

The Trillion Dollar Market for Medicines: Characteristics, Dynamics and Outlook

Johns Hopkins Bloomberg School of Public Health
Center for Drug Safety and Effectiveness
Safety, Value and Innovation Seminar

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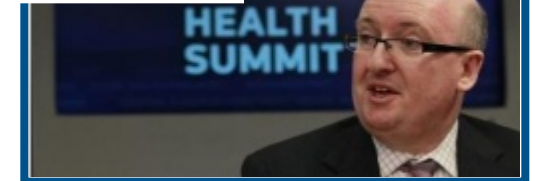
- About the IMS Institute
- Methodology and measures
- Global spending on medicines
- Mix of branded and generic medicines
- Transformations in disease treatment
- Implications and discussion

About the IMS Institute

Unbiased
Information

Academic
Research

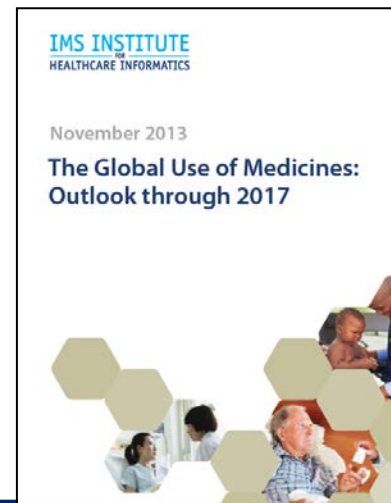
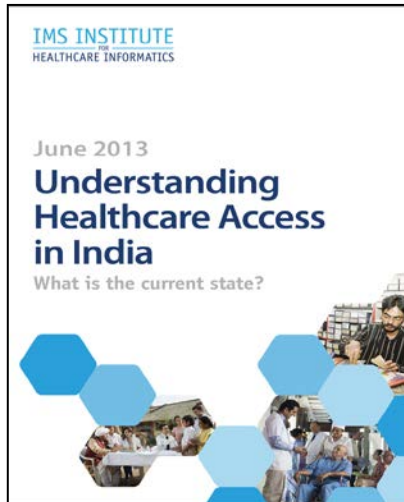
Public Policy
Support



BILL & MELINDA
GATES foundation



During 2013 we published six major reports



Methodology

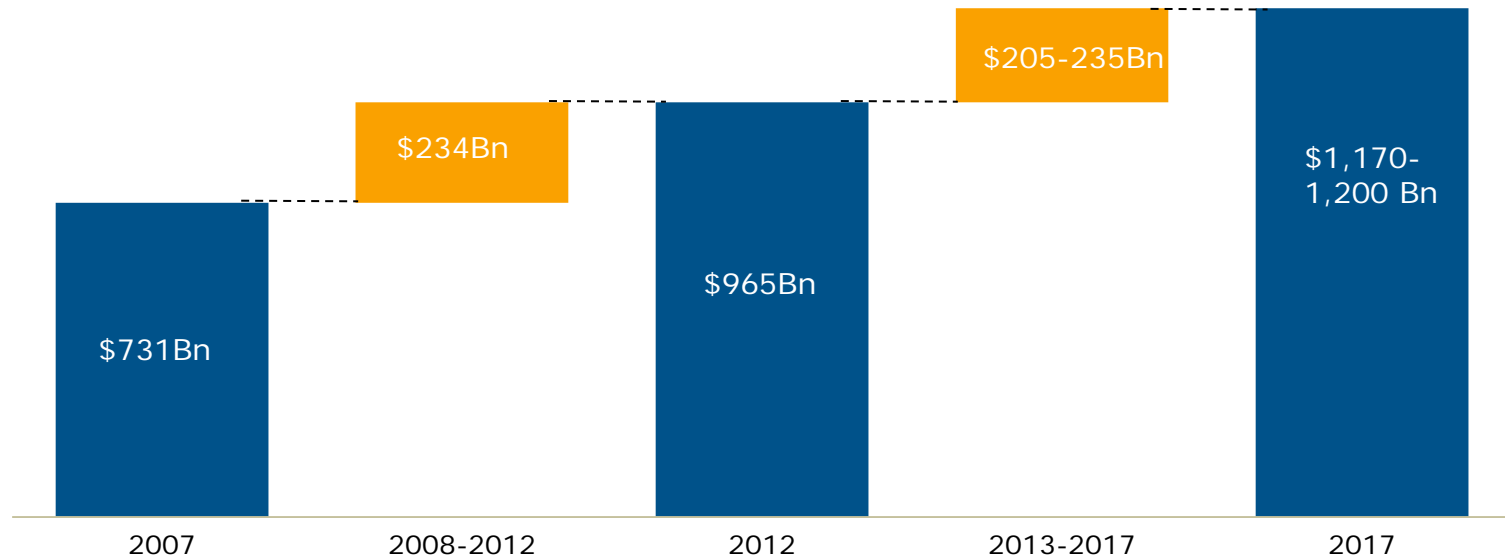
- Forecasts of spending on medicines globally are based on proprietary analysis performed by IMS Health and published as **IMS Market Prognosis** reports for 42 countries, 11 regions, and globally
- Methodology for each country forecast combines:
 - Collection of historical data by sector as captured by IMS audits, estimates of unaudited market sectors, and 5 most significant macroeconomic indicators based on historical correlation
 - Quantitative projection of baseline based on historical trends and macroeconomic indicator forecasts provided by the *Economist Intelligence Unit*
 - Identification, evaluation and quantification of specific events that are used to refine the baseline based on IMS expertise and insight within each country
- Evented 5-year forecasts are produced for retail and hospital, price and volume, as well as total market
- Additional proprietary analysis of the *IMS Market Prognosis* reports is performed by the IMS Institute to generate additional analytics and insights, some of which are incorporated in the IMS Institute report

Notes on measures

- Market sizes are measured in U.S. \$, converted at Q2 2013 average exchange rates
- All growth rates are measured in constant dollars (local currency growth)
- “Spending” refers to the amounts paid to pharmaceutical companies for medicines, not the cost incurred by the end-user or payer

Total global spending on medicines will reach about \$1.2Tn in 2017, an increase of \$205-235Bn from 2012

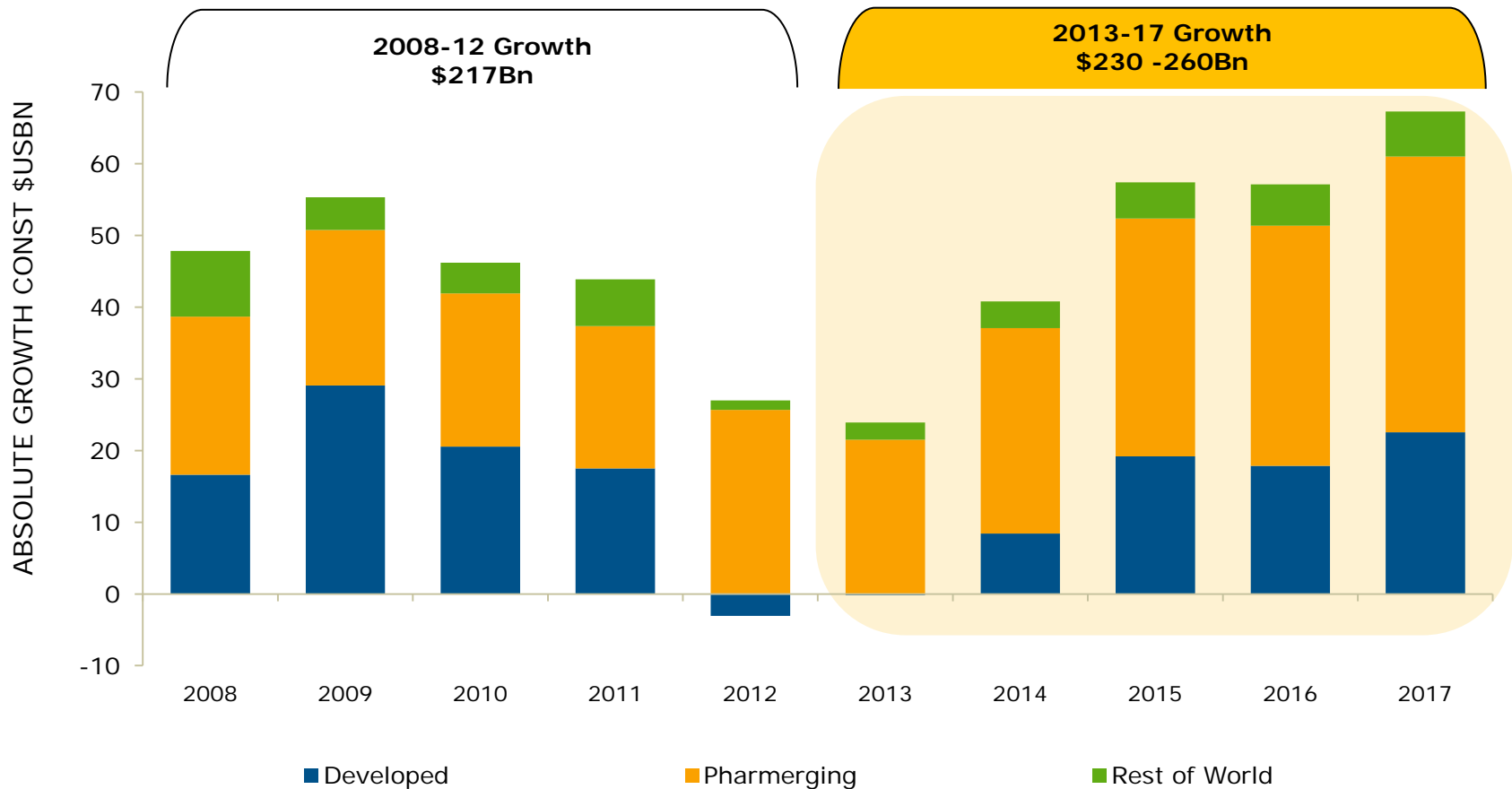
Global spending and growth, 2008-2017



Source: IMS Health Market Prognosis, September 2012

Annual spending growth will reach a low point in 2013, followed by increased growth particularly in developed markets

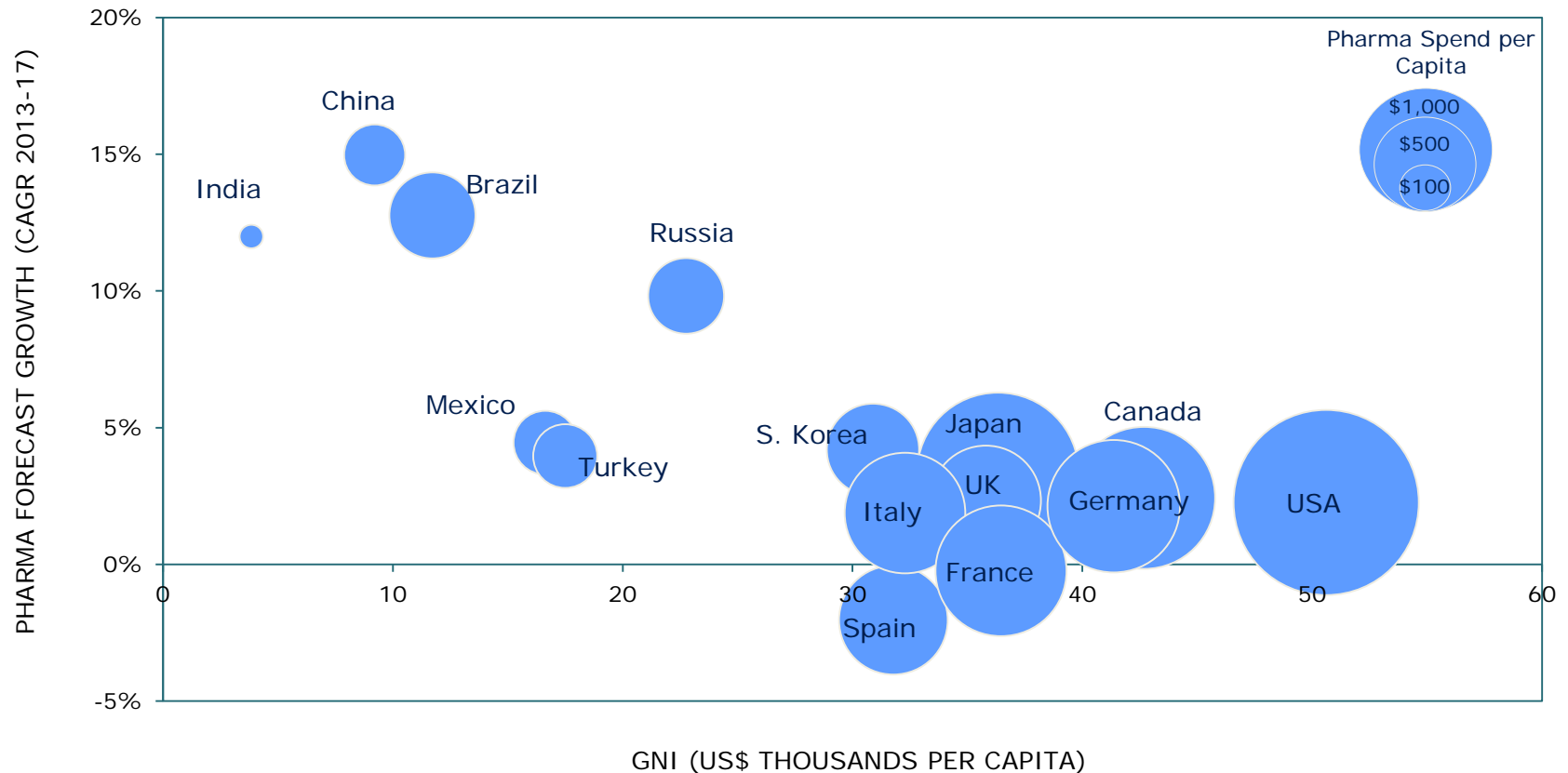
Global Growth, 2008-2017



Source: IMS Health Market Prognosis, September 2013

Medicine spending per capita and growth rates are starkly different between high income countries and those with income under \$25,000 per capita

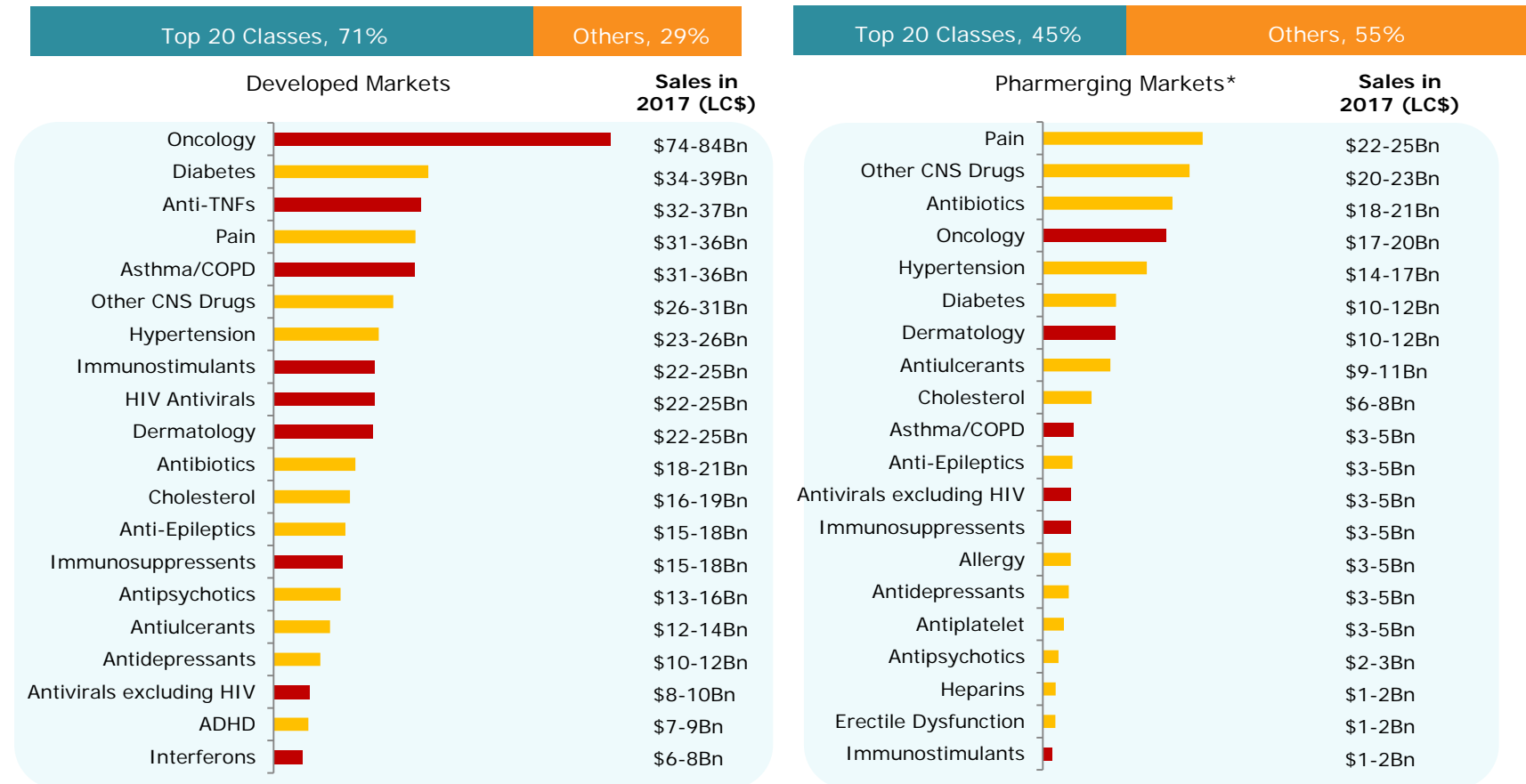
Per capita Gross National Income 2012 (GNI) vs. Forecast Pharma Spend



Source: World Bank, 2012; IMS Health Market Prognosis, September 2013

Spending levels in 2017 on medicine for specific disease areas will differ significantly between developed and pharmerging markets

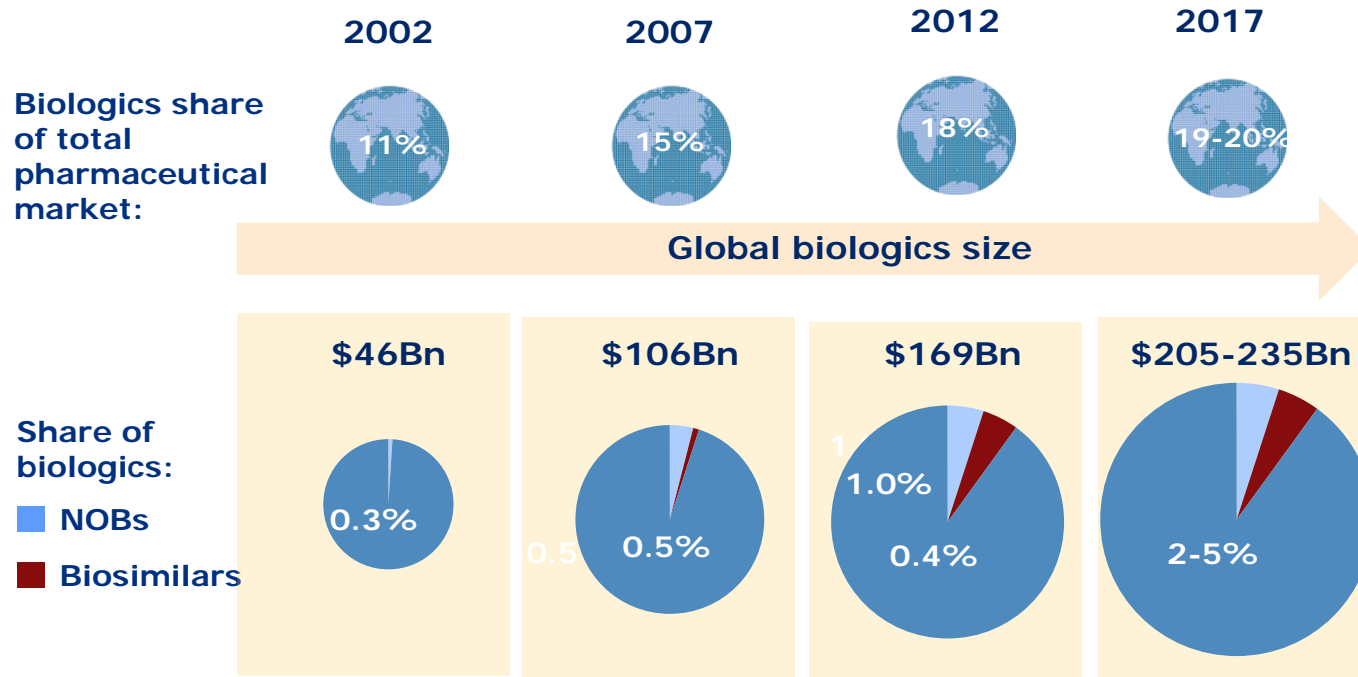
Spending by Therapy area in 2017



Source: IMS Health Thought Leadership, September 2013

A growing share of all medicines are biologic, with biosimilars and non-original biologic (NOB) products now taking a small share of the total market

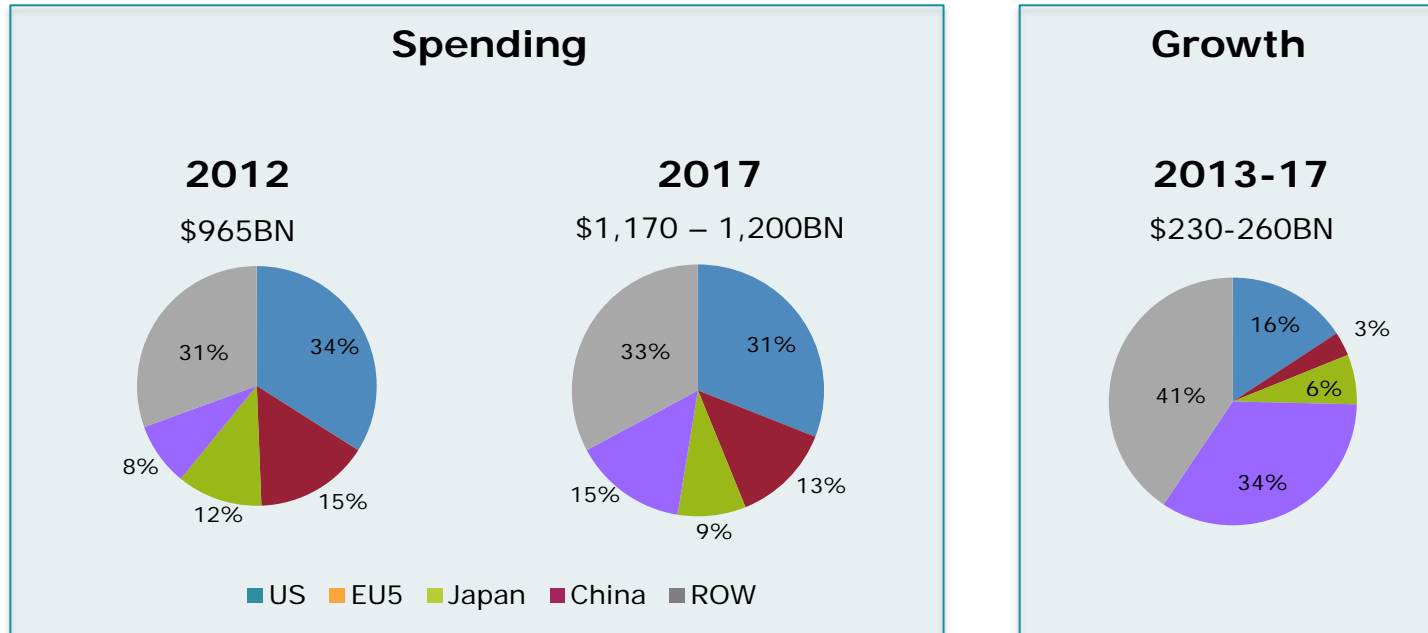
The biologics market



Source: IMS Health Thought Leadership, September 2013

The U.S., EU5, Japan and China account for just under 70% of total global medicine spending

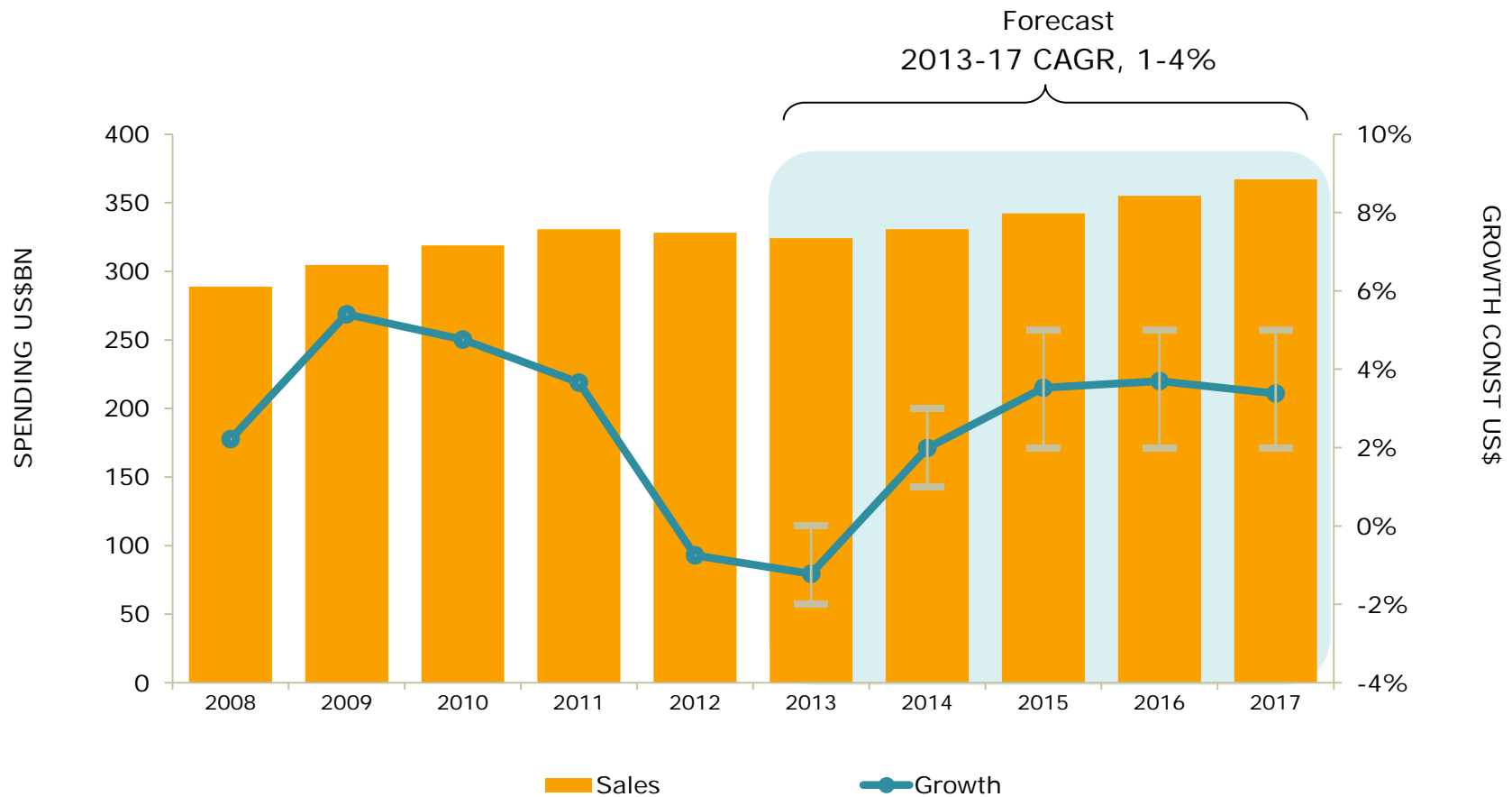
Geographic distribution of medicine spending



Source: IMS Health Market Prognosis, September 2013

Base case forecast for the U.S. is for 1-4% CAGR

U.S. Spending and Growth, 2008-2017



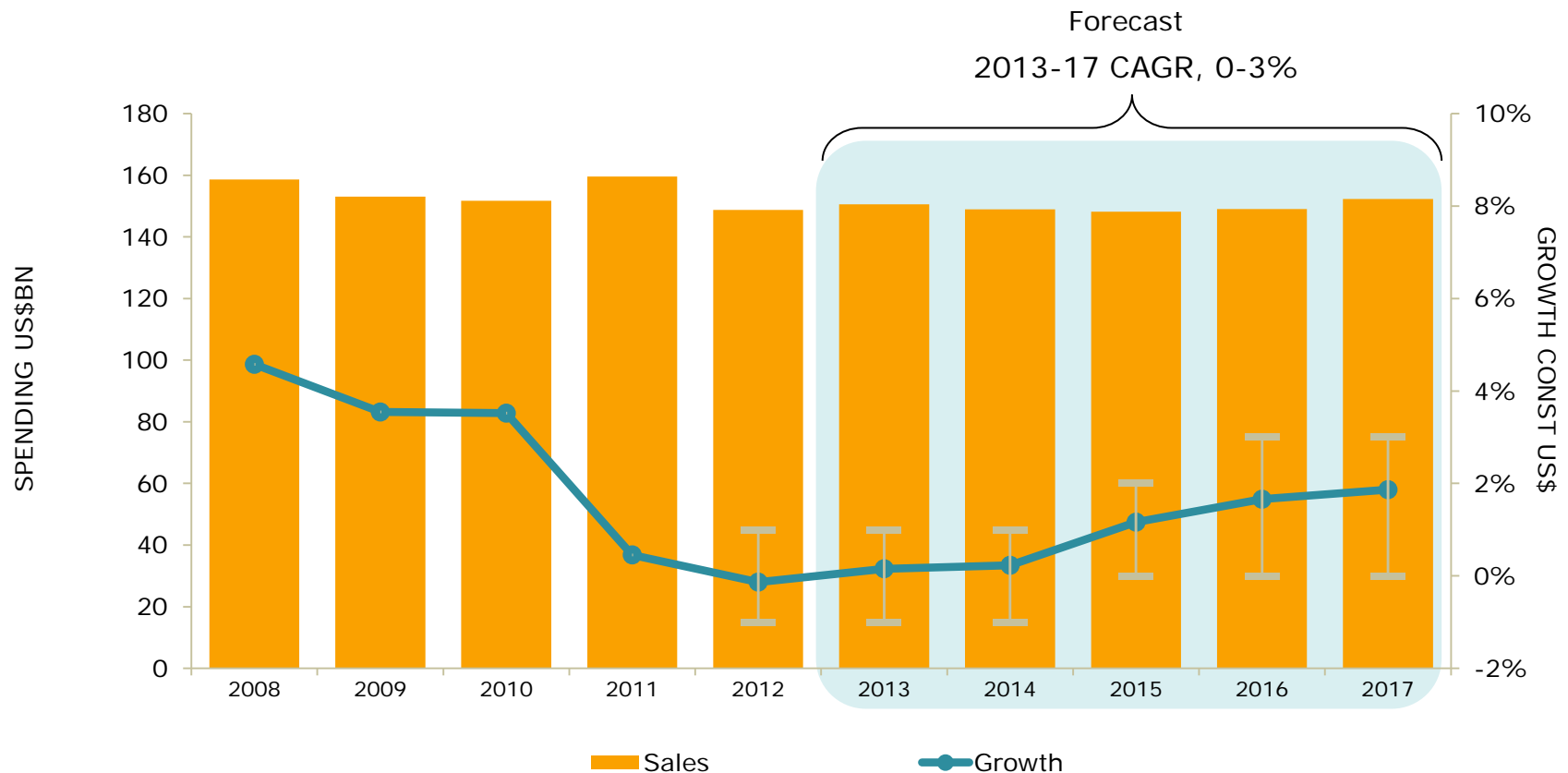
Source: IMS Health Market Prognosis, September 2013

Alternative scenarios for the U.S. focus on the implementation of healthcare reform

Scenario	Healthcare Reform Implementation	Implications for Medicine Spending
<p>Scenario 1: Reforms lead to expanded access and performance-based healthcare system</p>	<ul style="list-style-type: none"> • Almost full enrollment of the currently uninsured according to original government estimate • Rapid movement toward performance-based system and organization of healthcare delivery 	<ul style="list-style-type: none"> • Increased demand for medicines resulting from increased enrollment, screening, removal of caps, and management of existing conditions • Cost-effective medicines with clinical value being used more extensively • Continued premium places on innovative medicines with strong clinical profile • Total spending on medicines in 2017: \$420-460Bn
<p>Scenario 2: Slow pace of change but some expansion in access and incremental changes to payment system</p>	<ul style="list-style-type: none"> • Initial enrollment of currently uninsured 1/3 of target level, though improvement over time • Payment system remains largely fee-for-service • Uncertainty of political support slows or stalls reform implementation 	<ul style="list-style-type: none"> • Modest incremental demand for medicines and primarily for generics • Incremental pressure by payers and employers limit price increases to current levels at most • Positioning of competitive medicines primarily based on price • Newly launched medicines see slow uptake and limited commercial returns • Total spending on medicines in 2017: \$350-380Bn
<p>Scenario 3: Implementation leads to major unintended consequences and change</p>	<ul style="list-style-type: none"> • Exchanges fail to enroll “young invincibles” and insurance model fails • Employers move large number of employees to private exchanges • Significant decline in healthcare utilization for prevention and treatment of chronic illness 	<ul style="list-style-type: none"> • Decline in medicine demand volume • Major reduction in formulary access for insurance plans or major cost reductions from manufacturers • Limited acceptance of new medicines with price premium • Total spending on medicines in 2017: \$300-320Bn

The base-case scenario for the Top 5 European markets is for spending growth to be flat through 2017

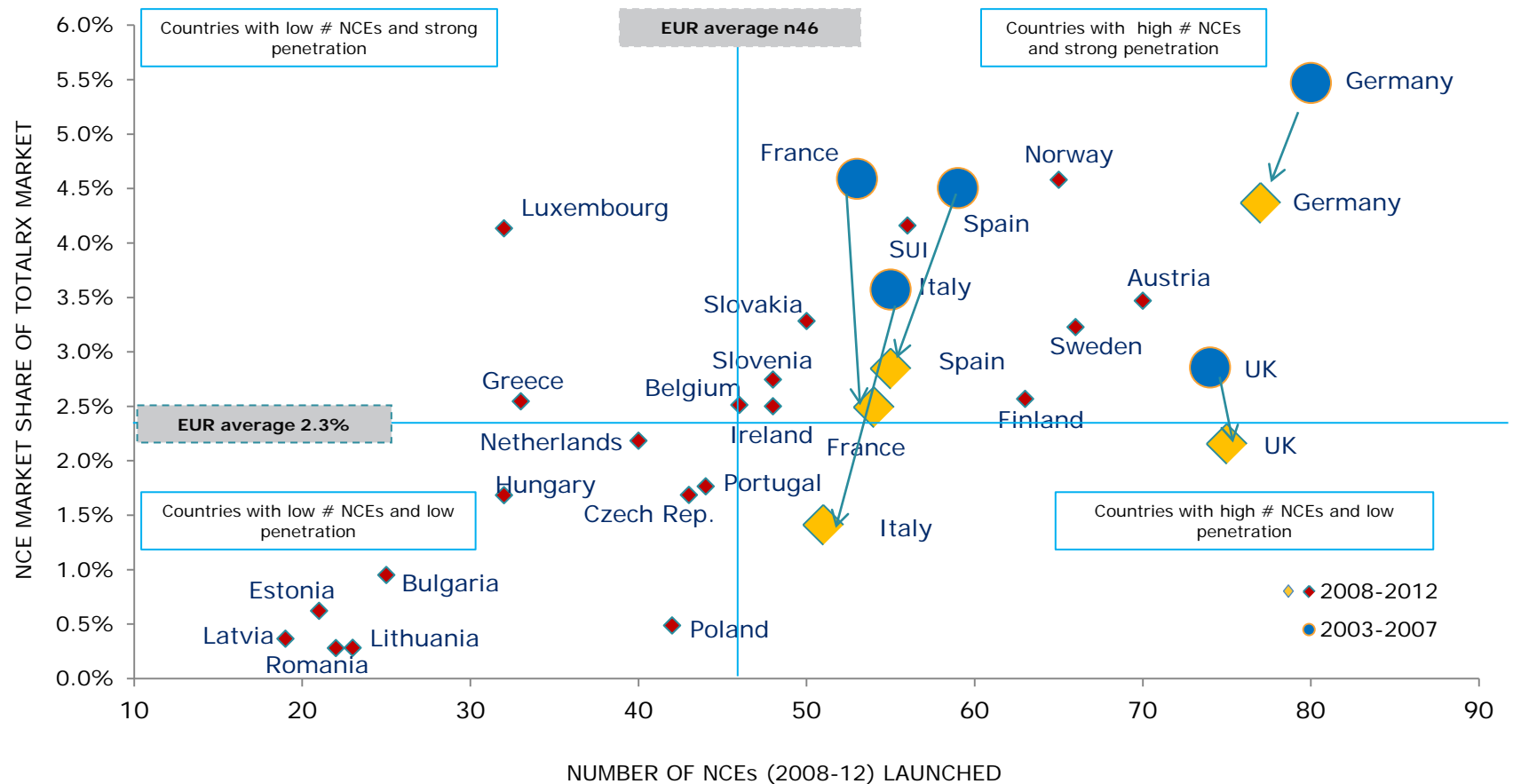
Top 5 Europe Spending and Growth, 2008-2017



Source: IMS Health Market Prognosis, September 2013

The economic crisis has had a direct impact on the number of launched products and their uptake

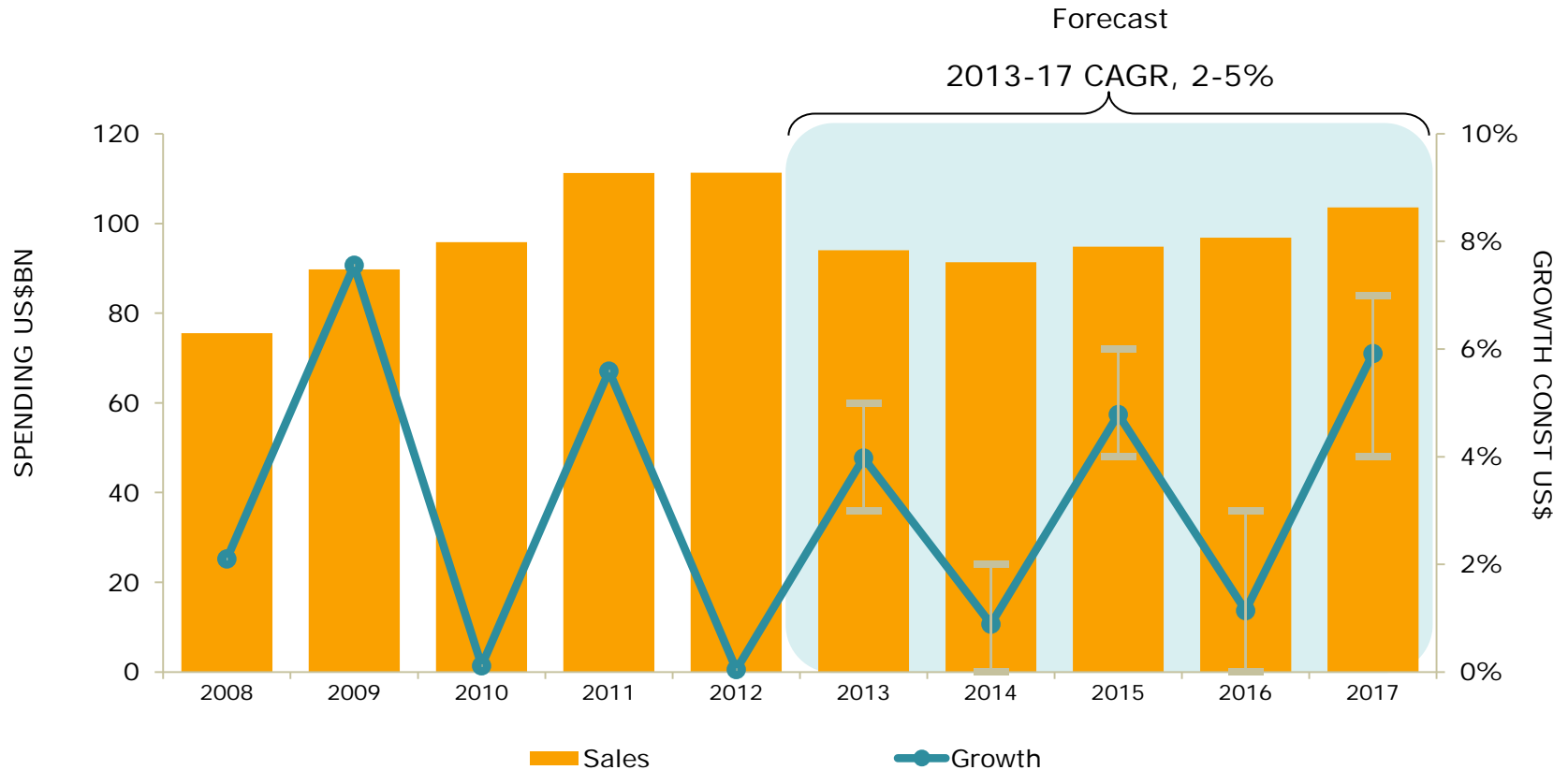
NCEs launched vs. market share achieved



Source: IMS Health MIDAS, September 2013

The base-case scenario for Japan's spending growth is for a slight acceleration through 2017

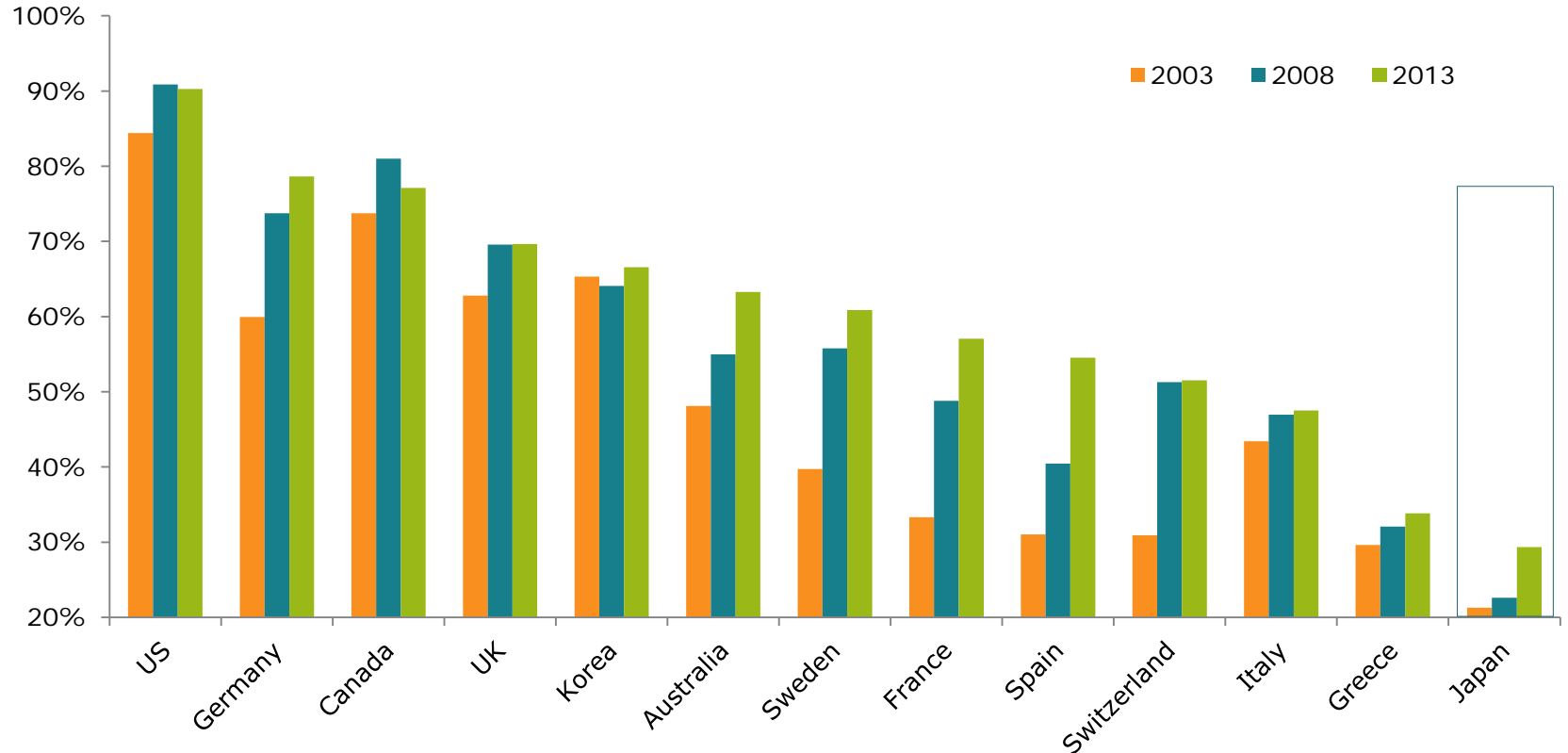
Japan spending and growth, 2008-2017



Source: IMS Market Prognosis, September 2013

Alternative scenarios for Japan's efforts to dramatically increase the use of generic medicines

Generics volume share of the unprotected market by country in 2003, 2008 and 2013



Source: IMS Health MIDAS, September 2013

The base-case scenario for China's spending growth is a slowing trend and stability through 2017

China spending and growth, 2008-2017



Source: IMS Market Prognosis, September 2013

Alternative scenarios for the 2017 outlook are driven by the depth of reform implementation in the next 5 years

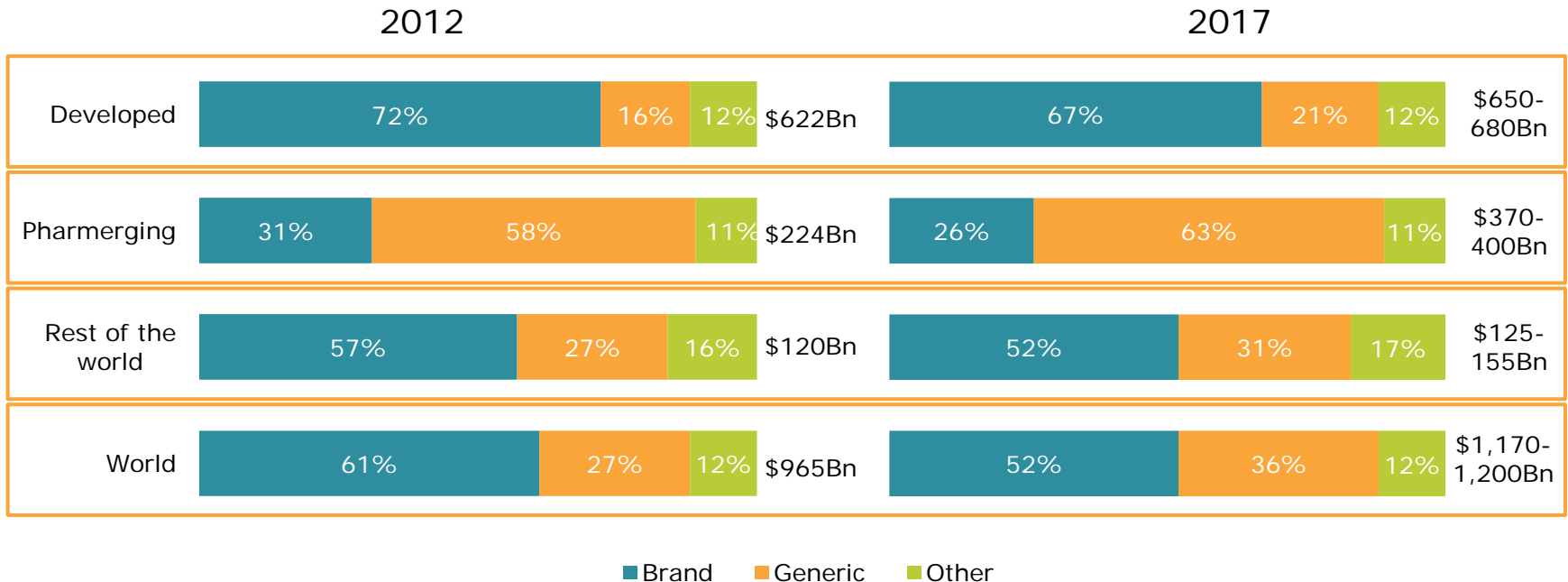
Scenario	Reform implementation depth	2017 Implications for Medicine and Spending Growth
Scenario 1: Rapid rise of private insurance	<ul style="list-style-type: none"> The rise of private insurance (30-50% uptake in urban areas) will fund >70% of cost for innovative drugs for critical diseases. Substantial increases in private hospitals will provide both higher quality healthcare and access to innovative drugs. The update of the NRDL in 2014 will increase the coverage of international drugs with price cuts expected to be <15%. The EDL usage ratio, which means more local generics in Tier 2 and 3 hospitals, will remain limited. Single reimbursement price based on generic pricing will not be implemented. CGMP guidelines widely implemented leading to an improvement in the quality of local generics. 	<ul style="list-style-type: none"> Quality generics will enjoy strong representation in primary care institutions and lower tier cities, while international off patent drugs will retain a price premium and will be widely used in large hospitals and big cities. The rise of private insurance will fund on patent branded products prior to their inclusion on the state reimbursement list (which may take years and be a relatively low level of access). The rise of private insurance together with a faster regulatory system will result in an expanded on-patent branded market for international companies. <p style="text-align: center;">CAGR 2013-17: 15-18%</p>
Scenario 2: Moderate change in medicine reimbursement	<ul style="list-style-type: none"> Some private insurance (30% uptake or less) will fund 50% of the innovative drugs cost for critical diseases. There will be some increase in the number of private hospitals to provide higher quality healthcare but access to new innovative products will be contained. The NRDL list will be updated in 2014 but with some delays in implementation and price cuts >15%. The actual usage ratio of EDL will increase to be closer to governments targets. Single reimbursement price based on generic pricing will be implemented in some provinces. CGMP guidelines will be implemented to a lesser degree 	<ul style="list-style-type: none"> Some private insurance (30% uptake or less) will fund 50% of the innovative drugs cost for critical diseases. There will be some increase in the number of private hospitals to provide higher quality healthcare but access to new innovative products will be contained. The NRDL list will be updated in 2014 but with some delays in implementation and price cuts >15%. The actual usage ratio of EDL will increase to be closer to governments targets. Single reimbursement price based on generic pricing will be implemented in some provinces. CGMP guidelines will be implemented to a lesser degree <p style="text-align: center;">CAGR 2013-17: 14-17%</p>

Alternative scenarios for the 2017 outlook are driven by the depth of reform implementation in the next 5 years

Scenario	Reform implementation depth	2017 Implications for Medicine and Spending Growth
<p>Scenario 3: Delays and limited change</p>	<ul style="list-style-type: none"> • Private insurance will not take off; negligible uptake and funding of new products. • The NRDL update will be delayed and coverage for innovative products will be limited; The NDRC will implement aggressive price cuts across the board for branded products. • Despite government efforts to encourage foreign investment in private hospitals, barriers will remain and only a small number of private hospitals will emerge. • The extensive use of the EDL will result in losses due to tendering of international off-patent brands. • Single reimbursement price based on generic pricing will be widely implemented. • CGMP is sparsely implemented to minimal effect. 	<ul style="list-style-type: none"> • China will fail to build a high quality locally sourced off patent segment. • Private insurance failure will perpetuate the funding gap for innovative agents. • International off-patent drugs will have a significant drop in usage as the government will only reimburse them at a price equivalent to a local generic. • The market will remain very difficult for innovative agents, which will have to wait years for a possible NRDL inclusion. <p style="text-align: right; background-color: #008080; color: white; padding: 5px; display: inline-block;">CAGR 2013-17: 12-15%</p>

Generics will represent a larger share of the market in volume and value terms

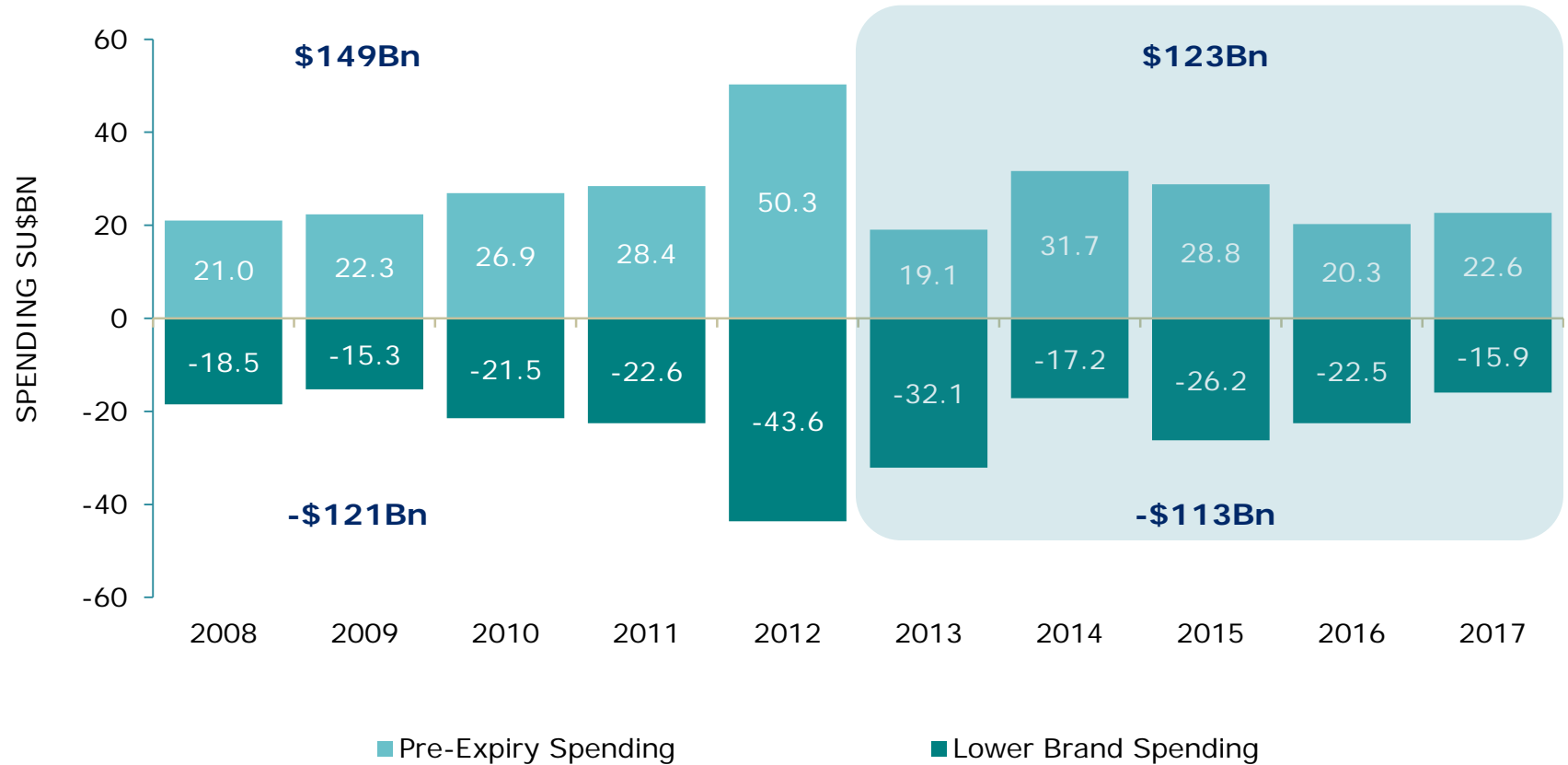
Global spending, 2012 and 2017



Source: IMS Health Thought Leadership, September 2013

Patent expiries on small molecule products will reduce brand spending on developed markets by \$113Bn through 2017

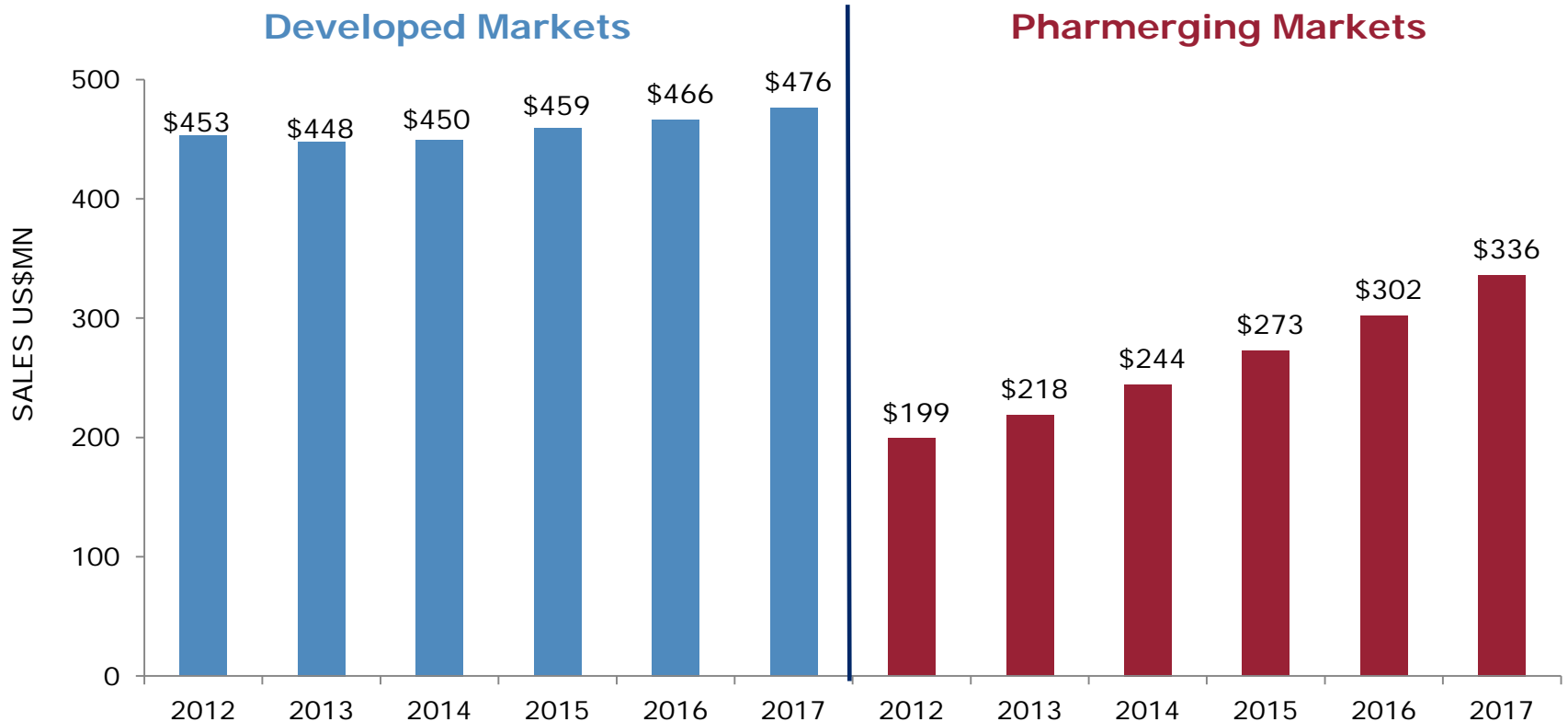
Developed Markets Patent Expiry Exposure and Impact



Source: IMS Institute for Healthcare Informatics, September 2013

Spending on traditional pharmaceuticals will increase by 5% in developed markets and by 69% in pharmerging markets over the next 5 years

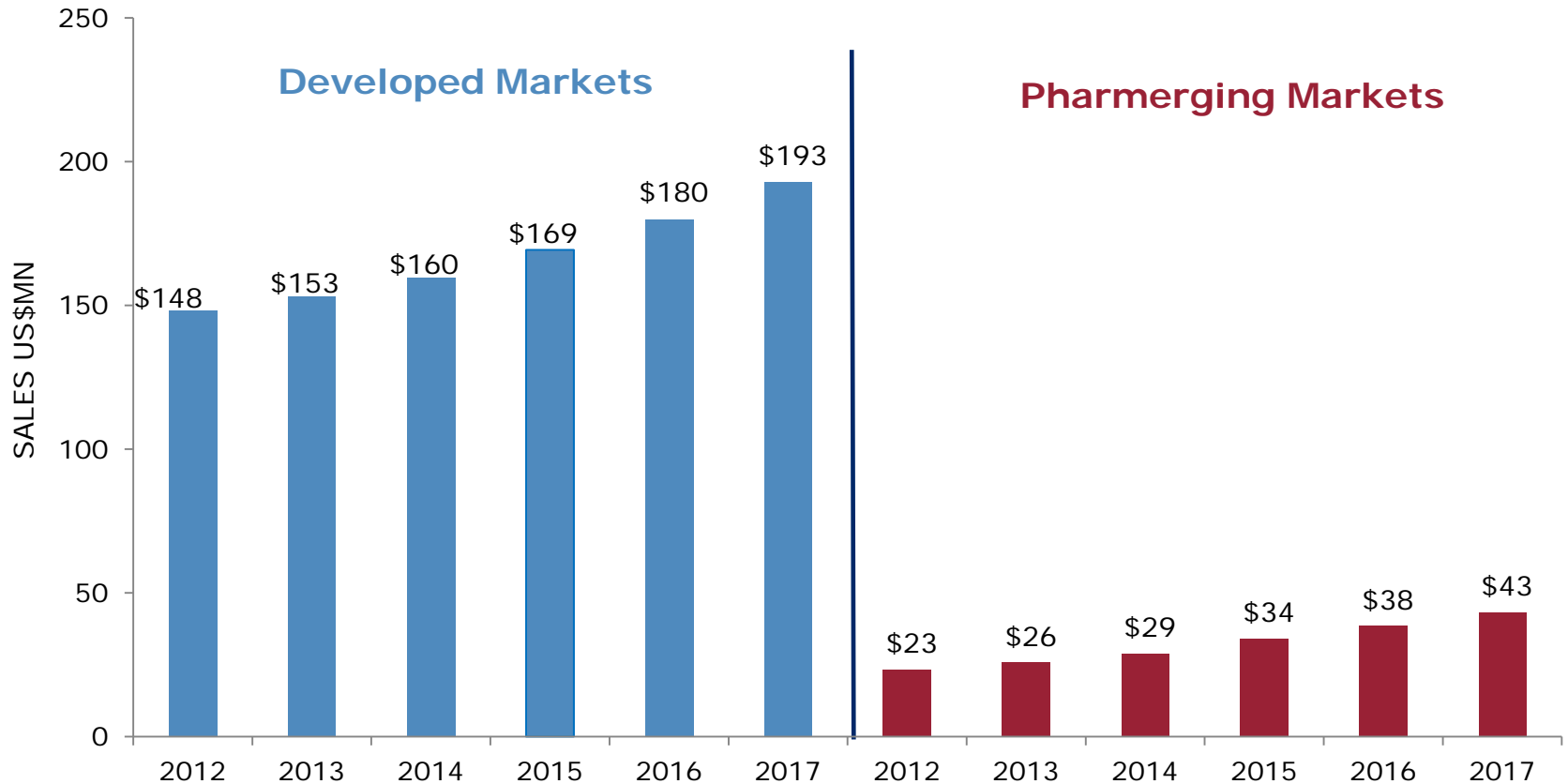
Traditional Spending between 2012 and 2017



Source: IMS Health Thought Leadership, September 2013

Spending on specialty pharmaceuticals will increase rapidly in both developed and pharmerging markets

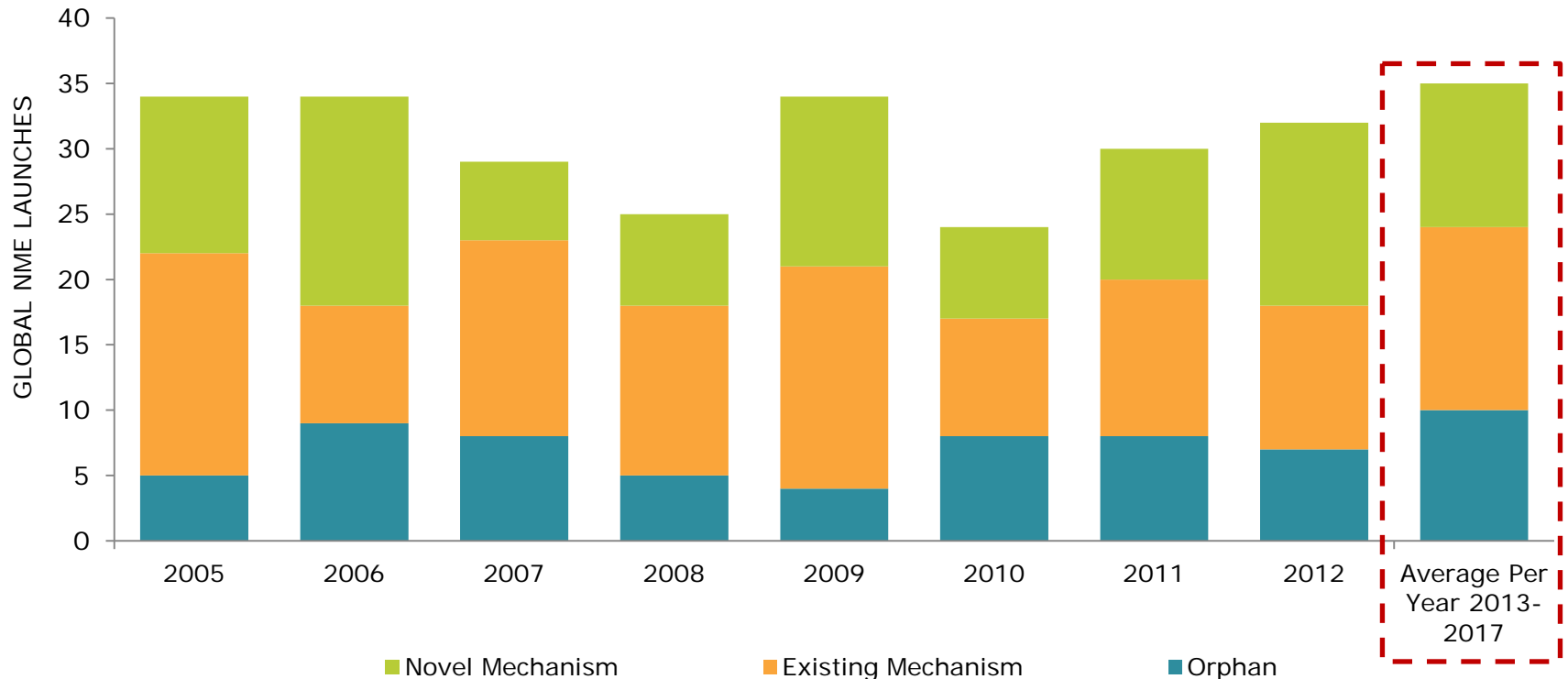
Specialty Spending between 2012 and 2017



Source: IMS Health Thought Leadership, September 2013

Increasing numbers of innovative new medicines and orphan drugs are expected to be launched

Global Launches of New Molecular Entities



Source: IMS Institute for Healthcare Informatics, October 2013

Treatment will be transformed by new and existing mechanisms

Selected Product Launches 2013-2017

Disease area	Existing mechanisms	New Mechanisms
Rheumatoid Arthritis	<ul style="list-style-type: none"> JAK inhibitor (adelatinib VX-509, baricitinib, fostamatinib) 	
Cystic Fibrosis	<ul style="list-style-type: none"> Transmembrane conductance regulator corrector (Lumacaftor, VX-661) 	Ribosome interaction for readthrough of nonsense mutations (NM) in NM cystic fibrosis (Ataluren)
Melanoma	<ul style="list-style-type: none"> BRAF kinase inhibitor (dabrafenib) MEK kinase inhibitor (trametinib) Program cell death MAB (nivolumab, lambrolizumab) 	<ul style="list-style-type: none"> Oncolytic HSV vector (talimogene laherparepvec)*
Breast cancer	<ul style="list-style-type: none"> Mab (trastuzumab emtansine) Cyclin dependent kinase inhibitor (palbociclib) 	
Ovarian cancer	<ul style="list-style-type: none"> Folate-targeted drug conjugate (vintafolide) VEGFR inhibitor (nintedanib) 	<ul style="list-style-type: none"> PARP inhibitor (olaparib)
Multiple sclerosis	<ul style="list-style-type: none"> Lipophilic molecule (dimethyl fumarate) 	
Heart Failure	<ul style="list-style-type: none"> Human peptide synthetic version (ularitide) 	<ul style="list-style-type: none"> Human relaxin-2 hormone recombinant (serelaxin)
Hepatitis C	<ul style="list-style-type: none"> NS3/4A proteinase inhibitor (asunaprevir, sofosbuvir, simeprevir) 	
Malaria		<ul style="list-style-type: none"> RTS,S Adjuvant System (P. falciparum / P.Vivax circumsporozoite protein)

Source: IMS Institute for Healthcare Informatics, September 2013

Some of the diseases with highest global burden have fewer new treatment options from recent or forthcoming launches

High Income Countries

Disease	DALYs%
IHD	8.2%
Stroke	4.7%
Depression	4.3%
Lung Cancer	3.5%
COPD	3.2%
Musculoskeletal	3.1%
Diabetes	2.8%
Alzheimer's	2.3%
Anxiety	1.9%
Colorectal	1.8%
Alcohol Abuse	1.8%
LRI	1.7%
Breast Cancer	1.4%
Osteoarthritis	1.3%
Other Circulatory	1.3%
Migraine	1.3%
Asthma	1.2%
Other Neoplasm	1.1%
BPH	1.0%
Stomach Cancer	1.0%















Global

Disease	DALYs%	Pipeline	Launches
IHD	5.2%	183	191
LRI	4.6%	53	73
Stroke	4.2%	41	45
Malaria	3.3%	17	6
COPD	3.1%	48	24
Depression	3.1%	44	58
Other HIV	2.7%	45	33
Tuberculosis	2.0%	53	5
Diabetes	1.9%	120	89
Neonatal Sepsis	1.8%	4	0
Diarrhoea	1.6%	6	6
Lung Cancer	1.3%	141	18
Musculoskeletal	1.2%	7	6
Anxiety	1.1%	11	11
Alcohol Abuse	1.1%	25	9
Meningitis	1.0%	12	21
Asthma	0.9%	67	29
Migraine	0.9%	21	19
Liver Cancer	0.8%	53	4
Other Neurological	0.7%	14	9

Source: IHME Global Burden of Diseases, Injuries, and Risk Factors Study 2010; IMS Health R&D Focus, July 2013

The availability of new medicines varies widely by country and disease













Global New Molecular Entities 2007-11 Available to Patients in 2012

	 Global	 U.S.	 Japan	 Germany	 France	 Spain	 Italy	 UK	 Canada	 Korea	 Brazil	 Russia	 India	 China
Total	146	94	59	88	65	70	65	88	63	52	45	42	38	37
% of Total		64%	40%	60%	45%	48%	45%	60%	43%	35%	31%	29%	26%	25%
Anti-infectives & Antivirals	16	6	10	7	6	5	3	6	7	3	4	4	1	4
Arthritis/Pain	6	3	3	3	2	3	2	3	2	2	1	1	1	2
Blood	8	6	2	3	3	3	3	5	3		1	2	1	1
Cardiovascular	17	12	8	13	8	11	10	12	8	9	8	5	9	7
CNS	20	13	5	13	10	10	9	12	8	5	5	5	9	5
Dermatology	4	2	2	2	1	2	2	2	1	2	2	1	1	1
Diabetes	5	3	4	3	3	4	3	4	3	3	4	4	4	4
Gastrointestinal	9	4	1	3	2	3	2	4	4	2	1	1	3	
GU & Hormones	10	4	3	5	1	5	5	4	1	7			1	
Immune System	11	9	3	10	7	8	8	9	6	3	3	5		3
Metabolic	2	1	1	1	2	1	1	1	1					
Oncologics	23	19	8	18	16	9	11	19	14	9	8	9	2	6
Ophthalmics	5	4	3	2	1	1	1	2	1	2	3		2	
Other	3	1	1							1		1		
Respiratory	6	3	4	4	3	4	4	4	3	3	4	3	3	3
Vaccines	1	1	1	1	1	1	1	1	1	1	1	1	1	1

Source: IMS Institute for Healthcare Informatics, October 2013

China will be the second largest market in 2017 and approaching half the size of the U.S. market

Rank	2007	Index
1	U.S.	100
2	Japan	27
3	 France	13
4	 Germany	13
5	 China	11
6	 Italy	8
7	 UK	7
8	 Spain	7
9	 Canada	7
10	Brazil	5
11	Mexico	4
12	Australia	4
13	South Korea	3
14	 Russia	3
15	 Turkey	2
16	 India	2
17	 Netherlands	2
18	 Greece	2
19	 Poland	2
20	 Belgium	2

Rank	2012	Index
1	U.S.	100
2	Japan	27
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7	 Italy	8
8	 UK	7
9	Canada	7
10	 Spain	6
11	 Russia	5
12	Australia	4
13	 India	4
14	 Mexico	4
15	 South Korea	3
16	 Venezuela	3
17	 Turkey	3
18	 Poland	2
19	 Argentina	2
20	Belgium	2

Rank	2017	Index
1	U.S.	100
2	 China	45
3	 Japan	29
4	 Brazil	13
5	 Germany	13
6	 France	10
7	Italy	8
8	 Russia	7
9	 UK	7
10	 Canada	7
11	 India	6
12	 Spain	5
13	 Mexico	4
14	 South Korea	4
15	 Australia	4
16	 Turkey	3
17	 Venezuela	2
18	 Argentina	2
19	 Indonesia	2
20	 Poland	2

 Change in ranking over prior 5 years

Source: IMS Market Prognosis, September 2013

Region and leading country spending

US\$ billions	2012	2008-2012 CAGR	2017	2013-2017 CAGR
Global	965.4	5.4%	1,170-1,200	3-6%
Developed	621.6	2.9%	650-680	1-4%
U.S.	328.2	3.0%	350-380	1-4%
EU5	148.7	2.4%	140-170	0-3%
France	36.7	0.3%	30-40	(-2)-1%
Germany	42.1	3.8%	41-51	1-4%
Italy	26.2	2.9%	23-33	0-3%
Spain	19.9	1.7%	13-23	(-4)-(-1)%
UK	23.9	3.4%	20-30	1-4%
Japan	111.3	3.0%	90-120	2-5%
Canada	22.0	3.1%	20-30	1-4%
South Korea	11.3	6.3%	10-20	3-6%
Pharmerging	223.9	15.0%	370-400	10-13%
China	81.7	22.3%	160-190	14-17%
Tier 2	59.6	15.6%	90-110	10-13%
Brazil	28.5	14.6%	38-48	11-14%
Russia	17.1	17.7%	23-33	8-11%
India	14.0	15.1%	22-32	11-14%
Tier 3	82.6	9.4%	100-130	5-8%
Rest of World	120.0	4.7%	125-155	2-5%

Source: IMS Market Prognosis, September 2013

Implications and discussion

- Medicine spending growth rebounding across developed economies and tapering of “patent dividend” over next five years will bring new dynamics to the medicines marketplace
- Spending growth of 10-13% CAGR across pharmerging countries brings extraordinary stresses to funding and healthcare delivery systems
- Recent and future novel therapies bring new options and dynamics to treatment of multiple therapy areas including diabetes, hepatitis C, melanoma, multiple sclerosis and thrombosis/acute coronary syndrome
- Role and penetration of generic drugs remains very uneven across developed markets even as policy levers are being applied
- Levels of spending on new NCEs are at historically low levels bringing inadequate returns to investment capital
- Visibility of \$1 trillion medicine cost is high – but not the context and impact on healthcare systems or patients

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Johns Hopkins Bloomberg School of Public Health
Center for Drug Safety and Effectiveness
Safety, Value and Innovation Seminar

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