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Helping Generic Customers Lower Elastomer Acquisition Costs In A Competitive US Environment



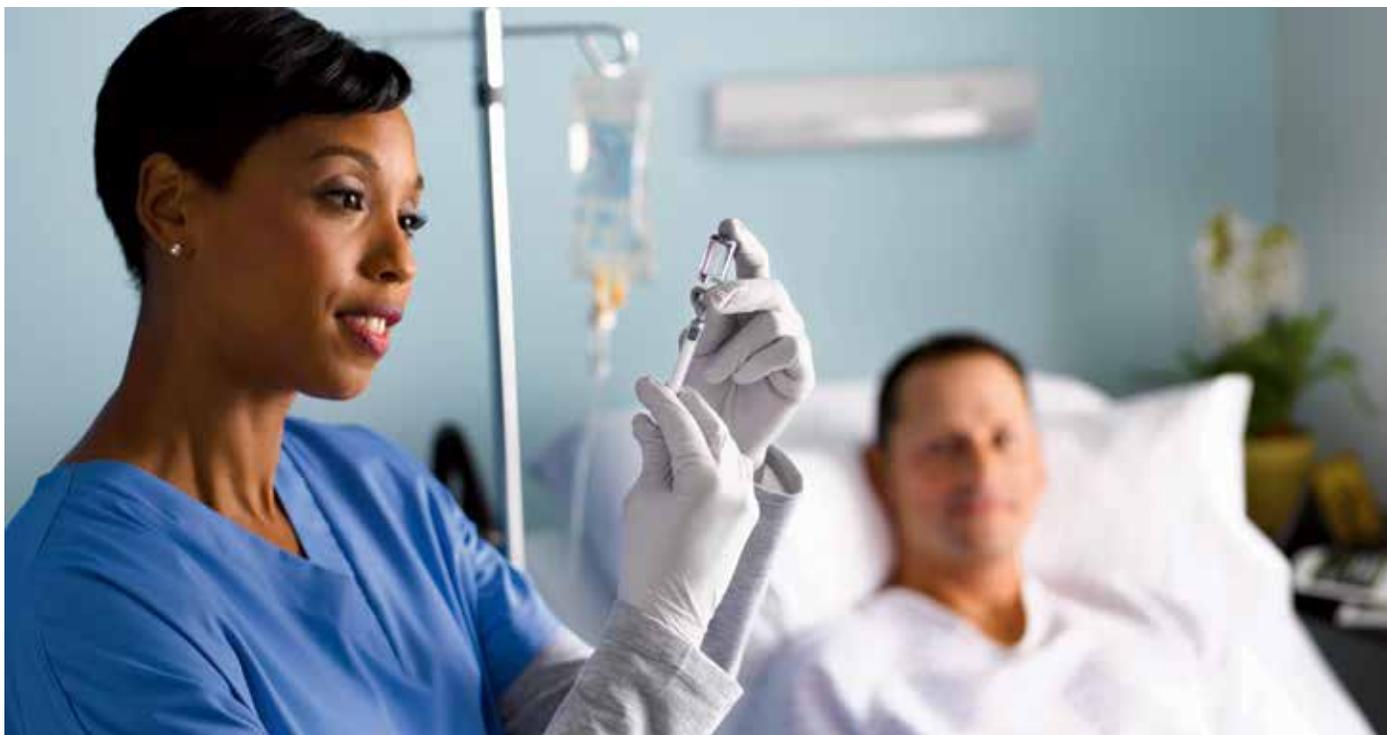
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Generic drug approvals are happening faster than ever before. But significant drug shortages, a highly competitive US market, and few distributors and purchasing consortia have led to commercialization and pricing pressures for generics. West Pharmaceutical Services, Inc. aims to help manufacturers leverage quality, speed and simplicity through use of its high-performing AccelTRA™ elastomer formula to control costs and bring products to market quickly.

Given the authorization of the Generic Drug User Fee Act (GDUFA) in 2012 and its reauthorization in 2017 (GDUFA II), the approval rate of Abbreviated New Drug Applications (ANDAs) by the US Food and Drug Administration (FDA) has been a success by many measures. However, this, as well as certain ongoing, significant generic drug shortages, has created an environment where generics organizations vying for a piece of the US market experience significant pressures to commercialize their products quickly.

On the one hand, GDUFA has led to a faster rate

of generic drug approvals than ever before. This has enabled patient access to a greater number of drug products, some helping to treat life-threatening ailments at a lower, more accessible cost to patients. In turn, that access has brought tremendous positive social benefits, some of which are readily quantified in policy models. Though patients have had access to a greater number of generic drugs since 2012, one could argue that the full benefits of the competitive forces between generic versus branded drugs remain to be realized.



On the other hand, the greater approval rate and highly competitive US market, along with the few distributors and generics purchasing consortia, have led to significant pricing pressures for generic drug products, forcing many drug manufacturers to reconsider their go-to-market strategies, including whether they have or need a greater mix of products to balance their portfolios. Today, generics manufacturers may be reconsidering a number of strategies to create better margins for their drug portfolios, including: reconsidering previously shelved branded generics plans that were seen as too costly; reevaluating 505(b)(2) submission opportunities that can potentially garner greater market share and product exclusivities, but were seen as requiring extended timelines; and right-sizing their regional/global footprint to diversify the inherent risk in their global product portfolios.

Whichever path a generics company is contemplating, controlling costs is important. The acquisition of elastomers for the primary packaging of biopharma products is an aspect that, depending on the company and the drug product, is often reviewed carefully. More and more companies are considering total cost of ownership for ready-to-sterilize and ready-to-use elastomer products. While the need for a low-cost elastomer product is often at the forefront of a manufacturer's buying decision, other factors, such as technical and regulatory support or the need for an elastomer compatible with multiple biopharma molecules, are sometimes overlooked.

When selecting a West AccelTRA™ elastomer, customers are not only purchasing a high-performing elastomer product, but they're also provided with

additional laboratory, regulatory and technical support from West. Furthermore, certain customers have noted that standardizing, as much as possible, with one high-performing elastomer formula may enable lower elastomer inventory costs and reduce the need to carry diverse elastomer formulas in their product portfolio. In essence, this is what the AccelTRA component program offers customers. AccelTRA components provide a high-performing, quality elastomer formula that leverages West's expertise. Additionally, AccelTRA components offer optimized lead times to help customers speed their products to the market quickly, and aid in simplicity when customers begin wanting to standardize on one platform to help lower their costs.

To learn more about how AccelTRA components can help your organization leverage *quality, speed and simplicity* to bring products to market quickly, please contact one of our West account managers or visit www.westpharma.com/AccelTRA to download relevant information and order samples.

AccelTRA™ is a trademark of West Pharmaceutical Services Inc. in the US and other jurisdictions.

