IMS INSTITUTE FOR HEALTHCARE INFORMATICS

November 2015

Global Medicines Use in 2020

Outlook and Implications

Introduction

The unprecedented expansion of access to healthcare globally over the past ten years – ranging from hundreds of millions of people in low- and middle-income countries getting access via government programs and/or rising incomes to the reduction in the uninsured populations in the United States – has prompted a shift in the focus of this year's report to the volumes and types of medicines consumed around the world, and how volumes and costs are interrelated.

In this report, we provide an outlook on the use of medicines and spending levels through 2020. We take a global view of the markets for all types of pharmaceuticals, including small and large molecules, brands and generics, those dispensed in retail pharmaceutics as well as those used in hospital or clinic settings. We measure the use of medicines in doses, which while limited when comparing dissimilar forms, provides a useful view of relative volumes between countries and a counterpoint to measuring spending alone.

Over the next five years, we expect to see a surge of innovation emerging from the research and development pipeline, as well as a range of technology-enabled transformations that will expand the evidence-basis for interventions and bring measurable improvements to health outcomes by 2020. With unprecedented treatment options, the greatest availability of low-cost drugs, and better use of evidence to inform decision-making about the optimal use of medicines, stakeholders around the world can expect to get more "bang for their medicine buck" in 2020 than ever before.

This study was produced independently by the IMS Institute for Healthcare Informatics as a public service and without industry or government funding. The contributions to this report of Kim Pennente, Jennifer Lyle, Bernie Gardocki, the IMS Health forecasting team and many others at IMS Health are gratefully acknowledged.

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Executive summary

The volume of medicines used globally will reach 4.5 trillion doses by 2020 and cost $1.4 trillion, both representing significant increases from 2015. The largest pharmaceutical-using countries will be the pharmerging markets, with two-thirds of the global medicine volumes, mostly comprised of generic medicines and dramatic increases in the utilization of medicines due to broad-based health system expansions. Developed markets will continue to account for the majority of medicine spending due to both higher prices per unit and the mix of newer medicines that bring meaningful clinical benefit to patients facing a wide range of diseases.

Medicine use in 2020

In 2020, more of the world's population will have access to medicine than ever before, albeit with substantial disparities. Patients will receive 4.5 trillion doses, up 24% from 2015, with most of the increase from countries closing the gap in per capita usage of medicines between developed and pharmerging countries. Over 50% of the world's population will consume more than 1 dose per person per day of medicines, up from one third of the world in 2005, driven by India, China, Brazil and Indonesia. Developed markets will continue to use more original branded and specialty medicines per capita while pharmerging markets will use more non-original brands, generics and over the counter medicines. The use of new medicines – first available in the prior 10 years – will represent 0.1% of volumes in pharmerging markets, compared to 2-3% in developed markets.

Medicine spending in 2020

Global spending on medicines will reach $1.4 trillion by 2020, an increase of 29-32% from 2015 compared to an increase of 35% in the prior 5 years. Spending will be concentrated in developed markets, with more than half for original brands and focused on non-communicable diseases. Specialty therapies will continue to be more significant in developed markets than in pharmerging markets and different traditional medicines will be used in developed markets compared to pharmerging markets. Spending growth will be driven by brands in developed markets and increased usage in pharmerging markets, while being offset by patent expiries. Brand spending in developed markets will increase by $298 billion in the 5 years to 2020 driven by new products and price increases primarily in the U.S., but will be offset by an estimated $90 billion in net price reductions. Small molecule patent expiries will have a larger impact in 2016-2020 than in the prior five years, and there will be an increased impact from biologics. In 2020, the U.S., EU5, and Japan will have important differences in spending and growth dynamics from today. Pharmerging markets' spending will grow primarily from increased use of medicines while China, the leading pharmerging country, will reach $160-190 billion in spending with slowing growth to 2020.

Transformations in disease treatment

The overwhelming inertia in medicine use - where 97% of medicines used have been available for more than 10 years - masks the contribution from transformative disease treatments, orphan drugs for rare diseases and technology-enabled changes in care that can harness big data to better inform decisions, help drive patient behavior changes and improve outcomes. The seemingly intractable problems of neglected tropical diseases, compounded by poverty and war in Africa, appear to finally be responding to philanthropy-funded research and engagement resulting in fundamental changes by 2020.

The use of medicines in 2020 will include 943 New Active Substances introduced in the prior 25 years, and new medicines in recent years will be weighted to specialty and biologics. Patients will have greater access to breakthrough therapies and clusters of innovation around hepatitis C, a range of cancers, autoimmune diseases, heart disease, and an array of other rare diseases. The ubiquity of smartphones, tablets, apps and related wearable devices combined with electronic medical records and exponentially increasing real-world data volumes will open new avenues to connect healthcare information while offering providers and payers new mechanisms to control costs.

Implications

The continued expansion of healthcare access around the world portends a fundamental gap in delivery capacity where added patient access outruns staffing, infrastructure and funding sources. By 2020 we will see a substantial shift in many major markets away from the siloed budgeting that manages drug spending separately from other healthcare costs. Emerging economies will be focused on providing access and essential medicines to those in need to close endemic healthcare gaps.

Providers in more parts of the world will be subject to performance or outcomes-based contracts and payment systems, bringing sharper scrutiny to patient outcomes and costs associated with patient care. More healthcare will be delivered using technology-enabled means, by providers other than doctors and in patients' homes, pharmacies and community-based facilities. The use of technology will be key to the advancement of healthcare, especially in emerging markets where the expense of large scale infrastructure projects would delay progress.

Patients will have many more treatment options, especially in cancer and rare diseases, and will be informed, motivated and engaged partners in treatment choices. Their financial stake will also rise as private and public payers in developed economies have already begun to increase patients' levels of copayment. In low- and middle-income countries direct out-of-pocket cash payments will shift to premiums for private or supplementary insurance as countries strive for universal health coverage.

The outlook to 2020 includes higher levels of medicine spending and therefore higher revenues for manufacturers than in the last five years. The extent and nature of the issues faced by healthcare stakeholders and the sources of the spending growth projected in this report belie a more complex challenge to the sustainability of the pharmaceutical industry. Critical adaptations will be necessary to thrive into the next decade, and key among them will be listening and providing valuable solutions to the problems their customers face.

Medicine use in 2020

Access to medicines increases by 2020 but significant differences exist by country

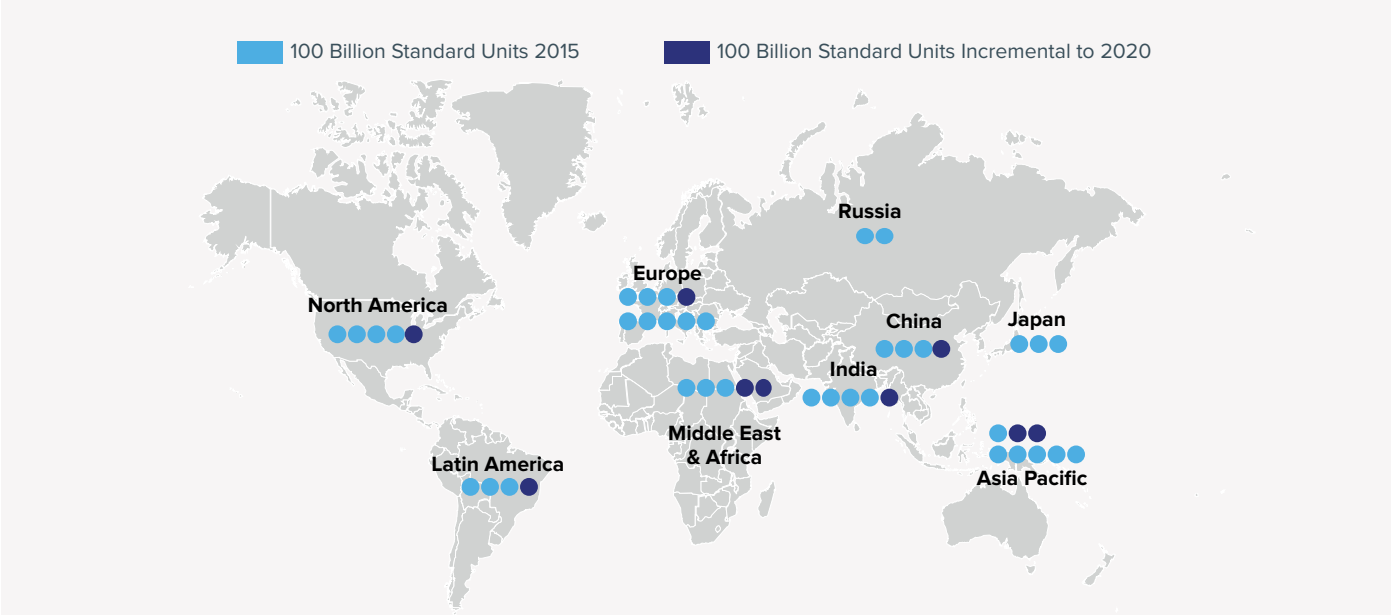
- Global medicine use in 2020 will reach 4.5 trillion doses, up 24% from 2015
- Over 50% of the world's population will consume more than 1 dose per person per day of medicines, up from one third of the world in 2005, driven by India, China, Brazil and Indonesia
- Closing the gap in per capita use of medicines differs by country; increased usage is primarily in emerging markets, while developed markets volumes remain more stable
- Developed markets will continue to use more original branded and specialty medicines per capita while pharmerging markets use more non-original brands, generics and over the counter medicines
- In 2020 the use of new medicines, introduced in the prior 10 years, will represent 0.1% of volumes in pharmerging markets, compared to 2-3% in developed markets

Medicines in 2020 will include a vast array of treatments ranging from those that provide symptom relief available without a prescription to lifesaving genetically personalized therapies unique to a single patient. Total use of medicines in 2020 will reach 4.5 trillion doses, up 24% from 2015 levels. Over half of the world's population will consume more than 1 dose per person per day of medicines, up from one-third in 2005 and driven by India, China, Brazil and Indonesia. Success in closing the gap in per capita use of medicines differs by country; increased usage is primarily in emerging markets, while developed markets' volumes remain more stable. Developed markets will continue to use more original branded and specialty medicines per capita while pharmerging markets will use more non-original brands, generics and over the counter products. Furthermore, the adoption of newer medicines will remain higher in developed markets than in pharmerging markets.

Medicine Use Comparisons

Most of the global increase in the volumes of medicines used in the 5 years to 2020 will be in India, China, Brazil, Indonesia, and Africa (see Exhibit 1). The largest increases align to areas with the most development gains and often in areas with the lowest usage previously.

Exhibit 1: Doses Consumed by Country in 2020



Source: IMS Health, Market Prognosis, September 2015; IMS Institute for Healthcare Informatics, October 2015
Note: Standard Units are a measure of doses (see Definitions & Methodologies section). Regions and countries shown are mutually exclusive. Standard Unit values are rounded to the nearest whole 100 Billion and are intended to identify the relative scale and largest areas of growth.

Usage of medicines in Africa and Middle-Eastern countries will increase from 300 to 500 billion standard units in 2020. Within the region, Saudi Arabia and other gulf states will substantially close the gap to developed markets' per capita usage of medicines, while millions of people in sub-Saharan Africa will make modest gains from some of the lowest levels of volume usage in the world.

China and India will have each completed ten years of healthcare access expansion by 2020, with nearly all of the Chinese population having basic medical insurance. Most of the rest of the Asia-Pacific increased usage will come from Indonesia.

Methodology Note: *This analysis of medicine use is based on standard units, which is defined as a dose of a particular medicine. Since medicines may be dosed very differently and are delivered in different forms, simply counting doses is an imperfect measure of usage of medicines e.g. injections which are intended to be given weekly or less often count the same as a pill which is intended to be taken four times a day. In this study, we do not use this measure as a view of the clinical value of the volumes used, as it would understate the importance of less frequently dosed medicines. The level of differences in usage between countries does however clearly show a gap between the developed and the developing world. This conclusion is supported by a range of other health metrics such as life expectancy and causes of mortality. While purely increasing volume will not be the only action necessary to improve global health, it is clear that it is an important – albeit imperfect – indicator of progress in advancing healthcare. See Definitions & Methodologies for more detail on methodologies used throughout this report.*

In 2020, Europe's 889 million people will have only modest increases in usage rising from about 818 billion to 916 billion doses, mostly occurring in central and eastern European countries such as Poland, which will approach developed market average usage.

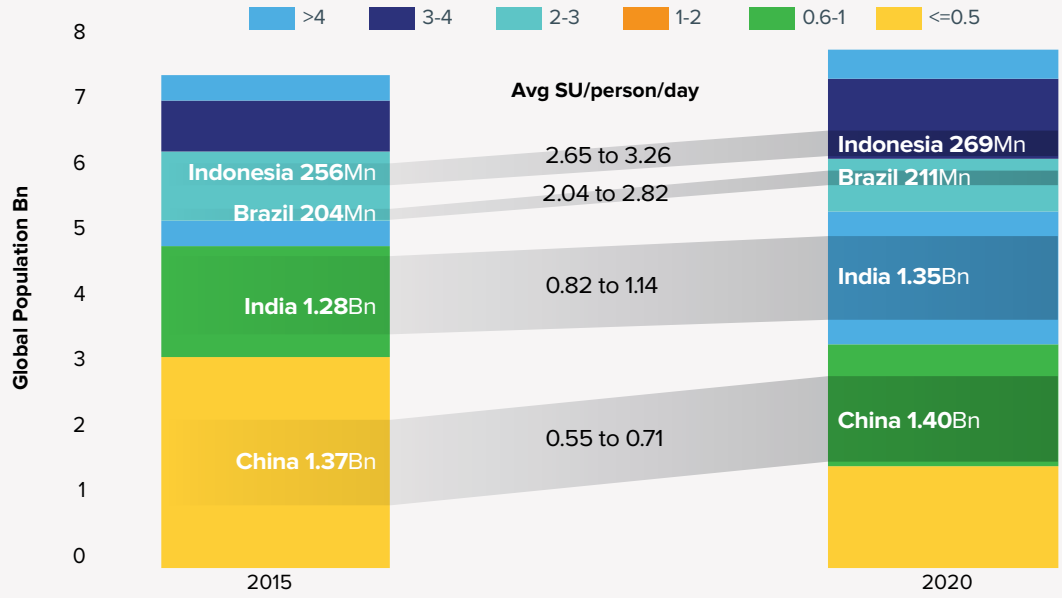
Asia Pacific, with 1.3 billion people (excluding China, India and Japan) will increase usage substantially, with half of the increase from Indonesia's shift to 3.26 standard units (SUs) per person per day in 2020.

The Middle East and Africa region with 1.6 billion people and 2.5 times the population of Latin America (657 million) will have only 20% more usage overall.

Rising per capita use in pharmerging markets

As the world's population tops 7.6 billion in 2020, per capita usage of medicine will reach about 1.6 SUs per person per day. Most developed countries have usage above 2 SUs per person per day and much of the increased usage in 2020 is driven by China, India, Brazil and Indonesia where substantial increases will have been made in average medicine volume usage (see Exhibit 2).

Exhibit 2: Country Population by National Average Standard Units per Person per Day



Source: IMS Health, Market Prognosis, September 2015; IMS Institute for Healthcare Informatics, October 2015
Note: Population estimates by country were assigned to bands of standard units per capita per day. The measure of usage per person per day is based on total volumes in a country and population and does not reflect uniformity of usage within a country or actual observed patient usage.

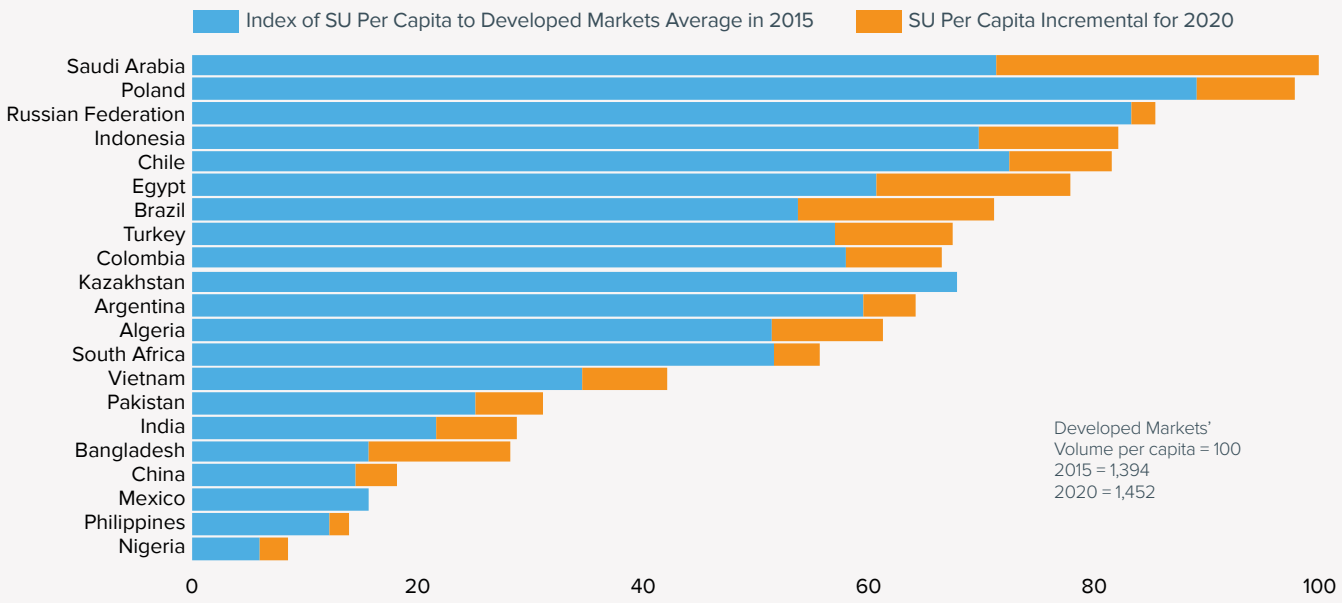
These four countries with a combined population of 3.23 billion in 2020 – up from 3.11 billion in 2015 – will account for nearly half of the increased volume in medicine usage globally from 2015–2020.

India's level of medicine usage is a reflection of both a very basic healthcare infrastructure and the ease of access for medicines where even the most complex medicines can be obtained at a corner pharmacy if the patient can afford them.

China's increased usage belies a more complex system where nearly all citizens will be covered by health insurance but access to medicines will usually require a hospital visit and out-of-pocket costs, discouraging some patients from seeking and adhering to treatment.

The gap in average medicine usage between developed markets and pharmerging markets is closing, albeit slowly (see Exhibit 3). The use of medicines requires both the healthcare infrastructure to diagnose diseases and administer drugs appropriately, as well as the financial wherewithal to pay for them. While costs are often substantially lower for medicines in pharmerging markets, so is the ability to pay. The rise of government safety nets and private insurance is one key factor that will increase volume usage across pharmerging markets. The extent and pace of investments, both public and private, will be a key determinant of continued increases in usage.

Exhibit 3: Pharmerging Market Standard Units per Capita 2015 and 2020



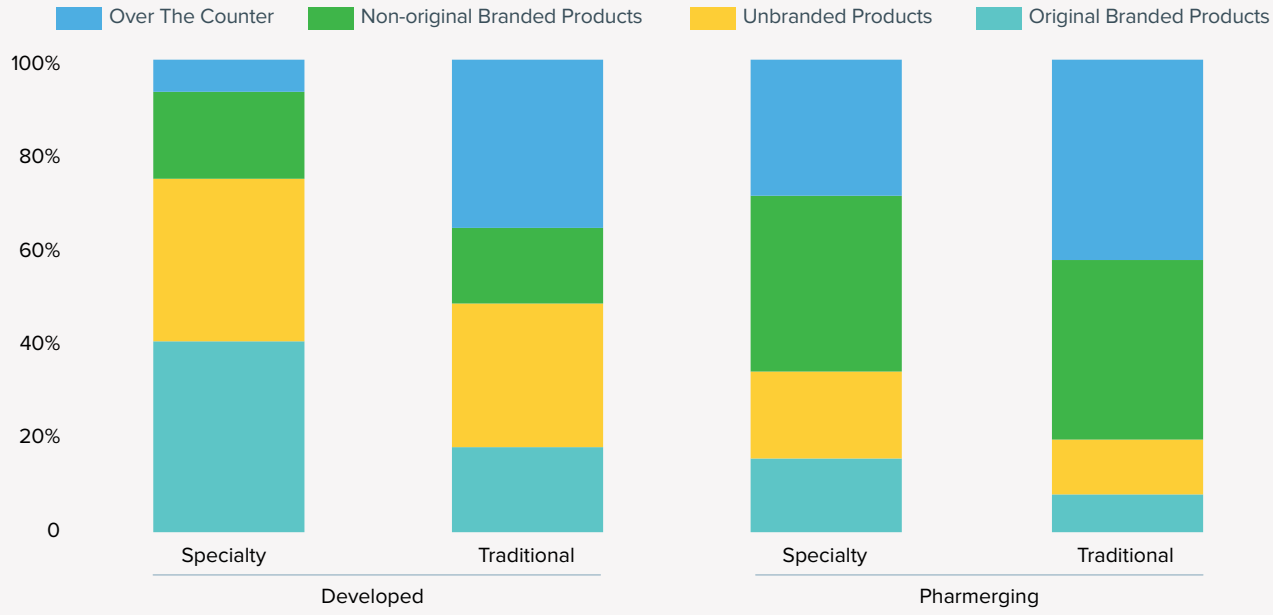
Source: IMS Health, Market Prognosis, September 2015: IMS Institute for Healthcare Informatics, October 2015
Note: Developed markets are known for more modern healthcare systems and wider adoption of newer therapies whose clinical importance is often understated in Standard Units. Pharmerging markets are known for historically less well resourced health systems and often use oral and older medicines to a greater extent. The index may overstate the gains being made by Pharmerging markets relative to more clinical or health outcomes based measures.

Saudi Arabia's commitment to wider healthcare access brings it to roughly the same level of usage as the average developed market by 2020, and represents the largest increase among the pharmerging countries. Other countries that will see a closing of the usage gap in 2020 by ten percentage points or more include Brazil, Egypt, Bangladesh, Indonesia, Turkey, Colombia and Algeria.

Analysis by types of medicines

The types of medicines used varies substantially between developed and pharmerging countries (see Exhibit 4). The largest volume of medicines will be generics and non-original branded products, primarily in pharmerging markets, often at lower costs than original brands and contributing significantly to increased access to medicines in these countries. The wider use of original branded medicines in developed markets reflects both earlier adoption of these medicines and historic differences in the application of intellectual property laws. By 2020, 18% of traditional product volumes in developed markets will be for original brands, compared to 8% in pharmerging markets. In general, specialty medicines are much more rarely used, but are used proportionately more in developed markets. Developed markets are also more likely to use original branded specialty products capturing 40% of specialty volumes in developed markets compared to 15% in pharmerging markets.

Exhibit 4: Standard Units in 2020 by Product Type in Major Developed and Pharmerging Countries

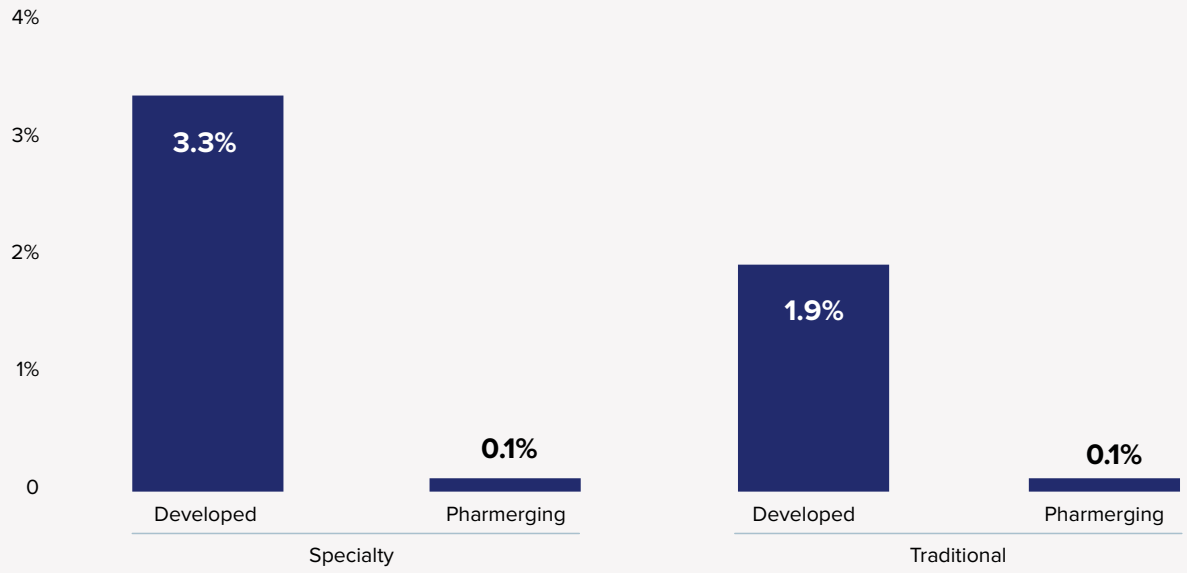


Source: IMS Health, Market Prognosis, September 2015; MS Institute for Healthcare Informatics, October 2015
Note: Specialty medicines are products that treat chronic, rare or genetic diseases (see Definitions & Methodologies section).

Pharmerging countries will continue to be much more likely to use non-original branded products or over the counter medicines than brands or unbranded products.

Newer medicines often take decades to be widely used, even in developed markets. By 2020, the vast majority of traditional medicines consumed will have been available for more than 10 years, and only 1.9% of volumes in developed markets will be for recently launched medicines, compared to 0.1% in pharmerging countries. Specialty medicines are adopted more quickly in developed markets and 3.3% of specialty volumes will be less than ten years old in 2020, compared to only 0.1% in pharmerging markets (see Exhibit 5).

Exhibit 5: Volume Usage in 2020 of Medicines Available Since 2010 by Product Type



Source: IMS Health, Market Prognosis, September 2015; IMS Institute for Healthcare Informatics, October 2015
Note: Shares shown are based on standard units and represent an estimate of medicines launched for the first time globally 2011-2020 and their share of all available medicines. Traditional medicines for all forms are shown and specialty medicine projections are based on injectable-only.

As many as a third of the newest medicines are specialty medicines with very low volumes of patients and pharmerging countries are much slower to adopt them. This reflects the healthcare infrastructure requirements (hospitals, infusion centers, and medical practices capable of managing complex diseases) which are often absent or less common in pharmerging countries. The differences in disease prevalence for recent specialty innovations could mean that fewer people in pharmerging countries are suffering from diseases treated by these newer medicines, but the gap in volume usage is too large to suggest that disease prevalence alone accounts for the difference.

Global spending on medicines in 2020

Global spending on medicines will reach $1.4 trillion by 2020, an increase of 29-32% from 2015 compared to an increase of 35% in the prior 5 years

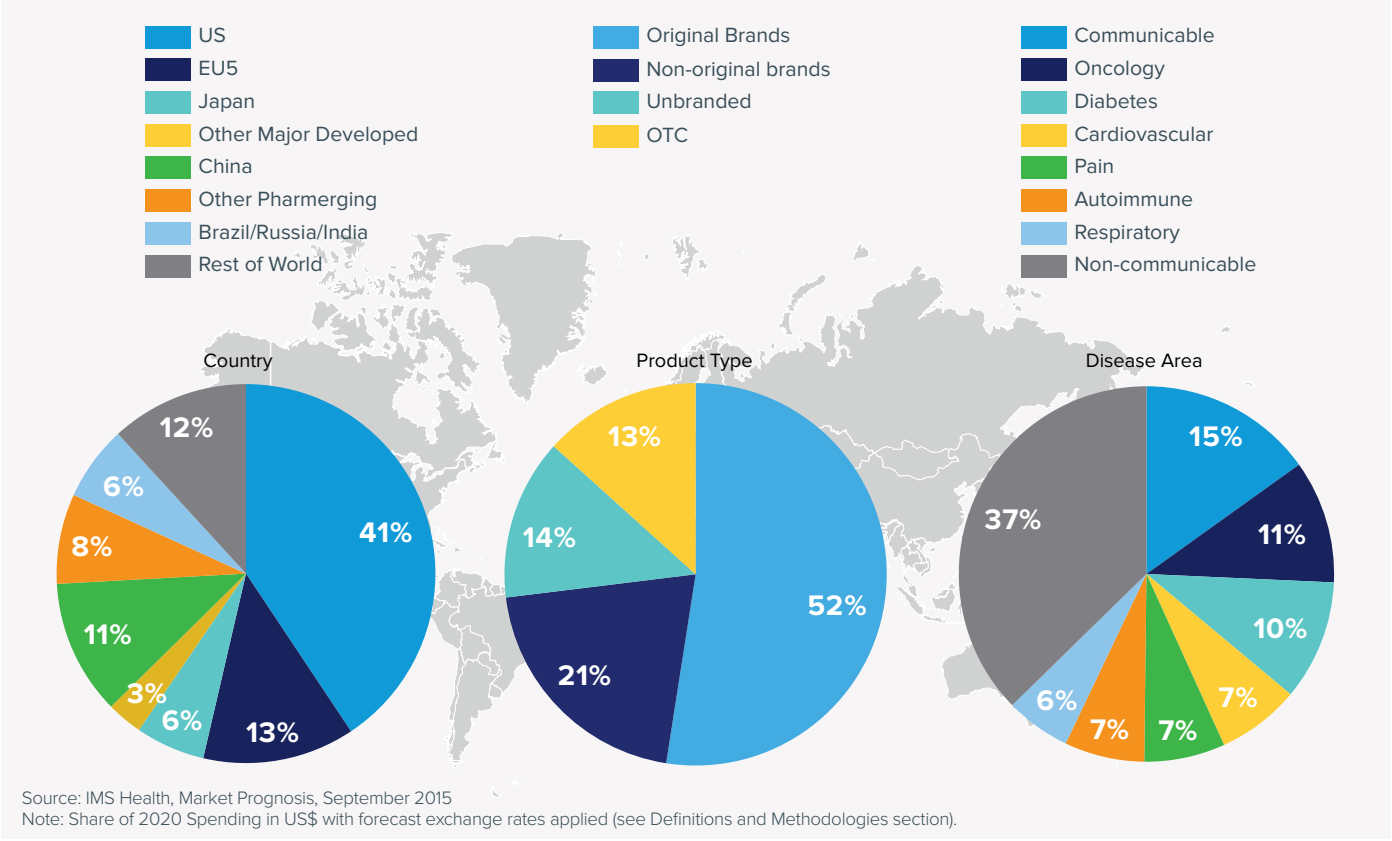
- Spending on medicines in 2020 will remain concentrated to developed markets with more than half for original brands and focused on non-communicable diseases
- Specialty therapies will continue to be more significant in developed markets than in pharmerging markets and different medicines will be used in developed markets compared to pharmerging markets
- Traditional therapies will continue to focus on different diseases in developed and pharmerging markets
- Spending will increase by $349 billion over 2015, driven by brands and increased usage in pharmerging markets and offset by patent expiries
- Brand spending in developed markets will increase by $298 billion in the 5 years to 2020 driven by new products, wider usage and price increases, primarily in the U.S., but will be offset by net price reductions
- Small molecule patent expiries will have a larger impact 2016-2020 than in the prior five years, and there will be an increased impact from biologics
- In 2020, the U.S., EU5 and Japan will have important differences in spending and growth from today
- Drug spending per capita will increase substantially for most pharmerging countries, however, China's growth is expected to slow to 2020

Global spending on medicines will reach $1.4 trillion by 2020, an increase of 29–32% from 2015 compared to an increase of 35% in the prior 5 years. Spending on specialty therapies will continue to be more significant in developed markets than in pharmerging markets, and different traditional medicines will continue to be used in developed markets compared to pharmerging markets. Spending growth will be driven by brands, as well as increased usage in pharmerging markets, and will be offset by patent expiries and net price reductions. The patent expiry impact will be larger in 2016–2020 than in the prior five years on an absolute basis and will include $41 billion of impact from biosimilars.

Spending and growth to 2020

Developed markets will contribute 63% of the spending, led by the U.S (see Exhibit 6). Original brands will represent 52% of spending and 85% of global spending will be for medicines to treat non-communicable diseases. These distributions of costs belie the very different perspective on a volume basis where lower-cost/higher-volume medicines dominate the overall use of medicines.

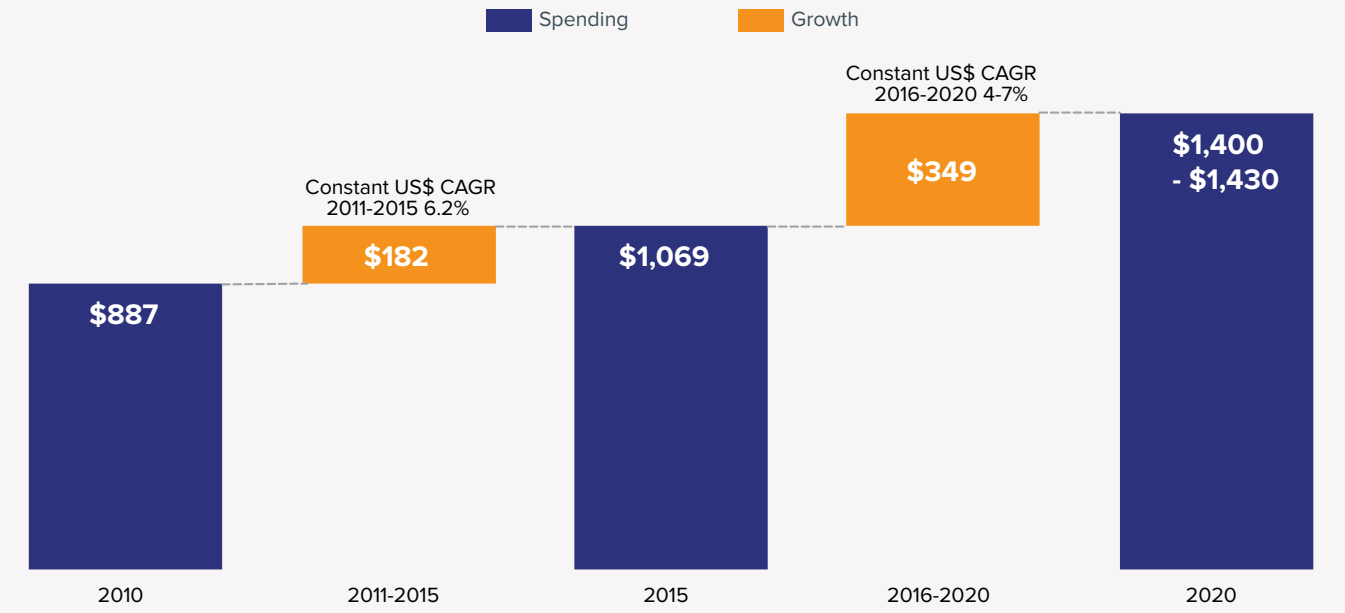
Exhibit 6: Medicine Spending in 2020 US$ by Geography, Product Type and Disease Area



Source: IMS Health, Market Prognosis, September 2015
Note: Share of 2020 Spending in US$ with forecast exchange rates applied (see Definitions and Methodologies section).

Using actual and forecast exchange rates, the absolute global spend for pharmaceuticals will change by $349 billion in the 2016-2020 time period compared to $182 billion in the 2010-2015 period (see Exhibit 7). The last five years had a $100 billion reduction of growth due to currency effects, while the next five years will be lifted by $26 billion by the weakening of the dollar against global currencies.

Exhibit 7: Global Spending and Growth, 2010–2020



Source: IMS Health, Market Prognosis, September 2015
Note: Growth in 2011-2015 was reduced by $100Bn and in 2016-2020 increased by $26Bn due to exchange rate effects.

Methodology Note: *This analysis of medicine spending is based on prices reported in IMS Health audits of pharmaceutical spending, which are in general reported at the invoice prices wholesalers charge to their customers including pharmacies and hospitals. In some countries, these prices are exclusive of discounts and rebates paid to governments, private insurers or the specific purchasers. In other countries, off-invoice discounts are illegal and do not occur. The mix of true prices and opaque pre-discounted prices means the analyses in this report do not reflect the net revenues of pharmaceutical manufacturers. As a part of this report, the IMS Institute has compared IMS audited spending data to reported sales, net of discounts, reported by publicly traded companies and made estimates of future off-invoice discounts and rebates and their impact on the growth of branded medicines (see Exhibit 11).*

The global economic crisis has been a key global issue during the past five years though much of its worst effects have now passed. Some pharmerging countries like China, Brazil, Argentina, and Venezuela have had severe economic and social issues recently which are expected to contribute to slowing growth during the forecast period.

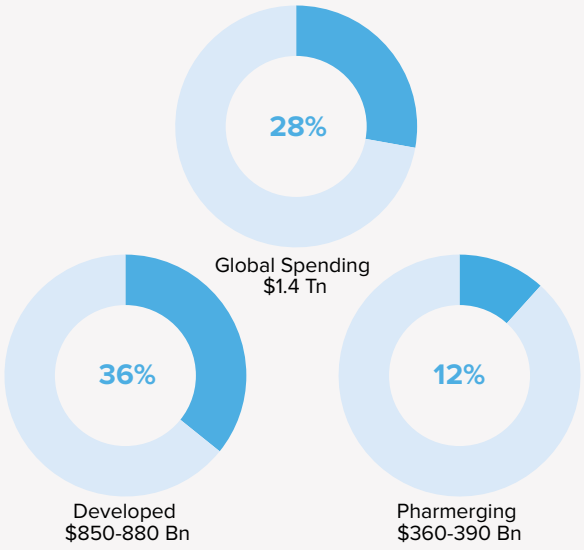
Significant risks of further economic slowdown continue as a result of the ongoing disruption in the Middle East, the weaker Chinese economy, and Latin American countries with severe economic distress and some with hyperinflation.

Medicine spending will increase 31–34% over the next five years (29–32% on a constant dollar basis) compared to a 24% increase in the volumes of medicine used. Volume growth will be driven by demographic trends such as an aging population in developed markets and rising incomes and expanded access to healthcare in pharmerging markets. The remainder of the increase in spending will be driven by the costs of medicines which increase due to the wider adoption of newer more expensive therapies and an increase in prices per unit which occur in some countries, notably the United States.

Specialty and traditional medicines

A rising proportion of medicines are specialty medicines. In 2020, 28% of global spending will be for specialty medicines, up from 26% in 2015. Spending will be more focused on specialty medicines in developed markets accounting for 36% of spending in 2020, compared to only 12% in pharmerging markets (see Definitions & Methodologies section for definition of specialty medicines; see Exhibit 8).

Exhibit 8: Specialty Medicines and Leading Therapy Areas in 2020



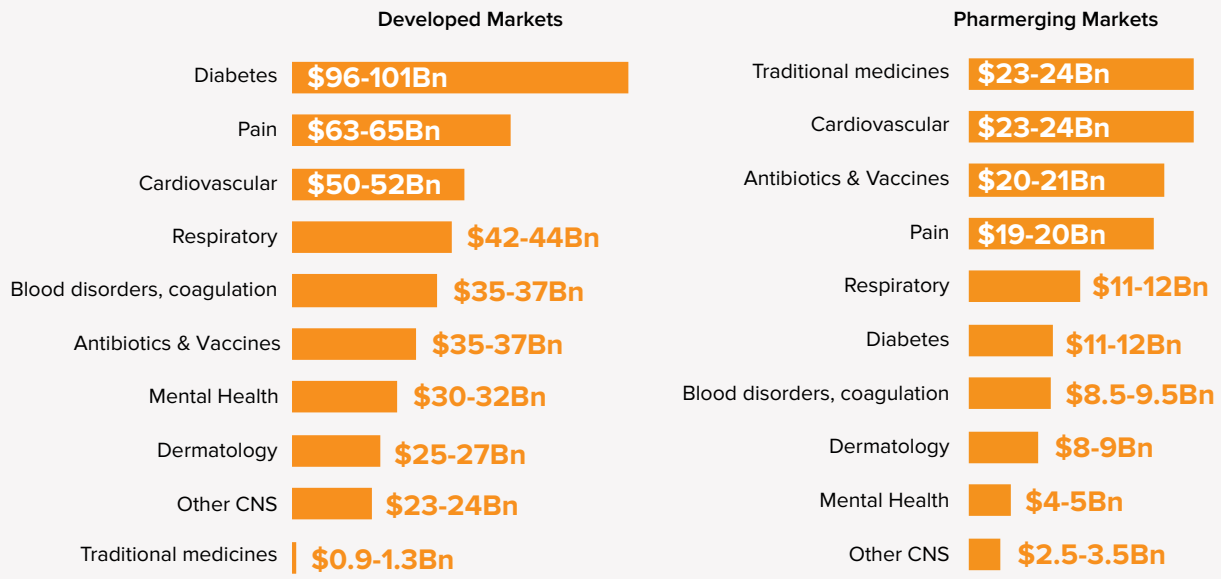
Leading Specialty Therapy Areas	*Sales in 2020	CAGR 2016-2020
Oncology	$100-120Bn	9-12%
Autoimmune	$55-65Bn	11-14%
Viral Hepatitis	$45-55Bn	7-10%
Immunosuppressants	$20-30Bn	11-14%
HIV Antivirals	$20-30Bn	1-4%
Immunostimulants	$15-18Bn	2-5%
Interferons	$7-9Bn	1-4%
Erythropoietins	$7-9Bn	0-3%
Macular Degeneration	$6-8Bn	6-9%

*Sales represented in constant US dollars.
Source: IMS Health, IMS Therapy Prognosis, Sept 2015; IMS Institute for Healthcare Informatics, October 2015
Note: Leading traditional therapy areas shown for 8 developed countries and 6 pharmerging countries (see Definitions & Methodologies section).

Oncology is the leading class of specialty medicines with over $100 billion in spending in major developed and pharmerging markets by 2020. Viral hepatitis, including recently introduced treatments for hepatitis C, will reach about $50 billion in 2020 for major markets. By 2020, a substantial amount of the volume of treatment for hepatitis C is expected outside major markets, as millions of people in other developed and pharmerging countries will receive access to these treatments (see Exhibit 20).

The use of traditional medicines – those that are not specialty – account for the majority of medicine spending globally, but there are very different patterns of usage and spending in developed markets compared to pharmerging markets (see Exhibit 9). In developed markets, some of the major classes of medicines have experienced reduced spending due to patent expiries whereas differences in disease morbidity and the adoption of innovation drive the remainder of differences.

Exhibit 9: Traditional Medicines Spending in 2020, Constant US$BN



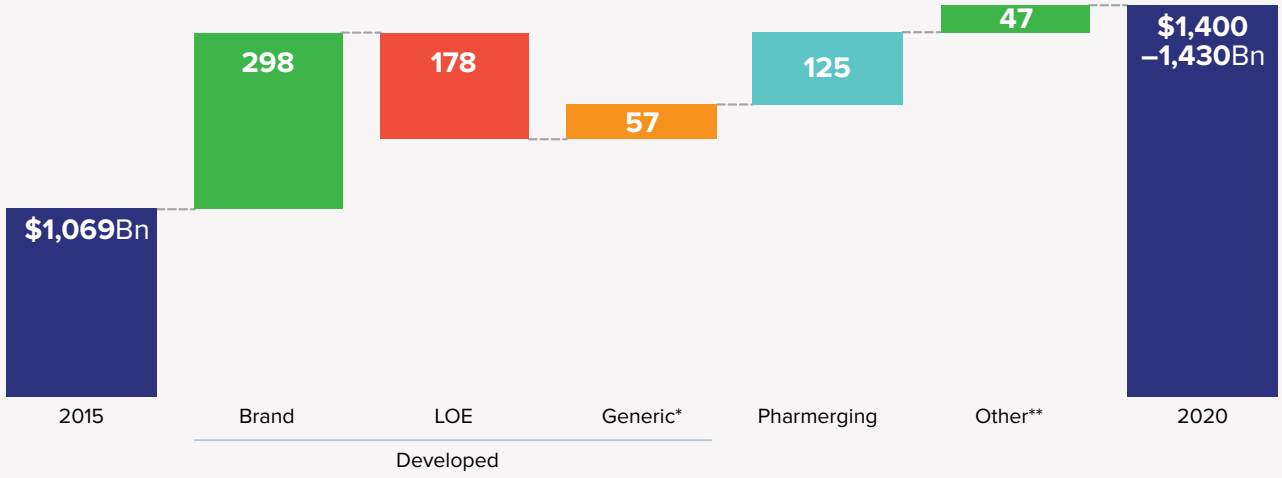
Source: IMS Health, Therapy Prognosis, September 2015; IMS Institute for Healthcare Informatics, October 2015
Note: Traditional therapy areas are defined as all therapies other than Specialty medicines (see Definitions & Methodologies section).

These ten major categories of medicines will account for 75% of 2020 spending in the eight developed markets analyzed while representing only 53% of spending in the six pharmerging markets where proportionately more spend will be for the remaining classes not shown here.

Drivers of growth

The key drivers of the $349 billion in growth over the next five years will be due to access expansion in pharmerging countries, greater use of more expensive branded medicines in developed markets, and greater use of cheaper alternatives when loss of exclusivity occurs (see Exhibit 10).

Exhibit 10: Drivers of Spending Growth 2015–2020 US$Bn



Source: IMS Health, Market Prognosis, September 2015; IMS Institute for Healthcare Informatics, October 2015
Note: Growth is shown in constant US$ with an exchange rate adjustment in the Other category as the aggregate difference between constant and forecast exchange rates. Brands lower spending due to loss of exclusivity (LOE) is shown for developed markets only. Brand spending in 2020 will be $120Bn greater than 2015 including $298Bn of growth and offset by $178Bn of LOE. Spending is shown at list and invoice price levels and does not reflect off-invoice discounts and rebates.
* Generic in developed markets includes Generics +$24Bn, Non-original Brands +$23Bn, OTC +$10Bn. ** Other includes Rest of World +$21Bn and exchange rate effects +$26Bn.

Of the $298 billion of growth to 2020 from brands in developed markets, $135 billion will result from new medicines that will be launched in the next five years with the largest portion of that coming from new oncology medicines (see Exhibit 11).

Exhibit 11: Developed Markets Brand Spending Growth 2016-2020 Constant US$BN

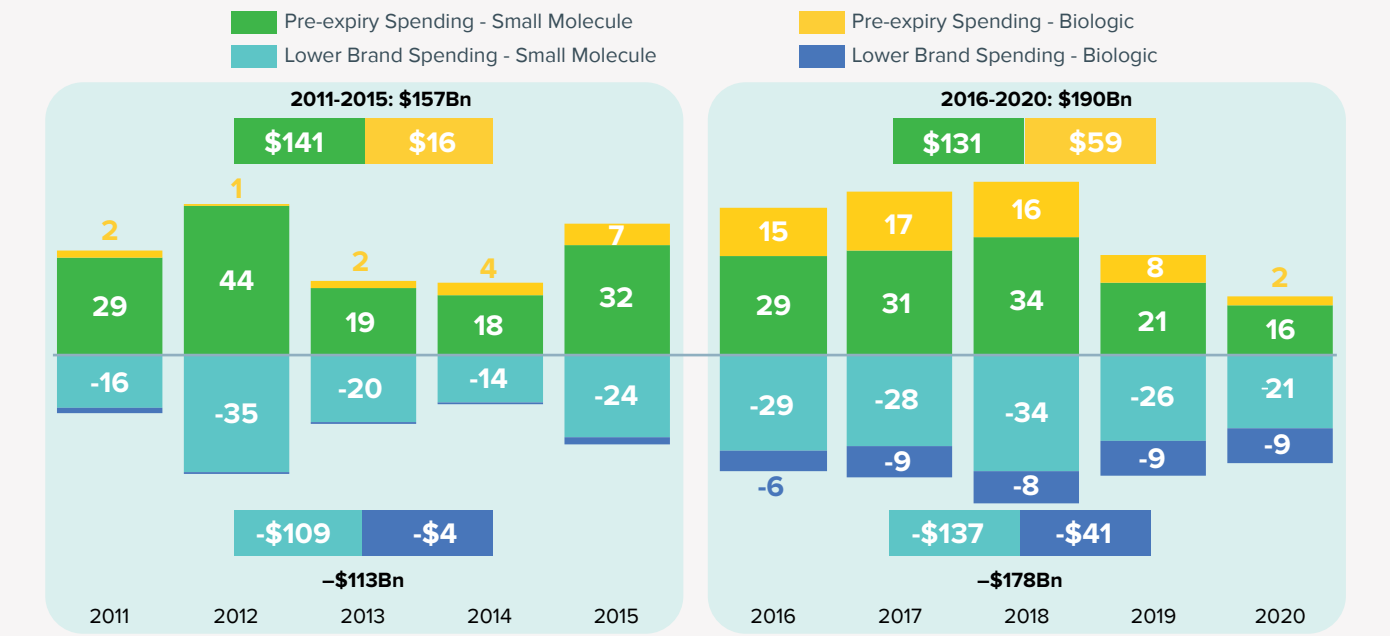
Element	Contribution to spending growth constant US$Bn	Comment
Volume	$48	Volumes of medicines remain largely unchanged on a per capita basis; Mix of newer medicines contribute to higher average costs; Moderate growth/mix effect in EU5 and Japan similar to 2010–15 impact; small positive impact from the US market is expected 2016–20, which had declining volume 2010–15
Price	$115	Primarily from U.S. market and based in invoice price; subject to reduction from rebates and discounts
New	$135	Robust flow of new medicines especially in oncology and with high value/price levels
Forecast Growth	$298	Brand growth before adjusting for patent expires and off-invoice discounts and rebates
Incremental Net Sales Adjustment (NSA)	-$90	Estimated impact on branded medicine growth from increased rebates and discounts, reflecting payer consolidation, heightened competitiveness in many therapy classes and statutory price reduction mechanisms from European payers
Estimated Net Growth	$208	

Source: IMS Health, Market Prognosis, September 2015: IMS Institute for Healthcare Informatics, October 2015

Greater usage of branded medicines will contribute about $48 billion to spending growth, while invoice price increases, primarily in the U.S., will contribute $115 billion. However, the price increases will be offset by off-invoice discounts and rebates. The net brand spending growth is expected to be $90 billion lower, which would decrease the five year growth rate globally by about 1% and reduce the absolute growth in the 5 year period by 25%.

Small molecule patent expiries will have a larger impact 2016-2020 than in the prior five years and there will be an increased impact from biologics (see Exhibit 12). The loss of exclusivity for branded products is expected to reduce brand spending by $178 billion in the next five years, a larger amount than the last five years, despite the often reported cluster of patent expiries in 2011 and 2012. The exposure of brands to loss of exclusivity will be higher, at $190 billion, over the next five years and the impact of those expiries on brand spending will be greater as biosimilars begin to have a larger impact.

Exhibit 12: 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.

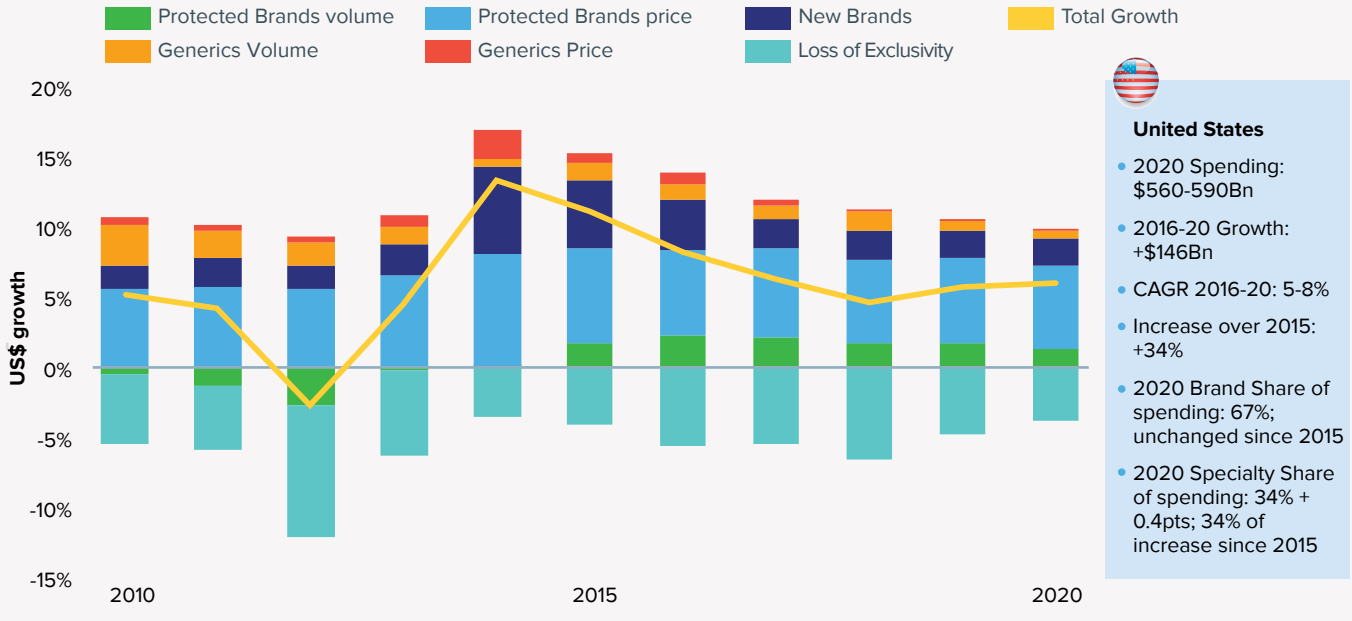
Small molecule patent expiries have historically resulted in rapid switching of medicines to generics, particularly in the U.S., and this trend will have spread across other developed markets by 2020. The resulting impact of generics on brand spending will therefore be more impactful in coming years. The addition of a U.S. biosimilar pathway to those already present in Europe will contribute substantially to the larger impact from biologic patent expiries in the next five years, mainly because the U.S. spends more on biologics than other developed markets and the reductions in costs will be larger. Key biologic patent expiries include a number of autoimmune treatments, insulins, and cancer treatments, however, the specific products and dates are elusive due to the still evolving U.S. biologics patent law situation. The next five years will see nearly every biologic patent and biosimilar launch challenged in the courts. The net result will be a lower level of biosimilar impact than some have reported previously but an important and meaningful amount of "savings" for the health systems in developed markets.

Developed and pharmerging market overviews

U.S. spending on medicines

U.S. spending on medicines will reach $560–590 billion in 2020, a 34% increase in spending over 2015 on an invoice price basis. This growth will be driven by innovation, invoice price increases (offset by off-invoice discounts and rebates) and the impact of loss of exclusivity (see Exhibit 13). Spending growth in the next five years will differ from the last four which included the largest patent expiry cluster ever in 2012 and the largest year for new medicines in 2014. Of the $24 billion in new brand spending for 2014, $12 billion was driven by hepatitis C treatments as 140,000 more patients were treated than in the prior year. This increased volume accounted for about $9 billion of the increased spending with the remainder due to higher treatment cost per patient relative to earlier, less effective and less well tolerated treatments.

Exhibit 13: U.S. Spending Growth, 2010–2020



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

The impact of patent expiries over the next five years, while higher in absolute dollars, will be lower in percentage contribution than the past five years and no single year will reach the level of 2012. Generic medicines will continue to provide the vast majority of the prescription medicine usage in the U.S., rising from 88% to 91-92% of all dispensed prescriptions by 2020.

Invoice price growth – which does not reflect discounts and rebates received by payers - will continue at historic levels through 2020 after a period from 2013 to 2015 where increases were much higher but substantially offset by off-invoice discounts and rebates. Net price trends for protected brands remain constrained by payer negotiated discounts and rebates and net prices are expected to grow at 5-7% per year. Brands, on average, will concede as much as one-third of their invoice prices in discounts to payers over the forecast period.

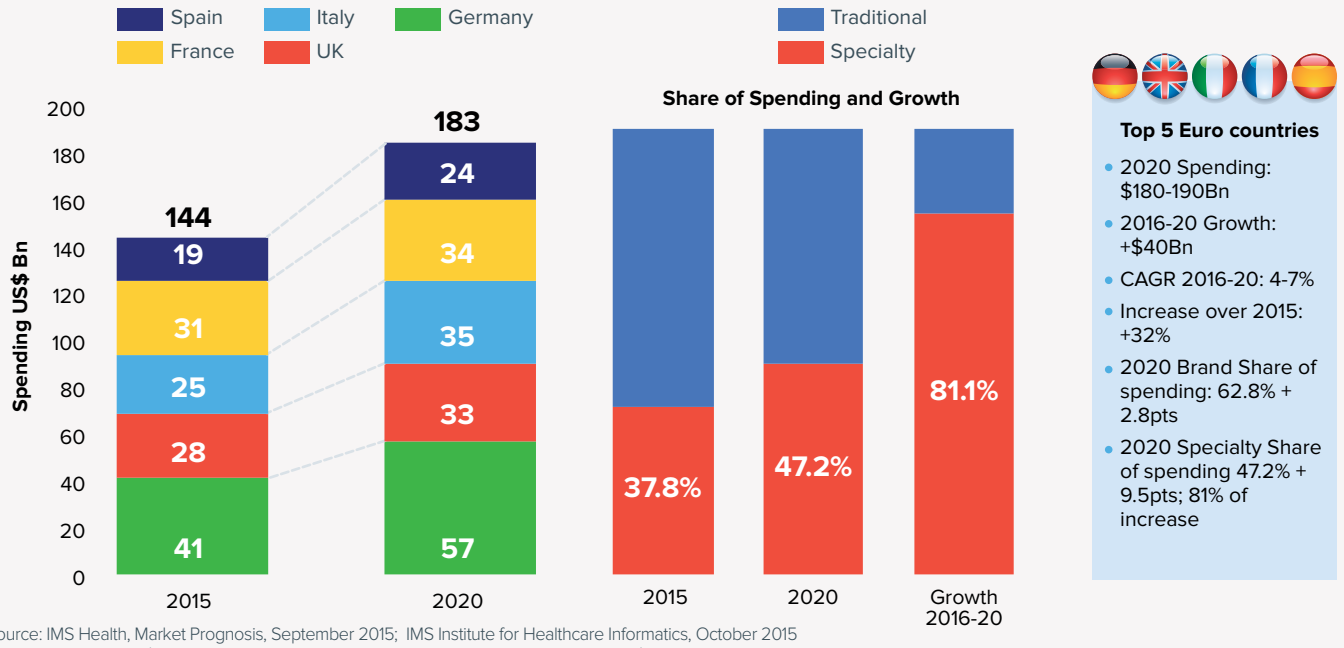
The Affordable Care Act (ACA) will continue to have an effect on medicine spending during the next five years primarily due to expanded insurance coverage. ACA access expansion will be largely complete by 2020, bringing modest new demand for medicines, but an increasing share of medicines will be paid for by Medicare, Medicaid, and other government funded or mandated programs (including 340b) each commanding substantial discounts from list prices. The wider adoption of provisions of the law that encourage greater care coordination will see at least a third of healthcare covered by Accountable Care Organizations (ACOs) under the Medicare shared savings program or ACO-like arrangements negotiated between commercial insurers and institutions. These organizational and payment changes will reinforce the shift to outcomes and evidence-based payments as opposed to the volume of services provided.

By 2020, the Affordable Care Act will be ten years old and moving into adolescence in terms of major implementations, with further evolution and maturing still to come. The impacts of the various provisions of the law are cumulative and in important ways they are the underpinning of the general growth trend in the volume of medicines. Some parts of the ACA will enable conversion to a more rational system based on a better understanding of outcomes and costs. There will be some unintended consequences, that will likely impact patients before they are addressed with future policy amendments, and some of them can be expected to be non-trivial. The rising use of high-deductible insurance plans, for example, which have demonstrable impacts on patients' adherence rates, in some ways put employers and patients who choose these plans at odds with holistically-focused ACOs.

Top 5 Europe spending on medicines

The Top 5 European markets will spend $180-190 billion on medicines in 2020, an increase of $40 billion, which includes $19.4 billion of exchange rate effects and is mostly driven by Germany and the wider adoption of specialty medicines (see Exhibit 14). Germany will increase spending from $41 billion to $57 billion, an increase of $16 billion (including $7.9 billion of exchange rate effects) largely a result of wider adoption of innovation and supported by health technology assessments, including reassessments of already marketed products.

Exhibit 14: Top 5 European Countries Spending US$Bn, 2015 and 2020



Source: IMS Health, Market Prognosis, September 2015; IMS Institute for Healthcare Informatics, October 2015
Note: Spending in US$ with actual and projected exchange rates. Growth in constant US$ based on average rates in Q2 2015 and projections of actual rates.

Other major European countries will face budget challenges and France, alone among developed markets, will see a decline in the volume of medicines used on a per capita basis. The U.K., after a Conservative Party election victory, is reexamining the organization of the National Health Service (NHS) and historic pricing agreements with the pharmaceutical industry. Spain and Italy each continue to find their economies challenged by the global economic crisis and have been slow to recover.

A common lever used by European countries to control medicine spending is to shift medicine usage to generic medicines and realize associated savings. However, much of the potential savings through the use of generics have already been achieved and lower patent expiry rates in the coming five years will limit the impact of this approach through 2020. European governments were the first to adopt biosimilar legislation that enables non-original competition to biotech drugs and by 2020 they will still account for most of the savings in developed markets associated with the adoption of biosimilars.

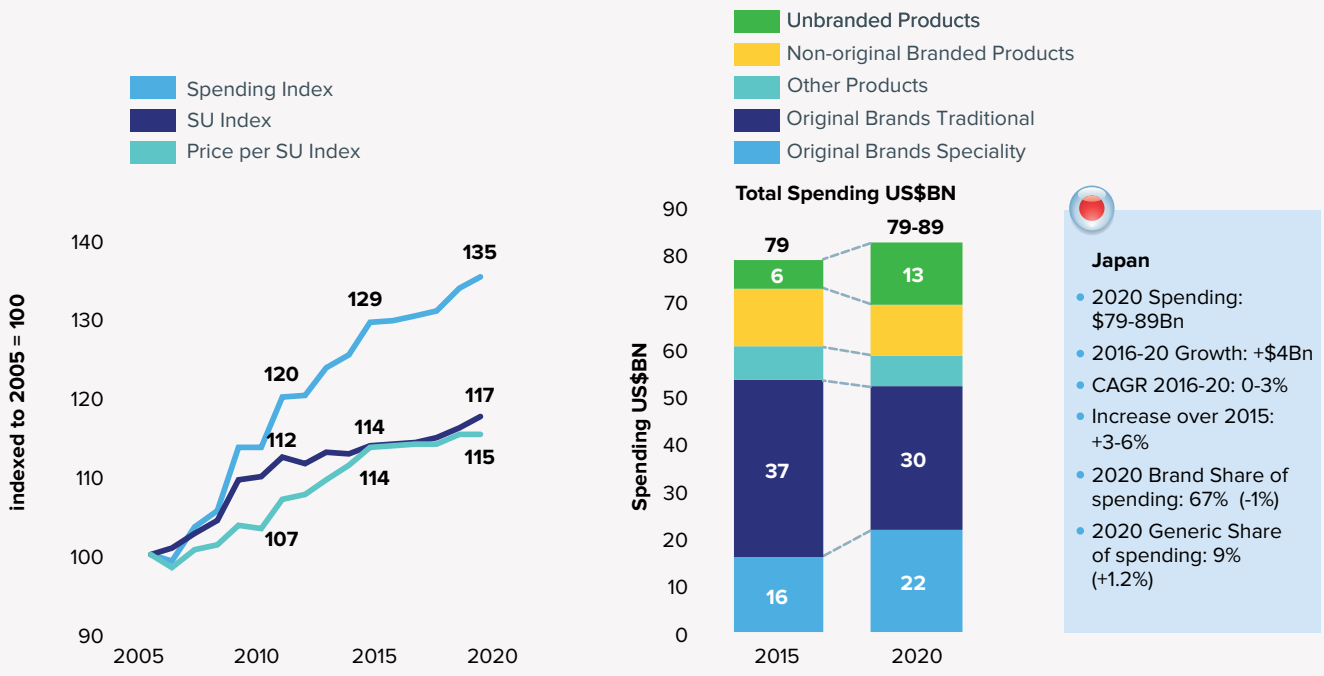
Across Europe, the adoption of specialty medicines will drive higher spending growth to 2020, and whereas 81% of the increase will be driven by specialty medicines, that is in part due to a recovery in traditional medicine spending. In 2011–2015, spending on traditional medicines declined in Europe with only specialty medicines increasing within the time period.

Japan spending on medicines

Japan's growth is expected to return to historic patterns through 2020 and the long-term effects of the new price regime will see average prices at a market level be essentially unchanged from 2015 (Exhibit 15). Spending will increase by 3-4% over the next five years, the lowest aggregate increase of any developed market. The price regime, in effect since 2010, applies biennial price cuts differentially more to older off-patent brands, less to newer original brands, and separately incentivizes generic dispensing. Spending in 2020 will see wider use of specialty original brands but lower overall brand spending as older brands will face more severe price cuts.

The incentives to wider generic usage will double generic spending, as generic penetration of the unprotected market is targeted by the Ministry of Labor Health and Welfare (MLHW) to reach 80% by 2020, up from 54.4% for the quarter ending June 2015.[1] The 2010-2015 period saw substantial increase in the average prices of medicines as policies designed to reward innovators were implemented. The introduction of a value added tax (VAT) in 2014, as part of national economic reforms, slowed growth, but it is expected to return to historic levels of mid-single-digit growth to 2020. Further planned increases to sales taxes in the 2016-2018 time period could offset the expected growth and result in a zero growth scenario in those years.

Exhibit 15: Japan's Spending Volume and Priced Indexed to 2015



Source: IMS Health, Market Prognosis, September 2015; IMS Institute for Healthcare Informatics, October 2015
Note: Spending, Standard Units (SU) and price per SU based on constant US$ and indexed to Japan in 2005.

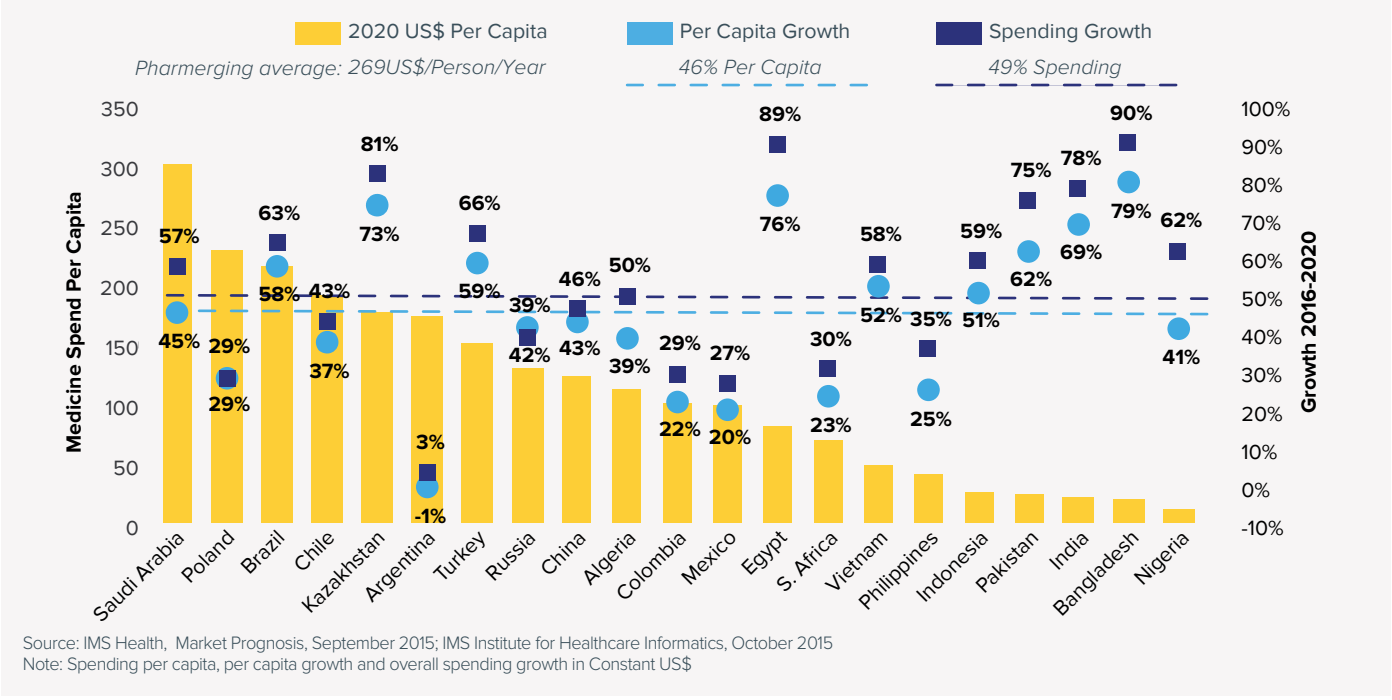
Pharmerging markets spending on medicines

Growth in spending on medicines in pharmerging markets of $125 billion to 2020 is driven primarily by wider use of medicines. The per capita increases in volume and spending reflect the strong commitment to wider access to healthcare from government and expanded private insurance markets that many pharmerging countries are experiencing.

The difference in per capita spending growth and overall spending growth over the next five years is indicative of population growth, while the overall high level of per capita spending growth reflects both access expansions and the rising mix of higher cost medicines being used in pharmerging markets (see Exhibit 16).

Saudi Arabia is notable in that it will spend $300 per person in 2020, with nearly the same volume per person as average developed markets. Many of the countries with the highest per capita spending growth to 2020 have the lowest spend per capita, suggesting that most people in those countries have substantially worse healthcare than in higher spend pharmerging or developed markets and that the increases will go some way but ultimately still fail to address global healthcare inequities.

Exhibit 16: Medicines Spend and Change per Capita Constant US$

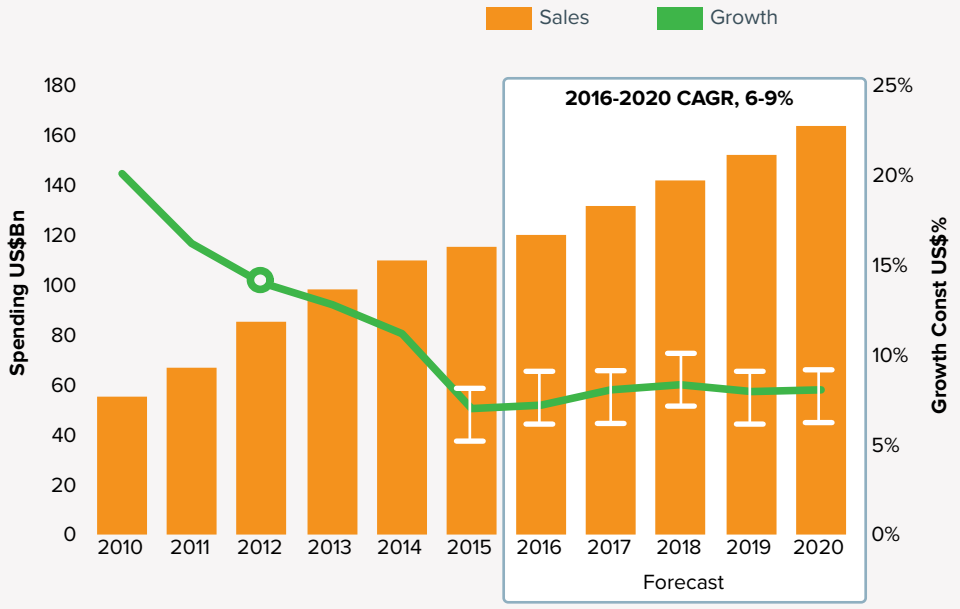


Source: IMS Health, Market Prognosis, September 2015; IMS Institute for Healthcare Informatics, October 2015
Note: Spending per capita, per capita growth and overall spending growth in Constant US$

China spending on medicines

China's decade long access expansion will have provided basic medical insurance to nearly the entire 1.4 billion population by 2020 but further rapid growth in spending is not expected. Per capita medicine volumes will continue to increase but at a slower rate than earlier in the decade and spending growth will slow to below 10% through 2020 (see Exhibit 17). China's economy has slowed recently and most medicine spending will still require substantial patient contributions, which will hamper increased spending overall. China remains the largest pharmerging market and, while slower than earlier in the decade, is expected to be at or above GDP growth through 2020.

Exhibit 17: China Spending and Growth, 2010–2020



China

- 2020 Spending: $150-180Bn
- 2016-20 Growth: +$54Bn
- CAGR 2016-2020: 6-9%
- Increase over 2015: +45-48%
- 2020 Brand Share of Spending: 23% +5pts
- 2020 Generic Share: 25% (-3pts)
- 2020 Non-Orig Brand Share: 35% (-3pts)

Source: IMS Health, Market Prognosis, October 2015
Note: Growth in 2012 estimated due to trend break in data collection.

Transformations 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 and clusters of innovation around hepatitis C, autoimmune diseases, heart disease, orphan diseases and others by 2020
- 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 increase 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 drugs is expected to be 1-2%, it will be as much as 10% in developed markets such as the U.S.

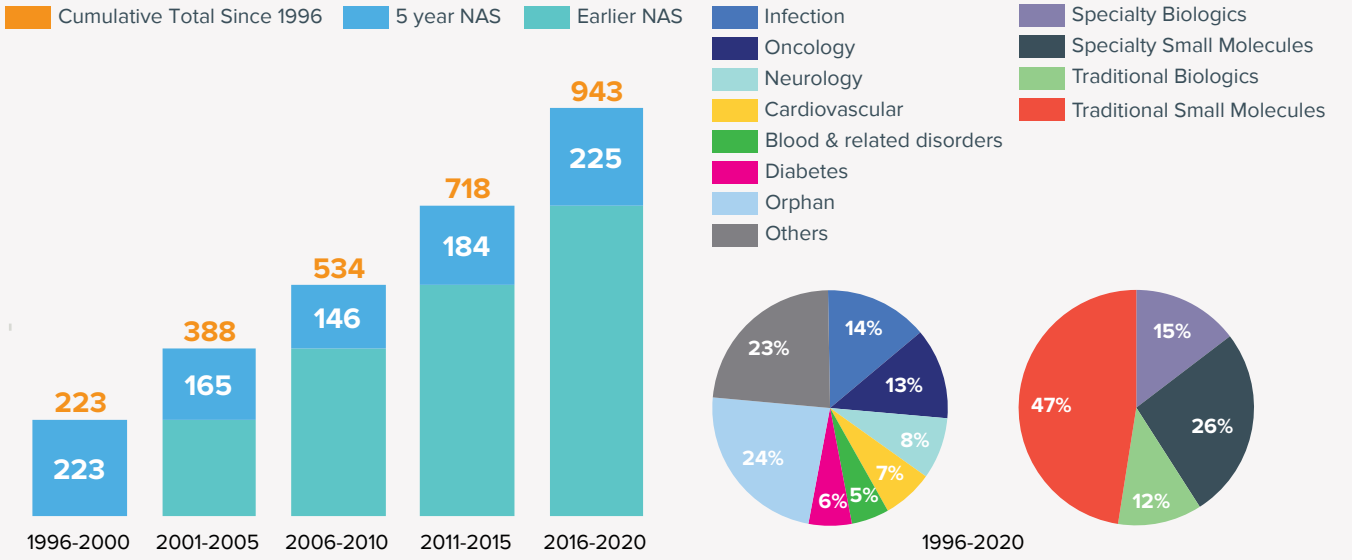
An increase in the number and quality of innovative new drugs will drive transformation of disease treatments by 2020, as the investments in research and development made in the last two decades emerge and reach patients in growing numbers.

Key aspects of innovation include biomarkers, genomics, genetic testing to match patients with treatments, improved success rates in clinical development, and addressing concerns about rising costs. The evolution of development incentives including fast-track approvals for "breakthroughs", continued pre-competitive collaborations, patient pooling of data, and large real-world evidence collaborations will all continue to stimulate research and development activities into the next decade.

New medicines available in 2020

In 2020, there will be 943 New Active Substances (NAS) introduced in the prior 25 years and the vast majority will be widely available to populations around the world (see Exhibit 18). These treatments often take years to reach patients outside the major developed markets, so the cluster of innovations in the next five years will be less widely available. Increasingly, the new medicines available will treat oncology and orphan diseases and provide a range of specialty small molecule medicines.

Exhibit 18: Global New Active Substances (NAS) Available Since 1996



Source: IMS Health, IMS Institute for Healthcare Informatics, October 2015
Note: Disease categories based on therapy areas and expected launches 2016-20. Orphan drugs are those to treat small populations with rare diseases, and are defined separately by U.S. FDA and the European Medicines Agency (EMA). Any medicine with an orphan designation for an approved use within the first year after global launch are categorized as Orphan. Half of designated orphan indications are granted more than a year after original approval.

Patients will have greater access to breakthrough therapies and clusters of innovation around hepatitis C, cancer, autoimmune diseases, heart disease and orphan drugs by 2020. Cancer treatments represent the largest category of the 225 new medicines expected to be introduced within the next five years, including important new developments. For example, myeloma will see survival rates rise above 50% if the new treatments are as effective as early trials suggest. Over 90% of expected new cancer treatments will be targeted therapies – those that use a cancer cell process, mechanism or genetic marker to select or deliver treatment – of which one-third will use a biomarker. An estimated one-third of cancer treatments will target rare cancers deemed orphan diseases.

By 2020, over 470 drugs, including 75 incremental expected to be launched over the next five years, 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 drugs is expected to be 1-2% of global spending, it will be as much as 10% of in developed markets such as the U.S.[2]

A number of transformational treatments will be available in 2020 including functional cures for hepatitis C, a cluster of small molecule and biologic immunology treatments for rheumatoid arthritis and new treatments for an array of diseases which have previously only been treated with decades old, often generic, small molecule treatments. By 2020, there will be a small but important number of cell- and gene-based therapies available to patients, often with short or one-time dosing, for treating diseases with significant challenges including but not limited to cancers, HIV, genetic disorders and autoimmune diseases.

Oncology

The era of precision treatment for all cancer types will still be on the horizon by 2020 but important steps will have been made across a number of tumor types. Biomarkers are increasingly the target of clinical trials and more approved drugs are accompanied by a protocol to use a biomarker or a companion diagnostic to inform and direct their use. Increasing pressure from payers to restrict access or limit the use of expensive targeted treatments can be expected and, at the same time, those with biomarkers can expect that eligible patients will be tested and likely be approved for use.

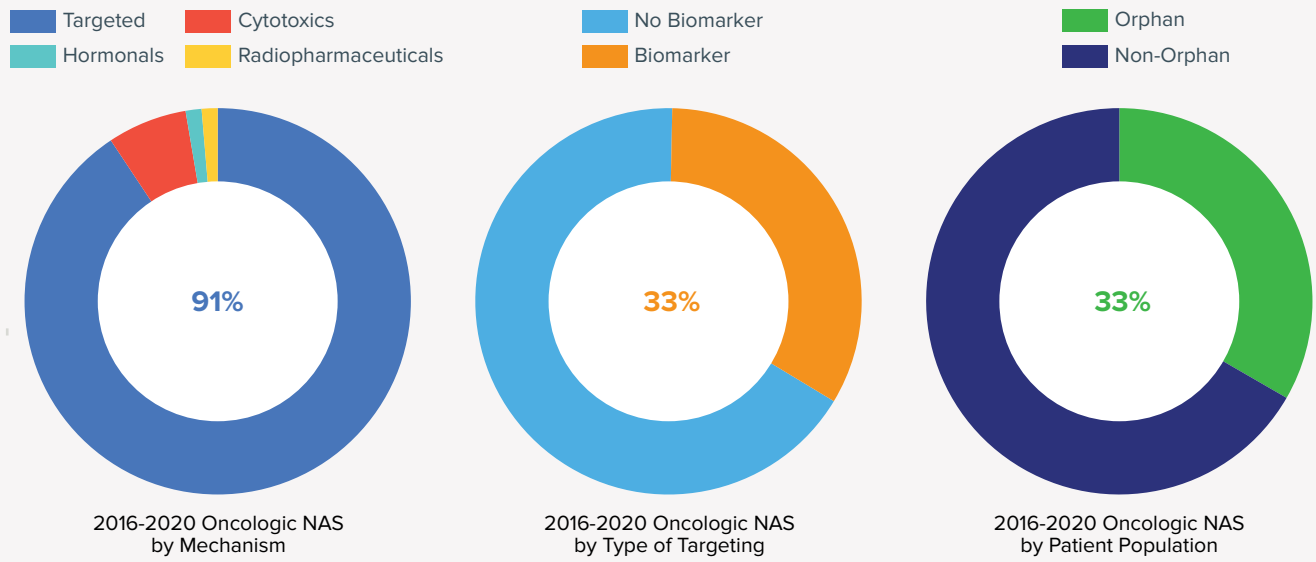
Oncology treatments will include more immunotherapies, targeted therapies and personalized medicines, sometimes used together in a regimen, improving further survival and life expectancy for many cancers. Over one-third of new cancer medicines in research are currently testing a biomarker and trials employing biomarkers for patient selection have a higher probability of success (see Exhibit 19).[3]

The largest part of research and development activity that will produce new therapies in the next five years are in larger population tumors such as breast, lung, colorectal, and leukemias and lymphomas, many of which have already had a number of new treatment options in the last five years. In these areas, most of the further development will bring the potential of efficacy, safety, and improved dosing administration. A smaller number of new cancer medicines will target hard to treat cancers including myeloma, pancreatic, aggressive ovarian, and melanomas, often providing diagnostics and with substantial improvements in survival expected.

There are currently five treatments for myeloma in late stage development, several with new mechanisms of action and one providing an oral option alternative to currently available infusion treatment which has less than 50% 5-year survival prospects for most patients.[4] Several of the new treatments can be expected to be approved quickly based on priority review and breakthrough designations from regulators, including the first oral proteasome inhibitor (ixazomib), a Signaling Lymphocytic Activation Molecule F7 (SLAMF7; elotuzumab) and a CD38-targeted monoclonal antibody (daratumumab).

There are 19 immunotherapies in development using the PD-1 or PD-L1 targeting mechanism and many tumors may show results from this approach of marshalling a patient's own immune system in treatment. Many of these treatments will be added to existing targeted treatments, raising the prospect of extremely expensive regimens for some tumors, which will require a strong evidence basis to determine appropriate use both clinically and financially.

Exhibit 19: Novel Active Substances (NAS) for Cancer by Mechanism, Targeting Type and Patient Population



Source: IMS Health, IMS Lifecycle R&D Focus; IMS Institute for Healthcare Informatics, October 2015

Orphan diseases

By 2020, the treatment options for orphan diseases- those affecting fewer than 200,000 patients in either the U.S. or Europe - will be at an all-time high. Some 470 orphan treatments will be available, including medicines with multiple uses and those with both orphan and non-orphan indications. Over the past three decades, incentives from U.S. and European policy makers have encouraged the development of these medicines by providing additional periods of market exclusivity- typically the period when companies make economic returns on their investments.

Some of the most transformative orphan drugs include new treatments for Duchenne Muscular Dystrophy, a rare degenerative muscle disorder primarily affecting boys starting from 3 to 5 years old, affecting 1 in 3,500 worldwide and treated only through symptom management with steroids.[5] The first disease modifying therapy treats approximately 13% of patients with a specific mutation and was approved in the EU in 2014. Several more treatments are expected to be approved and launched in the EU and the U.S. within the next couple of years.

This volume of new treatments is a substantial improvement for patients but still represents only a small fraction of the 7,000 rare diseases for which there are limited to no treatments.[6] Most rare diseases do not yet have ongoing drug development and will not have a treatment available by 2020 highlighting a need for continued incentives to address research and treatment gaps. Some diseases have drawn more research than others and will have multiple treatment options targeting different sub-populations.

Communicable diseases

Increasing numbers of philanthropy-led developments will have improved the treatment of neglected tropical diseases by 2020. New treatments will include vaccines for cholera and malaria, as well as a range of technology and societal solutions to begin to address last-mile issues. Oral vaccines, use of mobile technology, and room-temperature injectables will be explored in the hopes to eventually transform complex disease treatments in Africa, but will likely take more time to overcome persistent economic development issues.

Cholera, though rare in developed countries, affects millions annually and kills more than 200,000 globally each year especially in war-torn areas with poor hygiene conditions. Currently, there are new single dose vaccine administrations available rather than the two dose regimen which could reduce death rates significantly in low-income, developing regions, at least partly because of the higher rates of vaccination that will be possible.[7]

The first vaccine for malaria is expected to gain EU approval in the very near future. The partnership of GlaxoSmithKline (GSK) and the PATH Malaria Vaccine Initiative, established through a grant from the Bill and Melinda Gates Foundation, underscores the role of partnerships with not-for-profit groups in developing and distributing treatments to underserved populations globally. In addition, there is a new more effective treatment in development, tafenoquine (Etaquine), which works similarly to the familiar quinine treatments but is expected to prevent malaria relapse with a shorter treatment course. Fewer vaccinations and shorter treatment courses are key to overcoming some of the last-mile challenges in delivering treatments to remote areas and may be key to saving millions of lives.

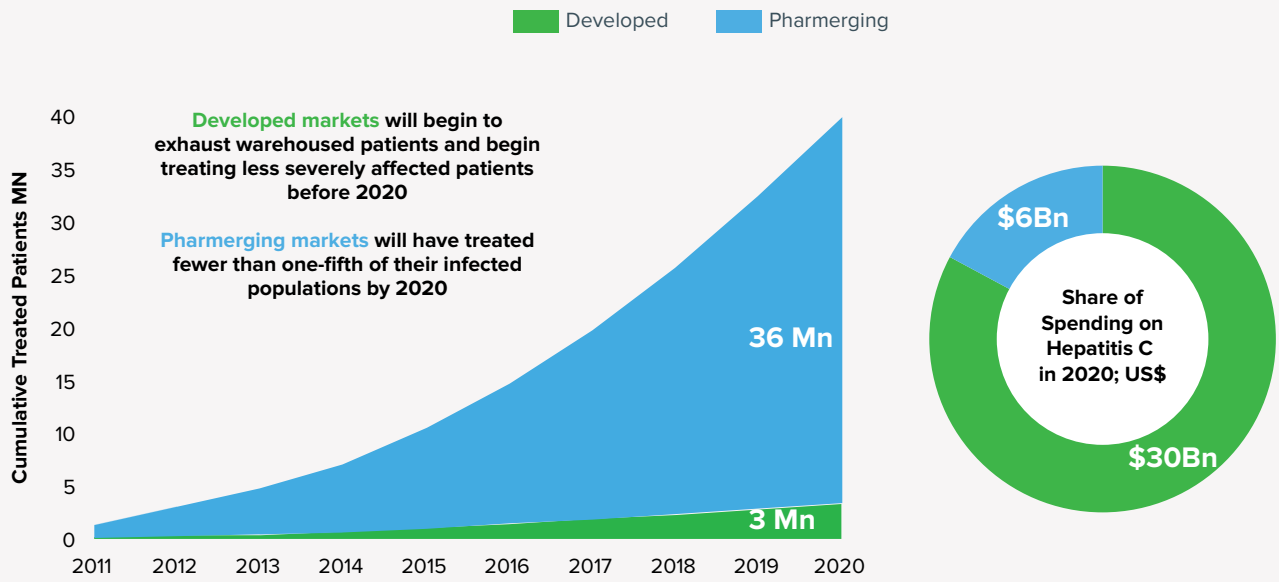
While mortality rates for HIV have been in decline, it remains a difficult disease to manage particularly in lower-income countries. Current treatments for HIV target several steps in the viral lifecycle but viral resistance is still a concern. There are fifteen new HIV treatments in late stage clinical trials many of which can be expected to be available in 2020 including a new medicine with an FDA breakthrough designation, (ibalizumab) which targets a mechanism with reduced potential for viral resistance, and has a less frequent dosing schedule which may improve adherence. In addition to new HIV treatments, wider use of existing treatments for pre-exposure prophylaxis (PrEP), and recommendations to begin treatment earlier, before patients express any symptoms are key components of UNAIDS plan to end the AIDS epidemic by 2030.[8]

Clinical transformations

Hepatitis C has seen several fundamentally transformative new treatments launched in the past two years, bringing highly effective treatments with few side effects, convenient oral dosing and a short 8-12 week treatment for most patients. With upwards of 90% of patients responding to treatment, these medicines essentially offer a cure for hepatitis C, and it is notable that cures for any disease are exceedingly rare. The introduction of breakthrough treatments for hepatitis C, beginning in 2011 with a major uptick in 2014, will begin to dramatically lower the size of the infected population globally (Exhibit 20). While developed markets have only 5-10 million of the estimated 130-170 million infected, they will treat a much higher proportion sooner and begin to see diminishing patient treatment volumes within the next decade.[9,10] While accurate measurements of the infected population are difficult, and there are very few reliable ways of determining how many of the infected have severe disease, it is expected that most of the treatment will have focused on severe patients and as that group is reduced,

less severe patients may be treated. Protocols that suggest deferring treatment until the disease is severe are, at least partly based on the idea that every treatment carries some risks but also stem from concerns about the level of costs that such treatment levels could generate.

Exhibit 20: Global Estimated Treated Patients and Spending on Viral Hepatitis through 2020; Estimated 180 Million Infected



Source: IMS Health, Market Prognosis; IMS Institute for Healthcare Informatics, October 2015

The ability of health systems to fund find and treat the millions of hepatitis C infected population outside the developed countries presents a challenge for health systems unsuited to support large scale primary care screening and/or diagnostics. Millions of people are estimated to have received the benefit of a functional cure for hepatitis C by 2020, although the full extent depends on the funding and access challenges being addressed. That is a remarkable achievement for a disease that has been intractable for decades. A substantial dent will have been put in emerging market infected populations via licensing arrangements to enable generic producers to make new medicines at lower costs.[9] By 2020, healthcare payers globally will have spent in excess of an estimated $200 billion on hepatitis treatments. The perceived cost burden of treating millions of patients will, however, likely dampen the enthusiasm for large-scale diagnosis initiatives, and therefore only the most severe patients will be treated in emerging markets for the foreseeable future.

Immunology for a variety of diseases including autoimmune diseases, respiratory, and even cholesterol will bring new options for the high-risk groups of patients not served by existing therapies. These treatments will be a combination of mechanisms of immune activation or suppression such as PD-1,PD-L1, CTLA-4[10], as well as specific biomarkers that are expected to indicate or identify responding patients.[11] In some cases, these new treatments will bring a biologic, highly effective treatment to a disease which has had an established standard of care supported by small molecule drugs, that are often generic and much lower cost. These new treatments will reach very narrow populations as payers and providers wrestle with the benefits they bring compared to their value within constrained healthcare budgets.

Treatments for rheumatoid arthritis, already served very well with a series of tumor necrosis factor (TNF) drugs, will see more treatments including those with mechanisms similar to marketed drugs such as IL-6R and small molecule treatments targeting the JAK1 and JAK2 receptors which may be oral treatments, reducing the need for injections. In addition to new treatments, by 2020 we can expect to see multiple biologics for autoimmune diseases face biosimilar competition in most developed markets including infliximab and adalimumab.

By 2020, a number of diseases will have new biologic treatment options available across developed markets including severe asthma, chronic eczema, atopic dermatitis, and familial or resistant hypercholesterolemia. The historic presence of treatments for these diseases means payers will have to make decisions about patient access to these new medicines; these will be some of the most high profile discussions of the value of innovative medicines in the next five years.

In some cases, the combination of multiple immunotherapies with other targeted cancer agents and a biomarker can dramatically increase the treatment cost for a single patient while at the same time reducing the waste associated with failed treatments for patients who do not respond to treatment. The rising use of biomarkers and evidence-based segmentation of patients, as part of the emerging era of precision medicine, will be key to optimize the selection of patients who will benefit most from these new medicines while balancing population-level priorities about healthcare costs. Without precise patient targeting, budget considerations could limit access to these new medicines to a very few patients.

Cell and Gene therapies are thought to offer some of the most powerful treatments for very hard to treat diseases and for very small groups of patients. These factors tend to result in faster clinical trials and faster approval so by 2020 there will be dozens of these therapies available. Cell therapies are treatments where cells are injected or genetic material is introduced to encourage a biologic response. Most cell therapies are either dendritic cells (which encourage an immune response) or CAR T-cells (which trick the immune system to hunt down cancer cells) and these approaches have disease targets varying from cancer, to HIV and autoimmune disease. In addition to specifically engineered cells, a range of treatments are in development that are based around stem cells. There are already several treatments with these mechanisms available and more are expected by 2020.

Most gene therapy research is focused on triggering or suppressing cell processes that result in disease. Gene therapies introduce genetic material into a patient either directly or using a virus to insert it into cells. For rarer genetic disorders, the specific treatment may ultimately be engineered for a single patient. There is only one gene therapy currently approved, alipogene tiparvovec (Glybera), but 5-10 are expected to be approved and available by 2020 and dozens more are in late stage research.[12] Early gene therapies are expected to treat diseases ranging from a rare blindness condition (Leber's Congenital Amaurosis) to sickle-cell anemia, beta thalassemia, a range of rare cancers, and genetic diseases.

There may be extremely high prices for some of these medicines, in part based on the limited numbers of patients, and some expect several of these treatments to be more than $1 million per patient. Existing mechanisms to assess and reimburse drug therapies will be largely unable to manage costs of this nature and new approaches will be needed, likely spurred by the increasing numbers of medicines and patients involved. As with any pioneering effort, little is known about how tolerable they will be and a number of failed attempts are expected alongside the few successes. Most of the research in these methods target cancers and autoimmune diseases but there are important clusters in cardiovascular disease,

nervous system disorders and HIV. The likelihood of widespread use of these therapies by 2020 is very low, but the transformative nature of these treatments will usher in a new era of precision and personalized healthcare where treatments not imagined possible will become more mainstream.

Technology-enabled transformations

Technology is permeating all aspects of life globally with mobile phones more common in remote Indian villages than computers or landlines and the prevalence of electronic medical records now reach almost every developed nation and many emerging ones. Smartphones, mobile apps, wearable technology, and the modularity with which these technologies can be used together have reached such critical mass that innovations are happening more quickly, cheaply, and with greater specificity to individual micro-populations. Much of the mobile health available today is in its infancy, and the mining of healthcare big data for better decision making is still more promise than reality, but by 2020 major changes will have occurred. Researchers and payers will have substantial and exponentially growing volumes of data proving evidence supporting the benefits of specific approaches, interventions, and drugs as well as refined approaches for using technology to develop insights faster and at lower cost. There will be large consensus by 2020 on issues including:

- **Adherence** initiatives will have been put into place as a result of substantial evidence around what works to manage and improve adherence encompassing technology, coordination of care and payer/provider incentives for improved performance and outcomes.
- **Wearable** devices will be widely used for monitoring activity, vital signs, and effectiveness of recommended treatment to actual patient experience. High quality clinical grade devices will be commonplace for high-risk patients and will build upon the ubiquity of mobile devices and connect health data between patients and providers rapidly during critical diagnosis and around health events.
- **Big data** will have driven a broad based normalization of care across a wide variety of diseases, informed by population health concepts, and measurable thanks to widely adopted electronic medical records in most developed and some pharmerging markets.
- **Diabetes** patients from diagnosis will be supported by a range of technology solutions related to diet, exercise, blood sugar testing, and drug adherence. A continuing stream of new medicines will increase the options for doctors and patients but also create a confusing array of therapies to navigate and highlighting the need for scientific evidence to support usage.
- **Behavior modification,** as a general concept, accounts for the majority of potential impact on patient outcomes with some diseases and more effective behavior changes (e.g. diet and exercise) may be better enabled with wearables and mobile health solutions.

In 2020, every patient with multiple chronic conditions will be able to use wearables, mobile apps and other technologies to manage their health, interact with providers, and connect with fellow patients and family members. Maximizing the benefit of these tools will still depend on evolving proof of concept technologies to evidence based and scalable solutions. By 2020, dozens of clinical trials will prove definitively which approaches are effective and enable the fundamental shifts in the use of technology to both advance healthcare outcomes and enable better outcomes at lower costs.

Implications

Evolutionary changes reframe stakeholders approach to medicine use and will ultimately determine how much of the promise of innovative healthcare reaches patients around the world in 2020 and beyond

There will be several important and evolutionary changes by 2020 that will reframe stakeholders approach to medicine use. The interconnected nature of decisions in healthcare will inevitably lead to tensions, and resolving those conflicts, will ultimately determine how much of the promise of healthcare reaches patients around the world in 2020 and beyond.

Fundamental change across stakeholders

The combination of demographic pressures – population growth, aging populations – and relatively slow or slowing economic growth will have built substantial pressure for most countries to develop new funding models for healthcare by 2020. Medicines in 2020 will include a vast array of treatments ranging from those that provide symptom relief available without a prescription to lifesaving genetically personalized therapies unique to a single patient. The role of medicines in global healthcare will have evolved to one which often replaces more complex interventions and in many cases will be accompanied by a societal expectation that medicines can achieve tremendous results, and that whatever the innovation, it should be affordable and accessible to those who need it. This consensus is clearly present in the discussions of access to treatments for HIV, hepatitis C, and many other medicines, and is included in the policies or ideologies of both developed and developing world countries. While the U.S. has long dominated the world's spending on medicines, the next five years will likely see key pharmerging markets, particularly India and China pass the U.S. in using the highest volumes of medicines, largely driven by their populations, and yet demonstrating that they continue to have limited access per capita to the most transformative innovative medicines.

The number of clinically desirable and costly breakthrough drugs, combined with the larger volume-driven costs of existing lower-cost treatment options will strain even the most well managed budgets. The expected growth of medicine usage implies by its very nature that healthcare delivery capacity will need to expand or change significantly. The wider use of newer technologies is likely to enable system expansion without linear cost growth, but difficult decisions that balance overall population benefit and individual patient need will remain challenging issues for stakeholders to resolve.

Health systems globally will largely be on sounder footing in 2020 than today, with broader population access, better evidence basis for the treatment protocols, a faster cycle in adopting better protocols informed by larger volumes of real world data, and a more uniform set of policies to appropriately adopt innovation. Key to this set of improvements and an ongoing evolution of better health and healthcare will be a sustainable set of rewards for innovation, including transparent price negotiation systems, and the wider adoption of intellectual property protection for innovation.

Implications for specific elements of healthcare systems include:

Payers:

- Payers budgets in 2020 will be more challenged than today and new mechanisms - or greater use of existing mechanisms – to evaluate health technologies, set priorities and allocate budgets will be in place.
- Payers will have reduced their practice of isolating drug budgets from other and related healthcare costs due to the growing realization – and availability of data - that healthcare budgets are best managed holistically.
- In emerging markets, the recognition of the importance of healthcare to economic development will see rising allocation of budgets to healthcare spending, including medicines in line with the World United Nations Sustainable Development Goals.

Providers:

- Providers will be using more decision-support tools at point-of-care to optimize patient treatment, utilize information technology and increase support due to the proliferation of treatment options especially in cancer.
- More providers in a greater portion of the world will be subject to performance or outcomes-based contracts or payment systems, bringing sharper scrutiny to the patient outcomes and costs associated with patient care.
- Following selective use of high-cost medicines – under the guise of "precision medicine" will occur as a consequence of cost pressure, greater availability of biomarker information, and predictive analytics.
- An increasing amount of healthcare will be delivered by technology-enabled means, including telemedecine, mHealth applications, in-store clinics and community-based healthcare facilities in low- and middle-income countries.

Patients:

- Patients will be more actively engaged in their own healthcare due to the availability of low cost technologies including wearables and sensors connected to mobile health apps, providing real time information to the patient that will promote wellness, disease prevention and more effective treatment when required.
- Patients will have greater access to healthcare systems and medicines in 2020, including more treatment options for disease areas such as cancer and rare diseases.
- In developed economies, patients will likely bear a greater share of their medicine costs as private and public plans struggle with budgetary constraints and shift greater amounts of risk to the patient directly.
- In low- and middle-income economies, the movement toward universal health coverage will result in greater access to drugs through some form of private insurance plan rather than requiring patients to pay out-of-pocket.

For manufacturers of medicines, these challenges represent complex issues for their customer's businesses, but also highlights that their continued success in a sustainable business model is one that is intrinsic to the overall healthcare model and stakeholders needs. The challenges ahead are clearly not insurmountable, but they will require collaboration and cooperation across sectors in ways which have often been in short supply historically. Some companies are better positioned than others to achieve these evolutions, and they will be the ones who achieve demonstrably better outcomes relative to the investments they make in healthcare for 2020 and beyond.

Notes on sources

This report is based on the IMS Health services detailed in the panel below.

IMS Market Prognosis™ is a comprehensive, strategic market forecasting publication that provides insight to decision makers about the economic and political issues that 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™ 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 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 predictions of future performance, and reference information on their regulatory stage globally.

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 Prognosis™ Includes sales forecasts for major therapy areas in 14 key markets, 8 developed (U.S., Japan, Germany, France, Italy, Spain, U.K., Canada and South Korea) and 6 pharmerging (China, Brazil, Russia, India, Turkey and Mexico) and includes interactive modeling and event-based forecasts and comprehensive market summary.

Appendices

Appendix 1 - Global Country Rankings

Exhibit	2010	Index	Exhibit	2015	Index	Exhibit	2020	Index
1	U.S.	100	1	U.S.	100	1	U.S.	100
2	Japan	22	2 ▲1	China	27	2	China	30
3 ▲2	China	19	3 ▼1	Japan	18	3	Japan	14
4	Germany	11	4	Germany	10	4	Germany	9
5 ▼2	France	10	5	France	8	5 ▲2	Brazil	8
6	Italy	7	6 ▲1	U.K.	7	6	U.K.	6
7	U.K.	6	7 ▲3	Brazil	6	7 ▲1	Italy	5
8 ▼3	Spain	6	8 ▼2	Italy	6	8 ▼3	France	5
9	Canada	6	9	Canada	5	9 ▲3	India	5
10 ▲1	Brazil	5	10 ▼2	Spain	4	10 ▼1	Canada	4
11 ▲2	South Korea	4	11 ▲4	Venezuela	4	11 ▼1	Spain	4
12	Australia	3	12 ▲1	India	4	12 ▲1	Russia	3
13 ▲1	India	3	13 ▲3	Russia	3	13 ▲1	South Korea	3
14 ▼4	Mexico	3	14 ▼3	South Korea	3	14 ▲2	Mexico	2
15 ▲12	Venezuela	3	15 ▼3	Australia	3	15 ▲3	Turkey	2
16 ▲7	Russia	2	16 ▼2	Mexico	2	16 ▼1	Australia	2
17 ▲1	Poland	2	17 ▲6	Argentina	2	17 ▲3	Saudi Arabia	2
18 ▲3	Turkey	2	18	Turkey	2	18	Poland	2
19 ▼4	Switzerland	2	19 ▼2	Poland	2	19 ▼2	Argentina	1
20 ▼4	Netherlands	2	20 ▲7	Saudi Arabia	1	20 ▲9	Egypt	1

Source: IMS Health, Market Prognosis, September 2015 ▼▲ Change in ranking over prior five years

Appendix notes:

Rankings based on Constant US$. Argentina and Venezuela based on US$ with variable exchange rates due to hyperinflation. Index reflects comparison to the U.S. of spending in Constant US$.

Appendix 2 - Region and Leading Country Spending				
US$ billions	2015	2010-2015 CAGR	2020	2016-2020 CAGR
Global	**1,068.8**	**6.2%**	**1,400–1,430**	**4–7%**
Developed	**684.3**	**4.8%**	**870–900**	**3–6%**
U.S.	430.0	6.1%	560–590	5–8%
EU5	144.0	2.9%	170–200	1–4%
Germany	41.2	3.8%	52–62	2–5%
France	31.3	0.1%	30–38	(–3) – 0%
Italy	25.1	3.1%	30–40	2–5%
U.K.	27.7	6.9%	28–38	3–6%
Spain	18.6	0.7%	20–28	1–4%
Japan	78.3	2.6%	79–89	0–3%
Canada	19.3	2.0%	23–33	3–6%
South Korea	12.7	2.3%	13–20	2–5%
Pharmerging	**249.2**	**11.9%**	**345–375**	**7–10%**
China	115.2	14.2%	150–180	6–9%
Tier 2	56.8	12.9%	85–95	9–12%
Brazil	28.1	13.8%	34–44	9–12%
Russia	12.1	10.9%	13–19	5–8%
India	16.6	13.0%	29–39	11–14%
Tier 3	77.2	8.2%	100–120	6–9%
Rest of World	**135.2**	**5.2%**	**150–180**	**1–4%**

Source: IMS Health, Market Prognosis, September 2015

Appendix 3 - Product Types By Geography

Spending US$ 2020	Original Brands	Non-Original Brands	Unbranded	Other Products	Global
Global	52%	21%	14%	13%	$1,400–1,430Bn
Developed	65%	12%	14%	8%	$870–900Bn
Pharmerging	24%	38%	14%	24%	$345–375Bn
Rest of World	48%	26%	9%	17%	$150–180Bn

2016-2020 CAGR Const US$	Original Brands	Non-Original Brands	Unbranded	Other Products	Global
Global	5.1%	6.0%	6.3%	4.8%	4–7%
Developed	4.9%	4.9%	4.6%	3.1%	3–6%
Pharmerging	8.6%	7.8%	12.0%	6.9%	7–10%
Rest of World	2.6%	3.4%	3.2%	2.7%	1–4%

Source: IMS Health, IMS Market Prognosis, September 2015; IMS Institute for Healthcare Informatics October 2015

Appendix notes:

Spending Share point values for guidance, Growth estimates +/– 1.5%
Other Products includes OTC products

Definitions & Methodologies

- **Countries:**
  - **Developed** countries in this report are defined as the U.S., Japan, Top 5 Europe countries (Germany, France, Italy, Spain, U.K.), Canada and South Korea.
  - **Pharmerging** countries are defined as those with >$1 billion absolute spending growth over 2014-18 and which have GDP per capita of less than $30,000 at purchasing power parity (PPP). Tier 1: China; Tier 2: Brazil, India, Russia; Tier 3: Algeria, Argentina, Bangladesh, Chile, Colombia, Egypt, Indonesia, Kazakhstan, Mexico, Nigeria, Pakistan, Philippines, Poland, S. Africa, Saudi Arabia, Turkey, Vietnam.
  - **Estimates for unaudited countries:**
    - **Spending** is estimated based on import/export data included in IMS Market Prognosis.
    - **Segmentations** (Innovation Insights, Specialty/Traditional) are based on audited countries and applied to unaudited countries based on regions.
    - **Standard Units** for countries which are not audited are estimated based on regional average prices per Standard Unit from audited countries and available import/export data.
- **IMS Innovation Insights** is a segmentation of products which are categorized as original brands, non-original brands, generics or other using IMS Health's proprietary MIDAS™ Innovation Insights segmentation methodology.
  - **Original Brands** Prescription-bound products marketed with a brand name, by the originator or their licensee.
  - **Non-Original Brands** Prescription-bound products marketed by a non-originator with a brand name, often but not exclusively without patent protection.
  - **Unbranded** Generic medicines marketed as the international non-proprietary name (INN) of the active ingredient(s).
  - **OTC** All other medicines, the largest subset of which are Over-the-Counter (OTC) products.
- **New Active Substances** (NAS) defined as an identifiable active ingredient or combination where one ingredient is entirely new, including biologics, and small molecules, and assigned to a year based on first global availability.

- **Specialty medicines** are products that treat chronic, rare or genetic diseases. There are multiple characteristics that can further define a specialty medicine and IMS Health defines them as having the majority of these characteristics:
  - Often initiated by specialists
  - Generally injectable and/or not self-administered
  - Require an additional level of care in their chain of custody, such as refrigeration
  - Distributed by specialized wholesalers or pharmacies
  - Typically very expensive, or treating very costly diseases
  - May require payment assistance where applicable
  - Requiring extensive or in-depth monitoring/patient counseling
- **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 (Q2 2015) exchange rates. Variable exchange rates abbreviated as US$, constant exchange rates abbreviated ConstUS$.
  - **Estimates of Net Spending** were derived from a historic analysis of company reported revenues compared to IMS Health audits of pharmaceutical spending in the U.S. and major markets. In the U.S. these analyses were based on a sample of 24 companies over 10 years. In other major markets, interviews with local experts form the basis of estimates.
- **Standard units (SU)** are a measure of volume defined by IMS Health in conjunction with the pharmaceutical industry to represent a dose of a particular formulation of treatment. Standard Units are consistently defined at form level and are not normally recommended for use across formulations.
- **Standard Units per capita** take aggregate SU data and divide by a country's population.
- **Therapy area/Diseases** have been aggregated differently for exhibits 6, 8, and 9 for this report. The tables below provide the aggregation definitions for each exhibit.

Exhibit 6 Disease Definitions	Includes
Communicable Diseases	Antibiotics, antivirals, antiparasitics, vaccines (ATC1=J, P)
Oncology	Therapeutic cancer treatments, excluding supportive care (ATC=L1, L2)
Diabetes	Insulins, traditional and newer generation diabetes treatments (ATC=A10)
Cardiovascular	Hypertension, Heart disease, cholesterol (ATC1=C)
Pain	Treatments for musculoskeletal pain, arthritis, anesthesia, analgesics (narcotic & non-narcotic), migraine (ATC=M,N1,N2)
Autoimmune	Treatments for rheumatoid arthritis, crohn's disease, ulcerative colitis, psoriasis, psoriatic arthritis and other related diseases (ATC=M1C,L4B)
Respiratory	Asthma, COPD, Allergy respiratory/inhaled treatments (ATC=R)
Other non-communicable	All other treatments not related to communicable diseases

Exhibit 8 Therapy definitions	Specialty Therapy definitions
Oncology	Therapeutic cancer treatments, excluding supportive care (ATC=L1,L2)
Autoimmune	Treatments for rheumatoid arthritis, crohn's disease, ulcerative colitis, psoriasis, psoriatic arthritis and other related diseases (ATC=L4B, not including traditional Autoimmune treatments in ATC=M1C)
Viral Hepatitis	Specific treatments for hepatitis, excluding interferons (ATC=J5B1)
Immunosuppressants	Suppression of immune response, often for use in organ transplant (ATC=L4 ex L4B)
HIV Antivirals	HIV antiviral treatments (ATC=J5C)
Immunostimulants	Colony-stimulating factors (ATC=L3A)
Interferons	Interferons (ATC=L3B)
Erythropoietins	Erythropoietin stimulating agents (ATC=B3C)
Macular Degeneration	Treatments for age-related macular degeneration (ATC=S1P)

Exhibit 9 definitions	Traditional therapies
Antibiotics & Vaccines	Antibiotics, antifungals (ATC=J1,J2), vaccines (ATC=J7) and antibiotics specifically for the eye and ear (S1A,S1C)
Blood disorders, coagulation	Antithrombotics, Platelet aggregation inhibitors, direct thrombin inhibitors (ATC=B, excluding B3C erythropoietins which are Specialty)
Cardiovascular	Hypertension, Cholesterol, nitrates/nitrites, diuretics, heart failure, varicose veins (ATC=C)
Dermatology	Dermatology treatments (ATC=D)
Diabetes	Insulins, traditional and newer generation diabetes treatments (ATC=A10)
Mental Health	Antipsychotics (N5A), Antidepressants (N6A), Psychostimulants (N6B)
Other CNS	Anti-epileptics, Anti-Parkinson's, Anti-Alzheimer's (ATC=N3,N4,N7)
Pain	Treatments for musculoskeletal pain, arthritis, anesthesia, analgesics (narcotic & non-narcotic), migraine (ATC=M,N1,N2)
Respiratory	Asthma, COPD, Allergy respiratory/inhaled treatments (ATC=R)
Trad Chinese/Indian/Japanese Medicines	Traditional medicines from China, India, Japan (ATC=V3 Kanpo, Ayurvedic & Chinese Medicines)
Others (not shown)	Alimentary products (Vitamins, minerals, digestive enzymes, anti-obesity medicines and laxatives (ATC=A excluding A10 Diabetes), Hospital solutions (K), antiparasitics (P), diagnostics (T), Erectile dysfunction (G4E), Genito-urinary hormones and contraception (G), Hormones (H), Gout (M4A), Osteoporosis (M5), Ophthalmic (S, anti-infectives are shown), All other non-human use (V)

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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 Health'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 Health 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:

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.

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