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India Pharmaceuticals Pre-Release 2017

India Pharmaceuticals 2017
PRE-RELEASE EDITION

Dear Readers,

Welcome to the pre-release of the 2017 edition of the India Pharmaceuticals Report, a joint CPhI-GBR analysis launched at this year's CPhI Worldwide. It has been two years since CPhI and GBR last reported on India's pharmaceutical industry, and the changes in the market have been pronounced, both in light of shifting global dynamics and developments at a national level. The final publication will be launched at CPhI India in November.

India's pharmaceutical industry, ranked third worldwide in terms of volume, is the largest supplier of generic drugs globally and a proponent of high-quality affordable medicines. The industry has posted double-digit growth over the last few years, rising to US$36.7 billion and projected to grow to US$40 billion by 2020.

However, as price erosion continues to impact the market and competition increases, many of India's pharmaceutical companies will be hard-pressed to continue pushing products into the market at ever-more affordable prices. A number of policies under discussion, outlined in the Draft Pharmaceutical Policy 2017, seek to address the challenges faced by Indian pharmaceutical companies. Implementation and open dialogue between government and industry will be key in ensuring its success.

This publication provides an in-depth B2B study into the dynamics of the market and how the country will adapt to changing tides, tightening regulations and increasing competition. In the following pages, we share with you a snapshot of our research into India's dynamic pharmaceutical sector thus far. In addition to our own market analysis, this pre-release is the product of over 70 interviews with key industry stakeholders, collectively evaluating industry trends and challenges, distilled into a comprehensive guide to India's pharmaceutical sector.

We would like to warmly thank our association partners at the Indian Drug Manufacturers' Association (IDMA), Pharmexcil and the Indian Pharmaceutical Association (IPA) for their continued support, as well as to all the executives and researchers who shared their valuable insights.

Alice Pascoletti
General Manager
Global Business Reports

Rutger Oudejans
Brand Director Pharma
UBM

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The Pharmacy of the World

Introducing India's Pharmaceutical Industry

The largest supplier of generic drugs globally, India continues to fortify its reputation as the leading producer of affordable quality medicines. From 2005 to 2016, the market multiplied by a factor of about six, from US$6 billion to US$36.7 billion, with some estimates projecting further expansion to US$40 billion by 2020. A large percentage of pharmaceutical revenue is generated through exports, with India's exported pharmaceutical products reaching US$16.89 billion in value in FY16. However, whilst the Indian pharmaceutical sector accounts for about 10% of pharmaceutical volume globally, ranking 3rd, it only accounts for about 2.4% in value, coming in at 14th.

According to Pharmexcil, 80% of domestic demand is met by the country's top companies, which are also the most prominent exporters to the regulated markets. Whilst these larger companies are also affected by shifting global dynamics, smaller companies in particular suffer from an overcrowded domestic market and face challenges further afield due to price erosion and an increasingly fragmented regulatory framework over many markets. "In the last two years, a number of disruptive moves have impeded the growth of the industry, such as the expansion of the National List of Essential Medicines (NLEM), the imposition of a potential ban on fixed-drug combinations, demonetization and GST implementation," commented a Lupin spokesperson.

In combination, these factors have greatly slowed industry growth and lowered expectations going forward. Cited as particularly restrictive by many small to medium-sized companies is price control, outlined under the Drug Price Control Order 2013 (DPCO). While India's national and state governments have a responsibility to improve accessibility and affordability of medicines within the country, heavy enforcement could be detrimental to the industry. "With the drug price control (DPC) policy and regulated-market guidelines, it is impossible to supply at the DPC rates," asserted RT Shah, founder of Ciron Drugs, a pharmaceutical formulation company established in 1966.

As a result, Ciron has discontinued production of products under the DPC Act, instead pursuing niche products requiring a high level of technical expertise, focusing on sterile products and lyophilized injections.

India's 2017 Draft Pharmaceutical Policy seeks to address many of the challenges currently faced by the industry to increase its international competitiveness. However, there are still many challenges that remain to be ironed out in consultation with industry and its representative associations.

"There has been a lot of recent outcry in the media regarding quality of pharmaceuticals in India. In 2014, the Indian government came out with the Pan-Indian survey on the movement of pharmaceuticals in the Indian market, leading to statistic planning and robust sampling, covering almost 90% of India, collecting over 42,000 samples of different molecules and dosage forms largely used by Indian citizens. The survey shows that the quality is in fact high, with only 0.002% spurious drugs."

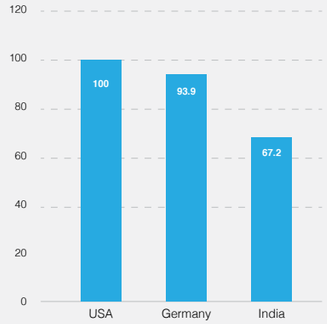
- Hemant Koshia, Commissioner, Food and Drug Control Administration Gujarat

India's competitive edge on the international stage comes primarily from its low cost of production, making the country an ideal manufacturing base for multinationals as well as smaller domestic companies. All the top multinationals, such as Johnson & Johnson, GlaxoSmithKline, Pfizer and Novartis, have manufacturing facilities in India, alongside international Indian leaders such as Sun Pharma, Lupin, Dr. Reddy's, CIPLA, Aurobindo and Glenmark. "India has a competitive edge because of cost efficiency, portfolio diversification, economic drivers and policy support," noted Daara Patel, secretary general at the Indian Drug Manufacturers' Association (IDMA), which has over 1000 members across India, comprising large, medium and small national manufacturers. "India's cost of production is approximately 60% lower than that of the United States and almost half that of Europe... In terms of portfolio diversification, India is the origin of 60,000 generic brands across 60 therapeutic categories and manufactures more than 500 different APIs. 35% of all drug master filings from India in 2015 were registered in the United States."

India's second largest export market is Africa, followed by Europe, with a growing focus on markets such as Latin America, Australia and Japan.

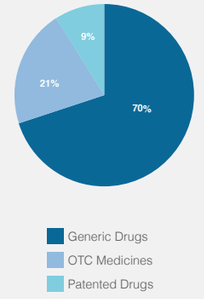
As India seeks to increase its prominence globally, the main barrier faced by companies is the requirements of highly-regulated markets. The U.S. Food and Drug Administration (FDA) continues to set the gold standard globally and, as the United States is India's primary export market, meeting these requirements is key for many companies. An increase in 483s from the United States to Indian manufacturers has been widely discussed as a reaction to poor-quality products exiting the Indian market and has affected many Indian exporters, even those with strong reputations. "Regulatory issues erode credibility with customers, employees, investors, increase time to market, and limit future growth options," commented Vivek Sharma, CEO at Piramal Healthcare, part of Piramal Group, a global conglomerate with operations in over 30 countries. "A preponderance of issues from specific geographies make all companies in the vicinity 'guilty by association', thereby undermining the entire sector. Compliance derailment can cause value erosion; an import alert or warning letter may trigger significant decline in stock prices of a firm. Moreover, it results in a delay or unavailability of drugs to patients. For drug manufacturers, recent events have underscored the importance of managing regulatory risk in order to remain a viable business. Despite this trend, a lot of op-

MANUFACTURING COST INDEX BY COUNTRY, 2016



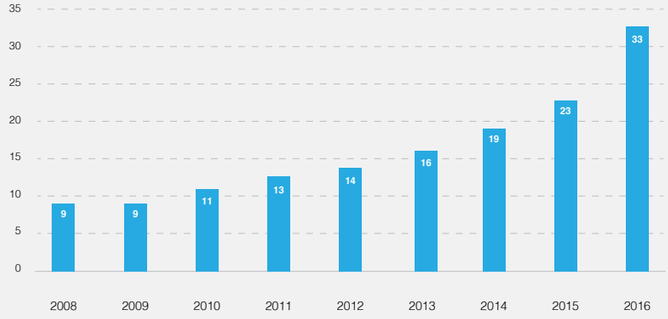
Source: Deloitte, BMI, Financial Express

REVENUE SHARE OF INDIAN PHARMACEUTICAL SUB SEGMENTS IN 2015 (%)



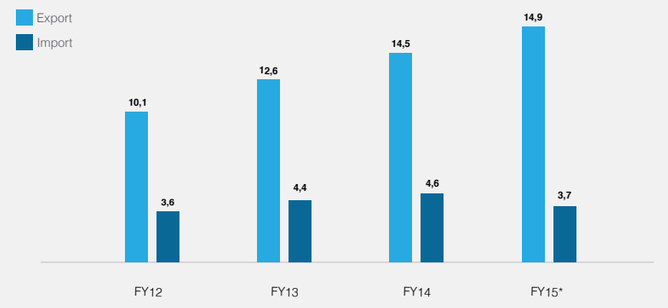
Department of Commerce India, IBEF

PER CAPITA SALES OF PHARMACEUTICALS (US$)



Source: BMI

TRADE DATA OF INDIAN PHARMA SECTOR (USD BILLION)



Source: Department of Commerce India, IBEF

Ravi Uday Bhaskar

General Director,
Pharmexcil

Pharmexcil is the key government agency for pharmaceutical exports in India. What role does the organization play in the industry today?

Pharmexcil was established to promote pharmaceutical exports as well as other commodities, such as APIs, Formulations Herbals, Ayush, Neutraceuticals etc. Pharmexcil provides assistance to its current 3,500 member companies, which range from OEMs to SMEs. The organization offers its members incentives whenever they register their products outside of India, as well as when they relay trade delegations to different countries where there is potential for Indian generic pharmaceuticals.

Pharmaceutical exports are expected to reach US$40 billion by 2020 and increase as a proportion of revenue for the pharmaceutical industry. Where do you expect to see most of this growth coming from?

US$40 billion is a very ambitious estimate, already revised from the initial estimate of growth of US$50 billion by 2020. There has not been much of an increase in growth since last year. There are many global factors that affect growth, the primary factor being price erosion as the prices of generic formulations fall. The second is that most countries are creating policies to develop their own indigenous pharmaceutical industry.

How have recent FDA audits impacted the Indian market?

In spite of the increased number of audits and import alerts since 2015, India's exports to the United States have slightly increased. Therefore, these complications have not caused a significant change to India's exports when compared to its previous financial years. In fact, India exports 35% of its generics to the United States and about 700 U.S. FDA-approved plants are in India, which is the largest number in the world outside of the United States itself. With such a large number of plants and exports, the frequency of inspections has naturally increased; with that came a natural increase in incidents.

What are the priorities for Pharmexcil in driving the industry forward?

An important issue Pharmexcil will be working on is reducing India's dependency on API, key starting material (KSM) and intermediate imports. A natural result of being able to manufacture entirely in India will be an increase in exports in future. •

Kal Sundaram

CEO ,
Sun Pharmaceutical Industries Ltd.

How has Sun Pharmaceutical Industries Ltd. (Sun Pharma) developed since 2015?

Sun Pharma is today the world's largest specialty generics company. United States is our largest market, accounting for about 45% of sales. In addition to investing in complex generics in the United States, Sun has invested in specialty products, particularly in R&D and front-end infrastrucutre to successfully commercialize our innovative pipeline products in the areas of dermatology, ophthalmology, CNS and oncology. The operations in India are end to end, from manufacturing intermediates to APIs and on to finished formulations to cater to our global requirements. Sun also has a significant R&D infrastructure in India.

Sun Pharma has extensive R&D capabilities. Are there any new developments in the pipeline?

Sun invests about 8% to 10% of its US$4.6 billion sales on R&D. We have filed Tildrakisumab, a biologic product with the FDA for approval. Sun also has a couple of late-stage products in ophthalmology. In addition, we have a few assets in CNS and oncology some of which have been already filed for approval in U.S.

India is very reliant on the Chinese market for APIs. How do you foresee the competitiveness of each country playing out going forward?

China has more capabilities in APIs while India is more proficient in complex formulations and branded products. China also has substantial talent, infrastructure and capacity in pharmaceuticals, allowing both countries to play a complementary role in the global pharma industry. Nevertheless, India should still aim to become a self-sufficient global player in APIs.

How do you expect to see dynamics between the patented and generic markets develop in India?

For the foreseeable future, the patented product market will continue to be fairly small in size. A select number of companies with patented molecules priced appropriately for India will grow in the country, but the overall total share will be limited and currently sits at less than 5%. The success stories of some patented molecules in India can be attributed to the appropriateness of the molecule to the country coupled with relevant pricing.

What are the key objectives for Sun Pharmaceutical going forward?

In addition to continuing to grow our generics business in the U.S., our focus will be on successfully launching our rich pipeline of innovative products globally. •

portunities remain for Indian companies to contribute to the global health care market."

Nevertheless, India still houses the highest number of FDA-approved facilities outside of the United States. "Inspections are routine as part of regulatory exercise," stated Patel. "The 483s from the United States go to every company and data shows that even a number of U.S. companies receive such warnings. There is nothing new in this. As the quantum of business increases, so does the chance of receiving these letters. Because of ever-increasing media activities and sensitive financial bourses these things are getting blown out of proportion; the quality of Indian medicines is well accepted all over the world."

In 2016, 30% of the ANDAs approved by the U.S. FDA came from India, according to Pharmexcil.

One of the main areas of focus in the immediate future will be documentation as many smaller companies struggle with requirements and a lack of training on correct procedures. As the North American pharmaceutical market is the largest in terms of value, India's companies will remain focused on attaining and maintaining FDA approval. Associations such as the IDMA are rolling out training programs and support to companies to assist in meeting these requirements and accessing regulated markets.

Going forward, the government's role in the development of India's pharmaceutical industry will be integral. The intended measures to be taken under its 'Pharma Vision 2020', aimed at making India a global leader in end-to-end drug manufacture, will go some way to securing greater market share and developing the country's sector, but depend heavily on effective implementation and open dialogue with industry. •

Introducing the Clusters

India's pharmaceutical Hubs

With a population of over 1.34 billion and land area of 1.27 million square miles, accessibility of medicine, whether in terms of affordability or actual physical access, has long been an area of focus in India. Across India's vast land mass, several pharmaceutical hubs have emerged as focal points of activity. A large number of India's pharmaceutical companies have their corporate office functions in Mumbai, India's commercial capital. Companies with headquarters across the city include Lupin, Sun Pharma, Glenmark and Cipla, accompanied by the presence of corporate offices for many foreign multinationals with a strong presence in India.

Bordering Maharashtra on either side are the states of Gujarat and Telangana, each widely recognized as strong pharmaceutical hubs. Gujarat, more specialized in formulations, has most of its companies spread between Ahmedabad and Vadodara, with notable players including Cadila Healthcare, Torrent and Nirma. Further to the north lie Haryana, where Delhi is situated, and neighboring state Punjab, each with a number of prominent companies.

Gujarat's pharmaceutical industry's 2015 to 2016 turnover was US$6.7 billion, with exports valued at US$3.06 billion. Despite accounting for only 5% of the population and 6% of India's landmass, Gujarat is responsible for almost a third of the country's pharmaceutical production and accounts for 28% of India's pharmaceutical exports. The state is also the largest producer of contraceptive pills in the world. In October 2016, the Government of India announced three landmark parks in Gujarat: an API park, formulations park and medical devices park. The state has also recently launched the first mobile testing van in India.

Telangana is most widely recognized for its strength in APIs, with nearly 200 bulk drug and intermediate manufacturer units, including the presence of key companies such as Dr. Reddy's and Aurobindo situated in the state's main city, Hyderabad. The state is, in fact, extremely diverse, covering a range of activities from drug discovery to formulations and clinical research. 49 out of the 169 U.S. FDA approved facilities in India are in Telangana. 30% of the medicines exported to USA are made in Telangana, with total exports amounting almost half of total production. Hence, Hyderabad has come to be recognized as the "Pharma Capital of India" and is home to some of the world renowned pharmaceutical companies.

Hyderabad is also home to the Genome Valley, which houses about 200 companies, both home-grown and international. Because of high demand for land, the Telangana State Industrial Infrastructure Corporation (TSIIC) is currently expanding the Genome valley by another 200 acres. The Government of Telangana is also setting up a Pharma City in Hyderabad and a medical devices park, valued at US$5 billion. •

Shri. KT Rama Rao

Hon'ble Minister for Industries & Commerce,
Information Technology,
Electronics and Communication,
Municipal Administration,
Urban Development and NRI Affairs
Government of Telangana

Jayesh Ranjan IAS

Principal Secretary,
Industries,
Commerce and Information Technology
Government of Telangana

Telangana is India's youngest state, formed only in 2014. How has the state developed to the present day?

Being the youngest makes Telangana the most energetic too. Our new industrial policy, which makes time bound clearances within 15 days a "right" for the investor, has set a new benchmark in transparency and efficiency and, to date, we have accorded approvals to over 4500 units, about half of which are already into commercial production. Furthermore, the entire process is based on an online self-certification mechanism. The state's capital city, Hyderabad, has been ranked as the top Indian city on Mercer's Quality of Living index consistently from 2014 onwards.

How diversified is Telangana's economy and how important is the life sciences industry in driving development and economic impact?

Telangana has been the front runner in pharmaceuticals and biotechnology in India. The state is home to the country's first and the largest systematically-developed life sciences cluster, the Genome Valley, which houses about 200 companies with a rich mix of home grown and international companies. On the other hand, Telangana has a dominant position in the pharmaceutical sector with nearly 200 bulk drug and intermediate manufacturer units and 400 formulation units. 49 of India's 169 U.S. FDA approved facilities are in Telangana. Hence, Hyderabad has come to be recognized as the "Pharma Capital of India".

Telangana recently announced a life sciences infrastructure fund. Could you elaborate?

The Life Sciences Infrastructure Fund is the first fund of its kind in the country, dedicated to the creation of specialized infrastructure, including sophisticated modular plug-and-play infrastructure, for the life sciences industry. The fund is established in partnership with Cerestra Advisors, a private equity firm which specializes in life sciences and education infrastructure.

In terms of available resources, in what ways is the government developing the state's workforce through initiatives such as the Telangana Academy for Skill and Knowledge (TASK)?

Telangana is home to educational and research institutions of international repute and is a magnet for national talent. The government is cognizant of the need to align the curriculum with the needs of the industry. The state's Skill Development Policy is on the anvil, with focus on increasing the employability of the youth. •

What is the significance of the life sciences sector in Hyderabad?

The city is and will remain the pharma production and innovation hub for the world and the proposed Pharma City will strengthen its position significantly. Over the years, Hyderabad has started dominating India's vaccine production output and contributes significantly to global vaccine production while inching closer to being recognized as the global disease-prevention capital of the world.

Genome Valley is a shining example of Hyderabad's dominant position in the life sciences sector. It has become the largest innovation and life sciences cluster in Asia and has the privilege of being India's first and only systematically developed R&D and clean manufacturing ecosystem. The cluster has grown tremendously to become home to over 200 companies, including over 50 global powerhouses, employing a scientific workforce of over 10,000.

How key will the pharmaceutical sector be in the government's economic development strategy?

The state accounts for more than 35% of the overall pharma production in the country. 30% of the medicines exported to the United States are made in Telangana. The upcoming Pharma City will certainly hold pride of place, at par with international standards. Furthermore, the state is simultaneously developing a Medical Devices Park, which is growing annually at the rate of 15%. Suffice to say, the pharmaceutical sector already has a key place in the government's growth strategy.

What are the contributing factors to the region's position as an innovation hub?

The first factor is the enabling ecosystem created by the Government of Telangana, owing to which the list of top-notch global and home-grown corporations present in the state is increasing at a fast pace. The second factor is the existence of educational institutions of excellence, with state-of-the-art infrastructure, churning out a skilled workforce in thousands. Of course, the enterprising nature of the people plays the most important role.

In order to promote innovation and entrepreneurship, the Government of Telangana created T-Hub, the country's largest incubator for start-ups providing an interface amongst start-ups, academia, corporate entities and the government. T-Hub now has become a role model and a national, perhaps even international, benchmark for incubation. •

Building Blocks

Bulk Drugs, Excipients and Intermediates

India's strength in pharmaceutical formulations depends on a high-quality, cost-efficient and reliable supply of the required raw materials and building blocks. Whilst India has strong capabilities in active pharmaceutical ingredients (APIs), the domestic market has become increasingly crowded, marked by a heavy reliance on imports from China. "India had to manufacture the drugs that were remunerative for the country," explained Jayant Tagore, national president at the Bulk Drug Manufacturers' Association (BDMA). "Because of the lagging infrastructure, the restrictions on expansion and the lack of needed facilities, the industry experienced a significant cumulative drop over 15 to 20 years. Whatever India dropped, China picked up."

Manufacturing sectors in countries such as China and Japan have seen a huge amount of government support in recent years in the form of subsidies and other means, far surpassing that of the Indian government for its pharmaceutical industry. Nevertheless, India's API capabilities are extensive and the scales may be tipping back in the country's favor in supplying both the national and international markets. Whilst China certainly has a cost advantage across many products, the mass-volume producer is considered by many to be an unreliable supplier, particularly due to unpredictable factory closure, primarily a result of environmental challenges. "China's price advantage must be weighed against the difficulties experienced by customers when their Chinese supplier is faced with a factory closure, for example, asserted Radheshyam Bhomavat, president at K. A. Malle, a global market leader in mebendazloe and albendazole. "Supply is often unreliable and quality is often of a lower standard than can be sourced in the Indian market."

"When comparing quality, India is preferred as an API source among developed countries, but improving quality automatically increases cost. This is where China maintains a competitive advantage. Quality plays a major role at Vigor and the systems are in place for implementing quality, resulting in a low number of rejections to date."

- Himani Hiran, Founder, Vigor Pharma

Companies are beginning to shift their sourcing preferences away from China in light of these challenges, a move that is accompanied by a push from India's government to encourage national production with its Make in India initiative. "There is a plan to de-risk Chinese supply as it can be unreliable, particularly since the government began to try to control the pollution issue, which has caused a lot of plants to close down or relocate their operations, creating an extreme disruption to supplies," commented Ketan Shah, managing director at Eskay Specialty Chemicals and Eskay Fine Chemicals. "This has resulted in buyers approaching Indian API-producing companies to overcome their dependence on China entirely. Therefore, whilst not yet that significant, there is a small shift towards preference for Indian API producers and stated government intent to indigenize or reduce dependence on all imports for India's pharmaceutical sector."

Eskay Specialty Chemicals and Eskay Fine Chemicals are each

"Vigor's competitive edge is its ability to cater to customers requiring complex quality specifications and product requirements. The key focus is not to expand volume but rather to focus and continue specializing completely on this niche segment of the industry."

- Himani Hiran, Founder, Vigor Pharma

divisions of SK Group, which also comprises Anuh Pharma and S Kant Healthcare. In APIs, the group's biggest focuses are antibiotics, steroids and some antimalarials. The group has an extensive global presence, with 55% of revenue from exports.

India would be much better positioned if a robust API network were in place in case of potential supply shortages. Although the Indian government is aware of a need to improve national API capabilities, even branding 2015 the "Year of the API", so far, not much improvement has been seen, to the frustration of the industry. However, change could be on the horizon. In line with the government's Make in India initiative, there is greater pressure on companies to procure raw materials from India and many companies anticipate a push in policy intervention amid discussions regarding import restrictions and the establishment of bulk-drug parks.

Environmental challenges remain of primary concern to Indian API manufacturers and a threat to their competitiveness. "The lack of support mainly comes down to environmental issues," commented Shah. "The government needs to coordinate with the Ministry of Environment and focus on resolving environmental problems so that other steps for improving the industry can fall into place. We need to improve quickly or else we will lose the opportunity to capture the global market. India has become the

"China does have an advantage in some respects; India cannot compete on certain fermentation products because 50% of the process requires electricity and the cost of power in China is much less. There is therefore a significant cost gap. Furthermore, the Chinese government used to subsidize its exports, which was not done by the Indian government. Cost of finances is also a significant contributor to India's distribution because Chinese interest rates are much less than those in India."

- Jayant Tagore, National President, Bulk Drug Manufacturers Association (BDMA)

most regulatory-compliant and cost-effective producer of APIs globally. It is a world leader in ibuprofen and naproxen among many others. With the right investments, the country is moving towards number one in the world by 2022."

Commenting further on environmental challenges faced by Indian API companies, Dharmesh Shah, chairman and managing director at BDR Pharmaceuticals International, a vertically-integrated pharmaceutical company focusing on life-saving medicines, echoed: "Over the last few decades, environmental clearance has been a daunting challenge in India. Companies like BDR are unable to expand because of the long drawn-out process of obtaining required permission from various departments and the concerned Ministry. Therefore, the Indian government should create special industrial zones specially for the pharmaceutical industry for both APIs and finished formulations with a common effluent waste management system and peripheral utilities. The government should also cut red tape and, if possible, overhaul the whole policy of granting clearance with a view to eliminate long delays to grant necessary clearances as quickly as possible."

"The market has grown a great deal. In the past, the Top 25 companies drove the entire industry. Now, although the Top 30 players possess the largest chunk of the Indian pharmaceutical market, there are a lot of therapy areas that have been strengthened by lower-ranking players. Because there are more brands available to choose from, it is more difficult for a company to make a successful multi-crore launch; it is a very distant reality at the moment. Additionally, the competition has become more intense. Companies have started proliferating and there has been a lot of change at a macro level."

- Prashant Menon, Director , India Formulations, Wanbury

A large number of formulation companies have chosen to venture into API production and vice versa, ensuring greater security of supply and demand. This move will also help to capture more value within the country – a big challenge in India's pharmaceutical industry, where international companies often add a great deal of value after the products are exported.

A global outlook

At a global level, India's contribution to the API business is relatively low. There is still a great deal of scope and opportunity, and Indian API manufacturers will likely find their sweet spot in more complex molecules with higher regulatory challenges. However, in order to fulfil the industry's potential, a more supportive framework is needed. "Currently, it is not easy to set up API manufacturing facilities in appropriate areas as there is a limited scope to set them up within one's desired timeframe and cost structure," highlighted Shireesh Ambhaikar, president operations, API, at Wanbury, a company specializing in APIs and domestic formulations. "The gestation periods are very long, and the permit process takes a long time too. A bit more leniency in the regulatory framework would be helpful."

Wanbury is widely known as a metformin company, producing about 10,000 tons per year and exporting to regulated markets

"With the drug price control (DPC) policy and regulated-market guidelines, it is impossible to supply at the DPC rates. Therefore, Ciron has decided to refrain from producing products which are under the DPC Act. Also, each audit the company faces makes it stronger. We are collecting all the details on our suppliers and tightening the screws considering the global scenario."

- Keyur Shah, Director, Ciron Drugs

such as the United States. The company also has a strong presence in tramadol and sertraline and plans to expand further into the U.S. and European markets and increase business in South and Central America, while continuing to focus on the domestic market.

As companies globally continue to seek high quality and affordability from their suppliers coupled with consistency of supply, Indian manufacturers are in a favorable position. However, like India, many countries are aiming to increase local production and reduce imports. Certain measures in place must therefore be circumvented. "Since President Trump's election, many companies are setting up small API facilities in the United States to complete the final step towards a finished product so that it may be labeled as "Made in the USA"," commented N. R. Munjal, vice chairman and managing director at Ind-Swift Laboratories Ltd and vice chairman at Ind-Swift Ltd. "By having an API plant with last-stage production in the United States, Indian companies are able to divide cost and product availability. Since the API is released in the United States, fewer questions are asked."

India's primary focus should be on developing its own national supply chain to cater to the domestic industry, which will require support at a policy level. In the longer-term, a well-established framework will provide self-sufficiency and security of supply, and potentially a leading position in the export markets.

Building blocks: Intermediates and Excipients

Projected growth in India's API sector also brings an opportunity for Indian suppliers of intermediates and excipients. However, there are relatively few domestic manufacturers of these formulation ingredients; many downstream companies source their raw materials and feedstocks from China, for example.

India's largest excipient company is Signet, reaching a turnover of US$177 million in FY 2016. Whilst the company does not manufacture itself, it provides an access point for companies to enter the Indian market through its range of partnerships and today has over 650 customers across 1250 manufacturing locations in India. "We offer a very synergistic approach because it is usually a big challenge for foreign companies to reach so many customers in India," stated Harish Shah, managing director at Signet. "Unlike other countries that have a few multinational companies dominating the pharmaceutical space, India has a fragmented market with hundreds of companies spread all over the country. As the industry has spread geographically, Signet's role has become more and more relevant… We

have a stellar track record and have never lost any of our current 29 partners."

Signet is also currently very active in the Middle Eastern markets and Bangladesh and has a growing presence in the Indian biotechnology space.

Also in the excipients business is S. A. Pharmachem, a specialty food and pharmaceutical manufacturing and marketing company supplying innovative specialty ingredients. The company has created a new concept through its product Dicom, a directly compressible granulated excipient premix, which has been submitted for patenting. "Customers are provided with premixes of different excipients for different APIs and different release forms and only requires the customer to purchase the API," explained Anil Jain, S. A. Pharmachem's director. "This allows customers to have complete control over the API quality and consistency, which is the heart of the product. By providing customers with the right delivery system, they are guaranteed the release profile that they desire."

Whilst capacity for the product currently sits at only 4,500 tons per annum, the company is optimistic for the potential scope and scale of Dicom. Indeed, the global excipient market is projected to reach US$8.1 billion by 2021, presenting an opportunity for companies with effective growth strategies in place to capitalize on.

One of the key advantages for India's oleochemical producers into pharmaceutical applications is their proximity to raw material markets. India's own large palm oil refining industry provides a strong benefit to local companies using its by-products to manufacture fatty alcohols and other excipients and intermediates. However, whilst India has a notable cost advantage over other parts of the world, companies supplying specialty chemicals and intermediates are still under a great deal of pressure. "Times are tough in the chemicals industry," noted Nadir Godrej, managing director at Godrej Group, an Indian conglomerate and household name, comprising divisions across consumer goods, real estate, appliances, agriculture and many other areas. "We need to lower costs and move on to more value-added derivatives and specialty chemicals. The focus is now largely on derivatives of basic oleochemicals and the fermentation products, such as sophorolipids. We are also open to opportunities in other fermentation products. We are very hopeful that bio-products (like sophorolipids) will in the medium to long term become a significant business for us. With longer approval processes, these initiatives would take time to fructify. Whilst we are not looking at biosimilars, there could be some pharmaceutical applications."
Godrej exports its products, including a range of long-chain fatty alcohols, glycerol esters, polyol esters and stearic acids, to over 80 countries worldwide.

India is well placed to develop its strengths across all aspects of the pharmaceutical supply chain, in turn providing a stronger manufacturing base and security of supply to the industry. By focusing on the sector's building blocks, the industry would be better positioned for growth and increased global competitiveness. Equally, with India's favorable production costs, export potential for companies in possession of the required accreditation and regulatory approval is immense. •

N. R. Munjal

Vice Chairman and
Managing Director,
Ind-Swift Laboratories Ltd.
Vice Chairman,
Ind-Swift Ltd.

How has the company developed over the years, and what has been the key to its success?
The group consists of two companies: Ind-Swift Laboratories (ISLL), which manufatures and marketing of APIs and advanced intermediates, and Ind-Swift Ltd. (ISL) which manufactures and marketing of finished dosage forms (FDFs). ISLL has two manufacturing faciliites: one state of the art facility in Dera Bassi, Punjab, stretching across 40 acres with a capacity of around 600kl with many global accreditations including FDA approval; the other in Jammu, J&K, which caters mainly to the domestic and less regulated markets. We also have one state-of-the-art R&D centre at Mohali.

Starting with Ind-Swift Laboratories, what are its core activities today?
To date, ISLL has developed around 50 products across 18 therapeutic segments and boasts a full-scale R&D segment, which is currently developing 10 new molecules. Our key molecules are clarithromycin (antibiotic), fexofenadine (anti-histamine), atorvastatin (cardiovascular) and clopidogrel (cardiovascular) .

Are there challenges arising from global regulatory disparities and any differences in the way Ind-Swift approaches various markets?
In the United States, we receive higher value in exchange for quality, whereas in the Indian market we compete with lower-cost and lower-quality products from countries such as China.

Have there been any recent changes to market dynamics?
India's dependency on China had risen beyond a comfortable level; 80% of the country's APIs were coming from China – but the Doklam conflict trigerred an awakening call and a realization of the danger of this situation and the need to develop an API policy and domestic clusters.

Since President Trump's election, many companies are setting up small facilities in the United States to complete the final step towards a finished product so that it may be labeled as "Made in the USA". This trend is expected to increase in coming years. •

Rajesh Bhayani

Director,
Apex Drug House

Could you briefly introduce the company and its current core competencies?
Apex excels in manufacturing a complete range of formulations in tablet, capsule, syrup, cream, ointment, injectable, soft gelatine capsules and ophthalmic solutions. Apex has its own manufacturing facility in Gujarat since the beginning of 2017.

What prompted the decision to build a facility of Apex's own after so much time?
Apex has its own team of FDA-approved chemists that manufacture the batches, analysis and examine the quality of production at manufacturing partners sites. Our plan to grow, expand and cater to our clients better led us to starting our own facility. Initially, the factory will provide contract manufacturing for Indian as well as multinational pharmaceutical companies.

Could you expand on Apex's packaging capabilities?
Packaging is an ever-evolving business and Apex has been very flexible to adopt rapid changes based on new market trends, client requirements and suitability of the product. We offer same products in different packaging styles based on the geographical demands like storage conditions or when affordability is a concern. Apex offers these customers ideal packaging options which are affordable and more secure for the stability of the product.

Apex has a strong R&D team. What are the areas of focus for the team?
Apex is striving to develop more sustained-release and mouth-dissolving products because they provide easier dose maintenance and quicker drug responses for patients.

What are the key objectives for Apex over the next few years?
Considering our business plans, dossier submissions and developments, the business is predicted to increase by about 20% over the next few years. Apex has invested over US$3 million into its new factory and has purchased enough land to expand further in the future. The strategy is to manufacture for established brands, expand into new dosage forms, research new molecules, and provide technology transfer services at our facility. We also aim to have our own analytical laboratory to continuously analyze the quality of products and perform stability studies on our premises. We follow an unwritten rule of complying with all pharmacopeias and meeting the same quality standards across the world. •

Anil Jain

Director,
S.A. Pharmachem

S. A. Pharmachem reached its 30th anniversary last year. How has the company grown and developed over the years?
S. A. Pharmachem grew 28% to 30% over the last year alone. Together with Gangwal Chemicals, we had a joint turnover of around US$37.6 million in 2016. S. A. Pharmachem focuses on nutraceutical actives and a few pharmaceutical actives. Meanwhile, Gangwal focuses on pharmaceutical excipients, drug delivery systems and manufacturing a couple of niche actives. However, because of the impacts of pricing and cost on the industry's growth, we are trying to move more into nutraceuticals because they have better-projected margins. Nevertheless, our margins in excipients and drug delivery systems are reasonably strong.

S. A. Pharmachem supplies both branded and generic products. Could you elaborate on the company's product portfolio?
We have a key product in the osmotic laxative market called Lactitol, which is one of our APIs. An increasing segment of focus is probiotics in both pharmaceuticals and nutraceuticals.

What are the main challenges for the Indian market from a quality perspective?
Pharmaceutical quality cannot be compromised and has to become more and more stringent without becoming a terror. The central point will be education. FDA have begun to give 483s to a very large number of Indian companies, many of which had been operating for some time with hardly any failures. There are certainly data integrity issues, which should be addressed, but had there been a persistent quality audit the situation would be better for both India and the United States, receiving affordable medicines of high quality. A third party authorized by the FDA would be an advantageous solution.

Going forward, what are the plans for S. A. Pharmachem and Gangwal?
We are trying to move further towards manufacturing; our emphasis is more on excipients and drug delivery systems and we are entering the services segment.
We also intend to enter commercial formulation development and have a laboratory approved by the Department of Scientific and Industrial Research (DSIR), the parent body for all innovation in India. This laboratory has already released a patented product, and we will continue to investigate new delivery systems using this infrastructure. •

Harish Shah

Managing Director,
Signet

Signet reached its 30th anniversary last year and is India's largest excipient company. How prominent is the company in the market today?
Signet experienced 20% to 25% growth each year from 2007 to 2015 but is currently posting growth at 13% to 15%. In the last three years, the market has plateaued somewhat because the Indian pharmaceutical industry has been under duress. Since we do not manufacture any products but instead move in tandem with the formulation industry, our growth has been impacted. We view this as a temporary lull because there is no structural defect in the market.

India continues to be a leading player in the formulation industry and Signet is very fortunate to have little global competition in this space. India has now reached about 600 FDA-approved plants; there is no other country with this kind of infrastructure in place.

Signet supplies excipients in various dosage forms. Are there any particular trends in demand in the Indian market?
In sustained-release dosage, Matrix tablets are the most common form and preferred over coatings because of their similar function with reduced process time. Oral dosage forms continue to be most common, with strong trends developing for Osmotic Drug Delivery System technology (ODDS). Other trending dosage forms are nasal and inhalation. Growth is also occurring in topical delivery systems, such as derma and transdermals, with more companies now offering them than before. Furthermore, a new trend is seen in biodegradable and noninvasive patches in an effort to eliminate silicone usage.

The global pharmaceutical excipients market is projected to reach USD 8.1 billion in 2021. Does Signet plan to increase its international presence accordingly?
Signet is one of the largest excipient suppliers to all Bangladeshi and Middle Eastern companies.

What are the key objectives for Signet going forward?
Signet's growth will be mainly organic and we have no plans to alter our business model. We see a great future and a lot of potential in this business and will stick to our core competence and expertise. •

Forging a New Path

Innovation in Drug Delivery

Recognized as the largest producer of generic medicines worldwide, India's patented product market is relatively small when compared to that of other countries. While there have been some movements towards encouragement of drug discovery, innovation in India's pharmaceutical sector tends to fall under the banners of processes and drug delivery.

Companies operating in India benefit from a favorable cost base and, in a market driven by affordability, have become attuned to process improvements and optimization of efficiency. In turn, these factors all contribute to the creation of an environment that is very much conducive to R&D. "Many state that the costs of their India [R&D] centers stand at about a third of the costs of their other centers globally," noted Nadir Godrej, managing director at Godrej Group. "Even if a patented drug is created, it is likely that an Indian company can make it at a lower cost, so there are advantages to outsourcing drug manufacture to India… Although historically India has not been so strong in drug discovery, with only a handful of companies in this area, we have had some success in vaccines."

Although there are a variety of traditional systems in place to develop drugs in different dosage forms, novel drug delivery systems (NDDS) are a growing area of focus for India's pharmaceutical companies as a key differentiator in an already-crowded market. In pursuing generic alternatives to innovator drugs, innovative companies may find ways to improve aspects of the medicine, from bioavailability to side-effect profiles and ease of administration.

Ahmedabad-based Troikaa is a shining example of a company that has achieved great success in NDDS. The company first achieved recognition with its diclofenac injection, of which it also developed a painless version - the Dynapar AQ IV bolus injection is the world's first painless diclofenac injection and the number-one brand on the market today. Another of Troikaa's products is a new-generation topical solution to treat chronic painful conditions, Dynapar Quick Penetrating Solution (QPS), which has an onset as fast as 20 minutes and duration of action of eight to 12 hours. "Benchmarked against a similar product from the United States, Troikaa's product is superior and has now become the number-one selling topical prescription and passed over 45 crores in volume," highlighted Ketan Patel, managing director at Troikaa. "An additional plant was built to accommodate more dosage forms and is fully automated for topicals."

While the company sees highest opportunity in West Africa, where it is now rated a top-10 company, followed by southeast Asia, it also has its sights set on the highly-regulated markets. Troikaa's diclofenac injection has been filed for approval with the European Union and clinical trials should start in March 2018. Dynapar QPS has a similar trajectory. Troikaa's new plant has also embarked on the U.S. FDA approval journey for topicals.

Recognizing the importance of differentiated products, a company that has come to specialize in providing drug delivery solutions is ZIM Laboratories. Capable of producing any aspect of drug delivery solutions and oral solid forms and currently holding 14 patents, ZIM creates drug delivery solutions for local complex generics companies to compete against imported medicines containing complex generics in the ROW and emerging markets. "We have been able to develop proprietary technologies for manufacturing controlled multi-particulates, taste-masking of bitter drugs, solubilization of poorly soluble APIs, stabilization of sensitive molecules and so on," outlined Anwar Daud, ZIM Laboratories' director. "Lately, ZIM has developed and commercialized fast dissolving oral thin films for increased patient convenience and adherence. Use of all these technologies in various combinations has helped ZIM to make its presence felt in niche markets with premium products."

"Today, the country exports generic medicines to all countries of the world but has not put a lot of effort into discovering and launching innovative novel medical entities. Rather than being completely driven by innovation, the industry is driven more by processes and formulation R&D to manufacture APIs and formulations. As the drive is not to create blockbuster drugs, research occurs as more of an internal process to generate products, APIs or formulations to export to the world."

- Rao Vadlamudi, President, IPA

"Because our platform technologies are therapy agnostic, they can be applied across many products, depending on the customer's needs. The target molecule can be differentiated from an existing generic or patent-expiring dosage form by the customer to a new thin film dosage form so as to extend their product's life cycle or give it a premium position with additional attributes such as convenience, adherence, minimization of side effects and greater effectiveness. This falls under our value proposition to our partners."

- Anwar Daud, Director, ZIM Laboratories

The company has a number of proprietary technologies, of which its oral film techology, which allows ingestion of the active ingredient without water, is particularly notable. "Our recent Thinoral® technology produces thin film dosage form that dissolves instantaneously on the tongue," explained Daud. "It obviates the need of water, thus enhancing the convenience of drug administration. So far, we have developed about 30 products on this technology platform catering to the needs of pediatric, geriatric, dysphagic, mentally challenged and bed ridden patients. We are among a handful of companies in the world possessing the technology with a significant number of products approved and commercialized in this dosage form."

ZIM's orally disintegrating strips (ODS) product is being positioned towards entering the U.S. and European markets.

As with ZIM's proprietary technologies, many companies look towards specialized processes as a differentiator to lend a competitive edge. Processes such as lyophilization require a certain degree of technical expertise and have clear advantages in drug development. Focused on injectables, GUFIC produces 2.5 million vials per month across two facilities, housing 12 lyophilizers, and has acquired six patents for injections over the last four years.

"Lyophilization, our main focus and niche, helps our products achieve a particular particle size to increase absorption level transfer," commented Pranav Choksi, executive whole-time director at GUFIC, the first company to import lyophilizers into India. "It also helps with making uniform complex mixtures. Because of the many advantages of lyophilization, the majority of our pipeline products utilize this process."

Focused on injectables, GUFIC produces 2.5 million vials per month across two facilities, housing 12 lyophilizers, and has acquired six patents for injections over the last four years.

Engineering an innovative framework

Whilst many of India's formulators are highly innovative and technically skilled, innovation comes at a cost which, for companies mostly operating on a high-volume, low-value basis, can be restrictive or even prohibitive. "More can be done to support innovation in India," asserted Patel. "Troikaa's diclofenac formula and Dynapar have been copied and numerous infringements have been made. In the last three years, Troikaa has sued 45 companies, and we have been waiting to receive an injection approval, which would immediately double the company's sales. However, no resolution has been reached since the judges lack the scientific expertise and the courts have huge backlogs.

"For the foreseeable future, the patented product market will continue to be fairly small in size. A select number of companies with patented molecules priced appropriately for India will grow in the country, but the overall total share will be limited and currently sits at less than 5%. The success stories of some patented molecules in India can be attributed to the appropriateness of the molecule to the country coupled with relevant pricing. With the right price and adequate promotion and distribution, patented pharmaceuticals can also become quite successful. However, it is expected that the Indian industry will remain dominated by branded generics for years to come."

- Vivek Sharma,
CEO,
Piramal Healthcare

Patent protection needs to be improved, but it is highly unlikely that any changes will take place. Surprisingly, there had also been no policy provisions for NDDS previously, although there is now a draft bill in place."

Commenting on competition and reimbursement in the market following commercialization, Patel continued: "In India, there is somehow the belief that top quality is feasible at throw-away prices, imposing narrower margins on companies such as Troikaa. Prices in India vary drastically; two matching products are often sold at completely different prices. It is difficult to assess whether the government will understand this fact. Indian brands are cheaper by 33% to 66% compared to the next lowest in countries such as Bangladesh and Pakistan."

IMAGE: Courtesy of Sajjan India Ltd.

Due to high levels of competition, companies are tending towards molecules with higher complexity where they expect to see lower levels of competition. Since the Indian market holds affordability second only to quality, a more effective and protective innovation framework would encourage companies to innovate with greater security without having to raise the price point of medicines to receive reimbursement on R&D expenditure.

"The Government should also focus on improving quality standards by ensuring GMP compliance, which would result in improving the quality of medicine available in the country and weed out non-serious and non-compliant players. Incentivizing in-house R&D through tax exemptions and other means is a very critical enabler to boost investments in research. Scale-back of some of the Income Tax benefits on R&D has not been conducive for the encouragement of in-house R&D in the country. A favorable regime and regulatory ease for conducting clinical trials would also be a promising step."

- Lupin
Spokesperson

"There has been some support for innovation from the Indian government in the form of incentives but there are very few grants available for innovation. There is much talk about the government providing significant support for innovation but we have yet to see how that translates into specific policies in this area. Much of RLS's R&D success comes from its own drive and a huge amount of internal stimulation."

- KV Subramaniam, CEO, Reliance Life Sciences

India's growing scope for biologics

India may have some way to go before achieving international recognition as a proponent of drug discovery but a new field on the horizon of great interest to many companies is that of biosimilars. "Progressively, more countries are opening up to and encouraging the production of biosimilars," remarked KV Subramaniam, CEO at Reliance Life Sciences. "India has recently announced the new biosimilar guidelines, which seem to be beneficial as they define the approval pathway. The country is encouraging more biosimilar activity, reflecting a similar focus in many other countries. It is merely a question of time before biosimilars become a significant opportunity and RLS is preparing to be well-positioned for these opportunities when they arise."

Reliance Life Sciences, India's top-ranking biosimilar company on a number of products in the market, boasts the largest number of monoclonal antibodies in the world and is the company with the largest number of biosimilars under development globally.

However, while biosimilars may be a logical step for India's pharmaceutical industry, other countries are already making moves in the same direction. "For biosimilars, Korean companies and some Chinese companies are making great strides," noted a Lupin spokesperson. "This is an area where Indian companies are slightly behind their counterparts and need to catch up as the next wave of patent expiration opportunities is likely in this area.

If large companies time their development activities well, they can reasonably scale up in certain molecules. Companies undoubtedly need to have a presence in biosimilars for capturing incremental patent expiration opportunity and sustaining growth on an elevated base. As we approach biosimilar acceptance and regulatory pathways improve in the U.S. market, this area will become increasingly important for Indian companies to focus on. In the next three to five years, we could see at least two Indian companies feature among the top 10 players in each product commercialized in the US market."

India's pharmaceutical industry is highly proficient in the field of generics and has earned its reputation as a provider of high quality, affordable medicines. However, the industry's potential reaches far beyond its current capabilities and, with a more effective framework in place and increased support, could forge a more innovative pathway and further increase its competitiveness globally. •

"The Indian government is now giving incentives to innovative companies conducting research and developing molecules for new therapeutic segments. It is proactively supporting the pharmaceutical industry through subsidies and other benefits. The Indian pharmaceutical industry is also becoming more aware of the need to invest in R&D and develop new chemical entities or new delivery forms for old molecules in order to have premium products and a leading edge in the global pharmaceutical business. ."

- Ajay Saxena, General Manager, Rusan Pharma

IMAGE: Courtesy of Athena Drug Delivery Solutions Pvt Ltd

Alexandre Williams

Managing Director,
Athena Drug Delivery Solutions

Athena Drug Delivery Solutions was originally a spin-off of Ethypharm's India operation, which you acquired in 2011. Could you briefly introduce the company and outline its background?
Ethypharm is a French company specializing in and leading the world in drug delivery. With the change in ownership of the company over the last five to 10 years, its B2B focus shifted to B2C and commercialization of Ethypharm products under its own brand. Following this change, in 2011, I got the opportunity to acquire Ethypharm's Indian division and, since then, we have been able to continue investment and to redirect the activity for European export. Over the last few years, we have been building capabilities and matching the quality requirements of the different export markets. Athena achieved GMP accreditation in 2013 and launched its first product in Canada in 2014 and in Europe in 2015.

Could you elaborate on Athena's facilities in India and their capacities and capabilities?
We have a small operation of 200 people. The facilities in India produce bulk products as well as finished formulations. Orally disintegrating tablets (ODTs) are some of our flagship products, as are modified-release products either in tablet, pellet or capsule form. We produce around 400 million doses in India in different forms. Due to a high number of upcoming launches, we must expand our factory and look for transfer opportunities in Europe as we will not be able to manufacture all of them in our Indian site.

Athena also has an operation in France and China. What is their significance within the company's wider operations?
We have a Chinese operation dealing with R&D for Chinese products, from which we have filed two products so far. Our France office is a holding facility, which will play an important part in the near future to transfer some products to CMOs in Europe. In five to 10 years' time, we feel India will no longer have a competitive manufacturing cost advantage so it is important to establish closer manufacturing relationships with our clients now. This is also why we want to begin transferring some of our manufacturing from India to Europe.

How does demand differ geographically?
Generic formulations are more appealing in some markets such as the France, Germany and Canada. However, most of our portfolio consists of differentiated branded generics. These are more appealing to emerging markets, in which branding and promotion are still in progress.

What kind of relationship does Athena have with its partners?
We provide all services to our partners except for launching and marketing. We choose the product, develop it, put together the full dossier and then license the product to be launched into the market by our partner either under their brand or as a generic. Thereafter, we look into supplying the product either directly through Athena or manage the supply from a CMO. Technically, these products fall under Athena's dossier. The current trend in European generics is to gain property over the dossier and control where the product is later manufactured. However, this trend should change over time as power shifts back to developers.

What drives the selection of products for the respective markets?
Product selection is of great importance. The decision requires an overview of many markets and knowing the difficulties in development, registration, launching and demand. It is also important to be a step ahead of market trends and at times be willing to take on risk. In our first years, our portfolio was not quite so interesting because we wanted to limit risk and therefore kept the same dossiers from the Ethypharm times. As we have become more attuned to market interests, our portfolio has become more and more appealing, entering into areas in which we have little or no competition.

What are the key objectives for the company over the next few years?
Some of Athena's objectives going forward include multi-site manufacturing, gaining approval for the Russian and Brazilian markets and being perceived as a good supplier for key international companies. Today, in terms of volume and value, emerging markets such as Brazil, Indonesia and Russia can be as interesting as countries such as France, Germany and the United Kingdom. When we negotiate a contract in Brazil, the volume is even better than in Europe in some key markets. Increasing our activity in the United States will be a five-year journey, dependent on us having products that are in tune with and interesting for the market. •

Jayesh Choksi

Managing Director,
GUFIC

GUFIC was established in 1970 and has many divisions under its umbrella. Could you briefly introduce the group and outline its structure?
GUFIC is a family-owned company that began manufacturing API and formulations of antibiotics; it is the first company to import lyophilizers into India in 1978. During that time, we began to produce oxytetracycline and we were one of the first to launch an Amoxycillin injection. Gufic launched blockbuster drugs like Mox and Zole in the 1980's and was one of the top companies in India developing antibiotics and antifungal formulations. However, in 1997, a conscious decision was made to sell the company to Ranbaxy and it exited the pharmaceutical business for about eight years, maintaining R&D innovation in developing a sustainable pipeline of products. We relaunched the business in 2006 and used our strength of lyophilization to develop antibiotics and antifungals injectables. In 2006, our manufacturing capacity was 50,000 lyophilized vials a month which increased to 1.2 million lyophilized vials by 2012. In 2012, we invested in setting up a new manufacturing facility in the same premises in Navsari, Gujarat, which attained completion in 2015. This facility received EU GMP approval in 2016 and now Gufic can manufacture a total of 2.6 million lyophilized vials per month which can be increased to 3.8 million vials per month in the future.

GUFIC also focuses on pharma and herbal products. The company manufactures the Sallaki/H15 brand used for osteoarthritis and neuro arthritis, which is a US$6 million brand being sold exclusively in India, Germany and Switzerland. Our niche is lyophilization and we will remain focused on developing life-saving injectables keeping in mind innovative options for affordable healthcare.

How important is the domestic market versus the export market for the business?
As construction of the new factory and gaining approvals happened only in recent years, exports have only reached 10% to 15% of GUFIC's total revenue as of yet. At the same time, this percentage is growing dramatically and we are confident that exports will eventually contribute to 40% of the company's revenue.

Currently, we our exporting to more than 23 countries worldwide and we shall soon be entering the regulated markets, including Europe, Canada, South Africa, Brazil and Australia. Though our manufacturing facility is designed to meet U.S. FDA standards, we will enter the United States in Phase 2 of our business plan. Currently, we are only looking to position ourselves as a toll manufacturer for companies for the U.S. market.

Could you shed some light on GUFIC's in-house R&D programs?
The main focus areas of R&D at GUFIC are life-saving and critical care products. As the aim is to cater to hospitals, GUFIC is focused on R&D ranging from antibiotics and antifungals to oncology, anaesthesia, and infertility. We are also working on an innovative formulation for botulinum toxin injections and other novel formulations to add to our existing product range.

Lyophilization, our main focus and niche, helps our products achieve a particular particle size to increase absorption level transfer. It also helps with making uniform complex mixtures. Because of the many advantages of lyophilization, the majority of our pipeline products utilize this process. We also place a great deal of R&D emphasis on new drug delivery systems.

Has GUFIC faced any challenges with the loose patent protection for new drug delivery systems in India?
Over the last four years, GUFIC has acquired six patents for life-saving injections. Despite grey patent protection areas, we have not faced much of a challenge thus far and there is a rising awareness for this issue and a lot of pressure on the Indian government to uphold patent rights. The risk is worthwhile as very good products will eventually receive patent protection.

What are the key objectives for the company going forward?
The key objective for GUFIC is to increase the product pipeline and be the first to produce new life-saving injectables and drug delivery systems with extensive use of our R&D capability. GUFIC's Mission is to achieve leadership in the specialized medicinal segments and make products available at a cost-effective rate using innovation and technology to enhance the welfare of the population worldwide.We are also interested in gaining international scientific partners that understand our unique products and can communicate the benefits of GUFIC products to doctors worldwide, specially in the field of antifungal, antibacterial, anaesthesia and oncology for critically-ill patients. •

Nature's Remedies

Phytochemicals and Nutraceuticals

As consumers become more health-conscious, there is a growing gap in the market for products formulated from natural sources, leading to the growth of the nutraceuticals and phytochemicals industry. The phytochemicals industry has evolved with the fundamental aim of providing care to patients without the side effects of regular pharmaceuticals and prescription drugs. Phytochemicals include compounds with essential nutrients in plants, while nutraceuticals incorporate products from food sources, designed to provide additional health benefits.

A key benefit of choosing phytochemicals as active ingredients is the possibility to provide preventive measures to certain ailments, in addition to relief. Furthermore, consumers are becoming more mindful of what they put in their body and, as such, medicines from natural sources are gaining in popularity. Nutraceuticals are also becoming more widely used as supplements to a healthy lifestyle, offering benefits such as boosted energy, improved physical endurance, mental alertness and prevention of chronic illness, improvement of health and increased life expectancy

Although the global nutraceuticals market is growing, currently the United States, Europe and Japan collectively account for 93% of the market. That said, as these markets have reached maturity, regional industries are now turning their attention towards emerging markets such as India and China for their high-volume tendencies. As for India, the market is currently worth US$2.2 billion, and is projected to grow at CAGR 20% to US$6.1 billion by 2020.

"Our mission is to bring about a paradigm change in pharmaceuticals. Our objective is to go back to nature, focusing on sustainable living. There are plenty of naturally-ocurring plants from which cures can be derived for a range of ilnesses and sicknesses, which feed into aryuveda and unani medicines."

- Randolph Alves, Chairman and Managing Director, Alves Group

On the treatment side, several companies are also investigating natural alternatives to chemically-synthesized active ingredients for medication. "There are many herbs available in India, but most people are unaware of the active constituents available in these herbs," says Manish Mishra, senior manager at Sarv Biolabs. "As India is heavily enriched with flora and fauna, there are many medicinal plants available in India and the environment is very favorable for their cultivation."

Sarv is one of the largest manufacturers of thiocolchicoside, a phytochemical for muscle relaxation, and also manufactures colchicine, an antibiotic derived from the Gloriosa Superba seed, which is only cultivated in the southern parts of India.

"More than 100 companies regularly purchase thiocolchicoside from Sarv and have noticed its greater effectiveness for all kinds of pain when compared to using equivalent APIs such as Aceclofenac, Diclofenac, Etoricoxib alone."

- Manish Mishra, Business Development Manager, Sarv Biolabs

The Gateway to Affordable Medicines?

The Future of India's Pharmaceutical Industry

India's pharmaceutical industry has experienced a great deal of growth in recent years but must adapt to global market dynamics to maintain its leading position as the number-one generics producer. As price erosion continues to impact the market and competition increases, many of India's pharmaceutical companies will be hard-pressed to continue pushing products into the market at ever-more affordable prices.

Growing presence in export markets is paramount to capture greater global market share and value for India's pharmaceutical manufacturers. Provisions must be made at a policy level for companies to maintain competitiveness and to allow the industry to continue to flourish. Equally, support for smaller companies in attaining accreditation and reaching new export markets will go a long way in developing the sector. "In India today, more than 300 companies have been approved by the U.S. FDA, over 250 by the EMA and 1,400 are WHO-GMP certified," commented P.K. Gupta, president at the Confederation of Indian Pharmaceutical Industry (CIPI), India's apex body of small and medium-scale manufacturers of drugs and pharmaceuticals, representing about 5000 pharmaceutical units. "Out of the 5,000 Indian companies in formulation production, around 3,000 are not certified outside of India. These companies are CIPI's focus as we seek to convince these companies to upgrade themselves and pursue further certification."

While less-regulated markets have a much lower barrier to entry, highly-regulated markets such as the United States and Europe are much higher in value and therefore highly attractive to India's pharmaceutical manufacturers. To this end, organizations such as the Indian Drug Manufacturers' Association (IDMA) assist companies with documentation training and support in their approach to different markets.

Further development of national capabilities in APIs will go some way into fostering a more competitive supply chain, de-risking current reliance on China and allowing formulation companies to take advantage of India's own high proficiency in producing high-quality, affordable pharmaceutical ingredients. Companies looking to mitigate supply risk are already backward integrating, steering the industry towards vertically-integrated supply chain models. A more formalized push in this direction and towards domestic API production would greatly benefit the industry in the coming years and ensure greater security of supply and captured value.

India's national government hopes to address the industry's challenges through measures such as the Draft Pharmaceutical Policy 2017 and 'Pharma Vision 2020'. Regional governments of states such as Telangana, recognizing the sector's potential for economic return, seek to further develop capabilities and attract new companies to the mix. With many positive forward-looking actions imminent, it may also be worth re-examining past measures put in place and reassessing their impacts on the market going forward. Price control, for example, if too stringently enforced and too restrictive could have an adverse effect on the industry. "In terms of price control, while there are about 300 products on the National List of Essential Medicine (NLEM), it is uncertain whether these products can be manufactured at these particular costs without compromising on quality," highlighted Rao Vadlamudi, president at the Indian Pharmaceutical Association (IPA). "It is probable that major pharmaceutical companies will not manufacture medicines on the NLEM because the cost to manufacture is not viable. Therefore, smaller-scale units may try to manufacture the NLEM medicines, incurring less cost due to their smaller infrastructure, but also compromising on quality because they are under less strict regulatory control. Compromise on quality affects patient health, which is very concering. More scrutiny must be in place in India to improve patient outcomes."

Although competition does contain prices to a great degree, some control and monitoring is necessary and it is highly unlikely that price control will be completely abolished. However, the right balance must be in place to align both with the government's push towards more affordable medicine for its population and the industry's development and growth.

The overall thrust of the government will remain towards improved access to medicine. The sector has long operated within this framework and achieved great success in the international market, accounting for 10% of the global pharmaceutical industry in terms of volume and responsible for 20% of global generics exports. With the right measures in place and effectively implemented, India's pharmaceutical industry will continue to be a primary player in the provision of affordable medicines not just to the Indian market but worldwide. •

Aarti Drugs	91 22 24019025	Mahendra Industrial Estate, Ground Floor, Road No-29, Plot No-109-D, Near Vvf Ltd, Road No 29, Sion (E), Mumbai, 400 022	http://www.aartidrugs.co.in/
ACG	91 22 3008 9444 / 45	Dalamal House, Nariman Point, Mumbai, 400 021	http://www.acg-world.com/
Albica Biocare	91 172-273 49 49	3/3, Subhash Nagar, Manimajra, Chandigarh, 160 101	http://www.albia.in/
Alves Group	91 22 445 9116 / 17 / 18	Our Lady of Vailankanni Towers, 101 & 102, 'A' Wing, 1st Floor, Mari Nagar, off. Senapati Bapat Marg, Opp. Mahim Railway Station, Mahim (West), Mumbai 400 016.	http://www.alvesgroup.com/#
Apex Drug House	91 22 26709200-300 / 26709700-800	404, D Square, Dadabhai Road, Vile Parle West, Mumbai, 400 056	http://www.apexdrugs.com/
Athena Drug Delivery Solutions	91 022 6737 0700	602, Star Hub, Tower II Sahar, Andheri (East), Mumbai, 400 099	http://athenadds.com/
Aurobindo	91 40 6672 5000	Plot no. 2, Maitrivihar, Ameerpet, Hyderabad, Telangana, 500 038	http://www.aurobindo.com/
BDMA	91 40 2370 3910 / 2370 6718 / 2370 4804	C-25, Industrial Estate, Sanathnagar, Hyderabad, 500 018	http://bdmai.org/
BDR Pharmaceuticals	91 22 4056 0560	Engineering Center" 6th Floor, 9th Matthew Road, Opera House, Mumbai, 400 004	http://www.bdrpharma.com/contact/
BELCO	91 82 8608 5961	515, M.I.E., Bahadurgarh, Haryana, 124 507	http://www.belcopharma.com/
Benzo Chemicals	91 22 4355 5888	Benzochem Industries Pvt Ltd. 26/28 A, Cawasji Patel Street, Fort, Mumbai, 400 001	http://bcipl.com/
Bharat Parentrals	91 26 6725 1680.	Jarod Samlaya Road, Vill. Haripura, Ta. Savli, Dist. Vadodara, Gujarat, 391 520	http://bplindia.in/
Biocon	91 80 2808 2808	20th KM, Hosur Road, Electronic City, Bengaluru, Karnataka, 560 100	https://www.biocon.com/
Canton Laboratories	91 265 2638084	110-A & B GIDC, Makarpura, Post Box No. 778, Vadodara, 390 010	http://www.cantonindia.com/
Chemexcil	91 22 22021288 / 330 / 22825861	Jhansi castle, 4th floor, 7-Cooperage Road, Mumbai, 400 001	https://chemexcil.in
CIPI	91 12 7622 5100	515, MIE, Bahadurgarh, Distt. Jhajja, Haryana, 124 507	http://www.cipi.in/
Cipla	91 22 2482 6000	Peninsula Business Park, Ganapatrao Kadam Marg, Lower Parel West, Mumbai, 400 013	http://www.cipla.com/
Ciron	91 22 3359 8000	Lotus Corporate park, C-1101 / 02, Jai Coach Junction, Western Express Highway, Goregaon (East), Mumbai, 400 063	http://www.cironpharma.com/
Concept Pharma	91 22 4241 8888	501 Jaisingh Business Center, 119, Sahar Road, Andheri (East), Mumbai, 400 099	http://conceptpharma.com/
Cooper Pharma	91 11 2365 3404 - 05 / 23653537	2nd Floor, Plot No.5, LSC Gulabi Bagh, Near Shakti Nagar Railway Bridge, Delhi, 110 052	https://www.cooperpharma.com/
Eskay Fine chemicals	91 22 6622 7575	3 – A, Shiv Sagar Estate North Wing, Dr. Annie Besant Road, Worli, Mumbai, 400 018	http://sk1932.com/eskay.htm
Espee	1 888 851 6667	1006/1007, Venus Atlantis, Anandnagar Road, Prahlad Nagar, Ahmedabad, Gujarat, 380 015	http://www.espeeusa.com/index.htm
Fablab Engineering	91 93 2301 2344	Unit No. 303, 3rd Floor, Bhoomi Velocity, Plot No. B39A, Near Tata Showroom, Road No.23, Wagle Industrial Estate, Thane, 400 604	http://fablabindia.com/
Federal Equipment Company	91 21 6271 3500	8200 Bessemer Avenue Cleveland, Ohio 441 27	http://fedequip.com/
Gandhi Automations	91 22 66720200 / 66720300	Chawda Commercial Centre, Link Road, Malad (West), Mumbai, 400 064	http://www.geapl.co.in/
Gepach	91 22 2821 0789 / 67022474 / 67022475	318/22-24, Kakad Corner, Sir M.V. Road, Andheri (E), Landmark - Opp Axis Bank, Mumbai, 400 059	www.gepach.com
Glaxo Smith Kline	91 22 24959595	Dr Annie Besant Rd, Hanuman Nagar, Worli, Mumbai, 400 038	http://india-pharma.gsk.com/
Glenmark	91 22 4018 9999	Glenmark Pharmaceuticals Limited, Glenmark House, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri (E), Mumbai, 400 099	http://www.glenmarkpharma.com/
Godrej Industries	91 022 2518 8010 / 20 / 30	Godrej One, Pirojshanagar, Eastern Express Highway, Vikhroli, Mumbai, 400 079	http://godrejindustries.com/
Gufic Group	91 22 6726 1000	37,1st Floor, Kamala Bhavan II, Swami Nityanand Road, Andheri (East), Mumbai, 400 069	http://gufic.com/
Gujarat Food and Drug Control	91 79 2325 3399 / 2325 3417	Block No 8, Dr. Jivraj Mehta Bhavan, Gandhinagar, 382010	http://dmla.guj.nic.in/mfg/myaccount/Home.aspx
GVK BIO	91 40 6692 9999	GVK Biosciences Private Limited Plot No. 28 A, IDA Nacharam, Hyderabad, 500 076	https://www.gvkbio.com/
Hemmo Pharmaceuticals Ltd	91 22 2542 8482	H/20, Natraj Chs Ltd, Eastern Express Highway Road, Naupada, Thane, 400 602	http://hemmopharma.com/
IDMA	91 22 2494 4624 / 2497 4308	102, Poonam Chambers,'A' Wing, 1st Floor Dr. A. B. Road Worli, Mumbai, 400 018	http://idma-assn.org/
IND SWIFT	91 17 2263 8781 / 2638782 / 2638786	781, Industrial Area - Phase II,Chandigarh, 160 002	http://www.indswiftltd.com/
Infionic	91 212 558 9087	#2A, Melange Towers, Patrika Nagar, Madhapur, Hyderabad, Telangana, 500 081	http://infionic.com/
Innovexia	91 172 466 0388	SCF-439, 1st & 2nd Floor, Motor Market Manimajra, Chandigarh, 160 101	http://www.innovexia.in/
IPA	91 22 2667 1072	Kalina, Santacruz (E), Mumbai, 400 098	http://www.ipapharma.org
KA Malle	91 22 4222 6111	Krishnadham, L.S.Raheja Marg Raheja Township, Malad East Mumbai, 400 097	http://kamalle.com/

Kilitch Drugs	91 22 6121 4100	37, Ujagar Industrial Estate, Waman Tukaram Patil Marg, Deonar, Mumbai, 400 088	http://www.kilitch.com/
Kirloskar Pneumatic co Ltd	91 20 2672 7000	Hadapsae Industrial Estate, Pune, 411 013	http://www.kirloskarkpcl.com/
Lason India Pvt	91 22 2644 1728 / 29	8, New Jagruti, 227, S. V. Road,Bandra (West), Mumbai, 400 050	http://lasons.com/
Lupin	91 22 6640 2222	B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051	http://www.lupin.com
Mac Chem Products	91 22 4093 9000 / 01	304, Town Centre, 3rd Floor, Andheri (East), Mumbai, 400 059	http://macchemgroup.com/
Mack Pharmatech	91 2551 230877	B 48, Malegaon MIDC, Sinnar Dist, Nashik, 422 113	www.mackpharmatech.com
Nirlife	91 79 2683 9100 / 98 7960 9679	Aculife Private limited 5th Floor, Commerce House 5, Near Vodafone office, Behind YMCA club Prahalad-nagar Road, Ahmedabad, 380 051	http://nirlifehealthcare.com/
P.R. Packaging Ltd.	91 12 750 4600	Sehrola/Chhaprola Road, Village Prithla, Near Bani Ka Mandir, District Palwal, Haryana, 121 102	http://www.prpack.net/
Parth Antibiotics	91 2562 8300 / 2566 5860	507/8/9, "Exim Link", 5th Floor,Opp. Indira Container Yard, Mulund – Goregaon Link Road, Near Nahur Rly. Stn., Nahur (w), Mumbai, 400 078	http://www.parthantibiotics.com/
Pharmexcil	91 40 2373 5462 / 5466	101, Aditya Trade Centre, Ameerpet, Hyderabad, 500 038	http://pharmexcil.com/
Piramal Healthcare	91 22 3802 3000	Ananta, Agastya Corporate Park, Opp Fire Brigade, Kamani Junction Kurla West, Mumbai, 400 070	http://piramal.com/
Polmon	91 40 2305 3046	Polmon House, Nizampet Road, Kukatpally, Hyderabad, Telangana, 500 072	http://www.polmon.com/
CI Precision	91 44 17 2242 4100	Brunel Road, Churchfields, Salisbury, SP2 7PX,UNITED KINGDOM	http://www.ciprecision.com/en/
Prudence Pharma Chem	91 26 4622 2825 / 650406	PLOT NO. 7407, GIDC ESTATE, ANKLESHWAR, Gujarat, 393 002	http://prudencepharma.com/
RA Chem Pharma	91 40 2776 4040	608 Saptagiri Towers Begumpet, Hyderabad, Telangana, 500 016	www.rachempharma.com
Reliance Life Science	91 22 6767 8000	Dhirubhai Ambani Life Sciences Centre, R-282, TTC Area of MIDC, Thane-Belapur Road, Rabale, Navi Mumbai 400 701	http://www.rellife.com/
Rusan Pharma	91-22-4238 3000 / 2868 2512	58-D, Government Industrial Estate Charkop, Kandivli (W), Mumbai, 400 067	http://rusanpharma.com/
S.A Pharmachem	91 22 2681 9999	220, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai, 400 063	http://www.sapharmachem.com/
Saga Laboratories	91 79 2583 1904	Plot No. 1409, Gidc Industrial Estate, Phase - III, Vatva, Ahmedabad, Gujarat, 382445	http://sagalabs.com/
Samarth Life Sciences	91 22 28719501 - 10	Samarth House, 168, Bangur Nagar, Off Link Road, Near Ayappa Temple & Kallol Kali Temple, Goregaon (W), Mumbai, 400 090	http://samarthlifesciences.com/
Sarv Bio Labs	91 11 4111 7652	# 209, Crown Heights, Twin District Center, Rohini, Sector 10, New Delhi, 110 085	http://www.sarvbiolabs.com/
SciTech Specialities	91 22 3070 6895 / 6817	1103 DLH Park, S. V. Road, Goregaon (West), Mumbai, 400 062	http://scitech.net.in/
Sergusa Solutions Pvt Ltd	91 22 4053 5800 / 2686 5801	256 Udyog Bhavan, Sonawala Road, Goregaon (E), Mumbai, 400 063	http://www.sergusasolutions.com/
SGD Pharma	33 1 4090 3600	Immeuble Le Bellini 14 bis, terrasse Bellini 92807 Puteaux cedex, France	https://www.sgd-pharma.com/
Sharda Chem	91 22 2651 8565 / 2651 8690	22, Santhal Building, ONGC Colony, Bandra Reclamation, Mumbai, 400 050	http://shardacropchem.com/
Signet Chemicals	91 22 6146 2725	A-801, Crescenzo C/38-39, G-Block, Bandra Kurla Complex, G Block BKC, Bandra Kurla Complex, Bandra East, Mumbai, 400 051	http://signetchem.com/
Srikem Laboratories	91 22 2405 5088 / 65167208	#311,Bldg No 6, Jogani Indl.Estate, Chunabhatti, Mumbai, 400 022	http://srikem.com/
Sun Pharmaceutical	91 22 4324 4324	SUN HOUSE, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, 400 063	http://www.sunpharma.com/
Supriya Lifesciences	91 22 4033 2727	207/208 Udyog Bhavan, Sonawala Road Goregoan [E], Mumbai, 400 063	http://supriyalifescience.com/
Suyog Life science	91 26 4625 2211 / 252200	Plot No.: 145/B, G.I.D.C., Ankleshwar, Gujarat, 393 002	http://suyoginc.com/
Synthokemlabs	91 40 2370 2061	P.B.No. 1911, B-5, Industrial Estate, Sanathnagar, Hyderabad, Telangana, 500 018	http://www.synthokemlabs.com/home.html
Taurian Pharma	91 22 6780 6019	Hallmark Business Plaza, 5th Floor, Sant Dyaneshwar Marg, Opp. Guru Nanak Hospital, Kala Nagar, Band City - Mumbai, Mumbai, 400051	http://www.taurianpharma.com/
Transasia Bio-Medicals Ltd.	91 22 4030 9000	Transasia House, 8, Chandivali Studio Road, Andheri (E), Mumbai, 400 072	http://transasia.co.in/
Troikaa Pharma	91 79 2685 6242 - 45	'Commerce House - 1', Satya Marg, Bodakdev, Ahmedabad, Gujarat, 380 054	http://www.troikaa.com/
Valfit Engineers Pvt Ltd	91 25 0239 0419 / 2390095	Plot No 38, Indo Industrial Estate No 4, opp Onida,, Navghar, Vasai East, District Thane., Samarth Krupa Nagar, Vasai East, Vasai, Mumbai, 401 210	http://www.valfitengineers.com/
Vigor Pharma	91 22 4256 5000	B/307, Kemp Plaza, Mind Space, Malad west, Mumbai, 400 064	http://www.vigoritd.in/
Wanbury	91 22 6794 2222	BSEL Techpark, 'B' Wing, 10th Floor, Sector 30-A, Vashi, Navi Mumbai, 400 703	http://wanbury.com/
Zim Laboratories	91 712 2588 070	Ground Floor, Sadoday Gyan, Nelson Square, Chhindwara Road, Nagpur, 440 013	http://zimlab.in/

This list contains those companies contacted during the course of research for this publication and as such represents only a limited selection of the companies operating in the pharmaceutical industry of India. It should not be considered a comprehensive guide. GBR holds an exclusive and extensive database for India and the wider region.
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