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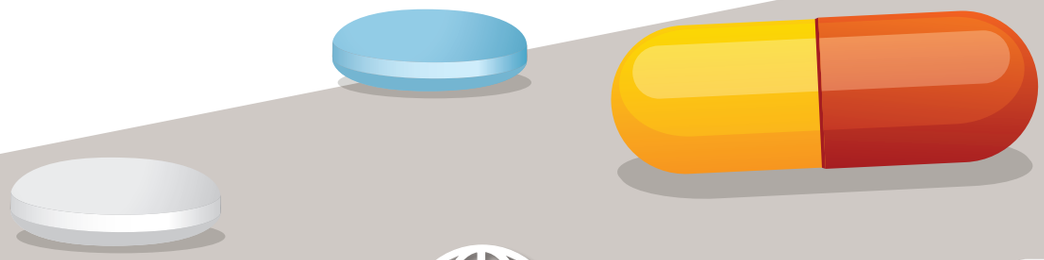
2014 Generics Industry Trends

The generic pharmaceutical industry remains one of the most entrepreneurial and dynamic facets of the healthcare system. According to IMS Institute for Healthcare, generic pharmaceuticals fill 80 percent of the prescriptions dispensed in the U.S., but consume only 27 percent of total drug spending. In addition, the use of FDA-approved generic drugs has saved U.S. consumers, patients, and the healthcare system more than $1 trillion over the past decade.[1] With several key issues and opportunities arising that will directly impact patient access and affordability, the coming year will be pivotal for the generics industry.

This report will discuss four trends shaping the generics industry, providing guidance on how companies can successfully navigate each.



Biosimilars

The competition is shaping up. Are you prepared to execute on your biosimilar strategy?

Compliance or Competitive Advantage

There are new regulations governing pharmaceutical supply. Will you just comply with these regulations, or realize their potential for competitive advantage?

Globalization of Quality

Can you extend your quality systems to support global supply networks and meet demand from emerging patient populations?

New Talent Strategies

Generic companies will need to rethink how they attract and retain talent in 2014. How will you win the battle for the best and brightest?

Biosimilars

With over $40 billion (in U.S. sales) of brand biologics coming off patent by the end of 2016, there is now more opportunity for generic drug makers than even before.[2] The industry will continue to see the focus shift from small-molecule drugs to biologics, but despite the potential for growth, this avenue still has many roadblocks. Generics companies are faced with a variety of challenges – from state legislative fights designed to impede access to new biosimilar medicines, to recent developments around the biosimilar naming convention. Addressing these challenges will allow the industry to expand its influence in the biosimilars market, while simultaneously increasing patient access to various medicines by lowering the cost of life-saving biologics.

State Legislative Fights

Although an opportunity for the generics market, biosimilars proved to be a significant threat for Big Pharma in 2013. This became evident when a series of bills were introduced in various states to impede patient access to new biosimilar medicines. A bill introduced by some of the country's largest biotechs "was designed to drive [Big Pharma] profits and thwart competition from biosimilars."[3] The legislation put forth in a number of states aimed to limit interchangeable biosimilar substitution, but several state legislatures – including California, Florida, Texas, and Indiana among others – refused to enact. Blocking these state bills is a victory for the generics industry in anticipation of the approval of biosimilars in the U.S.

Biosimilars Naming Convention

At the end of 2012, Swiss pharmaceutical company, Novartis, filed a petition with the FDA to allow the same international nonproprietary names (INNs) as reference products for biosimilars. The company said that "assigning different INNs to biosimilars would create 'unnecessary confusion' in the healthcare system," and would challenge the FDA's current review and approval process for biologics.[4] In 2013, the Generic Pharmaceutical Association (GPhA) continued this effort by filing an official Citizen Petition with the FDA, supporting the motion that all biosimilars approved by the FDA share the INN with the biologic products. To date, no consensus has been reached.

Accessibility for Patients

Above all, patient accessibility to drugs and cost savings are key drivers for the biosimilars market. A Congressional Research Service study found that "the cost of biologics is often prohibitively high, both for patients and the government."[5] Over the past ten years, generics have saved patients and the U.S. healthcare system more than one trillion dollars. Considering the benefits and success of generics, biosimilars are the next frontier. Since biosimilars are already approved in Europe, companies with a substantial global presence are well positioned to compete. However, distribution to patients – particularly in emerging markets – is still a significant challenge.

Navigating this Trend

- Determine your company's specific biosimilar strategy. There should be a balance between small-molecule drugs and biologics in your overall product portfolio. Include factors such as market opportunity, pricing, and of course, ability to execute. Executive leadership should stay informed of biosimilar strategies and development plans.
- Determine how you will support the planning, manufacture, sale, and support of biologic products. Consider scenario planning and pilots, along with ANDA submission activities. Ensure that internal processes and systems are equipped to manage and track these products separately.
- Continue to study and articulate the savings that can be generated from biosimilars. Focus on patient and prescriber education to ensure rapid adoption upon approval.
- Industry should continue to work with the GPhA and the FDA to implement a biosimilar approval pathway with workable regulations sufficient to ensure quality products and access to lower cost alternatives.

Compliance or Competitive Advantage

Biosimilars are one of the many fields supporting the effort to bring the right product to the right patient, with the right price, at the right time. Generics companies are actively working with to eliminate the disruption of supply to patients, and to increase availability in emerging patient populations. Through the Drug Quality and Security Act and track and trace technology, the generics industry is combating patient risks and developing a more secure supply chain. Leading generics companies are realizing how to turn these new regulations into a competitive advantage.

Accelerated Recovery Initiative

The Accelerated Recovery Initiative (ARI) is "the generic industry's unprecedented multi-stakeholder initiative designed to accelerate the recovery of critical drugs in short supply to patients in need."[6] The program is an FDA and industry partnership coordinated by data manager IMS that "forecast[s], prevent[s], and mitigate[s] the impact of drug shortages"[7] by providing the FDA with pertinent information prior to a shortage taking place. The program is a great compliment to the Generic Drug User Fee Act (GDUFA), which funds measures to bring safety, access, and transparency to the supply chain of generic drugs.

Drug Quality and Security Act

While the ARI supports access to generic drugs, the recently signed Drug Quality and Security Act will bring added safety and transparency to the entire pharmaceutical industry. The Drug Quality and Security Act, or H.R. 3204, is known as the track and trace or compounding legislation. The goal of the legislation is to more accurately track electronic prescription medicines, and to deliver them safely and securely into the hands of consumers. The execution, however, may be more difficult, requiring the implementation of traceability systems for the entire industry.

Supply Chain as Competitive Advantage

Leading generics companies have taken advantage of the techniques used in other industries, like consumer goods, where high volumes of product need to be moved quickly across vast global networks. These companies have implemented Intelligent Supply and Serialization/Traceability technology to not only counteract shortages, counterfeiting, and theft, but to also gain real-time information on supply and demand. By implementing these systems, generics companies can increase revenue and profit, and can also expand their ability to supply broader patient populations.

Navigating the Trend

- Make sure that your organization understands the latest status and implications of the Accelerated Recovery Initiative and The Drug Quality and Security Act. Consider their effects as you create your business plan for 2014 and beyond.
- All generics companies should be running Intelligent Supply and Serialization/Traceability pilots. Leading companies will implement solutions in advance of government regulation and use them to not only comply, but to also create business benefit and competitive advantage.

Globalization of Quality

In 2014, generics manufacturers will continue their efforts to maintain high quality standards. As outlined in our *Quality in Generic Pharmaceuticals* industry report, FDA data supports the conclusion that generics companies make up a very small percentage of the overall quality observations in the pharmaceutical industry. This is especially impressive, as generics account for 80 percent of the prescriptions filled in the U.S. This year will be characterized by continued investment in Quality by Design (QbD), as well as an ongoing focus on quality across an increasingly global supply chain.

Quality by Design

QbD is defined as building quality control and testing into the up-front and in-process activities of manufacture, rather than relying on post-manufacture testing to identify non-conformance. QbD is not new, and every branded and generic pharmaceutical company employs some kind of QbD activity in their testing and release strategy. However, with advances that couple QbD with the risk-based guidance set forth in Pharmaceutical cGMPs, leading generics companies will be able to further optimize their quality processes. This will provide them with the ability to meet higher and higher volume requirements to support the growing demand for their products, especially demand driven by the Rest of World (RoW) and pharmerging markets.

Increased Globalization of the Supply Chain

As the patient population increases globally, the need for global manufacturing, packaging, and distribution will also increase. And as the healthcare infrastructure expands in these massive global markets, the available patient population for generic pharmaceutical manufacturers will multiply. This, in turn, will require processes and systems that work together across global locations, ensuring high volume manufacturing and distribution that conform to specific country and government regulations. Globalization will continue to drive investment in quality programs that can scale across facilities and beyond U.S. borders.

Navigating the Trend

- Hire and grow global quality expertise in your organization. Quality has often been "designed and enforced" at the plant level. As generics companies continue to both manufacture and distribute on a global scale, the quality professionals supporting operations will need to recognize their position as part of a global supply network. This shift will require focus on organizational change management and business adoption, as well as processes and systems.
- Ensure that your quality organization has a strategy that combines QbD and risk-based principles. Challenge them to manage metrics such as first-time quality, QC conversion cost, and supplier conformance, in addition to more typical measures of investigation closure and release times.
- Build quality systems infrastructures that can scale to meet global requirements. Do not underestimate the cost and complexity of extending regional solutions to facilities across the globe. Have very clear and consistent quality nomenclature, process design, and standards for supporting technologies.

New Talent Strategies

Throughout the pharmaceutical industry, the battle for talent is certainly not new. However, there are three converging forces that are going to make it critical for generics manufacturers to rethink the way they hire, train, retain, and motivate their personnel. These forces include the need for: attaining skills in biologic drug development and manufacturing, guarding against key leadership accepting positions with emerging generics companies, and developing a workforce that truly understands how to operate in a global environment. In order to attract the best employees, generics companies will need to determine how they will differentiate themselves, and compensation is just one part of this critical equation.

Biologic Drug Development & Manufacturing

As industry maintains focus on the biosimilar market, traditional generics companies will need to add people with knowledge of biologic drug development and manufacturing. Although the biosimilar pathway has yet to be finalized in the U.S., it is clear that the process of bringing a follow-on biologic to market is different than that of their small-molecule predecessors. Further, the processes for manufacturing, testing, storing, and distributing these products is also different. Just as new equipment and technology will be required, so will people who understand the science.

Competition for Talent

The growth of new generics companies will continue in 2014. They will evolve from startups, from contract manufacturers looking to expand their offerings and leverage capacity, and also from established pharmaceutical or biotech companies hoping to defend against competition. Many of these established companies will have a specific competitive advantage: having experience with biologics. And they will seek out executives from generics companies who understand the "other half of the equation" (i.e., how to maximize market share and profit once a product is approved for release). The strict separation between branded and generics companies will continue to blur, and talent will start to flow both ways as market opportunities arise.

Demand for Global Talent

A key theme throughout this trend report has been globalization. The generic drug manufacturing supply chain will continue to expand globally as competitive pressures dictate the use of lower cost labor and suppliers. On the demand side, IMS Health reports that in 2012, the Brazilian and Chinese markets grew by 16 percent and 21 percent respectively, compared to an average market growth of minus two percent (-2%) for the five major European markets, and minus one percent (-1%) for the U.S. market.[8] This opportunity for growth in the RoW and pharmerging markets will increase the need for new partnership and distribution strategies, thus requiring generics companies to broaden their global expertise.

Navigating this Trend

- Remember that for retention, compensation is only part of the equation. Generics companies support the mission of the global healthcare system in various ways. Explore avenues to keep your employees close to, and aware of, the impact of their work. Also, increase strategies around enhanced responsibility and recognition, as opposed to financial reward.
- When considering talent needs in the area of follow-on biologics, think about the lessons learned from historical changes in other industries. The small-molecule generics business is not going away. Think about talent strategies that balance your knowledge and skill needs to best support long-term growth.
- Remember that shifting focus from a regional to a global organization will never be accomplished through hiring or acquisition alone. Focus as much on building a shared, unique culture as you do on creating a shared mission and vision, and achieving financial results. This will require investment in rotation of personnel in order to break down barriers and create a common platform for employee engagement.

Continue the Discussion

About the Authors

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Biosimilars

- Insights Paper: *Biosimilars are Coming. Are You Ready?*
  The Biosimilars Market Adoption Survey assessed the knowledge and perceptions of two critical stakeholder groups - prescribers and patients.

Compliance or Competitive Advantage

- Case Study: *Piloting Serialization*
  As you consider how current regulations can spur a competitive advantage, read how Clarkston's supply chain and life sciences industry expertise helped this company validate and implement their serialization solution.
- Solution Overview: *Serialization & Traceability*

Globalization of Quality

- Research Brief: *Quality in Generic Pharmaceuticals*
  This report examines the generics industry, identifying best practices for companies to maintain their high quality standards and manufacturing excellence as they serve a larger, more global patient population.

New Talent Strategies

- Blog: *Navigating the Bermuda Triangle of Growth*
  Our recent blog series discusses talent and growth strategies for globalization.

References

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2 Grant Thornton. Bio-dynamism: Insights into the Biosimilars market: An Overall Perspective. February 2013. (As cited by GPhA. "The Industry" Webpage. 2013)

3 GPhA. Press Release. "Statement from Ralph G. Neas, President and CEO of the Generic Pharmaceutical Association on California Governor Brown's veto of SB598." 2013.

4 LSIPR. "Novartis petitions FDA on biosimilar naming convention." 2013.

6 GPhA. Press Release. "GPhA Receives Positive FTC Advisory Opinion on the Accelerated Recovery Initiative." 2012.

7 International Pharmaceutical Quality. "The Accelerated Recovery Initiative on Drug Shortages is Gaining Momentum – Pilot Program Underway." 2013.

8 IMS Retail Drug Monitor. February 2013. (As cited in EFPIA's "The Pharmaceutical Industry in Figures." 2013.)

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