Global Healthcare Trends and Outlook

Joint 23rd Medicines for Europe and
20th IGBA Annual conference
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Principal, Thought Leadership

Outline

- **The global pharmaceutical market: description and trends**
- The global generic market trends
- Trends in new launches: innovator products and generic medicines
- Will the future generic medicines launches be sufficient to cope with the high costs of new innovative medicines?
- Will future biosimilar launches balance the new high cost innovative medicines?
- Summary

We live in difficult times….

Political instability

Ukraine, South Africa, Brazil

Oil price exposure; depreciating currency

Russia, Nigeria, Venezuela, Algeria, Brazil
ME and USA IMPACT

Runaway inflation, default risk

Venezuela, Argentina, Egypt

Terrorism

Nigeria, Pakistan, India, Egypt, Turkey
GLOBAL IMPACT

IP breakdowns, Bribery Allegations

India, China, Nigeria, Turkey

Refugee crisis

Syria, Turkey, Lebanon, Iraq
EUROPE IMPACT

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One constant, the need for healthcare

Terrorism

Nigeria, Pakistan, India, Egypt, Turkey

IP breakdowns, Bribery Allegations

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Refugee crisis

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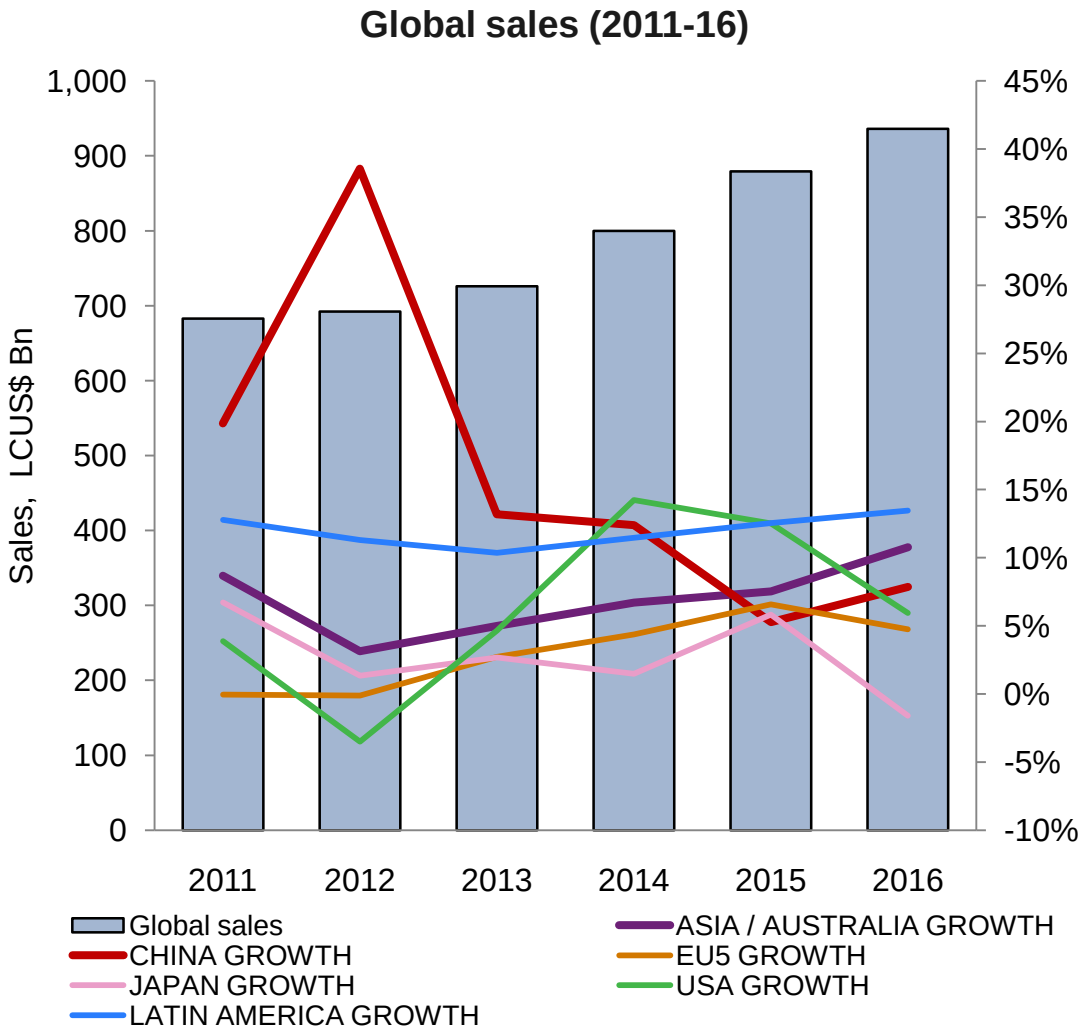
Global pharma has grown 6.5% over the last 5 years to $936BN



	Global Sales/Growth 2016		
	Sales $LCUS Bn	% Share	% Growth
Global Total	936		6.5%
USA	438	46.8%	5.9%
JAPAN	78	8.3%	-1.6%
CHINA	75	8.0%	7.9%
GERMANY	37	4.0%	4.2%
FRANCE	29	3.1%	3.4%
ITALY	26	2.8%	6.6%
BRAZIL	22	2.3%	11.1%
UK	20	2.2%	4.9%
SPAIN	20	2.1%	4.0%
CANADA	17	1.8%	4.1%

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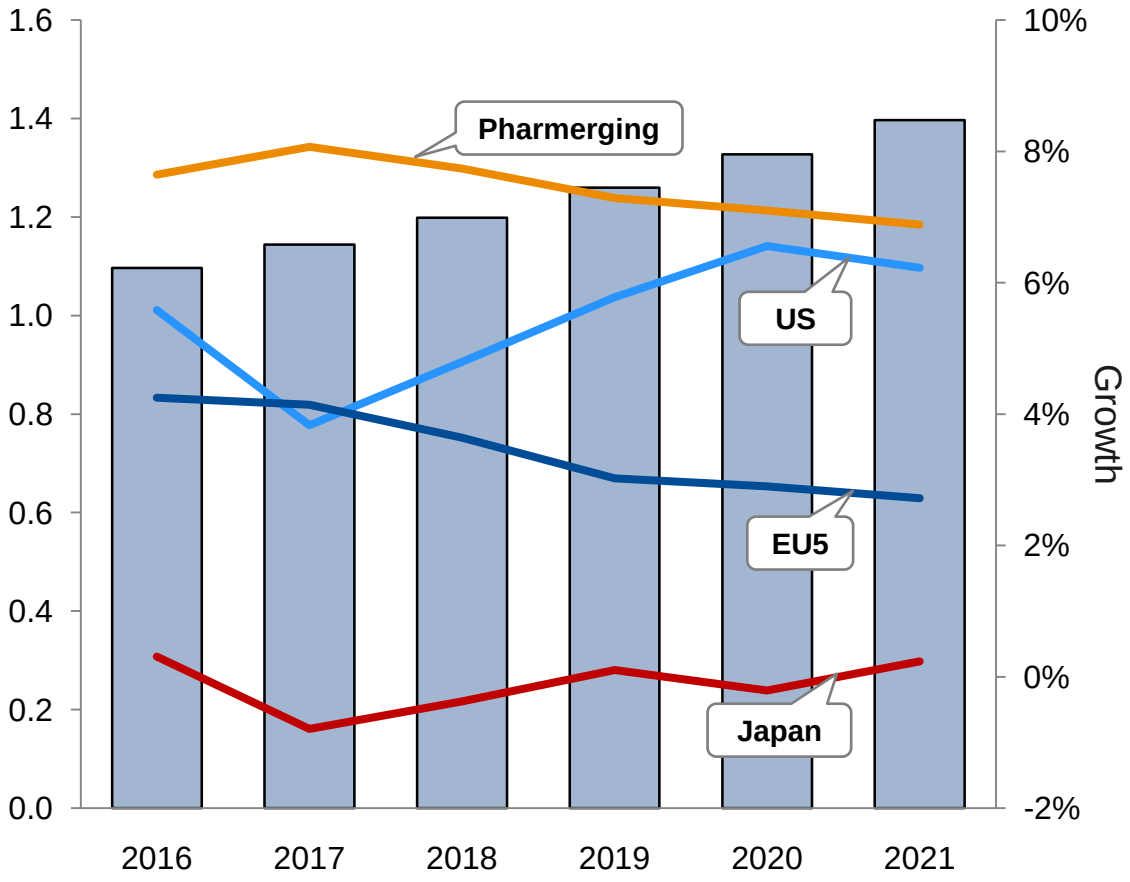
Source: QI MIDAS MAT Q4 2016

Growth projected at 3-6% CAGR to $1.4tn by 2021

USA to continue to dominate growth and sales. China and Japan slow down.

Global sales (2016-21) Trillions of USD (Constant)



CAGR 2016-21	
Developed	2-5%
US	5-8%
Japan	(-1)-2%
Germany	2-5%
UK*	2-5%
France	2-5%
Italy	2-5%
Spain	1-4%
Canada	2-5%
Pharmerging	6-9%
China	6-9%
Brazil	6-9%
India	10-13%
Russia	6-9%
Turkey	10-13%
Mexico	3-6%

Higher than region CAGR

On par with region CAGR

Lower than region CAGR

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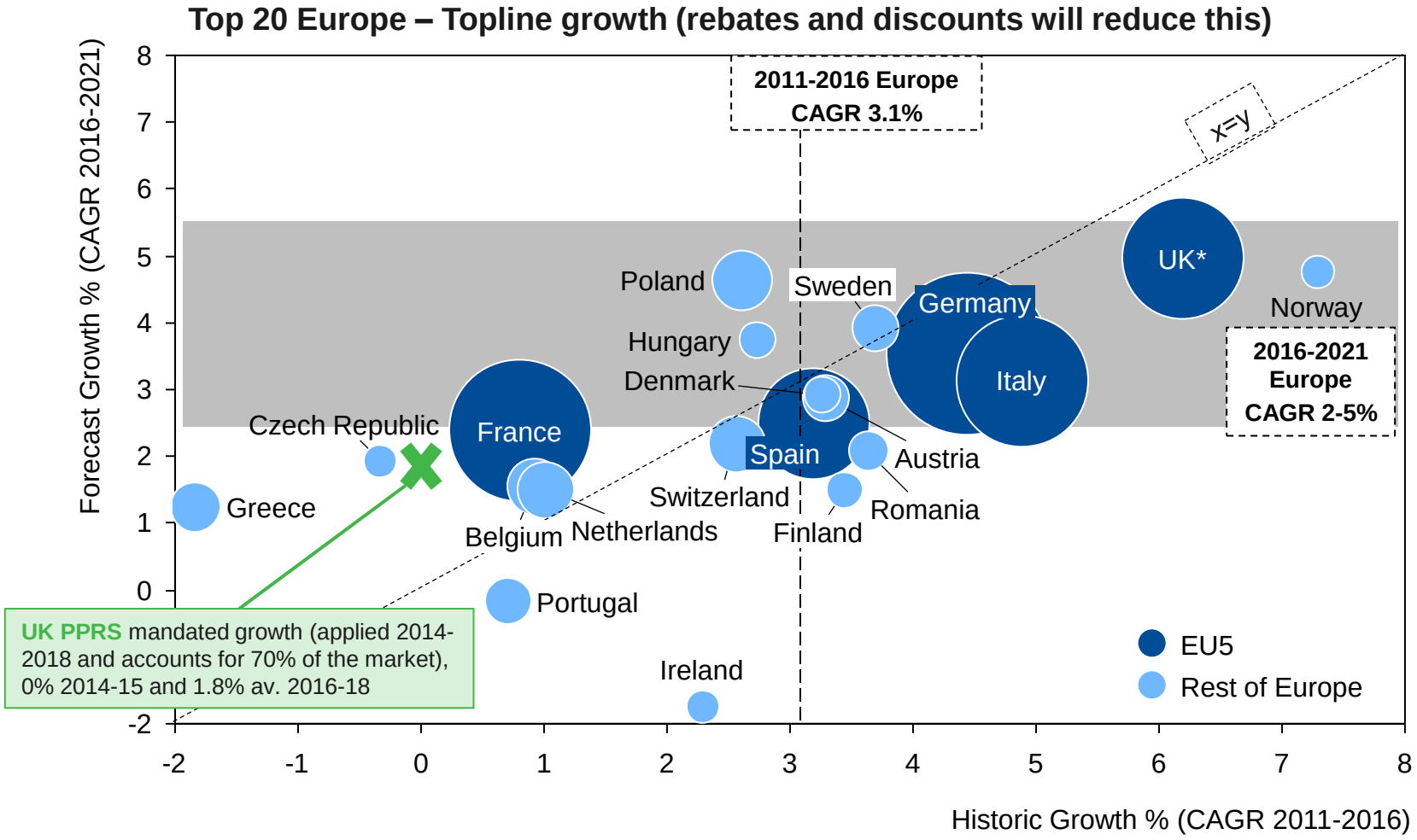
Notes: *Subject to PPRS rebate; Ex-manufacturer price levels, not including rebates and discounts. Contains Audited + Unaudited data; Growth considered on par if the there is overlap between country and region CAGR ranges

Source: QuintilesIMS Market Prognosis Q1 2017

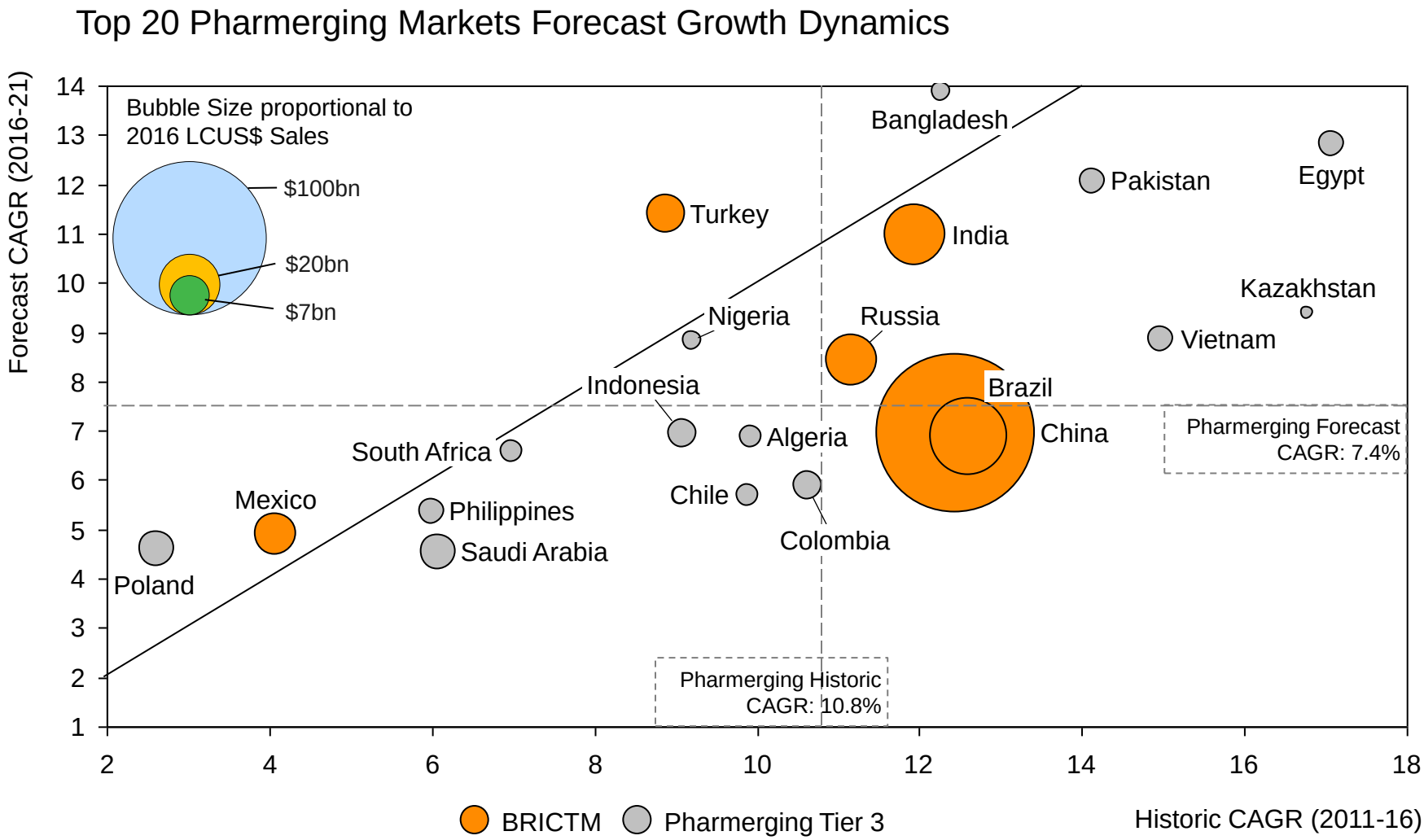
Healthcare policies mean European growth stagnant at 2.5% CAGR

Europe



Notes: *UK subject to PPRS rebates; **Current PPRS has capped growth to average of less that 2% per year to end 2018, growth for 2014 and 2015 was capped at 0%; Growth in LCUS$ unless otherwise stated; At ex-manufacturer price levels, not including rebates and discounts. Contains Audited + Unaudited data
Source: QuintilesIMS Market Prognosis March 2017

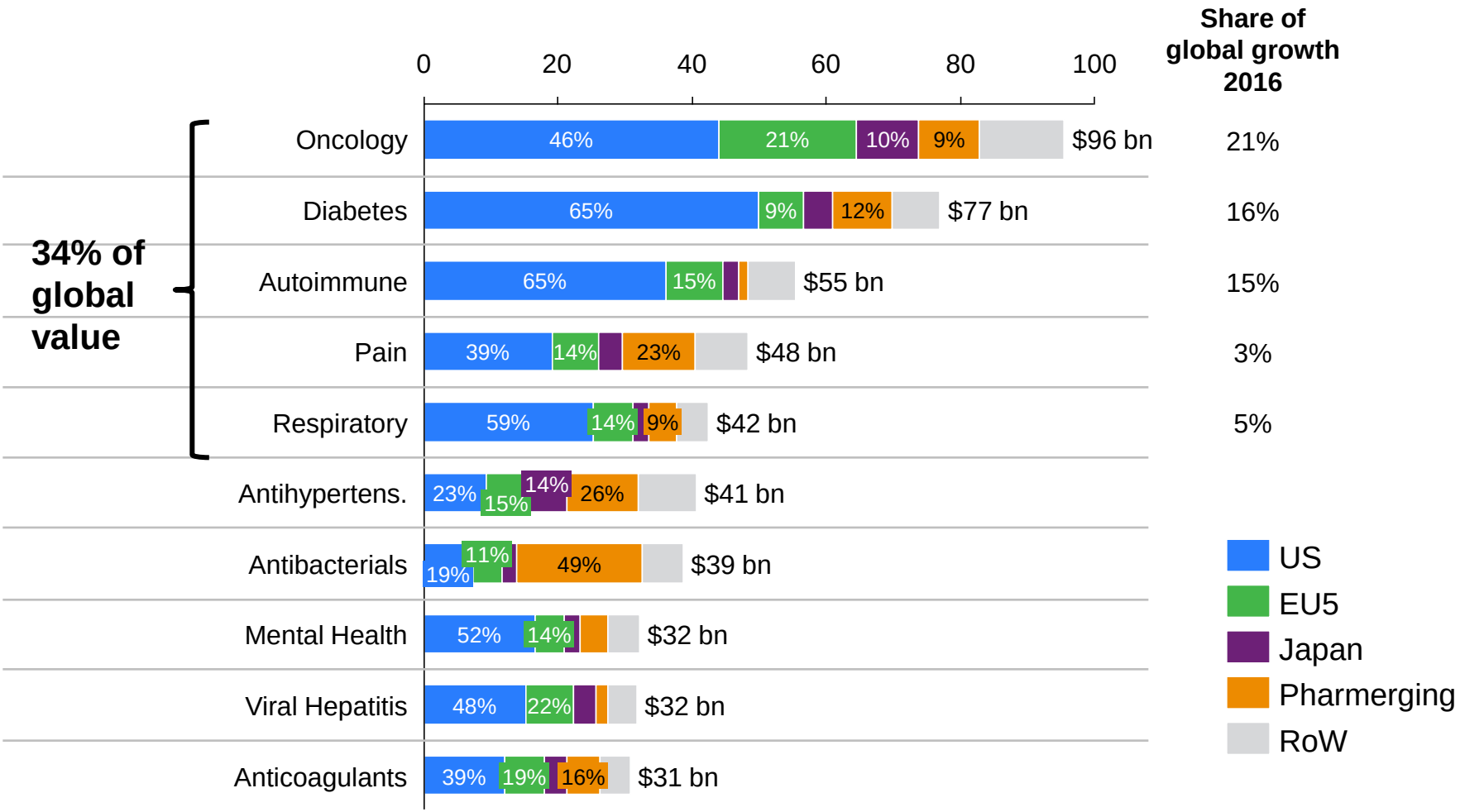
Wide dispersion in growth but CAGR falls to single digits…China dominates but moderating



Notes: At ex-manufacturer price levels, not including rebates and discounts. Contains Audited and Unaudited data; Argentina excluded due to hyperinflation
Source: QuintilesIMS Market Prognosis March 2017

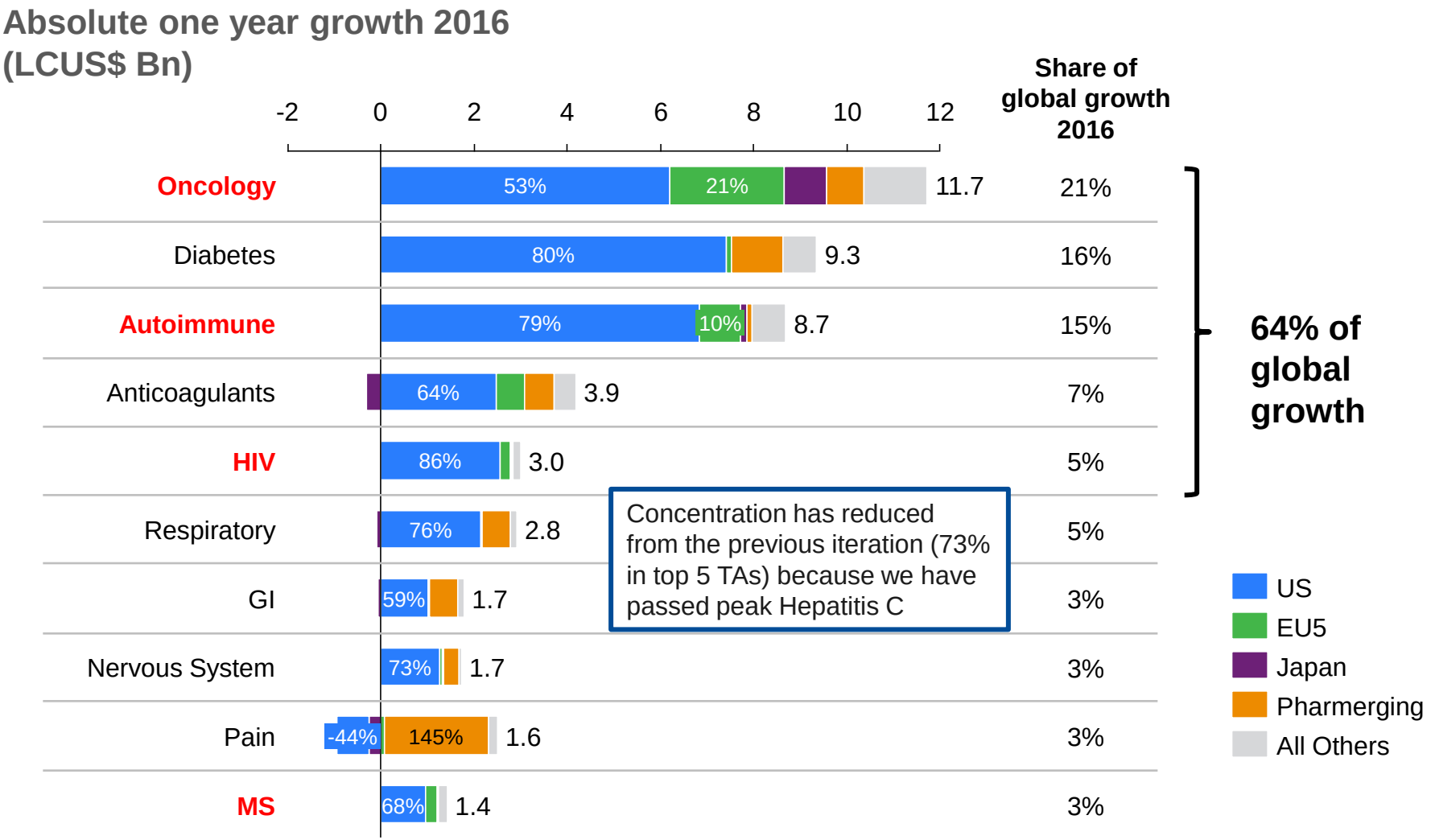
A third of global expenditure comes from five therapy areas

Therapy area sales (2016) bn USD



Source: QuintilesIMS MIDAS MAT Q4 2016, Rx only

Over 60% of global growth comes from just five TAs



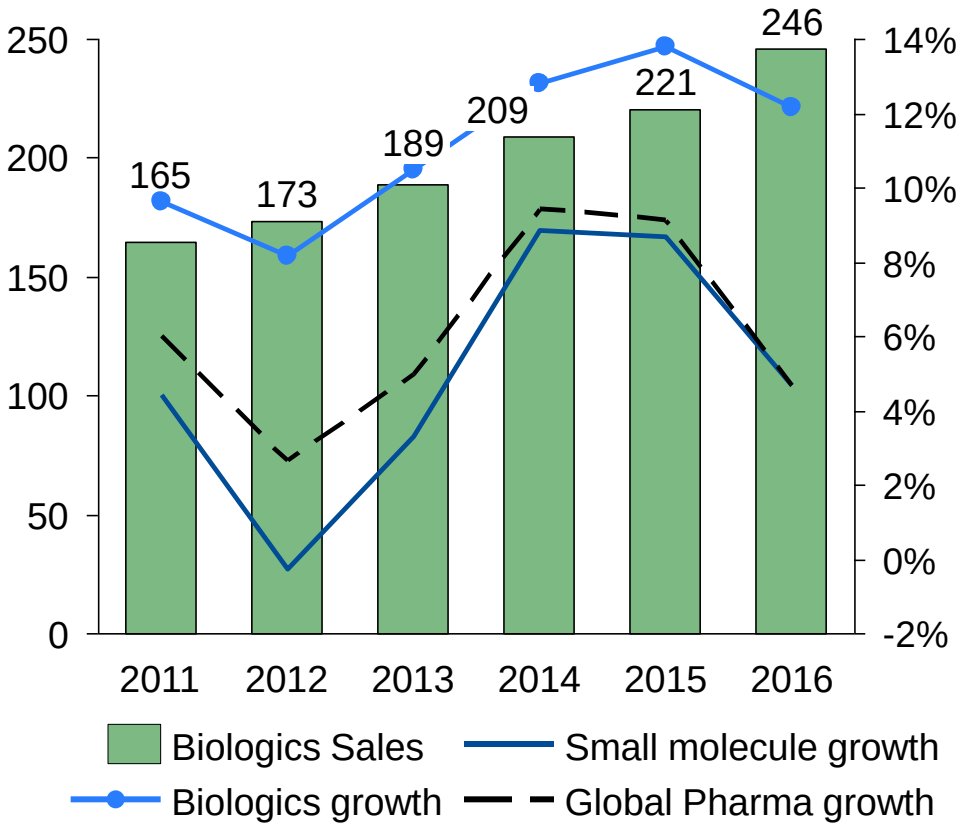
Source: QuintilesIMS MIDAS MAT Q4 2016, Rx only

Biologics have grown twice as fast as small molecules

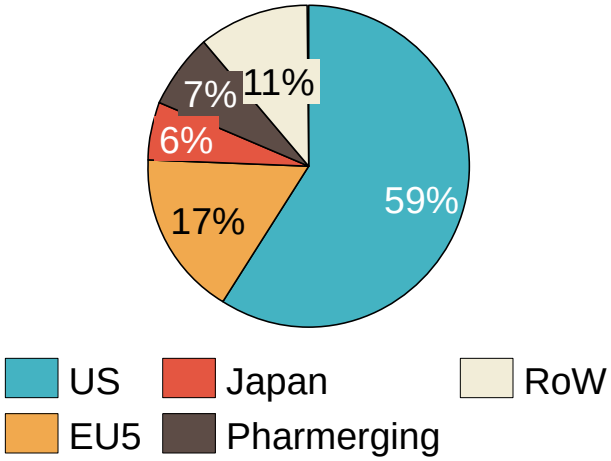
Small molecules faced increased genericisation from 2014

Global biologic sales and trends (2011-16)

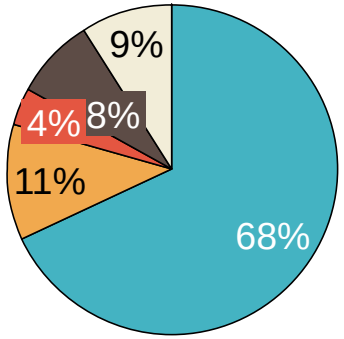
Billions of USD



Biologics – 2016 Share of sales



Biologics – Share of 5 yr growth



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Source: QuintilesIMS MIDAS MAT Q4 2016; QI Market Prognosis March 2017; Share of growth in LC$. Brazil and Mexico non-retail included

Impact of launches of Specialty products compared to earlier primary care products

Drug	Category	Paper	Indication	2-year global sales post launch
Celebrex	Primary care	LE1	Arthritis (OA/RA)	$3.9bn
Lipitor	Primary care	LE1	Lipid regulator	$3.0bn
Viagra	Primary care	LE1	Erectile dysfunction	$1.7bn
Avandia	Primary care	LE1	Diabetes	$1.1bn
Combivir	Specialty	LE1	HIV infection	$0.9bn

Drug	Category	Paper	Indication	2-year global sales post launch
Harvoni	Specialty	LEV	Hepatitis C	$33.0bn
Sovaldi	Specialty	LEV	Hepatitis C	$13.8bn
Tecfidera	Specialty	LEV	Multiple sclerosis	$5.1bn
Opdivo	Specialty	LEV	Cancer	$3.3bn
Sovriad	Specialty	LEV	Hepatitis C	$3.0bn

Orphan designation

Orphan designation

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Source: QuintilesIMS Midas LC US $ Q3 2016; QuintilesIMS Thought Leadership Launch Excellence model
Notes: Sales are normalised to take into account launch quarter and do not represent calendar sales

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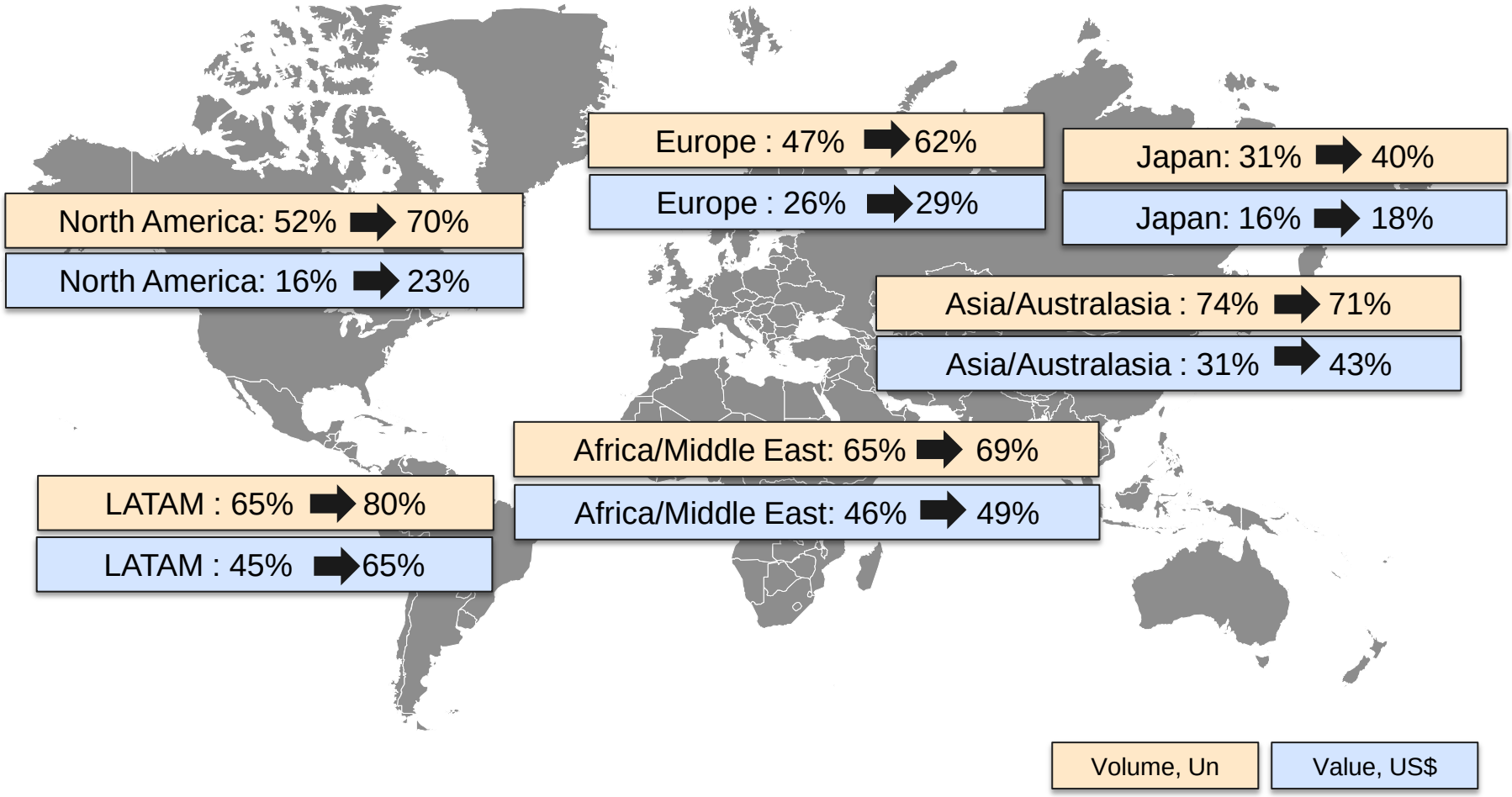
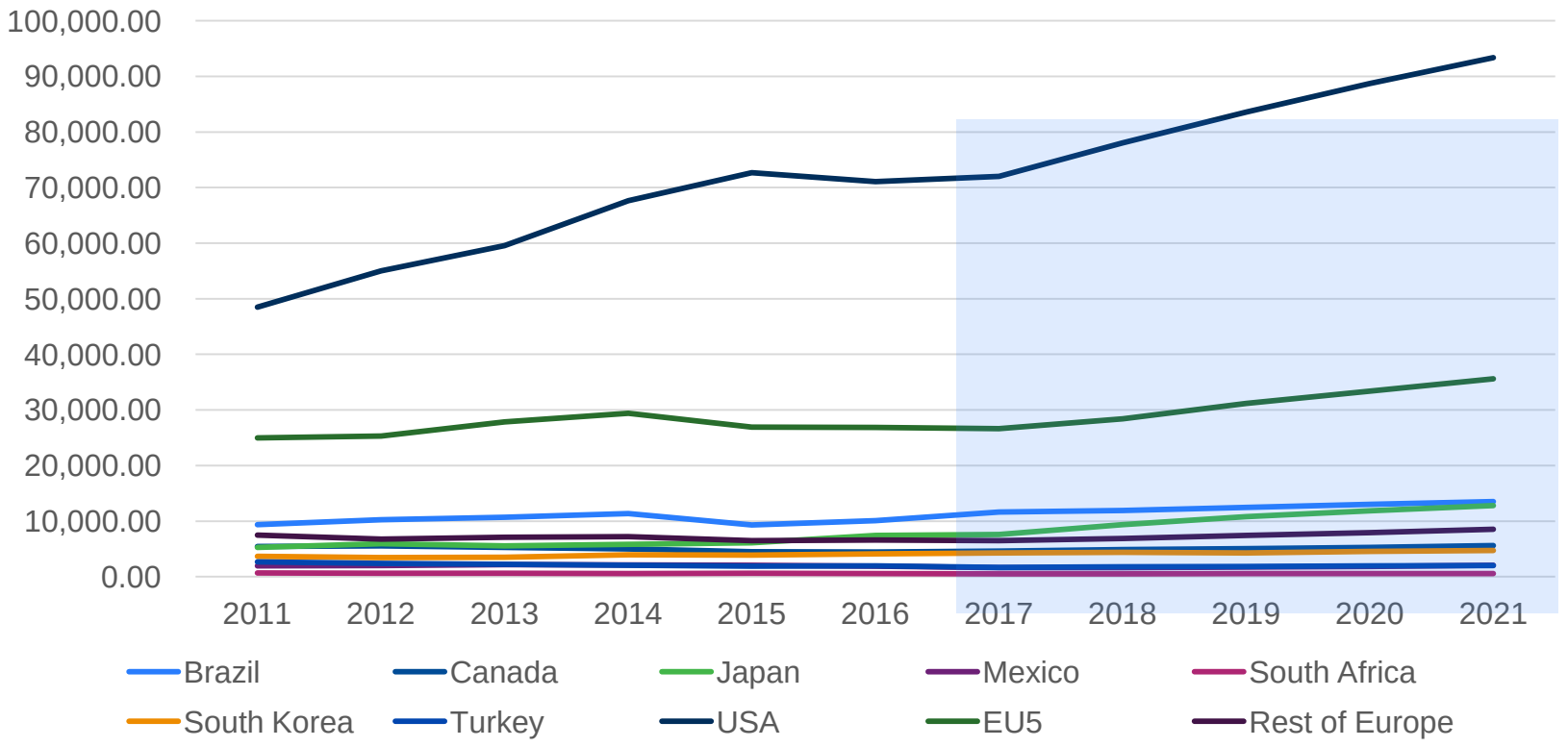
Generics are taking an increased share of the market

GENERICS MARKET SHARE (US$, Units) 2006 VS. 2016



Source: QuintilesIMS MIDAS MAT Q4 2016; Rx bound; Europe includes Turkey; Generics include Non-original branded products and unbranded products

The global generic market is forecast to grow at 5.8% CAGR

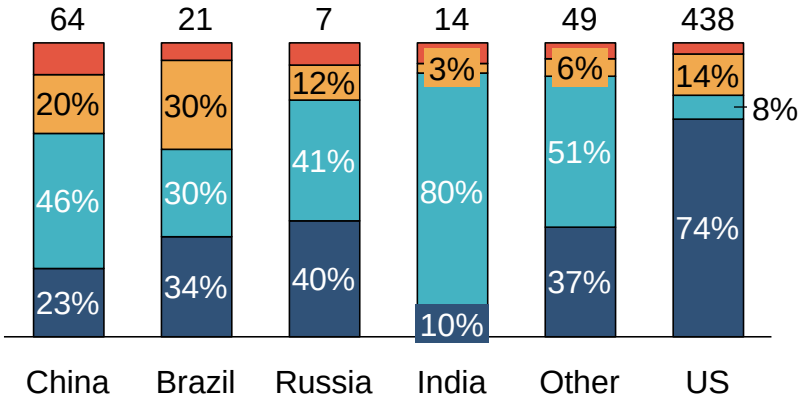


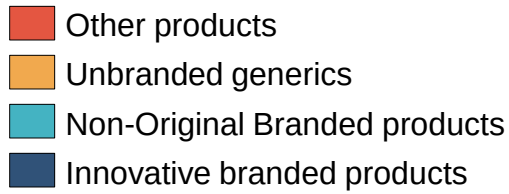
Source: IMS Generic Forecast May 2017

Pharmerging is dependent on generic products

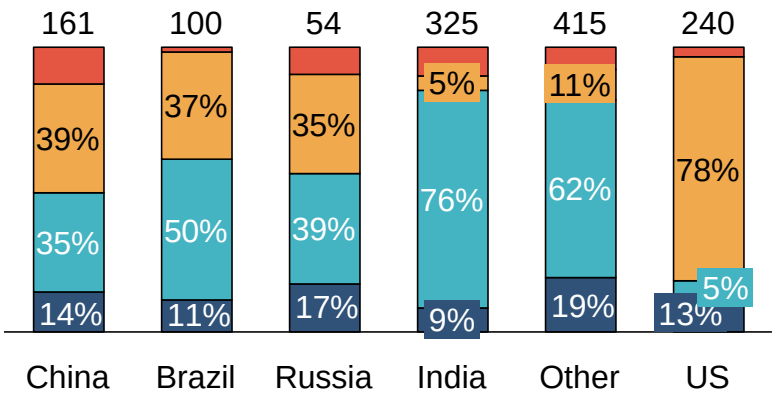
Preference for branded generics is coupled with increase OOP spend

Pharmerging Value (2016) bn USD





Pharmerging Volume (2016) bn SU



	Value CAGR 2011-2016	Volume CAGR 2011-16
Unbranded generics	9.2%	7.0%
Non-Original Branded	5.0%	6.1%
Innovative products	0.1%	4.9%
Pharmerging market	**4.1%**	**6.2%**

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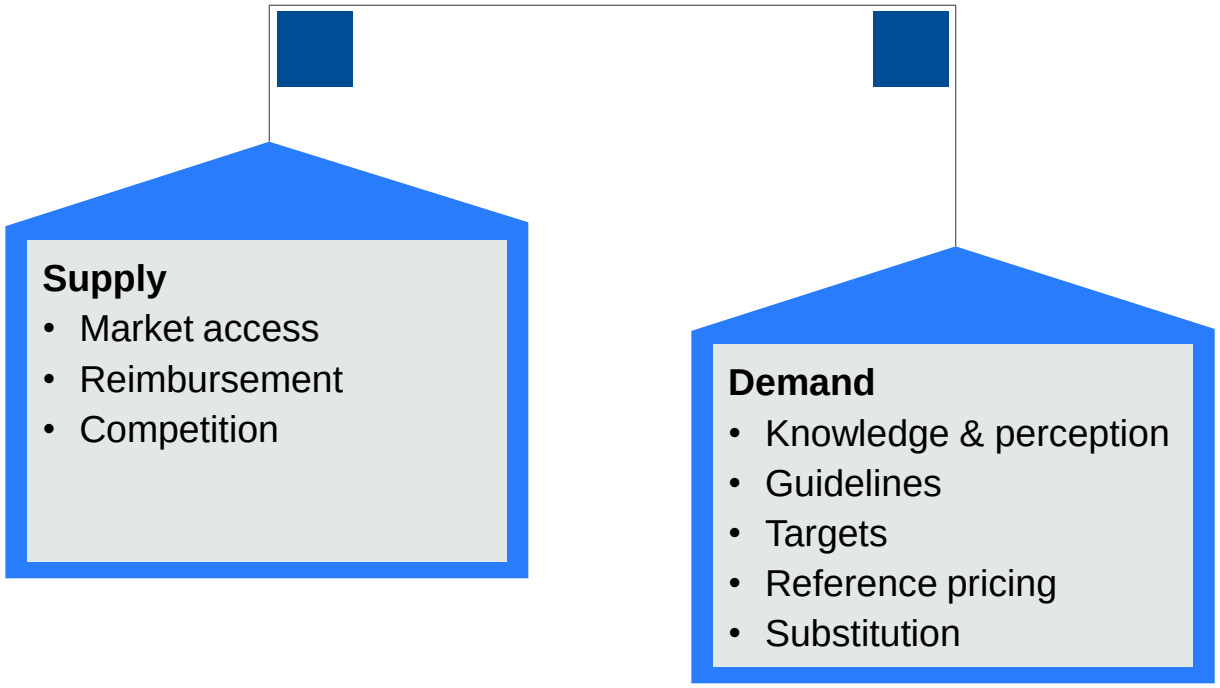
Source: QuintilesIMS MIDAS MAT Q4 2016; Innovation (2016); OTC excluded; Excludes traditional Chinese medicines

What is driving the generic market?

- Affordability
- Headroom in budgets for newer treatments
- Treatment guidelines
- Incentives/ budgets for prescribers
- Patient co-payments
- Earnings for pharmacist
- Products coming off patent

To have an effective generics market there needs to be a coherent generics policy

Addressing supply and demand aspects



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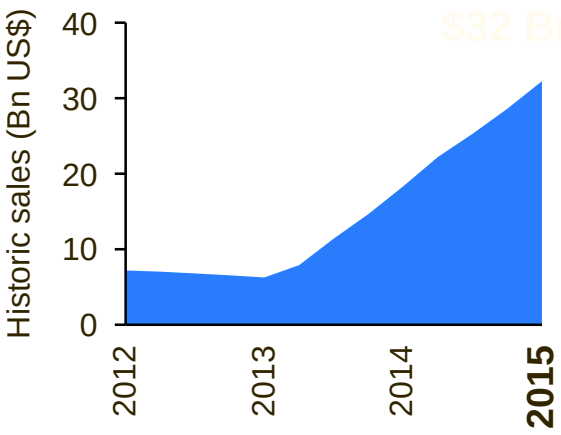
Sovaldi only the first of several potential tsunamis

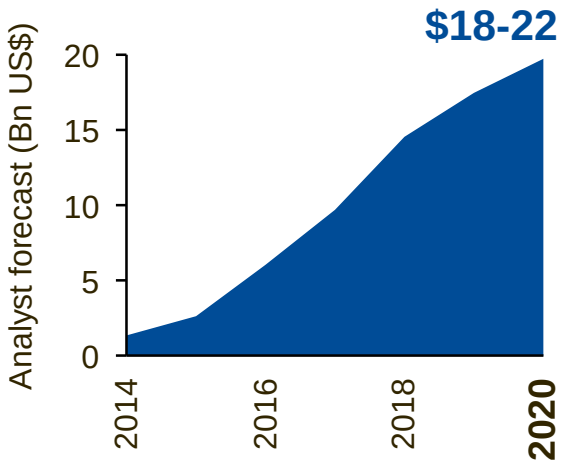
Are these innovations sustainable?

Hepatitis-C market

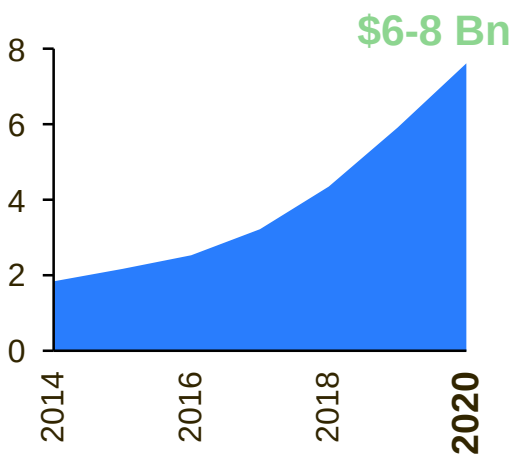
2012-2015



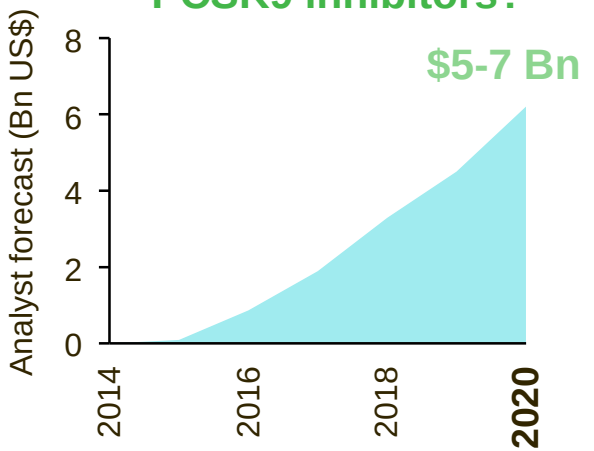
Immuno-Oncology



Respiratory biologics



PCSK9 inhibitors?



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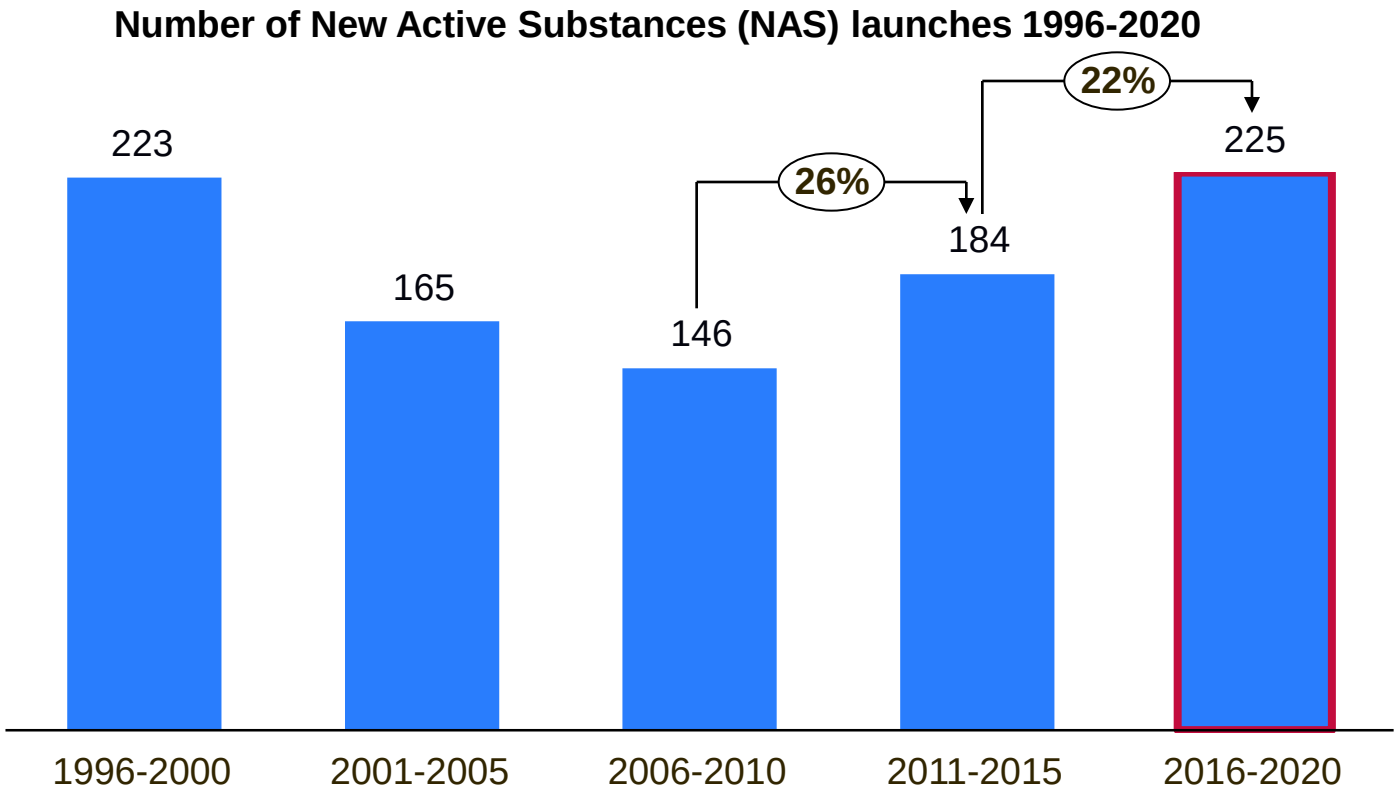
Source: IMS Health Analytics Link consensus analyst forecast; Drug analyst consensus; IMS Health MIDAS Q4 2015;

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

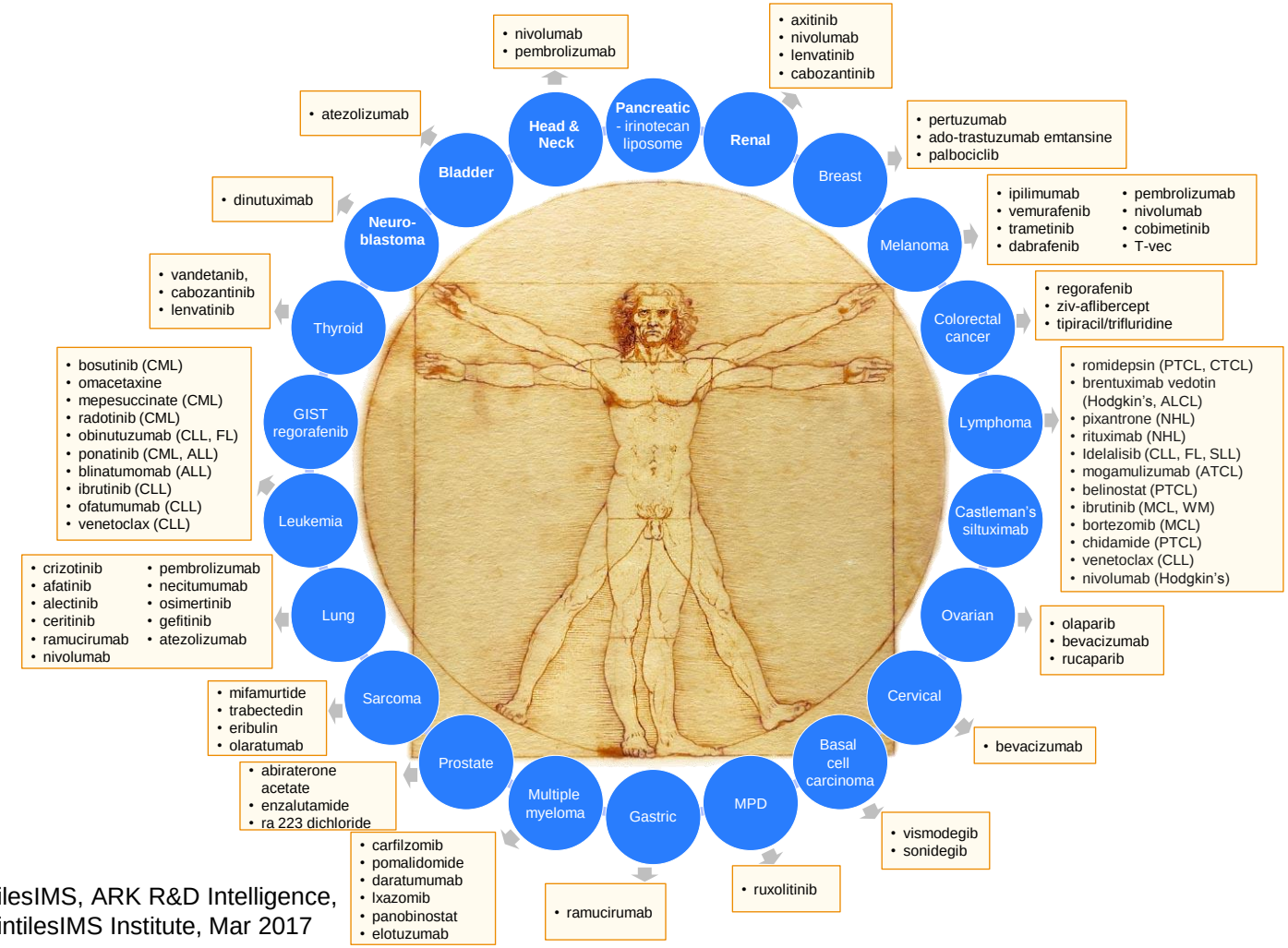
22% increase from the previous 5 years



Source: IMS Health, IMS Institute for Healthcare Informatics, October 2015

The cancer treatment landscape has been transformed since 2011 by new medicines targeting 22 different cancer types

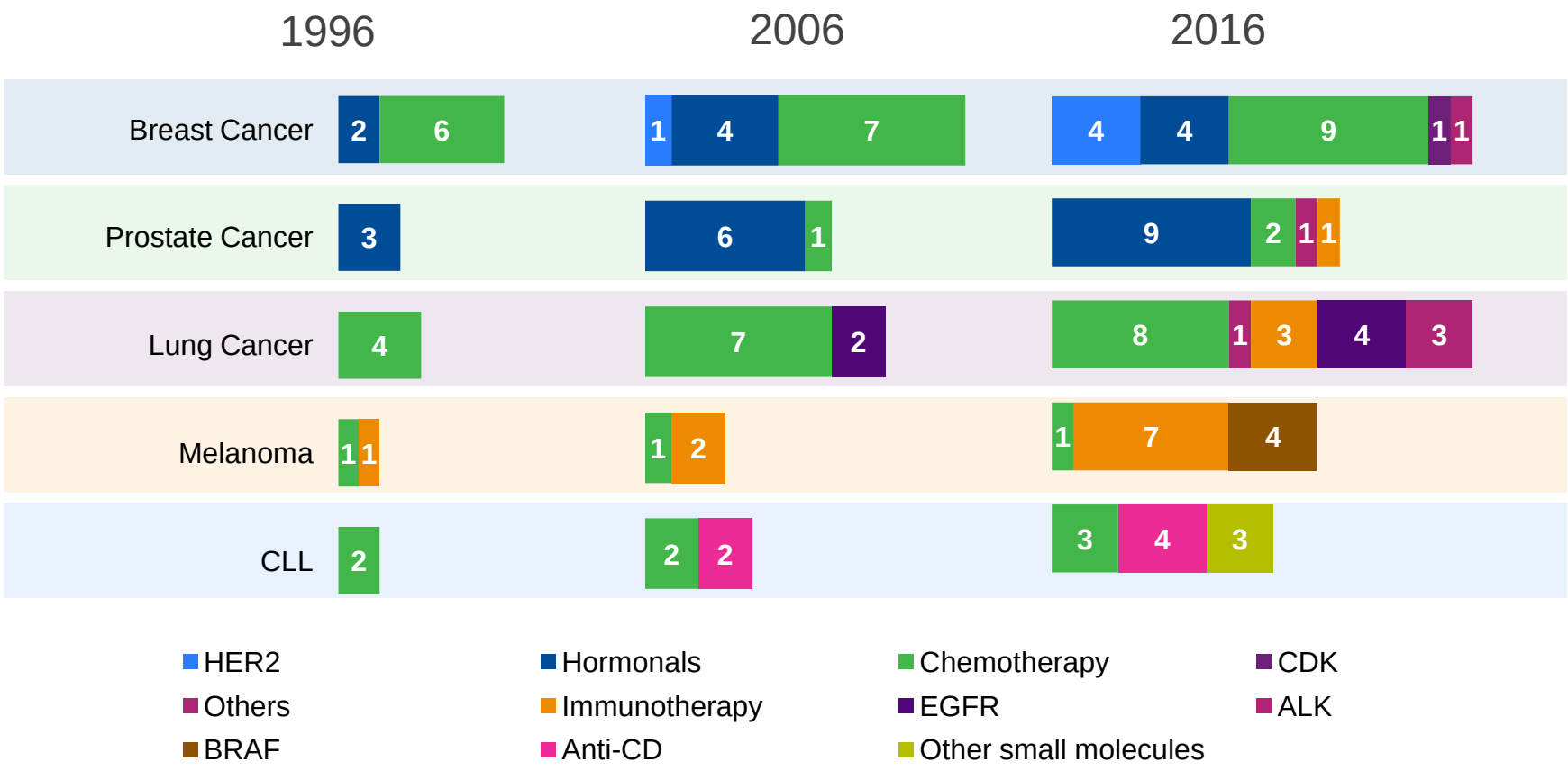
New Active Substance Launches 2011–2016 by Indication



Source: QuintilesIMS, ARK R&D Intelligence, Feb 2017; QuintilesIMS Institute, Mar 2017

Over the last 20 years, therapy options for multiple tumor types have increased significantly

Number of Treatment Options over Time for Selected Tumors (1996–2016)



Source: Drugs@FDA, Feb 2017; QuintilesIMS, ARK R&D Intelligence, Feb 2017; QuintilesIMS Institute, Mar 2017

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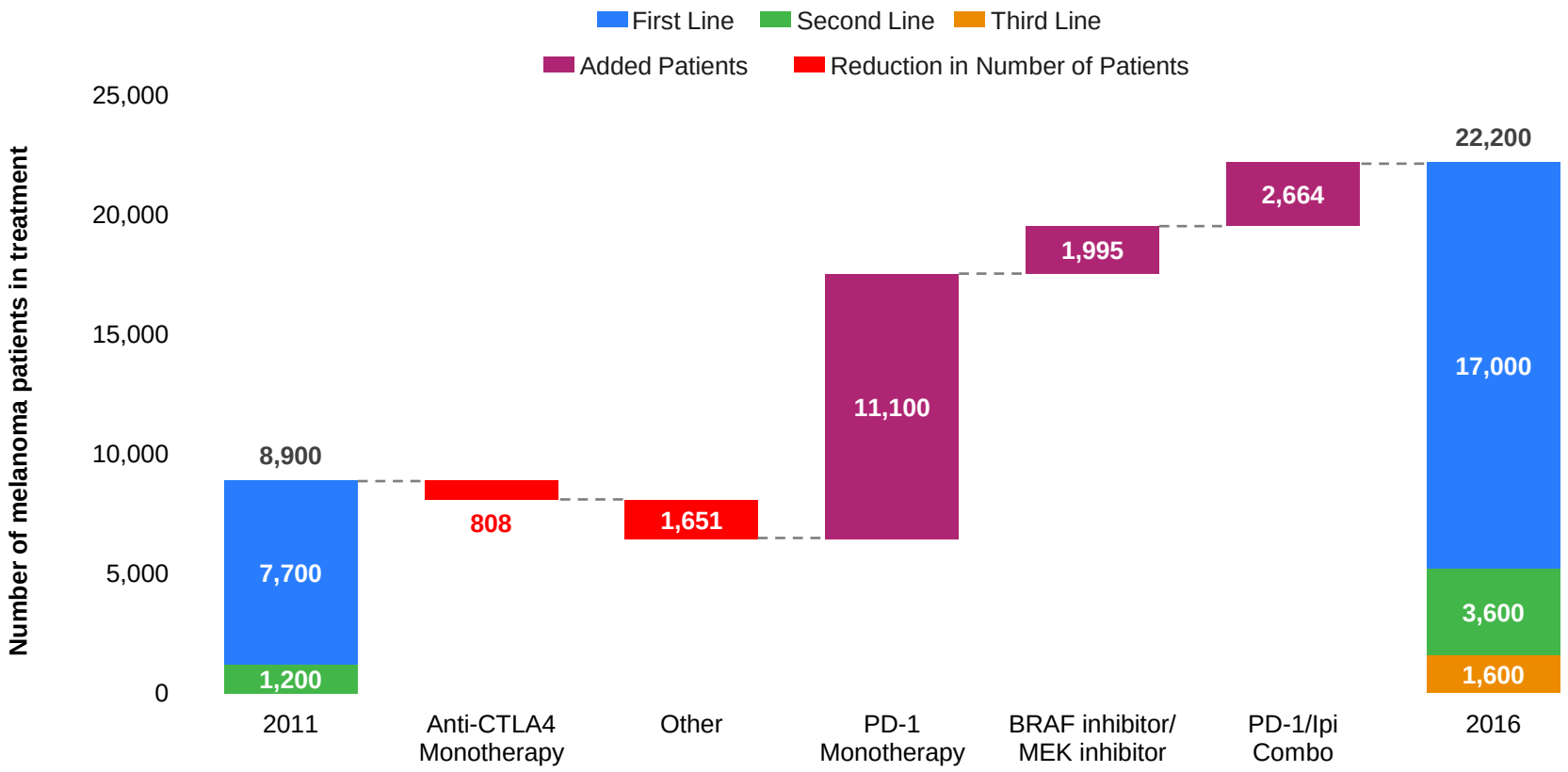
The number of treated melanoma patients has nearly tripled with the launch of novel agents

Increase in Number of Treated Patients for Melanoma



Source: QuintilesIMS, Real World Insights Oncology US EMR Data, Dec 2016; QuintilesIMS Institute, Mar 2017

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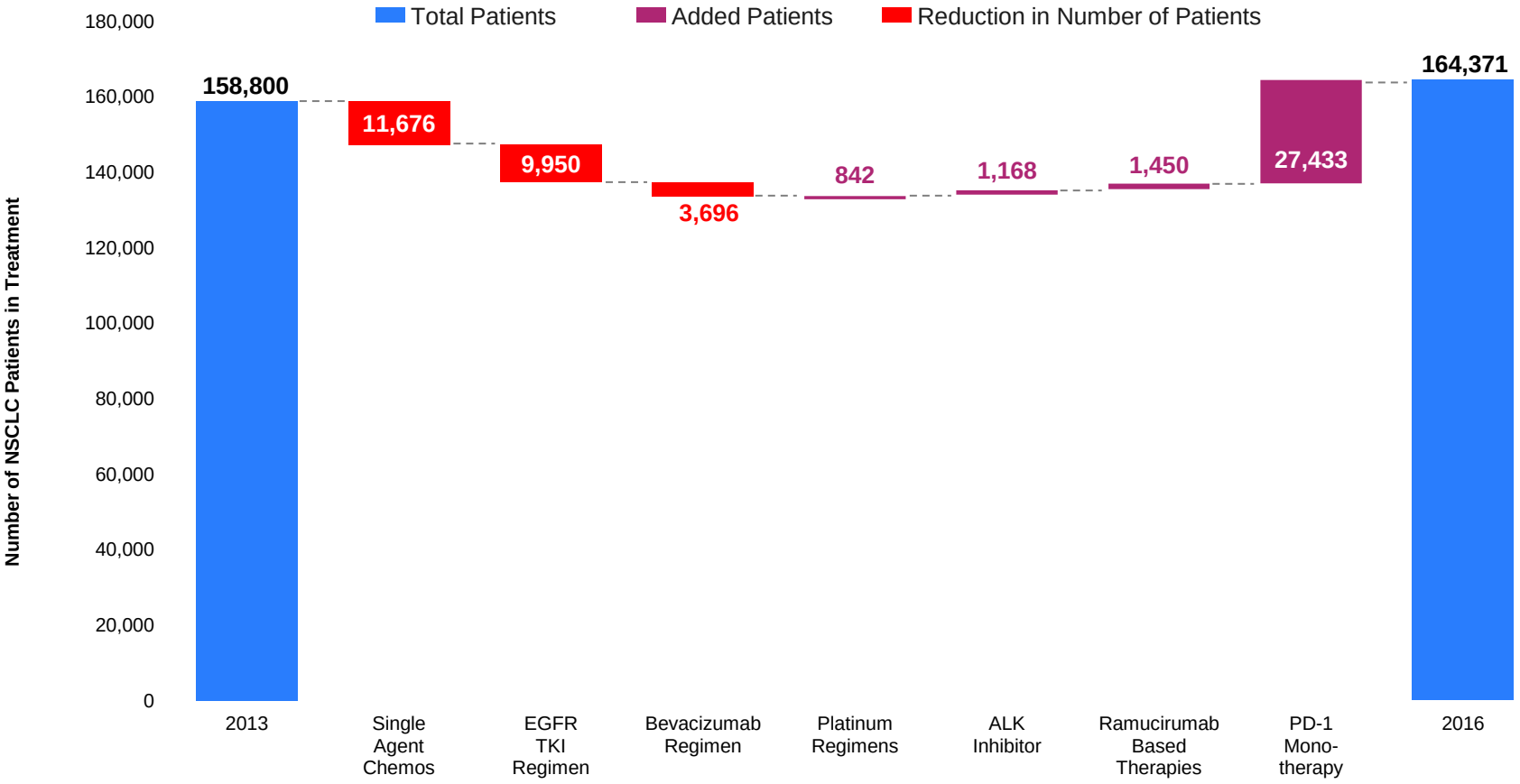
Availability of novel agents for NSCLC has also increased the number of treated patients

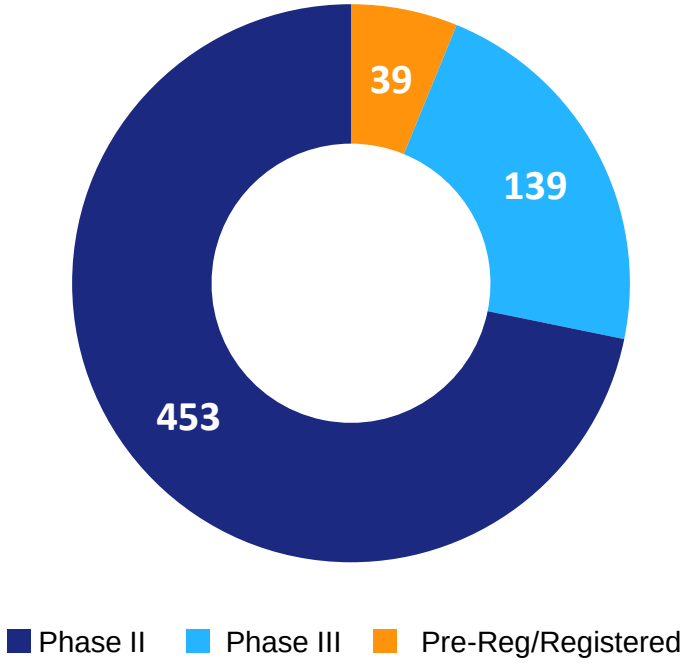


Source: QuintilesIMS, Real World Insights Oncology US EMR Data, Dec 2016; QuintilesIMS Institute, Mar 2017

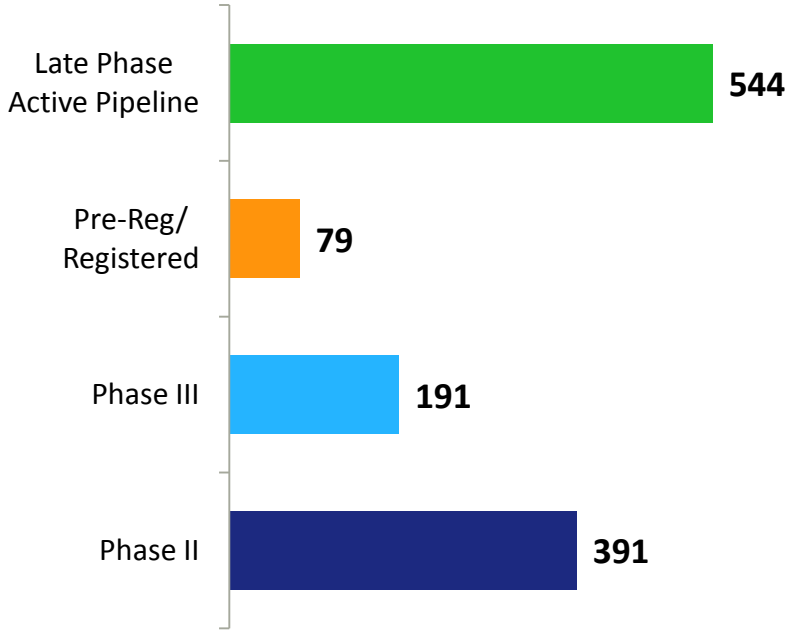
The global R&D pipeline for oncology remains robust with 631 unique molecules in late-phase development

Global Late Phase Oncology Pipeline in 2016

Molecules in the Late Phase Pipeline: 631

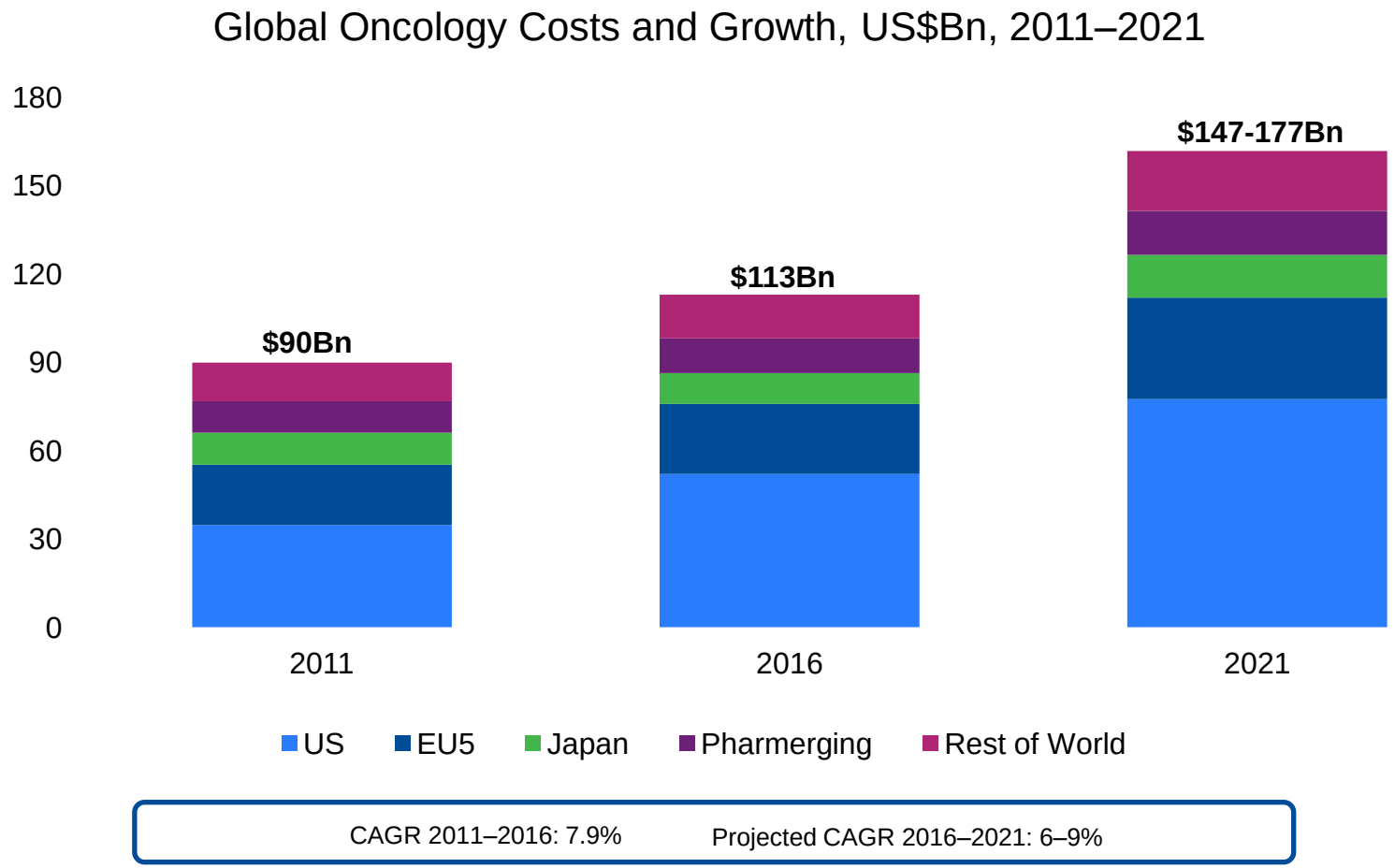


Companies with a Late Phase Pipeline: 544



Source: QuintilesIMS ARK R&D Intelligence, QuintilesIMS Institute, Dec 2016

Oncology growth is expected to be 6–9% per year through 2021, when global costs are expected to exceed $147Bn



Source: QuintilesIMS, MIDAS, Q4 2016, QuintilesIMS Institute, Mar 2017

Transformation in Disease Treatments

Innovation drives transformation of disease treatments in 2020

- Use of medicines in 2020 will include 943 New Active Substances introduced in the prior 25 years, new medicines in recent years will be weighted to specialty and biologics
- Patients will have greater access to breakthrough therapies, clusters of innovation around hepatitis C, autoimmune diseases, heart disease, orphan diseases and others
- Cancer treatments represent the largest category of the 225 new medicines expected to be introduced within the next five years
- Technology will enable changes to treatment protocols, shift patient engagement, accountability and patient-provider interaction accelerating the adoption of behavior changes proven to improve patient adherence to treatments
- By 2020, over 470 drugs will be available to treat orphan diseases for the 7,000 rare diseases with no or limited treatments available
- While global medicine spending on orphan is expected to be 1-2%, it will be as much as 10% in developed markets such as the U.S.

Global Medicines Use in 2020. Report by IMS Institute for Healthcare Informatics.

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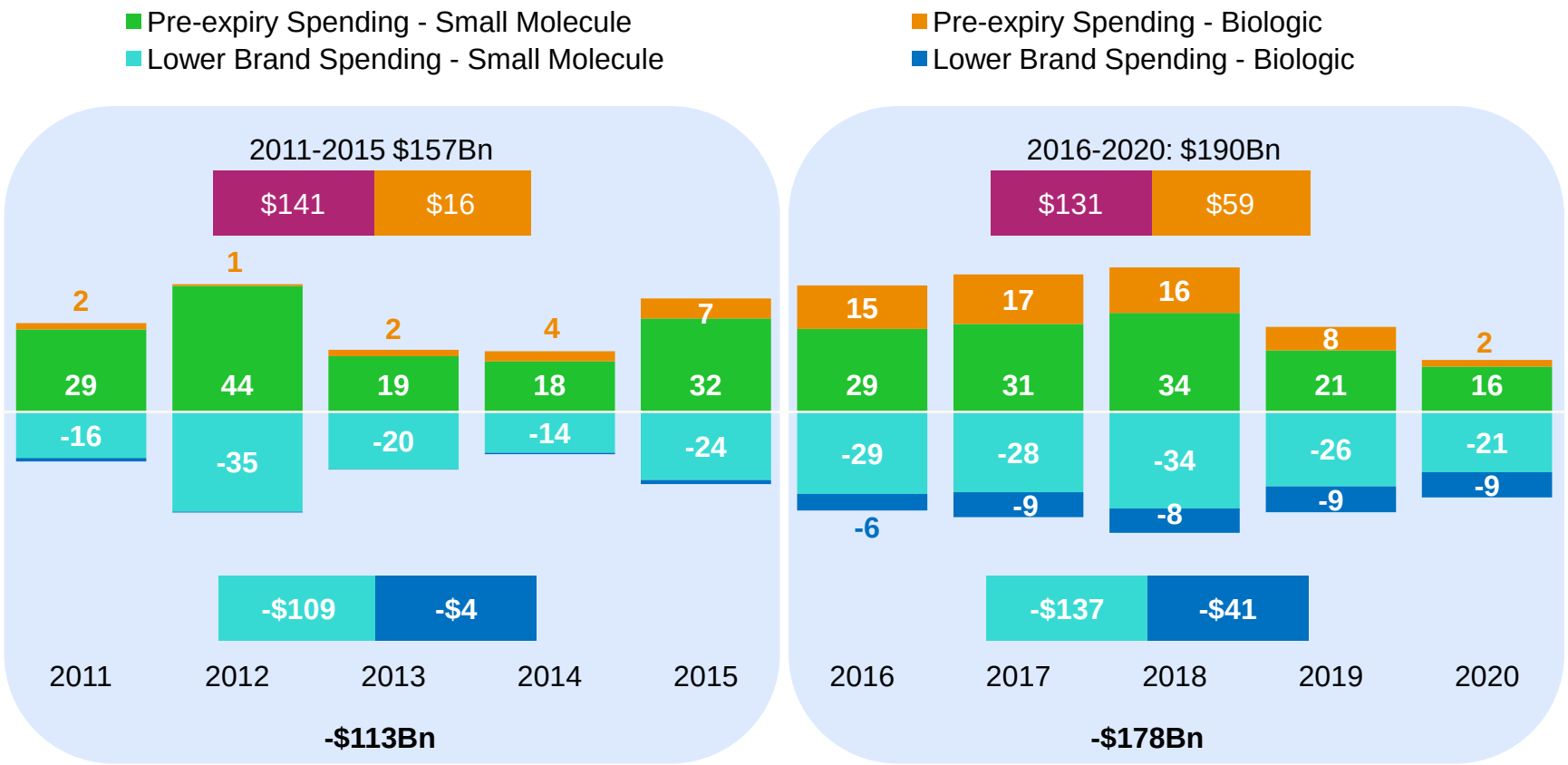
Developed Markets Patent Expiry Exposure and Impact Constant US$Bn

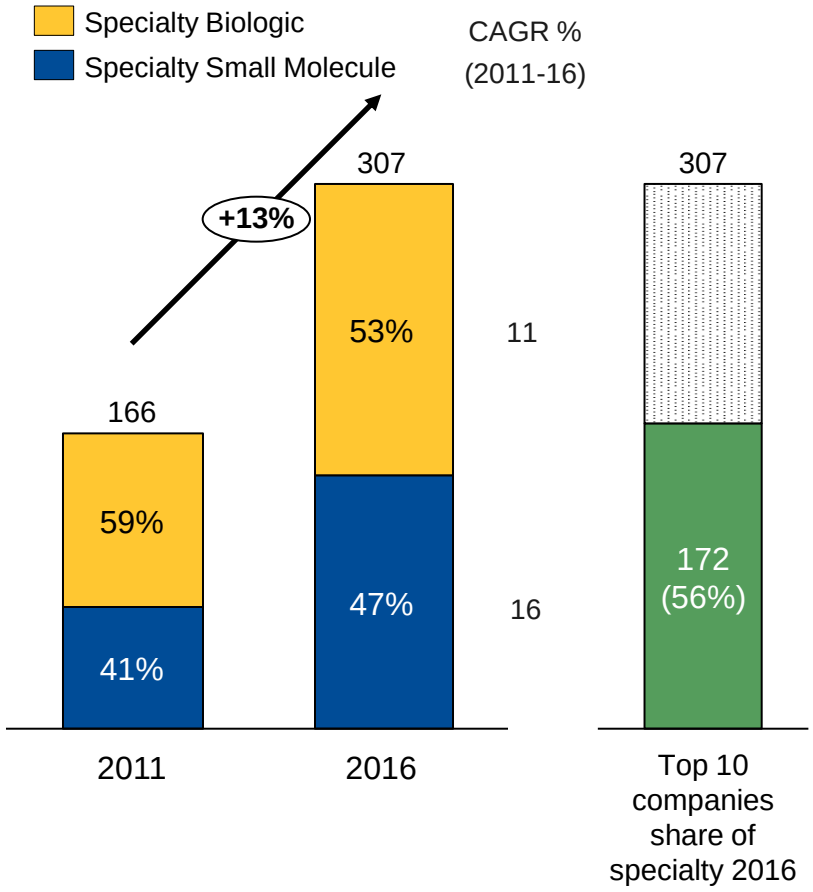


Source: IMS Institute for Healthcare Informatics, October 2015

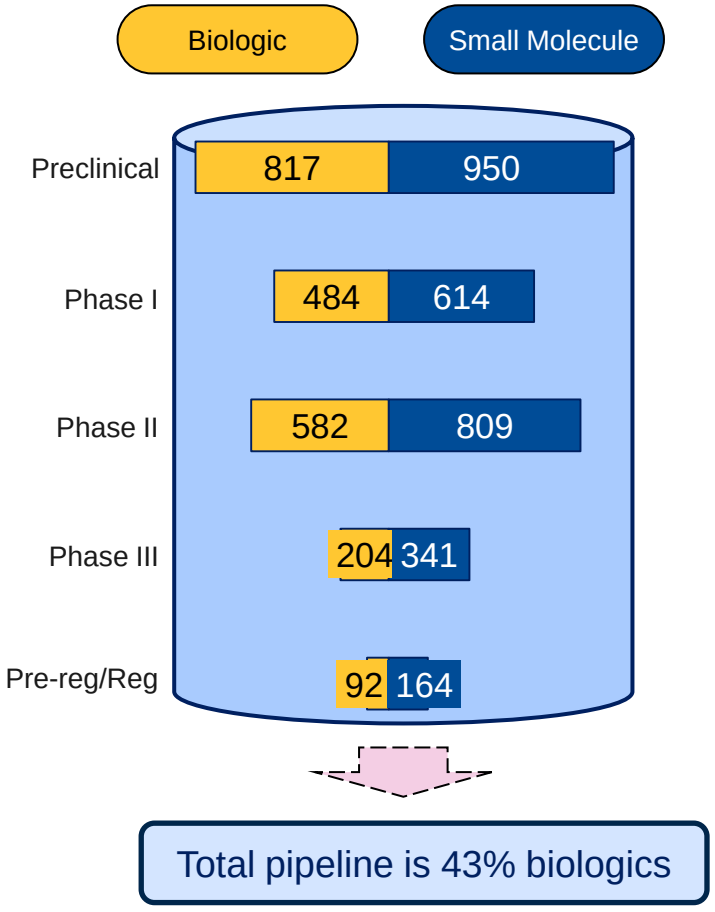
Note: Pre-expiry spending is the actual and estimated spending in the 12 months prior to loss of exclusivity (LOE) and is shown for developed markets only. Lower Brand Spending is the actual and estimated decline in spending on brands facing LOE. Estimates are based on patent expiry dates or expected generic/biosimilar availability, and historic analogues where available. Biologics and small molecules are modeled separately. Biologic brand losses are based on any non-original biologic competitor, regardless of approval type.

Small molecules are becoming increasingly important in the specialty field

Global Specialty Sales (2011-16)
bn LCUS$



Global Pipeline (Jan 2017)



Source: QuintilesIMS Market Prognosis Q4 2016; QuintilesIMS Institute Feb 2017

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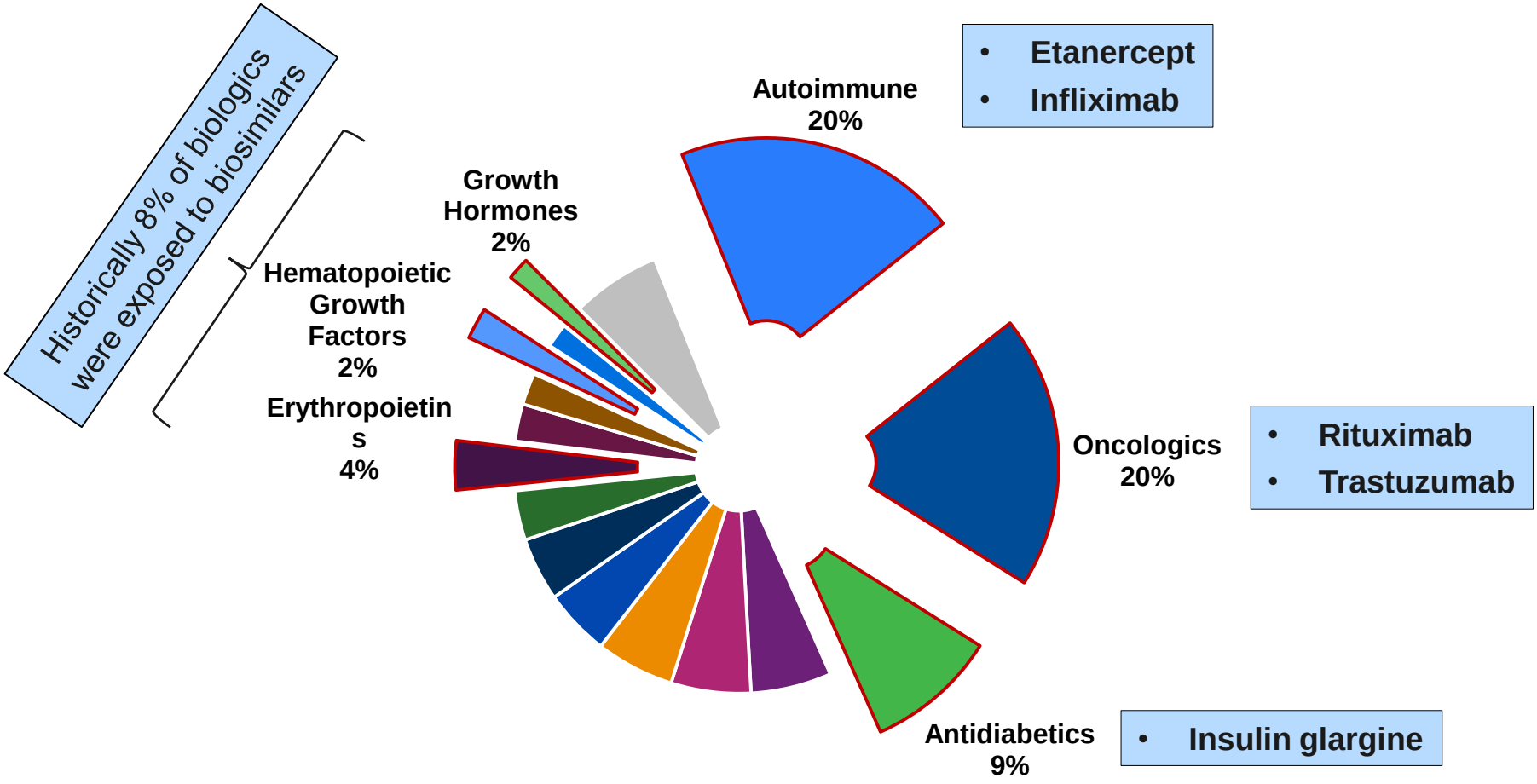
Historically biosimilar competition restricted but the future is very different

Europe

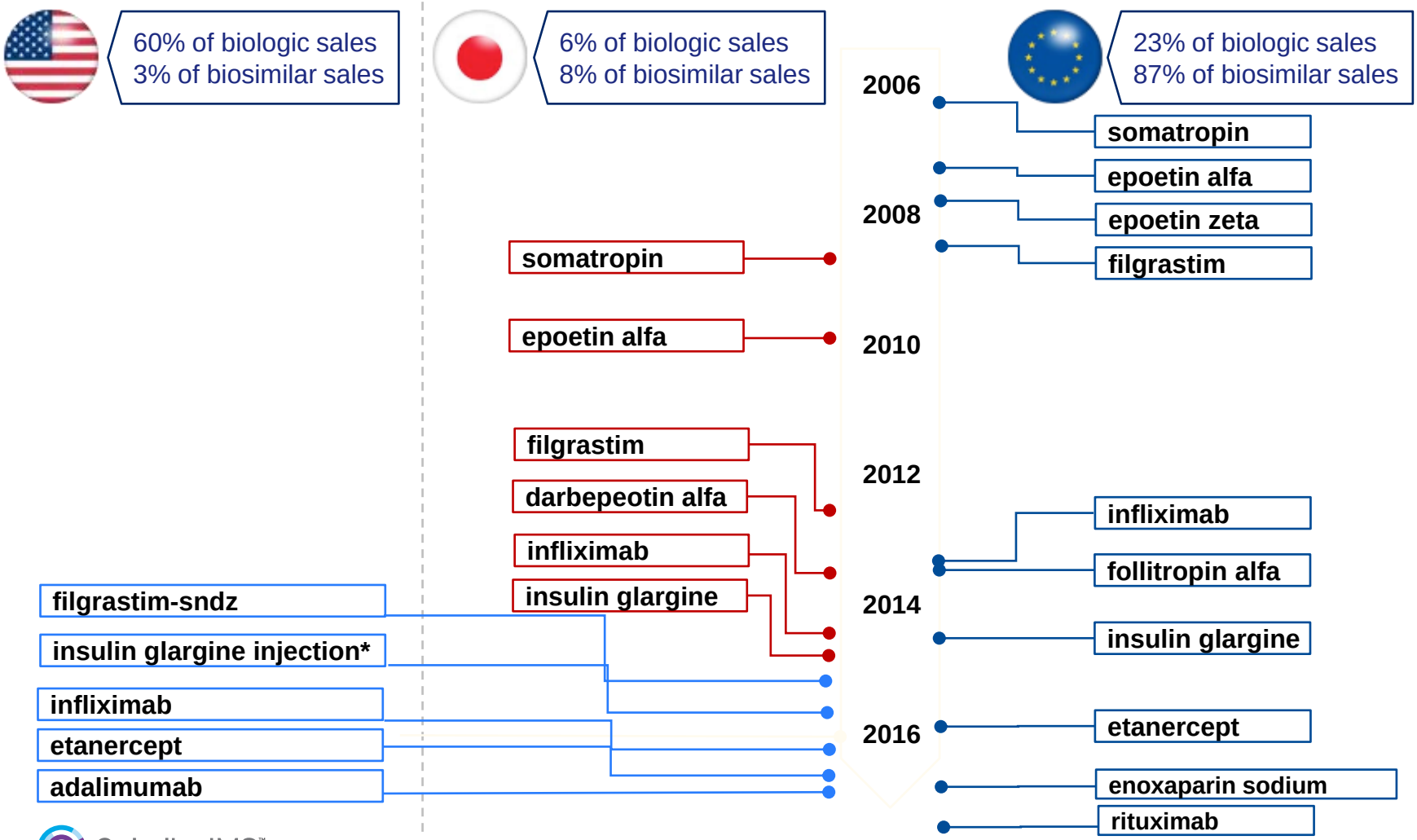
Top Biologic Therapy Areas, Europe sales (2016)



Source: QuintilesIMS MIDAS MAT Q3 2016; Europe excludes Russia and Turkey

Multiple Biosimilars are now approved in all three major regions

US, Japan, Europe Biosimilar molecule approvals to date



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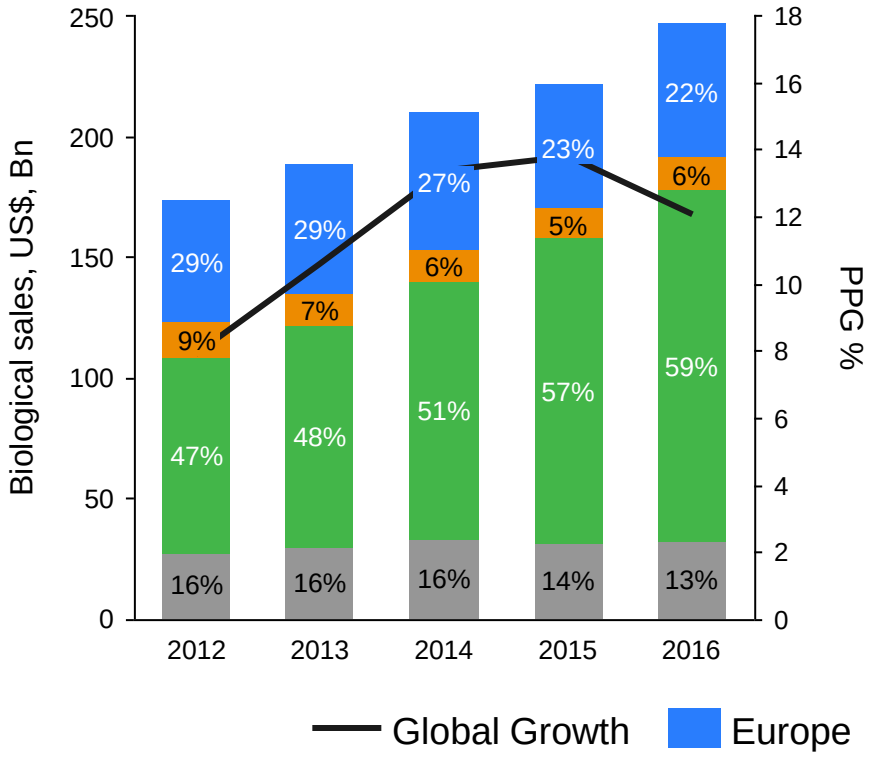
Source: IMS Health MIDAS Q3 2016 (Europe excludes Russia and Turkey); EMA website Jan 2017; FDA website June 2016; Japan approval dates from Gabionline April 2016; *Basaglar is not a biosimilar in the USA, it is a follow-on biologic; excludes Non-original biologics

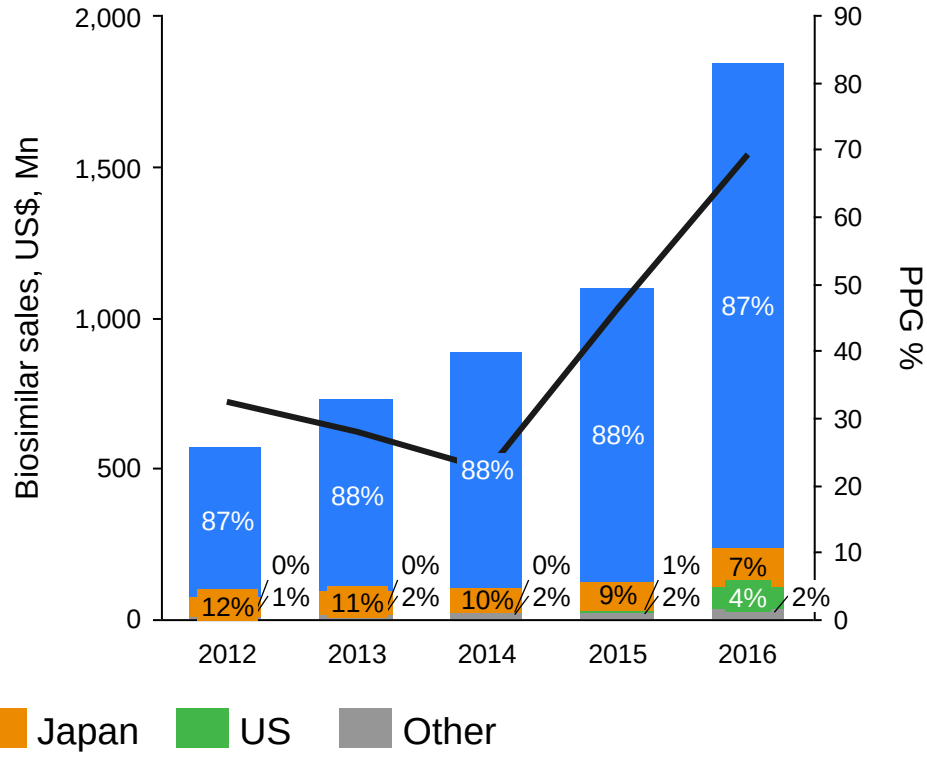
Europe makes up 22% of global biologic sales and 87% of biosimilar sales

All values are at list price before rebates

Global Biologic market dynamics, $247Bn



Global Biosimilar market dynamics, $1.8Bn



Global Growth | Europe | Japan | US | Other

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Source: IMS Health MIDAS MAT Q4 2016; Europe does not include Russia and Turkey

The next wave of biosimilars include trastuzumab, rituximab, adalimumab and bevacizumab in Europe

Europe: Recent biosimilar filings

Originator Name (molecule name)	Therapeutic area	Total pending EMA applications	Originator protection expiry	European revenue 2016 (Bn €)
Enbrel (etanercept)	Autoimmune	+ 1	Aug-15	€2.0 Bn
Lantus (insulin glargine)	Diabetes	+ 1	May-15	€1.1 Bn
Herceptin (trastuzumab)	Oncology	3	Jul-14	€1.8 Bn
Mabthera (rituximab)	Oncology	+ 2	Feb-13	€1.7 Bn
Avastin (Bevacizumab)	Oncology	2	Jan-22	€1.8 Bn
Humira (adalimumab)	Autoimmune	4	Apr-18	€3.4 Bn
Neulasta (pegfilgrastim)	Oncology	3	Aug-17	€0.5Bn

US: Recent biosimilar filings and approvals

INN name/ Common Name	Therapeutic area	Total pending FDA applications	Originator protection expiry	US revenue 2016 (Bn $)
Neupogen (filgrastim)	Oncology	1	Dec-2013	$0.6 Bn
Enbrel (etanercept)	Autoimmune	1	2022	$7.1 Bn
Humira (adalimumab)	Autoimmune	1	Dec-16	$13.2 Bn

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Source: EMA website January 2017; Quintiles website January 2017; Launch biosimilars have not been included; "+" indicates that biosimilars are already on the market for that molecule

Summary

- Ageing populations and social costs outpacing health care provision and in the absence of curative therapies will diminish share of budgets for medicines
- Specialty care innovation continues to grow but true innovation is happening in several therapeutic areas, not just specialty
- Payers will seek more intensive cost containment measures to drive down prices
- The need for affordable quality medicines remains key for sustainability of healthcare systems

Cutting medicine prices is not the solution to reduce costs; improving outcomes should be the objective

Efficient healthcare is the mantra

Thank you

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