



GLOBAL BUSINESS REPORTS

INDIA LIFE SCIENCES
2023



Pre-Release Edition



GLOBAL BUSINESS REPORTS

From research and analysis
to print and digital distribution,
GBR acquires, delivers and diffuses

Business Intelligence.

PHARMACEUTICALS
CHEMICALS
MINING AND METALS
OIL AND GAS
POWER
AEROSPACE
AUTOMOTIVE

If you are organizing an event or are the leader of a trade association or chamber of commerce, GBR can produce your official, industry-specific report according to the highest standards of quality. Contact info@gbreports.com for more details.

gbreports.com



Pharmacy of the post-pandemic world

India's pharma export volumes soar

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 advanced the industry with their extraordinary research programs backed up by even more extraordinary R&D budgets.

Keenly aware of this, Prime Minister Modi 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 turned the country into the

second-largest producer only 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, Pharmexil, 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 nearly US\$4 billion.

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).

The robust nature of India’s export market explains the fragmented nature of its players. “There are different types of companies in India working at various levels of quality standards based on the market they export to,” acknowledged Rahul Maheshwari, director of the Ahmedabad-based Derren Healthcare, a young CDMO that plans to work primarily with US FDA-approved companies. Given the abundance of life sciences companies with operations in his state of Gujarat, Maheshwari had the ability to select his target clientele with precision.

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 watched 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

"Our strategy is to develop products that are imported to India from China, or otherwise exported from China all over the world. We identify such molecules, develop them in our R&D center, then commercialize them."

**Ravi Jagtap,
Founder & Managing Director,
Aastrid Life Sciences**



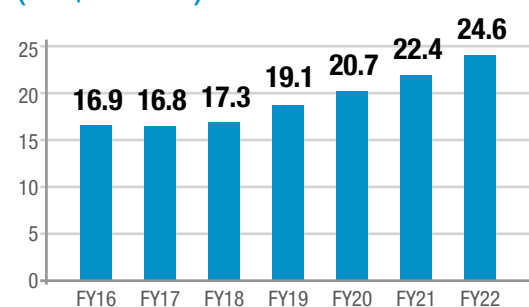
with the question: Is it better to be made domestically or to have the lower price?" The strength of the Indian pharmaceutical export market is that, as countries face the uncomfortable tension between wanting to increase their resilience while simultaneously wanting to reduce costs, India can help with 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, in which 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

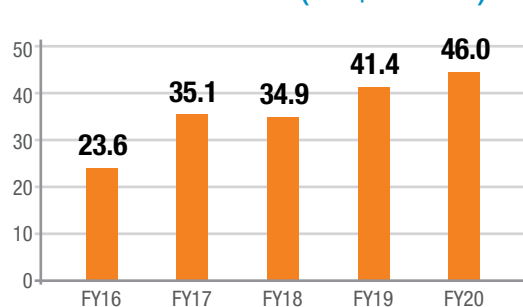
to Sehgal, the country's pharma market relies 80% on imports. As the Vietnamese government works to drop this to 50%, his company is liaising with public authorities and several manufacturing companies on tech transfers as well as assisting companies looking to establish factories with their design, 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. ■

Pharmaceutical Export from India (US\$ billion)



Government Expenditure on Health in India (US\$ billion)



Source: India Brand Equity Foundation

Daara Patel

**Secretary General,
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.

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, and every third child that is vaccinated gets its vaccine from 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. When we come out with new vaccines, they first go to our people before taking care of other countries.

What role do small-scale manufacturers play within India's pharmaceutical ecosystem?

Small manufacturers are the backbone 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.

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.

Lakshmi Prasanna Chundu

Director - Regulatory Affairs,
The Pharmaceutical Export
Promotion Council of India (Pharmexcil)



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

Can you speak of Pharmexcil’s role within India’s life sciences sector?

The Pharmaceutical 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.

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.

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 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.

Executive Insights

As India’s life sciences sector invests in reshoring its strategic supply chains, its historic dependence on China as a source of APIs is in flux – maybe. In anticipation of GBR’s analysis of the Sino-Indian relationship, which will be featured in depth within the full India Life Sciences 2023 Report, below are selected quotes from industry leaders on the subject.

“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.”

Riddhi Javeri,
Director,
InterMed Laboratories



“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.”

Atman Parekh,
Executive Director,
Atman Pharmaceuticals



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

Rahul Nachane,
Managing Director,
NGL Fine-Chem



“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.”

Ravi Jagtap,
Founder & Managing Director,
Aastrid Life Sciences



“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.”

Salim Shaikh, Founder &
Executive Chairman,
Symbio Generics



“The federal government is contributing to this effort by setting up free trade zones and large API parks. 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.”

Maulik Sudani,
Executive Director,
Farbe Firma



“We will continue to depend on China for intermediates and some finished products because of volume and cost effectiveness. But nowadays, 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.”

Srinivasan Subramaniam,
Managing Director,
Srikem Laboratories



India's take on R&D

Small-scale innovation generates large results

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 drug 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."

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.

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. ■

Salim Shaikh

Founder & Executive Chairman,
Symbio Generics



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

Symbio Generics India Private Limited is today a full-fledged API manufacturing, marketing, and sales organization. We have recently acquired two manufacturing facilities to keep up with demand and have set up our own R&D processes.

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

We are working on a disruptive idea WisOnGo (short for Wisdom-on-the-go), a platform that provides information on APIs and intermediates that 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 of the platform 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.

What topics within the life sciences hold the most potential for growth?

Decentralization of clinical trials and digital transformation.

Riddhi Javeri

Director,
InterMed Laboratories



Can you give an overview of InterMed within the context of India's life sciences industry?

InterMed has a range of 250+ products across various dosage forms like tablets, capsules, oral liquids, dry syrups, topical ointments, creams, gels and patches. We have our presence in 35+ countries globally.

What needs to be done to boost India's domestic R&D capabilities?

The country has the talent base to be a leader in innovation. What we need is increased support in terms of infrastructure and funding.

How has India's reliance on China as a source of APIs evolved over the past few years?

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. In addition to APIs, India must focus on being vertically integrated to be more cost effective and self-reliant.

What markets and products will drive growth for InterMed over the next few years?

InterMed is focused on complex technologies that will drive value. We are in the process of getting our plant EU GMP approved, which will give us access to many more countries. We are also venturing into ophthalmics and injectables.

Vishal Rajgarhia

Marketing Director,
Finecure Pharmaceuticals



What makes Gujarat a promising state to operate in?

Gujarat boasts of state-of-the-art infrastructure, investment friendly policies, single window clearances, unfettered electricity and a stable government that shows concern for its industries. Gujarat has the largest number of pharmaceutical colleges, generating skilled human resources year after year.

What therapeutic areas does Finecure address?

When it comes to cardiac, diabetic, and metabolic disorders, India is becoming the capital of the world, and these are amongst our focus areas, together with antibiotics.

How does Finecure approach innovation?

We have to keep prioritizing innovation. This innovation does not have to be the creation of a new chemical or drug. It can also be about engineering improvements to reduce costs or a packaging innovation or something that just makes things easier for the consumer.

Finecure has conducted its own innovations, including finding stable formulations for antibiotics that are not typically stable in atmospheric conditions. For instance, Co-amoxiclav is highly hygroscopic and sensitive and we made a formulation process that makes the finished formulation stable for its entire shelf life for all climate zones.

Brian Zehr

Managing Director,
Biofoundry Technologies



“Given the need for affordable molecular tools to accelerate research here, we identify strong demand within the domestic biotech sector.”

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. 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. Third is the need for cold chain, meaning a low temperature-controlled supply chain network that ensures products maintain their quality and safety.

Biofoundry tackles these 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.

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.

Vaishali Tawde

Managing Director,
Ideal Cures



“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.”

What role does Ideal Cures play within domestic and international pharmaceutical markets?

Ideal Cures is a leading Indian manufacturer and exporter of excipients and coating systems. We have four plants at multiple locations that help us to cater to fragmented domestic Indian pharma companies in various regions. These plants also support our international customers.

How can your company help its customers reduce their manufacturing timelines?

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. Ideal Cures has implemented strategies to speed up its own timelines to match those of its customers. We are the win-win partners for pharma industry where we support by providing desired ready mix coating material in optimum time. Lot of innovations are being done in ready mix, like INSTACOAT SFC, which is sprayable sugar coating mate-

rial that reduces multiple steps of coating and makes processes very efficient.

Another innovation by Ideal Cures is INSTACOAT 4G, a ready-to-use powder with 35% solid contents for the film coating of SODF, which reduces coating process time by 40-45 %.

Has Ideal Cures created innovations for nutraceuticals?

Ideal Cures offers clean label products (with few and simpler ingredients) to various nutraceutical companies. We are offering ready-to-use titanium dioxide and talc-free coating system with natural colorant and flavorants that are globally acceptable. We have range of products which will provide a targeted drug delivery systems specially in pH dependent scenario with immediate or delayed release drug kinetics.

What are the goals of the IDEAL Institute of Coating Technology?

The IDEAL Institute of Coating Technology provides a continuous education program for R&D scientists and healthcare professionals on various aspects of film coatings such as tablet core characteristics, process, coating formulations, and how they affect the coating outcome. The program is inclusive of hands-on application training and provides updates on the latest trends, advancements, and innovations in film-coating technology.



Subsectors on the rise

Nutraceuticals, digital health, and medical device companies take root

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.

Nutraceuticals

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.

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. 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 as it went. 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.

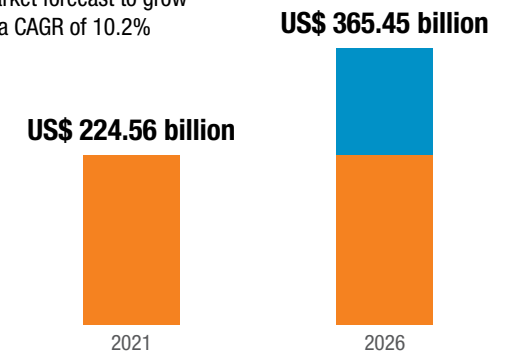
“India is a lead cultivator of opium, which is used for pain management for cancer and other chronic diseases,” explained Avnish Pandya, co-founder and chief research officer. Despite the country’s robust opium production, however, little goes to the Indian market given its high export potential. “As 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 carfentanyl, 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.

Across India’s life sciences sector, companies are springing up to offer plant-based or alternative medicines that offer con-

Global Nutraceuticals Market

Market forecast to grow at a CAGR of 10.2%



Source: Research and Markets

sumers new ways of taking care of their health or, as is the case with BOHECO, replacements to traditional pharmaceuticals.

Digital health

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.

Digital health, an umbrella term used to describe any tools or resources resulting from the confluence of healthcare and technology, existed in India 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.

“The pandemic elevated interest in ayurvedic products. Because of the shutdown of many conventional medical facilities and the prioritization towards treating patients with Covid-19, many people suffering from chronic pain turned to alternative therapies and medicines.”

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



Around the world, patients faced difficulties in visiting physicians due to extended lockdowns and unavailability, given the need to treat 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.”

In addition to emerging players in telehealth and the digital health space more broadly, large 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.

16>>

**Milind Antani &
Darren Punnen**

**MA: Lead – Pharma, Healthcare,
Medical Device and Digital Health Practice;
DP: Leader – Pharma and Life Sciences
Practice, Nishith Desai Associates (NDA)**



What does NDA’s expertise within the life sciences encompass, and what types of clients does the firm typically take on?

MA: NDA is a global research-driven law firm with offices in Mumbai, Bangalore and Delhi, as well as in Palo Alto, New York, Munich and Singapore, where we have the license to practice Indian law. Today, we work primarily with global companies, particularly those headquartered in the US and EU who are interested in expanding their operational presence to India. With these MNCs, we take on cases dealing with disputes as well as corporate, IP, and regulatory work, and we currently have 17 of the top 20 pharma companies as our clients.

There has been an increased interest from MNCs looking into India over the past few decades. Some look to open independent operations in India while others seek to join hands with Indian partners in the form of JVs or collaborations.

DP: NDA also specializes in crisis management. Because we represent MNCs, we also deal with issues that can trickle down from other countries that Indian regulators monitor and verify in terms of impact on the Indian population.

How did the pandemic impact the regulatory framework for medical devices?

DP: We have reached a turning point in the regulatory landscape for medical devices. Until 2020, this market was not heavily regulated, and a large number of medical devices did not fall within the scope of products that medical regulators had oversight of, meaning they had collected little information about what was already existent in the market. Covid-19 brought to the government’s attention how many substandard products were in circulation, such as ineffective PPE kits. As a result, the Indian government began expanding the regulatory framework, bringing products that had long been in the market into the regulatory fold for the first time. Foreign players have the relative advantage that they had already been concerned with meeting different regulatory requirements abroad, so they are now seeing a more level playing ground within India as domestic players have to meet these standards. As these standards balance out, prices may also go up accordingly given the compliance costs. To limit this to some extent, India has price control measures. Given all

of this, the medical device industry is currently in flux. By the end of 2023, the full extent of the revised framework should be in place for medical devices.

In what ways has the digital landscape transformed in recent years?

DP: NDA has been pushing for digital health and telemedicine to be regulated and legitimized for years, primarily because we saw these resources as a way to help overcome the issue our country faces in having a concentration of healthcare practitioners in urban areas yet very little healthcare practitioner access in rural areas. Despite its potential, for years digital health was complicated by cumbersome regulations. If a doctor

was sitting in Mumbai, whether that doctor was allowed to consult with a patient in Bangalore was something the medical council in India had previously taken a very conservative view towards. Pre-covid, they would not be permitted unless the doctor was registered in the same state as the patient, making telemedicine as a practice very difficult to implement. The workaround had been to have physician-to-physician consultations in which the final advice was given by a doctor located within that jurisdiction. Thus, Covid’s impact on the industry was transformative as the government finally put a legitimate stamp of approval on the entire practice. At a central level, the regulations allow doctors to now consult with any person in the country. This was immensely beneficial for rural populations, as you can leverage the use of primary care workers at rural areas who were not necessarily qualified from a medical background with support from practitioners in urban areas.

MA: 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. We are at the tip of the iceberg in terms of what telehealth will come to offer India.

What excites you most about the future of India’s life sciences sector?

MA: The most exciting fields will involve innovative technologies in healthcare, such as AI or robotics. It will not be long before tech dominates the sector. As a result, I foresee significant consolidation of hospitals to manage the costs of setting up infrastructure for these new technologies.

IDMA
INDIAN DRUG MANUFACTURERS' ASSOCIATION
Since 1961

INDIAN PHARMA - GLOBAL HEALTH CARE

Address: 102, Poonam Chambers, A Wing, 1st Floor, Dr. A. B Road, Worli, Mumbai 400018 India
Tel: +91-22-24944684 ; +91-22-24974308
Email: admin@idmaindia.com ; actadm@idmaindia.com
Web: www.idma-assn.org

Nilesh Mehta

CEO,
Premier Medical Corporation



"We are one of the premier suppliers of malaria, HIV and hepatitis tests for low- and middle-income countries."

How has Premier grown into the company it is today?

I founded Premier in 1996, and the company has grown since 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 also 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.

What approach does your Premier take to navigating the balance between quality and affordability?

Quality demands price, but we are trying to meet quality at the lowest possible cost. Since the outbreak of Covid-19, the market has shifted towards self-testing. We are planning to offer various diagnostics tests people can do at home because laboratory work can be very expensive. For this, we work closely with the WHO and the CDC to provide tests for

high incidence diseases and illnesses such as malaria, HIV and syphilis.

When it comes to making testing affordable, we specifically look for new technologies that are easy to use.

Can you outline the logistical and regulatory challenges that remain in implementing point-of-care testing tools on a large scale in India?

India has an incredibly fragmented distribution network. With no large-scale distributor to reach the lowest possible level, it is very inefficient to reach all levels of a consumer base at the clinical level. Given the costs associated with trying to do so, Premier has avoided India's consumer market. In addition, 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 still have yet to properly implement a centralized regulatory framework for these types of tools.

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. 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. Technology in IVD and POC testing is evolving very fast, especially in the wake of the pandemic, and I believe the POC game is going to be very exciting for the next decade.

What are Agappe Diagnostics' goals for the next few years?

BM: Agappe Diagnostics' strategic objective is to build a strong IVD organization that develops and delivers affordable solutions.

TJ: Another exciting space is the hematology segment, and Agappe Diagnostics is the first hematology reagent and equipment manufacturer in India.



28-30 November 2023 | India Expo Center, Greater Noida, Delhi NCR

India's Leading Pharma Event Returns to Delhi

1 venue, 40,000+ professionals, unlimited opportunities! CPHI & PMEC India provides an unparalleled platform to grow your business, maximise your visibility, build your network and generate high-quality leads in India and the region.

40,000+
Attendees

70+
Attendee countries

1,000+
Exhibiting companies

80,000+
m²

Contact

International enquiries:
salesoperations@informa.com

Enquiries from India:
jayesh.kanaskar@informa.com



Book your stand consultation at: GotoCPHI.com/india23

<<12

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.

Medical devices

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.

Helping spur on this growth is the Indian government’s assistance in establishing industrial parks dedicated to the creation of medical device manufacturing clusters. Recognizing the costly nature of investing in scientific facilities, state governments across the country are establishing industrial parks to be leased to manufacturers with the aim of decreasing the cost of products. Such parks are in the works or are already established in Himachal Pradesh, Tamil Nadu, Madhya Pradesh, and Uttar Pradesh, as well as in powerhouses like Gujarat and Maharashtra.

With all the progress the country is making, there is still 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.”

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. “Our company 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. ■

GLOBAL BUSINESS REPORTS

www.gbreports.com

This publication is a pre-release edition of GBR’s full India Life Sciences 2023 report, that will be published in Q1 2023.

If you wish to be interviewed for the report, please contact Kolby Kaller (kkaller@gbreports.com)



India Life Sciences 2023

Pre-Release Edition

Special thanks to our partners:



Project Director and Coordinator: Germaine About

Project Director and Business Analyst: Kolby Kaller

Project Coordinator: Marta Armengod

Project Assistant: Aarti Desai

Executive Editor: Mungo Smith

Graphic Design & Artworks: Özgür Ergüney

Operations Director: Miguel Pérez-Solero

General Manager: Alfonso Tejerina