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# Trends in the Global Pharma-Market and its Impact on the Supply Chain

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October, 20<sup>th</sup>, 2016

# Top line growth forecast at 4-7% CAGR to 2020 (in constant US\$)

Pharmerging growth declines to single digits



Developed Markets CAGR 2016-2020	
US	6%-9%
Japan	(-1)%-2%
Germany	3%-6%
UK*	4%-7%
Italy	2%-5%
France	(-2)%-1%
Spain	2%-5%
Canada	3%-6%
<b>Developed</b>	<b>4%-7%</b>

Pharmerging Markets CAGR 2016-20 LCUS\$	
China	5%-8%
Brazil	7%-10%
India	10%-13%
Russia	6%-9%
Turkey	12%-15%
Mexico	2%-5%
<b>Pharmerging LCUS\$</b>	<b>6%-9%</b>
<b>Pharmerging US\$</b>	<b>4%-7%</b>

\*Subject to clawback

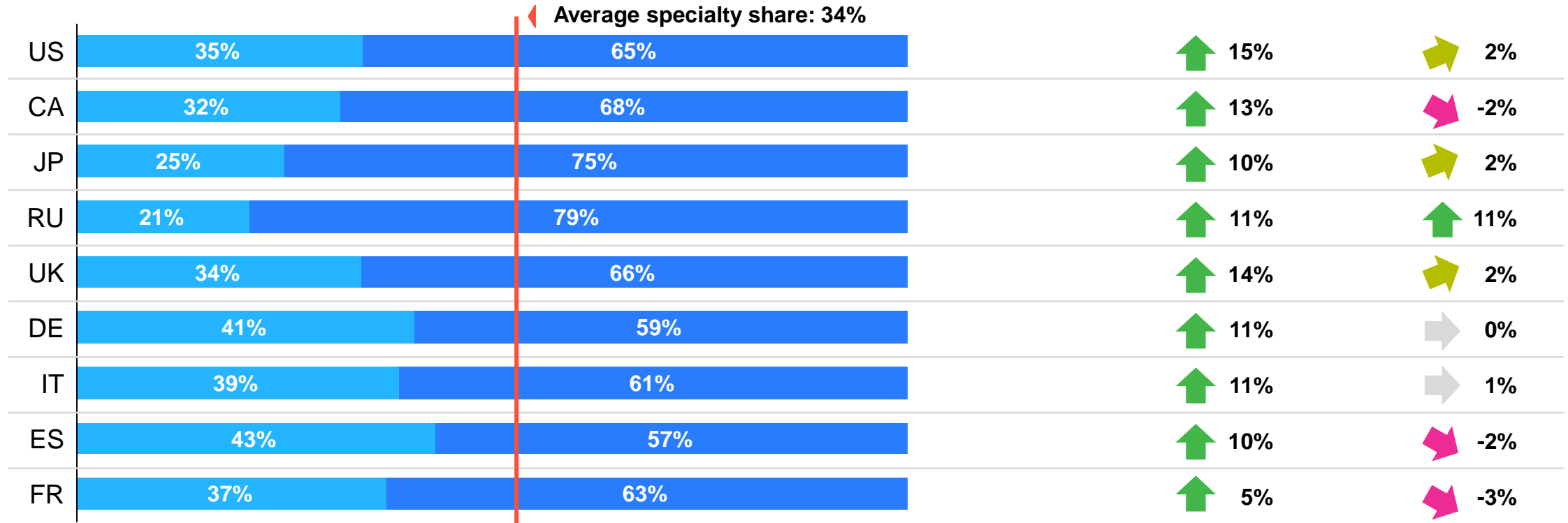
- At par with region CAGR
- Lower than region CAGR
- Higher than region CAGR

Source: IMS Market Prognosis March 2016; at ex-manufacturer price levels, not including rebates and discounts. Contains Audited + Unaudited data; Sept 2015 forecasts used for all countries outside of top 52

# Over time growth in specialty markets out-performed traditional markets in terms of value...

2015 value share specialty vs. traditional in TOP 5 EU + focus countries

5 year CAGR ('10-'15)

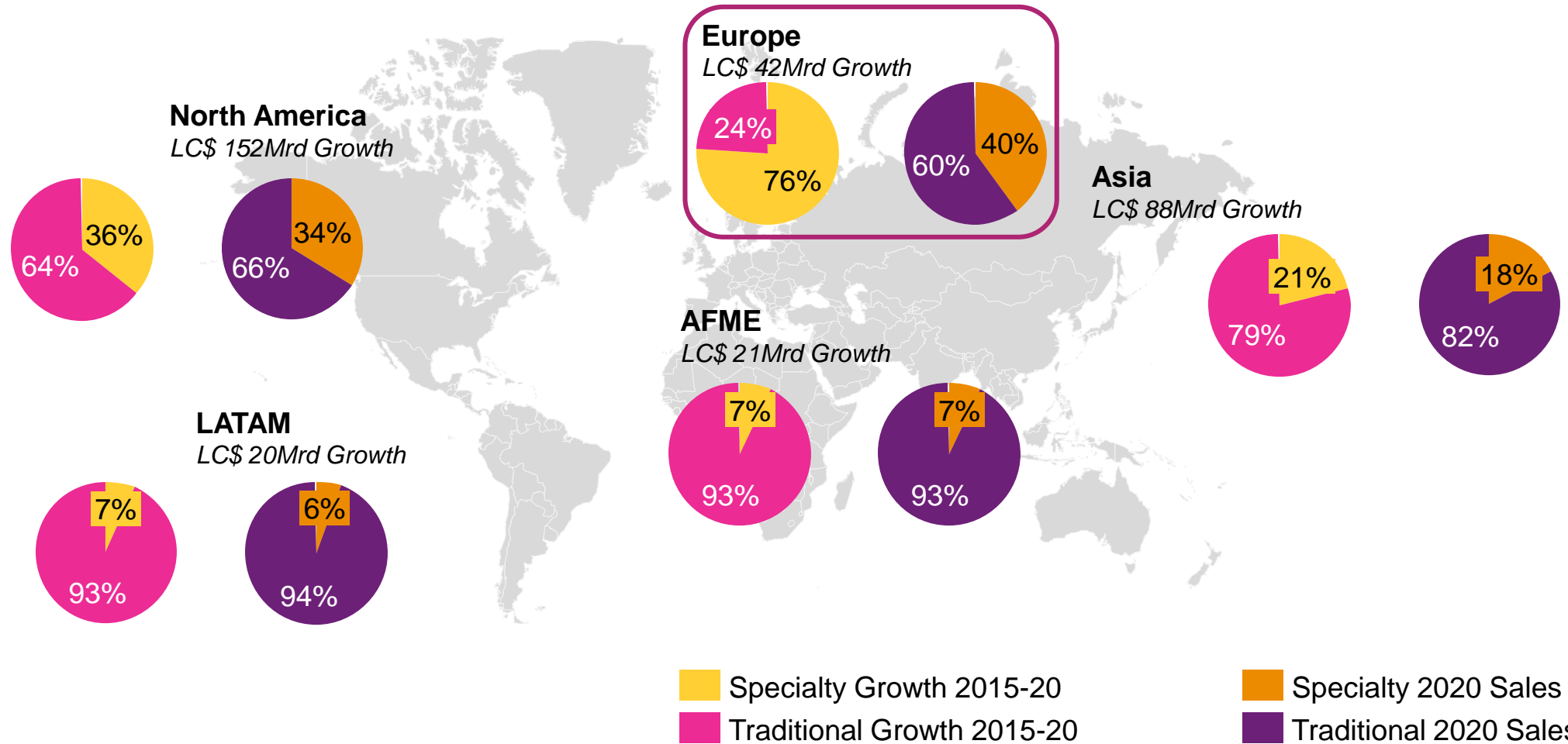


Specialty Traditional

Source: IMS Health, MIDAS, MAT Q4 2015

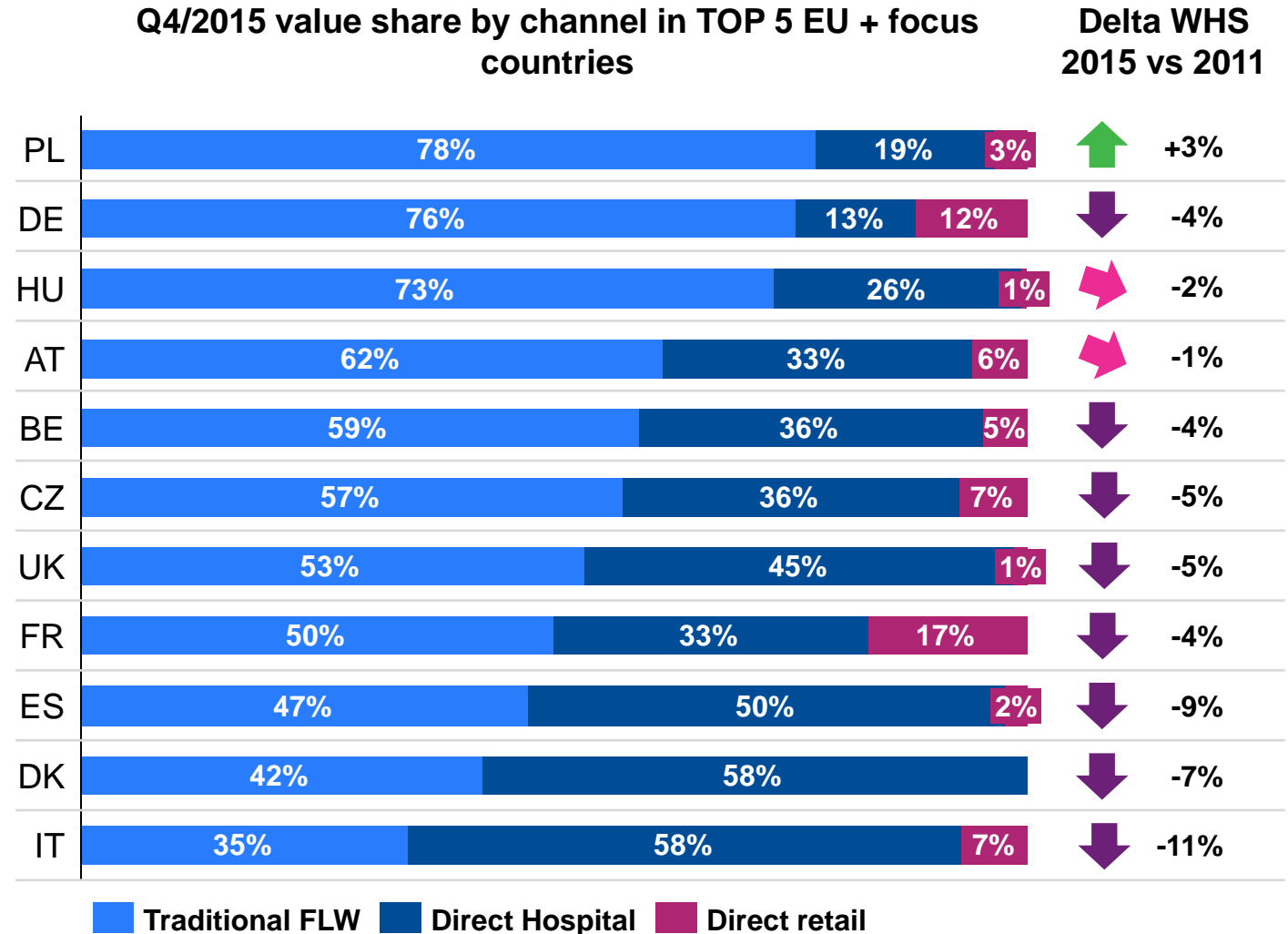
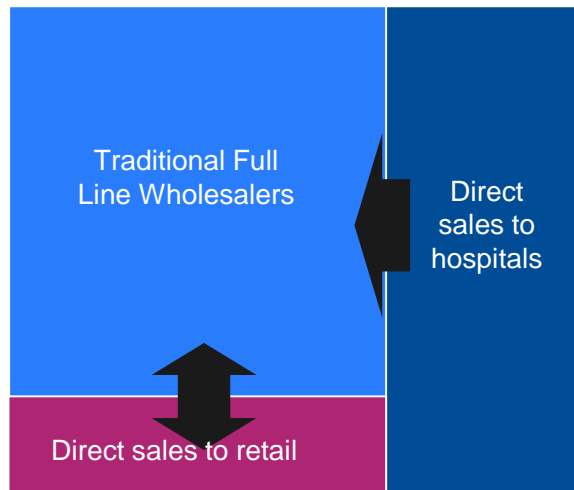
# .... and are expected to remain the main growth driver in Europe till 2020

## Share of Absolute Growth 2015-2020 and 2020 Sales by Region



Source: IMS Health Market Prognosis September 2015; at ex-manufacturer price levels, not including rebates and discounts. Contains Audited + Unaudited data; IHII analysis

# At the same time, wholesalers loosing ground amongst European countries



Source: IMS Health, total market, shares are based on value, Q4 2015, direct shares from local affiliates

# Specialty products require a special handling leading to a rise in new distribution models

## Distribution



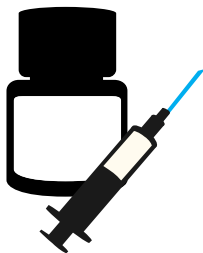
- Many specialty products need refrigeration or freezing
- Often requires maintaining cold chain distribution during the whole delivery process

## Preparation



- Specialty products can require compounding of individual ingredients in an exact strength and dosage form tailored to the patient's need

## Administration



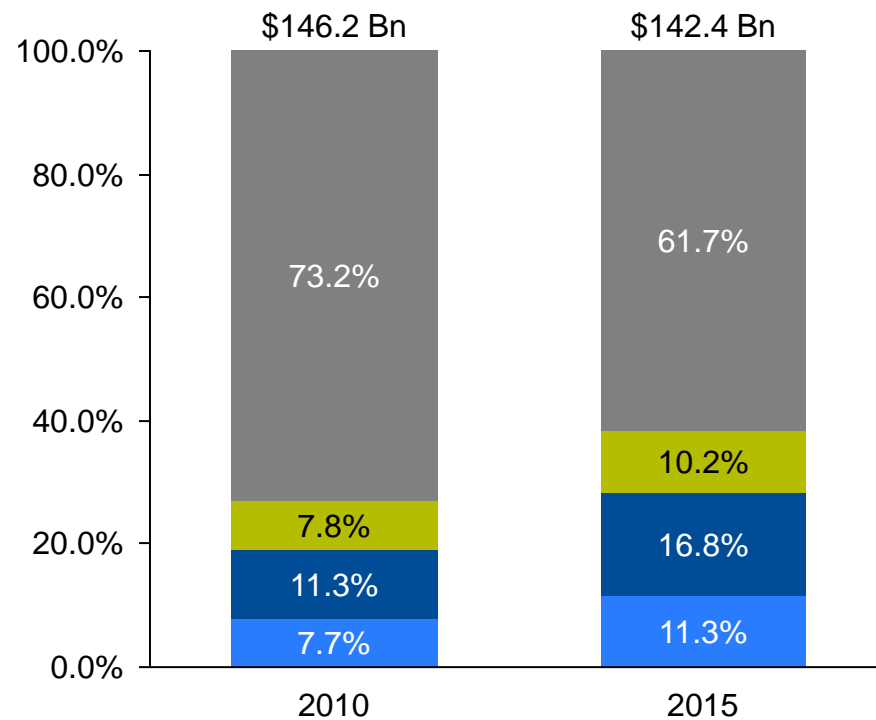
- Many specialty products are self-administered injectable
- Requires patient training to administer
- Support to achieve adherence needed

## Rise of Homecare and specialty pharmacies

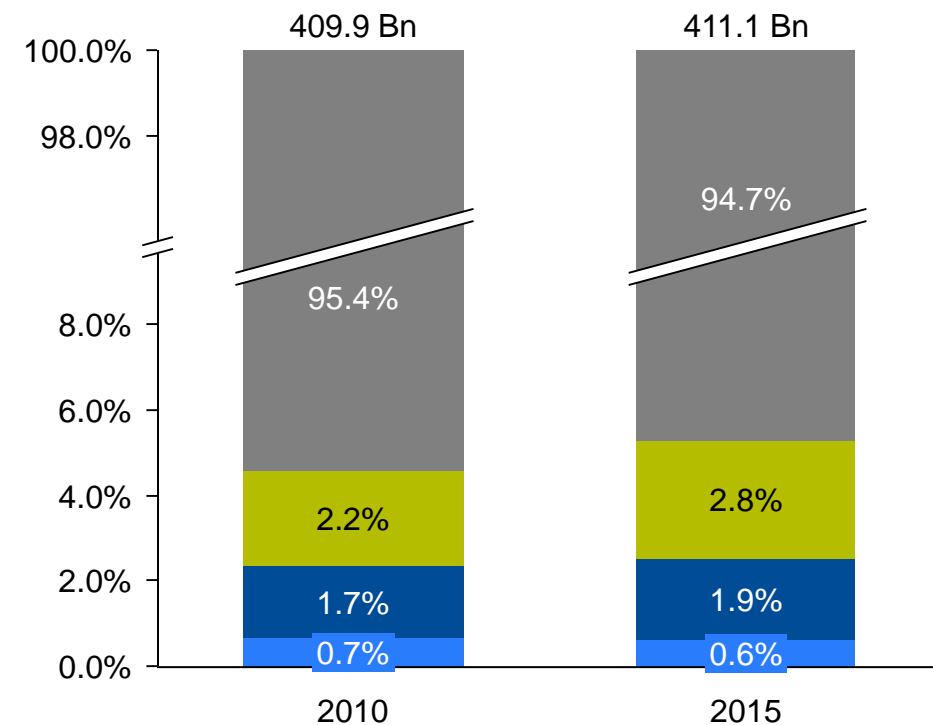
- “Total service” to patient
- Aseptic services (e.g. oncology)
- Compliance programs/ patient support
- Elimination of indirect payer costs

# Typically specialty products are high price products with simultaneously low volumes

**EU 5 – Concentration of product sales in bn US\$**



**EU 5 – Concentration of product sales volume in SU bn US\$**



■ Top 10 products 
 ■ Products 11-50 
 ■ Products 51-100 
 ■ All others

Source: IMS Health, MIDAS MAT Q4 2015, US\$ and SU

# They have a large impact on WHS margins – manufacturers try to keep those by direct sales

	Mark up	HUMIRA		ENBREL		GLIVEC	
		Price per pack €	WHS mark up	Price per pack €	WHS mark up	Price per pack €	WHS mark up
<b>AUSTRIA</b>	€23.74 fixed mark-up	975	<b>23.7</b>	858	<b>23.7</b>	2,705	<b>23.7</b>
<b>BELGIUM</b>	€2.30 + 0.9%	951	<b>10.9</b>	918	<b>10.6</b>	2,284	<b>22.9</b>
<b>FRANCE</b>	6.68% for first €450 (with a minimum mark-up of 0.30€) 0% above €450	829	<b>30.1</b>	732	<b>30.1</b>	1,737	<b>30.1</b>
<b>GERMANY</b>	Fixed fee of €0.70 plus 3.15% mark-up to a limit of €37.80 on the percentage mark-up element.	3,631	<b>38.5</b>	3,164	<b>38.5</b>	5,331	<b>38.5</b>
<b>SPAIN</b>	€7.54 where ex-MNF price excl sales tax is >€91.63	N/A		845	<b>7.54</b>	1,184	<b>7.54</b>

## Why direct sales?

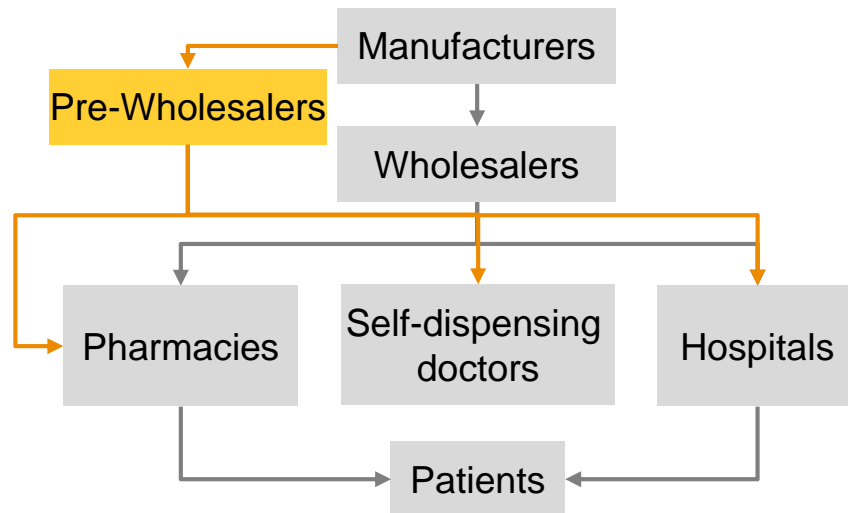
- Ability to control discounting
- Ability to receive information about the dispenser
- Eliminate wholesaler exporting
- Manage distribution costs

Source: IMS Health



# Wholesalers offer pre-wholesaling carrying out warehousing & logistic for manufacturers

## Classic distribution system for pharmaceuticals with pre-wholesalers

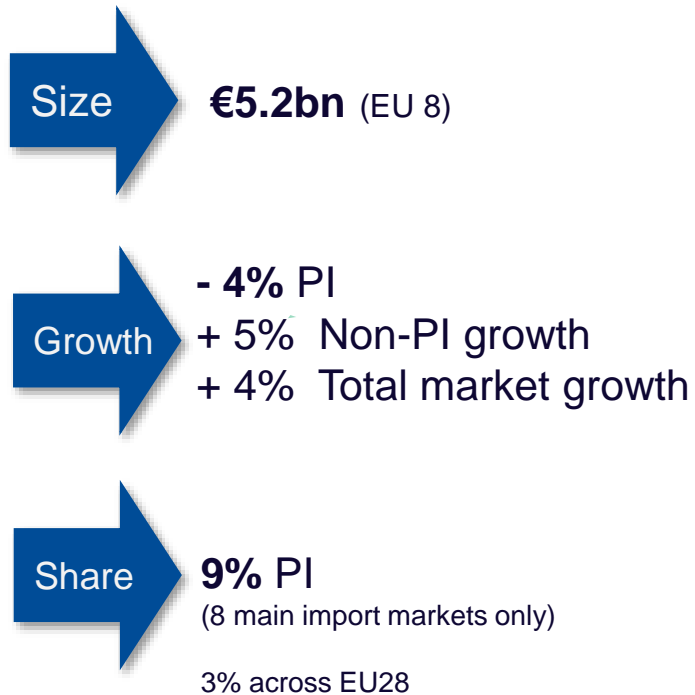


## Characteristics

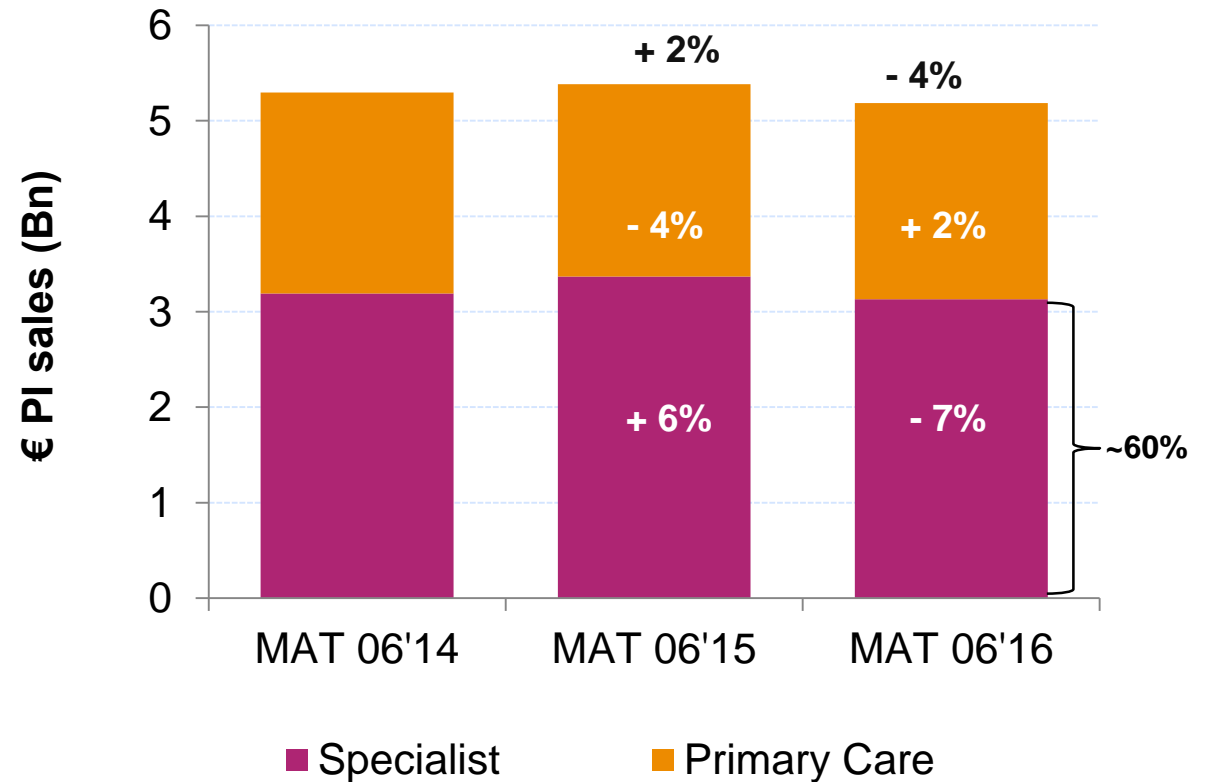
- Manufacturers outsource the warehousing and logistic to pharmacies, self-dispensing doctors and hospitals to so called pre-wholesalers
- Wholesalers often offer pre-wholesaling services

# Parallel trade is a huge threat for specialty products due to different price levels in the EU

## Import markets context

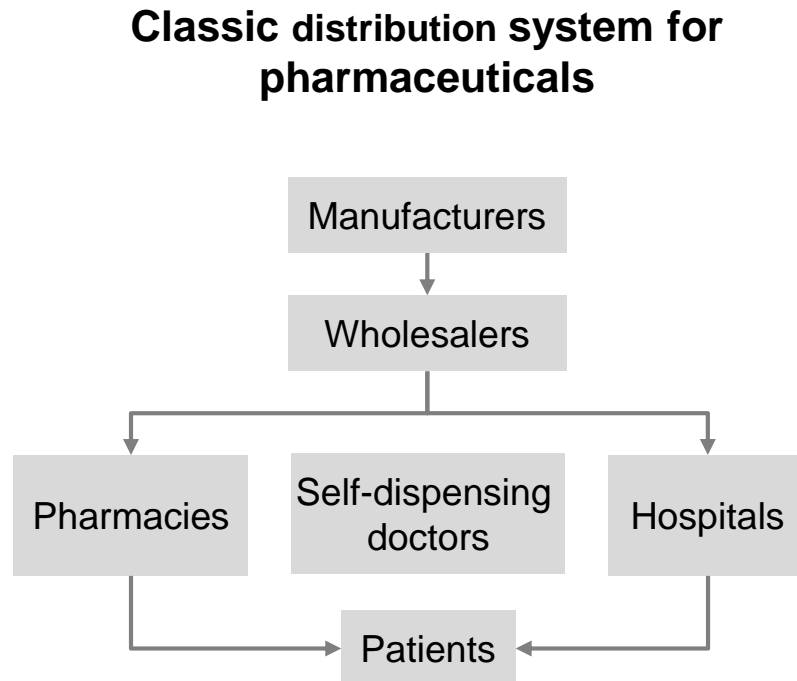


## European annual parallel trade



Source: IMS MIDAS and internal database, import markets: DEU, GBR, NLD, Nordics and IRL, All sales at ex-MNF level.

# The traditional dispensing and distribution model is changing...



## Trends:

### Manufacturers

- Aim to control the supply chain (reduce distribution costs – increase margin, control exports)

### Pharmacies

- Discounts driven (mainly generics and PI)
- Trend towards dispensing fees

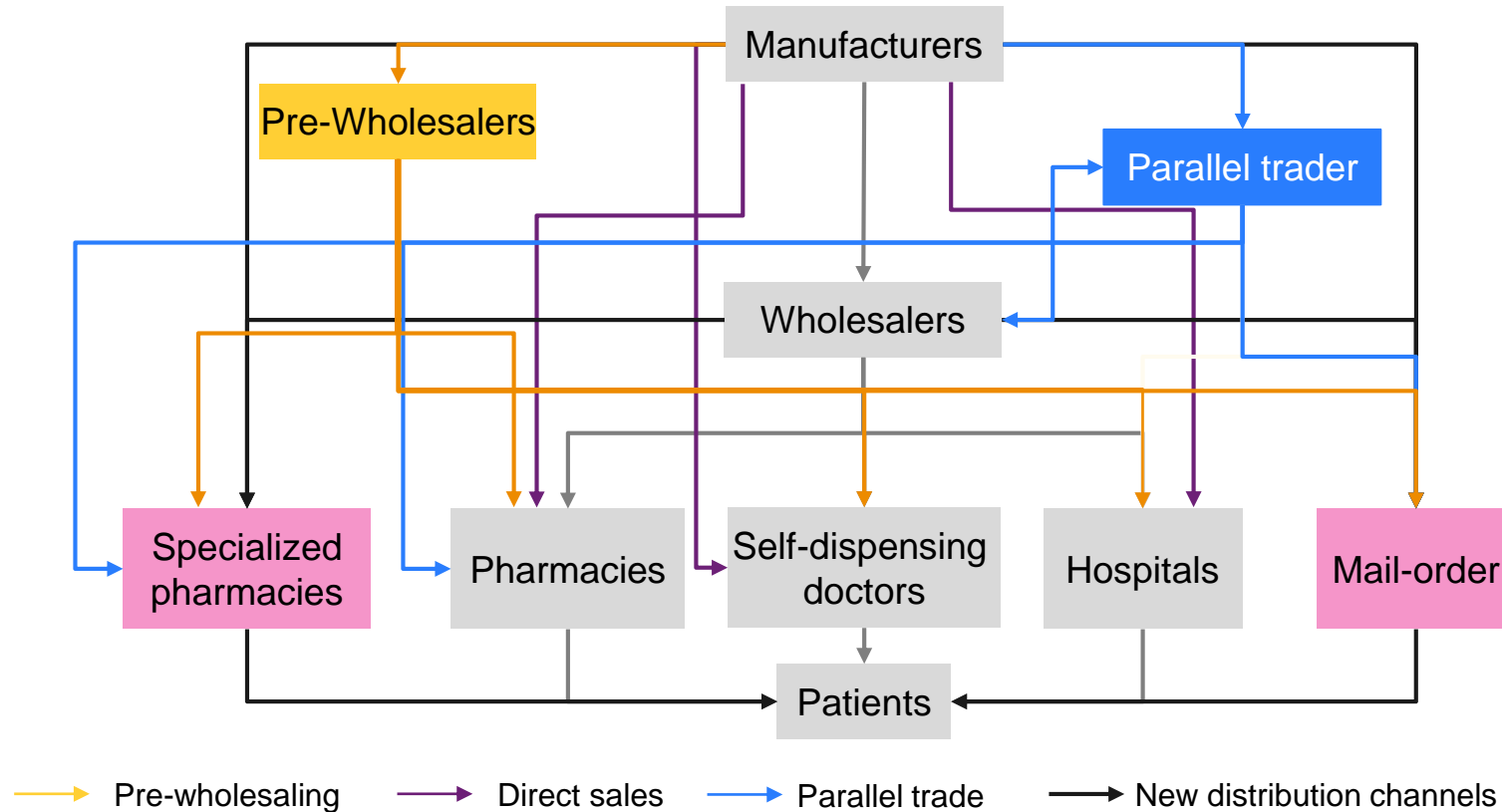
### Wholesalers

- Parallel Export important in several markets
- Offer pre-wholesaling to participate in direct sales business

### New market players

- Homecare and Specialty pharmacies

# ... to a highly complex environment



# Counterfeits are a high threat leading to another big challenge for distributing pharmaceuticals

## Inside the fake Viagra factory



Which one is the counterfeit?



# Politicians take actions and continue efforts to highly control the pharmaceutical supply chain

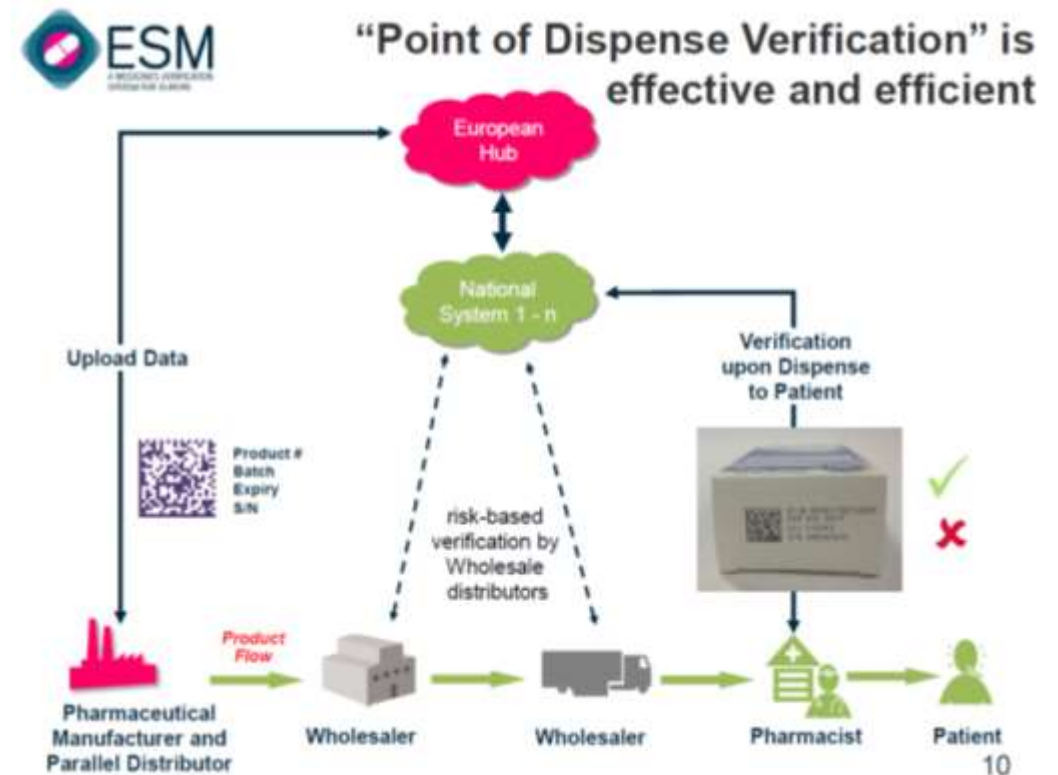
## Introduction of Falsified Medicines Directive

**Objective** Protection of patients from falsified medicines in the legal distribution chain

**Content** Pan-European system to verify the authenticity of medicinal products

**Scope** All Rx-bound products); OTC-products cannot be subject to authentication

**Due date** Implementation in all countries by Q1/2019, **Non – compliance puts sales at risk!!!**



## Additional tasks and new costs for the pharmaceutical supply chain

Source: EU "Falsified Medicines", ESM "A European Medicines Verification System"

# Key Insights to Take Away

- 1** Growth in the pharmaceutical market mainly comes from specialty care
- 2** Specialty products are typically high cost products with low volumes and require a specific handling in distribution, preparation and administration
- 3** Manufacturers seek to fully tap high margins for those products and keep control over the whole distribution process via direct sales
- 4** Wholesalers react to this development by expanding their business in offering manufactures pre-wholesaling services
- 5** Big threat of counterfeits leads to even stricter regulations (Falsified Medicine Directive) of the pharmaceutical supply chain in the next years

# Please contact me for more information



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