



Making Medicines Affordable

Sustaining EU Healthcare Systems Through Sustainable Generic Competition

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EGA Director General
Barcelona 4th May 2009



Generic Medicines - A Highly Competitive Industry

Generic Medicines Bring Savings of

25€ Billion p.a.

in the EU 27

Generic medicines account for
almost

50%

of volume share and

18%

of value share

One of the
Most
Competitive
Sectors in
Europe

More than **700** Generic Companies
Employing

130,000

Employees in Europe

Price cuts of **30-90%**

After Patent Expiry, with

10-30 companies competing on one
product

Generic Medicines- Key to Healthcare Sustainability

■ EU generic medicines companies:

- Cover a full spectrum of pharmaceutical needs

Cancer	Diabetes	Depression	High Cholesterol
Asthma	Osteoporosis	Viral Infections	Epilepsy
Bacterial Infections	Pain Relief	Inflammation	

- Also undertake incremental innovation

■ Generic competition increases access affordability and stimulates innovation



Generic Medicines: Healthcare Provision and Innovation

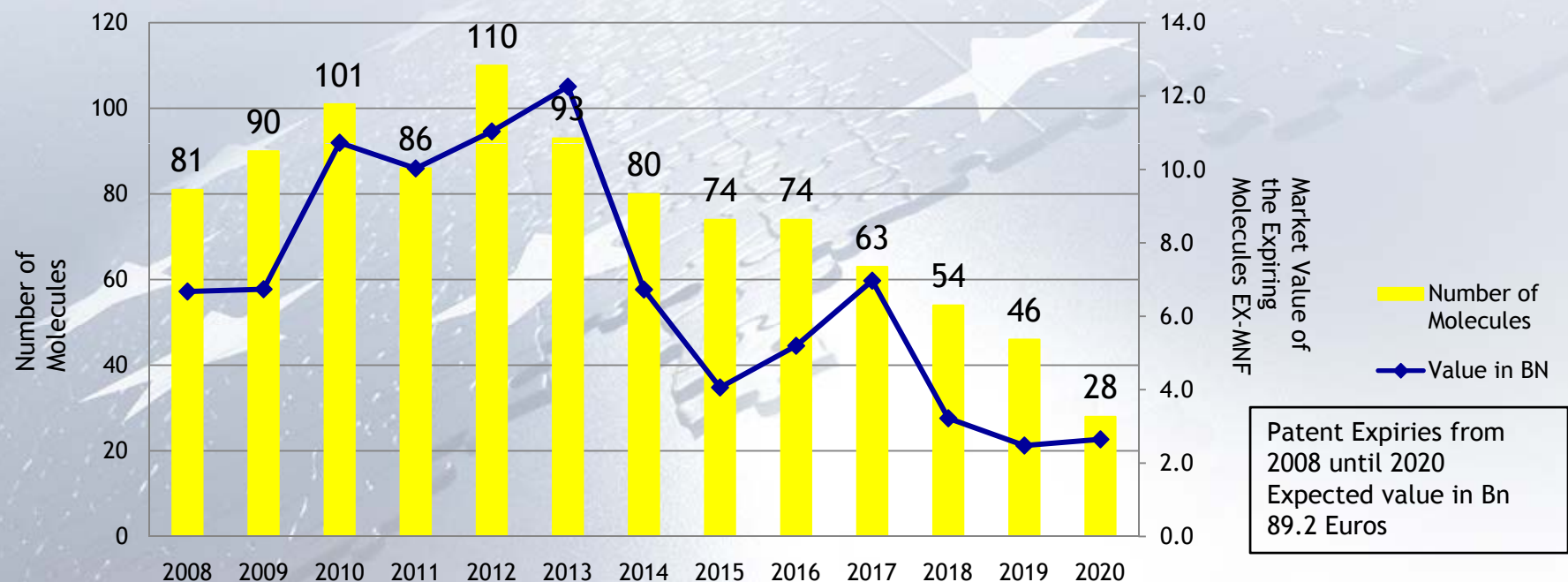
“Generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers, while liberating budgets for financing new innovative medicines.”

Pharma Forum
Progress Report June 2007

Pharmaceutical
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Patents Expiries in the European Countries: Opportunities for Affordability and Access

Europe: Opportunities for Affordability and Access



- Nominal patent expiries not corrected for supplemented patents, litigation probability
- Only molecules with associated sales were counted and from all European countries covered by IMS, sales of 2007



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)



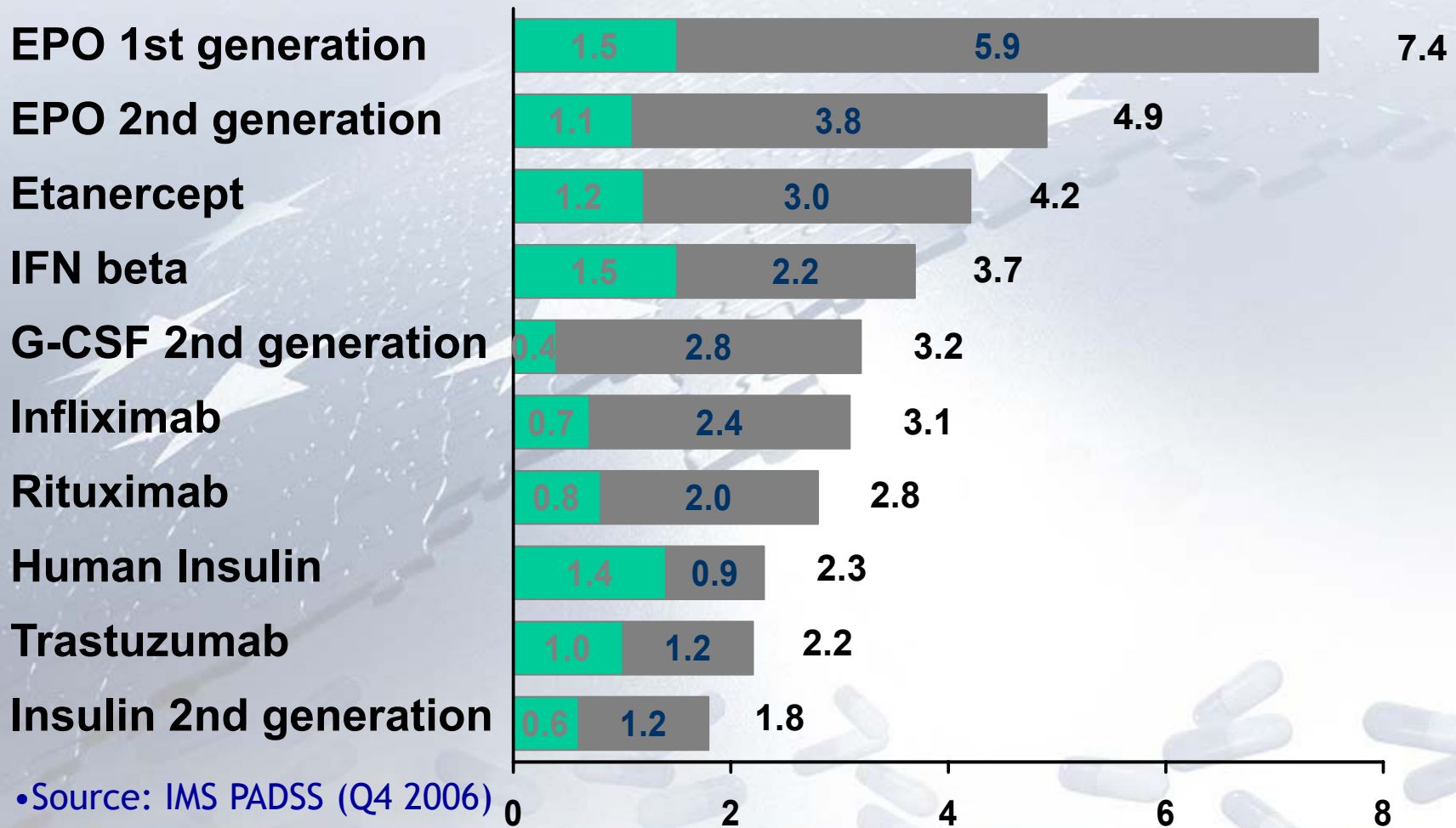


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Biopharmaceuticals with High Biosimilar Market Potential

Top 10 Biopharmaceuticals, in bn USD (2006)

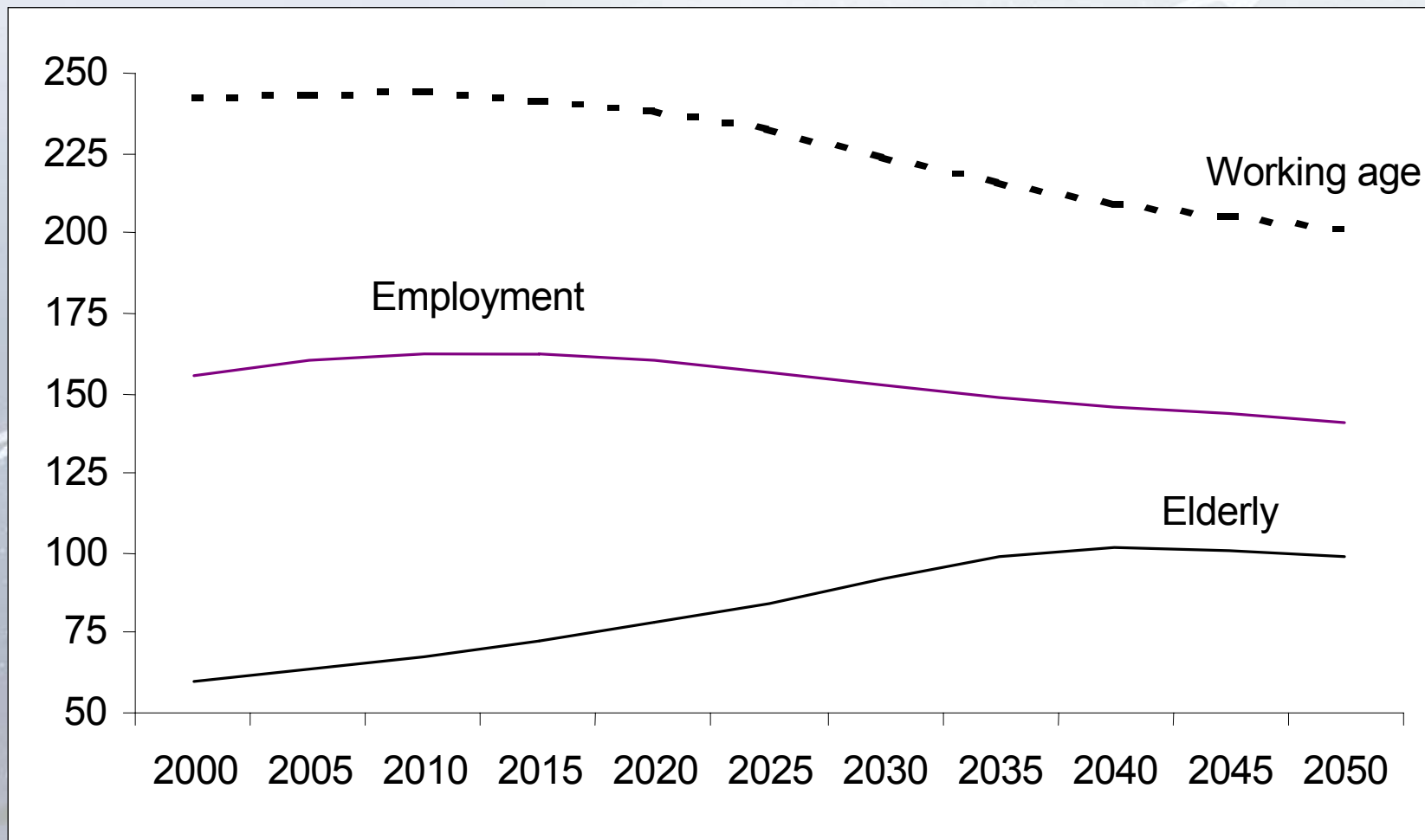
■ EU
■ US



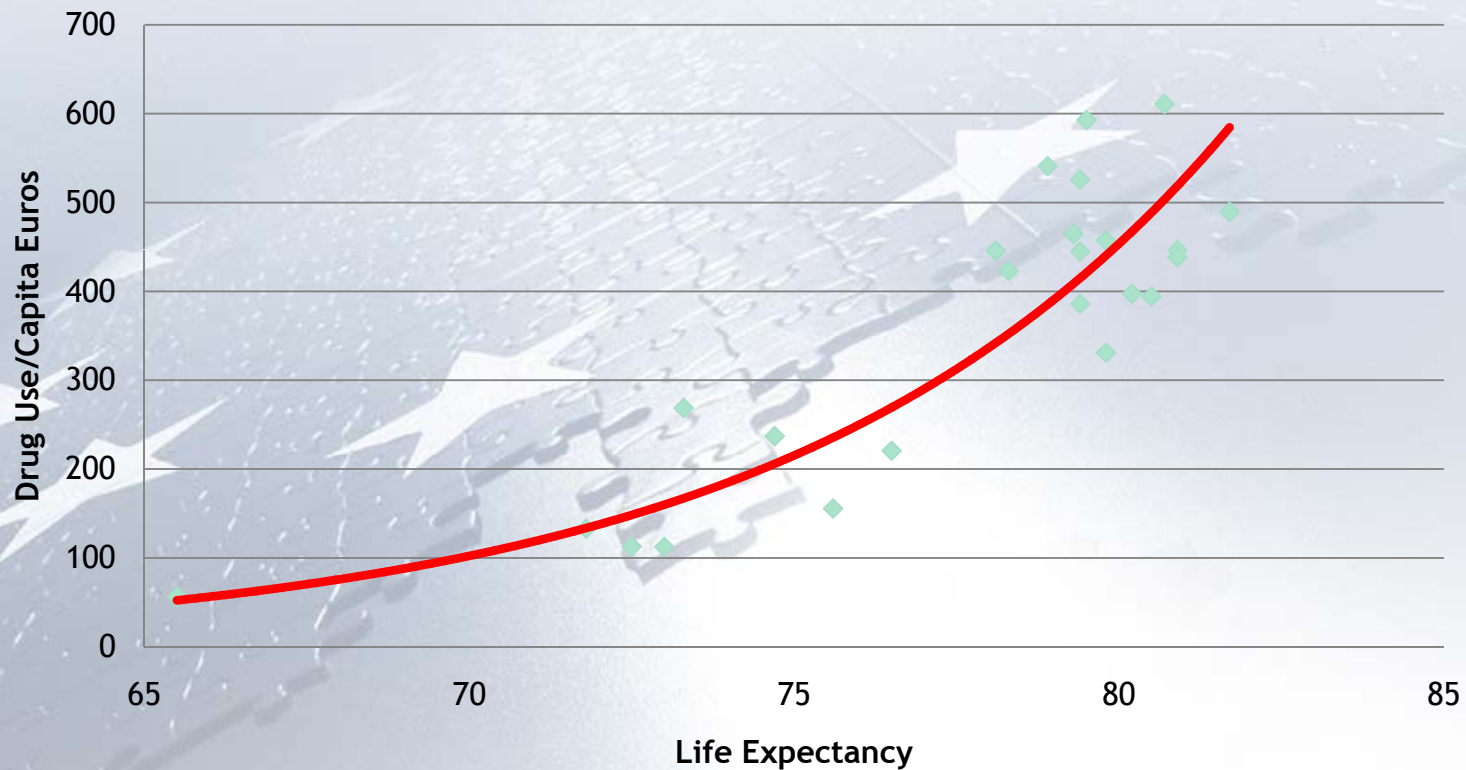
•Source: IMS PADSS (Q4 2006)



Europe's Ageing Population



Healthcare Expenditure Increases with Age



■ A long life could be linked to spend on medicines...

Source: Life Expectancy; United Nations (average for the 2005-2010 period)
Drug use per capita; IMS market prognosis, 2007, ex-manufacturing price

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!)



THE INDEPENDENT
NEWSPAPER OF THE YEAR

(Ireland €1.00) 65
Thursday 6 October 2005
www.independent.ie

Today
educator
& 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, 5% of the NHS budget

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

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

500% more are estimated to have diabetes - but don't even know it

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

10% Within six years, over 10 spent on the NHS will go on treating diabetes

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 10 times greater chance of developing diabetes

1-in-6 of six to 11 year-olds in Britain is obese - a rise of 300 per cent in 15 years.

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

The UK has the fastest growing rate of diabetes in the developed world. Britain also has the fastest growing rate of obesity

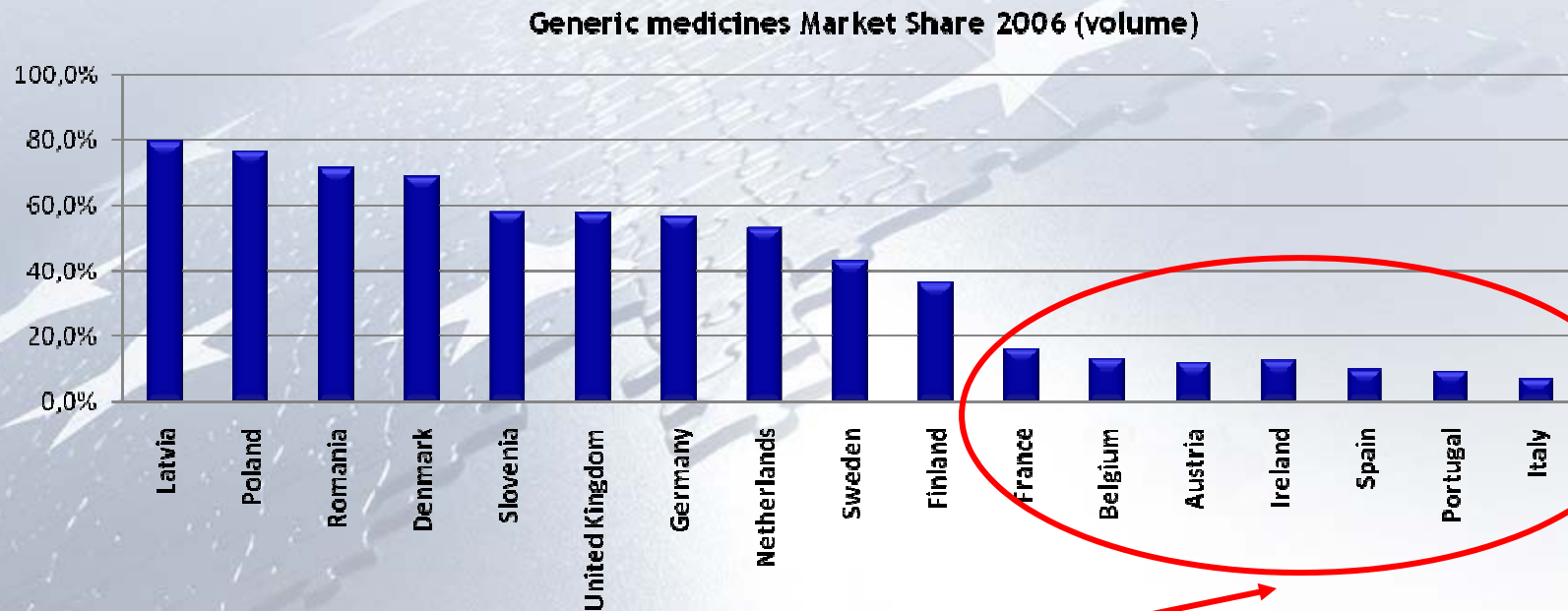
The World Globally, cases of diabetes have risen from 66 million in 1993 to 150 million in 2004, projected to grow to 300 million by 2025

41,000 people in the UK will die from diabetes in 2016. This marks a 25% increase on today's annual death rate

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

Full report and analysis, page 2

Potential Growth for Generic Medicines in the Total Pharmaceutical Market

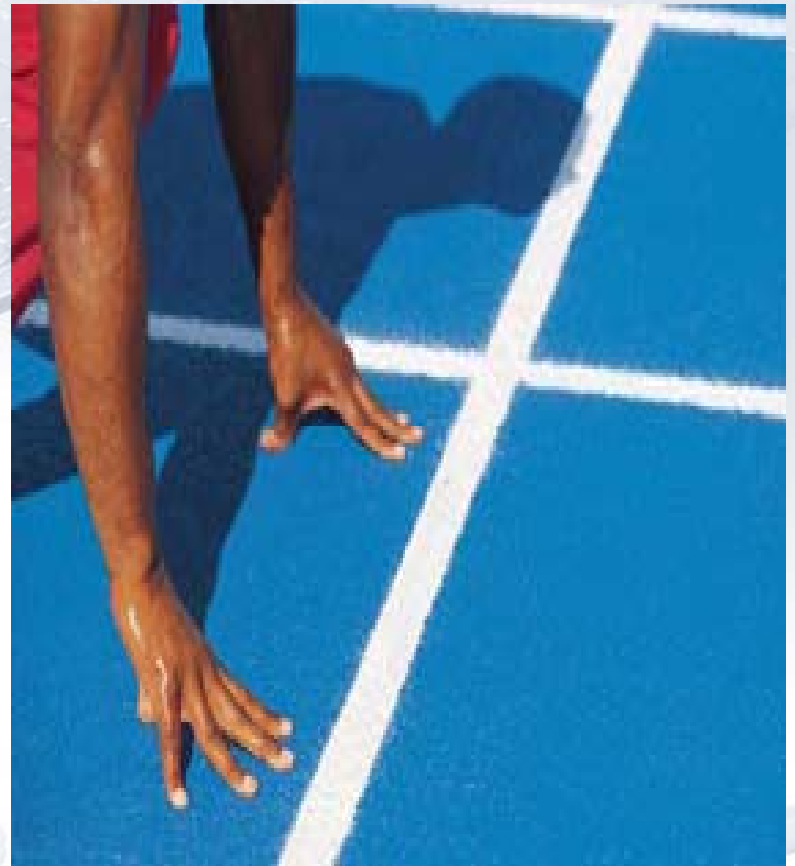


Major Potential Growth

Getting the Right Environment for Generic Competition

Three Foundation Stones:

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



The Regulatory System





Lack of Application Slots Key Issue for Generic Competition

- Major improvements in the regulatory system
 - But significant delays in obtaining a date for submitting a DCP application remain
 - The number of countries acting as RMS in MRP/DCP remains limited
 - Parallel full assessment by some CMS continues
 - This problem limits patient access to affordable treatment and hinders competition
-

EC Proposal on Counterfeiting: Wrong Focus - High Burden



Legal Supply Chain

Subject all actors of the distribution
chain to pharmaceutical legislation
GMP Supervision & Enforcement
> €12 Billion Track and Trace System

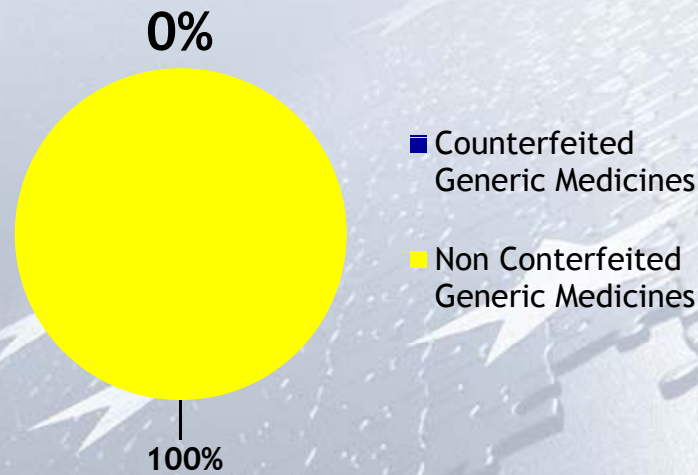
Illegal Supply Chain & Internet

No measures on the EC
Proposal to fight
Counterfeiting on the
Internet - Real Problem

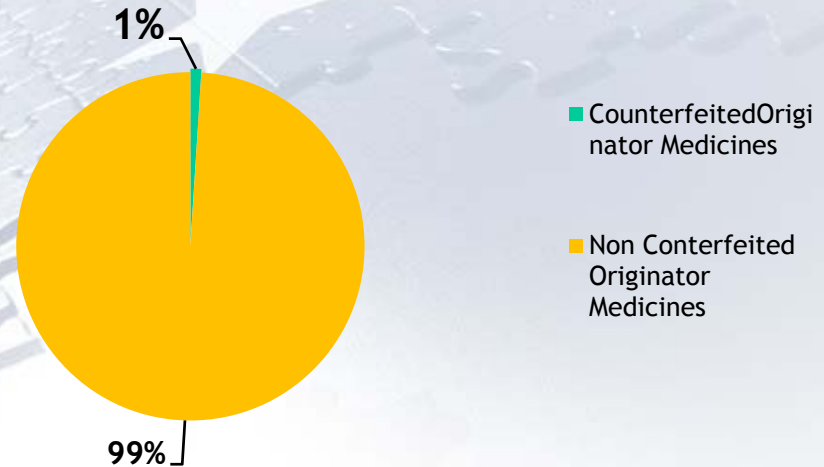
***Internet alone more than 50% of the
counterfeiting of medicines (source: WHO)**

How Big is the Counterfeit of Medicines Issue?

Generic Medicines



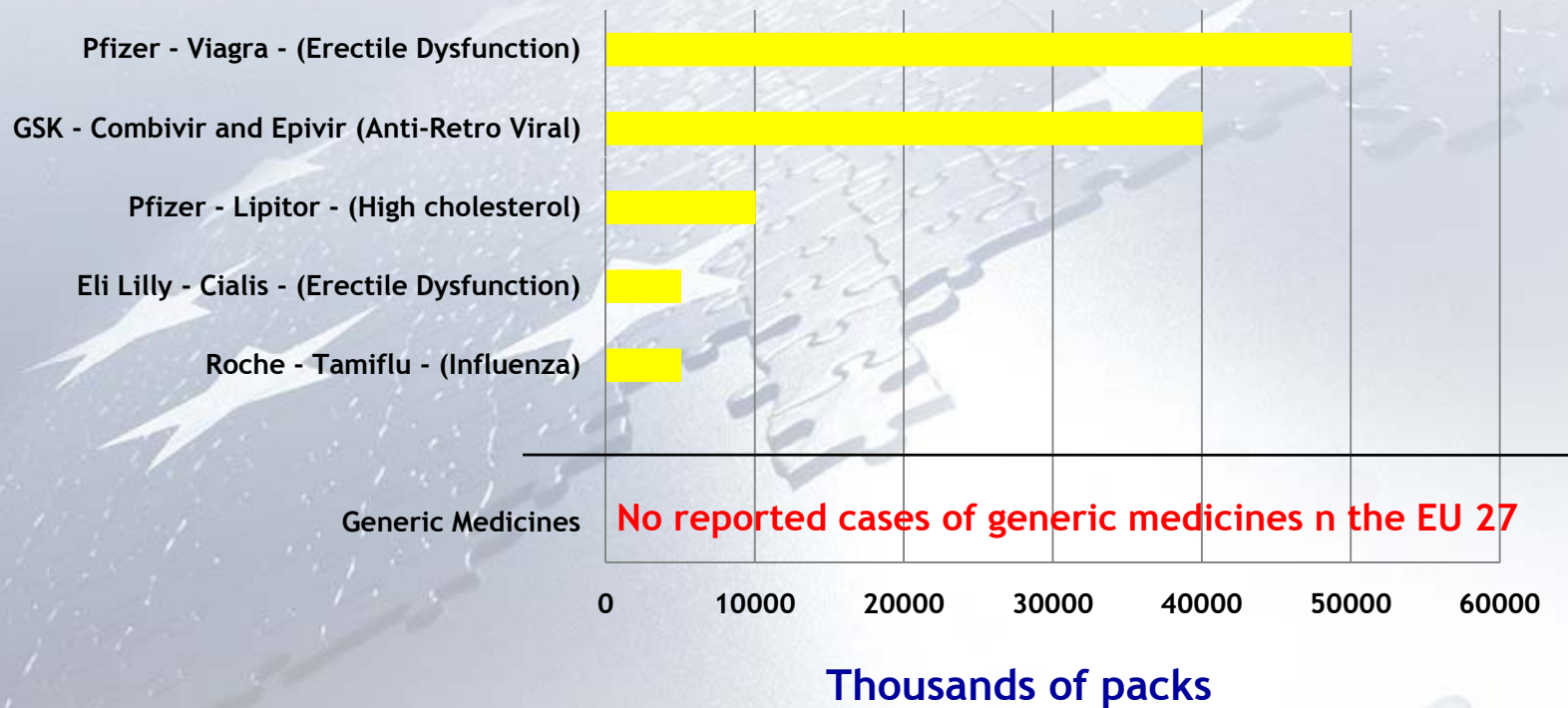
Originator Medicines



Source: WHO
Fact Sheet
N275,

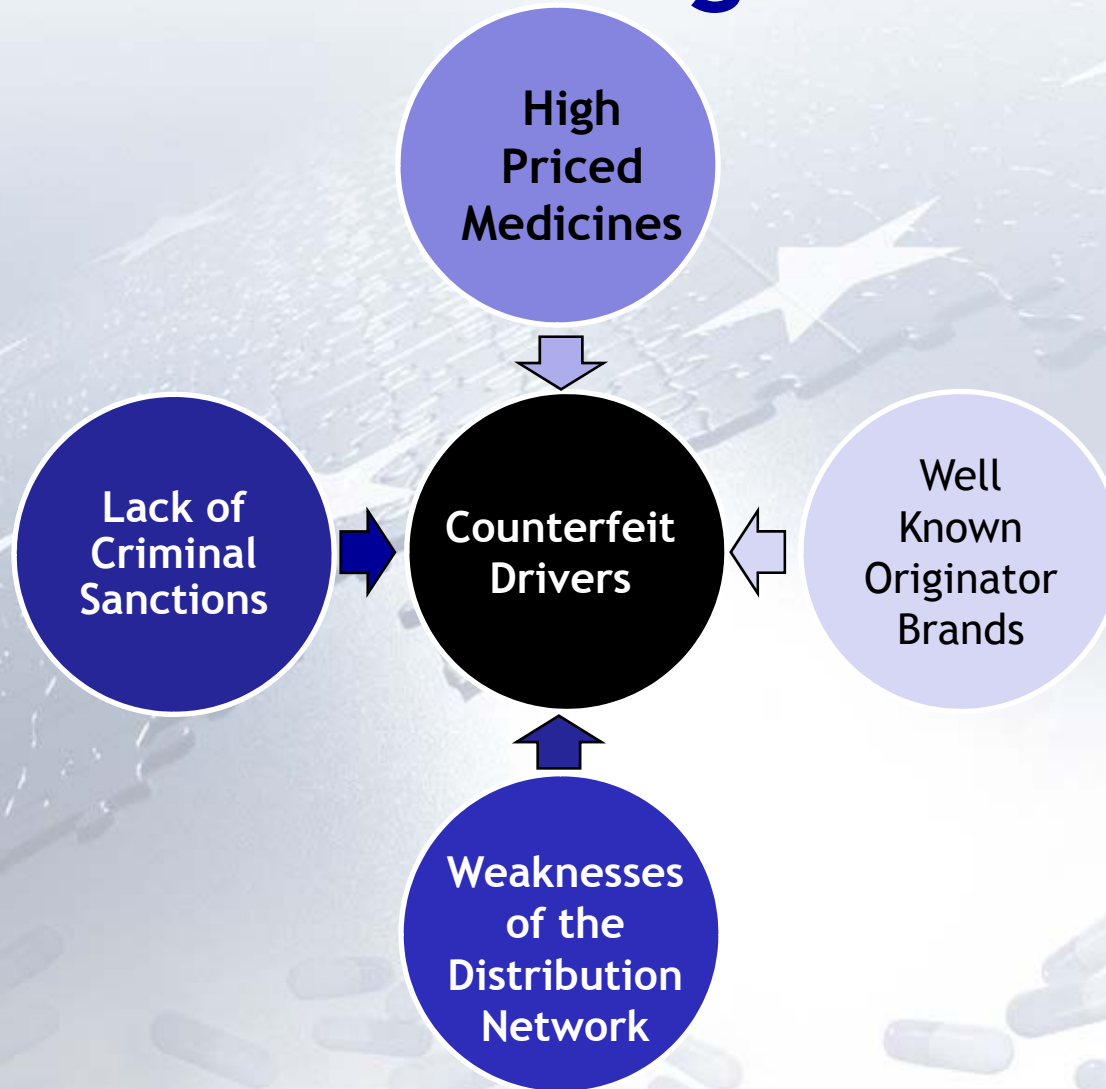
Counterfeiting of High Priced Popular Medicines

Examples of Reported Cases of Counterfeited Medicines

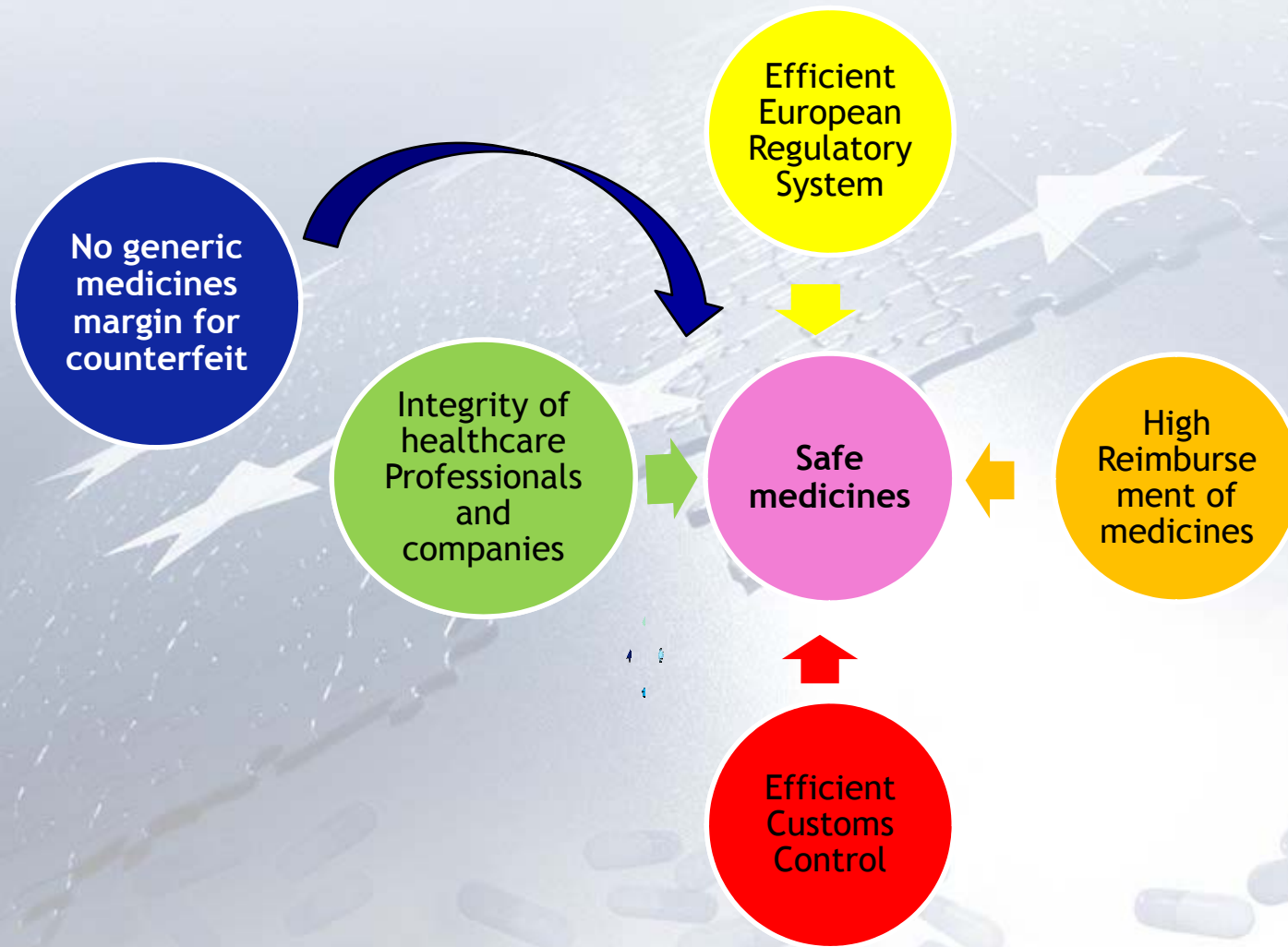


Source: WHO
Fact Sheet
N275, Council
of Europe
Report 2006

Driving Forces Behind the Counterfeiting of Medicines



European Barriers to Counterfeit 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



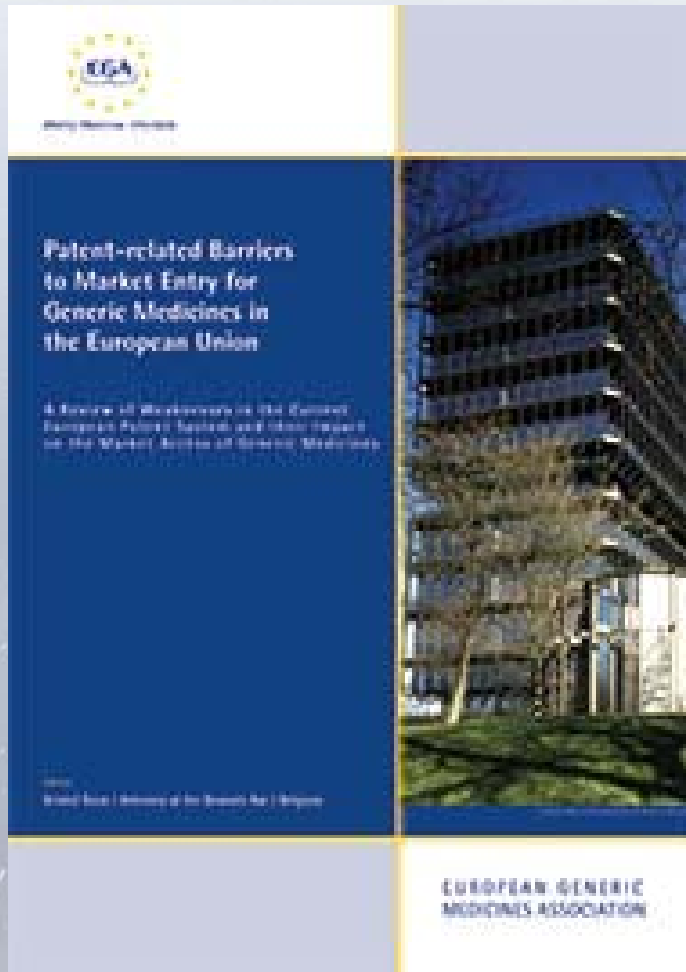
Increasing IP Protection: Example Europe

- 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.

Obtain this report from www.egagenerics.com



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



STOA report





EGA Recommendations to European Patent Office

- Rigorous assessment of patentability requirements and particularly of the inventive step
 - Improve quality of applications and full disclosure of relevant prior art by the applicant.
 - Introduce duty of candour on patentees to ensure that all information relevant to the patent is disclosed by the applicant
 - Involve third parties in the application process
-



EGA Recommendations to European Patent Office

- Accelerate opposition procedures
 - Grant examiners stronger rights and incentives to reject applications
 - Give applicants less incentives to build portfolios (increase fee schedules)
 - Prohibit filings for substantially identical divisional patents
-



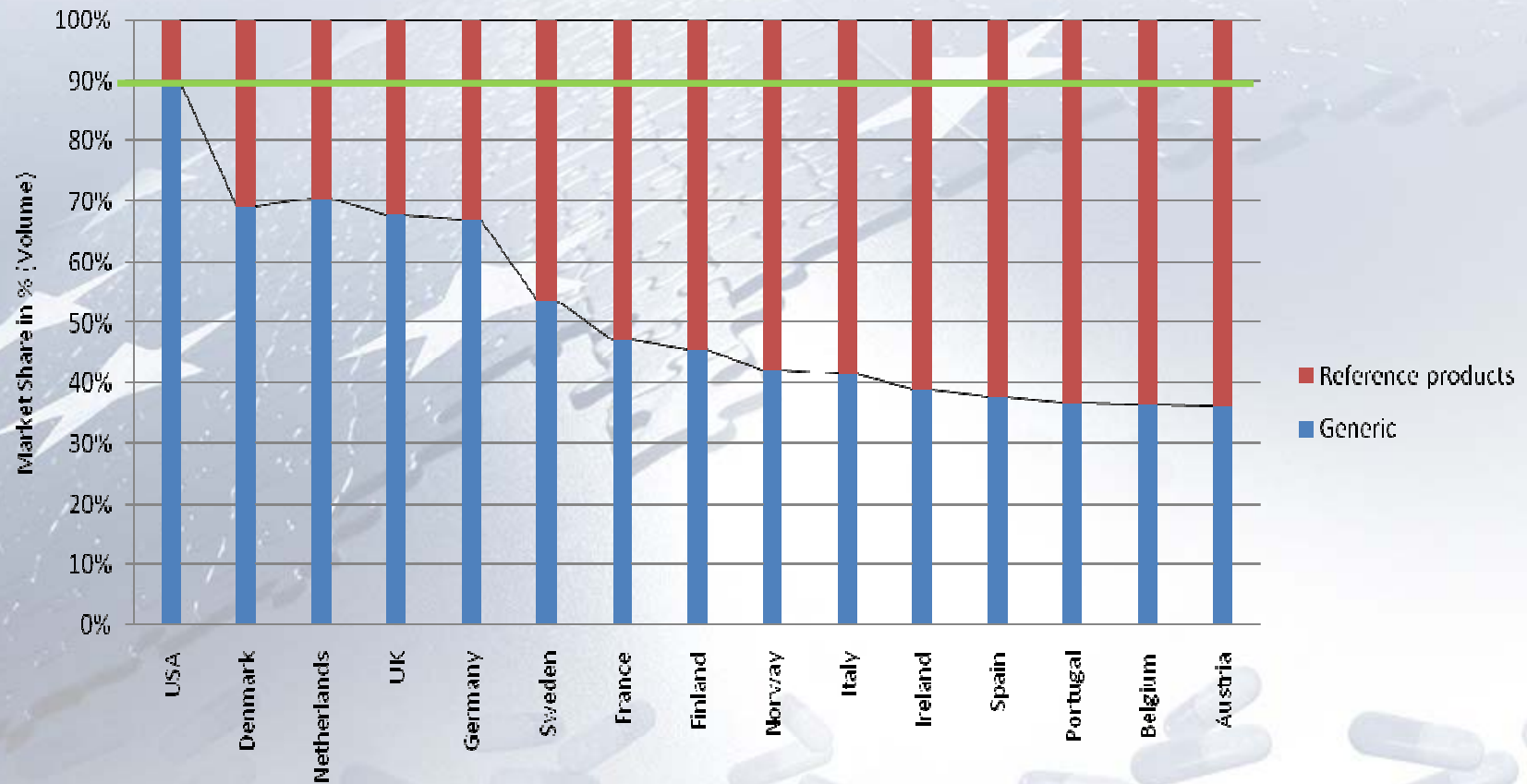
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Market Issues



Resistance to Generic Medicine Competition in Off Patent Sector

UNPROTECTED MARKET SEGMENTATION (VOLUME)



Source: IMS Health MIDAS Market Segmentation Plus MAT March 2007.
Ethical Market Only & Others excluded



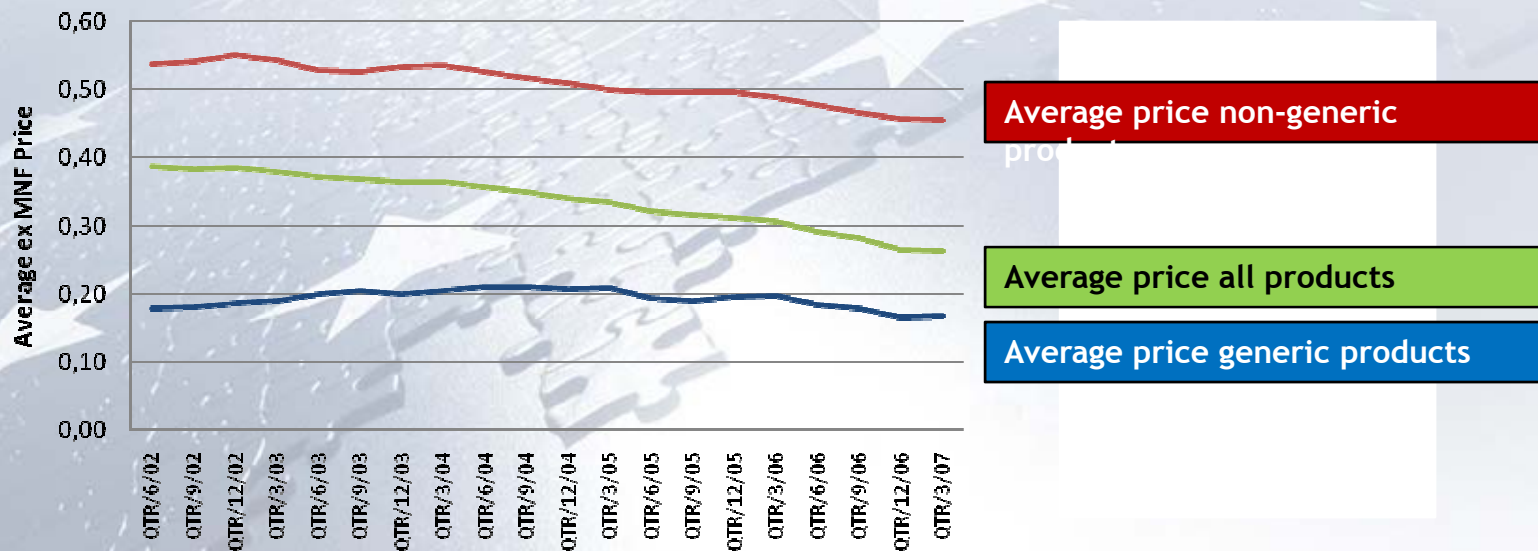
Importance of Volume for Generic Medicines Competition

“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 Prices Remain Substantially Lower than Off-Patent Originator Products

Average price evolution in the total market



Source: IMS MIDAS
DATABASE Q3 2007



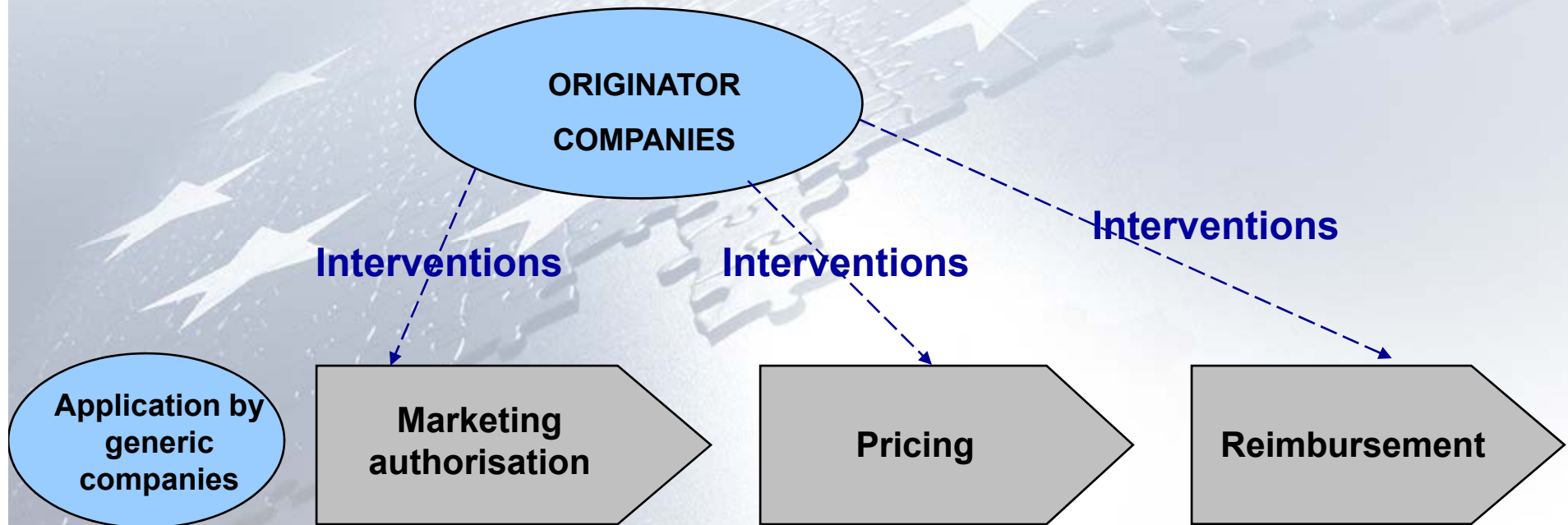
Limits to Sustainable Generic Competition in the EU

- **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



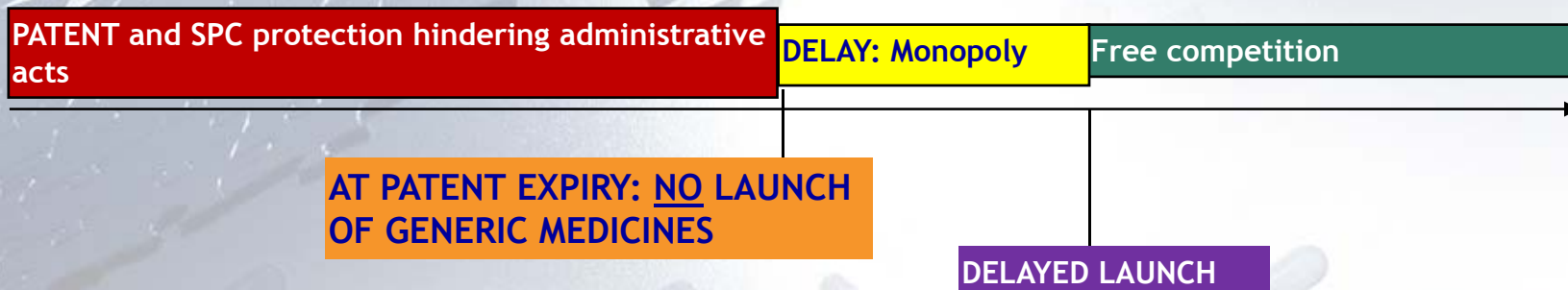
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Impact of Patent Linkage

1. No patent linkage

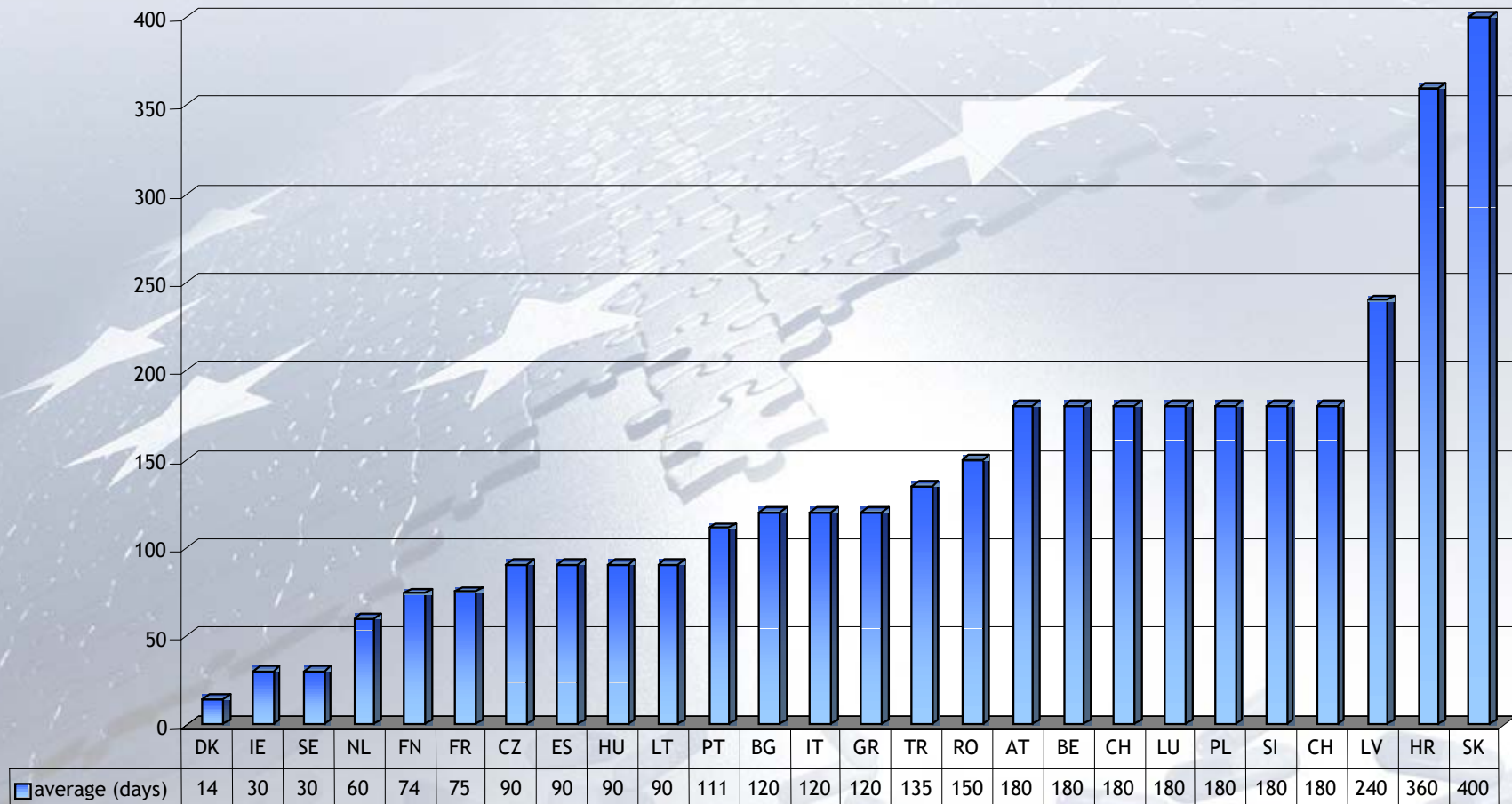


2. Patent linkage



Time Delays in Price & Reimbursement

- Time delay for generic price & reimbursement approval after granting of MA





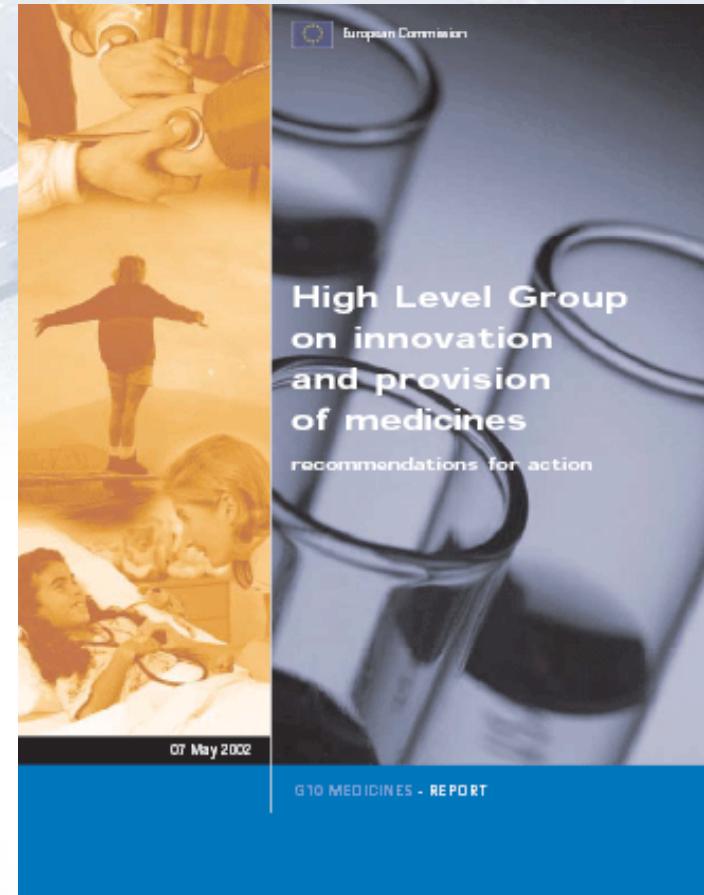
Tendering is Changing Market Dynamics

- **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

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Price & Reimbursement Systems Must be Dynamic

	LOW VOLUME MARKETS					HIGH VOLUME MARKETS				
High Regulation Measures	AT	BE	IT	FR	ES	DK	DE	NL	SE	UK
Price control	✓	✓	✓	✓	✓	✗	✗	✓	✓	✗
Price linkage	✓	✓	✓	✓	✓	✗	✗	✗	✓	✗
P&R delay in days	180	180	135	75	30	14	0	45	30	0

Source: EGA Market Review 2007

High regulation has an effect on the ability of the Generic Medicines industry to create market volume and therefore on **COMPETITION**

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 low volume markets, no or few incentives for the demand side are foreseen within the generic medicines policy

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



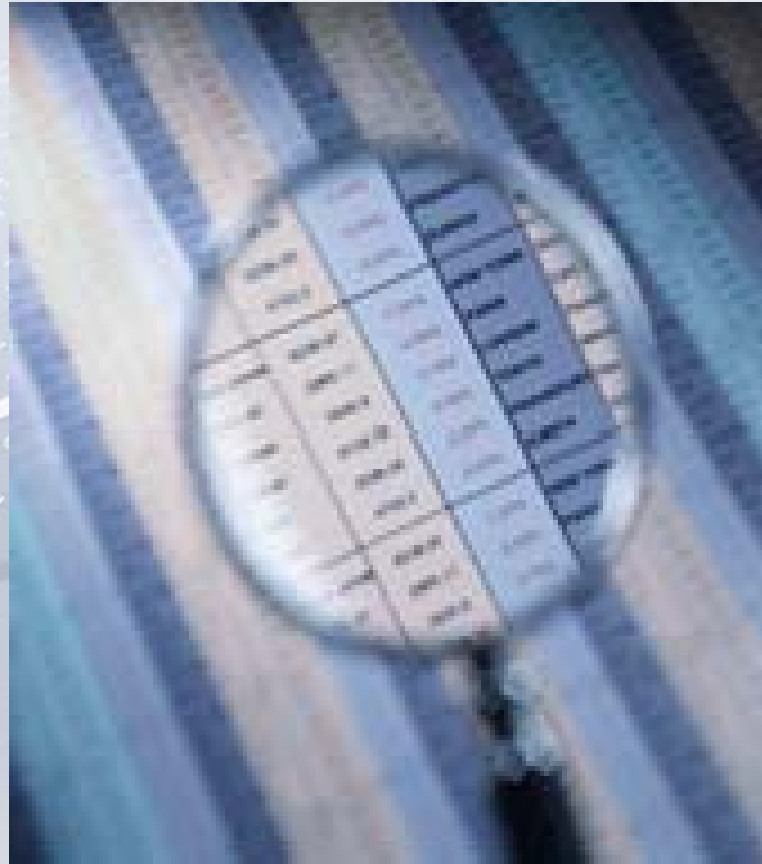
Measures for Sustainable Generic Competition (EGA)

1. Ensure that pharmacists are not financially discouraged from dispensing generics
 2. Encourage prescribing of generic medicines
 3. End price linkage with originator products - competition not control
 4. Immediate price and reimbursement status for generics
 5. No price-patent linkage
 6. 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
