Robert Matsuk – President, Glenmark North America



From an overall manufacturing perspective, regardless of regional geography, it pays to diversify manufacturing activities

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Robert Matsuk, president of Glenmark North America, introduces the scope of the company's operations in the US - including a manufacturing facility that obtained its first approval in 2019. Matsuk describes the unique business model a generic player in the US needs to maintain its competitiveness and conveys the role that the company plays in improving access to medicines.

Robert, please begin by introducing your career journey to Glenmark and the scope of the company's operations in the United States.

Prior to joining Glenmark in May 2014, I was a life science management-consulting executive. Taking the leadership experience I had as a consultant, I transferred these skills into the context of an individual company. Within the US operations, my responsibility is to oversee the company's generic and specialty brands.

Glenmark is a global organization, which generates approximately USD 1.5 billion annually. The US represents about 30 percent of this figure. In the US, about 80 million prescriptions per year are filled with Glenmark products and we currently have 162 products available on the market. About two percent of all prescriptions in the US are filled with our products.

What impact, if any, has the implementation of the Affordable Care Act had on the importance of generics for creating cost savings in the system?

On the generic side, there are already built-in incentives to drive penetration in the healthcare system. In fact, about 90 percent of prescriptions in the US are filled with generic products. Pharmacy Benefit Managers (PBMs) will typically advocate for the use of generics to create saving, even if sometimes there are debates on whether the first generic entering a market will be automatically covered on the formulary of a Medicare plan. Overall, generics are going to be more favourably priced compared to branded products except in specific situations. From a Medicaid and Medicare perspective, any opportunity to reduce the cost for the patient – in both generic and branded segments – will always be prioritized.

Speaking about Glenmark's portfolio, what does the company's American product offering look like and how do you go about harmonizing your product focus?

We have a combination of oral solids with a tendency to focus on selective high volume, low margin generics. We also specialize in dermatological formulations which is more of a niche area with somewhat larger margins. Looking forward, we are entering the injectables space, specifically for oncology with our recently launched product Fulvestrant. Overall, Glenmark has a robust pipeline targeted towards derma and injectables in the foreseeable future.

As a generic business, when it comes to product selection it important to establish a macro strategic direction. From there, we must identify where the best individual opportunities are depending on market size, competition, intellectual property, and our own production capabilities.

In a generic portfolio we constantly have to monitor our price erosions versus our price gains. We strive for new products to balance the price erosion of our existing portfolio – remaining stagnant is not an option. For Glenmark, this means getting anywhere between 12 to 15 product approvals per year to keep our competitiveness.

What factors do you take into consideration when defining the constitution of a successful product launch and pricing model?

Depending on how many competitors there are in the market we have our own internal metrics to determine what the target price and market share of a newly launched product should be. We will

also consider our own manufacturing capacities to triangulate around profit margin, share, and consistency to adequately supply the market.

Historically, there have been three major buying consortiums representing a majority of Glenmark's product sales. When the first consortium was established, we faced a steep price decline, but today we have steadied to what I would refer to as the 'new normal' for the sector. Furthermore, depending on the volume of competitors on the market we will have less price erosion for certain products. Typically, branded manufacturers will remain in the market after the expiration of their patent and introduce an authorized generic. Over time, the brand's market share will erode while still maintaining its set price.

What is the scope of Glenmark's manufacturing footprint in the US? What makes the country a strategic location for this kind of investment when operational costs are lower in other jurisdictions around the world?

It was several years ago that we initiated the development of our US manufacturing facility and we were finally granted our first approval in 2019. Moving forward, we are expecting the production plant to contribute more significantly to our US supply chain, particularly in the specialty pharmaceutical business of dermatology and injectables.

Globally, it is important to have capabilities in the geographies that a company is operating in. In the current administration, there is a "made in America" theme and Glenmark was certainly ahead of this curve in trying to establish production here in the US. Furthermore, having manufacturing locally opens the possibility to access some government markets which we would have not bee able to reach otherwise.

From an overall manufacturing perspective, regardless of regional geography, it pays to diversify manufacturing activities. If Glenmark were to hypothetically have all its manufacturing operations in India and something were to happen, it would be detrimental to the company. For a group like Glenmark with a global footprint, this principle applies to any country or production activity around the world. Therefore, having our production activities in the US finally starting to scale up is an important resource for the group overall.

How do generics play a role in ensuring access and affordability for American patients? Who should be the ambassador of this value proposition?

Generics are at the core of affordability. However, even though they represent 90 percent of drug volumes they only account for approximately 25 percent of the total value in the American marketplace.

As a generic company, we must keep lean operations to maintain our margins and profitability within this role we play in the healthcare system.

In the generic business, creating a conversation about the value our products bring in regard to affordability starts with the trade association, the Association for Accessible Medicines (AAM). This involves a lot of intricate work with the regulators to understand the entire value chain of generic products. What is important here are education and an understanding of how our products are priced. There can be a misconception where generics are accused of price gouging, despite facts that generic drugs have decreased over the last number of years.

In terms of the US political context, and with 2020 being an election year, what changes are you hoping to see with the authorities in terms of health conversations?

Currently, I anticipate that any pricing actions will be focused on the branded side of the pharmaceutical business rather than generics. Looking at the numbers in combination with what the current administration has communicated, what the government is focused on is the branded business, as roughly ten percent of US prescriptions represent 75 percent of the overall cost. However, from an industry perspective, we would like to see that pharma and especially generics can maintain its viability in the environment in which we are in. Furthermore, we hope to ensure that generics will never be disadvantaged compared to a branded player. Overall, having a fair competitive ecosystem is what I hope to see from government authorities.

When it comes to recruiting talent, what are the motivations for joining a generic player such as Glenmark?

Although we are a generic company today, our vision is to enter into the specialty pharma space and even develop innovative medicines with our Ichnos Sciences operations – our biotechnology division which is run as a separate company.

Glenmark prides itself on having a very entrepreneurial culture as opposed to other big innovative pharma companies. The generic business by definition is a very fluid environment and our people really have many opportunities to wear different hats in the organization – our employees

appreciate this flexibility to gain a width and breadth of experience.

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