A robust generic market: difficulties and complexities

Athens, 6th March 2013

SARAH RICKWOOD, Director Thought Leadership, IMS HEALTH

Agenda slide

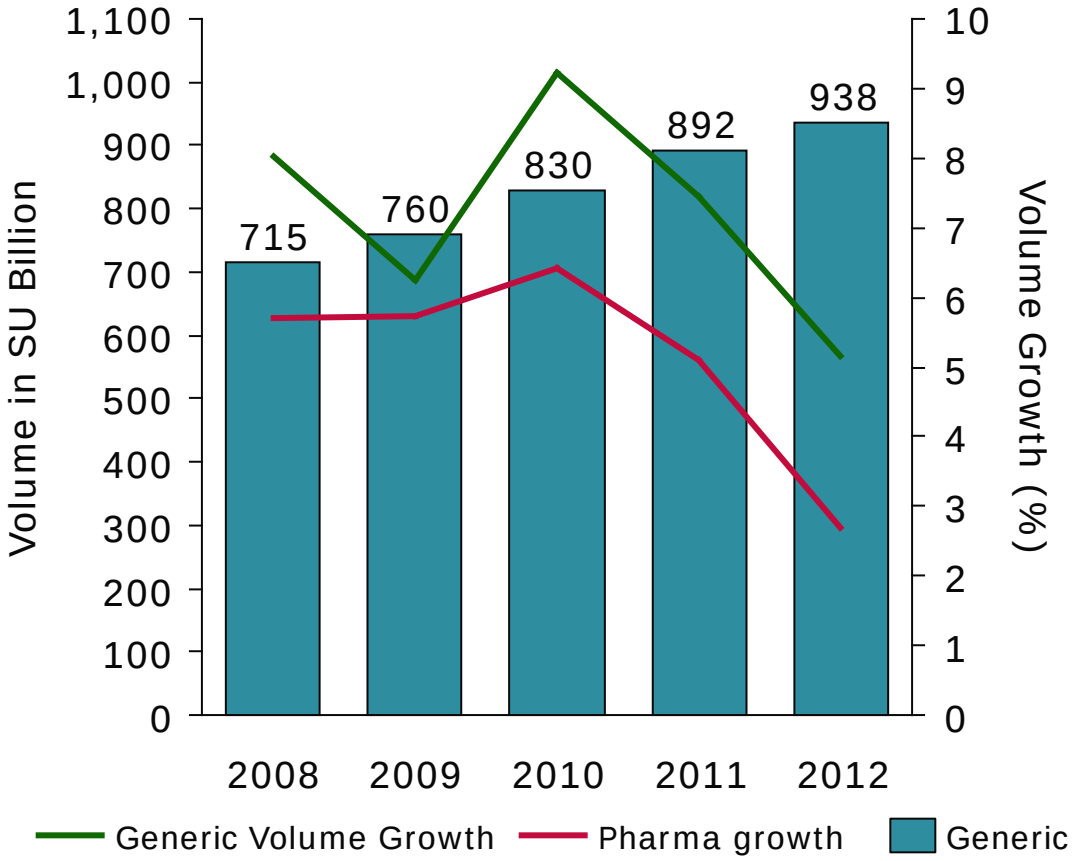
- **The Global Generics Market**
  - No Longer Protected Brands
  - Country Environment

- Key Factors for a Robust Generic medicines market
  - Net Cost of Treatment
  - Rules and Incentives: INN Prescribing Case Studies

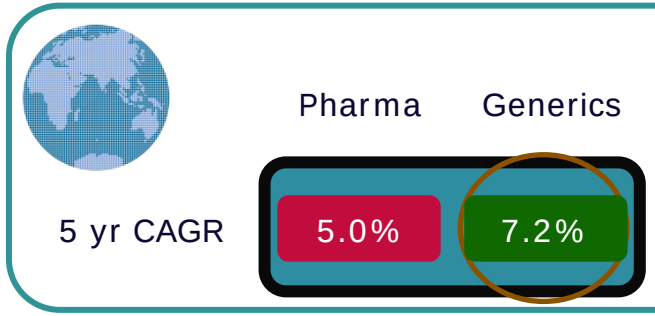
- The Future of Generics
  - Where growth will come from?
  - Biosimilars

Generics have seen superior growth performance for a number of years

2008-2012: Global Generic Volume Sales



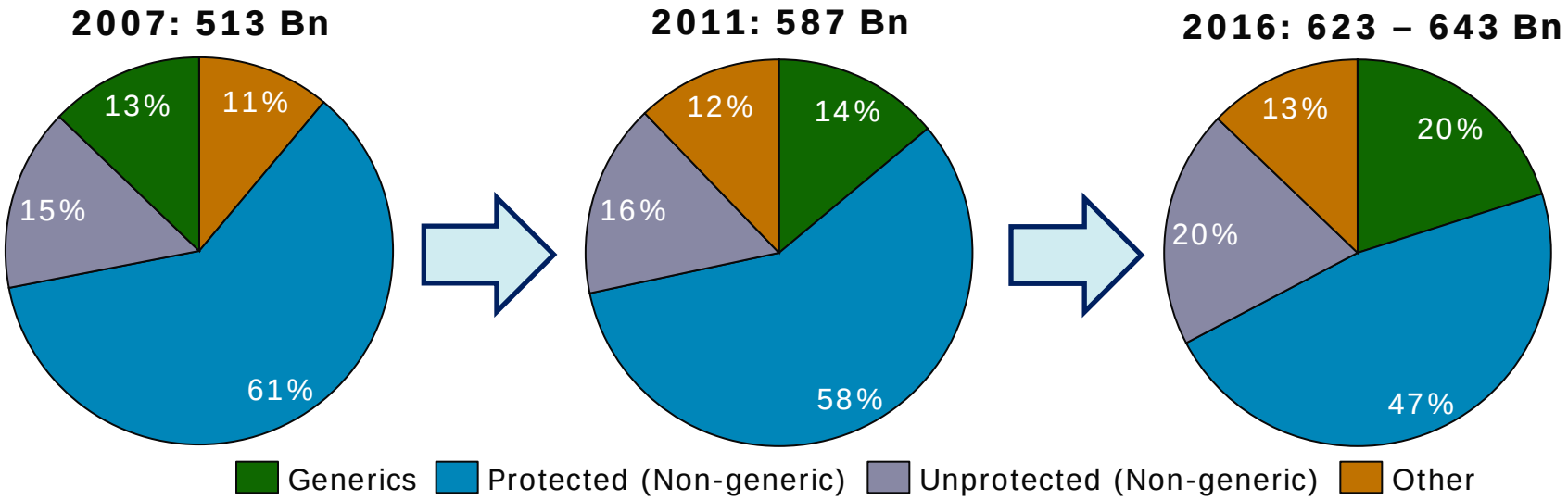
- Growth is driven by government that under high debt and fiscal deficits are pushing for even greater generication
- In Pharmerging countries growth is underpinned by generic growth
- Fewer, smaller small molecules going forward



Source: IMS Health, MIDAS, MAT Sept 2012, Rx only. Market Segmentation + LIC countries

Top 8 Mature

Accelerated shift in spending on generics is expected to continue to 2016 in the mature markets



- Globally, growth between 2012-2016 is forecast to slow to 3-6% CAGR compared to 6% over the past five years.
- Largest growth seen in Generics as a result of increased LOE, payer reforms and growth

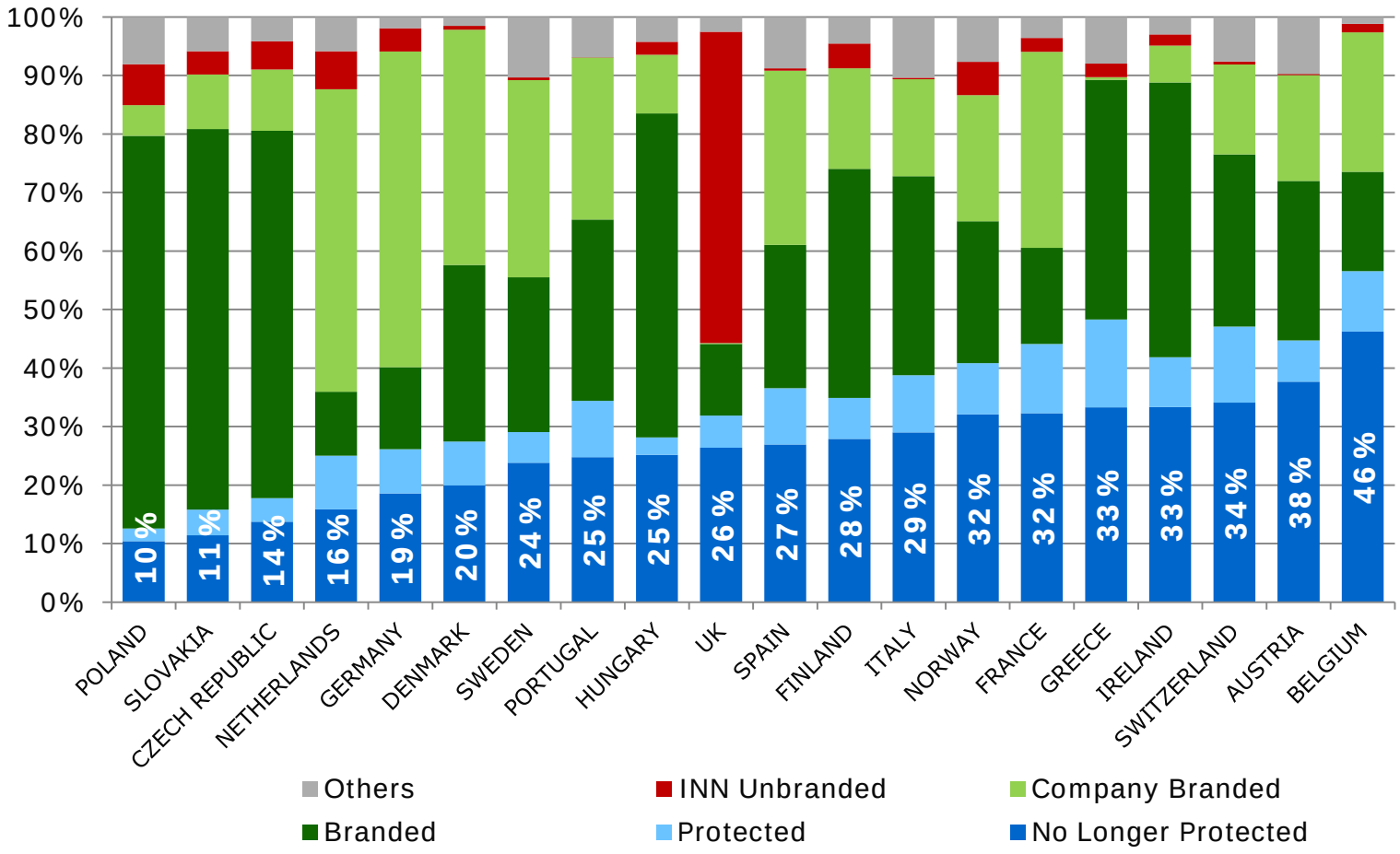
	5 Yr CAGR	
Region	2007 -2011	2012-2016
Top 8 Mature	4%	0 - 3%
Protected (Non-Generic)	3%	*(4) – (1)%*
Generics	*9%*	*8 – 11%*
Unprotected (Non-Generic)	*4%*	*4 – 7%*

Source: IMS Health Market Prognosis, Sept 2012 (*) at ex-manufacturer price levels, not including rebates and discounts. Audit data only. Market size represented in constant US$. All CAGR calculations are 5 years

ims

Each country shows a unique pattern of products in the protected and un-protected sector

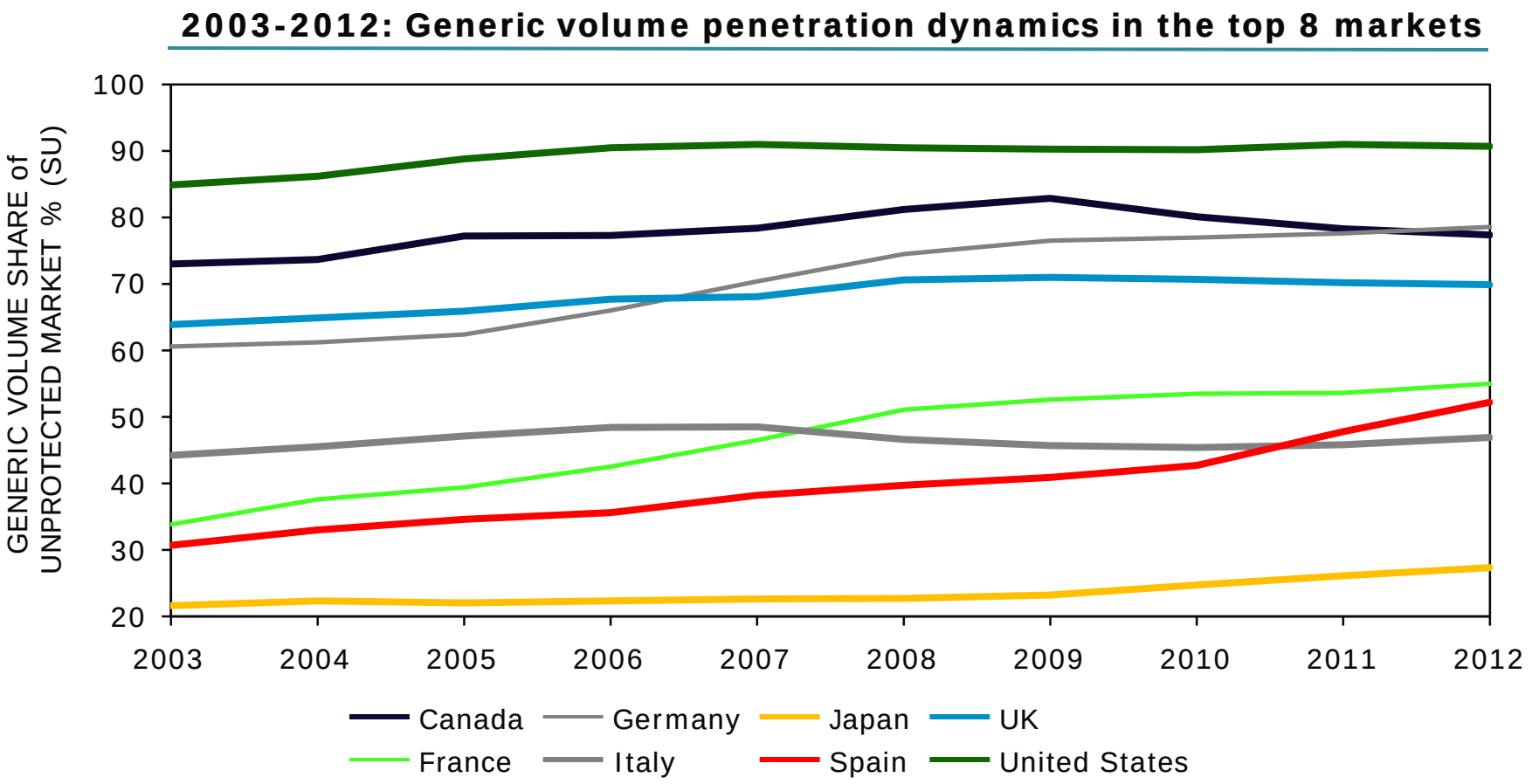
Market share segmentation ranked by no longer protected brands



Source: IMS Health, MIDAS, Market Segmentation, MAT Sep 2012, Rx only.

Top 8 Mature

Historically generic penetration moves slowly even in large markets: recently Spain has accelerated



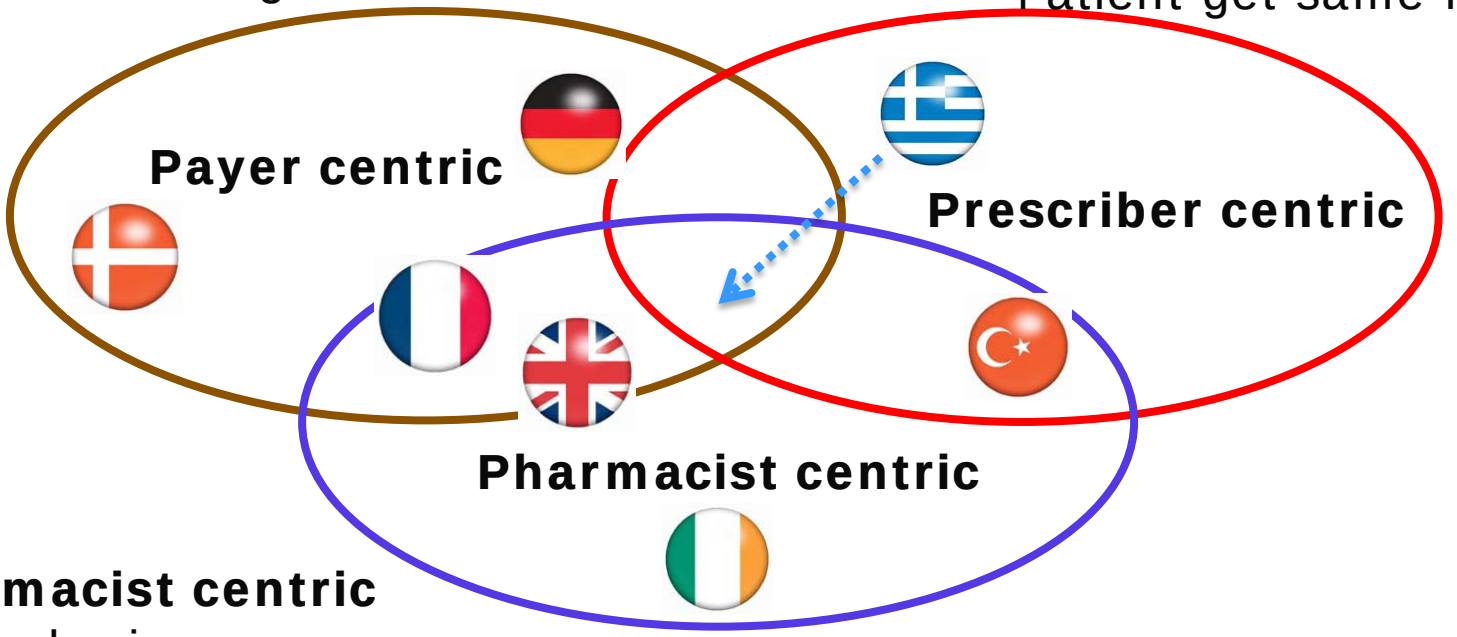
Source: IMS MIDAS Sep 2012 Ethical Total Market based on SU.

ims

We have several different models of generic systems

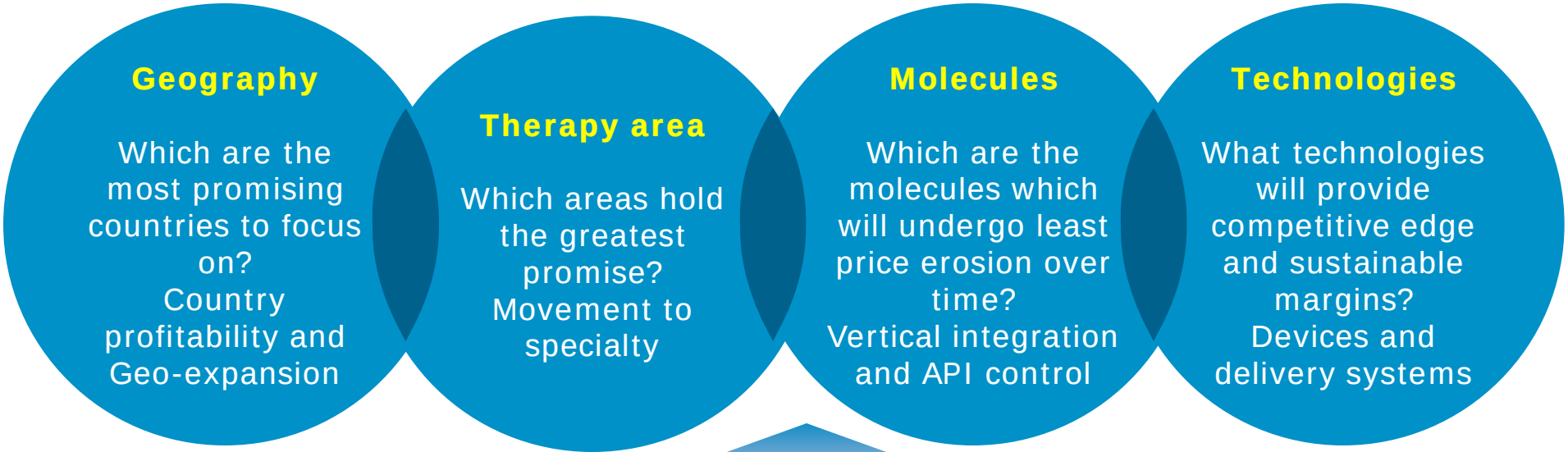
Payer centric
- Low prices
- Patient get different mfg
- Logistic challenges

Prescriber centric
- High prices
- No/low discounts
- Patient get same mfg



Pharmacist centric
- Varied prices
- High discounts
- Patient get same mfg

Generic companies are in a period of significant opportunity, but there are challenges



And not forgetting

Evolving structures, changing regulations, role of stakeholders and scope of new players in generics

ims

Agenda slide

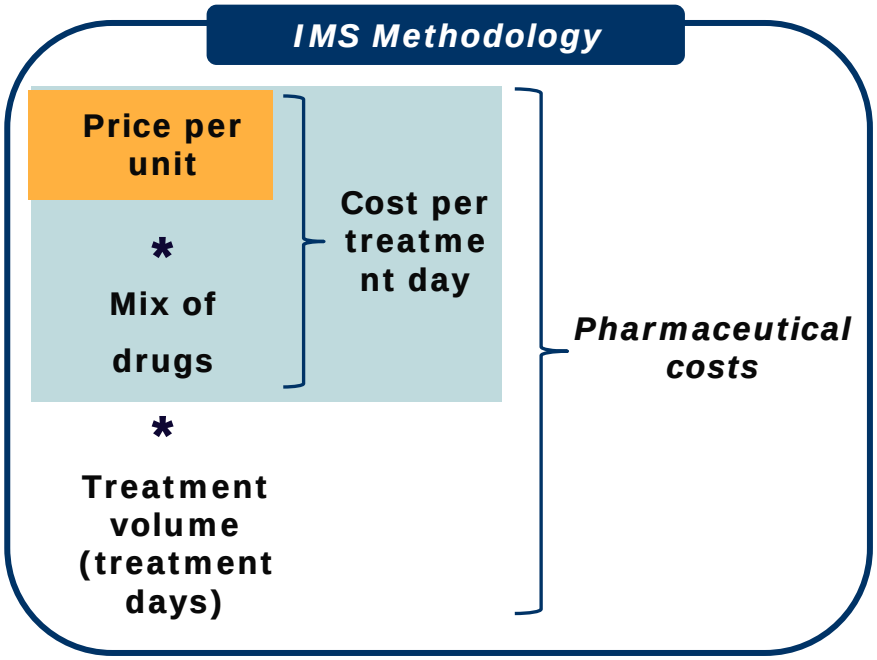
- The Global Generics Market
  - No Longer Protected Brands
  - Country Environment

- **Key Factors for a Robust Generic medicines market**
  - Net Cost of Treatment
  - Rules and Incentives: INN Prescribing Case Studies

- The Future of Generics
  - Where growth will come from?
  - Biosimilars

Payers tend to focus on price, however, medicine mix is key to cost reduction

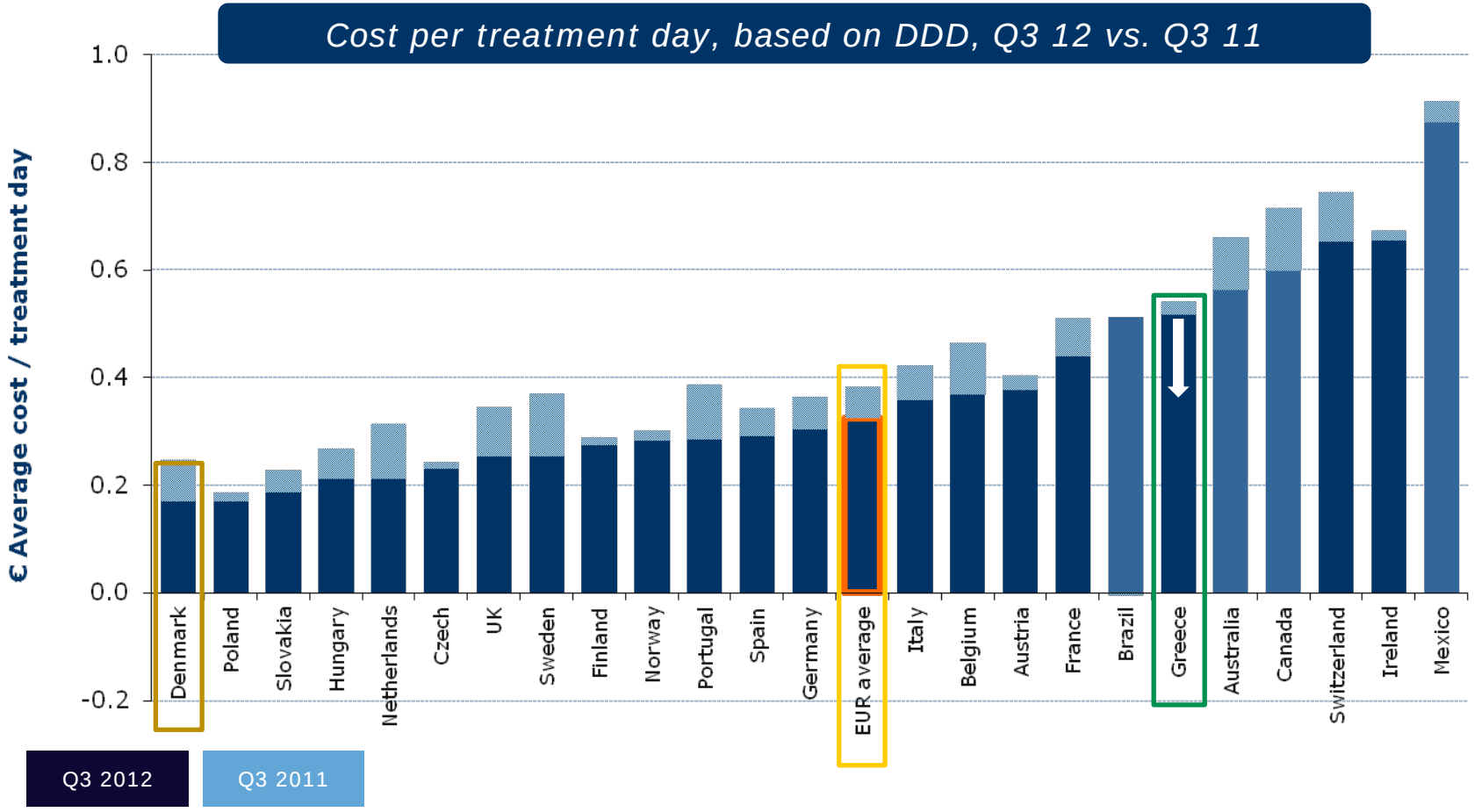
IMS developed a methodology to assess drug mix and prices across countries…



…based on a basket of medicines including seven therapy areas

- Angiotensin II antagonists, anti-depressants, anti-epileptics, anti-psychotics, anti-ulcerants, cholesterol regulators and oral anti-diabetics.
- The cost is calculated as each countries mix of patented/ NLP, and generic products
- The TA weights are the same for all countries

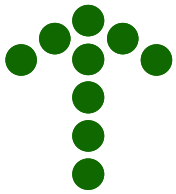
Greece has historically higher cost/daily dose than the EU average but recent reforms change this



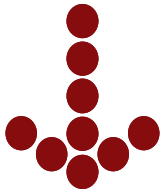
Selected therapy areas: Angiotensin II antagonists, anti-depressants, anti-epileptics, anti-psychotics, anti-ulcerants, cholestrol regulators and oral anti-diabetics. Source: IMS MIDAS, Q3 2012 and Q3 2011

Factors that have been shown to drive generic utilisation and factors that inhibit generic utilisation

Drivers



- Mandatory INN prescribing
- Generic first dispensing and prescribing
- Large price differential between generic and originator
- Reimbursement levels
- Patient Co-payments
- Incentives for dispensing/prescribing generics



Constraints

- Cultural resistance from doctors
- Lack of incentives for pharmacists to dispense
- Lack of margin for wholesalers to distribute
- Preference for brands in certain markets
- Across the board price cuts

In last years the Spanish healthcare environment has experienced continuous change driven by RDLs

The most crucial being the Royal Decree Law (RDL) 09/2011

RDL 04/2010

- Price reduction of generics
- Modification of the Reference Price System (RPS) – minimum price and gradual reduction

March 2010

RDL 08/2010

- 7.5% discount for reimbursed drugs
- Adaptation of the number of units per pack

May 2010

August 2011

RDL 16/2012

- Prescriptions general scheme
- Information systems to support the physicians prescription
- Delisting of drugs and sanitary products
- Reference Price System (RPS)
- Selected Prices System (SPS)
- Patients co-payment in outpatient pharmaceutical services

April 2012

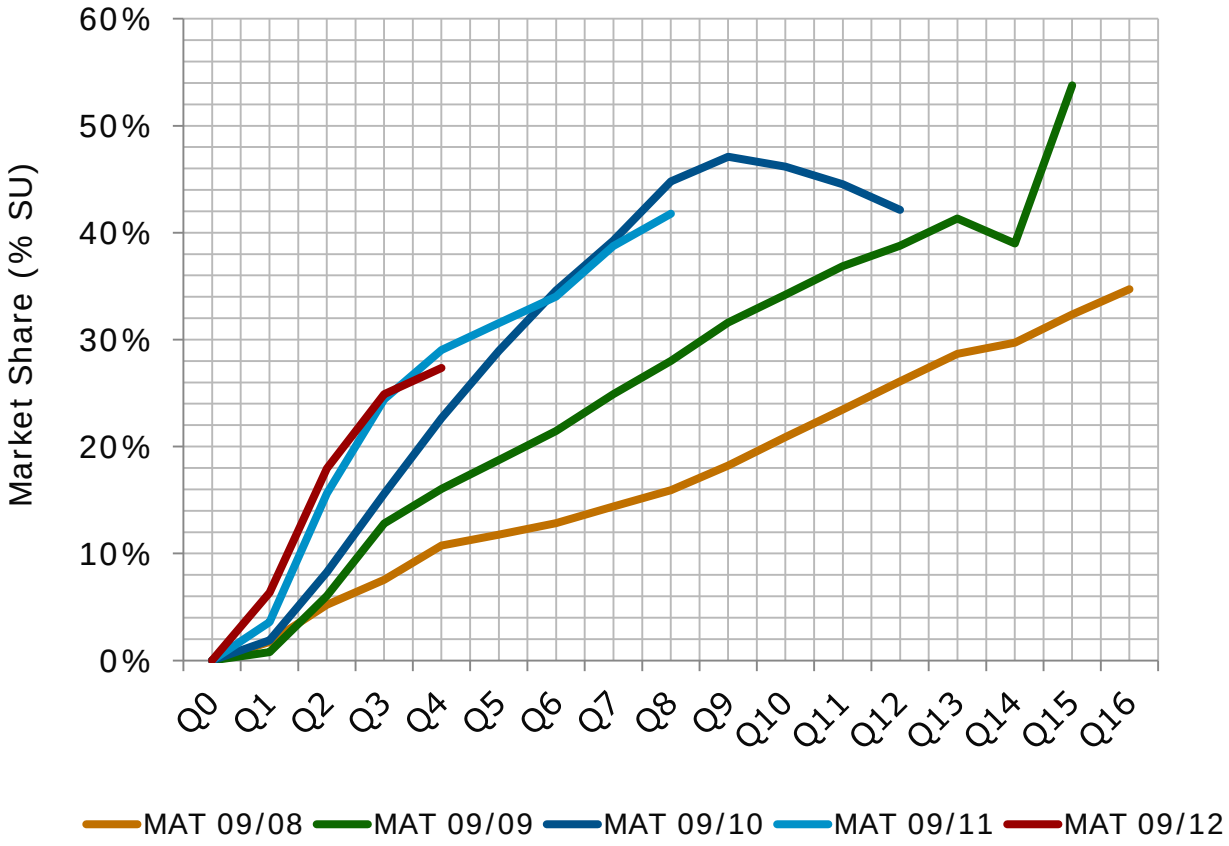
RDL 09/2011

- Elimination of the gradual price reduction in the RPS
- INN prescription (active ingredient)
- Extension of the 7.5% mandatory discount to 15% for non protected drugs with no generics or Biosimilars

Note: Main measures of each RDL (non exhaustive list)

Generics' penetration velocity has considerably increased during the last years

Comparison of generics' penetration evolution depending on generics' launch date (MS – % SU)



- Generics penetration at a molecule level is much more aggressive the more recent the generics' entrance.
- The yearly evolution of generics' penetration keeps an ascendant trend since 2008
- Despite the short historic available, molecules with generics entrance in the last MAT present higher generics penetration achieving a 37% MS the third quarter after the first generic launch.

Source: NPA: IMS Health analysis

Current model needs to change for generics to grow

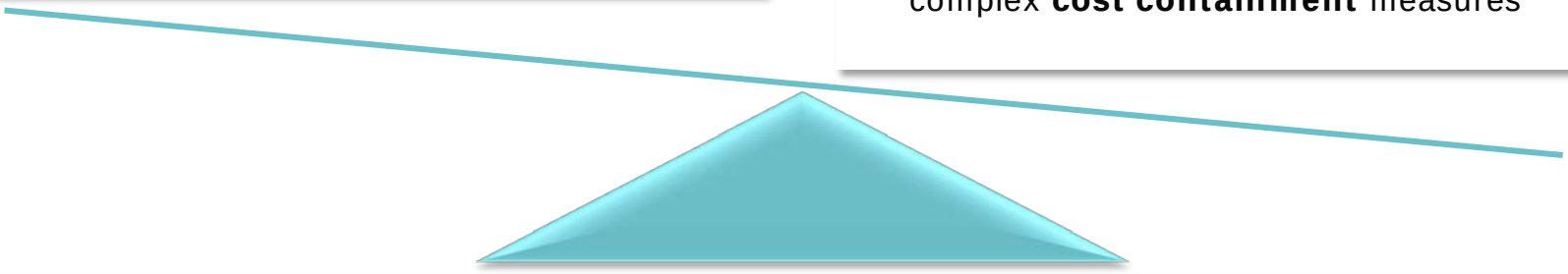
The potential for generics will rely on how key stakeholders and generic players shape the market

DRIVERS

- ✓ **Healthcare reforms** expanding access to the population with generics uptake benefiting in volume terms
- ✓ Introduction of **incentives** to increase generic prescribing and utilisation
- ✓ Incentives to the distribution system
- ✓ **Increasing penetration** in added value segments such as **specialist driven**; injectables; Biosimilars

CHALLENGES

- ✘ **Diminishing levels** of near term patent expiries and future revenue potential
- ✘ Increasingly competitive environment as **traditional branded pharma looks towards hybrid models** encroaching on the generic market space
- ✘ Delays in approvals and high regulatory costs
- ✘ Further scrutiny of pricing and margins as governments look towards ever more complex **cost containment** measures



ims

Agenda slide

- The Global Generics Market
  - No Longer Protected Brands
  - Country Environment

- Key Factors for a Robust Generic medicines market
  - Net Cost of Treatment
  - Rules and Incentives: INN Prescribing Case Studies

- **The Future of Generics**
  - Where growth will come from?
  - Biosimilars

Twelve of the world's top twenty products are small molecules that have or will genericise by 2016

Rank	Product / Company	2011 Sales (US$ Bn)
1	LIPITOR (Pfizer)	$12.5bn
2	PLAVIX (BMS / Sanofi)	$9.3bn
3	SERETIDE (GSK)	$8.7bn
4	CRESTOR (AZ)	$8.0bn
5	NEXIUM (AZ)	$7.9bn
6	SEROQUEL (AZ)	$7.6bn
7	HUMIRA (Abbott)	$7.3bn
8	ENBREL (Amgen)	$6.8bn
9	REMICADE (J&J)	$6.8bn
10	ABILIFY (BMS/Otsuka)	$6.3bn

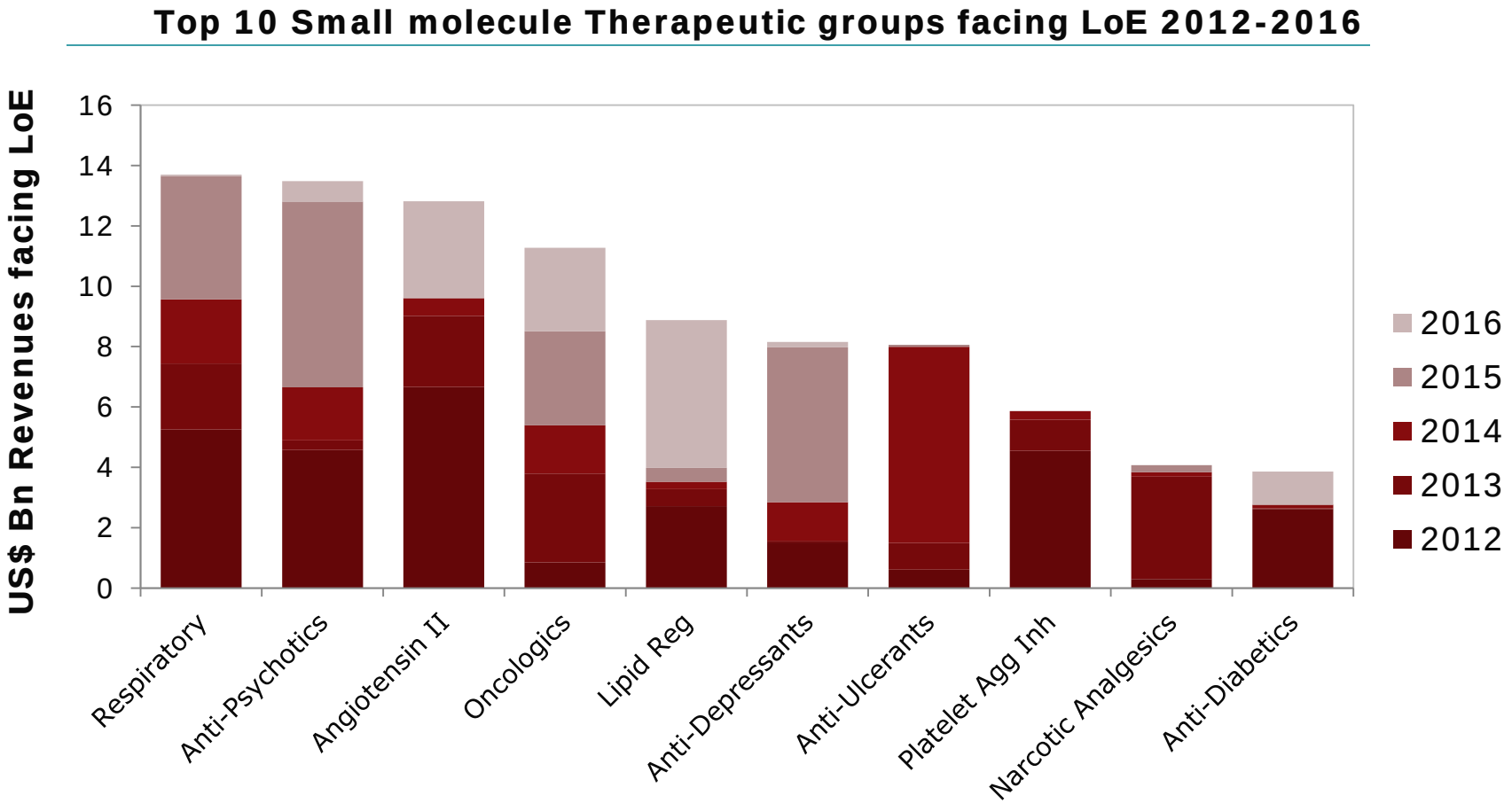
Rank	Product / Company	2011 Sales (US$ Bn)
11	SINGULAIR (MSD)	$6.1bn
12	ZYPREXA (Lilly)	$5.7bn
13	MABTHERA (Roche)	$5.7bn
14	LANTUS (Sanofi)	$5.5bn
15	AVASTIN (Roche)	$5.4bn
16	HERCEPTIN (Roche)	$4.8bn
17	CYMBALTA (Lilly)	$4.7bn
18	SPIRIVA (BI)	$4.7bn
19	NEULASTA (Amgen)	$4.2bn
20	GLIVEC (Novartis)	$4.1bn

Products off-patent or going off-patent by 2016

Source: IMS Health MIDAS, December 2011

ims

Generic players will see some new potential from select therapeutic areas

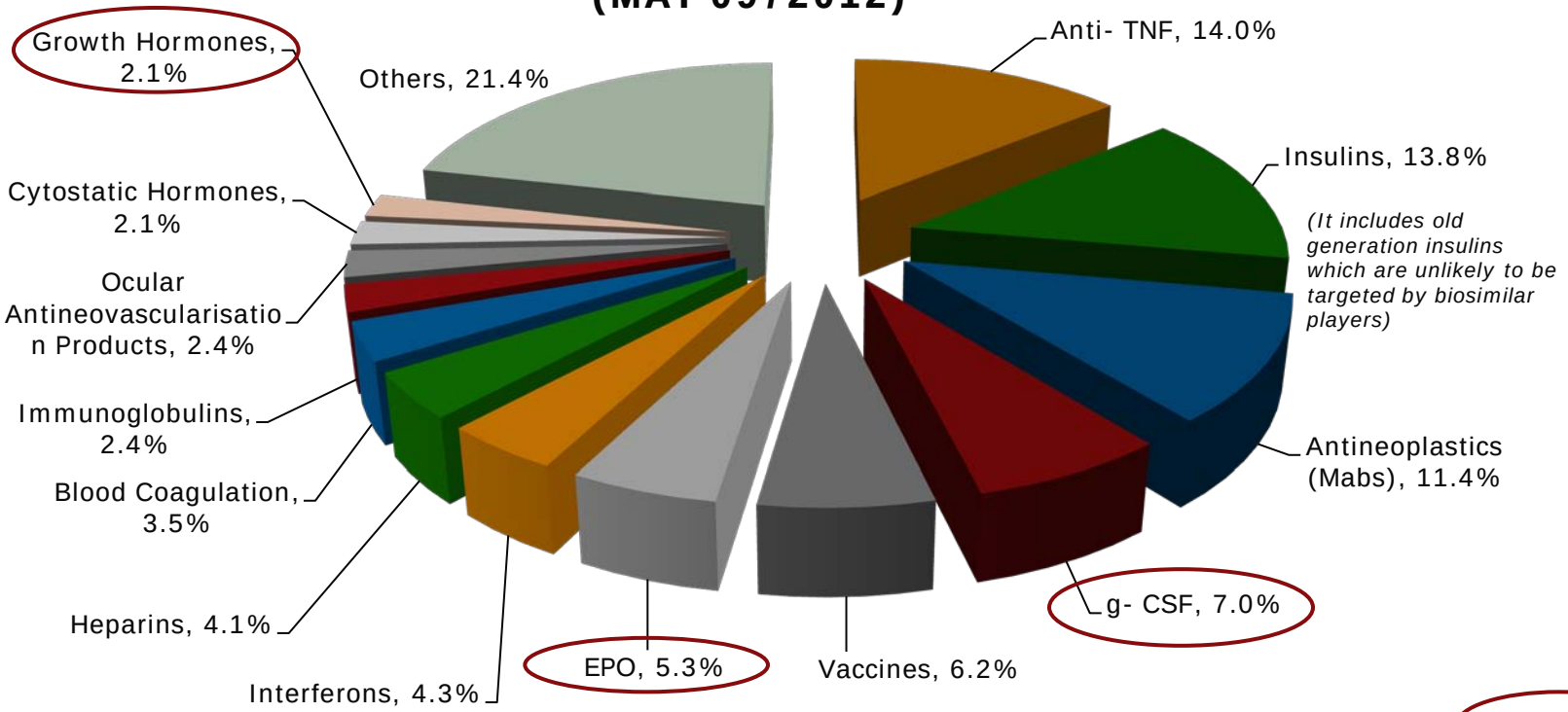


Source: IMS MIDAS Q3 2012. Based on ethical market. Revenues based on MAT 9/2012

For Biosimilars, anti-TNF and MAbs are the key ones

Along with insulins, another key investment area for biosimilar players, they account for more than 40% of the overall biologic market

Top Biologic Therapy Area, Global Sales (MAT 09/2012)

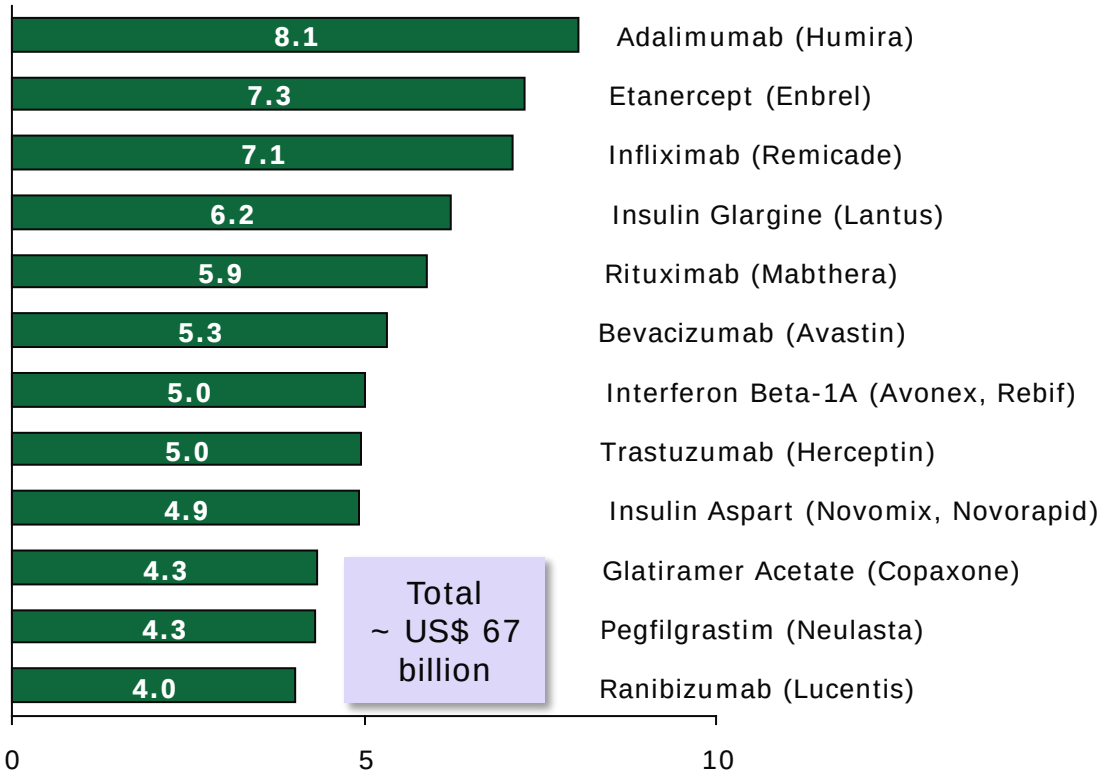


Source: IMS MIDAS, 09/2012

Twelve compounds will present a US$ 67 billion opportunity

All these products will lose patent protection by 2020, but Enbrel whose US patent has been extended until 2028

Global Sales (MAT 09/2012), US$ billion



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

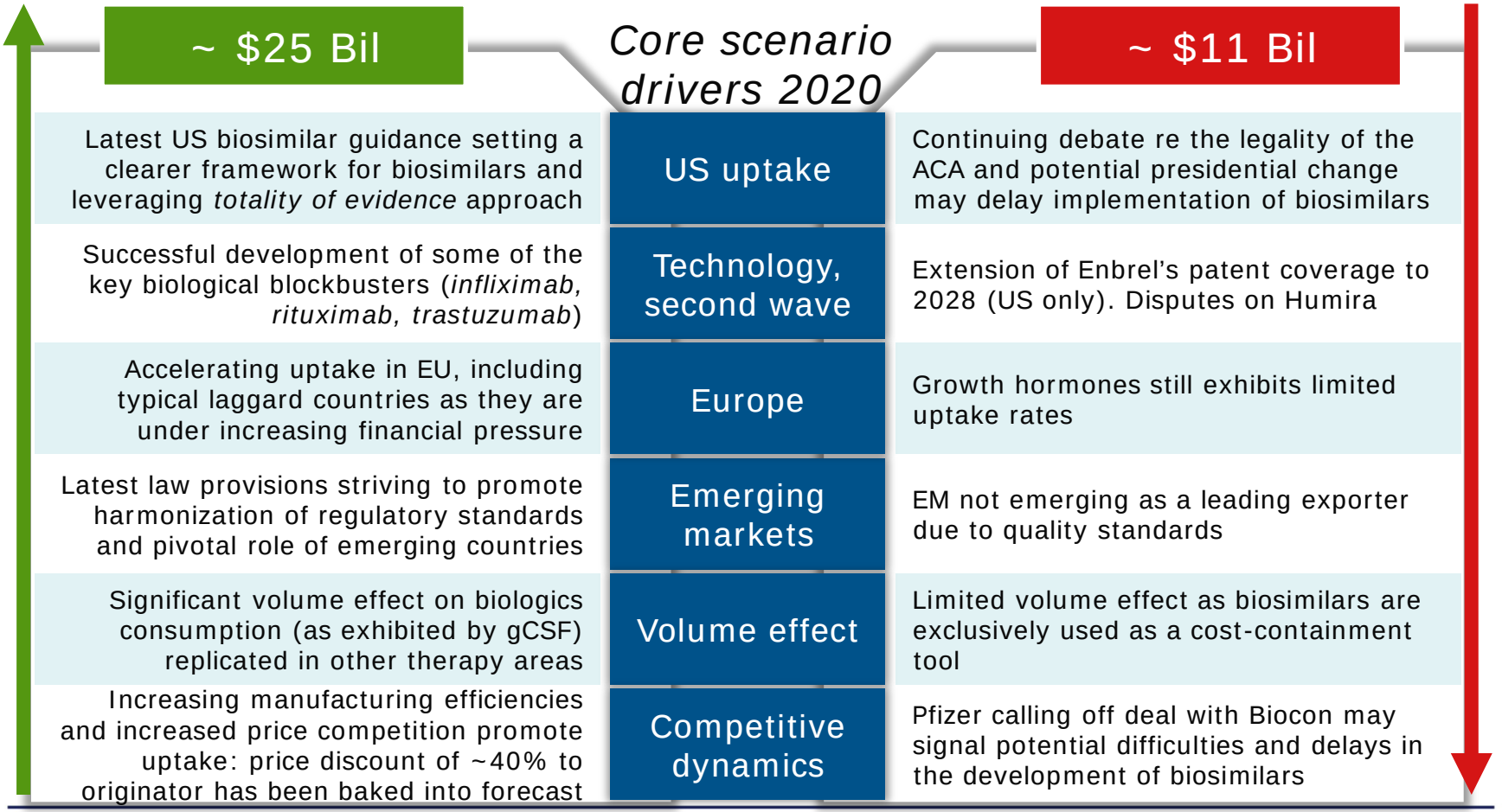
Not considered existing biosimilars such as Epoetin Alfa expired in EU, but still patent protected in US

Source: IMS MIDAS, 09/2012, IMS Patent focus

ims

Multiple factors will determine success or failure for biosimilars

The verdict on the new wave of biosimilars will act as a cornerstone for this market



10 things to consider for generics

1. More commoditization in Generics
2. Fewer, smaller small molecule opportunities going forward
3. More specialist small molecule opportunities
4. Success lies in moving up the value chain
5. The Quality of Innovation in value add is improving
6. Incremental improvements in innovation need strong case
7. Price pressure creates margin challenges
8. Countries favour local generics opportunities
9. Health care reform and more government involvement
10. Delisting and reimbursement changes impact

Thank you!

IMS Health