

2016 Global life sciences outlook Regional & country perspectives

Life sciences companies in 2016 will not only face challenges emanating from an increasingly global marketplace, there will also be region-specific issues to address.

Americas

Health care spending growth in North America is projected to rise by an average of 4.6 percent annually from 2015 to 2019, driven, in large part, by expanded insurance coverage in the United States under the Affordable Care Act (ACA), which will boost that country's spending by an average of 4.4 percent a year in the 2015 to 2019 time span.¹³⁸ Canada is projected to see even faster spending growth during the same period — 4.8 percent annually — reflecting its older population.¹³⁹

Latin America's health care spending tells a more subdued story: Spending slowed sharply in 2014 and is expected to enter a decline in 2015 as economies remain under pressure, particularly in Brazil and Colombia. Even so, several governments are trying to improve public health care systems as much as their budgets allow; as a result, spending across Latin America is expected to rise by an annual average of 3.1 percent in the 2015 to 2019 time period.¹⁴⁰

Pharma spending in North America should remain stable from 2015 to 2019, at around 41 percent.¹⁴¹ The U.S. pharma sector is projected to continue as the world's largest; however, its growth may decelerate due to increasing payer pricing pressure on new, expensive specialty drugs.¹⁴²

Country-specific issues

- **Brazil** is the largest pharmaceutical market in Latin America and the 10th largest in the world, accounting for around two percent of world demand.¹⁴³ However, near-term pharma sales are expected to be constrained by the country's continued economic weakness.¹⁴⁴ According to national accounts data released in August 2015, Brazil's economy contracted between January and July. This data not only underscores Brazil's recession, it also presents a challenging outlook for proposed fiscal adjustments in view of fears that the economic slump may extend well into 2016. According to EIU forecasts, Brazil's GDP will contract by around 2.5 percent in 2015 owing to political instability, diminishing consumer and business confidence, monetary tightening, and fiscal adjustments.¹⁴⁵ These factors combined with impending austerity measures and rising taxes may limit pharma growth.¹⁴⁶
- Implementing health care reform may be an important issue in **Mexico** in 2016 because doing so would change the government's monopoly on public health. Opening the market to competition could boost private health care and insurance coverage and create new opportunities for the life sciences sector. In addition, Mexico's medical tourism industry will continue to offer growth opportunities for medical device manufacturers and pharma companies. Mexico is already the world's second-biggest medical tourism destination (behind Thailand), generating \$3 billion in 2014.¹⁴⁷ Mexican agencies expect that with increased investment, the country could grow medical tourism revenues to \$10 billion to \$12 billion in the next seven to eight years.¹⁴⁸

- Life sciences companies in the **United States** are likely to see increasing demand for branded and generic drugs and medical devices in 2016 as the number of insured individuals continues to grow under ACA and Medicaid. However, pricing pressures show little sign of easing even though the U.S. economy appears to be faring well, especially in comparison with other developed countries. A divided, partisan Congress and an upcoming presidential election may preclude passage of any substantive health care-related legislation in 2016. See more about the outlook for the U.S. market at www.deloitte.com/us/lifesciences.

EMEA

Economic pressures and a decline in the euro will continue to limit health care spending in Western Europe, despite the health needs of an aging population. The EMEA region is projected to see the world's slowest growth in health care spending from 2015 to 2019, at just 1.4 percent annually. Spending in Germany, the United Kingdom, and Sweden is expected to fare better than in Greece, Italy, Ireland, Portugal, and Spain — the countries most impacted by the eurozone crisis.¹⁴⁹ In contrast, the Middle East and Africa are likely to post the fastest health care spending growth globally, at around 9.3 percent annually in the 2015 to 2019 time period. This growth will be driven by government policy changes, the expansion of health care systems, and rising populations.¹⁵⁰

Cost-containment measures in Western Europe may impede margins in pharma, as the region is expected to see its share of total global pharma spending fall from 21 percent to less than 18 percent by 2019.¹⁵¹

Country-specific issues

- The life sciences sector in **France** is expected to face another challenging year in 2016. To address a culture of over-prescription that has developed because the public health insurance system pays most drug costs, the government has focused on cutting the rate of reimbursement on many drugs, removing a number from health insurance system coverage, and promoting the use of generics.¹⁵² In addition, life sciences regulatory enforcement is likely to intensify, with the competition authority, the *Autorité de la concurrence*, becoming increasingly assertive.¹⁵³ Life sciences companies also will face obstacles created by a new market access (MA) requirement. The timeline to gain price and reimbursement in France once MA is granted is already one of the longest in Europe and it is not likely to improve. In addition, solutions for the financing of new integrated care solutions are yet to be invented, and the country lags in the use of health care data because of its legal framework and the constitutional "Principe de Precaution" (precautionary principal). Because of these and other obstacles, the French pharma industry's competitiveness has weakened and the country's attractiveness to foreign companies as an R&D site is eroding, despite a very generous research tax credit scheme. All in all, this means losing employees and investments and lower export sales. With the exception of Sanofi, which has critical mass in the global market, French pharma manufacturers may need to look for alliances, licensing, and other types of collaboration to gain share in existing and new markets.
- The gradual aging of **Germany's** population — more than 20 percent is aged 65 or older (behind only Italy and Japan among OECD countries) — is expected to increase demand for treatment of conditions related to the elderly¹⁵⁴ in 2016 and successive years. Although the public system will continue to play the most prominent role in health care provision and spending, the share of private spending is expected to rise as the German government continues its efforts to reduce public health budget expenditures.¹⁵⁵ For example, to control pharmaceutical spending, Germany reformed

its prescription drug market in 2011, implementing processes to better evaluate new drugs' effectiveness, strengthen competition, and improve efficiency.¹⁵⁶ Under the reforms, pharma companies can set prices only for the first 12 months after a new drug is introduced. Drugs that do not provide additional benefits to established medicines have to accept fixed prices.¹⁵⁷ Pharma companies argue that the drug pricing and reimbursement system is curbing innovation; however, the industry invests heavily in R&D and continues to focus on patented drugs rather than generics.¹⁵⁸ For example, manufacturers hope that multiple upcoming biosimilar launches will boost this product category's uptake and reimbursement in Germany.

- **Russia's** health care spending as a proportion of GDP is expected to continue to fall as sanctions related to the country's intervention in the Ukraine as well as the decline in global oil prices eat into tax revenues and prompt austerity measures.¹⁵⁹ Russia has the largest pharma market in Central and Eastern Europe; however, consumption per head remains far below Western European levels.¹⁶⁰ Prolongation of the current economic sanctions will likely accelerate government measures to hasten the process of import substitution and medicine production localization. A ban on certain imported medical devices to be sold at state tenders (if there are at least two offers of local products at a tender) was introduced in February 2015 and a similar measure for medicines is currently under consideration by the government. (The main issue is how a "local product" will be defined — it is likely that after a certain short transition period packaging differentiation will not be enough.) The ultimate aim of this measure is to localize production of APIs in Russia. The issue with localizing production is that the majority of APIs are currently imported. Also, because Russia's pharma sector depends heavily on imports (both medicines and APIs) the recent devaluation of Russia's local currency has led to production cost increases for local drug manufacturers.

- Pharma sales growth in **South Africa** accelerated from 2013 to 2014, to over 20 percent a year, and is projected to moderate to an annual average of 10 percent during the 2015 to 2019 time span.¹⁶¹ Despite this positive outlook, however, South Africa's overall economic environment remains challenging, adding considerable pressure to the government budget and possibly lowering its future spending on the procurement of drugs and therapies. Weak economic growth is also a challenge to consumer spending and may have a knock-on effect on the sale of all drugs, particularly over-the-counter (OTC) products. One potential benefit of current economic conditions is that the value of South Africa's currency (ZAR) has weakened, making the country's life sciences products more price-competitive. However, many of South Africa's key trade partners are also experiencing subdued economic performance, thereby limiting the potential of sector growth through competitive exports. A weaker currency also means more expensive import costs for key pharmaceutical inputs like APIs. The relatively small scale of local pharma manufacturing in South Africa means that imports play a major role in the market.¹⁶² South Africa's pharma supply chain also suffers from inefficiencies, which have resulted in drug shortages, especially in rural areas with underdeveloped health systems.¹⁶³
- Although **Switzerland's** pharma market is relatively small in Western European terms due to its low population, the country is a major European drug manufacturer, producing \$44 billion in pharmaceuticals in 2013,¹⁶⁴ more than Germany, Italy, France, and Ireland.¹⁶⁵ Some of the world's largest pharma companies are either headquartered or have a major presence in Switzerland. Life sciences organizations in 2016 are expected to continue leveraging the geopolitical stability and ease of doing business in Switzerland. For example, the country is seeing a high degree of inbound biotech segment investment due to its advantageous tax laws. This investment, combined with the global growth of specialty drugs and increasing focus on personalized medicine, may create opportunities for biotech M&A by large pharma companies. Despite the economic and political strength of Switzerland's research-based pharma industry,

however, health care policy aims to reduce spending on pharmaceuticals by negotiating prices down and by substituting generics for patented medicines where possible.¹⁶⁶

- The **United Kingdom** currently accounts for around four percent of world pharma consumption, and is expected to be among Europe's best-performing large pharma markets in the coming years: sales of prescription and OTC drugs are projected to rise from an estimated \$36 billion in 2014 to \$38.3 billion by 2019.¹⁶⁷ By most measures, the pharma sector is the United Kingdom's most successful research-based industry and remains a jewel in the United Kingdom's scientific and industrial crown. The sector has, over the past decade, generated an ever-widening trade surplus, and the people and capital employed in the pharma sector earn more income for the United Kingdom than if they were in any other sector of the economy.

Increasingly, the United Kingdom's pharma companies work with the NHS to ensure local health priorities are met, improve patient outcomes, and help local NHS organizations meet their objectives. These joint-working projects ensure a "win: win: win" for patients, the NHS and the industry. For example, the 100,000 Genomes Project, launched in late 2012,¹⁶⁸ is demonstrating the U.K.'s leadership in the area of genomics and providing the country's life sciences sector with a key competitive edge.¹⁶⁹ Genomics England, a company wholly owned and funded by the government, was established to deliver this flagship project, which will sequence 100,000 whole genomes from NHS patients, by 2017. Its four main aims are to create an ethical and transparent program based on consent; to bring benefit to patients and set up a genomic medicine service for the NHS; to enable new scientific discovery and medical insights; and to kick-start the development of a U.K. genomics industry.¹⁷⁰

Pharma investment activity in the United Kingdom has been consistently increasing over the last two years. The volume of FEED work being undertaken has increased greatly and the volume of new projects is much more consistent than even a few years ago. Tendering is very buoyant due to the number of potential project opportunities that exist, although these opportunities are becoming increasingly competitive and tend to result in tighter margins.¹⁷¹ M&A activity remains very high on the agenda in the U.K. pharma sector and carries some uncertainty for some projects. Despite tumultuous M&A activity, U.K. domestic pharma manufacturing and R&D remain strong, with major areas of investment such as cell therapy manufacturing centers for later-stage clinical studies.¹⁷²

The medtech industry also makes a vital contribution to economic growth in the United Kingdom. Medtech employs 76,000 people in over 3,000 companies, mostly small and medium-sized enterprises. The sector is worth \$26 billion (£17 billion) and has achieved growth of greater than six percent in recent years. Many medtech companies are working closely with universities and research institutions. In addition, the NHS is highly dependent on technology produced by the industry to enhance its productivity and performance.¹⁷³

Asia-Pacific

Although the **Asia-Pacific** region is experiencing an economic slowdown, the rollout of public health care programs combined with increasing private wealth is expected to boost the region's health care spending by an annual average of 6.6 percent from 2015 to 2019. The strongest anticipated growth, at a substantial 16.1 percent per year, will be in India, where the government has set a target of raising public health expenditure from its current equivalent of 1.2 percent of GDP to 2.5 percent of GDP within five years. (Note that India's spending is primarily allocated to health care infrastructure versus drugs.) China's spending growth in the 2015-2019 timespan is estimated to be 8.8 percent a year, although given the current economic uncertainty that number could end up being far lower. Australia and South Korea are expecting growth of over four percent a year. Due to continuing currency devaluation, Japan remains the region's most depressed market; spending is not anticipated to recover until 2016, with an average growth in dollar terms of just one percent.¹⁷⁴

Asia's share of global pharma spending is projected to rise from 25.5 percent to 28.4 percent from 2015 to 2019.¹⁷⁵ With developed markets stagnating, emerging economies — particularly China — are expected to fuel much of the pharma segment's growth in coming years. The total dollar value of the Chinese pharma market is likely to overtake that of Japan in 2015, leaving it second only to the United States.¹⁷⁶

Country-specific issues:

- After ten-years of “super” growth, **China's** life sciences sector has reached a turning point where MNCs' traditional business models are showing limitations. Sector revenues are projected to decline and operating challenges increase as a result of the country's economic woes and yuan devaluation.¹⁷⁷ In addition, compliance challenges persist and pricing pressures continue under the provincial tendering process, extensive benchmarking among provinces, and second-round price negotiation — which combined may have a considerable negative impact on MNCs' top-line growth. China's market is full of medium- and long-term potential due to its large market size, aging population, changing disease profile, and rapidly improving living standards. However, it is becoming more difficult for large-scale MNCs to compete there and increased divergence among winners and laggards is anticipated. Life sciences companies in 2016 will need to examine their existing assets, capabilities, and product portfolios and determine how to better adapt to local policy requirements, meet local health care needs, develop partnerships to improve market penetration, and maximize the value of their investments. Still, companies are keen on balancing short-term results and positive mid- and long-term prospects in China and finding ways to sustain growth. For example, Eli Lilly formed a partnership in 2015 with China's Innovent Biologics.¹⁷⁸⁰
- For domestic and foreign life sciences companies selling patented drugs in **India**, drug price control will continue to be a major issue in 2016. An available supply of locally produced generic drugs and vaccines — India ranks fourth globally in generic drug production¹⁷⁹ — combined with price controls has helped to keep drug prices low. But despite the fact that demand is rising

among India's fast-growing middle class for more advanced and expensive medicines,¹⁸⁰ the National Pharmaceutical Pricing Authority (NPPA) continues to bring more drugs under price control. In July 2014 the regulatory agency announced plans to add 108 more drugs belonging to the cardiovascular and anti-diabetic classes; this is on top of the 348 essential drugs that were brought under price control following the implementation of the new Drug Price Control Order (DPCO) in July 2013. Industry bodies have raised concerns but if the order stays, the local units of global life sciences companies will have to explore ways to lower prices. In other regulatory action, the government plans to set up monitoring cells across the country to keep abreast of price movements, collections, and drug availability. The move follows NPPA's proposal to the Ministry of Chemicals and Fertilizers to revise the existing scheme of consumer awareness and publicity by using various forms of mass media.¹⁸¹ As such, India is expected to remain a challenging market for patented drugs and MNCs.

- **Japan's** economy is still sputtering, despite a huge bond-buying campaign, structural reforms, and central government stimulus.¹⁸² Putting further pressure on the economy are Japan's rapidly increasing health care costs, driven by an aging society and increasing chronic diseases, as well as the emergence of innovative and expensive treatments. Japan's total health care spending reached an estimated \$478 billion in 2014, making it the third-largest spender on health care in the world, after the United States and China.¹⁸³ The Japanese pharma market is the world's second-largest by revenue, after the United States, with estimated 2014 sales of \$106.9 billion.¹⁸⁴ To control health care expenditures and sustain universal coverage, Japan's government has introduced a number of initiatives, such as encouraging the use of cheaper generic drugs, self-management of chronic diseases and preventive care. Although the generics market in Japan is currently dominated by domestic manufacturers, this may generate opportunities for multinational generic companies. Another pending challenge is a health technology assessment (HTA) that has been announced but keeps getting delayed.

In Japan, drug and medical device prices are under government control. A pricing review occurs every other year (the next review is in 2016) and usually results in a price reduction. The idea of an HTA for selected products is to strengthen pricing pressure on existing products, in addition to the existing program that reduces the gap between the reimbursement price and the actual price paid by hospitals and pharmacies. This is expected to make it more difficult for life sciences companies to maintain a product's price unless it is innovative and cost-effective. Fortunately, a proposed reform (starting in 2016-2017) allowing the use of treatments covered by the public insurance system along with privately paid treatments may help to boost the prospects of the life sciences sector.¹⁸⁵ Japan remains a market where innovation is rewarded and the country is increasingly seen as a potential area for growth, given many companies' innovative drug pipelines.

- Governments in **Southeast Asia (SEA)** continue to roll out universal health care systems amid rapidly growing demand for services. Indonesia, for example, implemented its coverage plan, Jaminan Kesehatan Nasional (JKN), in January 2014, later expanding and rebranding the program as the Healthy Indonesia Card (KIS).¹⁸⁶ However, most countries in the region face ongoing funding constraints and are looking for ways to reduce health care expenditures. One popular approach is the use of lower-cost generic drugs. In some countries, strong domestic generics manufacturers dominate the market, posing access and pricing challenges for new entrants. Implementation of the ASEAN Economic Community (AEC), scheduled to begin in late 2015, is likely to help the local pharma companies to expand their exports. AEC positions ASEAN as a single market and production base and promotes free trade and economic integration among ASEAN countries. Planned initiatives include the gradual harmonization of regulatory approvals and efforts to protect intellectual property.¹⁸⁷ Meanwhile, foreign companies trying to gain a foothold in SEA are establishing regional headquarters, especially in Singapore, and companies with established regional headquarters are reviewing the breadth and depth of services the AEC will provide to the markets. Many life sciences companies are evolving their business models to manage both emerging (e.g., Philippines, Vietnam, Indonesia) and mature (e.g., Singapore) markets in SEA. Others are preparing business cases for investing in operations in smaller markets, (e.g., Sri Lanka, Brunei, and Laos).

For global perspectives, please visit www.deloitte.com/lifesciencesoutlook. Please visit www.deloitte.com/lifesciencesoutlook/sources for a complete listing of the sources referenced in this report.

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