



QuintilesIMS™

European biosimilar and generics developments IHF Bucharest

Sarah Rickwood- VP, QuintilesIMS, European Thought Leadership

Agenda

- **The European prognosis to 2021**
 - Market forecasts
 - The importance of specialty

- The generic to biosimilar pivot
 - Generic market dynamics
 - Biosimilar uptake in Europe

Five year prognosis is very low growth

European sales and market growth forecast			
2016	2021 forecast	2011-2016 CAGR	2016-2021 CAGR
US\$ 213 Bn	US\$ 248 Bn	3.1%	2-5% [3.1%]

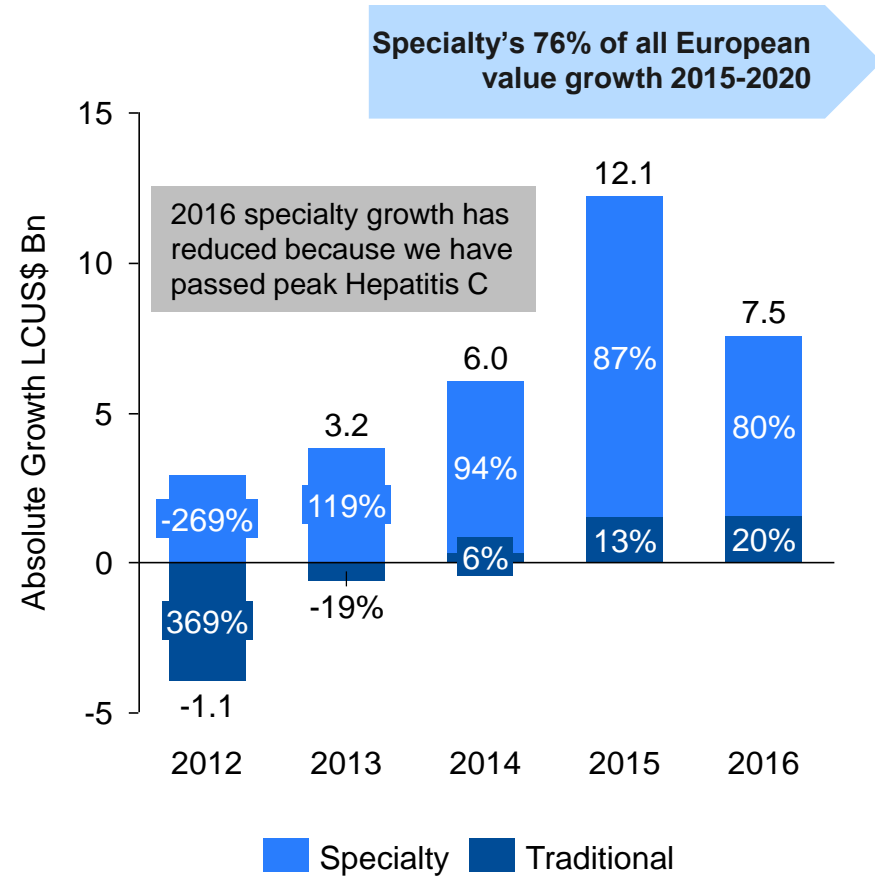
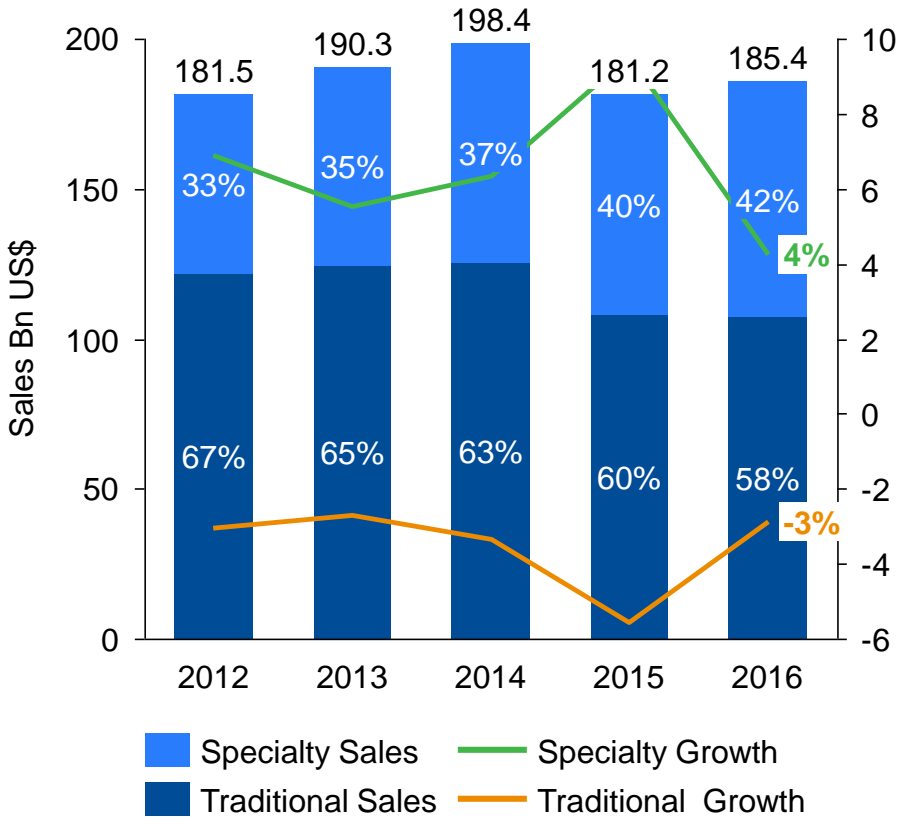
Key factors:

- Recent spike in growth as a result of uptake of HepC treatments in Italy/Spain, will return to more moderate levels as bulk of priority patients have been treated.
- BREXIT will only take place towards end of forecast period limiting short-to-medium term impact on pharma (neutral-negative)
- Macro-economic environment not likely to improve for Europe; budget management will become more **effective, selective, innovative and internationally collaborative**
- Over \$10Bn of biologics sales open to biosimilars: **this will drive real impact in autoimmune**, with oncology and insulins affected later

Value growth in Europe is driven by specialty

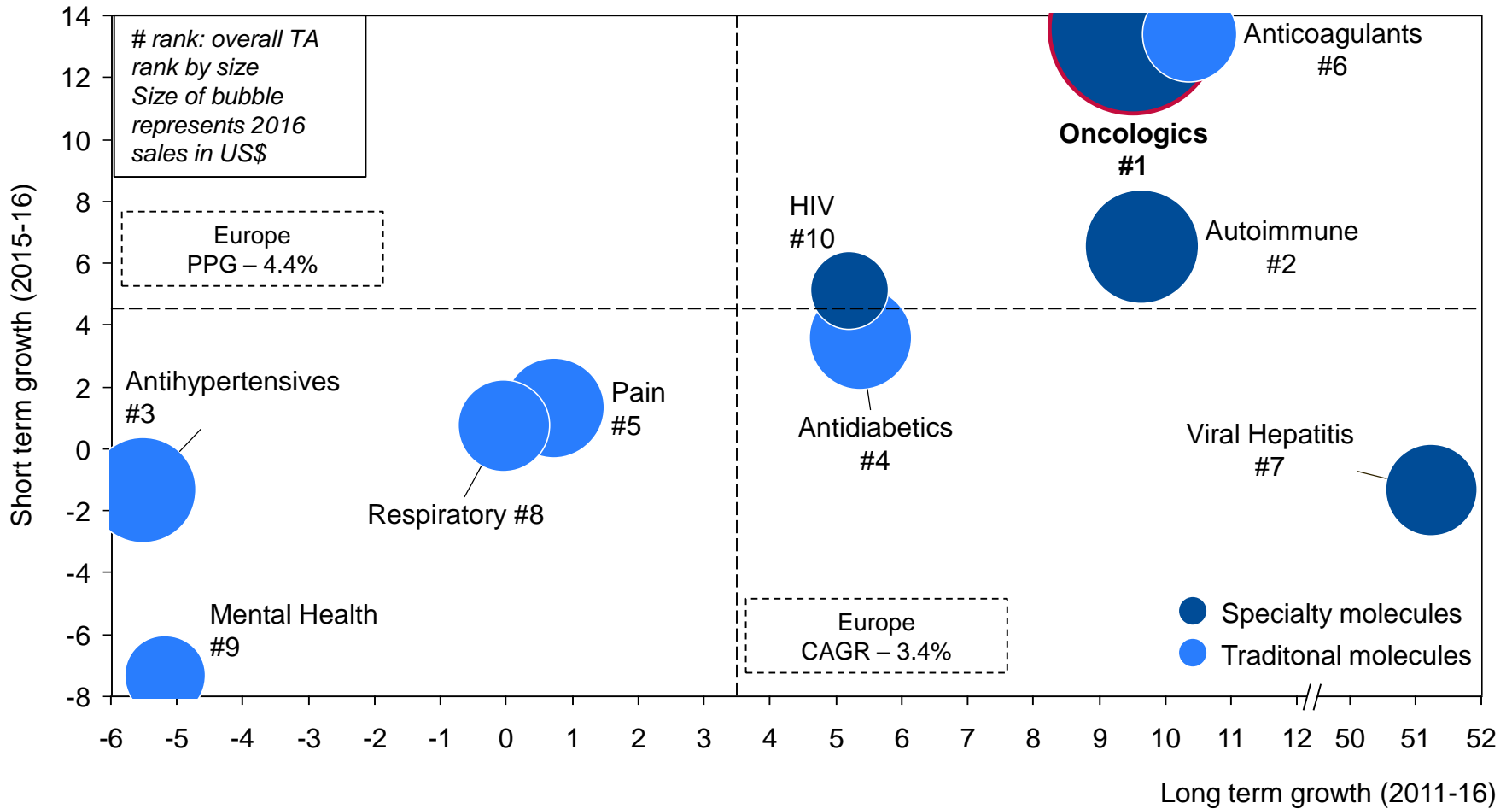
Specialty now 42% of European value much higher than the USA or global

Specialty has, and continues to be, the main contributor to European value growth



Oncology is the major growth driver in Europe

Europe: Top 10 Therapy Area Growth Dynamics

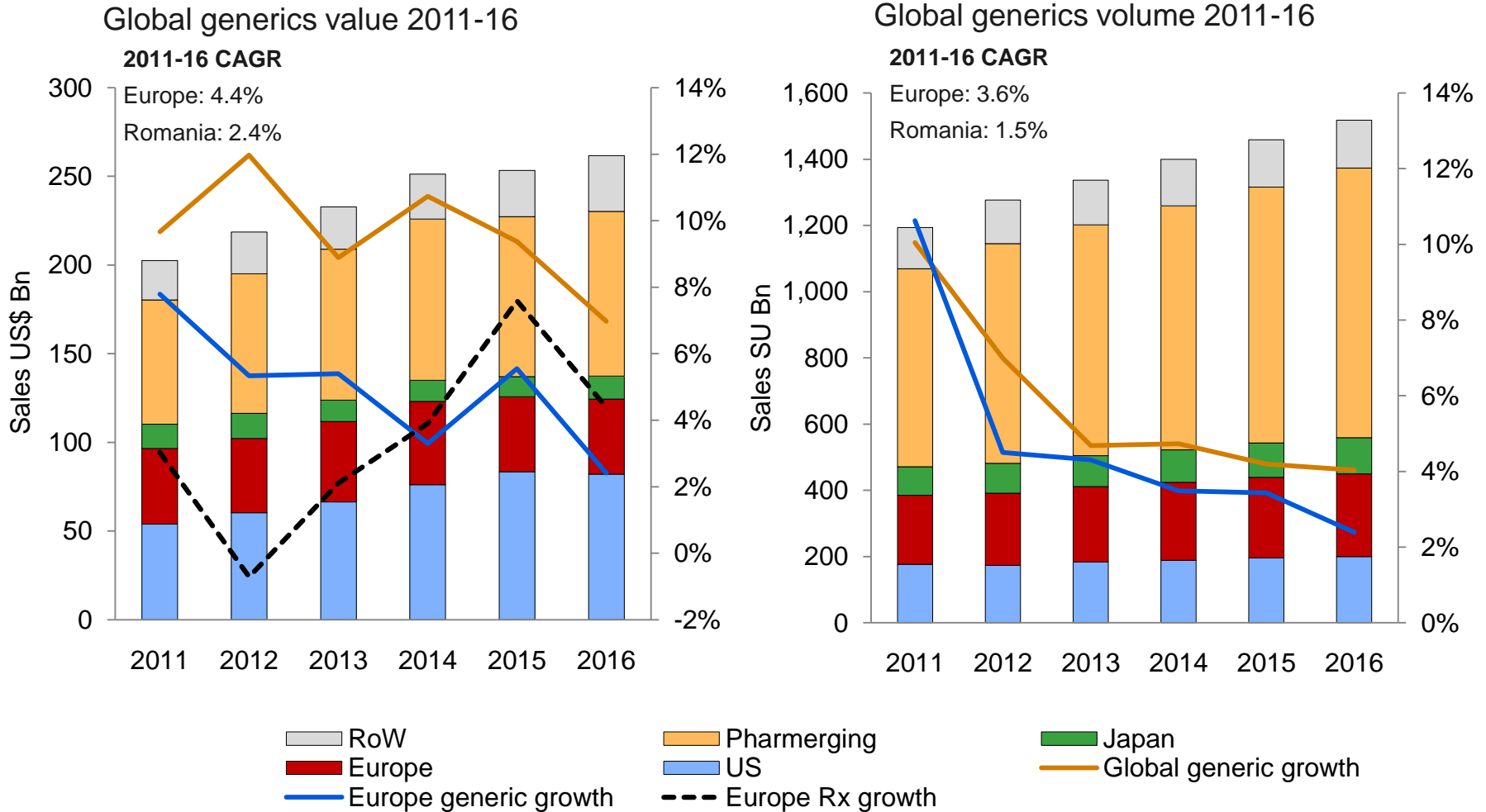


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Fall in European generic market growth



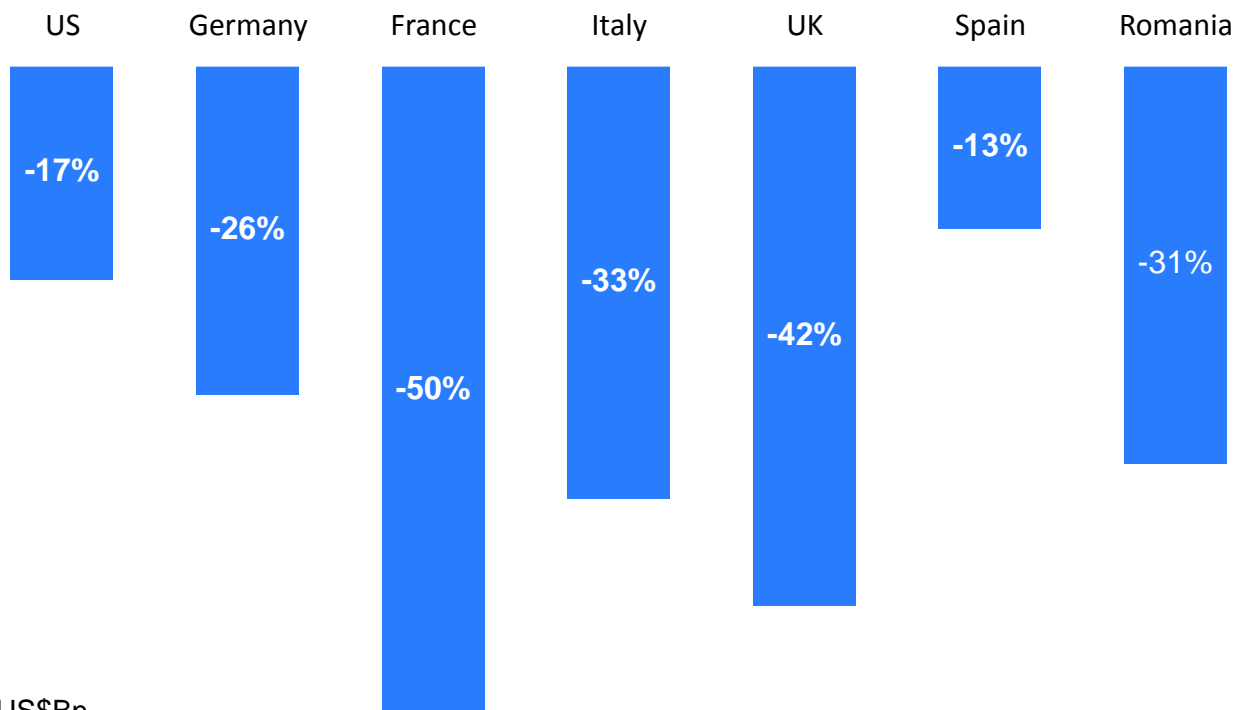
In developed markets the most evident shift is to unbranded generics

While the focus in pharmerging markets remains branded GX

	Generic sales 2016 (\$ bn)	2016 Value MS		*CAGR 2011-16	
		Branded generics	Unbranded generics	Branded generics	Unbranded generics
US	97.4	36%	64%	10%	8%
China	43.6	70%	30%	12%	17%
Japan	14.8	52%	48%	-1%	16%
Brazil	12.5	50%	50%	14%	21%
India	11.9	96%	4%	12%	9%
Germany	10.1	43%	57%	4%	4%
France	8.7	36%	64%	3%	6%
UK	7.0	33%	67%	9%	7%
Italy	6.5	63%	37%	3%	10%
Korea	5.1	89%	11%	3%	-1%
Canada	4.8	22%	78%	4%	1%
Spain	4.6	45%	55%	1%	6%
Rank 39 Romania	0.8	72%	28%	2%	1%

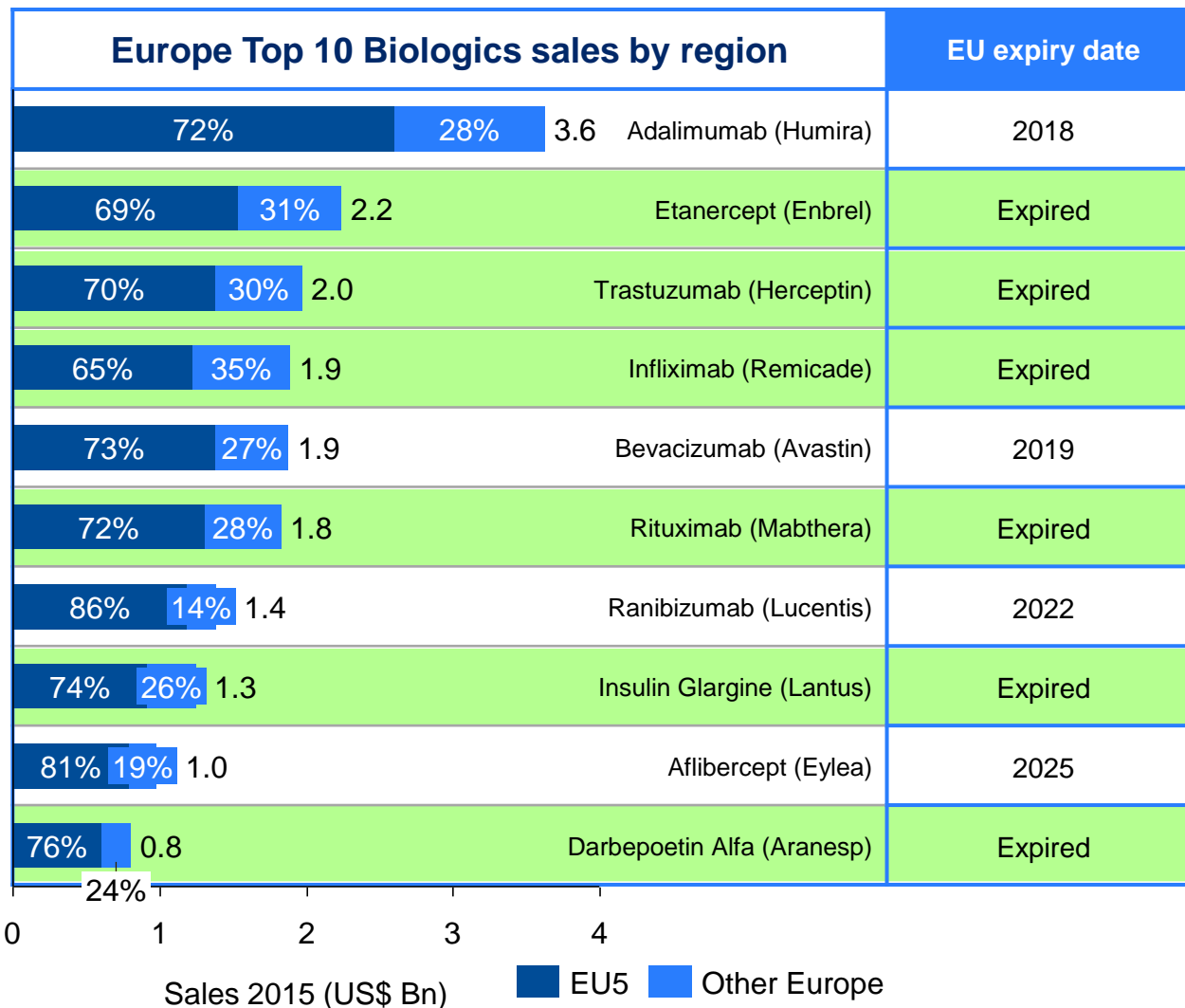
LoE opportunity will decrease moving forwards

2010-2015	96.9	6.9	7.8	5.1	4.5	3.7	0.38
2016-2021	80.7	5.1	3.9	3.4	2.6	3.2	0.26



LoE Exposure Cost US\$Bn
 % Change in Spending Exposed to LoE 2016-2021 vs. 2010-2015

Over half the top biologics have lost protection in Europe



Biosimilar delay factors:

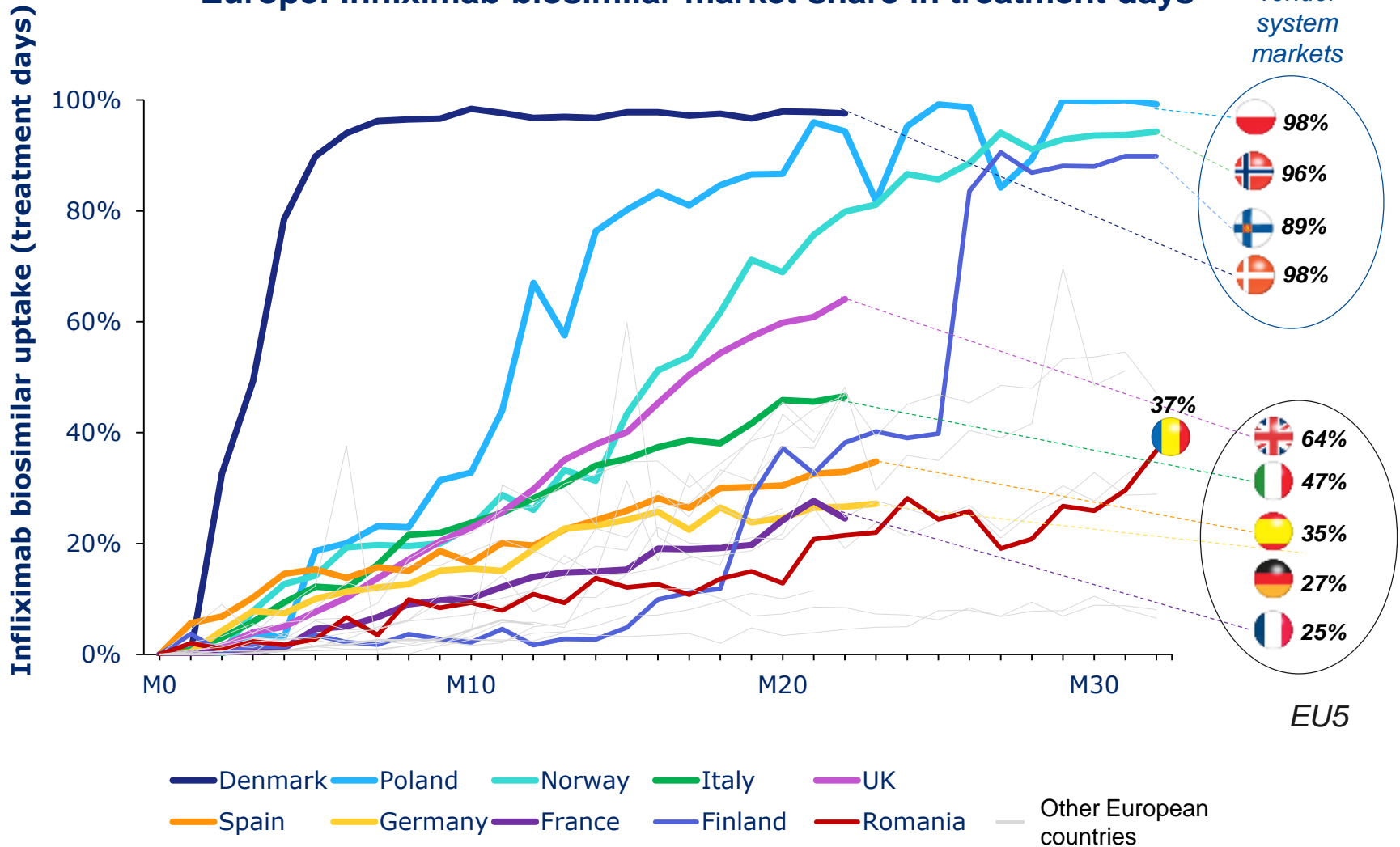
- Cost
- Complexity in development
- Patent Uncertainty, Europe wide/local
- Regulatory difficulties and uncertainties

Molecule no longer protected



EU5 countries show rapid uptake, UK moving up to 64%

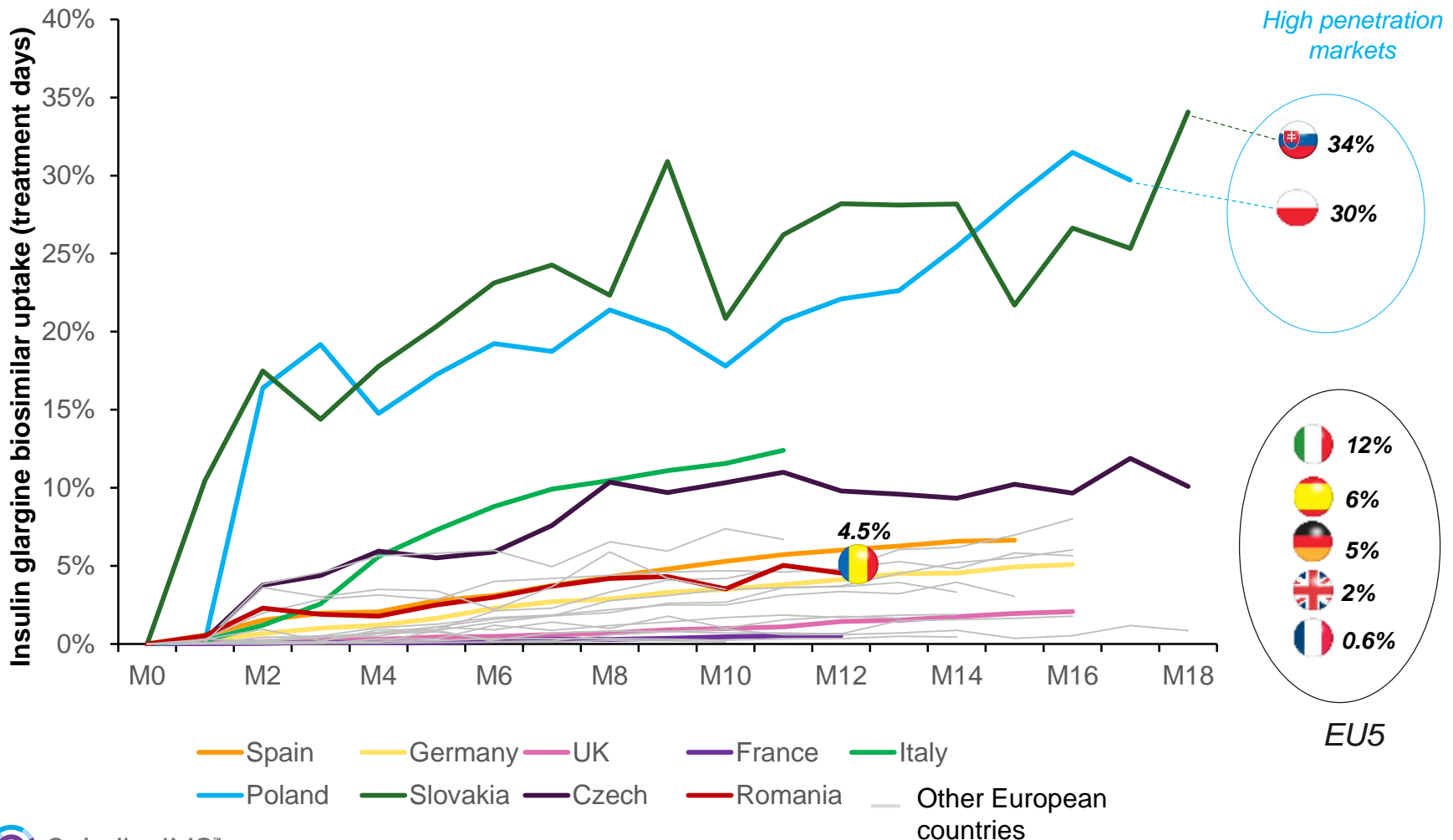
Europe: Infliximab biosimilar market share in treatment days





Insulin biosimilars maintain low penetration in EU5 countries

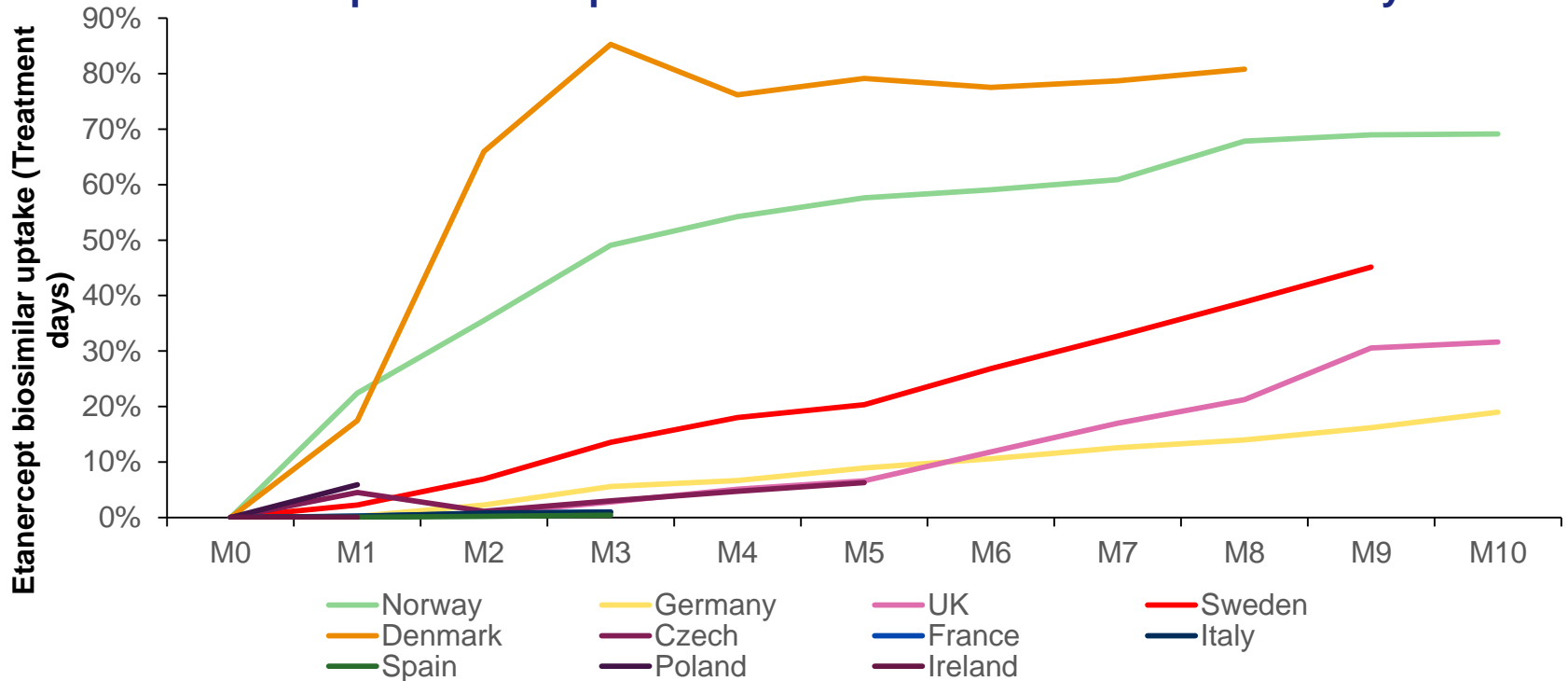
Europe: Insulin glargine biosimilar market share in treatment days





Etanercept uptake has been on par with Infliximab, slightly faster in the high uptake countries

Europe: Etanercept biosimilar market share in treatment days



Biosimilar share	Denmark	Norway	Sweden	Germany	UK	Czech	France	Italy	Spain	Poland	Ireland
	80.8%	69.1%	45.1%	19.0%	31.6%	6.3%	1.0%	1.0%	0.4%	5.9%	0.04%

Conclusions



- The USA will continue be critical for all players, Europe sees lower growth because of continued austerity and budget challenge
- Stark split between the specialty driven high value low volume growth of the developed world and high volume primary care growth of emerging markets
- Small molecule generics see declining developed world prospects; opportunities shift to biosimilars where savings to healthcare systems present a huge opportunity