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Taking Control Of Our Destiny: Biocon Biologics CEO Tambe Celebrates European Viatris Integration

Fresh Opportunities Loom, With Seven Biosimilars Already In Europe And Three On The Way

by David Wallace

With Biocon Biologics having previously integrated its acquisition of Viatris's biosimilars business in emerging markets and North America, the firm has now completed integration in Europe. In an exclusive interview, CEO Shreehas Tambe tells *Generics Bulletin* what this means for the company and reveals the opportunities it perceives ahead.

"Unless you control the business directly, you do not have control over your destiny. That was very clear to us from the beginning."

This is how *Biocon Biologics* CEO and managing director Shreehas Tambe describes the significance of the Indian firm's $3bn acquisition of the biosimilars business of former partner Viatris, a deal which has now completed integration in Europe following similar earlier milestones in emerging markets and North America.

Talking to *Generics Bulletin* about the transition in an exclusive interview, Tambe has highlighted the opportunities for Biocon Biologics to not only improve access to biosimilars in Europe and to have greater control over the business while enjoying the value-chain benefits that come with vertical integration, but

Key takeaways:

- Biocon Biologics has now completed integration of the Viatris biosimilars

also to venture into new business areas and markets as the company moves forwards.

"The integration of the Viatris biosimilar business in Europe ahead of schedule is another important milestone for Biocon Biologics in our journey as a global biosimilars leader," Tambe described.

"If we go back in time to just over a year ago," he said, "29 November 2022, that's when we completed the transaction with Viatris – and we paid for the deal, and we became the owners of the business." (Also see "*Biocon Closes $3bn Deal For Viatris Biosimilars*" - Generics Bulletin, 30 Nov, 2022.)

business in Europe.

- The firm has seven biosimilars approved and marketed in Europe, with three further products on the way.
- The company sees room for expansion in Europe and opportunities to address gaps in equity of access to treatment as well as high healthcare costs.

"We had structured it in a manner where we said we would transition the business over a series of stages," Tambe explained. After completing integration in emerging markets and North America – both ahead of schedule (Also see "*Biocon Biologics Integrates Viatris Business As It Introduces Adalimumab*" - Generics Bulletin, 13 Jul, 2023.) (Also see "*Biocon Biologics Moves Quickly To Integrate Viatris In North America*" - Generics Bulletin, 6 Sep, 2023.) – the firm turned its attention to Europe.

"We wanted to make sure that we we had control of these businesses sooner rather than later," Tambe outlined. "So although we had a two-year transitional service agreement [with Viatris], we said the sooner we have our feet on the ground, our people taking charge of the business and controlling it, we have a better control of what we want to do going forward."

"So I think that was what really drove us to transition North America on 1 September. And now exactly 12 months post the transaction closure last year in November, we've now been able to complete this in Europe as well."

Within a year of the Viatris deal closing, Tambe said, "95-plus percent of the value that we had acquired is now transitioned over, and we will have Biocon Biologics employees leading the business and making decisions on behalf of the business."

The CEO said he was "very proud of what the team has achieved in such a short time, given that we had no presence, no infrastructure, no employees, in this part of the world – to have gotten done in such a short time just talks to the commitment that the team has had to making this happen." This included staff from both Biocon Biologics and the former Viatris business, he

underlined. “I think it’s been a remarkable team effort.”

The final wave of integrations – the last “5% piece” – would be “Japan, Australia, New Zealand, and a few countries in emerging markets, five or six of them,” Tambe indicated. “We guided that we will do that before the end of the fiscal [year], but I think the team has always positively surprised us by doing it ahead of time. So I wouldn’t be surprised if if in the new year we would be a fully integrated company.”

Seven Biosimilars In The European Market; Three Waiting In The Wings

Offering greater detail on the firm’s interests in Europe, Tambe said the firm was “in a very unique position” with “seven biosimilars already approved and ready to market in this region.” These are insulin aspart and insulin glargine, bevacizumab, pegfilgrastim, trastuzumab, adalimumab, and etanercept.

“We we see a lot of headroom, because we haven’t really explored what more we could do with these products,” the CEO suggested.

And “more recently you’ve seen us be first to get approved for the ophthalmology drug aflibercept, both in the EU and now also in the UK,” Tambe highlighted. Market entry for the Eylea biosimilar “will of course be determined by the loss of exclusivity date,” he acknowledged, but “the good part is there is no question on the launch anymore.” This offered Biocon “an opportunity to make a difference in a new therapy area – because we weren’t focused on ophthalmology up until now.”

On top of aflibercept, he acknowledged, “we have publicly talked about two other products – one of which is in the process of of getting filed this year, which is a Stelara (ustekinumab) biosimilar; and then the Prolia/Xgeva (denosumab) biosimilar.” These were “two assets, in addition to aflibercept, where we believe that there are sizeable opportunities which can drive growth.”

“So seven products already in, three products in the wings. I think that’s a very, very exciting few years ahead.”

Addressing Inequitable Access And High Healthcare Costs

In terms of the overall opportunity that Biocon Biologics saw in the European biosimilars market as a whole, Tambe said there were “several positives that we take from this region.”

While all individual European markets had “different concerns and needs – not everything is a monolith,” the CEO said that “what is common across Europe is there’s a growing healthcare bill overall. And that bill is is anywhere in that $700bn-$800bn range, that is the overall healthcare cost…including not just the drugs, but also the hospitalization costs.”

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To address this "growing concern," Tambe said, "where we come in is to bring in biosimilars, which can allow the administrations to provide healthcare access to an ageing population."

"I think there's a big opportunity in the three therapy areas that we've chosen to be in," he outlined. "What we've chosen are debilitating diseases – we've chosen diabetes, which is chronic care; we've also chosen autoimmune, which is again chronic care; and then we've chosen to be in oncology, because these are life-threatening diseases. And we can have life changing treatments if we can do this right. And that's an area where we believe we can make maximum impact."

"That's why we believe we are in a very good place with a pipeline of almost 20 products to be developed. So that is something that we see – Biocon making a big difference as we now come to Europe as a fully integrated player."

Beyond Viatris: Kiran Mazumdar-Shaw Talks Next Steps For Biocon Biologics

By David Wallace

11 Sep 2023

As Biocon Biologics completes its integration of the biosimilars front-end business that it acquired from former partner Viatris, Biocon founder and chairperson Kiran Mazumdar-Shaw talks to *Generics Bulletin* about how the firm is now capturing the full value of its biosimilars, while also looking at expanding into new markets previously unserved by Viatris.

Read the full article here

On the question of improving access to treatment, Tambe said that "one of the things that the pandemic exposed is the is the big inequity, and that showed that the the access to medication was predicated by the affluence of countries. While there is a certain set of challenges that you see in the more affluent countries, you see a very different set of challenges that you're seeing in countries which are still trying to put things together."

"What we've looked at is to see how can we make a difference by accessing all of these markets, whether it is in the CEE region, or whether it is in the other Eastern European markets where there is an opportunity to reach many more patients."

"I think one of the one of the things that [founder Kiran Mazumdar-Shaw] touched upon as well, she always talks about it, is that from her perspective and the legacy that she's built, it's not always been just about profit maximization. It's always been about increasing access, it's about equity delivery for health care."

"And overall her view has been that even though we are in the business of making profits, we are in a humanitarian business. So that whole thing has guided everything we've done. That's really been the vision that has guided the company."

Meanwhile, in terms of expanding the scope of the business in Europe, Tambe said the question was "not so much about what Viatris has done or hasn't done [historically]. It's about our focus, to see that we want to bring all of these seven products to these markets."

"If you see our portfolio today, a significant amount of difference that we make in these markets is through adalimumab. That's one of our biggest products here. But we have a large opportunity to make that difference in oncology, where we still have a lot of headroom."

"We have not entered this for a short run, we are here for the long-term."

> *"The European agencies and all the regulators in the European market have always been driven very strongly by science."*

Meanwhile, interactions with European regulators had been "extremely positive" for Biocon Biologics, Tambe suggested.

"One of the things that we've seen, always with the European agencies and all the regulators there in the European market has been that they've always been driven very strongly by science," he observed. "And that's allowed them to frame their regulations overall, and their guidelines, on the basis of a very strong foundation and understanding of science."

"These are things that are evolving over time," he pointed out. "These are complex biologics. These are big molecular weight proteins. So it does require a lot of understanding. And I think the European agencies have invested a lot of time and a lot of energy. And there's there's a very constructive dialogue that we've personally experienced."

This was part of why biosimilars were "seeing a big uptake," he suggested. "There's a very good reception to biosimilars. There's a big market share because the physicians are involved in the process, the scientists are involved in the process. So the 'convincing' part is very short because they're convinced in the approval process itself. So we take this as a very positive, constructive science, science-driven environment, which we feel very comfortable about."

Biocon Group CEO Does Not Mean Operational Change For Biologics

During the interview, the Biocon Biologics chief also touched on the recent appointment of Peter Bains as the Biocon group CEO. (Also see "*Biocon Gets A New Group CEO As Aflibercept Approval Arrives*" - Generics Bulletin, 21 Sep, 2023.)

“Peter’s been with the company for a long time,” Tambe pointed out. “And we’ve all known Peter in his previous stint when he was with us heading Syngene, and took Syngene public. So Peter is not new to us – I’ve personally known him, having been in the company for over 26 years, for a very long time.”

But despite Bains taking a role overseeing all three Biocon companies – Biocon Limited, which houses the firm’s generics business; the Syngene CDMO business; and Biocon Biologics – there would be “no operational change to any of the companies,” Tambe said.

“These three companies have their own CEOs, their own managing directors and boards, they will run independently reporting to their respective chairman and board,” he described. “So the the operational pieces do not change, the strategic pieces do not change.”

“What changes – or rather, I would say what was being done by Kiran [Mazumdar-Shaw] as the founder – is that she was looking at synergies across the group to try and see how we can maximize value to the customer, to the patient, through all the three subsidiaries that she had founded, incubated and brought together.”

“Now Peter comes in to help out with that process to see how can we bring synergies to our end customers – how can we bring value to the end customer who is looking to, say, have a small molecule plus a biologic, and see our services offering. And all of that could be coupled and could be offered to a customer. This is just an example.”

A second example “could be if there are synergies within the group, if one company has capacity available. Typically you have ‘Chinese walls’, which prevent you from looking over, because that’s what is needed to run your business. But given that we [now] have a group level of visibility, you can access that – it would have to be as per the arms-length agreements, but there is now a possibility to look within the group and see if there is an opportunity for us to leverage investments that have been made at a group level in a more efficient manner.”

“So that’s the overarching value that Peter will bring, in addition to having group-level strategies that that each of these companies are doing.”

A Three-Step Approach For Future Growth

Looking ahead, Tambe set out his vision for where Biocon Biologics would go after integrating the Viatris biosimilars business.

“What has been very critical right now is the transition of the business from Viatris to us,” he acknowledged. “And we’ve been very focused [on that]. Because unless you control the business directly, you do not have control over your destiny. That was very clear to us from the beginning.”

“And while we had taken the cover of the two-year period that we had outlined in the contract, we were very focused on transitioning this sooner – a lot of management energy and focused strategy has been put together to get here.”

What the company had now evolved, he summarized, “is a three-step approach. That has been, one, to consolidate the business that we acquired; two, to preserve value in this acquired business – because there’s a lot of goodwill that’s there in the business today, and we need to make sure we preserve that; and three is, once you’ve done step one and two, you set out those growth strategies to take this business to the next level that it can go to.”

“We’ve put together a very robust plan over the next two years,” Tambe concluded, “so that we take the organization from where we are today – which was largely a science-driven, manufacturing focused company – to a fully integrated organization, which is now focused on making a difference to patients, customers, bringing bigger value of data and unlocking value to shareholders overall.”

“So I think that is really the way forward for us.”