

# The pharmaceutical market adapting to decreased public expenditure

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Bucharest September 12th 2013



# Agenda

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- Current market trends
- Generics
- Biosimilars
- Outcomes

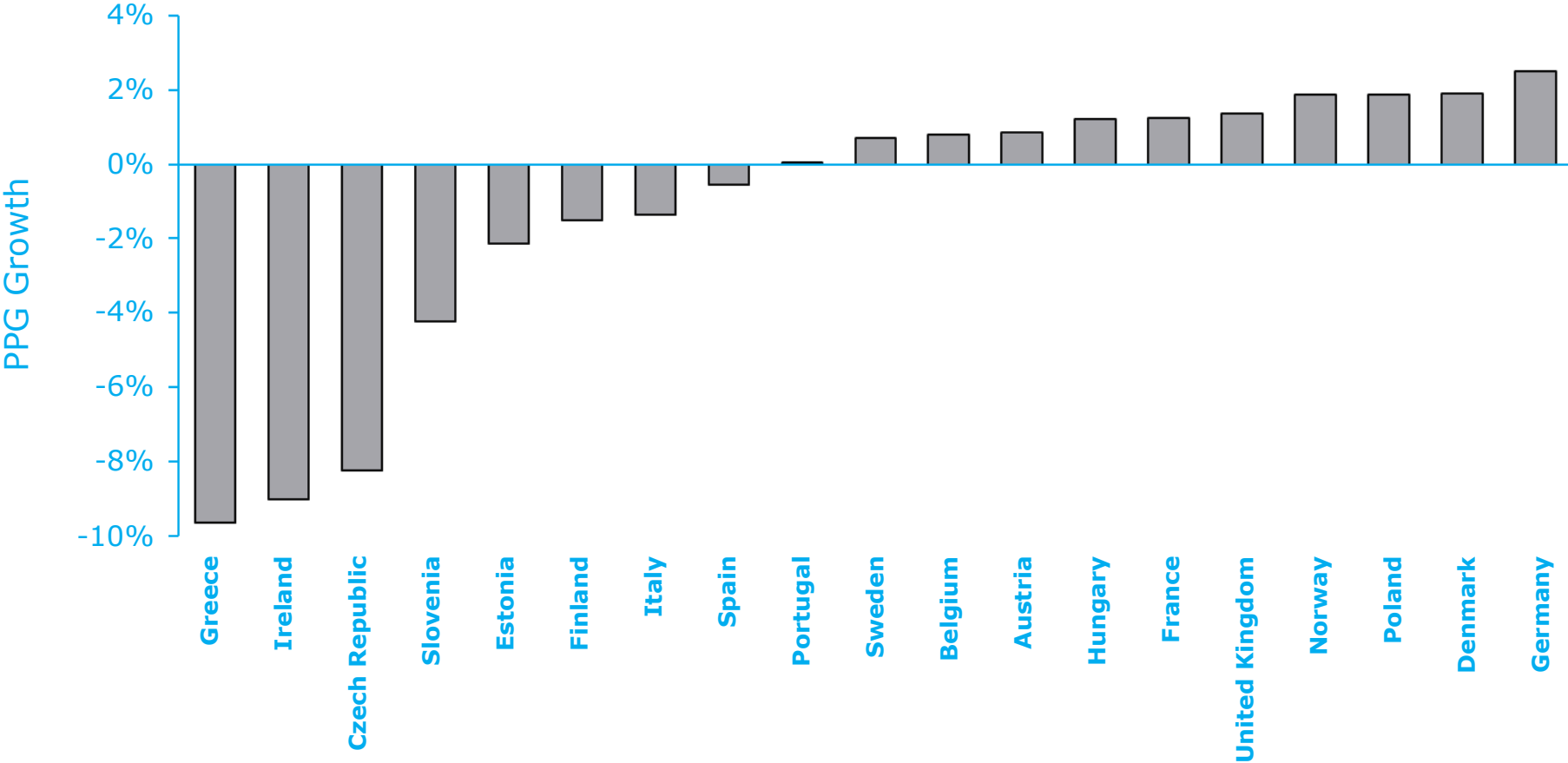
# Major Market Factors Influencing Growth

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- Economic situation and austerity measures
- Cost and risk of NME programmes
- Changing 'regulatory' requirements
- Loss of Exclusivity of major molecules
- Shift of costs to patients and affordability
- Market growth challenges in emerging markets
- Diversity and consolidation
- Generics and Biosimilars

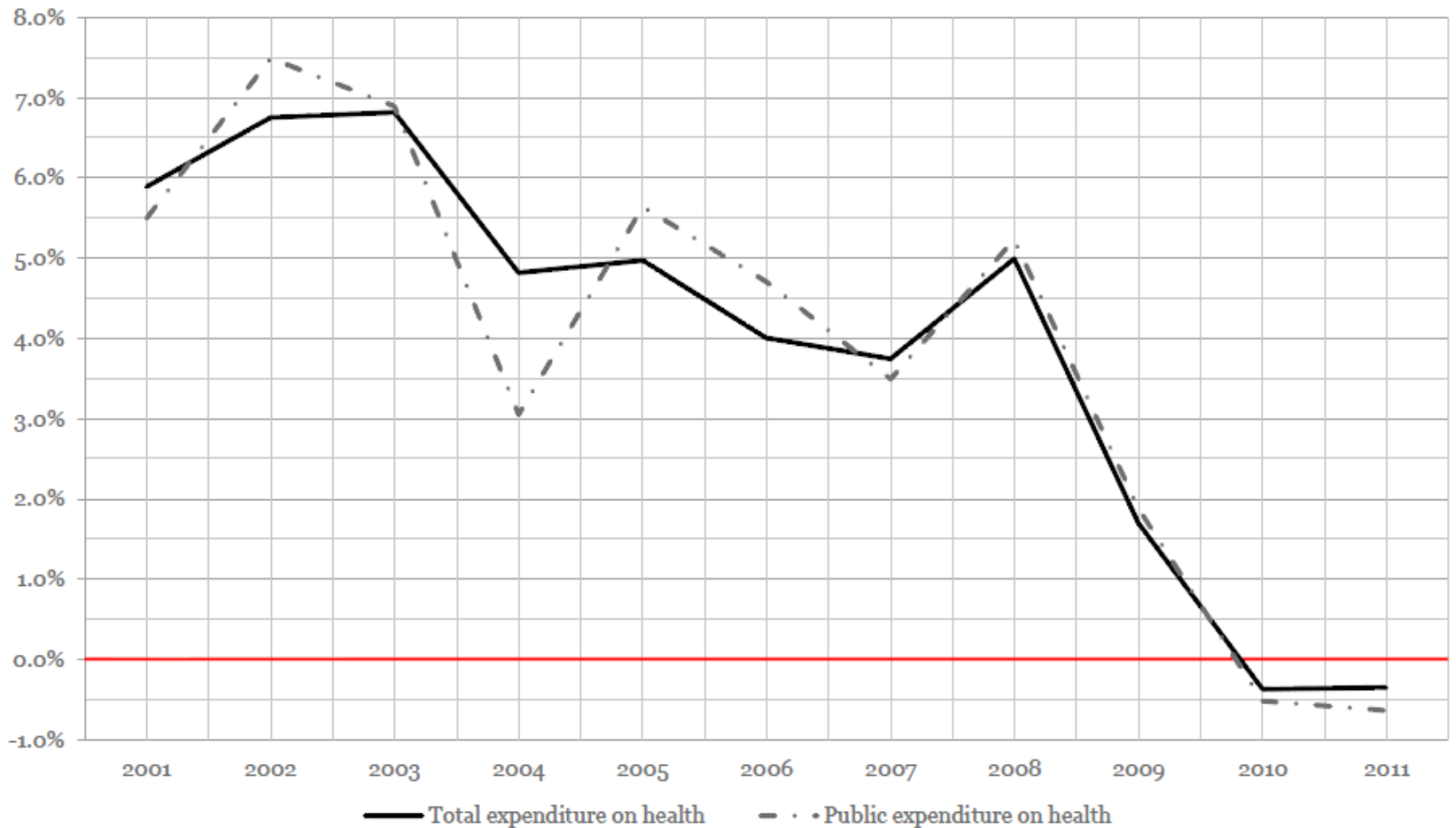
# Many European countries have seen decline or stagnation in public healthcare expenditure

Growth of government expenditure on healthcare 2009-2010

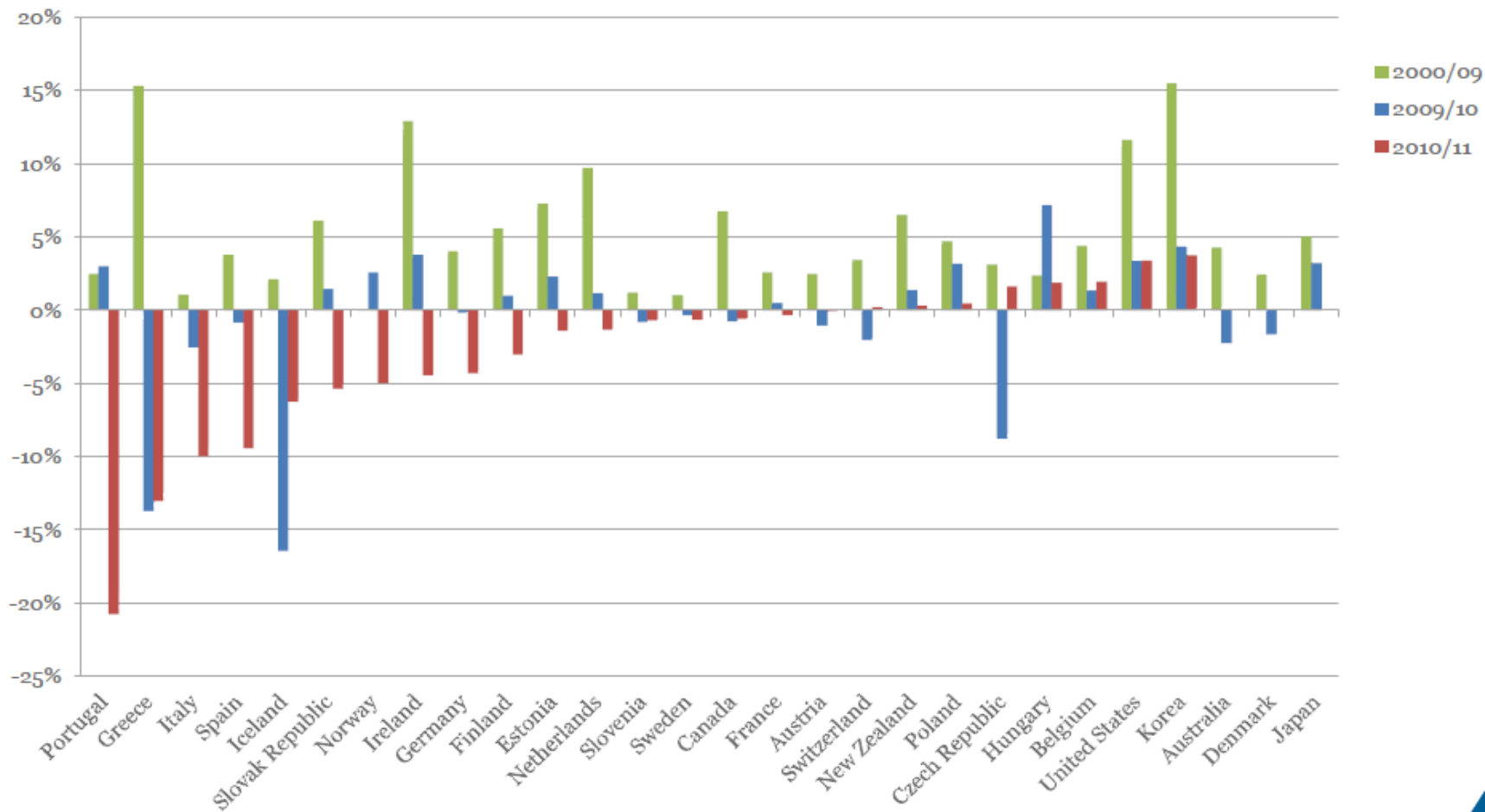


Source: OECD health accounts data. June 2012.

# Average EU-27 health expenditure growth rates now negative



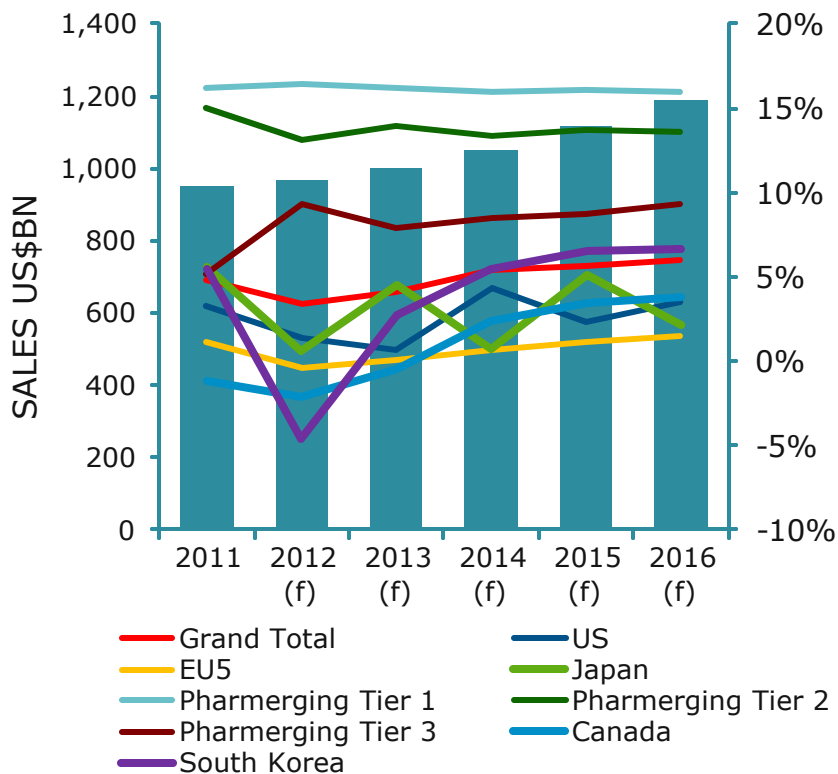
# Pharmaceutical spend also impacted



Source: OECD, 2013

# Developed market growth down at 1-4% CAGR to 2016

**Global Sales and Market Growth**



Developed Markets CAGR 2012-2016		Pharmerging Markets CAGR 2012-16	
US	1-4%	Tier 1 (China)	15-18%
Japan	1-4%	Tier 2	12-15%
Germany	0-3%	Brazil	12-15%
France	(2)-1%	Russia	10-13%
Italy	0-3%	India	14-17%
Canada	0-3%	Tier 3	7-10%
Spain	(4)-(1)%	Pharmerging	12-15%
UK	0-3%		
S. Korea	2-5%		
<b>Developed</b>	<b>1-4%</b>		

Yellow	At par with region CAGR
Red	Lower than region CAGR
Orange	Higher than region CAGR

(\* ) at ex-manufacturer price levels, not including rebates and discounts. Contains Audited + Unaudited data. All CAGR calculations are 5 years

Source: IMS Market Prognosis, Apr 2012



# Although pharmaceuticals are typically a small part of healthcare spend they remain a key target for cost containment

- 1 The proportion of pharmaceutical spend within total health spend varies dramatically by country
- 2 Efficiency across pharmaceutical spend is a quick way in which governments can easily save money
- 3 Where generic penetration is low, governments can instigate price and volume constraints on therapies open to generic/lower-cost alternatives



# Industry faces a range of cost control measures, some sophisticated some less so

## Payer Policy Sophistication Spectrum

Policy Characteristics	Examples
<p><b>National Level Cost Control</b></p> <ul style="list-style-type: none"> <li>Organised at National level</li> <li>Indiscriminate for therapy classes or types of product</li> </ul>	<ul style="list-style-type: none"> <li>Price cuts / freezes</li> <li>Top level pharma spend setting</li> <li>Industry claw backs</li> <li>Fixed wholesaler / retail margins</li> </ul>
<p><b>Harness Competitive Forces</b></p> <ul style="list-style-type: none"> <li>Cost comparison within therapeutic class</li> <li>Give pharmaceutical manufacturers incentives to restrain/cut prices</li> </ul>	<ul style="list-style-type: none"> <li>Reference pricing internal/external</li> <li>Positive/negative lists</li> <li>Promote generic competition (eg substitution)</li> <li>Promoting parallel imports</li> </ul>
<p><b>Alter Decision Maker Behaviour</b></p> <ul style="list-style-type: none"> <li>Regionalisation/localisation of budgets</li> <li>Cost/Benefit evaluation of products</li> <li>Incentives/penalties to alter behavior of prescribers, patients or pharmacists</li> </ul>	<ul style="list-style-type: none"> <li>Patient co-pays (selective)</li> <li>Prescriber budgets</li> <li>Promotional controls</li> <li>Mandatory HTA evaluations</li> </ul>

*Short term/less sophisticated*



*Long term/more sophisticated*

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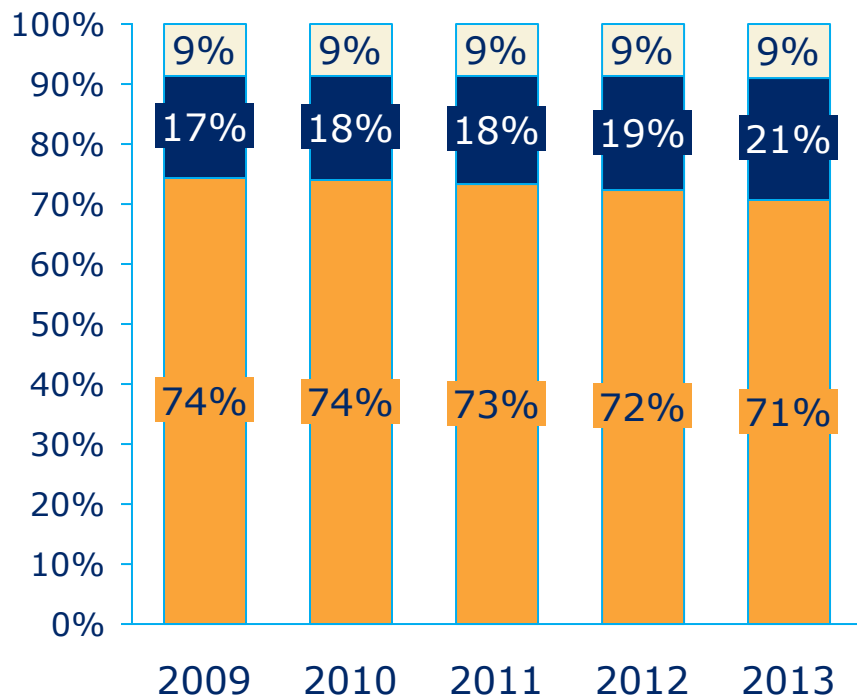
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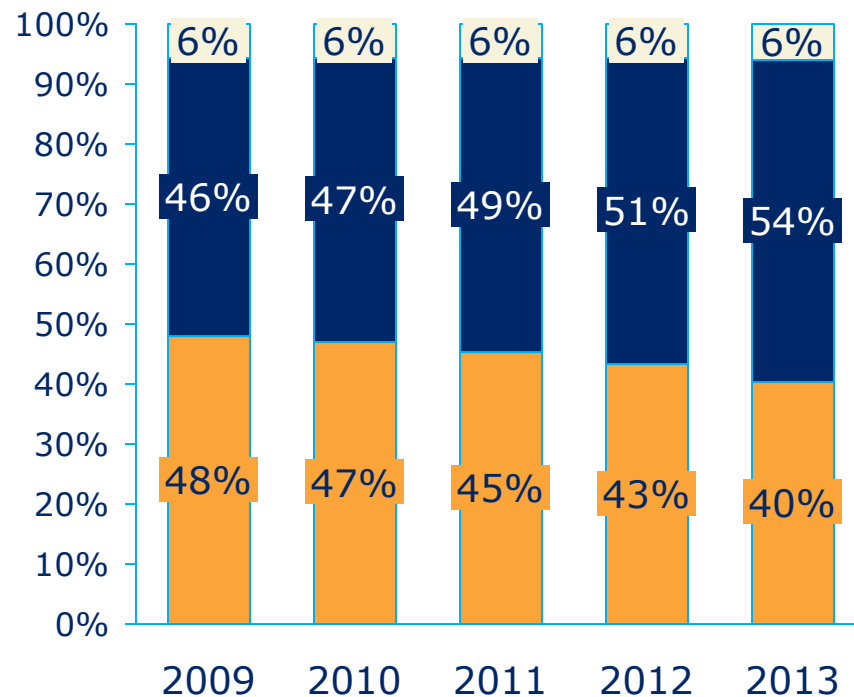
# Generic medicines provide payers with cost benefits as evidenced from the sales / volume mix



### Sales Mix Brands vs Generics



### Volume Mix Brands vs Generics

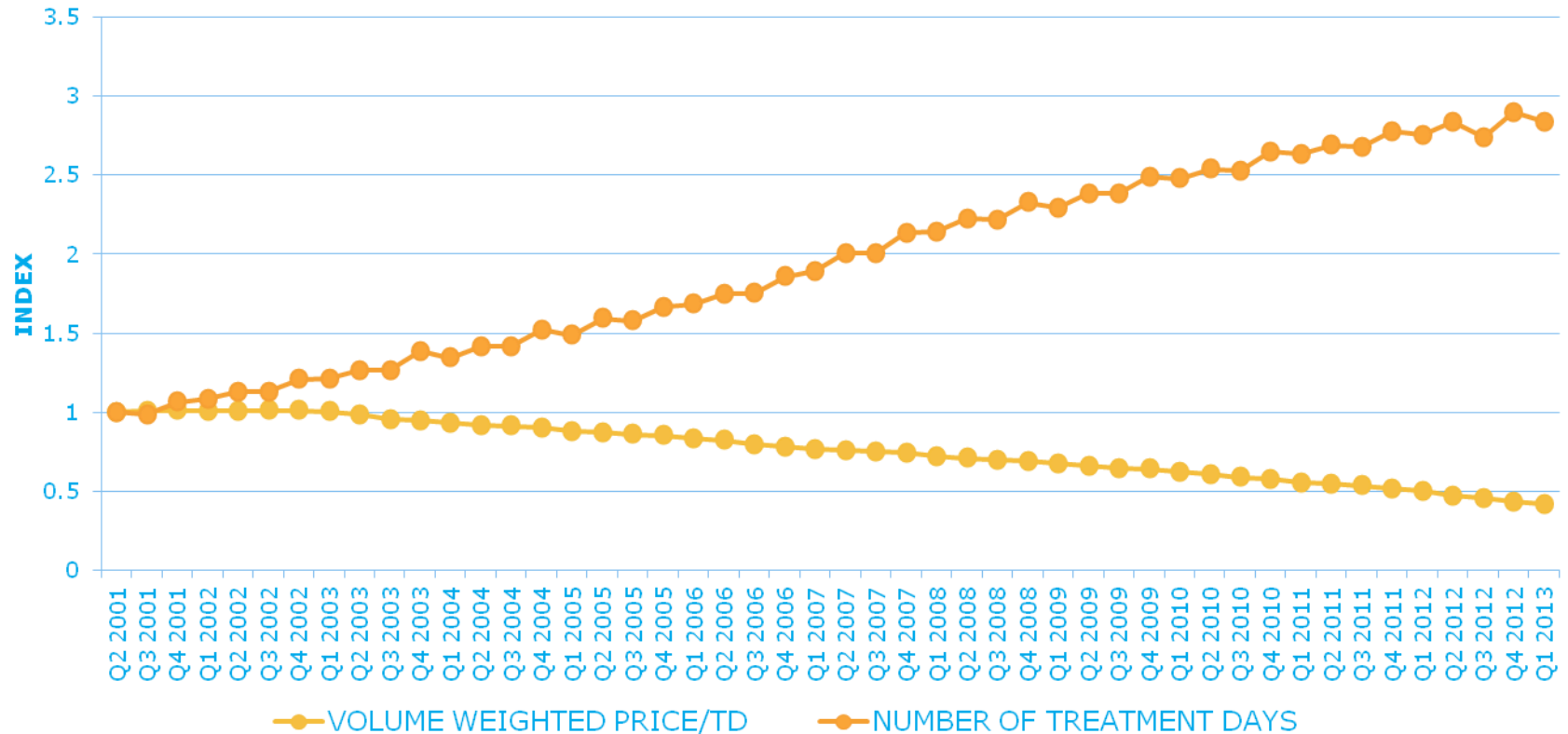


All Others
  Generics
  Non Generics

Source: IMS Health, MIDAS, Market Segmentation, MAT Jun 2013, Rx only. It doesn't include Denmark

Across 7 key therapy areas in Europe, the average price per treatment day has decreased 60%, while number of treatment days has increased nearly 200% over 12 years

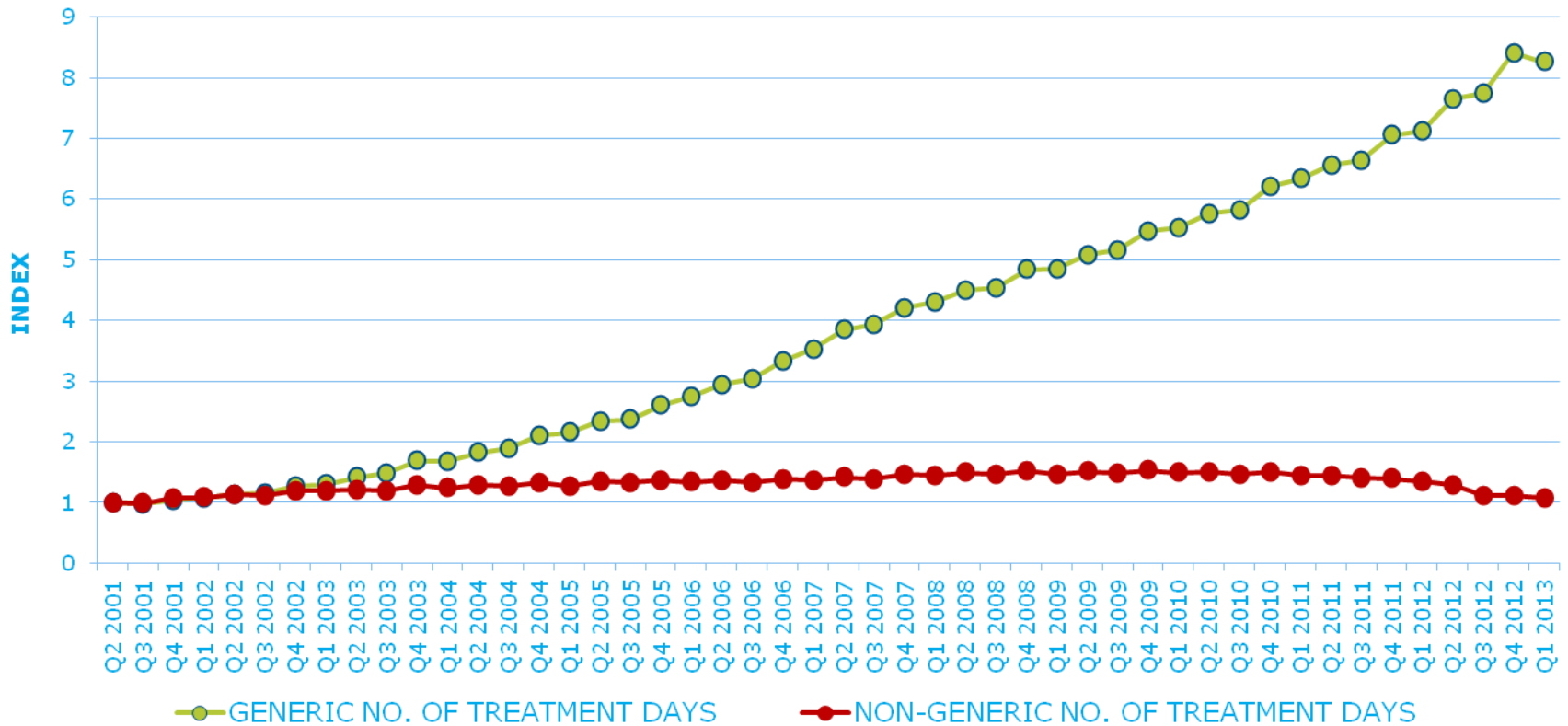
**EVOLUTION OF EUROPEAN VOLUME WEIGHTED PRICE/TREATMENT DAY VS  
NUMBER OF TREATMENT DAYS ACROSS 7 THERAPY AREAS**



Selected therapy areas: Angiotensin II antagonists, anti-depressants, anti-epileptics, anti-psychotics, anti-ulcerants, cholesterol regulators and oral anti-diabetics. Source: IMS MIDAS, MAT 09 2012

This trend has been entirely driven by generics, providing increased access to affordable medicines

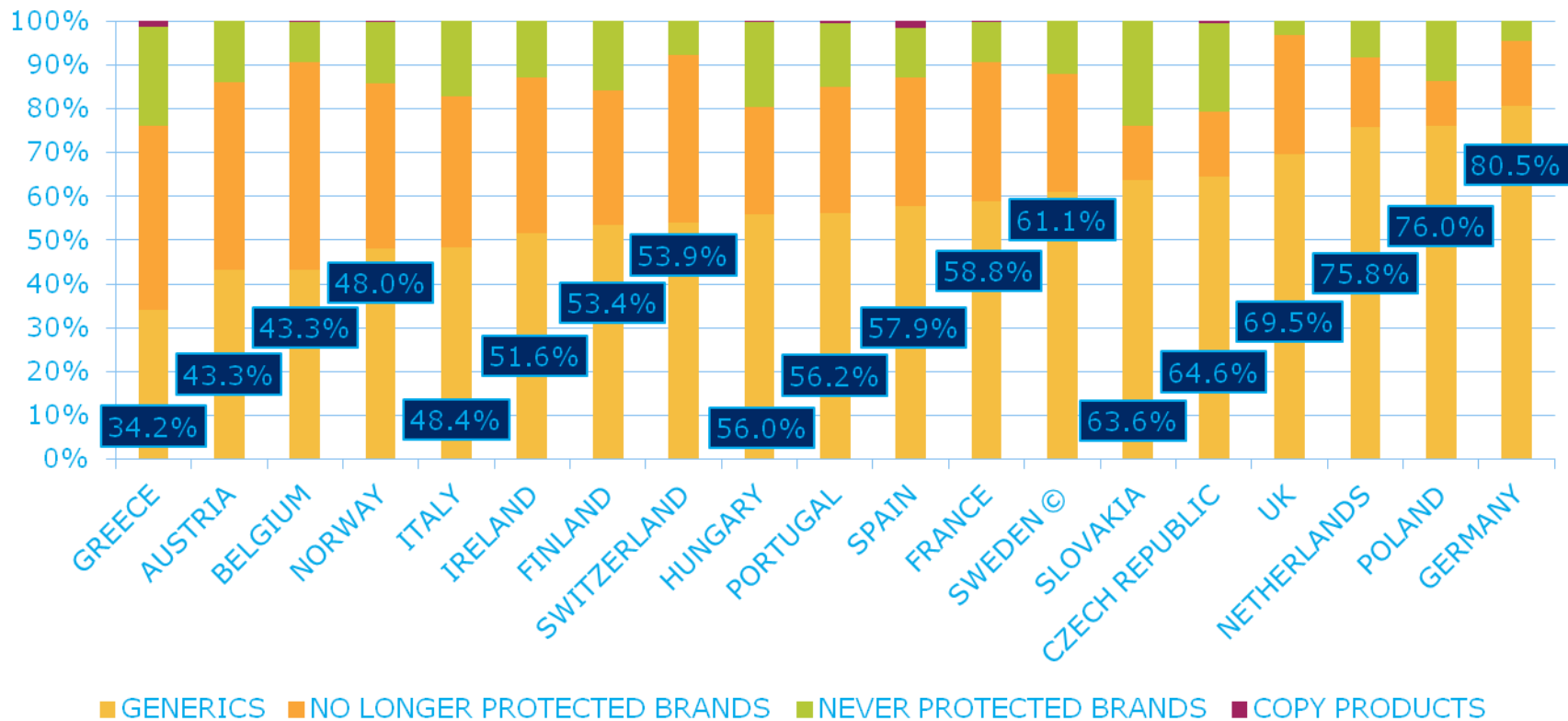
**EVOLUTION OF EUROPEAN NUMBER OF TREATMENT DAYS OF GENERICS VS. ORIGINAL BRANDS ACROSS 7 THERAPY AREAS**












Selected therapy areas: Angiotensin II antagonists, anti-depressants, anti-epileptics, anti-psychotics, anti-ulcerants, cholesterol regulators and oral anti-diabetics. Source: IMS MIDAS, MAT 09 2012

# Generic penetration differs greatly across Europe, ranging from 81% in Germany to 34% in Greece




Product type volume share of the Rx bound un-protected retail market, %, MAT Q2 2013 Ranked by Generic market share













# Prescriber freedom has declined in most markets - payers and pharmacists now make the decisions

IMS Research: Influence & power of stakeholder from 2008-2013							
		National Payers	Local Payers	Physician	Pharmacist	Patient Groups	KOLs
<b>US</b> 	Primary	↑↑	↑↑	↓↓	↔	↑	↑
	Specialty	↑↑	↑↑	↓	↔	↑	↑↑
<b>Canada</b> 	Primary	↑	↑	↓↓	↑	↑	↔
	Specialty	↑	↑	↓	↔	↔	↔
<b>UK</b> 	Primary	↑	↑	↑	↑	↔	↑
	Specialty	↑↑	↑↑	↔	↔	↑	↔
<b>France</b> 	Primary	↑	↑↑	↓	↑	↔	↓
	Specialty	↑	↑	↓	↔	↑	↓
<b>Germany</b> 	Primary	↑	↑↑	↓↓	↑	↑	↔
	Specialty	↑↑	↑	↔	↓	↑	↔
<b>Spain</b> 	Primary	↔	↑↑	↓↓	↑	↔	↑
	Specialty	↔	↑↑	↓	↑	↑	↔
<b>Italy</b> 	Primary	↔	↑↑	↓↓	↑	↔	↓
	Specialty	↑	↑	↓	↑↑	↑	↓
<b>Japan</b> 	Primary	↑	N A	↔	↑	↔	↔
	Specialty	↑		↑	↔	↑	↑
<b>Ireland</b> 	Primary	↑↑		↓↓	↑↑	↑	↓
	Specialty	↑↑	↑	↓	↑	↑	↔

**KEY**

 Increase
  Decrease
  Stay the same

# Implementation of value based evidence measures may be focused on a few countries but this is the future

Cost containment tools										
Promotional spending controls			✓		✓				✓	
Mandatory HTA				✓		✓			✓	✓
Generic substitution	✓	✓		✓	✓	✓	✓	✓		✓
Prescribing budgets / controls						✓			✓	
Patient contributions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
International price referencing		✓	✓	✓	✓		✓	✓		✓
Industry paybacks	✓				✓		✓	✓		
Mandatory price cuts		✓	✓	✓	✓	✓	✓	✓	✓	✓
Price controls		✓	✓	✓	✓		✓	✓		✓

Source: IMS Health Pharmaquery



# In Eastern Europe value based evidence is being used alongside an array of cost containment tools to control pharmaceutical expenditure

Country	Poland	Czech	Slovak	Romania	Bulgaria	Hungary	Croatia	Serbia	Slovenia	Russia
Price cuts/rebates	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Reference pricing systems	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
EU reference pricing systems	✓	✓	✓	✓	✓		✓	✓	✓	
Generic Product Preference	✓			✓	✓	✓	✓	✓	✓	
Reimbursement restrictions/delistings	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cuts in distribution margins	✓			✓	✓	✓	✓	✓	✓	
Patient contributions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Devolving responsibilities/prescribing budgets	✓	✓	✓			✓	✓	✓	✓	
Use of HTA	✓			✓	✓	✓				
Pharmacy chains buying power	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Risk Sharing agreements	✓					✓	✓			

 Exist in 2012
  New from 2013

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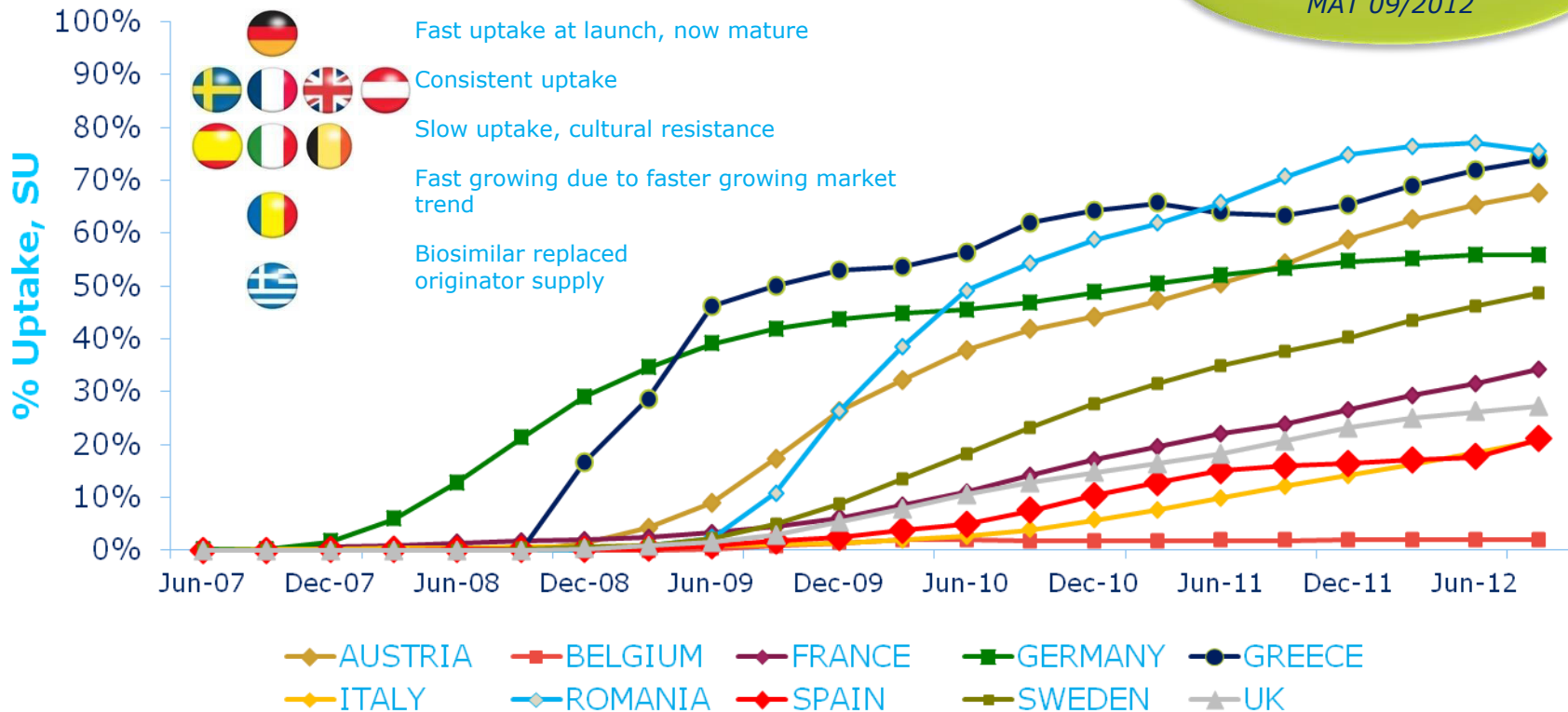
# In Europe, biosimilar uptake exhibits different rates

A few countries have reached or approaching the maturity stage

## Biosimilar uptake across Europe

MAT 06/2007 - 09/2012 (Volumes, SU)

Total 10 countries  
314M €  
MAT 09/2012

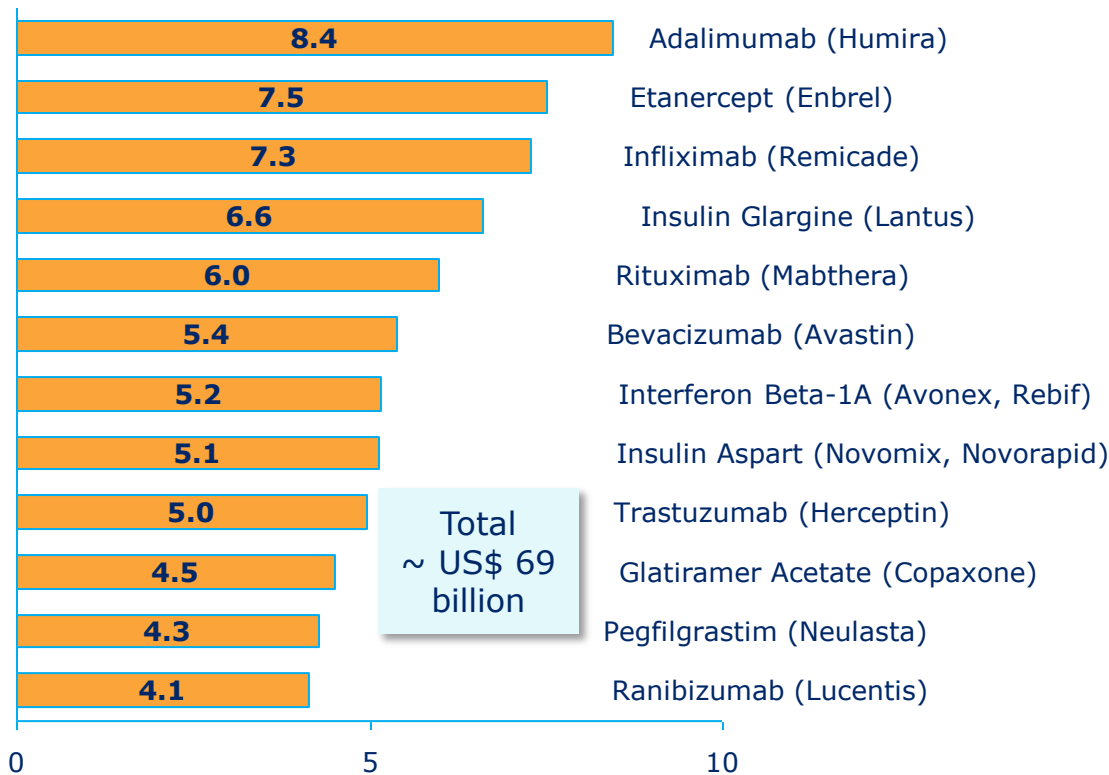


Source: IMS MIDAS, MAT 09/2012

# Twelve compounds represent \$69 billion revenues for originators

All these products will lose patent protection by 2020 except Enbrel

**Global Sales (MAT 12/2012), US\$ billion**



EU expiry date	US expiry date
2018	2016
2015	2028 (extended)
2015	2018
2014	2014
2013	2016
2019	2017
2012	Expired
2015	2015
2014	2019
2017	2015
2015	2014
2016	2016

*Not considered existing biosimilars such as Epoetin Alfa expired in EU, but still patent protected in US*

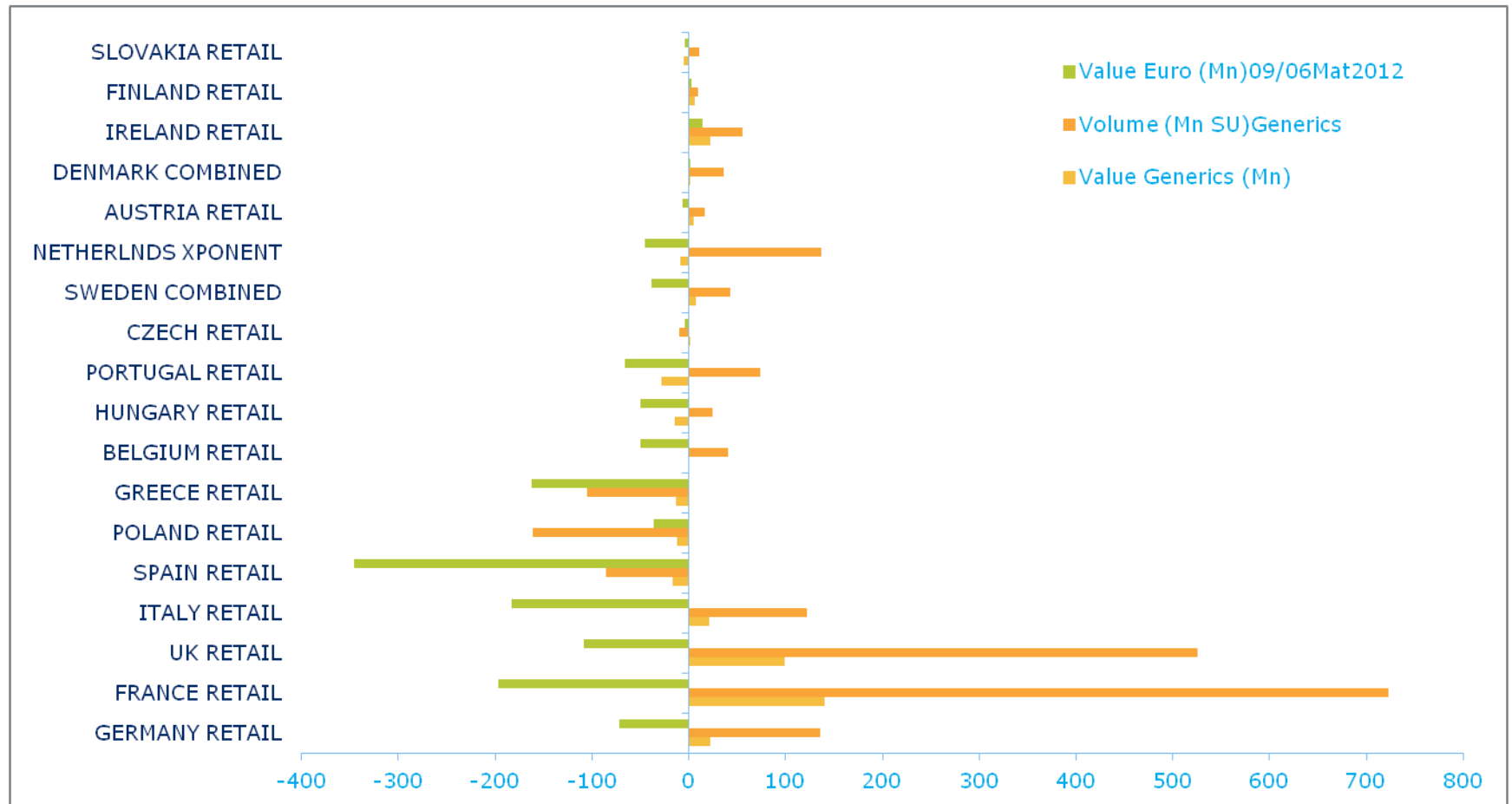
Source: IMS MIDAS, 12/2012, IMS Patent focus

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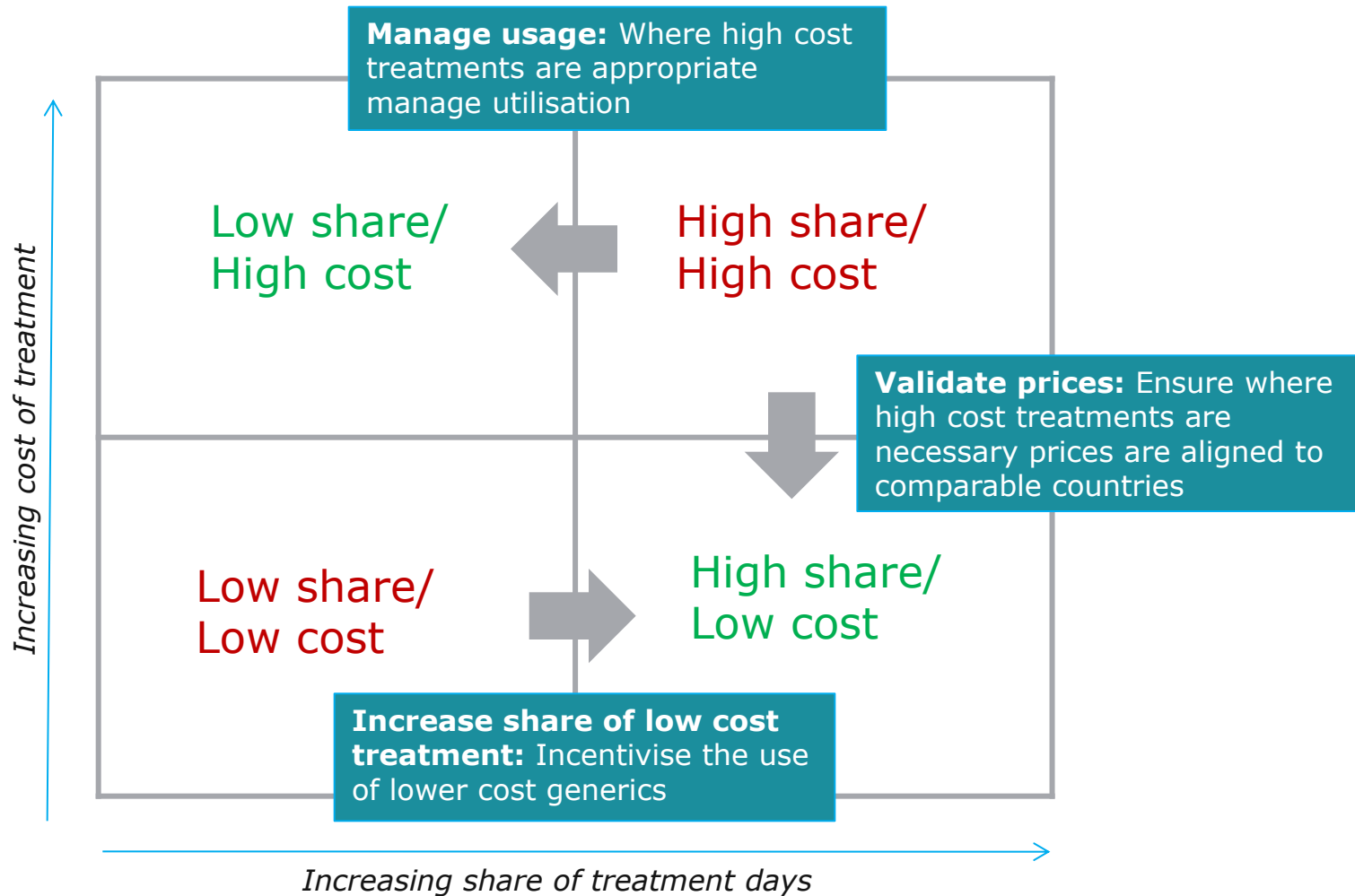
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# Austerity measures in Europe have had a significant impact on pharma sales with increasing generic usage in some countries, but at lower prices....in others all categories are down



Mat 09/12 compared to MAT 06/12

# In mature markets payers ensure effective mechanisms are in place to optimise mix/price to reduce cost



# The industry will have to continually adapt to the changing market place

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Prevention should always be the starting point

Compliance remains a challenge

Generic medicines represent gold standards

Earlier diagnosis and treatment initiation extends treatment periods

Value to payers and regulators is critical as drugs bill escalates

Government measures will hasten the penetration of generics and biosimilars

Price cuts continue to stifle growth

Demand for latest innovations in key therapy areas will increase, oncology will be the driver

Use of disease modifying drugs and biologicals in primary care indications will drive drug costs



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# Thank you

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