Fueling The Growth Of Generics Post-COVID

Generics companies have played a pivotal role during the global pandemic, ensuring essential medicines are accessible for patients as the health care industry faces ongoing challenges. As vaccines roll out globally and we move from pandemic to endemic, West Pharmaceutical Services' David Maier, Vice President and General Manager, Generics discussed with In Vivo what this means for the generics and biosimilars market.

In Vivo: What will be the lasting impact of the COVID-19 pandemic on the generics and biosimilars market, and how is West adapting its operations to continue to serve this key part of the industry?

Maier: The generics and biosimilars markets were growing at steady rates even prior to COVID-19. The treatment of people who become very ill from COVID-19 has also increased the demand for generic injectable medicines.

From the onset of the pandemic, West has taken proactive measures to mitigate risk and provide our customers continuity of supply by expanding our manufacturing capability through an increased and accelerated total capital investment over $300 million, which includes over 30 major facility modifications and over 400 incremental pieces of equipment, hiring over 1,000 new team members since the start of the pandemic and increasing production operations to run 24 hours a day, 7 days a week to meet this unprecedented global demand. The success of this approach requires partnership with our customers and suppliers, including a greater level of transparency regarding production demands and filling schedules to ensure we are addressing the right need at the right time.

You note that supply chains have been challenged by significant disruption during the pandemic. What do you believe are the lessons learned with regards to risk planning and demand fluctuations?

Maier: What the industry has learned is the value of doing risk mitigation early and having greater flexibility while also maximizing your global networks. When the pandemic hit, industry had to quickly develop hundreds of millions of doses for some medicines, from manufacturing sites that were already operating without much spare capacity. In West's case, we found ways to use our existing assets more efficiently, while at the same time installing new equipment and developing contingency plans. This has allowed us to respond quickly to this unexpected demand, as well as future demand resulting from hospitalizations that occur from new waves of COVID-19 and other diseases.

We are also accelerating our move towards automation and more robust scalable manufacturing processes using a global operations strategy. We have done this by leveraging our 90+ years of manufacturing expertise and utilizing our perpetual 5-year sourcing plan. This includes second source qualifications, strong supplier relationships with master supply agreements and negotiated capacity commitments. Additionally, it includes maximizing the efficiency of our global manufacturing network and our ability to flex our operations, including shifting resources from one site to another to address gaps at different facilities.

What potential is there for future innovation in the generics and biosimilars space?

Maier: As more novel biologics reach the end of their patent lives, our generics and biosimilars makers are capitalizing on and investing in these molecules and technologies, resulting in more robust pipelines.

However, we hope that industry and healthcare systems do not repeat the mistakes made in some generics categories. Pricing and competitive pressures have been so fierce that it has forced several manufacturers out of the market in certain small-molecule generic therapeutic areas, resulting in too

many situations where there is only one sole provider of a critical generic drug.

Strategically, generics and biosimilar companies face a copy versus improved dilemma. If the original treatment is going off patent, the least risky option is usually to replicate it – this is the "copy" strategy. However, there has been a notable rise in the number of 505(b)(2) filings in the US, where the generic seeks to improve on the innovator drug. One example is treatments administered intravenously in hospital settings. There are now an increasing number of devices, including West's own Smart Dose®injector , that can move drug administration into a home care setting, which is better for patients and reimbursement costs and ultimately helps lower overall healthcare costs. This "improve" strategy is riskier for our customers and for West, but potentially more rewarding for patients, healthcare systems, and the companies that invest in an "improve" strategy.

The industry's reaction to the pandemic has highlighted accelerated speed to market. What opportunities do you see here and what are the key challenges of faster drug development from a delivery perspective?

Maier: Health care systems and governments have a financial incentive to increase the use of generic medicines as soon as possible. Faster regulatory review processes and accelerated approvals existed before the pandemic, but these appear to have slowed down somewhat for generics while regulators prioritize COVID-19 vaccines and therapies for public health reasons.

The COVID-19 vaccines themselves were a rapid, robust proof of concept for mRNA technology. The global life sciences community proved that it could develop, obtain approvals for, manufacture and distribute a new vaccine in a matter of months rather than years. First, this should give hope that mRNA technology could be effective for future health crises, but beyond that it proves the world can rally together and produce treatments quickly.

Going back to supply chains, this forces us to rethink how they work and create the ability to scale quickly, with flexibility to reprioritize when something unexpected occurs. In drug development, the manufacturing and supply process is rarely the bottleneck and usually does not take longer than the clinical trials. That said, now they might , given the urgency to respond to a pandemic and get product(s) to market quickly.

The role of digital technologies across industries has been increased in order to continue business operations. What is West doing in the digitization space to keep up with the demand?

Maier: Digital technology is something that West is heavily investing in. We are implementing more robust manufacturing execution systems and SAP S/4 HANA across our entire global network, as well as looking at better in-process controls, data feedback and automating record-keeping. Digital tools will replace manual process throughout the commercial and production value change. This digital technology is enabling knowledge sharing across all value streams within our global manufacturing network, and by connecting our production equipment to the IoT platform, we are able to track site performance using real-time data to assist in quicker decision-making, preventative maintenance, equipment scheduling, and eliminating unnecessary manual efforts. Finally, by deploying increased automation capabilities, we've been able to increase the efficiency of manual processes, and in the future, we will be able to scale quickly and eliminate situations where the ability to onboard new employees is a limiting factor.

Beyond the impact of COVID-19, what are your predictions for the generics and biosimilars industry?

Maier: The good news is the outlook for the generics and biosimilars markets is a story of continued positive growth, even without the COVID pandemic demand. Nonetheless, there are also challenges. Some of these are not new, with the biggest one being margin compression and pricing pressures.

Biosimilar uptake has increased significantly in recent years across western markets and has resulted in savings of approximately $10 billion in the US alone over the past 5 years generating savings for patients, payers and employers. Thus, while biosimilar approvals in the US slowed down during the COVID-19 pandemic, future growth in approvals is expected, as defined savings, clinical benefit and market acceptance of biosimilars increase.

Additionally, there is increased focus on improving quality standards across the industry. This can hit generics companies particularly hard where manufacturing facilities, the regulatory filing and original drug itself may all be decades old. Standards need to catch up, and we've observed a rise in the number of 483s and warning letters issued during inspections, especially for small molecule and generic drug manufacturers, as well as an increased use of aseptic lines for drug development. Our customers need to balance keeping prices competitive while improving their manufacturing operations, which is a challenge for them and their suppliers.

Do you have any final thoughts?

Maier: In summary, COVID-19 itself has been a global tragedy, but also an opportunity for the entire healthcare ecosystem to prove it can respond quickly to tragedy. The response to COVID-19 from the global scientific and medical community, the biopharmaceutical industry, regulatory authorities, and logistics carriers has been unprecedented in speed and scale. West is happy to have been able to work with many of the originators of some of the COVID-19 vaccines and treatments and we continue to seek out ways in which we can better meet customers' global needs.

We recognize the importance of customers having partners from beginning to end as we navigate new challenges with biosimilars and increased regulatory and quality needs. Through our Integrated Solutions program, West is responsive to the unique needs of biologic, pharma and generic drug products as regulations continue to demand more in order to help deliver safety, quality and compliance.