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2016 Global life
sciences outlook
Moving forward with
cautious optimism



Overview and outlook

The life sciences industry has fared well in past economic recessions but how is it performing in today's volatile marketplace, one characterized by economic uncertainty, reform-driven pricing pressures, increased demand for innovation and value, more focus on the consumer and consumer engagement, and an ever-changing regulatory and risk environment?

The life sciences sector's growth correlates highly with countries' general economic strength and health care spending levels, and both of these vary widely around the globe. The Economist Intelligence Unit (EIU) reports that health care spending in the 60 countries that it covers rose by 2.6 percent in nominal U.S. dollar terms in 2014 but that spending is forecasted to dip in 2015, reflecting the current weakness of the euro and other currencies against the U.S. dollar.¹ And while spending growth is expected to pick up beginning in 2016, the pressure to reduce costs, increase efficiency, and prove value remains intense. Because of these contradictory trends, global health care spending is expected to increase by only an average of 4.3 percent in 2015-2019, more slowly than it did before the 2009 recession. Spending as a percentage of GDP is also expected to decline, from around 10.3 percent in 2014 to 10.1 percent in 2019.² Per-head health spending is projected to increase from \$1,145 in 2014 to \$1,412 in 2019. However, spending levels will vary greatly among developed and developing countries, ranging from \$11,038 in the United States to just \$58 in Pakistan.³

Entering the second half of this decade, most life sciences organizations appear to be adopting an attitude of cautious optimism. Significant opportunities exist in the global marketplace but challenges exist, as well. Spending growth in pharmaceuticals (pharma), biotechnology (biotech), and medical technologies (medtech) is projected to follow an upward trend due to increasing demand, but pricing challenges are still an issue. Industry margins are being eroded by high discounts, retail sector price controls, public sector purchasing policies, and the move to value-based care. Strong economic growth looks hard to come by in many countries; therefore, assumptions on health spending may need to be revised downward. In response to today's dynamically changing clinical, regulatory, and business landscape, pharma, biotech, and medtech companies are re-evaluating and adapting traditional research and development (R&D), pricing, supply chain, and commercial models.

This 2016 global outlook reviews the current state of the life sciences sector; explores trends impacting markets and organizations; provides regional perspectives; and suggests considerations for stakeholders as they seek to grow revenue and market share.

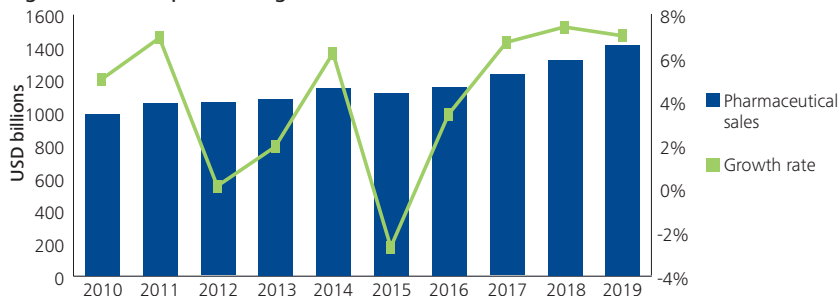
Life sciences sector overview

Pharma segment

Echoing the EIU's forecast of a 2015 dip in global health care spending, total global pharma sales (in nominal U.S. dollar terms) are expected to drop 2.7 percent that same year. However, the longer-term outlook is more positive: pharma spending growth should match health spending growth at an average of 4.3 percent during 2015-2019, and global pharma sales should reach \$1.4 trillion by 2019⁴ (Figure 1).

Pricing pressures in the United States and unstable economic conditions in Brazil, Russia, and China, which collectively drive 50 percent⁵ of global pharma revenue, have led to a slowdown in the pharma segment, as have tightening government health care budgets or reductions in out-of-pocket expenditures⁶ in these countries and others. Fortunately, the main factors driving health care demand — among them, aging populations, the rise of chronic diseases, and the advent of innovative and frequently expensive treatments (e.g., for cancer and Hepatitis C) — should lead to increased pharma spending in 2016 and subsequent

Figure 1: Global pharma segment sales



Source: DTL Life Sciences and Health Care Industry Group analysis of EIU data

years. However, steps many countries have taken to contain health care costs — price cuts, value-based pricing and reimbursement, pro-generic policies, and others — are posing key challenges to research-based pharma companies.

Some say the patent cliff has now passed its steepest point, but expiries and falling R&D productivity continue to affect the revenue of some research-based pharma companies, although the impacts are uneven.⁷ Several large global companies continue to report declines in revenues or net income and, in some cases, both. Other companies are registering more robust results, while some are booming.⁸ Big pharma continues to explore alternatives to its traditional, high-margin blockbuster business model, with a focus on models that will position companies for success in an outcomes-based environment. Also, with price and cost pressures mounting, the segment is likely to see continuing increased consolidation.

Pharma companies are adapting to current market dynamics and positioning themselves for growth through portfolio transformation, targeted deal-making, cost-cutting measures, and sharpened focus on high-performing therapeutic area (TA) and geographic markets.⁹

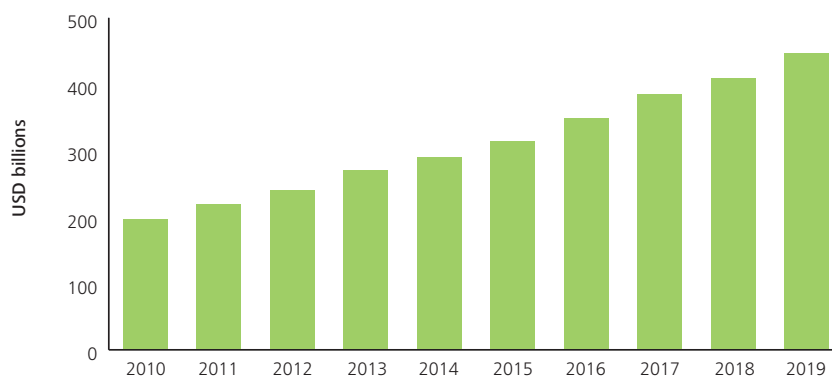
Biotech segment

Biotech drugs (vaccines, biologics) continue to gain traction in the life sciences sector. Of the top 10 pharma products by sales in 2014, the majority of them were biotech drugs, including monoclonal antibodies and recombinant products. Treatments for rheumatoid arthritis, Hepatitis C, and cancer figure most prominently in the list of the most sales-generating drugs.¹⁰

Biotech drug sales were an estimated \$289 billion in 2014 and are projected to grow to \$445 billion by 2019 (Figure 2).¹¹ In addition, biotech's share of worldwide prescription drug and over-the-counter pharma sales is projected to increase from 23 percent in 2014 to 26 percent in 2019 (Figure 3).¹²

Although biotech drugs have steadily carved a niche for themselves in the pharma market, traditional chemical-based drugs continue to dominate life sciences sector sales.

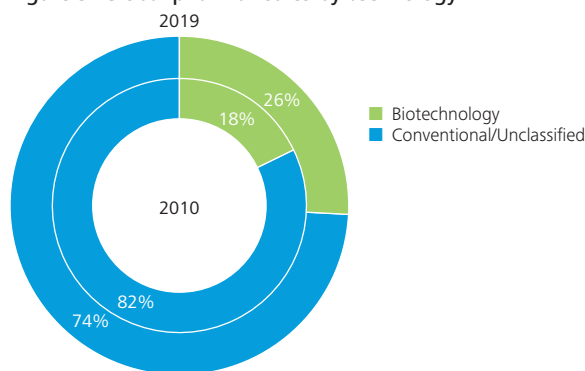
Figure 2: Global biotech market estimate



Source: D TTL Life Sciences and Health Care Industry Group analysis of Industry Report: Global Biotechnology, IBISWorld, January 2015

With the significant growth of specialty drugs and focus on personalized medicine, biotech companies are seeing increasing investment activity. In the United Kingdom, for example, equity market and venture capital funding for biotech firms in 2014 were at their highest levels in a decade.¹³ Biotechs also remain attractive acquisition targets. Switzerland sees a high degree of inbound biotech due to tax advantages; this may create opportunities for M&A transactions within the sector and non-traditional market entrants.

Figure 3: Global pharma* sales by technology



* Prescription drug and over-the-counter pharmaceuticals
 Source: D TTL Life Sciences and Health Care Industry Group analysis of World Preview 2015, Outlook to 2020, EvaluatePharma, June 2015

Generics and biosimilars segment

Demand for generic drugs should continue to rise as payers pursue avenues to reduce costs. Already, generics account for the majority of prescription drugs supplied in China and around two-thirds of total sales value.¹⁴ In the United States, generic drugs already comprise about 70 percent of the pharma market by volume.¹⁵ Generics' share is even higher in the United Kingdom — it accounted for around 84 percent of the pharma market in 2012.¹⁶ Mexico's generics share grew from 54 percent of total market volume in 2010 to 84 percent in 2013; due to increased competition, generic drug prices fell 60 percent, on average, during the same period.¹⁷ Generics sales in Brazil are increasing at a rate of 11 percent year on year.¹⁸ Japan's government recently raised the target for generic use from 60 percent by the end of April 2018 to 80 percent by April 2021, given a faster pace of generic penetration than expected. Indonesia's shift to Universal Health Coverage (PBIS) in 2014 is increasing generics consumption.

Generics should take a larger share of total global medicine spend, increasing from 27 percent (\$261 billion) in 2012 to 36 percent (\$421 billion) by 2017.¹⁹

The consistent growth of generics is challenging branded drug companies — they face revenue and market share loss in both developed and emerging markets — and generic drug manufacturers, which may have difficulty expanding their production capacity to meet demand. Another challenge for established generic pharma companies is that emerging market firms are growing at an increasing rate (fueled by a number of factors, including escalating demand in their home countries). The increased competitiveness of emerging market firms has resulted in generic companies in developed markets gradually losing global market share. However, the established companies are still likely to retain market dominance in the near term.

Development and sales of biosimilars, biologic products which are similar but not identical to reference/originator biologic products, are beginning to accelerate. Analysts expect the worldwide biosimilars market to reach \$25 billion to \$35 billion by 2020.²⁰

The European Union (EU) first approved a biologic in 2006; now there are more than 700 biosimilars approved or in the pipeline globally.²¹ In the United States, the Biologics Price Competition and Innovation (BPCI) Act, passed in 2010 as part of the Affordable Care Act (ACA), created an abbreviated licensure pathway for biosimilar products.²² It wasn't until March 2015, though, that the U.S. Food and Drug Administration (FDA) approved the first biosimilar product for the United States, Zarxio (filgrastim-sndz), a biosimilar alternative to Amgen's anti-infection drug Neupogen.²³ Six months later, in September, manufacturer Sandoz Inc. announced Zarxio's U.S. market launch.²⁴ In contrast, Zarxio has been sold in Europe since 2006.²⁵

The loss of patent protection between 2014 and 2022 for 11 established biologics products — representing 48 percent of total biologic sales — combined with increasing global focus on improving health care access and reducing the cost of care, presents growth opportunities for biosimilars manufacturers in both developed and emerging markets.²⁶ France, for example, has initiated automatic substitution of select biosimilars over the reference products²⁷ and upcoming biosimilar launches in Germany are anticipated to spur additional uptake and reimbursement opportunities. In most emerging markets, biologics currently have little-to-no presence. However, limited patient access to affordable biologics and provider openness to low-cost therapies may open the door to increased biologics use among large pockets of non-consumption and pent-up demand, especially within the growing middle class.²⁸ Biosimilar players likely will need to adopt a long-term strategy in emerging markets that entails growing sales (at a smaller margin than in developed countries) among increasingly affluent and health-conscious consumers, and selecting therapeutic areas (TAs) that have the largest potential impact for the local population.²⁹

Medical technology segment

Estimated global medical technology (medtech) segment revenues are expected to increase from \$369 billion in 2015 to \$454 billion in 2019, growing an average of 4.1 percent annually (Figure 4, next page).³⁰

Figure 4: Global medical technology segment sales



Source: DTL Life Sciences and Health Care Industry Group analysis of World Preview 2014; Outlook to 2020, EvaluateMedTech, September 2014

In vitro diagnostics (IVD) is medtech’s largest segment and it is projected to remain so for the next several years, growing annually by 5.1 percent between 2014 and 2020, generating sales of \$67.3 billion, or about 14 percent of the global market. Neurology is projected to be medtech’s fastest-growing segment, with 6.9 percent CAGR between 2014 and 2020, and achieving sales of \$9.5 billion by the end of the period.³¹ The future of companion diagnostics — medical devices that provide information for the safe and effective use of a corresponding drug or biological product — also looks bright. These diagnostics will likely continue to rapidly increase in number and application to disease areas in the coming years.³² Companion diagnostics are also increasing in importance in emerging markets as a way for governments to try to manage costs and ensure value from prescribed drugs.

There was a change at the top of the medtech leaderboard in 2015, with Medtronic displacing Johnson & Johnson as the company with the largest sales of medical technologies.³³ Medtronic’s \$50 billion purchase of Covidien — the biggest acquisition in the sector’s history — propelled Medtronic to the top, and it was the standout deal in a year that saw 86 mergers and acquisitions, totaling \$83 billion, in the first six months alone. 2015 could see closed deals worth more than \$100 billion for the first time ever in the segment.³⁴ Conversely, the medtech venture funding landscape in 2015 was disappointing. Just \$1.6 billion was raised in the first half of 2015, continuing a trend of falling investment levels over the past few years.³⁵ Early-stage businesses appear to be the most affected by the dearth of funding. In response, some start-ups are turning to less orthodox sources of cash (e.g., corporate venture capital’s investments and crowdfunding). If these funding patterns continue, 2015 could be challenging for young medtech companies.³⁶ One bright spot: venture capital firms continue to demonstrate interest in bioinformatics and biosensors.³⁷

On the regulatory front, the medtech product approval process remains complex; however, in certain cases, it is becoming somewhat quicker. In the United States, the FDA granted either a first-time premarket approval (PMA) or a humanitarian device exemption (HDE) to 26 devices during the first half of the year, compared with 33 during all of 2014 (a 43 percent increase over 2013).³⁸ If the pace continues, 2015 could see the most medical device approvals in a decade. Another positive development is that in April 2015, the FDA's expedited access PMA route became active, signifying the agency's commitment to speed up the regulatory process.³⁹ Meanwhile, Europe's medtech-specific regulation is intensifying. In June 2015, the Council of the European Union reached an agreement on two draft regulations aimed at modernizing EU rules on medical devices and in vitro diagnostic medical devices.⁴⁰ The draft regulations strengthen the rules on placing devices in the market and tightening surveillance once they are available.⁴¹ The new regulations are the culmination of three years' work to overhaul the EU medtech regulatory system.

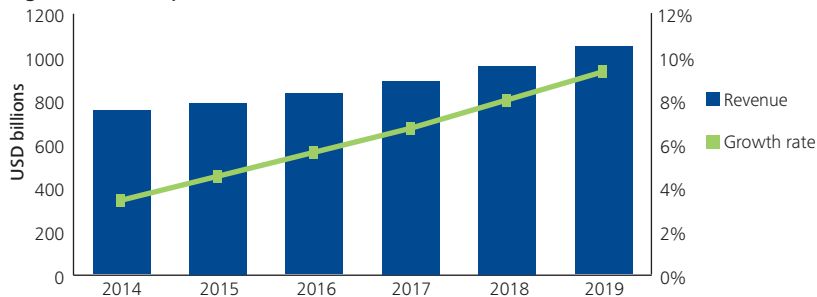
Many industry players — both traditional medtech organizations and new market entrants — are capitalizing on recent and emerging technological advancements and providing novel health care solutions using mobile health applications, sensor technology, data analytics, and artificial intelligence. One example of a smart medtech device that shows early promise and potential savings is the artificial pancreas, a technology that links an insulin pump with a continuous glucose monitor to provide automatic, real-time monitoring of glucose levels and insulin delivery. A study found that the artificial pancreas could generate a potential \$1.9 billion in savings over 25 years for the U.S. Medicare program.⁴² These new technologies are posing significant challenges for regulators, though, who are issuing directives/statements on a regular basis. There is a risk that, depending on how regulators respond, innovation could be stifled.

Wholesale and distribution segment

The global health care wholesale and distribution market is projected to grow an average of 6.82 percent annually in 2014-2019, with revenues increasing from \$752 billion to \$1.04 trillion during the period (Figure 5).⁴³ Key growth drivers include the rapid expansion of the pharma industry, technology advances, increased use of temperature-sensitive drugs, and growing demand for drug therapies in emerging markets.⁴⁴

In 2014, the Americas region dominated the pharma wholesale and distribution market, followed by Asia-Pacific. Key customer segments include hospitals and clinics, patients, and specialty/traditional wholesalers.⁴⁵ AmerisourceBergen, Cardinal Health, and McKesson are the leading players in the distribution and wholesale segment, and the three collectively hold more than 50 percent of the total global market share.⁴⁶ These companies have grown by acquiring local competitors and expanding internationally through M&A. In addition, they have invested in vertical integration by developing pharmacy chains, funding pharmacies where chains are prohibited, and introducing generic pharma firms⁴⁷ in certain markets. Some companies are also expanding their core offerings to include ambulatory surgery centers, hospital information systems, clinical management, diagnostic imaging, enterprise intelligence, home health care, laboratory and medical supplies, packaging solutions, patient support services, population health management, and telehealth solutions.⁴⁸

Figure 5: Global pharmaceuticals wholesale and distribution market, 2014-2019



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

The wholesale and distribution segment faces a number of challenges in 2016; among them, lack of data standardization and integration, and cost pressures. In addition, maintaining strict regulatory compliance and product safety is imperative: wholesalers and distributors are a critical link in the pharma supply chain and must comply with stringent government regulations to keep products safe for consumers. Despite these challenges, however, a number of trends indicate favorable conditions for market growth. For example, concurrent with the introduction of new drug therapies, manufacturers are seeking innovative new ways to deliver their products.⁴⁹

Outlook

Although economic woes are stunting pharma sales growth in certain regions, long-term prospects outweigh near-term challenges. During 2015-2019, both global health spending and pharma sales are expected to see positive growth, driven by population aging and expansion and the rollout of improved health insurance and services, particularly in developing markets.⁵⁰

“Life sciences companies should approach 2016 with cautious optimism. Opportunities to innovate in global, patient-centric, and value-focused approaches to growth are possible but each market’s economic, political, and social dynamics should be carefully monitored and assessed before moving forward.” (Greg Reh, DTTL Global Sector Leader, Life Sciences)

Biotech drugs have steadily carved a niche for themselves in the pharma market. However, they can be prohibitively expensive for many countries’ health care systems and are generating some challenges in terms of approvals. The expanding development of biosimilars, though, is expected to alleviate some of the cost burden.

Medtech growth opportunities appear to vary by market. Consumer demand for advanced medical technology and the relatively low market share of medtech in Brazil continue to offer considerable potential for expansion. In other markets, medtech is becoming commoditized and manufacturers are facing increased competition, stiffer regulations, and shrinking margins. Segment consolidation may be inevitable as the life cycle of products matures. Medtech companies also may seek to move more into the biotech space (e.g., innovative biomaterials to replace mechanical replacement joints).

Life sciences companies should approach 2016 with cautious optimism. Opportunities are plentiful but economic, political, technological, and social challenges remain. Four major trends that are expected to occupy the sector’s attention this coming year are navigating market dynamics, countering pricing and cost pressures, promoting innovation, and adapting to the compliance challenges of an evolving regulatory and risk environment. Read on to learn more about these trends and stakeholder considerations. Also visit www.deloitte.com/lifesciencesoutlook for regional perspectives as well.

Global life sciences sector trends in 2016



Navigating market dynamics



Economic uncertainty

Fluctuating economic conditions continue to challenge many of the regions in which life sciences companies operate. Although the U.S. economy has improved, multinational corporations (MNCs) must deal with other economic issues such as sanctions and falling oil prices in Russia; a stagnating economy in Japan; significant growth slow-down, rising debt levels, and currency devaluation in China; recession and inflation in some Latin American countries; and upcoming elections in the United States that may impact prescription drug price controls, to name just a few examples.

Due to the weakening of most emerging countries' currencies versus the U.S. dollar, those companies that import active pharmaceutical ingredients (APIs) and/or pharma products, and those with fixed-price/term contracts (especially with governments) may need to promptly re-negotiate their unit prices to avoid import losses. In addition, the relative cost of medicines likely will increase in line with the weakening of currencies, making the in-country price of medicines and devices more expensive — and for some countries, unaffordable. Government medical insurance schemes and health plans will likely need to manage their cost exposures to this and, as such, are likely to pass it back to the life sciences companies.

With U.S. and European market growth stagnating, it's anticipated that life sciences companies will continue to look to emerging market regions for new sources of revenue in 2016, even though doing so may expose them to varying types and levels of economic uncertainty. Looking beyond the immediate challenges of 2016, the projection for these regions remains promising, as underlying demographic trends and other factors are expected to drive demand for medical supplies as economies stabilize. Specifically:

- Brazil's market potential is still attractive due to strong demographic trends, such as the prevalence of chronic diseases, that are driving the expansion of pharma sales, provided the economy stabilizes.⁵¹
- The stable economy and ongoing health reforms in Mexico are expected to boost pharma sales.⁵²
- Global companies that are already invested in Russia are not planning to exit the market,⁵³ with some increasing their presence in the country.

- Global pharma companies are still seeking expansion in China despite the economic slowdown and are pursuing new approaches to deal with the challenges and risks.

Changing demographics

Aging populations, the growing prevalence of chronic diseases, rising consumer wealth, and other changing demographics are expected to boost health care spending and the demand for life sciences products in 2016 and beyond.

Population aging should remain a long-term growth driver in Western Europe and Japan as well as in countries such as Argentina, Thailand, and China, where it will combine with a sharp decline in the number of young people.⁵⁴ The combination of population aging and increased life expectancy — up from an estimated 72.3 years in 2014 to 73.3 years in 2019 — will bring the number of people aged 65-plus to over 604 million, or 10.8 percent of the total global population. That number is anticipated to be even higher in Western Europe (nearly 21 percent) and Japan (28 percent).⁵⁵ Among factors contributing to increased life expectancy are declining infant mortality, enhanced living conditions, improved sanitation, better prevention of communicable diseases, and growing access to medicine.

The proliferation of chronic diseases — in part, a consequence of increased life expectancy and other factors — is having serious repercussions in both developed and emerging countries. Obesity, cardiovascular diseases, hypertension, and diabetes are now persistent, widespread health problems and will challenge public health systems to meet increasing demand for drugs and treatments. Mexico's health reform program is strongly focused on this issue; public providers may partner with the private sector to treat these diseases and promote a culture of prevention.

The number of people with diabetes globally is estimated at 387 million and that number is expected to increase to 592 million by 2035, according to the International Diabetes Federation. China and India have the largest number of diabetes sufferers in the world, at more than 96 million and 66 million, respectively.⁵⁶

Population expansion and rising wealth should be strong drivers of health spending and life sciences sector growth in developing markets, particularly Asia and the Middle East. By 2019, the number of high-income households (those earning over \$25,000 a year) will likely rise to over 540 million globally; Asia is projected to generate more than half of that growth.⁵⁷

Accessibility and affordability

The trend towards adoption of universal health care continues, with more countries expanding public or private health care system coverage or deepening it in order to reduce out-of-pocket spending.⁵⁸ In perhaps the most visible example of expanding health care coverage, the U.S. federal and state governments continue to implement health insurance exchanges under the Patient Protection and Affordable Care Act of 2010 (ACA). As of June 2015, 9.9 million U.S. consumers have bought plans through the federal HealthCare.gov portal and a handful of state-run exchanges.⁵⁹ The proportion of the U.S. population lacking health insurance, meanwhile, has declined from 16.2 percent in 2009 to 11.1 percent (as of April 2015), and is likely to drop still further by 2019 as measures to enforce company-based enrollment are implemented.⁶⁰

The universal coverage principal remains the foundation of the French health care system. However, the government, which is struggling to reduce the country's huge Social Security deficit, is becoming more and more stringent in its pricing and reimbursement policy. So far, France has used all the traditional cost containment measures, ranging from price cuts to delisting or generic prescription incentives. However, lately there are early signals of more innovative approaches to control market access without jeopardizing coverage.

In Ireland, the government is using the eurozone financial crisis as an opportunity to institute extensive reforms that will replace the current two-tier public/private health care system with one universal fund.⁶¹ India's government has set a target of raising public health expenditure from 1.2 percent to 2.5 percent of GDP within five years; the end-goal is to establish a universal health care system based on insurance.⁶² Brazil has instituted mandatory pharmacy benefits in the private sector: under the plan, nearly 40 oral cancer drugs will be subsidized by payers, which should drive increased usage.

More insured individuals don't necessarily mean more revenue, however — some life sciences companies' OTC revenue may decline as prescription drug use goes up. For example, in Indonesia, which rolled out universal health insurance in 2014, OTC drug companies are seeing a drop in revenue.

Tax issues

As regulations around the world become both more numerous and stringent, and enforcement and penalties increase in the highly regulated life sciences sector, companies may benefit from taking a risk-based approach to tax planning compliance, execution, and tracking.⁶³ Virtually every transaction a company undertakes has tax considerations, from R&D and supply chain to the workforce to commercial operations and M&A. Even the most sophisticated global companies often struggle with balancing compliance details and long-term tax planning. Among focus areas are tax risk management, transfer pricing, business model optimization, international tax, tax data management and analytics, global mobility and talent management, and tax credits and incentives.⁶⁴

While M&A and strategic alliances still represent an important path to growth, the recent trend of tax-inversion M&A deals has subsided, following a regulatory crackdown. Until mid-2014, a number of companies (in life sciences and other industry sectors) took advantage of the interaction between the tax rules of different countries and used acquisitions to shift to a lower-tax location — a practice referred to as base erosion and profit shifting (BEPS).⁶⁵ The G20 asked the Organisation for Economic Co-operation and Development (OECD) to look at BEPS on a more global basis. The OECD's resulting Action Plan sets out 15 actions to address BEPS in a comprehensive and coordinated way. All 44 countries from the G20 and OECD have approved the Action Plan.⁶⁶ The 15 actions are expected to result in fundamental changes to the basis of international taxation and are based on three core concepts: coherence; restoring the principles of the international frameworks; and transparency. The Action Plan also calls for work to address the challenges posed by the digital economy. Countries will start to implement the agreed BEPS actions beginning in 2016.⁶⁷ In light of these evolving developments, some planned mergers were halted and other companies have proceeded more carefully.⁶⁸

Countering pricing and cost pressures



Reform-driven drug price controls

Amid the reform-driven shift to outcomes-focused, value-based payment and reimbursement systems, pharma companies may continue to bear the brunt of public and private payers' efforts to control costs. Truly innovative products may continue to command premium prices (and may help pay for future innovations), but patient and payer resistance is growing. Drug manufacturers are expected to continue to experience pressure to justify the cost of their products⁶⁹ based on, among other things, the product's comparative effectiveness against similar offerings. In addition, globalization of health care will intensify pricing pressure, as developing market drug manufacturers increase exports of less expensive generics while their governments demand price cuts at home.⁷⁰

Numerous countries are instituting reform-driven drug price controls. U.S. health plans try to control pharma costs through reference pricing, formularies, and co-payments. Germany moved to a highly regulated pricing regime from a free pricing market in 2011. Value dossiers are used that evaluate treatments as a summary of clinical, economic and patient-relevant therapeutic value.⁷¹ The United Kingdom's National Institute for Health and Clinical Excellence (NICE) uses quality-adjusted life years (QALYs) to evaluate the cost-effectiveness of treatments. The process leads to a high degree of rejection of expensive treatments of orphan diseases and rare forms of cancers.⁷² France's system compares the efficacy/safety of a drug against a standard of care so as to assess the incremental benefit/value. This allows for price negotiation in line with the level of innovation involved.⁷³

In China, the government's efforts to ensure affordable care for the general public is expected to lead to continued reduction in drug prices and a shift to lower-priced local generics. This "new normal" is forcing MNCs to consider adjusting their business models and product mix in certain parts of the world. In addition, China mandates that all public hospitals procure pharmaceuticals through a provincial, centralized bidding system. This, combined with the widespread practice of second-round price negotiation, is resulting in large price decreases as well as increased complexities and uncertainties in managing prices. The next round of provincial pricing tenders is in 2016, and additional cuts of five to twenty percent are expected for branded drugs. Also, the government has announced it will be rolling out medtech reform initiatives (including pricing reform) in the next year.

In Japan, drug and medtech prices are under government control. To control health care expenditures and sustain universal coverage, the government has introduced a number of initiatives, such as encouraging the use of generic drugs, self-management of chronic diseases, and preventive care. The government has also said it is going to introduce a health technology assessment (HTA) but it is not certain if or when that will happen. Implementing an HTA for selected products is designed to strengthen pricing pressure on current products, augmenting the government's existing scheme that reduces the gap between the reimbursement price and the actual price paid by hospitals/pharmacies. Despite governmental cost-control initiatives, Japan is an attractive market for innovative drugs because, in general, a company can maintain margin and price. A number of MNCs are turning back to Japan for growth, given the perceived difficulties in China and other emerging markets.

In December 2014, India's National Pharmaceutical Pricing Authority (NPPA) extended its pricing policies to cover 52 additional medicines, including commonly used painkillers and antibiotics and drugs for cancer and skin disease treatment. More than 450 drug formulations are now on the NPPA's price cap list.⁷⁴ As a way to counter these pricing pressures, the local units of global life sciences companies may have to boost the number of product launches, expand treatment portfolios, and improve sales agent productivity.

Companion diagnostics

Companion diagnostics — medical devices that provide information that is essential to the safe and effective use of a corresponding drug or biological product⁷⁵ in a specific therapeutic area — should continue to rapidly increase in number and application, especially in the United States and Europe. The commercial success of drugs such as Herceptin® (trastuzumab) and Gleevec® (imatinib), which both required testing with companion diagnostics before they can be prescribed, has moved the entire companion diagnostic field forward. From an initial start of a handful of oncology drugs with corresponding diagnostics, the field has expanded to include multiple TAs, and the number of combinations has grown 12-fold. Based on drugs in clinical trials, the rapid growth will likely continue for the foreseeable future.⁷⁶

One of the greatest challenges to future growth in companion diagnostics is aligning stakeholder incentives. While pharma companies are most interested in companion diagnostics that are theranostics (an emerging diagnostic therapy to test individual patients for a possible reaction to new medication and to tailor a treatment regimen based on the test results⁷⁷) and monitoring types of tests, payers appear to favor diagnostic tests that provide information on multiple potential treatment options in a TA. The current model of a single diagnostic test tied to a single pharmaceutical agent is unlikely to survive payer pressure for greater efficiency and cost-effectiveness. Regulators are also becoming more demanding in aligning development time lines between drugs and diagnostics. Finally, value-based care models may offer significant advantage in selecting the optimal drug based on diagnostic testing that compares the effectiveness of similar therapeutics.⁷⁸

Operational issues

Squeezing profit margins, patent expiries, and rising R&D costs are some of the factors putting significant pressure on life sciences companies to institute operational efficiencies.⁷⁹ However, as companies work to replenish pipelines, develop innovative offerings, and integrate acquisitions, organizations of all sizes are struggling with issues that span development, manufacturing, and distribution. Among the challenges:

- Many companies — especially large manufacturers — have yet to find a way to reduce the cost of early-stage research and development without reducing output. Budget “haircuts” in early development often diminish associated productivity. Research units do the same work more slowly; for example, progressing research sequentially rather than in parallel to perform target validation and lead selection. Hiring freezes can lead to low morale or loss of key employees.
- Most life sciences companies are seeking ways to reduce clinical development risks while also producing high-quality data to meet regulatory submissions and maintain compliance. Some organizations have implemented initial forms of adaptive design or central and/or risk-based monitoring but continue to look for additional ways to enhance their capabilities to reduce risk and improve data quality.
- Despite measures to streamline their manufacturing footprint, companies may remain unable to reduce their asset base, due to excess capacity as well as exiting costs and disposal difficulties in a challenging commercial real estate marketplace. An optimal number of facilities can help to reduce operational complexity and cost while maintaining compliance.
- Some life sciences companies have not optimized their outsourcing strategies. They also need to look for better ways to govern and measure performance in these relationships to gain the most operational benefits. Some continue to duplicate the efforts of “strategic partners” such as Contract Research Organizations (CROs) or Functional Service Providers (FSPs) and thwart their own efforts to get more leverage and performance from these relationships.
- Organizations often have difficulty operationalizing and optimizing acquisitions, resulting in costly and inefficient duplication of functions, services, facilities and equipment, as well as under-realization of post-M&A synergies.
- Persistent talent and leadership issues are both creating and exacerbating operational challenges as they inhibit top-to-bottom efforts to manage change and implement leading practices that could improve operational efficiency.
- Supply chain risks become more acute in an increasingly global marketplace. Companies will need to find ways to optimize their supply chain models. Compliance, safety, efficiency, and cost should be critical criteria.

In their efforts to reduce costs and boost operational efficiencies, some global life sciences companies have sold their domestic manufacturing plants to contract management organizations (CMOs) and others have established plants in emerging countries where labor costs are lower. In addition, some companies are reviewing their wholesaler strategies for product value optimization. In Japan, for instance, wholesalers take larger roles compared with other developed countries, including managing price negotiation with hospitals, clinics and pharmacies; and providing drug information to health care professionals. Since almost 100 percent of patented drugs are distributed through wholesalers and the largest four of these hold nearly 80 percent share,⁸⁰ optimizing collaboration with them while controlling margins is an important issue for companies to address.

Outdated IT infrastructure

Many life sciences companies are spending considerable sums to fix operational and compliance issues caused by an outdated IT infrastructure. For example, an infrastructure designed around an impermeable core may hamper external collaboration, an important element of open innovation in R&D. From a compliance perspective, outdated IT systems may stymie efforts to meet mandatory FDA GxP requirements for pharma manufacturing and product quality.

In the past, and to a lesser extent even today, pharma has tended to customize IT to fit its old process/organization/installed technology base; in the process, comprising benefits realization. However, there appears to be a growing appetite in larger-scale renewal of IT platforms and solutions in two distinct areas: 1) simplification of the enterprise resource planning (ERP) environment to fewer or a single ERP; and 2) movement to a cloud package for non-ERP systems. For small/mid-sized systems that aren't going to the cloud there is a big focus on Infrastructure cloud with both private clouds and contracts with Amazon Web Services (AWS) or others. With this in mind, Gartner predicts that IT spending in the life sciences sector will reach \$54 billion by 2019, growing at an annual average of five percent from 2015-2019.⁸¹

Leveraging the growing data explosion stemming from digital devices and electronic patient records is contributing to a need for updated infrastructure. Life sciences and health care industry stakeholders need to manage and leverage this data in order to enhance patient care. It is understandable, therefore, that analytics and big data are among key investment areas for companies looking to update their IT infrastructure. Already, niche companies and research groups are using analytics for data screening, next-generation sequencing, genomics, and image file processing, among others. However, analytics can be applied to numerous operational functions, including:

- **Customer (practitioner) analytics:** Despite life sciences companies investing in customer-facing actions and data sources, they struggle with extracting actionable insights. A dearth of predictive analytics in many current offerings is a challenge that most companies solve by adding analytical capabilities to their customer relationship management (CRM) solutions. Customer analytics is projected to become a high-impact area, as it enables predicting outcomes of promotional activities.
- **R&D informatics:** Scientific staff members, with the help of data scientists, have pioneered the application of R&D analytics. However, employees in other departments are requesting tools simplification so they don't have to depend on informatics-oriented technical assistance to visualize data and develop insights.
- **Social media analytics:** Although unclear regulatory guidance may prove to be a hindrance to this potential opportunity, increasing numbers of life sciences companies are interested in using analytics to optimize their social media activity. The readily available information in social media could potentially assist companies identifying trends and unforeseen insights about consumer health care behaviors.
- **Mobility:** Work in ePro (e.g., diary records), bring your own device (e.g., drug compliance updates), health monitoring (e.g., Fitbit, Garmin), and other mobile apps is contributing to new ways of driving advances in data collection capabilities as part of clinical trial conduct.

- **Outcomes measurement:** Outcome-based contracts (also known as risk-sharing agreements) have been leveraged frequently in Europe, and offer the potential for earlier access to new products by linking coverage and reimbursement levels to real-world performance or utilization of the product. Currently, there is a lack of such agreements in the United States — some factors are the associated transaction and administration costs, limitations of existing IT systems in terms of tracking performance, agreement on the outcome details, and lack of trust between payers and life sciences manufacturers. As more payers seek value-based contracts, coupled with the high cost of precision medicine drugs, it is expected that life sciences manufacturers will need to deploy sophisticated analytical systems to determine, track, and provide outcomes evidence to demonstrate comparative effectiveness and justify desired levels of reimbursement. The recently published paper on health care analytics by the Deloitte Center for Health Solutions further highlights this trend.⁸²

Investments in data analytics technologies that improve operational insights and efficiencies are expected to contribute substantially to IT spending in 2016. However, barriers to widespread adoption remain; among them, data complexity, security issues, and privacy restrictions. In addition, much work will be needed to educate health care providers, payers, and the general public about the benefits of sharing health-care-related data to accelerate R&D outcomes, monitor patient benefits, and respond to regulatory requirements.

Another technology trend that may have near- and long-term impacts on the life sciences sector is cloud-based systems. CRM has already embraced a cloud-based, software-as-a-service (SaaS) model, and this has made companies more comfortable with the concept of a service-based technology architecture. This trend has the potential to drive closer alignment on data models to the point where an industry standard may become more realistic. With increasing interest in pushing the boundaries of what life sciences companies can do in the cloud, this trend will likely increase. In addition, a switch to cloud-based solutions in clinical IT has been taking place over the last two-to-four years. Most new CTMS, EDC, PPM, safety and portal solutions gaining market share in the clinical space are cloud-based and modular in nature.

Talent issues

Persistent talent shortages and the need to develop and retain employees with critical business and technology skill sets will continue to challenge global life sciences companies as they try to navigate a “new world of work” — one that requires a dramatic change in strategies for leadership, talent, and human resources.⁸³

Many of today’s life sciences employees work on global teams that operate 24/7. In addition, an increasing number of skilled workers are employed on a contingent, part-time, or contract basis, so organizations must work to integrate them into talent programs. New cognitive technologies are displacing workers and re-engineering work, and demographic changes are also in play, as Baby Boomers enter retirement and Millennials take center stage.⁸⁴

Deloitte’s 2015 *Global Human Capital Trends* report identifies⁸⁵ 10 human resources (HR) trends that are likely to present talent-related challenges for life sciences organizations in 2016 and coming years. These include culture and engagement; leadership; learning and development; reinventing HR; workforce on demand; performance management; HR and people analytics; simplification of work; machines as talent; and people data everywhere. The report also calculates a “capability gap” for each challenge, measuring the difference between an issue’s importance and an organization’s readiness to address it. Unfortunately, comparing 2015’s results to 2014 data, the capability gap in many of these areas has increased in magnitude. This suggests that the accelerating economy and rapid changes in the workforce have created even more urgency in the need to adapt HR and people practices around the world.⁸⁶

Addressing talent issues is particularly important in emerging markets, as many have an acute shortage of skilled workers. Singapore, for example, is tightening the approval process for work visas and companies may need to revisit their operations in Singapore if appropriate staff cannot be employed. Other Southeast Asian governments are working to ease restrictions on the movement of labor but it remains to be seen if and how quickly those efforts will meet the region’s talent needs. Some life sciences companies are taking matters into their own hands. Kalbe Farma, one of the largest pharma companies in Indonesia,

has built its own university, the Indonesia International Institute for Life Sciences. The institution is dedicated to providing premium education, with satellite facilities for marine, forest, and health care research and a unique network of top-quality faculty, private sector leaders, and international research partners.

Promoting innovation

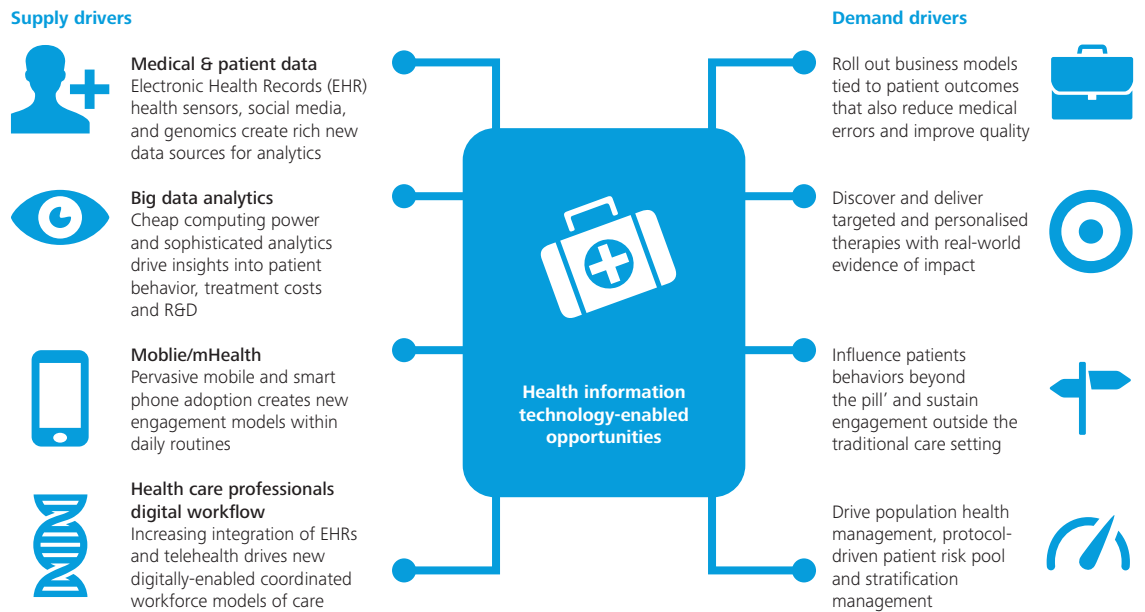
Executives at life sciences companies are facing dual imperatives to 1) deliver innovative therapies that address unmet patient needs and treat life-threatening conditions; and 2) deliver profitable growth. Achieving these often-conflicting objectives is likely to require that companies transform their business and operating models and embrace disruptive technology advancements that can concurrently reduce costs and speed time to market for new products and services.



Evolving business models

From product development through manufacturing and distribution, life sciences companies are evolving their business models “beyond the pill” to engage more fully with providers and patients throughout the product lifecycle and “transform what is possible” (Figure 6). Recent figures indicate these efforts may be starting to pay off. The current net present value (NPV) of the pharma sector’s pipeline surged 46 percent from 2013 to 2014, to an estimated total of \$418.5 billion in potential future revenue.⁸⁷ However, R&D expenditures are forecast to grow just 2.4 percent between 2013 and 2020, reaching \$162 billion, below sales growth and continuing the industry’s balancing act between fostering innovation containing costs.⁸⁸ In time, the benefits of new business models may also become apparent in more macro measures, such as total shareholder return (TSR).

Figure 6: New business models: ‘Beyond the pill’, outcomes, and real-world data are providing health data and transforming what is possible



Source: *Healthcare and Life Sciences Predictions 2020: A bold future?*, U.K. Centre for Health Solutions, 2014

Evidence of countries and companies evolving their life sciences business models to spur innovation can be seen around the globe. Singapore, China, and Australia are pushing to become centers of innovation for biotech. Australia changed its tax rules for start-ups, making it very attractive to do discovery work there. Singapore is heavily investing in a biotech cluster. Some pharma companies in Southeast Asia are reviewing and enhancing their product portfolios to meet the needs of specific health care providers, such as oncology drugs for high-end hospitals with medical tourism practices and vaccines for remote clinics. Japan's government provides incentives for innovations that promote growth of its life sciences industry. For example, a trial operation of a "sakigake" designation system was initiated in 2015; it grants several incentives including fast-tracking regulatory review and extending the drug re-examination period (during which generics cannot be marketed, regardless of patent status). To be eligible for the "sakigake" designation, products need to meet clear criteria such as having a novel Mechanism of Action (MoA), addressing high unmet medical needs, or being commercialized in Japan ahead of the rest of the world.

The Russian government supports R&D activities and local drug and API manufacturing by providing subsidies, tax benefits, and loans at beneficial interest rates; organizes and supports regional pharma clusters through infrastructure development; and gives preferential treatment to local manufacturers in state purchases. Further support measures are being discussed, such as guaranteed state purchases under special investment projects. South Africa has started making some major gains in R&D, especially in the area of communicable diseases. The country also has an opportunity to build on the considerable capabilities and information residing within its extensive life sciences laboratory system to support ongoing research efforts.

The government of India plans to establish a \$640 million venture capital fund to boost drug discovery, strengthen the country's pharma infrastructure, and make India a major hub for end-to-end drug discovery. In addition, the government is planning to develop a bulk drug manufacturing policy that will provide incentives such as land at concessional rates, tax holidays, soft loans, creating mega pharma parks, allocating power at concessional rates, and other benefits. This could trigger investments by India's domestic drug companies approaching INR 300-400 billion (\$5 to \$7 billion). Finally, the government is set to approve six pharma parks in the coming year at an estimated investment of INR 1.8 billion (\$27 million) for drug testing and treatment and professional training. The parks will be implemented through joint ventures: pharma enterprises will have a 51 percent stake, with the remainder being held by a government agency, financial institution, or strategic partner.⁸⁹

Personalized care

An important clinical development that is driving business model transformation is personalized care. Scientific advances can provide optimal value when targeted to particular consumers. Widespread adoption of "personalized/precision care" will likely be made possible through investments in offerings that integrate drugs and devices with low-cost diagnostics, disease management programs, and clinical decision support. For example, the proposed U.S. FY2016 budget includes \$215 million for the Precision Medicine initiative, which is focused on building a large research cohort for longitudinal studies and ensuring regulations are appropriate to facilitate sharing of patient data across institutions and agencies. Ultimately, the goal is to get more targeted treatments for a variety of diseases to patients faster.⁹⁰

Personalizing care based on genetics and individuals' health information has the potential to generate new therapies that may radically improve outcomes. For example, approximately 30 to 40 percent of patients take drugs for which the adverse effects outweigh the benefits.⁹¹ This is neither cost-effective nor therapeutic. Targeted therapies paired with genetic diagnostic tests help physicians to select an optimal treatment the first time, avoiding the possible costly and risky practice of trial-and-error prescribing. Other innovations in personalized care include specialty drugs, which show potential to improve life expectancy and quality of life.⁹² When used with biomarkers to target subpopulations, these drugs could improve outcomes, lower treatment cost, and even prevent disease.^{93,94} Specialty drugs are on the rise: they currently comprise 31.8 percent of total drug spending and are projected to reach 44 percent by 2017.⁹⁵

Although personalized medicine discoveries are increasing, payer reimbursement currently is "limited and highly variable." Additional research is needed to demonstrate a return on investment to payers.⁹⁶

Digital health

Digital health technology is creating a paradigm shift in life sciences. Health data captured by wearable devices, mobile health apps (mHealth), and social media are being used to transform aspects of health care that earlier seemed beyond the purview of such technologies. Digital health is also becoming an important platform for life sciences companies to strengthen patient engagement programs and collaborate with other stakeholders in the health care system.

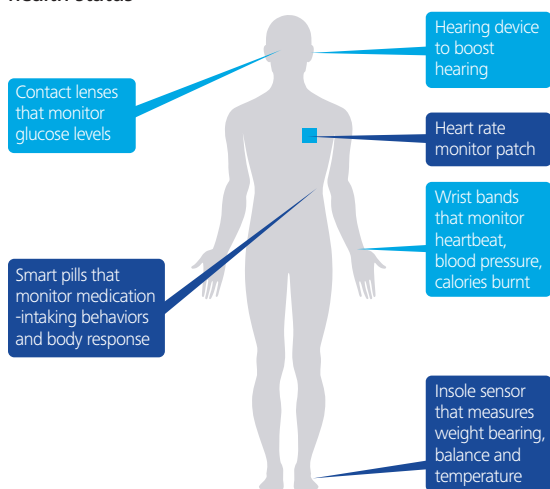
The size of the global digital health market comprising wireless health, electronic health records (EHR), electronic medical records (EMR), mHealth, and telehealth, among others, was \$60.8 billion in 2013 and expected to increase to \$233.3 billion in 2020, growing at a CAGR of 21.2 percent. Moreover, these offerings are leading to developments in related markets such as wireless network tools, sensors, and devices.⁹⁷ Digital health venture funding exceeded \$4 billion in 2014; telemedicine was the fastest-growing segment at 315 percent year-over-year growth from 2013 to 2014.⁹⁸

Digital health is now being used to accelerate the drug discovery process. The clinical trial space, in particular, provides a way to leverage mHealth technology to improve patient engagement with the aim of reducing the cost of clinical trials. Four areas in particular in digital health — telehealth, mHealth, wearables, and social media — are growing rapidly in use and influence and, thus, hold considerable implications for pharma and medtech companies along with nontraditional market entrants.

- **Telehealth:** For patients with congestive heart failure, diabetes, depression, and other chronic conditions, telehealth technologies such as home telemonitoring can reduce hospital readmissions and increase the ability of individuals to live independently⁹⁹ and adhere to their prescription drug schedule. It also can defer the need for and/or improve assisted living and nursing home care. According to the *Deloitte 2015 Survey of U.S. Health Care Consumers*, respondents are beginning to view telehealth as an acceptable care alternative.¹⁰⁰
- **mHealth:** Mobile health (mHealth) applies the power and reach of mobile communication to health care services. It plays a key role in transforming health care into a more-efficient, patient-centered system of care in which individuals (and providers) have real-time access to information to support engagement.¹⁰¹ A report estimates that by 2015, over 500 million of a total 1.4 billion smartphone users worldwide will be using mHealth apps.¹⁰² And by 2018, 50 percent of the 3.4 billion mobile device users will have downloaded mHealth apps. mHealth applications can range from basic (e.g., an app compiles reports on daily calorie, sodium, fat, and carbohydrate intake from manually entered user data) to intermediate (e.g., an inhaler with a built-in asthma sensor to measure air quality) to advanced (e.g., a portable device that measures temperature, heart rate, blood oxygen levels, respiratory rate, ECG, and blood pressure and transmits the data to a mobile device).¹⁰³

- **Wearables:** Many health-related wearable innovations leverage the power of biosensors, which can be placed in a watch, a patch on the skin, implanted under the skin, or swallowed like a pill (Figure 7). In addition to motion, light, pressure, temperature, moisture, and gas, biosensors soon may be able to monitor chemicals and biomarkers. For example, doctors may be able to use biosensors to determine how well a drug is metabolized and adjust the dosage and frequency accordingly.¹⁰⁴ Illustrating the market interest in this digital health trend, venture capital funding for bio-sensing wearables increased five-fold from 2011 to 2013, reaching \$282 million in 2013.¹⁰⁵

Figure 7: Examples of how wearables might transform information and understanding of people's health status



Source: *Healthcare and Life Sciences Predictions 2020: A bold future?*
U.K. Deloitte Centre for Health Solutions, 2014

Social media: There has been a rise in online patient community platforms that gather large volumes of data from patients about drug side effects and patient interactions. Pharma companies are trying to leverage such data, turning it into insights to help solve the unmet needs of patient communities. For instance, one of Merck's several digital health and big data projects at Merck Medical Information and Innovation (M2i2) group, initiated in 2014, is focused on capturing the patient voice — from sites such as PatientsLikeMe (an online patient network with more than 300,000 members) and applying them to larger company operations.¹⁰⁶

The spread of disruptive technology innovations such as mHealth and e-marketing is playing a leading role in reshaping China's health care eco-system. For example, Spring Rain provides preliminary consultation to patients online and offers an alternative channel for physicians and patients to connect with each other. DXY focuses on serving doctors and has accumulated two million members out of 2.7 million registered physicians.¹⁰⁷ It is turning into a powerful platform where pharma companies can look for ways to market their products. Online drug stores are not only selling products but also providing physician consultation to increase repeated sales. These changes are accelerating and call for close monitoring and thoughtful participation by MNCs with ambitions to win in China's market.

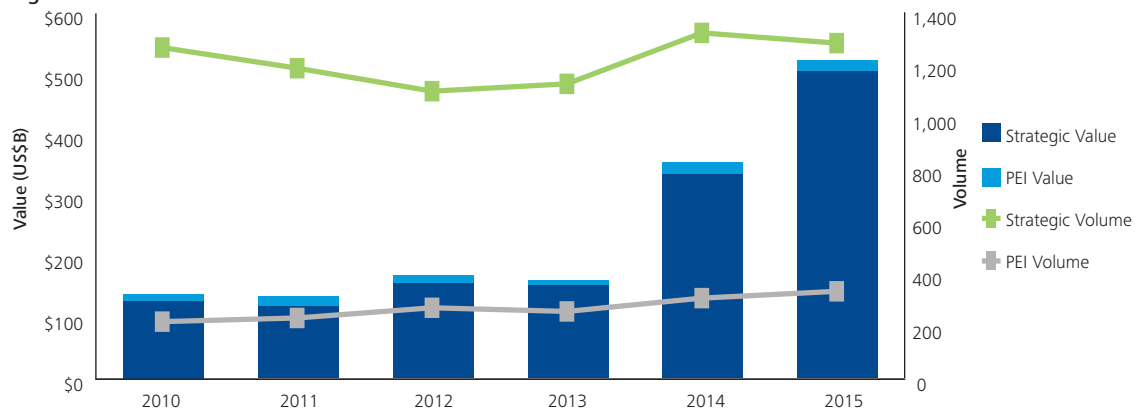
It is important to note that many life sciences technology innovations are being spearheaded by small-to-midsize biotech, biosimilars, and generics firms; high-tech giants (e.g., Baidu, Alibaba and Tencent, otherwise known as "BATs" — the three largest e-commerce conglomerates in China); niche companies; and cross-sector collaborators.

M&A and collaborations

Mergers and acquisitions (M&A) continue to be one of the life sciences sector's principal growth strategies. Most transactions focus on the following factors: consolidating in the face of pricing pressure; strengthening existing product portfolios; replenishing pipelines depleted by patent expiry; deepening capabilities in priority areas; entering new and/or emerging markets; and acquiring innovative technologies to leverage current assets or generate cost-saving synergies.

The total deal value (strategic and PEI value) of life sciences M&A in 2015 amounted to over \$520 billion, a hefty 47 percent growth rate over 2014 (Figure 8, next page).

Figure 8: Global life sciences M&A—Annual



Source: DITL Life Sciences and Health Care Industry Group analysis of Thomson Reuters

The first half of 2015 saw 304 pharma M&A transactions worldwide, worth a combined total of over \$221 billion. This compares with just \$62 billion during the same period in 2014.¹⁰⁸ The medtech sector, meanwhile, recorded 86 mergers and acquisitions in January-June 2015, with the total value of mergers closing at \$83 billion — the highest total ever recorded.¹⁰⁹ The biggest acquisition in the segment’s history, Medtronic’s purchase of Covidien for \$50 billion, comprised the majority of the total, although Zimmer and Becton Dickinson made sizeable purchases as well. By year-end, the medtech sector could see closed deals worth more than \$100 billion for the first time ever.¹¹⁰

On the pharma side, in April 2015, Mylan NV launched a bid to purchase Perrigo Co. PLC of Ireland for \$35.2 billion; Israel’s Teva Pharmaceutical Industries agreed to purchase Allergan PLC’s generic drug business for \$40.5 billion in July.¹¹¹

Pressure to reduce costs and boost shareholder value is prompting some large industry players to divest low-growth assets and presenting other companies with opportunities to invest in high-value niche product lines or specific TAs. In January 2015, for example, Aspen Pharmacare Holdings Limited, Africa’s largest generic drug manufacturer, acquired an anti-coagulant business unit from Novartis.¹¹² Two years earlier, Johannesburg-based Aspen purchased GlaxoSmithKline’s deep vein thrombosis unit.¹¹³ The deals signal that South African generic companies may be looking to break into innovative pharma by way of M&A.

Looking ahead, the life sciences sector is likely to see more technology deals — the drug will remain important but will represent a diminishing share of what comes together to deliver an overall outcome. Acquisitions of (drug) platform technologies to extend the value of pipeline products should continue and the integration of medtech and pharma is gaining traction. Pharma companies are looking at acquisitions, joint ventures (JVs) and other collaborations with technology firms. For instance, Novartis and Google (Alphabet) announced a partnership in which Novartis will license Google’s smart contact lens that could measure a wearer’s blood sugar levels.¹¹⁴

As evidenced by the Novartis/Google deal, JVs and other strategic alliances should continue to proliferate as pharma, biotech, generics, and medtech companies of all sizes look for ways to maximize assets, enrich portfolios, access local capabilities, expand market share, and share risks.

In Brazil, AmerisourceBergen and Profarma Distribuidora de Produtos Farmaceutico have established a JV for specialty distribution and services.¹¹⁵ The JV is part of AmerisourceBergen’s ongoing effort to expand into growing international markets.¹¹⁶ In Russia, foreign pharma companies that are not ready to invest into green field production are seeking partnerships and alliances with local producers (e.g., for contract manufacturing). There also are a few cases of foreign entities acquiring small- and medium-sized local players. Some pharma companies in Japan have increased the number of external alliances to help expand their product portfolio and optimize R&D costs.

Inking a deal doesn't necessarily generate immediate advantages. Some life sciences companies struggle to address post-M&A integration challenges and create value by developing scalable growth models that will generate cash returns. Integration issues may be particularly pronounced in cross-border deals, where operational and cultural differences may be difficult to reconcile.

Adapting to an evolving regulatory and risk environment



Life sciences stakeholders face increasingly complex operational risks and regulatory challenges emanating from technology

advances, clinician and patient expectations, and a globally connected health care market. Top-of-mind issues for the sector include cybersecurity and IT quality, regulations and compliance, drug and device safety, counterfeit drugs, and Intellectual Property (IP) protection.

"Clinicians and patients have exacting expectations of regulators and are unforgiving not only when regulators are perceived to impede the adoption of promising new technologies or treatment but also when they fail to protect patients from quality or safety issues. Regulators must invest in new capability to meet new expectations, such as assessing information governance and cybersecurity, which will gain increasing prominence in the light of increasing amounts of data." (David Hodgson, DTTL Global LSHC Enterprise Risk Services Leader)¹¹⁷

Cybersecurity and IT quality

Although the digitization of health care data and advancements in enabling technologies have improved life sciences R&D and operational efficiency, these improvements are being accompanied by pervasive, persistent cyber risks, which can leave companies vulnerable to debilitating business losses and brand image erosion. Among emerging threats that should prompt companies to implement enterprise-wide cybersecurity programs are:

- **Cloud-based computing attacks:** With the broad migration of software to the cloud (public/hybrid) as a main backup storage platform, the life sciences sector has been exposed to new security challenges from distributed denial of service (DDoS) and related types of cyberattacks. Such attacks could cause substantial downtime and affect productivity throughout the product development process, from clinical trials to manufacturing, to sales and distribution. Business losses from DDoS and other threats can range from \$10,000 to \$100,000 per hour,¹¹⁸ and such security breaches may lie undetected for several hours or even days, driving damages and costs into the millions of dollars.
- **Regulatory implications of cloud usage:** As the life sciences sector awaits formal regulatory guidance on the appropriate controls to consider for cloud usage, health authorities appear to be focusing their attention on risks related to unauthorized changes made to public cloud platforms that could inadvertently impact functionality that touches patient safety or product quality.
- **Medtech security concerns:** While medical devices are playing a transformative and beneficial role in health care, they also pose risks to patient safety and health information security. As innovation continues and the threat landscape evolves, securing medical devices becomes more crucial. The quantity and types of potential threats increase as awareness of cybersecurity vulnerabilities grows, potentially risking patient confidentiality and the integrity and availability of device and patient data. When a medical device itself, or the integrity and availability of its data, is compromised due to a security breach, the loss of integrity may lead to faulty data which, in turn, may cause the device to malfunction or result in incorrect care decisions by medical practitioners.
- **Big data management:** Increased access to company-owned data helps life sciences companies better understand research and clinical trial results and more effectively target patient populations. Sensitive intellectual property, personally identifiable information (PII), and protected health information (PHI) will need to be safeguarded throughout the product life cycle, and companies will need to comply with privacy laws and norms across an array of jurisdictions.

- **Third-party access:** Global ecosystems with vast numbers of third parties drive life sciences R&D, manufacturing, marketing, and operations. Relying on third-party data can improve formulary management and help drive the effectiveness of treatment protocols across patient populations; however, third-party involvement also greatly increases the risks of data breaches and IP leakage. Secure protocols for third-party data access are imperative.
- **Privileged access:** Privileged accounts with access to the most sensitive information have been around for years, and protecting them has never been more important. Privileged access management has evolved into a framework that improves cohesion among business processes, user management, and various tools. This framework enables improved operational effectiveness and reduces the risk of insider attacks while also complying with organizational security policies and offering auditing capabilities to meet various regulatory obligations.

Regulations and compliance

Regulatory agencies continue to exert pressure on life sciences companies, with increasing focus on off-label marketing, failures to disclose safety risks, and concerns about the clinical trial process.

Among recent developments with implications for 2016 and subsequent years is an upward trend in health authority findings: 483s and warning letters related to unreported adverse events (AEs) found within third parties and non-safety-related departments at pharma companies. This increased enforcement is driving companies to examine the way they are assessing non-traditional sources of AEs, such as patient support programs, market research vendors, and insurance assistance centers. Pharma companies are implementing ongoing AE reporting assurance and monitoring programs, leveraging technologies with natural language processing capabilities in order to continuously identify AEs in non-traditional sources and confirm that those AEs were properly reported to health authorities.

U.S. pharma companies are dealing with time-critical elements of the Federal Drug Quality and Security Act. The law mandated that, by January 2015, manufacturers had to incorporate product transaction data into a single document that is available, either electronically or on paper, each time ownership is transferred. This includes transaction data for lot-level information, a complete transaction history, and a transaction statement. The information must be maintained for six years after the transaction. By November 2017, that information must be available electronically, and the product identifier must be affixed or imprinted on the label at the product and case level.¹¹⁹ The mandate also provides for suspicious and illegitimate products, with the process comprising quarantine, an investigation with trading partners, FDA notification within 24 hours, and, by November 2017, the ability to verify the product at the package level with a standardized numerical identifier.¹²⁰ Since the United States lags other countries in serialization regulations – requirements are in various stages of development in the EU and its member nations, Turkey, India, China, Brazil, Argentina, and Korea — the U.S. law is likely to have little impact on overall global traceability requirements and programs.¹²¹

In a similar fashion, EU legislation is mandating the implementation of new data standards called Identification of Medicinal Products (IDMP). IDMPs allow for the unique identification of medicinal products on an international level by developing a method and process for generating global product identifiers that can then be used for product reconciliation and linkage across the entire product supply chain.¹²² Compliance for IDMP is expected to begin in the EU in July 2016 and continue to evolve throughout 2017 and 2018 via iterative rollouts addressing additional scope.

IDMP's breadth includes over 500 unique attributes that will enable consistent capture, communication, and exchange of product information among life sciences firms, global regulators, manufacturers, suppliers, and distributors. IDMP will require that significant investment be made to operationalize these standards and bring key product data into alignment, spanning a wide set of functions covering R&D, manufacturing and supply chain. Globally, IDMP will enhance data transparency, offering benefits beyond compliance to support a variety of product-related activities and events. These include

manufacturing, distributing, and use throughout the global health care marketplace; validating and monitoring correct product usage (based upon a product's labeling information); and tracking adverse events. These standards will be used to assist in the creation of an international drug dictionary, which can be used to populate and validate product information in electronic health records, pharmacy information and prescribing systems, product registries, pharmacovigilance systems, and adverse event reports.¹²³ IDMP data granularity can also support improved analytics and likely drive process improvements.

While current EU legislations affects all global life sciences companies that manage investigational and marketed products in the EU markets, it is expected that the other major worldwide agencies (e.g., FDA and PMDA) will also adopt and mandate these standards in the coming years.

In other regulatory developments, United Kingdom and European regulators are trying to control off-label use of medicines after the Italian and French governments passed legislation allowing for off-label reimbursement. In addition, in the near future, the European Medicines Agency (EMA) will release all information about clinical studies submitted to it by organizations seeking authorization for new treatments. Medtech regulation is also tightening. In addition to IDMP and other controls, the European Commission has agreed on a new system of oversight for the approximately 80 bodies responsible for certifying medical devices.¹²⁴

A regulatory action that is being well-received by the life sciences industry is Japan's amendment of the Pharmaceutical Affairs Act, renamed the Pharmaceutical and Medical Device Act (PMD Act), which promotes development and commercialization of regenerative medicines. The law grants conditional approval that allows companies to commercialize a regenerative medicine drug within two to three years at the earliest — compared to seven years under the previous legislation. Some foreign companies engaged in regenerative medicines have already established their R&D base in Japan to commercialize their technology as quickly as possible under these favorable regulations.

Developing countries are also addressing regulatory oversight, with varying degrees of success. India's government has prompted complaints from pharma companies with its new rules for clinical trials, which aim to protect patients from exploitation but have resulted in many trials being abandoned.¹²⁵ China's anti-corruption campaign continues and compliance remains a critical focus for companies operating there.

A cumbersome regulatory process or lack of adequate regulatory enforcement can be a barrier to life sciences companies seeking to enter or expand in certain markets. For example, product registration and approval can take between two and three years in most Southeast Asia markets. China requires local patient trials for product registration but simply getting the clinical trial application approved can take approximately 17 to 26 months. In contrast, Mexico is making strides in streamlining the drug approval process. Its pharmaceutical regulator, the Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS) has increased its approval rate for generic drugs. From September 2013 to July 2014, COFEPRIS released 20 active substances corresponding to 54 new generic drug registrations, addressing 71 percent of the causes of death in Mexico's population.¹²⁶

Counterfeit drugs

The proliferation of counterfeit medicines, particularly in emerging markets, is a serious concern and can be a significant barrier to life sciences growth. Both the public and private sectors are striving to reduce the potential clinical and financial fallout from counterfeit products, as India's current efforts illustrate.

To ensure that medicines sold in the country are genuine products, India's health ministry has developed a "track and trace" mechanism that will enable consumers to check a drug's safety and authenticity through the Internet. Under the system, a drug's primary, secondary, and tertiary packaging will carry a unique barcode allotted to its manufacturer. Consumers buying medicines at a retail pharmacy store can use the barcode to check online for product information such as manufacturing source, whether it is an approved drug, its expiration date, government-designated price, and other pertinent information. India's government had earlier introduced barcoding on export consignments of medicines to help

trace their point of origin. Now it has mandated that, as of 1 October, 2015, all drug exporters must label prescribed manufacturing data on various levels of packaging, while temporarily exempting barcode labelling on primary packaging.¹²⁷

India is compiling an extensive database on domestic pharma manufacturers and is granting access to drug regulators and retailers around the world following concerns about counterfeit drugs emanating from the country. The move is significant because India's large pharma market is highly fragmented, which makes it difficult for regulators and monitoring agencies to track medicines, especially in rural areas and distant villages, increasing the risk of inefficacious and low-quality medicines being sold in the market.¹²⁸

Meanwhile, the European Association of Euro-Pharmaceutical Companies (EAEP), European Federation of Pharmaceutical Industries and Associations (EFPIA), European Generic and Biosimilar medicines Association (EGA), European Association of Pharmaceutical Full-line Wholesalers (GIRP), and Pharmaceutical Group of the European Union (PGEU) on 13 February, 2015 announced the establishment of the European Medicines Verification Organization (EMVO).

EMVO, a not-for-profit organization incorporated in Luxembourg, represents a tool to combat the emergence of falsified medicines in the EU legitimate supply chain and improve patient safety. It represents the culmination of four years of work towards a dependable and secure pharmaceutical verification system. Financed in the initial stages by the pharmaceutical industry, EMVO will now assume responsibility for the European Hub, which links national verification systems throughout Europe, a design agreed upon by the European Stakeholders.

Through the engagement of the whole pharmaceutical supply chain, the EMVO's intent is to reinforce the value of the European Stakeholder Model, allowing end-to-end verification of medicine packs from the point of manufacture through to wholesale distributors. It will carry out risk-based verification to the dispensing point for patients, with the intent of securing of the entire supply chain.

Germany will be the first member state to contribute fully to the improved Europe-wide verification system under the auspices of EMVO, through its securPharm system. Meanwhile, countries that will need to comply with the Falsified Medicines Directive have the opportunity to join an existing product verification infrastructure designed by the EMVO (referred to as the national Blueprint System Template).

Intellectual Property (IP) protection

Nothing is more valuable to a life sciences organization than the formula for one of its new drugs or the specifications for an innovative new product/device. Pharma companies spend billions of dollars on R&D every year to develop patented drugs and their IP is an attractive target for criminal elements. The U.K. government claimed in 2011 that its life sciences and health care industry suffered \$2.9 billion in losses due to IP theft.¹²⁹ IP stolen from a U.S. medical device company, which was developing a device for more than five years, was transferred to China, allowing a competitor to launch the same device faster.¹³⁰

Without proper IP protection, the future development of new medicines may be at risk, because incentives for the research-based life sciences industry to invest more than a billion dollars and 10 to 15 years in the development of a single new medicine can be eroded. As outlined in the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, all World Trade Organization (WTO) members have committed to ensuring a policy environment that supports continued research for new medicines through a system of patents.¹³¹ The need for stringent IP protection is particularly acute in emerging markets, where regulatory oversight may not be as robustly enforced as in developed countries and, thus, can threaten to delay or derail product R&D.

With the life sciences industry growing rapidly and expanding globally, competition becoming fiercer, and cyberattacks arising and evolving more quickly, the need to protect new cures, drugs, and devices has emerged as a top business priority.

Stakeholder considerations

Health care's continuing and expanding transformation into a global, patient-centric, and value-focused marketplace holds important considerations for life sciences sector stakeholders as they seek to adapt, innovate, and grow in 2016 and beyond. The following areas are among the most relevant:

Navigating market dynamics

Faced with the complexities of managing product pricing and access issues in multiple geographical regions and under various government policies, life sciences companies need to think and act creatively to understand and navigate policy trends and market dynamics. In addition to relying on traditional information sources, companies should consider participating in local projects and partnering with local firms, academic institutions, and government entities to gain "real" insights into local needs and challenges. Life sciences organizations should also consider piloting alternative customer models and new customer engagement strategies, such as online learning modules for physicians or call centers for patients. Companies should also revisit the interface between sales and marketing, clarifying the ways marketing can effectively support the sales team. Finally, given the enhanced innovation capabilities of local firms and improved R&D ecosystem in many established and emerging markets, partnering with local firms on R&D could be a strategy to shorten approval times and reduce development and marketing costs.

Countering pricing and cost pressures

Pharma, biotech, and medical device manufacturers should expect that gaining approval, access, and reimbursement coverage for very innovative but also very expensive drugs may require extensive negotiations and novel pricing mechanisms (e.g., risk-sharing, outcomes-based, and managed-entry agreements). To improve their chances for product approval and favorable pricing, pharma companies may want to consider transitioning to a strategy of developing new drugs or drug delivery mechanisms that target complex disease areas that are high in value but low in competition. Furthermore, they should take the necessary steps to ensure that the effectiveness of these new drugs or drug delivery mechanisms is not easily replicable. Also, development of biosimilars may provide new avenues of cost-effective growth outside the innovative-generic dichotomy. Companies that can invest in the right combinations of these may be better placed to see more balanced growth in the medium to long term. Diagnostics companies, meanwhile, may need to think more broadly about companion diagnostics pricing than the historical match between a specific drug and a single diagnostic.¹³²

Life sciences companies wrestling with intensifying pricing pressure in developed countries may decide to focus their attention on entering or expanding in emerging markets. Firms that have a well-defined expansion strategy and have implemented cost-effective operational reforms are most likely to be able to capitalize on these growth opportunities. Finally, some organizations may decide to divest cost-intensive or under-performing product lines not deemed to be central to their growth strategies.

Operational issues

Life sciences companies should work to strengthen collaboration and information-sharing among internal functions and external partners to transform their global supply chain into an integrated, patient-focused strategic enabler.¹³³ Companies should also pursue operational excellence in terms of finance, manufacturing, R&D, and safety. By doing this they should be able to lower their total operating costs. In addition, companies engaging in M&A need to consider how best to operationalize and optimize acquisitions to realize the full value of post-deal synergies. Possible strategies include restructuring around shared services 3.0 and centers of excellence (CoE) to mitigate cost pressures and leverage existing resources. Finally, navigating the “new world of work” will require bold and innovative thinking, as well as a dramatic change in organizational strategies for leadership, talent, and human resources. Business and HR leaders will need to gain a clear understanding of their organization’s culture and re-examine HR and talent programs as a way to better engage and empower people.¹³⁴

Promoting innovation

Life sciences companies are facing patient, payer, and shareholder pressure to deliver truly innovative therapies that address unmet needs and treat life-threatening conditions. However, it typically takes 17 or more years to get from the basic science stage to commercializing and introducing a new clinical product into the market.¹³⁵ Among the approaches that pharma and biotech organizations are using to accelerate translational medicine (the process of going from laboratory observation to product commercialization) are leveraging “big data” and enhanced analytics to generate evidence and inform decision-making; putting patients upfront in the identification of new research topics; improving stakeholder connectedness and partnerships; and enhancing methods and distribution channels to disseminate learnings into practice.¹³⁶ Companies are also increasing efforts to move “beyond the pill” by focusing on personalization of care, providing value-added services to patients, and using digital technology as a platform for collaboration with other stakeholders in the health care system. Some organizations are building their own innovation ecosystems with external innovation networks, while others are partnering with payers and providers to pilot innovative care models.

Medtech companies, meanwhile, should equip themselves to take advantage of opportunities arising from smart technologies or risk losing business to both traditional health care competitors and new market entrants. Because smart medtech product development requires specialization and expertise in wide-ranging fields, companies should identify partners, alliances, and other collaborative opportunities to acquire the capabilities and expertise they need to develop next-generation “smart” devices.¹³⁷

Adapting to an evolving regulatory and risk environment

It seems the only constant is change in today’s life sciences regulatory environment. The more countries in which a company operates, the more policies and regulations which must be considered. Many of the focus areas for 2016 are recurring issues, such as drug and device safety, counterfeit products, and IP protection. Others are by-products of an increasingly global and connected industry; chief among them, cybersecurity. Life sciences companies should use all of the tools at their disposal — analytics, feedback mechanisms from procurers and consumers, evidence-based research findings, and more — to inform how they can improve products, grow revenues, and comply with current and emerging regulations.

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Winning with biosimilars: Opportunities in global markets

Analysts expect the worldwide biosimilars market to reach approximately \$35 billion by 2020. While developed markets will remain important for biosimilars manufacturers, Deloitte analysis indicates that long-term growth may be fueled by emerging markets. To remain competitive, manufacturers should develop a global biosimilars strategy that includes “where to play” and “how to win.”

High risk, high uncertainty: Measuring risk in biopharmaceutical research

The economic and societal value of Europe’s biopharmaceutical sector can only be sustained if risks to innovation are adequately rewarded, the study concludes, which was conducted by Deloitte and commissioned by Janssen. It compares six industry sectors: the biopharmaceutical industry, commercial aircraft manufacturing, the automotive industry, consumer electronics, food manufacturing and generic pharmaceuticals.

Healthcare and Life Sciences Predictions 2020: A bold future?

The Deloitte U.K. Center for Health Solutions has revealed a bold vision for the Healthcare and Life Sciences sector in 2020. The report, which launched at the 2014 FT Global Pharmaceutical and Biotechnology Conference, sets out ten provocative predictions for 2020.

Digital Health in the U.K.: An industry study for the Office of Life Sciences

This report presents findings from a research project commissioned by the Office for Life Sciences into the state of the digital health market. It looks at the current size, growth potential and industry composition of the market in the U.K. It also provides insight into the potential drivers and challenges in the market.

Supply chain in life sciences: What key trends are emerging?

This report, produced by LogiPharma, in collaboration with Deloitte, analyses the responses from leading figures in pharmaceutical supply chain on the key challenges, priorities and opportunities currently facing the industry.

Measuring the return from pharmaceutical innovation 2014

This fifth-annual study measures the pharmaceutical industry’s performance in generating a return from its significant investment in R&D. The report allows industry leaders to understand the drivers of successful R&D strategies that are tangible and, most importantly, actionable.

Development Trends and Practical Aspects of the Russian Pharmaceutical Industry – 2015 Survey results

Since the end of 2014, the Russian pharmaceutical industry has been affected by the overall economic situation in the country (devaluation of the national currency, economic slowdown and decreasing purchasing power of the population etc.) and the global geopolitical situation (sanctions imposed against Russia, etc.). See how pharma execs in the region are addressing these unique challenges.

The current and future state of companion diagnostics

Companion diagnostics are an indispensable part of personalized medicine and will likely continue to rapidly increase in number and application to disease areas. In order to survive and prosper, diagnostic companies will need to think more broadly about companion diagnostics than the historical match between a specific drug and a single diagnostic. They will also have to continue the process of consolidation and global expansion that the industry has already begun.

Health care consumer engagement: No “one-size-fits-all” approach

Imagine a future in which more consumers engage with the health care system—a future that holds the promise of more effective, efficient, and satisfying care experiences and better health outcomes for those individuals and the accountable care populations to which they belong. Findings from Deloitte’s *2015 Survey of U.S. Health Care Consumers* suggest we are moving closer to that future as consumer engagement increases in three important areas.

The convergence of health care trends: Innovation strategies for emerging opportunities

The convergence of powerful trends—new technologies, the demand for value, a growing health economy, and the government as an influencer—is transforming the traditional U.S. health care market. While this convergence is creating substantial challenges for health care stakeholders, it is also creating opportunities for innovation.

Executing an open innovation model

Biopharma companies’ reliance on a traditional, closed R&D model might stifle true innovation. However, companies that adopt a cooperative, open innovation framework are likely to spur product development, speed time to market, reduce costs, and increase competitiveness.

Health system analytics: The missing key to unlock value-based care

As health systems continue to face shrinking margins, tightening budgets, and evolving payment models, analytics are being touted as the missing key to unlock new sources of value.

Next-generation “smart” MedTech devices: Preparing for an increasingly intelligent future

Smart, connected medical devices are now technologically and economically feasible. How might this increasingly intelligent future reshape the MedTech industry?

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