

November 2013

# The Global Use of Medicines: Outlook through 2017



## Introduction

Total global spending on medicines will exceed one trillion U.S. dollars for the first time in 2014 and reach almost \$1.2 trillion in 2017. The role of medicines in improving health for hundreds of millions of people across the globe has never been more important. Many countries are moving toward Universal Health Coverage, ensuring access to medicines and other elements of healthcare for all. At such a time, understanding the market for pharmaceuticals of all types – small and large molecules, brands and generics, those dispensed in retail pharmacies and those used in hospital or clinic settings – is essential.

As we pass the fifth year since the beginning of the world's major economic slowdown, macroeconomic indicators are improving, though more slowly than previously forecast. Austerity measures taken by some governments, especially in Europe, continue to be applied to healthcare spending and especially medicines.

In this year's report, we have brought together the global expertise of our entire IMS Health team to report on our latest forecasts for pharmaceutical use and related costs. Due to the unusually high level of uncertainty surrounding some of the structural changes underway in key countries, we have included not only our base-case forecasts, but some alternative scenarios in the case of the U.S., EU5, Japan and China. While the probability of these alternative scenarios playing out may be low, we believe it is useful to enter the next five year period with these in mind. We will continue to monitor these situations regularly.

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## **Executive Summary**

In absolute terms, global spending on prescription medicines will increase by \$205-\$235Bn in the five years to 2017, reaching over \$1 trillion. The level of increase is comparable to the \$234Bn by which spending increased in the previous five year period.

The next five years, however, also sees a continuing growth split between developed markets and pharmerging markets. The developed markets of North America, Europe, and Japan will see very modest single-digit spending growth, due to a combination of economic and healthcare austerity measures and the savings realized from the growing availability of lower cost generic versions of brands following their patent expiry. Many (but not all) leading pharmerging markets, in contrast, show much higher double-digit growth rates due to a combination of economic growth, demographic and epidemiologic changes, and improved state and private insurance funding for healthcare and medicines.

Across the major developed markets, uncertainty exists to an unusual extent. The last five years in Europe have seen greater adoption of generics and more restrictive policies that have made patients in almost all European countries less likely to gain access to innovative medicines. In the next five years, whether Europe sees a widespread, patchy or severely limited economic recovery will have a profound impact on the overall contribution this important group of developed markets makes to overall innovative medicines spending.

Meanwhile, in the U.S. the next five years will see the greatest impact of the implementation of the Affordable Care Act. With it, this brings uncertainty ranging from the level of enrollment of the currently uninsured to the speed with which the payment system changes from one based on fee-for-service, to one based on performance and patient outcomes. The rapid shifts in service delivery including the corporatization of medical care has yet to fully play out, including the relative negotiating power between payers and providers. Such structural changes will impact medicine spending, though the direction and magnitude of the impact is difficult to predict with certainty.

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In Japan, the key variable driving different scenarios is the successful establishment of an effective generic market, driven by the Japanese Ministry of Health, Labour and Wealth's goal of increasing generic volume as a percentage of generic and listed drugs to 60% in 2018. By taking on this challenge, Japan aims to achieve a more rapid increase in generic utilization levels than has previously been achieved in any country.

Medicines spending growth in the IMS Health-defined pharmerging markets is very heavily influenced by the prognosis for the Chinese market, as the largest and one of the fastest growing emerging markets for prescription medicines. Chinese healthcare provision is in the process of massive expansion, with the goal being universal healthcare coverage by 2020. During this huge transformation, it is inevitable that segments of the medicines market will also transform. The most positive outcome of current change would be the development of a much larger high quality, low unit price locally-sourced medicines market, with a compensatory growth in the protected innovative medicines sector, funded by a rise in private health insurance.

Innovation, the ultimate engine of growth for the global provision of medicines, will see a revival of activity through 2017, with increases in the number of global innovative launches since 2010. The nature of these launches will also change – more specialty medicines, including an increasing number of very small patient population orphan drugs - will be launched, with a commensurate decline in the number of new medicines entering the traditional sector. This shift is driven by a range of factors, including the level of satisfaction with existing options for treating many diseases and conditions, leaving little or no room for expensive new medicines with only minor incremental benefits. This is in contrast with continued unmet needs in many serious diseases treated in the specialist sector, such as cancer. This has turned the focus of research and development activity towards the specialty medicines sector, with more than half of research projects at all stages from pre-clinical to late clinical development falling into that category, and one third or more of all projects at all stages being biologic.

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Current innovative launches are yielding significant transformations in some disease areas, including the development of new oral disease-modifying agents in the injectable-dominated treatment of rheumatoid arthritis, new therapies in cystic fibrosis highly targeted to specific patient sub-populations in an already small patient population area, and significant advances in the treatment of melanoma and prostate cancer. In addition, developments in the affordability or availability of existing agents can transform the treatment of disease in pharmerging markets; countries such as South Africa and Laos have recently adopted extensive and influential vaccination programs in girls for human papillomavirus to prevent cervical cancer. In countries where access to regular cancer screening and treatment may be limited or unavailable, the impact of such a vaccination program could be even more profound than in developed markets.

There is still work to be done. An analysis of the most significant diseases and conditions in terms of disability adjusted life year burden shows that the greatest research and development activity maps closely to the diseases and conditions that are significant burdens in developed markets. There are significant deficits, though, in research activity in several disease areas such as malaria which have a high overall global burden, driven by the needs of populations in emerging markets. Progress is being made, but the right combination of incentive and spend still needs to be pursued in order for medicines to play their full potential role in improving healthcare globally.

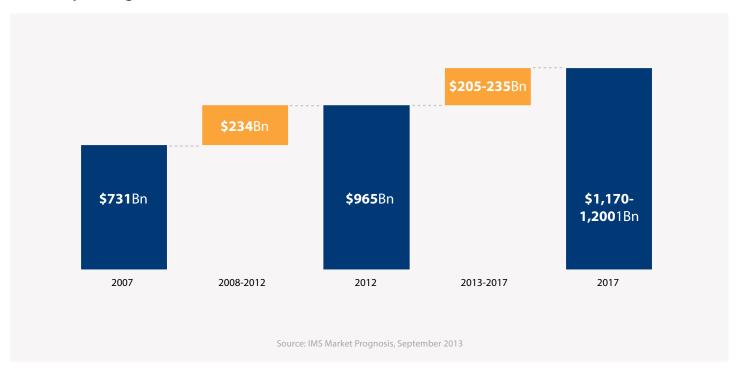
### Global spending on Medicines

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

- Medicine spending per capita and growth rates are starkly different between high income countries and those with mean income under \$25,000 per capita.
- Annual growth in spending levels will reach a low point in 2013, followed by increased growth particularly in developed markets.
- Spending levels on medicines for specific disease areas will still differ significantly between mature and pharmerging markets in 2017.
- A growing share of all medicines are biologic, with biosimilars and non-original biologics now taking a small share of the total market for biologic products.

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

#### Global Spending and Growth, 2008-2017



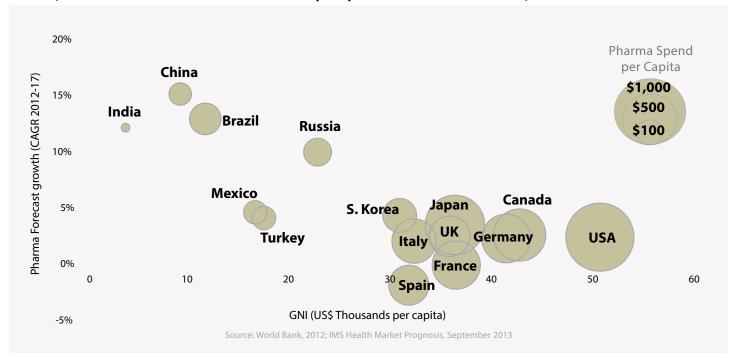
- Spending on medicines globally is expected to reach \$1Tn in 2014 and exceed \$1.17Tn by 2017.
- The absolute global spend for pharmaceuticals will increase by \$230-260Bn on a constant dollar basis, compared to \$217Bn in the past five years; using variable exchange rates, absolute growth is expected to be \$205-235Bn, compared to \$234Bn in the prior five years.
- Off-invoice discounts and rebates are not reflected in these forecasts but are estimated to be \$125-135Bn in 2012, rising to \$190-200Bn by 2016, resulting in net global spending growth being overstated by 0.5-1.5% per year through 2017.
- The slowing growth in the next five years reflects reduced spending increases in many developed markets facing continued austerity measures.
- China's growth has also been revised down following a slow down in GDP growth prospects.
- Medicine spending levels are also affected by launches of new products which are typically smaller, more specialty and niche products than in the past; at the same time, patent expiries of many small molecule products have successfully contained spending growth for traditional medications in developed markets.

#### Chart notes:

Spending in US\$ with variable exchange rates. Charted growth from 2008-12 and 2013-17 include impacts of exchange rate variability. In 2008-12, exchange rates contributed \$17Bn to growth. In 2013-17, they are expected to contribute approximately -\$28Bn.

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

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



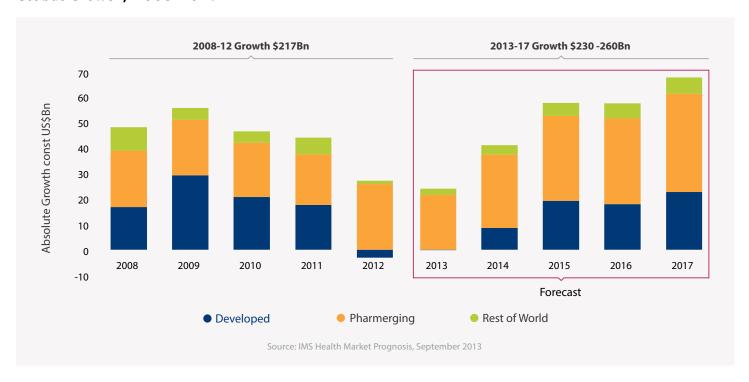
- In high GNI countries medicine spend levels have been contained or reduced due to patent expiries and growing emphasis on utilization of generics, particularly for many of the chronic diseases treated in primary care.
- Spending level increases in high income countries are primarily driven by specialty medicines and diabetes treatments.
- Pharmaceutical spend will continue to be targeted for cost containment in these countries, but as the peak of small molecule genericization passes - and without the prospect of significant cost relief from biosimilars or non-original biologics - increasing focus on containment of spending on innovative medicines can also be expected.
- In countries with income under \$25,000 per capita, higher levels of spending growth will be driven by increased diagnosis and treatment rates and a change in the nature of the disease burden from acute to chronic disease.
- These countries have a higher proportion of spend devoted to generics; however prices, particularly in out-of-pocket markets, can be high.
- Governments in these countries are typically committed to expanding access to healthcare in their populations, although the implementation of this has often been slow.

#### Chart notes:

GNI (Gross National Income) is based on Purchasing Power Parity (PPP)

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

#### Global Growth, 2008-2017



- In 2012, the developed markets in aggregate reduced their medicine spending for the first time, due to a raft of patent expiries and austerity measures, along with policy changes to increase generic penetration.
- Growth in developed markets will rebound from around negative \$3Bn in 2012 to \$20-25Bn by 2017, even as the European economic recovery lags that of the U.S. and Japan.
- The U.S. will resume increased spending levels in 2014 after 2 years of reduction, due to expansion of healthcare access and lower patent expiry levels.
- Growth in pharmerging markets will increase from \$26Bn in 2012, to \$30-50Bn in 2017, primarily due to increased access to medicines as infrastructure and health systems evolve.

#### Chart notes:

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

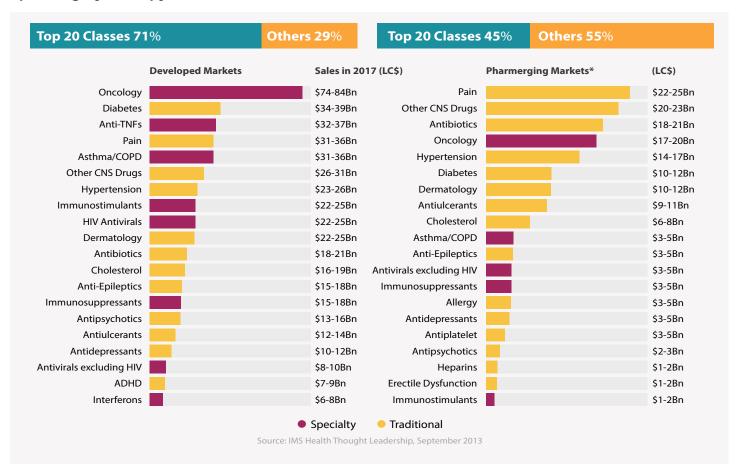
Pharmerging: Tier1: China. Tier 2: Brazil, Russia and India. Tier 3: Mexico, Turkey, Venezuela, Poland, Argentina, Saudi Arabia, Indonesia, Colombia, Thailand, Ukraine, South Africa, Egypt, Romania, Algeria, Vietnam, Pakistan and Nigeria.

Growth in Constant US\$, excludes the impact of exchange rate changes which are expected to have approximately -\$28Bn impact by 2017.

For Argentina & Venezuela, growth was measured using US\$ with variable exchange rates instead of US\$ with constant exchange rates in order to account for hyperinflation in those countries.

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

#### Spending by Therapy Area in 2017



- Populations in developed markets are increasingly aged and obese, driving spend in areas such as oncology and diabetes due to high prevalence; this effect is beginning to become apparent in pharmerging markets as well.
- Specialty pharmaceuticals that treat complex, serious diseases and are often administered by specialist doctors and in hospitals, will grow in importance in developed markets, while spending in pharmerging markets is driven more by traditional therapy areas.
- In developed markets spending is concentrated in the top 20 classes to a much larger extent than in pharmerging countries.

#### Chart notes:

Spending in US\$ with constant exchange rates (Q2 2013)

\*În Brazil and China, most HIV Antivirals are distributed through the donor market, which contributes to this data being underrepresented in IMS audits, which are typically collected through retailers and distributors. Therefore they have been omitted from the analysis in pharmerging markets.

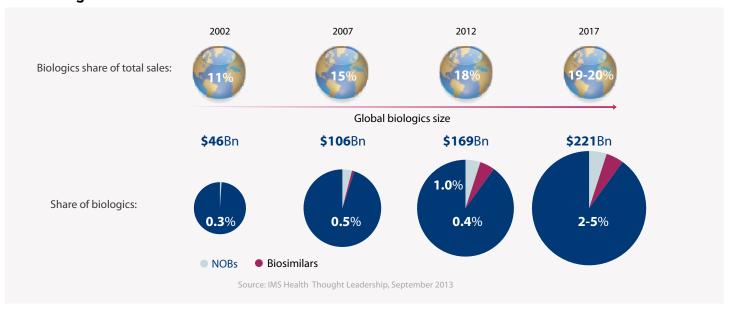
Specialty therapies are defined by IMS as products which are often injectable, high-cost, biologic or requiring cold-chain distribution. They are mostly used by specialists, and include treatments for cancer, other serious diseases, and often involve complex patient follow-up or monitoring.

Therapy Forecasts from IMS Health Therapy Prognosis Global September 2013 adapted by IMS Health Thought Leadership to represent global sales and to include additional therapy classes.

Abbreviations: ADHD: Attention-Deficit Hyperactivity Disorder; CNS: Central Nervous System; COPD: Chronic Obstructive Pulmonary Disease; HIV: Human Immunodeficiency Virus; TNF: Tumor Necrosis Factor.

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

#### The biologics market



- Biologic agents will continue to outpace overall pharma spending growth and are expected to represent 19-20% of the total market value by 2017.
- Biologics growth is driven by Monoclonal Antibodies (MABs) and human insulin, with four out of the top five biologics in 2012 being MABs.
- Development and production of biologics both branded and generic is increasingly competitive with a broad range of players, from small to large pharma companies now attracted to the market.
- In many countries with less rigorous IP protection laws we have seen a recent surge of NOBs.
- The price premium typically associated with biologics has turned them into an obvious target for government savings in some markets and consequently biosimilar pathways have been defined in Europe, U.S., and increasingly in pharmerging markets in an effort to encourage lower cost competition.
- In pharmerging markets, both governments and patients struggle to pay for biologics and hence NOBs, encouraged by market demand and government policy, have grown very quickly.
- To date, biosimilars account for less than 0.5% of the value of the mature markets biologic spend, whereas in pharmerging markets, non-original biologics are over 10% of all biologics spend.

#### Chart notes:

Biologic molecules are complex macromolecules with some form of polymer structure. They can be purified from naturally derived substances, produced by recombinant DNA technology or chemically synthesized. Biosimilars are defined as non-original biologic copies of innovative brands that have been approved by a dedicated regulatory pathway while non-original biologics (NOBs) are copies that have not been approved through such a dedicated pathway and generally did not undertake stringent comparability and bioequivalence studies.

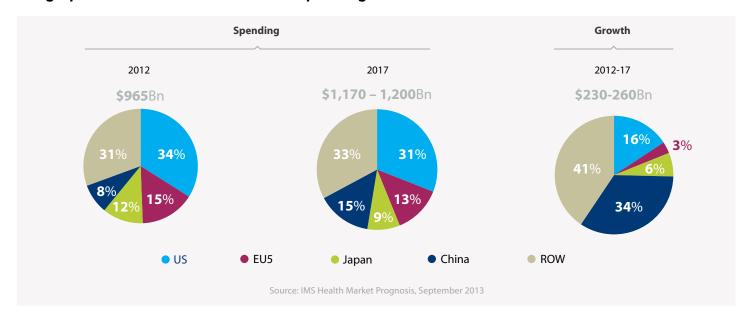
### Key Countries and alternative scenarios

The U.S., EU5 (the aggregate of Germany, France, Italy, U.K. and Spain), Japan and China will account for 67% of global spending on medicines in 2017, contributing 59% of the global growth in the 5 year period to 2017.

- In each of these countries, relatively high levels of uncertainty exist in forecasting future spending on medicines, primarily related to macroeconomic factors and the impact of evolving healthcare reforms:
  - In the U.S., the direct and indirect consequences of further implementation of the Affordable Care Act in terms of structural changes in healthcare delivery and payment systems will have a potentially significant impact on spending for medicines to 2017.
  - In the EU5 countries, the after effects of the economic crisis combined with the velocity of recovery will impact the potential for innovative pharmaceuticals to be accessed by patients and the reimbursement level for these medicines.
  - In Japan, the impact of governmental reforms will significantly impact the country's ability to generate savings through increased utilization of lower cost generics and to fund higher cost innovative medicines.
  - In China, the quality of healthcare and spending on medicines over the next 5 years will evolve in accordance with the level of implementation of healthcare reform.
- Modeling the impact of scenarios that are alternative to the base-case outlook provides a
  potential range of medicine spending levels for 2017.

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

#### Geographic distribution of medicine spending



- Developed markets are expected to grow much less in the next five years than in the last five, due to patent expiries, the sustained impact of the global economic crisis, and the increasingly specialist nature of many new medicines, coupled with a cautious approach to the uptake of innovation in Europe.
- U.S. growth will remain at historically low levels, and the country will have a smaller share of the global market through 2017, but a constant share of developed markets.
- Growth in spending among the EU5 countries will be negligible in aggregate as governments continue to apply a range of austerity measures across the region designed to shift usage to generics and restrict use of innovative launches.
- Japan's share of the growth of developed markets is expected to increase due to a combination of a weak generic market and a significantly improved environment for the uptake of innovative medicines.
- China's growth will remain robust, though lower than previously forecast as the macroeconomic outlook weakens and measures are taken to constrain expansion of medicine spending.

#### Chart notes:

Spending in US\$ with variable exchange rates.

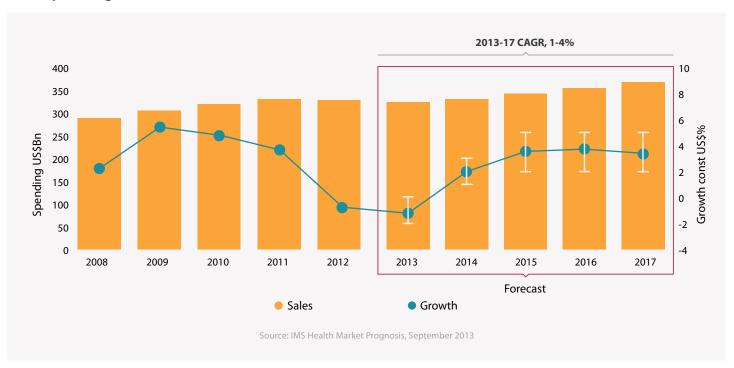
Growth in US\$ with constant exchange rates.

EU5 includes Germany, France, Italy, Spain and UK.

In 2008-12, exchange rates contributed \$17Bn to growth. In 2013-17, they are expected to contribute approximately -\$28Bn.

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

#### U.S. Spending and Growth, 2008-2017



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

#### Chart notes:

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

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

Spending in US\$ with variable exchange rates.

Growth in US\$ with constant exchange rates.

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

#### **Healthcare Reform Implementation**

#### **SCENARIO 1:**

### Reforms lead to expanded access and performance-based healthcare system

- Almost full enrollment of the currently uninsured according to original government estimate
- Rapid movement toward performance-based payment system and corporatization of healthcare delivery

#### **Implications for Medicine Spending**

- Increased demand for medicines resulting from increased enrollment, screening, removal of caps, and management of existing conditions
- Cost-effective medicines with clinical value being used more extensively
- Continued premium placed on innovative medicines with strong clinical profile

Total spending on medicines in 2017: \$420-460Br

#### **SCENARIO 2:**

## Slow pace of change but some expansion in access and incremental changes to payment system

- Initial enrollment of currently uninsured 1/3 of target level, though improvement over time
- Payment system remains largely fee-for-service
- Uncertainty of political support slows or stalls reform implementation

- Modest incremental demand for medicines and primarily for generics
- Incremental pressure by payers and employers limit price increases to current levels at most
- Positioning of competitive medicines primarily based on price
- Newly launched medicines see slow uptake and limited commercial returns

Total spending on medicines in 2017: \$350-380Br

#### **SCENARIO 3:**

### Implementation leads to major unintended consequences and change

- Exchanges fail to enroll "young invincibles" and insurance model fails
- Employers move large number of employees to private exchanges
- Significant decline in healthcare utilization for prevention and treatment of chronic illness

- Decline in medicine demand volume
- Major reduction in formulary access for insurance plans or major cost reductions from manufacturers
- Limited acceptance of new medicines with price premium

Total spending on medicines in 2017: \$300-320Br

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

Top 5 Europe Spending and Growth, 2008-2017



- Pharmaceutical spending growth in the EU5 is expected to be 0-3% for the period 2013-2017, compared to 2.4% for 2008-12.
- Higher growth is anticipated in Germany and the U.K., compared to Spain, Italy, and France as these were already generically efficient markets. Loss of exclusivity had translated to lower spending in many primary care therapy areas, and measures to contain medicines spend, such as the adoption of Health Technology Assessment (HTA), were already implemented prior to the financial crisis.
- All five major European countries have seen
  a lower uptake of new medicines in the most
  recent five year period; Germany and the U.K. had
  strong uptake controls prior to the financial crisis,
  and see the least deterioration.
- Direct actions by governments are expected to be taken to control spending growth or in some cases make real reductions, particularly in the hospital sector.

#### Chart notes:

Chart shading indicates forecast, and forecasted growth shows point forecast and high-low ranges. Spending includes retail pharmacy and institutional drug spending tracked by IMS audits. Spending in US\$ with variable exchange rates.

Growth in US\$ with constant exchange rates.

# Alternative scenarios exist for Europe based on macroeconomic factors and the impact on use of innovative medicines

#### **Macroeconomic factors**

- · Europe resurgent
- · High productivity
- Consumer confidence up
- Reduced unemployment
- · Favorable financing conditions
- Patchy recovery
- North Europe recovers strongly while South Europe's economy continues to deteriorate
- Ongoing austerity
- Low productivity
- Stagflation
- High unemployment
- Net exports only source of growth

#### Implications for innovative medicines

- Use of innovative medicines is high across Europe due to widespread economic growth and more efficient use of generics where available
- Support for innovative medicines is sustained, and new launches thrive in some countries where economic growth injects funds and use of generics frees up budget
- Innovative medicines use is restricted and a hostile environment exists based on austerity measures limiting market access

#### **SCENARIO 1: Innovative Medicines Supported**

- Europe attains pre-economic crisis GDP growth levels led by high productivity in Germany creating a more
  positive, investment-friendly environment across Europe. Generic efficiency (conversion of molecules
  that have lost exclusivity to low cost generic versions) improves to Northern European levels in Southern
  Europe, a permanent legacy of austerity measures.
- Spending on innovative products in 2017 is \$31-34Bn

#### **SCENARIO 2: Innovative Medicines Sustained**

- Europe's recovery is segmented into two regional clusters: fast-growing Northern Europe vs. recession plagued Southern Europe. Northern Europe grows as per Scenario 1, Southern Europe follows Scenario 3. Medicines management inefficiencies and local industry protectionism ensure that generic efficiency fails to improve in Southern Europe, and a combination of limited savings and poor economy motivates payers to severely limit new product entry in these countries. Increased use of innovative medicines will be limited to Northern European countries. In order to access Southern European countries, different price strategies will have to be considered which could lead to increased parallel trade and price erosion in Northern Europe due to international reference pricing.
- Spending on innovative products in 2017 is \$28-31Bn

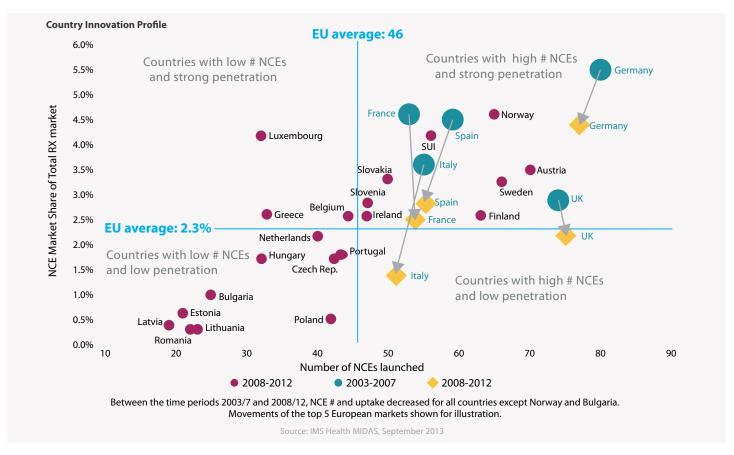
#### **SCENARIO 3: Innovative Medicines Restricted**

- Overall stagnation and a prolonged recession drives regulators and payers across the continent into even stricter austerity measures. Even in efficient markets, savings generated by genericization are not passed on to fund innovative launches. The worst case scenario is if Europe follows the Netherlands' blueprint, with high levels of genericization and low levels of innovation uptake.
- Spending on innovative products in 2017 is \$23-26Bn

#### Chart notes:

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

#### NCEs launched vs. Market Share achieved



#### **SCENARIO 1: Innovative Medicines Supported**

 Europe returns to being an easier environment for innovation uptake across the majority of countries, although an increasing proportion of specialist launches, and the development of a heavily genericized primary care sector will necessarily constrain the absolute size of many new products. Major European countries continue to be significant contributors to the first five years of global sales for most NCEs.

#### **SCENARIO 2: Innovative Medicines Sustained**

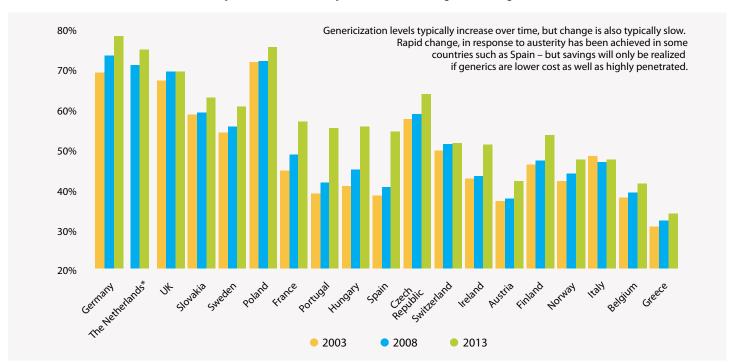
 Northern European countries will remain high priority in the international launch sequence while Southern European countries will see fewer innovative products entering the market. This divide will have implications for the European region as a whole which will see an increase in parallel trade for products, possible medical tourism for patients in Europe for therapy areas with high unmet need, and possibly civil unrest (already seen in Greece in 2010) due to limited access to medications.

#### **SCENARIO 3: Innovative Medicines Restricted**

New product launches will dramatically decrease due to ever increasing market access barriers, and a
consequent deprioritization of Europe in major multinationals' global launch agenda. The few products
that obtain access will see reduced market uptake levels, as the focus remains on reducing overall spend
rather than moving spend from older to newer agents.

# Innovation will depend on the ability of countries to generate enough savings to fund it through genericization

#### Generics volume share of unprotected European market by country



#### **SCENARIO 1: Innovative Medicines Supported**

 The "kick start" that generic markets in some countries received during austerity will continue with greater generic penetration, lower prices and cost savings realized in primary care. As economies recover, overall funding for healthcare will start to grow again, and a combination of greater efficiency and new funding will create a strong environment for the new, mostly primary care, innovation.

#### **SCENARIO 2: Innovative Medicines Sustained**

Northern European countries will continue to benefit from effective generic markets and efficient transfer
of savings from primary to specialist care, with an increase in the use of biosimilars, while Southern
European countries will continue to introduce aggressive austerity reforms encouraging the use of
generic products and the early entrance of biosimilars, but may struggle to realize savings if protectionism
prevents price cuts for older products from domestic medicines manufacturers.

#### **SCENARIO 3: Innovative Medicines Restricted**

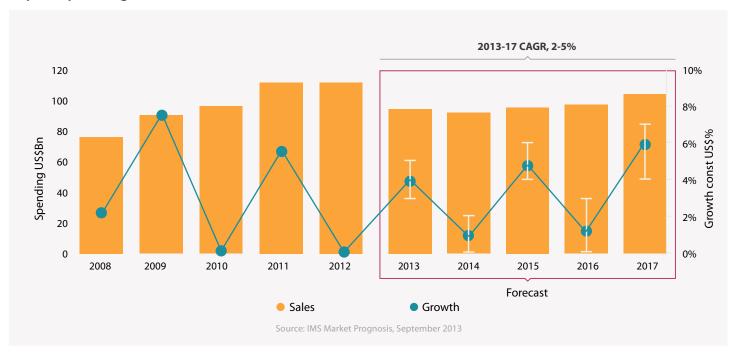
 Systemic austerity measures will be aggressively introduced in order to contain pharma growth to a minimum. Generic efficiency will be sought both in terms of value uptake and velocity.

#### Chart notes:

Volume measured in Standard Units. Unprotected Market: Never and No longer Protected Products \*Netherlands 2003 data not available.

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

#### Japan Spending and Growth, 2008-2017



- Forecast spending growth will be in the range of 2-5% with gradual increases, punctuated by biennial price cuts, which will lower growth in 2014 and 2016.
- The number of innovative new drugs and indications available to patients will increase, reflecting manufacturers' commitments made in return for access to premium pricing for new drug development and as part of reforms implemented in 2010.
- While Japan's total population will decline during this period, the number of retirees will increase, driving up demand for medicines.
- In April 2013, the Ministry of Health, Labor and Wealth (MHLW) announced a "Roadmap for further promotion of the use of generic medicines" with an explicit goal to increase the share that generic drugs have of the market to 60%, where share is defined as generic volume divided by the combined volume of the unprotected market.
- If the MHLW is successful, it would mean 2018 generic levels in Japan would be at a level similar to that of France and Spain.

#### Chart notes:

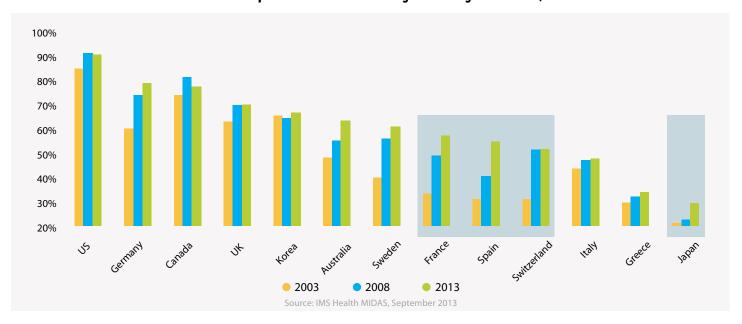
Chart box indicates forecast, and forecasted growth shows point forecast and high-low ranges.

Spending includes retail pharmacy and institutional drug spending tracked by IMS audits. Spending in US\$ with variable exchange rates. Growth in US\$ with constant exchange rates. Between 2013-2017, exchange rates are expected to contribute -\$24Bn to growth.

Unprotected Market: Never and No longer Protected Products.

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

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



#### **SCENARIO 1: Status Quo**

Current approaches to encouraging the use of generics continues as it has previously. The generic penetration of the unprotected market reaches just over 35% in 2017.

Savings of \$1-3Bn (1-3% of the total market) would be achieved.

#### **SCENARIO 2: Ramp Up in Effort and Results**

The MHLW ramps up its efforts to increase generic efficiency. The generic penetration of the unprotected market would reach 50%, a rise similar to one seen in Switzerland (2003 - 2008).

Savings generated would be \$6-8Bn (6-8% of the total market).

#### **SCENARIO 3: Historic Change**

The MHLW ensures its generic erosion forecast comes to pass. This places the generic penetration level for the unprotected market at 60% in 2017, which would be an unprecedented rise. This would disproportionately affect domestic Japanese-based manufacturers which account for over 80% of the unprotected market volume.

Savings of \$9-11Bn (9-11% of the total market) would be realized.

#### Chart notes:

Volume measured in Standard Units; Unprotected Market: Never and No longer Protected Products, MHLW: Ministry of Health, Labor and Welfare
Growth in US\$ with constant exchange rates.

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

#### China Spending and Growth, 2008-2017



- Pharmaceutical spending growth has been revised downward following a slowdown in GDP growth due to a loss in business confidence along with lower investment in the market.
- China's pharmaceutical market is expected to grow between 14% and 17% in the next five years.
- Efforts to expand the essential drug list together with the National Development and Reform Commission (NDRC) recent investigation into drug prices and cost might result in a cheaper off-patent original brand market.
- Volume-based growth will be driven by government efforts to improve healthcare and medical services, including expansion of insurance coverage to critical illness and increased use of private hospitals.
- A new revision of the National Reimbursement Drug List could result in a more comprehensive list of innovative products receiving reimbursement.

#### Chart notes:

Chart box indicates forecast, and forecasted growth shows point forecast and high-low ranges. Spending includes institutional drug spending tracked by IMS audits. Spending in US\$ with variable exchange rates.

Growth in US\$ with constant exchange rates.

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

#### **Reform implementation depth**

#### **SCENARIO 1:** Rapid rise of private insurance

- The rise of private insurance (30-50% uptake in urban areas) will fund >70% of cost for innovative drugs for critical diseases.
- Substantial increases in private hospitals will provide both higher quality healthcare and access to innovative drugs.
- The update of the NRDL in 2014 will increase the coverage of international drugs with price cuts expected to be <15%.</li>
- The EDL usage ratio, which means more local generics in Tier 2 and 3 hospitals, will remain limited.
- Single reimbursement price based on generic pricing will not be implemented.
- CGMP guidelines widely implemented leading to an improvement in the quality of local generics.

### SCENARIO 2: Moderate change in medicine reimbursement

- Some private insurance (30% uptake or less) will fund 50% of the innovative drugs cost for critical diseases.
- There will be some increase in the number of private hospitals to provide higher quality healthcare but access to new innovative products will be contained.
- The NRDL list will be updated in 2014 but with some delays in implementation and price cuts >15%.
- The actual usage ratio of EDL will increase to be closer to governments targets.
- Single reimbursement price based on generic pricing will be implemented in some provinces.
- CGMP guidelines will be implemented to a lesser degree.

#### **SCENARIO 3:** Delays and limited change

- Private insurance will not take off; negligible uptake and funding of new products.
- The NRDL update will be delayed and coverage for innovative products will be limited; the NDRC will implement aggressive price cuts across the board for branded products.
- Despite government efforts to encourage foreign investment in private hospitals, barriers will remain and only a small number of private hospitals will emerge.
- The extensive use of the EDL will result in losses due to tendering of international off-patent brands.
- Single reimbursement price based on generic pricing will be widely implemented.
- · CGMP is sparsely implemented to minimal effect.

### 2017 implications for medicines and spending growth

- Quality generics will enjoy strong representation in primary care institutions and lower tier cities, while international off-patent drugs will retain a price premium and will be widely used in large hospitals and big cities.
- The rise of private insurance will fund on-patent branded products prior to their inclusion on the state reimbursement list (which may take years and be a relatively low level of access).
- The rise of private insurance together with a faster regulatory system will result in an expanded on-patent branded market for international companies.

#### CAGR 2013-2017: \$164-187Bn

- The development of the private insurance market will make some inroads. However, this will not be enough to build a stronger, privately-reimbursed innovative sector.
- A small off-patent brand price premium will result in some savings being made through generic substitution.

#### CAGR 2013-2017: \$157-179BN

- China will fail to build a high quality locally-sourced off-patent segment.
- Private insurance failure will perpetuate the funding gap for innovative agents.
- International off-patent drugs will have a significant drop in usage as the government will only reimburse them at a price equivalent to a local generic.
- The market will remain very difficult for innovative agents, which will have to wait years for a possible NRDL inclusion.

#### CAGR 2013-2017: \$144-164BN

#### Chart notes:

NRDL: National Reimbursement Drug List; EDL: Essential Drug List; NDRC: National Development and Reform Commission; CGMP: China Good Manufacturing Practice

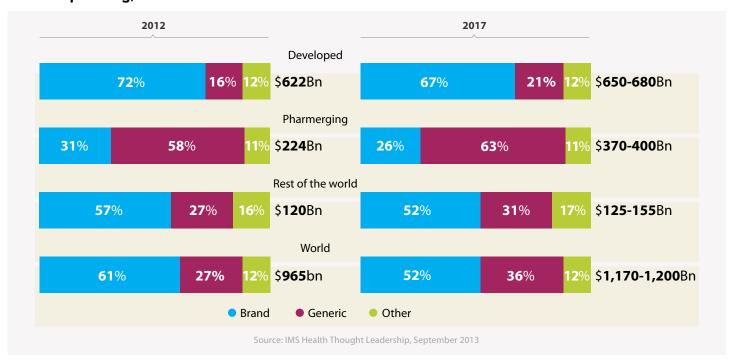
### Mix of branded and generic medicines

The mix of total global spending on medicines will shift toward generics over the next five years, rising from 27% to 36% of the total by 2017, even as brands will continue to account for more than two thirds of spending in developed markets.

- The mix of total global spending on medicines will shift toward generics over the next five years, rising from 27% to 36% of the total by 2017, even as brands will continue to account for more than two thirds of spending in developed markets.
- The use of generics will be at its highest in pharmerging markets where 63% of the spending will go to generic products.
- Absolute spending on brands in developed markets will decline by \$113bn over the next five years due to losses of exclusivity, slower uptake of new medicines and more restrictive access approaches.
- Traditional pharmaceuticals typically used to treat chronic diseases in primary care will increasingly be dispensed as generics and as a result total spending will only rise 5% by 2017 in developed countries.
- Conversely, patients in pharmerging markets will increasingly have access to affordable generics for primary care treatments and total spending on traditional pharmaceuticals in these markets is expected to rise from \$199Bn in 2012 to \$336Bn in 2017.
- Specialty medicines used for conditions that require complex treatment and usually command higher prices – will be the biggest driver of branded drug spend growth and most apparent in developed markets where spending is expected to increase by 30% over the next five years.
- Use of specialty medicines in pharmerging markets is at very low levels, but the costs are expected to rise by nearly 90% between 2012 and 2017.

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

#### Global Spending, 2012 and 2017



- Pharmaceutical spend in developed markets will continue to be dominated by brands as, frequently generics are significantly lower in unit cost, and developed markets will continue to comprise the majority of innovative new brand spend.
- Products losing patent protection in developed markets will drive a slight increase in spend on generics to 21% in 2017.
- Generics will continue to dominate growth in spending in pharmerging markets and will account for 63% of the total market at the end of the forecast period.
- While spending on brands in pharmerging markets will grow in absolute terms, their relative share will decline from 31% to 26% by 2017, reflecting more rapid expansion of access to generics compared to the uptake of innovative branded medicines.

#### Chart notes:

Segmentation Forecasts from IMS Market Prognosis September 2013 adapted by IMS Health Thought Leadership to represent global sales. Spending in US\$ with variable exchange rates.

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

#### **Developed Markets Patent Expiry Exposure and Impact**



- Patent expiries will save payers in developed markets \$113Bn in the next five years, and primarily in the U.S. This will be offset by \$40Bn of expected generic spending, resulting in a \$73Bn patent "dividend" in 2017.
- In the U.S., \$83Bn, or 34% of 2012 brand spending, will shift to generics at dramatically lower prices.
- In other developed markets, the average brand spending exposed to generic competition will be 22%, except in Canada where 30% of spending will be exposed.

- Overall, exclusivity expiries in one or more of the developed markets will impact four of the top ten products, including Cymbalta®, Abilify®, Crestor® and Nexium®.
- Two-thirds of the \$123Bn of sales exposed to competition by patent expiries in the next five years will be in the U.S.
- The expected expiry impact does not include biologic products, which are subject to different regulatory rules for biosimilars, which are not expected to have a substantial overall impact on biologic spending in the next five years.

#### Chart notes:

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

Lower brand spending reflects the expected impact on drug spending in each year of patent expiries (including continuing impact from expiries in prior years). Pre-expiry spending consists of projected spending in the year prior to expiry. Estimates of protection expiry from information available as of June 30, 2013.

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

#### Traditional Spending between 2012 and 2017



- In the developed markets, spend on traditional medicines will grow by only 5% to 2017.
- Peak small molecule genericization during 2012/2013 has left a legacy of significantly lower unit costs for medicines in hypertension, dyslipidemia, peptic ulcer, depression and other high volume traditional medicines areas.
- This is particularly apparent in countries, such as the U.S., with high volume penetration of significantly lower cost generics, with the consequence that even though volume demand continues to rise for developed country primary care medications due to aging populations, cost growth has slowed considerably.
- In pharmerging markets, traditional medicine spending will continue to grow, by 69% to 2017, as the burden of chronic disease rises in these countries, and overall volume demand for the medicines used to treat these conditions increases significantly.
- The vast majority of traditional pharmaceuticals used in pharmerging markets will be generics and produced by local manufacturers, particularly in the largest markets of China, Brazil, Russia and India.

#### Chart notes:

Class Forecasts from IMS Market Prognosis September 2013 adapted by IMS Health Thought Leadership to represent global sales. Spending values in constant US\$.

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

#### Specialty Spending between 2012 and 2017



- Spending growth on newer innovative specialty medicines will be one of the single biggest cost concerns for developed market healthcare systems.
- Innovative drug launches will be dominated by specialty medicines, reflecting a development pipeline that has an abundance of specialty products at all stages and particularly in the field of oncology.
- Spend on specialty medicines in developed markets will increase by 30% through 2017, driven by this strong pipeline, and with limited impact of patent expiries and introduction of lower cost biosimilars or non-original biologics.

- Spend on specialty medicines is forecast to grow by nearly 90% in pharmerging markets by 2017 from a very low base.
- Rapid GDP growth in pharmerging markets will allow for increasing levels of disposable income, and improved State coverage will also fund growth in specialty sales.
- Increasingly aged populations will drive demand for oncology medicines, where spend has increased particularly rapidly.
- In the pharmerging markets overall, specialty medicines spend remains low, with access, particularly to the latest medications, a continuing issue for patients in these countries.

#### Chart notes:

Specialty therapies are defined by IMS as products which are often injectables, high-cost, biologic or requiring cold-chain distribution. They are mostly used by specialists, and include treatments for cancer, other serious diseases, and often involve complex patient follow-up or monitoring. Class Forecasts from IMS Market Prognosis September 2013 adapted by IMS Health Thought Leadership to represent global sales. Spending in US\$ at constant exchange rates.

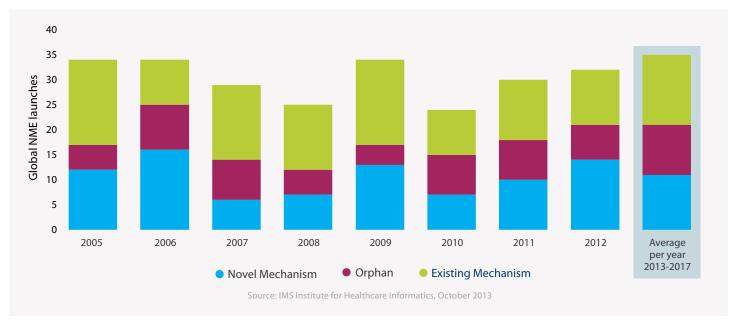
### Transformations in disease treatment

The current pharmaceutical industry's research and development pipeline holds the potential to transform care across a wide range of disease areas.

- An increasing number of new molecular entities (NMEs) are expected to be launched each year, a continuation of the trend that started in 2010, though similar to the levels launched in the mid-2000's.
- The majority of the new launches will address unmet needs in specialty disease areas, orphan diseases, and target smaller patient populations and include medicines that could transform treatment in rheumatoid arthritis, cystic fibrosis, melanoma, breast and ovarian cancer, multiple sclerosis, heart failure, hepatitis C, and malaria.
- Recent and near-term launches of new medicines mainly address the disease profile of patients in high income countries and while a growing number of these diseases are also prevalent across the globe, several of the most burdensome diseases have few new treatment options, including malaria, neonatal sepsis and tuberculosis.
- Access to new medicines varies by country and disease, and while most NMEs are quickly available in mature markets, patients in pharmerging markets typically face fewer of the recently launched treatment options.

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

#### **Global Launches of New Molecular Entities**



- New product launches are forecast to average 35 per year over the next five years, similar to the level in the mid-2000s.
- These launches will include more specialty drugs, orphan drugs and medicines for diseases affecting small patient populations.
- The expansion of treatment options resulting from newly launched medicines will bring increased scrutiny by payers, providers and patients as to the value they bring either in improving patient outcomes or lowering total cost of care for the patient.
- Future new launches will also bring greater emphasis on so-called ultra-orphan drugs for diseases with extremely small patient populations.

#### Chart notes:

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

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

## Treatment will be transformed by new and existing mechanisms

#### Selected Product Launches 2013-2017

Disease Area	Existing Mechanisms	New Mechanisms
Rheumatoid Arthritis	<ul> <li>JAK inhibitor (adelatinib VX-509, baricitinib, fostamatinib)</li> </ul>	
Cystic Fibrosis	Transmembrane conductance regulator corrector (Lumacaftor, VX-661)	Ribosome interaction for readthrough of nonsense mutations (NM) in NM cystic fibrosis (Ataluren )
Melanoma	<ul> <li>BRAF kinase inhibitor (dabrafenib)</li> <li>MEK kinase inhibitor (trametinib)</li> <li>Program cell death MAB (nivolumab, lambrolizumab)</li> </ul>	Oncolytic HSV vector (talimogene laherparepvec)*
Breast cancer	<ul><li>MAb (trastuzumab emtansine)</li><li>Cyclin dependent kinase inhibitor (palbociclib)</li></ul>	
Ovarian cancer	<ul><li>Folate-targeted drug conjugate (vintafolide)</li><li>VEGFR inhibitor (nintedanib)</li></ul>	PARP inhibitor (olaparib)
Multiple sclerosis	Lipophilic molecule (dimethyl fumarate)	
Heart Failure	Human peptide synthetic version (ularitide)	<ul> <li>Human relaxin-2 hormone recombinant (serelaxin)</li> </ul>
Hepatitis C	<ul> <li>NS3/4A proteinase inhibitor (asunaprevir, sofosbuvir, simeprevir)</li> </ul>	
Malaria		<ul> <li>RTS,S Adjuvant System (P. falciparum / P.Vivax circumsporozoite protein)</li> </ul>

Source: IMS Institute for Healthcare Informatics, September 2013  $\,$ 

- There are approximately 641 products in the late stage pipeline, a third of which are biologics and more than half are specialty drugs.
- Among the medicines expected to launch by 2017 are several based on existing mechanisms of action for the treatment of hepatitis C, multiple sclerosis and breast cancer, and which offer the potential to deliver better efficacy, safety or convenience of administration.
- Expected near-term launches also include several medicines with new mechanisms of action in disease states such as rheumatoid arthritis, cystic fibrosis and various types of cancer, which have the potential to transform disease treatment, though not every therapy will become available or achieve its ultimate clinical aims.

#### Chart notes:

Table includes selected New Molecular Entities (NME) expected to be launched between 2013 and 2016. An NME is the first commercial launch of a novel therapeutic entity. \* Immunotherapeutic cancer vaccine.

Abbreviations: JAK: janus-like kinase inhibitor; MAb: monoclonal antibody; PARP: Poly ADP ribose polymerase; NS3/4A: non-structural protein 3/4A; HSV: herpes simplex virus; VEGFR: Vascular Endothelial Growth Factor Receptor; BRAF: v-raf murine sarcoma viral oncogene homolog B; MEK: mitogen-activated protein kinase enzymes: RTS/S: recombinant protein that fuses a part of the P. falciparum circumsporozoite protein with the hepatitis B virus surface antigen.

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

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

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

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

#### Commonality of interest

- Diseases that are among the most burdensome in high income countries as well as globally have higher numbers of medicines in the pipeline or recently launched.
- The average number for each disease area with commonality between high income countries and the entire world is 63 in the late-stage R&D pipeline and 48 new drug launches over the past decade.
- For diseases mainly prevalent in emerging markets, such as malaria, neonatal sepsis and diarrhea, there tend to be fewer products in the pipeline (26 on average) and fewer launches (11 on average).

#### Chart notes:

DALY: Disability-Adjusted Life Year calculated by the Institute for Health Metrics and Evaluation (IHME).

High Income Countries (as defined by IHME): US, Canada, Japan, South Korea, Singapore, Brunei, Germany, France, UK, Italy, Spain, Andorra, Austria, Belgium, Cyprus, Denmark, Finland, Greece, Iceland, Ireland, Israel, Lichtenstein, Luxembourg, Malta, Monaco, Netherlands, Norway, Portugal, San Marino, Sweden, Switzerland and Vatican City. The number of products in the Pipeline is defined as the number of compounds currently at a life cycle stage between Phase II clinical trials and Registration. Launches measured between 2004-2013; Pipeline measured between 2013-2017.

IHD: Ischaemic Heart Disease; COPD: Chronic Obstructive Pulmonary Disease; LRI: Lower Respiratory Infection; BPH: Benign Prostatic Hyperplasia.

## The availability of new medicines varies widely by country and disease

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

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Country	world	USA	Japan •	Germa	krance	Spair ©	reland	71k	Canada (••)	South Kor	Brazil	Russia	Mexico	China
Total	146	94	59	88	65	70	65	88	63	52	45	42	38	37
% of Total		64	40	60	45	48	45	60	43	35	31	29	26	25
Anti-infectives & Antivirals	16	6	10	7	6	5	3	6	7	3	4	4	1	4
Arthritis/Pain	6	3	3	3	2	3	2	3	2	2	1	1	1	2
Blood	8	6	2	3	3	3	3	5	3		1	2	1	1
Cardiovascular	17	12	8	13	8	11	10	12	8	9	8	5	9	7
CNS	20	13	5	13	10	10	9	12	8	5	5	5	9	5
Dermatology	4	2	2	2	1	2	2	2	1	2	2	1	1	1
Diabetes	5	3	4	3	3	4	3	4	3	3	4	4	4	4
Gastrointestinal	9	4	1	3	2	3	2	4	4	2	1	1	3	
GU & Hormones	10	4	3	5	1	5	5	4	1	7			1	
Immune System	11	9	3	10	7	8	8	9	6	3	3	5		3
Metabolic	2	1	1	1	2	1	1	1	1					
Oncologics	23	19	8	18	16	9	11	19	14	9	8	9	2	6
Ophthalmics	5	4	3	2	1	1	1	2	1	2	3		2	
Other	3	1	1							1		1		
Respiratory	6	3	4	4	3	4	4	4	3	3	4	3	3	3
Vaccines	1	1	1	1	1	1	1	1	1	1	1	1	1	1

Source: IMS Institute for Healthcare Informatics, October 2013

- The countries with the highest availability of all New Molecular Entities (NMEs) launched 2007-11 continue to be the higher income countries, including U.S., Germany, U.K., Spain, France and Italy.
- Pharmerging markets have a lower percentage of possible NMEs across all medicine classes, with the exception of vaccines and diabetes.
- This continuing differential is a product of slow pharmerging regulatory processes, actual and perceived relative commercial potentials, and consequent launch country prioritization by pharmaceutical companies.
- About 35% of NMEs launched in at least one country are not available in the U.S., often due to the medicines being focused in therapy areas with low patient need such as anti-infectives and antivirals.
- Compared to a comparable analysis of the availability in 2011 of the 2006-10 cohort of NMEs, China has achieved the biggest increase in availability – from 10% of the launch cohort in 2011, to 25% availability in 2012.

#### Chart notes:

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

## Notes on sources & definitions

This report is based on the IMS products and services detailed in the panel below and the research of the IMS Institute for Healthcare Informatics.

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

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

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

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

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

#### **Definitions and conventions:**

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 2013) exchange rates.

Products are categorized as brands, generics or other using IMS's proprietary MIDAS™ market segmentation methodology.

Developed markets are defined as the U.S., Japan, Top 5 Europe countries (Germany, France, Italy, Spain, UK), Canada and South Korea.

Pharmerging countries are defined as those with >\$1Bn absolute spending growth over 2013-17 and which have GDP per capita of less than \$25,000 at purchasing power parity (PPP). Tier 1: China; Tier 2: Brazil, India, Russia; Tier 3: Mexico, Turkey, Venezuela, Poland, Argentina, Saudi Arabia, Indonesia, Colombia, Thailand, Ukraine, South Africa, Egypt, Romania, Algeria, Vietnam, Pakistan and Nigeria.

33 **APPENDIX 1** 

### Global country rankings

Rank	2007	Index
1	US	100
2	Japan	27
3 🛕	France	13
4 <b>V</b>	Germany	13
5 🛕	China	11
6 <b>V</b>	Italy	8
7	UK	7
8 🛕	Spain	7
9 <b>V</b>	Canada	7
10	Brazil	5
11	Mexico	4
12	Australia	4
13	South Korea	3
14 🛕	Russia	3
15 🛕	Turkey	2
16 <b>V</b>	India	2
17 🔻	Netherlands	2
18 🔔	Greece	2
19 🛂	Poland	2
20 🔻	Belgium	2

Rank	2012	Index
1	US	100
2	Japan	27
3 🛕	China	25
4	Germany	13
5 <b>V</b>	France	11
6 🛕	Brazil	8
7 <b>V</b>	Italy	8
8 <b>V</b>	UK	7
9	Canada	7
10 🛂	Spain	6
11 🛕	Russia	5
12	Australia	4
13 🛕	India	4
14 🔻	Mexico	4
15	South Korea	3
16 🛕	Venezuela	3
17 🔻	Turkey	3
18 🔔	Poland	2
19 🛕	Argentina	2
20	Belgium	2

Rank	2017	Index
1	US	100
2 🔔	China	45
3 <b>V</b>	Japan	29
4 🛕	Brazil	13
5 <b>V</b>	Germany	13
6 <b>V</b>	France	10
7	Italy	8
8 🛕	Russia	7
9 <b>V</b>	UK	7
10 <b>V</b>	Canada	7
11 🛕	India	6
12	Spain	5
13 🔔	Mexico	4
14 🔔	South Korea	4
15	Australia	4
16 🔔	Turkey	3
17 <b>V</b>	Venezuela	2
18 🔔	Argentina	2
19 🛕	Indonesia	2
20 🛂	Poland	2



Change in ranking over prior 5 years

Source: IMS Market Prognosis, September 2013

#### Appendix notes:

Ranking in all years based on spending in constant US\$ at Q2 2013 exchange rates. Index in each year based on ratio of country spending to U.S. sales (in constant US\$) in the year. APPENDIX 2 34

### Region & leading country spending

LIGHT W	2242	2000 2010	2045	2012 2015
US\$ billions	2012	2008-2012	2017	2013-2017
Global	965.4	5.4%	1,170-1,200	3-6%
Developed	621.6	2.9%	650-680	1–4%
U.S.	328.2	3.0%	350-380	1–4%
EU5	148.7	2.4%	140-170	0-3%
France	36.7	0.3%	30-40	(-2)-1%
Germany	42.1	3.8%	41-51	1-4%
Italy	26.2	2.9%	23-33	0-3%
Spain	19.9	1.7%	13-23	(-4)-(-1)%
U.K.	23.9	3.4%	20-30	1-4%
Japan	111.3	3.0%	90-120	2-5%
Canada	22.0	3.1%	20-30	1-4%
South Korea	11.3	6.3%	10-20	3-6%
Pharmerging	223.9	15.0%	370-400	10-13%
China	81.7	22.3%	160-190	14-17%
Tier 2	59.6	15.6%	90-110	10-13%
Brazil	28.5	14.6%	38-48	11-14%
Russia	17.1	17.7%	23-33	8-11%
India	14.0	15.1%	22-32	11-14%
Tier 3	82.6	9.4%	100-130	5-8%
Rest of World	120.0	4.7%	125-155	2-5%

Source: IMS Market Prognosis, September 2013

#### Appendix notes:

Spending in US\$ with variable exchange rates.

Growth in US\$ with constant exchange rates.

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

Tier 3 Pharmerging: Mexico, Turkey, Venezuela, Poland, Argentina, Saudi Arabia, Indonesia, Colombia, Thailand, Ukraine, South Africa, Egypt, Romania, Algeria, Vietnam, Pakistan and Nigeria.

### **Authors**



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Director, European Thought Leadership

Sarah Rickwood is Director of IMS Health's European Thought Leadership team, and has over 20 years' experience as a consultant to, and commentator on, the global pharmaceutical industry, having worked in Accenture's pharmaceutical strategy practice prior to joining IMS Management Consulting. She has a wide experience of international pharmaceutical industry issues, having worked with most of the world's leading pharmaceutical companies on issues in the U.S., Europe, Japan, and leading emerging markets.

At IMS Health, Sarah has played a key role in developing Launch Excellence Thought Leadership and IMS' Health's Launch Excellence thought leadership studies and Launch Readiness offerings which provide IMS Health pharmaceutical clients with comprehensive and critical guidance during the crucial pre-launch and launch periods for their key brands. She has written and presented on a wide range of global medicines issues, developing IMS Health's perspective on the opportunities for growth in the African pharmaceutical market, on the development of biosimilars and non-original biologics, and on specialty medicines and the changing nature of blockbuster drugs.

Sarah holds a degree in biochemistry from Oxford University.



Michael Kleinrock Director, Research Development

Michael serves as Research Director for the IMS Institute, setting the research agenda for the Institute, leading the development of reports and projects focused on the current and future role of biopharmaceuticals in healthcare in the U.S. and globally.

Each year Michael leads the development of IMS Health's perspectives included in its annual "Year in Review" presentations as well as its review of the future outlook for the global pharma market. Michael writes and speaks regularly on these and other topics and he is sought after for his unique and pragmatic perspectives, backed by rigorous analysis and research, on issues of interest to pharmaceutical companies, financial analysts, trade groups, policy advocates and regulatory agencies.

Michael joined IMS Health in 1999 and has held roles in customer service, marketing, product management, and in 2006 joined the Market Insights team which in 2011 became the IMS Institute for Healthcare Informatics.

Michael holds a BA in History and Political Science from the University of Essex, Colchester, UK, and an MA in Journalism and Radio Production from Goldsmiths College, University of London, UK.

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### Maria Núñez-Gaviria Project Manager and Researcher, European Thought Leadership

Maria Núñez-Gaviria is a project manager and researcher in the IMS Health European Thought Leadership Team, leading the development of reports and analyses focused on biopharmaceuticals and healthcare in Europe and around the world.

Maria's primary and secondary market research experience spans therapy areas including diabetes and oncology, emerging markets, and the yearly pharmaceutical strategic management review. Maria joined the Thought Leadership team at IMS Health in 2008 and has supported both the European region and more specifically the South Europe business unit.

Maria holds a degree in Business Management and Administration from Deusto University.

## 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.

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#### **Research Agenda**

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

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

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

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

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

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

#### **Guiding Principles**

The Institute operates from a set of Guiding Principles:

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

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

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

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

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

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

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



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