

Pharmaceutical Industry Outlook

Together, industry regulations and healthcare reform are impacting how pharmaceutical companies do business. Drug makers are experiencing a heavy financial burden, due not only to required rebates and the Branded Prescription Drug Fee, but also from investments to secure their supply chain. In addition, increasing pressures from consumer advocacy groups and regulatory agencies are forcing drug makers to reconsider how they engage customers and prove the value of their products.



Healthcare Reform

With the Affordable Care Act in full effect, how will your company engage ACOs, payers, and consumers, and prove the value of your products?



Innovation & R&D

The industry dynamic is shifting, and larger pharma companies are looking to smaller, more nimble firms to supplement their pipelines. How will your company engage these firms and prepare for future growth?



Regulatory Changes & Emerging Markets

Is your company prepared to address tightening regulatory demands and quality or ethical issues that may arise on an international scale?

Healthcare Reform



While the pharmaceutical industry has been a key supporter of the health reform agenda, the Affordable Care Act (ACA) has already begun to impact companies, both financially and operationally. Pharmaceutical companies are responsible for the Branded Prescription Drug Fee, which is expected to cost the industry an estimated \$30 billion by 2021, and drug makers are also required to provide rebates to offset the benefits provided to the uninsured.¹ To offset these rising costs, many companies are reevaluating how they market and sell their products in the US.

Value Based Services and ACOs

The ACA creates incentives for providers to move away from a fee for service to a value based model. Many providers are forming Accountable Care Organizations (ACOs) to provide better value, particularly as they bear greater risk when determining which therapies are best for patients. ACOs want to ensure that patients get the right care at the right time, while avoiding duplication of services and medical errors. ACOs will be responsible for a significant portion of healthcare spend, so pharmaceutical companies will have to develop strategies to engage with this new customer base, and effectively demonstrate the value of their products to them.

Payer Collaboration

Along with ACOs, payers are also demanding evidence of value before considering therapies for their formularies. The ACA is already impacting payer margins, and as new requirements around individual coverage and pre-existing conditions go into effect, their financial burden may increase. Pharmaceutical companies marketing differentiated products with demonstrated value will have more control over the product's pricing; however, these companies

should proactively perform post-market studies, continuously evaluating real world data to ensure their product effectiveness claims are being met. More now than ever, pharmaceutical companies will need to collaborate with payer organizations to provide valuable therapies while also considering ways to reduce associated costs and risks.

Evolving Sales Models

As the ACA goes into full effect, pharmaceutical companies are also reconsidering how they engage medical professionals to promote products. GlaxoSmithKline recently announced that it intends to suspend a long-standing practice of compensating physicians to speak about products on its behalf, and others are also drastically reducing such promotional expenditures. As the Physician Payment Sunshine Act is implemented later this year, patients and consumer advocacy groups may see this type of activity as a conflict of interest. While some companies are reducing these types of expenses because they simply have less drugs to promote, all are considering new ways to sell in this changing healthcare marketplace.

Navigating the trend

- How will you collaborate with payers, ACOs, and potentially competitors to provide value to patients and physicians?
- How will the introduction of new ACOs affect R&D, sales, and marketing at your company?
- Considering the increasing influence of ACOs, payers, and consumers, how will you adjust your sales and marketing tactics?



R&D & Innovation

Historically, large pharmaceutical firms have outsourced drug development while maintaining research internally to ensure confidentiality. While discovering new drugs has long been the core competency of Big Pharma, innovation is now occurring at a faster pace among smaller, more nimble firms. The industry is showing more interest in helping new biotech startups, particularly those that may produce therapies to fill depleting pipelines. Even though such research agreements could put new products in the hands of competitors, the pharmaceutical industry is realizing that creating this revolutionary ecosystem will benefit market players and payers alike.

Managing Product Portfolios

The number of drugs in pharmaceutical pipelines is dwindling, as is their return on R&D investments. Pharma companies are urgently trying to bring new products to market, driven by the emergence of generics, the patent cliff, pricing pressures, and emerging market demands. In this post-blockbuster era, companies must aggressively manage their resources and pipeline, carefully evaluating and controlling which products are pushed through the development cycle, and ensuring that those valuable enough move along efficiently. With increasing pressures to demonstrate efficacy and value, organizations need to objectively assess each therapy and determine if, and how, they will be differentiated from others in the marketplace.

Building a Growth Strategy

Over the next decade, with the market and regulatory landscape shifting, pharmaceutical companies will need to assess their capabilities and reevaluate their business strategies with these factors in mind. Pharmaceutical organizations need to weigh the risks and rewards involved with each investment and when bringing new drugs to market. They should also consider whether the new product or service will enhance the core business and whether

knowledge and expertise can be leveraged from other areas of the business. Whether through organic growth or mergers and acquisitions, pharma companies will need to consider how their strategy will fare in an increasingly competitive environment driven by an evolving healthcare system.

Emergence of Personalized Medicine

The use of personalized medicine has grown rapidly, proving that there is great value in developing therapies and tests that are tailored to the individual patient. While still in a growth phase, pharmaceutical companies have a unique opportunity to help shape the personalized medicine model; by facilitating collaboration among physicians, clinicians, and patients, companies can help ensure that the complexities of diseases and associated diagnoses are clearly understood. This type of collaboration will enable an accurate and efficient transfer of knowledge and information, allowing physicians to better diagnose patients and allowing pharmaceutical companies to better understand the demands and preferences of the patient populations they serve. In turn, this model would support the development of innovative therapies or services for patients and physicians.

Navigating the trend

- New patents will be more critical than ever. How will you maintain a robust pipeline of drugs while mitigating R&D costs?
- How will the emergence of new services such as personalized medicine drive innovation and new product development?
- How will the evolving healthcare system and the need for innovation shape your growth strategy?



Regulatory Changes & Emerging Markets

Compliance is critical, and the risks of being non-compliant are escalating across the globe. The Drug Quality and Security Act (DQSA) which passed in the US in 2013, imposes serialization and track & trace requirements for manufacturers over the next few years, and many other countries have similar guidelines in place. Fluctuating demographic and regulatory dynamics, particularly in emerging markets, will continue to impact demand and compliance requirements for pharmaceutical organizations.

Securing the Supply Chain

Pharmaceutical organizations have been grappling with how to best to secure their supply chain to mitigate diversion, counterfeiting, and theft for years. With the recent passage of DQSA, federal legislation provides guidance on incrementally implementing systems and processes to identify and track pharmaceutical product as it moves through the supply chain. In addition to DQSA, organizations that distribute products internationally will have to abide by country specific regulations. Pharmaceutical companies need to understand the various timelines, and ensure that they design and implement serialization processes that are integrated across the global supply chain.

Changing Regulatory Environment

The FDA, Brazil ANVISA, and European EMEA are a just a handful of agencies that are introducing regulations to control the manufacture and distribution of pharmaceutical products. While their goal is to ensure patient safety by eliminating fraud and corruption, these regulatory changes, along with changes in the healthcare landscape, will require pharmaceutical organizations to divert significant resources

to ensure compliance. In addition, maintaining quality requirements and safeguarding information security and privacy will require robust closed systems, which will place an additional burden on pharma companies.

Engaging Emerging Markets

It is estimated that between now and 2017, the compounded annual growth rate for developed markets will be between one and four percent, while the growth rate in the pharmerging markets will be between 11 and 14 percent.² China and India are among the top five emerging markets and are experiencing double digit growth. This growth has been accompanied by intellectual property violations, corruption surrounding incentives, and challenges related to third party interactions, accountability, and controls. As western pharmaceutical organizations develop strategies to enter emerging markets, they must conduct thorough assessments to ensure their intellectual property, supply chain, and product quality will not be compromised. If companies do not understand and mitigate these challenges, they risk not only losing revenue, but also customers and brand equity.

Navigating the trend

- What is your firm doing to prepare for evolving global regulatory requirements?
- If operating in emerging markets, what controls are in place to ensure the quality and security of product and information?
- How is your firm poised to engage companies in India and China? Does your organization have a strategy for dealing with potential supply chain and quality issues?

Continue the Discussion



About the Authors

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Thought Leadership to Reference

- Research Report: *2014 Life Sciences Trends Report*
- Case Study: *World-Class Solution Injects Consistency & Efficiency in Supply Planning*



- Case Study: *Piloting Serialization*
- Insights Paper: *Build an Effective Merger, Acquisition & Divestiture Execution Capability*



- Insights Paper: *Contract Manufacturing Partnerships: Identifying the “Best Mix” of the Right Partners*
- Insights Paper: *One More Look at Quality Systems Maturity*
- Solution Overview: *Serialization & Traceability*

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- 1 Japsen, Bruce. *Obamacare Will Bring Drug Industry \$35 Billion in Profits*. May 2013.
- 2 Cook, Elisabeth. *IMS Health. Global Pharma Market Outlook – With a Focus on Emerging Markets*. 2013.

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