribing of generic medicines
 3. Immediate price and reimbursement status for generics
 4. No patent linkage
 5. Pricing systems should preclude switching to non added value patented products away from generics
-



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Conclusions





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Headroom for Competition

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

“Headroom for Competition” - Basic Principles

- Ensure that no regulatory, patent or market hurdles exist to the immediate entry of generic medicines on patent expiry
 - Introduce mechanisms to stimulate competition from generic medicines
 - Create a price & reimbursement system for long term competition, not short term cost savings
-



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Thank you

www.egagenerics.com

Greg Perry
EGA Director General
