Health care reform and life sciences: Threat, opportunity or both?
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In the past, the life sciences industry has been focused on developing the next blockbuster drug, or expanding to markets that can offer considerable growth. But now, companies also have to contend with a wave of dramatic changes in many markets. Countries like the United States, China, Brazil, Germany, France and the United Kingdom have recently passed substantial health care legislation that will have a significant impact on the life sciences industry. Indeed, senior executives say health care reform in much of the world needs to be one of their leading priorities, but they also admit that their firms are responding reactively rather than strategically. However, if companies are able to understand and adapt to these changes, they may reap the benefits that these reforms offer.

This Economist Intelligence Unit study, developed in collaboration with Deloitte, examines the common elements of the recent wave of global reform, national differences through three case studies, and how life sciences companies are reacting.

Key survey findings include:

**Reducing costs, enhancing innovation and widening market access are the defining goals of health care reform.** Reducing costs is a universal objective of reform in both developed and emerging markets. At the same time, many countries are seeking to enhance innovation in life sciences and medicine more generally. As a result, some are adopting value-based pricing structures for life sciences products, while others are combining cost containment with assistance for companies investing in R&D.

**Respondents expect the main impact of reform eventually will be on innovation and sales models.** Dealing with new government agencies that are still working out how to operate is the most common reform-related challenge (42%). Accordingly, regulatory/compliance functions have been the biggest beneficiaries of increased spending within businesses (43%). Sixty-five percent of respondents, however, say they have changed or will change their innovation processes in three years, and 58% will adapt their sales models in light of legislative reforms.

Specific elements of reform vary by country, requiring companies to have national approaches. In China, recent reforms have put intense pressure on the prices of generic and over-the-counter (OTC) medicines, while increasing the size of the market for proprietary, patented drugs. Overall, survey respondents find the Chinese market more attractive now than before reforms, especially as government policy is now more transparent. In Brazil, a growing pharmaceutical market, driven in part by an increase in judicial decisions about government spending on drug expenditures, is making branded generics and proprietary drugs of greater interest to pharmaceutical companies. Finally, reforms in Germany have the “stick” of cost-cutting, but seem to lack the “carrot” of expanding market size apparent in other markets.

**Leading companies are remodeling their innovation and sales activities in the face of reforms.** Respondents who benchmark their company’s financial performance most highly compared with peers see the benefits of changing their innovation processes and sales models most clearly. They are more likely to see opportunities arising from reforms (61% of this group do, compared to a survey average of 47%), have been more active in responding to them, and are more likely to believe that these responses have positively affected profits (56% compared to 35% on average).

About the research

This report is based, in part, on a survey of 295 senior executives from the life sciences sector conducted in November 2012. Respondents represent pharmaceutical companies (36%), medical devices companies (20%), service providers such as contract research organizations (20%), biotechnology firms (13%) and others. Some 43% of respondents are C-level or above. Respondents are distributed globally, with a third each in Western Europe and North America, 26% in the Asia-Pacific region, and the balance from the rest of the world. Respondents also come from companies with a broad range of sizes: 54% represent businesses with less than US$1bn in annual revenue, while a quarter work for companies with more than US$10bn in annual revenue.

In addition to the survey, six in-depth interviews were conducted with senior executives and other leading stakeholders, along with in-depth desk research. The report was written by Paul Kielstra and edited by Rozina Ali of the Economist Intelligence Unit.
I. Introduction: Health care reform: one size does not fit all

Frequent reform is a fact of life in health care, but life sciences companies worldwide have had a difficult time adapting to recent changes. One reason is that policy changes are predominantly shaped by specific national contexts. For example, the debates surrounding legislation such as the United States’ Affordable Care Act (ACA), Britain’s Health and Social Care Act and the laws arising from China’s Guidelines on Deepening the Reform of the Healthcare System, have many elements that are unique to their national systems.

That said, reforms over the past few years in both developed and developing markets include some common themes with significant implications for life sciences companies. Certain broad goals of health care reforms—specifically, reducing costs, spurring innovation and improving market access—can pose both opportunities and risks for this sector.

Reducing costs: With stagnant economic growth and increasing health care spending in developed countries, and limited resources in emerging markets that are seeking to expand health care coverage to a growing population, cost containment has become a universal concern.

Strategies to address these costs vary. Most national health care systems have been encouraging greater use of generic drugs. In the U.S., the proportion of prescriptions filled by such products has risen from around half to 80% over the last decade. More recently, several countries, such as Germany, have turned to value-based pricing to address the cost of new drugs. This involves allowing a price differential from existing offerings—including generics—based on the demonstrated superiority of a new product. The focus on value is also making detailed economic analysis a more important part of pricing negotiations. Meanwhile, other countries are increasingly mandating prices: India, Brazil and China, for example, have created national lists of essential drugs with set prices.

Regardless of the approach, it is evident that the objective is to rein in spending. In fact, the industry perceives reform in some of these countries to involve little else. Tjeenk Willink, recently retired board member responsible for marketing worldwide at Boehringer Ingelheim, says of recent changes to the German system, “They are not really focused on value for money but are a tool to arrive at the lowest price.”

Chart 1: Health care spending steadily increasing around the world
Public and private health care expenditure by region (US$ per head)

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</thead>
<tbody>
<tr>
<td>Asia and Australasia</td>
<td>211</td>
<td>230</td>
<td>262</td>
<td>282</td>
<td>328</td>
<td>374</td>
<td>397</td>
<td>422</td>
<td>454</td>
<td>491</td>
<td>534</td>
</tr>
<tr>
<td>East-Central Europe</td>
<td>569</td>
<td>718</td>
<td>922</td>
<td>796</td>
<td>827</td>
<td>928</td>
<td>875</td>
<td>945</td>
<td>1,009</td>
<td>1,079</td>
<td>1,211</td>
</tr>
<tr>
<td>Latin America</td>
<td>476</td>
<td>567</td>
<td>647</td>
<td>648</td>
<td>804</td>
<td>908</td>
<td>893</td>
<td>931</td>
<td>999</td>
<td>1,068</td>
<td>1,125</td>
</tr>
<tr>
<td>Middle East and North Africa</td>
<td>304</td>
<td>334</td>
<td>384</td>
<td>400</td>
<td>483</td>
<td>527</td>
<td>559</td>
<td>582</td>
<td>625</td>
<td>687</td>
<td>756</td>
</tr>
<tr>
<td>North America</td>
<td>6,810</td>
<td>7,179</td>
<td>7,443</td>
<td>7,666</td>
<td>8,074</td>
<td>8,404</td>
<td>8,742</td>
<td>9,072</td>
<td>9,464</td>
<td>9,857</td>
<td>10,242</td>
</tr>
<tr>
<td>Sub-Saharan Africa</td>
<td>159</td>
<td>175</td>
<td>176</td>
<td>168</td>
<td>195</td>
<td>224</td>
<td>220</td>
<td>232</td>
<td>251</td>
<td>273</td>
<td>299</td>
</tr>
<tr>
<td>Western Europe</td>
<td>3,469</td>
<td>3,951</td>
<td>4,340</td>
<td>4,151</td>
<td>4,101</td>
<td>4,444</td>
<td>4,237</td>
<td>4,345</td>
<td>4,383</td>
<td>4,415</td>
<td>4,597</td>
</tr>
<tr>
<td>World</td>
<td>951</td>
<td>1,041</td>
<td>1,125</td>
<td>1,128</td>
<td>1,199</td>
<td>1,292</td>
<td>1,308</td>
<td>1,359</td>
<td>1,418</td>
<td>1,480</td>
<td>1,558</td>
</tr>
</tbody>
</table>

Spurring innovation: Policymakers may want to pay less, but they are also eager to increase medical and life sciences product innovation. A value-based pricing system works to reward products that can demonstrate substantial innovation. But it’s not the only method policymakers are adopting. China, for example, has declared biotechnology to be one of seven strategic industries in its latest five-year reform plan, giving firms in that sector easier access to financing. Meanwhile, the Brazilian government is in the midst of a ten-year biotechnology development program, in which it is investing US$3bn. Also, the United Kingdom has reduced taxes on exploiting British-owned intellectual property, in part to reward companies for doing research in the country.

Improving market access: The current trend toward development of universal health care in much of the world has led to a massive increase in government purchasing of expanded insurance coverage or direct purchase of products that life sciences firms produce. For example, in 2012 India set aside US$5.4bn to purchase generic products for patients in government hospitals and rural clinics.

Although the need to widen access is most pressing in emerging markets, it is also an objective of health reform in the world’s largest market—the United States. The Affordable Care Act assesses higher taxes on biopharmaceutical companies and medical device manufacturers and, according to the Congressional Budget Office, will increase the number of insured people by 27 million over the next decade, a substantial addition to the market. This may explain why those surveyed for this study were most likely to name the U.S. as the country where reform presented both the biggest risks and the biggest opportunities.

Change entails drawbacks in any market: 61% of respondents describe reforms in major markets as representing a high or very high risk to their business, and only 8% see the risk as low. Forty-seven percent see a higher financial risk in early-stage development, in particular, as investment may not yield drugs deemed “valuable” by government bodies. “In practice… you have to consider if your product has any pharmaco-economic advantage, and that you can show cost savings when the drug is applied,” says Wolfgang Soehngen, CEO of PAION, a German biopharmaceutical company, of reforms in Germany.

Still, nearly half (47%) of survey respondents say that reforms represent a great opportunity. Some of this potential lies in developing products that meet the goals of reformed systems, such as more patient-focused care (cited as a reform objective by 39%). More than a third (36%) of pharmaceutical respondents cite expanded market access as the leading reform-related opportunity. This opportunity is more than a further increase in the growing sales of generic products: it means a wider market for proprietary, precision drugs, as well. Richard Connell, head of external research solutions at Pfizer, explains of China, “Once you get a billion people getting used to off-patent treatments [generics], there will be a demand for the next tier up of higher-value, more differentiated products. If you didn’t have that foundational health care baseline that generics provide, the bar for innovative products would be much more difficult to reach. It will soften up the ground for speciality products.”

This paper looks at how the life sciences industry is responding to the common elements found in recent health care reforms around the world, as firms seek to minimize the impact of price pressures by demonstrating the superior value of their products over existing offerings, and as they seek to take advantage of market expansion in certain countries. The paper also takes a closer look at reform in three countries—Brazil, China, and Germany—to give a more rounded view of the challenges and opportunities reform poses to life sciences companies in three very different major markets.
II. The industry reaction: a global perspective

Adjusting to health care reform is currently one of, or the single, leading priorities for their companies, according to 64% of life science respondents. Looking ahead, 77% of those surveyed expect health care reform to be a similarly prominent challenge for their businesses over the next three years. Among respondents from pharmaceutical firms, this figure reaches 88%.

Major markets are indeed being dramatically reshaped. Mr. Tjeenk Willink says, “the change for us has been huge” in Germany, with the historic method for price-setting being replaced by a completely different system. Similarly, reforms in China have had diverse effects on the pharmaceutical market, and the change in “each area is fairly complex,” says Christian Hogg, CEO of Hutchison China MediTech, a leading pharmaceutical and health care group in that country.

However, many companies in the life sciences industry have not been acting strategically in the face of this challenge. More than twice as many respondents say that their company’s response to reform has been reactive (41%) rather than being part of a broader strategy (cited by 20%). Worse still, four in ten respondents do not know if their company is ready to respond to reform, and 8% say it is definitely not.

One of the reasons that companies are still struggling to find their way is that many regulatory environments remain in a state of flux. Indeed, the main focus of companies so far seems to be to develop the relationships needed to work within the new landscape most effectively. Dealing with recently created or reformed government agencies that themselves are still working out how to operate is the most frequently cited reform-related challenge in the survey (42%). Adjusting the company’s commercial model to the new realities (41%) comes a close second. Accordingly, the resources spent in responding to reforms have focused on regulatory compliance, overall strategy, government relations, and sales and marketing.

Chart 2: The challenges of reform

What are the biggest challenges that your organization has faced, or that you foresee as a result of health care reforms globally? (Respondents selected up to three)

**42%**

Dealing with new/reformed government agencies that are still working out how to operate in the new environment

**41%**

Adjusting our commercial model to reflect changes in reformed marketplaces

**35%**

Proving value of our products compared to existing ones, especially generic products

**30%**

Developing a comprehensive response to the diverse reforms in different countries

**29%**

Gathering new types of data (e.g., economic data, more detailed outcomes data)

**28%**

Refocusing innovation on medical areas that may yield more profits (e.g., areas with greater unmet need)

**23%**

Responding to reduction to our income that has resulted from reform designs

**4%**

These reforms do not represent any significant challenge

Companies also have been resisting change. More than a quarter of life sciences respondents say their company has lobbied or publicly spoken out against elements of reforms, including 32% of North American respondents, where it has been the second-most widespread response by the industry after changes to innovation processes to demonstrate value. However, such lobbying is rarely well received by the public. In Europe, “the general feeling [among the public] would be that these guys are whining and should come up with better medicines,” says Dr. Soehngen. A significant number in the industry seem aware of the dangers of alienating customers: nearly twice as many respondents say that their companies have been too vigorous in publicly resisting reforms (41%) compared with just 22% who disagree.

Another indication that companies are still finding their way is that no single response strategy seems to dominate among survey respondents. Looking ahead to the next three years, however, respondents at over half of companies (53%) expect to change innovation processes and 44% report that they intend to modify their sales models. When combined with those that say they have already taken these steps, respondents at 65% of companies say that they will have changed their innovation processes and 58% their sales models in light of legislative reforms.
Fortune favors the brave

On the front page of its June 2012 edition, the Chinese journal *Health News* published a poem by Chen Zhu, the minister of health. It read, in part, “The wind and thunder moving health reform across the country herald glad tidings/.../The deep pool is nothing to be afraid of…Heroes dare to cross.” Unorthodox though it was for a strategy memo, it turns out that this call to action may contain good advice for companies.

Those respondents who benchmark their company’s financial performance as much better than peer companies are more likely than average to see health care reform as presenting high levels of opportunity (61% versus 47%). Accordingly, they are more likely to have taken a variety of proactive steps in response to health care reforms [see Chart 5].

Executives at these companies also believe that their efforts are paying off: 56% of those with much better financial performance say that steps taken by their firms in response to health care reform have positively affected profits; the equivalent number for the rest of the survey is just 35%. Reform is inevitable. For the “heroes” willing to leap the abyss, health care reform may indeed bring glad tidings.

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1 “Heroes dare to cross,” The Economist, 21 July 2012.
Chart 5: Those who dare, win

What steps has your organization taken in the last three years in response to government health care reforms? (Respondents selected all that applied)

<table>
<thead>
<tr>
<th>Much better financial performance*</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Built/strengthened our relationship with regulators</td>
<td>50%</td>
</tr>
<tr>
<td>Changed our innovation processes to demonstrate value in new and different ways</td>
<td>44%</td>
</tr>
<tr>
<td>Changed the medical conditions on which we focus</td>
<td>39%</td>
</tr>
<tr>
<td>Lobbied or publicly commented on new reforms to encourage adjustments/withdrawal</td>
<td>39%</td>
</tr>
<tr>
<td>Changed sales model from a physician-centered to a more payer- or patient-centered one</td>
<td>33%</td>
</tr>
<tr>
<td>Began or increased production of generics alongside innovative drugs</td>
<td>28%</td>
</tr>
<tr>
<td>Limited our activity in or withdrew from a national market</td>
<td>17%</td>
</tr>
<tr>
<td>Have not taken significant steps to respond</td>
<td>3%</td>
</tr>
</tbody>
</table>

*As benchmarked by survey respondents.
III. Three tales of reform

Although having an understanding of trends in global health care reform can be beneficial, ultimately, health care reform is based on local policies—and each market has its own individual nuances. This study considers three leading markets that have seen substantial reform of different types: China, soon to be the world’s second-largest pharmaceutical market, is undergoing changes designed to make basic health care affordable to the entire population; Brazil is an emerging market that is pursuing similar goals through multiple, smaller initiatives; and Germany, long the leading life sciences market in Europe, is seeking to scale back its health care spending as part of a greater austerity push.

China

Size of pharmaceutical market 2012 (US$): $69.7bn
Market in global terms: 3rd largest (2nd by 2016)
Expected annual growth rate 2012-2016: 18.8%
Annual pharmaceutical spending per person 2012: $52
Expected annual growth rate 2012-2016: 18.2%

Chart 6
Pharmaceuticals sales (US$)

China launched a substantial health care reform program in 2008 with the broad aim of providing universal health care through inter-related improvements in overall spending, the level of basic insurance, the use of primary care, and the availability of hospitals. This has huge implications for the life sciences industry. One is market access: the proportion of the population with at least some type of insurance coverage has virtually doubled from just 43% in 2006 to 95%, or 700 million people, in 2012. Looking ahead, in January 2013 the government announced spending to increase the extent of coverage in rural areas and to raise the proportion of medical costs paid by insurance. In addition, although not part of reform itself, the country’s most recent five-year plan identified biotechnology as a strategic industry, promising state investment in the field of over US$300bn between 2011 and 2015.

Huge as the Chinese market is, per capita spending there is only a fraction of that in developed countries. Even with the expected rapid growth of the pharmaceutical market, by 2017 per-person spending on drugs is expected to be just $10/month. Low-price generics—whether over-the-counter (OTC) or prescription—make up the vast majority of the market by volume, and will likely continue to do so. Nevertheless, patented drugs—usually foreign-made—have prices that are comparable to other countries and currently still account for 70% to 75% of China’s sales revenue, according to EIU figures.

In the face of expected rapid growth in pharmaceutical spending, the government, which is the biggest payer, is taking a variety of steps to keep prices down. The most important is the ongoing expansion of the essential drug list. Created in 2009, it included some 300 basic medications for which prices are fixed. In September 2012, the government announced that this number would more than double to 800, and in January 2013, it added that it foresaw further expansion.

At the same time, the government is looking at ways to reduce costs by encouraging provincial health administrations to experiment. The result of one such effort has been the “Anhui model,” which involves centralized, bulk purchasing from the lowest bidder deemed technically capable of supplying a given medicine. The government is now encouraging other provinces to adopt this approach.

Nevertheless, global executives in the survey think that the benefits of reform outweigh the drawbacks. Moreover, despite its challenges—and many remain—China is simply too big an opportunity to neglect. Over half of respondents say that the changes mean their company is more likely to engage in commercial operations, manufacturing and R&D in China. Only a very small number believe the opposite. Similarly, roughly seven in ten expect their businesses to increase manufacturing, R&D and the number of products for which they seek Chinese formulary access, while 82% say the same about sales activity.

Chart 7: Reform has increased China’s attractiveness...

Thinking of your operations in China, have recent government health care reforms made it more or less attractive to do any of the following there? (Respondents selected one in each row)

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<thead>
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<th></th>
<th>More attractive</th>
<th>No change</th>
<th>Less attractive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engage in R&amp;D</td>
<td>62%</td>
<td>35%</td>
<td>9%</td>
</tr>
<tr>
<td>Seek formulary access</td>
<td>47%</td>
<td>48%</td>
<td>6%</td>
</tr>
<tr>
<td>Engage in manufacturing activity</td>
<td>56%</td>
<td>38%</td>
<td>6%</td>
</tr>
<tr>
<td>Engage in sales efforts/commercial operations</td>
<td>50%</td>
<td>45%</td>
<td>5%</td>
</tr>
<tr>
<td>Reach a wider population</td>
<td>69%</td>
<td>27%</td>
<td>4%</td>
</tr>
</tbody>
</table>

Mr. Hogg points out that the impact of reforms differs widely depending on the type of product. With regards to pharmaceuticals, reforms have put emphasis on highly competitive hospital price tendering in OTC medicine and generic pharmaceuticals. Given the intense competition, foreign companies have tended to leave increasingly low-profit OTC and non-branded generic products to the large number of domestic, low-cost manufacturers.

On the other hand, Mr. Hogg notes that changes have been generally positive for proprietary prescription drugs, as greater access to drugs on the essential medicines list helps to offset price pressures. The EIU projects that the proprietary prescription drug market is likely to grow along with the rest.

Dr. Connell adds that the Chinese government wants to see its domestic biopharma industry grow. As a result, it is creating a welcoming environment for major life sciences companies interested in joint ventures, such as the September 2012 arrangement between Pfizer and Zhejiang Hisun Pharmaceuticals. Underlying government policy is a recognition that providing the drug development needed for universal health care is a healthy private industry.

In some respects, reform has also improved the ease of doing business. This is especially important in the China market: according to the EIU’s analysis of the Chinese pharmaceutical and biotechnology sector, legal and regulatory risk is the third-biggest risk faced by companies after government effectiveness and labor market risks. The hope is that while reshaping the business landscape, the reforms will make it more predictable. “There are winners and losers, but the vast majority of players have been able to adjust and adapt,” Mr. Hogg adds.

**Chart 8: ...And companies will continue to ramp up activity**

*Again thinking of your operations in China, is your company likely to increase or decrease the following in the next three years? (Respondents selected one in each row)*

<table>
<thead>
<tr>
<th></th>
<th>Increase</th>
<th>No change</th>
<th>Decrease</th>
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<tbody>
<tr>
<td>R&amp;D activity</td>
<td>70%</td>
<td>29%</td>
<td>1%</td>
</tr>
<tr>
<td>Number of new products</td>
<td>70%</td>
<td>30%</td>
<td>1%</td>
</tr>
<tr>
<td>for which it seeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>formulary access</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturing activity</td>
<td>67%</td>
<td>31%</td>
<td>2%</td>
</tr>
<tr>
<td>Sales/commercial activity</td>
<td>82%</td>
<td>16%</td>
<td>2%</td>
</tr>
</tbody>
</table>

Brazil, like China, is an emerging economy with similar factors at play: the market and regulatory frameworks are still developing, income per head is lower than in established markets, and large swaths of the market are untapped. Comparisons between the two yield insights into the ways in which developing markets are reshaping the health care landscape.

In some ways, Brazil seems more alluring than China: per capita spending on pharmaceuticals is nearly four times greater than in China. This explains, in part, why the life sciences industry has such a positive view of Brazil. A higher proportion of respondents active in Brazil and China say that the former has become a more attractive place to engage in sales activities (57%) and reach a wider population (74%) as a result of reform than, say, the same of China (50% and 69%, respectively). Accordingly, a similar percentage of respondents plan to increase their commercial activity and the number of products for which they are seeking formulary access in each country.
Unlike China and Germany, Brazil’s health care system has not undergone a single extensive reform in the recent past. However, the country’s policymakers have pursued a series of policies over the past decade that improve access to care and are of clear relevance to the pharmaceutical industry.

The first is greater investment in the public health care system. The most notable examples are the Mais Saúde program of 2008 to 2011, which provided increased funding for primary care within the Unified Healthcare System (SUS) and the Farmácia Popular initiative. The latter distributes basic drugs at low or no cost through its own network and through partner private pharmacies.
Giles Platford, president of Takeda Brazil, notes that in the past his company had tended to focus on the out-of-pocket market. However, the remodeled public health system allows it to sell more products now, such as its new chronic obstructive pulmonary disease drug, Daxas, to publicly run facilities. “We’ve created a more robust market access structure, partly because of the government’s increased focus on health care and the expansion of a number of programs funded by the government,” he says.

Although reform has broadened access, the government continues to keep down drug prices through health technology assessment bodies. Since 2004, the Board for the Regulation of the Drug Market (CMED) has regulated prices in part based on the efficacy—the added value—of new products compared to existing treatments. In 2012, Brazil established the National Commission for Incorporation of Technologies (CONITEC) in the SUS, which measures drugs with stricter criteria than before. In particular, applicants will need to provide comparisons of efficacy and safety of any new product with those currently used by the SUS; economic evaluation studies compared to existing alternatives; and an estimated budgetary impact on the SUS.

Still, regulatory change has brought a welcome increase in transparency in Brazil. Companies will have a better idea of whether their products will be taken up by the SUS. CONITEC has not been reticent about rejecting applications, including four in September 2012, but it has to engage in a public consultation. “Previously, the criteria for the inclusion of medication [on the formulary] were not well defined. CONITEC has a more robust and transparent process and there is more fairness in the way the industry and submissions are treated. The direction is to have clearer criteria,” Mr. Platford explains.

In Brazil, government policy has long favored the prescription and purchasing of generic medicines, and domestic companies that specialize in this area—such as EMS, Teuto and Medley—have risen from relatively small beginnings to control some of the biggest market shares in Brazil’s growing pharmaceutical sector.

A number of high-profile deals indicate global companies’ interest in getting into the Brazilian generics market: in 2009, Sanofi bought Medley; in 2010, Pfizer purchased a 40% stake in Teuto; while in 2012, Takeda purchased Multilab, a maker of branded generics and OTC medicines. According to Mr. Platford, the acquisition “gives us important access to the emerging middle class, who consume 40% of medicine in the country. Many of the 90 million people in this class are getting access [to medicine through income growth], but often not taking premium products.”

Looking ahead, Mr. Platford is positive about the future of life sciences in Brazil. “Public funding will increase; the inclusion of new technologies will increase; the use of biologics will increase, the emerging middle class will drive medicine consumption; increased funding in Farmácia Popular will present an opportunity in branded generics. The market will continue to move forward.”
Reforms in Germany, particularly the introduction of value-based pricing, have taken on greater urgency as a result of wider austerity measures. The major reform affecting the life sciences industry in Germany came from the Act for the Restructuring of the Pharmaceutical Market in Statutory Health Insurance (AMNOG), passed in late 2010. Around the same time, the government instituted a three-year price freeze on existing pharmaceutical products and increased the mandatory rebate that drug companies had to provide the government for their products from 6% to 16%.

Whereas previously companies were free to set their own prices for medications, now, under AMNOG, they can do so for only one year after introduction of a new product. During that time, they must provide data to assessors in order to demonstrate their products’ superiority over existing therapies, including—potentially — generics. The data are examined by the Institute for Quality and Efficiency in Health Care (IQWiG), the country’s independent health technology agency, and subsequently by the Federal Joint Committee, a German body that makes reimbursement decisions and that can overrule IQWiG. If these bodies do not find that a new drug provides an added benefit over existing medications, it will be priced similarly to those offerings, meaning, in a worst case, a new molecule may be priced as a generic. The two bodies have not been shy about using their powers. In roughly half of the cases in 2011 and 2012, new products were determined to have no proven added benefits.
Where a new drug is deemed to have at least some benefit, the company and the National Association of Statutory Health Insurance Funds negotiate a single market price. These negotiations take into account both the price of existing competitors and the deemed increase in the value of the treatment. Even in such cases, though, companies will not necessarily achieve high returns. In 2012, Esbriet, Intermune’s new drug for idiopathic pulmonary fibrosis, was exempted from reference pricing because it was for an orphan disease, but was judged to provide only an uncertain additional benefit. It saw its price drop after negotiation by 11% beyond the 16% statutory price rebate.

Moreover, the system does not apply only to new drugs. In February 2013, Novartis lost a lawsuit seeking to prevent a cost-benefit review of two diabetes drugs which have already been on the market since 2008.

These changes need to be seen in perspective. If the reforms themselves seem more negative for the industry than those in emerging markets or even the U.S., that is because the previous environment was so positive. It allowed not just price freedom, but also nearly universal market access with no significant co-pay arrangements or multiple formularies.

The latter elements have not disappeared, and Germany remains a substantial market with a variety of attractions. Nevertheless, the reforms themselves contain much more bad news than good and, therefore, survey respondents are much less positive about these changes than those in China or Brazil. As the chart below shows, the changes have made manufacturing less attractive. Roughly equal numbers say that they have made engaging in R&D and in sales activity more or less appealing.

Chart 13: German reforms produce a more equivocal response

Thinking of your operations in Germany, have recent government health care reforms made it more or less attractive to do any of the following there? (Respondents selected one in each row)

<table>
<thead>
<tr>
<th>Activity</th>
<th>More attractive</th>
<th>No change</th>
<th>Less attractive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engage in R&amp;D</td>
<td>20%</td>
<td>62%</td>
<td>18%</td>
</tr>
<tr>
<td>Seek formulary access</td>
<td>21%</td>
<td>60%</td>
<td>19%</td>
</tr>
<tr>
<td>Engage in manufacturing activity</td>
<td>14%</td>
<td>61%</td>
<td>25%</td>
</tr>
<tr>
<td>Set remunerative prices</td>
<td>15%</td>
<td>56%</td>
<td>29%</td>
</tr>
<tr>
<td>Engage in sales efforts/commercial operations</td>
<td>21%</td>
<td>44%</td>
<td>27%</td>
</tr>
<tr>
<td>Reach a wider population</td>
<td>27%</td>
<td>56%</td>
<td>17%</td>
</tr>
</tbody>
</table>

The reforms are particularly problematic for pharmaceutical and biotechnology companies. Collectively, a quarter of these respondents say that the reforms have made R&D less attractive, and 38% say the same of commercial activity (compared to 24% of the average).

Many of the respondents who believe that sales opportunities are more attractive are from generics firms or service providers, both of which benefit from a lower-cost environment. When it comes to biotech and pharma respondents, Germany is cited second most often, after the U.S., as the country where health reforms present the biggest business model challenges. Of the biotechnology and pharmaceutical respondents who do see R&D and sales as more attractive following recent reforms, the majority are based in developing countries, where they are likely to be benefiting from lower cost structures.

Boehringer-Ingelheim’s Mr. Tjeenk Willink says the industry doesn’t object to value-based pricing itself, but rather to problems with the system. In particular, he notes that pharmaceutical companies and the authorities frequently disagree over appropriate comparator drugs—as was the case with Trajenta. Indeed, in most cases where IQWiG found no proven additional benefit, the reason it cited was that companies had not submitted data on comparators the organization deemed appropriate.

Mr. Tjeenk Willink argues that assessors are also defining value too narrowly: in the case of Trajenta, for example, they did not consider safety issues, such as the new medication’s lower risk of inducing hypoglycaemia or strokes compared to existing treatments. More generally, he says that using foreign reference prices to set prices in Germany does not recognize the value that new products might bring in the local context. This, he argues, essentially undercuts the concept of value-based pricing.

Some of these disagreements should be resolved over time. Dr. Rolf Koschorrek, a member of the German Parliament and chairman of the CDU/CSU parliamentary group in the committee on health, notes that reforms inevitably bring some complaints. However, he adds that “we take these things seriously.” He says that the legislation has led parliamentarians and the industry to engage in extensive dialogue, which has greatly enhanced mutual understanding and led to a number of improvements to the original law.

Mr. Tjeenk Willink agrees that discussions have brought useful changes, notably that companies and assessors will now be able to discuss appropriate comparators before phase III trials begin. Nevertheless, he insists that issues remain, such as price confidentiality and an ongoing sense that instead of rewarding value, the new system seems focused on reducing prices, however beneficial a new product might be. Ultimately, he adds, “if we feel that the decision of the German authorities is going in a direction that is not sustainable, it will lead us to critically reflect on whether any new product launch in Germany makes sense.”
Health care reforms worldwide are having a major impact on the markets in which life sciences companies operate. Companies know that these changes are important, but are struggling over how to understand and respond. This study suggests that action on two levels is needed.

First, life sciences firms need to take a strategic, global approach rather than reacting to change market by market. This involves a focus on the challenges that are common across major markets. Value-based pricing is becoming increasingly widespread, as are a variety of other strategies by payers to reduce costs. The most successful companies have responded by making substantial changes in innovation processes and sales models. Making a case against legislative change can help modify it—as seen in Germany—but will not reverse the broader trend of these reforms. Payers will not return to the more generous pricing methodologies of the past even when economic growth returns. Already, those who accept this and act are seeing better results.

Second, firms need to look at the particular opportunities that specific national reforms can bring. In China, that may mean a focus on prescription products, while in Brazil the generics field looks promising. In Germany, meanwhile, it might even make sense not to release a product in that market if it cannot be done profitably. Even if health care reforms in particular countries share many goals—such as cost reduction, improved innovation, and greater access—the specifics of how these are reached determine the nature of the opportunities in each market. The national tactics of a global strategy inevitably vary.

Although not the main focus of this study, reformers might also draw insights from it when reshaping health care landscapes. The savings that the reforms bring can be accompanied by negative impacts as well, be they restricted access to new medications or pricing of generics, which may drive manufacturers to take short cuts. In launching themselves across the abyss of fear, policymakers need to make sure that the life sciences sector is not merely more efficient, but also better able to meet the needs of their societies.
Survey results: 2012 online survey of 295 senior life sciences industry executives, conducted by the EIU in collaboration with Deloitte.

**How important has adjusting to major government health reforms been for your organization in the last three years?**

<table>
<thead>
<tr>
<th>Importance</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>The most important; our top priority</td>
<td>19%</td>
</tr>
<tr>
<td>Very important; among our highest priorities</td>
<td>45%</td>
</tr>
<tr>
<td>Somewhat important; we have addressed it but it is mid-priority</td>
<td>25%</td>
</tr>
<tr>
<td>Minimally important; it is low-priority</td>
<td>7%</td>
</tr>
<tr>
<td>Not important; it is not a priority at all</td>
<td>4%</td>
</tr>
</tbody>
</table>

**How high a priority do you expect adjusting to major government health reforms to be in the next three years?**

<table>
<thead>
<tr>
<th>Importance</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>The most important; our top priority</td>
<td>29%</td>
</tr>
<tr>
<td>Very important; among our highest priorities</td>
<td>48%</td>
</tr>
<tr>
<td>Somewhat important; we have addressed it but it is mid-priority</td>
<td>15%</td>
</tr>
<tr>
<td>Minimally important; it is low-priority</td>
<td>4%</td>
</tr>
<tr>
<td>Not important; it is not a priority at all</td>
<td>4%</td>
</tr>
</tbody>
</table>

Disclosure: Due to rounding, data may not equal one hundred percent.
In which countries have major government health care reforms presented the biggest challenge to your company's business model (e.g., by reducing ability to achieve expected ROI on new products or increasing barriers to market access)?
(Respondents selected up to three)

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States of America</td>
<td>25%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>11%</td>
</tr>
<tr>
<td>Germany</td>
<td>7%</td>
</tr>
<tr>
<td>France</td>
<td>7%</td>
</tr>
<tr>
<td>China</td>
<td>6%</td>
</tr>
<tr>
<td>India</td>
<td>5%</td>
</tr>
<tr>
<td>Spain</td>
<td>4%</td>
</tr>
<tr>
<td>Italy</td>
<td>3%</td>
</tr>
<tr>
<td>Brazil</td>
<td>2%</td>
</tr>
<tr>
<td>Australia</td>
<td>2%</td>
</tr>
<tr>
<td>Canada</td>
<td>2%</td>
</tr>
<tr>
<td>Japan</td>
<td>2%</td>
</tr>
<tr>
<td>Russia</td>
<td>2%</td>
</tr>
<tr>
<td>Other</td>
<td>22%</td>
</tr>
</tbody>
</table>
In which countries have major government health care reforms presented the biggest opportunities for your company (e.g., by increasing the market size for its products or increasing rewards in areas where it is stronger than competitors)?

(Respondents selected up to three)

<table>
<thead>
<tr>
<th>Country</th>
<th>Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States of America</td>
<td>19%</td>
</tr>
<tr>
<td>China</td>
<td>11%</td>
</tr>
<tr>
<td>India</td>
<td>7%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>7%</td>
</tr>
<tr>
<td>Brazil</td>
<td>5%</td>
</tr>
<tr>
<td>Germany</td>
<td>5%</td>
</tr>
<tr>
<td>Australia</td>
<td>3%</td>
</tr>
<tr>
<td>Russia</td>
<td>3%</td>
</tr>
<tr>
<td>Japan</td>
<td>3%</td>
</tr>
<tr>
<td>Canada</td>
<td>3%</td>
</tr>
<tr>
<td>France</td>
<td>2%</td>
</tr>
<tr>
<td>Other</td>
<td>32%</td>
</tr>
</tbody>
</table>

How big a risk, and how big an opportunity, does reform in major markets present for your organization?

(Respondents rated on a scale from 'very high' to 'very low')

| Risk (e.g., reforms will reduce ability to achieve expected ROI, or will increase barriers to market access) |
|---|---|---|---|---|---|
| 1 = Very high | 22% | 39% | 29% | 5% | 3% | 2% |
| 2 = Somewhat high | 32% | 51% | 32% | 12% | 6% | 2% |
| 3 = Moderate | 16% | 11% | 8% | 1% | 1% | 1% |
| 4 = Somewhat low | 10% | 7% | 3% | 1% | 1% | 1% |
| 5 = Very low | 6% | 5% | 3% | 1% | 1% | 1% |
| 6 = NA | 2% | 2% | 2% | 2% | 2% | 2% |

| Opportunity (e.g., reforms will increase rewards in areas of investment or increase market size for products) |
|---|---|---|---|---|---|
| 1 = Very high | 16% | 11% | 8% | 1% | 1% | 1% |
| 2 = Somewhat high | 32% | 51% | 32% | 12% | 6% | 2% |
| 3 = Moderate | 10% | 7% | 3% | 1% | 1% | 1% |
| 4 = Somewhat low | 6% | 5% | 3% | 1% | 1% | 1% |
| 5 = Very low | 2% | 2% | 2% | 2% | 2% | 2% |
| 6 = NA | 2% | 2% | 2% | 2% | 2% | 2% |
Which functions have seen the greatest increase in resources as part of your company’s response to major government health care reforms in recent years?
(Respondents selected up to three)

- Regulatory/compliance/legal: 43%
- Strategy/operations: 29%
- Government relations/outreach: 28%
- Sales/marketing: 27%
- R&D: 22%
- Manufacturing: 17%
- Risk: 14%

No function has seen a significant increase in resources in response to government health care reforms: 11%
Don’t know: 2%
Other: 7%

Which of the following frequently-cited goals of health care reform represent an opportunity that your organization has recently focused on?
(Respondents selected up to three)

- Developing patient-focused care delivery: 39%
- Increasing value: 34%
- Enhancing outcomes: 27%
- Expanding general access to pharmaceutical products: 27%
- Improving quality: 26%
- Changing payment mechanisms: 22%
- The reduction of total health care spending: 20%
- Improving chronic care/care for multi-morbid patients: 16%
- Prevention: 12%
- Other: 7%
What steps has your organization taken in the last three years in response to government health care reforms?  
(Respondents selected all that applied)

- Changed our innovation processes in order to demonstrate value in new and different ways (39%)
- Built/strengthened our relationship with regulators (38%)
- Changed sales model from a physician-centered to a more payer- or patient-centered one (34%)
- Changed the medical conditions on which we focus (30%)
- Lobbied or publicly commented on new reforms to encourage adjustments/withdrawal of recent ones (27%)
- Began or increased production of generics alongside innovative drugs (21%)
- Limited our activity in or withdrew from a national market (15%)
- We have not taken/do not intend to take significant steps to respond to government health care reforms that we would not take anyway (9%)
- Don’t know (4%)
- Other (7%)

What steps is your organization likely to take in response to government health care reforms in the next three years?  
(Respondents selected all that applied)

- Changed our innovation processes in order to demonstrate value in new and different ways (53%)
- Changed sales model from a physician-centered to a more payer- or patient-centered one (44%)
- Built/strengthened our relationship with regulators (43%)
- Changed the medical conditions on which we focus (37%)
- Lobbied or publicly commented on new reforms to encourage adjustments/withdrawal of recent ones (27%)
- Began or increased production of generics alongside innovative drugs (27%)
- Limited our activity in or withdrew from a national market (21%)
- We have not taken/do not intend to take significant steps to respond to government health care reforms that we would not take anyway (17%)
- Don’t know (8%)
- Other (5%)
- Other (4%)
What impact have the changes implemented in response to health care reform had on the following performance indicators at your organization?
(Respondents rated on a scale from 'highly positive' to 'highly negative')

<table>
<thead>
<tr>
<th>Performance Indicator</th>
<th>Highly positive</th>
<th>Somewhat positive</th>
<th>Neither positive nor negative</th>
<th>Somewhat negative</th>
<th>Highly negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understanding of patients</td>
<td>13%</td>
<td>33%</td>
<td>40%</td>
<td>5%</td>
<td>2%</td>
</tr>
<tr>
<td>Ability to develop innovative products</td>
<td>10%</td>
<td>29%</td>
<td>35%</td>
<td>11%</td>
<td>9%</td>
</tr>
<tr>
<td>Medical impact of new products</td>
<td>10%</td>
<td>29%</td>
<td>39%</td>
<td>17%</td>
<td>6%</td>
</tr>
<tr>
<td>Commercial effectiveness</td>
<td>7%</td>
<td>32%</td>
<td>36%</td>
<td>17%</td>
<td>2%</td>
</tr>
<tr>
<td>Overall profitability</td>
<td>8%</td>
<td>27%</td>
<td>32%</td>
<td>25%</td>
<td>4%</td>
</tr>
</tbody>
</table>

What are the biggest challenges that your organization has faced, or that you foresee, as a result of health care reforms globally?
(Respondents selected up to three)

- Dealing with new/reformed government agencies that are still working out how to operate in the new environment: 42%
- Adjusting our commercial model to reflect changes in reformed marketplaces: 41%
- Proving value of our products compared to existing ones, especially generic products: 34%
- Developing a comprehensive response to the diverse reforms in different countries: 29%
- Gathering new types of data (e.g., economic data, more detailed outcomes data): 28%
- Refocusing innovation on medical areas that may yield more profits (e.g., areas with greater unmet need): 28%
- Responding to reduction to our income that has resulted from reform designs: 23%
- These reforms do not represent any significant challenge: 4%
- Don’t know: 4%
- Other: 1%
What are the biggest benefits you foresee for your company arising from major government health care reforms?  
(Respondents selected up to three)

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Selection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greater rewards for our ability to innovate</td>
<td>36%</td>
</tr>
<tr>
<td>Greater rewards for meeting unmet medical needs with our current level of expertise</td>
<td>32%</td>
</tr>
<tr>
<td>Greater clarity over how reimbursement decisions are made</td>
<td>25%</td>
</tr>
<tr>
<td>Increasing income as a result of our products being reimbursed in growing developing markets</td>
<td>25%</td>
</tr>
<tr>
<td>Greater rewards for our ability to keep down manufacturing costs</td>
<td>25%</td>
</tr>
<tr>
<td>Greater access to health care system data (e.g., aggregated patient data) that we can use in our research</td>
<td>24%</td>
</tr>
<tr>
<td>These reforms do not represent any significant challenge</td>
<td>19%</td>
</tr>
<tr>
<td>Don't know</td>
<td>4%</td>
</tr>
<tr>
<td>Other</td>
<td>2%</td>
</tr>
</tbody>
</table>

Compared to peer companies, how would you rate your organization's performance in the following areas?  
(Respondents rated on a scale from ‘much better than peers’ to ‘much worse than peers’)

<table>
<thead>
<tr>
<th>Area</th>
<th>Much better than peers</th>
<th>Somewhat better than peers</th>
<th>On par with peers</th>
<th>Somewhat worse than peers</th>
<th>Much worse than peers</th>
<th>Don't know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial performance</td>
<td>12%</td>
<td>41%</td>
<td>36%</td>
<td>9%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Ability to get on formulary at desired price</td>
<td>8%</td>
<td>24%</td>
<td>41%</td>
<td>8%</td>
<td>18%</td>
<td>2%</td>
</tr>
<tr>
<td>Flexibility in the face of changing market conditions/payer demands</td>
<td>9%</td>
<td>40%</td>
<td>34%</td>
<td>11%</td>
<td>2%</td>
<td>4%</td>
</tr>
<tr>
<td>Ability to interact with regulators</td>
<td>10%</td>
<td>31%</td>
<td>43%</td>
<td>12%</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Ability to develop innovative products/enhance pipeline</td>
<td>15%</td>
<td>31%</td>
<td>43%</td>
<td>11%</td>
<td>2%</td>
<td>5%</td>
</tr>
</tbody>
</table>
What type of company will gain or lose influence in the new health care environment as a result of major health care reforms?

- Gain influence
- Remain the same
- Lose influence
- Don’t know

Health care providers:
- 28% Gain
- 39% Remain
- 27% Lose
- 6% Don’t know

Biotech companies:
- 24% Gain
- 44% Remain
- 16% Lose
- 4% Don’t know

Pharmaceutical companies:
- 24% Gain
- 34% Remain
- 38% Lose
- 4% Don’t know

Generics makers:
- 60% Gain
- 30% Remain
- 7% Lose
- 3% Don’t know

Medical devices companies:
- 24% Gain
- 49% Remain
- 22% Lose
- 5% Don’t know

Health care providers:
- 28% Gain
- 39% Remain
- 27% Lose
- 6% Don’t know

Health care payers:
- 49% Gain
- 28% Remain
- 17% Lose
- 5% Don’t know

Health care distributors:
- 20% Gain
- 43% Remain
- 28% Lose
- 9% Don’t know

Have major government health care reforms of recent years, and the changed role of government agencies in the marketplace, significantly increased any of the following? (Respondents selected all that applied)

- Financial risk of early-stage development of new products: 47%
- Regulatory risk: 45%
- The importance of political considerations in determining market success: 34%
- Clarity of payer expectations: 23%
- Corruption risk: 20%
- Certainty over intellectual property protection: 20%
- None of the above: 20%
- Other: 13%
- None of the above: 3%
Do you generally agree or disagree with the following?
(Respondents selected one for each row)

<table>
<thead>
<tr>
<th>Statement</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most major government health care reforms of recent years institute changes that life sciences companies would have to adjust to eventually anyway</td>
<td>67%</td>
<td>24%</td>
<td>9%</td>
</tr>
<tr>
<td>My company’s response to health care reforms tends to be reactive rather than part of broader, considered strategic change</td>
<td>41%</td>
<td>39%</td>
<td>20%</td>
</tr>
<tr>
<td>The life sciences industry as a whole has been too vigorous in publicly resisting some common changes in health care reform (e.g., value-based pricing)</td>
<td>41%</td>
<td>37%</td>
<td>22%</td>
</tr>
<tr>
<td>I expect other factors (e.g., economic environment, demographic shifts) to have a more significant impact on my organization’s business strategies than health care reform</td>
<td>46%</td>
<td>34%</td>
<td>19%</td>
</tr>
<tr>
<td>My organization is ready to meet the changes that health care reform requires</td>
<td>51%</td>
<td>40%</td>
<td>8%</td>
</tr>
<tr>
<td>Health care reforms worldwide will largely achieve their stated care improvement</td>
<td>23%</td>
<td>39%</td>
<td>38%</td>
</tr>
<tr>
<td>Health care reforms worldwide will largely achieve their cost mitigation aims</td>
<td>31%</td>
<td>36%</td>
<td>32%</td>
</tr>
</tbody>
</table>

Among the following group of countries, in which is your organization most active?
(Respondents selected up to two)

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>35%</td>
</tr>
<tr>
<td>Germany</td>
<td>31%</td>
</tr>
<tr>
<td>Brazil</td>
<td>20%</td>
</tr>
<tr>
<td>None of these</td>
<td>34%</td>
</tr>
</tbody>
</table>
Thinking of your operations in Brazil, have recent government health care reforms made it more or less attractive to do any of the following there? (Respondents selected one for each row)

<table>
<thead>
<tr>
<th>Activity</th>
<th>More attractive</th>
<th>No change</th>
<th>Less attractive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engage in R&amp;D</td>
<td>46%</td>
<td>51%</td>
<td>4%</td>
</tr>
<tr>
<td>Seek formulary access</td>
<td>36%</td>
<td>57%</td>
<td>7%</td>
</tr>
<tr>
<td>Engage in manufacturing activity</td>
<td>48%</td>
<td>43%</td>
<td>9%</td>
</tr>
<tr>
<td>Set remunerative prices</td>
<td>42%</td>
<td>62%</td>
<td>17%</td>
</tr>
<tr>
<td>Engage in sales efforts/commercial operations</td>
<td>57%</td>
<td>38%</td>
<td>5%</td>
</tr>
<tr>
<td>Reach a wider population</td>
<td>74%</td>
<td>23%</td>
<td>4%</td>
</tr>
</tbody>
</table>

Again thinking of your operations in Brazil, is your company likely to increase or decrease the following in the next three years? (Respondents selected one for each row)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Increase</th>
<th>No change</th>
<th>Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D activity</td>
<td>44%</td>
<td>53%</td>
<td>4%</td>
</tr>
<tr>
<td>Number of new products for which it seeks formulary access</td>
<td>64%</td>
<td>34%</td>
<td>2%</td>
</tr>
<tr>
<td>Manufacturing activity</td>
<td>57%</td>
<td>43%</td>
<td>19%</td>
</tr>
<tr>
<td>Sales/commercial activity</td>
<td>81%</td>
<td>19%</td>
<td></td>
</tr>
</tbody>
</table>

In Brazil, which of the following stakeholders understand the difficulties involved in commercial development and production at least somewhat well? (Respondents selected all that applied)

- Health technology agency officials: 64%
- Regulators: 61%
- Policy makers/politicians: 44%
- The general public: 8%
Thinking of your operations in China, have recent government health care reforms made it more or less attractive to do any of the following there? (Respondents selected one for each row)

- Engage in R&D: 62% More attractive, 35% No change, 3% Less attractive
- Seek formulary access: 47% More attractive, 48% No change, 6% Less attractive
- Engage in manufacturing activity: 56% More attractive, 38% No change, 6% Less attractive
- Set remunerative prices: 30% More attractive, 55% No change, 15% Less attractive
- Engage in sales efforts/commercial operations: 50% More attractive, 45% No change, 5% Less attractive
- Reach a wider population: 69% More attractive, 27% No change, 4% Less attractive

Again thinking of your operations in China, is your company likely to increase or decrease the following in the next three years? (Respondents selected one for each row)

- R&D activity: 70% Increase, 29% No change, 1% Decrease
- Number of new products for which it seeks formulary access: 70% Increase, 30% No change, 0% Decrease
- Manufacturing activity: 67% Increase, 31% No change, 2% Decrease
- Sales/commercial activity: 82% Increase, 16% No change, 2% Decrease
In China, which of the following stakeholders understand the difficulties involved in commercial development and production at least somewhat well?
(Respondents selected all that applied)

- Health technology agency officials: 60%
- Regulators: 56%
- Policy makers/politicians: 40%
- The general public: 14%

After health care reforms in China are fully implemented, do you expect a stable regulatory playing field in the medium term (5 years)?

- Yes, there will not be any further reform: 6%
- Yes, there will be very little reform: 29%
- No, there will be moderate reform: 41%
- No, there will be substantial reform: 12%
- Don’t know: 12%

Thinking of your operations in Germany, have recent government health care reforms made it more or less attractive to do any of the following there?
(Respondents selected one for each row)

- Engage in R&D: 20% more attractive, 61% no change, 19% less attractive
- Seek formulary access: 21% more attractive, 59% no change, 20% less attractive
- Engage in manufacturing activity: 13% more attractive, 61% no change, 26% less attractive
- Set remunerative prices: 14% more attractive, 56% no change, 30% less attractive
- Engage in sales efforts/commercial operations: 28% more attractive, 44% no change, 28% less attractive
- Reach a wider population: 27% more attractive, 56% no change, 18% less attractive
In Germany, which of the following stakeholders understand the difficulties involved in commercial development and production at least somewhat well?
(Respondents selected all that applied)

- Health technology agency officials: 58%
- Regulators: 51%
- Policy makers/politicians: 41%
- The general public: 14%

After health care reforms in Germany are fully implemented, do you expect a stable regulatory playing field in the medium term (5 years)?

- Yes, there will not be any further reform: 7%
- Yes, there will be very little reform: 27%
- No, there will be moderate reform: 40%
- No, there will be substantial reform: 16%
- Don’t know: 11%
Which best describes your organization?

- Pharmaceutical company: 36%
- Medical devices and diagnostics company: 13%
- Service provider (e.g., contract research organisation (CRO)): 8%
- Biotechnology company: 3%
- Generic pharmaceutical company: 2%
- Other life sciences: 20%

In which country are you personally located?

- United States of America: 30%
- India: 16%
- United Kingdom: 14%
- Switzerland: 5%
- Germany: 3%
- Spain: 3%
- Canada: 2%
- France: 2%
- Italy: 2%
- Australia: 2%
- China: 2%
- Other: 19%
In which region are you personally located?

- Western Europe: 33%
- North America: 26%
- Asia-Pacific: 22%
- Middle East and Africa: 4%
- Latin America: 3%
- Eastern Europe: 2%
- Other: 7%

What are your organization’s global annual revenues in U.S. dollars?

- $500m or less: 25%
- $500m to $1bn: 14%
- $1bn to $5bn: 42%
- $5bn to $10bn: 12%
- $10bn or more: 7%

Which of the following best describes your title?

- Board member: 2%
- CEO/President/Managing director: 22%
- CFO/Treasurer/Comptroller: 5%
- CIO/Technology director: 5%
- CMO/Marketing officer/Medical officer: 3%
- CRO/Risk officer: 1%
- Other C-level executive: 5%
- SVP/VP/Director: 20%
- Head of business unit: 5%
- Head of department: 8%
- Manager: 20%
- Other: 3%
What are your main functional roles?
(Respondents selected up to three)

- General management: 33%
- Strategy and business development: 32%
- Marketing and sales: 24%
- Finance: 18%
- Operations and production: 15%
- R&D: 14%
- IT: 12%
- Human resources: 7%
- Supply-chain management: 7%
- Information and research: 6%
- Procurement: 6%
- Customer service: 5%
- Risk: 4%
- Legal: 2%
- Other: 6%
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