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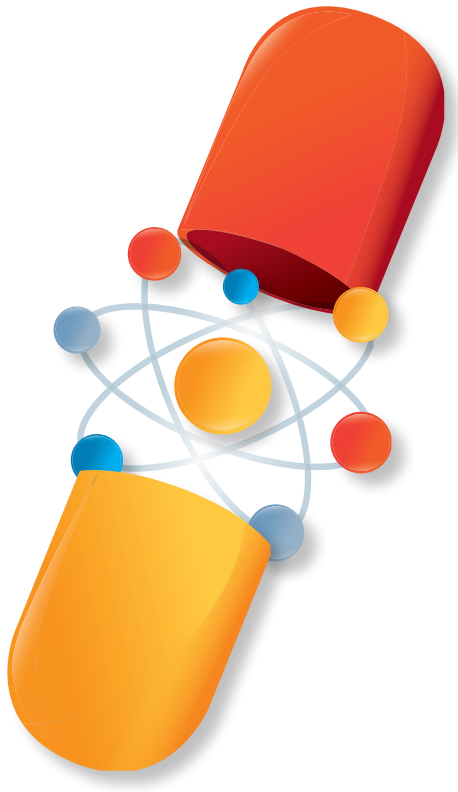
2015 Generics Industry Trends



Over the past decade, generics companies have saved the US healthcare system over $1 trillion.[1] Globally, generics companies continue to reduce the cost of medicines while also increasing access to life-saving medications.

This year will be transformational for the generics industry. Biosimilars, M&A, distribution and labeling changes, and advances in measuring health outcomes will create challenges – and opportunities – for those that think differently and move first. As a part of the life sciences industry that has always been defined by an aggressive, entrepreneurial spirit, look out for exciting times ahead.

01 | BIOSIMILARS

Since creating guidelines in 2005, biosimilar approval by the European Medicines Agency has saved Europe $2.2 billion in healthcare costs per year.[2] Using the US biosimilar pathway, Sandoz hopes to achieve the first US FDA biosimilar approval in 2015.

By now most generics companies have determined their strategy for the biosimilar market. As we outlined in our 2010 Market Adoption Survey,[3] generics companies should define their strategy in terms of products, partnership, investment, and regulatory analysis. As generics companies struggle to find scientific and technical expertise, and branded companies lack lower cost manufacturing and supply chain capabilities, hybridization will likely continue.

02 | ACQUISITIONS

Among M&A in 2014, global capacity, ability to scale, and product portfolio additions were the primary themes. These deals demonstrate the strategic intent as to where companies see their ability to execute and grow – traditional generics, generic biologics, new delivery mechanisms, hybridization, or all of the above.

While the mechanics of M&A are not new, the ability for companies to realize synergies are often sub-optimized by inadequately addressing the people and processes impacted. Further, when appropriate TSA measures are not enforced, integration budgets are often inflated. When using M&A to expand your portfolio, due diligence requires particular focus on skills, systems, and regulatory concerns.

03 | DISTRIBUTION CHANNELS

Distributor and pharmacy partnerships are reshaping the generic drug distribution channel. These partnerships increase scale and purchasing power, putting pressure on generic manufacturers.

Leading generic companies will try to think differently about the market. Value for the pharmacy will become a key differentiator with the growth of specialty pharmacies. Value for the payers will be driven by the quality of healthcare outcomes. Anything that can be done to differentiate using value-added services is going to be a critical strategy to combat volume pressure by the distributor channel. Also the ability to capitalize on generic launches of high-value branded drugs and continued global expansion are key strategies for success.

04 | LABELING

The FDA's new proposed generic drug labeling rules would have far reaching impacts on the healthcare system. While this proposed regulatory change continues to be challenged based on the foundation of "sameness", and based on its potential for driving costs and creating confusion, the FDA continues to stand by its desire to make the change.

Regardless of potential changes to labeling rules, other factors such as global expansion and the introduction of biosimilars will increase labeling complexity. Building agility and flexibility into packaging and labeling will better enable global generics companies to respond to tender offers, reevaluate sourcing and supply strategies, and capitalize on market opportunities stemming from disease outbreaks and drug shortages.

05 | THERAPEUTIC OUTCOMES

The focus on health outcomes in the pharmaceutical industry is certainly not new. As the complex web of providers, payers, prescribers, and patients has grown, pharmaceutical companies have tried to focus on drugs in categories where overall cost benefits, in addition to health benefits, can be achieved.

Oftentimes, success is measured by metrics such as revenues, profits, prescriptions, and markets served. With advances in analytics, serialization and traceability, generics companies can begin to correlate product availability and distribution with population health statistics. Such advances will enable global generics companies to assess therapeutic benefits while demonstrating direct impacts on the human health condition, especially in emerging markets.

Interested in Reading More?

- 2015 Life Sciences Trends Report
- Quality in Generic Pharmaceuticals
- Biosimilars are Coming. Are You Ready?
- Biosimilars: The Current State & Way Forward
- Proposed Labeling Rule Has Serious Implications for Generics Industry

Look for more detailed insights on these five trends throughout 2015.

References

1 Generic Pharmaceutical Association. "Issues: State Initiatives." Website.

2 McDonald, Gareth. "Biosimilar MAbs to Cut Europe's Healthcare Bill by €20bn by 2020." BioPharma-Reporter.com. September 16, 2014.

3 Clarkston Consulting. Biosimilars are Coming. Are You Ready? June 2013.

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