Sharvil Patel â?? Managing Director, Zydus Lifesciences

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27.05.2024

Tags:

India, Zydus Lifesciences

Managing Director Dr Sharvil Patel outlines the objectives behind the rebranding of the Indian pharma company from Zydus Cadila to Zydus Lifesciences, provides insights into the importance of the US generics market where it launches some 30 to 40 products per year, and Zydusâ?? newfound focus on innovation with a novel therapies portfolio that includes orphan indications such as primary biliary cholangitis (PBC) and an oral malaria molecule that addresses both resistant and non-resistant forms of the disease.

Could you please explain the rationale behind your companyâ??s rebranding from Zydus Cadila to Zydus Lifesciences?

Over the past two decades or more, our primary focus has been on enhancing access and affordability to medication. This has involved making drugs more cost-effective and readily available, as well as overcoming technological barriers to ensure accessibility.

However, in the last 15 to 20 years, our research and development efforts have expanded to encompass a broader spectrum of initiatives. We have shifted our focus towards patient-centric approaches, considering their needs and perspectives when designing our business strategies. Additionally, we have embarked on initiatives targeting neglected and rare diseases, aiming to make a significant impact in those areas. Furthermore, we have broadened our scope to include the larger

healthcare ecosystem beyond pharmaceuticals, recognizing that addressing chronic conditions requires a multifaceted approach.

As we continue to advance in scientific research and explore new diseases and therapies, we have embraced a transformation from solely a pharmaceutical company to a more comprehensive life sciences entity. This transformation prompted the rebranding to Zydus Lifesciences, aligning with our vision for the next 25 years and ensuring our brand remains contemporary and future-ready, both domestically and internationally.

How did Environmental and Social Governance (ESG) factor into this transition? Did it have a significant impact?

ESG considerations have played a crucial role in our rebranding journey. There has been a notable emphasis on these aspects both domestically, driven by Indiaâ??s national aspirations, and internationally, guided by global standards for large corporations. This shift towards ESG has brought about several positive changes. Firstly, it has introduced a clearer framework with quantifiable targets, making it easier for companies to track their progress and achieve specific milestones. From our perspective, our focus extends beyond just healthcare; we are committed to minimizing our environmental footprint, particularly concerning water and energy consumption. Additionally, integrating ESG into our operations serves as a vital component of our risk mitigation strategy. By addressing corporate social responsibility (CSR), ESG factors, and regulatory compliance, we ensure that we are not only aware of potential risks but also equipped to manage and mitigate them effectively. Looking ahead, our goal is to continually reduce our environmental impact and align our practices with sustainable principles.

Given your companyâ??s sizeable presence in the US, how do you perceive the competitive landscape within the US generics market? Additionally, how are you capitalizing on opportunities in this market?

The US generics market holds significant importance for us, given its impact on healthcare affordability in the country. The Indian pharmaceutical industry, including generics, has played a pivotal role in driving down healthcare costs in the US, resulting in substantial savings amounting to billions, if not trillions, of dollars.

As for Zydus, we have secured our position among the top five players in the US generics industry. Our contributions to cost savings and accessibility are paramount. Moving forward, our focus remains on sustaining this momentum by continuously introducing new generics to the market. Annually, we file over 30 product applications and launch 30 to 40 new generics in the US, underscoring our commitment to enhancing access to affordable medicines.

Beyond conventional generics, we have also identified opportunities to make a difference, particularly in the orphan and rare disease segment. By addressing diseases with unmet medical needs, we strive to create meaningful impact. While these endeavours may not always translate into substantial revenue, they represent our commitment to pioneering initiatives where the need is dire. We have commercialized one medicine in this space and have another in the pipeline awaiting FDA approval, reflecting our dedication to addressing critical healthcare gaps. Additionally, we have extended our focus to new-born infant disease areas, aiming to significantly enhance life expectancy and improve quality of life.

Building on the discussion about the US market, the Inflation Reduction Act (IRA) has garnered considerable attention, particularly among innovators. As an Indian generic manufacturer, how do you perceive the IRA? Do you see it as an opportunity to further expand your presence and drive cost savings?

The Inflation Reduction Act primarily impacts innovative brand companies, as it addresses price increases beyond inflation, providing some openings for additional generics. However, for generic manufacturers like us, the impact is less pronounced. The US generics market is well-established, with clear pathways for product development, launch, and access. We typically witness high conversion rates, with over 60 percent conversions to generics on day one, rising to over 90 percent within three months. This underscores the efficiency and effectiveness of launching generic products in the US market. Overall, the US generics industry has been robust and offers ample opportunities for expansion and cost savings.

Shifting gears to biosimilars, how do you perceive the market development for this segment of your business, particularly in the US?

Our focus on biosimilars has primarily been on India and EMEA markets, rather than the US. This strategic decision is influenced by several factors, including the high costs associated with biosimilar development and the challenges in converting brand biologics to biosimilars in the US market. The reimbursement methodology in the US poses significant hurdles for generics, as stakeholders within the system benefit from maintaining high prices. To address these challenges, we believe that regulatory frameworks need to evolve, incorporating measures such as interchangeability and streamlined approval pathways akin to those for generics.

Additionally, recent legislative efforts to reduce inflation in drug pricing may pave the way for a more balanced playing field. Until such changes occur, our focus remains on novel and new products. In markets where access to biosimilars is limited or non-existent, we concentrate our efforts on providing affordable alternatives to address unmet medical needs. Internationally, we prioritize R&D investments in therapies that offer similar risk profiles without the need for extensive clinical trials. This approach aligns with our commitment to innovation while ensuring efficient resource allocation.

Delving into your focus on novel therapies, beyond rare diseases, are there any other areas that your company is concentrating on?

We have several areas of focus within our novel therapiesâ?? portfolio. One notable indication where we have completed recruitment for clinical trials is primary biliary cholangitis (PBC), an orphan indication in the US. This programme represents our most advanced initiative in the US market. Additionally, we are developing an oral product for anaemia associated with chronic kidney disease (CKD), which has already received approval in India and is being considered for global expansion.

Expanding our efforts in the orphan disease space, we are exploring treatments for conditions such as amyotrophic lateral sclerosis (ALS) and potentially Parkinsonâ??s disease, contingent upon favourable data from our ALS program. Furthermore, we are targeting the chronic autoimmune blistering skin disorder (CABS) indication, another rare condition in the US. With a pipeline comprising approximately 20 molecules, we currently have four to six programs in clinical development.

Notably, we are advancing an oral malaria molecule that addresses both resistant and non-resistant forms of the disease, offering a single-dose treatment option. Currently in phase three clinical trials, this malaria treatment underscores our commitment to addressing neglected and tropical diseases. Our overarching goal is to not only create value for our company but, more importantly, to make a meaningful impact on patientsâ?? lives based on the data and outcomes we achieve.

Speaking of your international footprint, there has been recent investment in a vaccine technology centre in Italy. Can you shed light on why your company has chosen to intensify its focus on vaccines? Furthermore, could you outline any forthcoming partnerships or strategic directions in this realm?

Our venture into vaccines is rooted in our commitment to enhancing access and affordability within the healthcare sector. While we have long been involved in vaccine production, particularly with our rabies and typhoid vaccines, we recognized an opportunity to expand our capabilities in this field. By leveraging our scientific expertise, we identified key immunization programs, such as those for measles-rubella (MR) and typhoid conjugate vaccines (TCV), as critical areas where our contributions could make a significant impact.

With only a few major players dominating the global vaccine market, particularly in underserved regions. To this end, we have diversified our vaccine portfolio to include innovative vaccines targeting diseases like COVID-19, hepatitis E, HPV, and Chikungunya, among others. Additionally, we have ventured into the private market segment with vaccines such as the flu vaccine and hepatitis A to hepatitis C vaccines. While the vaccine development process is lengthy and complex, spanning several years, we remain optimistic about our prospects for success.

Given this internationalization push, how significant does the Indian market for Zydus Life Sciences?

India has always been, and continues to be, a cornerstone of our operations. It serves as our home market and holds immense strategic importance for us. The majority of our innovation efforts are initially directed towards addressing the needs of the Indian market. We are deeply committed to expanding beyond traditional medicine offerings and are rapidly evolving to provide comprehensive healthcare solutions encompassing services, care, hospitals, diagnostics, and more.

Our focus extends beyond pharmaceuticals to include consumer health, medical devices, and diagnostics, among others. Notably, we operate a substantial network of hospitals in Gujarat, underscoring our commitment to holistic healthcare delivery. Our aim is to play a comprehensive role in managing lifestyle chronic diseases, such as cancer, where we boast the largest portfolio of breast cancer products in India. From early diagnosis and treatment to post-care support, we strive to offer a seamless continuum of care to patients.

Our vision is to provide an end-to-end solution that addresses every aspect of a patientâ??s journey, recognizing that both pre-treatment and post-treatment phases are equally critical. India remains our primary focus, reflecting our dedication to transforming healthcare delivery and improving patient outcomes on a local scale.

With India experiencing significant economic growth and gearing up for elections, there is a palpable momentum in the country. How do you envision pharmaceutical players leveraging this conducive environment to invest more in innovation, especially when many are content with manufacturing quality generics?

The landscape is ripe for pharmaceutical companies to seize opportunities for innovation amidst Indiaâ??s economic growth trajectory. While many companies excel in producing quality generics, there remains ample room for innovation, both in incremental improvements and transformative breakthroughs. The governmentâ??s visionary 2047 agenda, with a strong emphasis on innovation across various sectors, including healthcare, provides a conducive environment for fostering innovation.

Through initiatives like public-private partnerships and funding for research and development, the government is paving the way for collaborative innovation endeavours. We have already witnessed early successes in areas like CAR-T therapies, with Indian companies venturing into ground-breaking clinical programs. This highlights the growing recognition of the importance of innovation across industry and academia. Looking ahead, the pharmaceutical sector is poised to witness a significant chapter in innovation, driven by a collective vision for the future of healthcare in India.

While our primary focus may have been on manufacturing in the past, the shift towards an innovation-driven approach is essential for ensuring sustained growth and competitiveness in the global arena. As I reflect on the progress made over the past two decades, it is evident that we are moving steadily towards becoming a hub for pharmaceutical innovationâ??a journey that holds great promise for the future.

We touched upon the topic of ESG, and I understand your company has manufacturing plants in various countries, including Brazil, Germany, and Spain. Given the industryâ??s tight margins, how do you justify the costs associated with adhering to ESG standards?

It is indeed a balancing act between short-term costs and long-term benefits. While investing in ESG initiatives may incur immediate expenses, the long-term gains are substantial. By embracing environmentally sustainable practices and leveraging innovative technologies, we aim to enhance operational efficiencies, reduce our environmental footprint, and mitigate risks associated with non-compliance. While there may be initial costs involved, such as implementing new technologies and fostering a culture of sustainability within the organization, we believe that these investments will yield significant returns over time.

Not only can ESG initiatives contribute to business continuity and resilience, but they also have the potential to generate cost savings in the long run. As we navigate through the dynamic landscape of inflationary pressures and increased consumption of resources, adopting ESG practices can help mitigate these challenges and pave the way for a more efficient and sustainable future. Ultimately, our long-term vision is to achieve greater efficiency, compliance, and resilience, thereby creating value for our stakeholders while minimizing environmental impact.

Looking ahead, what do you see as the next major challenge for Zydus Lifesciences, and what are the companyâ??s performance goals for the upcoming years?

Over the next five years, our primary focus is on maximizing value creation from our innovative portfolio. We have set an ambitious internal target where we aim for 50 percent of our value growth

to stem from innovation by 2028 or 2030. This goal underscores our commitment to pushing the boundaries of scientific innovation and commercial success. While we have made significant strides in scientific research and clinical development, the next frontier lies in translating these achievements into commercial triumphs.

Successfully bringing our innovations to market, both domestically and internationally, is paramount. Whether through strategic partnerships or independent ventures, we are dedicated to ensuring that our ground-breaking discoveries reach those who need them most. Additionally, our focus on nurturing talent and fostering a culture of excellence remains pivotal. As we expand our operations both within India and abroad, investing in our people and building a robust leadership pipeline are top priorities. After all, our success is ultimately driven by the dedication and expertise of our team. As we embark on this journey, we are excited about the possibilities that lie ahead and remain committed to delivering impactful solutions for patients worldwide.

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