

2014 Global life sciences outlook Resilience and reinvention in a changing marketplace

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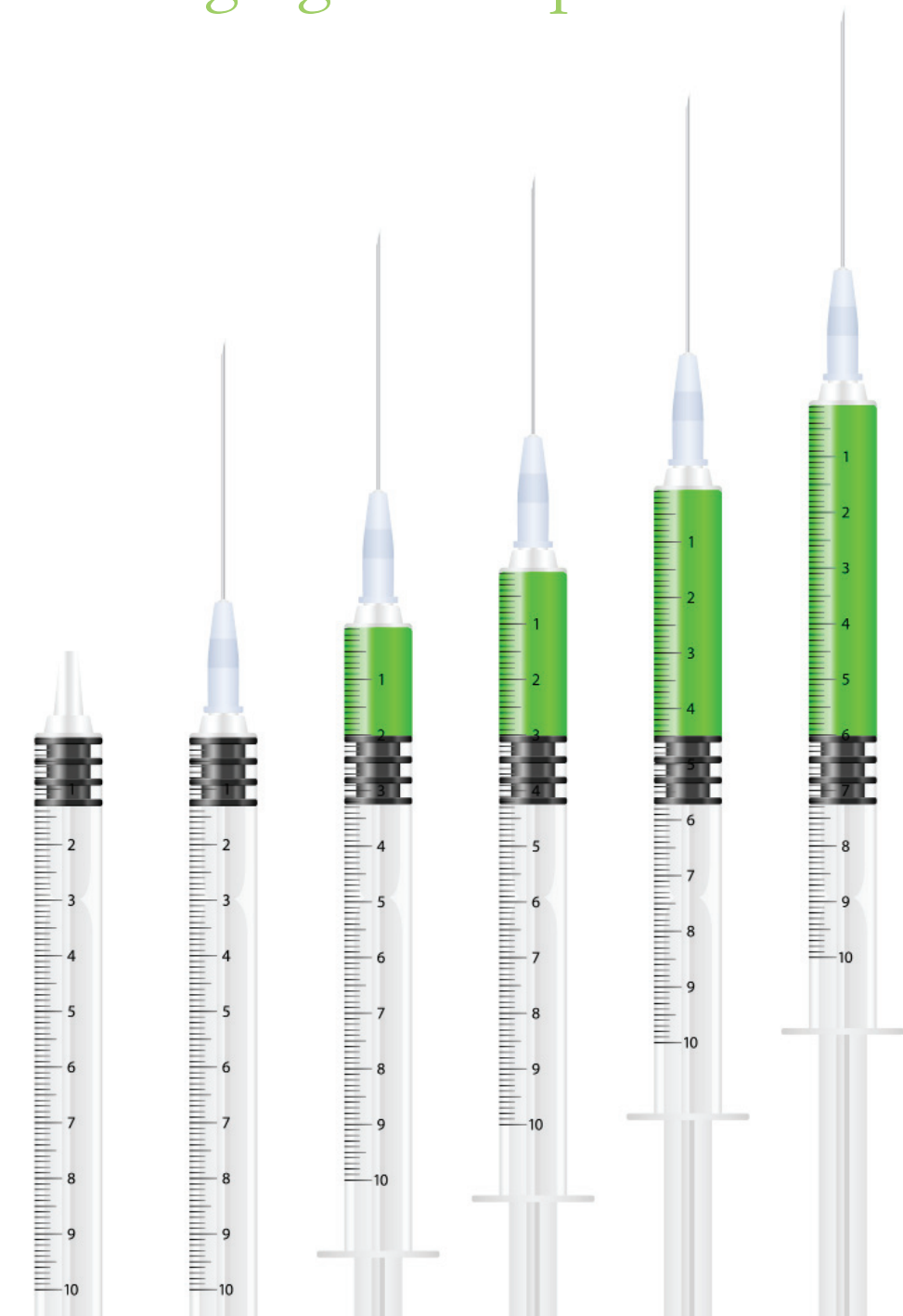
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Overview and outlook

Life science companies may have to consider adapting their business model to optimize their business portfolios. MNCs as well as domestic companies should consider alliances, in-licensing and/or M&A activities to enhance their pipeline and bring new and innovative technologies to the market.

To reduce costs, companies should assess spending allocations, such as commercial, R&D, supply chain, etc. For example, while the number of manufacturing representatives (MRs) has drastically declined in the U.S. and Europe, it has increased steadily over recent years in Japan, rising from 56,000 in 2007 to 64,000 in 2011.¹⁰⁴ Although MRs will continue to be the mainstay of detailing and customer contact in Japan, and products will be promoted until much later in their lifecycles than they are in other countries, pharmaceutical companies should seek ways to reduce marketing costs and improve speed to market.

Southeast Asia

Market Fact: Many companies, particularly those offering branded drugs, are facing pricing pressures from increasing governmental directives and policies on reimbursements, essential drugs and promotion of first-use generic drugs in the public hospital system. The continued margin erosion is forcing companies to review and seek alternate business and marketing models for new drug launches in their portfolio.

The outlook for the emerging markets in Southeast Asia is promising. As an example, Singapore is an important global trading hub that connects Southeast Asia and the West;

the city-state is a major re-exporter of pharmaceuticals. Singapore's pharma sales are forecast to rise from an estimated \$1.1 billion in 2013 to nearly \$4.6 billion in 2017, an average annual growth rate of 9.3 percent.¹⁰⁵ European and American pharmaceutical companies are expected to continue to invest and expand in the region as they benefit from its high productivity, proximity to large Asian markets, and free trade agreements. GDP growth among the more developed nations such as Singapore continues to be low and moderate; businesses are deploying aggressive cost leadership strategies to be more competitive.

The region's life sciences sector grapples with many of the issues confronting both developed and emerging markets: cost pressures, regulatory compliance, and the demand for product innovation. To address these challenges and grow revenue/market share, companies operating in the region will need to possess focused and well-defined core competencies, a solid understanding of their markets, and leverage technology to deliver the right products to the right people within regulatory boundaries. For many of these companies, it also will be necessary to develop new operating models, strategies, and processes to keep pace with changes in the global marketplace. Analytics, cloud computing and other technology advancements can further support this transformation.

Despite heightened regulatory scrutiny, continued pricing pressures and another year of impacts from health care reform in many countries, the global life sciences sector is exhibiting resilience and reinvention as it employs new research and development (R&D) and business models to cost-effectively deliver innovation, value, and improved patient outcomes.

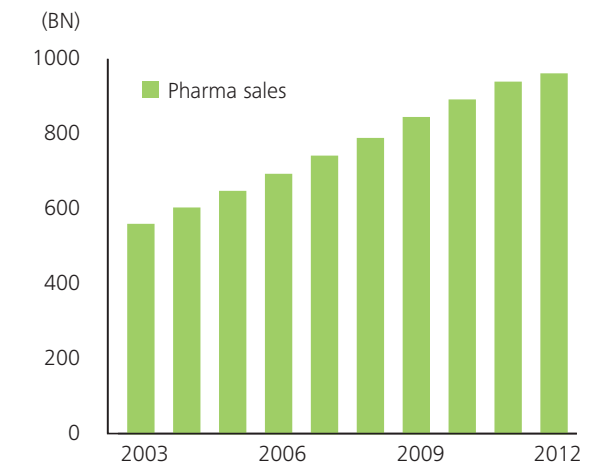
This 2014 global life sciences outlook examines the current state of the sector, describes the top issues facing stakeholders, provides a snapshot of activity in a number of geographic markets, and suggests considerations for companies as they seek to grow revenue and market share in 2014 and beyond. For those readers who are familiar with prior reports, we draw your attention to increased sector emphasis on innovation and the impacts of reform. Finally, the report includes Deloitte contact information for readers who are interested in discussing its contents in greater detail.

Sector overview

The life sciences sector — comprised of the pharmaceutical, biotechnology, and medical technology segments — remained less impacted by the recent global economic uncertainty in certain parts of the world; however, it is facing reimbursement pressure from escalating costs and overwhelmed health systems across the world. Still, an overview of recent sector performance shows that it is favorably positioned to achieve success in 2014 and beyond. Among drivers for growth are an aging population, rising incidence of chronic diseases, technological advancements and product innovation, and certain anticipated impacts from health care reform provisions including increases in government funding and insurance coverage. Opportunities in emerging markets could continue to be a driver, although many companies are looking more cautiously at these markets due to slowing growth and other pressures.

Pharmaceuticals generated total revenue of \$959.0 billion in 2012 (Figure 1), growing 2.4 percent from 2011 (considerably below the 5.3 percent increase posted the year prior).¹ Oncology is the leading therapeutic class; other focus areas include pain management, hypertension, diabetes, mental health, and respiratory.

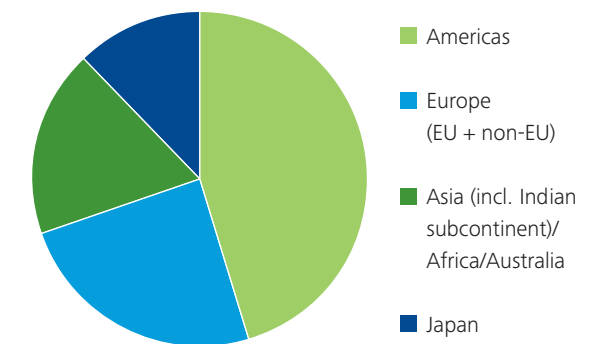
Figure 1: Global pharmaceutical sales, 2013–2012



Source: DTL Global Life Sciences and Health Care Industry Group analysis of IMS Health

The Americas region accounted for the largest share of the 2012 global pharma market (Figure 2), at \$417.6 billion, followed by Europe (European Union and non-EU countries) at \$224.3 billion, Asia/Africa/Australia at \$168.1 billion, and Japan at 110.5 billion.² 2012 growth rates by region were Americas, 9.9 percent (-1.0 percent NA, 10.9 percent LATAM); Asia/Africa/Australia, 12.8 percent; Europe, -.08 percent, and Japan, flat.³

Figure 2: Global pharmaceutical sales, by region — 2012



Source: DTL Global Life Sciences and Health Care Industry Group analysis of IMS Health

¹⁰⁴ MR Education & Accreditation Center of Japan

¹⁰⁵ EIU Singapore: Healthcare and Pharmaceuticals Report, March 2013

¹ IMS Health Market Prognosis, June 2013 <http://www.imshealth.com/portal/site/ims/menuitem.5ad1c081663df9b41d84b903208c22a/?vgnextoid=fbc65890d33ee210VgnVCM10000071812ca2RCRD&vgnextfmt=default>. Accessed September 17, 2013

² Ibid

³ Ibid

The **biotechnology** segment had total revenue of \$232.5 billion in 2012, representing an increase of 9.6 percent over the previous year.⁴ Focus therapeutic areas include oncology, autoimmune disorders, and infectious diseases.

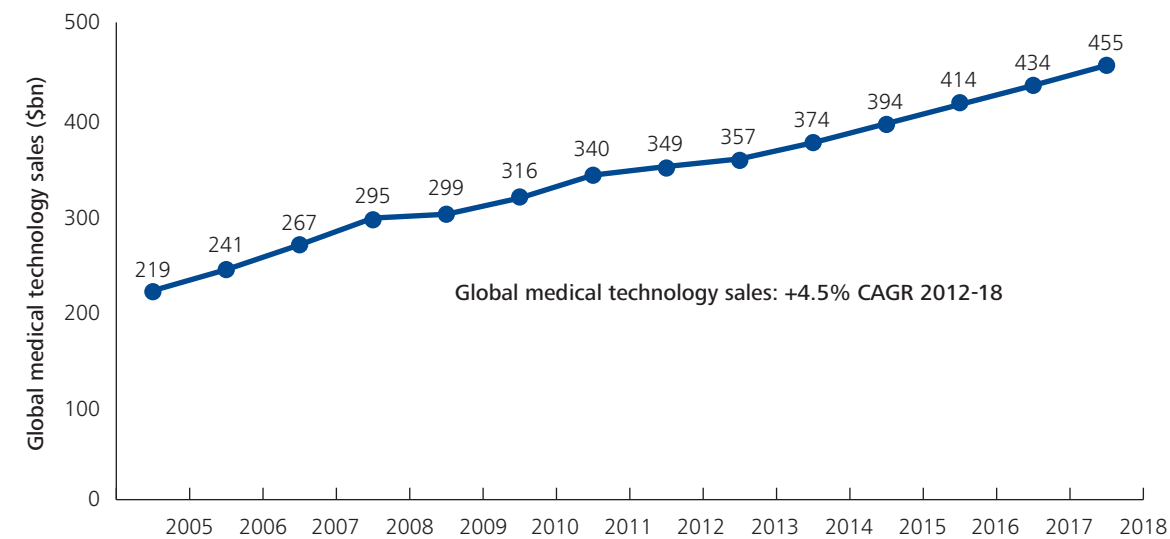
The vast majority of biotech revenue is generated in the U.S. and Europe, where the segment has shown growth over the past five years; however, major players have reported recent slower growth rates for U.S. sales compared with other regions. This trend is expected to continue over the next five years as standards of living and health care access improve in emerging nations, such as India, China, and Brazil.⁵

R&D is essential to biotech segment growth. Global R&D funding is expected to increase in 2013, representing an opportunity for the segment.⁶ Note, however, that biotech is heavily regulated, and some of its research areas generate ongoing political debate. Regulation has been increasing during 2013, posing another challenge.⁷

The global **medical technology** (medtech) market revenue grew seven percent annually between 2005 and 2012, driven by favorable demographics, disease trends, and technological advancements (Figure 3). A recent trend in the medtech industry is increased company specialization — via divestitures or pharma/medtech company splits — to help organizations become smaller and nimbler,⁸ and to leverage R&D investment and improve shareholder return.

In vitro diagnostics is the largest segment within medtech, as well as one of the fastest growing, at a rate of 5.1 percent.⁹ In contrast, the cardiology, imaging and orthopedic sectors are all growing more slowly than the industry average, perhaps because U.S. patients may be deferring these more costly/elective surgeries in tough economic times. Diagnostic testing is an essential part of the health care industry, providing essential information to help providers and patients make the right clinical decisions. Indeed, in the U.K., some 75 percent of clinical decisions are based on a diagnostic test, with demand for access to quicker, more accurate diagnosis rising at a rate of ten percent per year, increasing costs and putting pressure on the capacity and capability of diagnostic providers to deliver services effectively.¹⁰

Figure 3: Global medical technology sales, 2005-2018



Source: D TTL Global Life Sciences and Health Care Industry Group analysis of EvaluateMedTech World Preview 2013 Outlook to 2018

⁴ IBISWorld Industry Report L6724-GL, Global Biotechnology, April 2013

⁵ Ibid

⁶ Ibid

⁷ Ibid

⁸ EvaluateMedTech World Preview 2013, Evaluate Ltd., 2013

⁹ Ibid

¹⁰ Working differently to provide accurate diagnosis: improving access to diagnostics, Deloitte U.K. Centre for Health Solutions, September 2013.

In line with the trends, issues, and challenges in the global and Indian life sciences sector, Indian companies need to focus on accelerating drug discovery, advancing clinical trial efficiencies, actualizing end-to-end medical products, increasing manufacturing productivity, enhancing supply chain visibility, improving sales and marketing effectiveness, improving operational efficiencies and reducing costs. Among the measures taken by Indian companies are increasing IT investments to facilitate real-time communication and visibility between the R&D and marketing sectors; collaborating with IT companies for services and solutions covering the entire life sciences value chain; and channelizing their sales and marketing initiatives.

Japan

Market Fact: The Japanese economy is starting to show some signs of recovery after six years of negative growth. The government is looking to spur medical device innovation and increased transparency and is likely to change long-established promotion and sales practices.

The Japanese pharmaceutical market is the world's second-largest, after the U.S., with sales at an estimated \$134.4 billion in 2013. Japan accounts for around 12 percent of the global pharma market, compared with just over 37 percent for the U.S. and about 22 percent for Western Europe.¹⁰²

2014 could be a positive year for Japan's life sciences sector, although there are hurdles to overcome. Under Prime Minister Shinzo Abe's economic policy mix, the Japanese economy is starting to show some signs of recovery after six years of negative growth. The government aims to expand the life sciences market (pharmaceuticals, medical devices, and regenerative medicine) by approximately 30 percent — from \$120 billion to \$160 billion — by 2020.¹⁰³

To achieve its life sciences growth goals, Japan's government is considering providing incentives such as premium pricing for innovative products and technologies while curtailing prices of less-advanced, generically substitutable ones. The government is introducing a new category scheme to spur medical device innovation and has established an institute to promote the export of medical device technologies.

Concurrent with these initiatives, however, a rapid increase in health care expenditures due to Japan's aging society and the growing prevalence of chronic diseases is forcing the government to look for ways to keep medical spending increases under control, which could negatively impact life sciences firms.

In Japan, every citizen is required to participate in the National Health Insurance (NHI) scheme and the majority of health care spending is publicly funded. The government has begun a number of initiatives to control spending, such as encouraging the use of cheaper generic drugs, and increasing preventive care and self-management of chronic diseases by patients. In addition, the government conducts biennial pricing reviews, which usually result in price reductions. In 2012, the NHI price of prescription drugs was cut by an average of six percent; the 2014 review may negatively affect life sciences firms, as well. The government also is discussing the introduction of cost-effective assessments (such as QALY) for product approval and/or pricing.

In addition to dealing with pricing pressures, Japan's life sciences companies must comply with demands for increased transparency into their relationships with health care providers, which is likely to change long-established promotion and sales practices. Companies are now required to disclose payments to providers by industry code, from 2013 (for payments made in 2012) for pharmaceuticals and from 2014 (for payments made in 2013) for medical devices.

To address these issues, life sciences companies should seek ways to optimize their business portfolios while reducing costs. One important strategy is to develop a robust product portfolio and pipeline based on innovative technologies. For example, to offset reductions in standard drug pricing, certain pharmaceutical companies are focusing on developing drugs for rare diseases or markets with high unmet needs. Some of the major branded drug manufacturers are expanding their business into the generics industry so they can be winners in both areas. As these manufacturers have extensive R&D experience, they may have an advantage over generics manufacturers in the area of biosimilars, since clinical trial is mandatory to file a biosimilar in Japan.

¹⁰² EIU Japan: Healthcare Report, August 2013

¹⁰³ Japan Revitalization Strategy, Cabinet Secretariat, Cabinet Public Relations Office, June 2013

India

Market Fact: India has a fragmented life sciences industry, with stiff price competition, government price controls, and limited availability of infrastructure. Nonetheless, MNCs are increasing their operations in India and creating opportunities to drive industry growth in the country.

India's pharmaceutical sales were \$22.6 billion in 2012. They are expected to rise to \$23.6 billion in 2013 and reach \$27.0 billion in 2016. As a percent of health care expenditures, pharmaceutical sales were 22.6 percent in 2012; they are expected to reach 23.6 percent in 2013 and 27 percent by 2016.⁹⁷

India is among the top five pharmaceutical emerging markets.⁹⁸ The double digit growth registered by India's life sciences and health care industry can be attributed to several socio-economic factors, including increasing sales of generic medicines, continued growth in chronic therapies, and a greater penetration in rural markets. Other growth drivers are heightened health awareness, increasing affluence, changing lifestyles resulting in higher incidence of lifestyle diseases, increasing government expenditure on health care, and a nascent, yet fast-growing health insurance industry. In addition, the nation's low cost of production and R&D boosts the efficiency of Indian pharmaceutical companies and its comparative cost advantage enhances Indian pharmaceutical exports.

The worldwide demand for cost-effective generic drugs is leading India to rise as a hub of generic drug manufacturing. India accounts for over 10 percent of global pharmaceutical production, with over 60,000 generic brands across 60 therapeutic categories; it manufactures more than 400 different active pharmaceutical ingredients (APIs). The country is the front-runner in a wide range of specialties involving the manufacture of complex drugs. A number of pharmaceutical companies are increasing their operations in India, which has 119 manufacturing sites approved by the U.S. FDA, the highest in any foreign

country. The main focus of the Indian companies is on countries with aging populations such as Japan, Africa, and Latin America, which need cheaper drugs. It is estimated that Indian companies will benefit by about \$40 billion as 46 U.S. drug patents expire in 2012-15.⁹⁹

Despite the exponential growth, India's life sciences and health care industry still faces challenges. The outcome of new product patents, drug price control, poor regulatory enforcement, inadequate health care infrastructure, shortage of skilled workforce, increasing patient expectations, ever-changing technology, and quality management and conformance to global standards act as critical barriers in delivering products and services in a sustainable manner. The major challenges being faced by the Indian life sciences sector are:

- **Affordable pricing of drugs** — The government of India is close to having 348 drugs under price control, up from an earlier 74, which is set to impact the retail price of drugs.¹⁰⁰ The move would have far-reaching implications on brand-name pharmaceutical manufacturers with patented products rather than generics manufacturers, which are mostly domestic companies whose products are already available at relatively low prices.
- **Poor health care infrastructure** — India's primary health care infrastructure and physician base remain inadequate despite the Ministry of Health and Family Welfare (MoHFW) expanding access into tier 1 and 2 cities through the National Rural Health Mission (NHRM). Also, a high out-of-pocket-expenditure of patients (>70 percent of total health care costs)¹⁰¹ implies that many of them living in underinvested areas either do not have access to health care, or have to pay significantly higher for treatment because they travel to larger cities and often get treated at a later stage of the disease.
- **Fragmented supply chain** — In India, both pharmaceutical manufacturing and distribution remain fragmented, creating several inefficiencies for the broader system. Lack of effective inventory management systems results in high inventory holding costs, returns, etc. Lack of scale at the retail end of the value chain due to the domination of small chemists also results in lack of economies of scale and higher prices to consumers.

Regulations for medical device approvals are tightening in both the U.S. and Europe. Proposed changes to the comparative effectiveness (CE) marking process in the EU could require device makers to meet higher standards to sell their products, although the changes are not anticipated to take effect until at least 2015.¹¹ In the U.S., the Food & Drug Administration's (FDA) overall requirements have been getting stricter and the agency is considering bringing laboratory-developed tests, currently sold without requiring direct regulatory oversight, under its control. Of note, the FDA had permitted just 14 new pre-market approvals (PMAs) as of August 2013 — a 42 percent decline from the same time last year. The medical devices tax provisions of the U.S. Affordable Care Act (ACA) are also negatively impacting the segment.

Outlook

The fundamentals driving health care demand, combined with the advent of new and often more expensive treatments, will continue to push up global pharmaceutical sales by an annual average of 5.3 percent between 2012 and 2017.¹² Sales growth will continue to come from the U.S., U.K. and the BRIC countries. Among emerging markets, strong growth is forecast for China and India, where pharmaceutical sales are expected to more than double in U.S.-dollar terms by 2016. Brazil and Russia also are expected to see positive growth.¹³

Global biotechnology segment revenue is projected to reach \$262 billion in 2013, having increased at an average annual rate of 11 percent over the past five years. Growth in 2013 is expected to continue, with revenue expected to jump 12.7 percent.¹⁴ Over the next five years, the industry is anticipated to continue to prosper; revenue is forecast to reach \$407.3 billion in 2018, with average annual growth over the next five years projected at 9.2 percent. With some notable exceptions, such as the recent Amgen purchase of fellow biotech company Onyx Pharmaceuticals,¹⁵ larger players are expected to continue pursuing low-risk strategies, including buying out smaller firms to access successful research for commercial-ready technologies, and partnering with academic institutions. From a geographic standpoint, the

Asia-Pacific region is investing significant capital to gain a strong foothold in the segment.¹⁶

The medical technology market is expected to grow at 4.5 percent per year between 2012 and 2018, reaching global sales of \$455 billion. In vitro diagnostics is anticipated to be the industry's largest segment, with predicted worldwide sales of \$58.8 billion in 2018, followed by cardiology.¹⁷ The fastest-growing segment is neurology, which is projected to grow at 6.9 percent per year between 2012 and 2018, to reach \$8 billion. Diabetic care and orthopedics are expected to be the slowest growing segments, expanding 3.4 percent per year between 2012 and 2018.¹⁸ Global medtech R&D spending is expected to grow by 3.9 percent to \$26.7 billion in 2018. The overall R&D investment rate is expected to be around 5.9 percent of sales in 2018, slightly down from 6.1 percent in 2012.¹⁹

Growth drivers: Health care spending, demographics

Life sciences market growth correlates highly with global gross domestic product (GDP) growth, population growth, an aging population, and government spending. After total health care spending rose by just an estimated 1.9 percent in 2012, it is expected to pick up again, with global spending rising by 4.2 percent in nominal terms in 2013, and by an annual average of 5.3 percent from 2013-2017.²⁰

Population growth and government initiatives in emerging markets are expected to drive sector expansion for the next several years. India, China, Indonesia, Mexico, and Russia are pegged as main growth engines; companies are likely to continue expanding their presence in these and other emerging markets to compensate for North American spending growth that will be slightly below the global average, and even slower growth in Western Europe.

An aging population also may act as a long-term growth driver. Increase in life expectancy is projected to lead to an increase of around 10 percent in the global population above 65 years of age.²¹ In some regions, population growth and rising wealth will also drive life sciences spending growth. The number of high-income households

⁹⁷ IBEF Pharmaceuticals Industry March 2013, (<http://www.ibef.org/industry/pharmaceutical-india.aspx>), (<http://www.ibef.org/download/Pharmaceuticals-March-220313.pdf>)

⁹⁸ IBEF Pharmaceuticals Industry March 2013, (<http://www.ibef.org/industry/pharmaceutical-india.aspx>), (<http://www.ibef.org/download/Pharmaceuticals-March-220313.pdf>)

⁹⁹ Business Standard (http://www.business-standard.com/article/companies/drug-firms-to-gain-from-us-patent-expiries-111120700034_1.html)

¹⁰⁰ Businessline (<http://www.thehindubusinessline.com/companies/price-control-to-hit-revenues-by-5-gsk-pharma/article5003130.ece>)

¹⁰¹ IBEF Pharmaceuticals Industry March 2013, (<http://www.ibef.org/industry/pharmaceutical-india.aspx>), (<http://www.ibef.org/download/Pharmaceuticals-March-220313.pdf>)

¹² 2015, not 2014 looking more likely for EU medtech regs adoption, Clinica Medtech Intelligence, October, 2013

¹³ IMS Health Market Prognosis, June 2013

¹⁴ EIU Healthcare World Outlook

¹⁵ IBISWorld Industry Report L6724-GL, Global Biotechnology, April 2013

¹⁶ "Amgen buys Onyx Pharmaceuticals: Good news for biotech?", Barron's.com, August 26, 2013. <http://blogs.barrons.com/stockstowatchto-day/2013/08/26/amgen-buys-onyx-pharmaceuticals-good-news-for-biotech/>. Accessed October 9, 2013

¹⁷ Ibid

¹⁸ EvaluateMedTech World Preview 2013, Evaluate Ltd., 2013

¹⁹ Ibid

²⁰ Ibid

²¹ EIU Healthcare World Outlook

²² EIU-Global Forecasting Service, Economic Forecast, June 2013

(those earning over \$25,000 a year) is expected to increase globally by about 10 percent, to over 500 million, with over one-half of that growth coming from Asia.²²

Economic and demographic trends in the **Americas** remain favorable for the life sciences sector. For example, according to Economist Intelligence (EIU) estimates, the U.S. GDP is expected to grow at least 2.1 percent in 2013 — slightly lower than 2.2 percent growth in 2012 — mainly backed by positive consumer confidence and an increase in housing investments,²³ although ongoing uncertainty about U.S. debt ceiling limits could have an impact on the sector. The region's share of the aging population is expected to grow at a higher rate than the overall global level during 2011-16, average life expectancy is lengthening, and there is a rising incidence of chronic diseases, thus increasing the demand for life sciences products. U.S. pharmaceutical sales are expected to improve in the coming years, riding on an increase in employment levels and the nation's continued economic recovery. The presence of a large number of unknown and chronic diseases has been creating considerable need for innovative treatments, thereby boosting the medical biotechnology segment.

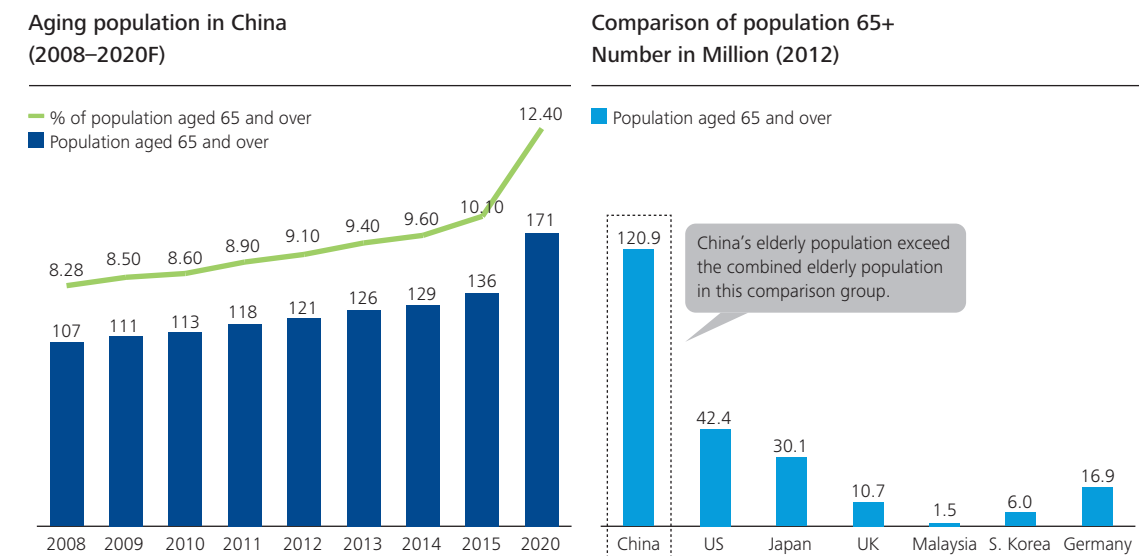
In contrast, continued policies by the nations of **Western Europe** to reduce budget deficits are expected to slow down annual average growth in health care spending to only 2.3 percent for the five-year period ending in 2017.²⁴ Although economic conditions within the EU appear more stable, the pressing need for continuing debt reduction in southern European nations is likely to lead to further reductions in public spending in these markets. However, an aging population should increase demand for health care services and for pharma and biotech products. The U.N.'s *World Population Prospects* report projects that the proportion of Europeans age 65 years and older will grow from 16 percent in 2000 to 24 percent by 2030.²⁵ The European share of the aging population will be much higher than the global average through 2011-16. Also, the life expectancy of the European population is projected to remain well above the global level of 73.7 years at the end of 2017, especially in Western Europe, where the life expectancy is forecast to reach 81.3 years by 2017.

The outlook for the life sciences sector in the **Asia** region is favorable, as economic and demographic trends continue to boost demand. The region's health care spending is expected to keep growing at a steady average rate of 7.6 percent through 2013-2017. For example, India has expanded its primary care policy priority and spending and is expected to increase spending at an average rate of 16.1 percent for the five years ending in 2017. About three-fourths of the country's health budget goes into addressing primary health care (PHC) through the National Rural Health Mission (NRHM). India spent close to \$3.9 billion (Rs.21,000 crores) in 2012-13 alone.²⁶ Indonesia and the Philippines are set to grow in double digits with expansion in their insurance systems.

The goal of China's health care reform is to "provide safe, effective, convenient, and affordable health care," including universal access to basic medical and health services by 2020. Health care expenditures in China are expected to expand at an average rate of 15.6 percent for the period 2012 to 2017, reaching 5.9 percent of its GDP by the end of 2017. The growth in health care spending in China is driven by an increase in pharmaceutical spending of almost 19 percent per year, reaching \$166 billion by the end of 2017; as well as changing lifestyles leading to new ailments (e.g., hypertension) that require more health care spending.²⁷

Despite encouraging economic and demographic trends, life sciences companies' growth prospects are being tempered by a number of challenging marketplace and enterprise issues: navigating health care reform; delivering innovation and value; complying with regulatory changes; and operating in a smaller and connected world. Read on to learn more about these macro issues, suggested considerations for stakeholders, and activity in specific geographic markets.

Figure 7: China's aging population vs. global comparison group



Source: Economist Intelligence Unit Monitor Deloitte Analysis

Despite a generally positive outlook, China's life sciences sector faces a number of uncertainties in 2014; chief among them the level of government spending. China's overall health care expenditures have been highly reliant on public spending. Public hospitals account for more than 90 percent of patient traffic, and public insurance has grown to achieve near-universal coverage over the past decade. In its effort to enhance access and affordability, the Chinese government has consistently increased its health care budget. This spending, however, correlates closely to China's overall GDP growth. The uncertainties surrounding China's much-publicized economic "soft-landing" may impact the continued growth of China's overall health care environment. Fortunately, the rapid expansion of private health care offers attractive opportunities for providers, payers, manufacturers and investors.

Another challenge is continued downward pricing pressure. In response to rapidly growing health care expenditures and continued concern over the pricing of branded generic products, the National Development and Reform Commission (NDRC) has adjusted drug price caps downward five times since 2011. The latest round effectively lowered prices an average of 15 percent for more than 400 drugs, with expectations that high-priced and high-margin ones are subject to further price cuts. NDRC

also indicated that Chinese herbal medicine will be the next priority for price adjustments in 2013. Unsurprisingly, the latest revision of the EDL list from National Health and Family Planning Commission (NHFP, previously MOH) is also expected to be coupled with significant reductions in the price ceilings for newly enlisted drugs, which could be 40 percent or even higher than the price drop the sector saw in 2009. Hospital budget constraints are also exerting pricing pressure: The growing usage of Diagnosis Related Groups (DRG) and prescription caps across hospitals has further limited prescription frequency and duration by patient type and disease area. These programs have resulted in significant changes in hospital spending and prescription volumes.

To meet China's health care goals and address its growing challenges, the public and private sectors will need to develop innovative solutions within a very distinct operating environment. The government will need to continue to alter investments and policies to meet the country's growing demand for access and quality of health care; payers will need to build networks and develop products specific to the country's consumer demographics and needs; and life sciences companies will need to develop innovative products to balance affordability and treatment applicability.

²² EIU Healthcare World Outlook

²³ EIU Database

²⁴ Ibid

²⁵ United Nations *World Population Prospects - The 2012 Revisions*, <http://ega.un.org/unpd/wpp/index.htm>

²⁶ *Forbes India*, <http://forbesindia.com/article/universal-health-care/indias-primary-health-care-needs-quick-reform/34899/1>

²⁷ Espicom Pharma Market Factbook and EIU Database

Government plans to introduce a new value-based pricing (VBP) system, to contain expenditure on medicines while raising purchasing power and improving access, have been deferred from January 2014 to late autumn. Under this system, the price the NHS will pay for a new drug will depend on the strength of clinical data demonstrating superior efficacy and safety compared with existing treatments, including the societal benefits.⁹³

A successor scheme to the current PPRS agreement is to be established to cover existing medicines. The industry remains concerned about the outcome as U.K. pharmaceutical prices are used widely in international reference pricing systems.⁹⁴ In response, the government is extending its \$350M-a-year special fund which provides patients with access to life-enhancing cancer drugs refused by NICE, to 2016.

Other positive developments include the launch, in April 2013, of a new “patent box” regime that gives companies tax breaks on revenue earned from innovation, aimed at making the U.K. a more favorable location for pharmaceutical R&D. Improved access to and analysis of real-world health data to generate insights is expected to help companies identify areas of unmet need and demonstrate product value to support pricing. There also will be an increasing emphasis on maximizing post-tax returns, including optimizing tax implementations.

The U.K. market for medical devices, valued at \$8.9 billion in 2012, vies with France as the second-largest in Europe, behind Germany. It is predicted to increase by six percent per annum to \$11.9 billion by 2017.⁹⁵ New diagnostic procedures are expected to increase accuracy and timing of diagnostics and lead to increasing personalization of medicine. Digital technology is expected to lead to an explosion of information in support of self-monitoring.

The U.K. life sciences sector cannot become complacent and believe that the worst is over. Companies should continue to plan for challenges, engage in scenario planning and business modeling, and make investments in digital technologies and analytics that will serve them in the years ahead.

Asia

China

Market Fact: Recent allegations of malpractice by certain companies in their go-to-market conduct have sparked organizations to tighten their compliance programs, particularly those associated with Anti-Bribery Anti-Corruption (ABAC) Act and Foreign Corrupt Practices Act (FCPA) regulations.

2014 is anticipated to be a positive year for life sciences in China. Pharmaceutical sales are forecast to grow an average of 17.7 percent per year in 2013-17, reaching \$166 billion in 2017. By 2016, the value of pharma sales in China is expected to be greater than that in Japan, currently the world’s second-largest market.⁹⁶

From an economic perspective, the central government spent an additional \$125 billion in health care expenses above and beyond its planned expenditures over the past three years, and is further increasing its 2013 health care budget by 27 percent to \$41 billion. In addition, China’s well-documented, rapidly rising income level has crossed a critical threshold — \$5,000/year in GDP per capita — at which point overall consumption tends to spike. Also, China’s rapid rise in both internet and mobile phone usage is changing patient access and awareness of different types of care. The number of Internet users in China reached more than 540 million at the end of 2012, taking Internet penetration to above 40 percent of the population.

Looking at demographic trends, China’s population is aging (Figure 7), bringing attendant health conditions and creating demand for life sciences products. In addition, China is becoming increasingly urbanized — the proportion of urban population has grown from 36 percent in 2010 to 52.6 percent in 2012. Urbanization and continued westernization of the population have driven lifestyle changes centered on an increasingly western diet, high prevalence of smoking, and increased pollution, which have materially changed the profile of disease in China.

There are four major issues that global life sciences companies face in 2014: navigating health care reform; delivering innovation and value; complying with regulatory changes; and operating in a smaller and connected world. Challenges and opportunities emanating from each of these areas can be both global and market-specific.

Issue one: Navigating global health care reform

Countries including the United States, China, Brazil, Germany, France, and the United Kingdom have recently passed substantial legislation that is accelerating the transformation of global health care from a volume- to value-based marketplace in some cases as well as the extent of coverage in others, and significantly impacting the life sciences sector. Companies know that changes emanating from health care reform are important, but some are struggling with how to respond. Those organizations that are able to understand and adapt to reform’s challenges and opportunities will likely be the leaders.

A recent EIU study, developed in collaboration with Deloitte Touche Tohmatsu Limited,²⁸ examined common elements of the current wave of global reform, national differences, and how life sciences companies are reacting. Among key survey findings:

- **Reducing costs, enhancing innovation and improving market access are the defining goals of health care reform.** Some countries are adopting value-based pricing structures for life sciences products, while others are combining cost containment with assistance for companies investing in R&D.
- **Respondents expect the main impact of reform eventually will be on innovation and sales models.** Sixty-five percent of survey respondents say they have changed or will change their innovation processes in three years, and 58 percent will adapt their sales models in light of legislative reforms.
- **Specific elements of reform vary by country, requiring companies to have national approaches.** Policy changes are predominantly shaped by specific national contexts. For example, the United States’ ACA, Britain’s Health and Social Care Act, and the laws arising from China’s Guidelines on Deepening the Reform of the Health Care System, have many elements that are unique to their national systems.

- **Leading companies are remodeling their innovation and sales activities in the face of reforms.**

Respondents who benchmark their company’s financial performance most highly compared with peers most clearly see the benefits of changing their innovation processes and sales models, and are more likely to see opportunities arising from reforms.²⁹

Cost containment is a common reform objective in both developed and developing markets; however, strategies vary. Most national health care systems have been encouraging greater use of generic drugs; in the U.S., for example, the proportion of prescriptions filled by generics has risen from around half to 80 percent over the last decade.³⁰ Brazil is making branded generics and proprietary drugs of greater interest to pharmaceutical companies, and in China, recent reforms have put intense pressure on the prices of all drugs, including generic and over-the-counter (OTC) medicines. In another cost-containment approach, Germany and several other countries have turned to value-based pricing for new drugs, which allows a price differential from existing offerings — including generics — based on a new product’s demonstrated superiority. Finally, some countries are increasingly mandating prices: India, Brazil and China, for example, have national lists of essential drugs with set prices.

Another common goal of health care reform is spurring medical and life sciences product innovation, via value-based pricing and other methods. For example, China has identified biotechnology as one of seven strategic industries in its latest five-year reform plan, giving biotech firms easier access to financing; the Brazilian government is in the midst of a ten-year biotechnology development program; and the U.K. has reduced taxes on exploiting British-owned intellectual property, in part to reward companies for doing research in the country.³¹

⁹³ Ibid

⁹⁴ Impact of austerity on European pharmaceutical policy and pricing: Staying competitive in a challenging environment. Centre for Health Solutions Deloitte LLP, June 2013

⁹⁵ Espicom Business Intelligence United Kingdom Medical Devices report Q2 2013

⁹⁶ EIU China: Healthcare and Pharmaceuticals Report, June 2013

²⁸ *Health care reform and life sciences: Threat, opportunity or both?*, A EIU/Deloitte Touche Tohmatsu Limited survey of 295 senior executives from the life sciences sector released in June 2013. Respondents represent pharmaceutical companies (36%), medical devices companies (20%), service providers such as contract research organizations (20%), biotechnology firms (13%) and others. Some 43% of respondents are C-level or above. Respondents are distributed globally, with a third each in Western Europe and North America, 26% in the Asia-Pacific region, and the balance from the rest of the world. Respondents also come from companies with a broad range of sizes: 54% represent businesses with less than US\$1bn in annual revenue, while a quarter work for companies with more than US\$10bn in annual revenue.

²⁹ Ibid

³⁰ Ibid

³¹ Ibid

Improving health care access, a third common goal of reform, is expanding insurance coverage to millions of consumers around the globe and increasing governments' direct purchase of life sciences products. In the United States, for example, the Congressional Budget Office (CBO) has estimated that, by 2020, approximately 24 million people will purchase coverage through the new health insurance exchanges³² established by the ACA — a substantial addition to the market. India in 2012 allocated \$5.4 billion under a policy to provide free generic drugs/products for patients in government hospitals and rural clinics. The move was initiated to expand the access to medicine across the country.³³

The broad goals of health care reform can pose both opportunities and risks to the life sciences sector; for example, the ACA increases U.S. consumers' access to life sciences products but assesses higher taxes on biopharmaceutical companies and medical device manufacturers. Sixty-one percent of survey respondents describe reforms in major markets as representing a high or very high risk to their business. Still, nearly half (47 percent) say that reform overall represents a great opportunity. Some of this potential lies in developing products that meet the goals of reformed systems, such as more patient-focused care.³⁴ More than a third (36 percent) of pharmaceutical respondents cite expanded market access — for generics as well as proprietary, precision drugs — as the leading reform-related opportunity.³⁵

Adjusting to health care reform is currently one of, or the single, leading priorities for their companies, according to 64 percent of life science respondents, and 77 percent expect health care reform to be a similarly prominent challenge over the next three years. However, many companies in the life sciences sector have not been acting strategically in the face of this challenge. More than twice as many respondents say that their company's response to reform has been reactive (41 percent) rather than being part of a broader strategy (20 percent). Worse still, four in ten respondents do not know if their company is ready to respond to reform.³⁶

One of the reasons that companies are struggling is that many regulatory environments remain in a state of flux. Dealing with recently created or reformed government agencies that themselves are still working out how to operate is the most frequently cited reform-related challenge in the survey (42 percent). Adjusting the company's commercial model to the new realities (41 percent) is a close second. Accordingly, the resources spent in responding to reforms have focused on regulatory compliance, overall strategy, government relations, and sales and marketing.³⁷

Issue two: Delivering innovation and value

As stated earlier, one goal of health care reform is spurring medical and life sciences product innovation. There are additional compelling reasons for the sector to focus on delivering innovation and value, as well. For example, the rising popularity of generics among both governments and consumers continues to exert downward pricing pressure on branded products and contribute to declining sales. Generics accounted for only 5.9 percent of global prescription sales in 2004 but are expected to account for 10.3 percent by 2018.³⁸

The patent cliff is now at its steepest point. In 2012, \$38 billion of worldwide prescription drug sales were lost as a result of expired patent protection.³⁹ The risk continues as governments and other payers intensify efforts to maximize savings from patent expirations by promoting the use of generics.⁴⁰ Indeed, many countries across the world have introduced programs to encourage generic use, including India and most European countries.⁴¹

The biosimilars market — engineering copies of high-priced biotech drugs — offers another growth opportunity for generics producers. The global market for biosimilars grew by 44 percent in 2011, to \$2.5 billion, and is expected to rise to \$3.6 billion by 2016, with the fastest growth in Asia-Pacific.⁴² The U.S., the European Union, Japan, and other countries have created regulatory pathways for biosimilar products, although U.S. health care reform also extended the patent protection on biotech drugs to

Turkey

Market Fact: Critical success factors for the life sciences sector in Turkey include promotion of investments and innovation (i.e., R&D activities and protection of intellectual property rights), quality, and sustainability.

Turkey's total pharmaceutical sales (including OTC sales) are projected to grow by 8.8 percent a year between 2013 and 2017, reaching \$19 billion.⁸⁸ Estimating the size and growth of the market is complicated due to the government's moves to cut pharmaceutical prices and their encouragement in the use of generics as part of its efforts to reduce public health spending. According to the Pharmaceutical Manufacturers' Association of Turkey (IEIS), the market share of generics rose to 38.1 percent in 2011 but fell back in 2012 to 37.7 percent.⁸⁹

The need for continuous innovation in life sciences R&D is driving companies in Turkey to seek new and different funding sources, as government and university support is not extensive. Tax and incentive legislation may provide much-needed financial resources for sector R&D; however, companies likely will have to lobby for the necessary changes. In addition, some companies may look to shift their R&D and manufacturing locations to those jurisdictions offering more favorable operating conditions.

Cost controls linked to increasing government pricing pressures on pharmaceuticals is another challenge facing life sciences companies in Turkey. In response, executives are working to ensure that their operations are efficiently managed and their business models reflect changing market conditions. Companies are closely monitoring their cost structures. However, it is critical that they follow a strategy and control mechanism which does not sacrifice long-term benefits just to maximize short-term profits.

Regulators and customers in Turkey are likely to increase calls for more privacy and security of personal information. There are already certain regulations in effect regarding the security requirements for software development in the health care sector. However, more strict requirements specifically to protect information security and privacy are expected to be introduced. In the meantime, life sciences

companies should implement awareness programs to address the security and privacy issues they face. This includes performing a risk assessment to understand their level of exposure as well as their need for protection.

United Kingdom

Market Fact: The U.K. has a strong outlook but constraints on public spending could impact the life sciences sector. Also, the impact of the proposed new value-based pricing (VBP) system should be closely watched.

Despite the challenging and dynamic market in which life sciences organizations operate in the U.K., the outlook is positive. In 2012, sales of prescription and over-the-counter medicines were estimated at \$32.2 billion and are expected to increase at an average annual growth rate of six percent over the next five years to reach \$39.5 billion by the end of 2017.⁹⁰

Overall spending on pharmaceuticals is expected to increase from 14 percent to 15 percent of total health care spending, despite the market share of generic medicines increasing from 52 percent in 2002 to 73 percent in 2012.⁹¹ Public expenditure on generic medicines now accounts for about one-quarter of the total public drugs bill. Further growth in the generics market will be driven by new products as blockbuster patents expire and drug consumption increases. The U.K. accounts for 10 percent of global pharmaceutical R&D and while there has been some scaling-back of R&D budgets in recent years, the response has been to close some major company facilities and re-site others closer to science and technology parks.

Constraints on government spending with flat rate increases until at least 2014-15 are leading to tighter drug pricing and reimbursement policies. Drug prices are regulated by the Pharmaceutical Price Regulation Scheme (PPRS), with the National Institute for Health and Care Excellence (NICE), evaluating the cost and effectiveness of treatments and agreeing which drugs should be publicly funded. Some of NICE's decisions to refuse access to new treatments have been politically difficult and unpopular, both with the pharmaceutical industry and the public.⁹²

³² Congressional Budget Office Projections. Health Insurance Exchanges: CBO's May 2013 Baseline. http://www.cbo.gov/sites/default/files/cbofiles/attachments/44190_EffectsAffordableCareActHealthInsuranceCoverage_2.pdf. As cited in Will they come? Consumers and health insurance exchanges: Awareness, preferences, and concerns, Deloitte Center for Health Solutions, 2013.

³³ Reuters. <http://www.reuters.com/article/2012/07/04/us-india-drugs-idUSBRE8630PW20120704>

³⁴ *Health care reform and life sciences: Threat, opportunity or both?*, EIU in collaboration with Deloitte Touche Tohmatsu, 2013

³⁵ Ibid

³⁶ Ibid

³⁷ Ibid

³⁸ *World Preview 2013, Outlook to 2018: Returning to Growth*, EvaluatePharma, www.evaluategroup.com/wp2013

³⁹ Ibid

⁴⁰ EIU Healthcare World Outlook

⁴¹ *Impact of austerity on European pharmaceutical policy and pricing; Staying competitive in a challenging environment*. Centre for Health Solutions Deloitte LLP, June 2013

⁴² EIU Healthcare World Outlook; Global Information Inc.

⁸⁸ EIU Turkey: Healthcare report, August 2013

⁸⁹ Ibid

⁹⁰ EIU United Kingdom: Healthcare report, August 2013

⁹¹ NHS Health & Social Care Information Centre, Prescriptions Dispensed in the Community: England 2002-12

⁹² Value based pricing can it work? BMJ 2013;347:f5941 doi: 10.1136/bmj.f5941 (Published 11 October 2013) Page 1

awareness; the growth of smaller health care clinics and ambulatory centers; and a strong medical tourism industry.

In the GCC, prescription drugs account for an average 89 percent of the region's total pharmaceutical sales. This is also driven by the use of medical insurance to buy all products, including items that otherwise would be considered OTC.⁸³ Within prescription drugs sales, patented products account for 90 percent of the total.⁸⁴ A key challenge is the speed of registering and approving new drugs. Each country has a government agency responsible for regulating the health care and life sciences industry; in addition, the Health Ministers' Council promotes coordination among member states to advance achievement in preventive, curative, and rehabilitative care. Price controls are quite stringent and are mainly driven by the pricing mechanism set by the Council.

There are several regionally based pharmaceutical manufacturers that produce solely generic drugs. Despite efforts to promote these products, doctors and consumers prefer international, recognized brands over local generics. The resident manufacturing companies also face stiff competition on their own turf from international firms, forcing them to target export markets such as Southeast Asia and Africa.

Russia

Market Fact: Almost 80 percent of drugs in the Russian market are imported. This share is decreasing but not very rapidly. Most multinational pharma companies have constructed or are in the process of constructing factories in Russia to avoid losing their share in the hospital segment, where the Russian government is trying to restrict access for imported drugs.

Since 2011, Russia's pharmaceutical market has undergone major expansion and is expected to continue growing steadily. Annual pharmaceutical sales are forecast to rise to almost \$32 billion by 2017, an average growth rate of 16.7 percent per year.⁸⁵ Almost 80 percent of products are imported.⁸⁶

The main task that lies ahead of the Russian government is to satisfy the market with Russian medicines, increase their quality, and contain their price increases. However, an imperfect pricing system, a lack of companies operating in accordance with the European GMP standard, divisiveness in the creation of a list of vitally important medicines, and many other issues remain unresolved.

The government's target program, "Development of the pharmaceutical and medical industry of the Russian Federation," details the goals to achieve by 2020: the share of Russian-manufactured medicines in the list of strategic medicines and vitally important medicines must reach 90 percent; the share of local medical drugs in the pharmaceutical market in monetary terms must be 50 percent; the share of local medical products and medical equipment in monetary terms must be 40 percent; and 75 percent of pharmaceutical and 85 percent of medical companies should be modernized.⁸⁷

The government has already introduced and plans to add a series of measures to restrict the access to state tenders for imported medicines — particularly in the hospital segment, which is supported by government purchases — in order to stimulate local manufacturing. However, pricing pressures, imperfect legislation, insufficient state financing of health care and manufacturer support, lack of spending capacity among the population, corruption at all stages from production to distribution, and a weak consolidation of local manufacturers create difficult conditions for manufacturing pharmaceuticals in Russia. While some pharma companies believe that current and projected market growth justify the higher costs of producing drugs in Russia, others are cautious and prefer to use a contract manufacturing model or place their manufacturing facilities outside the country. Pharma companies will need to select their preferred business model in the near future or risk losing their share of sales in the growing hospital segment.

12 years, potentially slowing U.S. biosimilars growth. A recent example would be Hospira's approval of Inflectra™ (infliximab), Europe's first biosimilar monoclonal antibody (mAb) therapy. Inflectra is a biosimilar medicine to the reference medicinal product, Remicade® (infliximab), and is the first monoclonal antibody (mAb) to be approved through the European Medicines Agency (EMA) biosimilars regulatory pathway.⁴³

Life sciences companies have adopted a multipronged approach to cope with the current and anticipated drop in sales revenue, including cutting costs and staff; engaging in joint ventures and mergers and acquisitions (M&A) to share R&D risk and improve their product portfolio; expanding in emerging markets; recalibrating business models and research priorities; and using real-world evidence and emphasizing a product's clinical, safety, and economic impact (e.g., comparative effectiveness) to articulate their value proposition by identifying new ways to demonstrate product value. The jury is still out on the impact of these strategies.

While, the U.S. Food and Drug Administration (FDA) approved 39 new molecular entities in 2012, up from 31 in 2011 and the highest number since 1996⁴⁴ (Figure 4), a Deloitte United Kingdom Centre for Health Solutions analysis of the late-stage pipelines of the leading 12 life sciences companies indicates that R&D returns have been declining since 2010. Life sciences innovators are feeling the impact of rising costs and a decline in forecasted sales revenues driven by an age of austerity and the

patent expirations of many blockbuster drugs. The cost of developing an asset from discovery to commercialization has increased by 18 per cent, from \$1,094 million in 2010 to \$1,290 million in 2013. Over the same time period, the forecasted peak sales (highest-value sales in a single year) of an asset have declined by over 40 percent, down from \$816 million in 2010 to \$466 million in 2013. Total forecast sales over the lifetime of a product have also declined since 2010 and, in 2013 are estimated to be \$4.6 billion.⁴⁵

One R&D category that is demonstrating both superior productivity and promising future returns is orphan drugs. In 2012, orphan drug sales increased 7.1 percent from the prior year to \$83 billion. The worldwide orphan drug market is forecast to grow to \$127 billion by 2018, representing almost 16 percent of the entire worldwide prescription market (excluding generics).⁴⁶ Lower development costs compared to more generalized medicines and the ability to charge a price premium make orphan drugs an appealing focus area for large and small pharma companies.⁴⁷ Similarly, biological products are making a growing contribution to company pipelines and overall worldwide sales. By 2018, about 50 percent of top-100 product sales are expected to be generated by biologics.⁴⁸ China's biologics market is poised to take off as policy initiatives, consumer awareness and reimbursement dynamics improve, although companies operating in China today or looking to enter the biologics market there will need to define precise, impactful strategies to unlock its potential.

Figure 4: U.S. FDA drug approvals, 1990-2012



Source: DTTL Global Life Sciences and Health Care Industry Group analysis of FDA's Center for Drug Evaluation and Research and Reuters

⁴³ <http://www.prnewswire.com/news-releases/hospiras-inflectra-infliximab-the-first-biosimilar-monoclonal-antibody-to-be-approved-in-europe-223098561.html>

⁴⁴ EIU Healthcare World Outlook

⁴⁵ *Measuring the return from pharmaceutical innovation 2013*, Deloitte Centre for Health Solutions, Deloitte LLP, December 2013

⁴⁶ Ibid

⁴⁷ Ibid

⁴⁸ Ibid

⁸³ BMI 2011, Deloitte research and analysis

⁸⁴ BMI 2011, Deloitte research and analysis

⁸⁵ EIU Russia: Healthcare and Pharmaceuticals Report, June 2013

⁸⁶ Farmexpert Market Research Centre

⁸⁷ *Trends and practical aspects of development of the Russian pharmaceutical market – 2013*, Deloitte

Some regions and/or governments are actively supporting life sciences innovation: As mentioned earlier, several nations have created/are creating regulatory pathways that support biosimilars production. France's government supports life sciences R&D with a favorable research tax credit regimen. The U.K. Patent Box tax legislation encourages innovation by providing an incentive to companies performing R&D in the U.K. India recently unveiled "Pharma Vision 2020," aimed at making it a global leader in end-to-end drug manufacturing — the initiative features a reduced approval time for new facilities to boost investments. Japan's government plans to expand the life sciences market by approximately 30 percent by 2020. China is seeing an era of partnerships across the public and private sectors. Local governments are cooperating with private insurance providers to manage public insurance funds, and life sciences companies are co-developing products and other core competencies by joining forces with distributors. Still, establishing and operating a joint venture in China can be a complex and time-consuming task.

A major challenge for life sciences companies is how to productively turn innovation into commercial products. Many innovations require more than traditional small-molecule chemistry or large-molecule-based biology; they tend to require expertise in a number of scientific disciplines. Consequently, there is considerable multi-disciplinary activity occurring around today's life sciences innovation, which requires collaboration and cooperation, both characteristics of new risk-sharing business models. Increasingly, companies large and small, domestic and international, are engaging in joint ventures, partnerships, and acquisitions to fulfill their R&D and product pipeline objectives.

Finally, life sciences R&D portfolio management is transitioning from its traditional vertically integrated scientific R&D model to one that focuses more on asset management. Financial performance in life sciences R&D is becoming increasingly important to the sector, which continues to operate in a capital-constrained environment. The pre-recession days of "easy capital" appear to be at an end, which is prompting life sciences companies to consider adopting an "asset management" perspective on R&D and sharpen their pencils when measuring the return on investment (ROI) from their R&D plays. Businesses

are also beginning to think shorter term — how do they optimize ROI while holding the asset, rather than holding it from discovery through commercialization and seeing what happens in 10 years? This transition is creating growth opportunities for big pharma as well as nimble, entrepreneurial companies that understand the sector's evolution.

Clearly, today's R&D model differs greatly from that of a decade ago: It is multi-disciplinary and requires an ability to collaborate and partner. It also tends to have an external, patient-centric focus and is driven by rigorous financial assessment. Another characteristic of the emerging models is that there is explicit consideration about investment, risk, and knowledge — and how partners will share this to maximize an asset's commercial viability. The industry is also seeing collaboration among non-traditional partners such as philanthropic organizations. For example — the new Global Health Investment Fund (GHIF), structured by JPMorgan Chase & Co. and the Bill & Melinda Gates Foundation, is designed to finance late-stage global health technologies to fight challenges in low-income countries such as malaria, tuberculosis, HIV/AIDS and maternal and infant mortality.⁴⁹

Issue three: Complying with regulatory changes

In the last decade, there has been a growing list of regulatory requirements or expectations imposed on the life sciences sector. With an increasing reliance on technology and collaboration to achieve transformation of commercial and R&D processes, companies around the globe are exposed to compliance risks in ways that can be unfamiliar and anxiety-inducing.

Regulatory compliance is a critical issue, particularly in emerging markets such as Southeast Asia, India, China and Latin America. Noncompliance can be costly: It can expose an organization to revenue losses, reputational risks, and patient safety issues or, worse, criminal sanctions against individual employees, and can jeopardize the future of an entire business unit or company. Compliance issues facing life sciences companies big and small include government policies and mandates, drug safety, counterfeiting, information security and privacy, intellectual property protection, corruption, and M&A/joint venture (JV) and other third-party risks.

organizations and consumers will continue due to general demographic trends. In addition, the September 2013 re-election of Chancellor Angela Merkel and her conservative bloc — which received 41.5 percent of the vote — their best result since 1994⁸¹ — may lead to new health system reform in 2014. What form this may take, and what regulatory constraints, price pressures, and business model/R&D impacts it may have on life sciences companies, are as yet unclear but bear watching. It will be of particular interest to see if Germany further develops its legislation towards value-based pricing allowing real-world evidence or real-world drug utilization to support its existing indication-based price negotiations. In the short term, however, it is more likely that the current AMNOG system, based on the assessment of additional benefit and subsequent central price negotiation, will be incrementally improved and further refined. (Figure 6)

In response to these and other market drivers, life sciences companies operating in Germany will have to clearly demonstrate and communicate a product's clinical and economic value to gain market approval, adoption, and reimbursement. In addition, closer collaboration with payers (sick funds) will become more important once a company's product is on the market. They also should consider M&A and JVs as a way to augment their product pipeline and continue to integrate their commercial and R&D functions. Finally, companies should focus on being consumer-centric and leverage new communications technologies to better understand patients and consumers, all while ensuring regulatory compliance.

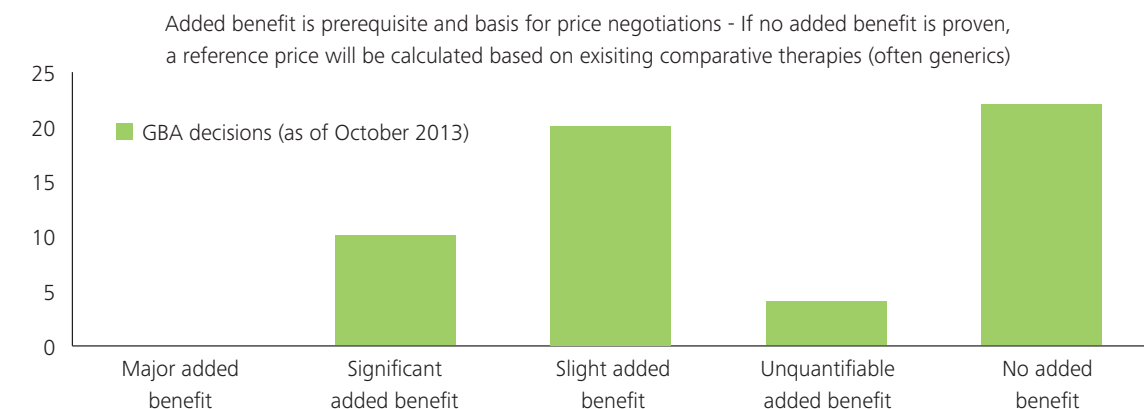
Middle East/North Africa

Market Fact: Product registration and pricing, and intellectual property (IP) protection are among the top issues facing life sciences firms operating in the Middle East/North Africa. When combined with the region's instability, these issues are expected to curb significantly the appetite of international drug companies to manufacture and/or do research in the Middle East.

The key life sciences markets in the Middle East/North Africa (MENA) region are Egypt, Saudi Arabia, United Arab Emirates (UAE), Jordan, and Syria, with activity also present in Bahrain, Kuwait, Oman, and Qatar. Given the current turmoil in some of these countries, life sciences market growth in 2014 is expected to be limited.

In the Gulf Cooperation Council (GCC) where the most significant economic activity takes place among countries in the Middle East, a growing and aging population and increasing total health care expenditures per capita are supportive of life sciences and health care industry growth. The GCC's population is expected to increase by five percent YoY, driven mainly by the influx of expatriates. While the dominant age group is estimated to be 30-44 year olds, the 45-65 and 65+ age groups are expected to grow cumulatively by an average of six percent between 2011 and 2020.⁸² Among other favorable trends are continually improving health care standards; governments' increasing investments in technological advancements and health

Figure 6: GBA (The Federal Joint Committee) decision on the level of added Therapeutic benefit granted to newly approved drugs



Source: D TTL Global Life Sciences and Health Care Industry Group analysis of GBA

⁴⁹ "New Investment Fund will Advance Late-stage Vaccines and Other Global Health Technologies," Yahoo Finance, September 23, 2013. <http://finance.yahoo.com/news/investment-fund-advance-stage-vaccines-040100472.html>

⁸¹ "Germany's Angela Merkel faces tough coalition talks," BBC News Europe, September 23, 2013. <http://www.bbc.co.uk/news/world-europe-24203909>. Accessed September 26, 2013

⁸² United States Census Bureau, 2009; Deloitte Development LLC research and analysis, Nov 2009

To strengthen their ability to compete, life sciences companies will need to shift their focus from competing on volume to competing on value. To do this will require a robust comparative effectiveness (CE) strategy and a fact-based evidence program that supports current commercial activities, informs late-stage clinical development, and provides forward visibility of the strategic needs to grow the business.

EMEA

France

Market Fact: To reduce a projected deficit to €6.2 billion, French authorities are proposing a set of measures in the draft of the 2014 financing law for social security that targets the life sciences sector: While drugs represent only 15 percent of total social security spending, they will support 56 percent of the targeted savings.

2014 is likely to be another difficult year for the life sciences sector in France, following shrinking sales in both 2012 and 2013. Because of the government's efforts to contain spending on pharmaceuticals, sales are forecast to rise only moderately from an estimated \$47.4 billion in 2012 to \$48.5 billion in 2017, an average annual increase of .05 percent in dollar terms.⁷⁸

The economic downturn is a contributing factor to the stunted growth; France's GDP growth will likely be zero in 2013 as it was the previous year, and unemployment is high (10.8 percent). These fiscal woes, combined with France's fast-growing aging population and long life expectancy (78.4 years for men and 85.0 for women) and the rising incidence of chronic diseases are making the economic equation of Social Security difficult to solve. Consumption of medicine is increasing substantially more than GDP, thus the deficit is chronic and every year a new adjustment plan is enforced to contain it. The successive plans are largely targeting the life sciences sector, and include measures to control the growth of health care spending via recurrent price cuts (€700 million planned for 2013) and product delistings to targeted programs to increase public acceptance of generic prescriptions as well as financial incentives to HCPs for better prescription monitoring.

⁷⁸ EIU France: Healthcare and Pharmaceuticals Report, June 2013

⁷⁹ Economist Intelligence Unit, 2013

⁸⁰ EIU Germany: Healthcare Report, September 2013

Market access is another complicating factor: a series of laws and decrees passed during 2011-2012 is expected to drive access based on comparative effectiveness and cost effectiveness data and post-marketing studies. As a consequence, launching new, innovative drugs may become even more challenging for pharmaceutical companies. So far, authorities have mainly relied on price-volume agreements to control the budgetary impact of expensive new drugs; they likely will add new requirements with more sophisticated risk-sharing agreements based on patient outcome or differentiated by indication to further strengthen the process for obtaining a premium price.

Despite these and other challenges, the life sciences sector remains a precious asset for France. It is the second-largest investor in R&D, behind the automotive sector. Authorities support life sciences R&D efforts with a favorable research tax credit regimen. The life sciences sector also is a major contributor to France's commercial economy, with significant exports and a large positive balance. To restore the life sciences sector's declining attractiveness and competitiveness, France's government and sector leaders will need to work collaboratively to address Social Security/health insurance funding issues as well as impediments to market access, especially for innovative drugs.

Germany

Market Fact: Germany is the fourth largest pharmaceutical market, and the largest in Western Europe. Although less impacted by the ongoing fiscal crisis than other EU countries, it is addressing pricing through assessment of additional benefit and subsequent central price negotiations.

Germany is the fourth-largest pharmaceutical market in the world and the largest in Western Europe, with sales of \$36.6 billion in 2012. The market is expected to grow at an annual rate of 2.7 percent from 2012-2016.⁷⁹ In terms of pharmaceutical production, it is the second-largest market in Europe, after Switzerland.⁸⁰

The impact of Europe's ongoing fiscal crisis has not yet had a significant negative impact on Germany. By contrast, Germany can be considered a beneficiary of the crisis as risk-averse money keeps the country's interest rates at record lows. However, price pressure from both payer

Government policies and mandates

The U.S. FDA, Europe's EMA, the Brazilian National Medicines Agency (ANVISA), and Mexico's Federal Commission for Protection against Health Risks (COFEPRIS) are among the scores of government agencies that regulate life sciences product approvals, and that investigate and litigate alleged fraud violations, product quality issues, corruption, and improper sales activities such as off-label promotion of drugs or improper contact with physicians. While each country develops and enforces its own regulations, such as the U.K. Bribery Act, and the U.S. Physician Payments Sunshine Act and the Foreign Corrupt Practices Act (FCPA), increasing numbers of countries are enhancing cross-border agency collaboration to strength regulatory decision making and enforcement actions.

Drug safety

Drug safety standards — particularly those associated with quality systems implementation, data integrity, and validation of processes in manufacturing or testing — continue to tighten in countries around the world. For example, in July 2012 the new Pharmacovigilance Committee at the EMA strengthened post-launch drug monitoring. In January 2013 the E.U.'s new laws on falsified medicines came into effect — all imported active pharmaceutical ingredients must be produced in compliance with the E.U.'s Good Manufacturing Practice. Following a succession of health scandals which have surfaced over the last three years, the industry and various governments are addressing drug safety; for example, the new Good pharmacovigilance Practice (GVP) modules which the EMA is proposing throughout the EU.⁵⁰ Some pharmaceutical companies are also taking voluntary steps to advance drug safety measures: GlaxoSmithKline (GSK) announced that it planned to make more of its trial data available.⁵¹ Others are investing in robust, long-term cleansing and archiving of data for compliance purposes and promote ongoing oversight through regular review of KPIs.

Certain countries struggle with drug safety issues more than others. For example, in 2012 more than 100 people died in Pakistan after taking contaminated medicine. The U.S. FDA found contaminants in drugs manufactured in India; as a result, pharmaceutical companies there have experienced regulatory actions, including drug recalls, warning letters, and penalties from the FDA for violating U.S. rules such as lapses in good manufacturing practices. To improve the situation, the Indian government in March 2013 gave approval for the FDA to add seven new drug inspectors in India. The FDA's expanded presence allows it to collaborate with its Indian regulatory counterparts and enables India to leverage the combined resources, harmonize science-based standards, and increase its regulatory capacity.⁵²

Counterfeiting

Although precise and detailed data on counterfeit medicines is difficult to obtain, World Health Organization (WHO) estimates range from around one percent of sales in developed countries to over 10 percent in developing countries, depending on the geographical area.⁵³ Other sources estimate between eight and 15 percent of all medicines sold worldwide are counterfeits.⁵⁴ Weak or incomplete supply chain security — particularly when many supply chains are expanding across the globe — is exacerbating the spread of counterfeit drugs, particularly in emerging markets. While the counterfeit market is hard to quantify, it is supposed to increase 15 percent a year, which is double the expected rate for legitimate pharma. Legislation such as the EU's Falsified Medicines Directive (FMD) has been enacted with the goals of reducing counterfeit products and bringing some transparency to the parallel trade.⁵⁵

⁵⁰ http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp

⁵¹ EIU Healthcare World Outlook

⁵² *Economic Times*. http://articles.economictimes.indiatimes.com/2013-09-24/news/42361200_1_medical-products-india-inspections

⁵³ http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/

⁵⁴ "Trade in illegal medicine hits pharmaceutical sector," *World Finance*, April 20, 2012. <http://www.worldfinance.com/home/special-reports-home/trade-in-illegal-medicine-hits-pharmaceutical-sector>. Accessed October 16, 2013

⁵⁵ <http://www.efpia.eu/articles/coding-identification-products-towards-safer-medicines-supply-0>

Information security and privacy

The transforming health care system is producing an immense volume of information, and much rides upon its availability, integrity, and confidentiality. However, new care models, health insurance models, electronic medical record (EMR) and other technologies, and permeable boundaries among industry stakeholders increase the complexity of managing protected health information (PHI) and compound an already challenging issue.⁵⁶ In addition, life sciences companies in the sector are increasingly challenged to protect their intellectual property (IP) and other valuable intangible assets. Finally, networked medical devices and other mobile health (mHealth) technologies may be a vehicle that exposes patients and health care provider organizations to safety and security risks. Among the unintended consequences of health care's digitization and increased networked connectivity are the risks of being hacked, being infected with malware, and being vulnerable to unauthorized access.⁵⁷

Increased government focus on information security and privacy is most evident in the United States, where the Department of Health and Human Services (HHS) has taken a series of steps to strengthen patient privacy protections and to monitor and enforce these protections. The Health Insurance Portability and Accountability (HIPAA) Omnibus Final Rule, with a compliance date of September 23, 2013, strengthens regulatory protections for patient information, increases penalties for breaches, and emphasizes agreements with business associates.⁵⁸

Potential patient safety, economic and reputational damage may arise if organizations lack appropriate security and privacy controls: lost productivity and other costs, brand and reputational loss, and loss of consumer goodwill, among others. Health care industry stakeholders — providers, health plans, retail health, bio-pharma, and medical technology companies — should consider whether they have a need to promptly assess potential capability gaps, define their security and privacy vision and needs, and develop appropriate remediation programs.⁵⁹

Intellectual property protection

Ineffective intellectual property (IP) protection is frequently an issue in emerging markets such as Russia, India, China and the Middle East, which may lack effective government legislation to protect foreign companies' IP holdings and where third-party manufacturers may not always be respectful of IP rights. Unless IP issues are sorted out, life sciences companies will need to adapt their drug portfolios and commercialization strategies to the particular local market conditions, depending on the level of IP enforcement.

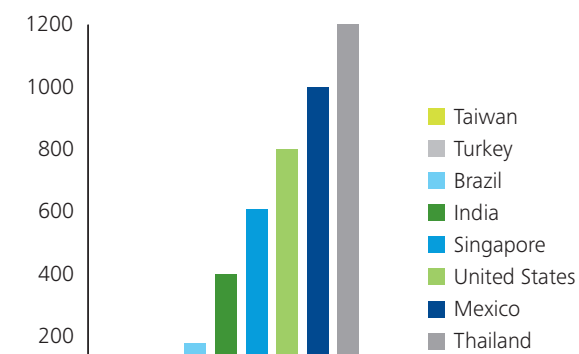
Corruption

Evidence of corrupt business practices continues to surface across the global life sciences sector, particularly in emerging markets, which frequently lack transparent business practices regarding employee incentives and interaction with third-party intermediaries (TPIs), and strong and effective accountability and controls. Moreover, local traditional business practices are frequently at odds with global corporate policies and international government regulators.

Recent cases of widespread corruption have generated considerable attention. Russia has been the site of several scandals related to pharmaceutical company illegal or anti-competitive business practices; government-paid hospital segment purchases have proved to be a particularly corrupt area. In response, multinationals are establishing and/or reinforcing anti-bribery procedures in their Russian subsidiaries, as well as increasing focus on compliance matters.⁶⁰ A crackdown in China amid bribery allegations against the pharmaceutical industry has impacted sales at both international and local pharmaceutical firms.⁶¹

Two trends are of considerable interest to life sciences companies operating in Mexico: Medical tourism has experienced rapid growth in recent years, offering significant economic advantages to the country and its health care, life sciences, and hospitality industries. With over one million patients a year, Mexico is the second leading destination for medical tourism globally, behind Thailand (Figure 5).⁷⁵ Of high importance is focusing on post-operative procedures and medicines to facilitate patient recovery. As most medical tourists come from the United States, the medical tourism industry is attempting to strengthen the links between American and Mexican health centers so they can coordinate the delivery of correct post-surgery services.

Figure 5: Medical tourism destinations in 2012 (thousands of patients)



Source: D TTL Global Life Sciences Industry Group analysis of Patient Beyond Borders data

The use of electronic medical prescriptions, which offers the possibility of avoiding human errors, optimizing fulfillment times, reducing operating costs, better controlling drug inventory, providing more efficient access to medical records, and improving patients care, is also on the rise in Mexico due to recent government mandates requiring that certain pharmaceuticals, particularly antibiotics, only be dispensed by prescription.⁷⁶ This offers potential benefits to health care providers and life sciences companies alike. However, implementing a certified system of electronic prescriptions that aligns and leverages government and commercial strategies is expected to take considerable time and investment.

United States

Market Fact: Changes related to ACA, competing on "value versus volume," new commercial models, and real-world evidence and how it informs much of the health care industry life cycle are major drivers in the U.S. life sciences market.

2014 is anticipated to be a positive year for U.S. life sciences companies, as they continue to obtain greater clarity on ACA implementation and its impacts, become increasingly better at capitalizing on emerging market opportunities, and incorporate real-world evidence into their strategic thinking and decision-making.

The EIU projects the U.S. pharmaceutical market, the world's largest at \$396 billion in 2011, will grow 6.4 percent annually through 2011-16.⁷⁷ Demographics and disease trends will boost drug consumption, while the expansion of insurance coverage to millions of uninsured Americans under the ACA (via health insurance exchanges and Medicaid expansion) is forecast to increase revenue for drug makers. However, ACA-related pharmaceutical sector fees, a new medical device tax, and lower government drug prices could negatively impact growth. The FDA's continued work to finalize a biosimilars pathway is also a concern.

The current Administration's policies are playing a key role in transforming the U.S. health care marketplace and shaping the life sciences sector's short- and long-term planning. Competing visions are the watchwords: Following re-election, the Administration has an opportunity to accelerate the implementation of key reform elements through the actions of HHS, and to drive funding appropriations through Congress. Heading into 2014, the country will see a fair number of initiatives, such as health insurance exchanges, beginning to go from proposed to enacted to implemented. The competing vision to this approach is: "What will be the priorities?" "What will be the impact?" and "What will be the marketplace and sector reactions?"

The U.S. health care provider landscape is also changing — physician-hospital consolidations are growing in frequency and combined purchasing departments are growing in influence. This is driving life sciences companies to employ new business models that recognize the power of new decision-makers in product pricing and selection.

⁵⁶ Issue Brief: Update: Privacy and security of protected health information: Omnibus Final Rule and stakeholder considerations, Deloitte Center for Health Solutions, Deloitte Development LLC, 2013
⁵⁷ Issue Brief: Networked medical device security and patient safety: Perspectives of health care information security executives, Deloitte Center for Health Solutions, Deloitte Development LLC, 2013
⁵⁸ Health Data Management. What HHS/OCR will look for in HIPAA compliance audits, Mar 21 2013, via Factiva
⁵⁹ Issue Brief: Update: Privacy and security of protected health information: Omnibus Final Rule and stakeholder considerations, Deloitte Center for Health Solutions, Deloitte Development LLC, 2013
⁶⁰ 2013 Global life sciences outlook: Optimism tempered by reality in a "new normal," Deloitte Touche Tohmatsu Limited, 2012
⁶¹ "Ouch! The Chinese Bribery Scandal is Hurting Big Pharma," Forbes, October 15, 2013. <http://www.forbes.com/sites/edsilverman/2013/10/15/ouch-the-chinese-bribery-scandal-is-hurting-big-pharma/>. Accessed November 4, 2013.

⁷⁵ PROMEXICO. (2013). *Turismo de Salud*, available at http://mim.promexico.gob.mx/work/sites/mim/resources/LocalContent/374/2/130925_DS_Turismo_de_salud_ESP.pdf
⁷⁶ GALAZ, YAMAZAKI, RUIZ URQUIZA. *El panorama en desarrollo de la prescripción electrónica. Oportunidades para la industria farmacéutica y sector salud*, available at [http://www.deloitte.com/assets/Dcom-Mexico/Local%20Assets/Documents/mx\(es-mx\)prescripcionELECTRONICA_121010.pdf](http://www.deloitte.com/assets/Dcom-Mexico/Local%20Assets/Documents/mx(es-mx)prescripcionELECTRONICA_121010.pdf)
⁷⁷ EIU Database; Medical Device Market – US – Espicom, Mind Power Solution Report

Market updates

Americas

Brazil

Market Fact: Brazil is the largest pharmaceutical market in Latin America. Pricing pressure, cost control, and product portfolio management are among the issues facing its life sciences sector in 2014.

Brazil is the largest pharmaceutical market in Latin America and the 10th-largest in the world, accounting for about two percent of overall demand. 2012 sales were an estimated \$36.9 billion (including taxes). Pharma sales are forecast to grow to \$48.7 billion by 2017, supported by rising household incomes but somewhat constrained by government efforts to hold down the prices of patented drugs.⁷¹

Pricing pressure, cost control, and product portfolio management are among the issues facing Brazil's life sciences sector in 2014. Pricing pressure occurs on two fronts: Manufacturers must submit all proposed drug prices to an independent organization, the Regulation Drug Market Committee (CMED), whose final market price may be lower than what the manufacturers submitted. Also, Brazil has a strong local generics industry (the largest in Latin America), which is supported by government policies aimed at extending the availability of medicines to low-income consumers.⁷² These pressures are prompting life sciences companies to employ various strategies to identify the optimal price for their key products.

Brazil's product registration and launch process through ANVISA, the national health agency, is complex and expensive; to control costs, life sciences companies need to carefully consider country-specific conditions (e.g., competitive offerings, proposed distribution system, regulatory issues) before moving forward with new market offerings.

Some life sciences companies in Brazil operate discount programs, which can present portfolio management challenges. Discount programs allow patients to buy drugs at a reduced cost, encouraging adherence. Companies usually have several discount programs for each product, which can complicate pricing and distribution.

To address these and other challenges, life sciences companies are investing in new processes and technologies, such as tools that can control and evaluate market pricing performance. Furthermore, companies are starting to implement new business models to optimize the regulatory process at ANVISA.

Mexico

Market Fact: Improving health care coverage, aging population, and medical tourism are supporting demand.

2014 could be a promising year for the life sciences sector in Mexico. The market is Latin America's second-largest (after Brazil) and accounts for a quarter of Mexico's health care spending. After falling by an estimated three percent in 2012, pharmaceutical sales are expected to rebound in 2013, growing by seven percent. Sales are forecast to grow by an average of over six percent in 2014-17, as improving health care coverage and an aging population support demand.⁷³

Health care spending as a percentage of GDP has increased 15 percent in the last decade (from 5.6 percent in 2000 to 6.4 percent in 2012) and the national government is advocating system improvements to "generate predictability for the market [...] and to have a better set of alternatives for consumers, hence protecting public health care."⁷⁴ As part of this initiative, the government is defining an effective structure for universal health care coverage, while also striving to improve service quality and reduce system costs. Mexico is also moving ahead with its Millennium objectives, which have helped to decrease the maternal mortality rate (MMR) 1.5 annual points since 1990. In fact, the national government is developing a strategy that requires state and local commitments to reduce the MMR from 2 to 2.5 points annually. In addition, the Mexican Health Ministry has launched a national strategy to prevent diabetes and obesity, highlighting the importance of investing in preventive health care because the costs of these chronic illnesses are extremely high.

To counter these and other misdeeds, governments are stepping up their anti-corruption activities. The United States continues to aggressively identify and pursue FCPA violations. Addressing incidents in the life sciences and health care industry is a key component of China's nationwide anti-corruption drive; the serious intent of the drive was underscored by the investigation of the multinational pharmaceutical company. This action against alleged bribe payers, as opposed to the traditional focus on bribe recipients, was the first of its kind against multinational drug companies operating in China.⁶² Chinese authorities are expected to continue tackling issues within the industry with the National Development and Reform Commission looking at overpricing by 60 Chinese pharmaceutical companies, and China's Food and Drug Administration launching a six-month campaign to clean up China's health care system, primarily to tighten industry regulations and rein in illegal online drug sales.⁶³

A deep understanding of the business practices and regulatory requirements that are particular to a specific country is crucial for mitigating instances of corruption. Increased global analytic techniques, trending assessments, and focused auditing and monitoring are important efforts in identifying suspicious patterns that may require further follow-up and investigation in a local market.

M&A and joint ventures

Increasingly, life sciences companies are conducting M&A and JV transactions or have key third-party contractual relationships in emerging markets. This can add considerable cultural and geographic complexity to the due diligence process, as well as the potential for increasing potential exposure and compliance issues, as these markets are still evolving and may have less reliable legal and regulatory systems, and different accounting practices. Among potential concerns are the quality and veracity of financial information; lack of infrastructure and substantive controls; inadequate reporting of liabilities; unclear legal title of assets; and questionable local governance and operational practices. It is important that companies allot additional time for due diligence when transacting

emerging market deals; it can be difficult to "get behind the curtain" because syndicated data and reliable research is not as well developed as the sources routinely consulted in developed markets. Drawing upon the (independently verifiable) knowledge of advisors with experience in specific country and market practices can facilitate the process; however, all local representatives should be thoroughly vetted to avoid FCPA issues. Important watch words: Know the relationship; know the partners.

Issue four: Operating in a smaller and connected world

Global life sciences players increasingly operate in a smaller and connected world, which presents both opportunities and challenges.

Large pharmaceutical companies are investing and expanding in emerging markets to offset revenue losses due to patent expirations, slower brand spending growth, and increased cost containment actions by payers in mature, developed markets. By 2016, developed markets are predicted to decline to 57 percent of global drug spending, down from 66 percent in 2011. In contrast, emerging markets' share of spending is projected to increase by 10-30 percent over the next five years, as population and economic growth drive higher use of medicines.⁶⁴ Despite these projected differences in drug spending, however, developed and emerging markets exhibit many of the same demographic trends that favor continued life sciences sector growth.

The aging population is a shared, long-term trend in markets including Western Europe, Japan, and — surprisingly — China, where it is expected to combine with a sharp decline in the number of young people. (China's decline may be related to the impact of family size policies.) Overall life expectancy is expected to increase from an estimated 72.6 years in 2012 to 73.7 years by 2017, bringing the number of people aged 65+ to over 10 percent of the total population.⁶⁵

⁷¹ EIU Brazil: Healthcare Report, July 2013

⁷² Ibid

⁷³ EIU Mexico: Healthcare Report, July 2013

⁷⁴ ARRIOLA, Mikel, Interview with COFEPRIS: Mikel Arriola, *Health Care & Life Sciences Review*, 18-19, México, 2013.

⁶² *Corruption risk in the Chinese pharmaceutical market*, Deloitte Touche Tohmatsu Certified Public Accountants LLP, 2013

⁶³ Ibid

⁶⁴ IMS Market Prognosis, May 2012

⁶⁵ Ibid

Stakeholder considerations

The biggest shared demographic trend is the spread of chronic diseases, which is due to the aging population, more sedentary lifestyles, diet changes, and rising obesity levels. Cancer and heart disease are becoming major causes of death, even in emerging markets. Africa, the Middle East, Asia and Latin America are experiencing epidemics in diabetes and cardio vascular illnesses. India has the largest number of diabetes sufferers anywhere in the world, at more than 30 million. That number is expected to more than double within the next 20 years,⁶⁶ bringing with it the need for treatment options at varying price points. The situation is similar in China, which has an estimated 100 million hypertension sufferers — and three million new cases every year.⁶⁷ In addition, diagnosis of diabetes in China is expected to nearly double to 114 million in 2025.⁶⁸ The cost of treatment for these various diseases — which may be out of reach for many consumers, especially in emerging markets — is expected to compel a more intense focus on disease prevention by governments and health care practitioners even as life sciences companies work to develop innovative new medicines.

Technology advancements are also connecting developed and emerging markets — and participants along the health care and life sciences value chain. Adoption of new digital health information technologies (HIT) such as electronic medical records (EMRs), telemedicine, and mobile health (mHealth) applications, and electronic medical prescriptions is driving change in the way physicians, patients and other sector stakeholders interact. In addition, the increasing use of M&A, JVs and other collaborative business models means that companies with disparate systems will need to synergize their local operations with global requirements; this can be a challenge because emerging markets often lack a reliable technology infrastructure. These and other technology-based changes are shifting the power balance within the health care system and driving different dialogues along the value chain. Life sciences companies should think about how to effectively leverage digital technologies to improve their engagement with partners and customers and to continue propelling growth. Already, top pharma manufacturers are focusing on optimizing their IT investments, concentrating their efforts on facilitating real-time communication and visibility between the R&D and marketing sectors.

The following are among important considerations for life sciences sector stakeholders as they look to address marketplace and organizational issues in 2014:

Health care reform: Health reform is going to accelerate the transformation of global health care from a volume-to value-based marketplace. And that means companies in pharma, biotech and medtech will be having different conversations with different people than they traditionally have. Going forward it is no longer a physician-preference world; governmental organizations, patient advocacy groups, hospital administrators, and other stakeholders will play a key role in product selection and purchase. Companies will need to be responsive to how the market wants to buy rather than fixating on how the company wants to sell. Also, what the market wants is important: Pharma companies need to develop what they can sell, not simply sell what they can develop. Real-world evidence and an ability to articulate their value proposition by addressing a product's clinical, safety, and economic impact will become determining factors in a company's future competitive position. Organizations that only have price as their strategic lever will be at a disadvantage.

Life sciences companies should take a strategic, global approach to health care reform by focusing on challenges that are common across major markets, such as value-based pricing and other cost-reduction strategies. Some organizations already have responded by making substantial changes in their innovation processes and sales models. Life sciences firms also should look at the challenges and opportunities that specific national reforms can bring because local tactics of a global strategy will inevitably vary. Given that many of the industry's challenges are impacting governments around the world, it is expected that changes in one market may influence other markets.

Innovation and value: Opinion differs on whether life sciences R&D productivity is improving, declining or remaining static. Some reports indicate that better quality new drug approvals in 2012 coupled with a sector that is returning to growth, signal that life sciences R&D productivity may be improving.⁶⁹ However, analysis of the late-stage pipelines of a cohort of 12 leading life science R&D spenders, conducted by the Deloitte Centre for Health Solutions, indicates that overall R&D returns have been declining since 2010. While the number of new compounds entering the late stage pipeline has remained static, the forecast value of those compounds has reduced. Although new compounds have delivered enough value

to balance losses due to approvals, this uplift in value has been insufficient to balance additional value leakage due to terminations, reductions in forecast value for existing compounds and increasing costs. The cohort results do hide variations between companies; indeed in 2013, five of the 12 companies analyzed showed improvements in both net commercial success (sum of approvals less terminations) and net pipeline replenishment (sum of new compounds plus changes in forecasts of existing compounds). Additionally, the average total value of a drug approved in the year to April 2013 increased by 55 per cent compared with the previous year. This suggests that companies have commercialized higher-quality assets during the 12 months to April 2013, compared with the 12 months to April 2011.⁷⁰ This is "higher quality" in the context of calculated value and not necessarily medical or individual patient value. This calculation is dynamic and can be impacted by changing forecasts and competitor new product approvals or changes in product lifecycle management, as well.

Regulatory compliance: Executives at many life sciences companies are deciding that it is worth pursuing stronger compliance risk management capabilities for their own sake, rather than to merely satisfy emerging legal requirements. They are re-evaluating their organization's entire approach to managing compliance risks, applying many of the methodologies used for financial reporting to compliance issues. They are putting formal governance and organizational structures in place, forming freestanding compliance and risk committees at the board level, and more. Taking a risk-based approach to compliance planning, execution, and monitoring makes good business sense in a heightened regulatory environment. It enables companies to focus on critical risk areas that need attention while reducing emphasis and effort on less critical ones.

Smaller and connected world: Thanks to the rapid advancement of technology, consumers now have access to more information than ever before. They can readily find out about and monitor their own health status; know what treatment options others in a similar situation have used; and find data on outcomes from drug therapy and other treatments. The "magic" of the science has been revealed, creating more of a level playing field than ever before — in both developed and emerging countries. The life sciences sector will need to respond appropriately by incorporating global knowledge and resources with new technologies to offer innovative, quality products and services that assist clinicians and consumers.

⁶⁶ EIU Healthcare World Market

⁶⁷ Ibid

⁶⁸ "'Catastrophe' as 114 million Chinese suffer diabetes thanks for economic boom," *South China Morning Post*, September 4, 2013. <http://www.scmp.com/news/china/article/1303257/catastrophe-114-million-chinese-suffer-diabetes-thanks-economic-boom>

⁶⁹ *World Preview 2013, Outlook to 2018: Returning to Growth*, EvaluatePharma, www.evaluategroup.com/wp2013

⁷⁰ Measuring the return from pharmaceutical innovation 2013, Deloitte Centre for Health Solutions, Deloitte LLP, December 2013