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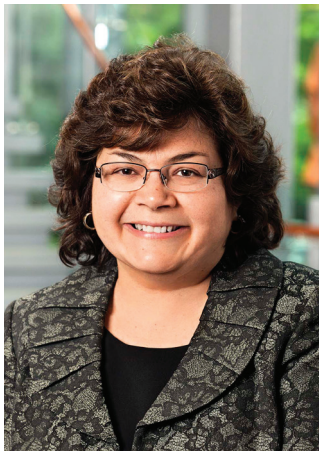
Challenges, Innovation And Value Creation In Generics And Biosimilars

The COVID-19 pandemic has highlighted the importance of a smoothly functioning supply chain in ensuring patients have timely access to much-needed medicines. In the fast-moving market for generics and biosimilars, delivering high-quality products at acceptable cost is even more imperative, with or without COVID-19. Here, Fran DeGrazio, Chief Scientific Officer of West Pharmaceutical Services, talks to *In Vivo* about current trends and challenges in the sector.



***In Vivo:* How did West plan for the potential impacts of COVID-19?**

DeGrazio: We really defined our priorities: first, the health and the safety of our teams, and then ensuring continued support for our customers and communities. Continued support is about maintaining uninterrupted supply of high-quality containment and delivery devices to customers and ultimately, the patient. We also focused on investing. We really accelerated our investment as soon as we saw what was going on with the pandemic.

We were already supporting growth of our base business, but we knew more production capacity would be needed to support COVID-19 vaccines and therapeutics. So, we had to move very quickly. One example is, about a month ago, we installed new manufacturing equipment at one of our high-value product sites to prepare for future demand, especially in respect of our FluroTec® and NovaPure® product lines. That capacity is already operational, and additional equipment is being installed at several other sites.

The other thing, of course, is making sure we continue to communicate and be transparent with our customers, so everybody understands any potential impacts of the pandemic on our business.

How has West navigated maintaining supplies as countries opened and closed borders periodically in response to the pandemic?

We are very fortunate to have manufacturing capabilities throughout the world. We can use that global network to really help ensure supply. The ability to deliver quality product consistently and in a timely manner has never been more important than now. We're constantly monitoring our supply chain to make sure we can minimize any disruption. Our sites and facilities are open, and we comply with all restrictions based on country, state, regional or local guidance.

There's always a lot of planning for unexpected delays. All of this is monitored daily by our supply-chain organization. Another key piece is our ability to access dependable transportation. That goes for the raw materials we receive, and our ability to transport finished goods to our customers. We have experienced some delays in air and sea shipments. There have also been some delays in certain areas of the US that are starting to see an increase in COVID-19.

Again, we've really been able to manage that through good communication with our suppliers and our customers. Another benefit is that we have long-term agreements in place with our suppliers. We have risk-mitigation plans, and we've increased our safety stock of raw materials. We created a task force to ensure that we're prioritizing COVID-related needs and matching those needs as we look at our global capacity.

Leaving aside COVID, what other trends, developments and updates are you seeing in your sector?

Although COVID is on everybody's mind, the reality is that there are many other drugs in development that are vital to patients. One trend we're seeing is continuing diversity in the drug pipeline: for instance, increased growth in biologics, and not just simple monoclonal antibodies, but also the addition of many cell and gene therapies. When you look at these trends, they really connect quite well with some of our product lines, like our NovaPure® stoppers and plungers, Daikyo Crystal Zenith® ready-to-fill syringes and RU vials and the SmartDose® on-body delivery system.

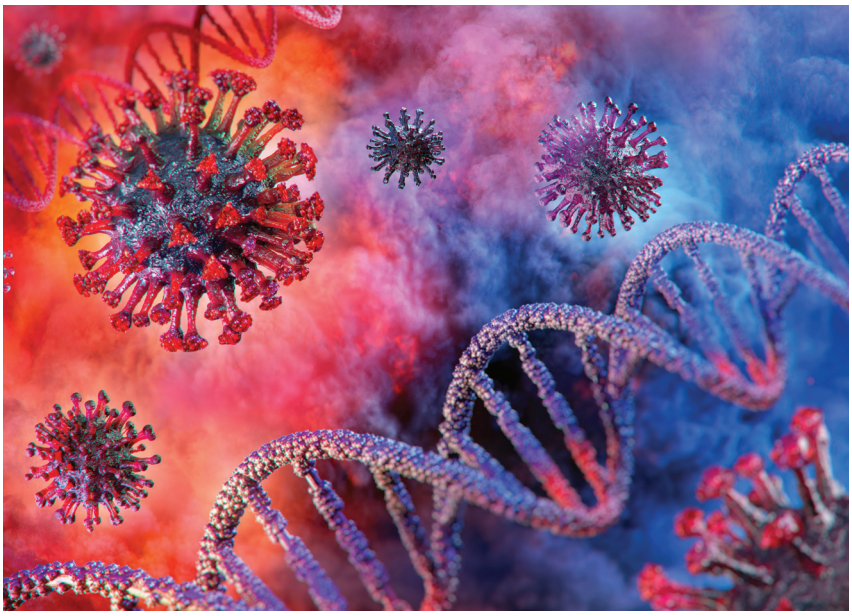
What role do you see generics and biosimilars playing in the future?

We're seeing continued growth from both generics and biosimilars. The compound annual growth rate right now is estimated at seven to eight percent, with a market value that should be close to $5 billion by 2024. This is really driven by some key markets: the US, of course, and China. And the demographics are also changing,

i.e., there is an aging population across the board: the US, China, and certainly in Europe as well.

For all the growth in generics and biosimilars, though, the quality standards don't change. We are very much challenged by the need to keep costs manageable, while maintaining good quality and patient safety priorities.

And the regulations can vary in each region. In the US, for example, we have a 505 (b) (2) submission which allows generics companies to leverage data they perhaps didn't generate *per se* to accelerate development. But that kind of avenue is specific to the Food and Drug Administration. There may be similar regulations in other countries. But how documentation gets assembled and how it is submitted is somewhat different for every country or every region.



There are also a lot of updates of commonly used standards. For instance, the United States Pharmacopeia has just updated USP Sections 381 and 382. Those are directly applicable to elastomeric components. USP 381 relates more to chemistry and the physicochemical characteristics of the elastomer.

USP 382 generally states that you can't expect your suppliers, for instance, to provide data on how a component functions, because what's critical is the interplay between all the components as a system. That's just one example of how we're seeing more and more complexity, even from the standards viewpoint. Ultimately, the standards now recognize that you can't evaluate function as a singular component. You need to know what system the pharma company is going to use.

In this environment, what kind of innovations are you seeing from generics organizations?

Instead of just considering price, companies are now looking at the total cost of ownership. Many companies are moving away from a simple vial format and towards, for example, putting a product in a prefilled syringe, or a prefilled syringe with an additional delivery device, like an auto-injector. It's just easier to use a syringe system versus a disposable syringe and a vial, as it removes the step of having to first withdraw the drug from the vial with the syringe before making the injection. It's also about potential differentiation in the market.

You have mentioned some changes in the regulatory environment. What is their impact on product development?

Both from a generics standpoint and across the board, there are a lot of changes in regulation globally. One change that has caused perhaps the most complexity is where customers want to develop drug-device combination products.

A prefilled syringe system, for instance, is a combination product. On-body delivery systems are combination products. A syringe with an auto-injector is a combination product. There is a lot of activity in that space. Certainly, it's innovation, but it's driven by people looking for more at-home self-administration of drug products.

Combining the drug or biologic with the delivery device eases self-administration. Also, due to COVID, people are much more hesitant about going to a doctor or clinic. So, the industry is exploring how it can accelerate at-home treatment. This whole trend is not just easier on the patient, in the long run, it will provide a cost savings as well.

These products are a little more challenging from a regulatory standpoint. There has been a whole set of guidelines, certainly from the FDA, because when you combine a drug and a device, you need to meet the regulatory requirements for both pathways.

In Europe, companies are being challenged by the update to medical devices regulations. The update was supposed to take effect earlier this year, but it has now been pushed back to 2021, due to COVID. Pharma companies are really trying to understand what this regulatory change means for them in executing drug-device combinations.

What role does technology play in how West conducts its business?

Probably the biggest area of focus is - how do we stay connected to our customers? In the past, we have participated in many in-person events, including conferences and trade shows. Of course, today, everything has gone virtual. So, we've really worked hard to create a kind of West virtual world [**https://www.westpharma.com/360/**], offering a more immersive and fully interactive experience for our customers.

In addition, we're actively involved in hosting even more webinars and training programs virtually. Fortunately, several years ago we developed our West Knowledge Center, which is accessible online through our website. It's really a repository of publications and other literature focused on the science in the injectables space. We offer a lot of technical information, regulatory information and, for our customers, certain product information they may need.

Any final thoughts?

Although the COVID situation is a challenge, it has really accelerated some out-of-the-box thinking, showing people different ways of doing things that can be very effective.