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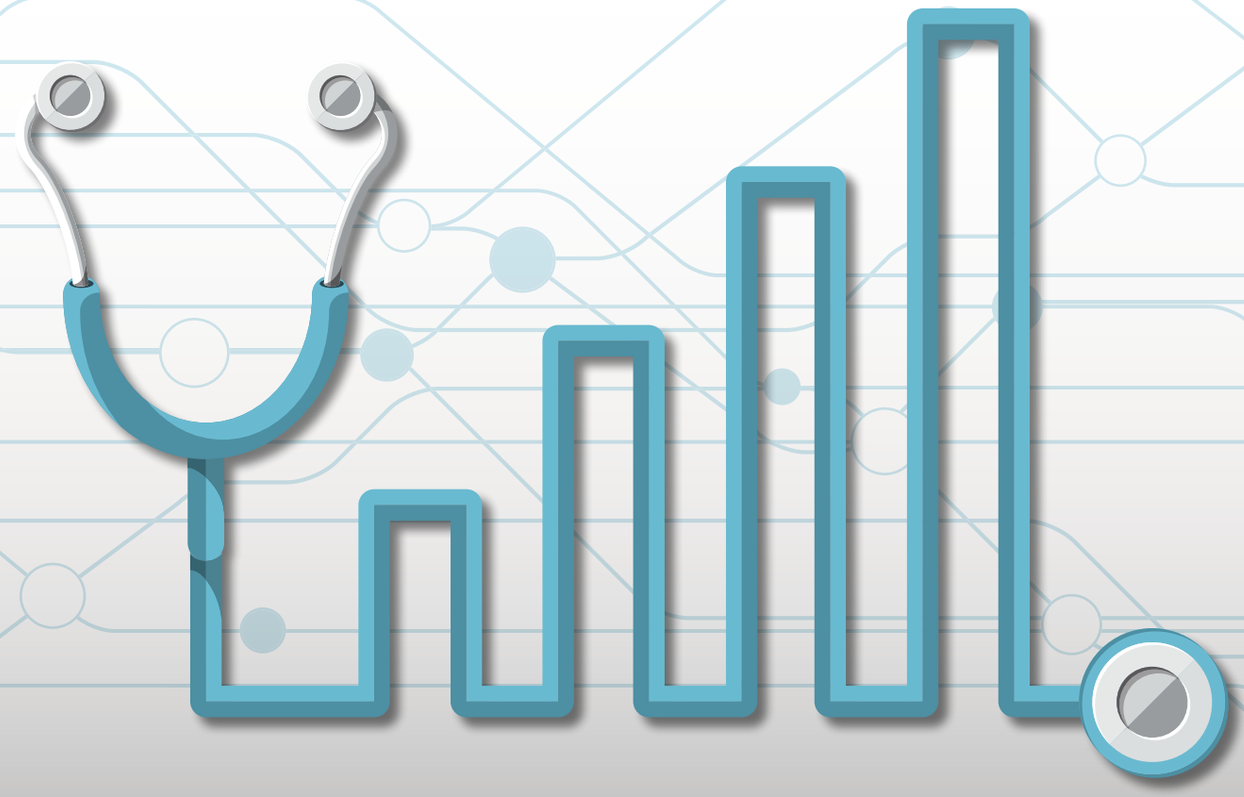
2015 Life Sciences Trends

Moving into 2015, life science companies will continue to find new avenues for decreasing costs, streamlining operations and improving shareholder value. Companies will maintain focus on therapies, technologies and investments that capitalize on their core business strengths, whether through partnerships or by divesting underperforming units. Commercialization and regulatory hurdles will remain a primary concern, particularly as generic and biologic drugs further penetrate world markets and governments and payers push for lower prices. A top priority for many life science companies is how to mitigate these challenges while also proving the value of their therapies to payers and patients.



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01 | STRATEGY

Whether by divesting underperforming units or investing in complementary treatments, life science companies are looking for ways to improve their bottom line. As they examine their long-term strategies, they must take into account how expanding global patient populations and increasing competition from generic and biologic drugs will impact their business models.

Industry Consolidation

In 2015, life science com¬panies will continue to refine their portfolios and redefine their business models through mergers, acquisitions and divestitures. While much of the 2014 M&A activity was attributed to tax inversions, others were aimed at gaining a strategic advantage, whether by strengthening their pipeline or eliminating underperforming or costly units. GlaxoSmithKline Oncology and Novartis Vaccines, Bayer and Merck Consumer Health, and Eli Lilly and Novartis Animal Health were a few that gained attention doing the latter. Additionally, contract manufacturer exits are increasing due to limited capacity for their own product manufacturing, growing demand for injectables (driven by biopharma and biosimilars), and quality issues; notable exits include Boehringer-Ingelheim Contract Manufacturing, Bayer Pharma Manufacturing Services, and Ben Venue.[1]

Innovative, Orphan & Specialty Drugs

As more drug patents expire, and generic competition strengthens, companies will continue to look for innovative, high-value treatments to add to their pipelines. The number of orphan and breakthrough designation applications is increasing, with steady approval rates predicted through 2018. Specialty medicines will drive approximately 40 percent of global growth over the next three years, the majority of which focus on oncology, anti-infectives and antivirals, and central nervous system (CNS) disorders.[2]

Emerging Market Expansion

As drug spend and consumption increases, companies will have to find ways to reach global patient populations safely and cost-effectively. With turmoil in the Middle East and unrest in other areas, disruptions will continue to impact global supply chains. In addition, local and regional regulations regarding labeling, packaging, pricing, and licensing deter companies from entering markets like India and China.

To curb the high costs of medication and improve access, governments in emerging markets may impose price controls or regulations that require drugs to be “manufactured in country.” Depending on the governing body, “manufactured in country” could mean repackaging or the complete manufacture of product; either of these will undoubtedly increase costs for companies with branded product unless they have infrastructure in place to support in-country operations. Similarly, compulsory licensing legally forces these companies to license their product to a local company, and also requires them to take on the fees dictated by the government.

The majority of growth in pharmerging markets, however, will be attributed to generics and non-branded medicines.[3] Many of these drugs are manufactured by multiple companies; as with their brand counterparts, quality will remain a primary concern.

02 | INNOVATION *and* R&D

The melding of healthcare, technology and big data has, and will continue to, improve drug access, adherence and tracking over the coming years. With these advances – whether 3D printing, cloud-based platforms, or wearables – HIPAA and data storage, transmission and security are primary concerns. In addition, with the cost and skills that technology development requires, pharma and biotech companies will seek partnerships with tech and medical device companies, and vice versa.

Big Data & Analytics

Even though big data is a buzzword across industries, life science companies are approaching it cautiously. The volume of information will only increase over the coming years; and when partnered with HIPAA guidelines, companies are unsure of which data to analyze and how to do so efficiently and effectively. Companies at the forefront are investing in e-clinical applications, cloud-based drug discovery platforms, EHR-based clinical studies, and cloud-based electronic laboratory notebooks (ELNs) among other technologies – each of which can help reduce cost, streamline the clinical trial process and improve data sharing and collaboration among partners throughout the value chain.

Particularly within R&D, mining clinical trial data, genetic information and demographic/population data could provide insight for determining which therapies may be most valuable, defining potential risks and side effects, and even targeting future research.[4] To capitalize on any such scientific big data initiative, companies should first evaluate the size and complexity of the challenge and then ensure that the solution is scalable.[5]

Personalized Medicine

While personalized medicine has been gradually gaining interest for the past several years, companies are beginning to see its importance in their long-term strategies. Particularly with the development of more powerful sensors, the emergence of 3D printing and big data advancements, companies have a tremendous opportunity to cater their therapies to the needs of specific populations, and even individuals. David Guzman, CIO of healthcare distributor H. D. Smith, says the transformation towards more prescriptive therapies is already underway, but will only be successful if data is delivered back upstream just as it is relayed and captured going downstream.[6] This shift, however, will require close collaboration among IT, quality, security, legal and regulatory teams, in addition to the integration of IT and health data systems. Evaluating health economics and proving value to both payers and patients will be critical to the success of personalized medicine.

Merging Health & Technology

While healthcare data and technology work together to refine therapies for optimal patient outcomes, life sciences and tech are also looking to each other for business partnerships. In 2014, Novartis signed deals with both Google and Proteus Digital Health to develop technologies that would help with tracking real-time patient data and adherence (contact lens and tablet-embedded microchips).[7] Following suit, other tech industry leaders like Samsung and Apple are also exploring opportunities to introduce health applications into their wearable products. With investment in medical devices declining nationally due to a restrictive regulatory environment and unreliable returns, tech companies can provide a level of financial stability and innovation that may further advances in remote monitoring, real-time data capture or even 3D printing of medical devices – all of which contribute to the overall improvement of patient outcomes and demonstrate the economic value to payers.

03 | SUPPLY CHAIN

With expanding global patient populations, manufacturer consolidation, and big data and technology advancements, supply chain effectiveness is vital to business success. Life science companies are finding ways to better forecast demand and build more agile supply chains, capitalizing on real-time data solutions. In addition, to comply with U.S. Drug Supply Chain Security Act requirements, companies at the forefront are collaborating with trading partners and strategically investing in serialization solutions and pilot programs that can improve efficiency and drug safety.

Globalization & Consolidation Impacts

Whether considering contract manufacturing consolidation or delivering medicines to global patient populations, impacts to the supply chain can be problematic and costly. For pharmaceutical companies, consolidation may prove more difficult as retailers and wholesalers begin to form joint ventures to increase their buying power. Especially as companies attempt to evaluate inventory and accurately forecast demand, historical information is no longer accurate, creating a classic bullwhip effect. To mitigate this issue, and potential future impacts, companies are assessing their supply chains and implementing systems that will capture relevant, real-time data and improve forecasting accuracy.

Supply Chain Agility

With strengthening competition among generics and branded drugs, and the increasing ability to capture real-time information, life science companies are being pushed to develop more agile supply chains. Many pharmaceutical companies are trying to shift from the standard industrial manufacturing mentality to the current state: where demand for product can easily shift among manufacturers. Companies must determine which methods and technologies will allow them to better sense demand and immediately respond, which may include postponement or decoupling strategies, rapid response systems, or tailored ERP or cloud solutions. Considering industry demand volatility, coupled with impacts from quality and global unrest, companies can only benefit from building flexibility into their supply chains.

Serialization and Track & Trace

DSCSA requires that all manufacturers, repackagers, wholesalers, and third party logistics providers (3PLs), have a means of transmitting lot level product, transaction and legal information to trading partners either electronically or on paper by January 1, 2015 (dispensers have until July 1, 2015). Parties must also develop verification methods to determine whether a product is a valid, suspect or illegitimate, and notify trading partners if such a product is identified. While not currently mandated, DSCSA strongly suggests that companies implement secure electronic databases so that they can quickly locate information and respond to federal or state officials within 24 hours of an investigation or recall.

While not immediate, the deadline for serialization by all manufacturers is November 27, 2017. At which time, each package and homogeneous case of pharmaceutical product manufactured or sold in the United States and its territories must be identified by a unique product identifier. Many companies have begun implementing serialization solutions, and trading partners will likely begin to require such systems for efficiency and compliance.

04 | COMMERCIALIZATION

Globally, healthcare costs are impacting how life science companies bring therapies to market. Companies are focusing on building their pipelines in specialized areas, subsequently considering demand and the likelihood of regulatory approval. However, to garner an affable return, companies will need to collaborate with payers and providers to demonstrate improved adherence, innovation, and overall improved patient outcomes.

Emergence of Biosimilars

Despite limited U.S. FDA guidance on developing biosimilars, globally, biologics make up 36 percent of late-stage pipelines.[8] While analysts are predicting the global market for biologics to increase dramatically over the next five years, they will likely have a limited impact in developed markets.

Sandoz and Celltrion[9] applied for approval under the 351(k) pathway midway through 2014, which will likely force the FDA to answer the industry's questions surrounding substitutability and naming of biosimilars.[10] Even with this incremental push forward, the cost to develop biosimilars may currently outweigh the benefits; Sandoz estimates that developing biosimilars costs approximately $75 to $250 million, compared to $2 to $3 million for generic small molecules.[11] Generics manufacturers will need to examine their long-term growth strategies to determine if the benefits will outweigh the potentially lofty investment in biosimilars.

Pricing Pressures

Drug spend in the U.S. will remain one of the highest in the world,[12] and spend will continue to rise in emerging markets due to population growth, rising income levels, and increasing access to healthcare. Despite this increase, companies are under even more scrutiny to prove the value of their therapies, particularly since expanding healthcare coverage is straining payer budgets. With slightly fewer drugs coming off patent this year, and generics competition escalating, brands and generics will continue to offer price concessions, and many will begin looking for partnerships that will help them both analyze and validate the full value of their products.[13]

CONTINUE *the* DISCUSSION

About the Author

Janel Firestein leads Clarkston Consulting's Life Sciences practice and has been helping senior executives in pharmaceutical, medical device, and biotechnology firms address their business challenges for the past decade. During her tenure with Clarkston Consulting, she has become a recognized expert, delivering business results in the areas of regulatory compliance, business process improvement, change management, product development, quality systems, and strategy.

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References

1 Miller, Jim. "CMO Industry Thins Out." PharmTech.com. October 2, 2014.

2,3 IMS Institute for Healthcare Informatics. Global Outlook for Medicines Through 2018. November 2014.

4 Shanler, Michael & Stephen Davies. Hype Cycle for Life Sciences, 2014. Gartner, Inc. July 30, 2014.

5 Shanler, Michael. Scientific Big Data Opportunities in R&D Require a Stricter Framework for Evaluation. Gartner, Inc. May 2, 2014.

6 Bendor-Samuel, Peter. "Personalized Medicine Rests On Cloud At H.D. Smith. Information Week." September 16, 2014.

7 Hirschler, Ben. "World's top drugmaker Novartis takes aim at tech." Reuters Online. November 17, 2014.

8 IMS Institute for Healthcare Informatics. Global Outlook for Medicines Through 2018. November 2014.

9 Garde, Damian. "Celltrion targets J&J's Remicade as biosimilars loom in the U.S. FierceBiotech." August 12, 2014.

10 Gaffney, Alexander. "Sandoz First Company to File for Biosimilar Approval in US Under New Pathway." Regulatory Affairs Professional Society (RAPS) website. July 24, 2014.

11 Amgen Inc. Biologics and Biosimilars Overview. Amgen website.

12 Chen, Caroline. "World's Drug Bill Will reach $1.3 Trillion in 2018: Study." Bloomberg website. November 20, 2014.

13 The Economist Intelligence Unit. Value-based healthcare: The implications for pharma strategy. March 2014.

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