Shailesh Siroya – Managing Director, Bal Pharma Limited

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Shailesh Siroya explains the rationale behind Bal Pharma's strategic focus on niche products within the API segment, avoiding the broader, more competitive commodity markets and enabling it to establish a significant global presence. Siroya also outlines how Bal Pharma has evolved from its initial focus on the export market to a more diversified approach, and how it has managed to maintain a competitive edge by prioritizing high-quality standards, timely delivery, and regulatory support.

Can you provide a brief overview of your background and your reasons for entering the pharmaceutical industry 30 years ago?

My family originally comes from a small village in Rajasthan, India. We've been in Dubai since 1974, where we were involved in the jewellery business and even set Guinness World Records for manufacturing the world's longest gold chain during shopping festivals. After completing my college education in Mumbai and obtaining an MBA in the US, I ventured into the family business.

Following my return from the US in 1990-91, we saw an opportunity to capitalize on India's opening market and decided to shift our focus towards manufacturing. In 1992, we initiated commercial production after acquiring a sick unit through a bank auction. This marked the inception of our company.

As for why the pharmaceutical industry specifically, we were influenced by our business associates who were already active in the pharmaceutical sector. Initially, we aimed to manufacture general Active Pharmaceutical Ingredients (APIs), the raw materials for pharmaceuticals. However, an opportunity arose to acquire a formulation unit in 1991, and that's when we entered the formulation sector. Our group company, Lake Chemical, was established for API manufacturing, while Bal Pharma emerged as our formulation-focused venture.

Can you elaborate on Bal Pharma's journey and its association with Micro Labs? How did the company evolve from its initial focus on the export market, and what segments does it cover today?

Bal Pharma's journey is tied to that of Micro Labs, a group that has grown to be a significant player in the Indian pharmaceutical industry. Initially, Micro Labs wasn't involved in API manufacturing, so we decided to explore that space collaboratively. Beginning with a strong focus on the export market, Bal Pharma has expanded over the years and currently operates six manufacturing units, with plans for restarting one with modernization. Three of these units specialize in API and intermediate production, while the other three focus on formulations.

In the API segment, we strategically targeted niche markets rather than commodity products. Today, we boast a portfolio of approximately 25 niche products, including our flagship product, Gliclazide, an anti-diabetic compound. Gliclazide, originally developed by Servier in France, has become a significant part of our identity. We hold approvals not only from Europe but also from countries like Australia, Japan, and Canada. While we haven't entered the U.S. market due to non-approval by Servier, we've established ourselves as a leading generic API supplier globally. In fact, we manufacture around 25 percent of the world's volume of Gliclazide, showcasing our strong global presence.

However, despite our success on the international front, our domestic operations haven't seen the same dominance in the formulation segment. While we were pioneers in launching the Indian brand of Gliclazide after Servier in India, our focus on creating leadership positions domestically has been a work in progress.

Could you explain the process of manufacturing Gliclazide and your role in it? How has the competition landscape evolved over the years, considering your initial position as a

single player in India?

The manufacturing process of Gliclazide involves in-house research and development of the chemistry. We handle the entire process, starting from raw material manufacturing to the final product. Initially, we were the sole player in India for a considerable period. However, in the last two to three years, we've witnessed an emergence of other players in India, introducing some internal competition.

When we commenced production, Italy was a major source for this compound. As we gained prominence, we replaced Italy in the market. Subsequently, China entered the scene, becoming an aggressive player and introducing a new dimension of competition. Despite the evolving competitive landscape, our commitment to maintaining high-quality standards and our long-established presence in the market have been crucial in sustaining our leadership position in Gliclazide manufacturing.

Your success in securing a significant market share for compounds like Gliclazide and Ebastine is impressive. Could you elaborate on the key factors that contributed to this success, considering the competition from larger pharmaceutical companies?

Our success can be attributed to a combination of factors. Firstly, our cost competitiveness, maintaining high-quality standards and ensuring timely delivery have been pivotal. Regulatory support has played a crucial role, enabling us to strengthen our position in international markets.

In the highly competitive landscape, particularly against Chinese suppliers, we successfully navigated challenges, even resorting to filing anti-dumping duties to ensure fair competition. Our strategic focus on lifestyle products, specifically in therapeutic areas like diabetes, antihistamines, cardiac, and gastro, has been a key differentiator. We deliberately avoid acute therapies like antibiotics.

Looking ahead, our vision revolves around building a robust portfolio of lifestyle disease products. With a strategic emphasis on diabetes, antihistamines, cardiac, and gastro-related products, we aim to cater to the increasing prevalence of lifestyle diseases, especially in regions like India, often referred to as the diabetes capital of the world.

In terms of revenue, our international operations currently contribute around 70 percent, with a significant focus on Europe, Australia, and Japan. We are present in over 40 countries for APIs and over 70 countries when considering both API and formulations. The formulations are primarily

directed towards developing markets in Africa, Far East, and Latin America. This strategic approach positions us favourably for sustained growth in the global pharmaceutical landscape.

The dependence on API imports, particularly from countries like China (60 percent of India's APIs), is a significant aspect of the pharmaceutical industry in India. Could you shed light on the factors contributing to this reliance, especially considering the cost competitiveness and aggressive growth of China's API industry?

The reliance on API imports, notably from China, is rooted in the intense cost competition prevailing in the pharmaceutical market. Over the last few decades, China strategically and aggressively developed its API industry, enjoying substantial government support and subsidies. This allowed them to offer prices below the cost of production, leading to a situation where India, along with other countries, became dependent on Chinese supplies for a range of pharmaceutical ingredients, including antibiotics and vitamins.

China's ability to provide APIs at competitive prices led to a scenario where any attempt by India to increase its capacity was met with a reduction in prices by China, making it economically challenging for Indian manufacturers. This resulted in India sourcing a significant portion of its APIs from China.

Despite this reliance on API imports, India has positioned itself as the "pharmacy of the world" primarily due to its dominance in pharmaceutical formulations. Indian companies excel in exporting finished pharmaceutical products to numerous countries. While India may import certain APIs, it compensates by excelling in the manufacturing and export of formulations, leveraging a robust ecosystem of local and international sources for raw materials. This dynamic has allowed India to maintain a leadership position in providing affordable and high-quality medicines to global markets.

In response to the disruptions caused by COVID-19, there's been a shift in perspective towards reducing dependence on API imports, especially in India. Could you elaborate on the policies and programs initiated by the government to promote self-reliance in API manufacturing?

Post-COVID-19, the Indian government recognized the vulnerabilities associated with over-dependence on API imports, leading to a series of policy initiatives to strengthen the domestic API industry. Two key schemes have been instrumental in this effort. The Production Linked Incentive

(PLI) scheme focuses on critical raw materials where India faces a significant dependency. Under this scheme, the government provides support and incentives for enhancing the production capacity of identified key products.

Another noteworthy initiative is the PLI scheme for enhancing volumes, encouraging investment in facilities and overall business cycles to boost production. While these schemes aim to reduce reliance on imports, challenges exist, particularly in the efficiency of implementation. The release of incentives, though promised, faces delays and changes in guidelines, impacting the industry's ability to leverage the support effectively.

Our company qualified for the MSME listing under the PLI scheme. Initially, it was open-ended, allowing flexibility in reaching turnover targets over the next five years. However, subsequent changes in conditions, such as capping incentives for MSME upto the value of capital expenditure and also allowing claims at a maximum of 20 percent only in one year and balance distributed over the six year period and also new clause limitations on compulsorily claiming incentives in the fifth and sixth years, have added complexity.

The bureaucratic processes involved in claiming incentives pose challenges, and there is a need for more efficient release mechanisms. Despite the hurdles, the industry remains committed to contributing to the government's vision of reducing API imports and fostering self-sufficiency in pharmaceutical manufacturing.

Do you believe the Indian government should prioritize efforts to enhance the visibility and efficiency of its regulatory bodies? Are there ongoing initiatives or reforms addressing this aspect, especially in streamlining processes and moving towards a more centralized regulatory approach?

In the past, India's regulatory framework was decentralized, with each state having its own approval authorities, leading to variations in interpretations and standards. However, there has been a significant shift towards centralization and process improvements. The establishment of CDSCO (Central Drugs Standard Control Organization) reflects a move towards a more centralized approach.

While the transition is underway, digitization has played a crucial role in streamlining processes, making applications more accessible online. As the regulatory landscape evolves, it's anticipated that India will continue moving towards a more centralized regulatory structure, similar to

international counterparts like the FDA. Such a shift would not only enhance uniformity but also contribute to greater global recognition and credibility for Indian regulatory agencies.

Given that a significant portion of your business relies on exports, especially in a highly competitive pharmaceutical industry, what challenges do you face? how does your medium-sized company navigate this landscape?

The challenges in the pharmaceutical industry, particularly in exports, are multifaceted. One significant hurdle is the increasingly time-consuming regulatory processes across various countries. Obtaining product registrations is becoming a lengthy process, turning the development-to-market cycle into a multi-year endeavor. As a consequence, the competitive landscape is evolving rapidly, and price dynamics are changing during the lengthy registration period.

Price competition has intensified, with the generic market witnessing a flood of similar products. The rush to launch generics, particularly in the US and EU markets, leads to a high number of equivalent products available on the day of launch. This intense competition has driven down prices dramatically, sometimes up to a 95 percent reduction, challenging profitability for many players.

Moreover, the trend toward focusing solely on price overlooks the inherent risks associated with pharmaceutical manufacturing, such as batch inconsistencies and failures. The industry’s emphasis on aggressive pricing strategies may compromise quality and create challenges for companies committed to maintaining high standards in their chemical processes, especially for API production.

Another major concern is data privacy, and this issue is particularly prominent in India. Despite the government enacting laws to safeguard customer data from public disclosure, challenges persist. The Customs data, including details like customer information, product specifications, quantity, unit price, value, and port of shipment, is currently accessible to anyone. Although the Ministry has expressed the need for restrictions, effective implementation remains a challenge.

While there are regulations in place within India, certain entities have circumvented these restrictions by creating databases outside the country. This allows them to compile and share data from Indian Customs on various portals. This situation makes it challenging to operate in an environment where sensitive commercial information is readily available to competitors and stakeholders.

This lack of data privacy impacts industries across the board, with pharmaceuticals being a notable example. In the pharmaceutical sector, where product quality is defined by pharmacopoeial standards, pricing becomes a crucial competitive factor. With information on export prices widely available, a transparent market has emerged, leading to intense price wars. This phenomenon is not exclusive to pharmaceuticals but extends across various commodities in India.

The availability of detailed information on specialized websites, categorized chapterwise, further exacerbates the issue. Interestingly, the affordability of this data has contributed to its widespread accessibility, removing any potential price barrier that could have acted as a deterrent. This situation contrasts with some other countries, like China and the United States, where data protection measures are more stringent. However, the global trend indicates a growing challenge of maintaining data privacy in the era of increasing digital accessibility.

How does the confidence in the Indian pharmaceutical industry manifest, considering the domestic and international landscape, population size, evolving delivery systems, and the industry's ability to address health challenges?

The confidence in the Indian pharmaceutical industry is multifaceted, reflecting both domestic and international dynamics. One significant factor is the expanding market size driven by the country's large population. The increased access to medicines, facilitated by evolving delivery systems, contributes to a robust domestic market. The population's growing health consciousness, coupled with longer life expectancy and an uptick in lifestyle disorders, further fuels pharmaceutical consumption.

On the international front, India's pharmaceutical industry is regarded with confidence due to its capacity to deliver, ensuring a steady supply of medicines. This confidence is underscored by the industry's competitiveness in terms of pricing. The country's pharmaceutical sector boasts a well-developed ecosystem, encompassing the entire production chain from basic chemicals to intermediates and active pharmaceutical ingredients (APIs).

Despite global discussions about the importance of localized pharmaceutical production, India's industry stands out due to its established infrastructure and expertise. The country's pharmaceutical ecosystem has proven resilient even in the face of challenges like the COVID-19 pandemic. While there were initial concerns and efforts to qualify alternative sources post-COVID, India's pharmaceutical industry has demonstrated its adaptability and reliability.

The ability to provide a comprehensive pharmaceutical ecosystem gives India a strategic advantage. The industry's integrated approach, encompassing the production of basic chemicals, intermediates, and APIs, positions India as a reliable global pharmaceutical hub. This strength, combined with the industry's competitive pricing and established delivery mechanisms, contributes to the overarching confidence in the Indian pharmaceutical sector. Despite occasional discussions about the need for localized facilities, India's pharmaceutical industry remains a key player on the global stage, benefiting from its strong foundations and adaptability to evolving market demands.

In the current momentum of growth in the pharmaceutical industry, how is your business faring, and what strategies are you employing to capitalize on this trend?

Our Bal Pharma business is aligning with the industry's positive momentum, and we are strategically positioning ourselves for substantial growth. Our focus revolves around three key aspects: API, international formulation exports, and the domestic market. In API, where we already have a strong foothold, we plan to double or even triple our capacity over the next three to four years. We are in the process of identifying and building new facilities to support this expansion.

On the international front, we are enhancing our formulation exports, moving beyond developing markets to tap into regulated markets. We aim to transition from generic to more specialized products, particularly in areas like cardiac, diabetic, and lifestyle disorders. Recently securing EU GMP approval for one of our formulation plants, we are gearing up to register products in European markets, with plans to collaborate with marketing partners for strategic growth.

As for the domestic market, where we currently see room for improvement, we are undergoing a transformative phase. The goal is to boost our presence in the domestic prescription-oriented segment. We are actively working on enhancing manpower productivity, introducing innovative marketing approaches, and considering additional workforce to bolster our domestic operations.

While I can't provide specific figures due to our status as a listed entity, we are targeting a compounded annual growth rate of 25 to 30 percent over the next three to five years. This ambitious strategy sets the stage for an aggressive and transformative period for our company, and we anticipate significant progress when we revisit our trajectory in the coming years.

As an entrepreneur who has successfully grown a business, especially in exports, what key learnings or factors of success would you like to share?

Throughout my entrepreneurial journey, especially in the pharmaceutical industry with a focus on international markets, I've come to realize the importance of fostering collaborative partnerships. In this highly dynamic and competitive field, it's crucial to move beyond transactional relationships and work towards long-term collaborations. Bargaining on every order may lead to short-term gains, but true success lies in establishing win-win situations for both manufacturers and partners.

Moreover, I would emphasize the significance of focusing on niche areas and providing high-quality products consistently. Rather than engaging in price wars, companies should aim for sustainable growth by delivering value, adhering to regulatory standards, and maintaining a long-term vision. The pharmaceutical business is inherently complex, and adapting to changing regulations and market dynamics requires a strategic and collaborative approach for enduring success.

Is there anything specific that you'd like to share with our international audience?

As we move forward, our company is adopting an aggressive outlook for the next few years. We aim to increase our visibility on the international stage and are exploring opportunities for out-licensing. Collaborative approaches, especially in-licensing innovative products, are on our radar. India, with its diverse culture and market challenges, offers unique opportunities, and we remain open to building partnerships for mutual growth and success.

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