

2013 Global life sciences outlook

Optimism tempered by reality in a “new normal”

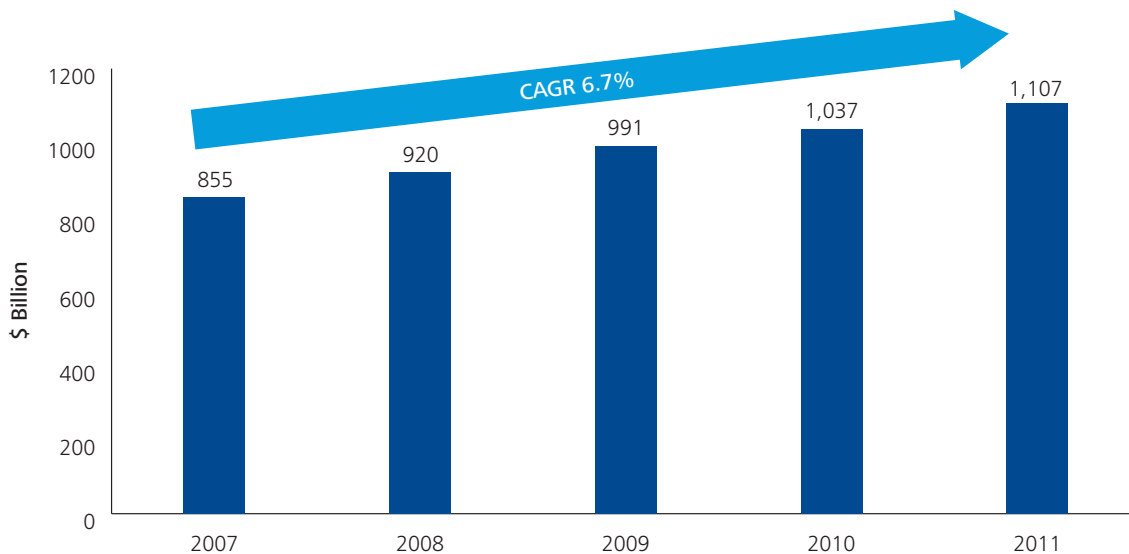


Overview

Call it a case of optimism tempered by reality: Following years of growth and favorable market trends, the global life sciences industry now finds itself facing a challenging “new normal.” A changing health care landscape, expiring patents and generic competition, pricing pressures, heightened regulatory scrutiny, expansion into emerging markets, increasing alliances and acquisitions, and a persistent economic slowdown are prompting global life sciences companies to adopt new business models designed to counter slowing sales growth and declining profitability, deliver better patient outcomes at lower cost, and position them for success in 2013 and beyond.

The global pharmaceuticals, biotechnology, and life sciences industry generated total revenues in excess of \$1.1 trillion in 2011, representing a compound annual growth rate (CAGR) of 6.7 percent between 2007 and 2011 (Figure 1).

Figure 1: Global pharma & biotech revenue, 2007-2011



Source: DTL Global Life Sciences and Health Care Industry Group analysis of “Global pharmaceuticals, biotechnology & life sciences industry profile” Marketline, May 2012, EIU database

Among specific market segments, pharmaceuticals accounted for \$798 billion in market revenue in 2011; and biotechnology accounted for \$289 billion. The Americas region accounts for the largest share of the global market, representing 46 percent of total revenues.¹

Several worldwide trends have fueled the industry’s growth and remain favorable in the long term:

- **Ageing population**, especially in the large markets (Americas and Europe). The growth rate for the world’s 65+ year-old population is projected to outpace that of the 0-4 year-old segment by 2020,² thus increasing demand for life sciences industry products and services.

¹ Ibid

² <http://www.prb.org/Articles/2011/agingpopulationclocks.aspx>

- **Rising incidence of chronic diseases.** As a result of changes in lifestyle and eating habits, people are becoming more prone to chronic diseases such as diabetes and hypertension which, in turn, are high risk factors for heart attack and stroke. The demand for and use of preventive drugs and medical devices and other assisted technologies like ehealth and mobile health are increasing, as a result.
- **Opportunities in emerging markets.** Companies increasingly are targeting growth in emerging markets as a way to offset sluggishness in developed regions.
- **Technological advancements and product innovation.** The areas of biotechnology and biosimilars, combination devices, and “big data” analytics are particularly active.
- **Health care reform provisions,** including increases in government funding and broader insurance coverage. In particular, the extension of health insurance to more than 30 million uninsured U.S. citizens under the Patient Protection and Affordable Care Act (PPACA or ACA) in 2014 is estimated to increase demand across the entire life sciences and health care industry in that country.

Yet, despite these trends, life sciences companies’ growth prospects are being tempered by a number of marketplace and operational challenges.

While the life sciences sector has remained partially immune to the current economic uncertainty in some parts of the world, the industry is facing reimbursement pressure from spiraling costs and overwhelmed health systems around the globe. The use of price cuts for life sciences products has been a feature of several governments’ successive attempts to control general spending on health care. Furthermore, the impact of any possible breakup of the European Union (EU) has potentially big implications for pharmaceutical pricing in that region.

In addition to dealing with fallout from the global economy, parts of the life sciences industry are facing slower sales growth and declining profitability, although R&D productivity seems to be stabilizing.³

Global pharmaceutical sales were projected to increase four percent in 2012 (~\$1,026 billion) compared to an annual sales growth rate of seven percent from 2007 to 2011.⁴ Also, the U.S., the world’s largest market, was projected to increase around one percent in 2012.⁵ Concurrently, life sciences companies are spending fewer resources (time, money and personnel) on developing new drugs. Globally, the pharmaceutical industry in 2010 spent ~\$68 billion on R&D, which was down nearly three percent from the \$70 billion spent in 2008 and 2009.⁶ Finally, company profitability is declining: Higher R&D and regulatory expenses, in addition to pricing pressures, are lowering margins. Globally, the Big Pharma operating margin for 2013 is forecast at ~20 percent, down from more than 24 percent from 2003 to 2009.⁷ This decline means that there are increasingly fewer dollars available for reinvestment in the business — just as regulatory and operational requirements are calling for major infrastructure investments, especially for regulatory reporting, drug safety systems, electronic pedigrees, “big data” analytics, commercial brand strategy, supply chain, M&A, and global business services. The decline also places significant pressure on making the right choices in R&D, especially late-stage clinical development to drive insights for product adoption, not just approval.

This report examines the current state of the global life sciences industry, 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 2013 and beyond.

³ Measuring the return from Pharma Innovation 2012, Deloitte United Kingdom

⁴ http://www.imshealth.com/deployedfiles/ims/Global/Content/Corporate/Press%20Room/Top-Line%20Market%20Data%20&%20Trends/2011%20Top-line%20Market%20Data/Global_Pharma_Market_by_Spending_2003-2011.pdf

⁵ Ibid

⁶ <http://www.reuters.com/article/2011/06/26/pharmaceuticals-rd-idUSL6E7HO1BL20110626>

⁷ Euler Hermes, “Does the global pharmaceutical industry need a new business model?”, Paris, France, March 20, 2012

Global life sciences industry issues in 2013

The major issues that global life sciences companies face in 2013 can be grouped into three primary focus areas: business portfolio evolution; regulatory landscape; and market and treatment changes. Challenges and opportunities emanating from each of these areas can be both global and market-specific.

Issue one: Business portfolio evolution

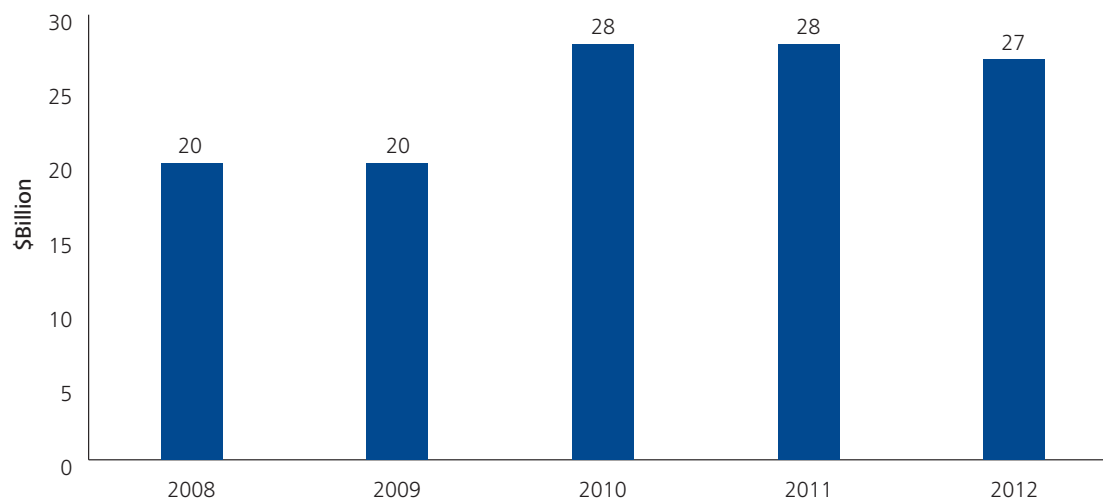
With the historic dynamics of western market growth, blockbuster drugs, and robust pipelines changing dramatically, the life sciences industry is engaged in evolving its business portfolio. This has happened before, when the industry faced pricing and competitive threats; at that time, the primary result was diversification. In the current evolution the focus is on narrowed pursuits in the forms of divesting to core pharmaceuticals, leveraging outside expertise, and partnering. While the concurrent challenges of looming patent cliffs and the associated quest to fill product pipelines, pricing pressures, M&A and licensing/collaborations, the role of emerging markets, and the growth of generics may impact players' evolution differently, the predominant result is increased focus. Let's examine how these trends are driving business portfolio evolution.

Patent cliff and product pipelines

A dramatic shift is taking place in the type of products coming out of life sciences company research labs — the reality of fewer billion-dollar blockbusters is being replaced by a focus on developing targeted treatments, which requires that companies invent and bring to market more products to fill the pipeline and generate comparable revenue levels.

This shift is one born of necessity and the evolution of chronic, "easier-to-treat" conditions to diseases with higher medical need. In fact, many of the world's top-selling drugs have gone or are going generic; over \$100 billion in drug sales were or will be lost to patent expiry between 2009 and 2012 (Figure 2).⁸ The year 2013 will be crucial for many pharmaceutical giants — especially U.S. and European companies — when it's expected to lose up to \$29 billion to patent expiry.⁹

Figure 2: Patent expiry by value (2008–2012)



- For the period, 2009-2012, drugs worth \$103 billion lost their patents.
- In 2009 alone, drugs worth \$20 billion lost their patent.

Source: DTL Global Life Sciences and Health Care Industry Group analysis of Global Generic, Cygnus

⁸ Global Generic, Cygnus

⁹ <http://www.fiercepharma.com/special-reports/top-15-patent-expirations-2013>

Several industry trends are indicative of pharma companies' efforts to address patent loss and shrinking product pipelines:

- **Cost-cutting** — Pharmaceutical companies have cut approximately 300,000 jobs since 2000; 150,000 of them since 2009. Also, global R&D funding by larger pharma companies is expected to drop by about 5.7 percent in 2012.¹⁰
- **New business segments and more flexible operating models** — Patent expiry and limited growth prospects have induced companies to look for faster ways to grow their business, such as expanding into emerging markets and embracing new commercial models with different types of engagement methods and expanded use of data analytics.
- **Increased M&A and alliance activity** — Many M&A deals and collaborations are aimed at expanding companies' portfolios in priority areas.
- **Focus on niche products** — Pharma companies increasingly are taking advantage of the commercial benefits of developing "orphan drugs," which have extra patent protections and a streamlined regulatory review process in some countries.

Pipeline-filling activities in Japan's life sciences market are indicative of global trends. Due to increasing challenges in their traditional lines of business, companies are expanding into other, allied areas. Many organizations are seeking to diversify their portfolios, rather than their businesses, by including products for orphan indications. Other, traditionally branded manufacturers are expanding into the generics industry. Finally, some companies are considering providing integrated health care-related services such as health care consultation and data management.

Pricing pressures

Worldwide, payers are pushing for lower drug prices to counter their own budget pressures resulting from the macroeconomic slowdown and to make health care more affordable for the public. Recent measures taken in Brazil, for example, have included drug price readjustments on nearly 24,000 drug presentations. This is a continuing trend, as Turkey several years ago lowered the ceiling prices for generic drugs and imposed a 12 percent reduction on patented drugs to curb health care costs, actions that still reverberate in that market. More importantly, price increases are becoming rarer while other operating costs have inflationary pressures.

Concurrent with pricing pressures, payers and drug regulators are demanding that products demonstrate superior patient benefits before granting reimbursement and marketing

approvals. In the United States, the ACA encourages comparative effectiveness research (CER) to compare medical treatments on the basis of safety, efficacy, and costs. Supporters of CER believe that the measure will discourage use of costly, ineffective drugs, and help to lower costs. However, branded drug manufacturers will likely struggle with declining revenue if their treatments are not proven to be more effective than cheaper alternatives. The ACA also establishes a new non-profit corporation, the Patient-Centered Outcomes Research Institute (PCORI), for conducting comparative effectiveness studies. The institute will not decide coverage or reimbursement policy, but the government will likely utilize the research outcomes in making coverage decisions.

The increasing influence of non-prescribing decision makers is evident in other markets, as well. Central organizations such as the National Institute for Health and Clinical Excellence (NICE) in the UK, the Health Minister's Council in the Middle East's Gulf Cooperation Council (GCC) states, and AMNOG in Germany are reviewing the clinical and wider economic benefit of new drugs in comparison with drugs already on the market.

Germany's latest health system reform requires pharmaceutical companies to prove the extent of an additional benefit of new products and introduces price negotiations so that pharmaceutical manufacturers are no longer free to set the price for innovative drugs.¹¹ If a company can satisfy the additional benefit requirement, the reimbursed price effective one year after market access will be negotiated between the manufacturer and the German statutory health insurance system, SHI.

Health systems around the globe also are increasing their focus on the outcomes of health interventions in patient populations. Clinical and cost outcomes data enables the real value of new drugs to be assessed after product launch, leading to the implementation of retrospective price adjustments or risk/reward reimbursement structures, including the development of real-world evidence and personalization of medicines (and of payments).

In response to increased product registration and pricing pressures, novel risk/reward arrangements are emerging that require new knowledge, skills, and capabilities for both drug companies and health systems. As a result, an explosion in health analytics as a service focused on market access and reimbursement strategies is taking place.

¹⁰ <http://www.forbes.com/sites/matthewherper/2011/04/13/a-decade-in-drug-industry-layoffs/>

¹¹ Managing Pathways to Convergence in the Life Sciences Industry, Deloitte Research, Deloitte Development LLC Fiercebiotech, Yahoo Finance, Technavio report, Espicom – Germany World Pharmaceutical Market Q4 2011

M&A and licensing/collaborations

Weak pipelines and diversification strategies to counter the threat of generic competition are driving life sciences M&A activity. According to Thomson Reuters, pharmaceutical and biotechnology transactions totaled \$103.9 billion in 2011, up from \$99.4 billion the previous year (Figure 3). More M&A activity is anticipated as companies face difficulty developing innovative products and seek to replenish their pipelines,¹² consolidate their core businesses, and access new areas of growth.

Large pharmaceutical companies are acquiring cash-strapped biotech firms or entering into new collaborative ventures and alliances to diversify their pipelines with high-margin biologics, which are less exposed to competition compared to prescription drugs. Pharma companies also are showing interest in medical device and technology companies due to higher margins and shorter product development time. Endo Health Solutions' acquisition of American Medical Systems for \$2.9 billion in 2011 is one example of this trend.¹³ As hospitals continue to cut costs, they are forcing companies to offer devices at reduced prices, driving the need for companies to consolidate. In addition, medical device companies are evaluating acquisitions of small emerging technology companies to help drive growth.

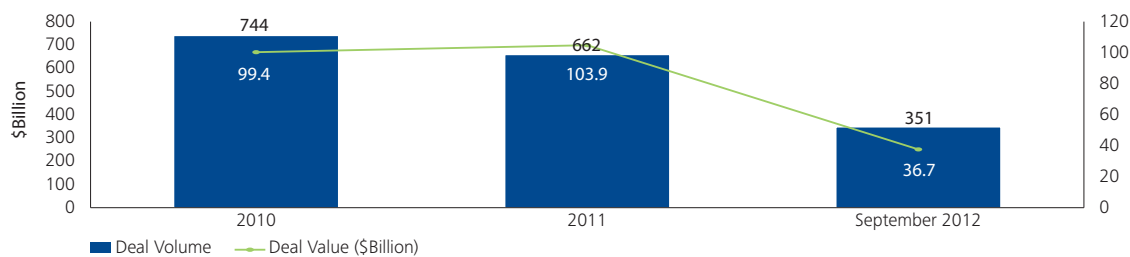
Mergers, consolidations and alliances will continue to transform the global life sciences market. With low interest rates and considerable cash on hand, global pharma players are penetrating burgeoning emerging markets by acquiring domestic generic manufacturing companies. For example, in April 2011, U.S. biotechnology company Amgen announced its acquisition of a privately-held Brazilian generics firm, Bergamo, for \$215 million.¹⁴ Following a wave of foreign-driven M&A, leading Brazilian pharmaceutical companies have strengthened their local operations via a number of partnerships, joint ventures, and acquisitions. In China, capital-rich pharmaceutical firms are considering mergers with and acquisitions of smaller pharma or biopharma companies to boost their product portfolios and reinforce their market presence.

Emerging markets

Life sciences companies increasingly are targeting emerging markets such as China, India, Brazil, and others to supplement sales in the U.S. and Europe (Figure 4).

Emerging markets accounted for 20 percent of global pharma sales in 2011.¹⁵ Key drivers fueling growth are an aging population, the rise of chronic disease in these locations, and a growing middle class with disposable income.

Figure 3: Pharmaceutical and biotechnology transactions



Source: DTL Global Life Sciences and Health Care Industry Group analysis of Thomson M&A

Note: Deal Volume and Deal Value is represented for completed deals only.

| Top LSHC transactions | | |
|--|---|---|
| 2010 | 2011 | September 2012 |
| <ol style="list-style-type: none"> 1. Novartis acquired the remaining 23% stake in Alcon/\$12.9 B 2. Merck KGaA acquired the entire share capital of Millipore/\$6.1 B | <ol style="list-style-type: none"> 1. Sanofi acquired the entire share capital of Genzyme/\$21.2 B 2. Johnson & Johnson acquired the entire share capital of Synthes/\$20 B 3. Takeda acquired the entire share capital Nycomed/\$13.6 B | <ol style="list-style-type: none"> 1. Bristol-Myers acquired the entire share capital of Amylin/\$7.1 B 2. GSK acquired the entire share capital of Human Genome Sciences/\$2.9 B |

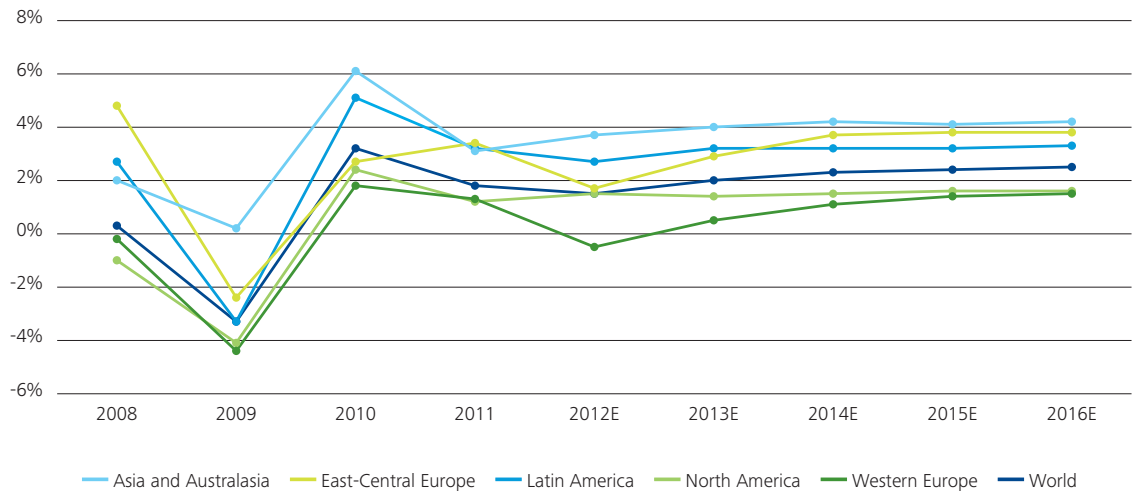
¹² <http://www.zacks.com/stock/news/73859/pharma-biotech-stock-outlook-april-2012>

¹³ Managing Pathways to Convergence in the Life Sciences Industry, Deloitte Research, Deloitte Development LLC Fiercebitech, Yahoo Finance, Technavio report

¹⁴ EIU Database; Medical Device Market – Brazil– Espicom, MOITI – Brazil Biotech Report

¹⁵ EIU Database; company annual reports and transcripts

Figure 4: Real GDP growth rates



Source: DTL Global Life Sciences and Health Care Industry Group analysis of EIU Database; company annual reports and transcripts

Favorable government policies are also driving emerging market growth. China’s policies, for example, could help draw an increasing number of players, particularly foreign entrants that are attracted by the country’s less expensive R&D environment. Inbound investment opportunities exist to boost product portfolios and reinforce market presence.

The challenge for life sciences companies is to make their entrance and ongoing presence in emerging markets both safe and profitable, as each market can present unique operational and financial challenges; among them, significant pricing issues (particularly when the government pays for the drugs), insufficient and/or outdated distribution networks, threats to IP protection, and problems with supply chain quality, cost, safety and security.

It is essential to identify risk factors in emerging markets which could lead to supply chain breakdowns and the introduction of sub-standard ingredients and counterfeit products. Life sciences companies are altering their business models as they increasingly source active pharmaceutical ingredients (API) from low-cost locations globally. However, monitoring the quality of these APIs is difficult and, thus, a cause for concern. Counterfeit products remain a serious threat, as well.

Drug makers should continue expanding in emerging markets to tap into the higher sales growth potential they offer versus developed countries. However, they will need to be selective about the products they choose to launch in these markets, based on market-specific disease profiles, patient affordability, operational infrastructure, and government patent protection policies.

Generics

Generic drug producers are expected to be the primary beneficiaries of the looming patent cliff. Patent expirations are projected to save payers in developed markets, primarily in the U.S., \$127 billion in the next five years. This will be offset by \$21 billion of expected generic spending, resulting in a \$106 billion “patent dividend” in 2016. In the U.S., \$103 billion, or 44 percent of 2011 brand spending, will shift to generics at dramatically lower prices.¹⁶

Rising cost pressures have resulted in an increase in generic drug usage worldwide — generics cost 30 to 80 percent less than their original equivalents.¹⁷ The global generic drug market is anticipated to grow at a CAGR of 10 percent through 2010-15, from an estimated base of \$87 billion in 2010, to over \$140 billion by 2015.¹⁸

¹⁶ http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/Global%20Use%20of%20Meds%202011/Medicines_Outlook_Through_2016_Report.pdf

¹⁷ http://www.geha.com/prescriptions/info_generic_drugs.asp

¹⁸ Espicom Pharma Market Factbook; EIU Database

Above-average growth of generic drugs is expected in the Americas region in the coming years, due to patent expirations and mounting pressure from government and private-industry, third-party customers for greater use of less expensive generic drugs. Brazil has the largest generic sector in Latin America; generic sales by value were expected to increase by 40 percent in 2011, reaching an estimated \$5.4 billion. By April 2011, there were 101 generic companies operating in the Brazilian market.¹⁹

In Mexico, growing generic drug sales are driving local manufacturer revenue growth. Generic drugs are expected to comprise nearly 14.8 percent of the country's total drug market by 2016 (up from 12.1 percent in 2011), rising to 17.5 percent by 2021.²⁰ Mexico's significant generics market growth is generating investment from foreign manufacturers, who are seeking access to Mexico and other Latin American markets through Mexican-based production.

Over the last 12 years, Germany has become one of the world's most attractive markets for the generics industry. Eighty percent of all prescriptions and 45 percent of sales in 2010 were generics. The majority of original drugs are replaced by generics shortly after patent protection expires. One reason for this fast replacement is Germany's legal framework, which allows health insurance funds to negotiate rebate contracts with manufacturers.²¹

In the Asia region, limited availability of funds and constraints on public spending are expected to boost demand for generic drugs in the coming years. In Japan, one of the government's initiatives to reduce health care expenditures is to encourage use of generics. The government's goal is for generic share (by volume) to reach 30 percent by April, 2013. As of mid-2012, generic share by volume had reached 25 percent²² — in part, due to government financial incentives to pharmacists to dispense generics rather than brands. This trend can be expected to continue.

Analysts project that generic drug demand will continue to rise as consumers and payers favor cheaper medicines, thus adversely affecting sales of branded therapies. However, the generics segment's trend of skyrocketing growth may only last a few years because it is largely fed by patent expirations, which will taper off after the 2012 cliff. In the meantime, generics manufacturers are taking advantage of a booming market and available cash to maximize opportunities through M&A and expansion into other business sectors, including branded drugs and biologics.

Issue two: Regulatory landscape

As typically happens, regulatory oversight and consumer/patient protection evolve in response to increasing consumer expectations and awareness, changing government mandates, industry growth and innovation that produce subsequent unintended consequences, and business practices that need to be more closely monitored. Regulatory-related issues currently impacting global life sciences companies are taking two forms: generally heightened regulatory activity and monitoring compliance with changing rules and operations.

Heightened regulatory activity

Regulatory bodies in various countries are stepping-up activity in a number of areas that impact the life sciences industry, including:

- Implementing more stringent quality measures and new drug approval regulations, and limiting sales force access to physicians in accordance with conflict-of-interest policies.
- Increasing scrutiny of manufacturing processes — particularly materials sourcing from China and other emerging markets — to ensure product safety.
- Using tariff and non-tariff restrictions (e.g., high import tariffs, prohibition on certain imports, and promotion of local production) to support domestic manufacturers against foreign competition.
- Instituting or changing tax rules to encourage and reward companies to facilitate and exploit IP in their local market.
- Improving collaboration among regulatory agencies in-country and in different markets to strengthen regulatory decision-making and enforcement action.
- New pharmacovigilance legislation from the European Medicines Agency (EMA), which will significantly increase data provision requirements and the burden on regulatory operations and systems.

¹⁹ Source: EIU Database; Brazil World Pharmaceutical market- Q1 2012– Espicom

²⁰ Source: EIU Database; Medical Device Market – Mexico– Espicom

²¹ VFA: Der Arzneimittelmarkt - Generika im GKV-Arzneimittelmarkt (2010)

²² EIU Database; Healthcare and Pharmaceuticals Report – Japan– Espicom

Among country-specific actions, Brazil's government has moved to align the drug regulatory environment with international standards, including significant intellectual property (IP) reforms carried out in recent years. In late 2010, the Brazilian National Medicines Agency (ANVISA), which is responsible for product registration, operating licenses and import and export approvals, conducted a public consultation for the introduction of similar regulation to the manufacturing of APIs, introducing standard procedures akin to those of the U.S., Europe, and Japan.

In Mexico, the Federal Commission for Protection against Health Risks (COFEPRIS), in its role as regulator, has made great efforts to help attain the improvement targets of the life sciences sector. With the arrival of a new Federal Commissioner in 2011, COFEPRIS prepared a diagnostic to identify the principal challenges in the country's medicines policy and determine the strategic actions that the agency would take to overcome them.

In the European Union (EU), the life sciences industry is working towards the implementation of a standardized identification solution for pharmaceutical products across Europe to validate drugs at the point of dispensing. The coding solution provides a method to meet the EU's requirements for pack identification put forth in the recently adopted Falsified Medicines Directive (FMD), with the goals of reducing counterfeit products and bringing some transparency to the parallel trade.²³

As part of China's health care reform program, the government has been enforcing more stringent policies to better regulate local drug manufacturers and improve drug safety, access, and affordability. These policies are expected to increase operating costs and impose price ceilings; manufacturers will need effective cost management to sustain profitability.

Compliance and transparency regulations in Japan have recently become stricter; in response, both multinational corporations (MNCs) and domestic companies are revising internal policies and procedures, and changing long-established practices in personal promotion to physicians by medical representatives. Given that personal promotion is still the main practice in Japan, this could present challenges; recently, companies have been searching for ways to establish cost-effective, multi-channel promotional approaches to health care professionals so that they can approach their targets more efficiently.

In the United States, the Physician Payments Sunshine Act requires companies to begin recording in 2012 any physician payments that are worth more than \$10 and to report the information on March 31, 2013.²⁴ This includes stock options, research grants, consulting fees, gifts, food, trips, samples, rebates, speaking fees and other types of compensation. The details will be posted in a searchable database starting Sept. 30, 2013.²⁵

Monitoring compliance with changing rules and operations

Weak or nonexistent Intellectual Property (IP) and patent protection, the spread of counterfeit drugs, and illegal or unethical sales and marketing practices continue to challenge the life sciences industry worldwide.

Ineffective IP protection is frequently an issue in emerging markets such as Russia, India, China and the Middle East (aka GCC countries, currently consisting of Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and United Arab Emirates), which may lack effective government legislation to protect foreign companies' IP holdings and where third-party manufacturers are not always respectful of IP rights. China, Russia and Turkey, for example, are among countries listed on the U.S. government's "Watch List" for weak patent enforcement mechanisms.²⁶ Similarly, IP protection and enforcement issues in the GCC are hindering the region's ability to attract research-based pharmaceutical R&D investment. 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.

²³ <http://www.efpia.eu/articles/coding-identification-products-towards-safer-medicines-supply-0>

²⁴ "New Health Law Will Require Industry To Disclose Payments To Physicians," Kaiser Health News, April 26, 2010. <http://www.kaiserhealthnews.org/Stories/2010/April/26/physician-payment-disclosures.aspx>

²⁵ Ibid

²⁶ <http://www.ustr.gov/sites/default/files/2012%20Special%20301%20Report.pdf>

Weak or incomplete supply chain security is exacerbating the spread of counterfeit drugs, which, according to WHO estimates, account for nearly 10 percent of the pharmaceuticals market and negatively affect companies' revenue and reputation.²⁷

Finally, a number of large, multinational life sciences companies are dealing with investigations and facing potential litigation in connection with alleged fraud, Foreign Corrupt Practice Act (FCPA) violations, product quality issues, and improper sales activities such as off-label promotion of drugs or improper contact with physicians. While the industry has made major investments to enhance compliance programs the level of regulatory oversight, particularly with respect to potential FCPA matters, has continued to intensify. In response, companies have expanded training and compliance programs for employees that might have roles that could be sensitive to potential FCPA matters.

Issue three: Market and treatment changes

There is a unique convergence of product innovation, lifestyle evolution, and government mandates/regulations taking place which is resulting in unprecedented treatment changes and developments. Companies are leveraging new techniques to develop improved treatments for high unmet medical needs for increasingly informed consumers. This process is being facilitated – or perhaps aggravated – by cost-constrained and protective governments. Among key developments are the shift to prevention/self-management, increased activity in the biotechnology/biosimilars market, and the continued growth of the medical devices, diagnostics, and technology market.

Shift to prevention/self-management

Consumers increasingly are a major cost driver of health care systems. A preponderance of chronic conditions and the spread of unhealthy lifestyles are driving up medical costs. The UK's adult obesity rate, at 24.5 percent, is the highest in the EU for both men and women, according to OECD health statistics.²⁸ According to the CDC, 35.7 percent of U.S. adults were obese in 2009-10, and the share remains on an upward trend. A further 34.2 percent of U.S. adults were overweight. Some 17 percent of U.S. children and adolescents between age two and 19 were obese in 2007-08.²⁹ Rapid urbanization, more sedentary lives, and rising obesity levels are helping to drive epidemics in diabetes and cardiovascular complaints across Africa, the Middle East, Asia and Latin America.³⁰

According to results from the Deloitte *2012 Survey of U.S. Health Care Consumers*, half of all consumers who believe that there is waste in the U.S. health care system attribute much of that wasteful spending to lack of individual health responsibility/unhealthy lifestyles.³¹

Yet, increasing numbers of consumers are starting to engage in wellness, prevention, and self-management activities, such as getting flu shots, visiting their physician for well visits and routine medical care, participating in healthy living programs, actively managing their chronic diseases, and choosing specific foods and supplements for presumed health benefits. In addition, consumers are becoming more savvy purchasers of health care services and products; easy access to information through online and other sources is making individuals more inclined to demand the latest (and likely expensive) drugs and other medical innovations when they visit their physician for care.

Building relationships and connectivity with medical service providers and consumers will gain increasing importance as the life sciences industry seeks to play a role in enabling informed decision-making when matching the needs of educated consumers with the provision of innovative pharmaceuticals and medical devices. As one element of a solution, comparative effectiveness information is expected to mature as an important means to communicate the value proposition of a medical technology to health care providers and consumers throughout the entire product lifecycle.

²⁷ <http://www.forbes.com/sites/johnlechteiter/2012/08/22/exposing-and-eradicating-the-dark-world-of-fake-pharmaceuticals/>

²⁸ EIU UK Healthcare and Pharmaceuticals Report Nov. 1, 2011

²⁹ EIU USA Healthcare and Pharmaceuticals Report – September 1, 2012

³⁰ EIU World Outlook – Healthcare – October 8, 2012

³¹ Deloitte Development LLC 2012

Biotechnology/biosimilars

The presence of a large number of new and increasingly prevalent chronic diseases — and life sciences companies' search for strategies to expand their product pipelines — has been creating demand for innovative treatments and boosting the growth of the medical biotechnology/biosimilars sector. The commercialization of novel therapeutic substances capable of being produced on a large scale is a key technology that is attracting increasing participation by global life sciences companies. According to the Biotechnology Industry Organization, more than 400 biotech drug products and vaccines are currently in clinical trials targeting more than 200 diseases.³²

The global biosimilar market was valued at \$420 million at the end of 2010 and is expected to grow at a CAGR of 52.2 percent through 2014. The Americas region accounts for 33 percent of present market share.³³ Cost-effective treatment, rising patent expirations in leading classes of biopharmaceutical products and favorable government regulation are supporting the industry's growth.

In the U.S., the FDA's process of approving pathways for generic biotech products is in a state of evolution and the industry is moving forward more slowly than originally contemplated by legislators who pushed for a follow-on biologic pipeline in 2009-2010. In February 2012, the FDA released guidance on the approval pathway, which has provided increased optimism and transparency into the strategic windows and challenges that lie ahead for interested investors and incumbent innovators. Those innovators once comfortable with monopoly or exclusivity periods not dictated by patent terms or data exclusivity have begun to focus more on the evolution of this pathway. Meanwhile, given the costs of proving similarity, scaling-up manufacturing capacity, and the material costs of marketing, selling, and monitoring biologics, profitable entry is far from guaranteed for potential competitive entrants in the U.S. market.

In Mexico, the government is seeking to develop biotech "clusters" in collaboration with the private sector and universities. For example, a new bio-cluster is expected to be operational in the state of Jalisco in 2012-2013. The bio-cluster will comprise 37 pharmaceutical companies which produce innovative human and veterinary pharmaceuticals. The development of this and similar bio-clusters should result in an increase in R&D activity by domestic firms and allow them to venture into the multinational-dominated prescription market. In addition, local manufacturers are investing in biotechnology. Landsteiner Scientific is developing six "biocomparables" in partnership with the Tecnológico de Monterrey's Biotechnology Centre over the next five years.

The Brazilian biologic sector is expected to grow rapidly in the coming years. According to data released by the Ministry of Health and ANVISA, Brazil's National Health Surveillance Agency, biologics represent about 41 percent of public drug expenditures by value and about two percent by volume. Monoclonal antibodies represent most of public drug expenditures on biologics, accounting for about 32 percent by value and one percent by volume. The Brazilian government is encouraging investment in the biotech sector: A fund of \$851 million is being made available to pharma companies interested in the production of biotech drugs by 2014. The government envisions investing another \$4 billion in a 10-year biotechnology development program to help attract further local and foreign interest.³⁴

Medical devices, diagnostics, and technology

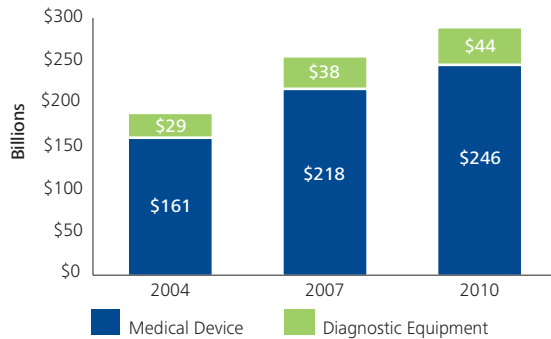
Global medical devices, diagnostics, and technology (MDDT) market revenue grew seven percent annually between 2004 and 2010, driven by favorable demographics (an aging population), disease trends, and technological advancements (Figure 5).

³² <http://test.bio.org/speeches/pubs/er/statistics.asp>

³³ Espicom Pharma Market Factbook; EIU Database

³⁴ EIU Database; Medical Device Market – Brazil– Espicom, MOITI – Brazil Biotech Report

Figure 5: Global Medic Devices, Diagnostics, and Technology Sales



Source: D TTL Global Life Sciences and Health Care Industry Group analysis of Espicom Global Medical Device Fact Book 2010, GBI Research

In 2011, both medical device and diagnostics sales grew 9.7 percent YoY.³⁵ Medical device sales increased across most segments, even though the industry has undergone a number of recalls. Increased public awareness and new technology further contributed to diagnostics growth. One of the fastest-growing areas is molecular diagnostics. Already an almost \$5 billion segment in 2010, it is expected to grow at double-digit rates to possibly hit over \$15 billion by 2021.³⁶

Analysts forecast that U.S. medical device sales will grow 4.9 percent annually through 2016, driven primarily by newer technologies and an increasing patient population.³⁷ The expansion of health insurance under the ACA to more than 30 million uninsured Americans will also generate revenue growth for the medical device sector, according to analysts. However, demand is being tempered because patients are delaying procedures due to higher co-payments and increased requirements by payers for pre-authorization for procedures; in addition, hospitals are delaying equipment purchases and opting for cheaper alternatives due to funding constraints. Finally, an ACA-mandated 2.3 percent excise tax imposed on medical device sales, which becomes effective in January 2013, could hurt device makers' margins.

Brazil has the largest medical device market in Latin America at \$4.3 billion in 2011, and has grown annually at a rate of 20.9 percent over the last five years.³⁸ Diagnostic imaging apparatus, followed by orthopedics and consumables, are the largest market sectors. Imports hold a relatively small share of the market, totaling \$2.6 billion in 2011 and a CAGR of 19.4 percent over the last five years.³⁹ Imports tend to be high-tech medical equipment not produced locally. In 2011, 70 percent of imports were supplied by Europe and the U.S.⁴⁰

The Mexican medical device market is dominated by imports, principally from the U.S., where manufacturers benefit from geographic proximity and preferential terms under NAFTA. The domestic industry is geared towards the export market, with the U.S. as the dominant export destination. Many U.S. companies use Mexico as a cheaper manufacturing platform to export back to the U.S. A 2010 health accord "fast tracks" medical device commercialized in the U.S. and Canada. Under the accord, the Mexican Health Authority allows medical devices approved in the U.S. and Canada to be sold in Mexico without meeting any additional substantial regulatory requirements, thus creating a favorable environment for manufacturers from these countries.

Additionally, other parts of the world are seeing solid growth in medical devices. In 2011, the UK medical technology industry is estimated to turn over approximately \$23.9 billion from 3,130 companies which employ 64,000 people. It is estimated that 38 million people in the UK come into contact with a medical device every day.⁴¹

The shape of the diagnostic imaging sector is expected to change as the industry is seeing more M&A transactions among medical device firms; some fairly large players have been acquired by others in their sector to increase opportunities for innovation and to build-out portfolios. Over 70 transactions representing more than \$3.5 billion have been announced by the sector during the last 18 months.⁴²

³⁵ Espicom Global Medical Device Fact Book 2012

³⁶ http://www.unitedhealthgroup.com/hrm/UNH_WorkingPaper7.pdf

³⁷ EIU Database; Medical Device Market – US – Espicom, Mind Power Solution Report

³⁸ Espicom Global Medical Device Fact Book 2012

³⁹ Ibid

⁴⁰ EIU Database; Medical Device Market – Brazil– Espicom, MOITI – Brazil Biotech Report

⁴¹ Responses to Innovation, Health and Wealth: Accelerating adoption and diffusion in the NHS, Department of Health, 5 December 2011

⁴² <http://www.massdevice.com/news/ma-top-15-acquirers-among-medical-device-companies>

Outlook

Life sciences industry demand is highly correlated with GDP growth and government spending across the world. After experiencing revenue growth of 8.1 percent in 2011, the global rate of spending on pharma and biotech is expected to fall in 2012⁴³ on the back of Western Europe's pharma spending cut, as it did in 2009 and 2010, due to substantial price cuts and falling reimbursement rates. The recovery in 2013 will be slight, with real growth expected to resume in 2016 (Figure 6).

The global pharma and biotech market will continue to be dominated by North America, which accounted for over 46 percent of total sales in 2011. Sales in the Americas region are expected to rise by an average of 6.5 percent a year between 2011 and 2016, slightly higher than the global average.⁴⁴

Asia is expected to grow at an annual average of 8.4 percent through 2011-12, but will be topped by the transition countries, where pharma sales will rise by 10.3 percent a year during the same period.⁴⁵

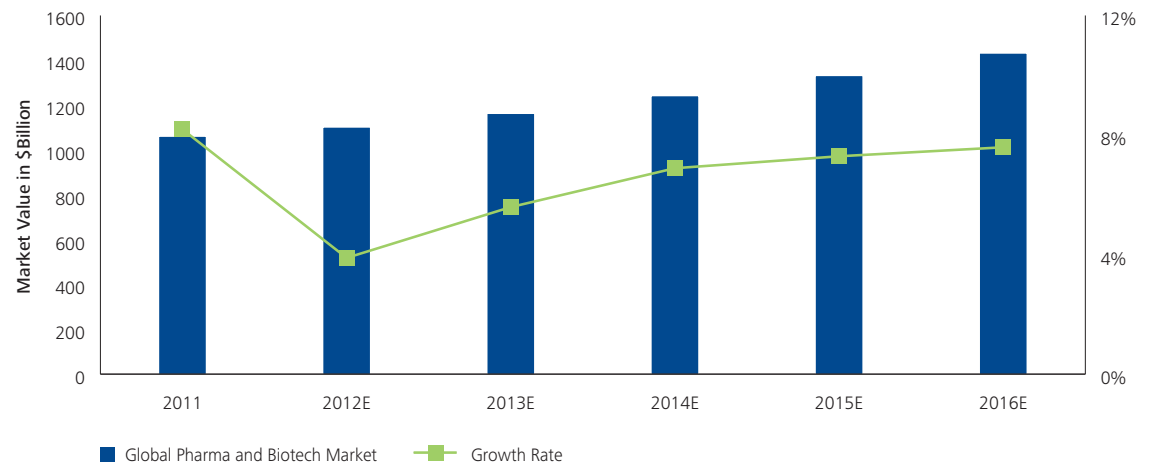
Of the major emerging markets, strong growth is expected in China and Russia, where pharma sales are expected to more than double in dollar terms by 2016. Argentina, Indonesia, India, and Ukraine will also perform strongly, according to EIU.⁴⁶

Demographic changes in the Americas, European, and Asian regions are expected to continue boosting demand for life sciences products.⁴⁷ Among long-term trends are an aging population in the large markets; the lengthening of average life expectancy; and a rising incidence of chronic diseases.

Sustaining health care spending levels in Europe is presenting funding and other challenges. Not only are the methods for raising funds to cover health care costs inadequate, costs are also spiraling up. Public expenditure on health care in the EU could jump from eight percent of GDP in 2000 to 14 percent in 2030, according to the World Bank.⁴⁸ Negative economic growth in Greece, Portugal, and Italy, as well as health care cost-containment schemes in many countries, could lead to a drop in health care spending through 2012-13.

Demographic trends remain favorable in the Asian region. Rising population in the large markets of China, India, Pakistan, and Indonesia and the lengthening of average life expectancy are driving demand for life sciences products. In addition, growing affluence and fast economic growth – stoked mainly by China and India – is anticipated to translate into a rise in pharmaceutical spending, projected to be up by 8.3 percent a year to \$360.4 billion by 2015.⁴⁹

Figure 6: Forecasted revenues for the global pharma & biotech industry



Source: D TTL Global Life Sciences and Health Care Industry Group analysis of EIU-Global Forecasting Service, Economic Forecast, February 2012

⁴³ EIU-Global Forecasting Service, Economic Forecast, February 2012

⁴⁴ Ibid

⁴⁵ EIU Database

⁴⁶ Ibid

⁴⁷ Espicom Pharma Market Factbook; EIU Database

⁴⁸ <http://www.managementthinking.eiu.com/future-healthcare-europe.html-0>

⁴⁹ EIU World Health Outlook October 2012

Stakeholder considerations

The life sciences industry is facing a number of impediments to revenue growth, including patent expirations, price cuts, reimbursement restrictions, and increasing regulatory constraints. While the industry's medium-term outlook is boosted by increased sales volume and longer exclusivity for biologics, pressure to deliver better outcomes at lower prices will not ease, as macroeconomic conditions are unlikely to improve drastically, especially in the developed countries. Additionally, generic competition will continue to eat into branded sales. It is imperative that companies gain a clear understanding of the changing ecosystem and shifting influence patterns that affect product utilization and adoption.

To sustain and grow in this challenging climate, the industry is transitioning away from a primary-care, small-molecule-driven sales model towards targeting specialist secondary care indications through the use of high-value biologic therapies in the developed markets (Europe and the U.S.), while also taking a global perspective by marketing branded and off-patent medicines in the fast-growing emerging markets. Cost savings facilitated by mergers and acquisitions are also set to bolster profits. Among specific considerations for industry stakeholders as they look to 2013 and beyond are the following:

R&D future models: Pharmaceutical companies should pursue open innovation opportunities by partnering with academic research centers, clinical research organizations and other drug makers to lower R&D costs while increasing their ability to develop new products that offset generic erosion of marketed drugs. Companies will need to be more nimble and should consider the real points of decision for advancing drug candidates to later, more expensive stages of development. Models and practices are emerging with more focused and independent evaluation of potential winners at earlier stages of development; this process is critical to improving the chances for identifying new, key medicines in a more cost-effective manner. Also, companies should invest in comparative effectiveness research/real world evidence and in analytics to develop drugs that deliver better outcomes and enhance overall drug safety, utilization, and compliance.

Brand strategy/pricing: To address pricing pressures, companies should compete on the basis of value, not unit cost. This means understanding the broad impacts that their offerings have and engaging in a comprehensive outcomes conversation with the individuals who have shared clinical and financial responsibility. Also, pharmaceutical and medical device companies will need to partner or connect with payers to develop branding strategies and pricing models that will ensure commercial uptake as well as profitability; comparative effectiveness and real-world evidence will be among the most impactful aspects of a company's basis for competition. That competitive differentiation is most likely to be realized via new drugs with proven medical differentiation for patients at a manageable price for payers. This may also better position the company for initial product approval in certain markets. Innovation will be needed to assure adoption of products (not just approval), drive late-stage clinical development, and drive corporate development activities. It is also expected that market forces and increased transparency will prompt an increased level of awareness about the value of in-line products and pipelines.

M&A and collaborations: Some life sciences companies are growing, restructuring, or refocusing their operations — making acquisitions to gain financial synergies and/or new products; diversifying into new product areas such as consumer health care; or divesting brands or business units to focus on their core strengths. Such companies need to align these transactions with long-term growth strategies. Companies also should consider an increased focus on strategies that have an externalization element as a way to spread risk. This includes increased use of CROs and CMOs, as well as external growth strategies that continue with M&A but increasingly involve licensing, JVs, and collaboration with other companies as well as providers and payers.

Operational efficiency: Pharmaceutical companies will need to improve operational efficiencies to grow margins. However, indiscriminate headcount or R&D investment reductions and other cost cuts for short-term gains could prove harmful in the long term. A better approach is to focus resources on core competencies by outsourcing support activities or leveraging shared service center structures. Also, in many cases, supply chains have evolved to be more nimble to address product development life cycles and risk. One solution is for a company to not always invest in its own supply capacity, particularly when the pipeline is evolving, as this could result in stranded assets and cost base.

New commercial models: Drug companies will need to rethink their marketing approach in light of tougher physician access and greater payer, hospital, and government influence on purchasing decisions. They should consider new sales models that recognize there are shifting influence patterns, such as the impact of patient advocacy groups and the increasing role of clinical departments in hospital purchasing decisions. Market forces such as bundled payments and accountable care organizations (ACOs) in the U.S. also are driving transformative innovation and shared clinical and financial responsibility among life sciences companies, health care providers, and health plans. The future model is likely to be better armed with technology and data that allow a very different discussion about the benefits of the medicine or device than a more mass marketing approach via scale in a primary care setting. In addition, company leaders are expected to use advanced data and tools to support the proper leveraging of scarcer resources in a cost-effective manner.

Health analytics: Companies are innovating through the increased use of analytics – “Big Data” provides opportunities to make better decisions more quickly and to develop insights that facilitate more efficient use of resources. Broader-based options for leveraging data for more effective patient solutions will be a key to success in the future. Should accessibility to markets become even more dependent on cost-efficient outcomes as well as broader-based disease management care, the cost-effective leveraging of technology and information will be important to better tailor patient care and demonstrate hard evidence of improved health at a lower cost.

Regulatory compliance: It is critical that life sciences companies develop, implement, and monitor product sourcing and distribution plans that assure product quality, provide for sufficient supplies, and provide line-of-sight security from the point of finished goods production through to dispensing or administration to a patient. Also, associated reporting and operational requirements will require further investment in infrastructure, especially for regulatory reporting, drug safety systems, and electronic pedigrees. A future differentiator could be first-mover players that leverage new packaging and delivery technologies to improve patient safety and regulatory accountability.

From an investment standpoint, the companies best-equipped to deal with current industry challenges are those with robust pipelines capable of offsetting the impact from patent expirations. Despite its challenges, the life sciences industry remains profitable and offers abundant opportunities for growth in 2013 and beyond.

Market updates

Americas

Brazil

Brazil is the third-largest pharmaceutical market in the Americas region (and the largest Latin America market), with a 2011 value of \$34.8 billion. Espicom projects a 2011-2016 CAGR of 5.4 percent in U.S. dollar terms and the market should reach \$45.3 billion in 2016.⁵⁰ Public health expenditures in Brazil increased to 47 percent of the country's expenditures in 2011 and are expected to grow at 7.4 percent through 2011-16⁵¹ following implementation of the 2008-2011 Mais Saúde program. Among the goals of this program to promote the national health industry are prioritizing the purchase of national products and reducing imports, encouraging local production, and increasing R&D investments.

Rising disposable income is bolstering demand for pharmaceutical products and services. Additionally, a favorable job growth outlook is fueling participation in private group health plans. Although the private health market is substantial in Brazil, trailing only that of U.S. in size, it still accounts for just 25 percent of the population, leaving 75 percent participating in the public health system. Additional factors contributing to a favorable market for life sciences companies include Brazil's increasing aging population, government incentives, and a high incidence of chronic diseases and cancer.

In addition to private investment (foreign and domestic) in the Brazilian life sciences sector, the government has been providing considerable support. In April 2012, it announced that to encourage the development of the local pharmaceuticals industry, domestically manufactured medicines in Brazil will be purchased at a 25 percent price premium (compared with imported medicines) through the public health system, known as the Unified Health System. There are 78 drugs and 44 biopharmaceuticals on the list. Additionally, various margins will be applied to different drugs – imported finished drugs (eight percent), locally

produced medicines (20 percent) and biopharmaceuticals (25 percent). The federal government and state governments will invest \$550 million each to cover the margin difference and support the domestic manufacturing program.⁵²

However, market conditions in Brazil are not entirely favorable. Pricing controls and intellectual property (IP) challenges could disrupt innovation. To improve health care affordability, the Brazilian government has been overriding branded drug patents in favor of cheaper generic versions. Also, the nation's regulatory processes are unduly lengthy. Finally, a high tax burden on pharmaceutical products continues to limit drug affordability. Drugs are taxed at 35 percent on average, with the largest portion of the tax (around 23 percent) paid for by drug manufacturers. In comparison, the average global drug tax rate is six percent.⁵³

Mexico

Pharmaceuticals is a priority sector for Mexico.⁵⁴ Its growth potential appears promising, and the industry is well-positioned to become one of the country's principal economic engines.

Mexico's pharmaceutical market in 2010 was \$14.9 billion.⁵⁵ The market is projected to grow 4.4 percent from 2011-2016 to \$19.5 billion.⁵⁶ Domestic production (by both local and multinational manufacturers) accounts for around 80 percent of pharma sales and imports contribute the remainder. A significant export industry also exists.⁵⁷

Mexico's favorable regulatory environment and increased health care access are expected to drive life sciences industry growth in the coming years. For example, in November 2011, the government introduced a bill to foster public-private partnerships, enhance hospital construction activities, and improve provisions.

⁵⁰ World Pharmaceutical Markets 4Q11 – Espicom, Brazil: Healthcare and Pharmaceuticals Report – EIU, Jan 2012, Brazil Pharmaceuticals & Healthcare Report - Q2 2012 – BMI

⁵¹ Ibid

⁵² Brazil Pharmaceuticals & Healthcare Report – Q3 2012 Published by Business Monitor International Ltd.

⁵³ Ibid

⁵⁴ Report "Administration of Public Health in Mexico," issued by the Federal Commission for Protection against Health Risks (COFEPRIS), using data collected from INEGI (2011), OECD (2010) and CANIFARMA (2010)

⁵⁵ World Pharmaceutical Markets Fact Book 2011

⁵⁶ EIU database-http://viewswire.eiu.com/index.asp?layout=ib3Article&article_id=1159370300&pubtypeid=1152462500&country_id=1520000152&category_id=775133077

⁵⁷ The Economist Intelligence Unit, Factiva, IMS Health

In addition to its positive regulatory environment, Mexico's aging population and increased consumer spending are projected to spur pharmaceutical sales. By 2016, around 7.3 percent of the Mexican population will be age 65 or older, placing a greater strain on public health care services. As a result, per-capita health spending is projected to grow at six percent CAGR through 2011-16.⁵⁸ This increase in public health spending is reflected directly in Mexico's active pharmaceutical market: between 2005 and 2011, public spending on medicines increased by 86 percent. According to the Organization for Economic Co-operation and Development (OECD), Mexico has the second-highest spending on medications as a percentage of total health spending (28.3 percent), much higher than the OECD average (17.2 percent).⁵⁹ Furthermore, spending on medications as a percentage of GDP (1.7 percent) is also higher than the OECD average (1.4 percent).⁶⁰

In response to considerable growth opportunities, local drug manufacturers are investing in R&D and foreign players are growing their generics presence through acquisitions. Mexico's regulatory environment is expected to boost generic sales, with consumption of generic medicines in the private sector projected to increase considerably between 2011 and 2019. As well, a number of patents for best-selling drugs will expire in the coming years, and this will likely accelerate generic market growth.⁶¹

Despite positive conditions overall, regulatory and access challenges persist in Mexico, posing potential roadblocks to industry growth. For example, government control of drug prices in the public sector appears ineffective due to poor enforcement. Also, public hospitals lack capacity to serve growing demand and frequently have a shortage of "essential" drugs due to limited budgets.⁶²

To meet growth expectations and to achieve the goal of the pharma sector becoming one of Mexico's critical growth drivers will require coordination among pharmaceutical stakeholders, such as laboratories, health care providers, insurance companies, regulators, and government. In addition, the industry needs to demonstrate a level of quality consistent with international standards.

United States

The biggest issue facing the U.S. life sciences industry in 2013 is the increasingly rapid movement to competing on the basis of a value proposition that is being defined and continuously redefined by the market. This health care transformation is quite different than the way the industry has traditionally operated as it relates to introducing and marketing products. There is a new focus on a broad transformation that includes health reform as well as transparency, comparative effectiveness, and changing stakeholder values.

The EIU projects the U.S. pharmaceutical market, the world's largest at \$396 billion in 2011, will grow 6.4 percent annually through 2011-16.⁶³ Demographics and disease trends will boost drug consumption, while the expansion of insurance coverage to more than 30 million uninsured Americans under the ACA is forecast to increase revenue for drug makers. However, ACA-related pharmaceutical industry fees and lower government drug prices may negatively impact growth.

Rising demand for cheaper drugs also could limit sales growth for branded drug manufacturers, as cost-conscious payers and consumers boost generic drug sales. In 2010, generics accounted for 78 percent of U.S. prescription volume, up from 68 percent in 2008.⁶⁴ The U.S. government also wants to promote the use of generics in an effort to control costs.

⁵⁸ The World Pharmaceutical Markets Fact Book 2011 – Espicom; Mexico Pharmaceuticals & Healthcare Report - Q2 2012- BMI, The Economist Intelligence Unit (Jan 2012)

⁵⁹ Report "Administration of Public Health in Mexico," issued by the Federal Commission for Protection against Health Risks (COFEPRIS), using data collected from INEGI (2011), OECD (2010) and CANIFARMA (2010)

⁶⁰ Ibid

⁶¹ The Economist Intelligence Unit, Factiva, IMS Health

⁶² The World Pharmaceutical Markets Fact Book 2011 – Espicom; Mexico Pharmaceuticals & Healthcare Report - Q2 2012- BMI, The Economist Intelligence Unit (Jan 2012)

⁶³ EIU Database; Medical Device Market – US – Espicom, Mind Power Solution Report

⁶⁴ EIU Database; Healthcare and Pharmaceutical Report– US – Espicom http://viewswire.eiu.com/index.asp?layout=ib3Article&article_id=1628698947

Analysts forecast that U.S. biotech sales will grow 8.7 percent annually through 2012-17, driven by cost-effective, innovative medicines.⁶⁵ The U.S. is a major contributor to the biotechnology industry worldwide, and government funding for biomedical research and tax aid are creating new opportunities. For example, a total of \$10.4 billion was made available to the National Institute of Health (NIH) under the \$787 billion American Recovery and Reinvestment Act of 2009, with the vast majority of those funds going directly to scientific research. This was one of the single largest boosts to biomedical research in American history.⁶⁶ However, a gradual decline in R&D spending and the lack of credit and access to capital markets in biotech remain major concerns. According to Thomson Reuters, biotech companies listed on the NASDAQ Biotechnology Index spent approximately \$54 million on R&D in 2010, down seven percent from 2009.⁶⁷

The ACA provides for 12 years of exclusivity for biologic drugs versus the seven-year exclusivity currently allowed. Although branded manufacturers will benefit from this legislation, it means that affordable generic treatments will be kept off the market for a longer period, impacting generic biologic companies. The ACA also introduces a new FDA regulatory process for the approval of follow-on biologics, which could increase generics competition in this sector longer-term.

U.S. medical device sales are forecast to grow 6.4 percent annually through 2017,⁶⁸ driven primarily by newer technologies and an increasing patient population. The expansion of health insurance as part of health reform will also generate revenue growth for the medical device sector, according to analysts. However, demand is affected by lack of affordability by consumers and lesser investment by hospitals in health care services. In addition, the ACA introduces a 2.3 percent tax on medical device companies beginning in 2013 to fund health coverage expansion.⁶⁹ According to industry experts, this tax could lead to job cuts and a reduction in R&D budgets for smaller companies, in particular.⁷⁰

2013 could prove to be a pivotal year for life sciences in the United States. The Supreme Court's mid-2012 ruling on health care reform has clarified a number of open questions for the world's largest market; however, numerous implementation and timing issues remain. Life sciences companies will need to move forward deliberately to deal with the "new normal." If a company is going to introduce new products they need to have an impeccable safety profile and demonstrably better effectiveness, and be at the right price point relative to existing offerings, or they may be approved for commercialization but not really adopted in the market. To strengthen their ability to compete, they will need a robust comparative effectiveness (CE) strategy and a program that supports current commercial activities, informs late-stage clinical development, and provides forward visibility of the strategic needs to grow the business.

EMEA

GCC States

The GCC States (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates [UAE]) comprise a dynamic life sciences and health care market, due to their growing and aging population and increasing total health care expenditures per capita. The Saudi Arabia pharmaceutical market, one of the largest in the region, is forecast to expand by 4.7 percent a year to reach \$4.7 billion by 2016.⁷¹

The GCC population is expected to continue growing at five percent YoY, driven mainly by the influx of expatriates to the region. While the dominant age group is estimated to be the 30-44 year old group, the 45-65 and 65+ age groups are expected to grow cumulatively by an average of six percent between 2011 and 2020. This aging population will further increase the burden on health care systems and costs.⁷²

⁶⁵ IBIS World Industry Report NN001 Biotechnology in the US, August 2012

⁶⁶ http://www.hhs.gov/secretary/about/opeds/building_strongerfoundation.html

⁶⁷ <http://www.reuters.com/article/2011/07/28/idUS238859+28-Jul-2011+BW20110728>

⁶⁸ IBISWorld Industry Report - Medical Device Manufacturing in the US, October 2012

⁶⁹ Medical Device Excise Tax – Are You Ready? Deloitte Development LLC 2011

⁷⁰ Ibid

⁷¹ EIU - Saudi Arabia: Healthcare and Pharmaceuticals Report August 2012

⁷² Unites States Census Bureau, 2009; Deloitte United States research and analysis, Nov 2009

GCC trends that are likely to impact life sciences companies operating in the region include governments' increasing investment in health awareness programs and technological advancements; the growth of smaller clinics and ambulatory centers; increased interest in medical tourism; and new health care regulations. Challenges include a heavy reliance on government financing; increasing health care costs; limited medical education options; capital-intensive health care for the private sector; a shortage of medical personnel; and a health care infrastructure that lags behind developed nations.

Navigating the GCC regulatory landscape is another challenge facing life sciences companies. Each GCC country has a government agency responsible for regulating the health care and life sciences industry; in addition, the Health Ministers' Council for GCC States promotes coordination among the member states to advance achievement in preventive, curative, and rehabilitative care. Also, as mentioned earlier, the Health Ministries Council has set a regulatory drug pricing mechanism for member states. This policy has important financial ramifications for life sciences companies engaged in the drug registration and pricing process: Patented products account for 90 percent of total prescription drug sales in the GCC. In recent years, price controls have been imposed on patented products as a way to reduce the cost burden on GCC governments and the local population. Despite the fact that there are several local GCC-based pharmaceutical drug manufacturers that produce generics, recent trends favor the procurement of more patented products, as doctors and consumers prefer using an internationally recognized brand over a local one.

Because GCC-based manufacturing companies face stiff competition from international companies on their own turf, these GCC manufacturers are forced to target export markets such as South East Asia and Africa.

Germany

Germany is the largest pharmaceutical market in Western Europe, estimated at \$62 billion including prescription medication in retail pharmacies and hospitals, as well as OTCs.⁷³ A major segment of the market is comprised of retail pharmacy expenditures, totaling \$51.9 billion in 2010. Growth is expected to dampen slightly over the coming years as a result of health system reforms passed in November 2010 that are designed to reduce the average price of drugs. However, in terms of volume the demand for pharmaceuticals is forecasted to grow gradually, driven by Germany's aging population and a wider range of products and treatments available.⁷⁴

Germany's aging and shrinking population creates both challenges and opportunities for life sciences companies doing business there. The country has a population of about 80 million, yet it is expected to shrink to about 65–70 million until 2060. Average life expectation is ~83 years for women and ~77 years for men, with an increase of 6.5 years for women and 7.8 years for men expected until 2060. Exacerbated by a shrinking number of births, the share of people above the age of 65 (20 percent in 2011) is increasing significantly.⁷⁵

Health care spending in 2011 accounted for 11.5 percent of GDP, equivalent to \$5,038 per head.⁷⁶ In Germany, health insurance is compulsory. There are Private Health Insurance companies (PHIs), but the majority of people are insured by SHI. The German SHI market is highly fragmented (145 competing sick funds, as of 2012). However, the number has decreased by 50 percent since 2004 — signs of both attrition and consolidation — and still is decreasing steadily.⁷⁷

In addition to the introduction of a new drug pricing and reimbursement process as part of health system reforms, Germany is also seeing a major push around transparency in outcomes and quality of service for providers, especially hospitals. The country is likely heading to differentiated pricing and reimbursement based on quality and/or incremental benefit over medium term, which will impact healthcare providers as well as suppliers including life sciences companies.

⁷³ Espicom – Germany World Pharmaceutical Market Q4 2011

⁷⁴ Ibid

⁷⁵ 2011 / 2012 vdek-Basisdaten des Gesundheitswesens

⁷⁶ Economist Intelligence Unit Germany Healthcare Report 2012

⁷⁷ Kennzahlen der gesetzlichen Krankenversicherung, June 2012

Germany is considered a world-class research location. In 2010, Pharmaceutical R&D accounted for \$6.9 billion, representing 9.4 percent of all R&D expenditures in Germany. Pharmaceutical R&D is the third-highest expenditure after Automotive and Electronics in the German economy.⁷⁸ One major issue for biotechs that could limit Germany as an R&D location is the country's limited tax credit for R&D, which particularly affects companies that, as yet, have more spend than revenue; it also can impact purchase price during an M&A transaction.

Russia

There are positive forecasts for growth in the Russian pharmaceutical market — from \$23 billion in 2011 to \$30 billion in 2013.⁷⁹ In fact, Russia is considered one of world's priority markets for pharma companies, after China, in terms of growth potential. The challenge for life sciences companies operating here is how to use their resources (e.g., warehouses, medical representatives, etc.) more efficiently, how to mitigate the negative impacts of pricing regulations, and how to operate within new regulations designed to counter illegal practices.

Strong personal income growth is generating higher demand for quality health care in Russia. The country's per-capita GDP is projected to rise ~15 percent annually through 2014.⁸⁰ In addition, the government's "Health 2020" program is forecast to contribute to market growth, with a \$10 billion investment over the next two years in initiatives including improving access to medicines.⁸¹

Foreign companies control a large share of the Russian market and are using alliances, acquisitions, sales force expansions, and new drug launches to further increase their footprint. However, Russian distributor companies also play a very important role in the market.

Localization of production aimed at import substitution is becoming more important. Establishment of pharma clusters in various Russian regions is viewed as a market trend. Many of the first-tier pharma companies have already established production facilities, or have either signed or are in the process of signing licensing and production agreements with Russian partners. Many second-tier pharma companies are considering changing their business models (i.e., to direct importation by their Russian subsidiaries) to better control the market. This change could generate associated customs, regulatory, tax, accounting, and ERP integration issues that will need to be addressed.

Despite Russia's growth potential, government restrictions on price hikes and distributor markups of essential drugs are negatively impacting approximately one-third of the country's total pharma sales. All essential drugs (a range of drugs that the Russian government lists as "Vital and Essential"), which account for one-third of total drug sales in Russia, are currently subject to price caps. Also, past bureaucracy and lack of regulatory transparency could challenge growth. According to the Economist, foreign drug makers in the past chose not to manufacture in Russia due to "onerous" legal and bureaucratic hurdles.⁸² Fortunately, continued, positive changes in the country's regulatory environment, including Russia's recent admittance to the World Trade Organization (WTO), should have a positive impact.⁸³

Russia has been the site of several recent 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. The Federal Antitrust Service is making notable efforts towards the increase of transparency and the discontinuation of anti-competitive practices. In addition, new regulations as of January 1, 2012, prohibit promoting drugs and medical devices by visiting health care professionals, and giving payments and benefits to them (with certain exceptions, such as remuneration for clinical trials).

⁷⁸ BPI Pharmadaten 2011

⁷⁹ Source: EIU: Pharmaceutical report- Russia, Episcom

⁸⁰ The Economist Intelligence Unit, Espicom 3Q10 Russia Pharmaceutical Market Report, Factiva

⁸¹ The Economist Intelligence Unit, Pharmexpert – The Russian Pharmaceutical Market 2009, Espicom 3Q10 Russia Pharmaceutical Market Report, www.usrussiaintrade.org, DSM Group

⁸² The Economist Intelligence Unit, Espicom 3Q10 Russia Pharmaceutical Market Report, Factiva

⁸³ http://www.wto.org/english/news_e/news11_e/acc_rus_16dec11_e.htm

Turkey

Turkey's robust pharmaceutical market is projected to grow 14 percent annually to \$16 billion by 2014.⁸⁴ Rising affluence is driving industry growth, yet life sciences companies face revenue and operational challenges including price reduction and/or suppression due to government policies, and an increase in assessments and challenges by tax inspectors related to transfer pricing and value-added tax (VAT) issues.

Turkey's per-capita health care spending is projected to be strong through 2014.⁸⁵ The government plans to boost spending predominantly by introducing universal health care coverage by 2013. Total health care spending will likely rise from an estimated \$44 billion in 2008 to \$64 billion in 2014, according to EIU.⁸⁶

Turkey's pharmaceutical market is highly fragmented and dominated by foreign companies. Approximately 90 percent of drugs consumed are manufactured domestically, primarily by foreign companies or their domestic sub-contractors, which are simply local manufacturing companies or generic firms.⁸⁷ Both brand name and generic manufacturers are forecast to benefit from favorable government policies and growing domestic affluence. The introduction of universal health insurance and incentives to increase the use of affordable generic drugs could increase overall demand. Analysts project that by 2013, generics and branded consumption could grow 14 percent and 13 percent annually, respectively.⁸⁸

To attract foreign drug makers, the Turkish government is introducing financial incentives and simplifying administrative procedures. In addition, relaxation of regulatory rules and increased privatization initiatives could drive private sector participation in Turkey's pharmaceutical and provider segments. In response to this business-friendly environment, foreign drug makers increasingly are establishing operations in Turkey. Investment from multinationals is rising due to the ease of profit repatriation outside the country and the comparatively simple process to acquire domestic property.

Turkey also has introduced Good Manufacturing Practices (GMP) procedures which have increased the quality of its domestic production capacity. With this initiative, Turkey is attempting to increase its competitive advantage in production and exporting to the other regional locations including the CIS, Middle East, Eastern Europe, and Northern Africa countries. In addition, recent M&A activity in the Turkish pharmaceutical sector has highlighted the increased potential for the sector within the global market.

R&D activity is also forecast to grow as a result of favorable government funding incentives for foreign and local firms. Turkey introduced a new R&D law in 2008 with several incentives, including 100 percent tax reduction on R&D expenditures (increased from 40 percent) and additional government funding for biotechnology. However, heavy price controls as well as patent issues and tax challenges could negatively impact pharmaceutical companies' financial results and their resources available for R&D activities and, thus, limit overall industry growth.

United Kingdom

Eighty-four percent of healthcare spending in the UK, including spending on pharmaceuticals, assisted technologies and medical technology, is publicly funded, (in 2011 totaling over \$215 billion) equivalent to around 9.6 percent of GDP, an increase from 8.4 percent in 2007.⁸⁹ Healthcare is also largely free at the point of need. Spending on the National Health Service (NHS) has increased on average by around 5.5 per cent a year for the 10 years to 2010-11.⁹⁰ However severe financial constraints mean, for example, that from 2011-12, the English NHS is now expected to find savings of \$30.8 billion a year by 2015, or a decrease in spending of some 4 percent per annum.⁹¹

⁸⁴ IMS Health, Economic Intelligence Unit, Espicom 2Q10 pharma market report, Factiva, Wall Street Journal and Swiss Re (2007)

⁸⁵ Espicom 2Q10 pharma market report, UniCredit Turkish pharma report (2009), Deloitte Turkish healthcare industry report (DRT Kurumsal Finans Danışmanlık Hizmetleri A.Ş. ("Deloitte") January 2010), 4Q10 BMI Turkey health care and pharmaceutical report, September 2009 EIU Health care and pharmaceuticals report, Factiva

⁸⁶ EIU - Turkey: Healthcare and Pharmaceuticals Report, 29 March 2010

⁸⁷ Ibid

⁸⁸ Ibid

⁸⁹ OECD database

⁹⁰ National Health Service Expenditure Review: report by the Comptroller and Auditor General, HC 708 Session 2010-2011 available at http://www.nao.org.uk/publications/1011/nhs_landscape_review.aspx

⁹¹ The Operating Framework for the NHs in England 2011/12, Department of Health, 15 December 2010 available at http://www.dh.gov.uk/en/Publications/publicationsPolicyAndGuidance/DH_122738

Approximately 16 percent of UK citizens access some form of private healthcare (with 11 percent of the population having some form of insurance coverage). Independent hospitals provided some 14.5 percent of total surgical admissions in 2011-12, a record level of activity for the sector, but driven by increased NHS-funded elective admissions. Revenues generated by independent sector hospitals and clinics increased by 0.7 percent to around \$6.3 billion.⁹²

UK pharmaceutical sales in 2011 totaled some \$20.8 billion, including \$13.7 billion in primary care and \$7.1 billion in secondary care, and are projected to grow 1.4 percent annually through to 2014.⁹³ Although the UK will retain the largest share of the market, sales of branded (non-generics) are expected to decline by 0.8 percent between 2011 and 2016 as leading products become subject to generic competition and pressure remains on branded price growth. Sales of generic drugs are forecast to increase by 5.7 percent (CAGR 2011-2016) driven by government efforts to reduce the healthcare deficit, notably in the hospital sector. Over the same period, sales of OTC products are expected to increase by 3.7 percent driven by increases in self-medication.⁹⁴ Plans to allow pharmacists to substitute branded drugs with generics could further reduce branded drug sales. Other challenges include some 46 patent expirations,⁹⁵ and wide variations in access to care and clinical outcomes.

The current pharmaceutical pricing regulatory scheme runs until January 2014 and negotiations are under way for a new pricing system. This is expected to comprise a successor scheme to the PPRS for all products marketed before January 2014 and a value-based pricing system for newly marketed products.⁹⁶ Government initiatives to encourage investment in the UK include: the patent box tax relief scheme;⁹⁷ initiatives to promote early access to innovative medicines and medical technology;⁹⁸ and improved access to NHS patients' data to encourage clinical trials investment in the UK.⁹⁹

To date the UK medical technology market is growing at around 5 percent a year with revenues of approximately \$23 billion in 2011. Wide variation in prices paid due to variable procurement procedures and new austerity policies, including a 17 per cent reduction in NHS spending on capital in the next three years, are placing downward pressures on spending.¹⁰⁰ The UK market, as for most of Europe, has a high percentage of small- and medium-sized medical technology companies with high levels of new product innovation (improvements every 18 to 24 months after introduction).¹⁰¹ While the UK has traditionally had a relatively poor level of uptake of new technology,¹⁰² new government initiatives have been launched to stimulate uptake.¹⁰³

⁹² Laing and Buisson UK Private Acute Medical Care report: Laing's Healthcare market news Volume 16 Issue 8

⁹³ Pharmaceuticals in UK December 2009 – Datamonitor; U.K Pharmaceuticals and Health Care Report 3Q10 – BMI; UK Pharmaceutical Market Overview June 2010 – Datamonitor

⁹⁴ IMS Market Prognosis Europe 2012-2016

⁹⁵ <http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Drug-patents-which-will-expire-in-2009-and-2010/>

⁹⁶ <http://gp.dh.gov.uk/2011/09/27/government-response-to-value-based-pricing-consultation->

⁹⁷ Patent Box <http://www.hmrc.gov.uk/ct/forms-rates/claims/patent-box.htm>

⁹⁸ Innovation, health and wealth: Accelerating adoption and diffusion in the NHS, Department of Health, 5 December 2011. Available at: <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance>

⁹⁹ <http://www.bbc.co.uk/news/uk-16026827>

¹⁰⁰ Managing high value capital equipment in the NHS in England, Report by the Comptroller and Auditor General, HC 822, Session 2010-2011, 30 March 2011.

http://www.nao.org.uk/publications/1011/nhs_high_value_equipment.aspx

¹⁰¹ The medical technology industry in Europe, Eucomed, 25 May 2011: http://www.eucomed.org/uploads/Modules/Publications/110527_the_medical_technology_industry_in_europe.pdf

¹⁰² International diffusion of new health technologies: A ten-country analysis of six health technologies, Packer C, Simpson S, Stevens A, International Journal of Technology Assessment in Health Care, 22:4 (2006), 419 - 428

¹⁰³ Innovation, health and wealth: Accelerating adoption and diffusion in the NHS, Department of Health, 5 December 2011: <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance>

The regulatory landscape within the UK — and throughout the EU — is undergoing considerable change through the implementation of the new European pharmacovigilance legislation.¹⁰⁴ The legislation requires the implementation of new Good Vigilance Practice modules and periodic reporting formats, together with revised electronic reporting formats for medicinal product data and individual case safety reports (ICSRs). The regulation of medical devices is also under intense scrutiny, with adverse press coverage following high-profile cases concerning breast implants and hip replacements. The European Commission has published proposals for improved regulation of devices,¹⁰⁵ which the Medicines and Healthcare products Regulatory Agency (MHRA), has acknowledged are needed.

Asia

China

China offers high growth potential across the life sciences sectors, driven by favorable demographics and government investment to improve health care. Analysts forecast China's health care spending will increase nearly 20 percent annually from 2010 to 2016.¹⁰⁶ In addition, China's pharmaceutical market is predicted to grow to \$127 billion by 2015.¹⁰⁷

In a populous country like China, which is challenged by uneven economic growth and distribution of wealth, the government plays a critical role in providing essential medical care to help sustain long-term stability and prosperity. China is currently embarking on a major health care reform program, with the goals of establishing the basic framework for a universal health care system and providing basic health care for the national population by 2020. The goal of health reform is to extend near universal coverage from urban areas to include rural locations as well to offer basic medical insurance (BMI) coverage to greater than 97 percent of the population.

The government also is investing heavily in rural health care services and community hospitals, which should help increase drug sales and generate higher revenue for medical device manufacturers. Distribution channels will become a top priority for life sciences companies, which need a cost-effective distribution network to maximize sales, particularly commonly requested low- and mid-end medical devices and drugs.

To capitalize on sales growth opportunities, foreign drug makers are expanding their China footprint by making acquisitions, entering into alliances, establishing manufacturing and R&D facilities, and expanding headcount. However, foreign branded drug makers face significant pricing challenges and weak patent protection in China. The government cuts drug prices frequently and low-cost generics account for three-fourths of the total market,¹⁰⁸ resulting in pricing challenges.

Both domestic and foreign medical device manufacturers have significant potential for increasing their sales in China under the reform plan. For those interested in entering China's medical device market, the highly complex Chinese health care system — particularly, its reimbursement policies — can make it difficult for new foreign entrants.

2013 should be a positive year for China's life sciences sector. With its economic growth and continuous increase in health care expenditures, the country's standard of living has improved significantly, fueling residents' awareness of the importance of personal health as well as their demand (and ability to pay) for more sophisticated health care services.

However, strong competition in China's pharmaceutical sector and low profit margins are driving market consolidation, forcing unprofitable firms to withdraw or form alliances. In addition, the recent global financial crisis has caused a widespread credit freeze that impacts the global life sciences industry. In general, banks are reluctant to lend to small start-up companies such as biopharmaceutical firms. Chinese governments have taken steps to revive the credit markets; however, the results of their efforts to date are questionable, as the global economy continues to experience distress.

¹⁰⁴ Regulation (EU) No 1235/2010 and Directive 2010/84/EU, via Commission implementing regulation No 520/2012 of 19th June 2012.

¹⁰⁵ Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices

¹⁰⁶ IMS Health, Economic Intelligence Unit (December 2011), Espicom 2Q10 pharma market report, Deloitte Opportunities in China's pharmaceuticals market December 2011, Deloitte Touche Tohmatsu CPA Ltd.

¹⁰⁷ EIU: Healthcare and Pharmaceuticals Report- China, Espicom

¹⁰⁸ IMS Health, Economic Intelligence Unit (December 2011), Espicom 2Q10 pharma market report, Deloitte Opportunities in China's pharmaceuticals market December 2011, Deloitte Touche Tohmatsu CPA Ltd

India

The Economist Intelligence Unit (EIU) forecasts that India's pharmaceutical market will double to \$29 billion by 2016, growing 13 percent annually.¹⁰⁹ India's pharmaceutical market was 14th in terms of value globally in 2010, at \$14 billion.¹¹⁰ Various factors have contributed to the industry's growth in India, including the country's aging population, changing disease profiles, growing affluence/disposable income, increasing provider penetration, and continued foreign direct investment (FDI) inflow.

The Indian health care market is projected to grow in double-digits across sectors, driven primarily by favorable demographics.¹¹¹ Health care spending in the country will increase 18 percent annually until 2016.¹¹²

The country is essentially a branded generics market, with local manufacturers comprising nearly 75 percent of the total.¹¹³ While local demand for pharmaceuticals is largely met by Indian companies and products manufactured in India, the demand for medical devices is met largely by multinational corporations (MNCs) and imported products; only low-end devices are manufactured by Indian companies.

Indian companies have developed expertise in pharmaceutical formulation development and generic manufacturing, and have capitalized on the global patent cliff by capturing a substantial share of generic products marketed around the world. The large Indian companies which were initially focusing on the semi-regulated markets have now started establishing their presence in the developed and regulated markets. The next big opportunity for the Indian pharmaceutical sector is around development of biosimilars, which has become an emerging investment segment. FDI has increased significantly, with \$9.7 billion flowing into drugs and pharmaceuticals and \$0.6 billion into medical and surgical appliances.¹¹⁴

However, several challenges persist; among them, margin pressure from pharma generics; complex regulatory policies and low insurance penetration resulting in a self-pay market with considerable affordability and access barriers; lack of consumer awareness and education; and heavy market fragmentation. In the pharmaceuticals sector, the debate over compulsory licensing remains a contentious issue. In addition, the recent government thought process on linking patented drug prices to the country's per-capita income in relation to certain developed markets could result in delayed patented drug entry into India.

Despite challenges, the outlook for 2013 is promising, for three reasons: First, there is an inherent demand for health care products and services due to India's large patient base and increasing awareness of wellness by its growing population. Second, both the government and private sectors are increasing their initiatives to improve health/well-being and enhance population coverage (including access to rural and low-tier cities). Third, the government has indicated it will provide free drugs for the entire non-affording population and has allocated a budget of \$5.4 billion for this purpose, a large part of which will go towards the purchase of medicines.¹¹⁵

Japan

Health care expenditures in Japan are predicted to rise 5.5 percent annually through 2014, primarily due to Japan's growing elderly population and an increase in chronic diseases.¹¹⁶ Total pharma market sales were \$111 billion in 2010;¹¹⁷ however, according to EIU, sales growth will be just one percent (in U.S. dollars) between 2009 and 2014.¹¹⁸

¹⁰⁹ Espicom India, World Pharmaceutical Market Q3 2011, Economist Intelligence Unit, ICRA (November 2011)

¹¹⁰ World Pharmaceutical Markets Fact Book 2011

¹¹¹ Ibid

¹¹² Ibid

¹¹³ India World Pharmaceutical report

¹¹⁴ Department of Industrial Policy & Promotion FDI Statistics Data, July 2012, Numbers are cumulative FDI inflows during 2000-2012, http://dipp.nic.in/English/Publications/FDI_Statistics/2012/india_FDI_July2012.pdf

¹¹⁵ "\$5.4 billion policy unveiled to give free generic drugs to hundreds of millions," Economic Times, July 5, 2012, <http://economictimes.indiatimes.com/news/economy/policy/5-4-billion-policy-unveiled-to-give-free-generic-drugs-to-hundreds-of-millions/articleshow/14682563.cms>

¹¹⁶ Pharmaceuticals and Health Care Report – Business Monitor International (May 2010), Health Care and Pharmaceuticals Report – EIU (August 2010), Policy Options for Health Insurance (March 2005), and Pharmabiz.com

¹¹⁷ EIU: Healthcare and Pharmaceuticals Report- Japan, Episcom

¹¹⁸ Ibid

Perhaps the single biggest challenge facing life sciences companies in Japan is increasing government emphasis on health care cost control. Every citizen in Japan is required to participate in the public health insurance system; the government pays for the majority of health care expenses. The population in Japan is aging quickly (23 percent of the population was over 65 years of age in 2011, and this ratio is expected to increase to 25 percent in 2013 and 33 percent in 2035).¹¹⁹ As such, health care costs are rapidly increasing, and the government has begun a number of initiatives to stem the tide. These include encouraging use of cheaper generic drugs, increasing preventative care and self-management of chronic disease.

The government sets the price at which drugs are reimbursed under the national insurance. This effectively controls the price of drugs, since most people in Japan rely on national insurance to pay for health care expenses. Drug prices are reviewed every two years in Japan, and such reviews have tended to result in price reductions. As a result, the total value of domestic pharmaceutical sales has fallen in recent years, and future reviews will result in further downward adjustments.¹²⁰

The highly regulated Japanese medical device market is the second-largest in the world at \$30 billion,¹²¹ but is projected to remain nearly flat due to foreign exchange and economic challenges.¹²² The market will likely remain favorable for devices that are innovative, treat conditions for the elderly, and focus on minimally invasive procedures. Foreign players hold significant market share in the Japanese device market.

In order to ensure long-term profitability of life sciences businesses in Japan, development of innovative drugs and devices for diseases with significant unmet needs will be key. It will be important for MNCs and domestic companies to consider alliances, in-licensing and/or M&A activities to enhance their pipeline to bring new and innovative drugs and devices to the market.

As Japan's life sciences sector is not one that changes drastically year to year, the current positive growth trend should continue in 2013. In addition, there are many options to deal with the increasing difficulties in the industry, so activities in 2013 have the opportunity to serve as investments towards long-term goals.

¹¹⁹ EIU: Healthcare and Pharmaceuticals Report- Japan, Episcom

¹²⁰ Ibid

¹²¹ World Medical Market fact book

¹²² Pharmaceuticals and Health Care Report – Business Monitor International (May 2010), Medical Device Market, Japan (2007) and Japan Medical Device Overview – Department of Commerce, U.S.A. (April, 2008)

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