CLARKSTON CONSULTING

2016 | Generics Industry Trends

Over the past decade, generics companies have saved the US healthcare system over $1.2 trillion.[1] Globally, generics companies continue to reduce the cost of medicines while also increasing access to life-saving medications. Particularly over the past year, the first biosimilar was introduced in the US, GDUFA was reauthorized, mergers and acquisitions surged, and pricing became a hot-button issue. As such, generics companies have an opportunity to demonstrate their adaptability and ingenuity, as well as the value they bring to the healthcare system.

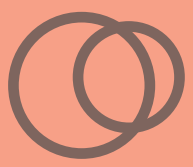
01 | GENERIC DRUG USER FEE ACT (GDUFA)

In 2012, the FDA initiated the Generic Drug User Fee Act (GDUFA) program.[2] The main purpose of the program is to expedite the FDA's review and approval process of generic drug applications by requiring generic manufacturers to pay a fee that funds the FDA's efforts. Ironically, since the start of the program, the median review time for approval has consistently increased.[3] In 2015, FDA launched its first ever reauthorization process of the act, and is seeking feedback from the industry.[4] As the act's expiration date approaches in September 2017, how generics companies contribute and respond to the FDA's decisions will be pivotal.

02 | BIOSIMILARS

Although biosimilars have been widely used in highly regulated markets, including Europe, Canada, Australia, and Japan, the first biosimilar in the US market was introduced last year. With a conservative domestic market projection of $5.5 billion by 2020, the biosimilar subsector holds ample opportunity for the pharmaceutical industry.

Companies should define their strategy in terms of products, partnership, investment, and regulatory analysis. Understanding market perceptions and the potential for adoption in the US, along with the necessary steps for a smooth transition towards biosimilar production, will be important areas of focus for generic drug companies in 2016.



03 | WHOLESALER CONSOLIDATION

The partnerships that led to stronger wholesaler and pharmacy relationships build scale that diminishes the bargaining power of drug manufacturers. Combined with corporate mandates employed at pharmacies like Walgreens and CVS, which drive pharmacists to choose lower cost substitutes over generics, drug pricing remains a primary focus. According to an AARP study, 27% of 280 widely-used generic drugs bore price increases over the past several years, particularly specialty drugs.[5]

Generics manufacturers will need to reevaluate their long-term business strategy to not only lower prices, but also provide value-added services that improve health outcomes and differentiate them from these wholesaler and pharmacy partnerships.

04 DATA INTEGRITY & FDA COMPLIANCE ISSUES

Although data integrity and FDA compliance issues are not new, the pharmaceutical industry has recently been under significant review. In 2015, the FDA issued at least five warning letters regarding data integrity to overseas pharmaceutical manufacturers in the fourth quarter alone.

Data deletion, password sharing, and a lack of audit trails point to inconsistent management in product manufacturing and testing areas. Whether through stricter enforcement, more engaged management or implementing new quality systems or technologies, companies need to consider how to meet regulatory demands and remain competitive.

05 MERGERS & ACQUISITIONS

Mergers and acquisitions will continue throughout 2016. While many companies will design deals to increase capacity, geographic scale and product offerings, others will build a foundation for biosimilar development. The latter will increasingly blur the lines among companies offering both generic and branded products.

While the mechanics of M&A are not new, companies often fail to realize synergies because they inadequately address the impact to people and processes. When using M&A to expand a product portfolio, due diligence requires particular focus on skills, systems and regulatory concerns. Finally, and most importantly, business model innovation will ensure that new entities are set up for scalable success.

RELEVANT INSIGHTS

- 2016 Life Sciences Outlook
- Biosimilar Adoption in the United States

REFERENCES

1,2 “Generic Drug Savings in the U.S.” Generic Pharmaceutical Association. 2013.

3 “Statement by David Gaugh, Senior Vice President, Sciences and Regulatory Affairs, GPhA, Regarding the Senate HELP Hearing on GDUFA.” Generic Pharmaceutical Association website. January 28, 2016.

4 Gaffney, Alexander. “Generic Drug Companies Call for Fixes to GDUFA, Citing Few Returns on Investment.” Regulatory Affairs Professional Society (RAPS) website. June 15, 2015.

5 Jaret, Peter. “Generic Drug and Brand-Name Drug Prices Increase.” AARP. July-Aug. 2015.

CLARKSTON CONSULTING

Headquarters
2655 Meridian Parkway
Durham, NC 27713
Phone: 800-652-4274

www.clarkstonconsulting.com