Interview: Jeremy B. Desai – CEO & President, Apotex, Canada

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Dr. Jeremy B. Desai, CEO & President of Apotex, the Canadian international generics powerhouse, discusses his mandate in 2014 to take the company global, the challenges and opportunities of increasing convergence between the generics, branded and biosimilars sectors globally, and the main growth engines for Apotex looking forward.

Jeremy, you were no stranger to Apotex when you assumed position as President and CEO in August 2014. What was your mandate then and where is the organization today?

One of the critical things I felt we had to achieve as an organization in August 2014 was to help Apotex operate more like a global organization – while retaining its Canadian heritage and respecting the legacy of Apotex's journey up to 2014 as a very successful Canadian company with a very Canadian focus. In the past three years, my team and I have developed and implemented a lot of processes, structure and governance in order to maximize the impact of our global footprint – so that whether you are in Australia or Mexico or China or India, you will have the same Apotex experience. Previously, people in other affiliates might have seen themselves as part of the local organization but not necessarily have felt a sense of belonging with the global corporate entity.

The new Apotex way is that, irrespective of where you operate, at which level, in your role, and so on, our employees have a one Apotex experience, embrace the corporate set of values and fully understand the role that they play to support the overall company vision.

Globally, generics giants are increasingly building a presence in branded pharmaceuticals, while at the same time, innovators have encroached on the generics space like Novartis with Sandoz, the global pioneer in biosimilars. How has that changed the playing field?

This is a big challenge for generic players like us. We are really on the cusp of this huge convergence within the industry; large pharma and biotech companies have seen their R&D productivity declining, especially in the aftermath of large M&A events that have occurred more frequently within the industry. As a result, they recognized that there is value to entering the world of generics and biosimilars. Particularly the latter, for instance, where you have the likes of Amgen partnering with Allergan and Mylan, and of course, Pfizer's acquisition of Hospira.

On the other hand, generics companies have recognized for a number of years now that it is increasingly inviable to remain a pure-play generics player, what with the increasing number of competitors, especially low-cost manufacturers, and the shrinking portfolio of opportunities to genericize. Generics companies like Apotex have to look at other ways of differentiating ourselves and moving up the value chain.

What is quite interesting is that this convergence has occurred within the HR and talent space. 15 to 20 years ago, it was very rare for someone from the generics industry to move into the branded industry, and vice versa. There was a level of discomfort that one side could not even begin to understand what the other world was like, and movement of employees was up the respective verticals. Now, with the fusion of brands, generics and biosimilars, these industries are much more inter-related.

Even at the regulatory level, there is increasing global convergence as Tier 1 agencies share information and best practices with each other, bringing along a level of complexity that did not exist five to ten years ago.

We are all playing in a common space now. With that brings challenges to us because we are now in a situation of competition with organizations that have many more resources than us.

Nevertheless, looking at the business, there is an increase in global demand for generics products. We are not operating in an environment of diminishing demand.

It may be an oversimplification, but success is all about having the right portfolio, at the right price, available at the right time, in the right place. If a company like Apotex can be successful in executing across the value chain from R&D to manufacturing to commercialization, there is still

ample opportunity to grow.

How ready is the global market when it comes to the use of biosimilars?

Education on biosimilars is one of the most critical success factors for the industry. We are at a point no different to where generics were in the mid-1980s, where there was a lot of lobbying from the brand companies saying generics are cheap and substandard. It took a while for stakeholders to trust in the safety, efficiency and value of generic drugs. Biosimilars are on that journey at the moment.

This journey varies for different types of biosimilars. Cytokines-based products are a lot easier to educate KOLs and decision-makers about. Once you move into the monoclonal antibodies, especially for oncology indications, you have a bigger hurdle to overcome. Unsurprisingly, Big Bio has invested in questioning the whole safety and efficacy issues surrounding them; the whole issue of immunogenicity has become a huge challenge. This is why we are having to spend a lot of time in reaching out to and educating regulators. The bar is high today because there is not enough experience, and while change will happen, it will take some time.

Europe is much more advanced on this front. In some cases, where the lead biosimilar required a full-fledged phase III clinical study, subsequent biosimilars have not. The US FDA is less advanced here, and Health Canada has not really had that much experience either. There are only a handful of biosimilars that have been approved in Canada as biosimilars, and Apotex is one of the few companies that have launched one in this market.

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Given these complex market dynamics, what will be the growth engines for Apotex in the future?

Apotex has made – and will continue to make – significant investments in biosimilars, bearing in mind that it is still a risky environment. The cost to develop biosimilars is an order of magnitude larger than conventional generics, and the regulatory framework has still not been clearly articulated in many jurisdictions. In the US, for instance, no position has been taken on interchangeability, which obviously adds to the uncertainty surrounding this space. We are developing our pipeline simultaneously as regulatory policies are being created, but the crucial question for Apotex is whether we can afford to not invest in this area of huge potential.

Another area is complex molecules, such as different dosage forms like controlled release-type formulations, long-acting injectables, dry-power inhalers (DPIs) and metered dose inhalers (MDIs),

and so on, which allows us to further differentiate our portfolio from other generic players.

The third area is OTC; we are still trying to firm up our strategy here. While OTC is typically associated with cough and cold products today, many governments, especially the UK, are encouraging Rx-to-OTC switches, as we have seen with statins and erectile dysfunction (ED) products. As we increasingly move the responsibility of drug purchases to the patients, there are certainly ample opportunities to take Rx products with an established safety profile into the OTC arena. Apotex has been very successful in marketing nasal sprays as OTC products in the US, for instance, under major pharmacy labels even as they continue to be marketed as Rx products.

Canada is notorious for having a very challenging market access environment. What challenges does Apotex face in your home market?

Generic penetration in Canada is around 70 percent, which is low compared to countries like the US, UK and Germany, which see around 88 to 90 percent. Increasing generic penetration to US levels will generate around CAD 8 – 9 billion of additional savings for the public healthcare system! Even one percent more generics utilization would save CAD 500 million, so we are talking about significant figures. There are many reasons for this disparity and one is the difference in IP regimes, but a significant factor is also the fact that for many types of generics, Health Canada still does not have defined regulatory pathways for market approval. This is particularly true for complex or niche generics. There are many complex products whose patents have by and large expired, but because of the lack of regulatory pathway for market approval of generic versions, Canadians are missing out on them – in many cases, products that have been genericized several years ago in the US, Europe and even smaller countries like Australia.

Many generics companies will not invest in the R&D and clinical studies if there is no regulatory pathway established. We – at Apotex and as an industry – are trying to drive the dialogue to expedite these processes. Another challenge is that Canada does not have a consistent reference when it comes to regulatory decisions because they sometimes take guidance from the US and sometimes from Europe, and the result often ends up being slower access than both jurisdictions!

With this new focus on areas where the Canadian regulatory system is perhaps slower than other key markets like the US and EU in adopting innovations, how important will the Canadian market continue to be for Apotex in the future?

Canada will always be important because it is our home market! It goes back to my opening comment about preserving Apotex’s Canadian legacy and heritage. In terms of number of prescriptions filled in Canada, Apotex is the largest pharma company in Canada! Like-for-like, we

are launching the most number of new products each year. We are very proud of our top positioning here.

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At an enterprise level, outside the emotional and strategic reasons, Canada is still a CAD 26 billion pharma market, with generics representing CAD 5 billion. From a healthcare costs perspective, there are still plenty of products to be launched as generic versions – and even more so when we look at biosimilars.

Apotex is one of the few companies to have significant manufacturing facilities in Canada as part of a global network. How competitive can Canada remain in terms of pharma manufacturing?

This is one of the discussions we as an industry are having at both the political and academic levels. How do we, at the government, academic and industry levels, work together to preserve innovation and support a viable manufacturing industry?

Many companies – branded and generics – have pulled out of manufacturing in Canada due to M&A or strategic reasons. The industry's manufacturing footprint – worth around 10,000 jobs today – is shrinking, and a very pressing question for Canada is how to preserve this.

Apotex is one of the few companies that can truly claim to be selling products truly made in Canada. Of the 89 million prescriptions we fill yearly, 90 percent are manufactured in Canada – not only as finished products but along the entire manufacturing cycle. A large amount of the APIs for our products is also manufactured here; Apotex has the largest fine chemical facility in Canada based in Brantford, Ontario, where we also conduct R&D. We even manufacture the plastic bottles that we put our products in!

Canada can remain competitive in manufacturing provided that our manufacturing processes are as efficient as possible. Incidentally, the Founder and Chairman of Apotex, Dr. Barry Sherman, is also our 'Chief Formulation Officer'! He has more or less designed every solid dose formulation that Apotex has brought to market in the past 43 years of our business. Today, over 80 percent of his time is still focused on designing new formulations. He is a true scientist and we are very fortunate to have him as an asset. A key priority is looking at older formulations – which were developed based on suboptimal manufacturing processes – to simplify them for more cost-efficient manufacturing. For instance, historically, most generics tablets have a large percentage of excipients. Dr. Sherman is going through the relevant subset of our portfolio and systematically

removing as much excipient as possible. This reduces excipient costs, cycle time, QC time and so on, resulting in significant manufacturing savings overall. Such innovations will allow Apotex to continue to manufacture competitively in Canada!

As a country, however, we also need to ensure that we have the technical skills and people to meet the needs of the pharma manufacturing industry. We are finding it difficult to recruit people with the necessary skillsets, firstly because the sector is shrinking, and secondly because the curricula of educational institutions are not necessarily designed to support our needs. This means having to source workers from outside of Canada, which may take around 8-12 months for work permits, and more often than not, Canada is often used as a stepping stone into the US.

Apotex currently exports to over 115 countries. What is your strategy for further internationalization?

We are currently undertaking a very detailed review of our existing markets to identify opportunities in new markets or even potential exits, based on factors like portfolio fit and core competences. Over the coming six to twelve months, we will have a much better definition of what our international footprint should look like. Nevertheless, our core market will remain North America.

I do see tremendous potential in the Gulf region. We are investing significantly in our R&D program to support the stability of our products in what we call the ‘Zone 4 conditions’ present in the Middle East and North Africa (MENA) area. Latin America (LATAM) is also another region with huge potential, and we are looking at this region over and above our existing successful presence in Mexico. In fact, we are actually looking to expand our manufacturing footprint in Mexico over the next 1-2 years. Japan is another market many companies, including Apotex, are wrestling with. The government had previously stated that they wanted to achieve generic penetration of 60 percent by 2017, so there are huge opportunities for us in Japan, but it is an extremely tough market to break into, and many companies have tried unsuccessfully. If we do pursue this opportunity, we expect to enter through a local partner.

What differentiates Apotex from other generics companies?

> “As a private company, we are able to make long-term decisions to build value for the company and patients. Even if we face challenges, without the pressure of having to satisfy quarterly earnings targets and stakeholders’ expectations, we do not have to deviate too far from our overall strategy.”

As a private company, we are able to make long-term decisions to build value for the company and patients. Even if we face challenges, without the pressure of having to satisfy quarterly earnings targets and stakeholders' expectations, we do not have to deviate too far from our overall strategy. The great advantage is that as long as we are doing the right things to build value, we are prepared to endure lean periods. We have one principal shareholder to whom I report, and he is extremely aligned with us on this approach. Our founder and chairman Dr. Barry Sherman always says that he does not want to mortgage his future for some short-term blips, and in fact, some of our biggest investments have been made during times of greatest challenges. This industry is inherently risky and it is necessary to play the long game.

To begin wrapping up, what is the next step for Apotex?

Firstly, we certainly want to consolidate and gain market share in the US. We currently have a small fraction of what is albeit a huge market, and with our company organization and pipeline investment, we can certainly increase this. I also want to consolidate Apotex's presence in other international growth markets, build a pipeline of biosimilars within the oncology space, and to provide an attractive portfolio of complex generics to our customers.

With my pharmacy background, I am personally passionate about the products we bring to market, and ensuring that, irrespective of where we are selling globally, the patient benefits from our products. I have since worked in this sector from the research side and the corporate side, which has really impressed on me the power that we have and the indispensable role we play within society. This is why I always tell my team: never forget what we are here for – it is to make people feel better.

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