



The Global Use of Medicines:
Outlook
Through 2016

July 2012

Key 2016 Numbers

Spending ~ \$1.2 Trillion

Spending on Brands \$615-645Bn

Spending on Generics \$400-430Bn

Developed Country Spending Per Person \$609

Pharmerging Country Spending Per Person \$91

Key 2012-2016 Numbers

New Molecular Entity Launches 160-185

Global Spending Growth CAGR 3-6%

U.S. Spending Growth CAGR 1-4%

Pharmerging Spending Growth CAGR 12-15%

"Patent Dividend" \$106Bn



IMS Institute for Healthcare Informatics

11 Waterview Boulevard Parsippany, NJ 07054 USA info@theimsinstitute.org www.theimsinstitute.org

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Introduction

The future level of global spending on medicines underscores the similar challenges of access and affordability which face those who consume and pay for healthcare around the world.

In the developed markets, including the United States and Europe, the current economic downturn will amplify many of the long-term concerns about aging populations afflicted with expensive chronic diseases and the desire by all healthcare stakeholders to control costs. Across countries, similar policies are already being implemented to rein in spending on expensive therapies, increase the use of generics, address pricing directly through price cuts or indirectly via discounts or rebates, and develop a market for biosimilars as a lower-cost alternative to original biologics.

Alternatively, the fast growing pharmerging markets will be driven predominantly by economic gains and rising incomes. This rise in incomes, particularly for the lowest earners, coupled with government commitments to support expanded access to basic healthcare services, will make medicines more broadly available and affordable to millions of people.

Further, new therapies for a range of diseases affecting both developed and developing world populations are currently, or will soon become, available transforming patient care. Despite this progress, however, significant gaps remain in the drug arsenal.

In this report we quantify these factors and examine the spending and usage of medicines globally through 2016. We intend this report to provide a foundation for meaningful discussion about the value, cost and role of medicines in healthcare over the next five years. Our report was developed as a public service without industry or government funding.

Michael Kleinrock

Director, Research Development
IMS Institute for Healthcare Informatics

Executive summary

GLOBAL SPENDING ON MEDICINES

Annual global spending on medicines will reach nearly \$1.2 trillion by 2016, as the pharmerging markets, biologics and generics contribute more to spending. In the developed markets, including the United States, Europe and Japan, spending will decline to 57% of the global total due to expiring patents for a number of significant brand-name drugs, slower increases in spending on branded products, and increased cost containment measures by payers. Alternatively, pharmerging markets will reach 30% of global spending by 2016, as population and economic growth contribute to dramatically higher use of medicines in these markets.

Overall, the top 20 therapy areas will account for 42% of global spending, led by cancer, diabetes and asthma/COPD.

An accelerated shift to the use of generic medicines is expected, both from an unprecedented level of patent expiries in the U.S., and from volume-driven growth in the largely generic-using pharmerging markets. At the same time, lower-cost versions of expensive biologic medicines, or biosimilars, will continue to be launched, though slowly, and will account for only \$4-6Bn, or 2%, of the \$200-210Bn in spending on biologics by 2016.

By 2016, net spending on medicines, after off-invoice discounts and rebates, will surpass \$1 trillion globally. Off-invoice transactions will continue to rise, particularly for generics, representing in aggregate an estimated \$180-190Bn in 2016.

TRANSFORMATIONS IN DISEASE TREATMENTS

New medicines will transform patient care in a large number of diseases including cancer, heart disease and central nervous system disorders. Few medicines are available uniformly to all patients globally following launch, and the time lag in some countries for gaining access to these medicines can be significant. Proven medicines, which were only previously available in a few countries, will become more widely available over the next five years, bringing important advances in care for diabetes, cancer and autoimmune diseases to millions.

Global launches for New Molecular Entities (NME) will rebound, as 32 to 37 NMEs per year are expected to be launched, through 2016. Innovative therapies are anticipated for Alzheimer's and autoimmune diseases, diabetes, cancer, and infectious, cardiovascular and respiratory conditions, as well as orphan diseases.

In 2004, the World Health Organization reported that significant gaps existed in pharmaceuticals available to treat certain priority diseases, and issued a call to action to address these gaps. In the years since, significant efforts have been made to address some of these disease areas, though gaps will remain.

GLOBAL SPENDING GROWTH

Annual global spending growth will increase from \$30Bn in 2012, to \$70Bn in 2016, driven by volume growth in pharmerging markets and higher spending by developed nations. The pharmerging countries will double their spending on pharmaceuticals over the next five years, as annual growth is forecast to increase from \$24Bn in 2012, to \$35–45Bn in 2016.

Spending on medicines in the pharmerging markets will increase by \$150-165Bn, driven by rising incomes and macroeconomic expansion, and increasing access to medicines supported through a range of government policies and programs.

The developed markets are expected to grow slowly due to patent expiries and the sustained impact of the global economic crisis felt in these countries since 2008. Patent expiries will reduce brand spending by \$127Bn through 2016, yielding a five-year "patent dividend" of \$106Bn.

In the U.S., spending growth will recover, but remain at historically low levels. Patent expiries and the introduction of low-cost generics will reduce spending throughout the forecast period.

In Europe, growth is expected to be in the -1% to 2% range through 2016, compared to 3.8% for 2007-2011, as national debt incurred due to the global economic crisis is anticipated to be addressed through austerity programs and healthcare cost containment. Limited savings from patent expiries are also prompting policy shifts that encourage the greater use of generics and lower reimbursement, such as those already enacted in Spain in 2010.

The Japanese market for pharmaceuticals will increase slightly over the next five years with growth forecast between 1-4% and punctuated by biennial price cuts. Reforms, implemented in 2010, will continue to encourage greater adoption of new medicines and also shift usage from off-patent brands to generics. While Japan's population as a whole will decline, an aging population is expected to drive up demand for medicines.

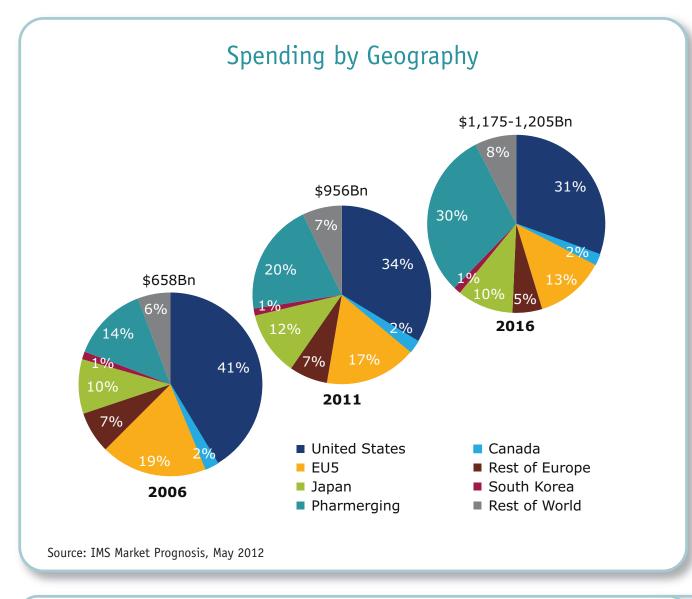
Global Spending on Medicines



Global spending on medicines annually will grow to nearly \$1.2 trillion by 2016, as the pharmerging markets, biologics and generics contribute a greater share of spending.

- By 2016, developed markets will decline to 57% of global spending due to patent expiries, slower brand spending growth and increased cost containment actions by payers.
- Pharmerging markets share of spending will increase by 10 percentage points to 30% of global spending over the next five years, as population and economic growth will drive a dramatically higher use of medicines in these markets.
- There will be an accelerated shift in spending to generics; biologic medicines are expected to account for \$200-210Bn of global spending, while biosimilars will be between \$4-6Bn, or 2% of biologics spending.
- Off-invoice discounts and rebates will represent an estimated \$180-190Bn in 2016, which would lower estimated global spending by 15-16% to \$995-1,005Bn.

Global spending will reach nearly \$1.2 trillion by 2016



- Developed markets will account for 57% of total spending, down from 73% in 2006.
- The U.S. share of global spending will decline from 41% in 2006 to 31% by 2016, largely due to patent expiries and slower brand growth.
- EU5 share of spending will decline to 13% in 2016, as slower economic growth prompts more aggressive cost containment measures.
- Pharmerging markets surpassed EU5 in total spending in 2010 and will reach 30% of global spending in 2016, as millions more people gain access to basic medicines.
- Japan will retain 10% of drug spending in 2016, essentially unchanged except for the impact of the biennial price cuts expected in 2012, 2014 and 2016.

Chart notes

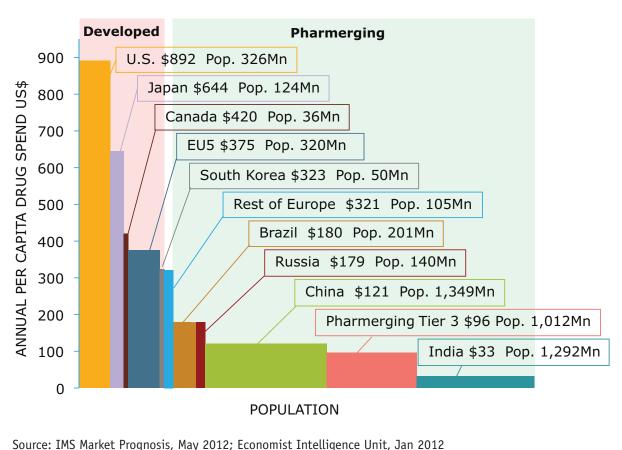
Spending in US\$ with variable exchange rates.

Pharmerging countries are defined as those with >\$1Bn absolute spending growth over 2012-16 and which have GDP per capita of less than \$25,000 at purchasing power parity (PPP). Pharmerging markets include China, Brazil, India, Russia, Mexico, Turkey, Poland, Venezuela, Argentina, Indonesia, South Africa, Thailand, Romania, Eqypt, Ukraine, Pakistan and Vietnam.

Rest of Europe excludes Russia, Turkey, Poland, Romania, Ukraine, which are included in the pharmerging markets.

Significant differences in spending per person will remain





- Developed markets include countries with the most advanced health systems and economies, and are expected to spend an average of \$609 per person in 2016.
- Pharmerging countries, which account for nearly two-thirds of the world's population, will average \$91 in drug spend per capita in 2016.
- Many pharmerging countries have been making significant efforts to cover more of their populations with health insurance and basic medical services; however, millions still have limited access to healthcare, often because they must pay a significant portion of their healthcare costs.

Chart notes

Real spending in 2005\$ at variable exchange rates, adjusted for purchasing power parity.

Region average drug spend weighted by population.

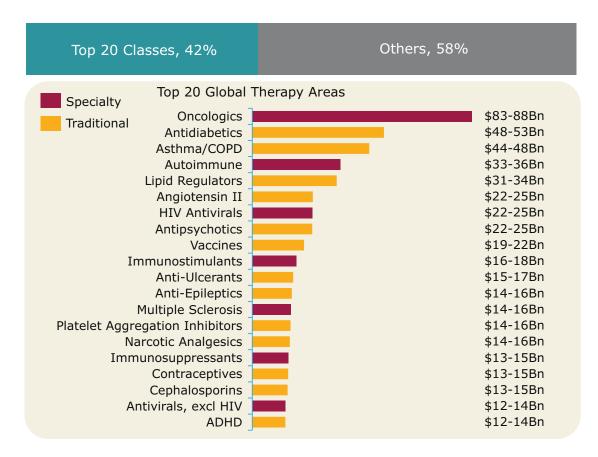
Pharmerging Tier 2: Brazil, India, Russia.

Pharmerging Tier 3: Argentina, Egypt, Indonesia, Mexico, Pakistan, Poland, Romania, South Africa, Thailand, Turkey, Ukraine, Venezuela, Vietnam.

Rest of Europe excludes Russia, Turkey, Poland, Romania, Ukraine, which are included in pharmerging.

The top 20 therapy areas will account for 42% of spending





Source: IMS Institute for Healthcare Informatics, May 2012

- Classes with the highest levels of spending on medicines in 2016 are expected to include cancer, diabetes and asthma/COPD.
- Overall, the top 20 therapy areas will account for 42% of total spending.
- Seven of the top 20 classes are specialty medicines, often with novel mechanisms and improved efficacy, and represent many of the most important and recent innovations in global medicine.
- These medicines include breakthroughs for melanoma, prostate cancer, autoimmune diseases, lupus, multiple sclerosis and hepatitis C.

Chart notes

Spending in US\$ with constant exchange rates.

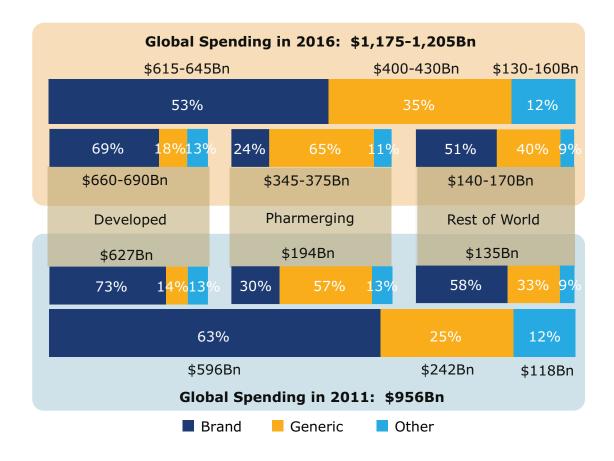
Specialty therapies are products which are often injectables, high-cost, biologic or requiring cold-chain distribution. They are mostly used by specialists, and include treatments for cancer, other serious diseases, and often involve complex patient follow-up or monitoring.

Therapy forecasts from IMS Therapy Forecaster adapted by the IMS Institute to represent global forecasts and to include additional classes.

Abbreviations: COPD: Chronic Obstructive Pulmonary Disease; HIV: Human Immunodeficiency Virus; ADHD: Attention Deficit Hyperactivity Disorder.

An accelerated shift in spending to generics is expected





Source: IMS Institute for Healthcare Informatics, IMS Market Prognosis, May 2012

- Global brand spending is forecast to increase from \$596Bn in 2011 to \$615-645Bn in 2016, primarily from developed markets.
- Global generic spending is expected to increase from \$242Bn to \$400-430Bn by 2016, of which \$224-244Bn of the increase is from low-cost generics in pharmerging markets.
- Increased generic spending in developed markets in the next five years will be driven by generic competition due to patent expiries, with some additional increases due to expanded generic use for off-patent molecules.
- In pharmerging markets, generic and local companies will drive most of the increases in spending.

Chart notes

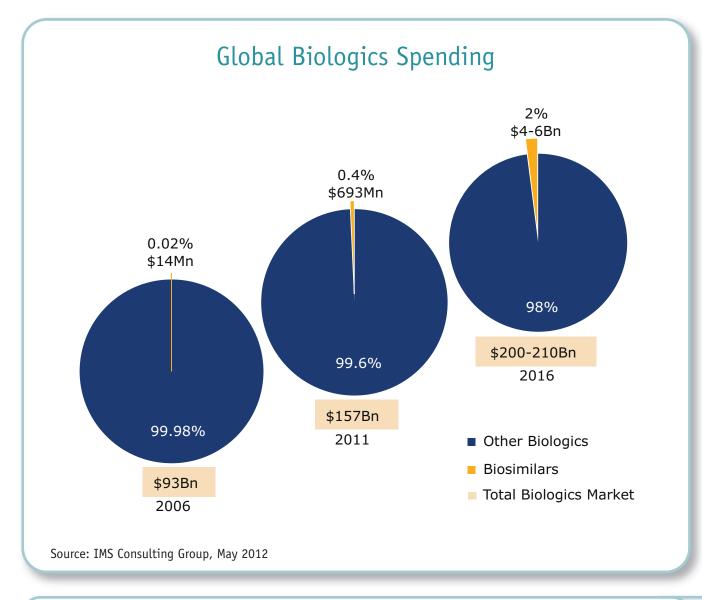
Spending share in US\$ with variable exchange rates.

Brands defined using IMS's proprietary market segmentation methodology and include vaccines, but exclude branded generics.

Generics are defined as unbranded generics and branded generics but exclude OTC.

Other products include OTC, diagnostics and non-therapeutics.

Biosimilars' adoption will expand, but will remain modest to 2016



- Biologics will account for an increased share of spending by 2016, as important clinical advances continue to emerge from research, and patients around the world are treated.
- Spending on biosimilars will increase from \$693Mn in 2011 to \$4-6Bn by 2016, which represents 2% of biologic spending.
- Adoption is expected to remain modest through 2016, largely because most biologic medicines will stay protected by patents or market exclusivity in many countries.

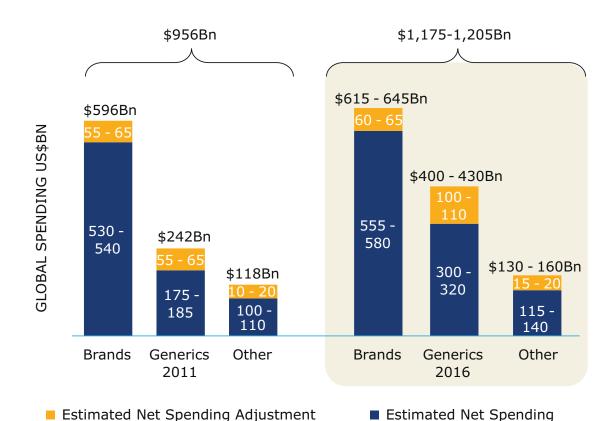
Chart notes

Biologics include single identified components, whole cells, and include some forms of polymers. They can be purified from human, animal, plant or micro-organism sources. Biologics can be produced by recombinant DNA technology or chemically synthesized.

Biosimilar products are biologic products approved in a country which has an abbreviated approval process for biologic products that reference an originator biologic in the regulatory submission.

Net spending is expected to be over \$1 trillion by 2016

Global Spending and Estimated Net Spending



Source: IMS Institute for Healthcare Informatics, IMS Market Prognosis, May 2012

- Discounts and rebates are expected to increase for branded products through 2016.
- Off-invoice discounts for generics will continue to grow as companies compete with each other with increasing intensity.
- Off-invoice discounts and rebates in 2011 are estimated to be \$130-140Bn, rising to \$180-190Bn by 2016.
- The U.S., France and Germany have recently increased government-mandated rebates, while other countries, including Italy and Canada, have banned some rebates, joining many other countries around the world with more transparent pricing systems.

Chart notes

Estimated Net Spending Adjustment is based on a comparison of company reported net sales and IMS reported sales. IMS estimates of total spending are based on IMS audits, most often collected at invoice prices from wholesaler transactions and which do not reflect off-invoice discounts and rebates in most markets.

Brands defined using IMS's proprietary market segmentation methodology and include vaccines, but exclude branded generics.

Generics are defined as unbranded generics and branded generics but exclude OTC.

Other products include OTC, diagnostics and non-therapeutics.

Transformations in Disease Treatment

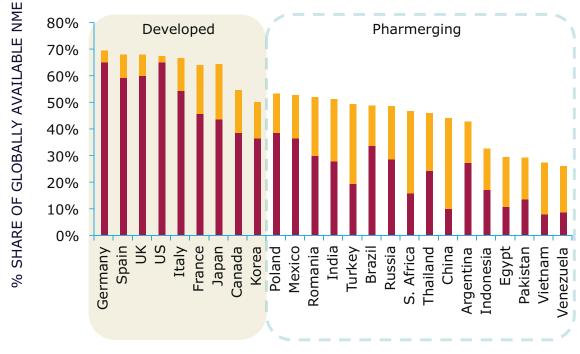


New medicines will transform patient care in a large number of diseases including cancer, heart disease and central nervous disorders, though significant gaps will remain in several global priority diseases.

- From 2006–2010, 140 NMEs were launched globally, with the developed markets gaining the most from these new product introductions. While few medicines are uniformly available across most countries, the most innovative ones are broadly available, across developed and pharmerging markets, including medicines for treating diabetes, HPV and thrombosis.
- Greater availability of existing and new medicines will transform care as treatments for global priority diseases improve and clusters of new therapies, with existing or novel mechanisms of action, provide more options for patients.
- More new medicines will be launched per year during the next five years, including innovative therapies for Alzheimer's, autoimmune diseases, diabetes, and a number of cancers and orphan diseases.
- Treatments for priority diseases will improve, but gaps will remain.

Greater availability of existing medicines will transform care





- Additional 2006-2010 NME available in 2016
- 2006-2010 NME available in 2011

Source: IMS Institute for Healthcare Informatics, May 2012

- Of the 140 NMEs launched globally from 2006–2010, most developed markets saw launches for half to two-thirds by 2011, compared to only 20–30% in pharmerging markets, though more will launch in the next five years.
- Products are often launched first in the most commercially attractive markets, whose characteristics include the pricing and reimbursement environment, the extent of regulatory requirements and in some cases the impact of reference pricing systems, whereby the reimbursed price in some markets is used to set the price in others.
- Typically, more expensive therapies are launched later in pharmerging markets.
- Recently enacted policies in Germany and the UK may make these markets less attractive as early launch countries, while the opposite is likely the case in Japan which has begun to reverse decades of delayed launches with pricing reforms.

Chart notes

Chart contains NME (New Molecular Entities) never marketed in any country, and launched for the first time between 2006-10, and launched by end of 2011, or expected to be launched by 2016.

Availability of new medicines varies by country and disease

Global New Molecular Entities 2006-10 Availability as of 2011

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	Global	U.S.	Japan	Germany	France	Spain	Italy	UK	Canada	S. Korea	Brazil	Russia	India	China
Total	140	91	61	91	64	83	76	84	54	51	47	40	39	14
% of Total	-	65%	44%	65%	46%	59%	54%	60%	39%	36%	34%	29%	28%	10%
Anti-infectives & Antivirals	14	7	9	6	6	6	6	6	6	7	6	5	3	2
Arthritis/Pain	8	4	3	4	1	5	5	4	3	2	-	-	2	-
Blood	8	6	3	4	4	4	4	4	2	1	2	3	-	-
Cardiovascular	18	13	6	14	7	13	12	12	7	7	7	3	6	2
CNS	17	10	4	12	8	10	8	11	6	4	6	5	7	2
Dermatology	4	2	3	3	1	2	2	2	1	2	2	-	2	-
Diabetes	5	3	4	4	4	4	4	4	3	3	4	4	4	4
Gastrointestinal	8	5	1	3	3	2	1	3	3	1	1	-	2	-
GU & Hormones	7	3	2	5	2	5	3	3	-	6	-	1	2	-
Immune System	10	9	5	9	7	9	8	9	5	1	3	3	1	-
Metabolic	3	2	1	2	2	3	2	2	-	1	-	-	1	-
Oncologics	22	17	10	15	13	11	13	14	12	9	9	10	4	4
Ophthalmics	4	2	3	2	1	2	2	2	2	3	2	1	-	-
Other	5	3	2	3	1	2	1	3	-	1	-	2	-	-
Respiratory	5	3	3	3	2	3	3	3	2	1	3	1	3	-
Vaccines	2	2	2	2	2	2	2	2	2	2	2	2	2	-

Source: IMS Institute for Healthcare Informatics, May 2012

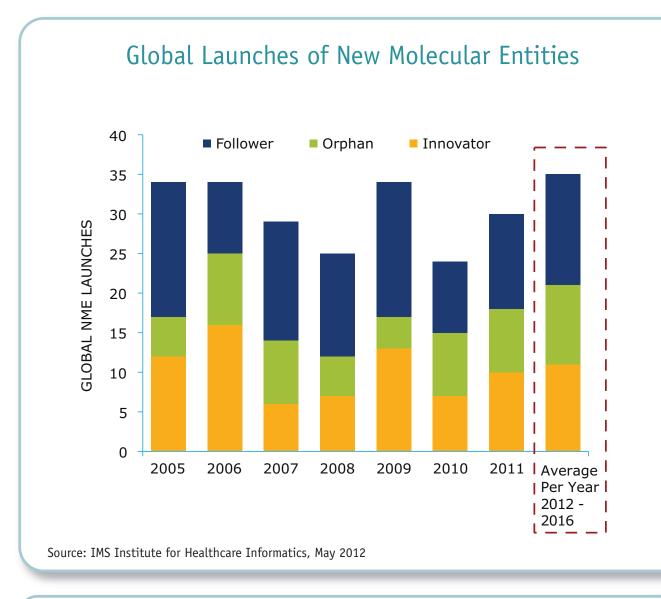
- Few products are available uniformly across all countries. However, four DPP-IV inhibitors for diabetes, five HIV antivirals, two HPV vaccines and four antithrombotic agents are already available to patients in most developed and pharmerging countries.
- In contrast, of the 22 new cancer therapies, two-thirds are available in the developed countries compared to fewer than half in the pharmerging countries.
- Novel CNS, cardiovascular and immune system therapies are yet to become broadly available outside developed countries.
- The most common reasons for lack of availability are the commercial priorities for the innovator, relatively difficult regulatory environments, unfavorable assessment by either FDA or EMA and orphan drug status.

Chart notes

New Molecular Entities include novel small molecule, biologic, or novel combination products (where at least one of the ingredients is novel), with global launch in at least one country between 2006-10 and measured by availability in specific countries by end of 2011.

CNS: Central Nervous System; GU: Genito-urinary.

More new medicines will be launched per year



- In four of the last seven years fewer than 30 NMEs have launched, though this is expected to rebound through 2016, to 32–37 per year.
- Innovative therapies are anticipated for Alzheimer's, autoimmune diseases, diabetes, and a number of cancers and orphan diseases.
- Clusters of new therapies, with existing or novel mechanisms of action, will provide more options for patients.

Chart notes

New Molecular Entities include novel small molecule, biologic, or novel combination products (where at least one of the ingredients is novel), launched for the first time globally.

Innovator therapies are those with novel mechanism of action applied for the first time in the approved indication. Follower therapies have mechanisms of action already used in their approved indication, though may still represent important clinical advances. Orphan therapies are approved for orphan-designated indications.

Treatment will be transformed by new and existing mechanisms

Selected Product Launches 2012-2016

DISEASE AREA	EXISTING MECHANISMS	NEW MECHANISMS
Autoimmune		 JAK inhibitor (tofacitinib)
Alzheimer's disease		 MAb (bapineuzumab, solanezumab)
Breast cancer	• MAb (pertuzumab, trastuzumab emtansine)	
Diabetes	 GLP-1 (albiglutide, dulaglutide, lixisenatide) DPP IV (anagliptin, gemigliptin, teneligliptin, trelagliptin) 	 SGLT inhibitor (canagliflozin, dapagliflozin, empagliflozin, ipragliflozin, tofogliflozin)
Hepatitis C	 NS3/4A proteinase inhibitor (asunaprevir, BI 201335, simeprevir) 	NS5A inhibitor (daclatasvir)
HIV	 Reverse transcriptase inhibitor (elvitegravir + emtricitabine + tenofovir disoproxil + cobicistat) 	
Lupus	Fusion protein (atacicept)MAb (epratuzumab, tabalumab)	
Melanoma	BRAF kinase inhibitor (dabrafenib)	 Oncolytic HSV vector (talimogene laherparepvec)
Multiple sclerosis	Immunomodulator (laquinimod, teriflunomide)MAb (daclizumab, ocrelizumab)	
Ovarian cancer	 Folate-targeted drug conjugate (vintafolide) 	 Kinase inhibitor (nintedanib)
Obesity	 Appetite suppressants (lorcaserin, phentermine/topiramate) 	
Thrombosis/ACS	 Blood clotting factor Xa inhibitor (idraparinux sodium, otamixaban) 	
Prostate cancer	Antiandrogen (enzalutamide/MDV3100)	 Kinase inhibitor (cabozantanib) Radiotherapeutic (radium-223 chloride)

Source: IMS Institute for Healthcare Informatics, May 2012

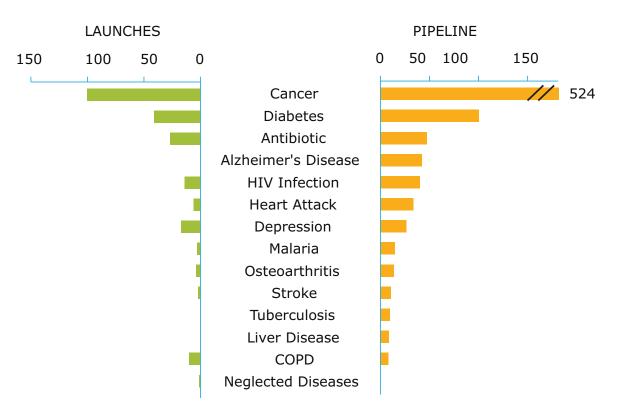
- Between 32–37 innovative products are expected to be launched per year over the next five years.
- These developments include new mechanisms of action in several disease states such as Alzheimer's, autoimmune diseases and various types of cancer, which have the potential to transform disease treatment, although not every therapy will become available or achieve its ultimate clinical aims.
- There are also further developments in areas of research where some therapies have already launched including hepatitis C, multiple sclerosis and prostate cancer, which offer the potential to deliver better efficacy, safety or convenient administration.

Chart notes

Table includes selected not yet launched New Molecular Entities (NME) expected to be launched by 2016. An NME is the first commercial launch of a novel therapeutic entity. Abbreviations: JAK: janus-like kinase inhibitor; MAb: monocloncal antibody; GLP-1: glucagon-like peptide-1; DPP-IV: dipeptidyl peptidase-IV inhibitor; SGLT: sodium-glucose cotransporter inhibitor; HSV: 5-HT2C: immunotherapeutic cancer vaccine, 5-hydroxytryptamine 2C; Xa: Xa coagulation factor inhibitor; NS5A: non-structural protein 5A; HSV: herpes simplex virus; ACS: acute coronary syndrome.

Treatments for priority diseases will improve, but gaps will remain





Source: IMS Institute for Healthcare Informatics, May 2012; Kaplan, W., Laing, R., 2004. "Priority Medicines for Europe and the World". World Health Organization.

- Treatments for global priority diseases will improve due to availability of new medicines, especially in cancer.
- Recent launches, and those expected through 2016, will only partly fill the pharmaceutical gap identified by WHO in 2004.
- The largest pharmaceutical gaps remain in diseases that affect the developing world.

Chart notes

WHO report concluded that there were 13 priority disease areas with a "pharmacetuical gap."

Launches from 2004-11, anywhere in the world with approved indications for the listed diseases, but may relate to products first launched prior to 2003 for other indications and are not limited to New Molecular Entities (NME).

Pipeline includes products in research phases II, III and pre-registration shown based on likely time to approval but are not adjusted to reflect likelihood of launch.

Neglected diseases include Chagas disease, dengue fever, trypanosomiasis, schistosomiasis and leishmaniasis.

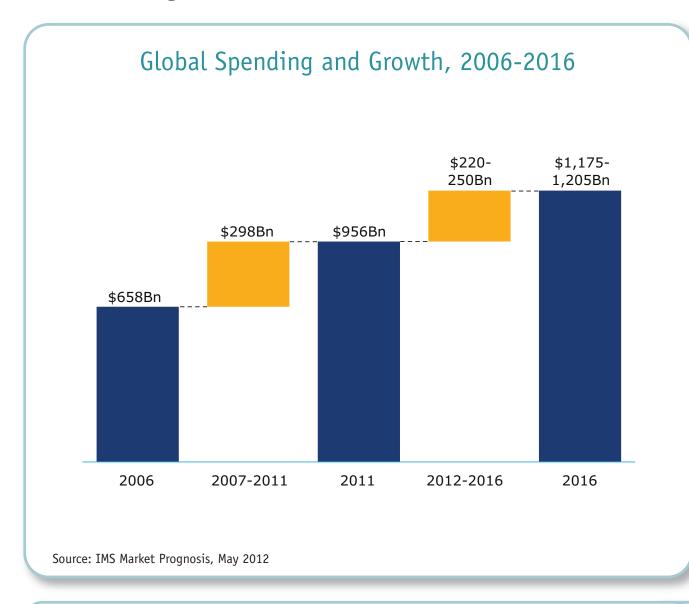
Global Spending Growth



Annual global spending growth on medicines will increase from \$30Bn in 2012 up to \$70Bn in 2016, driven by volume growth in pharmerging markets and higher spending in developed markets.

- Spending on medicines is expected to exceed \$1 trillion in 2013, reaching nearly \$1,200Bn by 2016 despite slowing growth and reduced contribution from developed markets due to patent expiries and the sustained impact of the economic crisis.
- The pharmerging markets will double their spending on pharmaceuticals, growing \$150-165Bn by 2016, and driven by rising incomes, continued low cost for drugs, and government sponsored programs designed to increase access to medicines.
- Patent expiries will reduce brand spending in developed markets by \$127Bn over the next five years offset by generic spending, and yielding a "patent dividend" of \$106Bn through 2016.
- In the U.S., spending growth will increase, but remain at historically low levels; European growth will be significantly less through 2016 in the -1 to 2% range; spending on medicines will grow between 1-4% in Japan over the next five years, and it will continue to be punctuated by biennial price cuts in 2012, 2014 and 2016.

Absolute growth is forecast to be \$220-250Bn over the next five years



- Spending on medicines globally is expected to exceed \$1 trillion in 2013 and to reach nearly \$1,200Bn by 2016.
- Absolute growth is expected to be \$220-250Bn, compared to \$298Bn in the prior five years.
- Removing the effect of exchange rate fluctuations, growth will be \$235-265Bn on a constant dollar basis, compared to \$240Bn in the previous five years.
- The slowing growth in the next five years will be largely due to reduced contribution from developed markets.

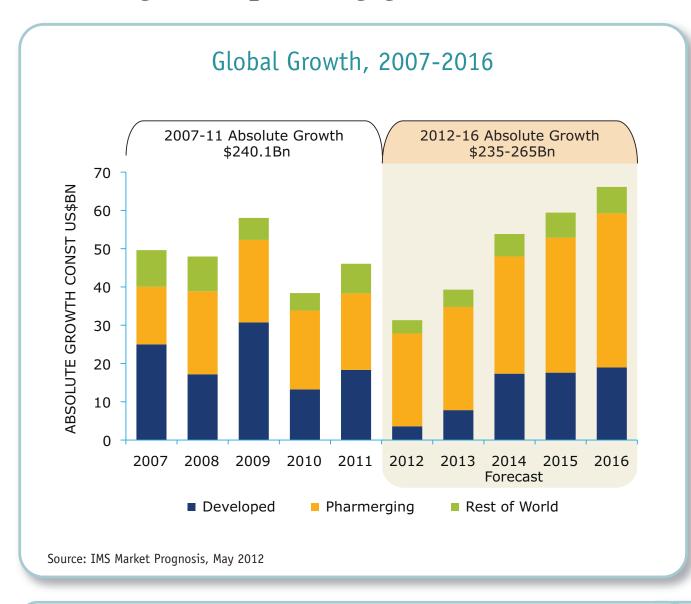
Chart notes

Spending in US\$ with variable exchange rates.

Charted growth from 2007-11 and 2012-16 include impacts of exchange rate variability.

In 2007-11, exchange rates contributed \$58Bn to growth. In 2012-16, they are expected to contribute ~\$15Bn.

Annual global spending growth will increase through 2016



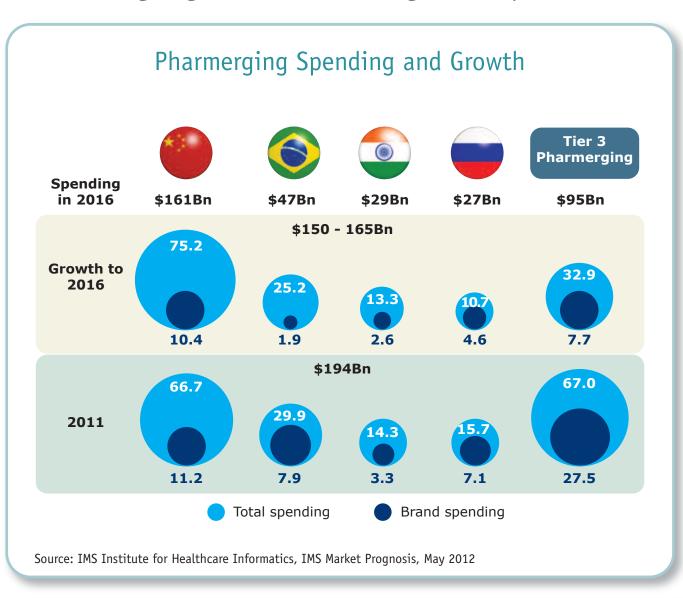
- Growth in pharmerging markets will increase from \$24Bn in 2012, to \$35-45Bn in 2016, primarily due to increased access to medicines as infrastructure and health systems evolve.
- Growth in developed markets will rebound from \$3Bn to \$18-20Bn as U.S., EU5 and Japan all contribute more later in the five-year period.
- The U.S. expansion of healthcare access, expected in 2014, will be the largest contributor to the doubling of growth in that year.

Chart notes

Developed: U.S., Japan, Germany, France, Italy, Spain, UK, Canada, South Korea.

Absolute growth in US\$ with constant exchange rate, excludes the impact of exchange rate changes which are expected to have approximately -\$15Bn impact by 2016.

Pharmerging markets will grow by \$150-165Bn over five years



- Rising incomes, combined with continued low costs for medicines, will drive significant increases in affordability of basic medicines.
- Pharmerging countries are expected to nearly double their pharmaceutical spending, adding \$150-165Bn by 2016. Generic and other products will account for approximately 83% of the increase.
- Patients face substantial out-of-pocket costs in these markets, with a few exceptions, which limits the usage of brands and expensive newer medicines.
- Government-supported or funded programs will continue to increase access to medicines, limit patients' exposure to costs and encourage greater use of medicines.

Chart notes

Spending in US\$ with variable exchange rates.

Growth in US\$ with constant exchange rates.

Spending in 2011 plus growth to 2016 will not equal spending in 2016 due to estimated future exchange rate changes, which are excluded from forecasted growth.

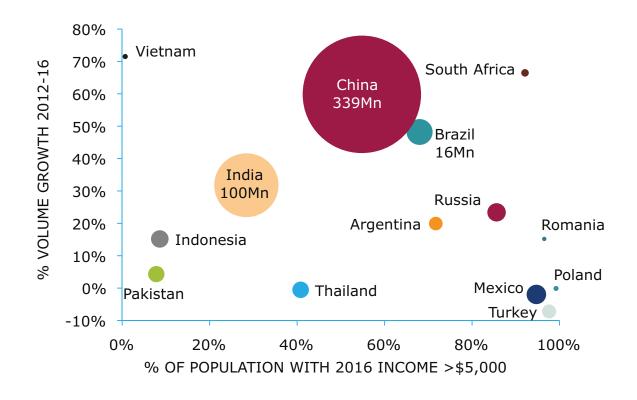
Brands defined using IMS's proprietary market segmentation methodology and include vaccines, but exclude branded generics.

Total spending includes generics and other products, which include OTC, diagnostics and non-therapeutics.

Tier 3 Pharmerging in descending order: Mexico, Turkey, Poland, Venezuela, Argentina, Indonesia, South Africa, Thailand, Romania, Egypt, Ukraine, Pakistan and Vietnam.

Economic development will drive volume growth

Volume Growth and Populations With >\$5,000/Year Income by Country in 2016



Source: Institute for Healthcare Informatics, IMS Market Prognosis, May 2012; Economist Intelligence Unit, Jan 2012

- Countries with the lowest incomes will drive relatively low volume growth, as basic medicines remain out of reach for most.
- Rising incomes, particularly at the very low end of incomes, will continue to be strongly correlated with the incremental use of medicines.
- In pharmerging countries, 40% of the population will have yearly household incomes over \$5,000 by 2016; an increase of 494 million people compared to 2011.
- Incomes will continue to rise based on macroeconomic expansion, which increases access to medicines, and is supported through a range of government policies.
- Spending on medicines in these countries will rise by \$150–165 billion in the next five years, mostly due to volume growth.

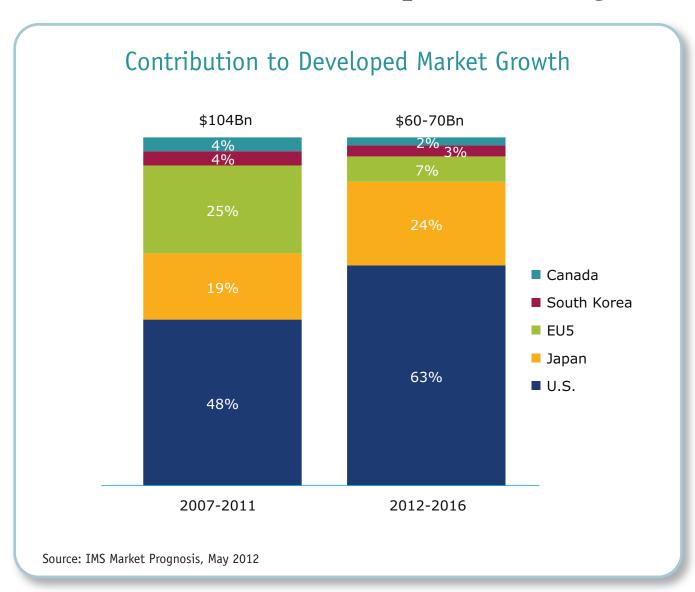
Chart notes

Volume growth reflects growth without the impact of price changes.

Income distribution provided by Economist Intelligence Unit, and reflects disposable income, after taxation and insurance deductions.

Bubble size on chart reflects incremental country population with household incomes >\$5,000/year between 2011 and 2016.

Redistribution of developed market growth will be significant

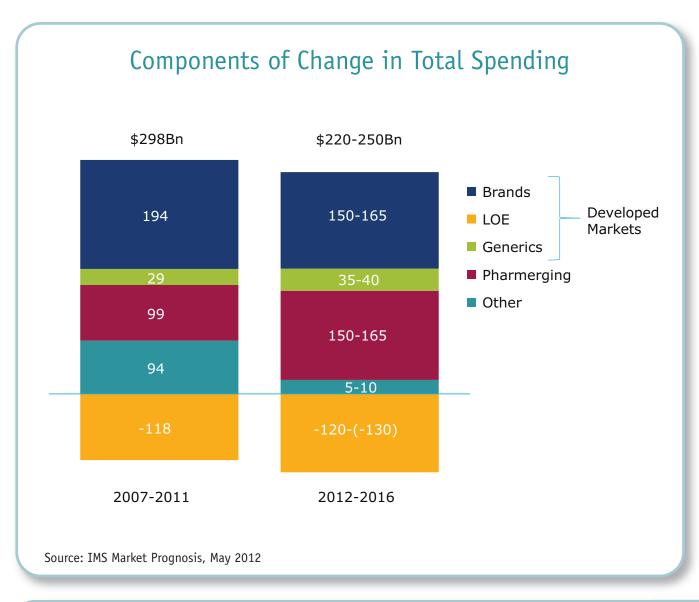


- Developed markets are expected to grow much less in the next five years than in the last five due to patent expiries and the sustained impact of the economic crisis.
- U.S. growth will remain at historically low levels, and the country will have a smaller share of the global market through 2016, but a larger share of developed markets.
- EU5 markets are expected to grow more slowly and their growth will range from -1 to 2%.
- Most EU5 governments did not significantly reduce healthcare expenditures in the immediate aftermath of the economic crisis, incurring debt which is now prompting austerity measures across the region.
- The most common policies being implemented are designed to shift usage to generics and restrict use of newer brands.

Chart notes

Growth in US\$ with constant exchange rates. EU5 includes Germany, France, Italy, Spain, UK. Contribution to growth may not add to 100% due to rounding.

Brands, pharmerging markets and generics will drive spending



- Despite the largest period of patent expiry in history, brands will offset expiries with organic growth and new products, but to a lesser degree than in the last five years.
- The largest segment of growth in the next five years will be pharmerging markets, driven by increased access through a variety of healthcare reforms and economic growth.
- Generic spending will increase by \$36Bn, approximately 60% from increased utilization of existing generic products, and 40% from newly available generics.
- The rest of the world is expected to make a small contribution to increased spending, but masks a disparate and volatile expansion of health spending globally.

Chart notes

Spending in US\$ with variable exchange rates.

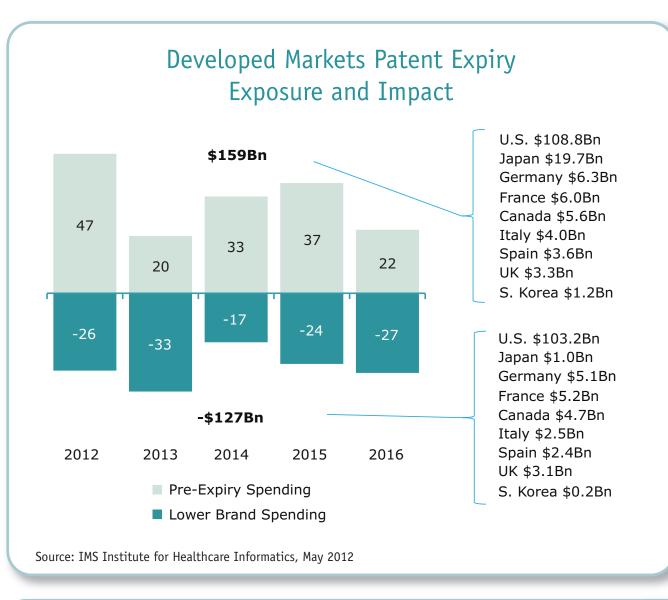
Developed countries are U.S., Japan, Germany, France, Italy, Spain, Canada, UK and South Korea.

Brands (including vaccines), Generics and Loss of Exclusivity (LOE) are defined using IMS MIDAS market segmentation methodology.

Other includes Rest of World absolute growth and exchange rate changes.

In 2007-11, exchange rates contributed \$58Bn to growth. In 2012-16, they are expected to contribute ~\$15Bn.

Patent expiries will reduce brand spending by \$127Bn through 2016



- Patent expiries will save payers in developed markets \$127Bn in the next five years, and primarily in the U.S. This will be offset by \$21Bn of expected generic spending, resulting in a \$106Bn "patent dividend" in 2016.
- In the U.S., \$103Bn, or 44% of 2011 brand spending will shift to generics at dramatically lower prices.
- In other developed markets, the average brand spending exposed to generic competition will be 23%, except in Canada where 42% of spending will be exposed.
- Overall, exclusivity expiries in one or more of the developed markets will impact 13 of the top 20 products, or 7 of the top 10 current leading medicines, including Lipitor[®], Plavix[®], Advair Diskus[®], Crestor[®] and Nexium[®].

Chart notes

Spending expressed in US\$ with constant exchange rates. Chart covers developed markets shown.

Lower brand spending reflects the expected impact on drug spending in each year of patent expiries (including continuing impact from expiries in prior years).

Pre-expiry spending consists of projected spending in the year prior to expiry.

Estimates of protection expiry from information available as of March 31, 2012.

U.S. spending growth on medicines will be 1-4% through 2016



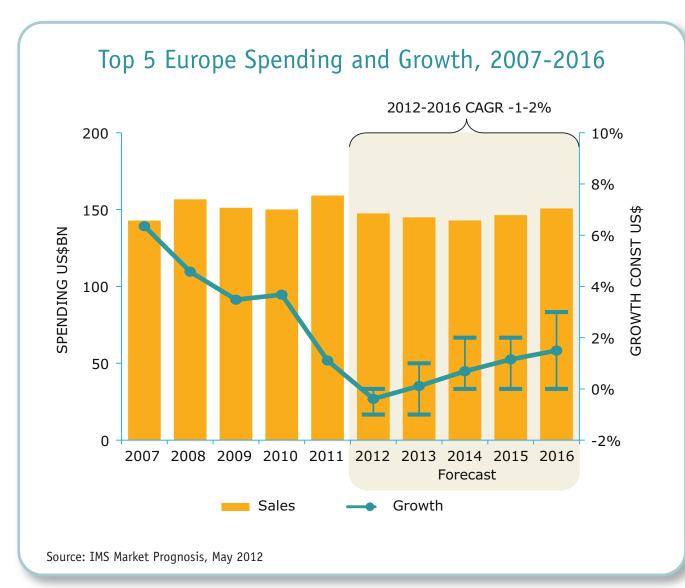
- Patent expiries and the impact of low-cost generics will affect spending growth throughout the forecast period, peaking in 2012 and 2013.
- Less impact from expiries will contribute to approximately half of the higher market growth in 2014, relative to 2013.
- Impact of health insurance reforms will positively impact growth in 2014; the majority of the impact will be seen in the retail and primary care sectors.
- Patent protected brand volume growth is expected to slow in advance of key patent expiries.
- Branded price increases above inflation will continue, though they are expected to be offset by off-invoice discounts and rebates, which are not included in the forecasts.
- New brands contribution to spending will increase slightly to \$10-12Bn per year as the number of approvals increases.

Chart notes

Chart shading indicates forecast, and forecasted growth shows point forecast and high-low ranges.

Spending includes retail pharmacy, mail order, long-term care and institutional drug spending tracked by IMS audits.

Top 5 Europe spending growth will be flat through 2016



- Growth in the EU5 is expected in the –1 to 2% range through 2016 compared to 3.8% for 2007–11, as national debt incurred due to the global economic crisis will be addressed through austerity programs and healthcare cost containment.
- Limited savings from patent expiries in the forecast period are prompting policy shifts to encourage greater use of generics and lower reimbursement, particularly in Spain.
- Policies to examine the value newer medicines bring, when assessing their reimbursement prices, are being adopted in the UK with "value-based pricing" and in Germany with assessments under the AMNOG program.
- Governments will take direct actions to control spending growth, or in some cases make real reductions, particularly in hospital spending.

Chart notes

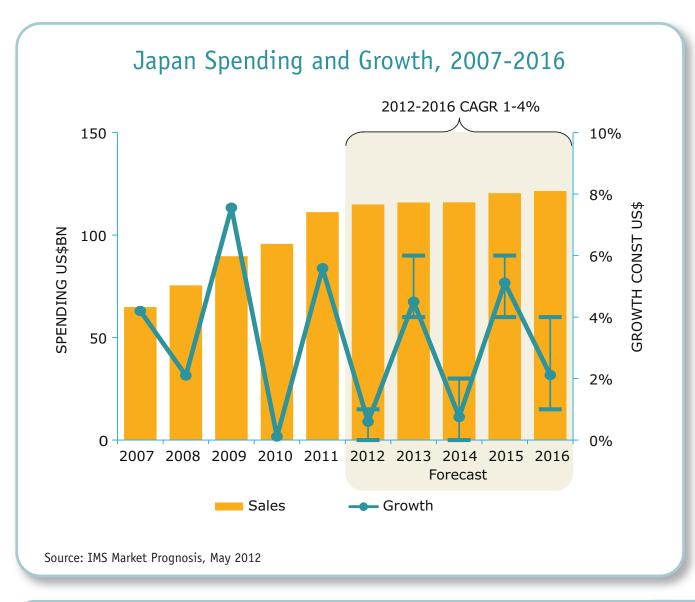
Chart shading indicates forecast, and forecasted growth shows point forecast and high-low ranges.

Spending includes retail pharmacy and institutional drug spending tracked by IMS audits.

Spending in US\$ with variable exchange rates.

Growth in US\$ with constant exchange rate.

Japan's growth is expected to increase slightly through 2016



- Forecast growth will range between 1–4% with gradual increases, punctuated by biennial price cuts which will lower growth in 2012, 2014 and 2016.
- The number of innovative new drugs and indications will increase, reflecting manufacturers' commitments made in return for access to premium pricing for new drug development as part of reforms implemented in 2010.
- While the population as a whole will decline, the number of retirees will increase, driving up demand for medicines.
- The use of generics is expected to increase as the government steps up policies to promote generics and major products face generic competition for the first time.

Chart notes

Chart shading indicates forecast, and forecasted growth shows point forecast and high-low ranges.

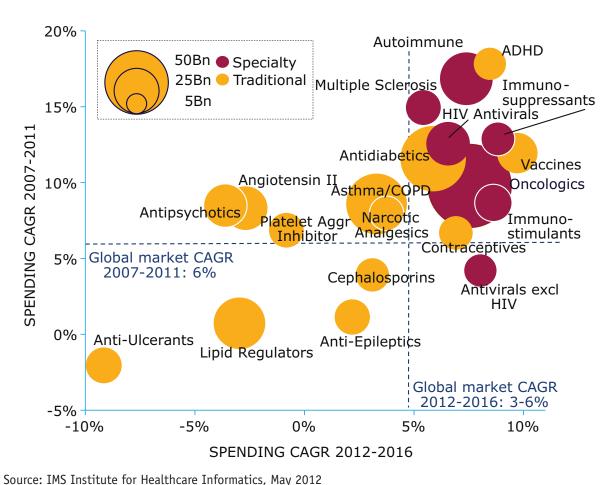
Spending includes retail pharmacy and institutional drug spending tracked by IMS audits.

Spending in US\$ with variable exchange rates.

Growth in US\$ with constant exchange rate.

Spending growth will be driven by areas of innovation





- Growth is decelerating in most therapy areas due to patent expiries and the lack of significant new treatment options.
- Of the 20 largest therapy areas, only classes with anti-epileptics, contraceptives and antivirals (excl HIV products) will grow faster than in the past 5 years.
- Specialty medicines will experience continued growth in the mid-term, driven by novel mechanisms, improved efficacy and relatively large patient populations leading to increased uptake.

Chart notes

Spending in US\$ with constant exchange rates.

Specialty therapies are products which are often injectables, high-cost, biologic or requiring cold-chain distribution. They are mostly used by specialists, and include treatments for cancer, other serious diseases, and often involve complex patient follow-up or monitoring.

Therapy forecasts from IMS Therapy Forecaster adapted by the IMS Institute to represent global forecasts and to include additional classes.

Abbreviations: COPD-Chronic Obstructive Pulmonary Disease; HIV-Human Immunodeficiency Virus; Multiple Sclerosis; ADHD-Attention Deficit Hyperactivity Disorder.

IMS INSTITUTE HEALTHCARE INFORMATICS

Definitions and conventions:

- This report is based on the IMS products and services detailed in the panel to the right and the research of the IMS Institute for Healthcare Informatics.
- Spending is reported at ex-manufacturer prices and does not reflect off-invoice discounts and rebates.
- Values are converted from local currencies to US\$ using variable exchange rates, except where noted.
- Growth is calculated using US\$ at constant (Q4 2011) exchange rates.
- Products are categorized as brands, generics or other using IMS's proprietary MIDASTM market segmentation methodology.
- Developed markets are defined as the U.S., Japan, Top 5 Europe countries (Germany, France, Italy, Spain, UK), Canada and South Korea.
- Pharmerging countries are defined as those with >\$1Bn absolute spending growth over 2012-16 and which have GDP per capita of less than \$25,000 at purchasing power parity (PPP). Tier 1: China; Tier 2: Brazil, India, Russia; Tier 3: Mexico, Turkey, Poland, Venezuela, Argentina, Indonesia, South Africa, Thailand, Romania, Egypt, Ukraine, Pakistan and Vietnam.

NOTES ON SOURCES

IMS Market Prognosis™ is a comprehensive, strategic market forecasting publication that provides insight to decision makers about the economic and political issues which can affect spending on healthcare globally. It uses econometric modeling from the Economist Intelligence Unit to deliver in-depth analysis at a global, regional and country level about therapy class dynamics, distribution channel changes and brand vs generic product spending.

IMS MIDAS™ is a unique data platform for assessing worldwide healthcare markets. It integrates IMS national audits into a globally consistent view of the pharmaceutical market, tracking virtually every product in hundreds of therapeutic classes and providing estimated product volumes, trends and market share through retail and non-retail channels. MIDAS data is updated monthly and retains 12 years of history.

IMS LifeCycle™R&D Focus™ is a global database for evaluating the market for medicines, covering more than 31,000 drugs in R&D and over 8,900 drugs in active development worldwide. It includes information about the commercial, scientific and clinical features of the products, analyst predications of future performance, and reference information on their regulatory stage globally.

IMS LifeCycle™ New Product Focus™ is a comprehensive worldwide tracking service of historical product launches since 1982. It includes information about product launches in each country, including the indication and price at the time of the initial launch, and covers more than 300,000 launches.

IMS PharmaQuery™ is an online research tool designed to unravel the complexities of pricing and reimbursement in 31 key world markets. It provides detailed information on the rules and regulations, theories and practices, trends and developments, in pricing and reimbursement in both developed and emerging markets.

IMS Therapy Forecaster[™] includes sales and volume forecasts for major therapy areas in 10 key markets, and includes interactive modeling and event-based forecasts and comprehensive market summaries.

Global country rankings

RANK		2006	INDEX
1		United States	100
2		Japan	35
3	1	France	13
4	1	Germany	13
5	4	China	9
6	V	Italy	8
7	1	Spain	6
8	2	UK	6
9	2	Canada	6
10		Brazil	5
11		Australia	3
12		Mexico	3
13		South Korea	3
14		Russia	3
15	1	India	2
16	8	Turkey	2
17	2	Netherlands	2
18	2	Belgium	2
19	1	Greece	2
20	2	Poland	2

	Change	in	ranking	over	prior	5 v	ears
V	change			0 1 01	P. 101	- 9	cuis

Source: IMS Market Prognosis, May 2012

RANK		2011	INDEX
1		United States	100
2		Japan	36
3	2	China	21
4		Germany	14
5	2	France	12
6	4	Brazil	9
7	1	Italy	9
8	1	Spain	7
9		Canada	7
10	2	UK	7
11	3	Russia	5
12	1	Australia	4
13	2	India	4
14	1	South Korea	4
15	3	Mexico	3
16		Turkey	3
17	3	Poland	2
18	<u> </u>	Venezuela	2
19	2	Netherlands	2
20	2	Belgium	2

RANK		2016	INDEX
1		United States	100
2	Λ	China	39
3	1	Japan	36
4	2	Brazil	15
5	1	Germany	13
6	1	France	11
7		Italy	8
8	5	India	7
9	2	Russia	7
10	1	Canada	6
11	1	UK	6
12	4	Spain	5
13	1	Australia	4
14	8	Argentina	4
15	1	South Korea	4
16	V	Mexico	3
17	1	Venezuela	3
18	2	Turkey	3
19	8	Indonesia	2
20	3	Poland	2

Appendix notes

Ranking in all years based on spending in constant US\$ at Q4 2011 exchange rates.

Index in each year based on ratio of country spending to U.S. spending (in constant US\$) in the year.

Region & leading country spending

US\$ BILLIONS	2011	2007-2011 CAGR	2016	2012-2016 CAGR
Global	955.5	6.1	1,175-1,205	3-6%
Developed	626.9	3.7	660-690	1-4%
U.S.	322.0	3.4	350-380	1-4%
EU5	159.1	3.8	135-165	(-1)-2%
France	41.3	2.3	32-42	(-2)-1%
Germany	45.0	4.8	39-49	0-3%
Italy	28.6	4.1	23-33	0-3%
Spain	22.7	4.4	13-23	(-4)-(-1)%
UK	21.5	3.9	18-28	0-3%
Japan	111.2	3.9	105-135	1-4%
Canada	22.4	4.4	19-29	0-3%
South Korea	12.2	9.4	10-20	2-5%
Pharmerging	193.6	16.3	345-375	12-15%
China	66.7	23.5	155-165	15-18%
Tier 2	59.9	15.6	100-110	12-15%
Brazil	29.9	15.6	42-52	12-15%
Russia	15.7	15.7	23-33	10-13%
India	14.3	15.4	24-34	14-17%
Tier 3	67.0	11.2	90-100	7-10%
Rest of World	134.9	6.8	140-170	2-5%

Source: IMS Market Prognosis, May 2012

Appendix notes

Spending in US\$ with variable exchange rates.

Growth in US\$ with constant exchange rate.

Compound Annual Growth Rate (CAGR) expressed in US\$ with constant exchange rates.

Tier 3 Pharmerging in descending order: Mexico, Turkey, Poland, Venezuela, Argentina, Indonesia, South Africa, Thailand, Romania, Egypt, Ukraine, Pakistan and Vietnam.

Major protection expiries by country and year

PROTECTION EXPIRY YEAR	U	S	JAPAN	UK	FRANCE	GERMANY
2012	Plavix® Seroquel® Singulair® Actos® Lexapro®	Diovan® Diovan HCT® Geodon® Boniva®	Nu Lotan Myslee® Preminent Haigou Seroquel®	Lipitor® Amias Seroquel® Aricept® Singulair®	Tahor Singulair® Pariet® Ixprim Aprovel	Seroquel® Atacand® Atacand® Plus Sortis® Aricept®
2013	Oxycontin® Aciphex® Zometa®	Xeloda [®] Opana [®] ER Asacol [®]	Diovan® Plavix® Livalo® Elplat®	Viagra® Xeloda®	Seretide® Coaprovel Xeloda® Micardis® Viagra®	Viani® Zometa® Atmadisc® Coaprovel Viagra®
2014	Nexium® Cymbalta® Celebrex® Symbicort®	Lunesta® Restasis® Evista® Sandostatin® LAR Actonel®	Prograf® Glivec® Abilify®	Abilify® Cipralex® Risperdal® Consta®	Seroplex® Abilify® Ebixa® Risperdal® Consta® LP	Axura Risperdal® Consta® Blopress Plus®
2015	Abilify® Copaxone® Gleevec® Namenda®	Provigil® Combivent® Zyvox® Prezista® Avodart®	Zyprexa® Adoair® Alimta® Spiriva® Symbicort®	Spiriva® Cymbalta® Alimta®	Alimta® Spiriva® Copaxone® Protelos® Cymbalta®	Spiriva® Copaxone® Alimta® Cymbalta®
2016	Crestor® Benicar® Benicar HCT® Cubicin®		Blopress Baraclude®	Glivec® Vfend®	Glivec® Cancidas® Vfend®	Glivec® Zyvoxid Vfend®

Appendix notes

Source: IMS MIDAS, May 2012 Largest products (U.S.:>=\$500Mn, Others: Top 2-5) with protection expiries in the 2012-2016 period, listed in descending order by country sales in constant US\$ at Q4 2011 exchange rates. Estimates of protection expiry from information available as of March 31, 2012.



About the Institute

The IMS Institute for Healthcare Informatics leverages collaborative relationships in the public and private sectors to strengthen the vital role of information in advancing healthcare globally. Its mission is to provide key policy setters and decision makers in the global health sector with unique and transformational insights into healthcare dynamics derived from granular analysis of information.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved patient care.

With access to IMS's extensive global data assets and analytics, the Institute works in tandem with a broad set of healthcare stakeholders, including government agencies, academic institutions, the life sciences industry and payers, to drive a research agenda dedicated to addressing today's healthcare challenges.

By collaborating on research of common interest, it builds on a long-standing and extensive tradition of using IMS information and expertise to support the advancement of evidence-based healthcare around the world.

RESEARCH AGENDA

The research agenda for the Institute centers on five areas considered vital to the advancement of healthcare globally:

Demonstrating the effective **use of information** by healthcare stakeholders
globally to improve health outcomes, reduce
costs and increase access to available treatments.

Optimizing the **performance of medical care** through better understanding of disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.

Understanding the future **global role for biopharmaceuticals**, the dynamics that shape
the market and implications for manufacturers,
public and private payers, providers, patients,
pharmacists and distributors.

Researching the role of innovation in health system products, processes and delivery systems, and the business and policy systems that drive innovation.

Informing and advancing the healthcare agendas in **developing nations** through information and analysis.

GUIDING PRINCIPLES

The Institute operates from a set of Guiding Principles:

The advancement of healthcare globally is a vital, continuous process.

Timely, high-quality and relevant information is critical to sound healthcare decision making.

Insights gained from information and analysis should be made widely available to healthcare stakeholders.

Effective use of information is often complex, requiring unique knowledge and expertise.

The ongoing innovation and reform in all aspects of healthcare require a dynamic approach to understanding the entire healthcare system.

Personal health information is confidential and patient privacy must be protected.

The private sector has a valuable role to play in collaborating with the public sector related to the use of healthcare data.



IMS Institute for Healthcare Informatics

11 Waterview Boulevard Parsippany, NJ 07054 USA info@theimsinstitute.org www.theimsinstitute.org



IMS Health is a leading provider of information, services and technology for the healthcare industry around the world. With a presence in 100+ countries and more than 55 years of industry experience, IMS helps stakeholders across healthcare - providers, payers, governments, pharmaceutical manufacturers, researchers and others - access the right insights, make smarter decisions and operate more efficiently. For more information go to www.imshealth.com. The IMS Institute for Healthcare Informatics is a research-driven entity of IMS that works with healthcare stakeholders across academia and in the public and private sectors to advance healthcare globally.