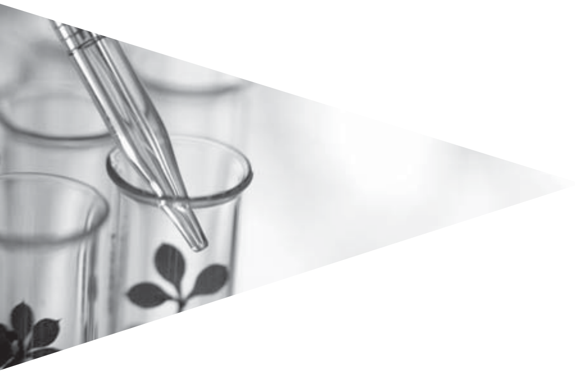
Perspectives from
the Ernst & Young
Global Pharmaceutical Center

Prescriptions



Optimizing supply chain management

A combination of reduced growth, lower margins and less productive outcomes in drug discoveries and therapeutic breakthroughs is forcing a major overhaul of the traditional business model for the pharmaceutical industry. Supply chain optimization and operations effectiveness to "right-size" the business have become an important part of that change, as companies turn their focus to more sustainable efficiency gains for their business. This shift can only be obtained by reassessing cost structures across the entirety of the enterprise.

From finding raw materials to manufacturing products to distributing them to customers, pharmaceutical companies are offloading non-critical functions to intermediaries, particularly in new and developing markets where they have limited experience. As the business model transforms and new "ecosystems" of business networks and alliances are formed, we are seeing shifts in how companies approach product sourcing, manufacturing and distribution, as well as how they set up the financing, taxation and capital allocation around processes and operations.

With more and more new players and new markets entering the pharmaceutical value chain, there can be increased vulnerability to counterfeiting and safety lapses, and the subsequent negative publicity and increased scrutiny from government authorities. Many emerging market countries, which are increasingly essential to the pharmaceutical industry, are trying to figure out how to best regulate drugs and medicines, leading to a complex array of new rules, regulations and tax obligations. The global financial crisis also adds a new dimension of stress and strain to the objective of continuity and predictability

As the industry's revenue growth becomes more dependent on emerging markets and less on developed countries in North America and Europe, the agility of a company's supply chain becomes critical to serving these new and often disparate markets. Performing at its best, a supply chain must be able to maintain quality and cost efficiencies, yet be able to quickly adjust as marketplace, supplier and distribution conditions change with the fluctuations of customer and product demand.

Fostering a "cash culture"

The pharmaceutical industry has long been among leading industries when it comes to creating tax-effective manufacturing structures. For decades, drug companies have actively focused on reducing costs through manufacturing in tax-favored jurisdictions, which optimized their worldwide effective tax rates and increased earnings per share. While almost all companies have focused on shifting manufacturing to low-tax jurisdictions, many opportunities still exist for tax optimization in other parts of the supply chain, such as distribution or a centralized procurement function.

This is one of a series of articles, written by thought leaders from the Ernst & Young Global Pharmaceutical Center, on current topics of interest to pharmaceutical and medical device companies. Reflecting our worldwide commitment to the pharmaceutical and medical device sectors, the Global Pharmaceutical Center is dedicated to offering relevant insights and industry leadership on the accounting, tax, risk, transactions, and industry issues facing executives and boards in today's complex, competitive and risk-driven environment. Through the Center, we link client service professionals from Ernst & Young member firms around the globe, facilitating collaboration and knowledge sharing, and the provision of seamless, consistent, high-quality client service worldwide.

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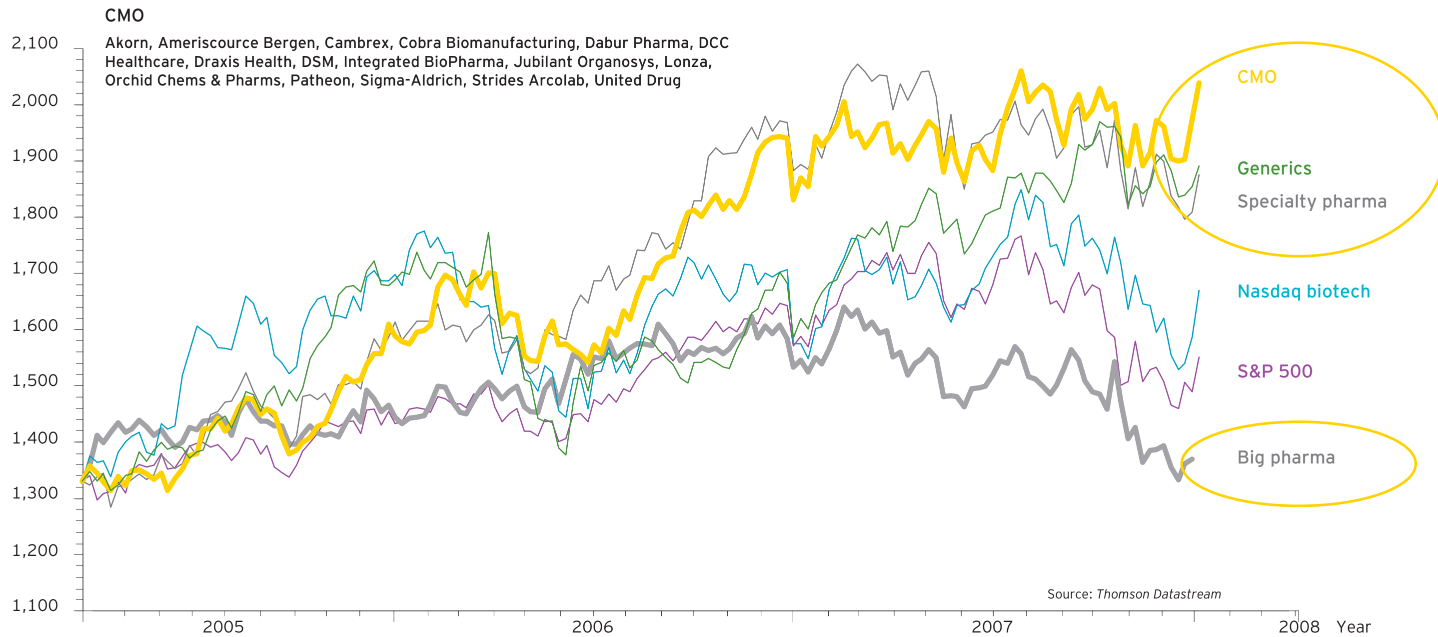
Quality In Everything We Do

A focus on core competencies seems to pay off

► The contract services segment is outperforming its adjacent peer groups



Big pharma

Abbott, Amgen, Astellas AstraZeneca, Bayer Schering, Bristol Myers Squibb, Daiichi Sankyo, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Novartis, Pfizer, Roche, Sanofi-Aventis, Schering-Plough, Takeda, Wyeth

Generics

Alpharma Aurobindo, Barr, Cipla , Dr. Reddy's, EastPharma, Gedeon Richter, Glenmark, Hikma, Hospira, Krka, KV Pharma, Lupin, Matrix, Mylan, Ranbaxy, Stada, Sun, TEVA, Veropharma, Watson, Wockhardt, Zentiva

Specialty pharma

A.P. Pharma, Allergan, Biovail, Elan, Endo Pharma, Forest, Ipsen, King, Lundbeck, Merck KgaA, Novo Nordisk, Recordati, Sepracor, Shire, Solvay, UCB, Vertex

Optimizing the supply chain may also offer significant operational savings by helping to reduce inventory levels and thus freeing up working capital. Today, manufacturing and supply chain efficiencies are becoming more critical as the industry's operating margins come under pressure and finance leaders seek the most cost-effective means for delivering their products to the marketplace.

Large, integrated pharmaceutical companies are also taking a cue from specialty companies, custom manufacturing organizations and generic makers, all of whom have optimized performance by specializing in just one or two niche areas of the supply chain. And the markets have rewarded these companies for the performance improvements and efficiencies gained. The contract services segment of the industry, for example, is outperforming the rest of the sector, enjoying the highest difference in valuation – 76.5% – against large integrated pharmaceuticals. The spread seems be widening, with the valuation of contract manufacturing organizations increasing by 50% over the past two to three years.

These companies recognized early on that effective supply chain management presented meaningful opportunities for achieving long-term, sustainable efficiencies. Investors are flocking to specialty pharma companies in part because of their success in developing a "cash culture" – or an operating environment that places heavy emphasis on rigorous working capital management. By comparison, big pharmas' lack of focus in this area has left literally billions tied up in its operating lines of business. In a survey Ernst & Young conducted in 2008 of the 16 leading US and European pharmaceutical companies, we found that between US$17 billion and US$35 billion of cash was unnecessarily locked up in working capital accounts, equivalent to 3% to 7% of their sales.

Lessons from other industries?

In an effort to reduce the amount of cash tied up in inventories, big pharma is reaching out to new partners across the supply chain and optimizing their manufacturing and distribution networks. Some are entering into inventory management agreements with wholesalers, while many are adopting fee-based and direct-to-pharmacy services to capture a greater share of the supply value chain.

Still others are looking to lessons learned from fast-moving consumer goods companies, which have spent the last decade outsourcing their manufacturing operations to low-cost markets to better compete with cheaper imports from abroad. Of course, some of the risks associated with those moves are amplified in an industry focused on positive health outcomes. Stock-outs of popular consumer goods are an inconvenience; shortages of essential drugs can ruin a pharmaceutical company's reputation and, in some cases, threaten lives.

Yet for most companies, the reality is that manufacturing represents a very valuable avenue for lowering profit in high-tax jurisdictions and moving it to lower-tax jurisdictions, which results in a lower effective tax rate. And they still have a long way to go in employing those means, with many companies outsourcing only select business functions without regard to the entire enterprise. Big pharma is still short on results and long on potential, especially compared with other industries like Japanese automakers or US information-technology firms that are far ahead in gaining cost efficiencies from multi-tiered supplier networks. Only about 22% of the pharmaceutical industry business practices that could be outsourced currently are, according to research by Goldman Sachs.[1]

Companies could benefit even further from considering the expansion of the role of their tax-favored locations to include processes outside of manufacturing. Cost reductions often can be had from eliminating redundancies in the executive corps, and spreading the talents of a smaller group among more regions. Similarly, key procurement, production scheduling, quality, marketing, logistics and distribution, and even research and development, for a particular region can all be centralized in a tax-favored jurisdiction. These activities are then taxed at a lower rate, and companies can minimize their indirect taxes on the movement of materials and goods.

From an operations perspective, a central hub can pull procurement levers like contracting volumes, integrate planning with key customers and suppliers, strengthen compliance with centralized export control regulations, and increase overall operating efficiency through improved control and visibility.

Companies that take such an integrated approach to streamlining the enterprise across and throughout its supply chain achieve four primary benefits:

- The successful management of risks: those functions within the business which actively manage the risks the company faces (such as financial, environmental, market and product liability risks)
- Exploitation of value-added functions: those functions which drive the company's competitive advantage and enable it to outperform industry peers
- Excellence in core operations: those functions necessary to operate in the market
- Major financial or organizational changes to support the business purpose for moving functions and risks to tax-favored jurisdictions.

For many, this systemic review is in the infant stages. Market conditions are changing quickly, and companies once able to stay on top of one or two principal markets are now charged with monitoring rapidly evolving developments in a widening collection of vastly different markets and countries.

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New markets, new customers, new risks

As the pharmaceutical industry extends its supplier networks to new domains, they are likewise trying to expand their customer base into new geographies and demographics. With the era of blockbuster drugs on the wane, some executives are looking to emerging markets to monetize the value of mature brands that have lost patent protection. Here, outsourcing the production of an active pharmaceutical ingredient or its supporting supply chain functions can help extract value from a mature brand. Marketing off-patent drugs in these markets at a price point that can be supported by the market can effectively extend the company's brand into an emerging market.

Enabling "glocal" access

Companies are beginning to think about strategies such as opening branded health clinics that stock their own drugs, and teaming with the makers of generic drugs or consumer products to increase their market access. A growing desire to be socially responsible is also driving efforts to make global access to medicine a real priority, particularly in underserved markets where affordability is a chief constraint.

"Think globally, act locally" is new for the pharmaceutical industry and will prompt market participants to adopt new market-specific business models. Just as important, this new global reach will necessitate a renewed focus on risk management, because as the supply chain becomes more fragmented and complex, the number of potential failure points increases exponentially. A growing collection of contract manufacturers, distribution partners and other service providers means the moving parts are multiplying, increasing the importance of a secure supply chain network that can stay on top of cross-border compliance risks.

Securing drug safety

Drug safety issues in this environment become more pronounced as lapses in this new supply chain paradigm pose real reputational and financial risks for all companies involved. While an optimal supply network takes advantage of efficiencies offered by individual companies, it also harbors incentives for organizations to cheat the system. The 2008 melamine contamination of baby formula in China underscored the horrific lengths some low-cost producers will go to save money and the challenges in ensuring adequate monitoring of individual suppliers.

For pharmaceutical companies, some sources of active pharmaceutical ingredients are

1 "One Step Ahead", PharmaTimes.com, November 2007

still not easily traceable; the challenge is putting systems in place to track products around the globe, and sniff out unscrupulous partners before their errors can do real harm. This kind of back-end risk is increasing as companies obtain active pharmaceutical ingredients, intermediates and packaging materials from a complex network of new and traditional sources from around the world.

Drug safety is a complex system of functions such as, validation, quality assurance and control, compliance, and monitoring and managing adverse events. Centralizing all or part of these functions for a product or a region can enhance control and potentially generate meaningful tax savings.

Evolving regulations

Due to rising public pressure, governments of new market participants are scrambling to develop their own regulatory standards associated with medicines and put the onus on industry participants to comply with these regulations. This is creating a quickly evolving patchwork of national rules and regulations, adding another layer of risk and cost for global pharmaceutical companies that don't have the capacity to continuously monitor these market-specific developments. The US Food and Drug Administration, for one, is starting to pay closer attention to current good distribution practices and the overall regulation of the drug supply chain.

Managing tax risk

Tax authorities around the world are becoming more and more sophisticated and tax treaty partners share more and more information. Aligning tax planning with business strategies facilitates tax risk management. The operational reengineering suggested in this article is intended to reduce costs and increase profits. Increased profits manifest themselves in the form of both additional shareholder value and taxable income. To support the sustainability of the location of taxable income in tax-favored jurisdictions, the business and tax models have to be aligned. If they are, the tax-favored jurisdictions will be housing employees with the requisite managerial talent and authority to fulfill these important, centralized functions, and the various economic substance requirements of the affected tax jurisdictions would be satisfied.

The costs of complying with international tax rules and trade agreements continue to rise. Within the last decade, the number of value added tax (VAT) systems in place around the world has proliferated. Noncompliance costs are keeping pace – with fines now common in the millions of dollars – as tax authorities around the world are beginning to share more and more information with each other. With global trade flows changing constantly, companies that are not set up to track them are paying dearly. In one case, a poorly conceived IT system resulted in a pharmaceutical company overpaying €60 million of non-recoverable VAT.

Uncovering peak performance

Large pharma has not given enough consideration to attaining the prerequisites for a smooth entry into emerging markets: local knowledge and selection of the right trade partners, distributors and brokers. Companies need to establish qualification criteria for these partners and compare them against local trade behaviors. They also need to better identify and leverage opportunities such as minimizing import duties and earning tax and excise relief.

In this era of shortening credit, shrinking margins and heightening risks, a system-wide evaluation of a supply chain can yield both big financial wins and long-term insights into strategy and innovation for the whole business. From optimizing tax-effectiveness, to improving inventory management and companywide cash flow, to focusing on core competencies and leveraging global partners and alliances, the pharmaceutical industry can take big strides towards uncovering peak performance.

The views reflected in this article are the views of the author and do not necessarily reflect the views of other members of the global Ernst & Young organization.

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