

## 2015 Global life sciences outlook Adapting in an era of transformation





# Overview and outlook

Aging populations, chronic/lifestyle diseases, emerging-market expansion, and treatment and technology advances are expected to spur life sciences sector growth in 2015. However, efforts by governments, health care providers, and health plans to reduce costs, improve outcomes, and demonstrate value are dramatically altering the health care demand and delivery landscape. It is becoming increasingly evident that the global life sciences sector is operating in an era of significant transformation. A dynamically changing clinical, regulatory, and business landscape is requiring that pharmaceutical, biotechnology, and medical technology companies adapt traditional research and development (R&D), pricing, supply chain, and commercial models to:

- Support value-based payments — Many countries' public and private health care systems are moving from volume-based to value-based payment models.
- Contain costs — Governments and other payors are instituting price controls and increasing their use of generics and biosimilars to contain drug and device costs.
- Maintain regulatory compliance — A growing list of regulatory requirements and expectations are imposing new challenges on the sector.
- Focus on emerging markets — Slowing revenue growth in developed countries is prompting entry and expansion in new, up-and-coming markets.

This 2015 global outlook examines the current state of the life sciences sector; describes trends impacting markets and organizations; and suggests considerations for stakeholders as they seek to grow revenue and market share. For those readers familiar with prior reports, we draw your attention to the sector's increasing emphasis on innovation, shareholder value, and "the next wave" in scientific and marketplace developments.

## Life sciences sector overview

Growth in the life sciences sector — comprised of the pharmaceutical, biotechnology, and medical technology (medtech) segments — is closely tied to economic and demographic drivers that fuel a continual transformation of the broader health care industry. Life sciences companies have demonstrated their ability to survive and thrive amidst recent periods of economic recession, health care spending cutbacks, geographic market swings, and changing population profiles. If history is any indication, 2015 will again test the sector's ability to adapt in an era of transformation.

## Economic drivers

Life sciences sector growth correlates highly with countries' general economic strength and health care spending levels. In 2013, global health care spending increased around 2.8 percent after decreasing in 2012; the Economist Intelligence Unit (EIU) expects that growth to accelerate by an annual average of 5.2 percent in 2014-2018 as the global economy continues to recover from recession.<sup>1</sup> However, health care spending is likely to rise more slowly than in the past decade — when growth averaged seven percent a year — due to intensifying government and payor pressure to reduce costs and demonstrate value. The EIU also projects health care spending as a percentage of GDP to decline, from around 10.6 percent in 2013 to 10.3 percent in 2018.<sup>2</sup>

On a regional basis, health care spending in **North America** is expected to increase, on average, 4.9 percent during 2014-2018. Growth is being driven, in part, by expanded consumer access to health care in the United States through the 2010 Patient Protection and Affordable Care Act (ACA).<sup>3</sup> Growth in **Western Europe's** health care spending is likely to remain slow, at 2.4 percent annually, as countries claw their way back from the eurozone crisis.<sup>4</sup> Across **Latin America**, health care spending is projected to increase an average of 4.6 percent annually over 2014-2018; several governments are trying to improve public health care systems amid general budget constraints.<sup>5</sup> In **Asia and Australasia**, the rollout of public health care programs combined with growing consumer wealth are anticipated to boost health care spending an average of 8.1 percent in 2014-2018.<sup>6</sup> The most rapid growth is expected to be in the **Middle East and Africa**, which could see an annual average increase of 8.7 percent over 2014-2018 — due, in part, to population growth and efforts to expand access to care.<sup>7</sup>

## Demographic drivers

Demographic trends in both developed and emerging markets create the basis for life sciences sector growth. These include an aging population/lengthening life expectancies; increasing population growth and rising wealth; and an increase in chronic diseases.

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<sup>1</sup> *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014

<sup>2</sup> Ibid

<sup>3</sup> Ibid

<sup>4</sup> Ibid

<sup>5</sup> Ibid

<sup>6</sup> Ibid

<sup>7</sup> Ibid

An aging population in many developed countries, coupled with lengthening life expectancies globally, should generate increasing demand for life sciences products to treat age-related diseases such as Alzheimer's, diabetes, and arthritis. According to EIU, life expectancy is expected to increase from an estimated 72.7 years in 2013 to 73.7 years by 2018 (due, in part, to dropping infant mortality rates and the fight against communicable diseases), bringing the number of people globally over age 65 to around 580 million, or over 10 percent of the total global population. In Western Europe the proportion will reach 20 percent and in Japan it will near 28 percent.<sup>8</sup> People over the age of 65 currently represent 8.87 percent of China's population;<sup>9</sup> that total is projected to reach 11.92 percent in 2020.<sup>10</sup> As a result, health care services for the elderly will account for nearly 23 percent of China's health care expenditures. That expenditure is projected to rise to more than 50 percent by 2020, as the average elderly person consumes three-to-five times more health care resources than a younger person.<sup>11</sup>

Concurrently, increasing population and rising affluence in emerging markets — stoked mainly by China and India — should translate into a rise in global health care and life sciences spending. The number of high-income households (those earning over \$25,000 a year)<sup>†</sup> is expected to rise globally by about 30 percent, to nearly 570 million, with over one-half of that growth coming from Asia.<sup>12</sup> China's average income in terms of purchasing power parity now exceeds \$5,000 per year in GDP per capita,<sup>13</sup> the point at which overall consumption tends to spike,<sup>14</sup> augmented by a rapid rise in disposable incomes, which nearly tripled between 2000 and 2012, health care budgets have increased roughly 200 percent among China's urban residents and 600 percent among rural residents since 2005.<sup>15</sup> In response to consumers' growing affluence, governments in China and other newly prosperous markets are rolling out public health care services to meet citizens' rising expectations.

Finally, the widespread rise of chronic diseases — fueled by rapid urbanization, increasingly sedentary lifestyles, changing diets, and rising obesity, is creating a huge need for innovative treatments across the value chain. Even in emerging markets, cancer and heart disease are becoming the main causes of death. China and India now have the largest number of diabetes sufferers in the world, at more than 98 million and 65 million, respectively.<sup>16</sup> Globally, the number is expected to rise from the current 382 million to 592 million by 2035, according to the International Diabetes Federation.

While research in certain disease areas — diabetes and cancer, for example — is delivering some promising results, new treatments can be extremely expensive in both mature and emerging markets. In 2015 and beyond, governments, providers, and payors are expected to intensify their efforts to engage consumers in wellness and disease prevention programs.

#### ***Life sciences sector landscape: Pharma, biotech, medtech***

Buoyed, in part, by generally positive health care spending trends, the **pharmaceuticals** segment is expected to generate all-time-high total revenues of \$1.23 trillion in 2014, up from \$1.15 trillion in 2013 and \$1.13 trillion in 2012.<sup>17</sup> Oncology was the top contributor among all therapeutic areas in 2013<sup>18</sup> and is expected to remain so.

The North America region accounted for the largest share of the estimated 2014 global pharma market (Figure 1), at 41.9 percent, followed by Asia/Australia at 26.8 percent, Western Europe at 19.8 percent, Latin America, and transition economies.<sup>19</sup>

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<sup>†</sup> Monetary figures referencing the \$ symbol represent USD unless otherwise stated

<sup>8</sup> *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014

<sup>9</sup> National Bureau of Statistics of China, Sixth National Population Census of the People's Republic of China, 2010. Cited in *Fortune favors the bold: Unlocking the future of China's pharmaceutical market*, Deloitte China, 2014

<sup>10</sup> National Bureau of Statistics of China. Cited in *Fortune favors the bold: Unlocking the future of China's pharmaceutical market*, Deloitte Development LLC, 2014

<sup>11</sup> National Bureau of Statistics of China, State Development Research Institute. Cited in *Fortune favors the bold: Unlocking the future of China's pharmaceutical market*, Deloitte, 2014

<sup>12</sup> *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014

<sup>13</sup> International Monetary Fund. Cited in *Fortune favors the bold: Unlocking the future of China's pharmaceutical market*, Deloitte Development LLC, 2014

<sup>14</sup> World Bank and Credit Suisse estimates. Cited in *Fortune favors the bold: Unlocking the future of China's pharmaceutical market*, Deloitte Development LLC, 2014

<sup>15</sup> National Bureau of Statistics of China. Cited in *Fortune favors the bold: Unlocking the future of China's pharmaceutical market*, Deloitte Development LLC, 2014

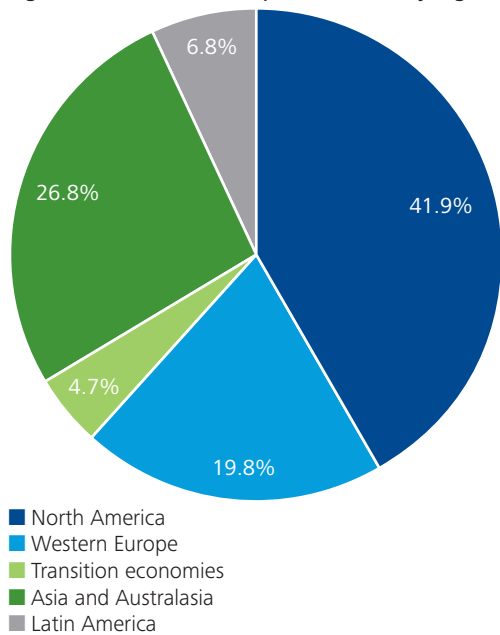
<sup>16</sup> National Bureau of Statistics of China. Cited in *Fortune favors the bold: Unlocking the future of China's pharmaceutical market*, Deloitte Development LLC, 2014

<sup>17</sup> *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014. Figures converted from \$ billions.

<sup>18</sup> *World Preview 2014, Outlook to 2020*, EvaluatePharma, June 2014

<sup>19</sup> *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014. Also, EIU database

Figure 1. Estimated 2014 pharma sales, by region



Source: DTL Life Sciences and Health Care Industry Group analysis of *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014. Also, EIU database

In other favorable news, Thomson Reuters unit CMR International reports that the number of New Molecular Entities (NMEs) launched in 2013 — 27 — was the third-highest in the last decade and the second-highest in the last five years. This, despite the fact that the number of NME approvals by the U.S. Food and Drug Administration (FDA) fell by more than 30 percent between 2012 and 2013.<sup>20</sup>

While these trends are encouraging, pharmaceutical companies around the globe continue to be buffeted by blockbuster drug patent expirations, rapidly increasing competition from generics manufacturers, and government and health care industry efforts to control costs — evidenced by price controls, pro-generics policies, and patent challenges. Some breakthrough branded specialty drugs (e.g., for cancer treatments and Hepatitis C treatment) can still warrant premium prices;<sup>21, 22</sup> however, manufacturers face growing

pressure by governments and health care authorities to justify product costs. In developed countries this is being driven by payors instituting value-based health care models and in emerging markets by local governments expanding exports of less-expensive generics while enacting domestic price cuts.<sup>23</sup>

The global **biotechnology** segment is expected to post revenues of \$288.7 billion in 2014, culminating a five-year average annual increase of 10.8 percent.<sup>24</sup> Products are mainly targeted at diseases such as cancer, Alzheimer's, heart disease, diabetes, multiple sclerosis, HIV/AIDS, and arthritis.<sup>25</sup> An increase in pharmaceutical/biotech M&A is blurring the lines between the two segments, as large pharma companies elect to purchase new innovations rather than develop them internally.

The vast majority of biotech revenue is generated in Europe and the United States (where the segment has exhibited growth since 2009).<sup>26</sup> Major players have, however, recently reported slower growth rates for U.S. sales compared with other parts of the world. This trend in revenue growth from emerging markets is expected to continue over the next five years as living standards and health care access improve, particularly in India, China, Brazil, and other emerging markets.<sup>27</sup>

While biotech R&D risks exist (e.g., manufacturing complexity, social and ethical issues), the segment continues to see great potential and that is representative of market innovation and investment. Global biotech investor confidence — and, by extension, R&D funding — is expected to increase in 2014, although investor confidence lags pre-recession levels and limits revenue growth somewhat.<sup>28</sup> In addition, recent years have seen some positive news in relation to FDA approvals and U.S. IPOs, which may improve the segment's attractiveness. However, biotechnology companies need to focus on improving R&D efficiency in the face of limited resources and investor skepticism.

<sup>20</sup> "Pharma Industry Sales to Hit \$1 Trillion in 2014, Says CMR Report," Outsourced Pharma, September 12, 2014. <http://www.outsourcedpharma.com/doc/pharma-industry-sales-to-hit-trillion-in-says-cmr-report-0001>. Accessed September 15, 2014

<sup>21</sup> Ibid

<sup>22</sup> "Maker Of \$1,000 Hepatitis C Pill Looks To Cut Its Cost Overseas," National Public Radio, February 7, 2014. <http://www.npr.org/blogs/health/2014/02/06/272519954/maker-of-1-000-hepatitis-c-pill-looks-to-cut-its-cost-overseas>. Accessed September 29, 2014.

<sup>23</sup> *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014

<sup>24</sup> *IBISWorld Industry Report: Global Biotechnology*, July 2014

<sup>25</sup> Ibid

<sup>26</sup> Ibid

<sup>27</sup> Ibid

<sup>28</sup> Ibid

The global **medical technology** (medtech) segment had a difficult 2013 — U.S. manufacturers, in particular were challenged by fewer reimbursement options, reduced FDA approval rates, and the ACA-driven 2.3 percent medical device excise tax levied on the sale of medical devices sold by manufacturers, producers and importers.<sup>29</sup> Still, most of the segment's top 10 companies enjoyed moderate year-over-year revenue gains. Also, beginning in 2014, the segment saw across-the-board improvements and increased M&A activity, the latter highlighted by the proposed Medtronic-Covidien merger, the largest single transaction the medtech segment has ever seen.<sup>30</sup> In addition, the FDA awarded 17 first-time Premarket Approvals (PMAs) in the first half of 2014, nearly twice as many as it did during the same period in 2013.<sup>31</sup> The FDA also reduced its average time to grant PMAs from an average of 35.9 months to 18.4 months. It is hoped that these positive regulatory trends might help to stimulate more venture capital funding of small medtech firms and start-ups, drive additional M&A activity, and spur overall segment growth.<sup>32</sup>

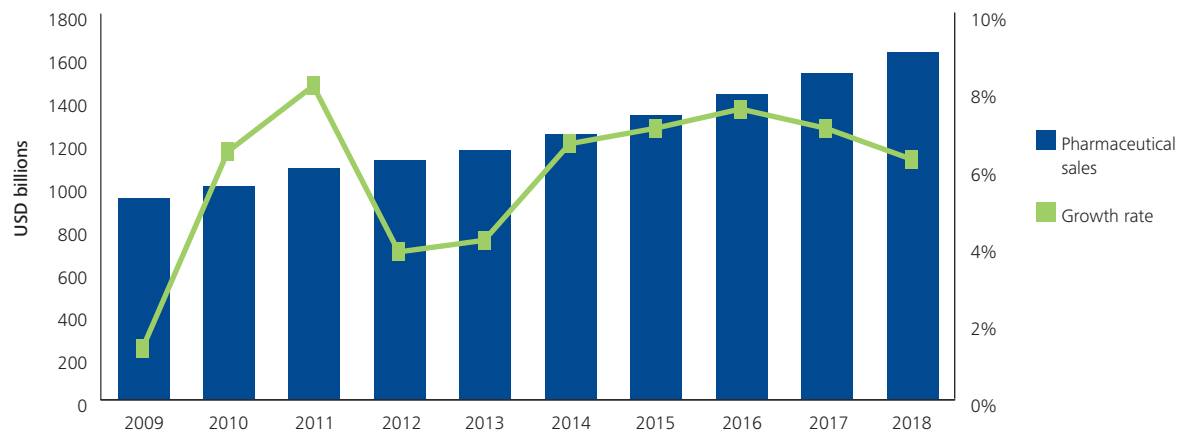
At an estimated \$127.1 billion in 2013, the U.S. medtech market is the world's largest.<sup>33</sup> Anesthesia and respiratory devices, and irradiation devices currently comprise the greatest

share of the market, at 22 percent each.<sup>34</sup> Large U.S. medtech companies are eyeing partnership opportunities with start-ups and established players, both in the U.S. and worldwide. Concurrently, global companies are balancing weak demand in developed markets for mature products with double-digit growth in emerging markets, and new product introductions that address new patient populations. Pricing pressures continue to be an issue for all.

### Outlook

According to the EIU, pharmaceutical sales are projected to increase an average of 6.9 percent annually over 2014-2018, outpacing the estimated global health care spending rate of 5.2 percent during that same period.<sup>35</sup> Total pharma revenues are expected to increase from \$1.23 trillion in 2014 to \$1.61 trillion in 2018<sup>36</sup> (Figure 2). In addition to oncology drugs, the cardiovascular therapeutic class will likely prosper, with four of the 10 projected blockbuster drugs belonging to the category.<sup>37</sup> Spending on midmarket prescription drugs used for treating common chronic diseases is likely to stagnate as prices fall. Demand for generic drugs will continue to rise as payors take advantage of patent expiries to reduce costs.<sup>38</sup>

Figure 2. Global pharma segment revenues



Source: D TTL Life Sciences and Health Care Industry Group analysis of *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014

<sup>29</sup> *IBISWorld Industry Report 33451b: Medical Device Manufacturing in the US*, IBISWorld, August 2014

<sup>30</sup> *Medtech Half-Year Review 2014*, Evaluate Ltd and EP Vantage, 2014

<sup>31</sup> *Ibid*

<sup>32</sup> *Ibid*

<sup>33</sup> *Fierce Medical Devices*

<sup>34</sup> *IBISWorld Industry Report 33451b: Medical Device Manufacturing in the US*, IBISWorld, August 2014

<sup>35</sup> *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014

<sup>36</sup> *Ibid*

<sup>37</sup> *FiercePharma*

<sup>38</sup> *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014

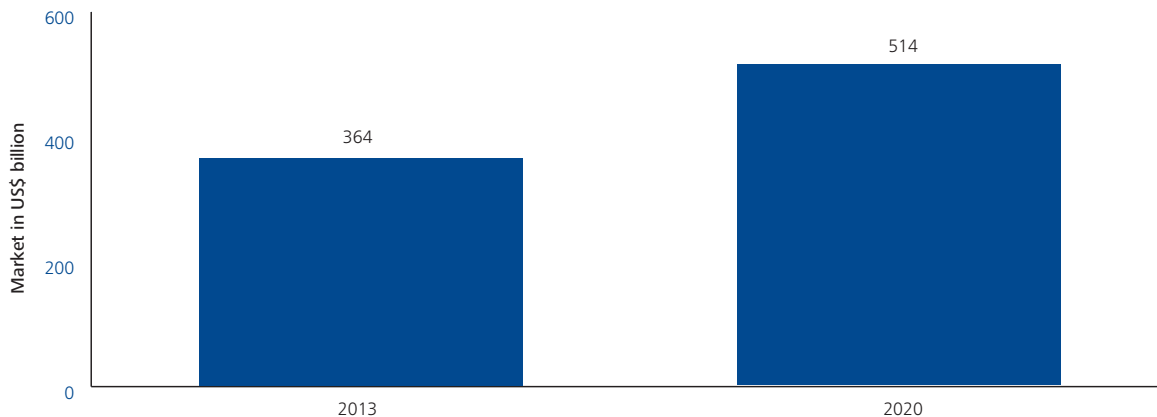
Pharmaceutical spending growth in North America is expected to rise an average of 6.4 percent annually, bolstered by rising employment, continued economic recovery, and the expansion of insurance coverage in the U.S. Latin America's projected growth rate is slightly lower, at around 6.1 percent annually in 2014-2018. Western Europe's pharmaceutical spending growth is expected to be minimal, at an average of just 2.2 percent a year in 2014-2018. In contrast, pharmaceutical sales in Asia and Australasia should rise by an average of 10 percent in 2014-2018, aided by the roll-out of public health programs in China, where pharmaceutical spending will rise by over 18 percent a year in dollar terms.<sup>39</sup>

Revenues for the global biotechnology segment are projected to grow at an annual rate of 9 percent during the five years to 2019, to \$444.9 billion.<sup>40</sup> Greater overall investment, particularly in emerging economies, will largely drive this growth. In addition, a projected increase in the total number of adults aged 65 and older will likely cause an increase in demand for medical care and, in turn, biotechnology health products.<sup>41</sup> Despite the growing proliferation of biosimilars (generic versions of biotech drugs for which patent protection has expired), biotech products are becoming increasingly difficult to duplicate and will likely prompt pharmaceutical companies to prioritize biotech-based product development in coming years.<sup>42</sup>

The global medical technology market is expected to grow at 5.0 percent per year between 2013 and 2020, from global sales of \$363.8 billion to \$513.5 billion (Figure 3).<sup>43</sup> In vitro diagnostics likely will be the industry's top segment by 2018, generating sales of \$71.6 billion and outpacing cardiac devices and diagnostic imaging technologies.<sup>44</sup> Neurology devices are expected to post the fastest growth, expanding 7.1 percent per year to \$9.8 billion.<sup>45</sup> The expansion of health insurance to more than 30 million uninsured Americans as part of health reform is likely to drive growth for the U.S. medtech segment, while device makers' recent focus on emerging markets such as China should also boost revenues. However, the industry will need to take a more cost-conscious approach in the developed world.

The extended nature of life sciences product development mandates that sector stakeholders adopt a long-term focus to strategic planning, portfolio management, and market expansion. However, organizations must also prepare for and react to near-term challenges and opportunities. Four major trends are expected to capture the sector's attention in 2015: searching for innovation and growth; changing regulatory and risk environment; preserving and building shareholder value; and preparing for the "next wave." The resulting challenges and opportunities can be both global and market-specific. Read on to learn more about these trends and suggested considerations for stakeholders.

Figure 3. Global medtech segment revenues



Source: D TTL Life Sciences and Health Care Industry Group analysis of Evaluate MedTech 18 Sept 2014

<sup>39</sup> *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014. [www.eiu.com](http://www.eiu.com)

<sup>40</sup> *Ibid*

<sup>41</sup> *IBISWorld Industry Report: Global Biotechnology*, July 2014. [www.ibisworld.com](http://www.ibisworld.com)

<sup>42</sup> *Ibid*

<sup>43</sup> *Ibid*

<sup>44</sup> *Evaluate MedTech 18 September 2014*

<sup>45</sup> *Ibid*

# Global life sciences sector trends in 2015

## Searching for innovation & growth

### M&A/scale to prosper

Life sciences companies tallied over \$700 billion in completed or announced M&A transactions globally during the first half of 2014 (Figure 4),<sup>46</sup> surpassing the entirety of 2013 and nearing the totals of mega-merger years 2008 and 2010.<sup>47</sup>

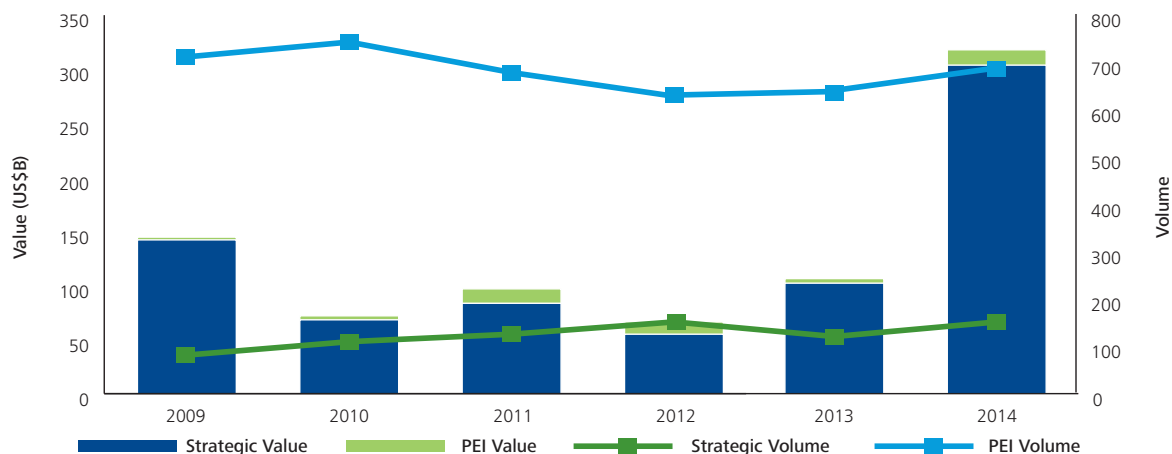
As with venture capital funding, transactions have been skewing toward fewer, bigger deals. Also, for business reasons, companies operating on a global scale are looking to restructure in ways that allow for the efficient use of foreign capital.<sup>48</sup> Partnerships and informal collaborations also will comprise an important part of the picture as companies continue to grapple with a rapidly shifting landscape,<sup>49</sup> grow distribution networks, and leverage previous investments. New insurance and payment models, rapidly changing consumer demographics, and an explosion of technology-based treatment innovations are driving both horizontal and vertical M&A activity.

In the pharmaceuticals segment, rising demand for generic drugs and the loss of revenue from blockbuster patent expiries is driving consolidation,<sup>50</sup> with both research-based and generics companies looking for acquisitions of all sizes. Among notable first-half 2014 deals were Actavis's \$25 billion acquisition of specialist drug manufacturer Forest Laboratories.

In addition to purchasing other drug makers, large pharmaceutical companies are acquiring biotech firms, especially if their products are in late-stage development or showcase new technology. In many cases, purchasing a biotech firm is a more attractive option than buying the rights to the drugs the firm develops.<sup>51</sup> Such a transaction can be a win for biotech firms, too, because large pharma companies typically possess the manufacturing facilities needed to commercialize drugs, which biotechs often lack.<sup>52</sup> Finally, in a step outside the sector, some drug manufacturers and distributors are acquiring health care service providers, and talking with insurance companies about joint ventures as they look for growth opportunities across the entire health care value chain.

Due to a continued tight funding environment, strategies of some biotech players have varied – from exiting the industry altogether, while others have engaged in mergers and acquisitions. Some companies with enough capital to acquire other entities and their intellectual property (IP) and labor force, are helping to reduce risk exposure and improve time to market.

Figure 4. Global Life Sciences M&A — YTD July



Source: D TTL Life Sciences and Health Care Industry Group analysis of Thomson Reuters data

<sup>46</sup> Thomson Reuters

<sup>47</sup> *Pharma and Biotech Half-Year Review 2014*, EvaluatePharma, July 2014

<sup>48</sup> *M&A trends in life sciences and health care: Growth at the global intersection of change*, Deloitte Touche Tohmatsu Limited, September 2014

<sup>49</sup> *Ibid*

<sup>50</sup> *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014. [www.eiu.com](http://www.eiu.com)

<sup>51</sup> *Ibid*

<sup>52</sup> *IBISWorld Industry Report: Global Biotechnology*, July 2014. [www.ibisworld.com](http://www.ibisworld.com)



Medtech M&A deal values totaled \$30 billion in the first half of 2014, a huge increase of 363 percent over the \$7 billion recorded during the same period in 2013. Despite the growth in deal value, the number of overall deals actually fell by 10 percent, to 95, during first-half 2014. The dramatic jump in deal value was largely due to Thermo Fisher Scientific's acquisition of Life Technologies for \$13.6 billion and The Carlyle Group's purchase of J&J's Ortho-Clinical Diagnostics unit for \$4.2 billion.<sup>53</sup> This total does not include the Medtronic/Covidien and Zimmer/Biomet megadeals, which have not yet closed and are expected to dwarf the year's earlier acquisitions.<sup>54</sup> Whether the segment's recent uptick in M&A activity signals the beginning of a general recovery or is the only way companies can grow in an industry that faces considerable pricing pushback from payors and patients remains to be seen.<sup>55</sup>

### **R&D productivity**

The global life sciences sector's general decline in R&D productivity is a frequent topic of conversation among industry stakeholders, investors, and analysts. Total projected value of late-stage pipelines for the 12 largest pharmaceutical companies showed a decline from \$1,369 billion to \$913 billion in 2013.<sup>56</sup> However, a number of recent trends indicate a turnaround may be under way. Among positive news:

- The 2013 net current value (NPV) of the sector's R&D pipeline surged 46 percent from 2012, to \$418.5 billion.<sup>57</sup>
- The U.S. FDA approved 35 new drugs in 2013 composed of 25 new molecular entities (NMEs) and ten new biologicals, the best year for new drug approvals since 1997<sup>58</sup> and the third-highest number of NME first launches in the last decade.<sup>59</sup>
- The newly approved products have a sales potential of \$24.4 billion, 43 percent higher than NMEs approved in 2012.<sup>60</sup>

- While there has been a decline in pipeline volumes and success rates in early-phase drug development, the number of halted Phase III projects has also tapered off and the submission phase has posted a stable success rate. This suggests the industry is leveraging its ability to "fail fast, fail cheaply,"<sup>61</sup> which gives promising compounds more room and resources to succeed in later stages of development.
- Some pharma companies are restructuring their R&D units to focus on the most promising areas.<sup>62</sup> The line-up of diabetes and cancer drugs in late-stage development is extensive, with about half of all NME launches for specialty drugs for diseases like cancer and HIV. Anti-cancer treatments still attract the largest investments across all therapeutic areas.<sup>63</sup>
- Governments in emerging markets such as China and India are providing robust funding to kick-start their countries' biotechnology industries, with impressive results: The number of product patents coming from emerging economies has increased by double digits over the past few years.<sup>64</sup> Recognizing these countries' growing capabilities, many leading pharma and biotech companies are outsourcing certain R&D activities to these markets (especially the more labor-intensive ones).<sup>65</sup>
- Medtech R&D spend is projected to grow by 4.2 percent annually, to \$30.5 billion by 2020.<sup>66</sup>
- Some smaller biotech firms with limited R&D budgets are securing financial support from large pharmaceutical companies through licensing and collaborative R&D deals. Others are getting assistance from academic institutions. Advantages of the lower-risk, academic model include no capital outlay, low-cost labor, a collaborative research model, and access to new intellectual property.<sup>67</sup>
- Specialty pharma could experience a growth surge, as well. As global health concerns determine immediate treatment needs, some manufacturers are seeing positive outlooks.<sup>68</sup>

<sup>53</sup> 2014 World Preview, Outlook to 2020, EvaluateMedTech, September 2014

<sup>54</sup> Ibid

<sup>55</sup> Medtech Half-Year Review 2014, Evaluate Ltd and EP Vantage, July 2014

<sup>56</sup> Measuring the return from pharmaceutical innovation in 2013, Deloitte Centre for Health Solutions, November 2013

<sup>57</sup> 2014 World Preview, Outlook to 2020, EvaluatePharma, June 2014

<sup>58</sup> 2014 World Preview, Outlook to 2020, EvaluatePharma, June 2014

<sup>59</sup> 2014 CMR International Pharmaceutical R&D Executive Summary, Thomson Reuters, May 2014

<sup>60</sup> 2014 World Preview, Outlook to 2020, EvaluatePharma, June 2014

<sup>61</sup> 2014 CMR International Pharmaceutical R&D Executive Summary, Thomson Reuters, May 2014

<sup>62</sup> World industry outlook: Healthcare and pharmaceuticals, The Economist Intelligence Unit, May 2014. [www.eiu.com](http://www.eiu.com)

<sup>63</sup> "Pharma Industry Sales to Hit \$1 Trillion in 2014, Says CMR Report," *Outsourced Pharma*, September 12, 2014, <http://www.outsourcedpharma.com/doc/pharma-industry-sales-to-hit-trillion-in-says-cmr-report-0001>. Accessed September 15, 2014

<sup>64</sup> IBISWorld Industry Report: Global Biotechnology, July 2014. [www.ibisworld.com](http://www.ibisworld.com)

<sup>65</sup> IBISWorld Industry Report: Global Biotechnology, July 2014. [www.ibisworld.com](http://www.ibisworld.com)

<sup>66</sup> 2014 World Preview, Outlook to 2020, EvaluateMedTech, September 2014

<sup>67</sup> IBISWorld Industry Report: Global Biotechnology, July 2014. [www.ibisworld.com](http://www.ibisworld.com)

<sup>68</sup> <http://buzz.money.cnn.com/2014/09/23/ebola-drug-tekmira-stock/>

Life sciences R&D spending is projected to grow 2.4 percent per year from 2013 to 2020, reaching \$162 billion.<sup>69</sup> This percentage is below the projected sales growth rate and illustrates a continuation of the strategic theme of cost containment.<sup>70</sup> However, the sector's growing focus on areas of high unmet medical need and specialty care, combined with improving late-stage success rates and NME approval levels, may be the impetus it needs to boost R&D productivity.<sup>71</sup>

### Acclimating to a changing regulatory & risk environment

Today's global life sciences sector has been likened to the financial services industry of five to 10 years ago, with product safety issues, security & privacy breaches, intellectual property (IP) tangles, inappropriate marketing practices, and corruption incidents pushed to the forefront—each of which can result in government fines, product recalls, adverse media coverage, brand recognition damage and revenue/market share losses. In the past, regulatory fines have been relatively small; however, they are growing in size and significance; precisely what happened in the banking world, which today sees a very different story in the magnitude of fines, sanctions, and public condemnation.

The life sciences sector is characterized by a robust, complex, and evolving regulatory landscape. The primary driver is patient health and safety; however authorities' approaches to protecting patients can vary widely from market to market. Adding to this complexity are the factors of rapid change, increased scrutiny, more sophisticated risk-monitoring techniques, and coordination across agencies and regions.

Legislation forms the basis for drug regulation.<sup>72</sup> In Europe, for example, a major overhaul of regulations (Good Pharmacovigilance Practices or GVP) was launched in mid-2012 and new rules on falsified medicines and pharmacovigilance came into force in 2013, requiring companies to control ingredients' manufacturing standards and monitor drugs more carefully after launch.<sup>73</sup> Developing countries are also tightening up, although not without difficulty. The FDA continues to clamp down on off-label marketing and the failure to disclose safety risks.

While the Southeast Asia/Asia Pacific region is generally regarded as having a fragmented regulatory framework with patchy enforcement, governments have been moving independently and collectively towards establishing a more organized regulatory framework and harmonizing tariffs and common dossier templates. For example, the member states of the Association of South-East Asian Nations (ASEAN) have a goal of forming the ASEAN Economic Community (AEC) by 2015<sup>74</sup> to enable closer economic integration and define the regulatory landscape for the region.

In general, the regulatory approval process is associated with a high degree of uncertainty that complicates an innovator's ability to predict review times, pre-approval requirements, and post-approval requirements.<sup>75</sup> For example, oversight has increased dramatically in the form of stringent demands for product data. The FDA recently instituted the Global Unique Device Identification Database (GUDID) to collect substantial volumes of manufacturing and registration information. The European Medicines Agency (EMA) is leading the charge (with the FDA soon to follow) on Identification of Medicinal Products (IDMP) requirements for pharmaceutical and biologic products. These initiatives will require companies to invest heavily in data capture and cleansing projects to maintain accurate, detailed product data with the agencies. Failure to comply could lead to significant fines and, potentially—as it has in the past—a company having to pull its product from the market.

Investigators are growing more knowledgeable about how companies operate and where potential compliance irregularities may exist—risk-based inspections allow authorities to identify weak links in life sciences manufacturing, supply chain and R&D operations. And with increasing globalization of supply chains and marketing, authorities' oversight is becoming more coordinated across jurisdictions. Inter-agency information sharing is a growing trend, leading to cascading inspections around the world once an issue has been identified. This is particularly relevant, as there is a strong trend towards consolidation and globalization, of legacy systems into a single, global drug safety system with harmonized business processes.

<sup>69</sup> <http://buzz.money.cnn.com/2014/09/23/ebola-drug-tekmira-stock/>

<sup>70</sup> Ibid

<sup>71</sup> "Pharma Industry Sales to Hit \$1 Trillion in 2014, Says CMR Report," *Outsourced Pharma*, September 12, 2014, <http://www.outsourcedpharma.com/doc/pharma-industry-sales-to-hit-trillion-in-says-cmr-report-0001>. Accessed September 15, 2014

<sup>72</sup> *Substandard and counterfeit medicines*, WHO fact sheet, <http://www.who.int/mediacentre/factsheets/fs2003/fs2003/en/>. Accessed September 28, 2014

<sup>73</sup> *2014 World Preview, Outlook to 2020*, EvaluatePharma, June 2014

<sup>74</sup> <http://www.asean.org/communities/asean-economic-community>

<sup>75</sup> *In the face of uncertainty: A challenging future for biopharmaceutical innovation*, Deloitte LLP, 2014

The life sciences industry has been working hard to catch up. Variations in requirements are often not adequately factored into planning and process management, resulting in rework and delays in secondary market submissions and approvals. Even within a company, centralized versus local responsibilities can vary from market to market and are not always clear in a global, dispersed operating model.<sup>76</sup> As regulators and regulations continue to “grow teeth,” life sciences companies will need to demonstrate that they have active and comprehensive compliance programs across their business and clinical operations, including commercial, R&D, and supply chain.

### **Transparency**

Government, investor, and public calls for increased transparency in life sciences companies’ business and clinical operations are shining an ever-brightening light on product commercialization, executive pay, financial information accuracy, manufacturing processes (ePedigree and Unique Device Identification), and clinical trial quality. Several high-profile incidents, particularly in emerging markets, have pushed transparency even more to the forefront. Currently, transparency can be broken into two segments: transparency of payments made by life sciences companies to health care professionals (HCPs) and institutions, and transparency of clinical research data. While, at present, these two segments are treated separately, they are inextricably intertwined and life sciences companies will need to deal with them in an integrated fashion.<sup>77</sup>

In the U.S, implementation of 2012’s Physician Payments Sunshine Act (now called Open Payments), which aims to empower patients by requiring disclosure of physician-life sciences company interactions, is under way.<sup>78</sup> In May 2014, with some limitations, pharmaceutical companies had to submit data on all transfers of value they made to doctors and teaching hospitals in the fourth quarter 2013, for publication online in September.<sup>79</sup> Meanwhile, the Federal Trade Commission (FTC) continues to challenge reverse payment (pay-for-delay) deals, in which pharmaceutical companies pay an agreed-upon sum to generics companies to avoid the protracted litigation around defending patents, thereby effectively delaying the generic product’s entry into the marketplace.<sup>80</sup> The trend towards greater physician payment

transparency is expanding beyond the U.S., as France, Japan, and Australia recently adopting transparency regulations. By 2015, 70 percent of pharmaceutical sales will occur in countries which have HCP transparency regulations.<sup>81</sup>

The clinical trials industry has seen tremendous growth over the last decade and, with that, has attracted government scrutiny around the veracity and accuracy of clinical trial data. India has emerged as a global destination for clinical trials, given its burgeoning population with varying treatment needs. While the number of clinical trials there has gone up over the years, the nation’s capacity to regulate trials has not kept pace. This has resulted in unethical practices such as no compensation given to patients (or their relatives) in case of unforeseen events; drug approvals without clinical trials; and lapses in informed consent procedures.<sup>82</sup> In response, the Indian government has enhanced regulatory controls such as mandatory trial registration and is creating committees to oversee trial approval and trial execution.

In other trial-related regulatory action, the European Medicines Agency (EMA) secured agreement for its policy on the publication of clinical trial data at the end of 2013, after months of negotiation over how to balance demands for transparency against the commercial interests of pharmaceutical companies. At a national level, several European countries have stepped up competition investigations against a few global life sciences companies based in the region.<sup>83</sup>

While the disclosure of clinical trial data, both positive and negative, is becoming the norm, the battle lines around how far transparency should extend have already been drawn, and will involve whether patient-level clinical trial information should be disclosed.<sup>84</sup>

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<sup>76</sup> *Regulatory Information Management, The Emerging Landscape*, Deloitte Development LLC, 2014

<sup>77</sup> *Physician Payment Sunshine Act: Physicians and life sciences companies coming to terms with transparency?* Deloitte Touche Tohmatsu Limited, 2013

<sup>78</sup> Press Release by Senator Charles Grassley, February 1, 2013

<sup>79</sup> *2014 World Preview, Outlook to 2020*, EvaluatePharma, June 2014

<sup>80</sup> *Ibid*

<sup>81</sup> Deloitte 2014 Global HCP Transparency, January 2014 Study [www.deloitte.com/us/2012globalHCPstudy](http://www.deloitte.com/us/2012globalHCPstudy), Deloitte Development LLC

<sup>82</sup> *Suba, EJ; 2014 Jul-Sep;11(3):167-75*

<sup>83</sup> *Ibid*

<sup>84</sup> Much, T et al. *Pain* 2014 Jul;155(7):1313-7

### ***Drug & device safety***

Product safety standards — particularly those associated with quality systems implementation, data integrity, and validation of manufacturing or testing processes — are tightening in countries around the world. Heightened regulatory scrutiny is set against a backdrop of increasing patient advocacy, social media, and affiliate marketing programs. This is resulting in uncertainty around the sources of adverse event reporting, as well as pharma companies looking to outsource one, or both, of the case processing and software/hardware platform burdens. As the product safety landscape shifts, so do the methods for safety and adverse event reporting. Traditional sources of reporting were predominantly focused on clinical trial investigator sites and post-marketing medical information call centers. However, potential adverse events can occur in any patient interaction program and a programmatic process to identify and report such events requires increased focus with the industry's move towards patient-centricity.

Despite an overall tightening of the regulatory environment, there are some indications of a growing industry-friendly stance. For example, Japan is said to be relaxing its overly rigid regulatory control to be more competitive globally. The FDA plans to implement an expedited review process for the most innovative medical devices (those capable of treating diseases for which no therapy exists) and to regulate laboratory-developed tests (LDTs), a type of diagnostic it has previously not overseen. Both of these changes are expected to result in the granting of more pre-market approvals (PMAs).<sup>85</sup>

### ***Security & privacy***

Health care's digitization and the proliferation of electronic medical records (EMR), networked medical devices, mobile health (mHealth) applications, cloud-based technologies and data sharing among industry stakeholders increase the complexity of managing all information assets, particularly protected health information (PHI) and Intellectual Property (IP). Additionally, the frequency and pace of cyber-attacks are increasing, and the timeline to respond is shrinking. Still, governments, health care providers, payors, and life sciences companies are working collaboratively and independently, and investing in protection solutions to reduce the risks and the victims of unauthorized access.<sup>86</sup>

Government focus on information security and privacy is particularly evident in Europe and the United States. In the U.S., the Department of Health and Human Services (HHS) in 2013 instituted the Health Insurance Portability and Accountability Act (HIPAA) Omnibus Final Rule, which strengthens regulatory protections for patient information, increases penalties for breaches, and emphasizes agreements with business associates.<sup>87</sup> That being said, this has become a global concern as threats may appear from any part of the world.

With cyber threats and other security breaches on the rise, life sciences companies should consider whether they need to assess potential capability gaps, define their security and privacy needs, coordinate their efforts with their partners along the care continuum, and develop appropriate prevention and remediation programs.<sup>88</sup>

### ***Intellectual property protection***

Pharmaceutical companies continue to struggle in their efforts to globally enforce IP protection, particularly in some emerging markets. Some of these countries may view IP rights as a way for Western pharmaceutical companies to restrict access of critical medicines to their populations. Others may lack effective government legislation to protect foreign companies' IP holdings, may require compulsory licensing, or simply refuse to enforce the patent claim. Where some third-party manufacturers may not always respect IP rights, there may be tacit government support. Unless IP protection and enforcement are standardized, life sciences companies will need to adapt their drug portfolios and commercialization strategies to local market conditions. In any event, Western life sciences companies will need to tackle and solve the access-to-treatment issues in the developing world if they wish to convince developing countries to honor their IP claims.

In a positive move, major emerging economies in regions such as Eastern Europe, South America, and Asia in recent years have tightened IP laws in a bid to increase foreign investment and technology transfer. This change better protects companies' intellectual property and enables U.S. and European Union (EU) biopharma companies to forge joint ventures with their counterparts in emerging regions. Doing so allows them to take advantage of significantly reduced wage costs and fewer legislative barriers to research. Increased protection also may lead to investment in offshore manufacturing plants, as well.<sup>89</sup>

<sup>85</sup> *Medtech Half-Year Review, 2014*, Evaluate MedTech, 2014

<sup>86</sup> *Issue Brief: Networked medical device security and patient safety: Perspectives of health care information security executives*, Deloitte Center for Health Solutions, Deloitte Development LLC, 2013

<sup>87</sup> *Health Data Management*. What HHS/OCR will look for in HIPAA compliance audits, Mar 21 2013, via Factiva.

<sup>88</sup> *Issue Brief: Update: Privacy and security of protected health information: Omnibus Final Rule and stakeholder considerations*, Deloitte Center for Health Solutions, Deloitte Development LLC, 2013

<sup>89</sup> *IBISWorld Industry Report: Global Biotechnology*, July 2014. [www.ibisworld.com](http://www.ibisworld.com)

### Preserving & building shareholder value

Global life sciences companies deal daily with pricing pressures, generics competition, margin erosion, supply chain issues, and regulatory constraints, all of which can limit their ability to grow revenues. On the cost side, rising R&D expenses, marketing & sales outlays, and general operating cost increases can exert pressure on gross margins. Still, companies are expected to preserve and build shareholder value.

Fortunately, improving R&D productivity, recent increases in NME approvals, and expanding product pipelines—combined with ongoing cost containment—suggest that fundamentals are aligning to increase shareholder value. Operational transparency and addressing risks and improving processes within finance & accounting (F&A) operations—via treasury solutions and services such as controls testing, balance sheet integrity, gross-to-net (GtN) forecasting, cost management, and reporting optimization—can help to foster shareholder confidence. In addition, optimizing the mix of sales, marketing, and market-access expenditures at the local market level is essential to increasing shareholder value. However, a number of external and internal forces have the potential to move the needle up or down; among them, price controls & access, generics, and supply chain operations.

### Pricing controls & access

A primary focus for governments in both developed and emerging markets is to minimize pharmaceutical spending growth by enacting pricing and reimbursement legislation. While reference pricing systems have already brought prices down in many countries, they have not stopped health care payors from pushing for even greater savings. In the past few months, the governments in both Sweden and the United Kingdom (UK) have secured pricing deals with drug manufacturers, on top of other efforts to drive down costs.<sup>90</sup> Such policies can be controversial, leading to reversals in some markets. Germany, for example, is under pressure to revise its value-based pricing scheme for pharmaceuticals.<sup>91</sup>

All drug prices in Brazil are controlled by an independent organization, CMED (Regulation Drug Market Committee). In Japan, a biennial National Health Insurance (NHI) pricing review usually results in price reductions, and the government is introducing other schemes to further control prices. For example, a new health technology assessment (HTA) which is expected to be implemented in 2016, will make it more difficult for life sciences companies to obtain market access with competitive launch pricing unless the new treatment is innovative and cost-effective.

China's government has honed in on two cost-control methods. The first is continued and expanded use of the Essential Drug List (EDL) to help control the overall price and cost of therapeutics in China. The second is a series of more targeted experiments at the local or hospital level to control the total amount of therapeutics prescribed and correspondingly limit the total cost.<sup>92</sup> The pricing challenge has been exacerbated by limits to the number of brands that can be listed within a given province or hospital. As a result, losing a single tender for a large hospital can materially impact the growth of a brand.<sup>93</sup>

In India, domestic and international pharmaceutical companies are dealing with the Drug Price Control Order (DPCO), which places a ceiling on the prices of certain essential medicines. DPCO brought 348 medicines under price control following its 2013 implementation. Subsequently, India's National Pharmaceutical Pricing Authority (NPPA) announced in July 2014 that it plans to bring under price control an additional 50 drugs belonging to the cardiovascular and anti-diabetic segment. The move is likely to have far-reaching implications for branded rather than generics manufacturers, as the latter are mostly domestic companies whose products are already available at relatively low prices.<sup>94</sup>

Even as some governments, such as Japan's, are awarding incentives such as premium pricing to certain innovative drugs and devices, they are also curtailing prices of less-innovative, generically substitutable products. As a result, life science companies are being challenged to deliver breakthrough therapies that address unmet needs, such as treatments for orphan/rare diseases and less-invasive diagnostic and treatment technologies, to maintain desired levels of profitability.

<sup>90</sup> IBISWorld Industry Report: Global Biotechnology, July 2014. [www.ibisworld.com](http://www.ibisworld.com)

<sup>91</sup> Ibid

<sup>92</sup> Fortune favors the bold: Unlocking the promise of China's pharmaceutical market, Deloitte China, 2014

<sup>93</sup> Ibid

<sup>94</sup> "How new price control list impacts Indian pharma cos," Moneycontrol.com, July 23, 2014. [http://www.moneycontrol.com/news/business/how-new-price-control-list-impacts-indian-pharma-cos\\_1134746.html?utm\\_source=ref\\_article](http://www.moneycontrol.com/news/business/how-new-price-control-list-impacts-indian-pharma-cos_1134746.html?utm_source=ref_article). Accessed October 3, 2014

With pricing pressures expected to continue, life sciences companies will need the capability to model the global margin impacts of reference pricing when responding to regional tender offers. There can be ripple effects of not knowing the global margin impacts of regional pricing decisions.

### Generics and biosimilars

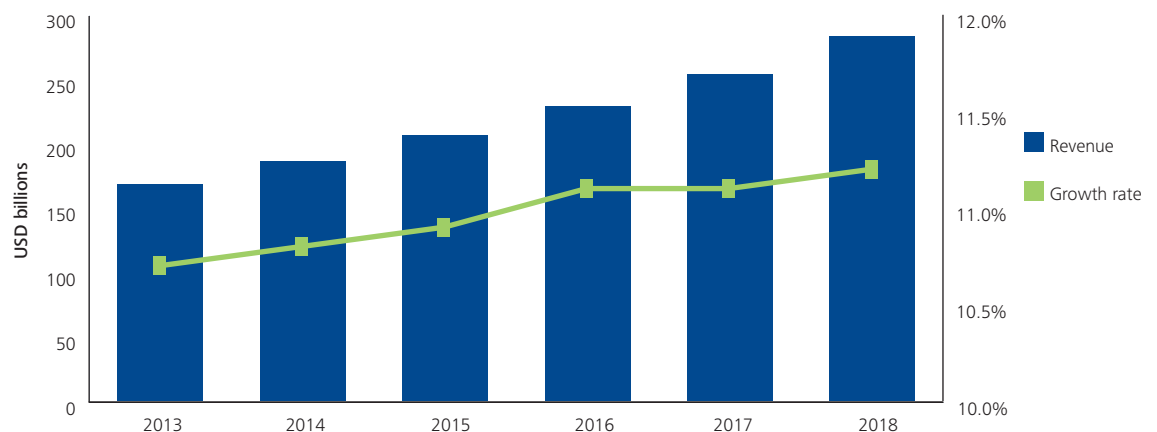
The patent cliff has passed its steepest point, but a steady flow of patent expiries continues to depress the revenue of many pharmaceutical companies, as cost-conscious governments and other health care payors increasingly endorse the use of generic drugs. The global generics market was valued at \$168 billion in 2013 and is expected to reach \$283 billion by 2018, growing at a CAGR of 11 percent (Figure 5).<sup>95</sup>

Generic drugs account for around 70 percent of the U.S. drug market by volume. In Europe they account for around 50 percent, although the proportion differs significantly by country.<sup>96</sup> To a large extent, the magnitude of savings from generics that each country achieves depends on the utilization levels and price differentials between the generic and branded versions. In the U.S., generics use is almost 90 percent within the off-patent (unprotected) market. However, in many European countries, potential savings are not fully exploited due to lower utilization of generics in key therapy areas.<sup>97</sup>

Countries including Japan, Italy, Spain, Poland, and France have adopted pro-generic policies that encourage doctors or pharmacists to substitute generics for branded products. But many governments are concerned that the transition is not happening fast enough. In December 2013, France's competition authority proposed a shake-up of pharmacies and distributors to promote stronger competition.<sup>98</sup>

Even though industry analysts project that generic drug demand will continue to rise as consumers and payors prefer to purchase cheaper medicines, the road ahead is not worry-free. Recent results from major generic drug producers show that tighter price controls and other sales constraints are impacting revenues.<sup>99</sup> Generics manufacturers are also beginning to see the downstream effects of slowing patent expiries, which means they can no longer count on rapid growth for new products. Accompanying these pressures is increased global competition, with local drug manufacturers in developing countries looking for ways to grow export revenue. In India, for example, companies are eager to expand their market access although they complain that trade barriers are high.<sup>100</sup>

Figure 5: Global generic segment revenues



Source: D TTL Life Sciences and Health Care Industry Group analysis of TechNavio Analysis 2014-2018; Generic Medicines: Essential contributors to the long-term health of society, and IMS data

<sup>95</sup> TechNavio Analysis 2014-2018; Generic Medicines: Essential contributors to the long-term health of society, IMS  
<sup>96</sup> IMS Health, as cited in *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014. [www.eiu.com](http://www.eiu.com)  
<sup>97</sup> TechNavio Analysis 2014-2018; Generic Medicines: Essential contributors to the long-term health of society, IMS  
<sup>98</sup> *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014. [www.eiu.com](http://www.eiu.com)  
<sup>99</sup> *Ibid*  
<sup>100</sup> *World Preview 2014, Outlook to 2020*, EvaluatePharma, June 2014

Although recent pharmaceutical sales growth in developed economies has been modest, biological drug sales have been increasing significantly. In fact, by 2020, biological products are projected to account for more than 50 percent of sales within the top 100 prescription products.<sup>101</sup> However, expiring patents are giving rise to a market for biosimilars<sup>102</sup> which may threaten this future revenue stream.

In the United States, ACA provisions allow government-approved biosimilars, creating low-cost competition for off-patent branded biologics. Previously, only small molecule products faced generic competition in the country. In Brazil, the potential approval of a new regulation allowing interchangeability of biosimilars at the point of sale likely will mean stiffer competition for market share and the possible introduction of compulsory price discounts for biosimilars in relation to the originator product.

Some industry observers express concern that branded biologics with expiring patent protection will see revenue and market share losses from the entry of biosimilars. However, based on forecasts to 2020, EvaluatePharma reports that equity analysts modelling the situation expect a softer landing for biologics and limited biosimilar substitution.<sup>103</sup> In fact, biosimilars may become “market-makers” in emerging markets where penetration of innovators’ biologics has never been high more so than a competitive threat in established biopharmaceutical markets.

### **Supply chain operations**

Learning how to understand and control supply chain operations at “arm’s length” is an inherent challenge for life sciences companies doing business in the global marketplace, especially those that have major R&D and/or manufacturing operations in less mature markets such as Latin America, Southeast Asia, and the Middle East/Africa. Sourcing and procurement irregularities and supply chain fraud can be difficult to detect and eradicate when corporate oversight is thousands of miles away or entrusted to local agents. Adding to this complexity, organizations are increasingly virtualizing their manufacturing, looking at external partners to operate across a wider range of activities across manufacturing and distribution, trading-off flexible capacity and (in some cases) cost for complexity.

Weak or incomplete security — particularly when many supply chains are expanding across the globe — is exacerbating the spread of counterfeit drugs, particularly in emerging markets. Counterfeit drugs are a \$35-\$40 billion-a-year global business<sup>104</sup> and, along with counterfeit medical devices, a widespread safety concern. The World Health Organization (WHO) estimates that up to 30 percent of branded drugs sold in developing nations are counterfeit, which can have profound implications for patients, governments, and life sciences organizations.<sup>105</sup>

In wealthier countries the most frequently counterfeited medicines are new, expensive lifestyle products, such as hormones, steroids, and antihistamines. In developing countries the most counterfeited medicines are those used to treat life-threatening conditions such as malaria, tuberculosis, and HIV/AIDS.<sup>106</sup> For example, tuberculosis and malaria counterfeits are estimated to kill some 700,000 people a year. In response, WHO, the partnership for safe medicine (PSM), and various governments are putting in place initiatives to combat counterfeit drug manufacturing. Efforts include equipping state drug testing laboratories, enforcing serialization, non-clonable packaging and 2D barcoding, and investing in more new drug manufacturer inspectors. Among country-specific actions, Brazil is stepping up efforts to tackle counterfeiting and other illegal activity through the introduction of a new traceability scheme, which will be mandatory for all drugs by the end of 2016.

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<sup>101</sup> Ibid

<sup>102</sup> *IBISWorld Industry Report: Global Biotechnology*, July 2014. [www.ibisworld.com](http://www.ibisworld.com)

<sup>103</sup> *World Preview 2014, Outlook to 2020*, EvaluatePharma, June 2014

<sup>104</sup> World Health Organization (WHO)

<sup>105</sup> “Challenges Facing India’s Pharmaceutical Industry,” Deloitte Centre for Health Solutions, January 20, 2014. <http://blogs.deloitte.co.uk/health/2014/01/challenges-facing-indias-pharmaceutical-industry.html>

<sup>106</sup> *Substandard and counterfeit medicines*, WHO fact sheet, <http://www.who.int/mediacentre/factsheets/fs275/en/>. Accessed September 28, 2014

Even as supply chain leaders face new complexity and new risks to their products, the ongoing industry transformation — fueled by global reform efforts, formulary pressure, and shifts in product mix — presents an opportunity for supply chain executives to play a more strategic role in shaping future business models. These executives still will be expected to take on traditional roles of developing tactics to maintain or improve margins under new cost constraints and to meet regulatory demands; however, they also will be called upon to develop broader strategies to transform the supply chain from an enabling function to one that drives innovation and profitability. Supply chain-driven innovation, such as novel manufacturing techniques, alternative modes of distribution, supply chain segmentation, and partnerships with third-party service providers infusing innovation where it makes sense, will be critical to sustaining a new business model focused on different types of products, services, and methods of patient engagement.

#### Preparing for the “next wave”

##### *Transition to a value-based market*

Government, provider, and payor efforts to control health care spending, reduce variations in care, and engage consumers in self-care are among the driving forces behind the health care industry’s transition from volume-based to value-based care (VBC). As part of this transition, comparative effectiveness research (CER) — which compares different interventions for a health condition based on real-world effectiveness rather than controlled efficacy — is becoming a major factor in a treatment’s market uptake. Products not proving to be comparatively effective may struggle to generate demand or attain reimbursement. Payors are using CER to manage formularies, providers are leveraging it to guide clinical decisions, and governments are supporting (and, in some cases, funding) CER.

Life sciences companies will need to develop capabilities to provide real-world evidence of positive patient outcomes to avoid exclusions and sales losses. Organizations will likely use CER as a framework to evaluate how potential products will be viewed by payors and customers and decide which products are worth moving forward. Manufacturers also will need CER capabilities to decide the right strategies for trial design, value-based pricing and contracting, reimbursement, market access, and marketing.

##### *New stakeholders, new conversations*

The number and diversity of life sciences customer segments suggest that “one-size-fits-all” approaches to understanding and addressing their needs will be ineffective in an era of transformation. The importance of physicians as the sole influencer in prescription volume or product purchase is rapidly diminishing, as the industry explores new engagement models with an ever-evolving set of customers. Among emerging dynamics:

- Key opinion leaders and medical societies are publishing guidelines that increasingly form the basis for new treatment protocols and drive adoption of best practices across providers.
- Hospital administrators and management committees increasingly are moving final treatment and purchasing authority away from physicians and towards management.
- Private insurance companies are becoming more prevalent, representing yet another source of potential coverage for pharmaceutical companies.
- Regulatory agencies have always been important, but the increasing focus on compliance, product safety, and value requires greater transparency.<sup>107</sup>
- Consumers are becoming more educated about and engaged in the treatment selection and payment process, and are voicing their opinions to their care providers.
- Governments and employers are shifting more of the health care cost burden to citizens and employees in the form of higher deductibles, co-pays, and out-of-pocket (OOP) expenses for drugs and medical devices.

The changing roles and influence of stakeholders along the care continuum call for a more cross-functional, collaborative customer model that effectively targets all critical decision-makers. Life sciences companies will need to shift from brand-centric to personalized, customer-centric marketing across multiple communication channels to better engage all customers and improve return on investment (ROI) on their marketing spend. In addition, life sciences companies will need to elevate the role and competencies of their account managers so that they can effectively interact with the C-suites of their most complex and demanding accounts, such as accountable care organizations (ACOs) and Integrated Delivery Networks (IDNs).

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<sup>107</sup> *Fortune favors the bold: Unlocking the future of China’s pharmaceutical market*, Deloitte China, 2014



### ***Personalized medicine***

The alignment of science, education, research, informatics, and training is enabling a more personalized approach to life sciences product development and, in the process, transforming the future of health care decision-making and delivery.

The goals and evolution of personalized medicine are illustrated by the increased use of molecular biomarkers in drug development and medical decision-making. In oncology, the largest therapeutic area in life sciences research and comprising more than a third of R&D pipelines by value, biomarkers are associated with the majority of targeted and immunotherapies under development. Companion diagnostics, predictive biomarkers approved along with a new therapeutic, also have become an important part of clinical decision-making. Groups of biomarkers are being tested in combinations called “panels” to support the more complex care planning needed to fulfill the vision of personalizing treatment.

The growing complexity of care planning for cancer patients, stoked by the rapid discovery of new driver and resistant mutations in cancer and therapies to treat them, has created demand for clinical decision support (CDS) tools. These tools, ranging from advanced clinical pathways through web and mobile application-supported treatment algorithms, are now being developed by payors, life sciences companies, and providers. Beginning with cancer, these CDS tools are changing provider workflows and medical informatics as they capture, integrate processes, and share data and treatment choices.

As payors seek to reduce health care costs, they are demanding new treatments that are more complex and personalized, such as those targeted to specific therapeutic areas or genetically compatible with an individual user.<sup>108</sup> Increasing collaboration between health care providers and life sciences companies, coupled with the use of real-world evidence to inform the R&D process, is expected to improve patient diagnosis and treatment, and to support the roll-out of predictive prevention and personalized health improvement plans. As personalized medicine becomes more affordable, expect to see the coming of age for genomics, nanotechnology, robotics, and other innovations.

### ***Technology-enabled health care***

Applying technology innovation to health care delivery can help to drive down costs and improve treatment regimens. New developments include wearable technologies and sensors to track vital signs, patient non-compliance, and clinical trial activity; digital medicines such as ingestible smart pills with microchips; and novel drug delivery systems. In an example of the latter, Novartis recently announced a partnership with Google to develop smart contact lenses that can non-invasively track blood glucose levels through tears and send the data wirelessly to a mobile device. The company hopes the lenses will be on the market within five years.<sup>109</sup> Similarly, the use of big data and analytics can drive actionable insights and help life sciences companies improve quality and work more efficiently. Companies can rely on the data to understand existing unmet medical needs, as well as identify patient segments that could most benefit from a therapy. Clinical and translational research capabilities can enable personalized genomic medicine, support comparative effectiveness analyses by leveraging real-world evidence, and improve safety and disease surveillance programs.

### ***The “next” emerging markets***

As growth in developed markets slows, life sciences companies are expected to continue expanding their presence in emerging markets through acquisitions and joint ventures. Key growth drivers include an increase in wealth and income levels, increasing government and consumer awareness about the benefits of a good health care system, and a trend towards healthier lifestyles.

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<sup>108</sup> *IBISWorld Industry Report: Global Biotechnology*, IBISWorld, July 2014

<sup>109</sup> “Smart contact lenses move closer to reality: Novartis and Google announce partnership to develop the new glucose-sensing technology,” *DiaTribe*, July 1, 2014. <http://diatribe.org/issues/65/new-now-next>

Already, leading organizations are looking beyond the “traditional” emerging markets of China, Russia, India, and Brazil for opportunities to establish or increase their presence in the “next” emerging markets. Among these are Eastern Europe (where health care spending growth is forecast to average 7.7 percent a year in 2014-2018), particularly Poland (growing at 9.9 percent a year); Venezuela (projected 12.5 percent growth per year),<sup>110</sup> the Philippines (increasing by an average of 10.2 percent annually),<sup>111</sup> and Mexico (8.6 percent annual growth).<sup>112</sup> Pharmaceutical sales are expected to rise even more strongly: EIU forecasts annual average growth from 2014-2018 at 12.1 percent, driven by increasing demand for advanced medicines and technology, as well as the comparative ease of conducting trade in these markets.<sup>113</sup> Yet, traditional commercialization strategies, based on reach frequency and saturation, may not be effective in these next emerging markets. Life sciences companies likely will need to develop novel commercialization approaches that engage both product regulators and users.

### **Talent acquisition & development**

Life sciences companies are competing globally for increasingly scarce technical and professional skills. According to the Deloitte University Press report, *Global Human Capital Trends 2014: Engaging the 21st-century workforce*, 75 percent of survey respondents rated workforce capability as “urgent” or “important”; however, only 15 percent believe they are ready to address it.<sup>114</sup> Rapid expansion into new markets is challenging Human Resources (HR) functions to build global workforce capabilities, either through internal development or acquisitions. At issue are finding, accessing, and developing employees which possess a growing list of desirable skills. To establish a robust talent pipeline, organizations will need to understand skills gaps today and into the future; identify where key skills are located, where they are going, and how to source or locate talent hubs; investigate new skill pools and explore relationships with educational institutions; recognize the length of time needed to develop key skill sets; and foster a culture that encourages continuous learning.<sup>115</sup>

Life sciences organizations also face an urgent need to hire and develop leaders at all levels which possess global fluency and flexibility, the ability to innovate and inspire, and a deep understanding of the sector’s rapidly changing landscape. The challenge is to develop leadership pipelines that are global and deep, reaching every level of the organization. Tomorrow’s leaders must be able to quickly formulate and implement enterprise-wide responses to marketplace trends, aligning business objectives with the organization’s structure, culture, talent, and HR function.

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<sup>110</sup> *World Preview 2014, Outlook to 2020*, EvaluatePharma, 2014

<sup>111</sup> *Industry Report, Healthcare: Philippines*, The Economist Intelligence Unit, June 2014

<sup>112</sup> *World Preview 2014, Outlook to 2020*, EvaluatePharma, 2014

<sup>113</sup> *World industry outlook: Healthcare and pharmaceuticals*, The Economist Intelligence Unit, May 2014

<sup>114</sup> *Global Human Capital Trends 2014: Engaging the 21st-century workforce*, Deloitte University Press, 2014 [www.deloitte.com/hctrends2014](http://www.deloitte.com/hctrends2014)

<sup>115</sup> *Ibid*

# Stakeholder considerations

As the global health care industry shifts and transforms so, too, must the life sciences sector. The following are among important considerations for stakeholders as they seek to adapt, innovate, grow, and prosper in 2015 and beyond:

**Innovation & growth:** From an R&D perspective, companies are commercializing effectively but failing to match this level of performance in other drivers of R&D returns, such as cost containment and rate of innovation. Companies need to maintain their current trajectory in terms of moving compounds into the late-stage pipeline and on to commercialization. However, the pace of change in factors underlying the economics of R&D needs to accelerate for the sector to achieve sustainable levels of returns. Companies should focus on improvements in R&D returns by maximizing the value of science, preserving and developing talent in R&D, and harnessing the power of analytics to enhance R&D decision-making.<sup>116</sup>

Life sciences companies should also move “beyond the pill” to focus on developing patient-centric suites of products and services to improve the overall health of their customers. For example, the “bionic pancreas,” a hardware/software solution that combines implantable continuous glucose monitors and insulin pumps managed by updateable treatment algorithms. Furthermore, device and therapeutics companies are also joining in strategies anchored by the “internet of things.” Large modality companies are taping device-data “connector” applications to capture diagnostic data to support many enterprise and individual patient use cases. Finally, life sciences companies are tapping large consumer networks using mobile platforms from iPhones to wearable devices in an attempt to engage and modify patient behavior.

Other companies have begun wrapping health care services, such as cellular therapy, around their products. Expanding external collaboration with academia, technology-based companies, and governments can also accelerate R&D innovation. For example, pioneering biotech research in China, India, parts of Southeast Asia, and Latin America is progressing quickly, thanks to domestic and imported labor working under public sector funding and a favorable regulatory environment.<sup>117</sup>

**Regulatory & risk environment:** The life sciences sector is highly regulated and product commercialization can only occur after many years of compliance with required product standards. Taking a risk-based approach to compliance

planning, execution, and monitoring makes good business sense in a heightened regulatory environment. A top priority for drug and device manufacturers is to identify ways to counter increasing instances of unsustainable pricing (extremely high-priced innovations), which elicit defensive legislative responses from government payors.

**Shareholder value:** To maintain and grow shareholder value, life sciences companies should continue to focus on therapeutic progress, novel delivery models, and solutions that address both biological illness and issues in real-world care. Increasing number of industry players are looking not only at product innovation as a way to build value but at making bold moves in business model innovation, such as reconfiguring the nature of their traditional business; creating a second brand; forging long-term strategic partnerships; and other transformative moves. In addition, large and small companies alike should continually survey the competitive landscape to counter incursions from non-traditional players. For example, some companies in heavy industry have been shifting their focus in the life sciences sector from diagnostics (e.g., CT/MRI machinery) to treatment (e.g., heavy particle radiotherapy machines) that could potentially compete with existing therapies.

**The next wave:** The ability to rapidly adopt and commercialize new technological and clinical discoveries will be essential to gaining a competitive advantage in a transforming marketplace. Life sciences companies should join other health care stakeholders who are embracing the “digital agenda” and using technology, big data, and analytics to advance product development and care delivery. For example, digitally enabled health care providers (HCPs) in Europe are becoming increasingly connected and spending more time online for clinical and business purposes. Life sciences companies should work to understand HCPs’ online needs and behaviors in order to deliver the best-possible user experience. In addition, pharma companies are beginning to harness the opportunities afforded by social media and digital marketing to improve sales, marketing, and education efforts. Finally, organizations should create a globally integrated, yet locally customized HR organization to support talent acquisition and development needs. Deep capabilities drive performance—and take years to build. Focusing on the future and building integrated, global HR and talent operating models will help position life sciences companies to rapidly scale and respond to opportunities in new, expanding markets.

<sup>116</sup> *Measuring the return from pharmaceutical innovation in 2013*, Deloitte Centre for Health Solutions, November 2013

<sup>117</sup> *IBISWorld Global Industry Report: Biotechnology*, July 2014, IBISWorld

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