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Dr. Raymond De Vré, senior VP and head of Business Operations and Strategy, Biologics at Dr. Reddy’s in Switzerland, discusses scaling up the Indian-headquartered company’s biosimilars business globally and the importance of selecting Switzerland as the location for regional headquarters.

After 15 years with McKinsey, advising life sciences companies on their business strategies, you crossed over into the world of pharma with Dr. Reddy’s and now find yourself helping Dr. Reddy’s scale their Biosimilar business globally. How would you describe your functions today?

That’s absolutely correct. After some 15 years as a consultant in which I gained strategic knowledge of the biotech and biosimilar industries, I took the decision to cross over onto the other side of the fence and play an active role in the development of Dr. Reddy’s biosimilars business. At the time, I had limited interest in joining the corporate world of big pharma, but a pioneering, listed, mid-cap company such as Dr. Reddy’s held great appeal for me, especially as they had already set themselves apart as one of the first movers from outside of the Western world to be betting big on biosimilars. Today I am very proud to be leading the business operations and

strategy functions, which means overseeing the commercial and technical operations, including manufacturing, supply chain, distribution as well as marketing, alliance management, strategy, IP and portfolio management. My team is largely based in India, but has also team members working from Basel, Switzerland and Princeton, New Jersey.

In addition to this role, I'm also head and board member of our office in Basel, Switzerland. This Swiss affiliate of Dr. Reddy's serves as our European headquarters and takes the lead in deal making with European companies.

Why was Switzerland selected as the optimum location for a regional headquarters of this sort?

Partly it is down to the historical legacy. For a long time, Dr. Reddy's has maintained a Swiss legal entity as a holding company for our international business. Switzerland also offers a favorable jurisdiction for making deals internationally while also being strategically located right in the heart of Western Europe.

From a business optimization standpoint, it made a lot of sense to build on this foundation, to enhance the capabilities operationally and to formally have a substantive regional headquarters. The reasons are manifold. Firstly, Switzerland, and especially Basel, forms the nucleus of a large life sciences ecosystem where there is ready access to an excellent talent pool irrespective of whether you are looking to source highly skilled business developers or specialist clinicians. It is also a great meeting place where industry, government and academia closely interact, so an excellent location for forging relationships and identifying and initiating new partnerships. If you're conducting deals with European companies, it is critical to have a permanent presence in Europe, and Switzerland lies in the backyard of all of these significant pharma markets, not to underestimate the importance of the Swiss life sciences technology ecosystem itself.

How would you describe the state of play of Dr. Reddy's biosimilars business right now?

At this point in time, our commercial activities are focused on emerging markets. Nevertheless, we have teams actively working on securing marketing authorizations of all our critical programs in Western, highly regulated markets as well. This is a work in progress and we expect it to take several more years before we get there.

Our biosimilars portfolio is an important element of Dr. Reddy's ongoing transition into a specialty pharma company. Dr. Reddy's is known as a pioneer and leader in quality generics, but our aspiration is to become much more than that in the future.

In 2001, we distinguished ourselves in being one of the first companies from the developing world to launch biosimilars with four products within the first decade of activity. 2010 to 2011 then marked a critical juncture in our history because that was when we committed to going beyond India and Emerging Markets and building a global business including highly regulated markets such as the USA and EU. But we also realized that we couldn't achieve that alone and would require external capital and manufacturing know-how. Our biosimilars partnership with the biosimilars business of Merck Serono (which is now Fresenius Kabi), which was signed in 2012, was a direct consequence of this decision. They were seeking a portfolio of products and we were searching for a partner that could assist us from a financial, development and manufacturing standpoint. This represented the starting point of our journey towards regulated markets.

We currently have three products in clinical development for highly regulated markets. The first time we approached the FDA was back in 2011 and we have learned a great deal in the intervening period with regards to our ability to fully design and execute on an end-to-end high quality biosimilar program. We believe that we are one of the few companies with this kind of end-to-end capabilities outside of the US and Europe. In this next phase we are actively looking at strategic ways to scale our efforts across the globe.

From a revenue perspective, in a five-year period, our biosimilar revenues from Emerging Markets have tripled and we strive to manage this as a consistent pace of growth going forward. Meanwhile, over the same period, our production volume has increased several-fold and we have been augmenting our manufacturing capacities by expanding and upgrading our facilities in India. This year, Dr. Reddy's became the first Indian company to install General Electric's FlexFactory platform, a biomanufacturing system based on single-use technologies. This should enable us to meet both the expected growth of our currently marketed biosimilars as well as support the launch of a significant portfolio of new biosimilar products in the years to come.

What are the main challenges of bringing biosimilars to regulated mature markets?

We have embarked upon a two-pronged strategy to rapidly scale our activities in emerging markets while simultaneously making headway into highly regulated ones. Until 2010 our emphasis was mainly on increasing patient access to biotech-based therapies in economies with low

purchasing power and limited state financial firepower like India. Introducing affordable biosimilar is obviously a great way to realize that goal and remains fundamental to our purpose at Dr. Reddy's, of "Accelerating Access to Affordable and Innovative Medicines." What has changed, however, is that biosimilars are also becoming to be highly valued in mature, developed markets. In these markets, they provide a way of cutting costs and generating savings in line with the prevailing need to optimize healthcare costs. So, we are eager to be able to make a difference here as well. Today our goal is to continue to provide high quality affordable biologics to emerging markets to help improve access to patients in these countries while simultaneously launching these same high-quality products in highly regulated markets.

The main challenge in the mature markets is the stringency of the regulatory frameworks: the sheer amount of clinical, non-clinical and analytical evidence that is required is extremely demanding and can be very expensive. We believe that we are one of only a handful of companies to have generated the appropriate high-quality evidence necessary to successfully navigate this process in highly regulated markets.

Emerging markets, meanwhile, are in general, less competitive from our perspective and we are already one of the more established actors leading the pack. These days, the regulatory bar is also increasing in most emerging markets, which is a good thing. While we are already amongst the established leaders in these markets, our strategy is to make sure that we keep a "One Product, One Quality" approach towards both emerging markets and highly regulated markets. It is also critical to recognize that the penetration of the typical life-saving biologic treatment remains extremely low in most emerging markets and that the risk-benefit balance in these countries is therefore different: while high quality biosimilars are a must, improved access is also critical to avoid patients dying from what are at times curable diseases.

What is your strategy for taking on companies like Pfizer, Amgen and Sandoz in the highly regulated markets (HRM)?

While I cannot comment on these specific companies and their respective strategies, our approach tends to differ from theirs, as in my experience big pharma companies usually do not take the risk of launching a new branded product in an emerging market first, whereas we do that routinely because India represents our home turf.

When we think about how we are going to position ourselves against competition in the highly regulated markets, we must remember to consider the value of the market, the product and

commercial complexity and the number of players likely to be involved.

In my view, the biosimilars segment will remain complex for the near term and a predictable return on investment will be challenging because of the time and expense involved in developing and producing what are in the end “undifferentiated” products. And as a new product class, there will also be a lot of market shaping, especially in the early days. It is this early period that I believe the large companies find very attractive, where they expect price erosion to be limited and the market to likely be shared amongst very few players.

However, we do not view this as a sustainable dynamic. Commercially speaking, once biosimilars go mainstream, we believe that the sales process will be closer to that of limited competition complex generics rather than originator products. The concept of product detailing will give way to more broad-based biosimilar advocacy which will slowly but inevitably give way to a limited competition but extremely price-sensitive contracting dynamic. That said, it’s also not going to resemble the small molecule generics environment where you can face a race to the bottom in terms of pricing and you can have as many as 20-30 players competing amongst themselves.

What next, then, for Dr. Reddy’s biosimilars business? How would you describe your immediate priorities looking forwards?

We are investing significant R&D each year on developing our biosimilars portfolio. Obviously, the mainstay of Dr. Reddy’s is generics, which is what we have achieved global acclaim for. We realize, however, that today 30 to 40 percent of the value of all new drug launches comes from biotech-based products and therefore we cannot miss out on this segment. And that’s why we view it as a core aspect of our strategy to remain highly involved in the biosimilars space as it evolves.

The near-term dynamics for biosimilars remain somewhat uncertain because there are a lot of unknown factors including the way in which regulatory frameworks will continue to evolve. So, this is very much a question of managing uncertainty, remaining flexible, adapting your strategy when needed, and preparing for the future in a systematic and realistic manner. We have already assembled a great backbone with strong capabilities and a talented, multidisciplinary team of several hundreds of people. We have something that is in-house, fully integrated, readily scalable, and very cost-efficient.

In the coming decade we will see some 20 to 25 new biologics coming off patent and we need to be in there with equivalent biosimilars to take advantage of this. We don’t yet have the scale to do

this all by ourselves, but we are chipping away at it one molecule at a time and remain open to strategic partnerships. Meanwhile we are happy with the progress being made in securing authorizations for both emerging markets and highly regulated markets.

Disclaimer: The views expressed in this interview are the personal opinion of Raymond De Vré and may not be the company’s position.

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