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INDIA LIFE SCIENCES 2023

Regulations and Markets - Generics - Innovation - Contract Services
Nutraceuticals - Medical Devices - Digital Health

Dear Reader,

Welcome to our *India Life Sciences 2023* special report.

India's pharmaceutical industry, ranked third worldwide in terms of volume, is the largest supplier of generic drugs and is well-regarded for the role it plays in making high-quality medicines and vaccines affordable to the global population. Fueled by domestic and foreign demand, the sector continues to grow; currently a US$50 billion industry, optimistic forecasts project the Indian pharmaceutical industry could reach US$150 billion within a decade.

Amid a competitive landscape, Indian companies operating in the life sciences have carved out niches for themselves in various ways – whether it be researching novel drug delivery systems, introducing new molecules and materials to the market, or securing funding for work in the country's nascent biotech sector, innovation abounds. At the same time, certain subsectors of the life sciences are witnessing a surge in interest in the wake of Covid-19, propelled by heightened consumer demand and a flourish of entrepreneurial activity to keep pace. This report will investigate the activities surrounding such advancements in the nutraceuticals, digital health, and medical devices spaces.

Of course, the magnitude of success does not rest squarely on the shoulders of only pharmaceutical and biopharmaceutical companies – contract service providers are crucial to the health of the life sciences ecosystem. Responding to the heightened complexity of the field, CROs and CDMOs are stepping up to create a more robust environment. For 2023, geopolitical trends seem to be working in their favor; against the backdrop of Sino-Western tensions, Indian service providers are in high demand amongst clients and partners from around the world.

The following pages bring together insights from interviews conducted with over 60 industry leaders whose experiences collectively span all areas of the sector. We would like to warmly thank these executives whose thoughtful contributions were invaluable to the report as well as our association partners at the Indian Drug Manufacturers' Association (IDMA) and Pharmexcil. We hope you enjoy reading GBR's *India Life Sciences 2023* report.

Alfonso Tejerina
Director and General Manager
GBR

Introduction to India's Life Sciences

The World's Pharmacy

Sub-Sectors on the Rise

Services and Support

INDIA LIFE SCIENCES 2023
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INTRODUCTION TO INDIA'S LIFE SCIENCES

"India is the biggest generic manufacturer and offers the most affordable source of quality pharmaceuticals. You ask for it, we manufacture it."

Daara Patel,
Secretary General,
IDMA

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Image courtesy of Annie Spratt (Unsplash)

Pharmacy of the Post-Pandemic World

India's pharma export volumes soar

Image courtesy of Cancer Institute (Unsplash)

For years, India has been calling itself the "pharmacy of the world." As a powerful manufacturing engine supplying more generic medicines by volume to the global population than any other country, the title carried an air of legitimacy. Yet, implicit in the nation's role was a clear limitation – India was a reproducer, skilled at churning out preexisting formulations at lower costs, but not an innovator in its own right. In this way, it would remain forever a step behind its counterparts in the West, whose scientists advance the industry with their extraordinary research programs backed up by even more extraordinary R&D budgets.

Keenly aware of this, Prime Minister Modi has sought to elevate India beyond its pure-play generics status and included the sector within his vision of an 'Aatmanirbhar Bharat,' or a self-reliant India. His Make in India initiative, focused on spurring manufacturing development across sectors through the introduction of new processes and new infrastructure, is felt most in the life sciences through the Production Linked Incentive (PLI) schemes, the first of which was announced in March 2020 by the Government of India to include a US$1.83 billion investment into the industry, focusing primarily on APIs and key starting materials, followed by an announcement in March 2021 of an additional US$2 billion investment.

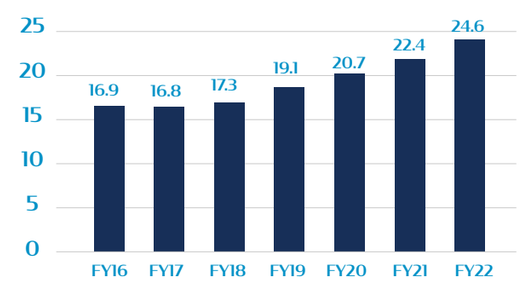
As the pandemic left countries grappling with an unprecedented level of unmet medical needs, India assumed, characteristically, its role as the "pharmacy of the world." The world's largest vaccine supplier – India produces roughly 60% of all vaccines – has exported Covid-19 vaccines to over 150 countries in need since the outbreak of the virus. The growth of the country's PPE sector from modest production capacity pre-Covid to 200,000 kits manufactured daily helped India's pharma export volumes soar, becoming the second-largest producer after China. This was heralded as a triumph of Aatmanirbhar Bharat.

According to Lakshmi Chundu, director of regulatory affairs at the country's pharmaceuticals export promotion council, Pharmexcil, Indian pharmaceutical exports recorded 18% growth from FY 2019-2020 to FY 2020-2021, marking the highest growth rate recorded for the industry. From 2020 to 2021, the total pharmaceutical export value jumped by nearly US$4 billion.

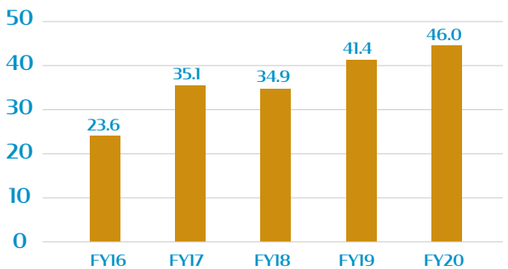
> The Indian government is proactively looking to provide industrial park facilities to grow the API, pharmaceutical, and nutraceutical industries in India to expand on the country's prominent role as the pharmacy of the world.

Arun Joshi,
Managing Director,
Surya Life Sciences

Pharmaceutical Exports from India (US$ billion)



Government Expenditure on Health in India (US$ billion)



Source: India Brand Equity Foundation

Rather than resting solely on the shoulders of MNCs and Indian mega corporations, this growth was the product of an industry-wide push. "India has the biggest menu card available in the world with 60,000 formulations made by 3,000 registered manufacturers and 10,000 manufacturing units," commented Daara Patel, secretary general of the Indian Drug Manufacturers Association (IDMA).

Over the past few years, the country's pharmaceutical sector has done far more than prove itself in terms of manufacturing volumes, however. It has emerged as a life sciences leader within the post-pandemic order through diligent investments into innovation and by seizing on macroeconomic winds that catch the sails of the world's largest economies.

India's life sciences to gain from macroeconomic instability

In mid-October 2022, The Indian Express reported that the IMF's latest world economic outlook presented cause for concern for the nation, bracing its readers that 'the worst is yet to come.' The largest economies continue to stall, it warned, as increasing price pressures undermine macroeconomic stability. Within the context of pharma, the rumblings of stagflation beg the question: Will the contraction of major economies like the US lead to fewer exports of Indian vaccines and medicines, or are the life sciences spared?

According to Peter DeYoung, CEO of Piramal Pharma Limited, India's pharma sector actually stands to benefit from mounting fiscal pressures. Just as India embarked on its Make in India campaign, other major economies around the world have adopted their own slew of government and corporate-led initiatives to reduce reliance on other nations for several steps along their goods supply chains in response to challenges they faced during the pandemic. DeYoung has watches as governments continue to run enormous stimuli over long periods of time, and he believes there will come a day when they must balance their budgets and face the reality that they will not be able to pay for more public services. This, in turn, will contrast with their reshoring efforts. "Right now, we still see more of a willingness to deal with this later, but the Inflation Reduction Act in the US is an example of where there will be pricing impacts on pharmaceuticals," explained DeYoung. "Governments will have to grapple with the question: Is it better to be made domestically or to have the lower price?"

The strength of the Indian pharmaceutical export market is that, as countries face the uncomfortable tension between wanting to increase their resilience while simultaneously wanting to reduce costs, India can help with both. Having identified gaps in product quality and manufacturing capabilities between advanced and developing markets, Mumbai-based pharmaceutical manufacturer Chempro Pharma found a way to center its business model around this conflict of interest. "Countries around the world are focused on becoming more self-sufficient, especially in critical industries like the life sciences," said Arun Sehgal, the company's managing director. "This is no different in places like Indonesia, Thailand, Vietnam, and throughout Africa, where governments are working to create ecosystems conducive for importing technology and setting up domestic production facilities."

With this in mind, Chempro espied Vietnam's US$60 billion pharmaceutical sector as an opportunity. According to Sehgal, the country's pharma market relies 80% on imports. As the Vietnamese government works to drop this to 50%, his company is liaising with public authorities and several manufacturing companies on tech transfers as well as assisting companies looking to establish factories with their design, machinery and technology. In short, Vietnam works to boost its domestic manufacturing capabilities, and India plays the supporting role – for a fee.

Furthermore, coined back in 2013 but garnering evermore attention in the business community is the notion of China-plus-one; the strategy to diversify business with other countries rather than investing solely in China. As the geopolitical wedge widens between China and the West, American and European companies are finding all the more incentive to bolster their supply chains and investment portfolios beyond Chinese-based enterprises. From its vantage point below the Himalayas, India watches its northern neighbor navigate this unfolding relationship and it waits with open arms to catch the business opportunities as they fall. ■

Daara Patel

Secretary General
INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

Today, India's pharmaceutical sector is a US$50 billion industry and we anticipate it growing to at least US$150 billion in less than a decade.

What is the IDMA's role within India's life sciences sector?
Headquartered in Mumbai, the IDMA has a Pan-India presence with eight state boards and over 1,100 members, making us the largest body of pharmaceutical manufacturers not only in India, but globally. We work to establish a presence wherever there are pharma clusters and have our eyes on expanding to Goa as well as various places in the north of the country.

India's pharmaceutical sector is a US$50 billion industry, with equal share in domestic and export markets, ranking it among the top five exporters in terms of net revenue. The country is the biggest generic manufacturer and offers the most affordable source of quality pharmaceuticals. We have the biggest menu card available in the world with 60,000 formulations made by 3,000 registered manufacturers and 10,000 manufacturing units. India supplies nearly 60% of the world's demand for vaccines. With all this in mind, the consolidation of IDMA members accounts for roughly US$20 billion revenue.

Can you share an example of an issue the association is working on?
We have several expert committees handling a variety of issues, such as increasing focus on R&D and innovation. Another of the key challenges the sector faces is the need for stronger collaboration between the life sciences and health care industries, not only for products but also solutions, to help meet the demand-supply mismatch. To be more patient centric, the ecosystem needs product push models to be complemented with service-oriented models.

What role do small-scale manufacturers play within India's pharmaceutical ecosystem?
Small manufacturers are the bloodline of the industry. The top guns do not have the wherewithal and capacity to manufacture everything, so the sector relies on these smaller players who may not have the marketing muscle but do have strong facilities. For this reason, we have to help them with certain issues like obtaining raw materials, packaging, and machinery. The government, associations and banks are doing this. The IDMA supports progressive small-scale players in particular.

In what ways has India proven its adherence to quality standards?
The fact that we are among the largest suppliers of pharmaceutical products to highly regulated markets around the world should provide people with ample confidence that India is a reliable provider of high-quality products that meet rigorous quality standards. The fact remains that every third tablet consumed in the world was made in India. The Central Drugs Standard Control Organization (CDSCO) conducted one of the largest surveys that included nearly 48,000 drug samples from all states in India. The spurious drug incidence was only 0.0245%. That said, India is a vast country, and as goods travel from one place to another, they undergo several climate changes. As we build our infrastructure, more efficient transport of pharmaceutical products will help them retain their efficacy.

Additionally, some people have a misconception that India has one quality standard for exports and another for local consumption. This is wrong. Everything is made in the same plant.

How do you see the industry evolving over the next few years?
As an industry, we are patient centric. The IDMA is very member centric. We do not want to leave any stone unturned in making sure our members fall in line with best practices, as we want our country to take advantage of the growing pharma market. Today, India's pharmaceutical sector is a US$50 billion industry and we anticipate it growing to at least US$150 billion in less than a decade. We want to keep doubling every five years, and we see IDMA as a key player in making that happen.

I also anticipate increased consolidation and collaboration. Whilst the pie is increasing, the number of manufacturers is bound to come down because everybody will take advantage of their strengths.

As a responsible industry association, IDMA members are committed to adding smiles to the faces of the ailing population, adding productive years to their lives, and improving the quality of their life, and we do so with the lowest possible cost as compared to anywhere else in the world. In an era when the world is facing serious disruption due to health crises, our role becomes even more important. ■

Indian pharmaceutical exports recorded 18% Growth from FY2019-20 to FY 2020-21, the highest growth rate ever recorded.

Lakshmi Prasanna Chundu

Director - Regulatory Affairs
PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA (PHARMEXCIL)

Can you speak of Pharmexcil's role within India's life sciences sector?
The Pharmaceuticals Export Promotion Council of India (Pharmexcil) is a council formed under the foreign trade policy to facilitate the exports of pharmaceuticals and allied products by way of assisting the Indian manufacturers in terms of international market exploration. We have approximately 3,700 members dealing with formulations, APIs, biologicals, vaccines, contract research and manufacturing, and analytical services.

Pharmexcil advocates for policy measures that support exportation, conducts market due diligence to identify areas of opportunity, and helps connect our members with international partners. With the support of government, we host international events and exhibitions for networking opportunities and focused B2B meetings. We also assist our members on regulatory developments happening in international markets and have capacity building programs and regulatory awareness workshops to educate them on international scenarios.

How have pandemic-related supply chain disruptions impacted India's volume of pharmaceutical exports?
The past two years have been crucial for the pharma industry as the pandemic has changed the entire supply chain mechanism. Governments are developing new strategies to strengthen their supply chain resilience and increase domestic manufacturing capabilities.

Pharmexcil conducted a study on strategies to reduce import dependence of APIs and identified the major APIs and key raw materials that the Indian industry currently lacks. This has helped the Department of Pharmaceuticals develop the PLI scheme to strengthen domestic industry capabilities to meet domestic needs.

Pharmexcil also facilitates procurement/sourcing of medicines by the global community, and we played a pivotal role during the pandemic during which many countries needed critical medicines. With all our efforts coupled with industries capabilities in meeting the global demands, Indian pharmaceutical exports recorded 18% Growth from FY2019-20 to FY 2020-21, the highest growth rate ever recorded. Our exports jumped from US$20.7 billion in FY-2020 to US$24.4 billion in FY-2021.

What role does the MAI scheme play in promoting sustainable growth of India's life sciences sector?
The MAI (Market Access Initiative) scheme encourages new entrepreneurs to embark on exports by taking them to BSM's giving them exposure of different markets with assistance in providing information and introducing them to the reputed importers.

MAI scheme also helps all companies to obtain market authorizations, GMP certifications etc. from different countries meeting their clientele specifics in terms of GMP and quality of the final product by providing financial assistance to meet 50% of the basic cost they have incurred for statutory compliances to a max of Rs.2.00 Cr per year. This would encourage the industry to get Market authorisations of their range of products and is even applicable for Patent filings, Bio Equivalence studies, Quality certification of Natural products. This will increase industry's access to global markets. MAI also encourages the MSME units with 30Cr FOB for installation of bar-coding facilities with a max incentive of Rs25 Lakh to meet the Regulatory compliance of DGFT notification on Track & Trace obligation for exports.

What work can be done to improve India's image as a reliable provider of high-quality pharmaceutical products?
Pharmexcil has recently conducted Global Regulators Conclave at IPHEX 2022 inviting over 75 officials from 50 overseas regulatory agencies on the theme "International Regulatory Convergence to Promote Accessibility and Affordability of Quality Medicines". This interaction among the Global Regulators & procurement agencies with Indian Regulators has paved a way for enhanced collaborations among the agencies by way of MoUs & Mutual Reliance Mechanism.

It has provided opportunities for showcasing the high-quality India companies adhere to, while understanding the latest outlook of the visiting regulatory agencies' requirement.

What are your projections for India's pharmaceutical market in the coming years?
For 2022, there is a target of US$27.4 billion for Indian pharma exports, which we are optimistic the industry will hit. The international generics market is projected to grow at a 6% CAGR for the next five years. The Indian generics export market has been recording almost 2.5 times growth compared to the global generics market, and in that sense, we could extrapolate the growth of the Indian pharma industry to 10% CAGR for the next five years, with exports then possibly reaching US$40 billion in the next five years. ■

Hemant Koshia

Commissioner
FDCA (FOOD AND DRUG CONTROL ADMINISTRATION) GUJARAT

In addition to pharmacy graduates, the pharmaceutical industry requires support from other industries like chemicals and petrochemicals, as well as top quality pharmacy machinery manufacturers. In Gujarat, we have all of this.

What role does the FDCA play within India's pharmaceutical industry?
The FDCA enforces the Drugs and Cosmetics Act and the Food Safety Act to ensure that companies in Gujarat are manufacturing safe food and pharmaceutical products. Our state is recognized for having the highest quality standards in India, and I attribute this to the awareness and strength of my team of 1,500 members. The FDCA runs several training programs with stakeholders for better compliance. I find it important to interact personally with the managing director of a company to make sure his or her motives are in alignment with the motives of the pharmaceutical industry, which is to provide safe and effective treatments to patients. It is these personal relationships that ensure we are able to consistently maintain excellent quality standards across the board.

How does the administration make effective use of innovative technologies?
To expand the FDCA's oversight requires resources. The government is not always in favor of providing us with more manpower, and it is far more willing to provide technology and machinery. As commissioner, I scan the latest technologies available globally that I can bring to Gujarat, and this has helped us respond to market needs more effectively. As an example, when Covid-19 broke out, the demand for injectables surged. The standard test for these takes 14 days because a colony of bacteria is only visible under a microscope after that time frame. With our rapid microsystem, the FDCA in Gujarat could ensure product quality within three hours, and we could run 60 batches in the same machine. As a result, we could run far more tests at a faster rate, making products available earlier to patients when there was a dire demand.

What makes Gujarat so successful at creating robust pharmaceutical companies?
In Gujarat, we have over 5,000 licensed manufacturers, over 3,000 of which manufacture allopathic drugs. There are many Gujarati MNCs that started small-scale and grew impressively such as Zydus Cadila. These companies are led by technocrats with a quality-first mindset. Part of the reason Gujarat is home to such successful companies is because it is home to India's first pharmaceutical college, which was established in Ahmedabad in 1947. Now in Gujarat, we have over 65 pharmacy schools.

In addition to pharmacy graduates, the pharmaceutical industry requires support from other industries like chemicals and petrochemicals, as well as top quality pharmacy machinery manufacturers. In Gujarat, we have all of this. We also have the printing, packaging, and transportation infrastructure in place to support the pharma sector as it grows.

How does the FDCA assist medical device companies in navigating the shifting regulatory framework?
India has a categorization of medical devices, with categories A and B being lower risk, and categories C and D considered higher risk. Gujarat has several medical devices companies that fall into different categories. As these rules evolve, the FDCA acts as a facilitator in helping these companies to make sure they are complying with the updated framework.

Looking ahead, what excites you most about the future of India's pharmaceutical sector?
Right now, chemistry dominates the pharma industry. The future, however, will be in biologics. We are already seeing this shift take place. For example, throughout the pandemic, Covid-19 vaccines were distributed to billions of people globally. These were biologics. We also have proteomics, genomics, monoclonal antibodies, biosimilars. There are many small companies doing great work on novel drug delivery systems. I see this as the treatment of the future. This transition will also help India minimize its gap in pharmaceutical exports in terms of volume and value.

To help support this, the Indian government is coming out with an R&D policy in which they plan to give incentives to promote research and development in the pharma industry. Within this policy, even a small company will be able to come out with new products. This will play a huge role in boosting financial turnover of the industry over the next few years. ■

Indian Pharma & Life Sciences: 2023 Outlook

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Expert Opinion Article by
Darren Punnen, Leader – Pharma & Life Sciences Practice and Milind Antani, Lead – Pharma, Healthcare, Medical Device and Digital Health Practice, Nishith Desai Associates

As India and the rest of the world come out of the pandemic, the question on every change-maker's mind is this – how can we be better prepared for such a situation? More importantly, how can healthcare systems be reformed to better support the Indian population?

While healthcare reform has been on the cards for years, the unprecedented spotlight it has received in the recent past has provided the right push to get over systemic inertia.

Starting with the principal law governing the quality and safety of drugs, medical devices and cosmetics – the Drugs and Cosmetics Act – a law that has foundationally remained unchanged since 1940 is undergoing its first major update with the introduction of the Drugs, Medical Devices and Cosmetics Bill. As with many other jurisdictions, medical devices are finally being brought out of the umbrella of being regulated as a drug, and is being provided its own standing. This should significantly improve the compliance burden with requirements that are targeted towards devices. Additionally, the bill also seeks to legitimize and regulate an entire industry that has been operating in the grey – online pharmacies. Online pharmacies, while not without its risks, have proven to be beneficial in improving both accessibility and affordability for medicines in India. The associated risks that have been identified such as counterfeit medicines leaking into the distribution channel should be mitigated once the sector is brought within the regulatory fold and quality control requirements are introduced.

India has also been witnessing a significant digital health boom. The disruption seen in the ride hailing industry through aggregation is also being seen in the healthcare space, with platforms being set up for a variety of areas. There has been a rise in telemedicine platforms offering services covering most specialties and even expanding into homecare as well as diagnostic services. These disruptions are positively impacting the accessibility of healthcare services even in smaller towns and cities, which has been a challenge to tackle through offline means for a while.

Affordability of medicines has always been an important aspect of healthcare delivery, especially given that out of pocket payments continue to be one of the primary ways for patients to receive healthcare. However, policy makers have to walk a fine line so as to ensure that efforts in making medicines affordable do not disincentivize the industry from bringing innovative products to the market. There have also been proposals to move away from the existing market based pricing approach and towards a trade margin capping for certain medicines, which again has brought out debates on whether the policy for pricing should first be revised before undertaking these changes. Price control changes are likely to be unraveling over the course of 2023, after which it would be interesting to see how the industry players react to such changes.

In a bid to curb unethical practices between healthcare practitioners and the industry, the government is also in the process of revising the professional ethics code for healthcare practitioners. While the first draft of the revised law appears to have restricted interactions between the two to a bare minimum, it is hoped that with stakeholder feedback, a revised draft will be issued allowing for legitimate and ethical interactions, while filtering out current issues such as high value gifts and hospitality being provided to influence prescription decisions. Additionally, the Government is also coming down hard on the industry from a tax perspective to curb unethical practices. Disallowances in marketing expenditure that went against the existing code of ethics are now being enforced strongly, and is already serving as an effective way to reduce the occurrence of such practices.

The government's mammoth exercise of providing a universal healthcare insurance cover through the Ayushman Bharath Scheme is also being improved in a timely manner. Over the past few years, the Government has been focused on using the scheme to standardize healthcare delivery, bring down treatment costs and also bring more of the population within the cover. Over the course of 2023, it is expected that there would be strides in digitizing healthcare records through the scheme. One of the primary challenges for the scheme continues to be attracting healthcare players to onboard, especially because of the costs within which they would be required to operate if they participate. To this end, feedback is being provided and actioned, and we expect that changes will be made to the scheme in a manner that makes it more lucrative for more healthcare providers to sign up.

The core principles of improving quality, affordability and accessibility have been at the heart of every healthcare reform. With this holistic push cutting across various parts of the healthcare ecosystem, we expect that by the end of 2023, India will see stability and certainty in regulations, improved access through digital health penetration, and improvements in affordability through the expansion of the ongoing universal healthcare cover. These improvements are already signaling increased interest in domestic and foreign investments, as well as more players looking to enter the Indian healthcare space. With every step taken towards improving the space, it is hoped that the Indian healthcare infrastructure will be strengthened from the ground up, and consequently be better equipped to handle any new threats to public health that may come our way. ■

THE WORLD'S PHARMACY

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Image courtesy of spopov (Depositphotos)

"As a country, we have to keep prioritizing innovation. This does not have to be the creation of a new drug – it can also be about finding engineering improvements to reduce costs, or a packaging innovation, or even something that just makes things easier for the consumer."

Vishal Rajgarhia,
Marketing Director,
Finecure Pharmaceuticals

Access, Affordability and Quality

The origins of affordable Indian pharmaceuticals

Image courtesy of Alexraths (Depositphotos)

Pharmaceutical success, for individual companies as well as the industry in aggregate, rests on three pillars: access, affordability, and quality. While all are necessary, organizations can carve out a competitive edge for themselves by finding a blend that suits their unique capabilities and strategic vision. Even in a crowded landscape, no two companies are identical, and it is this diversity in approach that makes India's life sciences sector so vibrant and resilient.

At a time when medicines were mostly imported to India, the country faced some of the highest drug prices in the world. Access to modern medical care was a luxury only the wealthy enjoyed. It was amid this environment that the Patents Act of 1970, which essentially abolished product patents for pharmaceutical ingredients in India, sparked a flourish of activity. Coming into force in 1972, the goal of the legislation was to guarantee low-cost access to medication while simultaneously fostering the development of domestic industry over a purely import market. As a result, the number of pharmaceutical companies domiciled in India more than doubled from 1970 to 1980, and most of these companies focused on reverse engineering innovative products that had been previously introduced to the market. As the industry honed its reverse engineering capabilities, the duration between an original drug's introduction and the Indian generic's equivalent shortened. Thus, an industry was born whose express purpose was to provide access to affordable medication, and the emphasis was placed on improving and expanding reverse engineering capabilities rather than focusing outright on R&D.

This had a profound impact on who could receive medical treatment. "India's global impact as a supplier of affordable quality medicine is profound," remarked Viranchi Shah, director of Saga Lifesciences and national president of the IDMA. "In the late 1980s and early 1990s, many Indian companies were critical in supplying HIV drugs to Africa because they were able to bring down the costs of these treatments. Since then, India has been the most important source of affordable quality medications to the developing world."

When the WTO's TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) came into effect in 1995, many within India's pharmaceutical industry feared it portended the death of the sector. The multilateral agreement on intellectual property, which remains the most comprehensive of its nature to date, provided a more rigid view on the adherence to patents. "Everybody thought the Indian pharma industry would die. On the contrary, because Indian companies were trained in the field of innovation and patenting, the growth after 1995 has been tremendous," said Gopakumar Nair, managing director and owner of the intellectual property consultancy and legal advisory firm Gopakumar Nair Associates (GNAs). "After WTO was introduced, through learning the tricks of the trade of the new regime, India is now filled with masters of IP and continues to innovate and bring new developments to market."

As Indian companies started to invest more into R&D, the number of new drug compounds coming out of the country increased. All the while, the generics industry maintained its momentum. Today, India's pharmaceutical sector is renowned for its innovations in healthcare that offer affordable solutions to patients.

» Regulatory standards and the associated costs are very dependent on the market you are looking to serve. If I want to sell something in India, I must meet a specific set of requirements that are different than if I want to sell the same product in the US or any developed country.

Chetankumar Domadia, Marketing Director, Gujarat Pharma Lab Pvt. Ltd. «

» If you are delivering a high value product and receiving a good price, there is no reason to bypass the system and the procedures required for quality.

Maulik Sudani, Executive Director, Farbe Firma «

Setting the record on quality

While India is commended for its work manufacturing and distributing affordable medicines to the global population, there remains a disconnect between public perception of the quality of these drugs and the standards that most Indian drug makers are upholding.

To an extent, this may because India was too successful at revolutionizing the accessibility of low-cost medicine. Rather than seeing the delicate dance at play between affordability and quality, many are quick to assume that one must be sacrificed in order for the other to thrive.

Gambir Chordia, director of Medopharm is insistent that this is not the case. "It is a myth that quality medicines have to cost more," he said. "Economies of scale and consistent production with skilled manpower and high productivity can ensure that process loss can be minimized through following quality standards and practices. Thereby, generic medicines can be cost effective and of high quality."

That said, the industry is not exempt from scandals over drug quality that reach a worldwide audience. In mid-October 2022, Maiden Pharmaceuticals made headlines in its linkage with the deaths of 66 children in The Gambia. The company claimed its image was hastily tarnished by the media without clear evidence that its cough syrups were responsible for the incident. Irrespective of whether the blame was deserved, Aligns International CEO Rajiv Maniyar believes the story to be a case of strategic media bias. "Five years ago, statistics showed that China and India were supplying 80% of the world's medicines in terms of volumes," Maniyar said. "These medicines are sold at affordable prices, and because big multinationals then have to lower their prices, they try to tarnish the Indian image by grabbing at any straws to state their claims that India has inferior quality products."

He sees the headlines connecting the deaths in The Gambia with the Delhi-based cough syrup manufacturer as publicity that sullies the reputation of many Indian companies that consistently do the right thing and adhere to the highest quality standards without receiving any level of heightened recognition.

While there is no proof that MNCs are launching a premeditated media assault against Indian-based pharmaceutical companies, Maniyar's assertion that many domestic manufacturers uphold stringent quality standards is an inarguable fact. As testament to the volume of companies upholding the measures outlined by rigorous regulatory frameworks, the country is home to the highest number of US-FDA approved plants outside the United States.

Dr. Hemant Koshia, commissioner of the FDCA in Gujarat, explained the approach he takes to ensure that pharmaceutical companies operating within his state are appropriately qualified to create drugs that will ultimately be consumed by patients: "In order to get a license to drive a vehicle, one must first pass a driving test. Here, I am giving a license to manufacture a medicine, which is far more consequential than a driver's license."

For this reason, Dr. Koshia makes a point to personally interact with the executive leadership of Gujarati pharma companies to confirm their motives are in accordance with the sector's mission to provide safe and effective treatments to patients.

Logistical issues remain

While India has taken strides to provide affordable, quality medicines to the global population, the country still has work to do in improving access to healthcare at home. The unfortunate reality is that medical coverage within India remains strained not due to inhibitory costs but because of the difficulty in reaching much of the population.

Complications during Covid-19 revealed the importance of supply chain resilience, but within India, the problem has more to do with creating distribution channels rather than fortifying them. "Indian distribution networks are very fragmented because people make purchases from local mom-and-pop shops scattered throughout the country,"

> It is a myth that quality medicines have to cost more. Economies of scale and consistent production with skilled manpower and high productivity can ensure that process loss can be minimized through following quality standards and practices.
>
> **Gambir Chordia,**
> **Director,**
> **Medopharm**

explained Sahil Dharia, CEO and founder of Soothe Healthcare, a manufacturer of personal hygiene products including fem hygiene, baby diapers, and adult diapers.

As his products deal with a taboo topic in India – female reproductive organs – his company faced the dual barrier of a lack of awareness. According to Dharia, this challenge is being solved rapidly by the internet, which is standing in for conversations that parents and teachers feel uncomfortable having with girls and young women. "If one girl in a class goes online and decides to use a sanitary pad, her peers will follow. Market penetration is all about awareness, which is being accelerated through technology."

While the internet may play a role in tapping into a broader swath of the populous, it cannot overcome India's fundamental shortcoming. "Logistics is a major challenge in India, as transport from one side of the country to the other can take a long time," said Rajendra Shah, director of Mercury Laboratories.

To mitigate the challenge, Mercury established a system of depots with available stock throughout the country, ensuring the company can get medicines to patients within 24 to 48 hours. Shah acknowledged the work the Government of India is doing to invest in providing a comprehensive range of affordable healthcare services to a broader spectrum of its country's population. According to Shah, the public health insurance fund program known as Ayushman Bharat will not only provide healthcare to millions of people otherwise unable to afford it, but it will also create 150,000 government-supported 'health and wellness centers' that will provide a variety of healthcare services.

Long-standing logistical issues have been compounded in recent years by higher than normal transportation costs, which impacts transport within India as well as the shipment of products overseas. "Freight prices went up during Covid-19 and mostly have not yet reduced," commented Chetankumar Domadia, managing director of Gujarat Pharma Lab. "When you are dealing with the export of an inexpensive product, as air freight costs rise, they can become higher than the total cost of the goods. This is an issue we are grappling with today."

Moving forward, the Indian government should continue to make overcoming such obstacles a priority, providing more robust and expansive distribution networks to insulate against high cost volatility and ensure better national healthcare coverage.■

Mohal Sarabhai

CEO
ASENCE PHARMA PRIVATE LIMITED (AMBALAL SARABHAI ENTERPRISES LTD [ASE] GROUP)

> **We are working closely with our US partners to bring one of the most affordable point-of-care (POC) testing devices to the market that will be saliva-based to provide the accuracy of a PCR machine on a POC device.**

How was Asence prepared to step up Covid-19 relief efforts?

After we spoke in 2019, Asence had ventured into molecular diagnostics and entered into a joint venture with the US-based company Co-Diagnostics Inc. to form CoSara Diagnostics, which meets the need for cost-effective and accurate PCR based diagnostic tests. We found molecular diagnostics to be the need of the hour, especially in India, where early detection of infectious diseases could literally save lives. At first, we were mainly focused on India-specific diseases like TB, but when Covid-19 hit, we were able to turn our affordable, molecular diagnostics technology into Covid-19 PCR tests and thereby became one of the first companies in India to offer these tests. We are aggressively moving towards covering just about any diseases with our molecular tests.

Additionally, before the outbreak of Covid-19, Asence, through its group company Synbiotics, was the only Indian manufacturer of the antifungal API Amphotericin B. Once the medical fraternity realized that this was the only treatment for black fungus (mucormycosis), a fungal infection that occurred in certain post-Covid instances, demand for Amphotericin B surged. We received an unprecedented number of requests and worked overtime to match demand across India.

Can you highlight the logistical benefits to point of care testing?

The main benefit of a point of care molecular testing is its ability to better penetrate semi urban and rural populations. Thanks to Covid-19, PCR machines became widespread globally, but in countries like India, they still remain located primarily in urban hubs. Asence, through its group company CoSara, is taking this a step further to make point of care devices tests available at many collection centers in class two or class three towns in India. We are working closely with our US partners to bring one of the most affordable point-of-care (POC) testing devices to the market that will be saliva-based to provide the accuracy of a PCR machine on a POC device. We are in the process of getting USFDA approval and are doing the regulatory work to submit it to the CDSCO in India.

How does Asence select products to create for the Indian market?

Asence, through its group companies, focuses on diseases that are very prominent in India. Kala azar/ leishmaniasis is a sandfly disease which greatly affects people in the eastern part of India and is fatal when left untreated. Our company is the sole Indian company that has an API for its treatment. This is an example of how Asence focuses on niche and significant molecules that are not manufactured by many. We are also doing R&D work on something in the diabetes area which will be like a nutraceutical product that can regulate blood sugar levels. We are always looking to bring innovative products to the market such as an effervescent form of curcumin, which can have anti-tumor capabilities, and we want to bring old Indian knowledge and wellness practices into the nutraceutical space globally.

Why should the international pharma community pay close attention to India?

People around the world are coming to acknowledge the quality of pharmaceutical products India supplies, and as more companies move away from China as a source of APIs and intermediates, they turn to us. Now is the time for India to shine, and that is why Asence will continue investing in expanding our infrastructure to further our mission to improve and enhance the quality of human life through supplying quality pharmaceutical preparations to the global markets.

Looking at the year ahead, what are your main objectives for Asence?

Asence is constructing a new API plant in Vadodara which we hope to have operating by January 2023. This new facility will be dedicated to oncology on the one side where we will manufacture Hydroxyurea and other oncology APIs, and on the other one side, we will focus on very niche synthetic APIs, which maybe have two or three manufacturers in the world. ■

RS

JS

Rajendra Shah and Janki Shah

Directors
MERCURY LABORATORIES

How has Mercury Laboratories grown into the company it is today?
RS: Mercury Laboratories started in 1962 as a small company providing medicines to government agencies. In 1993, the company shifted its focus to mother and child healthcare. For the past six decades, we have been at the forefront of formulating, developing, marketing, and distributing safe, innovative, and cost-effective pharmaceutical products. Our main product lines include antihypertensive drugs, medicines for PCOS and uterine disorders, haemostats, iron and vitamins, pain management drugs, preterm Labor management medications, and antiemetic drugs. Blood loss during labor is a global issue, and we have developed various products for the treatment of postpartum hemorrhage.

We have two state of the art modern manufacturing facilities that are designed, equipped, and operated to deliver high quality products within defined cost and delivery schedules. These manufacturing facilities have flexibility to operate in various dosage forms and a wide range of batch sizes. We have built a third manufacturing plant and are working on two new technologies – prefilled syringes and parenterals – that we want to bring to market in the near future. We are also working on sustained release formulations for patient convenience.

What geographies does Mercury export to?
RS: We have approximately 400 medical representatives across India to serve the domestic market, and our facilities are WHO GMP and EU GMP compliant as we export to Philippines, Myanmar, Sri Lanka, Vietnam, and Cambodia in East Asia; the DRC, Ghana, Nigeria, Mozambique, Zambia, Kenya, Ivory Coast, Mauritania, Burundi, and Togo in Africa; Guatemala, Costa Rica, Colombia, Peru, and Ecuador in Latin America; as well as to the UK, USA nutraceuticals market, Moldova, and Jamaica. Our third line of revenue comes from still supplying the Indian government hospitals with medicines.

What are Mercury's plans for its new manufacturing plant?
JS: Most companies have a vision and a goal to achieve sustainable growth and contribute towards country's economy by following green initiatives. It is also requirement of time to meet increasing demands from domestic and export markets. To reach our destination it is time for us to invest and grow in Small Volume Parenteral. Instead of expanding our current facilities, we decided to manufacture an altogether new manufacturing facilities as per the latest regulated market requirements and guidelines which can comply to stringent norms of cGMP. We are focusing to enter in regulated markets as soon as we can with our range of ampoules, vials, eye/ear drops and pre-filled syringes. With this new set up we are focusing on untapped markets along with expansion in existing markets offering high quality products and supply ability.

How is India's government working to overcome logistical challenges towards ensuring access to healthcare?
RS: Logistics is a major challenge in India, as transport from one side of the country to the other can take a long time. To mitigate this challenge, Mercury established depots with available stock across India, and from these depots, it takes between 24-48 hours to get medicines to patients. On a national level, the Indian government is currently investing into ensuring good quality and affordable healthcare is more accessible to the entire population. The Ayushman Bharat scheme is a public health insurance fund program supported by the Indian government to provide healthcare to millions of people that cannot otherwise afford it, entailing the creation of 150,000 government supported "health and wellness centers" that feature a wide variety of healthcare services. The Indian government is simultaneously investing in telemedicine services to help alleviate some of the dire shortages that rural areas in the country are facing and is subsidizing private industry to make medicines more affordable.

Do you have a final message for our international audience?
RS: India is coming up very well as a pharmaceutical industry that can provide new molecules, quality products, and innovative technologies at competitive prices globally. The country has great manufacturing facilities as well as talent to support these facilities to continue to grow its pharmaceutical sector. After the pandemic, India has become one of the most recognized medical suppliers to the world as the country has shown that it can supply to ever increasing demands. ■

Dharmesh Shah

Chairman & Managing Director
BDR PHARMACEUTICALS INTERNATIONAL

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We are venturing into the Biosimilars segments with monoclonal antibodies and will deploy close to US$100 million into this space over the next five years. Over the past year, BDR has grown almost by 100%.

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Where has BDR focused its growth over the past few years?
BDR is focused on delivering quality generics at an affordable price to the Indian as well as emerging markets. We have invested approximately US$70 million into building a new facility spread across 60,000 square meters that includes an injectable facility, oral solid dosage facility and state of the art R & D center, which has obtained European approval. We are also now venturing into the Biosimilars segments with monoclonal antibodies and will deploy close to US$100 million into this space over the next five years. Over the past year, BDR has grown almost by 100%. The private equity firm Multiples Alternate Asset Management picked up a 9.3% stake in the company for INR 685 crore. These funds will be used to build additional R&D capabilities, invest in manufacturing capacity expansion, and enhance the degree of vertical integration.

Can you share highlights of products BDR has commercialized recently?
BDR played an important role in response to Covid-19 by responding quickly to the increased demand for drugs used for treatment, as we were already manufacturing the antiviral medication for the treatment of Ebola. We also manufactured Favipiravir and have partnered with Mankind Pharma to manufacture Molnupiravir and Eli Lilly for Baricitinib, as well as Liposomal Amphotericin B Injection for Black Fungus.

We continue to bring innovative products in the oncology and critical care segments to the market. BDR recently announced the launch of a first in India generic, Furmecil; an oral drug for the treatment of advanced gastric cancer, and S-1 will soon be available in the Indian market. We were also successful in launching the prostate cancer treatment drug Enzalutamide in a convenient dose of 160 mg strength, meaning patients had to consume many tablets per day. We have also realized that there is a lot of resistance cases to existing antibiotics, and we became the first to identify, develop, conduct clinical studies, and get DCGI (Drug Controller General of India) approval for Biapenem, which can treat a broad spectrum of infections.

We have also developed Sugammadex, a pioneer in anesthesia drugs in the Indian market, offering safe, rapid, and complete reversal of neuromuscular block, resulting in the removal of anesthesia effects on the body.

What work is BDR doing to amplify its API-related activities?
We are in the process of a US$50 million expansion, and expect to have our new world class facility where we will start manufacturing some complex molecules in operation by Q1 2023. Our idea is that over the course of 2023, we will create a technical hub in India, where we will have a world class R&D center of over 6,500 square meters for formulation development. We are also setting up another R&D facility of almost 100,000 square meters, which will focus on synthetic chemistry and peptide chemistry.

What is your assessment of India's regulatory ecosystem for the life sciences sector?
Our regulators have done a great job, particularly during Covid-19, to control and support the life sciences sector. As an industry, we need continuous implementation of regulations to ensure we work towards a point when all companies comply with international standards. There is a strong degree of collaboration and respect between regulators and life sciences companies, which is testament to where the country is heading.

Can you share your plans for BDR's geographic expansion?
We have made a strategic investment in setting up a manufacturing unit in Algeria, which will be taking care of French speaking African countries. We are also entering Europe and will set up a manufacturing unit in Hungary, focused on complex injectables and oncological molecules. Strategically, our next move is entering the US, where we plan to build a manufacturing plant in 2024/2025. We are working on complex injectables and have partnered with some of the largest players in the US for this development project. Today, we have three filings for processing to enter the market in 2023. We have also entered the Canadian market and are very close to closing a deal to acquire a finished dosage facility in Australia. ■

> India is picking up pace in clinical trials, and decentralization of these trials is the way ahead, where technology will make them more accessible in local settings.

Salim Shaikh

Founder & Executive Chairman
SYMBIO GENERRICS INDIA PRIVATE LIMITED

How has Symbio Generrics evolved into the company it is today?

The companies I have been a founding member of are present in various sectors of the life sciences industry, including APIs, Global Supply and Distribution of Comparator Drugs, clinically backed Nutraceuticals, and an Intelligence-powered integrated Pharma B2B platform. Symbio Generrics India Private Limited operates in the API space. What started out as a sales and distribution company is today a full-fledged API manufacturing, marketing, and sales organization. We are poised for growth; we have recently acquired two manufacturing facilities to keep up with demand, and have set up our own R&D processes. Over the past twelve years, our team of brilliant professionals has grown Symbio into a US$40 million company with 120 employees.

In what ways is India's government helping the pharmaceutical industry become more self-reliant?

In the early 2000s, the Chinese government, to boost manufacturing of pharmaceutical APIs, provided incentives on exports, which were successful at making the country very aggressive in the international market, and led to global reliance on China for several APIs. In similar fashion, our Prime Minister Shri Narendra Modiji and his team have consulted with industry leaders and have focused on levelling out this relationship. An obvious step India has taken is the implementation of its PLI scheme, which since 2021 has brought down the industry's dependence on China by 2-4%. There is still huge room for improvement in public-private partnerships, which will help strengthen the position of Pharmaceutical manufacturers in the country at global levels.

As a case example of how our dependence on China can be reduced, a product worth investigating is Gabapentin that is used in diabetic neuropathy. The product has a value of approximately US$1.6 billion in the global market. From that, an intermediate that historically comes from China accounts for US$144 million. If the PLI scheme took on Gabapentin, we could reduce that US$144 million import to less than US$1 million.

Can you introduce our readers to WisOnGo, highlighting what inspired you to launch the platform?

Many companies make decisions based on feelings that are not necessarily backed by intelligence. We are working on a disruptive idea WisOnGo (short for Wisdom-on-the-go), a platform that provides information on APIs and intermediates which will enable manufacturers to make intelligence-based decisions on critical issues. For instance, decision making on buy versus make, capacity expansion, consumption coefficient, etc. for a product. Additionally, companies will be able to map the competitive landscape of their product portfolio. One of the key highlights is that it will help mitigate risk by tracking the dependency of a manufacturer on any particular market.

Our differentiator lies in the fact that we are looking beyond merely providing data, we provide our clients with actionable insights that they can use for effective decision making. Our core belief is that intelligence is greater than information.

Where do you see the nutraceutical industry evolving?

Since the onset and with incidences of Covid-19, the common man has become more understanding of the importance of preventive health. The Indian market for Nutraceuticals is witnessing explosive growth following the pandemic scare. There is a rapid rise in demand for products that have natural ingredients that help prevent diseases.

Looking ahead, what topics within the life sciences hold the most potential for growth?

India is picking up pace when it comes to clinical trials, and decentralization of these trials is the way ahead, where technology will make them more accessible in local settings. Pioneers in this process will have high potential to earn and retain loyalty from customers, since it would significantly reduce the time and expense that a trial conventionally incurs.

Development in digital technology has been bolstered by the pandemic, and the pharma industry is struggling to keep up with it. While the industry is growing increasingly aware of the potential of digital transformation, the decision makers often face challenges in deciding how to fully utilize this potential. The involvement of various stakeholders in the identification of the how and trials and errors in implementation of it is the only sure shot way of achieving success in the long run. ■

India's Take on Innovation

Small-scale R&D generates large results

Image courtesy of Christina Victoria Craft (Unsplash)

As evidence that the life sciences are more human driven than profit driven, the sector is often insulated from the turbulence that slows down other facets of the economy. In the face of uncertainty, global innovation in pharma prevails.

The word 'innovation' in a pharmaceutical context often evokes thoughts of emerging fields like cell and gene therapy, or perhaps a protein structure that could hold the cure to Alzheimer's. We envision start-ups with millions of dollars in funding pushing for a breakthrough cure. Yet this is not the only formula for innovation, and India is home to tinkerers who have proven over the past few years that a company does not need to introduce a new molecule to the market to make a significant impact on its surroundings.

One way Indian companies are pushing the pharmaceutical sector forward is by working to dramatically reduce the amount of time it takes to develop and manufacture a drug, whether it be at the discovery phase or further along during the coatings application process. Naresh Raisinghani, CEO and executive director of the India division of the consulting company BMGI, likens the approach to improving a company's hiring process. "A simple process like recruitment may take two or three months to complete. If you were to analyze the process, you would see it takes the HR personnel perhaps an hour to conduct the initial interview and scan the person's CV," he said, explaining that most HR staff might invest around four hours of work into the process during the entire three-month timeframe. "The same thing happens in the drug discovery process. You have to run experiments, conduct research, and do analysis. But between all this, the time lapse is significant. There is an equally significant opportunity to extract waiting times."

Wait times can be caused by the lack of timely availability of necessary materials. Brian Zehr noticed many Indian biotech companies were ordering their critical specialty reagents from MNCs with long lead times. This was one of the main reasons he decided to help create Biofoundry Technologies, a start-up that manufactures recombinant proteins and kits for end users with a focus on specialty proteins used in biopharma. "When you are developing a product, long lead times can compound delays in arriving at answers," said Zehr. "If I have to wait a month to receive new raw materials to run experiments each time I order them while in the R&D phase, my three-month product sprint can turn into a year-long endeavor."

> We do our portfolio selection targeting products that are either near patent expiry, and we believe will be on a day one launch with some competitive advantage, or that are niche, older molecules with limited competition.

Vishwa Savla,
Managing Director & CEO,
Pinnacle Life Science

A speed-based approach to innovation can also help reduce bottlenecks at certain time-intensive stops towards the end of a product's journey to the consumer, and Indian generics companies have excelled at demonstrating how effective it can be to make downstream processes more efficient. Vaishali Tawde, managing director of excipients and coatings supplier Ideal Cures, believes many Indian companies have created a competitive advantage in identifying ways to shorten processes that may have otherwise taken years to generate a finished formulation. "Coating is one of the most time-consuming steps in the entire process of developing solid dosages. Sugar-coating in particular can become a bottleneck for the entire production of a product," Tawde said, explaining that this was the driving force behind her company's development of its INSTACOAT 4G offering, a ready mixed powder that can reduce the time required for coating from 10 hours down to four. "With this product, the batch can be ready in one shift, which is especially helpful for customers with high volumes who otherwise experience bottlenecks."

In addition to cutting production processes to increase output, another spin on innovation that Indian companies have found success with is finding improvements to be made within molecules that are already on the market. "Innovation does not have to be the creation of a new chemical or drug that is not currently in the market. It can also be about finding engineering improvements to reduce costs or a packaging innovation, or even something that just makes things easier for the consumer," said Vishal Rajgarhia, marketing director of Finecure Pharmaceuticals, while explaining that his company has conducted its own innovative work in this way, including in finding stable formulations for antibiotics that are not typically stable in atmospheric conditions.

Bharat Parenterals is working to develop products that rule out the need for the lyophilization of injections, an expensive and time-consuming process that takes nearly 72 hours to complete. "Our products will be more user-friendly for doctors as well as have the commercial benefit of being more affordable," said Bharat Desai, managing director of the company. "In the US, hospitals are only allowed to administer injectable products. When there is a powder injection, hospitals have a separate division that deals with the reconstitution of that powder for an additional cost. By ruling out lyophilization, we will be enabling hospitals to avoid this step."

The reason so many companies take efficiency-based or enhancement-oriented approaches to innovation rather than aim for a therapeutic step change is because India's funding ecosystem still favors SMEs expanding their development of generic products over innovative drug development. There may be further logic supporting this more conservative strategy. In September 2022, global consulting firm McKinsey & Company released a report stating that financial productivity has fallen in most life sciences subsectors as the cost of developing innovative drugs continues to rise. According to the study, the average internal rate of return from innovation is around 3%, which is below the cost of capital. As large pharmaceutical companies around the world seek the solution to long-lasting productivity gains, many smaller Indian players have already found their answers.

> While R&D itself cannot be rushed, downstream processes can be made more efficient – Indian generics companies have done a remarkable job in demonstrating this.

Vaishali Tawde,
Managing Director,
Ideal Cures

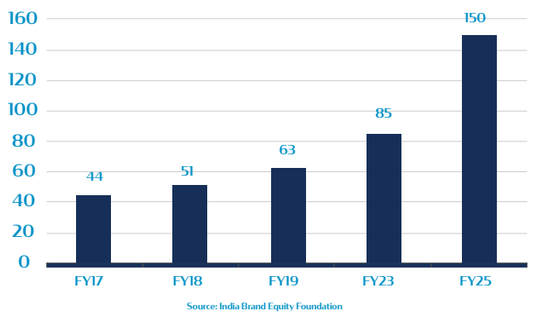
Will Indian biotech have its day?

Chemistry still dominates India's pharma industry. The sharp eye will see, however, the potential that biologics hold to reshape the landscape. This shift is already underway; the Covid-19 vaccines distributed to billions of people around the world are a great example of what lies on the horizon for the nascent sector. The talent and the will are present; what Indian biologics companies need now is the funding.

To understand the extent to which large molecules hold the power to propel the industry, it is helpful to look at projections for the growth of the sector as a whole. The Indian pharmaceutical industry currently generates around US$50 billion in revenue per year. According to Viranchi Shah, director of Saga Laboratories and national president of the IDMA, the CAGR has been over 10% for the last decade, and many trends predict the sector will scale up to a US$500 billion industry before 2050.

"To put this into perspective, the Indian pharma industry took 75 years to go from zero to US$50 billion, but may go from US$50 billion to US$500 billion in just 25 years," Shah commented. "In this journey, however, the generics growth story alone is not going to be sufficient, and that is why there is the necessity for India to develop and manufacture innovative value-added products. Historically, India has been strong in small molecules, and we lag a bit in the areas of biologics. The Indian pharma industry needs to strengthen itself in the large molecules space as this is where we can add more value for what we are doing."

Indian biotechnology industry valuation (US$ billion)



Source: India Brand Equity Foundation

> While the future of IP law in India is dynamic and likely will present new challenges, the entrepreneur-driven India pharma industry will emerge as a global pharma superpower within the next 10 years.

Gopakumar Nair,
Managing Director & Owner,
Gopakumar Nair Associates

Despite being an area of high growth potential, investment is perceived as too high risk for many potential investors. "The risk appetite in India is still not there," observed Bhaskar Krishna, managing director and CEO of Maiva Pharma. "There is so much money to be made in innovation, but the preference seems to be towards expanding pre-existing manufacturing capabilities."

Compounded to the lack of funding is the fact that whatever resources become available are often fragmented across the sector. "Although significant progress has been made, becoming a large player in molecular discovery is still a bit distant for the Indian pharma industry as the country does not yet have the mechanisms to play in this space," said Gopakumar Nair of GNAs. "The Indian pharma industry, compared to any other pharma industry in the world, is highly fragmented – there are so many players, and investments are extremely broadly distributed."

Nair believes industry and academia should learn to collaborate more effectively to create a more robust network of drug discovery research and an ecosystem that will enable breakthrough innovations in molecular drug discovery.

Though India's biopharma sector remains constrained when it comes to access to risk capital, industry leaders like Ajay Tandon, managing director of Veeda Clinical Research, see potential. "While it may not be to the same extent as in the US, the emergence of venture capital available for innovative biopharma companies to develop their programs has increased substantially over the past decade in India," Tandon commented.

He also pointed to the work India's government is taking to amplify industry capacity to support innovation, including phase 1 clinical pharmacology, analytical and bioanalytical facilities. "There are discussions currently underway regarding how to build this infrastructure, in collaboration between the government, academia and industry to create the right ecosystem," Tandon added. "Overall, I believe these cross-industry collaborations to build the right ecosystem for innovation along with the push for risk capital are driving the industry forward. If this all gets into rhythm, I see the industry in a very different place five years from now."

Whether it takes five years or 10, the seeds that are already being planted for a frenzy of biotech activity create an exciting atmosphere within India's life sciences, because while nobody knows exactly how and when the space will explode, there is little doubt that it will. ■

Brian Zehr

Managing Director
BIOFOUNDRY TECHNOLOGIES

We identify strong demand within the domestic biotech sector, and we hope to leverage our capacity in India to bring our robust and user-friendly products to users around the globe.

What gaps did you identify within India's biotech landscape that led you to create Biofoundry Technologies (Biofoundry)?
Biofoundry is a biomanufacturer of recombinant proteins and user-friendly kits. Focusing on specialty proteins used in biopharma, particularly enzymes, our expertise lies in protein engineering, assay design, and recombinant manufacturing technology. We identified three gaps in life sciences in India that informed our business model. First, we saw a lack of timely availability of critical specialty reagents domestically. Companies typically order specialty enzymes or proteins from an MNC, and these are often imported with long lead times. When you are developing a product, this can compound delays in arriving at answers. For example, if I have to wait a month to receive new raw materials to run experiments each time I order them while in the R&D phase, my three-month product sprint can turn into a year-long endeavor. Second, we saw the need for more lot-to-lot consistency of key raw materials, particularly those derived from animals and plants for which the source can vary dramatically. This is critical for GMP manufacturers of course, but even for researchers in academia, consistency is key for demonstrating reproducibility in experiments. Third is the need for cold chain, meaning a low temperature-controlled supply chain network that ensures products maintain their quality and safety. Particularly when it comes to tier-II and tier-III cities where many companies have manufacturing plants, secondary delivery partners often struggle with maintaining proper temperatures.

Biofoundry tackles these three issues through the product design itself, and in doing so, is a significant enabler of biotech growth in India. Given the need for affordable molecular tools to accelerate research here, we identify strong demand within the domestic biotech sector, and we hope to leverage our capacity in India to eventually bring our robust and user-friendly products to users around the globe.

How startup friendly is India's financing ecosystem?
India's startup culture is having a moment, and this has translated over to biotech. MNCs historically have had the largest footprint, alongside a few large indigenous players, but now more than ever there are big opportunities for startups that can provide customized solutions to the Indian market. Nonetheless, R&D budgets in Asia are conservative, and it is important for companies to tackle product development with this in mind. Unlike in Silicon Valley, where biotech funding can happen on hope, funding in India is more conservative as investors want to see customer commitment before pouring money into an emerging company. This can be a bottleneck for companies with good capabilities and products but limited market access. However, this also forces good business discipline. To overcome this, companies need to be creative in mitigating investor risk towards funding the growth of the sector.

In what way does the nature of life sciences innovation differ in India from in the US?
In the US a lot of funding and innovation goes into developing breakthrough products, and the scale of this funding environment unlocks a rapid pace of R&D development. In India, my observation is that a lot of innovation happens around business models. Here, innovation is more methodical and sustainable, as companies need to validate their ability to produce a product at a certain cost for a specific customer before building out capacity. Biofoundry developed pilot products that were validated at or above MNC benchmark performance before moving forward with our launch and GMP facility.

What are your goals for Biofoundry for the coming year?
In 2022, we privately launched our portfolio to a select group of users, underwent market validation, and inaugurated our GMP manufacturing line. By the end of 2022, we will go public with our first full phase portfolio of products. One product we are working to patent. Over the next year, we also hope to close a large commercial partnership that will make our products accessible to all. ■

We are looking into new ways to reap the benefits of artificial intelligence, particularly on the clinical side. On the physical side, we will have a new factory and lab up and running by the end of 2024.

Gaurav Kaushik

Managing Director & CEO
METEORIC BIOPHARMACEUTICALS

What are the core business lines of Meteoric Biopharmaceuticals?
Meteoric Biopharmaceuticals was founded in 2006 with a focus on biological enzymes used for animal healthcare. The company quickly expanded its portfolio for other industries and is currently working on the probiotics side. With probiotics, we work on natural isolates of bacteria to study their health benefits before running clinical trials and launching products to companies targeting a particular need-based therapy. Meteoric Biopharmaceuticals is also focusing on expanding its portfolio of synthetic alternatives to animal-derived biologicals. Alongside strong support from the government and other stakeholders, we invest much of our earnings back into our R&D efforts.

Can you provide an example of an innovative enzyme your company has brought to the market?
The enzyme portfolio for any company is dominated by animal-derived enzymes like pepsin and pancreatin that often come from pigs or cows. As the world is moving towards veganism, Meteoric Biopharmaceuticals developed a vegan alternative to pancreatin. This has been very popular in countries that do not consume pork for religious reasons. Additionally, the science supports our product because it is completely virus and antibiotic free. When extracting a product from an animal, there is always room for variation based on which part of the world the animal lives in and what health conditions it has. Our products overcome these challenges.

In what other product categories is your company innovating?
We are working on the prebiotic side, exploring Indian herbs and materials that could be excellent prebiotics. Besides helping the healthy bacteria metabolize well, we are looking into how to make these products more stable. When you isolate a prebiotic, there are risks that it cannot sustain industrial pressures and other conditions, so making these molecules suitable for handling is very important. Meteoric Biopharmaceuticals is also looking into the oral care sector of prebiotics because in addition to the gut, the mouth is an important part of the body for bacteria. This is an emerging field, and we have already conducted a tech transfer to a European company launching a product in this space.

How is the regulatory landscape for enzymes evolving?
We have always focused on highly regulated markets such as the US, Canada, Korea, and European countries including Germany, Poland, Belgium and Italy. In India, we have worked closely with domestic and international regulatory agencies for the manufacture of our ingredients. High standards of regulations are important not just for molecules that go into doctors' prescriptions, but nowadays many consumers self-educate. People want strong information and analyses on the uses of what they ingest. As the customer becomes increasingly more involved in their health and wellness plans and demands more information, we want to make them feel equipped to make informed decisions.

What are your goals for your company for the next year?
Meteoric Biopharmaceuticals will continue to increase its global footprint and improve its sustainability. We are looking into new ways to reap the benefits of artificial intelligence, particularly on the clinical side. We also continually educate our team members, so they can be best suited to collaborate with our clients. On the physical side, Meteoric Biopharmaceuticals will have a new factory and lab, up and running by the end of 2024 that will work on advanced fermentation processes. ■

Anwar Daud

Managing Director
ZIM LABORATORIES

» ZIM sees great opportunity in improving the functioning of the overall healthcare system through providing more patient centric drug delivery systems. «

ZIM Laboratories listed on the National Stock Exchange (NSE) in November 2022. What does this milestone mean for the company?
ZIM Laboratories Limited is a pharmaceutical company, focused on providing innovative drug delivery solutions that improve patient convenience and adherence of drug treatment using a therapy agnostic approach. ZIM works on products that are coming off patent or that are complex to manufacture, often partnering with midsize pharmaceutical companies that do not have their own strong R&D bases.

NSE is the leading Stock Exchange in India in terms of traded volumes. Listing of ZIM's equity shares on the NSE, in addition to the BSE, is a key milestone in our pursuit for continued growth and in opening investment possibilities with a wider investor community.

Where is ZIM working to expand its presence?
Over the last few years, we have developed Novel Innovative Products (NIP), which are complex generic pharmaceutical products using non infringing unique process technologies. These products are undergoing clinical studies and dossier completion and our focus for the next few years will be to file for Marketing Authorization for these products in the EU and pharmerging markets on our own or jointly under license contracts with marketing partners.

In addition, ZIM has a small presence in nutraceuticals in Europe and Latin America where we partner with local players who market these products. The company is planning to expand its presence in these geographies more substantially.

Can you share an example of an innovative drug delivery system ZIM has developed?
ZIM focuses on developing innovative drug delivery platform technologies using non-infringing process innovation that may be applied to bring differentiation in the delivery mechanism. Some of our technologies include Micro Emulsion Coating Technology (MECT), Liquid In Pellets, Pellet Cold Forming Technology (PCFT), Rapid Gelation Drug Release Technology (RGDCT), Matrix Pore Forming Tablet Technology (MAPOTAB) etc., which it leverages to develop innovative generic pharmaceutical products. We also manufacture Oral Thin Films (OTF) as a dosage form using our patented Thinoral® technology. Some of these platform technologies may also be used for developing nutraceutical products.

How significant is the problem of patient non-adherence, and can you share an example of ZIM's work in this space?
According to Patient Safety & Quality Healthcare (PSQH), around half of Americans do not take their medications as prescribed by their doctor. This accounts for roughly 16%, or US$500 billion, of the entire US healthcare spend each year. We have the same problem in India. People discontinue their prescriptions if they do not like the taste or experience negative side effects. Given the scope of the issue, ZIM sees great opportunity in improving the functioning of the overall healthcare system through providing more patient centric drug delivery systems.

As an example, there is a product marketed by a multinational pharma company for benign prostatic hyperplasia (BPH) that comes in the form of a large pill. The problem is that prostate patients tend to avoid drinking water because of their difficulty going to the bathroom, so consumers of this pill were reluctant to take it given the fact that it needed to be taken with water. We developed a micro emulsion coating technology that enabled us to reduce the size of the pill. ZIM will submit this product in at least seven European countries, which will open the company's pathway into these new markets.

Similarly, we believe that out Oral Thin Film provides a unique drug delivery platform for certain type of patients with resistance to conventional dosage forms and consequently non-adherence to treatment.

What are ZIM's strategic objectives for the next few years?
We aim to enter regulated markets like the EU and pharmerging markets like Latin America, SE Asia, Australia and South Africa, as well as select large and attractive markets in MENA, CIS, Africa and Asia. Our strategy includes maintaining a continuous pipeline of innovative products, and we expect eight to 10 products each year to go into the development phase. ZIM will also continue to build on its nutraceutical presence across markets in which it grows its pharmaceutical business. ■

» The Indian pharma industry needs to strengthen itself in the large molecules space as this is where we can add more value for what we are doing. «

Dr. Viranchi Shah

Director
SAGA LIFESCIENCES LTD
National President
IDMA

What is the geographical reach of Saga?
Saga is a formulations company with a focus on the development, manufacturing, marketing, and distribution of finished dosage forms (FDFs). We are present in over 50 markets and have several global accreditations including EU-GMP, TGA Australia, Health Canada, PIC/s and SAHPRA South Africa. We are not US-GMP yet, but we see a great opportunity for us in the US in the future.

Which segments of the life sciences industry are receiving considerable attention?
In India, two areas are growing quickly. One is the chronic segment. Over the past 5-10 years, the demand for treatments for diabetes, cardiovascular diseases, and cancers has significantly increased. The second area is the wellness sector. Especially after Covid-19, people are focusing on wellness rather than illness and therefore on segments like vitamins and supplements.

What role does India play in providing affordable medicines to developing nations?
India's global impact as a supplier of affordable quality medicine is profound. In the late 1980s and early 1990s, many Indian companies were critical in supplying HIV drugs to Africa because they were able to bring down the costs of these treatments. Since then, India has been the most important source of affordable quality medications to the developing world. That said, the country has the largest number of US-FDA-approved API and formulation plants outside the US, and a significant number of EU-approved plants. Almost half of India's exports go to the developed world, India thus plays an important role in serving more regulated markets.

How is India's pharmaceutical industry working to bridge the gap between production volume and value?
As a nation, we consciously made the effort to understand and serve the gap present in both the domestic and international markets for quality affordable medications. This led to enormous results. The Indian pharmaceutical industry today generates around US$50 billion in revenue per year, and the CAGR has been over 10% for the last decade. Most trends indicate that by 2047, we are likely to scale from a US$50 billion to a US$500 billion industry at a CAGR of almost 10-11%. To put this into perspective, the Indian pharma industry took 75 years to go from zero to US$50 billion but may go from US$50 billion to US$500 billion in just 25 years. This is a massive growth trajectory but is definitely possible. In this journey, however, generics growth story alone is not going to be sufficient, and that is why there is the necessity for India to develop and manufacture innovative value-added products. Historically, India has been strong in small molecules, and we lag a bit in the areas of biologics. The Indian pharma industry needs to strengthen itself in the large molecules space as this is where we can add more value for what we are doing.

How are India's government, industry and academic institutions collaborating to drive the industry forward?
In the last few years, India's government has taken important steps toward promoting and supporting innovation. For example, the first PLI scheme was to support API production in India, as the industry had previously been dependent on imports. The second PLI scheme is geared more towards innovation, as the government saw the need to push for the development and manufacture of complex generics, specialty excipients and biologics. As we understand, the government has also planning to launch a series of steps to promote innovation. A research-linked incentive (RLI) scheme for the Indian pharmaceutical industry is one such step to help the industry focus on R&D and move up the innovation value chain. The IDMA is also focused on creating spaces to enable interaction between industry and academia, as academic institutions play an important role in developing new molecules and therapies as well as innovative ways of doing business. The IDMA today is on almost every platform that deals with policymaking with respect to the pharmaceutical space, and there is very open interaction between industry and government to take the industry forward.

What are your main objectives for Saga Lifesciences for the next year?
Moving forward, Saga will shift its focus from manufacturing to development, trying to create something innovative that helps to add value and differentiate us in the market. There are many opportunities domestically and globally, and we believe that Saga has a very bright future. ■

India and the World

Competition with China

Image courtesy of Myriam Zilles (Unsplash)

Competition with China

One of the prevailing sentiments shared across the broad sector of India's life sciences is the need to decrease reliance on China as a source of pharmaceutical materials, primarily APIs.

The country has come a long way in recent years, thanks in large part to efforts made by the national government under its Make in India scheme, by investing billions into boosting domestic manufacturing capabilities. "The federal government is contributing to this effort by setting up free trade zones and large API parks," said Maulik Sudani, executive director of Farbe Firma. "The government also provides capital subsidies to pharma companies, and there are subsidized or reduced interest rates for pharma companies taking out loans from banks."

As a result, the landscape has changed over the past few years. "Today, India's dependence on China is still high but is significantly less compared to four years ago and we will continue on this downward trend for the years to come," commented Rajiv Maniyar, CEO of Aligns International. According to him, much of this has to do with the shift many companies have taken to backwards integrate. "Instead of companies manufacturing 20 products, importing the N-1 or N-2 stages from China, and doing the final steps in India, they are starting to look to manufacture fewer products, but from the basic stage all the way through to final API."

As an example, Ahmedabad-based CORONA Remedies had been importing the gynecological API progesterone from China when the company decided to look for a local supplier instead. "This is how we discovered La Chandra PharmaLab in Palanpur, Gujarat, a science-driven pharmaceutical company focused on manufacturing hormone APIs, and we completed a strategic deal," explained the company's president and CFO, Bhavin Bhagat. "We acquired a 33.5% stake in this company as a part of backward integration to build our product portfolio and to strengthen our presence in the market."

The potential financial gain from further decoupling the pharmaceutical supply chains is immense. Salim Shaikh, founder and executive chairman of Symbio Generrics, likes to use gabapentin as an example: "Gabapentin, a product used in diabetic neuropathy, has a value of approximately US$1.6 billion in the global market. From that, an intermediate that historically comes from China accounts for US$144 million. If the PLI scheme took on Gabapentin, we could reduce that US$144 million import to less than US$1 million."

When it comes to attracting foreign business away from China, one way Indian companies have carved out a strategic edge against their Chinese counterparts is through the adoption of more environmentally friendly practices. "In the past 10 years, India has done tremendous work in terms of environmental responsibility," acknowledged Arun Joshi, managing director of Surya Life Sciences. "Across India there is good awareness, and most companies are adopting environmentally friendly and green chemistry. Because of this, India is now dominating certain product categories that the country historically relied on Chinese supply for."

Dinesh Khokhani, managing partner of J. B. Khokhani & Co., has noticed a similar trend, and he attributes much of it to conscious efforts made by the Indian government. "World-class standards and best practices are being encouraged by the government, and in our facilities, we have been mandated by local governments to reduce discharges and pollution," Khokhani commented. "Licensing is becoming more stringent with every passing year. In terms of quality and dependability, there is globally more trust in Indian products over Chinese products."

Benzo Chem, an exporter of pharmaceutical and agrochemical products, has spent the past few years undergoing a carbon disclosure program after fielding requests from European and US-based customers to have more detailed information on the carbon footprint of their operations. The program has provided Benzo Chem with more accurate information on the company's emissions, thereby making it easier to identify areas for improvement. "For example, we recently switched our stackers from diesel to battery powered," said the company's director, Gaurav Mohatta. "India has set a goal to be carbon neutral by 2070, which is still pretty far away. Many European countries have set the same goal for 2030. By assisting our European clients on this objective, we are settings ourselves up to be ahead of the game domestically with regards to our environmental footprint."

According to Srinivasan Subramaniam, managing director of Srikem Laboratories, the shift towards India that is in part due to environmental concerns is already starting to be felt by Chinese competitors. "Now, even China has realized that they are losing money in overseas markets, and they want to go back to the domestic market for price-related reasons," Subramaniam said.

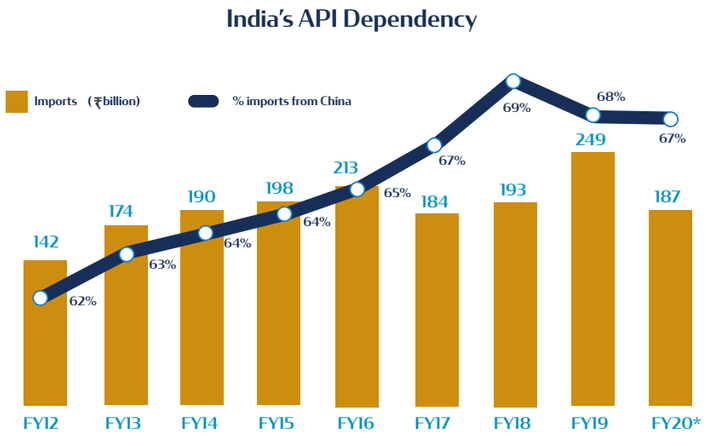
This transition within the global pharma sector is, of course, part of a broader macroeconomic shift of Western companies moving away from doing work with China. "We are seeing increased interest from foreign companies; particularly as global manufacturers are paying more attention to the China-plus-one strategy," commented Jay Bhatt, director of strategic business development at Vital Chemtech Limited. "Contract manufacturers in the US and Europe are looking for intermediates being manufactured in India, and this is a powerful trend for our country's markets. In chemicals, with advanced intermediates we have seen more inquiries from MNCs because of macroeconomic instability."

Despite the headway, certain limitations remain when it comes to weaning India off Chinese supply. Certain materials naturally occur in abundance in China, making it virtually impossible to compete in their production. For others, the East Asian country already has such expansive manufacturing capabilities that it would not be cost beneficial for India to attempt to replicate the scale. For this reason, while future relations between the two pharmaceutical powerhouses remain uncertain, the likely truth is that a degree of dependence will never fully disappear.

Are MNCs helping India, or is India helping the MNCs?

As pharma players from around the world make moves to take advantage of India's robust pharmaceutical sector, disagreements abound over the role these multinational corporations play within the development of the industry and the impact this has on indigenous companies.

India has proven itself to be an attractive destination for foreign pharmaceutical companies, particularly those looking to conduct clinical trials at reduced costs, given the low fees when compared to the US, Europe, Japan, and even China. According to Nilesh Thosani, CEO of Rihim Pharma Consultancy, it is also the flexibility of the country's regulators that appeal to an international crowd. "The regulatory framework is practical with regards to documentation, processing, and fees," Thosani explained. "In terms of documentation, India focuses only on what is necessary to ensure the safety, efficacy, and quality of products."



India's API Dependency

FY20* refers to imports between April 2019 and December 2019

Source: Forbes India

> Nowadays, even China has realized they are losing money in overseas markets, and they want to go back to the domestic market for price-related reasons.
>
> **Srinivasan Subramaniam, Managing Director, Srikem Laboratories**

> While many Chinese companies have greater profit margins, when it comes to smaller volumes, India can edge China out in many cases.
>
> **Arun Sehgal, Managing Director, Chempro Pharma**

Additionally, Thosani, who has extensive experience providing regulatory consulting services to importers, manufacturers and suppliers within the life sciences, believes the speed at which Indian regulators operate makes a difference. Unlike other countries where the timeline to obtain an approval can take years, in India, it is approximately six months. While the country's regulatory framework attracts a fair number of foreign companies looking only to outsource abroad, it also entices many to set up their own operations on Indian soil.

The effort of the regulators does not go unnoticed by industry members themselves. "Our regulators have done a great job, particularly during Covid-19, to control and support the life sciences sector," said Dharmesh Shah, chairman and managing director of BDR Pharmaceuticals International. "There is a strong degree of collaboration and respect between regulators and life sciences companies."

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Executive Insights: Competition with China

How do industry executives view their country's relationship with the Chinese pharmaceutical industry?

Riddhi Javeri,

Director, InterMed Laboratories

"Through government incentives like the PLI scheme, significant investments have led to the creation of new innovation hubs where companies are incentivized to invest in the API space. We have yet to fully realize the benefit of this, as it does not happen overnight."

Atman Parekh,

Executive Director, Atman Pharmaceuticals

"We are already exporting APIs directly to China, and with India becoming increasingly competitive, we believe China will soon be dependent on India for various raw materials instead of the other way around."

Rahul Nachane,

Managing Director, NGL Fine-Chem

"China has historically been the dominant player in animal health, but India is emerging as a strong substitute."

Ravi Jagtap,

Founder & Managing Director, Aastrid Life Sciences

"The truth is that India will always have to do business with China. We can reduce our dependencies, and we do see price advantages for certain basic chemicals being manufactured in India, but I do not see a dramatic shift in dependency within the next 10-15 years."

Ramesh Chodvadiya,

Managing Director, Prudence Pharma Chem

"One thing that differentiates India's pharma sector from China's is the emphasis we place on long-term relationships with our customers. These relationships are based on quality and on time delivery."

» Many of our European and US-based customers have requested in recent years that we disclose more detailed information about the carbon footprint of our operations.

Gaurav Mohatta,
Director,
Benzo Chem

« The major challenge in India is not the regulations themselves but rather the fact that it is much cheaper for local manufacturers to register their products than for multinational manufacturers, and importing products remains extremely costly. This can create a barrier to entry for international companies to enter the Indian market.

Parth Thosani,
Business Development Manager,
Rihim Pharma Consultancy

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Opening or expanding operations in India can also be a strategic move for overseas companies looking to expand their presence within Asia more broadly. Azelis, a chemical manufacturing company headquartered in Belgium with over 3,000 employees across 57 countries around the world, announced in November 2022 the inauguration of its first pharmaceuticals and healthcare laboratory in India. "Equipped with state-of-the-art equipment, the India Pharma lab will be able to support customers, and the Asia Pacific region, with advanced projects," said Aparna Khurana, managing director of the company's India operations. "Thanks to the lab, our technical expertise and innovation resources will be accessible to a wider audience within the pharma industry, allowing us to further grow our business in the region."

While it is clear that foreign players stand to gain from tapping into the Indian life sciences ecosystem, MNCs may also pose a benefit to the domestic market. For its part, the US-headquartered pharma giant Merck, which has had a presence in India for over 55 years, believes global players play an important role in introducing new technologies into India, particularly when it comes to the manufacturing of vaccines. Additionally, MNCs can help provide the right platforms for collaboration. "MNCs that have a presence in India are able to provide great platforms for the domestic industry to collaborate and exchange knowledge to produce the right medicines, drugs and vaccines," commented Aditya Sharma, leader of the BioProcess business at Merck Life Science, India.

The company's head of science and lab solutions Dhananjay Singh pointed to a specific point in the drug development process that MNCs can be of particularly help to Indian companies: "To launch a new product, phase three is the real challenge because that is where a lot of funding is required. This is an area where collaboration opportunities between MNCs and domestic players is particularly helpful."

Singh explained that as part of Merck's CSR strategy, the company is funding a company working on a diagnostics kit for five different diseases including Covid-19, chikungunya, dengue, malaria, and typhoid.

Sanjay Shah, managing director of Sakar Healthcare, observed that his company's connections with foreign players provided exposure to developments being made in other parts of the world that Sakar could then implement at home in India. "Our relationships with diversified multinationals grant us exposure to their preferences based on the cultures they come from," Shah said. "We are able to customize our offerings and provide timely delivery based on their specific needs. Through these partnerships, we advance alongside our clients. Plus, we can build more meaningful relationships through this partnership model."

Perceived benefits notwithstanding, entering the Indian pharmaceutical market is no easy feat, and many MNCs face limitations to the extent they are able to make their mark on the subcontinent. Mitanshu Shah, SVP of finance at Alembic Pharmaceuticals, believes there is a reason that the companies experiencing the most growth in the domestic branded business are Indian companies, not foreign entities. "Foreign companies did not invest as much as they should have in creating a strong presence on the ground in terms of product offerings and manpower, and it is too late to do this now," Shah said.

From his perspective, companies hoping to succeed in India must have an entire product range rather than just their own line of researched products. This is where the distinction is made. "For example, GSK will not sell a Novartis researched products in India, but Indian companies can very well do so," Shah explained. "From Alembic's perspective, a generic is a generic. Once it is off patent, it does not matter who originally formulated it. Multinationals do not come with that mindset, and that is why they are unable to capture the kind of market share as top Indian players like Sun Pharma, Glenmark, or Lupin."

The resilience of India's pharmaceutical sector means it is often in the strategic interest of MNCs looking to enter the sector to partner with local industry to license out patented products to Indian companies in order to tap into the domestic market. In India, marketing and selling take priority over product and price, and local companies can bring down the price to where multinationals cannot operate. It is in this way that India's business culture works to its advantage: the complexity in navigating the crowded environment forces a system of mutual benefits in which foreign entities introduce innovative technologies and processes into the Indian ecosystem in exchange for access to an immense market that is otherwise far too complicated to navigate as a non-Indian. ■

Sreenath NS, Dhananjay Singh & Aditya Sharma

SN: Managing Director
DS: Head - Science and Lab Solutions
AS: Leader of BioProcess Business
MERCK LIFE SCIENCE, INDIA

» MNCs that have a presence in India are able to provide great platforms for the domestic industry to collaborate and exchange knowledge to produce the right medicines, drugs and vaccines. «

How important is India for Merck's global operations?
SN: When we began our presence in the country, we focused primarily on the life sciences. It is my vision for Merck's growth since becoming managing director of the company's India operations in December 2021 to add healthcare R&D services and improve our IT landscape. We see great opportunity at the intersection of technology and pharma.

Manufacturing for life science business for our global requirements continues to be a focus. Merck Group is investing in ramping up manufacturing in India in our sites in Peenya and Jigani to cater to global business requirements.
DS: Merck offers one of the broadest portfolios in the industry of best-in-class products for pharmaceutical, academic, and industrial research as well as development and manufacturing. We have a fully integrated service organization to support CDMOs and contract testing services across traditional and novel models.
SN: Our vision for Merck's Healthcare business is clear. Make the maximum impact to patients by discovering unique ways to treat the most challenging diseases. The main therapeutic areas the company focuses on are oncology, fertility, CM&E and N&I. These areas have promising approaches that can tremendously reduce the burden on the healthcare systems, coupled with innovative digital solutions to drastically improve the patient experience throughout, which will impact the overall outcome. Regarding the company's clinical trials, we continue to sustain-dialogue and involvement of the country in all future clinical trials and seek support to ensure that India is always included in global clinical development programs.

How did Covid-19 impact the way medical professionals and the public think about vaccines?
AS: Merck had been collaborating with the leading vaccine manufacturers in India even before the outbreak of Covid-19. We focused on bringing vaccines to the market faster and at affordable prices, and we leveraged our technical support team to help our customers scale up at speed. What the pandemic did was bring awareness to the public about the importance of this type of work and encourage medical professionals and public officials to collaborate on how we can better prepare our communities for the next pandemic.

What role do MNCs play in fostering innovation within India's life sciences sector?
AS: If you look at the domestic vaccine manufacturers in India, they still largely get their technologies from global players. Yet if you look at the research going on here, there is an incredible focus on innovation backed by support from the government of India to ensure investments are being made to target the right diseases for the Indian population's needs. For example, there is a vaccine in the pipeline for dengue, which is very prevalent here. MNCs that have a presence in India are able to provide great platforms for the domestic industry to collaborate and exchange knowledge to produce the right medicines, drugs and vaccines.
DS: To launch a new product, phase three is the real challenge because that is where a lot of funding is required. This is an area where collaboration opportunities between MNCs and domestic players is particularly helpful. As part of Merck's CSR strategy, we are funding a company that is working on a diagnostics kit for five different diseases including Covid-19, chikungunya, dengue, malaria and typhoid.

How is Merck supporting the development of the next generation of scientific leaders?
SN: Merck runs a program that encourages its employees to innovate by supporting them in bringing their ideas to the market through significant financial investments. We also provide scholarships to students and run curiosity labs to generate interest in science amongst young minds to help turn them into the next breakthrough scientists. Importantly, we aim to tap into the talent pool that exists beyond urban areas to help provide opportunities to promising students in more rural areas that traditionally lack the resources and connections to enter the industry.
DS: In India, academia and industry only recently began collaborating. Most academic institutions are still at the basic stage of their research. Covid-19 accelerated a shift towards translational research that can be directly helpful to society. Over the past few years, we have seen more public-private partnership programs to help facilitate this. ■

» Azelis has focused on ensuring growth in India through strategic acquisitions and key mandate wins, all while actively developing its portfolio of specialty chemicals and food ingredients in the country. «

Aparna Khurana

Managing Director - India
AZELIS

Can you share with our readers the history of Azelis' presence in India?
Azelis India was established in 2012, and is currently active in nine market segments across the life sciences and industrial chemicals industry, including pharma, food, chemicals, CASE, agri and personal care to name a few.

With offices and warehouses in Mumbai and Delhi NCR, the Azelis India team of over 150 employees include some of the best industry professionals in the country, as well as skilled technical experts for the Pharma, CASE, Food, Personal Care and Agri markets, who manage dedicated laboratories for each of those markets.

Azelis has focused on ensuring the growth of its business in India over the past few years through strategic acquisitions and key mandate wins, all while actively developing its portfolio of specialty chemicals and food ingredients in India.

How does the company leverage its footprint in India to serve local markets as well as assist principals in expanding their business to India?
By building strong relationships with key local and global players in the industry, Azelis India is able to offer a comprehensive range of chemicals and ingredients from first-class manufacturers that allow us to support customers with their formulation challenges.

Our strong partnerships with our principals help them reduce complexity by acting as an extension of their sales organization and bringing their portfolio of products to new audiences in the local market, allowing us to not only serve the local markets but also to offer our principals a route to market in the Indian economy.

What types of clients does Azelis typically take on within India's life sciences sector?
Our customers range from small medium enterprises to multi-national corporations.

To further support our customers, we introduced our Customer Portals for various market segments to provide customers with information on trends, formulation inspiration, product documentation, and 24/7 access to our technical expertise. By leveraging our digital solutions, we will also be able to accurately capture additional information, allowing for further insights into ingredient recommendations and formulation requirements for both our technical experts and our principals.

Azelis announced in November 2022 the inauguration of its first pharmaceu- ticals and healthcare laboratory in India. How will this lab enable your company to better service the Indian pharmaceutical industry?
Thanks to the lab, our technical expertise and innovation resources will be accessible to a wider audience within the pharma industry. The lab's capabilities ensure we will continue to develop innovative solutions that are market-leading and incorporate leading trends, allowing us to deliver on our brand promise, 'Innovation through formulation'.

We will make certain that our solutions leverage market trends such as well-being and health, as we also strengthen our lateral value chain with nutraceuticals

Can you provide an overview of Azelis' Pharma portfolio?
Constant development, changing regulations and evolving healthcare demands are all challenges our partners in the pharmaceutical market face day in day out. We are a one-stop shop for all our customer's needs and offer them ingredients, cleaning solutions, packaging material and testing equipment. We offer various products including functional pharmaceutical excipients which helps in taste masking, moisture protection, film coating, tablet coating, drug delivery, anti-cracking, binding for solid and oral dosage forms. We also offer Halal, Cosher, RSPO certified products.

How does Azelis approach the topic of sustainability?
Sustainability is engrained in everything we do, which is why we are actively reviewing our portfolio to identify sustainable products, which can then be used to develop sustainable formulations, and allow us to suggest sustainable alternatives to our customers. This is especially important as consumers are increasingly more conscious about their impact on the planet and desire a more sustainable lifestyle.

We aim to advance the sustainability agendas of our stakeholders by leveraging our lateral value chain and technical expertise to develop new or alternative sustainable formulations, cascading sustainable materials into the supply chain and innovating for a better tomorrow.

Azelis is proud to have received the EcoVadis Platinum rating, the highest ESG ranking in our industry from Sustainalytics, and be part of Together for Sustainability, all of which reflects our commitments and achievements towards building a sustainable future. ■

Sudheendra Kulkarni

CEO - South Asia & ASEAN
FERRING PHARMACEUTICALS

As we watch India transition from being known primarily as a generics country, to focusing a lot more on R&D and innovation, MNCs play an instrumental role in providing the technologies that are required to make that happen.

What does Ferring Pharmaceuticals' presence in India encompass?
We operate across all three major verticals of the value chain – manufacturing, R&D and commercial operations. In India, we have an API manufacturing facility for one of our global APIs, a R&D facility in Genome Valley, and we are building a formulation manufacturing facility in Hyderabad as well. Here we have qualified scientists working on improving our existing product lines and new products for emerging markets. We also have commercial operations based in Mumbai. From India we serve the domestic market as well as other South Asia & ASEAN markets.

What type of work does Ferring take on in the maternal and reproductive health space?
The demand for maternal health and reproductive medicine is one of the fastest growing segments within the Indian pharmaceutical industry. In 2021, we launched a product geared towards the prevention of blood loss during birth to help prevent deaths by postpartum hemorrhage (PPH). We collaborate closely with the WHO and have launched the Safe Birth initiative in our commitment to protect women around the world. The challenge is that this standard of care requires cold chain transport and storage for products maintain their efficacy. In many low- and lower-middle income countries, particularly in remote areas where the burden of PPH is the greatest, access to cold chain storage is not readily available. Ferring has developed a room temperature stable formulation of PABAL (carbetocin) for intravenous administration which need not be refrigerated and is given as a one-shot injection for women in labor to control blood loss. Additionally, India's consumer segment is rapidly expanding, and with this increasing disposable income people are proactively seeking maternal and reproductive health products, especially in the IVF and infertility segment for treatments to build families. Ferring also provides this type of treatment.

Can telehealth play a role in expanding reproductive healthcare coverage?
No single organization or intervention methodology can overcome the challenge of reaching all remote populations. We are exploring digital means to reach more people as face-to-face interactions can at times be very constrained. We also work closely with state governments and the central government in India, who has been extremely supportive in providing avenues for us to educate people.

India has done a tremendous amount of work in terms of reducing maternal mortality. We used to have approximately 130 maternal deaths per 100,000 births in India due to PPH. Today, the count has come down to 100 per 100,000 of women giving birth. The Global Sustainable Development Goal for maternal mortality called for by the WHO is to bring this count down to 70.

What role do MNCs play within India's life sciences sector?
Multinational companies are working closely with their local affiliates and have strong partnerships with local companies as well. For example, Ferring has its own manufacturing facilities but also joined hands with other pharmaceutical companies to boost its manufacturing scale. MNCs are bringing significant technological innovation and knowledge to local companies in India, and thereby drive down the cost of manufacturing and ultimately make medicines more affordable. With our partners, Ferring is able to manufacture our room-temperature-stable formulation, PABAL, in India, at a very cost-effective price. This cost-effective benefit is not only for the Indian population but reaches all other low and middle income countries such as in Africa, the Middle East, and Asia. As we watch India transition from being known primarily as a generics country, to focusing a lot more on R&D and innovation, MNCs play an instrumental role in providing the technologies that are required to make that happen.

How important will India be for Ferring in the coming years?
India and other ASEAN countries comprise the fastest growing markets for Ferring. Here, we will continue looking for expansion and partnership opportunities to bring affordable medicines to the market. India stands out as one of the largest economies which is expected to grow, despite all odds, at 7-8% GDP. We will continue to focus our strategic expansion efforts here. ■

Mitanshu Shah

SVP Finance
ALEMBIC PHARMACEUTICALS

We continue to launch new products because this provides traction in the market. We are spending a disproportionate amount on R&D to get as many filing and approvals as possible.

Can you remind our readers of Alembic's role within India's pharmaceutical industry?
Alembic was formed in 1907. In the 1980s, we expanded our antibiotic range and geographic footprint. Initially, we partnered with large pharma companies and distributors to sell in the US, but in 2015 Alembic set up an office in New Jersey to strengthen its footprint here. To do so required significant investment, which is consistent with the company's tendency to spend nearly 12-13% of its top line on R&D. As a result, Alembic has become one of the largest filers of ANDAs – we file close to 25-30 ANDAs and 7-8 DMFs per year. This has helped the company go from very modest sales in 2015 to US$300 million in the US today. Simultaneously, Alembic has invested into ROW markets, which currently account for 15% plus of the company's sales.

How does Alembic evolve its product lines in accordance with macro market trends?
Our presence in the American markets was originally only in oral solid dosages, meaning tablets and capsules. We figured that to be a full-fledged player, we needed to invest in other therapeutic lines. Around 2016, we began investing into dermatology, oncology and ophthalmologic. We build capabilities and capacities with injectables and derm plants. Of late, the generics business has become less rewarding in terms of profits on account of increase in input and freight costs. Also, the cost of running operations in America continues to rise with rise in inflation. Multi-year high inventory levels in US have led to a frenzy amongst pharma companies to liquidate their products in the US market at any given price again adding to earnings. There has been consistent price erosion in the American market over the past two years. To mitigate the effects of this on Alembic, we continue to launch new products because this provides traction in the market. We are spending a disproportionate amount on R&D to get as many filing and approvals as possible.

What is your assessment of the level of enthusiasm for R&D in India today?
Many Indian companies have focused on R&D as an area of cost reduction over the past 12-18 months because they are not getting commensurate revenue for their investments in innovation. That said, there are very exciting opportunities ahead in India's pharma sector. Looking at the patent cliff, there are wonderful molecules that will be genericized towards the end of this decade, and many Indian companies have their eyes on these future blockbuster drugs. Today, management should strategically decide which molecules to work on because current revenue streams do not support magnitude of investment in R&D as it used to be.

Why do MNCs in India remain limited in their presence within the country?
The companies experiencing formidable growth in the domestic branded business are the Indian companies, not foreign entities. Foreign companies did not invest as much as they should have in creating a strong presence on the ground in terms of product offerings and manpower, and it is too late to do this now. To succeed in India, a company needs an entire product range instead of just their own line of researched products. For example, GSK will not sell Novartis researched products in India, but Indian companies can very well do so. From Alembic's perspective, a generic is a generic. Once it is off patent, it does not matter who originally formulated it. Multinationals do not come with that mindset, and that is why they are unable to capture the kind of market share as top Indian players like Sun Pharma, Glenmark or Lupin.

Can you share Alembic's key goals for the next year?
Alembic is in the process of commissioning two large plants. One is for general injectables and opthal, and the other is for oncology. From the oncology plant, we are launching our first product in January 2023. We plan to be formidable player in oncology and injectables in years to come. Nearly 80% of our capital allocation has gone into these lines of business over the past few years, and now that we see the light at the end of the tunnel, we are excited to commercialize these products in US and rest of world. ■

SUB-SECTORS ON THE RISE

"Whether it is from climate conditions, pollution, continuous population growth, or stressful lifestyles, new health issues will continue to emerge. To counter these issues, people will have to turn to the Indian system of health."

Rajiv Maniyar,
CEO,
Aligns International

GBR SERIES • INDIA LIFE SCIENCES 2023

Image courtesy of Olddesign (Depositphotos)

Nutraceuticals

Demand skyrockets

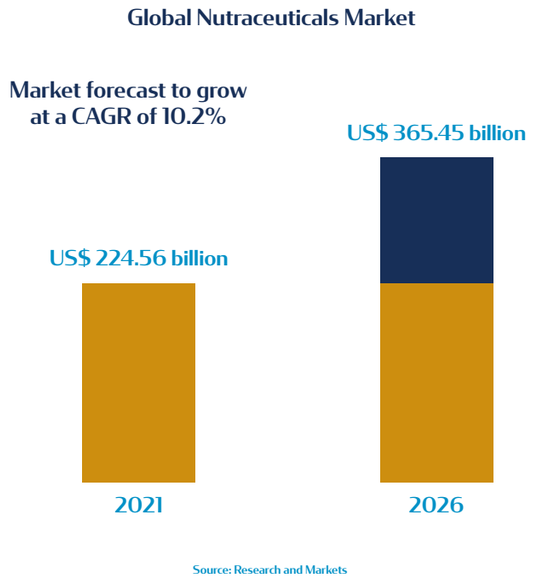
Katherine Hanlon (Unsplash)

Fueled by the pandemic, a growing population, and increased access to technologies, certain sectors of the life sciences have attracted attention for how quickly they are growing. Not only do these areas of innovation generate revenue and create employment opportunities, but they often can be used to amplify domestic healthcare coverage, adeptly penetrating rural and suburban regions of India that are often excluded from centralized health schemes.

India's soaring population, set to overtake China as the world's largest by 2028, is witnessing a transformation. Life expectancy is on the rise and middle-class incomes are growing, driving greater demand for healthcare products coupled with the financial means to better afford them. Many consumers, taking the pandemic as a wakeup call to become empowered in making choices about their health, are increasingly conscious about lifestyle-related treatments and therapies that can help prevent illness before it occurs.

Despite having a deep tradition of ayurvedic medicine, India's health industry pre-Covid was driven nearly exclusively by prescriptions, even when it came to OTC products like vitamins. Yet industry stakeholders are observing a paradigm shift unfold as people realize that if they take proper care of their health, they are more likely to survive diseases. "Within India, people are starting to take vitamins and exercise more, for example, without waiting for direct instructions from a doctor to do so," explained Vishal Rajgarhia, marketing director of Finecure Pharmaceuticals.

In this way, the life sciences industry is making headway into the personalized medicine, and in doing so, is harkening back to a style of medicine that was practiced thousands of years before the world adapted its current, one-size-fits-all model. Enabling this transition are modern online educational resources and commercial platforms that consumers can access to make purchases directly. "We see a clear trend in the e-commerce segment in which people now have more trust and acceptance towards nutraceutical products and herbal supplements that emphasize health and wellness," commented Sagar Patel, director of Vasu Healthcare.



Source: Research and Markets

In addition to the catalyst of a global pandemic and the advent of digital tools that empower consumers, the rising prevalence of certain health conditions may in itself be amplifying the need for nutraceuticals. "Beyond the shock of Covid-19, chronic ailments are becoming more prevalent, and pharmaceuticals do not necessarily have clean solutions for many chronic health issues," said Chintan Gandhi, managing director of Millennium Herbal Care. "Even if you look at something as simple as high cholesterol, the patient is prescribed statins, which have side effects. This is where herbals and nutraceuticals have a large role to play."

As the industry shifts from illness to wellness, the nutraceutical space has received more regulatory attention. In March 2022, the Food Safety and Standards Authority of India (FSSAI) drafted a new framework, the FSS (Nutra) Regulations 2022, that encompasses health supplements,

nutraceuticals, food for special dietary or medical use, prebiotics, and probiotics. Two months later, the FSSAI provided slight amendments regarding the use of certain additives and enzymes.

Beyond enacting regulations, the Indian government also established an AYUSH export promotion counsel to help develop marketing for Indian companies and streamline regulations for exports to other countries with the overall aim to boost demand for the Ayurvedic sector. As part of this global ambition, in March 2022 the Government of India signed an agreement with the WHO to establish the WHO Global Centre for Traditional Medicine, which will create new methods of publishing information on traditional medicine from around the world in addition to outlining standards for testing and certification. This flurry of activity underscores how important the alternative medicines space has become within the life sciences, which is an immense advantage for patients around the world who now enjoy access to treatments that had not previously existed in the market.

Bombay Hemp Company, known as BOHECO, was established nearly a decade ago with a focus on the use of cannabis in the health and wellness sector. As India's first medical hemp company, BOHECO was in many ways forging a new path. In doing so, the company identified an avenue to provide Indian patients seeking pain management for cancer and other chronic diseases an attractive alternative to narcotics. "India is a lead cultivator of opium, which is used for pain management for cancer and other chronic diseases," explained Avnish Pandya, co-founder and chief research officer. Despite the country's robust opium production, however, little goes to the Indian market given its high export potential. "As a result, there is a huge void in terms of analgesic and anti-inflammatory drugs that come from natural substances. This is where we see the historical use of cannabis having a significant impact on today's patient population."

In addition to its high export value, opiates are classified as narcotics, unlike cannabis, which is classified as an intoxicant. This distinction makes it all the more difficult for domestic patients to receive pain management. "We have heard from practitioners who have patients with stage 3 or stage 4 glioblastoma and have not been able to get access to carfentanil, codeine, or any other morphine derivative to manage pain because in order to get a small amount, they have to go through enormous amounts of paperwork," commented Jahan Peston, a fellow co-founder and the company's chief strategy officer.

The evolution in consumer preferences in other sectors can also have an effect on the life sciences, as companies that are attuned to these changing demands can carve out new niches for themselves by adapting accordingly.

Gaurav Kaushik, managing director and CEO of Meteoric Biopharmaceuticals, a company founded in 2006 with a focus on biological enzymes that has since expanded its

> We combine indigenous knowledge passed down over thousands of years with modern extraction techniques.

Avnish Pandya,
Co-Founder and Chief Research Officer,
Bombay Hemp Company

focus to probiotics, highlighted an innovative enzyme his company has brought to the market that fits within this framework. "The enzyme portfolio for any company is dominated by animal-derived enzymes, like pepsin and pancreatin that often come from pigs or cows," Kaushik explained. "As the world is moving towards veganism, Meteoric Biopharmaceuticals developed a vegan alternative to pancreatin."

According to Kaushik, his company has found commercial success for its product not only amongst people looking for alternatives to animal-derived products but also in countries that do not consume pork for religious reasons. Though not a pure-play nutraceuticals company in its own right, Meteoric Biopharmaceuticals demonstrates the power at play when life sciences innovators apply a forward-thinking approach to innovation.

With all the activity in the sector, the biggest task the nutraceutical sector currently faces is not to attract talent and resources or to come up with the next exciting innovations but rather to create an identity for itself separate from its pharmaceutical counterpart. As it stands, the recognition and legitimacy of Ayurvedic practices often relies on secondhand exposure from allopathic medicine.

"In many ways, the Indian nutraceutical industry is dominated by the pharma industry," said Ankit Khokhani, director of Generex Pharmassist. "Unlike in the West where most consumers understand the difference between a company like Pfizer and a company like Nature's Way or GNC, in India the space is very amalgamated, and it is actually pharma companies driving the growth of the nutraceutical industry. Here, the perception is anything that comes in a pill or a capsule is a drug."

Gandhi of Millennium Herbal Care agrees. "Nutraceuticals and herbals deserve their own place within the life sciences," he said, highlighting that unlike prescriptions that are only consumed for a specified time period, nutraceuticals, herbals, and probiotics should be seen as supplements that function as lifestyle additions. "It is the responsibility of alternative health companies to educate consumers on preventative medicine, an area the pharmaceutical industry is failing at."

This process will take time, though with the work nutraceuticals companies and consumers alike are doing to increase awareness about what practices may best serve an individual's health needs, the dialogue has already begun. ■

JP

AP

Jahan Peston & Avnish Pandya

Co-Founder and Chief Strategy Officer (JP) & Co-Founder and Chief Research Officer (AP)
BOMBAY HEMP COMPANY

How has Bombay Hemp Company (BOHECO) evolved?
JP: As India's first medical hemp company, we started by focusing on three branches: policy and regulation, research and biotech, and category creation and industry building. Bombay Hemp Company/BOHECO was one of the first companies to receive licensing for using cannabis in the health and wellness category, and the company built a strong foundation of scientific research that enabled some of the first human clinical trials using cannabis as an ayurvedic medicine.

AP: India is a lead cultivator of opium, but, few Indians see access given its high export potential. As a result, there is a huge void in terms of analgesic and anti-inflammatory drugs that come from natural substances. This is where we see cannabis having a significant impact on today's patient population.

JP: We realized that much of the healthcare system is lacking immediate analgesics. We have heard from practitioners that have not been able to get access to carfentanil, codeine, or any other morphine derivative to manage pain. Bombay Hemp provides immediate access to an analgesic alternative that has shown marked alleviation of symptoms. ■

Ankit Khokhani

Director
GENEREX PHARMASSIST

How has Generex Pharmassist (Generex) created a name for itself in India's nutraceutical sector?
Generex has been marketing world-renowned, patented, proprietary nutraceutical ingredients to the industry for nearly 20 years. We have around 15 very innovative ingredients that are extensively clinically-backed. Generex has a focus on bringing 'First time in India' concepts. As a value added service, we also forward integrate and develop customised finished formulations on a contract basis for our customers, thereby reducing the go-to market time drastically.

In what ways is public perception towards nutraceuticals undergoing a transition?
The Indian nutraceutical industry is dominated by the pharma industry and it is actually pharma companies driving the growth of the nutraceutical industry. The perception is anything that comes in a pill or a capsule is a drug. Additionally, Indian consumers are not as self-educating and instead rely on instructions from their doctors, even on which multivitamin to take.
We are seeing a preventative mindset setting in. I anticipate a generational shift within the next decade. This all feeds into the ambition of the nutraceutical industry, which is to have its own footing without having to piggyback on the pharma sector. The sector is on the cusp of tremendous growth . ■

Chintan Gandhi

Managing Director
MILLENNIUM HERBAL CARE

How has Millennium Herbal Care evolved?
Millennium Herbal Care has focused on Vedic medicines for the past 20+ years. From there, we have grown the portfolio into Ayurvedic medicines, personal care products, and lifestyle management supplements. We operate in nine therapeutic categories, including ortho, fertility, digestive, skin and hair, cardiac, and mental health. We are also entering the wound care and wound management space, and we recently completed a clinical study for a natural spray used on veinous and diabetic ulcers with an excellent response rate towards the recovery and repair of those wounds. Millennium Herbal Care has also developed a CDMO business in topical anti-fungals and cosmeceuticals, which supplies white labeled products to the dermatology divisions of large Indian pharmaceutical companies. This is growing rapidly, and it is where we invest around 70% of our R&D funds.

What are the goals of Millennium Herbal Care's online platform?
We offer consultations that go beyond prescribing supplements and nutraceuticals to offer information on diet and exercise regimens, and even provides check-ups on mental health. This is a free service. The goal of the platform is to help people, not to generate revenue, and we are actively looking to hire more doctors. ■

Digital Health

The digitization of patient care

Image courtesy of Myriams Fotos (Pixabay)

India has become an ideal testing ground for innovations in digital health, and for good reason: with a foundation of preexisting technical capabilities – India is home to the second largest smartphone market in the world, for example, and boasts a strong IT presence worldwide – and a significant percentage of its population in rural areas beyond the reach of national healthcare infrastructure, it has both the resources and the need to enable the transformation.

"I see more people looking to leverage the digitization of patient care, such as through telemedicine or the creation of wearable technologies," said Karan Singh, managing director of ACG. "In most cases, it is about pharmaceutical companies going beyond the hospital setting to connect with patients in a more comprehensive way that accounts for their lifestyles."

Digital health, an umbrella term used to describe any tools or resources resulting from the confluence of healthcare and technology, has existed in India since before the pandemic. Recognizing its rise, the Indian government launched its flagship Digital India Campaign in 2015, including public health initiatives aimed at how digital technologies could be used to increase access to healthcare services in rural regions. Two years later, the Digital Health Mission in India was borne from the National Health Policy's vision of a fully digitized healthcare system in the country. This laid the groundwork for market innovation and investment into digital health.

When Covid-19 hit India, the pace of development in the sector took off. This is particularly true for telehealth; the use of telecommunications tools to provide healthcare remotely.

Around the world, patients faced difficulties in visiting physicians due to extended lockdowns and unavailability, given the great numbers of people infected with the virus. The dichotomy that had already been present in India regarding access to healthcare in urban areas compared with rural regions became even more stark.

For years, members of the law firm Nishith Desai Associates (NDA) had pushed for digital health and telemedicine to be legitimized by the Indian government as tools to help overcome this uneven distribution of healthcare practitioners. Prior to Covid-19, digital health had been complicated by regulations preventing inter-state medical consultations; doctors in Mumbai could not treat patients in Bangalore, for example. After a considerable time encouraging such a shift, Darren Punnen, leader of the pharma and life sciences practice at NDA, watched as regulators quickly mobilized guidelines for the practice of telemedicine nearly immediately after lockdowns were announced. "Covid's impact on the industry was transformative as the government finally put a legitimate stamp of approval on the entire practice," Punnen recalled. "At a central level, doctors could now consult with any person in the country."

With regulations in place, adoption is now possible on a broad scale as the country already contained many of the required resources to build out telehealth infrastructure. "Many doctors who had retired or were not very active in their practice became very busy again, as all they needed was a laptop and strong WIFI," said Milind Antani, lead of NDA's pharma, healthcare, medical device and digital health practice. "We are at the tip of the iceberg in terms of what telehealth will come to offer India."

MedPrime Technologies is perhaps the hallmark example of an Indian company putting a digital twist on a traditional practice to facilitate the goal of pan-Indian healthcare coverage. The Thane-based medical equipment manufacturing company was the first globally to create a digital microscope that can be used to run tests in a professional lab setting.

Traditional microscopes require users to note their observations by hand, and Greeshma Unnikrishnan, a co-founder of MedPrime, realized that this had been posing a limitation. "The sample and the observer (a pathologist) would have to be in the same physical location," Unnikrishnan explained. "In places like India, pathologists can be found in cities but not in small villages. Additionally,

there is a globally low pathologist to patient ratio because the number of patients is increasing as is the number of diseases requiring microscopy for diagnosis, yet the number of pathologists is not increasing accordingly."

In India, it can take up to a week for samples from rural areas to be sent to a nearby city and analyzed. This, in turn, leads to delays in treatment, which can cause grave complications when dealing with diseases like malaria that require immediate treatment.

With the introduction of MedPrime's digital microscopes, this issue becomes obsolete. "Digitization brings everything online," Unnikrishnan said. "The need for physically transporting samples is diminished because you can send images over the internet or livestream instead. Now, you can look at a sample on a screen, capture images, record them, make measurements, run analyses, and project visuals. In the context of India, pathologists no longer need to physically go to each lab to sign off on diagnoses. Instead, they can work remotely, making the pathway to treatment faster for patients."

In addition to emerging players whose business models center on harnessing the power of digital technologies in a medical context, large pharma companies are looking for ways to incorporate its benefits into their existing offerings. "We are exploring digital means to reach more people as face-to-face interactions can at times be very constrained," said Sudheendra Kulkarni, CEO of South Asia & ASEAN for the multinational biopharmaceutical company Ferring Pharmaceuticals.

> As an IT hub, India is seeing a rise of interest by startups and other IT firms leveraging concepts of artificial intelligence in the life sciences.
>
> **Naresh Raisinghani,**
> **CEO and Executive Director,**
> **BMGI – India Division**

As a company focused on reproductive and maternal health, one of the fastest growing segments within the Indian pharmaceutical industry, the ability to reach broader swaths of the population to help treat issues such as death by postpartum hemorrhage (PPH) allows for more lives saved. "If the education at the point of care is appropriate and sufficient, it will allow people to make the right decisions. Those right decisions will eventually lead to the right interventions, and the right interventions will lead to the right results," Kulkarni said.

Digital health remains one of the most exciting subsectors on the rise in India given the near boundless potential applications there are for incorporating digital tools into a healthcare context. ■

Greeshma Unnikrishnan

Co-Founder
MEDPRIME TECHNOLOGIES

Can you introduce our readers to the mission of MedPrime Technologies?
MedPrime Technologies is a medical device company founded in 2014 by four Masters students who recognized the need for medical equipment developed and manufactured in India. We were the first company globally to create a digital microscope that can be used not just for educational purposes but to run tests in a professional lab setting for diagnostics pertaining to patient lives. Our digital microscopes are integrated with mobile phones or tablets for various benefits such as digital viewing, image capturing, sharing, live streaming, projection and analysis. We are also moving towards automation of microscopy to make the process smarter, faster and more efficient.

What are the company's main product lines?
MedPrime offers three lines of products. Our first is our Portable line. These are more compact and battery operated. Second, our Benchtop line, which is similar to a traditional microscope in structure but, instead of viewing the sample in an analog manner, you see it digitally. Third, we offer our Transform line, which is geared primarily towards pathology students.

How do the digital and automation components of your microscopes improve the diagnostics process?
In India, samples from rural areas have to be sent to a city to be analyzed, resulting in delays. There are places where this lag is up to one week even for simple tests like malaria, which must be completed quickly for immediate treatment. With a delay in testing, there is a delay in treatment, and the quality of life goes down. Digitization brings everything online. The need for physically transporting samples is diminished because you can send images over the internet or livestream instead.

By bringing in machine learning to assist with some diagnoses, such as through counting cells or other relatively simple processes to reduce the workload of a pathologist, we can help bridge the gap between pathologists available and diagnoses that need to be run. ■

Sahil Dharia

CEO & Founder
SOOTHE HEALTHCARE

What market potential do you see for Soothe Healthcare's hygiene products in India?
Soothe Healthcare manufactures, distributes, and markets personal hygiene products including fem hygiene, baby diapers, and adult diapers. The Indian market for this type of product is immense. When I founded the company 10 years ago, only 12% of women in India used sanitary pads. This has grown to 25% today, which is still low. Additionally, less than 10% use baby diapers, and less than 2% use adult diapers. These three categories currently total roughly US$1.7 billion. In China, whose market for these products is around 10 years ahead of India, the market is worth over US$25 billion. We see immense opportunity to develop this market further in India. The simplicity of our product means this can happen on a grand scale with significant impact. Our approach is to take simple, affordable, and scalable consumer healthcare products that can be distributed to the masses.

How is the market evolving?
Indian distribution networks are very fragmented because people make purchases from local mom-and-pop shops scattered throughout the country. Additionally, fem hygiene is currently a taboo topic in India that mothers and teachers do not feel comfortable educating young girls on because it involves reproductive organs. As a result, the biggest barrier is awareness. This is being solved rapidly by the internet

Looking ahead, what are your strategic objectives for Soothe?
When we started the company a decade ago; it was on a leap of faith that the segment would grow. We now have three strong brands and are setting our sights on being a billion-dollar company. As a local company, we have a first mover advantage over multinationals in the space, and we want to become a household brand name. ■

Medical Devices

Indian entrepreneurs on the move

Image courtesy of Olga Guryanova (Unsplash)

Alongside the rise in digital health tools has been a surge in companies focused on medical devices. According to Invest India, the country's national investment promotion and facilitation agency, the medical devices market in India is estimated at US$11 billion, and is forecasted to reach US$50 billion by the end of the decade. Growing at two and a half times the rate of the global average, India's medical devices market is the fastest amongst all emerging markets.

With all the progress the country is making, there still remains significant growth potential. As of 2021, roughly 70% of medical devices in India were imported, offering manufacturers a significant opportunity to fill the gap through indigenous manufacture and sales. One area that has proven to be particularly promising is point-of-care diagnostics (POC). This method of testing is ideal for resource limited settings, as unlike conventional clinical diagnostic procedures that require pricey and sizeable instruments often used at a hospital or in a laboratory, POC devices are portable and can be used on-site.

Bhaskar Malladi, head of strategy of in vitro diagnostics manufacturer Agappe Diagnostics, points to the evolution of POC testing as prices begin to drop: "POC testing used to be expensive, but with the rapid evolution of the technology, it has become more affordable and competitive in the marketplace. For example, diagnostics for sickle cell anemia previously required extremely high cost, high performance liquid chromatography (HPLC) testing, which requires expert staff and centralized lab testing. Today, POC technology allows for testing at approximately US$1,000 less, at only US$2 to US$3 per test, while providing the same quality of results."

Looking at the benefits of POC testing, particularly in countries like India, Mohal Sarabhai, CEO of Asence Pharma Private, decided to enter the molecular diagnostics space. As Asence traditionally focuses more on providing finished dosage forms and APIs to international markets, the company's move in 2017 to enter a joint venture with the US-based company Co-Diagnostics Inc. to form CoSara Diagnostics was a strategic decision that proved to be very timely.

"At first, we were mainly focused on India-specific diseases like tuberculosis, but when Covid-19 hit, we were able to turn our affordable, molecular diagnostics technology into Covid-19 PCR tests and thereby became one of the first companies in India to offer these tests," recalled Sarabhai.

His company's mission is to make these tests available beyond urban hubs where PCR machines are typically concentrated by distributing the devices at collection centers in class two or class three towns in India. Looking forward, Asence is working closely with its US partners to bring what they hope will be one of the most affordable POC devices to market. According to Sarabhai, the device, which has been submitted to the US-FDA for approval, will be saliva-based to provide the accuracy of a PCR machine on a POC device.

A lag in regulations

The largest challenge currently impacting the health of India's medical device sector is not funding or interest but rather a lag in its regulatory framework. Prior to 2020, the market was barely regulated, as medical devices did not fall within the portfolio of products over which medical regulators had oversight. Although Covid-19 brought to the government's attention the quantity of substandard products in circulation, such as ineffective PPE kits that were delivering people false results, India still lacks a uniform regulatory approach to the market.

"The regulatory landscape is unfavorable for companies like Premier that produce medical devices that adhere to high quality standards," remarked Nilesh Mehta, CEO of Premier Medical Corporation, one of the top three global diagnostics providers and manufacturer of over 200 million tests per year.

Given the costs associated with competing against lower quality manufacturers and trying to navigate an incredibly fragmented distribution network, Mehta acknowledged that his company tends to avoid India's consumer market. "Premier Medical has the efficiency of scale by being among the largest manufacturers of point-of-care tests, meaning we have our manufacturing costs basically as low as possible. Yet there are Indian companies that claim to manufacture the same product much cheaper," he said. "How are they able to do so? They create products that are far inferior or even defective."

As the Indian government collaborates with industry stakeholders to define regulations in the coming years, hopefully a more level playing field from a quality perspective will encourage players to take advantage of the sector's potential. ■

Nilesh Mehta

CEO
PREMIER MEDICAL CORPORATION

How has Premier grown into the company it is today?
I founded Premier in 1996, and the company has grown into one of the top three global diagnostics companies, currently manufacturing over 200 million tests per year, all from India. We are one of the premier suppliers of malaria, HIV, and hepatitis tests for low and middle-income countries. We work with some universities in the US to come up with novel technologies for infectious disease testing, which is why our development operations are based in New Jersey. In this way, we transfer new technologies and knowledge from the US to India, where we manufacture at a high volume and low cost.

What approach does your company take to navigating the balance between quality and affordability?
When it comes to making testing affordable, we specifically look for new technologies that are easy to use. For example, a PCR machine may cost US$30,000, which not every testing site can afford, and countries may require thousands of these. Premier works to devise a middle ground technology, such as one that detects an enzyme in a pathogen responsible for infections.

Can you outline the regulatory challenges that remain in implementing point-of-care testing tools on a large scale in India?
The regulatory landscape is unfavorable for companies like Premier that produce medical devices that adhere to high quality standards. India had no policy for self-testing before the pandemic, and they have yet to properly implement a centralized regulatory framework for these types of tools. Our company has the efficiency of scale of being among the largest manufacturers of point-of-care tests, meaning we have our manufacturing costs basically as low as possible. Yet there are Indian companies that claim to manufacture the same product for much cheaper. How are they able to do so? They create products that are far inferior or even defective. ■

TJ

BM

Thomas John & Bhaskar Malladi

TJ: Managing Director
BM: Head of Strategy
AGAPPE DIAGNOSTICS

What types of diagnostics tests does Agappe Diagnostics offer?
TJ: Agappe Diagnostics is an Indian in vitro diagnostic (IVD) manufacturer. Our reagents range includes clinical chemistry, immunoturbidimetry, coagulation, hematology, urinalysis, and most recently molecular biology reagents. We have the biggest reagent manufacturing facility in India at approximately 200,000 square feet, where we employ over 400 people. We also have a separate facility for equipment manufacturing where we manufacture semi-automatic and entry level automatic analyzers. In the molecular diagnostics space, we have a specialized line of LAMP equipment, and are the first to introduce the LAMP test in India. Agappe Diagnostics already manufactures 45% of our equipment lines in India, with the strategy being to manufacture 80% of equipment in-country within the next four years. The company also has a global presence, with our international business managed from our Swiss entity. From there, we serve customers in countries including Indonesia, the Philippines, and Egypt. We have a strong presence in the Asia Pacific and see great opportunity to expand further into Latin America, Europe, and Africa.

How is point of care testing helping India's healthcare systems reach rural populations?
BM: The point of care (POC) segment in India is approximately US$400 million. India's current government is working to bring health care to rural populations, and it is towards this goal that POC plays a crucial role. POC testing used to be expensive, but with the rapid evolution of the technology, it has become more affordable and competitive in the marketplace.

How does India compare to other countries in terms of legislative involvement within the industry?
BM: India's regulatory system is evolving and becoming more aligned towards the new IVD regulations that are going to be in place. The country has a very fair system both for multinational and local companies where the same regulatory controls apply. ■

SERVICES AND SUPPORT

"When services are provided under one umbrella, you are not dependent on several different service providers, and this helps both financially and from a time standpoint."

Jay Mandal,
Managing Director,
APDM Pharmaceuticals

Image courtesy of National Cancer Institute (Unsplash)

Contract Services

CROs thrive

Image courtesy of Roberta Keiko (Unsplash)

To say the Indian contract research organization (CRO) market is doing well would be an understatement. According to the Noida-based market intelligence firm BlueWeave Consulting, the market grew at a CAGR of 5.51% from 2017 to 2020 with a valuation of US$956.8 million in 2020. The firm predicts the market will grow to US$1,883 million by 2027 at an impressive CAGR of 10.75%.

BlueWeave Consulting attributes this growth to the rising number of cancer research studies taking place in India as well as the health of the pharmaceutical sector more broadly. According to Bindi Chudgar, managing director of Lambda Therapeutic Research, an Ahmedabad-based CRO providing full spectrum drug development services to a global client base, the pricing dynamics of the global pharma sector are the real wind in the sails of India's CROs. "Given the latest dynamics in the pharmaceutical industry, and the increasing cost of drug development, the CRO domain is set to grow further, along with the fact that pharmaceutical companies worldwide are under pressure to replace revenue loss caused by generics, increasing patent expiry, rising disease prevalence, and rising R&D costs," Chudgar explained.

In addition to industry-wide cost hikes, global economic trends may also be at play. Beyond the desire of many Indian pharmaceutical companies and their Western counterparts to decrease reliance on China as a source of materials such as APIs, the broader shift away from working with Chinese companies may have an inverse impact on the health of India's contract services sector. "In light of global repositioning, I think there will be significant growth in the CRO/CDMO sector in India as companies need to offset or at least complement the scale of capacity coming out of China," said Krishna Kanumuri, CEO and managing director of Sai Life Sciences. "The need to diversify and decrease dependence on China has significantly taken off, and over the next five years, I expect to see a great bull run in terms of where the Indian CRO-CDMO industry is going."

While there are many factors currently working in the favor of Indian CROs, proactive companies are still making strategic decisions rather than passively waiting to see benefits from the evolving market dynamics. For example, the global shift towards complex generics requires different capabilities on the part of contract research organizations, and the ones that are able to keep the pace with the transition by updating their offerings accordingly are best suited to attract these types of business opportunities.

"As our clients, both in India and globally, are increasingly moving onwards from simple generics towards complex generics, our focus has been to transition alongside them through offering the clinical development support they need," said Ajay Tandon, managing director of Veeda

Clinical Research, a global clinical development partner that acquired a majority stake in Bioneeds India in 2021 to amplify its preclinical capabilities. "Our investments into the preclinical space have proven helpful for our clients as they come to us for services such as additional toxicity tests or impurity qualification work for the development of novel generics before initiating clinical studies. Previously, we would have had to refer these clients to another preclinical company to do this work, but now Veeda, through Bioneeds, can assist them from this stage through to clinical studies."

Contract manufacturing

As the life sciences landscape shifts to accommodate more small and emerging biopharma companies, integrated service providers that can offer full-service capabilities are better able to take on this line of work without sacrificing the ability to meet the needs of larger players.

Regardless of size, many pharma and biopharma companies appreciate the opportunity to partner with the same service provider throughout the development and manufacturing process to avoid site and tech transfer complications. "We have clients come to us to co-develop a product from scratch," said Bhaskar Krishna, managing director and CEO of Maiva Pharma, a sterile injectables CDMO. "It can be a challenge to find a CDMO with the capability to develop, license, and manufacture a product, and this is a strength of Maiva."

Derren Healthcare, a CDMO that does general small volume parenteral (SVP) manufacturing, finds itself at an advantage when compared to other SVP manufacturing companies given its ability to assist with R&D along with production. "If a client has to develop something then do a tech transfer to another company then go to another supplier for commercial batches, this becomes costly and time consuming. When it comes to SVP in glass and vials, clients can come to Derren for development as well as the exhibit, engineer, or commercial batch all together," commented the company's director, Rahul Maheshwari.

In a similar vein, Jay Mandal, managing director of APDM Pharmaceuticals, acknowledges there is both a time and a cost standpoint associated with offering integrated services: "When services are provided under one umbrella, you are not dependent on several different service providers, and this helps both financially and from a time standpoint."

Krishna Kanumuri, CEO and managing director of Sai Life Sciences, has found there are particular therapeutic areas in which clients stress the importance of having an integrated service provider from a speed perspective. "Especially with rare diseases and oncology, there is pressure to decrease the development and manufacturing timeline from 10 years down to five years," Kanumuri said. "This need to get to market faster, gives companies very little time to move between service providers. The ability to provide high caliber, fully integrated CRO and CDMO services under one roof, saves time and avoids unnecessary bottlenecks."

Just as forward-thinking contract research companies anticipate growth patterns in emerging sectors, such as Veeda with complex generics, Indian CDMOs are working overtime to keep their business strategies a step ahead of the curve.

"Around four years ago, we decided to expand the business through a niche segment of oncology services because we recognized this sector comprised roughly 20% of the world's pharmaceutical market," said Bikramjit Ghosh, head of strategy and business development at Sakar Healthcare, a CDMO formed in 2004 that has expanded its presence to over 60 countries worldwide.

Understanding the importance of cancer-related treatments, Sakar established its own API integrated oncology formulation and manufacturing unit. The company has since undertaken a joint development with a Greek company on a product that is, according to Ghosh, in the top 10 patented molecules in the oncology segment worldwide.

With an eye on the market growth potential for peptides, Piramal Pharma Limited, which demerged from Piramal Group in October 2022, acquired Hemmo Pharmaceuticals to add peptide API development and manufacturing capabilities to the company's CDMO business. "We added Hemmo because they had been around for several decades and provided us with the ability to do development work for on-patent clients working with peptides," commented the company's CEO Peter DeYoung. "The company already had an established on-market generic portfolio and a pipeline of generics, meaning we can serve both the services segment and the generics segment for peptides, an area we believe is attractive and growing."

According to Piramal Pharma's estimates, there are over 80 approved peptides in the market in the US, about 250 under clinical development, and around 500 in preclinical development. According to DeYoung, even if Piramal Pharma takes on a small fraction of this peptide work, it has the potential to become a relevant player given the room to grow. "We see the space growing at roughly five to eight percent per year, and of that, two thirds is outsourced. As such, there is opportunity to grow a meaningful clinical development pipeline with our services business on top of the existing generic business Hemmo was already doing."

Piramal Pharma has partaken in other recent inorganic activities as part of its growth strategy, including adding a new drug product facility in the US and a minority investment in a gene therapy and vaccine development company in Hyderabad.

While it may be the pharma and biopharma innovators that often make headlines, the behind-the-scenes activities of contract service providers are what enable the industry to develop at such a rapid pace. ■

Bindi Chudgar

Managing Director
LAMBDA THERAPEUTIC RESEARCH

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With our expanding global footprint, we are well positioned to create benchmarks and shape the future of the clinical research industry by ensuring quality, reliability, and value-added services.

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Can you share with our readers key highlights of Lambda Therapeutic Research (Lambda)'s operations since 2019?

Lambda Novum Therapeutic Research is among the world's leading CROs, providing full spectrum drug development services to the global Big pharma, innovator, biopharmaceutical and generic industries. The company is headquartered in Ahmedabad – India, with facilities and operations in Mehsana (India), London (UK), Pittsburgh (USA), and Las Vegas (USA). Every day, over 1,500 employees collaborate in perfect harmony to take revolutionary leaps in life sciences.

Lambda Novum is a market leader in both early phase and late phase clinical research activities. The company's overall focus remains on the late phase oncology studies both in new entities as well as NDDS molecules, biosimilars and of course pharmacovigilance, as we consolidate our undisputed leadership in the BA/BE segment.

Our cutting edge infrastructure, capabilities to conduct global multicentric trials across various therapeutic domains, complex NCE studies and early phase studies, complex Biosimilar trials, and advanced digital platforms are but some our differentiators.

Are there any therapeutic areas or client profiles that Lambda has seen an uptick in demand from?

From a client perspective, we have seen an uptick on the number of research projects and clinical trials being carried out for a mix of Innovator, biotech and generic clients from both the US and Europe.

There has also been an increased demand from generic clients to submit dossiers to EMENA and South Asia markets like Malaysia, China and Thailand, along with LatAm countries like Brazil.

What is Lambda's value proposition as a research partner with a presence in both North America and India?

Novum enjoys a fairly enviable reputation of being the front-runner in the dermatology domain over the last 25 years in the US CRO Industry and we now hope to further build upon the same by building up capabilities in the oncology and biosimilar late phase clinical trials domains. We have now consolidated operations of both our entities under the single umbrella of Novum Pharmaceutical Research Services in the North American markets.

Novum was a strategic fit for Lambda as it provided a natural platform for growth in the US. This combined entity of Lambda Novum helped scale up our operations and create one of the largest and most comprehensive offerings of on-demand and on-premise solutions to our global clients.

Are there any innovation areas within India's life sciences ecosystem that excite you most?

We have been front-runners in adopting most of the technological advancements including machine learning and artificial intelligence to the extent possible, which helps in faster regulatory submissions and approvals. This is the value addition that both Indian as well as global clients expect in the present environment and we are well positioned today to meet the same.

What are your strategic objectives for Lambda's growth over the next few years?

Mrs. Bindi Chudgar is currently aiming at revenues of US$130 million by the year FY 2025-26 and growing at a CAGR of 28% YoY. We have one of the industry's finest credit ratings, which speaks much about our financial health. This enables us to pursue other M&As in the near future for our late phase clinical trials unit, biosimilar labs, and pharmacovigilance divisions, which will propel our growth even further.

Her vision is to continuously improve and adopt technological advancements which suit the pharmaceutical industry. Lambda Novum enjoys a fairly enviable reputation of being the front-runner in the Dermatology domain over the last 25 years in the US CRO industry, and she aims to further build upon the same by building up capabilities in the oncology and biosimilar late phase clinical trials domains. ■

We now offer end-to-end modular technical services, encompassing both pre-clinical and clinical development of biosimilars addressing global regulatory requirements.

Ajay Tandon

Managing Director
VEEDA CLINICAL RESEARCH

How has Veeda grown since GBR last spoke with you in 2019?
In addition to maintaining our focus on increasing our capabilities surrounding healthy volunteer studies for generics, Veeda has focused on building capabilities in clinical trials, investing in biosimilars, supporting clinical development of novel drugs and adding preclinical capabilities. Since 2019, we have become a significantly broader based integrated service provider.

On the infrastructure side for healthy volunteers, we added an additional 162 beds to now have 588 bed capacity as well as added an 18-bed phase 1 clinic for doing first in human (single ascending dose studies and multiple ascending dose studies) and phase 1 studies. In clinical trials too, we have grown substantially over the past three years, with our team expanding from around 20 people to over 80. We added preclinical capabilities to our group portfolio by investing in Bioneeds India, a leading preclinical CRO based in Bangalore. We also entered into a joint venture with Canadian based Somru BioScience to establish Ingenuity Biosciences, for fast tracking our growth in biosimilars.

Collectively across Ingenuity, Somru and Bioneeds, we now offer end-to-end modular technical services, encompassing both pre-clinical and clinical development of biosimilars addressing global regulatory requirements.

What led your company to amplify its focus on complex generics?
Veeda continues to focus on servicing the generics industry with healthy volunteer as well as clinical trials. Over the years, the company has developed deep domain capabilities across diverse dosage forms, routes of administration and complexities, including injectables, inhalation studies, dermatology, oral solid tablets and capsules. As our clients, both in India and globally, are increasingly moving onwards from simple generics towards complex generics, our focus has been to transition alongside them through offering the clinical development support they need. Our investments into the preclinical space have proven helpful for our clients as they come to us for services such as additional toxicity tests or impurity qualification work for the development of novel generics before initiating clinical studies.

Why do you believe CROs are particularly important in the life sciences today?
More work in the life sciences is being done by small and emerging biopharma companies, and this plays in favor of integrated, wider-based platforms like Veeda. We continue to focus on this segment of clients because we see an opportunity to bring in full-service capabilities even though functional service engagement with big pharma also remains an important part of our business.

What steps are critical to propel the industry forward in terms of innovation?
The Indian government has placed a concerted effort on building capacity within the industry and supporting innovation. India's biopharma sector remains relatively constrained when it comes to access to risk capital, but there is significant potential. The emergence of venture capital available for innovative biopharma companies to develop their programs has increased substantially over the past decade in India. There are also a lot of incubation centers that have come up in universities and outside, especially in places like Pune and Hyderabad, and this is very encouraging to see.

The government is also working on building industry capacity to support innovation, such as phase 1 clinical pharmacology, analytical and bioanalytical facilities. There are discussions currently underway regarding how to build this infrastructure, in collaboration between the government, academia and industry, to create the right ecosystem. Overall, I believe these cross-industry collaborations to build the right ecosystem for innovation, along with the push for risk capital, are driving the industry forward. If this all gets into rhythm, I see the industry in a very different place five years from now.

To conclude, can you share your main goal for Veeda for the coming years?
Veeda is transitioning from being a clinical research organization into a broad based and integrated contract research organization. We see significant growth for preclinical and clinical research services in India over the medium to long term. With our comprehensive portfolio of drug development services and our continuing investment in infrastructure, people and process to build new capabilities relevant to our clients, we believe that we are very well positioned to be preferred partners for global small and emerging biotech companies for their novel drug development programs. ■

With changes in business dynamism from small molecules to large molecules, Bioneeds contract services has gleaned its focus to cater to this opportunity and we foresee a YoY growth of around 15-30%.

Vinay Babu

Managing Director
BIONEEDS

Can you introduce Bioneeds to our international audience?
Bioneeds is a Bangalore based, multi segment, multi vertical, preclinical Contract Research Organization (CRO).

We are OECD GLP certified, AAALAC & OLAW accredited, CCSEA registered, and also US-FDA audited, and we extend support to discovery and development programs & testing services for diverse industry segments including pharma, biopharma, medical devices, agrochemicals, industrial chemicals and cosmetics.

Our range of service offerings includes GLP studies- acute studies, genotoxicity, inhalation, repeat dose studies- short term & long term, DART studies, teratology and carcinogenicity studies, including formulation and bioanalytical (PK/TK) assessment.

Could you highlight any key milestones the company experienced in 2022?
Enhancing current capabilities, increasing lab space and animal rooms from 85 to 100, dedicated lab areas for inhalation, ecotoxicology, DART and bioassays and adopting new technologies have been few of the highlights to maintain business continuity. Successful US-FDA audits, ISO-17025 (2017) accreditation by NABL, AAALAC re-accreditation and recognition of the animal facility by NIH's OLAW have been some of the key milestones during 2022, apart from expanding the biopharma services and long-term toxicology projects. Since the pandemic we have worked on several Covid vaccines successfully and currently a few repeat dose intranasal vaccines studies are underway.

What services does Bioneeds offer the biopharmaceutical sector, and how have you seen this space evolve over the past few years?
Infrastructure, technologies, expertise, and tools are in place, and some of the key highlights include preclinical toxicity assessment for biologics, biosimilars, repeat dose toxicity with ADA/NAb assessment, bioanalytical method development, method validation and sample analysis under GLP and GCLP compliant practices and as per US FDA, EMA guidance, PK & PD biomarker assessments. Apart from these we also offer analysis from clinical plasma samples and other sample matrices, flow cytometry, ELISpot based analysis, innate immunogenicity assessment using in-vitro cell models and isolated Human PBMC's, cell based assays (neutralizing antibody assessment, functional assessment, ADCC/CDC and customization for specific needs), receptor binding assays (using OCTET BLI system), physicochemical characterization using high end systems like LCMS, HPLC etc., biosimilarity assessment including structural, physical, chemical, functional similarity and bioidentity assays, critical reagent generation and qualification and custom PAb/MAb production.

There is an increased investment in the R&D of new drugs and their clinical trials along with increased investments by the government to develop the biopharmaceutical industry. The monoclonal antibodies are one of the most-important class of biologics, which account for more than 20% of all the therapeutic candidates authorized by the FDA. Specifically, due to their extensive use in cancer treatment, they are becoming more prevalent in developed countries. In the same way, the demand for anti-inflammatory mAbs is growing at a good pace. The COVID-19 pandemic had a significant impact on the biopharma industry. Most biopharmaceutical companies strive extensively for the development of vaccines and increasing acceptance and huge market demand for biopharmaceuticals and the ability of biopharmaceuticals to treat previously untreatable diseases are driving the current biopharma market.

The above service offering and the strategies adapted by biopharma companies, like outsourcing, has propelled contractual business significantly and had a positive business impact of around 12% of revenue generation. Over the years, with changes in business dynamism from small molecules to large molecules, Bioneeds contract services has gleaned its focus to cater to this opportunity and we foresee a YoY growth of around 15-30% in the coming years.

What do you foresee will be top growth drivers for Bioneeds?
For Bioneeds, the growth drivers continue to be testing services for pharmaceuticals, biopharmaceuticals and medical devices. Capabilities and creating a niche for end-end services for drug discovery and development from bench scale to NDA, and focus on support to generics for ANDA and 505(b)(2) application would impel Bioneeds to have an edge over other competitors.

Furthermore, pricing strategies, quality of service, versatility, customer focus, reproducible and high-quality data generation that is accepted by global regulatory agencies, timely completion of projects, company accreditations and certifications, and reliability of services will drive Bioneeds growth in the coming years. ■

Peter DeYoung

CEO
PIRAMAL PHARMA LIMITED

Can you share some recent updates of Piramal Pharma's operations?
Perhaps most obviously, we demerged Piramal Pharma from Piramal Group because we felt it would allow us to better align our patients, employees and investors. We successfully concluded the demerger in October 2022, with Piramal Pharma Limited now listed on the two main Indian stock exchanges, BSE and NSE. In terms of inorganic growth, the company added a drug product facility in the US, a peptide capability in Navi Mumbai, and a minority investment in a gene therapy and vaccine development company in Hyderabad. On the organic side, Piramal has conducted or is currently working on expansions at its facilities in Canada, Scotland and the US. In India, we are expanding both the peptide facility and the gene therapy facility. We are also in the process of expanding our API facility in Telangana.

What led to your company's acquisition of Hemmo Pharmaceuticals?
We observed that many of our customers were doing small molecule work and investing in this category of drug substance, which was not previously a focus area for us. We added Hemmo because they provided us with the ability to do development work for on-patent clients working with peptides.

To what extent is 'Make in India' possible?
There are three strong trends happening simultaneously. First, there is a reshoring trend within most major economies, including in India. Second, I see a fiscal discipline trend. Governments have been running massive stimuli for long periods of time. At some point, they will have to sort out balancing their budgets, and they will not be able to pay for more public services, which may be in direct opposition to their reshoring efforts. This will have to be grappled with in a world of high inflation. The Inflation Reduction Act in the US is an example of where there will be pricing impacts on pharmaceuticals. Third, the strategy of China-Plus-One is gaining popularity. ■

Karan Singh

Managing Director
ACG

Can you provide an overview of ACG's broad offerings to the pharmaceutical industry?
ACG has been serving the pharmaceutical industry for over 60 years. With a presence in 138 countries on six continents, ACG is now the world's largest integrated supplier of solid dosage products and services – providing hard-shell capsules, film and foil barrier solutions, track and trace systems, and process, packing and inspection equipment.

How do price control mechanisms impede innovation?
Price control is a unique bind for Indian pharma. Unlike mature markets, where drug prices are market-controlled, here the government and regulators play a pivotal role in the entire process. Regulators fix both the price companies pay for bulk drugs and the price they sell their products in the market, leaving little leeway to build profitable businesses. The list of price-controlled drugs, by the Department of Pharmaceuticals under Ministry of Health and Family Welfare, has swelled from 74 in 1995 to almost 384 in 2022. For Indian pharma this is a double-edged sword—companies have learnt to maximize efficiency from this system by squeezing every ounce of efficiency out of their processes—but with slim margins, they have little incentive to modernize and upgrade their manufacturing capabilities and capacity. On the world stage, this places our industry at a distinct disadvantage, as companies can't compete with their rivals worldwide and don't invest in R&D to develop breakthrough high-margin drugs.

Are there any areas of the life sciences that you find particularly exciting?
Personalized medicine will disrupt the pharma industry, especially with the new technologies that will arise to enable this shift. I also see more people looking to leverage the digitization of patient care, such as through telemedicine or the creation of wearable technologies. In most cases, it is about pharmaceutical companies going beyond the hospital setting to connect with patients in a more comprehensive way that accounts for their lifestyles. ■

COMPANY	WEBSITE
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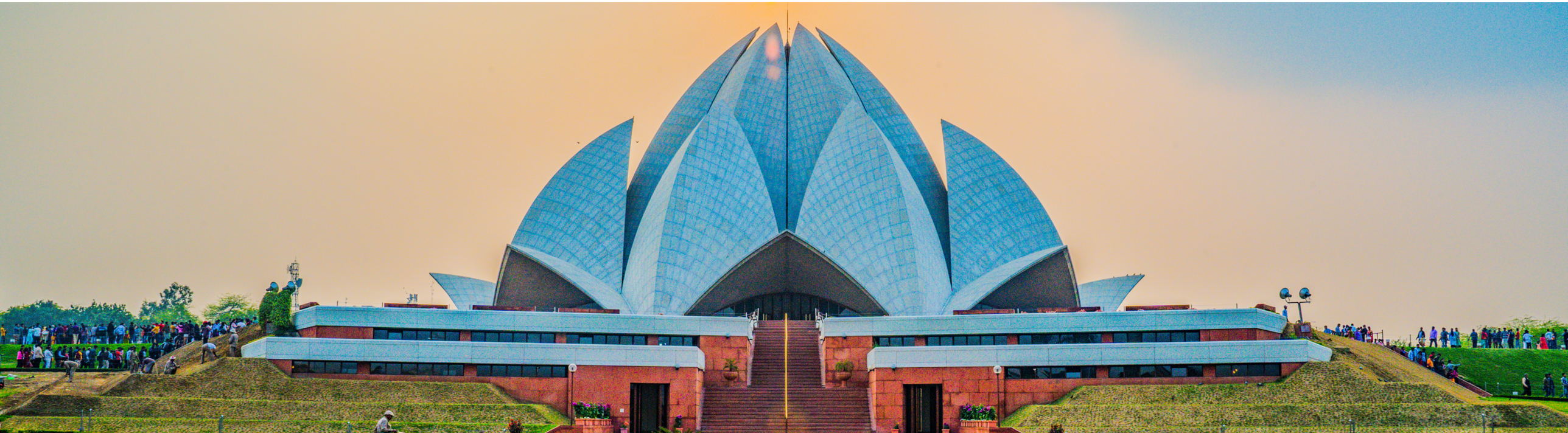

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