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India's thriving ecosystem, coupled with the increasing demand for the right partners and investments, makes it an ideal destination for those looking to be part of a journey marked by growth and innovation

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Dr Viranchi Shah of Saga Lifesciences and the Indian Drug Manufacturers Association (IDMA) outlines the Indian pharmaceutical industry's potential for growth and its role in global health initiatives. He highlights IDMA's focus on scaling operations, affordability, accessibility, quality, and compliance to drive positive change across the sector. Dr Shah also explains how there has been significant shift from aspirational discussions to actionable strategies in terms of innovation within India's pharmaceutical sector, as well as an important upgrading of regulatory standards to align with global benchmarks without adversely affecting existing SMEs.

In addition to your role at Saga Lifesciences, you also serve as president of the Indian Drug Manufacturers' Association (IDMA). What is your vision for driving positive change across the entire sector?

I am both an entrepreneur and a pharmacist, and as such am well-placed to observe the vast potential and opportunities within the pharmaceutical industry. This sector is not only poised for significant expansion but also presents a unique chance to contribute to global health initiatives and the overarching mission of making healthcare more affordable—an imperative goal for IDMA.

IDMA, as one of the world's largest pharmaceutical associations boasting over 1100 manufacturing members, provides a robust platform. My vision aligns with the broader objectives of IDMA,

focusing on key areas such as scaling operations, affordability and accessibility, quality, and compliance.

Has the pharmaceutical agenda in India witnessed a significant shift in recent years, moving beyond repetitive surface level discussions on transitioning from volume to value, and addressing the crucial question of India's capacity for innovation?

There has been a significant shift in India's pharma agenda. While discussions on innovation were once merely aspirational, they have now evolved into actionable strategies. The shift is evident in regulatory changes and an overall transformation of the ecosystem. The government of India has introduced schemes like PRiP (Promotion of Research in Pharmaceuticals and MedTech), providing funding for innovation at various stages, including startups, clinical-stage ideas, and those ready for global launch.

Moreover, the pharmaceutical industry has witnessed changes in global manufacturing practices. A recent development includes the formulation of a new GMP code for India, Revised Schedule M, aligning with WHO GMP and PIC/s standards. This shift indicates a commitment to raising manufacturing standards to global benchmarks.

The government is also paying significant attention to the API manufacturing sector, especially post-COVID-19, with the rollout of incentive schemes like PLI (Production Linked Incentive). These schemes aim to strengthen the API supply chain, recognizing its critical role in the pharmaceutical industry.

While the financial support provided by these government schemes is valuable, equally significant is the impact on the ecosystem. Setting a clear agenda sends ripples across a wide range of stakeholders, including financial institutions, local governments, technology providers, and academic institutes. The alignment of various stakeholders with the government's agenda expedites processes such as obtaining clearances, which would otherwise be time-consuming.

The enduring nature of the current government has played a role in providing a stable and long-term perspective for these policies. The assurance of continuity allows industry players to make strategic investments and commitments in long-term activities. Overall, the pharmaceutical landscape in India is witnessing a transition from aspirational discussions to concrete actions, driven by government initiatives and an evolving ecosystem.

You touched upon the need for India to upgrade its regulatory standards, potentially aligning them with tier one regulators like the FDA/EMA etc. Given the significant manufacturing presence in India, why do you think this was not prioritized earlier?

India's historical focus on providing affordable healthcare has shaped its regulatory priorities. The emphasis was initially on basic healthcare accessibility for the population, reflected in the low per capita spending on healthcare. The goal was to achieve a significant increase in life expectancy, and India has successfully accomplished that with a limited budget. As a developing nation, the priority was effective and affordable healthcare for the masses.

The current transition towards upgrading regulatory standards is seen as a natural progression. As the country has achieved certain healthcare milestones, there's an acknowledgment that upgrading regulatory standards is essential to move to the next level. While the industry is keen on aligning with global standards, it's crucial to ensure that this transition doesn't adversely affect existing SME businesses, preventing unemployment and economic challenges. The focus is on a gradual and inclusive scaling up of the industry to meet higher regulatory standards without jeopardizing its stability. The journey involves stepping stones, from upgrading to GMP standards to potentially seeking memberships in international regulatory bodies in the future, all while ensuring the sustained growth of the pharmaceutical industry.

Saga Laboratories recently rebranded to Saga Lifesciences; why, and what does "life sciences" mean to your company?

The decision was motivated by a need to better align our identity with the full spectrum of our activities. The term "Laboratories" didn't accurately represent our role as a pharmaceutical company. By transitioning to "life sciences"," we aimed to convey a broader engagement in various life science pursuits.

Saga Lifesciences operates as a comprehensive Formulation Development and Finished Dosage Form (FDF) company. Our activities span formulation development, manufacturing, and international business. Our business model includes three main components:

Firstly, we have a b2b model where we collaborate with importers and local partners to leverage their strengths for product distribution and promotion, particularly in emerging markets focusing on branded generics and OTC products.

Secondly, the b2c model involves direct engagement with customers in certain markets. For OTC products, we interact directly with retailers, while for prescription products, we engage with doctors to establish a direct connection with end-users under the Saga brand.

Thirdly, we are involved in the Contract Manufacturing and Contract Development and Manufacturing business (CMO/CDMO), where we receive technology from another CMO or technology holder, transfer it to our manufacturing facilities, and produce products with the branding of the labeling or marketing authorization holder. This primarily targets the Indian market.

The rebranding signifies our commitment to the broader life sciences sector, encompassing pharmaceuticals, formulations, and international business. Our diverse business model allows us to engage with various markets and stakeholders while maintaining a holistic approach to our activities in the life sciences domain.

Is the businesses mix you have chosen the most strategic, and if so, what factors contributed to this choice?

The initial focus of Saga Lifesciences was on our own brands and products, primarily following a b2b model. However, as we progressed, we recognized the limitations of this model, especially in terms of value addition and customer proximity. To address this, we ventured into the b2c business, establishing our own teams in specific markets to bring our products directly to customers. This approach allowed us to take more control, manage risks, and enhance our value proposition.

The CMO/CDMO business is a relatively recent addition, starting around 2017-18. While the CMO/CDMO business currently contributes a smaller percentage to our overall revenue, it is a segment that we are actively growing. We acknowledge the importance of integrating with large multinational companies that dominate the global pharmaceutical supply chain. By manufacturing products for these industry giants, we aim to tap into a more substantial portion of the market and foster growth in the CMO/CDMO segment.

In summary, the combination of our own branded business, both formulations and OTC products, along with the growing CMO/CDMO business, provides a diversified revenue stream. Each pillar plays a strategic role, allowing us to adapt to market dynamics, mitigate risks, and capitalize on emerging opportunities in the life sciences sector.

How did you differentiate your CDMO business in a highly competitive market, especially when acquiring your first customers?

In the competitive CDMO landscape in India, where numerous companies compete for opportunities, standing out becomes crucial. The key differentiators lie in the scientific capabilities, product quality, and adherence to GMP standards. The ability to accelerate manufacturing processes, ensuring timely delivery in a post-pandemic scenario, has gained significant importance. Supply chain reliability and the commitment to meeting deadlines emerged as focal points, helping us navigate the challenges and build trust with our partners.

Building and sustaining long-term contract relations in the pharmaceutical industry involves a gradual and meticulous process. Our approach focuses on demonstrating our scientific capabilities and commitment to quality. When negotiating contracts, we prioritize the development phase, which typically spans around a year. During this period, we emphasize systematic development, ensuring compliance with regulatory requirements and adherence to agreed timelines.

Effective communication is crucial in the process. If unexpected issues arise or there are deviations from the plan, we promptly notify our partners, providing transparency about any challenges and discussing potential solutions.

Post-pandemic, the significance of timely delivery has heightened, making it a key factor in establishing and maintaining solid, sustainable partnerships.

How are the Indian generic manufacturers preparing for the increasing number of FDA biologic drug approvals every year? What challenges and opportunities does this present?

The landscape of pharmaceuticals is evolving, especially with a surge in FDA drug approvals, prominently in the biologics sector. While biologics constitute a significant portion, it’s essential to recognize the role of small molecules and peptides in driving the valuation of companies. For instance, semaglutide is a notable example of a peptide, not a biologic, contributing to the industry’s growth.

Biologics, with their high prices, are crucial in markets like the US and Europe, where insurance coverage and income levels support such treatments. However, the challenge arises in countries with lower income levels, where accessibility to expensive treatments becomes limited. India, being a major player in serving the healthcare needs of low and middle-income countries (LMICs),

is poised to address this gap.

The dream for the future involves developing technologies to reduce the cost of high-priced biologics, making them more affordable and accessible to a broader population. While advancements in areas like CAR-T therapies showcase promising steps, applying similar approaches to traditional chemistry-based drugs is seen as a challenging yet crucial goal. The focus remains on finding solutions that balance innovation, cost-effectiveness, and accessibility, aligning with India’s commitment to providing healthcare solutions to diverse demographics.

What are the key priorities and focus areas for Saga Lifesciences in 2024 and beyond?

As we look ahead to 2024 and beyond, our primary focus is centered around contract manufacturing. We aim to align ourselves with global players for the manufacturing of their flagship products, with a specific focus on oral solid dosage forms (OSDs). Additionally, we plan to concentrate on the production of over-the-counter (OTC) and wellness products, recognizing the growth in demand for preventive and wellness medicines post-pandemic.

When it comes to financing our endeavors, we don’t perceive finance as a limitation, especially in the current landscape in India. There are various avenues such as private equities, IPOs, and healthcare-related funds (HAIs) that we can tap into. The availability of finance is not a hurdle if the business idea is strong, and we have observed that having the right idea and execution capabilities is crucial for success in the pharmaceutical industry. Saga Lifesciences has experienced consistent growth, exceeding 25 percent annually for the past decade, which is considered commendable for a midsize company. Looking forward, we remain optimistic about the market and do not perceive a lack of financing opportunities for Indian industrialists.

What are the guiding principles that make Saga Lifesciences a trustworthy partner in the pharmaceutical industry, especially when compared to multinationals?

Being a family of pharmacists, our focus is on the scientific aspects of the industry. This emphasis on science allows us to provide assurance to our partners that we maintain a strong scientific foundation, overseeing the technical and scientific aspects of our operations. Additionally, our commitment to maintaining a robust supply chain enhances our position as an ideal partner for the CMO model. Our organizational culture is deeply rooted in a drive for excellence, making us a reliable and trustworthy player in the industry.

As a closing remark, I would like to emphasize that India represents a significant opportunity for growth in the pharmaceutical sector over the next two decades. The country’s thriving ecosystem, coupled with the increasing demand for right partners and investments, makes it an ideal destination for those looking to be part of a journey marked by growth and innovation. Invest in India or with Indian partners, and become part of this transformative and dynamic landscape.

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