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Abhijit Zutshi, commercial head global generics & SVP marketing at Indian firm Biocon highlights the challenges inherent in the US generics market, the process of setting up an affiliate in the US, and how Biocon's level of vertical integration allows it to be highly competitive and stand out from the crowd.

Abhijit, could you please briefly introduce yourself and your scope of responsibilities as commercial head global generics & SVP marketing for Biocon?

I joined Biocon in 2001 and I currently manage the global commercial operations for our generics formulation business. To explain the structure of Biocon, we have Biocon Limited as the holding company; Syngene, a publicly-listed company focusing on the provision of research services in chemistry and biology in which we hold a majority stake; Biocon Pharma, our small molecule APIs and generic formulations business; and then Biocon Biologics, which is our biosimilars business unit. Both Biocon Pharma and Biocon Biologics are subsidiaries of Biocon Limited, at 100 percent and 97.5 percent respectively.

For a little context, Biocon was established in 1978 by our current executive chairperson, Kiran Mazumdar-Shaw, which initially founded the company as an enzyme manufacturing company. She trained to become a brewmaster, a very non-traditional field for women at that time in India, after

she returned from her training in Australia , she found it difficult to break into the old boys' club. She realized that her skills and expertise in fermentation could be leveraged in the manufacture of certain complex enzymes and fermentation-based APIs. This is how Biocon entered the statins business and today we are a leading global player for statins. Subsequently, the company realized that fermentation could also be used in the manufacture of monoclonal antibodies and insulins and we started moving in this direction. Most of the other Indian generics and biosimilars companies entered the formulations and biosimilars business because of the competitive economics of manufacturing in India versus other parts of the world. We did not jump on the bandwagon, we did things differently by leveraging on our in-house expertise and know-how.

Today, we are a global provider of biopharmaceuticals across small molecules, recombinant proteins, peptides and monoclonal antibodies. We are among the world's largest producers of statin and immunosuppressant APIs globally. On the biosimilar side, we are the fourth-largest insulin manufacturing group globally. We have a pipeline of about 28 biosimilars – one of the largest biosimilar pipelines globally – and this has required a lot of dedication and purpose. In the US, our Mylan-Biocon Biologics partnership has already launched two biosimilars in the market: Ogivri™ (trastuzumab-dkst), a trastuzumab biosimilar, and Fulphila®, a pegfilgrastim biosimilar.

How challenging was it to establish the US affiliate?

I was very fortunate to have been able to hire good talent. We also have a very compelling story in the US, which revolves around creating affordable access to complex medications in a reliable and safe way. The question of continuity of supply has been a huge issue in the last few years because there has been a lot of supply chain disruption. Supply chain is a competitive advantage for Biocon because we have strong quality systems and vertical integration, which ensures reliable and effective control over our supply chain.

We have had a very good track record with different regulators worldwide. Every year, we go through more through 40 external regulatory audits from the EMA, US FDA, ANVISA, COFEPRIS, PMDA, etc. Any time you walk into our facilities, that is how it is supposed to be. Nowadays you do not receive advance notice or warnings of these inspections so we are always prepared. What you see is what you get.

This supply chain reliability and continuity, coupled with our strong global portfolio, has really helped us build a strong Biocon brand in the US in a very short span of time. While our generics formulations business has only been present in the US for two years and we only have three

products in the market at the moment, we already have between 15 to 18 percent market share. Our customers have given us overwhelmingly positive feedback. Some of our buyers have told us that if they knew the drugs they were buying had been made with Biocon APIs, they did not have to worry about any supply disruption. That is a huge endorsement for us.

In terms of portfolio selection within the US, we are looking at products vertically integrated within our global supply chain as well as complex either in terms of APIs or formulations. We do not want a generics portfolio with hundreds of products, we want to have a selective portfolio. We are looking at complex injectables and complex peptides as well. In terms of therapeutic areas, we see huge opportunities in complex drugs with a strong patient base, for instance, in immuno-oncology, organ transplantation, diabetes and cardiovascular diseases.

How do you see Biocon’s value proposition within the extremely competitive US generics landscape?

You have to always assume the presence of competition, especially in the generics space. As mentioned, the level of vertical integration we have allows us to control our costs and supply chain, making us extremely competitive. It would be naïve to say we can avoid competition but with a complex portfolio, competition is more limited. For instance, with our rosuvastatin, even though it was the 18th or 19th generic approved in the US, we still managed to gain 17-18 percent market share.

In the US, we do not work directly with physicians and prescribers but through a model of automatic substitution. Our buyers are thinking strategically about the longer term. Price is important but with complex generics, we are seeing a shift where price is no longer the only deciding factor. They are looking for reliability, regulatory track records and strong quality systems. There is an element of close monitoring of the manufacturer’s operations. This is something we can capitalize on in order to communicate a more differentiated value proposition for our portfolio.

As our technology is complex and has been developed in-house, it requires close adherence to our quality management systems. This is something we want to keep close to us. We do also manufacture in the US but the costs in India are still more competitive compared to in the US or Europe. We are evolving constantly to keep up with the competition. For instance, we also use various analytical tools to anticipate any potential disruptions with our suppliers, right down to tertiary supplies. This is another example of the value-add we can deliver to our customers. We are looking at the long-term game here.

Access to affordable medicines is obviously one of the most pressing themes in the US as well as globally. How do you assess the level of access to generics over the past few years?

From the Association for Accessible Medicines (AAM), we have data highlighting that generics represent 90 percent of the volume of dispensed prescription drugs but only around 23 percent of the value. Part of this disparity can be attributed to the fact that from around 2011 or so, huge advancements in specialty medicines including biologics have been made, which have contributed to significant increases in healthcare spending, particularly as a proportion of the US GDP. There is a lot more work to be done in terms of increasing the penetration and value contribution of both generics and biosimilars.

In terms of regulations, we are advocating for certain changes. For instance, Medicare has been a great initiative since it was launched in 2006, helping to lower the costs of generics. However, we believe that the regulations should be made more favourable to generics. The Medicare Generics Penalty introduced in 2017 – where the prices of generics cannot be raised beyond the inflation rate – is not a fair practice. This percentage cap might make sense for branded products where a five percent increase could mean hundreds of dollars more but a five percent increase for generic products could be a few cents, due to the lower cost base of generics.

In addition, we are also advocating for certain generics, particularly if they are the first generic to be launched, to be moved to Tier 1 (preferred generic drugs), meaning that the co-pay is zero. This is something that the AAM and Congress are working on and we believe that it would be a win-win situation for the system, patients and industry.

Without going too much into the biologics portfolio, we also know that the price of insulin has caused heated debates in the US. Our Biocon Biologics team is doing a lot of work to create and increase affordable access to insulin in this country. We are working actively with the US FDA and they have been very responsive. I can relate to this topic personally because my mother is also diabetic and I appreciate how important it is for patients to not skip an insulin dose.

In general, AAM is really doing a great job in addressing these important issues and at Biocon, our views are aligned with theirs. With regard to innovators, I believe we all understand that they do have to generate revenues to fund research into new molecules and technology but we also see certain companies attempting to game the system to delay the launch of new generics and biosimilars.

The other pertinent topic I would like to address is the topic of the localization of pharmaceutical manufacturing. There has been a lot of chatter on Capitol Hill regarding the need to increase domestic pharma manufacturing in the US to secure supply chains. But I believe a longer-term view needs to be taken rather than any kneejerk reactions.

Yes, there is additional security in terms of having certain essential drugs manufactured in the US but the fact is that lower manufacturing costs in other parts of the world, including but not limited to India, is something that has helped lower the costs of medicines for patients in the US. There need to be more regulations to help patients gain access to affordable medicines rather than shutting down that access. We need to approach this strategically.

While we are in particularly challenging moments, could you preview your plans and priorities for the upcoming year or two ahead?

That is a very interesting question. These have been testing times but I truly believe that in these times of difficulties, we have demonstrated the value proposition we bring to this market and our patients here: affordable access and continuity of supply. The way we manage our supply chain, our vertical integration, our inventories, and so on has stood the test of COVID-19; the way we stockpile inventories in the US to address any eventualities means that we have not had a single disruption to supply. This dedication can be seen in our manufacturing facilities in India as well. I really have to take my hat off to our global teams, who have ensured that drugs can reach patients even during these challenging times.

We have just started our operations in the US and we are now preparing for the upcoming launches of our existing pipeline of complex molecules. We are excited to really make a huge impact on increasing affordable access to medicines in the US. It is an important journey. Biocon globally may have been playing a more behind-the-scenes role as a developer of complex APIs and formulations but soon you will start seeing us on the frontlines of the generics market in the US.

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