

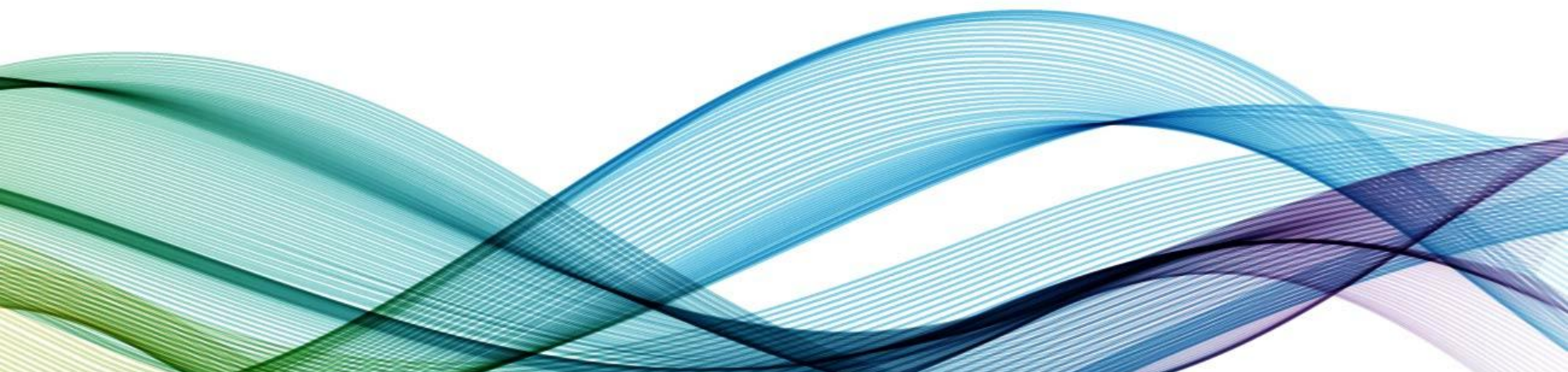


QuintilesIMS™

# Global and local Pharma distribution - trends and challenges

Klaus Perera, Senior Principal, Global Supply

QuintilesIMS



# Topics

**Global forecasts and regional growth trends**

The payers response to innovation

“The wholesaler dilemma”

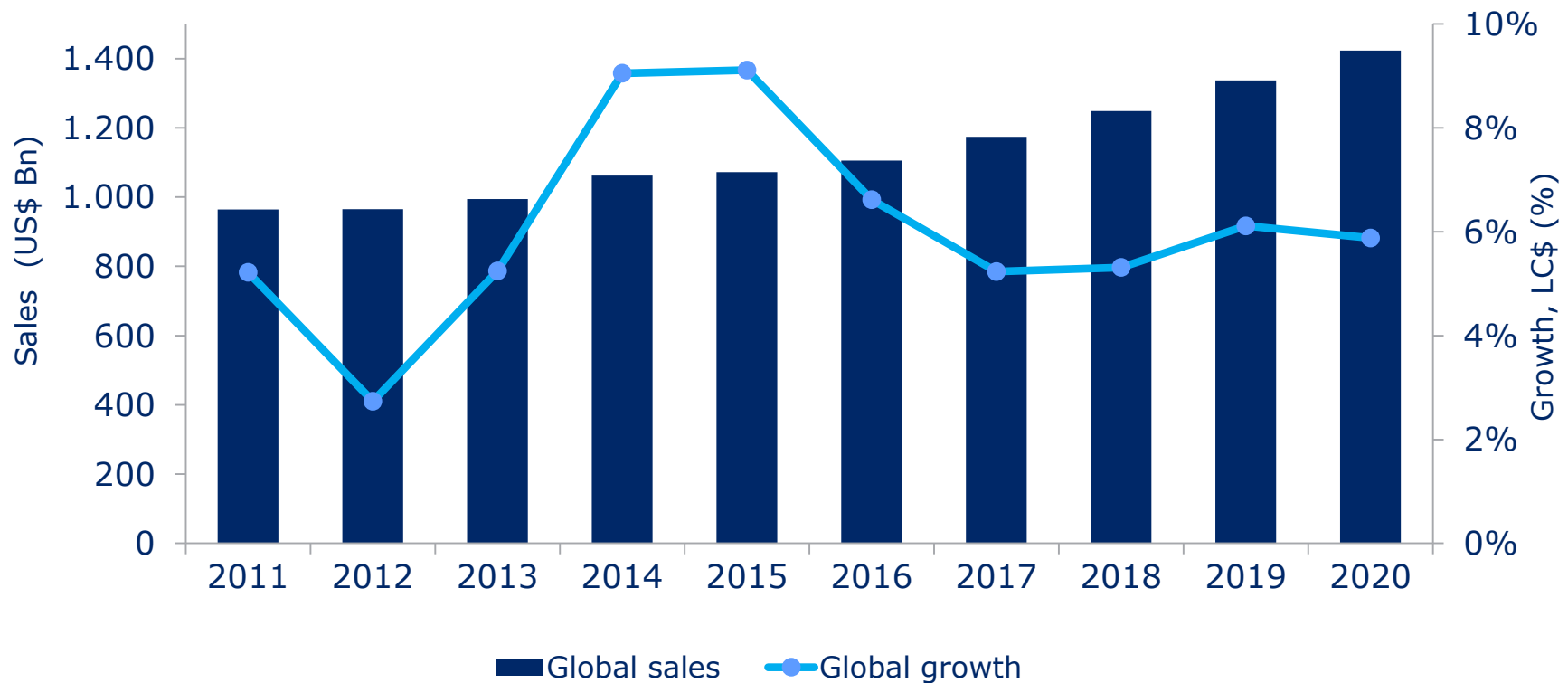
Conclusions



# Total global pharmaceutical market will reach \$1.4 trillion by 2020

The forecast suggests that 2015 growth will not be sustained

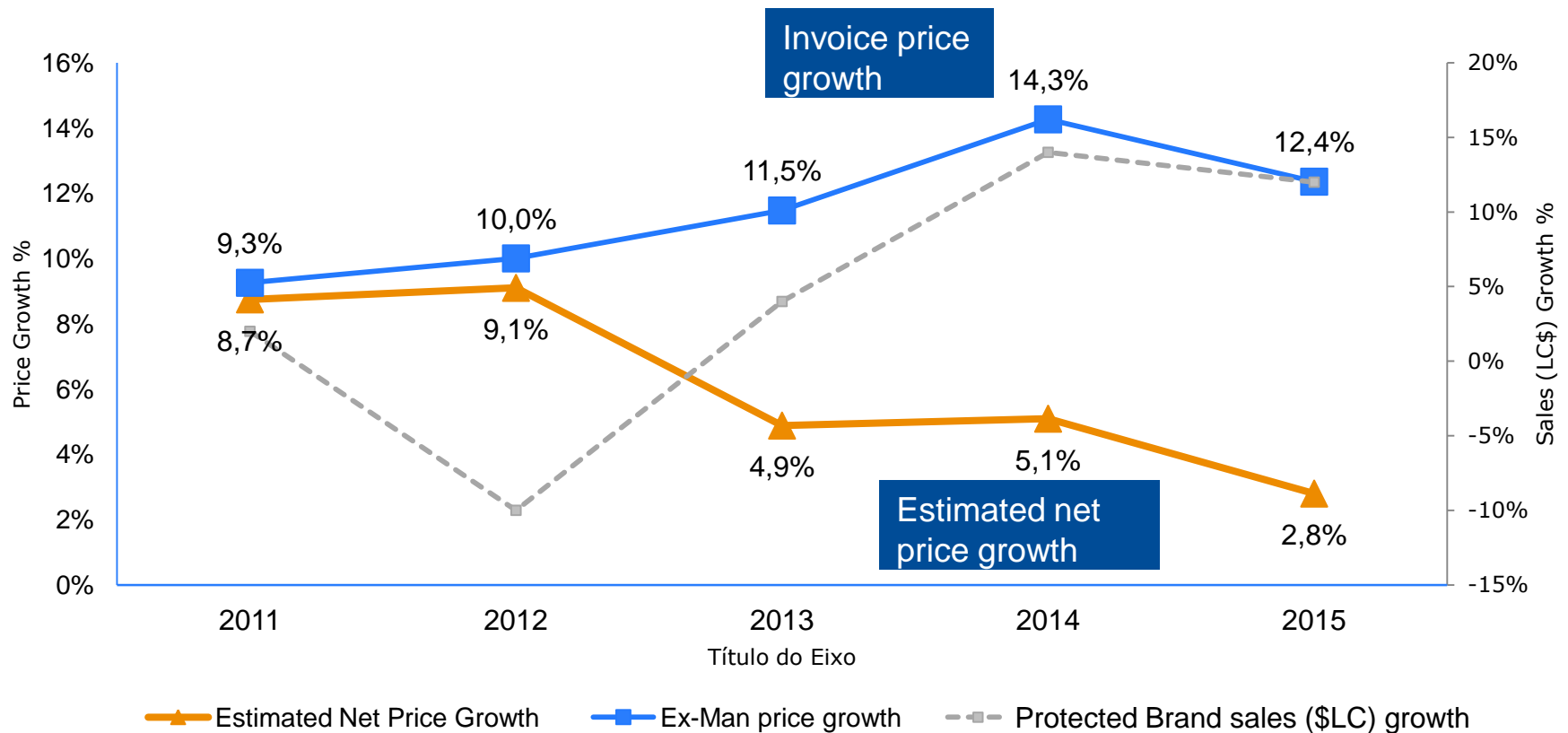
Global Sales and Growth, 2011-2020





# US illustrates that net price growth is much lower

## Ex-Man list price growth vs net price growth 2011-2015

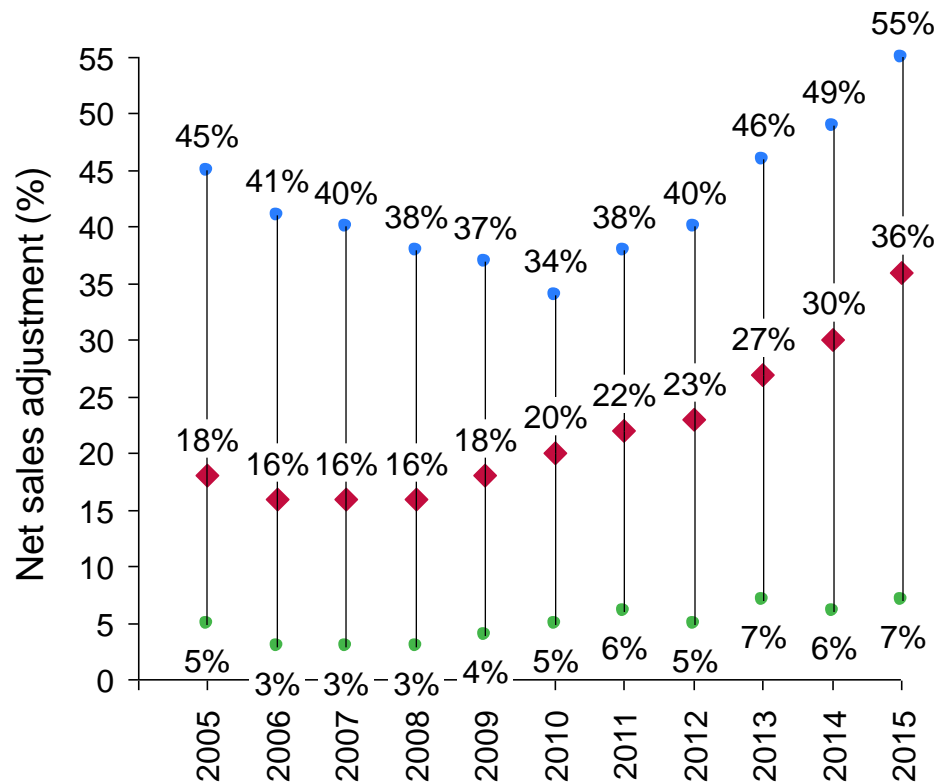




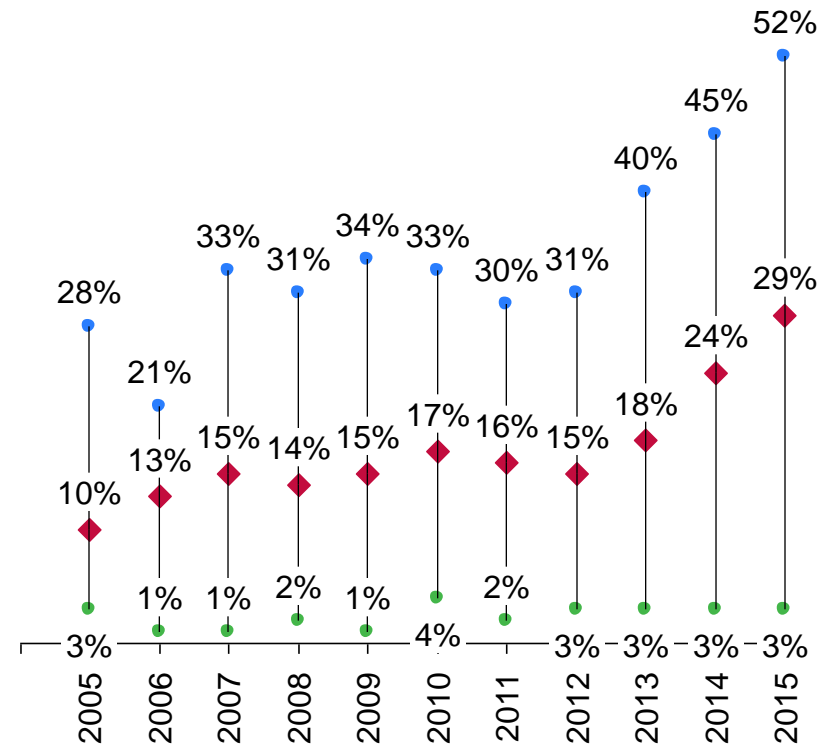
# Rebates/discounts continue to grow for both large and small molecules

Lower biologic average discount/rebate at 29%

Small Molecules, Net Sales Adjustment (%)



Biologics, Net Sales Adjustment (%)

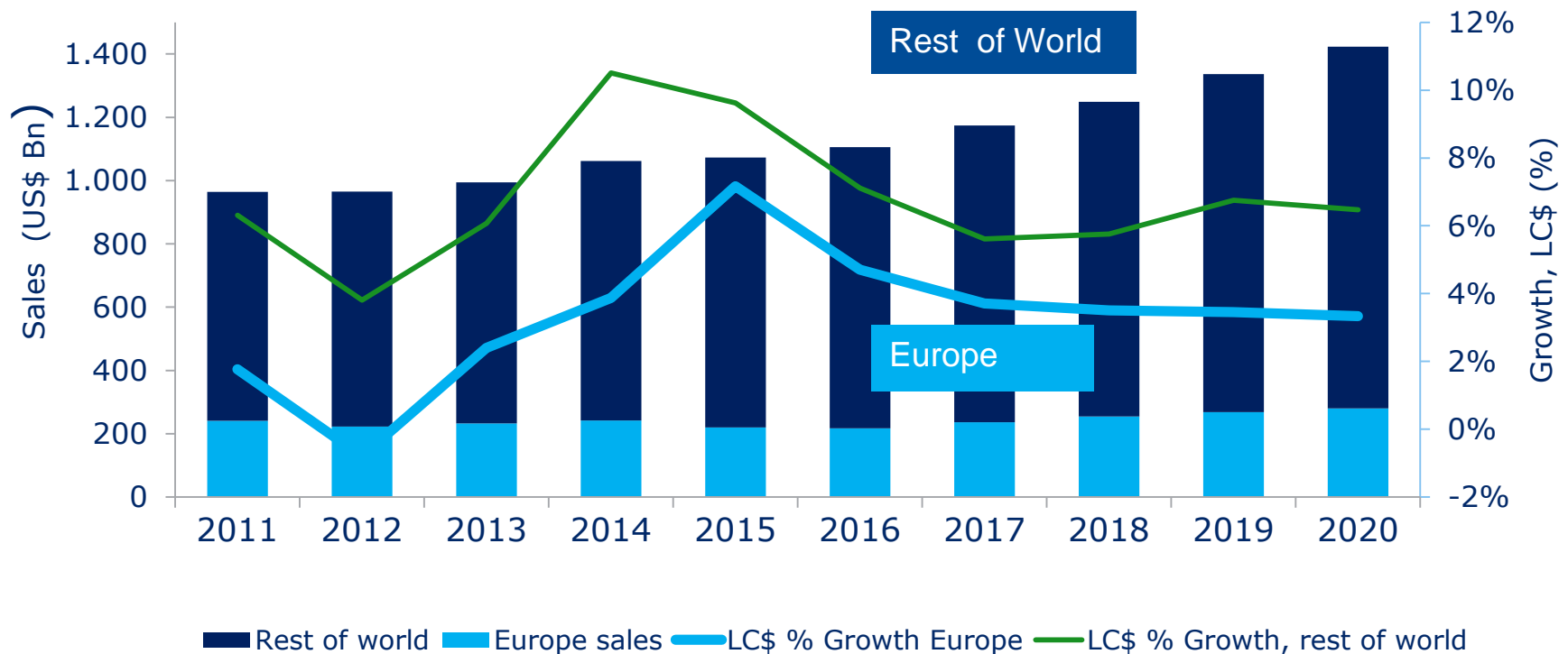


• Upper Quartile • Sales weighted average • Lower Quartile



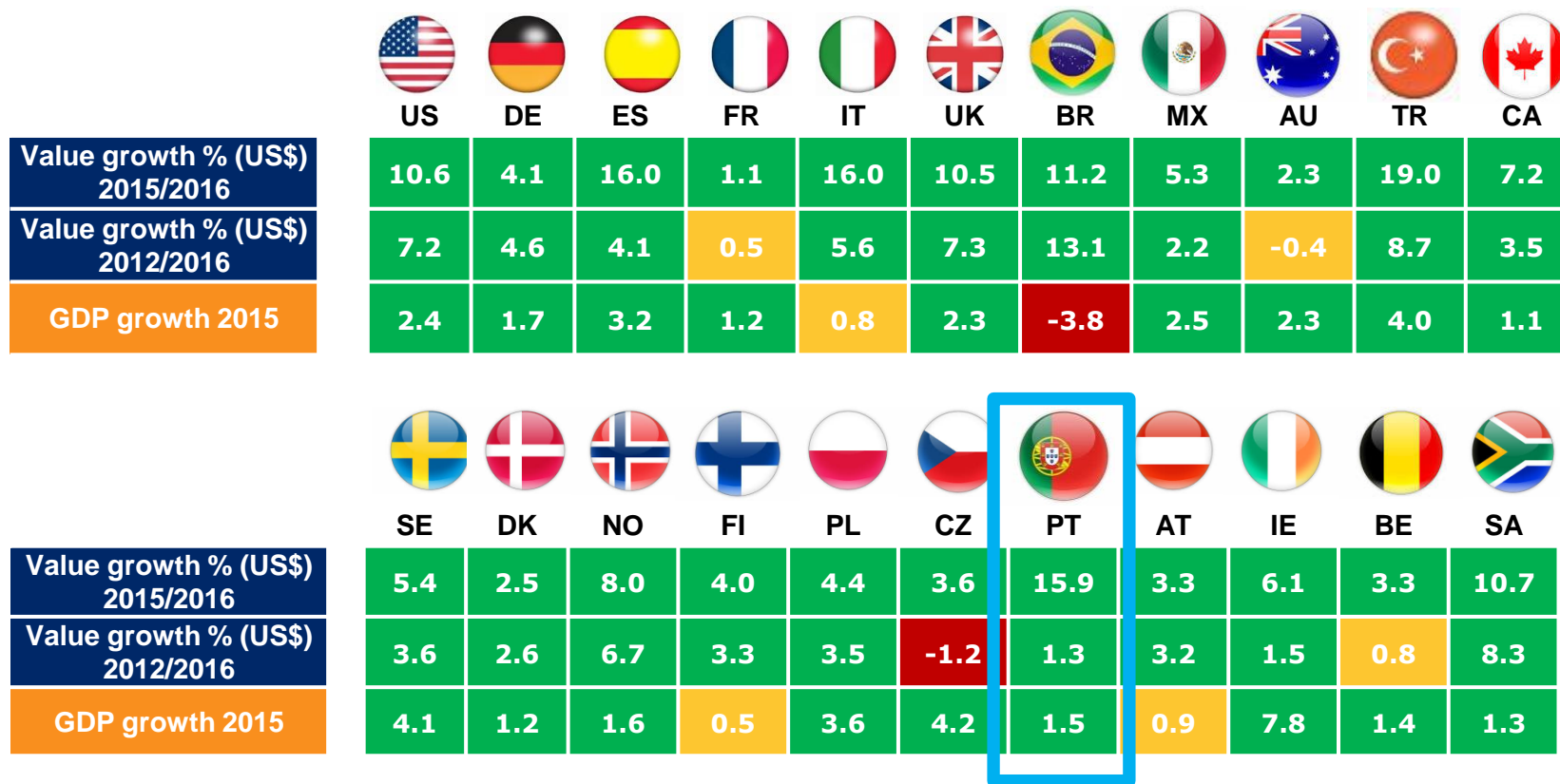
# Growth in Europe will lag behind Global growth

## Global Sales and Growth, 2011-2020



# 2016 pharmaceutical spend KPIs vary across countries

## Elements of Market Growth Total, Rx Pharmaceutical Market Priced at ex-mnf level before rebates and discounts



# 2016 Sell in & Sell out market in Portugal (Retail only)

## Total Pharmaceutical Market (Channel: Pharmacies)



PT

	UN	EUR
<b>Value Growth % MAT/9/2016 of Sell in Market</b>	<b>0.6</b>	<b>2.4</b>
<b>Value Growth % MAT/9/2016 of Sell out Market</b>	<b>0.1</b>	<b>1.1</b>

SOURCE: IMS HEALTH Dataview IFP (Sell in Market) and ICH (Sell out Market) MAT September 2016.

## Forecast Retail Sector (2015-2020)

Year	Volume (Standard Units*)		Average Price per Standard Unit		Sales	
	SU (million)	Annual Growth (%)	€	Annual Growth (%)	€ (million)	Annual Growth (%)
<b>2017</b>	10571	0.4	0.181	0.2	1916	0.6
<b>2018</b>	10611	0.4	0.182	0.2	1927	0.5
<b>2019</b>	10641	0.3	0.182	0.2	1936	0.5
<b>2020</b>	10667	0.2	0.182	0.1	1943	0.4

Notes: \*Standard Units equate the number of milliliters of liquid preparations to the standard solid dosage of one tablet, therefore making solid and liquid preparations comparable.

SOURCE: IMS HEALTH Market Prognosis Q3 2016



# Agenda

Global forecasts and regional growth trends

**The payers response to innovation**

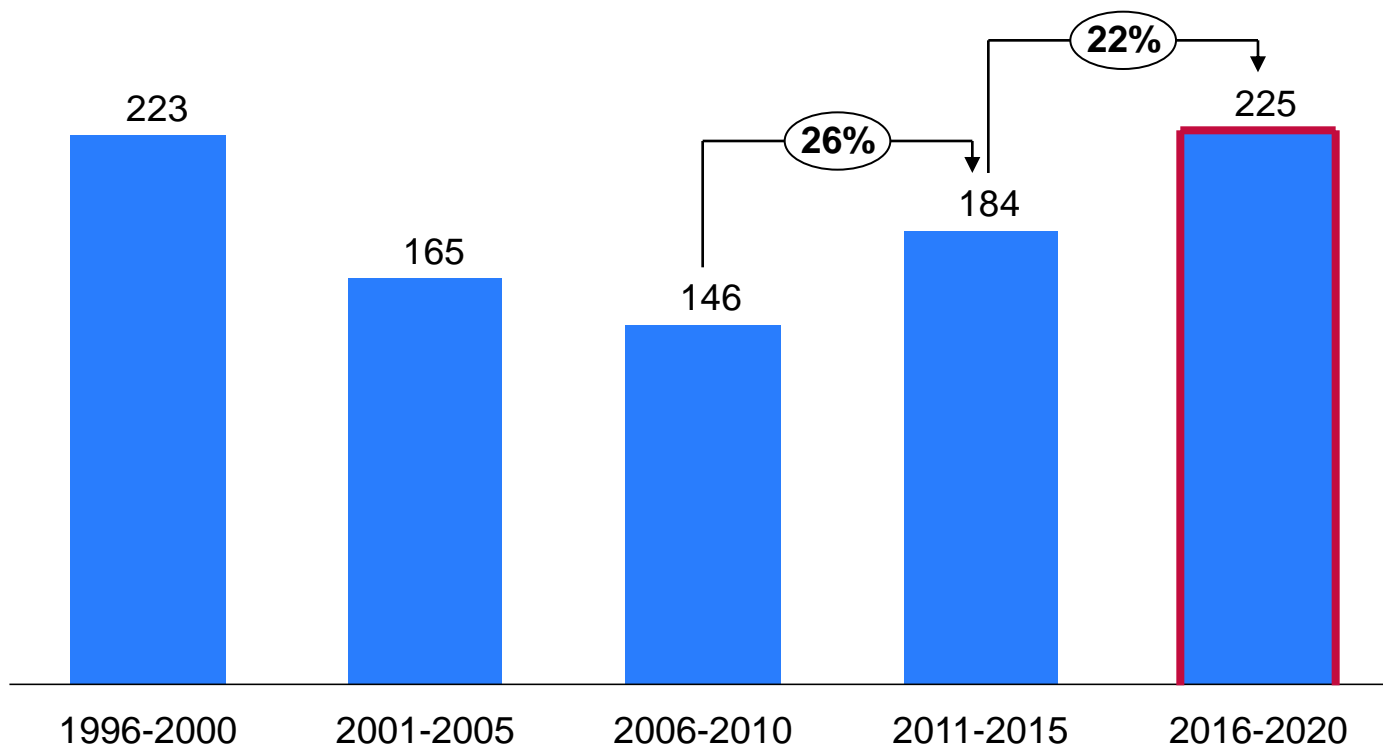
The wholesaler dilemma

Conclusions

# 2016-2020 will set a record for launches when the current innovation rich pipeline approved

22% increase from the previous 5 years

**Number of New Active Substances (NAS) launches 1996-2020**

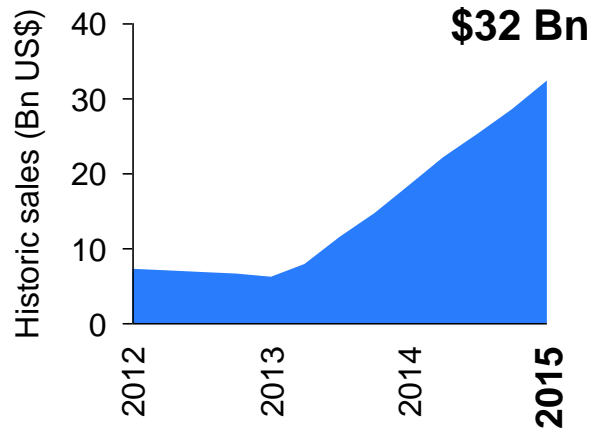




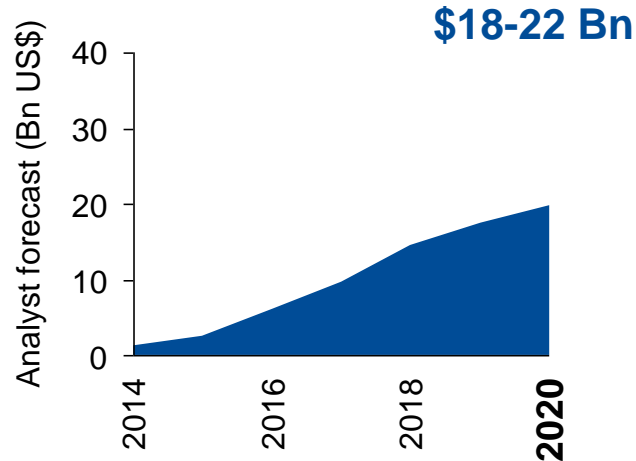
# Hep C only the first of several potential tsunamis

Are these innovations sustainable?

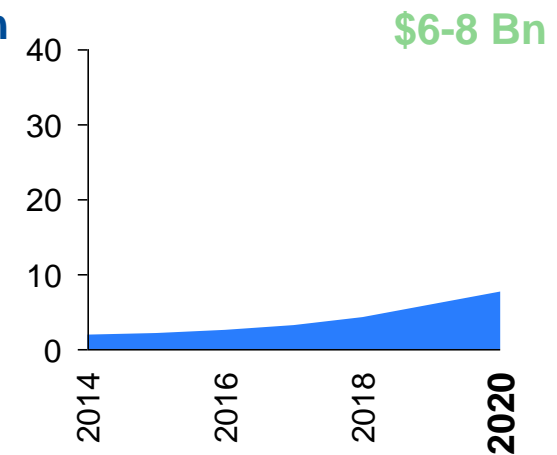
**Hepatitis-C market**  
2012-2015



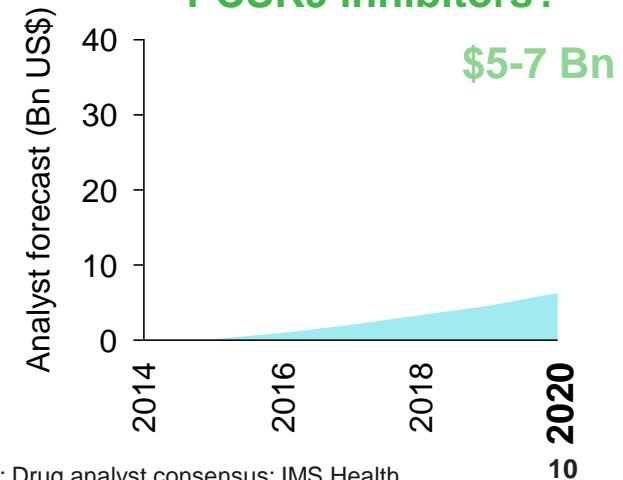
**Immuno-Oncology**



**Respiratory biologics**

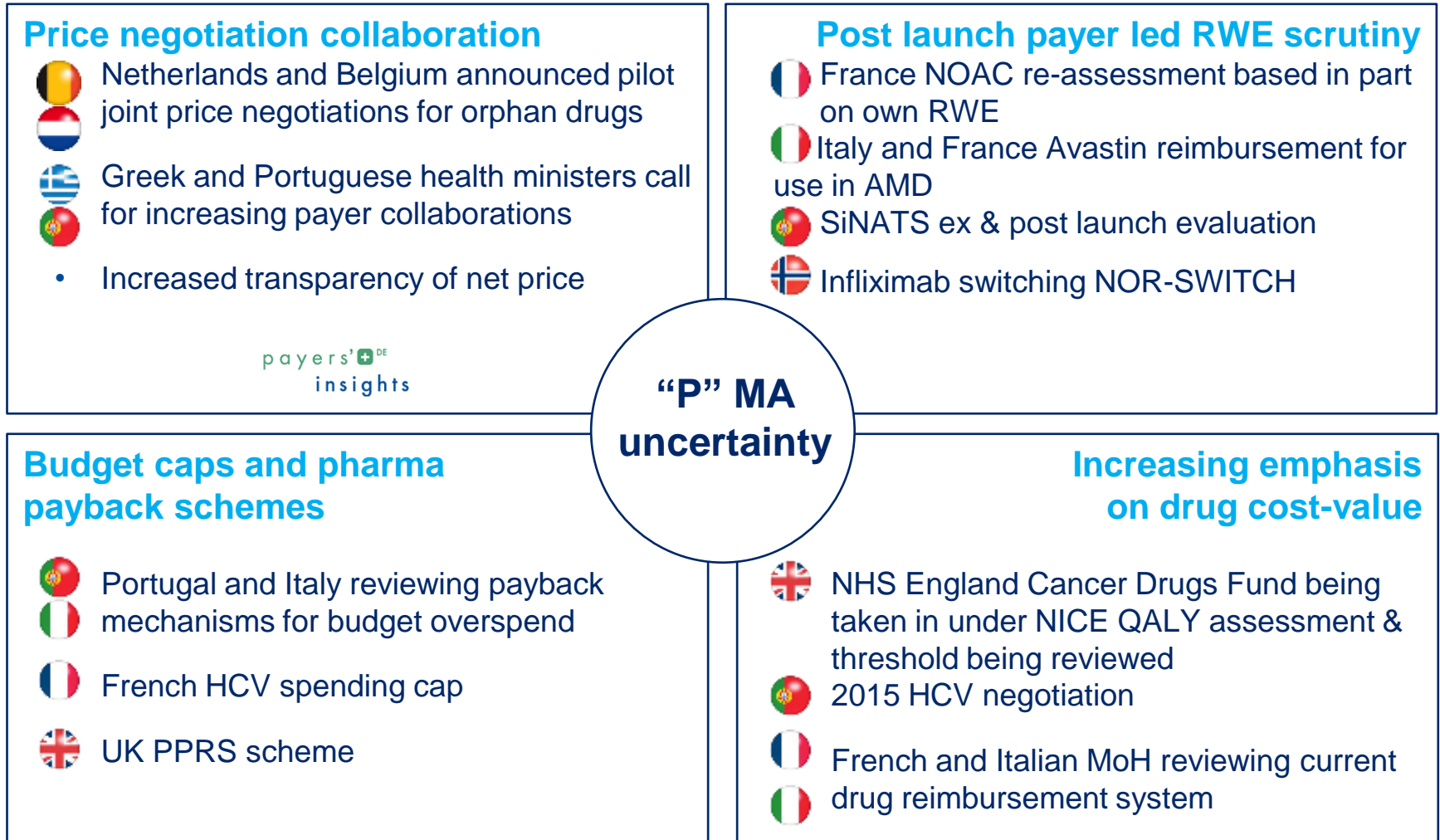


**PCSK9 inhibitors?**





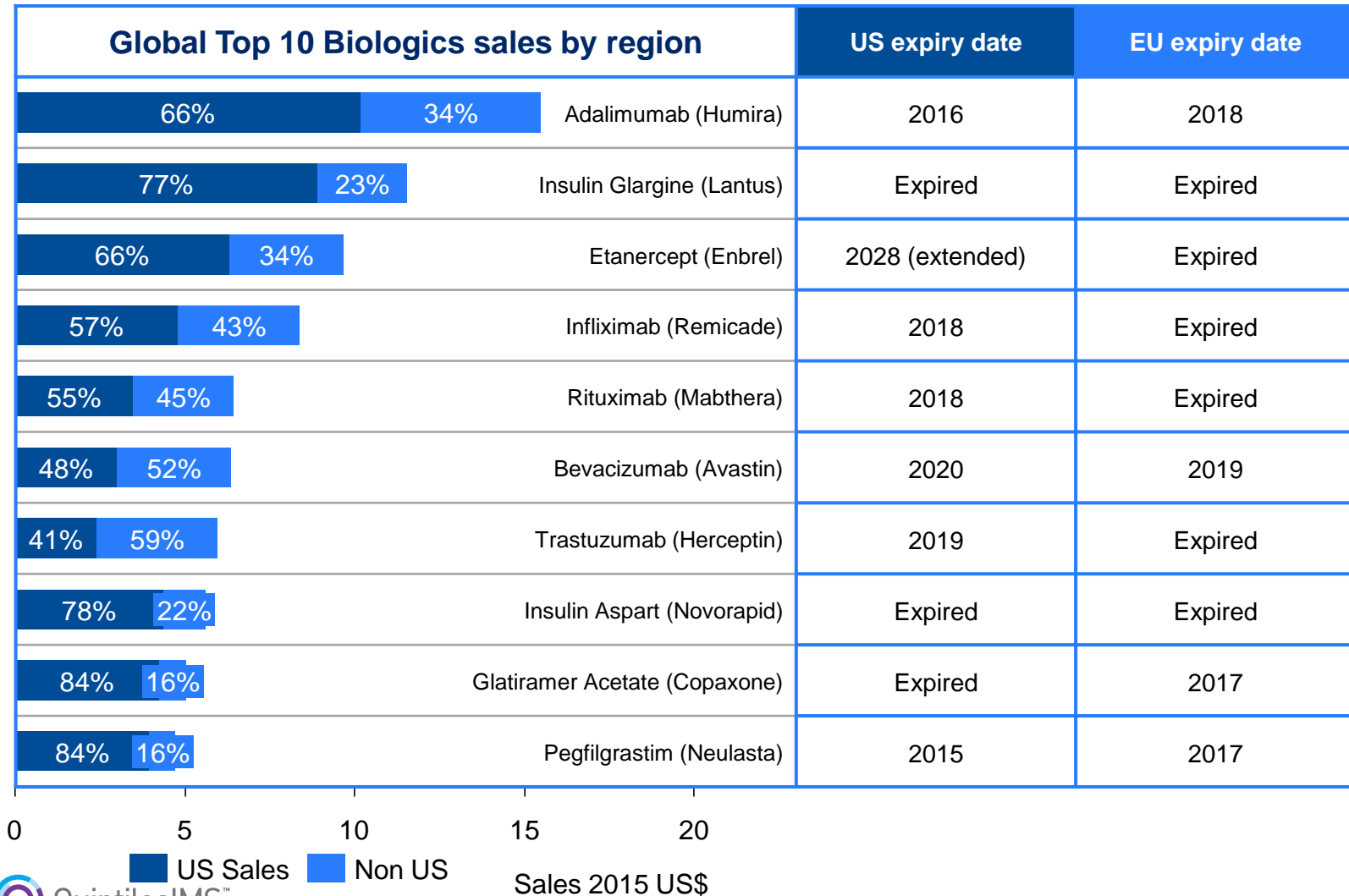
# Price challenges in Europe are numerous





# Many key biologics losing protection by 2020

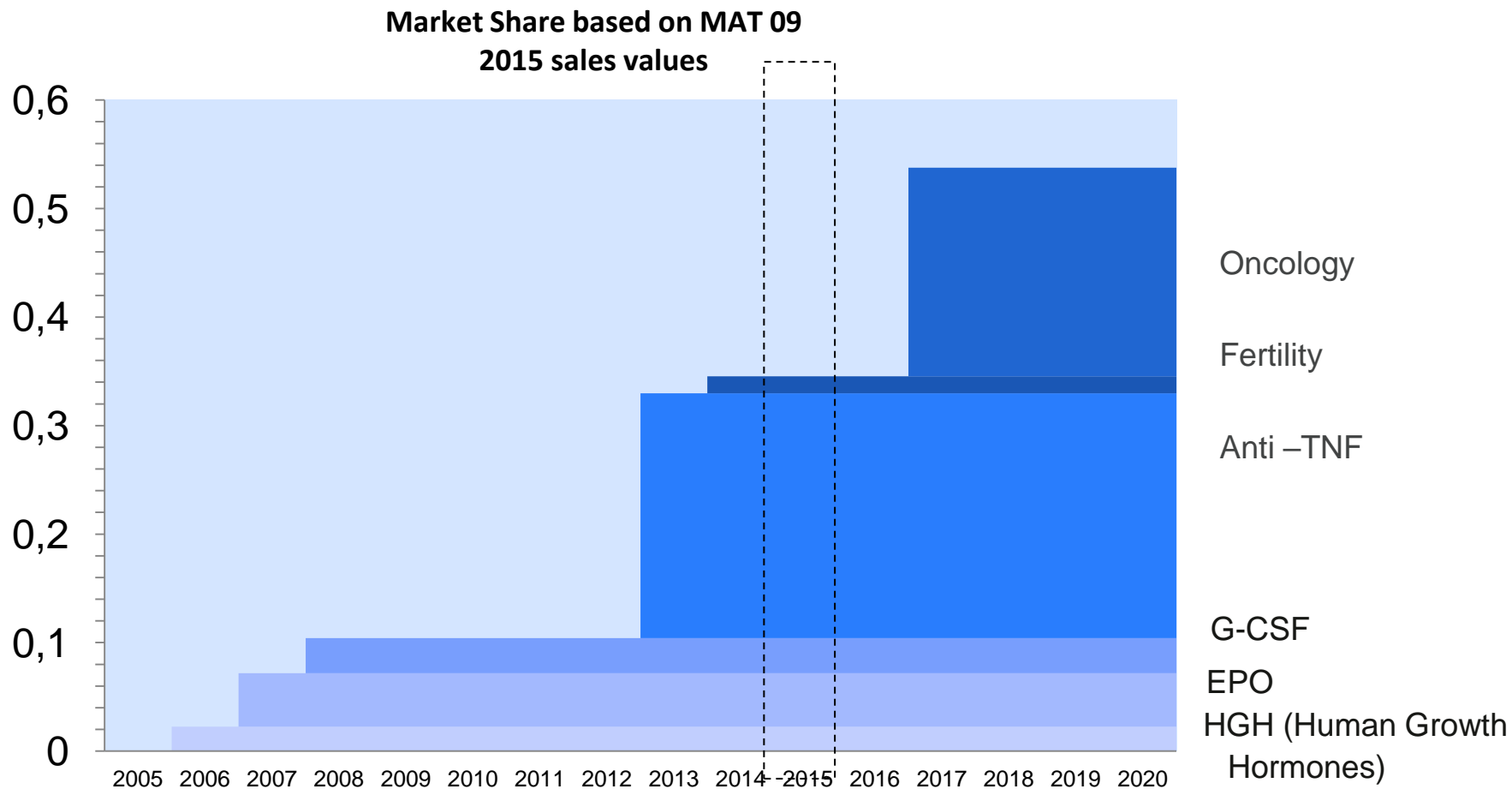
Top 10 biologics total \$79Bn sales globally



# Therapy classes exposed to biosimilar competition in Europe

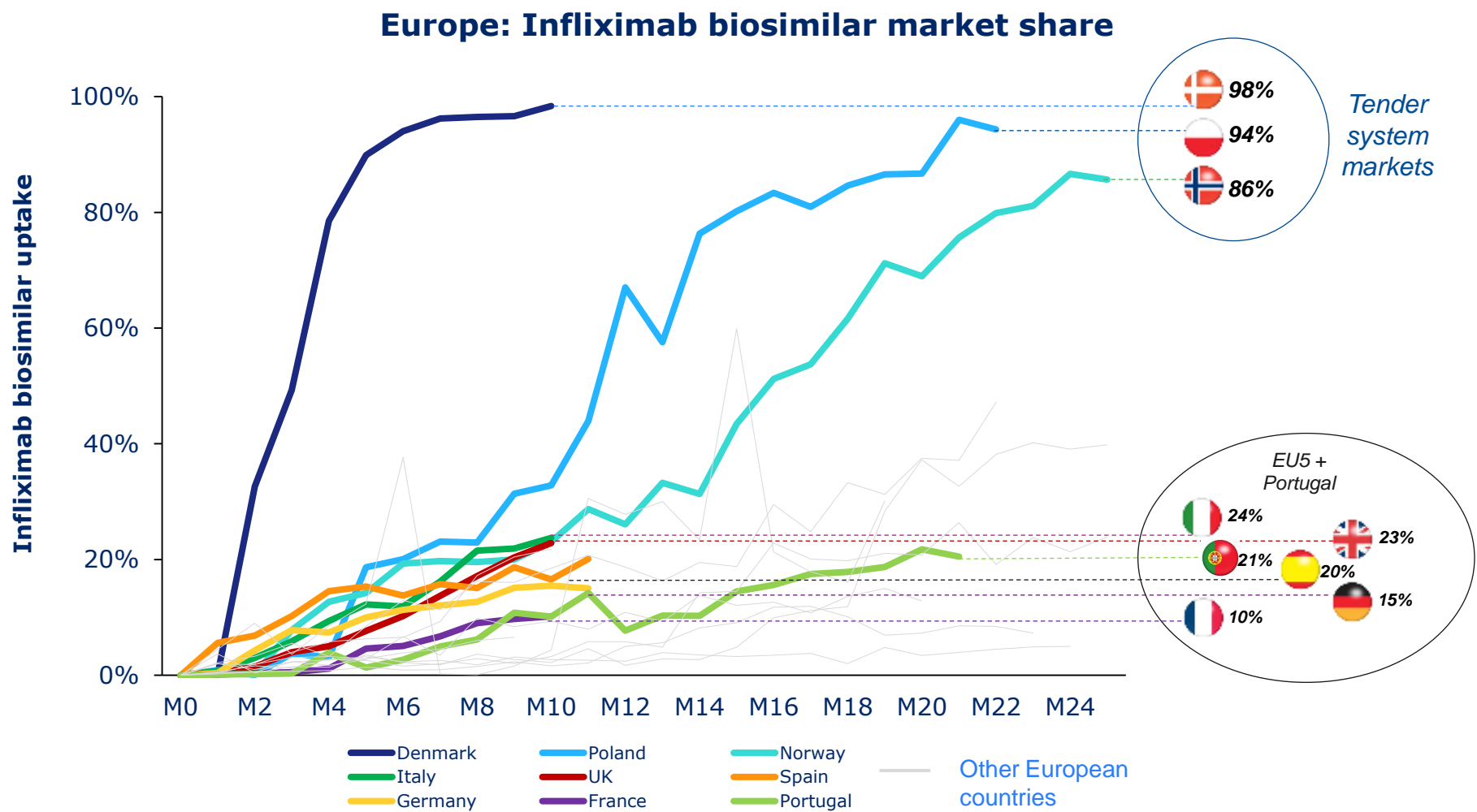


Size of classes in 2015 sales versus total European Biologics market



# In Europe, there is a large variation in the uptake of infliximab

EU5 penetration 10-24% in under a year



# Agenda

Global forecasts and regional growth trends

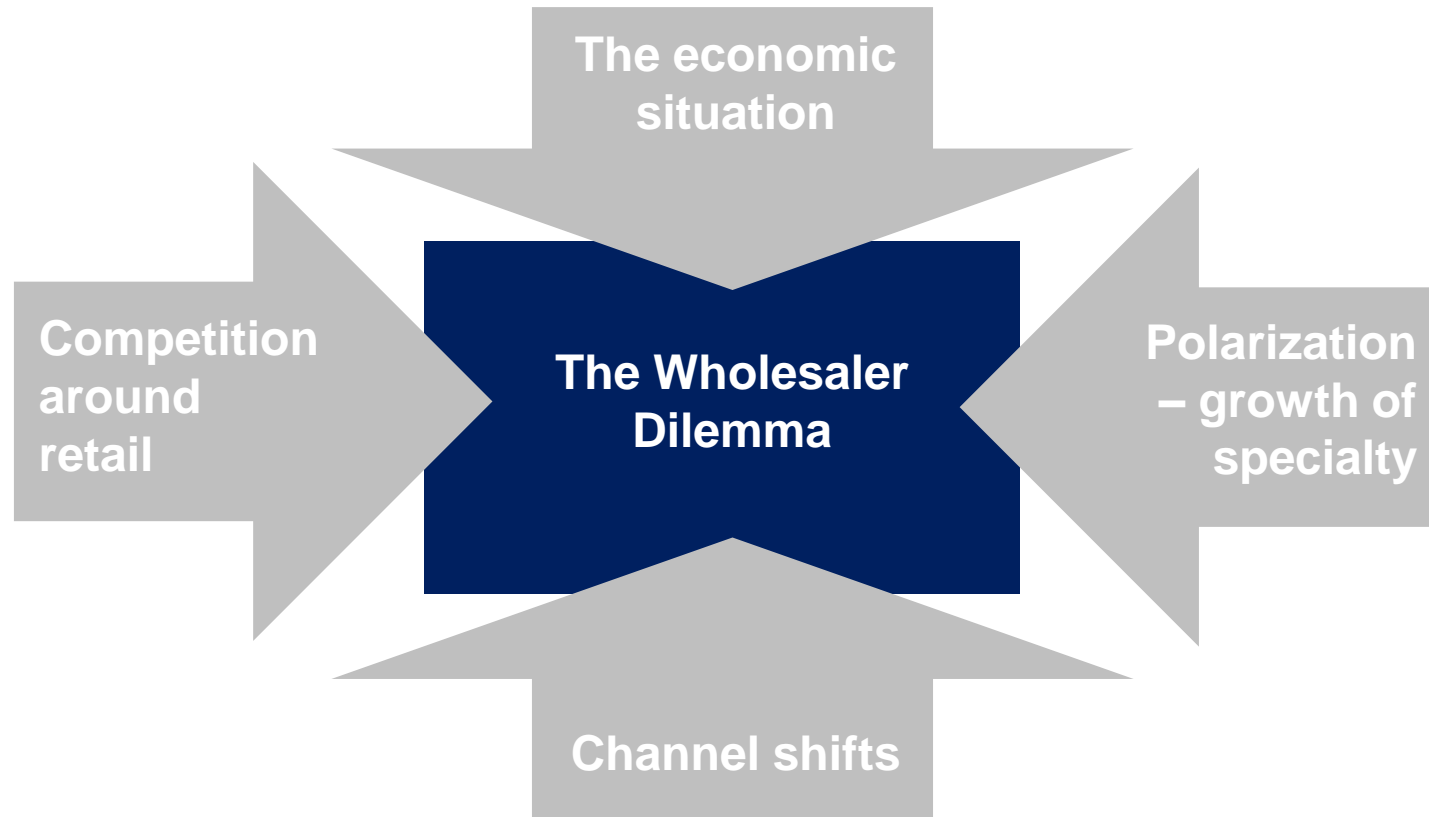
The payers response to innovation

**The wholesaler dilemma**

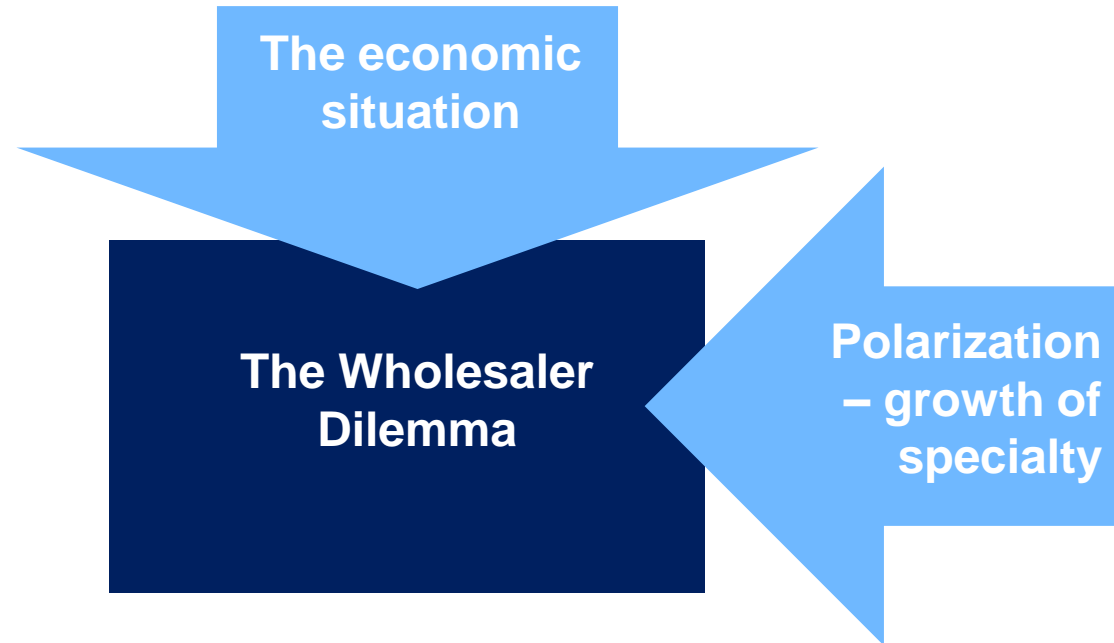
Conclusions



# The wholesaler dilemma

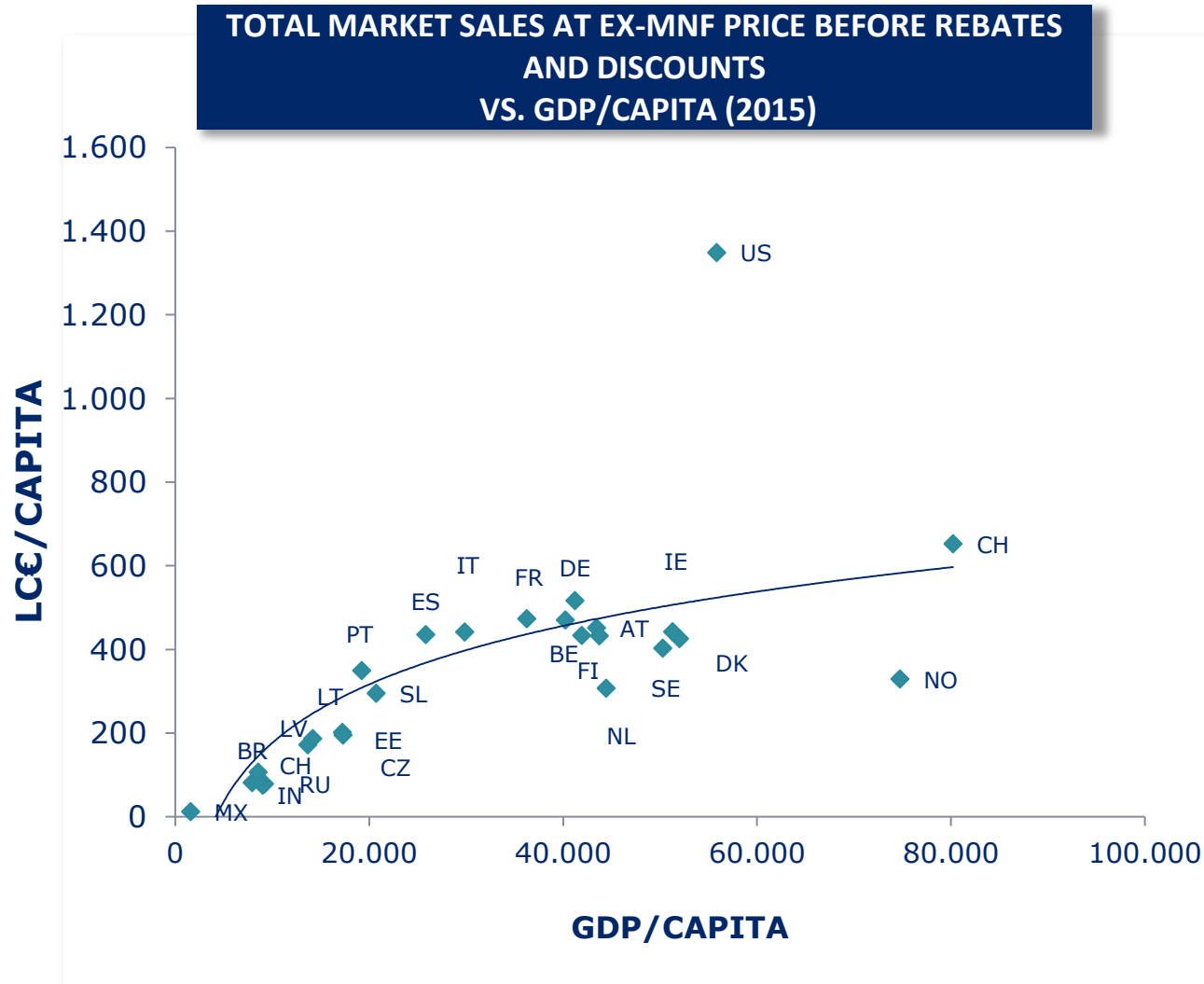


# The wholesaler dilemma



# Pharmaceutical spend closely linked to GDP

Economic growth  
important driver  
for healthcare &  
pharma spend



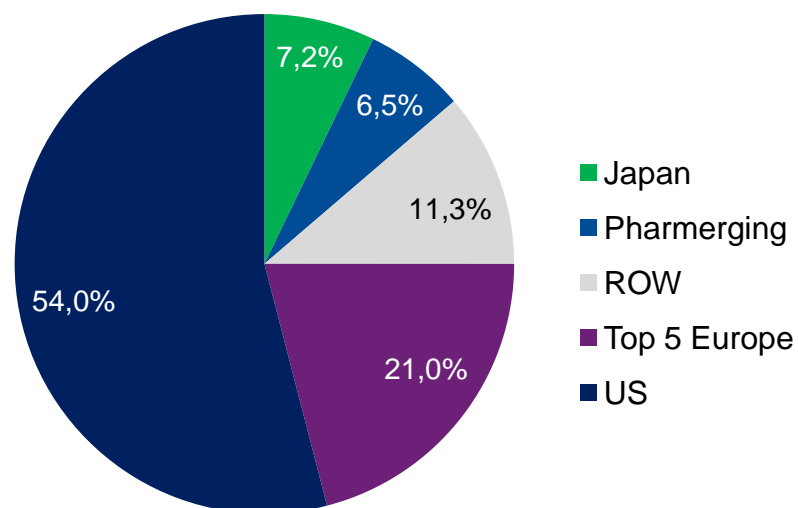
- The amount spent on pharmaceuticals is linked to the GDP per capita
- Very low GDP countries spend also a very low share
- As GDP growth, pharmaceutical spend growth faster
- At a certain level, the rate of increasing need declines (ie when all drugs are funded)

# Growth of Specialty outpaces the total market

**Global market trends**  
Sales and Growth



**Specialty: Region Market Share 2015**



# Europe and US illustrate growing importance of specialty therapies

## Europe Top 10 products 2011-15

	2011	2012	2013	2014	2015
1	HUMIRA	HUMIRA	HUMIRA	HUMIRA	HUMIRA
2	SERETIDE	SERETIDE	ENBREL	ENBREL	HARVONI
3	LIPITOR	HERCEPTIN	HERCEPTIN	HERCEPTIN	SOVALDI
4	HERCEPTIN	ENBREL	SERETIDE	MABTHERA	ENBREL
5	ENBREL	MABTHERA	MABTHERA	SERETIDE	HERCEPTIN
6	MABTHERA	REMICADE	REMICADE	REMICADE	AVASTIN
7	LOVENOX	LOVENOX	AVASTIN	AVASTIN	MABTHERA
8	REMICADE	AVASTIN	LOVENOX	LOVENOX	REMICADE
9	GLIVEC	SPIRIVA	LYRICA	LYRICA	SERETIDE
10	AVASTIN	GLIVEC	LUCENTIS	LUCENTIS	LOVENOX

## US Top 10 products 2011-15

	2011	2012	2013	2014	2015
1	LIPITOR	NEXIUM	ABILIFY	LANTUS	HARVONI
2	PLAVIX	ABILIFY	NEXIUM	SOVALDI	HUMIRA
3	NEXIUM	SERETIDE	LANTUS	HUMIRA	LANTUS
4	SEROQUEL	CRESTOR	HUMIRA	ABILIFY	ENBREL
5	ABILIFY	HUMIRA	SERETIDE	ENBREL	CRESTOR
6	SINGULAIR	LANTUS	CRESTOR	NEXIUM	SERETIDE
7	SERETIDE	CYMBALTA	CYMBALTA	CRESTOR	REMICADE
8	CRESTOR	ENBREL	ENBREL	SERETIDE	ABILIFY
9	ENBREL	REMICADE	REMICADE	REMICADE	NOVORAPID
10	HUMIRA	COPAXONE	COPAXONE	COPAXONE	COPAXONE

 Traditional

 Specialty

# Top products vary in Developed and Pharmerging markets

## Top products 2015

	 <b>KR</b>	 <b>JP</b>	 <b>BR</b>	 <b>MX</b>	 <b>CN</b>
1	BARACLUDE	HARVONI	HERCEPTIN	HERCEPTIN	PLAVIX
2	LIPITOR	AVASTIN	CIT SILDENAFILA MG	HUMIRA	SHEN JIE
3	HERCEPTIN	PLAVIX	HUMIRA	CELEBREX	LIPITOR
4	VIREAD	SOVALDI	LOSARTAN HYPM	AVASTIN	XUE SHUAN TONG
5	JANUMET	CRESTOR	SYNFLORIX	DOLO NEUROBION	BEI TONG
6	TWYNSTA	NEXIUM	AVASTIN	LANTUS	SOD CHLORIDE KELU
7	PROGRAF	BENICAR	LOVENOX	CIALIS	SODIUM CHLORIDE
8	PREVNAR	REMICADE	TORSILAX	NEXIUM	ADEGOLD
9	VARIVAX	LYRICA	ENBREL	CELESTONE	DANSHEN DUOFENSUAN
10	ARICEPT	SECTOR	MABTHERA	KALETRA	LANSOPRAZOLE



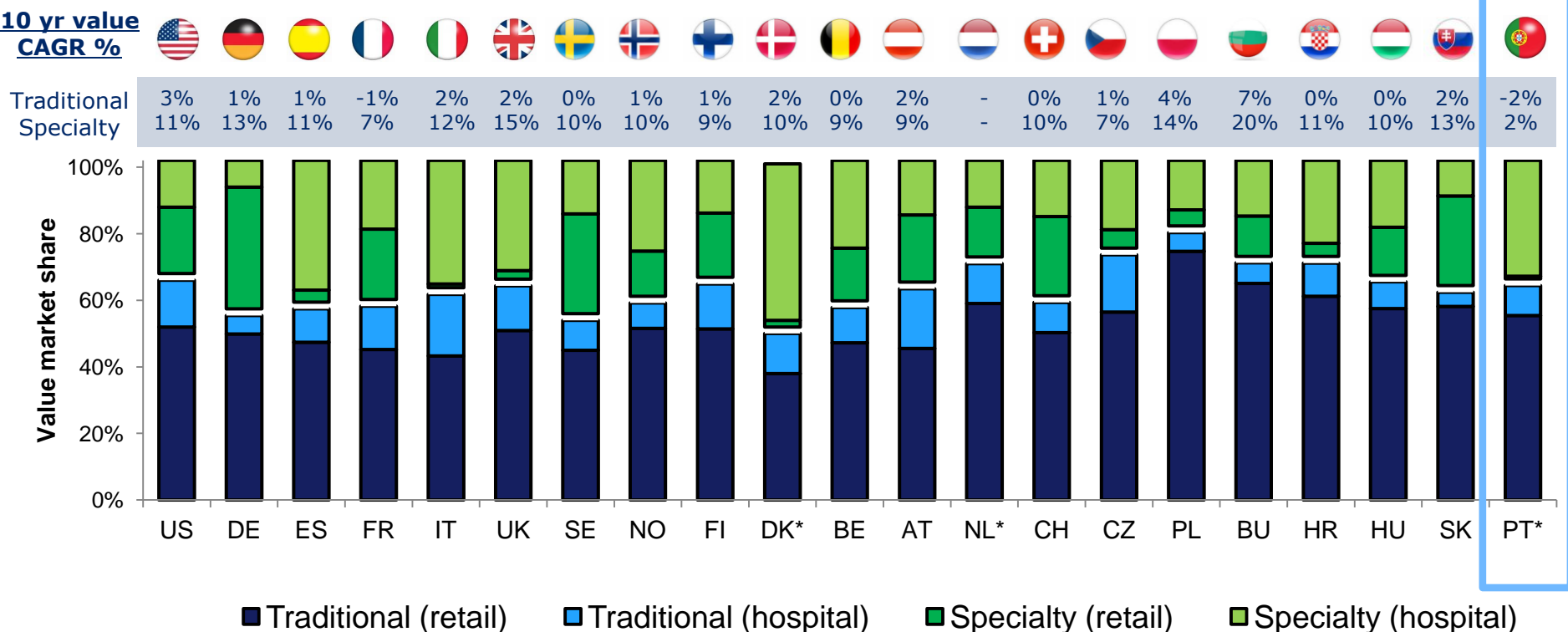
Traditional



Specialty

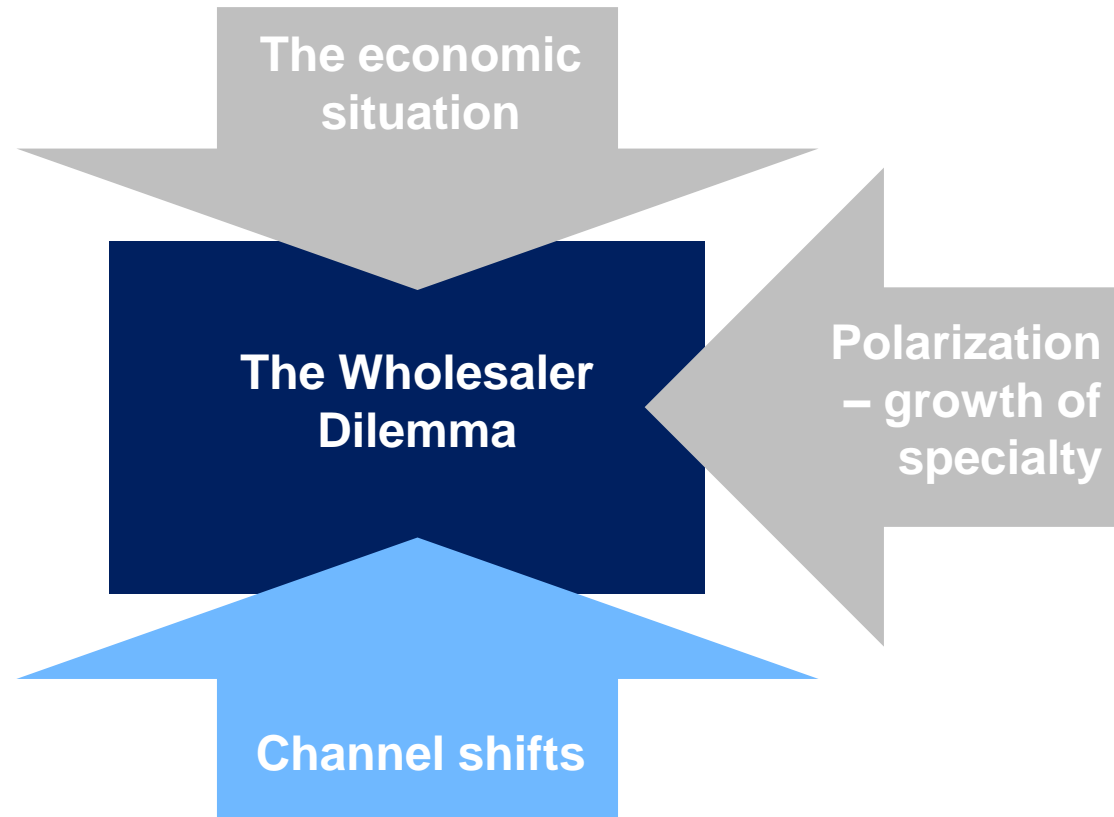
# High specialty growth is a long term trend

## Specialty versus traditional medicine market value dynamics (2015 value market share vs. 10 year value growth (2006-2015))



\* NL CAGR n/a, PT CAGR for retail only,

# The wholesaler dilemma





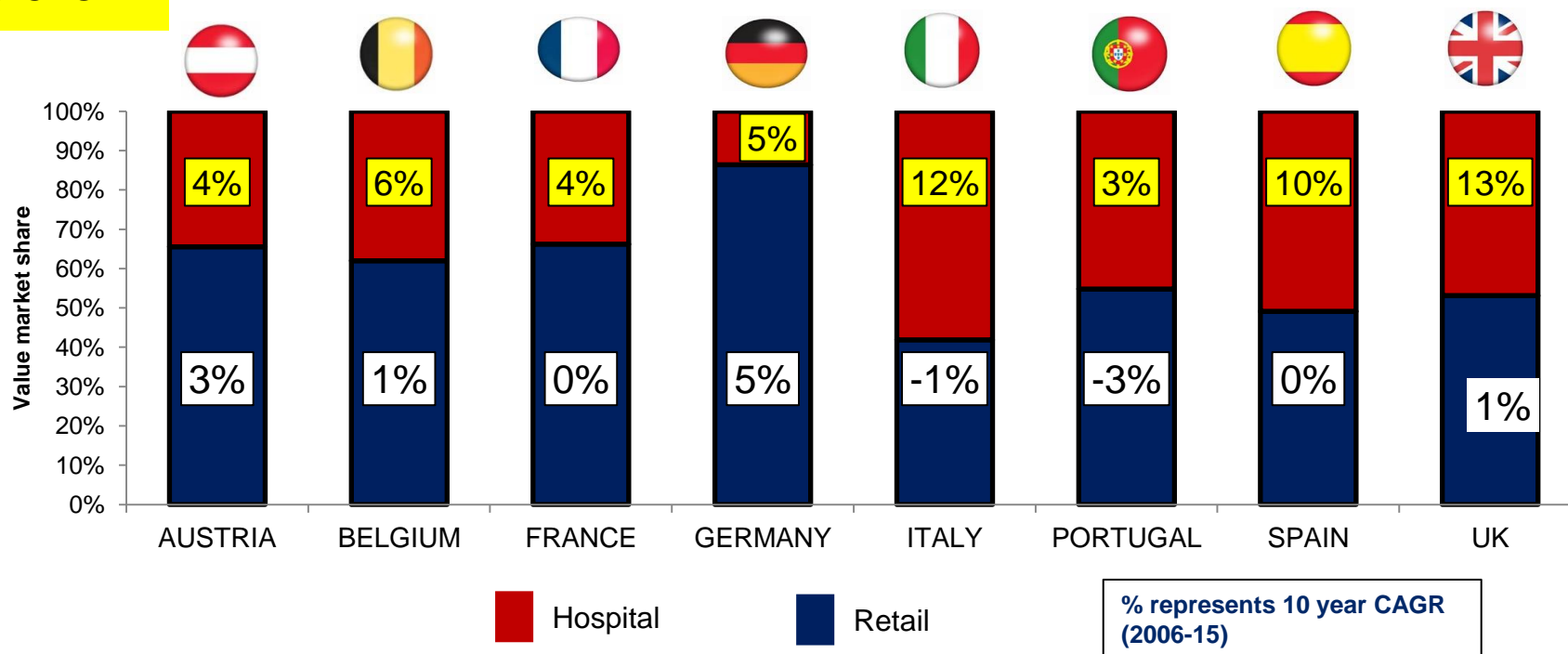
# Channel shifts express differently by market

Shifts contains threat and opportunities for wholesalers

- US;
  - > Growth of specialty distribution, pharmacy, specialty mail
- Europe;
  - > Significant shift to hospital
  - > Homecare in UK, NL
- China;
  - > Shift from hospital to retail

# There is longer term shift to hospital in many markets

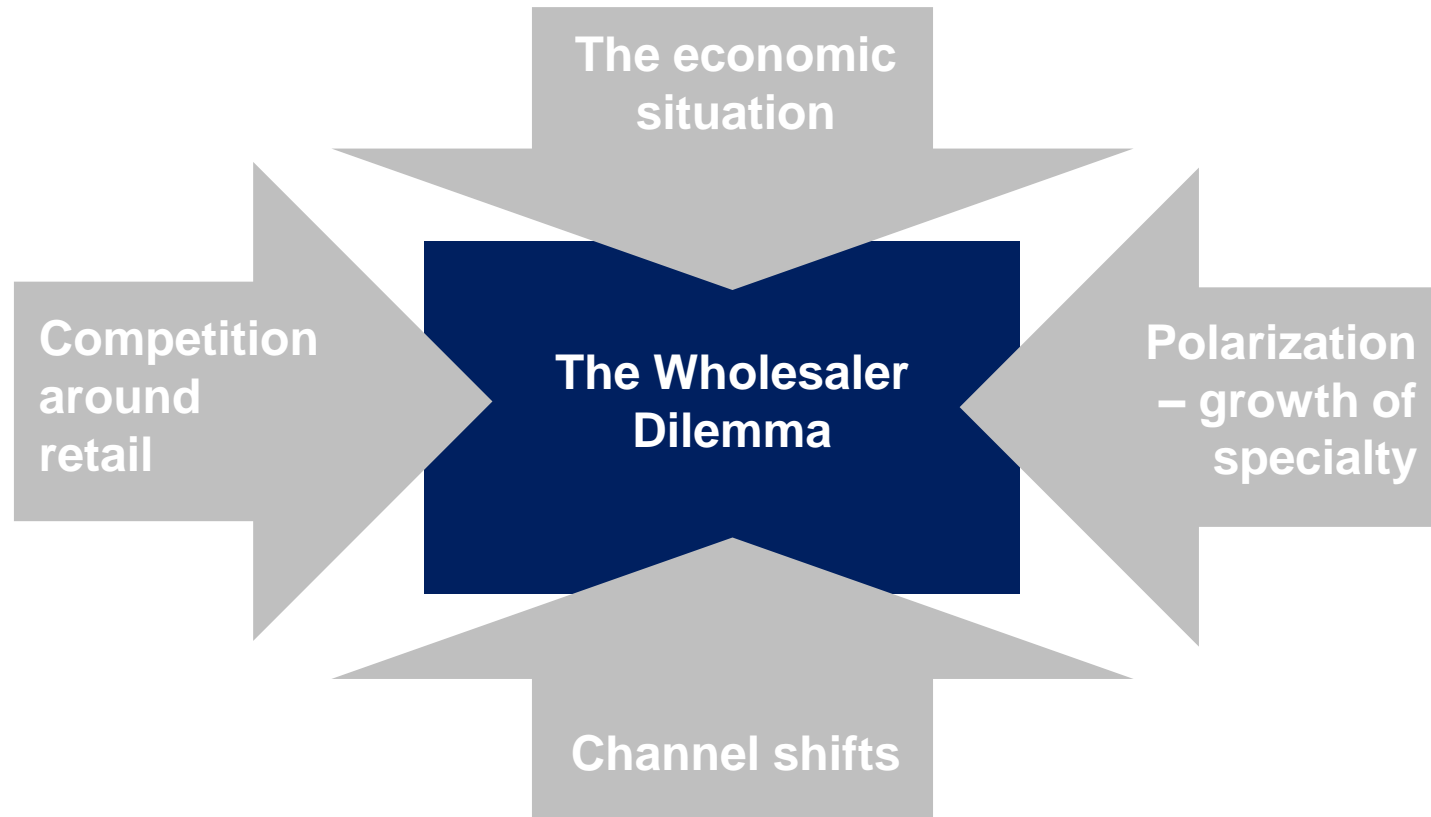
Evolution of hospital share of Rx Pharmaceutical Value Sales  
(2015 value market share vs. 10 year value growth (2006-2015))



Typical reasons for hospital based dispensing (distribution often direct):

Medical need, controlling prescribing, avoiding wholesaler & pharmacy margins and the ability to negotiate discounts

# The wholesaler dilemma



# Competition around retail

- Retail focus becomes “traditional” (versus Specialty) medicine.
- The majority of dispensed packs have very low cost
- Most products are generic/ multisource products
- OTC has increased importance in many countries

# The case for retail dispensing of speciality drugs

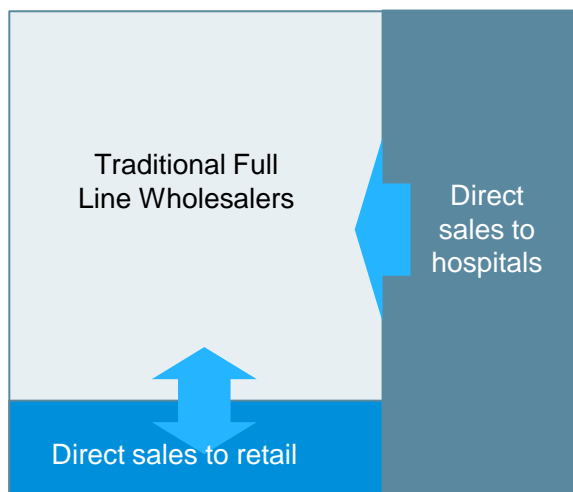

## Patient

- Integration of medicine care
- Patient convenience
- (driving adherence and compliance)

## Payer versus the provider

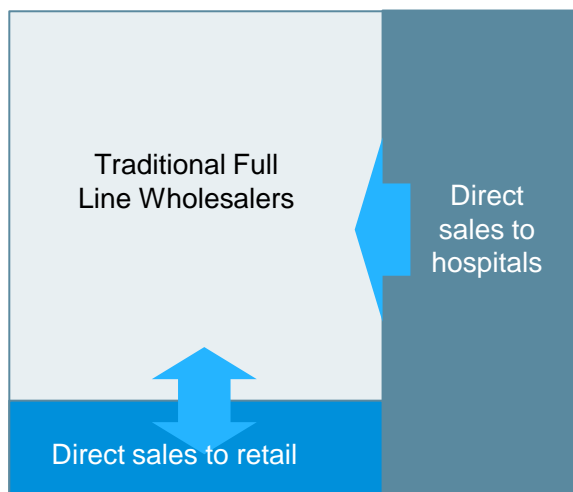
- Who will benefit from potential rebates?

# The loss of the “market” continues for wholesalers

	Hospital Q4 2015	Direct retail Q4 2015	Traditional FLW Q4 2015	Delta WHS 2015 vs 2011
Italy	58.5%	16.5%	34.7%	-11.2%
Spain	50.3%	4.7%	47.4%	-9.2%
Portugal	43.4%		56.6%	-8.4%
Netherlands	41.0%		59.0%	-7.7%
Czech Republic	35.5%	11.0%	57.4%	-5.3%
Croatia	35.2%	4.2%	62.0%	-7.1%
Denmark	57.5%	0.0%	42.5%	-6.5%
Ireland	23.8%	11.2%	67.7%	-5.4%
UK	45.4%	2.6%	53.2%	-5.0%
France	33.4%	25.0%	49.9%	-3.6%
Poland	18.8%	4.2%	77.8%	-3.5%
Belgium	36.4%	7.2%	59.1%	-3.7%
Hungary	26.2%	0.8%	73.2%	-2.4%
Norway	32.0%	0.0%	68.0%	-2.3%
Slovakia	13.6%	1.2%	85.3%	-2.1%
Bulgaria	19.7%	1.5%	79.1%	-1.7%
Switzerland	22.2%	12.9%	67.8%	-1.0%
Austria	32.7%	8.5%	61.6%	-0.7%
Romania	19.0%	0.1%	80.9%	-0.8%
Finland	26.5%	0.1%	73.4%	0.3%
Sweden	23.1%	0.0%	76.9%	1.2%
Germany	12.7%	13.4%	75.6%	2.6%

# Issues that needs to be addressed to “win”



## 1. Handling of Rebates

- Sales to hospitals frequently require rebates to be handled as pass-through
  - Example in the Nordics
- Selected situations require that also rebates to retail can be tracked
  - Increased transparency as for virtual chains
  - DTP eg UK

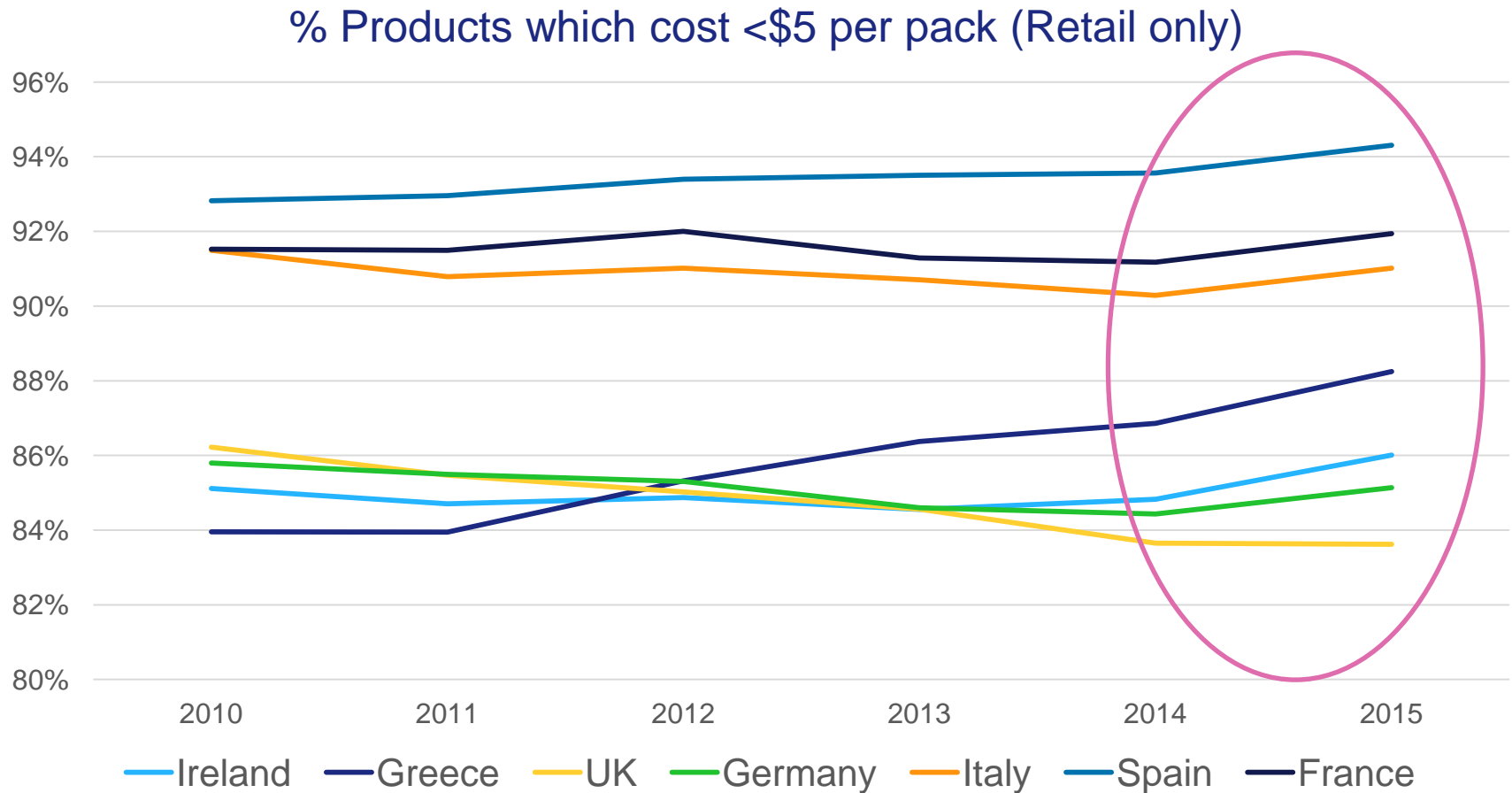
## 2. Increased Service offerings

- **Better logistics:**
  - Orphan drugs handling
  - Solutions for click and collect” of specialty
  - Just in time delivery etc
- **Supporting better care:**
  - Support systems for dispenser
  - Data collection
  - Data exchange

## 3. Smart Remuneration Model

- Need to cover both direct cost, capital, and risk
- Value of services needs to be rewarded

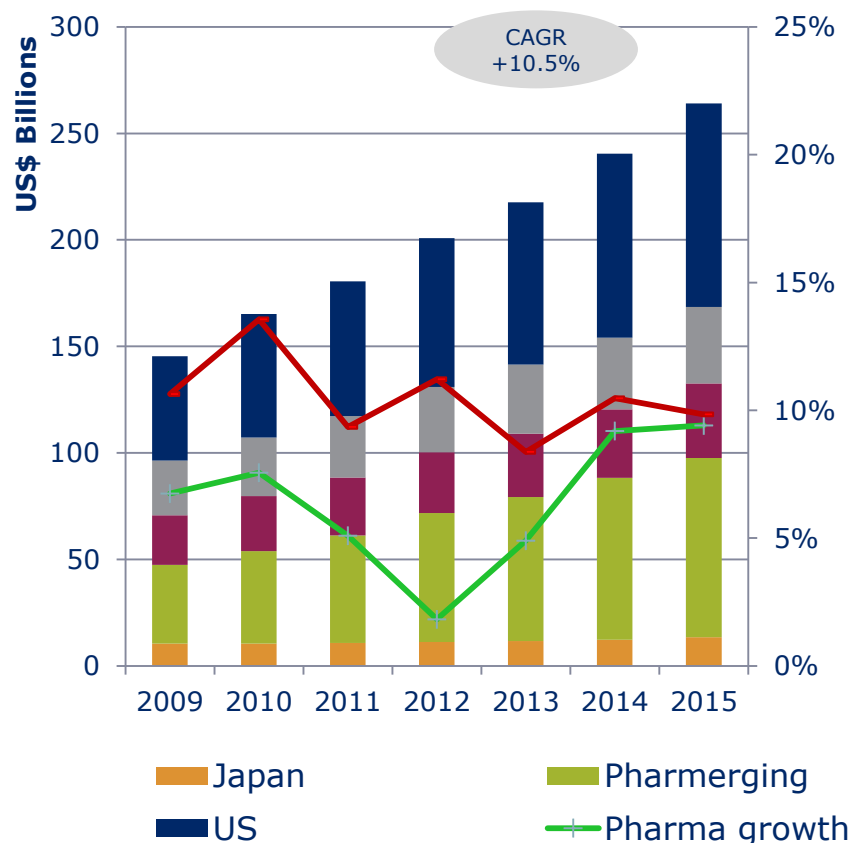
# The progressive dominance in retail of low cost packs



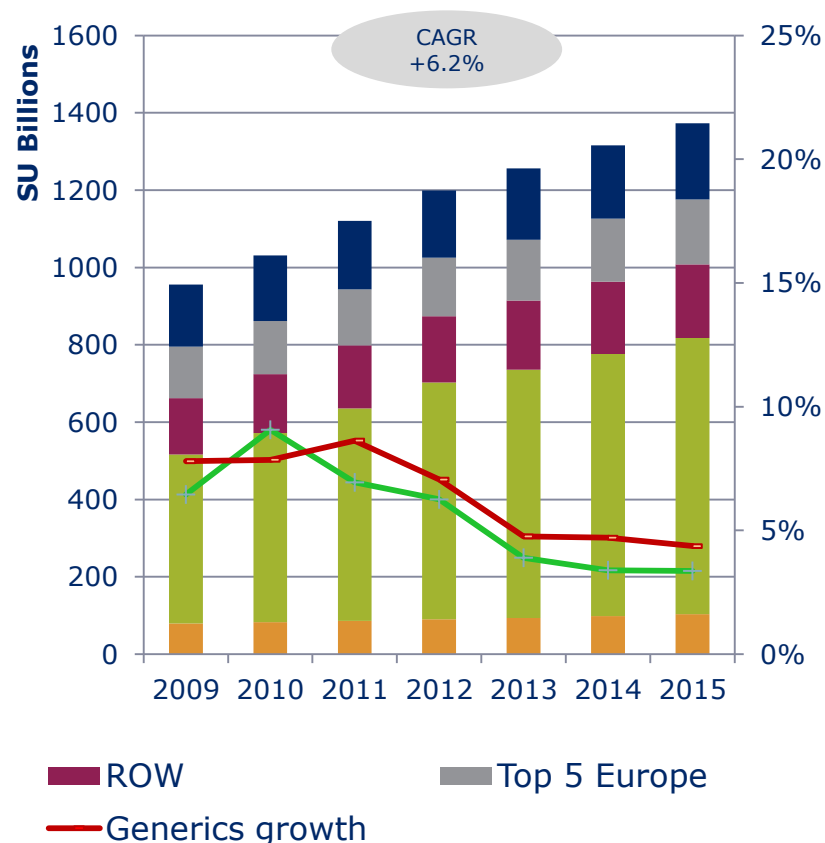


# Global generics market is growing in volume and value

**Global Generic Rx market,  
Value, US\$ at ex-mnf price  
before rebates and discounts**



**Global Generic Rx market,  
Volume, SU**



# In developed markets the most evident shift is to unbranded generics

While the focus in pharmerging markets remains branded GX

Sales  
US\$

	Generic sales 2015 (\$ bn)	2015 Value MS		*CAGR 2009-15	
		Branded generics	Unbranded generics	Branded generics	Unbranded generics
US	95.6	33%	67%	9%	13%
Canada	4.5	23%	77%	5%	1%
China	40.5	70%	30%	15% <span>-----&gt;</span>	21%
Japan	13.5	54%	46%	-1% <span>-----&gt;</span>	17%
Korea	4.7	89%	11%	3%	1%
Germany	9.8	43%	57%	3%	5%
Spain	4.3	45%	55%	0%	10%
France	8.1	34%	66%	3%	6%
UK	7.3	30%	70%	8%	9%
Italy	6.3	63%	37%	4%	12%
Portugal*	0.9	53%	47%	0%	1%
Brazil*	8.3	50%	50%	15% <span>-----&gt;</span>	28%
Mexico*	2.5	84%	16%	6% <span>-----&gt;</span>	17%

# In developed markets the most evident shift is to unbranded generics

Volume  
SU (TABS)

While the focus in pharmerging markets remains branded GX

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# Purchasing strategies are key in most markets

## RATIONALE FOR COMPANY MERGERS/CONSOLIDATION

### Walgreen's – Alliance Boots - AmerisourceBergen

*"...streamline the distribution of pharmaceuticals to Walgreens' stores and **leverage global supply chain efficiencies** while improving patient access to affordable pharmaceuticals to increase the efficiency of the healthcare system."*

Source: AmerisourceBergen Press Release March 2013

### McKesson – Celesio –RITE AID

*"A Celesio acquisition will allow McKesson to buy as much as \$10 billion a year in generic drugs for distribution, compared with \$6 billion to \$7 billion on its own"*

Source:  
<http://www.bloomberg.com>  
January 2014

### CVS – Cardinal Health

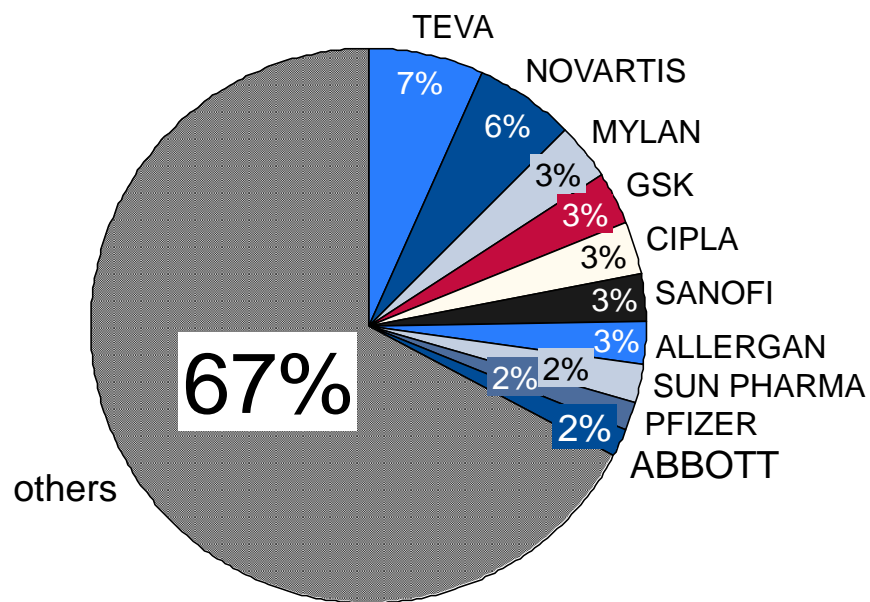
*"This partnership will enable us to maintain our leadership role in navigating the dynamic U.S. generics market. With its combined volume and capabilities, the joint venture will develop innovative purchasing strategies with generic manufacturers and enhance supply chain efficiencies."*

Source: Cardinal health press release<sup>1</sup>

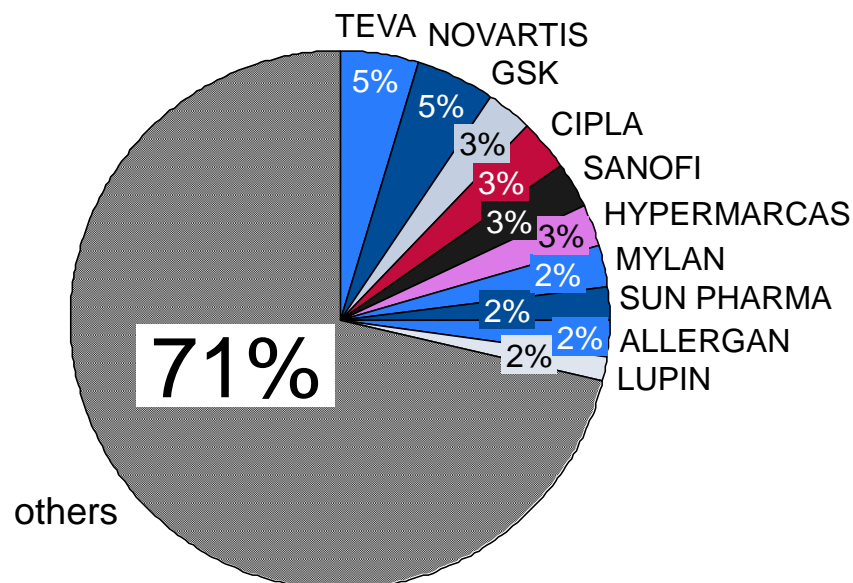
84% of the US generic market consolidated to 4 buying consortia  
15% of Europe added to the US consortia

# Global generic competition more fragmented

**Generic volumes 2010**  
**1056 bn SU**



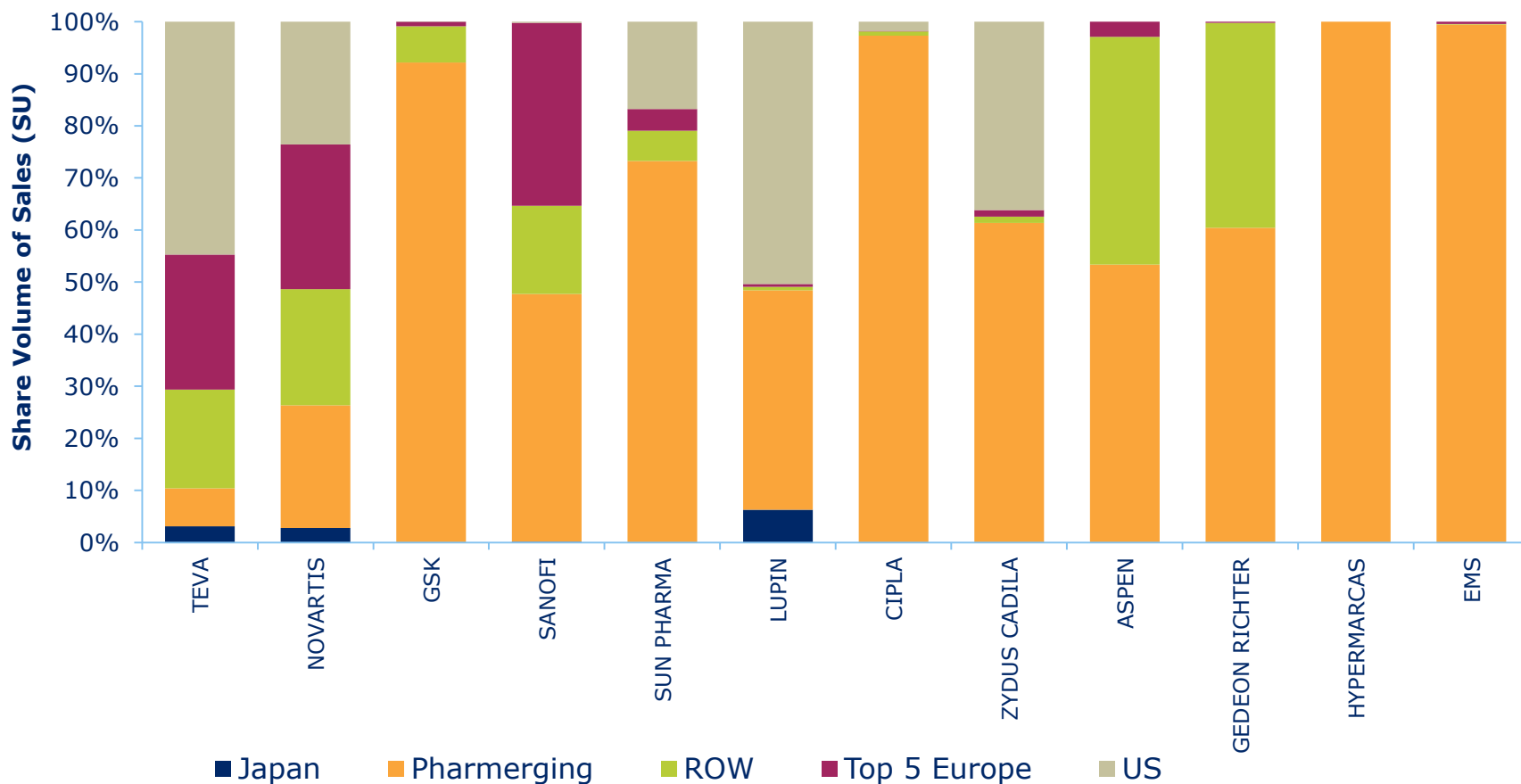
**Generic volumes 2015**  
**1449 bn SU**



Outside top 10 grows share

# Very few generic corps have a truly global footprint

## Selected top GX companies – Volume sales breakdown 2015



# Key dynamics in global pharmaceutical market

## Regional

- US innovation
- Pharmerging volume

## Specialty

- Dominates launch and pipeline
- Small populations
- High per capita prices

## Payers

- European payer environment hardening because of increasing demands on specialist /hospital budget

## Biosimilars

- Large variation in uptake of some biosimilars
- Budget relief?

## The Wholesaler Dilemma

- Economic situation
- Retail competition
- Growth of Specialty
- Increase use of hospital

My colleague, Hugo Mendes, asked me to also say something innovative ...



Drones Set to Deliver Medicine to Remote Parts of the U.S. Whitehouse asks Zipline following success in Rwanda

Why not ?

- Can travel 100km in 30 minutes
- No refrigeration necessary
- Cost effective for rural areas (low weight / high value goods)
- Can be life saving.

Never say crazy idea !

..we used to say that about Mail Order or internet shopping...



# Thank you!

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