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08.05.2020

Tags: USA, Sandoz, Generics, Biosimilars, Coronavirus

Carol Lynch of Sandoz US talks candidly on the US generics market from an international perspective, market access, biosimilars uptake, talent attraction, and navigating the COVID-19 crisis.

Carol, you were appointed president of Sandoz US as well as the Head of Sandoz North America in March 2018, having previously been with the Novartis organization as well as other pharma companies. How do you define your mandate and how has it evolved since Richard Saynor became the CEO of Sandoz in July 2019?

I have worked for a number of different pharma companies in different countries including Belgium, Germany, Switzerland, Japan and now the US I actually moved to the US in 2001 with Novartis but in the past nearly a decade I have had stints overseas in Switzerland and Germany before returning to the US in March 2018 for Sandoz US.

The US is the largest generics market in the world, so it is an absolutely key market for Sandoz, representing around 26 percent of our global revenues. In line with the global strategy, here we have identified the core market segments for us, specifically injectables, biosimilars, ophthalmology – many of which we are already market leaders in. With the recent decision to terminate our previous agreement to sell our US generics oral solids and dermatology businesses

to Aurobindo Pharma, we are seeking to strengthen our positions in these two businesses as well.

Under the leadership of Richard Saynor, we have seen renewed commitment to our core generics business, which is a large part of our global business, as well as the intention to translate that growth and leadership into other areas, particularly in biosimilars, where we have a global reputation. Sandoz has always been clear in our ambition to be the world's leading and most valued generics company so there was no major change, just increased clarity for our key product areas and key geographies.

While pricing is critical for success, it is not the only factor. We need to have a comprehensive channel strategy to address the key segments of the business and meet the needs of the country and continent. This means looking at wholesalers, payers, as well as healthcare providers and patients. Another critical element is the ability to supply high-quality products on time and reliably. This is one of the strengths we will continue to leverage from the US perspective.

The COVID-19 situation has sparked fierce debate about the reliability and security of global pharmaceutical manufacturing and supply chains. What is the Sandoz perspective on this?

Like most generics and innovative medicine manufacturers, we have a broad manufacturing network globally with sites across multiple regions, including the US. The important thing is maintaining reliability throughout the network. There will be instances where specific circumstances require or incentivize local manufacturing in some form, but, generally, a broad manufacturing network is a way to guarantee the reliability of supply.

As a result of COVID-19, every country is examining their manufacturing and supply chain networks, not just in the pharma industry but also across various sectors to understand the level of their exposure. Understandably, many stakeholders are advocating for more national and local manufacturing. But the reality is that not every country can build its own manufacturing capabilities in every industry. That is simply not feasible or sustainable. We will have heightened attention on this topic of pharmaceutical supply chains for a while, and we are engaging with the appropriate public and private stakeholders on this topic.

In the short term, the most important thing is that governments across the world continue to keep their borders open so that the global integrated supply chains can continue to function and patients everywhere can receive access to the necessary medicines, therapeutics and medical

supplies. I do not believe any single country in the world is self-sufficient in this area.

At Sandoz, we have been incredibly fortunate so far. We have experienced some delays in terms of some order fulfilment, but we have not had to deal with situations where our orders have been cancelled due to manufacturing, supply chain or logistics issues. But we are monitoring the global situation closely.

You have spent a number of years with both Novartis Pharmaceuticals as well as Sandoz in the US and Europe. What is your experience when it comes to product launches in the innovator vs the generics space?

In terms of developing, manufacturing and commercializing therapeutics, the core business is the same. The basics – understanding what your customers want, how products flow through the value chain, how you create value in that supply chain, what you can do to build reputation so people choose to do business with you rather than someone else – are the same. It is just the way you go about all of these processes that is different.

With generics, you are managing a much broader portfolio with thousands of products. It is more complex and the pace of the business is also much faster. The environment is more volatile and so you have to be a bit more agile, as well as stay incredibly close and responsive to the customers.

About the three channels I highlighted, in the generics business, the wholesalers are much more prominent customers so the relationships you have with them hold much more importance compared to the pharmaceutical side. The payers are a bit less prominent but still important, especially when it comes to biosimilars and some of the more differentiated products that are not as substitutable. We do still maintain some presence in front of the prescribing population but obviously in the hospital setting, the purchasing pharmacists are our primary customers. In this setting, we are much stronger on the economics sell-side of the value chain than the feature and benefits sell-side.

How do you view access & affordability in the US and how it impacts the way Sandoz can operate across its whole portfolio?

If you look at the small molecule side of the business, access and affordability is in a strong position. 90 percent of prescriptions are for generics, but generics only represent 20 percent of

total drug spending. The value of regular generics has been proven and well accepted, and the system is functioning very well.

There is a clear disparity between generics and biosimilars. We still do not see a high percentage of prescriptions written for biosimilars, so we are still continuing on our journey, but the benefit has absolutely been proven. With Zarxio®, for instance, we can demonstrate that in the last two years, USD 500 million in savings have been delivered to the US healthcare system. Multiplying that across the 26 biosimilars approved in the US, the savings add up very quickly. When you deliver savings to the healthcare system, it creates headroom for new innovative therapies. There is a lot of desire from the FDA and healthcare institutions in the US to encourage biosimilar uptake and adoption, and at Sandoz, we are committed to working with these stakeholders to harmonize policies and remove barriers that impact patient access to more affordable, potentially life-changing treatments.

Biosimilars is a huge topic globally and Sandoz launched the first biosimilar in the US, Zarxio®. While we see that regulatory institutions and payers in the US express a lot of enthusiasm for biosimilars, it seems that the high hopes have not crystallized into widespread adoption and penetration of biosimilars in the US market. What is your perspective on this?

I used to head our global biosimilars business from Germany where I managed the development and commercialization of the first wave of monoclonal antibody biosimilars in the European environment. We need to recognize that the European and the US markets are in different stages of development. Europe has a well-established regulatory framework and therefore a well-functioning market with many products already approved. It is ahead of the US in terms of both regulatory structure and commercialization. A lot of learnings have also been shared across the different healthcare systems in Europe in terms of what is required to drive the adoption of biosimilars in different country settings. The key learning there is how to adapt to the needs of different countries.

The US is often seen to have a fragmented healthcare system due to the many intermediates and actors involved, but I would say that European countries often have the same challenge. Taking the UK as an example, the National Health Service (NHS) manages costs through different trusts, the physicians often have their own budgets to manage, and social services are run through a different budget. This creates a situation where different stakeholders are questioning in which pockets

savings from biosimilar adoption, for instance, would end up. That is one of the learnings we have brought over from Europe: how to help the different stakeholders work across the silos and barriers to help the overall system.

From a regulatory perspective, the US did not have a biosimilars pathway until the Affordable Care Act was passed in 2010. The Biologics Price Competition and Innovation Act (BPCIA), the biosimilar regulatory pathway in the US, arrived a number of years after the pathway was set out in Europe. On this aspect, I must say that the US has really accelerated through the learning curve. There are 26 biosimilar products approved in the US and we hope to see a good flow of biosimilar approvals in the future.

However, even after the product is approved, to bring the products to the market, the legal framework in the US is quite different to that in Europe. In Europe, you are allowed to litigate the patent prior to product launch so that upon regulatory approval, you can launch immediately. In the US, the time frame is dictated under the BPCIA, and while the intention was to help companies accelerate through the litigation process, the reality is that this process is taking longer than anticipated.

When it comes to commercialization, this is where the disappointment in terms of expectations versus reality has been. Sandoz's Zarxio® was the first biosimilar launched in the US and we are happy that it is also the first biosimilar success story in the US Comparing the US launch of Zarxio® to other countries, it achieved volume market share leadership within three years, which is unprecedented. With Zarxio®, we proved that biosimilar adoption can be successful in the US. Our other products in other therapy areas are also performing well but generally speaking in terms of the penetration and adoption of biosimilars in the US, there are still areas for improvement.

What kind of policies or changes would Sandoz like to see to facilitate higher uptake of biosimilars?

There is no magic bullet, but we have identified a number of different aspects from both regulatory and policy perspectives to support the adoption of biosimilars. But first and foremost, there is a continuing need for education. The FDA has done a good job around providing education about what a biosimilar is and is not, including the recent collaboration with the FTC to address companies potentially disseminating misinformation about biosimilars. I really applaud these ongoing efforts from independent bodies like the FDA because they are unbiased sources of information.

There are four areas where we would like to see improvement. Firstly, under Medicare Part B, we have physician-administered products, which must be administered within a hospital setting by a doctor. We believe a greater reimbursement incentive in the form of an add-on payment to physicians is required in order to support biosimilar adoption in this setting.

In terms of Medicare Part D, we would like biosimilars to have their own pricing tier in the formulary as opposed to being lumped into an existing tier with branded products.

From a patient perspective, we would also like to eliminate co-pays or any other additional out-of-pocket costs to ensure that patients receive the benefits of biosimilars as well.

The last one relates to reducing bureaucracy for physician offices. Currently, in the US, many states have prior authorization policies for the use of biologics. This means that before a physician can decide to prescribe a biologic, he needs to apply for 'prior authorization' to demonstrate that the biologic has been recommended and is necessary because the patient has tried a number of other medications that had been unsuccessful. The issue is that after that, if the doctor then wants to switch to a biosimilar of that biologic molecule, he needs to go through the authorization procedure again! We do not believe this is necessary.

We need to work together with all stakeholders to improve the marketplace so patients can gain more access to transformative medicines. It requires articulating potential benefits to all the key stakeholders in the system so that they can all come together and do their part.

As the most innovative biopharma country in the world, there is no shortage of innovative companies to work for. How does Sandoz attract the kind of talent you need within the organization?

Fortunately, we do not have any difficulty attracting great talent due to the culture of the organization. This is probably the first positive surprise I had when I joined Sandoz: the organizational culture is incredibly purpose-driven, and this is something very tangible you feel the moment you walk through the doors of our organization. Our associates come to work every day excited because they know how important their work is to improving patient access to medicines. This is something deeply ingrained in our culture.

This culture is absolutely key in helping us attract the diverse sets of talents and skills we need to manage our diverse and broad portfolio across both generics and biosimilars. What I particularly love about Sandoz is the opportunity to bring both sets of skills and expertise together. The US

market is continuously evolving, and Sandoz continuously provides the corresponding agility and variety in terms of opportunities for growth within our organization, which really makes us extremely attractive to potential employees.

To conclude, what final words to share with global colleagues about Sandoz US?

I am so proud of our organization here. We have a wonderful team that has received a lot of recognition internally and externally. The external recognition certainly carries a lot of value; we have been recognized as one of the Top Employers not only within the US but also the region for a number of years now, and we have also gained a lot of recognition from the organizational and diversity perspectives. We have a team of associates that quite rightly feel proud of their work and achievements.

For instance, with COVID-19, Sandoz has undertaken a number of initiatives that demonstrate our commitment to putting patients at the front and centre of everything we do. For instance, in February, we committed to keeping prices stable for a number of essential medicines needed for the treatment of COVID-19. In March, as part of the global Novartis response, Sandoz donated a significant amount of antimalarial therapy to governments around the world to support COVID-19 clinical trials. We have also launched fundraising efforts to support healthcare practitioners and hospitals treating COVID-19 patients. At Sandoz US, we are committed to putting patients at the front and centre of everything we do.

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