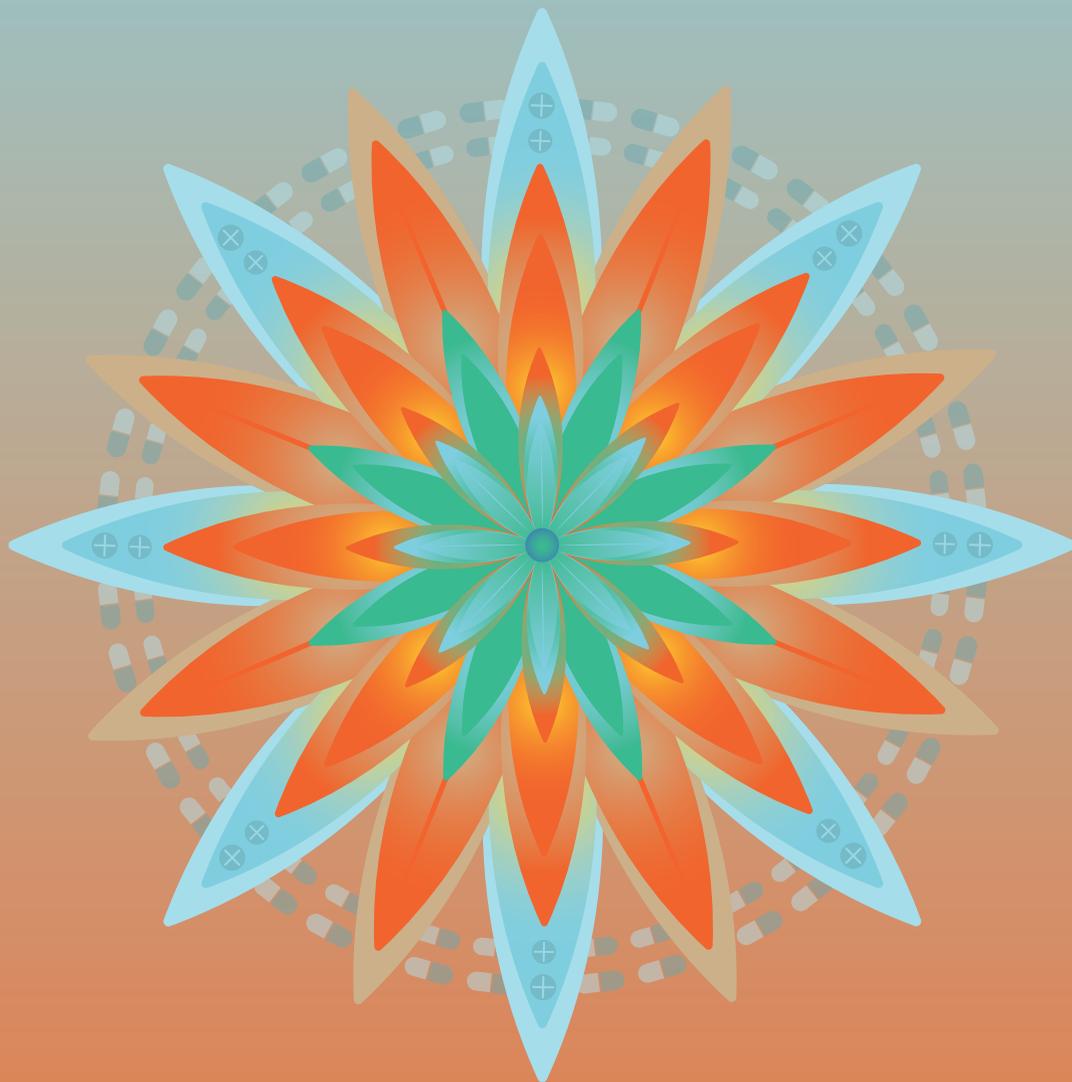




GLOBAL BUSINESS REPORTS

INDUSTRY EXPLORATIONS



INDIA PHARMACEUTICALS 2017



*Generics - Formulations - Clusters - Innovation - Regulations and Markets
APIs, Excipients and Intermediates - Packaging and Medical Devices - Nutraceuticals and Phytochemicals*



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Dear Reader,

Welcome to the 2017 edition of the India Pharmaceuticals Report, a joint CPhI-GBR analysis launched at this year's CPhI India. 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.

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 our research into India's dynamic pharmaceutical sector. In addition to our own market analysis, this research 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.



Rutger Oudejans
Brand Director Pharma
UBM



Alice Pascoletti
General Manager
Global Business Reports

Exclusive Interviews

Leading industry and government figures from India's pharmaceutical industry discuss market trends, opportunities, challenges, strategy and plans.

12, 13, 15, 20, 21, 22, 26, 27...



Data and Infographics

Including GBR's exclusive survey of industry opinion.

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Global Business Reports' journalists provide unique and first hand analysis and insights into all aspects of India's pharmaceutical industry after a period of three months research on the ground.

8, 16, 32, 42, 52, 72, 84, 88...



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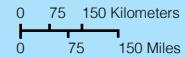
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- ★ Capital City
- State or Union Territory Capital

MALDIVES

SRI LANKA

Indian Ocean





INTRODUCING INDIA'S PHARMACEUTICAL INDUSTRY



“India has a competitive edge because of cost efficiency, portfolio diversification, economic drivers and policy support. Low cost of production and R&D boosts efficiency of Indian pharmaceutical companies – India’s cost of production is approximately 60% lower than that of the United States and almost half that of Europe.”

- Daara B. Patel, Secretary General,
Indian Drug Manufacturers’ Association

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.

Indian companies are currently facing an overcrowded domestic market but come up against challenges further afield due to price erosion and an increasingly fragmented regulatory framework over many markets. "In the last two years, a consistent number of disruptions have occurred that have impeded the growth of the industry, such as the abrupt 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 resulted in 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.

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



“

Indian companies have developed faster than other global pharmaceutical companies due to their skilled manpower, their reputable intelligence in chemistry and math and the favorable policies put forth by the government. The Indian pharmaceutical industry contributes to about 10% of India's health care costs. Hospitalization, doctors, post-operative and post-recovery costs are significantly higher than the cost of pharmaceuticals being used for treatment.

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

”

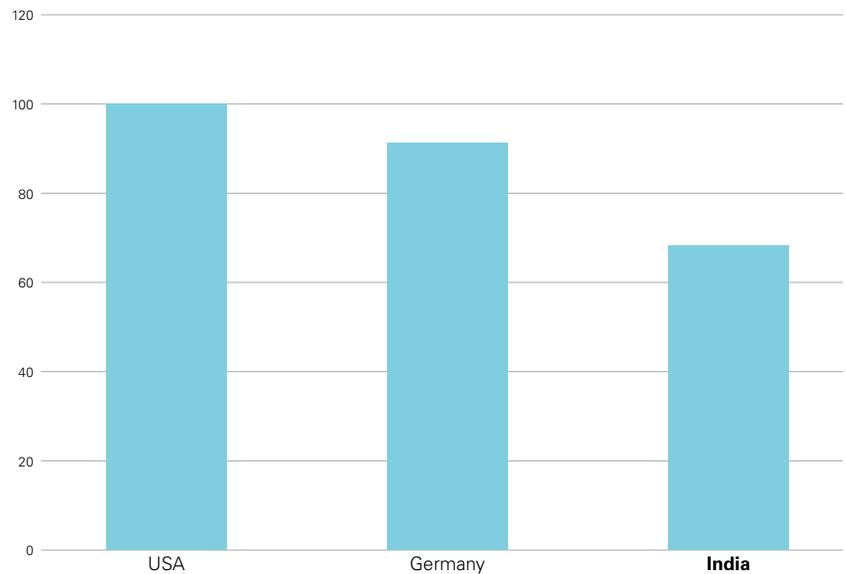
India, alongside international Indian leaders such as Sun Pharma, Lupin, Dr. Reddy's, CIPLA, Aurobindo and Glenmark. "India has a competitive edge because of cost efficiency, portfolio diversification, economic drivers and policy support," noted Daara Patel, secretary general at the Indian Drug Manufacturers' 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 Pharma Solutions, 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

MANUFACTURING COST INDEX BY COUNTRY (2016)

Source: Deloitte, BMI, Financial Express



India's cost of production is nearly 33% lower
than that of the US

Labour costs are 50-55% cheaper
than in western countries

The cost of setting up a production plant in India is 40% lower
than in western countries

**Cost-efficiency continues to create opportunities for
Indian companies in emerging markets and Africa**

**India has skilled workforce as well as
high managerial and technical competence**
in comparison to its peers in Asia

“

The global pharmaceutical business is currently very challenging for small second-tier companies, particularly in the regulated market. ANDA filing fees have doubled and they will increase on a yearly basis. The market is also shrinking in terms of the number of existing players for each molecule. Because the market is overcrowded, Espee chooses to manufacture specialized molecules with less competition.

- Swapnil Shah,
Director,
Espee Group



”

trend, a lot of opportunities remain for Indian companies to contribute to the global health care market.”

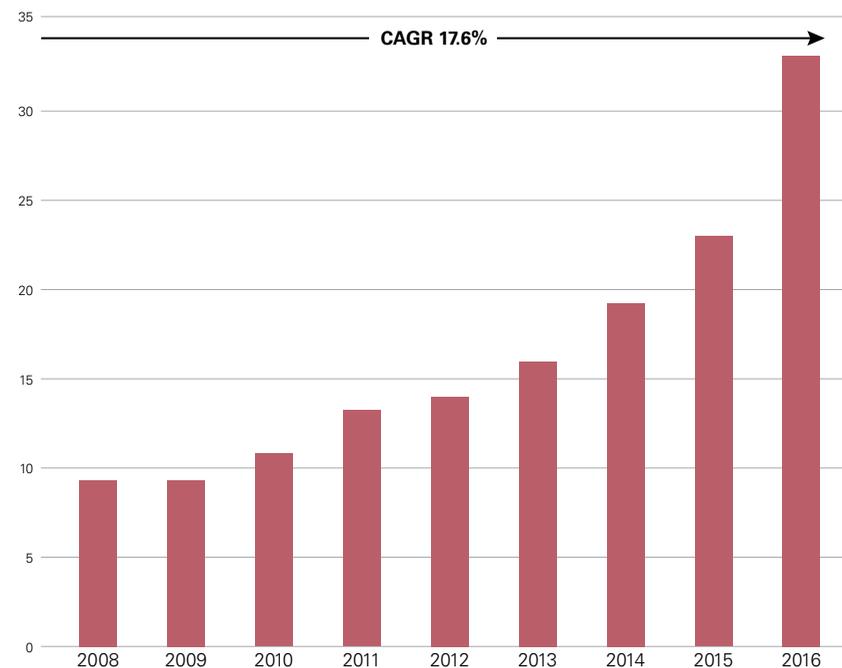
Nevertheless, India still houses the highest number of FDA-approved facilities outside of the United States. “Inspections are routine as part of regulatory exercise,” stated Patel. “The 483s from the United States go to every company and data shows that even a number of U.S. companies receive such warnings. 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.”



Image: GVK Bio

PER CAPITA SALES OF PHARMACEUTICALS (US\$)

Source: BMI



India has the **2nd largest** number of *USFDA-approved manufacturing plants outside the US*

India has **2,633 FDA-approved drug products**

India has over **546 USFDA-approved company sites, the highest number outside the US**

Growing per capita sales of pharmaceuticals in India offers ample opportunities for players in this market

Per capita sales of pharmaceuticals expanded at a **CAGR of 17.6 per cent to US\$ 33 in 2016**

Economic prosperity would improve affordability for generic drugs in the market & improve per capita sales of pharmaceuticals in India

“

The government must collaboratively engage with pharma companies through regulations that encourage business transactions in India. Getting the western industry familiar with the quality of science, innovation investments, and the focus on quality that exists in India will also be of big help to the Indian life science industry, in them being able to meet the mandatory quality requirements and achieving greater levels of accessibility. Providing the Indian regulatory authorities with the training that may be needed to keep the local agencies on par with the west will also assist in improving local quality standards.

- Vivek Sharma,
CEO,
Piramal Pharma Solutions



”

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

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.. —



Ravi Uday Bhaskar

General Director
PHARMEXCIL

The Pharmaceutical Export Promotion Council (PHARMEXCIL) was established in 2004 by the Ministry of Commerce and Industry, Government of India, to promote pharma exports.

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

Pharmexcil was established by the Ministry of Commerce and Industry under Foreign Trade Policy to promote pharmaceutical exports as well as other commodities, such as APIs, Formulations Herbals, Ayush, Nutraceuticals etc. Through this process, 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 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 to 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. US\$40 billion is not a very practical estimate, but Pharmexcil is very optimistic because, in 2016, 30% of the ANDAs approved by the U.S. FDA came from India. Also, the last year, India experienced negative growth of 0.43%, which is a lot less than what was expected. At the same time, exports to the United States, India's major export market for pharmaceuticals, slightly increased.

Surprisingly, despite volumes being quite low this year, there has been a significant positive growth of 227% in herbals and nutraceuticals exported to the United States. Africa is India's second largest export market, followed by Europe. Many countries are leaning towards patented drugs, so Pharmexcil would like to explore new opportunities and study new markets, such as Australia, Japan, New Zealand, Cuba and other Latin American countries.

What are some of the key challenges faced by Indian exporters?

Looking at domestic players of Indian origin, 80% of domestic demand is met by the top companies. It is these same companies that are most prominent in bringing exports to the regulated markets. Because they are already registered and are established global players, they do not run into regulation issues. In fact, out of the 20 top generic companies, eight are from India. Furthermore, companies interested in exploring the markets of developing countries, work on preparing themselves to meet all of the regulatory expectations. Audits are also constantly taking place. Hence, Pharmexcil does not expect these companies to have any export problems in the coming years.

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 has about 700 U.S. FDA-approved plants 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. India was the fourth largest importing partner of USA in 2016 to 2017.

Some Indian companies continue to gain U.S. FDA approval with zero observations. The media has magnified the situation, making 483s seem very serious when, in reality, some of them can be complied with in 10 to 15 days. The inspections, 483s and import alerts are part of the system. The Indian pharmaceutical industry can now take an introspective look to find the missing links within itself, if any.

What role does Pharmexcil play in supporting the export industry in meeting regulatory requirements?

Pharmexcil has a program called the International Knowledge Exchange Program (IKEP). Pharmexcil used to invite regulatory authorities from different countries to meet with India's exporters and member companies in attendance. Some of the invited regulatory authorities were EDQM, AN-VISA, NAFDAC and the U.S. FDA. These meetings were a valuable addition for our members to eliminate barriers with respect to culture and communication. In terms of documentation, changes need to be made at a few companies (very negligible in number) and they need to work very seriously on fixing their processes.

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

Our priorities are to consolidate our capabilities and strengths and to focus on countries with strong market potential for us. We also aim to move into some of the newer segments, such as Ayush, Nutraceuticals and APIs. Pharmexcil will play the role of government liaison for policies in these new segments. 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. —



Daara B. Patel

Secretary General
**INDIAN DRUG
MANUFACTURERS'
ASSOCIATION**

The Indian Drug Manufacturers' Association (IDMA) has over 1000 members comprising large, medium and small national manufacturers across the country.

How has the industry performed since we met in 2015?

India's pharmaceutical sector touched US\$36.7 billion in revenue in 2016, of which exports accounted for US\$16.9 billion. The country's pharmaceutical industry is expected to expand at a CAGR of 12.89% over 2015 to 2020 to reach US\$55 billion with exports touching US\$40 billion. The Indian pharmaceutical sector accounts for about 2.4% of the global pharmaceutical industry in value but 10% in volume and also accounts for 20% of global generics exports.

India is the largest generics producer in the world but has a growing emphasis on R&D. In what ways are the dynamics shifting?

So far, the thrust has always been towards generics, but it is now being spread to

biotechnology. Major Indian pharmaceutical companies have been spending 8% to 9% of their revenue on R&D to produce innovative drugs in many therapeutic areas including cancer. Manufacturing of all-important vaccines and biosimilars has been growing at a steady pace since 2005. Our companies are also focusing on Novel Drug Delivery Systems (NDDSs) and value-added generics.

The IDMA has been working on a strategy to make India the largest global provider of safe and efficacious quality medicines at reasonable prices by 2020. How has this strategy developed?

The Government's "Pharma Vision 2020" strategy is aimed at making India a global leader in end-to-end drug manufacturing. The policy will reduce approval time for new facilities to boost investments and, in the pharmaceutical sector, 100% foreign direct investment (FDI) is allowed under an automatic route.

IDMA's "Journey towards Pharma Vision 2020 and Beyond" white paper is based on our suggestions to the government and deliberations with the government committees over many years. The document points towards a vision of the Indian pharmaceutical industry as a potential world leader by calling on government support to facilitate faster approvals to produce efficacious and affordable drugs, revive API and intermediate manufacturers to compete with countries like China, making provisions for cluster development, skill development and training, IPR, CROs and by addressing issues related to Indian and global regulatory agencies, export-import dynamics, brand building, accessibility and affordability, and so on.

In FY16, India exported pharmaceutical products worth US\$ 16.89 billion, with the number expected to reach US\$ 40 billion by 2020. How does India fare in competition for market share worldwide?

India has a competitive edge because of cost efficiency, portfolio diversification, economic drivers and policy support. Low cost of production and R&D boosts the efficiency of Indian pharmaceutical companies – India's cost of production is approx-

imately 60% lower than that of the United States and almost half that of Europe. Due to lower cost of treatment, India is emerging as a leading destination for medical tourism. 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.

What are the repercussions of increased U.S. Food and Drug Administration (FDA) stringency and other regulatory changes?

It is noteworthy that the highest number of FDA-approved units outside the United States is in India. Inspections are routine as part of regulatory exercise. 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. Our main focus should be on documentation, which is the main challenge in India. If not correctly documented, the FDA believes it is not done. Our companies have now started documenting properly and we have rolled out data integrity training programs.

What are some of the key challenges to address going forward?

We have our own set of problems; there is a misnomer that certain products are under price control and others are not. From what we gather, everything is controlled. Prices of medicines under the national list of essential medicines, for example, cannot be increased because the government fixes the ceiling price and everyone must fall in line. Equally challenging is that if raw material prices increase across the country, we still do not get an automatic price increase. Each company must apply and seek a price increase. However, if the raw material price decreases, the price will be reduced immediately. —



Rao Vadlamudi

President

INDIAN PHARMACEUTICAL ASSOCIATION

The Indian Pharmaceutical Association (IPA) was formed in 1939 and is one of the oldest associations representing pharmaceutical professionals.

Could you provide a brief introduction to the association and its primary mission?

The Indian Pharmaceutical Association (IPA) has 13,000 members of which over 10,000 are life members, opting for a 20-year membership at a single fee. The association represents pharmaceutical professionals in India across all disciplines including industry workers, government regulators, teachers, researchers, community pharmacists, hospital pharmacists and a large force of students. There are 21 state branches spread across the country and 40 to 45 local branches across the states. The IPA was involved in setting up the Indian pharmaceutical industry alongside entrepreneurs and the government to make India self-sufficient in terms of essential medication. Through provision of trained manpower, IPA also contributed to pharmaceutical education for the development of the industry. A significant number of

IPA's senior presidents were previously university professors and industry leaders who established pharmaceutical education and pharmaceutical industry within the country. India also has a huge education network with more than 1,000 institutions imparting pharmaceutical education and Ph.D. programs for graduates to be well-equipped to enter the pharmaceutical industry.

Are universities becoming more collaborative with the industry on research projects?

Ideally, there should be a strong interface between the pharmaceutical industry and universities to drive innovation. However, this is not currently occurring in India at the desired rate. 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.

What improvements could be made to further facilitate the production of affordable and accessible medicines?

Affordability and accessibility comes from making processes cheaper and more economically viable. Indian manufacturers therefore have a clear advantage. There is huge price variation with respect to exports and domestic consumption. Although the prices of exported generics in regulated markets are much lower than innovative products, the cost of the exported generics are higher when compared to the cost of the same medicine in India. When exporting products to different countries at different price points, the question arises whether those at lower prices are of the same quality. All exporters in India are under some kind of regulatory control. There are more than 3,000 facilities approved by various regulatory bodies of which 380 are FDA approved. 1370 are approved by the United Kingdom, European Union and Japan combined. Countries with no regulatory body fall under WHO regulations—over 1,400 WHO-approved facilities exist in India, where the approval is essential for manufacturing products and marketing them to countries that lack strong

regulatory networks. Furthermore, an equal number of small and medium-scale facilities in addition to the larger scale facilities that also export are used for manufacturing products for domestic consumption, which fall under the regulatory supervision of the Indian regulation.

Are there marked differences between the quality of medicines distributed in India compared with export markets supplied by the same manufacturers?

There is no clear answer to whether Indian citizens receive the same quality of products as global citizens. It also remains questionable how many counterfeit, spurious and substandard products have infiltrated the market. Government and independent surveys have conflicting indications of the negligible existence versus the high prevalence of these products. However, the important measurement is the outcome these medicines have in providing better healthcare to Indian citizens. Currently, Prime Minister Jan Aushadhi's initiative aims to ensure non-branded generics are available to everyone but there is no available data to demonstrate that all the generics are bioequivalent.

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. 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 concerning. More scrutiny must be in place in India to improve patient outcomes.

What are the key objectives for IPA going forward in support of the industry?

IPA advocates support of the industry without a potentially negative impact on the patient. IPA has a greater responsibility towards ensuring better healthcare and better outcomes in patients. The association is focused on ensuring that quality medicines and pharmaceutical care is established in India in order to give the best counsel and advice to patients, leading to better treatment outcomes. —



P.K. Gupta

President
CIPI

Confederation of Indian Pharmaceutical Industry (CIPI) is the apex body of the manufacturers of drugs and pharmaceuticals in the country representing small and medium scale units, representing about 5000 pharmaceutical units.

The Confederation of Indian Pharmaceutical Industry (CIPI) was established in 2001 to represent small and medium-sized companies. What role has the association played in the development of the industry?

CIPI looks after the interests of small and medium-scale companies in India and assists in their education. When they encounter any legal or FDA issues, CIPI brings these to the attention of government officials to try to resolve them. All of its members are from the Indian state associations. CIPI represents about 5,000 units with its numbers slightly decreased of late due to FDA crackdowns and factories closing as a result. There are a total of 30 association locations across India and meetings are held quarterly. While most meetings are held in Delhi, others are held in different states to update members on current news and upcoming changes.

How have changes in global dynamics impacted India's pharmaceutical industry?

Currently, there are global hardships in the industry due to high market competition. 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. 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.

What are the main challenges faced by the companies you work with?

Most of the products available in India are fixed dose combinations (FDCs); 2500 molecules are represented by a total of 60,000 brands in the Indian market. While these drugs have been approved by all state governments of India, only the central government has ultimate control over these drugs. The issue with FDCs is a very serious one that is addressed in the new draft pharmaceutical policy.

Could you provide any updates on the key areas of the pharma policy?

The FDC policy has already been drafted and we have now submitted our proposed changes to the government for discussion with its officials. One thread of discussion has been the mindset that each company should produce its own product and that contract manufacturing should be halted. The government's view is that very high levels of production will not help improve the quality of drugs. CIPI has argued that contract manufacturing is present all around the world, so there can be no harm to continue with this model if capacity is available. Without the option of contract manufacturing, capacity and volumes will be limited. Pharmaceutical companies supplying many products would have to vastly increase their manufacturing capacities but then risk having excess capacity if demand decreases. Therefore, this new policy may be detrimental to big companies like Sun Pharma. The other concept mentioned by the government is that each company should only have one brand and one molecule. Limiting companies to having one brand will have the same

effect as getting rid of contract manufacturing. The third discussion regards licensing; licenses allow those without a pharmaceutical company to rent another company's facility to manufacture their product. This differs from contract manufacturing in that the licensee will own their company name and be responsible for their products.

You are also chairman of Belco Pharma, which has been manufacturing pharmaceutical formulations since 1975. How has the company evolved to the present day?

Belco Pharma gradually developed over the years through many investments to become the successful plant it is today. The Indian government's adoption of WHO GMP certification for export approval pushed Belco to make further modifications and adjust the business. Today, Belco has 300 registered products with a strong focus on injectables. We acquired the WHO certification 15 years ago – there are over 1,500 WHO-certified companies today compared to only about 100 when Belco was founded. Belco has been solely exporting with this certification for the last 20 years but business is now declining from growing competition. As additional certification is required for other markets such as Europe and the United States, the plant is in the process deciding on next steps for growth.

In which regions do you see greatest opportunity?

Highly regulated countries require further certifications aside from the WHO GMP that Belco holds. Therefore, the company's highest demand is found in African, Middle Eastern and Asian countries. These are the markets that Belco currently works in. The company has successfully worked in Myanmar for 27 years and developed a good reputation there. It also has a large market in Sri Lanka.

What are the key objectives for the company going forward?

As of now, it is undecided whether we should expand further in this industry or diversify into another business. Belco will continue to work with its current markets but the direction of growth is presently undecided. —

Raising the bar: India's generic players compete for market share

India is home to many generics players that have gained a solid reputation on the global stage. Generic manufacturers Sun Pharma, Lupin, Dr. Reddy's, CIPLA, Aurobindo and Glenmark, for example, all enjoy international recognition whilst also holding a prominent position in the domestic market.

The success of many of these companies can be partly attributed to India's relatively low cost of production, which lends itself well to the generics market, which holds affordability as one of its main pillars. In fact, according to the Indian Drug Manufacturer's Association (IDMA), India's cost of production is approximately 60% lower than that of the United States and almost half that of Europe. The size of the Indian market coupled with the country's manufacturing advantages has also attracted top multinationals such as Johnson & Johnson, GlaxoSmithKline, Pfizer and Novartis.

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. Nevertheless, smaller Indian players also have an important part to play both in the domestic market and internationally. Although market entry barriers for regulated markets such as the United States and Europe are extremely high and difficult to reach for many smaller companies, many of India's pharmaceutical drug manufacturers set their sights on gaining market share in the domestic and less-regulated markets whilst they build their reputation, capabilities and capacities before invest-

ing into facilities with a great number of accreditations. After the United States, India's second largest export market is in fact Africa, which falls under the World Health Organization (WHO) regulatory governance, followed by Europe, with a growing focus on markets such as Latin America, Australia and Japan. "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," noted P. K. Gupta, president at the Confederation of Indian Pharmaceutical Industry (CIPI), which represents about 5000 small and medium-scale drug manufacturers. "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."

Pharmaceutical companies, both large and small, are currently suffering due to market crowdedness. Those unable to compete with differentiated product baskets, proprietary technologies or niche areas of specialization must compete primarily on price. This aspect is further enforced in the Indian market through the government's price control measures. "[T]he downside of price control is that drug manufacturers have been unable to invest heavily in innovation and R&D compared to large global multinationals due to narrower profit margins," commented Karan Singh, managing director at ACG Worldwide. "As a result, we lacked sufficient funds to invest in new molecule development and our innovation

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Although the pharmaceutical industry is growing, many products are going off-patent, resulting in changing product dynamics in the next five to ten years. The rapid rate of change creates a challenging situation for SMEs like Premier.

- Ashish Sanghvi,
CEO,
Premier Intermediates

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landscape. Therefore, although India today is strong in manufacturing, we are relatively weak in our innovation. This is a space in our market that has potential to grow." However, high levels of competition and a need to cater to particular price parameters have forced India's pharmaceutical companies to innovate in other ways, par-

Top 10 Generics Companies: (2016 Revenue)

Teva

REVENUE: US\$9.85 billion

HQ: Petah Tikva, Israel

INDIA CORPORATE OFFICE: New Delhi

Mylan

REVENUE: US\$9.42 billion

HQ: Pennsylvania, United States

INDIA CORPORATE OFFICE: Bangalore

Novartis (Sandoz)

REVENUE: US\$9 billion

HQ: Basel, Switzerland

INDIA CORPORATE OFFICE: Mumbai

Pfizer

REVENUE: US\$4.57 billion

HQ: New York City, United States

INDIA CORPORATE OFFICE: Mumbai

Sun Pharmaceutical Industries

REVENUE: US\$4.6 billion

HQ: Mumbai, India

Allergan

REVENUE: US\$4.5 billion

HQ: Dublin, Republic of Ireland

INDIA CORPORATE OFFICE: Bangalore

Fresenius

REVENUE: US\$2.8 billion

HQ: Bad Homburg, Germany

INDIA CORPORATE OFFICE: India

Endo International

REVENUE: US\$2.57 billion

HQ: Dublin, Ireland

Lupin

REVENUE: US\$2.49 billion

HQ: Mumbai, India

Sanofi

REVENUE: US\$2.05 billion

HQ: Paris, France

INDIA CORPORATE OFFICE: Mumbai

Top Indian Generics Companies:

1. Sun Pharmaceuticals

Global Revenue: US\$4.6 billion

HQ Location: Mumbai, India

2. Lupin Limited

GLOBAL REVENUE: US\$2.55 billion

HQ LOCATION: Mumbai, India

3. Dr. Reddys

GLOBAL REVENUE: US\$2.2 billion

HQ LOCATION: Hyderabad, India

4. Aurobindo

GLOBAL REVENUE: US\$2.1 billion

HQ LOCATION: Hyderabad, India

5. Cipla

GLOBAL REVENUE: US\$1.6 billion

HQ LOCATION: Mumbai, India

6. Glenmark

REVENUE: US\$1.25 billion

HQ LOCATION: Mumbai, India

7. Torrent Pharmaceuticals

REVENUE: US\$1.1 billion

HQ LOCATION: Ahmedabad, India

8. Cadila Pharmaceuticals

REVENUE: US\$800 million

HQ LOCATION: Ahmedabad, India

ticularly in process innovation, to maintain an advantage.

A perceived risk brought on through regulated price control is potential impact on quality if companies begin to cut corners. “When exporting products to different countries at different price points, the question arises whether those at lower prices are of the same quality,” explained Rao Vadlamudi, president at the Indian Pharmaceutical Association (IPA).

As in the export markets, there has also been concern over counterfeit and low-quality drugs in the domestic market too. “There has been a lot of recent outcry in the media regarding quality of pharmaceuticals in India,” noted Dr. H. G. Koshia, commissioner at the Food and Drug Control Administration, Gujarat. “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.”

Commenting further on Gujarat’s pharmaceutical market specifically and the work done at its own laboratory, one of the largest in Western India, analyzing over 13,000 samples per annum, Koshia continued: “Our analysis demonstrates that the NSQ (not of standard quality) drugs percentage in Gujarat market is improving year after year; the failure ratio of drugs in the market has come down from 12% eight years ago to 3% at present. This is thanks to our strong enforcement team and quality-conscious manufacturers.”

Indeed, whilst concerns will likely remain in an industry that centers around human care, quality is held as the pinnacle of requirements for drugs entering the market; a prerequisite to any competitive advantages a company might have to offer. “All exporters in India are under some kind of regulatory control,” underlined Vadlamudi. “There are more than 3,000 facilities approved by various regulatory bodies of which 380 are FDA approved. 1,370 are approved by the United Kingdom, European Union and Japan combined. Countries with no regulatory body fall under WHO regulations—over 1,400 WHO-approved facilities exist in India, where the approval is essential for manufacturing products and marketing them to countries that lack strong regulatory networks.”

One of the main challenges faced by India’s pharmaceutical companies is documentation, the most-cited factor for the receipt of warning letters from the regulatory authorities. This can result in a knock-on effect for the rest of the industry. In response, associations such as the IDMA are rolling out training programs and support to companies in meeting these requirements and accessing international markets. India’s better-established pharmaceutical companies continue to pursue strong growth trajectories through diversification and supply chain integration. Careful portfolio selection and streamlined timelines to market are key in ensuring continued success. Many companies are tending towards selection of products with more complex chemistries where they foresee less competition or the possibility of differentiating themselves beyond price competitiveness. —

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The government must collaboratively engage with pharma companies through regulations that encourage business transactions in India.

Getting the western industry familiar with the quality of science, innovation investments, and the focus on quality that exists in India will also be of big help to the Indian life science industry, in them being able to meet the mandatory quality requirements and achieving greater levels of accessibility. Providing the Indian regulatory authorities with the training that may be needed to keep the local agencies on par with the west will also assist in improving local quality standards. Higher transparency from the government agencies will also help the business community. By providing technology for improved documentation processes and building guidance platforms and tools for support, some of the current challenges faced by Indian companies could be overcome.

- Vivek Sharma,
CEO,
Piramal Pharma Solutions



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“Price control continues to be a major challenge in the market. For example, Srikem can no longer sell its silver sulfadiazine molecule in India at all because of the 1972 pricing for its basic materials. This has caused all Indian formulators to discontinue the product. However, Srikem continues to manufacture this product for war-zone countries as the most effective drug for burns.”

- Srinivasan Subramaniam, Managing Director,
Srikem Laboratories

“Government support is present in India but is not very strong. All manufacturing companies in India are self-developed. They develop their own advanced technology and meet the requirements needed for exports. The government could better support the industry by being more supportive of R&D and providing financial assistance to companies for future brand building.”

- Sushil Kumra, President,
Concept Pharmaceuticals Ltd



“The Make in India campaign is a serious attempt towards supporting Indian companies. Initial hiccups are to be expected, and the current adverse reactions are more based on vested interests than fundamentals. GST is also a great idea which will greatly decrease costs including initial investment. These initiatives will make India’s manufacturing and cost base more dynamic.”

- MP Aggarwal, Chairman,
Sajjan India Limited



“The intent and desire to make healthcare more affordable and to improve the quality and reliability of products are brilliant. However, although the principles and direction are principally right, the lack of detail and directional thought have caused the principles to come into conflict. A lot of deliberation and discussion between the government parties and industry players need to take place to properly implement these changes. Both the organized and unorganized sectors need to be focused on creating pathways for improvement. If more time is spent on having these discussions, the results should be positive.”

- Naresh Raisinghani, CEO & Executive Director,
BMGI India



“7 out of every 10 products approved in the U.S. generic market are either made in India, made by Indian companies, or contain raw materials that come from India. Therefore, India’s prominence in the U.S. generic business remains strong. As for the regulatory issues, the expectations of regulators has risen over the years, and companies are now becoming more attuned to these new expectations. Once everyone is more aware, these regulatory issues will cease to exist. India’s dominance in the generic business continues, and nothing has dramatically changed yet in that regard.”

- Rajeev Nannapaneni, Vice Chairman & CEO,
NATCO





Kal Sundaram

CEO (India, EM & CHC Business)
SUN PHARMACEUTICAL INDUSTRIES LTD.

Sun Pharmaceutical Industries Ltd. is a multinational pharmaceutical company manufacturing formulations and APIs. It has presence across the six continents and sells products in over 150 markets.

HQ location: Mumbai, India

Other office locations

(national + international):

Mumbai and Pune, India; Baltimore, USA; Zug, Switzerland.

Company size (number of employees): ~20000 in total

Number of facilities and capacities for core products:

18 manufacturing facilities globally

Revenue (rupees/USD):

Year 2016 : Rs.137 bn / USD 2.09 bn

Year 2017 : Rs.171 bn / USD 2.55 bn

Company type:

Pharmaceuticals (APIs and Formulations)

Key products and services:

Cardiovascular, Anti-Infective, Diabetology, Ophthalmology, Dermatology

Key markets served (% by country or region):

US – 48%; India – 22%; APAC – 13%;

EMEA – 6%; LATAM – 3%; ROW – 1%;

API – 7%

How has Sun Pharmaceutical Industries Ltd. (Sun Pharma) developed since 2015, particularly with the completed acquisition of Ranbaxy?

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 infrastructure to successfully commercialize our innovative pipeline products in the areas of dermatology, ophthalmology, CNS and oncology. As buyers have consolidated, the U.S. market has become more demanding for generics, particularly over the last 12 to 18 months. However it continues to be the most attractive market and we are confident of our continued success in the United States.

Sun Pharma has a number of facilities outside of India. What is the significance of its India operations?

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 which focuses on developing products for global markets. In India, it has a staff of about 9,000 sales representatives in 35 business units that reach about 300,000 doctors and half a million domestic pharmacies. We are the market leader across 11 doctor categories in terms of our prescription share. In the United States, we have significant infrastructure in manufacturing and R&D in addition to commercial structure to support our U.S. operations.

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 and the specialty pharmaceuticals 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. In addition to these, we have ongoing R&D programs addressing over 150 ANDAs in the 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. This is definitely an area not to be overlooked.

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. 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.

How could an increasing emphasis on biologics in the United States impact demand for India's products?

In terms of volume, almost 90% of prescriptions in the United States are generics, which mostly consist of small molecules. Even though biologics are sizeable in value in the United States, they are still quite small in volume. Similarly, looking at the oncology products launched in India in the last 15 years, while they have played a meaningful role meeting some of the unmet needs of patients, overall they continue to be niche both in volume and value terms.

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. Our key goals in India will be to maintain our market leadership. We have successfully partnered with a selected large multinational pharma majors and in-licensed their patent-protected products, and we will continue to focus on expanding those partnerships. We will also continue to develop innovative products for India. —

Lupin Spokesperson

LUPIN

Lupin is a multinational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products and APIs globally.

HQ location: Mumbai, India
Other office locations (national + international): Sun Pharma has presence across six continents
Company size (number of employees): 30,000+ global employees
Number of facilities and capacities for core products: 42 manufacturing sites across the world
Revenue (rupees/USD): FY17 Sales - USD 4.6 billion
Company type: Formulations & API
Key products and services: Specialty products, branded generics, complex generics, pure generics & APIs
Key markets served (% by country or region): USA – 45%, India – 26%, Emerging Markets – 15%, Western Europe & other markets – 9%, API & others – 5%
Exports (%): 74% of Sun Pharma's revenues come from international markets.

Lupin will reach its half-century anniversary in 2018. Where does the company position itself in the market leading up to this major milestone?

Lupin is currently at Phase 2 of its evolution and will reach Phase 3 by its upcoming anniversary. Phase 1 involved Lupin's shift from API exports into domestic formulations and moving into the developed markets. Phase 2 entailed moving up the value curve and gaining in scale in terms of execution, distribution and customer relations. Lupin is now investing in its future to continue growing over the next five to seven years. Our R&D expenditure has grown from 7% to 13.5% of revenues over the last four years. The company has ventured on the path of complex generics and is now focused on the areas of inhalation/respiratory, biosimilars and complex injectables. With rising competition, time to market is very important. We intend to be among the first five players for each of our molecules that are currently in development or undergoing clinical trials.

Where do you see the highest opportunity in terms of new markets or areas of focus?

India currently accounts for about 25% of turnover, the United States for 45% and Japan for around 13%. This year, some of Lupin's large products in the United States have faced increased competition, possibly making its potential percentage slightly lower. These three markets account for around 83% of the company's revenues. For the foreseeable future, the U.S. market will remain the largest. India will continue to grow in the high double digits of the mid-teens for the next five years. Lupin is the sixth-largest generic company in Japan and the government's push for more generic prescriptions will continue to benefit the company.

Over the last four years, the company has entered emerging markets such as Brazil, Mexico and the Philippines through acquisitions. We have a formidable presence in South Africa and are the sixth-largest generic company there.

What is the Lupin's strategy for approaching each market and growing its presence?

The United States remains a fairly lucrative market in terms of profitability. With backward integration and the right throughput coming in, one can make a decent profit from this market. Although high generic price erosion and increased fragmentation of supply

chains are affecting the profitability, the market remains attractive. Despite entry barriers, the upcoming ease in the regulatory environment will be conducive to profit. To achieve incremental revenue growth, the company will focus more on products that are difficult to produce. The R&D cost and pricing of these products will be higher but are balanced out by the stability of the revenue that will be achieved from the exclusivity period and subsequent 90% erosion in value. The company's brand business currently amounts to 8% out of the 17% U.S. revenue. We aim to increase this percentage by solidifying our presence in three key areas in which we have connections with doctors: women's health, pediatric, and a selected base of CNS. In order to grow in the specialty business, we must leverage our existing position and develop a level of ownership in the space to gain long-term value through credibility. We have not ruled out acquisition on this front because patent introductions are a challenge for Indian companies. We are interested in Phase 4 assets that are nearing FDA approval with a balanced risk-reward profile.

What are Lupin's research capabilities and the current areas of focus?

Lupin has very cohesive and comprehensive research capabilities, reflected in its nine global R&D centers. The largest center in Pune has end-to-end capabilities such as intellectual-property development, exhibit batches, biosimilars, bioequivalent and biopharma studies and all R&D activities related to formulation development. Our Netherlands facility conducts research on complex injectables and the Florida center has 55 expert scientists who exclusively conduct respiratory R&D. They receive support from the Pune team and work together to bring the molecules to market. Lupin's R&D operations in Japan have a different setup but also work with the Pune center for large-scale transfers and scaleups. In the recent past, Lupin has been one of the highest-spending companies in R&D, which is in line with the goals the company aims to meet.

An example of a pipeline project is Tiotropium, a multibillion-dollar asset in the respiratory field that other companies have not yet begun clinical trials on. Lupin successfully designed the complicated device and is now pursuing the clinical trial. This product has the potential to reach first-to-file status if it meets the expected endpoints. —

Image: GVK Bio



22

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 geographic area, 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.

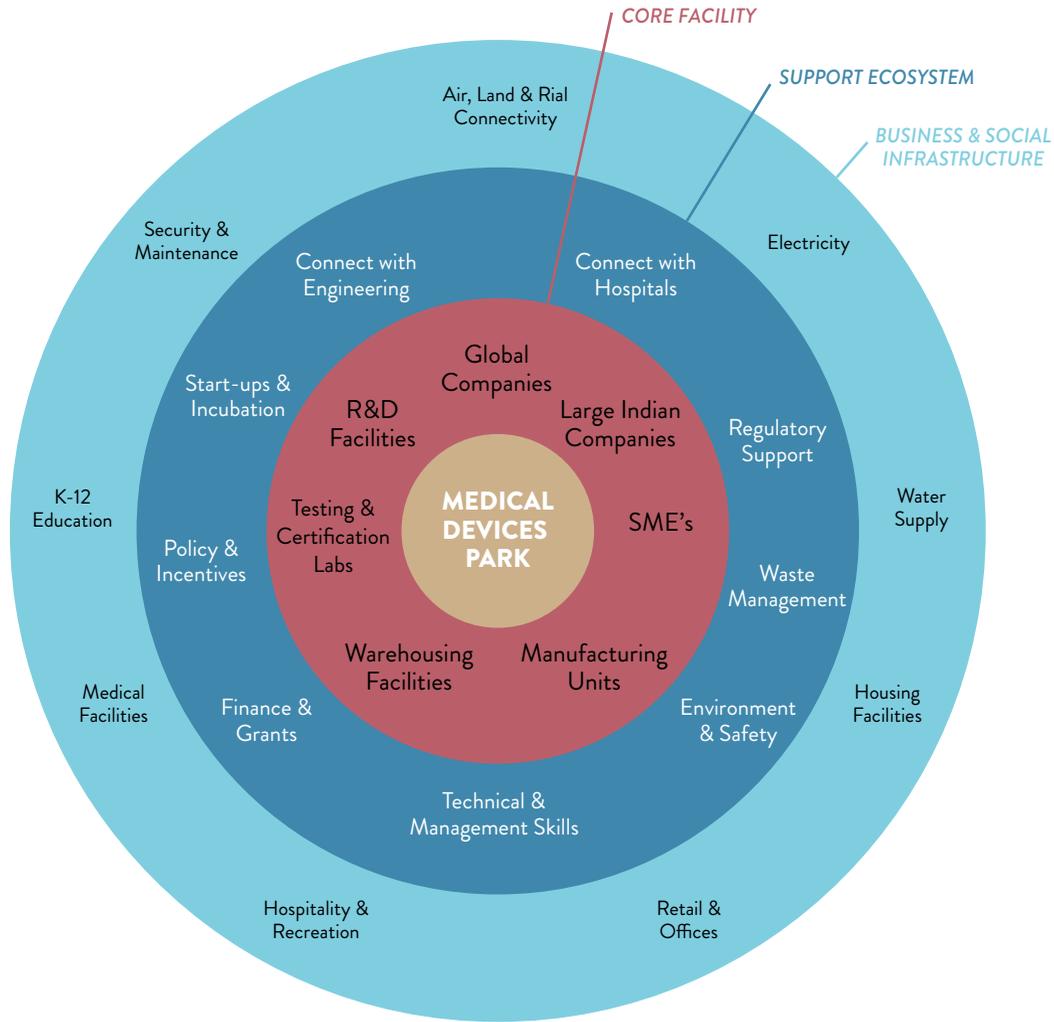
In October 2016, the Government of India announced 3 landmark parks in Gujarat: an API park, formulations park and medical devices park. The state has also recently launched the first mobile testing van in India.

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 a total exports amounting to an estimated extent of Rs 32,600 Crores per annum out of total production of 65,200 Crores per annum. 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. —

MAIN STATE HUBS





TELANGANA'S LIFE SCIENCES ECOSYSTEM

Over **600 pharma and 200 biotech companies** with combined value of **\$50 billion**

1 in 3 vaccines exported globally from India, are **manufactured in Hyderabad**

Home to country's largest animal testing facility and centre for **excellence in bulk drugs**

Best healthcare infrastructure with about **50** public and **165** private hospitals, **4,000** clinics and nursing homes, and **500** diagnostic centres

HYDERABAD'S LIFE SCIENCES ECOSYSTEM

Dynamic ecosystem with strong capabilities in **healthcare, engineering and life sciences**

A number of healthcare innovation centers, incubators, accelerators including the **country's largest technology incubator, the T-Hub**

30+ globally renowned R&D institutions

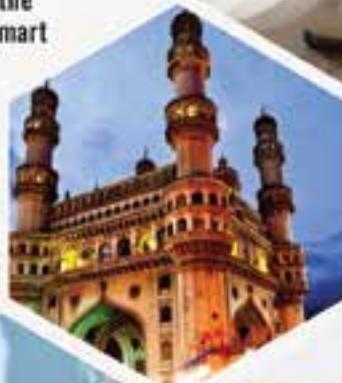
India's **first and largest life sciences cluster** called Genome Vally



TELANGANA Pharma Capital of India and Next Big Destination for Medical Devices

Leveraging the State's leadership position in the Pharma sector, Government of Telangana is developing 'Hyderabad Pharma City' at an area of which will be the largest and first of its kind, smart ecosystem creating a new international benchmark for Sustainable Industrial cities. Situated just about from the Hyderabad International airport, the cluster will provide centralized smart infrastructure solutions for R&D and manufacturing units.

Government of Telangana is also developing a first of its kind park in India for Medical Devices & Electronics, focused on Medical Innovations, R&D and Manufacturing. Hyderabad already has a holistic ecosystem in terms of research facilities, engineering and medical talent, connect between research and medical ecosystem, manufacturing infrastructure, a strong local market, and supply chain and connectivity to all the important global export market. Telangana's overall ecosystem coupled with the Government's commitment, makes us the most attractive and unmatched destination for the global medical devices companies.





KT Rama Rao

Hon'ble Minister for Industries & Commerce, Information Technology, Electronics and Communication, Municipal Administration, Urban Development and NRI Affairs
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. The state achieved GSDP growth of 10.1% in 2016 to 2017, which is higher than the national growth, and the share of Telangana's economy in national GDP has increased by seven basis points in 2016 to 2017. 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. It is thus no surprise that we have consistently ranked number one on the World Bank's EODB ranking of all Indian states. 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. The top four most-valued companies in the world – Google, Apple, Microsoft and Facebook – have set up their largest technology development centres in Hyderabad outside of their headquarters in the USA. Equally illustrious names figure as investors in the manufacturing sector, such as Boeing in the aerospace sector, and a host of top companies in the pharmaceuticals and life sciences sectors.

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. 30% of the medicines exported to the United States from India are made in Telangana with total exports amounting to an estimated Rs. 32,600 crores per annum out of total production of 65,200 crores per annum. Hence, Hyderabad has come to be recognized as the "Pharma Capital of India" and is home to several world-renowned pharmaceutical companies. The life sciences sector in the Hyderabad cluster overall achieved a CAGR of 13.5% and exports registered a growth of 17.3% since 2010, which is the highest among the three major pharmaceutical locations of India: Hyderabad, Bangalore in Karnataka and Mumbai-Pune in Maharashtra.

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

With an initial corpus of about Rs. 1000 crores, 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. As global life sciences companies prefer asset-light business models and are in-

sistent upon long-term leases for their facilities, the government believes that the fund will be a game-changer and accelerate the growth of life sciences sector in the country.

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. TASK is a not-for-profit institute of the Government of Telangana which aims to offer quality human resources and services to the industry. Life sciences is one of the major focus segments of TASK and a number of programs are already being conducted.

What are the plans in the pipeline for further development of life sciences sector?

In order to accelerate growth and respond to the changing global environment for pioneering pharmaceutical manufacturing investments and R&D, Telangana is also developing a first-of-its-kind Pharma City, spread across 14,000 acres at international standards with its thrust on bulk drugs and formulations. With concepts like Zero Liquid Discharge, a common effluent treatment facility, regulatory enclave, 24/7 water and power supply, dedicated land for social infrastructure like housing, entertainment and commerce, the cluster promises to be a highly environment-friendly ecosystem. More importantly, the cluster will have N-block environmental clearance making it easy for the individual industries to set up units directly without having to seek any separate clearances. We are confident that the Hyderabad Pharma City will help our companies become more cost competitive in the international market and reemphasize India's position in the global market.

In addition, a first-of-its-kind park for Medical Devices & Electronics has been launched with a focus on medical innovations, R&D and manufacturing. The overall ecosystem for the life sciences sector coupled with the government's unmatched commitment to enabling ease, quality and cost of doing business, makes Telangana the most attractive and unmatched destination for life sciences companies. —



Jayesh Ranjan

IAS, Principal Secretary, Industries,
Commerce and Information Technology
**GOVERNMENT OF
TELANGANA**

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

Hyderabad has always been known as the top pharmaceutical destination worldwide. 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. It is indeed a very unique cluster and the kind of cutting-edge scientific efforts happening in Genome Valley are just unmatched by any other cluster in India and perhaps Asia. It is home to companies with varied capabilities – pre-clinical research, drug discovery, contract manufacturing, vaccines, clinic research, pharma-biotech research, biologics and agriculture-research.

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

Hyderabad, the capital city of Telangana, is renowned worldwide as a pharmaceutical hub. 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, with total exports amounting to an estimated Rs. 32,600 crores per annum. The upcoming Pharma City will certainly hold pride of place, at par with international standards. With an estimated investment potential of about Rs. 62,000 crores, the project will contribute significantly to the economic growth of the state. Furthermore, the state is simultaneously developing a Medical Devices Park for the benefit of the sector, which is growing annually at the rate of 15%. Suffice to say, the pharmaceutical sector already has a key place in the govern-

ment's growth strategy. The sector has been and will continue to be the engine of growth for the state, with the mushrooming of not just pharmaceutical companies but the complete ecosystem associated with them, including facilities for human resource development. We are committed to leveraging the state's present dominant position for a wide spectrum of beneficial development in the future.

Telangana is very focused on innovation. 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 Government of Telangana is committed to enable and encourage the growth of these and other institutions. 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.

Do you have a final message to add?

Telangana's vibrant life sciences ecosystem coupled with the new initiatives of the government will help strengthen the position of Telangana as the epicenter of the life sciences sector in India and perhaps Asia. Needless to say, companies cannot afford to overlook India in the current times given its extraordinary potential and there cannot be a better alternative to Telangana in India. We are committed to providing the companies with complete support to grow. Our focus is to enable and encourage - enable through world class infrastructure and encourage through proactive government policy and a hassle-free operating environment. I would like to invite global life sciences companies to pay us a visit in Hyderabad. It is our commitment to make things happen for our state's companies. —

GUJARAT

Source: Food & Drugs Control Administration

MANUFACTURING UNITS				
ALLOPATHIC	AYURVEDIC	COSMETICS	HOMEOPATHY	TOTAL
2910	712	391	8	4021

WHO GMP COMPLIANCE		
MFG. UNITS	LOANEE FIRMS	TOTAL
171	143	314

PHARMA TRADERS			
PHARMACIES	WHOLESALE	PHARMACIES & WHOLESALERS	TOTAL
17617	15497	3760	36874





Dr. H. G. Koshia

Commissioner

**FOOD AND DRUG CONTROL
ADMINISTRATION GUJARAT**

In 2015, Gujarat was responsible for 33% of national pharmaceutical production despite containing only 5% of the country's population. How has the industry grown since we last met?

These figures have remained more or less consistent; despite accounting for only 5% of the population and 6% of geographic area, Gujarat is responsible for almost a third of the country's pharmaceutical production. Gujarat's pharmaceutical industry's 2015 to 2016 turnover was US\$6.7 billion, with exports valued at US\$3.06 billion. It is also worth noting that Gujarat accounts for 28% of India's pharmaceutical exports, is home to 40% of CRO companies and is also the manufacturing base of 40% of machinery for India's pharmaceutical sector. The state is also the largest producer of contraceptive pills in the world. The industry's economic impact is also immense, accounting for the employment of around 85,000 people. The state also holds more than 280 WHO-GMP compliant manufacturing facilities and accounts for 53% of the total medical devices manufacturers in the country. Compared to other hubs, our strength lies in formulations.

In what ways are Gujarat's life sciences companies supported at a state level?

Gujarat has many initiatives in place, including a number of subsidies. For example, the Assistance of Capital Investment subsidy offers 10% on companies' loan amount in municipal corporation areas and 15% in other areas. Companies can also seek out assistance for quality certification in the form of a subsidy of 50% of capital cost for installing an Enterprise Resource Planning (ERP) system, obtaining ISO certification, for obtaining WHO GMP certification or for testing equipment and machinery required. The state government also offers assistance on 75% of expenditure incurred for obtaining patents and grants for technology acquisition at the rate of 50% of the cost.

How high are the states current quality standards?

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 statistical 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. In Gujarat, we have one of the largest laboratories in Western India, established in 1947, analyzing over 13,000 samples per annum. Our analysis demonstrates that the NSQ (not of standard quality) drugs percentage in Gujarat market is improving year after year; the failure ratio of drugs in the market has come down from 12% eight years ago to 3% at present. This is thanks to our strong enforcement team and quality-conscious manufacturers.

What measures are taken by Gujarat's government and the Food and Drug Control Administration to ensure only quality medicines enter the market?

When a drug passes through our laboratory, if a drug fails, we send a message to all laboratories to recall the drugs. We have also recently received an award for our e-governance system, pioneered by Gujarat and now rolled out across 16 states, covering 70% of the country. All 3,000 companies across these states are thereby linked, providing direct dialogue between user and regulator. We have 250,000 products in our database.

Do you see price control as a potential threat to companies, making it harder to uphold quality without cutting corners?

Prior to the Drug Price Control Order (DPCO) of 2013, price control was dependent on a company's cost base, from manufacturing to packaging and post-marketing expenses. Now, price control is dependent on the marketplace and the percentage of market share held by companies. If market share is more than 1%, the government takes the mean and fixes the price.

The FDCA launched India's first mobile testing lab in June 2017. What role does this initiative play in increasing access to medicine?

This is the first mobile testing lab in India and is able to test 450 molecules, equipped with handheld instruments for on-site testing.

What plans are in place to support the growth of Gujarat's life sciences industry going forward?

In 2016, the Government of India announced the establishment of three landmark parks in Gujarat: an APU Park, a formulations park and a medical devices park. India's first national government medical devices laboratory will also be established in Gujarat. —





ADAPTING TO GLOBAL MARKETS - INDIA'S FORMULATORS



“With a population of around 2 billion people, the potential of the Indian market can never be underestimated nor ignored. With a low GDP compared to most developed countries, India affords us a large playing ground if the right products are selected at affordable prices.”

- Dharmesh Shah, CMD,
BDR Pharmaceuticals International

Image: Athena Drug Delivery Solutions



Adapting to global markets: India's formulators

As global competition increases, India's formulators are adapting their strategies in order to gain market share and increase their international footprints. Staying attuned to market requirements and arising opportunities, many companies are pursuing new business models in order to remain competitive and differentiate themselves from other market players.

Whilst many generics companies have traditionally pursued molecules with lowest entry barriers and fastest entry routes, a number of companies are now choosing to develop more complex molecules, applying niche expertise and specialized technologies to enter market segments in which they expect to see less competition. By pursuing more complex chemistries, other companies are less likely to follow suit. Furthermore, less competition will generally translate to less pressure on price once the product enters the market.

In another bid to increase competitiveness, drug manufacturers are continuing to vertically integrate for supply security and cost advantages. "Vertical integration is common in the Indian market," commented Ravi Yerra, executive director at RA Chem Pharma, a vertically-integrated pharmaceutical company with capabilities in APIs, formulations and clinical research. "Only a few large manufacturers have not yet entered formulations. Get-

Image: Athena Drug Delivery Solutions



ting APIs can sometimes be problematic, so many companies begin to manufacture them themselves. Half of our formulation projects are integrated in that we also have control over the API manufacture. This is a key advantage. With other projects, we have overseas partnerships to supply different markets and, in some cases, we sell directly into a market.”

RA Chem’s focus is to identify niche, smaller molecules that can be manufactured at an affordable price. The company aims to reach US\$100 million by 2019 and already exports 75% of its products, with Europe as its largest market.

With many Indian companies reliant on China for API supply and the prevalent disruptions resulting from environmental challenges and factory shutdowns, entering independent API manufacture is a logical step for many. As well as increased supply security, companies are then able

to innovate across different steps of the development process and engineer leaner cost structures.

Market selection is of course also hugely important. Markets such as the United States are of course higher value, but market-entry barriers are also higher. “[P]ricing is favorable in the United States over the domestic market, reflected in relatively low sales in India, at around 20% to 30%,” highlighted N. R. Munjal, vice chairman and managing director at Ind-Swift Laboratories Ltd and vice chairman at Ind-Swift Ltd. “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. Despite this, we uphold quality as the culture for our plants and the prerequisite for the chemistry of our products.”

Any company with a long-term vision

“

The global pharmaceutical business is currently very challenging for small second-tier companies, particularly in the regulated market. ANDA filing fees have doubled and they will increase on a yearly basis. The market is also shrinking in terms of the number of existing players for each molecule. Because the market is overcrowded, Espree chooses to manufacture specialized molecules with less competition.

- Swapnil Shah,
Executive Director,
Espree Group



”

Image: Athena Drug Delivery Solutions



must uphold quality above all else, including price. Although regulatory hurdles may be lower for less-regulated markets, it is widely accepted that the patient should remain at the center of the focus. Therefore, removing players that do not uphold adequate standards from the market is a key focus for regulatory bodies.

Although less-regulated markets are more high volume than high value, there is greater opportunity to address unmet market needs with the right market entry strategy and price point. Because affordability is key, companies that are more innovative in their processes and therefore have leaner cost structures are more likely to succeed.

Another market trend sees companies stepping away from the “one-stop-shop” model to more specialized portfolios focusing on particular therapeutic segments or areas of expertise. Many companies are also seeking to add differentiating aspects to their product baskets, particularly through novel drug delivery systems (NDDS).

India’s formulators will continue to find their niche and market entry points to strengthen their international positions and gain market share. For many companies, this will mean adapting and streamlining their business models in order to increase competitiveness and play to their strengths. —



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Randolph C. Alves

Chairman and CEO
ALVES GROUP OF COMPANIES

Alves Group comprises four companies across pharmaceutical formulations and medical devices.

Alves Group started out in 1990 and today comprises four distinct companies. How is the group structured around its main focus areas?

Initially a trading company, Alves Group has grown in scope and size, now encompassing pharmaceuticals and medical devices. In addition, we have brought a new dimension to our portfolio by adding a nutrition aspect - "Make Food Your Medicine" and sustainable living by being in harmony with the environment, with the intention to prevent diseases rather than just treat them. We have two companies focused on medical devices: Goldwin Medicare, our flagship company, and Medicross Instrumente. Randwin Exim is our export house, which deals with exports for our group companies and trading products.

The fourth division is Alves Healthcare, a generic manufacturers with contract manufacturing capabilities for government tenders and exports; we are strategically poised to now enter into brand marketing. Today, we supply about 600 pharmaceutical dosage forms. We have 2 plants that are WHO-GMP-approved and our present target markets are Africa, Latin America, South-East Asia Pacific and a few CIS countries. In India we are presently looking at government tenders and in the critical care space.

What are the focus areas for enhancing the pharmaceutical product portfolio?

We are mostly working on improving the purity profile of existing molecules. 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-occurring plants from which cures can be derived for a range of illnesses and sicknesses, which feed into ayurveda and unani medicines. However, we are planning for

exponential growth in the healthcare space and are planning to set up Pharmaceutical Units in Africa, Latin America, Middle East and look at strategic acquisitions of companies in Europe and the United States.

Could you comment on the dynamics of the Indian medical devices segment?

India is not even in the nascent stages for medical devices and has only just started regulating the segment with its Medical Device Rules 2017, which will be applicable from 1st January 2018. However, the government has not understood the industry; there are over 500,000 medical devices and hardly 800 manufacturers in India. Most of these manufacturers are small, fragmented and disorganized cottage industries operating out of shanties.

The Indian market size is currently about US\$5 billion, of which 70% to 80% is imported. India's medical device segment is likely to grow from US\$5 billion to US\$20 billion in the coming years and this is just the tip of the iceberg; the global market size is about US\$500 billion. Currently, higher-end products are coming from the United States and Europe and, in low end products, India cannot compete with China. The Chinese government has set up modernized factories and adopted technologies to achieve greater efficiency and their labour output is ten times that of India. If India could really take medical devices seriously and take steps the way it gained foothold in the generic pharmaceuticals market, the potential could be huge.

In what ways could the government better support the industry?

The quality and standards of India's fragmented medical device industry should be assessed and raised to international standards where possible. Research centers for medical devices and training colleges



should also be established. The government regulatory mechanism – and their approved technical personnel who oversee manufacturing whether it is Pharmaceuticals or Medical Devices are often inefficient and corrupt. This must be changed and the system must be cleaned up. India should be adopting or developing technology, counting on the innovative intelligence of its Entrepreneurs and support the Industry through simple and friendly rules, efficient infrastructure, reduce interference by Government Officials and take serious steps to make India a “Manufacturing Hub for Medical Devices”. A Road Map conjunct with a coherent strategy backed by a robust mechanism will help India take at least 20% share of the World Market business.

What are the main objectives for Alves Group in the coming years?

We are looking to exponentially grow in the healthcare space as we already have a substantial range of fast moving medical devices and generic formulations that will make our presence felt so as to build a platform for our brand marketing and also give a fillip for our primary products where there are only a handful of players in the world.

It goes without saying that we are already a one-stop-shop both in India and globally. Our dream is to have a presence across all continents, establishing research centers and provide high-quality products at affordable prices. We are looking into acquisitions for inorganic growth moving our headquarters to Ireland. We have a vision to become one of the world's largest companies in the healthcare space by offering the best healthcare solutions and making healthcare affordable and accessible through sustainable living and spiritual healing. —



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N. R. Munjal

Vice Chairman and Managing Director
IND-SWIFT LABORATORIES LTD
Vice-Chairman
IND-SWIFT LTD.



Ind-Swift is a pharmaceutical manufacturing and marketing company based in Chandigarh with its strength in innovative pharmaceutical products.

Ind-Swift has now surpassed its 30th year of operation and ranks within the Top 50 Indian pharmaceutical companies. 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 is into manufacturing and marketing of APIs and advanced intermediates and Ind-Swift Ltd. (ISL) which is into manufacturing and marketing of finished dosage forms (FDFs). Beginning with general molecules in 1996, Ind-Swift Laboratories' focus shifted from 1999 onward to the regulated and mass markets, introducing clarithromycin, which was subsequently approved by the U.S. FDA and became Ind-Swift's largest manufactured product. ISLL has two manufacturing facilities: one state of the art facility in Dera Bassi, Punjab, stretching across 40 acres with a capacity of over 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. 80% to 90% of the Derabassi facility's production is supplied to the highly-regulated and semi-regulated markets. Ind-Swift Ltd (ISL) focuses on FDFs. ISL is present in all markets aside from the United States. By strategically avoiding the U.S. market, we achieved fast acceptance from global customers, who were assured that ISL had no intention of coming to the United States and competing with them.

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. Ind-Swift Labo-

ratories has worked on various molecules and has almost achieved a commanding position worldwide after the innovator. Our key molecules are clarithromycin (antibiotic), fexofenadine (anti-histamine), atorvastatin (cardiovascular) and clopidogrel (cardiovascular). This year, ISLL will cross Rs. 700 crore in turnover with 60% coming from exports. ISLL has one subsidiary in the United States which caters to the North American market and another subsidiary in Dubai which owns the investment made into the Middle East market in partnership with a local Iranian company.

What is the process for deciding which molecules to pursue?

The first factor ISLL considers is who the original developer is and its patent status to avoid likelihood of court disputes later on. The second factor is chemistry; a multi-stage product with complex chemistry is of utmost interest to us as it gives ISLL a challenge and creates a barrier for other companies to follow suit. The third factor is the global demand and potential for growth of the molecule and its therapeutic area. A major achievement of ISLL is that it never had any of its products rejected. This has established the company's brand as being reputable for consistently producing high-quality products.

Are there challenges arising from global regulatory disparities and any differences in the way Ind-Swift approaches various markets?

Global harmonization is important but it is also important to note that the quality system is one across Ind-Swift. Nevertheless, pricing is favorable in the United States over the domestic market, reflected in relatively low sales in India, at around 20% to 30%. 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. Despite this, we uphold quality as the culture for our plants and the prerequisite for the chemistry of our products. There are more than 100 highly qualified staff members working in quality assurance (QA).

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 triggered an awakening call and a realization of the danger of this situation and the need to develop an API policy and domestic clusters. Now that the government has understood these challenges, it recognizes the need for creating clusters, skill-development centers and one-time licensing. A push in policy intervention is anticipated to occur this year. This is a welcome change that gives some importance to the Indian API industry.

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". This trend is expected to increase in coming years. Because companies' formulations are based on a specific API, changing to a different supplier could cost millions of dollars. There is therefore a greater concern for a consistent supply than price. In terms of cost competitiveness, FDF development is in fact cheaper in the United Kingdom and Scotland than in India because of higher competition. In any case, the price of APIs in any FDF is no more than 25%. By having an API plant with last stage production in the United States, Indian companies are able to divide cost and product's availability. Since their API is released in the United States, fewer questions are asked.

What is the vision for both companies and their final message?

Within the next three years, these two companies will be merged to save on administrative costs. The merger will also provide more efficiency in R&D as well as better utilization of technical manpower. Additionally, untapped markets will be tapped, such as finished-dosage forms in Russia. The biggest growth market for finished-dosage forms in the upcoming years will be Europe, with Australia quickly catching up. —

Dharmesh Shah

CMD

BDR PHARMACEUTICALS INTERNATIONAL

BDR is a vertically integrated company manufacturing pharmaceutical APIs and formulations in India.



BDR was established in 2003 as a merchant exporter. How has the company transformed itself into an API and formulation manufacturer in a relatively short space of time?

BDR is a vertically integrated group of companies. Backward integration ensures cost effective molecules, timely deliveries and tight control on the quality of products to our large and ever-expanding clientele, both in India and overseas. Our main thrust and focus is on life-saving molecules and more specifically for cancer treatment. Being a native company, we are aware of the constraints of Indian patients and the difficulties and shortcomings they face and price our products accordingly. With over 32 years of international exposure and vast experience in development and marketing of cheap generic drugs, I have leveraged my knowledge into establishing BDR as a trustworthy alternative generics company in India.

Could you elaborate on the company's product basket and areas of focus?

BDR primarily focuses on five therapeutic categories, with the oncology segment taking the center position, followed by critical care. BDR has a strong presence in the critical care segment and a significant share in the Indian market. Gynecology and neurology (CNS) are the other two segments we are strong in, in addition to dermatology. Going forward, the company has ambitious plans and is working on cardio molecules.

In oncology, BDR has been very successful, particularly with the launch of its prostate cancer drug with a huge price advantage to patients across India. The product has received an overwhelming response from the industry due to its phenomenal price difference with

the originator. Our generic version for breast cancer has also given us and our marketing partners our rightful place with its affordable price tag.

How has the company achieved such great success in international markets, particularly South America and Asia?

BDR expands its geographic reach by concentrating on molecules which are off patent or nearing expiry in respective countries. We first concentrate in the domestic market and, looking at the response, carefully select the international market in conjunction with representatives over there. We have already established ourselves in South Asia, the Middle East and Latin America. Having gained considerable knowledge in these markets, we are now concentrating on pooling our resources to enter Europe and the United States.

With a population of around 2 billion people, the potential of the Indian market can never be underestimated nor ignored. With a low GDP compared to most developed countries, India affords us a large playing ground if the right products are selected at affordable prices.

In terms of R&D, what are the areas of focus for the company?

BDR's dynamic scientific team is the driving force of the company and is key to our success. Our R&D team is currently working on target-based therapies and water soluble complexes since monoclonals and biosimilars may not be affordable to many. At BDR, we are always trendsetters and always concentrating on new chemistry. With the high level of abuse of current drugs, immunity has grown among users and there is an immediate need for new medication and new delivery systems. In tandem with our skilled scientific team, we

are concentrating on unique portfolio selection. While taking care of the evolving situation, this will also offer a niche advantage over other generics players.

What more should the Indian government be doing to drive the industry forward?

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. The Indian government should create special industrial zones specifically 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.

In addition, the government should work closely with the industry to overcome hardships and impracticalities of applying a generalized uniform pricing structure across all medicines. Every medicine has its own costing structure and is unique. To overcome this hurdle, we suggest that government should consider appointing an Expert Committee to evaluate products individually in consultation with industry stalwarts and apply appropriate price control. Since India is already one of the cheapest countries for medicines, companies will find it less lucrative without adequate support in terms of margins and will have to start cutting corners and be unable to re-pool into their R&D activities. Therefore, while price control is important, implementation of this regime in a rationale manner is vital in ensuring its success.

Where do you see greatest opportunity for the company going forward?

The Indian and international markets are equally important to BDR. In terms of international growth, we are not leaving any stone unturned in obtaining the necessary accreditations required in each territory. We have already commenced our work in conducting research into new chemical entities (NCEs) in neuropsychiatry. For example, we are investing heavily into a NCE for Alzheimer's. Our Phase 2 studies should be completed by mid-2018, at which point we will move onto the next phase depending on the outcomes and success of Phase 2. —



Bharat Desai

CEO
BHARAT PARENTERALS

Bharat Parenterals manufactures and markets pharmaceutical formulations for the domestic and international markets.

Bharat Parenterals has been in the market for over 25 years and has extensive contract manufacturing capabilities. Could you briefly introduce the company?

Bharat Parenterals started with a very small facility, which on joining the company in 1986, I realized did not have much opportunity to grow in light of changing market conditions. We therefore established a new plant in 1997 and the original plant was subsequently shut down in 2000. Because the new plant construction exhausted all Bharat's working capital, the company turned to contract manufacturing for big companies and began exporting to African countries. The company gradually built itself back to a more favorable financial position and became debt-free in 2005. It has been growing steadily since. Although last year was a difficult time for

the entire pharmaceutical industry, Bharat experienced little degrowth and in current financial year hopes to return to double-digit growth.

Bharat has a multi-dosage facility that manufactures tablets, capsules, liquids, injections and external preparation. Having everything available under one roof has proven to be an advantage for the company. In 2002, exports barely equated to 10%, with 90% attributed to contract manufacturing and government supply. Today, however, we export to various countries in Central and West Africa such as Ghana, Mozambique, Kenya, Nigeria, Ivory Coast and Uganda. Whilst we no longer provide contract manufacturing services and 60% of business is direct export and 40% is domestic government business, purchased by the central and state Ministry of Health.

How has Bharat adapted to the dynamics of different export markets?

As Bharat's exports initiated in Africa, the company was heavily affected by the worldwide currency devaluation, which affected Africa the most. As 65% of the company's exports were to Africa, the business was impacted and did not achieve double-digit growth for this reason in 2016-17. Strong growth in South East Asia was nullified by the degrowth in Africa. With medication almost doubling in price, it was not a feasible proposition for most. This is why Bharat decided to diversify its customer base. Through the help of its merchant exporters, the company was able to indirectly export to Thailand, the Philippines, Vietnam, Cambodia, Sri Lanka and Myanmar. In the last three years, the company explored the possibility of directly exporting to Southeast Asia and the results have been successful since. Last year, Bharat was able to achieve product registration in the Philippines, Myanmar, Cambodia and Vietnam.

Now, Africa has improved and the market is bouncing back, the currency has stabilized and the devaluation panic has finally subsided. Therefore, Bharat should reach its goal of double-digit growth by increasing market presence and expanding geographic reach through the addition of South East Asia and some of Latin America, along with the existing business in Africa.

Are there any areas of specialization in Bharat's product portfolio for the different markets it serves?

Bharat develops its portfolio according to the markets it serves. We are currently focused on three different segments. The first is antibiotics, which is our core strength. Antiretrovirals (ARVs) are the second segment, largely supplied to Africa. Registration of ARVs in Latin America is being explored as exports are already underway to Paraguay, Uruguay and Peru. Last month, Bharat received registration and an order for seven of its products from Chile, Peru and therefore will be starting exports to these countries towards the end of 2017. The company will be expanding to Costa Rica, Honduras and Columbia soon. In the next two years, Latin America should become a very good market for Bharat's exports. The third segment in the portfolio includes anti-hypertensives and cardiovascular products.

What sets Bharat's products apart from its competitors'?

Bharat's current edge is in its pricing and quality. On both fronts, the company is ahead of its competitors and hopes to receive a good market share because of it. There are only about eight - nine multinational ARV companies targeted in Latin American countries, and a market size of almost US\$ 8-10 Billion. As there is no local manufacturing in Chile, Bharat should have a good entry into this market and its neighboring regions thereafter.

What is the vision for Bharat going forward?

Bharat is mainly focused on generics but has a few new drug-delivery products in development for existing molecules. Two of these products have received international patents, but the approval from Drug Controller General of India (DCGI) is still pending. By 2020, the target is to reach Rs. 500 crores. A new plant is also being built to support a venture into South Africa specialized ARV, oncology for regulatory market and compliance to PICS. Another target is to build a dedicated facility by 2019 to enter the regulated markets of the United States and some parts of Europe. —

Venkat Ramana

Regional Sales Manager
MICRO LABS

Micro Labs is a multi-faceted healthcare organization functioning across APIs and formulations.

Micro Labs was established in 1973 and has grown to leadership positions in several segments while ranking fourth in prescriptions in India. Could you briefly introduce the company and how it has grown over the years?

Micro Labs is a family-owned business that had a focus on moving into finished-dose formulations and hence created offices across the globe, including in Europe, the United States, the Philippines and Russia. The company aims to use its capabilities to manufacture high-quality formulations for India and the global market at affordable prices. Currently, Micro Labs has over 400 branches in India and is one of the top companies in prescription medicines in the country. The company's brand, Dolo-650, is the number-one prescribed brand in India.

What are the areas of portfolio focus today?

Micro Labs is currently focused on ophthalmics, anti-infectives, antidiabetes, antihypertensives, anti-inflammatories and antibiotics. Its facilities are approved for APIs and formulations, and the company is working towards expanding its product portfolio in specific areas. As per pharmaceutical guidelines, Micro Labs has independent facilities for different therapeutic categories. The facility in Goa is focused on oral dosage forms and the API facility in Bangalore is focused on ophthalmics and butyrolactone. Micro Labs is present across the entire value chain from research and development to API and formulations. It has around 400 scientists working on different dosage forms across the three R&D centers, which all have state-of-the-art equipment and the most modern processes for product development. There is a lot of focus on innovation at Micro Labs because the company believes in empower-

ment and teamwork with each regional team working as an independent strategic business unit that contributes to the growth of the entire company. The team of scientists and their extensive expertise have helped Micro Labs grow into a vertically-integrated structure with supply security and streamlined costs. Until last year, the APIs were only for internal consumption. However, once Micro Labs developed a portfolio of 40 to 50 products, it began marketing APIs in the international market and received a very good response. The company is focused on niche and high-value products to provide regulated markets with high-quality medicines and low-impurity profiles and offer documentation and all the necessary approvals at its sites, including U.S. FDA and EDQM.

Which markets are the greatest focus in terms of demand?

Micro Labs has a huge presence in the Indian market, which accounts for 60% of business. It also has a large presence in the European market and is one of the strongest suppliers to markets like France, where it has strong partnerships for supplying finished formulations. Micro Labs is known as the leading company for medicine supply to Israel and the Middle East and is very well known in African countries such as Nigeria and the Democratic Republic of Congo. All of Micro Labs' products are branded generics. We file about 15 to 20 ANDAs in the United States every year and are partnering with marketing agents to start building our portfolio in the U.S. market. Four to five products have been launched in the commercial markets so far.

How strong is the reputation of Indian companies in markets such as the United States at the moment?

Most Indian companies have resolved their

warning-letter situations, but they must maintain their documentation and quality standards so that the country can rise above China in the global industry. Most of the products that are imported in the United States come from the U.S. FDA-approved plants, so the quality is already certified by the FDA. Many Indian companies are also consolidating into one entity, leading towards the establishment of a clearer common standard across the Indian pharmaceutical industry.

What are some of the areas of current focus in Micro Labs' pipeline?

There is a large focus on injectables and improving our ophthalmic range of products with drug delivery systems for oral solid dosage forms. We have partnered with a couple of companies in the United States to build up our injectable portfolio.

What are the objectives going forward and the strategy for growth of the company?

Micro Labs recently declared entry into the U.S. market where the company aims to grow and build its formulations portfolio. Another area of growth for APIs is the Japanese market; Micro Labs will gain approval for a couple of products over the next few months and manufacture products as per the Japanese quality and standard requirements. Additionally, the company strives to partner with innovative companies to support them with Micro Labs' products.

Since many of Micro Labs' products will expire around 2024, it plans to connect with other companies to become their first source for relaunching. With an existing presence in 100 countries, we plan to pursue opportunities in other countries to ultimately achieve presence in every country of the world in a few years' time. Furthermore, we have acquired an US\$80 million company focused on APIs, finished dosage forms and CRO services. We aim to expand and grow that business further and double the sales in the next couple of years. Finally, we strive to expand into new areas that will allow us to have our own in-house manufacturing of intermediates. We are acquiring a manufacturing company for intermediates in India in order to follow the Made-in-India trend and reduce reliance on China, where documentation is not as readily available. This step will help us become a fully-integrated US\$1 billion company over the next few years. —

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 tend 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 8 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

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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



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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 have helped ZIM to make its presence felt in niche markets with premium products.”

The company has a number of proprietary technologies, of which its oral film technology, 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





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- Licensing out
 - Oro-dispersible
 - Sublingual
 - Sustained Release/Enteric Coated
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EMAIL:

Global: awilliams@ddsathena.com
 Europe: patel.shradha@ddsathena.com
 MENA: patil.arniv@ddsathena.com
 South East Asia: wasim.shaikh@ddsathena.com

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. “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 more-often-than-not 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. 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 NDSS 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

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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



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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.”

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. —



Alexandre Williams

—
 Managing Director
**ATHENA DRUG
 DELIVERY SOLUTIONS**

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 Athena Drug Delivery Solutions is a drug delivery company specializing in the new formulation of oral solids.

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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.

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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.

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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.

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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.

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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.

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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. —



Anwar Daud

Managing Director

ZIM LABORATORIES

Established in 1989, ZIM Laboratories is a drug delivery solutions provider.

Could you start with a brief introduction to the company and how it developed along these lines?

Coming from a background in formulation development and technology transfer, I promoted ZIM Laboratories in 1989. Although beginning with a very conventional oral solid product portfolio, we slowly shifted focus to develop and manufacture differentiated products for niche markets, positioning them as innovative drug delivery solutions. The initial target was various modified drug release technologies such as sustained release, site-specific release and delayed release, ensuring cost competitiveness and covering a wide range of generic therapeutics so that the offerings could have wide marketability. Over time, these new drug delivery solutions became the company's true strength and today we are known for our innovative products manufactured using innovative process technologies. The fact that these products are manufactured using customized processes make them more affordable, which has been ZIM's objective over the years: "To make quality health care affordable through drug delivery solutions focusing on patient convenience and adherence". We have been able to develop proprietary technologies for manufacturing controlled multi-particulates, taste-masking of bitter drugs, solubilisation of poorly soluble APIs, stabilisation of sensitive molecules and so on. 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 have helped ZIM to make its presence felt in niche markets with premium products.

How extensive is the company's current offering?

ZIM is capable of using multiple aspects of drug delivery solutions for producing a wide range of differentiated generics in semi-finished and finished formulations in oral solid dosage forms encompassing tablets, pellets, directly compressible granules, taste masked powders/granules, dry suspensions and fast dissolving thin films. Our products are currently marketed in over 40 countries. Our understanding

of regulatory requirements of all these regions help us to mark our presence very strongly in these geographies. The company has filed many patent applications in various regions across the globe for protecting its differentiated products and processes.

With an approach towards differentiation through technology platforms, we use our delivery technologies to create drug delivery solutions and differentiated complex generic products for local mid-sized companies so they may compete against imported high-technology-based medicines in the ROW and emerging markets. We also support these mid-sized companies with dossier applications, regulatory queries and marketing queries so that they can leverage on our R&D strengths as needed. Because of product affordability, these companies can compete with their large technologically-capable competitors in the market very well. Having such a wide variety of solutions in our technology platforms, we are able to propose a wide range of drug delivery solution and products to meet our customers' diverse needs. We also aim to partner with pharmaceutical companies for joint development of products that can be launched in specific markets under various licensing arrangements. Primarily a B2B company, ZIM is also diversifying itself into a B2C company for select products and for select markets.

How important are the regulated markets for potential growth of the company?

The regulated markets are very important to ZIM and we will attempt to enter these markets in a gradual manner. Presently, ZIM possess EU GMP accreditation along with certification from many other ROW and emerging markets and is in the process of leveraging these accomplishments. In the last two years, ZIM has received a lot of interest from Europe. The company's products have a large opportunity to grow in these markets because affordability is the key today irrespective of the region and conventional product offerings are under intense pricing pressure due to aggressive competition.

A big opportunity for ZIM also is in the

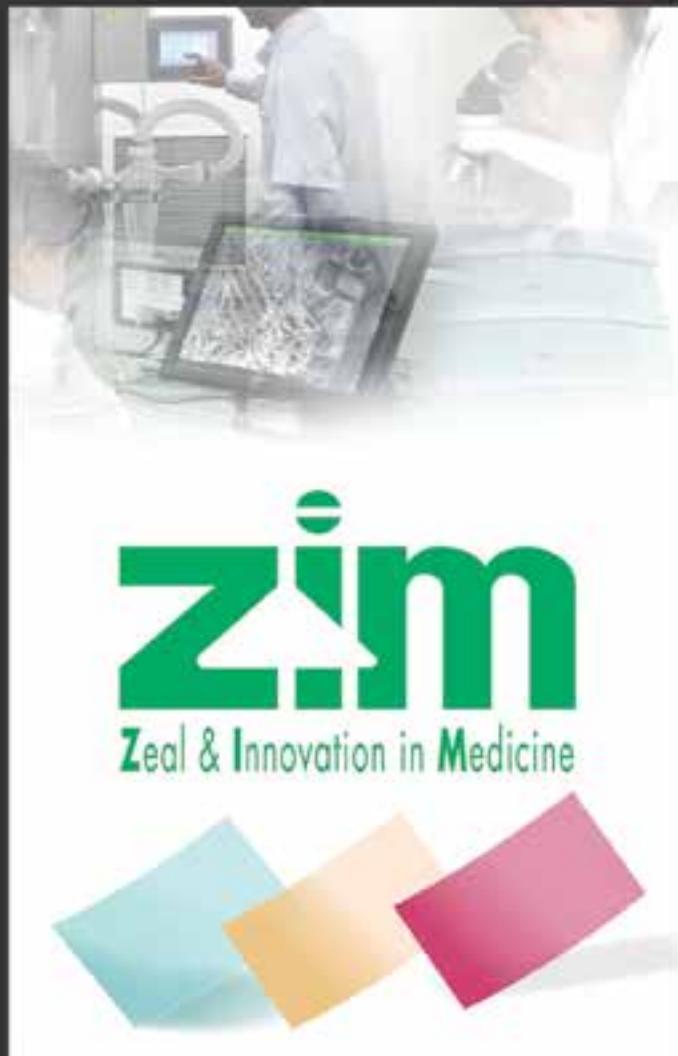
ROW and emerging markets of the Middle East, Latin America, CIS, SEA and Africa. Because of cost pressures in the ROW markets, ZIM is in the process of establishing marketing partnerships with local companies in various markets for distribution of products in these markets. We intend to expand initially into Europe and then enter the United States within the next five years. We also have five collaborations for co-development and manufacturing for companies in Europe and our ODS product basket is being positioned towards entering the European and U.S. markets. We are closely examining alternate routes to ANDA filings and considering nutraceuticals as a secondary strategy to enter these markets.

Could you provide some further insight into ZIM's proprietary technologies?

ZIM aims to develop differentiated products for special need patients with improved convenience. Achieving controlled release of APIs without changing the stability is our core aim. Various technologies are used for various patient needs – for example, taste masking is the essential part of all the formulations intended for children and aged population. Over the years, ZIM has developed expertise in molecular complexation, coating, addition of proprietary taste modifiers and hybrid techniques to mask the taste of very bitter drugs, holding a unique position in this area. Similarly, many poorly soluble drugs have been developed into oral solid dosage forms with desired dissolution and controlled release characteristics. Our recent Thinoral® technology produces thin film dosage form that dissolves instantaneously on the tongue. It obviates the need of water, thus enhances 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. 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.

What are the key objectives for ZIM going forward?

We envision ZIM being a leading technology company with an expanding product portfolio, continuing to specialize in novel ways of drug delivery and providing its drug delivery solutions worldwide. —



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Jayesh Choksi

Managing Director
GUFIC

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GUFIC Group comprises a number of divisions operating across APIs, formulations and herbal products.

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 are 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. —

Dr. Ketan Patel

Managing Director
TROIKAA
PHARMACEUTICALS



Troikaa Pharmaceuticals is primarily focused on Novel Drug Delivery Systems (NDDS).

Could you introduce the company and its key areas of focus?

It was Troikaa's diclofenac injection, of which the company also developed a painless version two to three years later, that originally caught the attention of the market; we began selling over 500,000 doses a month. This came as a revelation to the kind of respect innovation commands. Although Canada and Europe then began developing diclofenac, Troikaa improved its own version and created the Dynapar AQ IV bolus injection, which is the number one brand on the market today. Troikaa's diclofenac injection has been filed for approval with the European Union and clinical trials should start in March 2018.

Today, Troikaa has a strong product base in gynaecology and a product basket comprising almost all drugs related to cardiology, including injectables and critical care. The company also has a line of 120 injectables with a separate sales force to supply all the hospitals with this product.

How supportive is India's innovation environment?

More can be done to support innovation in India. 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. Patent protection needs to be improved, but it is highly unlikely that any changes will take place.

In India, there is somehow the belief that top quality is feasible at throw-away prices, imposing narrower margins on companies such as Troikaa.

What are the key objectives for Troikaa going forward?

Troikaa's new plant has embarked on the U.S. FDA approval journey for topicals. Aside from this, the predominant focus will be on marketing our innovations in almost every part of the world. —

Sachin Patel

Director
THEMIS MEDICARE



Themis Medicare manufactures APIs and formulations, mainly focused in injectables.

Could you briefly introduce the company and its areas of focus?

Themis Medicare was formed under the Themis group of companies in 1969 as a joint venture with a Hungarian trading company, Medimpex. When Themis Group separated, Themis Medicare maintained its joint venture, which later translated into a relationship with Gedeon Richter when it acquired Medimpex. This relationship continues to be very strong, and Themis began a new joint venture with Gedeon in 2006 to specifically manufacture APIs and intermediates for their European and worldwide markets. This relationship is very important to Themis, and we hope to build similar relationships with other companies to support them in manufacturing APIs for their global requirements.

In what areas is Themis' R&D focused?

Themis is exploring current products in the injectable area where there is potential for improvement. Painless injectables are the first area of focus. Other R&D projects include intramuscular injections, again with a focus on pain reduction. Another challenge being addressed is lyophilized injections in oncology; these are high-potency chemo products that are dangerous for hospital staff to handle. Themis is working on ready-to-use or ready-to-dilute versions of these products and converting the powders into refill syringes, vials or ampoules. This transformation will reduce the need for hospital staff to perform the currently required reconstitution. We are also developing suspension-based injections.

Where do you currently see the greatest opportunity geographically?

Themis is focused on expanding into the European and ROW markets within the next year. Besides the less-painful intramuscular injections, the biggest opportunity for the company lies in the United States.

What are the objectives for the company going forward?

Anesthesia will be key for growth in this market; Themis is currently the second-largest supplier for this product in India and growing faster than others. The second area of focus is differentiated injectables and discovering how to license our strategies and form partnerships in this area. —





BUILDING BLOCKS: APIS, EXCIPIENTS AND SPECIALTY CHEMICALS



“The percentage of India's contribution to the global API business is currently low. However, the scope is immense and there are many opportunities, especially in niche and complex-molecule areas where regulatory challenges are quite high.”

- Shireesh Ambhaikar, President Operations, API,
Wanbury

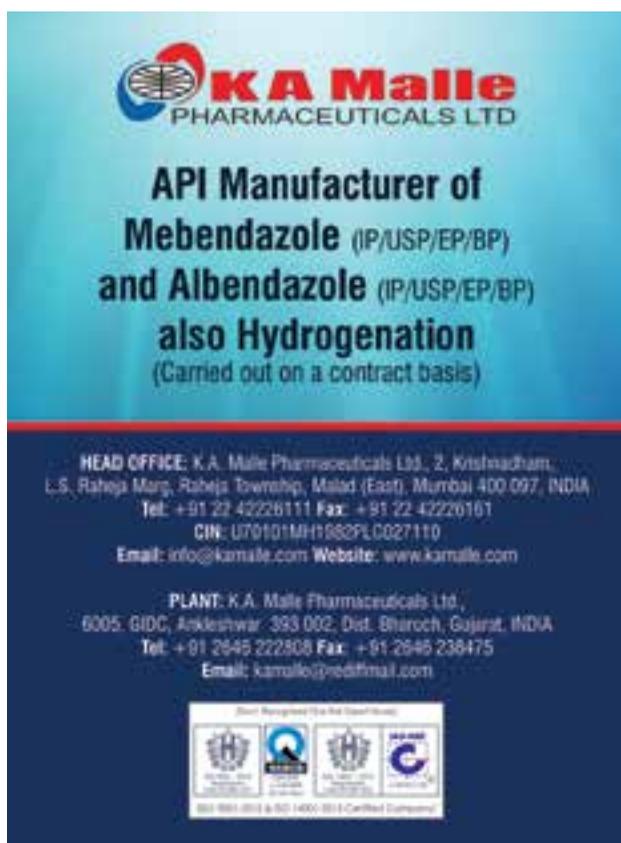
Strengthening India's API industry: Evening out the playing field

India's strength in pharmaceutical formulations depends on a high-quality, cost-efficient and reliable supply of the required raw materials and building blocks. With 7.2% market share, IBEF places India as the third-largest global generic API merchant market in 2016.

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 mebendazole and albendazole. "Supply is often unreliable and quality is often of a lower standard than can be sourced in the Indian market."

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 opera-



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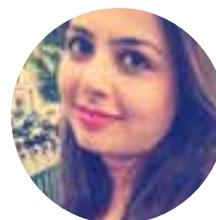
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When comparing quality, India is preferred as an API source among developed countries, but improving quality automatically increases cost.

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



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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

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tions, 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 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. The government has indeed already begun to act in this direction, allocating special economic zones (SEZs) to support manufacturers. Benzo Chem Industries, which specializes in intermediates for the pharmaceutical and agrochemical industries, has erected its Dalhej SEZ manufacturing facility to take advantage of the tax break offered. “In China, the manufacturing cost is beginning to rise because many of the companies are moving to Europe, the United States and India,” argued Gaurav Mohatta, Benzo Chem's marketing director. “India is the most favorable location for manufacturing due to strong supply access across all industries.” 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

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Manish Jain

Director
MAC-CHEM



Mac-Chem was established in 1991 and now has a global presence, also selling into the highly regulated markets. Could you start with a brief introduction to the company and outline its key milestones?

Mac-Chem specializes in APIs, while its parent company, Naprod Life Sciences, is specifically geared towards formulations. Today, Mac-Chem has a presence in around 25 countries and a U.S. FDA-compliant facility. It has also acquired accreditation from the EDQM, ANVISA Brazil, COFEPRIS Mexico and KFDA and awaits a U.S. FDA audit in the next two years. The business is oncology-focused for both formulations and backward-integrated APIs. Mac-Chem supplies APIs to the top 15 oncology players in India for export to the European markets. Currently, exports comprise about 25% of the business. Half of the remaining 75% at one point fell under in-house consumption but this has now decreased to 10%. Our investments have been mostly geared towards exports, especially to the European markets, to hopefully achieve an export figure of around 50% in the next couple of years.

Could you elaborate on the company's API portfolio and infrastructure?

Mac-Chem's portfolio centers around niche molecules in the API market, where volumes are relatively low. For example, one kilogram of a particular API could potentially serve the entire global market. Therefore, the strategy of the company is to acquire molecules that are new to the market with a technological barrier of complex chemistry. Mac-Chem is the only player in India that manufactures certain molecules. Many molecules in oncology are going off patent and the company is almost ready to acquire these molecules when the opportunities arise.

What are the contributing factors to Mac-Chem's success in the oncology field?

Mac-Chem is a family-owned company established by technocrats. Rather than focusing on gaining more customers, we have consistently focused on optimizing our operations. Some of our success can be attributed to our lyophilization proficiency, which we have built on since the early 1990s, a time when only multinationals had begun working in this area of complex engineering. Currently, Mac-Chem has 10 lyophilizers. Another key contributor to Mac-Chem's success has been the management's great focus on top quality since the 1980s. The investment into quality is demonstrated in the company's acquisition of LIMS from LABWARE a quality control software that is only otherwise used in India by Cipla. Another example is our QMS software for document control and process management from MASTER CONTROL, a software produced by a U.S. company and used by the U.S. FDA, that no other India company has implemented.

Mac-Chem is constantly making changes towards better operations. We believe that quality is not to be circumvented but used as a tool to achieve better outcomes. Another key advantage is the vertical-integration of our services.

How do you see the dynamics in India changing in terms of competition from countries like China and Japan?

Competition dynamics are changing but so are the policies in India. With its new policies, the Indian pharmaceutical domain is now beginning to have a level playing field. The policies are much more advantageous to companies like Mac-Chem. India differentiates itself by having a vast pool of English-speaking graduates that are readily

available, giving it a technical strength advantage over China. Although India is still about 60% dependent on China for raw materials, the push from the Indian government towards manufacturing raw materials in India should change that dependency in the next few years. Removing this dependency is currently being given serious thought at Mac-Chem.

What are the areas of focus at Mac-Chem in terms of portfolio development and R&D?

The company is mainly focused on moving new molecules into the market through different methods. One area of investment is into new molecules. Mac-Chem's R&D expenditure for APIs is at about 7% to 8% of revenue. 20 of our 30 R&D staff members have PhDs. The second method is building a sustainable quality culture. While there are still several areas to address, the software we have purchased will enable us to reach our quality goals.

Where would you like to see the company in a few years' time?

We hope to increase our exports to account for 50% of sales, which will mainly be acquired from Europe, the United States and the semi-regulated markets. We have been working directly with distributors but have not seen much success. We are therefore changing our approach according to the specific market of interest. We are looking to appoint our own representatives to work in the European markets and serve the company remotely. We believe this will make a big difference in our sales growth in years to come. —

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lose the opportunity to capture the global market. India has become the 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 ef-

fluent 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.”

Other companies have begun to differentiate themselves through greener chemistries and environmentally-friendly practices. Sajjan India, for example, prides itself on its environmental friendliness. The company is an Indian contract manufacturer with expertise in large-scale production of active ingredients, electronic chemicals, specialty chemicals and intermediates with applications in agrochemicals, pharmaceuticals and dyestuff. “We have even discarded some products that were producing unmanageable amounts of waste,” commented MP Aggarwal, Sajjan’s chairman. “We have been awarded by the Gujarat government for being one of the top companies for environmental compliance and waste-reducing innovation.”

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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 finance 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)



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Rajesh Bhayani

Director

APEX DRUG HOUSE

Apex Drug House was established in 1975 as a trader and importer of APIs and today manufactures and supplies pharmaceutical formulations worldwide.

Could you briefly introduce the company and its current core competencies?

The issuance of the Liberation Policy by the government of India in 1994 allowed Apex Drug House to begin exploring the international market. Within its first year in exports, the company acquired clients in Africa. From 1999 onwards, Apex expanded its global growth in different continents. Since 1999, Apex excels in manufacturing a complete range of formulations in tablet, capsule, syrup, cream, ointment, injectable, soft gelatine capsules and ophthalmic solutions.

Apex was founded with core values of Commitment, Quality and Service. Our team has expertise in developing stable formulations and has in-depth knowledge

of regulatory requirements of different countries and its laws. Apex has commenced with its own manufacturing facility in Gujarat, Daiwik Pharmsphere in the beginning of 2017. The imminent EU GMP, UK MHRA plant is geared up for inspections in 2018. The first phase of the factory will focus on topical preparations, with an aim to become one of the top five players for topicals in India, in the years to come.

What prompted the decision to build a facility of Apex's own after so much time?

Apex has been catering to clients with number of supporting manufacturing units. Apex has its own team of FDA-approved chemists that manufactures the batches, analysis and examines 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. Some countries prefer to manufacture directly through Apex for security and liability reasons. Whilst Apex completely manages its contract manufacturing, we also wanted to accommodate this preference with our expansion plans.

Initially, the factory will provide contract manufacturing for Indian as well as multinational pharmaceutical companies. All validations are complete and we have started contract manufacturing at this unit. Once the audits are complete, we can set off with production for export markets which has stringent regulatory guidelines.

In terms of the product portfolio, are there any areas of increased demand different markets?

Apex's portfolio is quite large thanks to various supporting manufacturers with loan licensing facilities. While every country has different therapeutic areas of focus, stress, diabetes and cardiac products are in high demand everywhere. Even lifestyle requirements, such as weight loss measures, have seen an increased demand. Many companies are moving from pharmaceuticals to supplements or cosmetic products because they are less regulated. Based on the current trends, lifestyle drugs, such as blood pressure control, will be in highest demand in the future.

The latest technologies in dosage forms

are Multiple-Unit Pellet System (MUPS), sustained release and mouth-dissolving tablets. Apex is looking into adopting MUPS technology in the future to offer smaller companies quality products at affordable prices. We also have strong capabilities to develop herbal formulations. The company offers mono and poly herbal substances through its group company HerbaPex Botanicals, which have been sold in the United States for the last 2.5 years.

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. Apex also takes into consideration that some customers, particularly in remote areas, cannot read and use other visual aids to identify a product, such as color of the packaging or capsule or the shape of the tablet. We offer packaging which helps them to identify contents or products.

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?

Apex has been growing every year. 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. —

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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. Supply is often unreliable and quality is often of a lower standard than can be sourced in the Indian market.

- Rahul Bhomavat,
President,
K. A. Malle

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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 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



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Jagadeesh Babu

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 Founder & Chief Executive Officer
BIOPHORE

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 Biophore is a manufacturer and developer of niche pharmaceutical products for the generics industry.

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Biophore has been in the market for about a decade and grown a great deal, from 10 chemists to over 300 scientists. What are the company's current areas of focus?

Biophore is currently focused on expanding from simple APIs to specialty and complex APIs. The company currently has close to 75 drug master files (DMFs) and plans to file at least 15 more each year going forward. The main regions of focus are the U.S. and European markets, where Biophore aims to expand into a global pharma company and provide APIs to the global market.

Biophore's first fully-owned manufacturing facility will be launched in 2018. How are the developments for the facility progressing?

Biophore's new API facility should become operational by May 2018 as the construction is progressing very well. This facility will be capable of easily manufacturing 50 products. Currently, Biophore is an acting partner in two manufacturing companies, which both manufacture exclusively for Biophore: Sionc Pharmaceuticals and Azico-Biophore. The new facility will be situated with the other two at the Pharma City Industrial Park in Vizag, focusing on products where a high level of capabilities is required, such as peptides and oncology. It will also cater to processes with high infrastructure requirements, such as lyophilization, dialysis and ultra-filtration. The idea will be to address segments that most API companies are not interested in.

70% of Biophore's business comes from the U.S. market. How is the remaining percentage distributed?

The remaining 30% of business comes from Europe. However, even though Biophore can grow significantly in the United States, it plans to reduce its total U.S. business dependency to 50% in order to focus on other markets such as Europe, Canada, the United Kingdom, Australia and New Zealand. The company also aims to move into the formulation business wherever possible. The key focus will remain on APIs while Biophore plans to manufacture formulations and collaborate on selected products with customers.

Many Indian API companies see a lot of competition from other new companies

on price, especially Chinese ones. What gives Biophore a competitive edge over other players?

From Biophore's inception, the focus has always been on differentiating the selection of products it offers. Because of this differentiation, the company is not competing with the big Indian manufacturers. We have found our own niche in which to excel. Biophore's success is the result of several factors. One is having a high level of focus on research and innovation through product development and portfolio selection. Other key differentiators are the creation of intellectual property and working with different collaborative manufacturing partners to develop more products and file DMFs.

What are the current areas of R&D focus?

Biophore continues to focus on complex generics where the products are difficult to categorize or there is a high potential for creating intellectual property. Other major R&D focuses are peptides and any products that can be differentiated from other API manufacturers. It is important to always focus on different areas than those everyone else is focused on.

How could India's API industry be better supported to make it more competitive?

More support is still required from the government. Compared to Chinese companies and the government support they receive, the support Indian companies get from their government is relatively low. More incentives need to be provided for conducting research; otherwise, R&D expenditure will remain in the single digits in India. The government needs to encourage Indian companies to focus on research.

One of the Biophore's visions is to become one of the Top 10 API players in the industry. What are the company's plans to achieve that vision over the upcoming years?

The current challenge in the API industry is intellectual property. Therefore, the company is focused on products that are in Phase 3 or close to approval to create intellectual property and be ready for the generic market from the first day. By implementing this plan, Biophore will continue along its path to attain a Top 10 position over the next five years. —

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Mac-Chem's portfolio centers around niche molecules in the API market, where volumes are relatively low. For example, one kilogram of a particular API could potentially serve the entire global market. Therefore, the strategy of the company is to acquire molecules that are new to the market with a technological barrier of complex chemistry. Mac-Chem is the only player in India that manufactures certain molecules. Many molecules in oncology are going off patent and the company is almost ready to acquire these molecules when the opportunities arise.

- Manish Jain,
Director,
Mac-Chem



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that it may be labeled as "Made in the USA"," commented N. R. Munjal, vice chairman and managing director at Ind-Swift Laboratories and vice chairman at Ind-Swift. "Because companies' formulations are based on a specific API, changing to a different supplier could cost millions of dollars. There is therefore a greater concern for a consistent supply than price. In terms of cost competitiveness, FDF development is in fact cheaper in the United Kingdom and Scotland than in India because of higher competition. In any case, the price of APIs in any FDF is no more than 25%. By having an API plant with last stage production in the United States, Indian companies are able to divide cost and product's availability. Since their 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. —



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DMFs Filed

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US DMFs available for reference

120

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20

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2

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Jayant Tagore

National President

**BULK DRUG
MANUFACTURERS
ASSOCIATION (BDMA)**

Established in 1991, the Bulk Drug Manufacturers Association (BDMA) represents the majority of bulk drug manufacturers of India as a coordinator and catalyst between the government and the industry.

Could you briefly introduce the association and the role it plays today?

BDMA originated from the need for a common platform for the fast-growing pharmaceutical industry in India. It created a representative body to approach various government agencies within the states of the respective units and the central government. Initially, the association faced many issues with import, export and drug regulatory matters. Today, however, some of the services BDMA provides include facilitating policy matters, clarifying orders passed by the governments, requesting changes in policy and requesting interpretations of laws. BDMA acts as a facilitating association without actively representing any individual companies. When there is a broad issue that many manufacturers are facing, BDMA discusses the issue with the concerned government department and seeks to resolve the issue.

How have the industry's dynamics shifted in recent years?

Good availability of talent has helped in spurring the growth of the industry. Indian companies have developed faster than other global pharmaceutical companies due to their skilled manpower, their reputable intelligence in chemistry and math and the favorable policies put forth by the government. The Indian pharmaceutical industry contributes to about 10% of India's health care costs. Hospitalization, doctors, post-operative and post-recovery costs are significantly higher than the cost of pharmaceuticals being used for treatment.

How balanced is the framework of the government policies in terms of being favorable to the industry while promoting accessible and affordable medicine to as much of the population as possible?

India's infrastructural development has not kept pace with the needs of the industry. As a result, the industry has either moved out of the country or curtailed its activity and restricted it to certain therapeutic areas that make more economic sense to pursue. Therefore, some therapeutic sectors have been dropped or overlooked because the return on investment does not commensurate with what would be obtained from other sectors. Consequently, India's dependence on imports of inexpensive or outdat-

ed commodities has increased as a result of the lack of manufacturing of particular medicines within the country.

How would you describe current dynamics for APIs in the Indian market?

India had to manufacture the drugs that were remunerative for the country. 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. For this reason, India currently imports the products it does not manufacture from China. However, this is not a reflection on India's capability of producing them.

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.

2015 was already indicated as the "Year of the API" but not much has changed since. Are APIs still a focus area for the government?

The focus is even greater, particularly in light of recent geopolitical changes regarding the government's concerns for health security in the form of basic medicines for the common man.

What are the main objectives for BDMA going forward in terms of its role in driving the industry?

BDMA is working towards getting drug controllers to harmonize their way of thinking and will potentially enter into an agreement with USP and EP to establish a globally-accepted uniform regulatory mechanism for agency approval. This would be a positive method to ensure safety and quality medical care. A message to the government is to nurture the existing domestic manufacturers, ensure they are being taken care of, pay attention to their requests and give them what they need and deserve. —

Prakash Patil

Chief Managing Director
AARTI DRUGS



Troikaa Pharmaceuticals is primarily focused on Novel Drug Delivery Systems (NDDS).

Could you provide a brief introduction to Aarti Drugs and its position in the market today?

Aarti Drugs began as an API manufacturing company in 1979 and today focuses on pain management products. Aarti is a domestic leader in most of the products it currently manufactures and a global leader in antidiarrheals and antibiotics, while the company has a presence in almost all therapeutic categories.

Aarti Drugs has a U.S. FDA-compliant facility for API production and is otherwise GMP-approved as well. Which geographic regions are of greatest focus for the company?

Aarti has a strong presence and a large share in the domestic market but the export market accounts for 60% of current business. The company has a good presence in many countries around the world but has yet to firmly ground itself in the U.S. market. One of Aarti's plants is expecting an FDA inspection very soon and another will potentially have an inspection next year. The company currently exports specialty chemicals to the United States from other plants as they do not require the same level of accreditation. We are looking to increase our presence in export markets because the domestic market has become quite saturated and we already have 70% to 80% share of the current products on the market.

What are the current areas of R&D focus for Aarti?

Aarti currently has 17 API products under development and has filed 30 formulation dossiers in seven countries, of which four are now in business and three in the advanced stages of approval. These international businesses are more profitable than Aarti's entire domestic formulation business.

What are the main objectives for the company over the next three to five years?

While the price erosion and recession in the past two years has hindered Aarti's growth, the company is predicted to grow by 50% next year and to double capacity within the next three years. Our current objective is to diversify our API offering and potentially expand into other industrial chemicals as well. —

Madhu Utamsingh

Managing Director
HEMMO
PHARMACEUTICALS

Themis Medicare manufactures APIs and formulations, mainly focused in injectables.

Hemmo Pharmaceuticals has been in the market for over 35 years. How has the company developed over this time?

Hemmo Pharmaceuticals is a family-owned company that began in the trading business, where pharmaceuticals were bought from around the world and sold in India. One of the products that was bought and traded was Oxytocin. However, there was a constant push from the Indian government for companies to manufacture in the country. Because this required specific technology, Hemmo partnered with the Central Drug Research Institute (CDRI) and began manufacturing Oxytocin from as far back as in 1979.

With the intention of expanding capacities for Oxytocin and also add other peptides to its basket, Hemmo invested in a new, fully cGMP facility which was commissioned in 2006. The company also

invested in technology for additional peptides. Currently, Hemmo is licensed to manufacture 23 peptide products. Our goal is to add two new products every year; this is becoming more challenging due to the increasing complexity of the newer peptide products today. We are ranked in the top five peptide-manufacturing companies worldwide and considered to be the leading peptide API manufacturing company in India.

What are Hemmo's current areas of R&D focus?

We have a multi-step approach to R&D and try to ensure that we will be among the earliest players for each product we develop. Hemmo also works with companies focusing on clinical projects for new molecules. Hemmo focuses on products going into Phase 2A, where some amount of scale is required.

What are the key objectives for the company going forward?

We are focusing on launching complex peptides from internal resources and aim to establish an independently-housed research center with access to more significant scientific equipment. We will increase our R&D investment going forward to exceed our goal of two molecule launches per year. Formulations related to peptides is an area of longer-term interest. It will be a huge step up but it is definitely the direction to move in. We are open to creating new partnerships to achieve that goal in the future. —

Shireesh Ambhaikar & Prashant Menon

SA: President Operations
API

PM: Director – India Formulations
WANBURY

Wanbury has a strong presence in APIs in the global market and domestic branded formulations.



SA



PM

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Could you briefly introduce the company and its background?

SA: Wanbury is widely known as a metformin company; the company is one of the largest metformin manufacturers in the world, producing about 10,000 tons per year across three facilities in India. Today, metformin and tramadol are Wanbury's two biggest pillars in the API business, and the company has a good position in the market for other products such as sertraline. There are now plans to strengthen the portfolio with new product offerings.

Two of Wanbury's API plants are FDA-approved. How extensive is the company's global reach?

SA: In terms of portfolio scope, we are mainly interested in antidiabetics that will complement the metformin business. As metformin is the mainstay in the management of diabetes and India is one of the leading growth contributors to diabetic cases globally, this market should always remain open to us. Nevertheless, the customer base is widespread across the globe.

What distinguishes Wanbury from its competitors?

PM: Our specific technological know-how

and our product composition differentiate us from our immediate competitors, especially in brands within the gynecology and orthopedic spaces. Another area of focus is improvement of our sales team's skills. While the API business requires very little contact with customers, the formulation business allows for meeting with doctors and other potential clients.

How has the Indian market developed in recent years?

PM: The market has grown a great deal. 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.

What more should the Indian government do to help the industry grow?

SA: 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. 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. —

Rohit Bhuwania

Managing Director
CORAL DRUGS

Coral Drugs manufactures and supplies a wide range of pharmaceutical ingredients.



pharmaceuticals, initially with a specific focus on oncology, manufacturing only one product for Europe for a couple of years as a side business. In 1999, the company's chemical business was sold, and its increased interest in the pharmaceutical business resulted in the addition of a couple more oncology products to its product portfolio.

In 2004, Coral selected steroids as its focus at a time when Cipla was the only company with strong interest in this therapeutic segment, focusing specifically on inhalation. In 2008, Coral invested in a brand-new facility also focusing on steroid manufacturing. The company received U.S. FDA approval in 2010 and EU GMP approval shortly after.

Outside of India, in which markets is Coral most active?

While the business had previously been reliant on exports for 70% of business, volumes are now distributed more equally between the domestic and international markets.

What are the areas of R&D focus at Coral Drugs?

Coral's focus on R&D prompted the construction of its new R&D facility two years ago. A lot of

research is now done internally and the company has also expanded its capabilities to offer contract R&D and contract manufacturing services.

Could you elaborate on Coral Drugs' manufacturing infrastructure?

Coral conducts all its work in-house and all of its product lines are equipped with particle engineering capabilities. The other value-add at Coral is the analytical support. Our well-equipped lab has multiple testing capabilities, including in areas such as particle size and microbiology. We are also developing new capabilities for more enhanced studies of particle shape and polymorphism. Additionally, we can offer our clients impurity synthesis and reference standards.

Where would you like to see Coral Drugs in a few years' time?

Coral will remain focused on APIs, rather than integrate downstream and risk becoming a competitor to its customers. Coral plans to build two facilities for different therapeutic segments in 2018. The company strives to expand the R&D space and partner with innovative companies from around the world to learn their research methods. —

Building blocks: Excipients and Intermediates

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 feedstock 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.

Although there has not been such a great emphasis on innovation in pharmaceutical excipients in the past, this could be changing as the industry begins to tend towards functional excipients. Many companies are focusing more on excipients to address issues such as segregation, low dissolution and poor bioavailability. Arihant In-

nochem, for example, is a Mumbai-based distributor and promoter of pharmaceutical excipients, personal care, home care and food ingredients, focusing on functional excipients with a focus on innovation. "Apart from the main excipients, Arihant also offers binders, fillers and protein agents," outlined Jinesh Shah, Arihant Innochem's managing director. "These products mainly act as adjuvants for the main products in the company's portfolio. An example is tartaric acid pills, which work as functional excipients. They form the heart of the formulation rather than just adding value to the drug. Other examples are bioavailability enhancers and solubility enhancers, as well as functional coatings. Arihant is also working on gaining two new Japanese suppliers and one Swiss supplier with different matrices to add value to its product portfolio."

Arihant Innochem now plans to develop its involvement in excipients linked to devices, such as inhalers, so that the material can be simplified and the delivery system can be much more economical and effective.

The sourcing advantage

When it comes to pharmaceutical feedstock, one of the key advantages for India's oleochemical producers working on products with 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

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Harish Shah

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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%. For FY 2016 to 2017, it has achieved a turnover of Rs.1150 cr US\$177 million. In the last three years, the market has plateaued somewhat because the Indian pharmaceutical industry has been under duress. As a result, exports to the U.S. market, the most significant in the world, have been relatively flat in the last two years. Since we do not manufacture any products but instead move in tandem with the formulation industry, our growth has been impacted. Despite this setback, we have managed to beat the trend through organic growth and consistently acquiring new partners. 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. Aside from the number of plants, India has the right mindset, training and experience to assist the industry in maturing and maintaining FDA standards.

Signet imports excipients from its worldwide partners. Could you elaborate on the company's supply chain and partnerships?

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. Due to the extensive process of commercializing new pharmaceutical products, Signet has well-defined agreements with all of its partners, assuring long-term commitment and guaranteed progress towards successful business. We have a stellar track record and have never lost any of our current 29 partners.

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 func-

tion with reduced process time. Oral dosage forms continue to be most common, with strong trends developing for Osmotic Drug Delivery System technology (ODDS). This technology is a specialized coating that sustains the release of a drug over a 24-hour period and is now beginning to be offered by more companies. Other trending dosage forms are nasal and inhalation. Sometimes grouped together, these forms are gaining growth in the industry. Whilst oral delivery systems are very common, injectables have also gained a lot of popularity. 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.

How extensive is Signet's involvement in the biotechnology space?

Signet has a significant presence in the biotechnology space and a broad project range for downstream processing, such as stabilizing drugs after purification. There is a growing presence of research biotechs in Indian cities such as Hyderabad, Bangalore and Pune and there is now a growing number of biotech divisions within pharmaceutical companies. Signet also works with nutritional companies by providing many raw materials for nutritional products such as fillers, gummies and minerals that increase bioavailability.

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. We are currently very active in the Middle Eastern markets, as they are widely considered extension markets to India. We are also very active in Bangladesh; it's pharmaceutical market is similar to India's 20 years ago and is doing very well. It is merely a matter of time before it reaches a substantial size.

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. —

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Excipients are increasing in importance, and functional excipients are coming into the picture, which is where the main growth for Arihant will come from. Arihant also sees derma and topicals to be the upcoming opportunity fronts for the next decade. Because a lot of APIs being developed have solubility issues, solubilizers will be a big focus for Arihant in the coming years, as well as specific excipients that would closely react with APIs to modify and form the complete functionality of a product. Additionally, the company is also on the lookout for certain niche excipients to add to its portfolio basket wherever there is an opportunity to add value.



- Jinesh Shah,
Managing Director,
Arihant Innochem

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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. —

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Anil Jain

Director, S.A

PHARMACHEM

S. A. Pharmachem is a specialty food and pharmaceutical manufacturing and marketing company supplying innovative specialty ingredients.

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. Pharmaceuticals account for 80% of the business. 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. Lactitol, an equivalent to lactulose in dosage and mechanism of action, is a monopoly product that S. A. Pharmachem created, which produced 26 brands in the Indian market and a combined market value of around US\$30.1 million. An increasing segment of focus is probiotics in both pharmaceuticals and nutraceuticals. S. A. Pharmachem is pursuing both types of probiotics for their different uses of therapeutic and overall health maintenance. Whilst this business is growing in importance within our portfolio, it is yet to reach maturity.

Vitamin premixes are another offering within the pharmaceuticals and nutraceuticals portfolios. An absolutely new concept created is a new product called 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. 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. This entire concept further allows our customers' pharmaceutical factories to be converted into smaller setups of just the tableting line. Customers simply need to dry-blend the premix and compress it, allowing for a reasonably large pharmaceutical factory in an office building.

Why has this not been more widely offered in the past?

This concept has never been developed mainly because of regulatory challenges, of which S. A. Pharmachem has faced many. The regulatory agencies are requesting quantitative analyses of each ingredient included in the premix. Now that the R&D work has been completed, the biggest challenge facing S. A. Pharmachem is from the researchers.

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 have recruited a number of very qualified employees in quality assurance and Regulatory. We expect to achieve 100% growth by 2021 through our new activities and some new products. We are also working with Japanese partners; whilst their quality systems are the best in the world, they still have some way to go in terms of documentation, an area in which we can provide support. We will be looking for further distribution partners across Asia.

Our GLAS division has a public testing laboratory and regulatory services for DMF preparation, third-party audits and support in setting up projects. 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. —



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Jinesh Shah

Managing Director
ARIHANT INNOCHEM

Arihant Innochem is an importer and distributor of high-quality specialty chemicals.

Could you briefly introduce the company and its core areas of focus?

Arihant Innochem began as a chemical trader, initially called Arihant Trading Company. Around 1994, the company started moving into specialty chemicals and exploring specialty ingredients and excipients for the pharmaceutical industry. In 1996, it partnered with a US company, BF Goodrich to promote carbopol polymers for pharmaceutical applications. In 1999, the company began to distribute cellulose derivatives and continued to grow by adding prominent Japanese suppliers. Today, the company has evolved into one of the leading distributors of pharmaceutical excipients, personal care and home care ingredients.

In 2014, the company was christened as Arihant Innochem, with the same quality but a renewed identity as a supplier of innovative excipients. Arihant has an application lab that supports its personal and home care businesses.

How important is the pharmaceutical segment to the overall business?

The pharmaceutical segment accounts for a major share of Arihant's business. Arihant's excipients are focused in the regulated markets because they are all USP/EP compliant and having Excipient DMF. The company provides technical and analytical support and has an excellent regulatory team to support its customers in the regulated markets with their regulatory documentation. Apart from the regulatory team, Arihant has a quality assurance team that takes care of the quality and analytical aspects of the products. As these niche products have very specific applications; it is intrinsic that we provide a lot of technical support to customers to understand how to use them and what benefits they can extract from them.

In what ways does Arihant add value for its clients?

A major advantage offered by Arihant is that it manages the stocks necessary for the entire supply chain. Secondly, Arihant regularly updates and educates its customers about excipient usage by providing local training and technical support. Customers come to us because of this complete value package we add to our products.

Some of Arihant's excipients address issues such as segregation, low dissolution and poor bioavailability. Could you elaborate on the product portfolio and key new products in high demand?

Apart from the conventional excipients like binders, fillers and lubricants, Arihant has a wide array of "functional excipients". These products mainly act as the main part of the formulation along with the API and is the integral part of the dosage form. An example is core pellets, which work as functional excipients. They form the heart of the formulation rather than just acting as an adjuvant to the drug. Other examples are bioavailability enhancers and solubil-

ity enhancers, as well as functional coatings. Arihant has also collaborated recently with a new Japanese supplier and one Swiss supplier with different matrices to add value to its product portfolio.

Arihant is now focusing on functional excipients. The market is changing – the role of excipients is becoming very important going forward. Arihant is closely collaborating with its key customers in promotion of these excipients.

The global pharmaceutical excipients market is projected to reach US\$8.1 billion by 2021. Where do you see most opportunity coming from?

As India has become a pharmaceutical hub for the world, the generics business will grow. Excipients are increasing in importance, and functional excipients are coming into the picture, which is where the main growth for Arihant will come from.

Arihant also sees derma and topicals to be the upcoming opportunity fronts for the next decade. Because a lot of APIs being developed have solubility issues, solubilizers will be a big focus for Arihant in the coming years, as well as specific excipients that would closely react with APIs to modify and form the complete functionality of a product. Additionally, the company is also on the lookout for certain niche excipients to add to its portfolio basket wherever there is an opportunity to add value.

What are the key objectives for Arihant going forward?

Our vision is to become a knowledge-based one-stop solution for our customers by continuously strengthening our excipient basket and gaining more speciality and functional excipients. We plan on moving into nutrition as it is becoming a very important segment of the future. We are also focusing on excipients for injectables and some food ingredients. The next logical step for us is to develop our involvement in excipients linked to devices, such as inhalers, so that the material can be simplified and the delivery system can be much more economical and effective. Additionally, we are trying to expand geographically and convert Arihant into a regional distributor in the next five years. —

The government has good schemes and initiatives but lacks the application and implementation of these plans. The biggest challenge for the Indian API industry right now is data integration. India is also lacking in digitalization. Hence, the prime minister's efforts towards increasing digitalization will be helpful.

- Snehal Devani, Managing Director,
Suyog Life Sciences



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. This is definitely an area not to be overlooked.

- Kal Sundaram, CEO (India, EM & CHC Business),
Sun Pharmaceutical Industries Ltd.



On a global level, India is stronger than China in drug master files (DMFs). India mainly imports from China because of the price advantage. However, many Indian companies are becoming more integrated and stronger in APIs, and many of them have successfully entered regulated markets in countries around the world. It is important for Indian companies to develop their own strength within the country in case of any sudden shifts in international markets. We must be self-reliant and not so dependent on external markets for supply.

- Sushil Kumra, President,
Concept Pharmaceuticals Ltd



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With its new policies, the Indian pharmaceutical domain is now beginning to have a level playing field. The policies are much more advantageous for companies like Mac-Chem. India differentiates itself by having a vast pool of English-speaking graduates that are readily available, giving it a technical strength advantage over China. Although India is still about 60% dependent on China for raw materials, the push from the Indian government towards manufacturing raw materials in India should change that dependency in the next few years. Removing this dependency is currently being given serious thought at Mac-Chem.

- Manish Jain, Director,
Mac-Chem



India's API market will definitely undergo a great deal of growth in the coming years. Although environmental issues exist in both India and China, larger global companies want complete control over their supply chain to avoid any unexpected disruptions to their key API businesses and the consequent expenses. Therefore, these companies are focusing on working with fewer companies in the API space to ensure a more secure supply chain. We have established a secure supply chain relationship with Gedeon Richter, for example, and many more Indian API companies will adopt a similar model in the future.

- Sachin Patel, Director,
Themis Medicare







THE INDIA ADVANTAGE: SERVICE AND SUPPORT SECTORS



“India is definitely very competitive compared to other countries; the cost structure is 33% to 50% lower in certain areas than in other parts of the world.

While China has increased in competitiveness in many ways, India holds a significant advantage in its knowledge capital. The combination of high intellect with the ability to produce cost-efficient throughputs is one of India's biggest differentiators from its competitors.”

- Naresh Raisinghani, CEO & Executive Director,
BMGI India

Image: Lambda Therapeutic Research



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The India Advantage: Growing demand for contract services

As well as realizing the benefits of India's competitive manufacturing environment through sourcing local suppliers and establishing manufacturing bases in the country, demand for contract services are also on the rise. Outsourcing trends continue to pick up pace globally as pharmaceutical companies respond to pressure for faster and more cost-effective routes to market. As contract service organizations become a more widely accepted component of supply chains across all areas of development, India is a pertinent choice for companies looking to streamline their cost structures. Primarily due to high levels of competition and price erosion, many Indian companies have focused on optimizing processes and accelerating development timelines to achieve quicker market entry at the lowest possible cost, all the while maintaining the required quality levels. "India is definitely very competitive compared to other countries; the cost structure is 33% to 50% lower in certain areas than in other parts of the world," asserted Naresh Raisinghani, CEO and executive director at BMGI India. "While China has increased in competitiveness in many ways, India holds a significant advantage in its knowledge capital. The combination of high intellect with the ability to produce cost-efficient throughputs is one of India's biggest differ-

entiators from its competitors. The country's key export drivers are I.T. and pharmaceuticals; knowledge is a key addition to both industries.”

However, India's contract research and manufacturing services (CRAMS) market is highly fragmented, with more than 1,000 players. The CRAMS industry is, nevertheless, expected to reach US\$ 18 billion in 2018 and expected to witness strong growth at a CAGR of 18% to 20%, according to IBEF. Some proposed policy changes may see a decline in India's contract services, however. “One thread of discussion has been the mindset that each company should produce its own product and that contract manufacturing should be halted,” highlighted P.K. Gupta, president at the Confederation of Indian Pharmaceutical Industries (CIPI). “The government's view is that very high levels of production will not help improve the quality of drugs. CIPI has argued that contract manufacturing is present all around the world, so there can be no harm to continue with this model if capacity is available. Without the option of contract manufacturing, capacity and volumes will be limited. Pharmaceutical companies supplying many products would have to vastly increase their manufacturing capacities but then risk having excess capacity if demand decreases. Therefore,

this new policy may be detrimental to big companies like Sun Pharma.”

As companies in developing countries pursue more aggressive internationalization strategies, global players and companies in more developed markets will continue to look to India for its cost advantage. As well as manufacturing, this also extends to R&D, with an emphasis on development. “R&D costs are low in India,” noted Nadir Godrej, managing director at Godrej Group “Hence, many global companies conduct R&D here. Many state that the costs of their Indian centers are about a third of the costs of their other centers globally. 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.”

In response to rising pressure to identify new drugs and competition from generics along- side increasing R&D costs, outsourcing of research is also increasingly common. Grand View Research expects the global healthcare Contract Research Organization (CRO) industry to reach US\$45.2 billion by 2022, highlighting stringent timelines as a key driver for increased demand for outsourcing of research activities. Perhaps surprisingly, several Indian companies are stepping up to the mark, offering not only high levels of expertise

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There are many small companies starting up but they do not invest enough so they cannot grow. In this day and age, companies will not utilize the services of a CRO that is small or lacking in terms of infrastructure or highly qualified human capital. Entry barriers for new companies in this space are therefore much higher.

- Manni Kantipudi,
CEO,
GVK Biosciences



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but relatively low associated costs. “There is a significant opportunity for contract research in the Indian market,” commented Rohit Bhuwania, managing director at Coral Drugs, a manufacturer of steroids, oncology and a few hormonal products, also offering contract R&D and manufacturing services. “The expertise is readily available in various therapeutic segments and, combined with a younger work force, it is a great destination for pharma majors for contract research. Coral provides the entire scheme, from lab to pilot and then finally GMP manufacturing. And customers appreciate this valuable and differentiating service at Coral because they can perform a pilot-scale test of their process at an affordable cost in order to improve it before moving into GMP.”

As the source of a great deal of innovation begins to shift away from large companies with varied pipelines to small biotech startups and universities, opportunities for

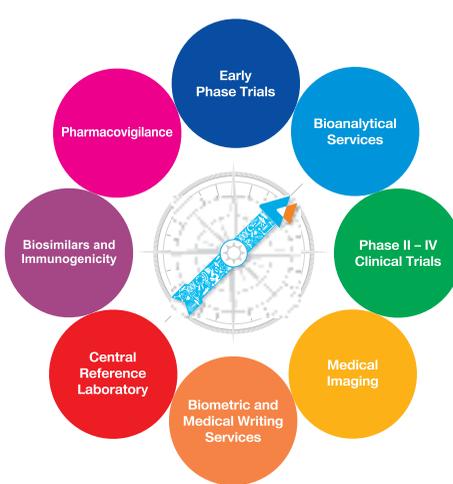
contract research organizations (CROs) are on the rise. Leading the way on several fronts in India is GVK Biosciences (GVK BIO), the country’s largest drug discovery services company by revenue, employees, customers and productivity. “There is huge potential,” affirmed Mani Kantipudi, GVK BIO’s CEO. “The big trend in the United States is what can be seen in Boston and San Francisco – the investment going into drug discovery and development is mostly being fed into small startups with no laboratory of their own. These companies have good ideas and knowledge but prefer to stay virtual. This is the where GVK BIO has its strength.”

The challenge for a company like GVK BIO is managing such a large number of customers. “We work with about 400 companies and these are primarily small and mid-size biopharma customers,” said Kantipudi. “This can be a challenge because, in spite of the potential risk factor, one

customer accounting for 50% of revenue is much easier to manage. Different customers require different infrastructure and approaches to project management.”

To allow the company to interface with a higher number of customers, GVK BIO has recently released its eCule mobile application. The app allows a prospective client to upload a picture of a chemical entity and request a quote for how much its synthesis would cost. The project can then be taken forward via the app, communicating five key milestones over the course of the project.

With outsourcing on the rise across the board globally, India’s contract service organizations are well placed to capitalize on growth in this segment. Companies worldwide will continue to pursue more streamlined cost structures, selecting reliable partners to form this integral part of their supply chains, and are likely to view India favorably for the foreseeable future. —



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Bindi Chudgar

Director

LAMBDA THERAPEUTIC RESEARCH

Lambda Therapeutic Research is a leading CRO with facilities in India, North America and Europe.

Could you briefly introduce the company and its global operations?

Lambda Therapeutic Research is a leading full-service CRO in the Clinical research domain. Headquartered in Ahmedabad, its global footprint encompasses strategically located offices in Mumbai, India, Poland, the United Kingdom and Canada.

Lambda's global infrastructure comprises of an impressive tally of over 700 clinical beds dedicated to Phase-I clinical studies and bioequivalence studies. It has conducted multiple Phase-I, bioavailability / bioequivalence and/or drug-interaction studies of over 300 different chemical entities. Our proven track record on the global stage has earned us repeat business from our existing client base.

We strive to stay ahead in the CRO field by continuously upgrading our infrastructure and expanding our service portfolio. Therefore, over the years, we have diver-

sified into Late Phase Clinical Trials, specializing in Oncology trials, Medical Writing, Medical Imaging, Data Management & Biostatistics, Immunogenicity Assay development and Pharmacovigilance.

Lambda operates across many geographies. How do market requirements and dynamics differ?

Since its inception in 1999, the company has grown both organically and inorganically and has gone on to establish a truly global presence. Our prime locations worldwide ensure ground-level support in addition to easy access to a competent blend of human expertise and state-of-the-art infrastructure in the most efficient yet cost effective way. We have BA/BE and Phase-1 facilities in India and Canada helmed by dedicated and experienced teams who are well versed with the regulatory requirements of all the regulated markets in the world.

We have been pioneers in adopting 21 CFR compliant U.S. FDA electronic data capture platforms across the various phases of clinical trials, seamlessly bridging globally scattered sites and labs. We have successfully imbibed software technology as an infrastructural necessity and raised its prominence in the field of clinical research v/s competition.

Could you provide some further insight into Lambda's bioanalytical services?

We have one of the largest infrastructure across the world in the bioanalytical domain. With over 850 validated methods and more than 10 methods at various stages of development at any given point of time, we are perfectly geared up to handle bioanalytical requirements. Our bio-analytical experts are capable of developing and validating new methods in a time span of approximately 06-08 weeks.

This gives us an unparalleled advantage with respect to timelines which is a key differentiator and looked upon favorably by all generic companies.

What are some of the advantages and

challenges of conducting clinical research and trials in India?

India has been a favored destination for clinical trials over the past few decades and we do not anticipate any paradigm shift in this thought process since the availability of patient pool and unmet medical needs that India offers is unparalleled in the world. Now with the ease of approvals and streamlining of process in the regulatory environment, we are very optimistic of continued growth.

What are the main objectives for Lambda going forward?

People are the backbone of our success. We believe that an engaging and empowering work culture is the key to building a strong scientific team. With periodic training, the company strives to sharpen the skill and help its employees stay abreast with the latest know-how. We strive to inculcate strong beliefs and capabilities that help challenge conventional ideologies and expedite trials for our clients.

Another important area and where Lambda is directly involved is extrapolation of indications. Global requirements of PK, biodistribution and immunogenicity to be evaluated in different patient population among other parameters are some areas where we need attention.

We have harnessed our strength of ultramodern infrastructure, cutting edge software technology and human capital of more than 500 scientists across the clinical development hierarchy to carve a niche and become an undisputable leader in the Indian CRO space. The early phase deliverables are path breaking while the late phase deliverables are in the space of NDSS and biosimilars. Furthermore, we aim to be the preferred partners in the development of first-to-file, para IV filing and 505 (b)(2) drugs.

We intend to keep striving along the same lines and in parallel also continue to look at M&A's for inorganic growth and be known globally as a true and dependable partner in our client's clinical development programs. —



Naresh Raisinghani

CEO & Executive Director
BMGI INDIA

BMGI India offers expertise in improving efficiencies in strategy, innovation, problem solving and business transformation.

BMGI India operates across many different industries and as part of a global company. Could you briefly introduce BMGI India and outline the importance attributed to the pharmaceutical sector?

BMGI is sector agnostic and operates four service lines. One is strategic planning and strategy deployment, whereby the company assists large firms in deploying their strategies. The second is innovation, assisting firms in deploying innovation practices. The third line is problem solving in several forms; BMGI handles complex problems and challenges that organizations find difficult to address. For example, we assist companies with mega-change

techniques and statistical problem solving techniques to assist them in making significant improvements to their operations and achieving cost reduction. BMGI also provides various e-learning platforms for enabling firms and their employees to learn problem solving methodologies such as Lean and Six Sigma. The fourth line of service is business transformation, where BMGI assists firms in significant changes including setting up a new business. We mainly work with larger firms, but we also work with aspirational medium and small firms who are wanting to scale up rapidly and improve their operations.

In what ways can BMGI assist companies in their growth plans?

One way to expand a business is to add new product lines. Another is to improve processes using the existing CapEx, which is where we can help. If a line has a throughput of a certain number of capsules or tablets, BMGI would examine this line and identify ways to optimize the operational parameters and improve the throughput of the line, usually achieving results of a 10% to 25% increase. Additionally, BMGI can help improve product yields, such as an increase in API yields from 94% to 95% up to 98% to 99%. Improving sales productivity is another dimension the company assists with. We also specialise in supply chains optimization and offer services for process efficiency improvements.

How is India's competitiveness changing in light of shifting global pharmaceutical dynamics?

India is definitely very competitive compared to other countries; the cost structure is 33% to 50% lower in certain areas than in other parts of the world. While China has increased in competitiveness in many ways, India holds a significant advantage in its knowledge capital. The combination of high intellect with the ability to produce cost-efficient throughputs is one of India's biggest differentiators from its competitors.

India has largely been a follower in patent processes but there is an awakening in India regarding the concept of innovation and several MNCs are trying to set up

innovation hubs in India. Due to the patent cliff, India's pharmaceutical industry, which is mainly in generics, is facing large price pressures due to a substantially lower number of molecules to pursue. As a result, Indian firms are moving towards specialty generics and improving their work in this area. There may not be new innovator products emerging in India at this time but there are many examples of CRO and speciality drugs being attempted.

What has caused India to take so long to embrace innovation when it comes to drug discovery and development?

The first hindrance is time – the entire drug discovery process takes about 12 to 24 years. The second is the cost involved. Ease of innovation can be improved significantly by availability of financial, regulatory and technological resources. Many companies are currently attempting to acquire innovation rather than develop their own processes or molecules as it is not very easy for them to innovate at this time.

How far does the government's Draft Pharmaceutical Policy go in addressing the needs of the market?

The intent and desire to make healthcare more affordable and to improve the quality and reliability of products are brilliant. However, although the principles and direction are principally right, the lack of detail and directional thought have caused the principles to come into conflict. A lot of deliberation and discussion between the government parties and industry players needs to take place to properly implement these changes. Both the organized and unorganized sectors need to be focused on creating pathways for improvement. If more time is spent on having these discussions, the results should be positive.

Could you provide some examples of the main challenges that BMGI helps its clients address?

Most pharmaceutical companies that are trying to improve cost and operational efficiency. We are seeing interest in yield improvement, throughput improvement, productivity improvement and cost reduction in raw materials as focus areas. —



Vivek Sharma

CEO

PIRAMAL PHARMA SOLUTIONS

Piramal Group is a global diversified business conglomerate with operations in over 30 countries across sectors such as pharmaceuticals, health care information management, financial services, specialty glass packaging and real estate.

Where does Piramal Pharma Solutions stand in the market today?

From its humble beginnings as an India centric firm, Piramal has now evolved into a trusted partner and a global leader in a number of its health care verticals. The Piramal Pharma Solutions (PPS) business that I am responsible for, has witnessed significant growth in revenue over the past three years. We have expanded our global customer base and have also increased wallet share among current customers. We have added capabilities in high potency API and sterile injectables, while becoming a global leader in providing integrated

solutions. We now have thirteen global manufacturing plants and R&D centers between Europe, North America and Asia. Our capabilities to provide services from discovery to clinical development and commercial launch for drug substances and drug products has allowed us to offer a unique platform that aligns well with the outsourcing needs of our customers.

Piramal Critical Care (PCC) is one of the top 3 global providers of inhaled anesthetic solutions with product availability in more than 110 countries and is globally renowned in the domain of critical care. Our Consumer Products division is growing every year while adding to its portfolio of products and our Healthcare Insight & Analytics business, Decision Resources Group (DRG), is viewed as a premier partner in the health care information services space.

In 2015, 90% of Piramal's market revenue came from the regulated markets of the U.S. and Europe. Is this still the case?

We continue to generate the majority of our revenue from Europe and North America as that is where our customers are. Nevertheless, we continue to augment our presence in the ROW markets. In Japan, for example, PCC is the market leader in inhaled anesthetics.

Could you provide more details on the activities and capacities of Piramal in India compared to its branches in other parts of the world?

Piramal Pharma Solutions has several facilities in India, including API manufacturing sites in Chennai and Telangana, and two sites in Ahmedabad, one dealing with Discovery R&D services and the other for development of oral solid dosages, and an injectables R&D site in Mumbai. Additionally we have a manufacturing site in Pithampur, India, for commercial manufacturing of Oral solid dosages. Finally, we have a nutrition site in Mahad that caters to customers who manufacture supplements and food additives. Pharma Solutions has a strength of about 2500 employees based out of India.

Do you think the government could play a more supportive role in ensuring access to quality medicines in the market?

There is always more that the Government can do to assist the life sciences business in India. While access to cost effective, life saving medicines is key, especially to the population in the third world, this needs to be balanced with clear laws that protect intellectual property. The government must collaboratively engage with pharma companies through regulations that encourage business transactions in India. Higher transparency from the government agencies will also help the business community. By providing technology for improved documentation processes and building guidance platforms and tools for support, some of the current challenges faced by Indian companies could be overcome.

How have companies been impacted by increased FDA activity?

Regulatory issues erode credibility with customers, employees, investors, increase time to market, and limit future growth options. 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. 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 opportunities remain for Indian companies to contribute to the global health care market.

What are the key objectives going forward for Piramal in India and globally?

Piramal wants to be the 'Partner of Choice' for its customers, and assist in supporting the development of life saving medicines that can save lives. It is our belief that if we deliver on that larger goal, we will positively impact shareholders and create value for our investors. Piramal plans to invest in adding capabilities and capacities that will help meet the future needs of our customers and patients. We will work together with our partners to bring these breakthrough therapies to the market, quickly and cost effectively. —



Satish Sawant

CEO, MD & Co-Founder
ACCUTEST

Accutest is a global independent and internationally accredited contract research organisation.

Accutest was founded in 1998, offering CRO services. How has the company developed over the last two decades?

As the pharmaceutical industry was not fully developed at the time of its inception, Accutest's journey has not been easy. In 1998, there were not many CROs because the concept of independence was not widespread and very few pharmaceutical companies were engaged in outsourcing clinical trials and bioequivalency studies. Some companies had their own dedicated CRO and hence conducted their studies in-house.

With a background in analytical chemistry, Accutest began with testing laboratories. The company gained an understanding of

testing requirements and was advised to move into bioequivalency studies because the industry was finally emerging. In 2001, Accutest began bioequivalency testing, and the company grew from a team of 10 to its current 650 employees.

Today, the company operates across Asia and Brazil. What is the global scope of the company and how important are the different markets?

From 2001 to 2004, Accutest focused its efforts on the Indian domestic market because it had yet to gain in reputation in its early years. After completing projects for Indian companies and receiving good responses, it became necessary to step outside of India in order to scale up the business. However, when the company approached the global market, it was considered too small in terms of accreditations and approvals, having only the local regulatory approval.

Potential clients expected the company to have U.S. FDA approval, prompting Accutest to complete a study and submit it to the U.S. FDA, which it did in 2001. In 2004, Accutest became the first independent CRO to achieve U.S. FDA approval in India. Following this, Accutest gained recognition in the industry and today has 28 U.S. FDA approvals. From 2004 onwards, the company gradually grew its U.S. business and increased its overseas revenue from zero to 75%. Today, the four most important markets for Accutest are the United States, China, Latin America and Europe.

India is not traditionally known for innovation. What are the advantages for overseas companies outsourcing their research to Indian companies like Accutest?

Although Indian companies mostly conduct applied research versus innovation research, talent is amply available here and it is mainly a question of funds. R&D expenditure is low in India and companies are not encouraged to invest funds into this area.

One of the advantages of conducting research in India is its position as the third-largest pharma market after the United States and China. The quality of Indian

products is very high but exceptions to the standard exist in every country and they unnecessarily tarnish the country's reputation. However, Indian companies learn from their mistakes fast and quickly improve. Outside of the United States, India has the highest number of U.S. FDA-approved manufacturing sites. India is also English speaking, which eases communication with many other countries across the world. Furthermore, labor costs are very low in India and hence more affordable for interested companies.

What are some of the most recent developments in the biosimilar space?

Unlike other countries where generic players do not work in biosimilars, India's big generic players are focused on this space. They have the aptitude, intent, talent and financial power to enter and succeed in this area. Accutest has an advantage in this sector because it was an early entrant, has the bioanalytical testing capabilities for biosimilar development and established a laboratory two years ago for testing biosimilars and biologics. Nevertheless, biosimilars and biologics are capital-intensive programs and require a lot of investment so the decisions to outsource are moving very slowly in the industry. However, people are moving in the right direction.

What are the objectives for Accutest going forward?

Aside from increasing activity in the bioequivalency area, Accutest already ranks in the top 10 CRO's in terms of infrastructure, regulatory achievements and the stability of its team and management staff. The company strives to become one of the Top Three in biologics and chemical development and research in the next five years. Expansion outside of India is difficult because the cost of labor is higher. We are open to partnering with global companies but do not plan to set up a facility outside of India. In terms of growth, there is a lot of opportunity in the United States and we have only just scratched the surface so far. It is a big market but also with high levels of competition. Despite the competition, we have maintained a standard for cost with a threshold that will not be exceeded. —



Karan Singh

Managing Director
ACG WORLDWIDE

Pharmaceutical products and services company providing integrated packaging solutions to the pharmaceutical industry.

ACG is a global market leader in hard empty capsules, in addition to providing manufacturing and R&D services across various solid dosage forms. Could you tell us more about the company?

ACG has been present in India for five decades and has grown by partnering with pharmaceutical companies. Our original expertise lay in capsules, after which we expanded into films and then machine manufacturing. To facilitate growth of the Indian pharmaceutical industry, we ventured into the engineering business to provide machinery and automate pharmaceutical manufacturing. Over the years, we have continued to invest relatively large sums of money into R&D to enhance

our engineering capabilities and provide more automated solutions to customers. We constantly cater to our customer demands through investment into machines with higher output and efficiency, which is what has kept us in the game.

Could you elaborate on ACG's service diversification, particularly its investment into R&D?

ACG's R&D investments have grown in two strategic directions: first in higher efficiency machines and the second is in solutions for small-batch production runs. As many manufacturers have started producing molecules that have come off patent, we notice that customers seek flexibility - be it more flexible machines, faster changeovers or shorter batch runs. India has today become a global manufacturing hub for generics; as a result, we see that demand for producing bigger batch sizes has also gone up, whereas globally we have seen the opposite.

We have also seen an increase in high potency products and are aiming to cater to this demand by developing containment machines for the safety of personnel operating these machines.

ACG is attempting to augment its production through setting up plants in overseas markets. Could you tell us more about your plans for growth in this sphere?

We have recently invested in manufacturing facilities in Croatia, with the aim of better serving the European pharmaceutical market. We have invested €40 million in this facility expansion and a further US\$40 million in a facility in Brazil, which will be commercialized early next year. We also have plans to expand into the Americas, South East Asia and possibly China. In addition to this, we have also opened an engineering office in Croatia for our Inspection business, with the aim of providing complete integrated solutions complying to the European Union's Falsified Medicines Directive (FMD) including serialization, compliance reporting and verification requirements.

How supportive is India's pharmaceutical environment?

The pharmaceutical industry in India has gone through a tremendous wave of

growth in the last 15 years and this wave will only continue. A few elements have enabled this success. For example, the government's drug price control policy, although not favorable to pharmaceutical manufacturers in terms of profit margins, has reduced the overall cost of manufacturing by forcing efficiency within the industry. This is what has enabled Indian manufacturers to be so globally competitive today.

How could greater innovation be encouraged?

One positive measure by the government was the possibility for companies to write off R&D costs against tax. Another potential measure is to re-examine price control and the price ceiling when it comes to certain drugs. In 1994, India signed the TRIPS treaty mandated by the World Trade Organization - which laid the foundation for the Indian Patent law which finally came into effect in 2005. This tied all Indian industries to the Global patent law, whereby Indian companies are unable to produce generic forms of patented products. A potential case for consideration could be an allowance of local manufacture and supply in case of a crisis in a country and a need for a certain drug under patent. This of course would only happen in the case of an epidemic.

What is ACG's strategy of growth moving forward?

We expect to see consolidation and greater presence from multinationals in India. Conversely, Indian companies will also expand their manufacturing geographically in the years to come. Our vision has always been to be a preferred partner of the global pharmaceutical industry. We have been successful in India and moving forward we would like to replicate this success in international markets. One of the reasons for our success is our proximity to customers. As a result, we are absolutely committed to set-up manufacturing facilities in all our focus markets globally.

Another area of growth is in the biotechnology industry. We are seeing tremendous growth in this sector and are constantly exploring missing links in our value-chain to offer integrated solutions to this sector. —

Image: P.R. Packagings



Thinking outside the box: Packaging according to market requirements

For many pharmaceutical players, packaging plays a key role in product marketing as the primary interface with the consumer. However, price sensitivities can inflict great restrictions in less developed markets, both in terms of expenditure by the company and in terms of the final cost breakdown of the product when it reaches the consumer. “Specifically in pharmaceutical packaging, costs will likely go down,” commented Lakshay Gupta, director at P.R. Packagings. “Prices are generally lowered every quarter. Pharmaceutical companies often see packaging as the primary area in which cost can be reduced, so every measure will be taken to improve efficiency and manufacture at lower costs to accommodate this demand. We will also look for materials that tread the line between being sufficient and cost effective; looking at lower GSM paper, for example.”

Responding to trends in textured and metallized packaging, P.R. Packagings is focusing on its evolution towards a higher level of finishing and more sophisticated designs, investing in material exploration and structural innovations as well as implementation of holographic lamination. Awareness of how to best cater to market dynamics before penetration is paramount and each market comes with its own set of considerations. “In Latin America and Africa, affordability is the biggest concern, plus storage conditions are often mishandled,” highlighted Rajesh Bhayani, director at Apex Drug House. “Therefore, Apex prefers to offer these customers old-

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Marketing in a new country is a difficult task. First and foremost, one must understand the requirements of that specific market, including consumer preferences, packaging and dosage requirements and the doctors' preferences as well. The acceptance of pharmaceutical products differs depending on the area, the country and consumer habits. Therefore, Saga offers a variety of packaging for each product to cater to specific markets and their requirements. In markets where the cost of medicines is higher, there is greater flexibility in terms of experimentation.

- Vinit Shah,
Managing Director,
Saga Laboratories



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style packaging, which is more secure for the stability of the product. While there are options for more expensive packaging, Apex also takes into consideration that some customers, particularly in remote areas, cannot read and use other visual aids to identify a product, such as color of the packaging or capsule or the shape of the table. Dark bottles may have better storage specifications but if the contents are unidentifiable, it may be better not to implement the newest material.”

Having started as a trader and importer of APIs, Apex Drug House manufactures and supplies pharmaceutical formulations worldwide, offering a number of packaging options to its customers to cater to different markets.

Beyond its traditional functional aspects, packaging is also a means to make a product uniquely identifiable to a customer as belonging to a particular manufacturer. Counterfeit drugs present a substantial problem in the Indian market as in other parts of the world. “Counterfeit drugs are a huge issue in the Indian market,” commented Vincent Swamy, director at Sergusa Solutions, a multi-product technology firm providing niche solutions in the printing and packaging industry. “Some estimates say that up to 40% of circulating medicines are counterfeit. However, our laws are not so strict and anti-counterfeit measures are not that extensive. We were recently approached by a large multinational to create a unique anti-counterfeit product for one of their blockbuster brands. They

claimed to lose over Rs. 2 crore – roughly US\$300,000 – per month due to counterfeit drugs.”

In response, Sergusa is developing a product with anti-counterfeit solutions called PackMark™ with L'Université Jean Monnet, France and with Jadavpur University in Kolkata. The innovation is a pack mark; part of the printed product. “The purpose of any counterfeit solution is to protect the manufacturer – there is often no way for the end user to really identify whether a product is a counterfeit or not,” underlined Swamy. “Holograms were one of the early measures for assurance but even so, knowing if that hologram belongs to a particular company is still a challenge. We are trying to produce packaging that addresses this challenge and is easily identified by the end user.”

The company is currently growing its presence in India and Bangladesh before expanding further afield. With commercial plants in Mumbai and Ahmedabad, Sergusa will focus on markets such as Africa and other WHO-regulated regions until it has secured U.S. FDA approval.

When it comes to packaging, many Indian companies are playing to the market's strengths: an innovative and resourceful environment coupled with a focus on affordability. Balancing these aspects is paramount, particularly in less-developed markets, and India's companies are well-placed to cater to various market requirements concerning cost and various aspects of functionality. —

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There has been an improvement in demand for quality, which is a result of increased interest in the regulated markets. In 2015, the U.S. FDA gave approval to about 109 plants for the regulated market, which has since almost doubled to 201 plants in 2016. The resulting increase in volume brings a sense of responsibility, with double and triple checks performed on products. Although the chemical composition of molded vials produced at SGD Pharma India is the same for all clients, various specifications are required from one client to another.

- Akshay Singh,
Managing Director,
SGD Pharma India



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Akshay Singh

Managing Director
SGD PHARMA INDIA

Cogent Glass, recently acquired by SGD Pharma, is a manufacturer of Type I moulded and tubular glass vials for the pharmaceutical industry.

How has Cogent Glass developed, particularly now as a division of SGD following the acquisition?

SGD Pharma India (Cogent Glass) has grown significantly over the last few years with an average CAGR of 34% from 2013 to 2017. This is very promising when compared to the CAGR of pharmaceutical companies in India, which is at about 16%. The rebranding from Cogent to SGD was significant as SGD is the world leader in pharmaceutical glass packaging. Although already JV partners, the formal acquisition by SGD brought changes to processes, quality systems and the approach to future business, taking six to eight months for the transition to be completed. A dedicated PMO was appointed for this change and more than 1,400 action points were implemented in the span of six months to reach the branding goals of SGD Pharma.

In the meantime, SGD Pharma India also proceeded with ISO-15378 recertification in line with all other international SGD plants. This shows SGD Pharma India maintains the same quality system and processes as the other companies of the group. Additionally in 2016, a 1,350m² clean room was installed for molded and tubular glass. SGD Pharma India is the only company in India with a certified ISO Class 8 clean room for molded glass, illustrating our dedication towards quality. As glass is the primary material interacting with pharmaceutical products, SGD Pharma India products play an important role and the company aims to always maintain the trust it has gained from the industry.

SGD Pharma India specializes in glass packaging. Could you provide more insight into the division's product offering?

From 2013 - 2017, SGD Pharma India only produced and sold Type 1 flint for molded glass. Consequent to the Group Executive Committee decision to produce amber glass in the existing furnace, the ability to offer both products to customers simultaneously improved the company's portfolio and increased its market share. This development will also help in supporting a consistent growth rate for the company. In terms of tubular glass, SGD Pharma India produces both vials (1ml to 100 ml) and ampoules (1ml to 30 ml) in both flint and amber. In the next two years, SGD will invest over INR 100 crores to build a new

furnace with improved product profile and also a new unit of about 3,500 square mts to accommodate 20 more tubular converting machines, which would also increase SGD Pharma India capacity for tubular production by almost double.

How has packaging demand developed in line with changing regulatory requirements?

There has been an improvement in demand for quality, which is a result of increased interest in the regulated markets. In 2015, the U.S. FDA gave approval to about 109 plants for the regulated market, which has since almost doubled to 201 plants in 2016. The resulting increase in volume brings a sense of responsibility, with double and triple checks performed on products. Although the chemical composition of molded vials produced at SGD Pharma India is the same for all clients, various specifications are required from one client to another.

As the value of medicine increases, the price of packaging generally increases as well. Does SGD Pharma India adapt its packaging to include high-cost as well as low-cost packaging for customers?

Not exactly; the price of the container depends on the type of the glass. Being generally more expensive than Type 3, Type 1 is used for parenteral applications & sensitive molecules. We at SGD Pharma India only produce Type 1 in both flint/amber to cater to this specific market. We also produce tubular vials which have similar applications and it has different quality levels based on the input raw material wherein we use only 5 expansion glass approved for regulated markets.

Going forward, what are the key areas of focus and the objectives for SGD Pharma India?

SGD Pharma India has acquired a substantial market share since 2013. The addition of amber glass in our portfolio and new technology to produce larger bottles should help us to further gain market share of Type 1 in India and internationally. The result of 34% CAGR growth reflects the trust on quality levels SGD Pharma India has maintained over the years and we will continue to do so to establish ourselves as the market leader for Type 1 glass in India. —

Lakshay Gupta & Vishesh Gupta

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LG: Director

VG: Director

P.R. PACKAGINGS



Could you briefly introduce P.R. Packagings and outline the development of its service offering?

Our father started the company in 1991 offering primarily EPS manufacturing, later pivoting into printed mono cartons in 1997. In 2015, the company added laminate tubes to its offering, hence becoming a one-stop-shop for companies' packaging needs. We also have multiple value additions to our printing press, including metallized printing, UV coating and matt and gloss lamination. Pharmaceutical customers account for about 20% of our client base.

With 25 years of experience in the packaging market, have you observed any particular demand trends of late?

Specifically in pharmaceutical packaging, costs will likely go down. Pharmaceutical companies often see packaging as the primary area in which cost can be reduced, so every measure will be taken to improve efficiency and manufacture at lower costs to accommodate this demand.

One of the major trends is the uptake in metallized packaging. Ever since generic drugs

have been boosted in India and promoted by government tenders, there has been high demand for textured and metallized cartons in the pharmaceutical industry.

Packaging can play a key role in anti-counterfeiting. Does P.R. Packagings seek to address the challenge of counterfeiting within the pharmaceuticals industry?

Holographic lamination facilities have been developed by companies to produce a very unique lamination to the customer. Our R&D right now is into material exploration and structural innovations as well as implementation of these holographic laminations.

Where do you see the biggest growth opportunities?

While the demand in the Indian market is currently high, we are expanding to the international pharmaceutical market as well. Our competitive advantage comes from our one-stop-shop setup. —

Vincent C. Swamy

—
Director

SERGUSA SOLUTION



Could you start with a brief introduction to Sergusa?

Sergusa, as it stands today, is about five years old, growing from a company with a 32-year background in printing, catering to newspapers and packaging. Sergusa was formed to cater specifically to the pharmaceutical sector, offering services such as foil conversion and inspection. We also have a software division related to the pharmaceutical industry, through which we offer a pdf comparison report. Another important aspect we deal with is brail inscription, which is becoming much more prominent in the Indian market.

In what ways does Sergusa seek to overcome challenges around counterfeit drugs?

Counterfeit drugs are a huge issue in the Indian market. Some estimates say that up to 40% of circulating medicines are counterfeit. However, our laws are not so strict and anti-counterfeit measures are not that extensive. We were recently approached by a large multinational to create a unique anti-counterfeit product for one of their blockbuster brands. They claimed to lose roughly US\$300,000 per month due to counterfeit drugs.

We are developing anti-counterfeit solutions called PackMark™ with L'Université Jean Monnet, France and with Jadavpur University in Kolkata. Holograms were one of the early measures for assurance but even so, knowing if that hologram belongs to a particular company is still a challenge. We are trying to produce packaging that addresses this challenge and is easily identified by the end user. The innovation is a pack mark, part of the printed product and will be launched at CPhI India in November 2017.

How do you plan to grow the company in the coming years?

We currently want to focus on the markets in India and Bangladesh and need to further establish ourselves in these two countries before expanding our customer base further afield. We have commercial plants in Mumbai and Ahmedabad and are adding capacity, which will put us in a better position to access different export markets. Until we have secured USFDA approval, we will focus on markets such as Africa and other WHO-regulated regions. —

Supporting India's Medical Devices Sector

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Another key area within India's life sciences sector is its medical device industry, which is only just starting to receive attention at a policy level. Although about US\$5.5 billion in value and Asia's fourth-largest market, demand in the segment is mostly met by foreign companies. "The Indian market size is currently about US\$5 billion, of which 70% to 80% is imported," commented Randolph Alves, chairman and managing director at Alves Group. "India's medical device segment is likely to grow from US\$5 billion to US\$20 billion in the coming years and this is just the tip of the iceberg; the global market sits at about US\$500 billion. Currently, higher-end products are coming from the United States and Europe and, in low-end products, India cannot compete with China. The Chinese government has set up modernized factories and adopted technologies to achieve greater efficiency and their labor output is 10 times that of India. If India could combine the scientific intelligence of its people with the dynamics of China and take medical devices seriously, the export potential could be huge."

As with pharmaceuticals, the key challenge in the market is affordability, recently highlighted by India's government slashing prices for medical devices such as knee implants and heart stents by up to 75%. As home to

some of India's main medical device suppliers, including Boston Scientific Corp and Abbott Laboratories, the United States is highly opposed to these moves as restrictive to innovation and profit. Until India further develops its domestic medical device segment, which remains in its nascent stages, there will likely be some compromise on this front.

The Indian government has begun to pay some attention to the sector - the Medical Device Rules 2017 will be implemented from 1st January 2018 and aims to coordinate the fragmented industry. However, the regulations have been met with criticism for not properly taking into account the nature of the Indian market.

Indeed, India already relies heavily on imports, particularly for technologically advanced products and equipment, which generally come at a much higher price point. Suresh Vazirani, founder & managing director at Transasia, India's largest in-vitro diagnostic company, noted: "India is not traditionally known for innovation. When Transasia started, its objective was to bring affordable equipment to India and other emerging markets. Consequently, we were less focused on innovation at that time. Therefore, whilst Transasia is the number one Indian diagnostic company, we have a

long way to go to be a global leader due to this lack of innovation."

Since its establishment in 1979, Transasia has acquired 11 companies and continues to expand its technology portfolio. The company caters to market requirements, particularly the affordability aspect, offering equipment at much lower price points to imported equivalents. "Since diabetes is highly prevalent in India and many emerging markets, Transasia has developed a fully automated, indigenously manufactured instrument, Hb-Vario, for diabetes detection and monitoring," commented Vazirani. "Competing U.S. products are sold at around US\$45,000, while Transasia sells this product at US\$7,000. Although 12% of the Indian population has diabetes, more than 80% are unaware that they have the disease. Therefore, we hope our equipment can reach every small town in India so that labs can diagnose the disease more widely. We are very happy that we can address this large need when no other company is doing so."

In order to develop its medical devices, industry will require a deeper understanding of the groundwork already laid and how to enhance current capabilities. With India's manufacturing advantages, the country is ideally placed to meet its own affordability requirements with the right support. —



Suresh Vazirani

Founder & Managing Director
TRANSASIA

Transasia is India's leading in-vitro diagnostic company, manufacturing and marketing equipment and reagents across India and worldwide.

Transasia was established in 1979 as a small marketing firm and has grown to become India's leading diagnostic company. How has the company developed over the years?

Transasia Bio-Medicals was set up in 1979 to cater to India's need for essential diagnostics. At that time, almost all of the medical equipment had to be imported. To add to this, the after-sales services of the imported equipment were a big concern, leading to frequent breakdowns and no one to service it. I realized that this was a lacuna in the healthcare facilities and doctors faced a problem in terms of offering quality medical and preventive care to the patients. We have followed a simple strategy - AIM - Affordable, Innovative and Make in India products to be recognized today as India's leading In-vitro diagnostic company.

In 1991, we started manufacturing IVD instruments. Eventually we became the No. 1 supplier of blood analysis systems in India. Thereafter, we also started our own R&D facility and expanded our manufacturing base by setting up plants in Mumbai, Daman, Baddi and Seepz. Transasia's main focus remains on emerging countries in Asia, Africa, the Middle East, Latin America and Eastern Europe.

Transasia has acquired a number of companies over the years in several western countries, including the ERBA Mannheim GmbH Group in Germany. How have these acquisitions helped the company to grow?

Some years back, we discovered that over 70% of Indians had never done any blood tests and hence they were not aware of the diseases they had. However, it was apparent that imported equipment were unable to meet India's need for affordable diagnosis. We decided to acquire companies globally to bring world class technology to India and the emerging markets. ERBA Mannheim, Germany, was the first company. Thereafter, we further acquired more companies to bring world-class technology to India combined with efficient, low cost manufacturing and unparalleled market expertise. Over the last eight years, Transasia has acquired 14 companies globally and successfully expanded its technology port-

folio to soon become a complete solutions company offering every equipment that a lab would require.

Are there any trends in the domestic market or globally that have impacted demand for Transasia's products?

Transfusion Transmitted Infections are a growing concern in India. A lot of blood available to hospitals from blood banks is contaminated because HIV and hepatitis tests are not very sensitive and hence the infections pass on through the blood undetected. Last year, around 60,000 patients were infected with HIV through blood transfusions. Transasia is developing low-cost tests that will detect blood contamination with 100% accuracy.

Tuberculosis is also a big concern in India, affecting over three million people every year and leading to deaths of about half a million. There are simply not enough people being tested and even for the ones who are tested, there is a high probability of false results. This is because the test being is not sensitive enough to detect the disease accurately. Moreover, because this is a disease of the poor, Indian companies do not find it lucrative to offer solutions as it would not cater to the U.S. or Europe markets. Transasia has acquired Lumora (now known as Erba U.K.), a U.K.-based provider of state-of-the-art patented molecular diagnostic products for accurate and precise detection of diseases such as tuberculosis, HIV, respiratory diseases, dengue, malaria, etc. As a result, we plan to soon develop molecular testing for emerging country specific diseases.

What are the objectives for Erba-Transasia over the next few years?

We plan to extend our reach and grow the company by continuing to develop innovative and affordable products. As 70% of Indian citizens have never received blood tests, there is a large market waiting to be tapped. There are also another 60 countries of interest for Transasia to expand into. Transasia's vision is to create a healthier happier world. We aim to be a global leader in emerging diagnostic markets and move from impacting millions of lives to billions of lives. —





INDIA'S GROWING INNOVATION FOCUS



“The general mindset is becoming more skewed towards innovation. The main impeding factor is the availability of capital. Other markets worldwide have more financial resources. In India, it is very difficult to raise capital and failure is much more momentous, making Indian companies more risk averse.

However, the government is trying to encourage the industry to innovate through various programs.”

- Manni Kantipudi, CEO, GVK Biosciences



Image: Troika

A New Frontier?

India's growing emphasis on innovation

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When asked to consider the top sources of pharmaceutical innovation and drug discovery worldwide, India sits far from the tip of the tongue. While the United States takes center stage as the innovation hub of the world, producing more than half of the world's new molecules in the last decade and investing over US\$50 billion into R&D annually, India is recognized for its proficiency in developing generic alternatives at affordable prices.

It is unsurprising that India has found its strength in generics over drug discovery and development given the nature of the domestic market and particularly when considering rising R&D costs and the extremely high stakes involved. "The first hindrance is time – the entire drug discovery process takes about 12 to 24 years," stated Naresh Raisinghani, CEO and executive

director at BMGI India. "The second is the cost involved, which is significantly high at about US\$1.5 billion."

Whereas other countries around the world have been very active in supporting innovation, India's government has focused on increasing affordability and accessibility for the domestic market. However, with an increasingly crowded market and price erosion, change could be on the horizon as moves are made to capture more value in international markets by encouraging innovation amongst India's pharmaceutical companies. IBEF forecasts India's biotech industry to grow to US\$100 billion by 2024, up from US\$11 billion in FY 2015. Commenting on the improvement of the ease of innovation through the availability of financial, regulatory and technological resources, Raisinghani continued: "Re-

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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

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Indian companies have suffered a huge blow in clinical trial-related issues and have historically used cash flow from domestic formulations to invest more into the regulated markets and gain export revenue. Therefore, it will take time for Indian companies to become more innovative. A few companies are making strides, but none will become sizable unless the clinical trials ecosystem is developed and quality compliance support is provided by the Indian regulatory authorities.

- Lupin Spokesperson

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ducing taxation when companies improve their R&D expenditure would be of great support. India's major players have improved their R&D expenditure by about 9% to 12% in the last five years, which is three to six times more than it used to be. The government could also provide tax suspensions whereby, for example, the I.T. firms in initial stages would have a tax moratorium for a 10 year period. One recent improvement to policies is the new 100% FDI route, which does provide easier access to finance and where required accessibility to technology.”

As seen in other countries, the creation of innovation parks could greatly support smaller companies in pursuit of new chemical entities (NCEs). The industry has also requested the government to invest US\$5 billion into research activities and develop infrastructure as well as human capital.

Another area of development which could realize heightened levels of early-stage research and drug discovery is the improvement of industry-university inter-

faces. Universities are becoming a prominent source of research in many parts of the world, where educational institutions and industries are recognizing the mutual benefits of working closely together. With extra financial support and a stronger drive to integrate universities into companies' research efforts, India could gain some ground when it comes to innovation. “There is currently a big gap in the interface between educational institutions and industry,” highlighted Arun Sehgal, managing director at Chempro Pharma. “Because of this, unless a company comes up with a groundbreaking drug through fundamental research and profits immensely from patenting it, it is difficult to gain a lot from R&D investment. Educational institutions should have bigger budgets to give greater support to fundamental research.”

India's biotech start-ups attracted investments worth only US\$2.8 billion between 2012 and February 2017. Greater access to funding would be critical to the industry's growth.

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.

The Indian government plans to allocate US\$ 70 million for local players to develop biosimilars, and the domestic market is expected to reach US\$40 billion by 2030.

“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 signifi-

cant 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 and have a head start in some instances. “For biosimilars, Korean companies and some Chinese

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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



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The Indian government is now giving incentives to innovative companies conducting research and developing molecules for new therapeutic segments, 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

In about five years' time, it will be easier to predict if India will become a key player in biosimilars. The issue over the last few years is the lack of clarity in the expectations of various health authorities for biosimilar registration. The exact expectations of Europe and in particular US regulators are becoming clearer, however, the development cycle for these regions takes at least four to five years so there is some time lag. In many cases, the delays caused by the uncertainty in regulatory requirements have led to a situation where many patents are now in the process of expiring hence ensuring very significant markets are opening.

- Binish Chudgar, Vice Chairman,
Intas



For biosimilars, Korean companies and some Chinese companies are making great strides. This is an area where Indian companies are slightly behind their counterparts and need to up their game. 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 incremental opportunity and continued relevance and growth. 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.

- Lupin Spokesperson

Progressively, more countries are opening up to and encouraging the production of biosimilars. 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.

- KV Subramaniam, CEO,
Reliance Life Sciences



The downside of price control is that drug manufacturers have been unable to invest heavily in innovation and R&D compared to large global multinationals due to narrower profit margins. As a result, we lacked sufficient funds to invest in new molecule development and our innovation landscape. Therefore, although India today is strong in manufacturing, we are relatively weak in our innovation. This is a space in our market that has potential to grow.

- Karan Singh, Managing Director,
ACG Worldwide



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We have a new guidance on regulatory requirements of similar biologics released in 2016. The new guidance is in line with the framework followed in US FDA and EMA, however, there are some areas which require continuous improvements. Global agencies emphasize aspects like setting specifications, number of batches of innovator and biosimilar used to establish analytical similarity, raw material testing and having a tiered approach of characterization of reference standard which all need to be rigorously monitored.

- Bindi Chudgar,
Director,
Lambda Therapeutic Research

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companies are making great strides,” noted a Lupin spokesperson. “This is an area where Indian companies are slightly behind their counterparts and need to up their game. 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 incremental opportunity and continued relevance and growth. 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.”

The biosimilars guidelines released by India’s Central Drugs Standard Control Organization in 2016 seek to encourage Indian manufacturers to capitalize on this industry, which is expected to grow to US\$6.2 billion by 2020, up from US\$2.29 billion in 2015. It does, however, remain to be seen how quickly the biosimilars arena will become profitable. Companies will only venture down the biosimilars pathway if the projects are commercially viable. “Looking at the return on investment globally, no company has yet profited from its biosimilar programs to date,” claimed Binish Chudgar, vice chairman at Intas, one of the pioneers for Indian biosimilars, having initiated activity in this area over 10 years ago. “Therefore, Indian companies must venture carefully and should develop capabilities in Indian and RoW markets first. They can subsequently increase their compliance standards for the U.S. and European markets as these are more difficult markets in which to achieve success. Another challenging element is marketing costs, which in this activity are particularly significant given a degree of recalcitrance on the part of clinicians less familiar with the equivalence of biosimilars.”

Intas has invested around US\$400 million into the development and manufacture of biosimilars, a huge sum when taken in comparison to its US\$60 million to US\$70 million turnover. The company plans to launch a product in the United States in 12 to 15 months’ time.

Whilst there is a growing emphasis on innovation, India’s pharmaceutical companies are generally likely to focus on process innovation, differentiators for generic products such as novel drug delivery systems (NDDS) and specialty generics. “For the foreseeable future, the patented product market will continue to be fairly small in size,” commented Kal Sundaram, CEO (India, EM & CHC Business) at Sun Pharmaceutical Industries. “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.”

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. —



GVK BIO
Accelerating Research

Fostering Innovation to deliver R&D solutions

SOLUTION-CENTRIC | COLLABORATIVE | RELIABLE

Globally, there is a huge growth in externalisation and outsourcing of drug discovery. With downsizing of internal discovery programs - small and medium pharma & biotech firms are looking for partners who can offer innovation and R&D of new molecules.

Find out why 400 global customers want to work with us to help them bring their products faster to market. Leverage our rich experience of over 16 years, strong scientific pool of 2000 scientists & customer focus across R&D value chain. Learn how we can help you go to market faster with innovative & cost-effective solutions.

Discovery → Development → Manufacturing

Discovery CRO of Choice **GVK BIO** Large Molecule Discovery Partner **ARAGEN** Leading CDMO **INOGENT** To know more, contact us at: bd@gvkbio.com India | USA | Netherlands

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KV Subramaniam

CEO
RELiance LIFE SCIENCES

Reliance Life Sciences is part of the promoter group of Reliance Industries Limited, established to develop opportunities in biotechnology.

The Reliance Group is India's largest private sector enterprise, of which Reliance Life Sciences (RLS) forms one component. How is RLS itself segmented?

Reliance Life Sciences (RLS) is focused on medical biotechnology with three core business lines: plasma proteins, biosimilars and later-generation small molecule oncology. The two longer-term initiatives are molecular medicine and regenerative medicine. RLS today is the largest plasma proteins company in India. A unique characteristic of all RLS products is that they are all hospital products used to treat patients in intensive or critical care.

RLS has emerged as India's top-ranking biosimilar company on a number of products in the market. It has the distinction of having the highest number of monoclonal antibodies in the world and is developing the largest number of biosimilars globally, including monoclonal antibodies. The company has 15 biosimilar products in the market, of which six are monoclonal antibodies. Our internal CRO also conducts clinical research services for external clients. The third business primarily includes oncology products but also some fermentation-based products. The molecular medicine initiative centers around high-end DNA-based diagnostics and RLS typically receives patients from across the country on a daily basis. Going forward, we believe that molecular medicine will work along the lines of companion diagnostics because many biosimilar products need them. Additionally, in regenerative medicine, RLS is conducting several clinical studies for stem cells for different disease conditions.

In these three core businesses, where does the company see the biggest demand geographically?

About 80% of RLS' business today comes from plasma proteins and biosimilars and about a third of revenue comes from exports. Plasma protein is the predominant business for the company but this is changing as more RLS products enter the domestic and global markets and it plans to expand into more geographies. The long registration process required for global expansion has inherently made it much slower to penetrate new markets. RLS currently has a presence in Southeast Asia, the Middle East, Africa and Latin America. The company has yet to enter the highly regulated markets of the United States, Japan and Australia. Two products have received European approval in the small-molecule business. One of our products is actively sold in the United Kingdom and four more oncology products will go through European registration this year.

How is the framework for biosimilars developing in India and globally?

Progressively, more countries are opening up to and encouraging the production of biosimilars. 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.

What advantages does the Indian operating environment offer to companies such as RLS that compete globally?

The biggest advantage is the very strong domestic market in India. This is of huge benefit for any country as it allows scale growth which helps in increasing competitiveness. Price control is another opportunity for the market to grow as it improves affordability. Another advantage is the high level of biology and chemistry talent in India. The country's large population also means greater access to patients for clinical trials.

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.

Where would you like to see the company in three years' time?

In three years' time, RLS aims to be marketing its products in the developed markets and will have a second manufacturing facility to expand its capacities. The greatest opportunity for Reliance is in biosimilars, driven primarily by these products becoming more affordable and being able to reach larger areas of the global population. The other opportunity lies in pushing our small-molecule products into the highly regulated markets as these pathways are more defined and shorter than for biosimilars. We are constantly exploring portfolio expansion options such as fermentation-based products and peptides for new business opportunities going forward. Long term, we are invested in clinical trials for stem cell therapy because there is great potential for them to improve clinical outcomes. —



Manni Kantipudi

CEO
GVK BIOSCIENCES

GVK Biosciences (GVK BIO) is a leading Contract Research & Development Organization that serves the global Biopharma industry and forms an integral part of the GVK Group.

Where does GVK BIO fit into the context of the wider GVK Group?

In 2000, Mr. Sanjay Reddy decided to diversify from the group's strong infrastructure focus and move into the knowledge economy. Although they looked at IT, the Indian industry was already quite mature by 2000, so the pharmaceutical industry was pinpointed based on the high levels of knowledge required. GVK BIO could be considered the Infosys of India's pharmaceutical industry. We offer companies the "India Advantage" when it comes to outsourcing: strong human capital, highly-qualified scientists with a strong work ethic and relatively affordable services.

We also classify ourselves as a Contract R&D Organization (CRDO) rather than just a CRO. Since its establishment in 2001, GVK BIO has grown rapidly, today employing about 2,300 personnel, 2,000 of which are scientists with advanced degrees. We are one of the largest pools of PhD-holders in the country, employing about 200. Our client base also tends to be international as we work primarily with innovator pharmaceutical companies.

How extensive are the company's capabilities?

We have world-class labs with a strong set of regulatory approvals for regulated markets, very strong scientific talent and are just commissioning a brand new plant. For small molecules, we start very early in the lifecycle of molecule discovery and then work closely with our partners to develop the molecule and can even manufacture the molecule once it approaches commercialization. Our capabilities also cover large molecule research and we acquired Aragen Biosciences, a facility in California in 2014, which specializes in large molecule research. In the future, we will be moving into development for large molecules as well.

How do you see demand for contract services in India developing?

There is huge potential. The big trend in the United States is what can be seen in Boston and San Francisco – the investment going into drug discovery and development is mostly being fed into small startups with no laboratory of their own. These companies have good ideas and knowledge but prefer to stay virtual. This is where GVK BIO has its strength. We work with about 400 companies and these are primarily small and mid-size biopharma customers.

GVK BIO recently launched a mobile application, eCule, for drug discovery services. Could you expand on this?

The app took us about a year to develop and enables the user to initiate a project, track data throughout and also conclude the project from a mobile phone. Initia-

tives like this allow us to interface with a higher number of customers at any one time. A prospective client could take a picture of a chemical entity in a journal, upload it to the app, and request a quote for how much its synthesis would cost. Our team receives the information and makes a proposal following evaluation. If the quote is approved, the project begins, tracking five milestones over the lifecycle of the project. This gives a lot of freedom, particularly when it comes to infrastructure. It is also unique in that we have extended the app to biology.

Could India potentially become a hub for contract research services?

India is unlikely to become the research hub of the world, particularly as China is very competitively positioned here. China has, to an extent, better infrastructure than India and is viewed by the pharmaceutical sector as more open to innovation and IP. India, on the other hand, is viewed as an environment in which companies will shortcut innovation and IP regulations – the government has made exceptions to patent protection in the past – in favor of affordable generics. Other markets such as the United States and Europe will also maintain strengths in this area.

What are the objectives for GVK BIO over the next few years?

The company currently sits at about US\$120 million in revenue and we would like to reach US\$200 million by 2021. We are the largest drug discovery services company in India by revenue, employees, customers and productivity. We want to leverage our strength to stay at No.1 in drug discovery and move with our customers further into development. We now have a new manufacturing plant coming up and also plan to ramp up our biologics capabilities. We want to become more competitive price-wise so that our U.S. facility can be more competitive against China in particular. Finally, we are also looking to grow our formulation and analytical services business segment. India is well ahead of China in formulations, and we want to leverage this strength. —



Binish Chudgar

Vice-Chairman
INTAS

Intas is a leading player in pharmaceutical formulation development and manufacturing, headquartered in India.

Could you briefly introduce the company and its areas of focus?

For the last decade, Intas has been focused on the chronic segment of the pharmaceutical market, including neuropsychiatry, psychiatry, neurology and cardiology. Thanks to the company's hard work in these areas, it has achieved leading market shares across a broad range of molecules. Apart from these segments, Intas is also present in the oncology, respiratory, gynaecology, fertility and animal healthcare segments. The company has around 23 specialist field forces operating in India and has been growing at a double-digit rate for the last five to seven years. De-

spite price erosion affecting the broader industry, Intas has been able to maintain a consistent growth rate of growth of 15% to 20% per year. Prescriptions are long-term in the chronic segment, which allows the company to maintain steady business as there is no seasonal effect.

Intas has a strong presence in India but is also present in more than 70 countries worldwide. Which areas are of greatest focus and opportunity for the company geographically?

International markets constitute more than 65% of Intas' turnover and our business is growing more rapidly abroad than it is in India. This results from our growing portfolio and expanding presence. Going forward the company is working on developing an exciting range of new chemical entities and improved drug delivery systems for international markets. It's worth noting that commercial launches of such novel products takes anywhere between five and ten years in highly regulated markets, so this program gives us great confidence in our long term future beyond our pure generic pipeline

Additionally, Intas' biosimilar basket also caters predominantly to the hospital channel. Many of the company's biosimilar products are used as supportive cancer therapies, especially as adjuncts to chemotherapy. Products such as long acting G-CSF and rituximab are being developed by Intas for the Western world. The company has been a trailblazer in this area and it is worth noting that with the launch of our biosimilar G-CSF (Accofil) in Europe we became the first company to supply a biosimilar product developed and manufactured in India into the European Union. We've dosed over 4 million cycles now and are the market leader in a growing number of countries.

Many Indian companies are struggling due to price erosion and market crowdedness. What are the contributing factors to Intas' success?

To maintain growth and achieve success, a pharmaceutical company needs to maintain a differentiated pipeline year after year and be well supported by its manufacturing plants. It is also important to have in-

novative products and more research-oriented products to maintain the company's growth rate. Intas has been committing over 6% of revenues to its R&D activities for a number of years to ensure sufficient development of differentiated products.

Furthermore, as the expectations of the Western world become stricter, Indian companies need to refurbish their manufacturing plants and ensure that their staff are highly trained and aware of new regulations. We have updated our business model to maintain our international growth rates. When plants are used at high capacity, a lot of resources need to be put into their maintenance and upholding their quality.

How supportive is the Indian government's framework for innovation in biosimilars?

Intas was one of the pioneers for Indian biosimilars, initiating activities in these areas over 10 years ago. The company's dedicated biologic manufacturing plant was the first in India to gain and maintain EU GMP approval and has subsequently undergone a two-year FDA inspection resulting in a small list of outstanding observations we expect to close out shortly. We plan to launch a product in the United States in 12 to 15 months' time. It is a slow process and requires a high level of investment – we have invested around US\$400 million into the development and manufacture of biosimilars whilst our current turnover is around US\$60 to US\$70 million.

What is the vision of the company going forward?

Intas aims to continue growing at a high rate of at least 15% to 20% per year over the next five years. We will be investing heavily in growing our staff base and the capabilities of our people. We want to remain a high performing organisation and our people are integral to that. We intend to continue to grow our base generic and biosimilar businesses and use this as a platform to bring to market our exciting range of novel chemical entities and delivery platforms to the benefit of patients around the world. —







NUTRACEUTICALS AND PHYTOCHEMICALS



“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.”

- Manish Mishra, Senior Manager,
Sarv Biolabs

Image: Pixabay



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, prevention of chronic illness, improvement of health and increased life expectancy. "We are seeing huge demand for the multivitamins, fish oils and children's health products," remarked Gaurav Aggarwal, director at Lasons. "Although there is a lot of hesitation surrounding children's nutraceuticals, the demand remains tremendous. Nutraceutical popularity is dependent on education and awareness; now, people are becoming more aware of the deficiencies we all face today, such as the 70% vitamin D3 deficiency in India and omega-3s. Doctors are also becoming more pro-nutraceuticals as preventive products and they play a large role in promotion. Usage will grow with the rising awareness of the need for nutraceuticals."

Lasons had its first commercial production of niacinamide in 1984 and today is one of the leading producers of niacin and niacinamide (Vitamin B3) worldwide. The company's reach spans over 90 countries.

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.

"Lasons is spread over 90 countries but North America remains the company's largest consumer as the largest user of vitamins in the world," commented Aggarwal. "China is very close behind

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The major difference between synthetic and natural products is that natural ones can be used as preventative medicine, which is an added value that provides better health. More than 100 companies regularly purchase thicolchicoside 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 United States in vitamin consumption and will most likely become the largest global vitamin user in the next five years. Therefore, there is much more potential growth for Lasons in China than the United States.”

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. “Although income is rising in India, the nutraceutical industry is very nascent because price points are much lower than in Europe and the United States,” explained Chandrakant Rathi, managing director at Advanced Enzyme Technologies. “Also, in Asia, those who are willing to spend more on their health usually purchase nutraceuticals through doctors’ prescriptions. Therefore, there is not much opportunity for Advanced to grow in these markets.”

Instead, Advanced is focused on Europe and the United States for expansion and claims to be the only company specialized solely in enzyme nutraceuticals in the world.

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 thicolchicoside, 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.

Because India is conducive to the provision of natural resources and raw materials, such as roots, seeds and extracts, it is a prime destination to supply and source from.

Despite promising growth prospects, there are some key challenges that face the phytochemicals market segment. The first is formulating the correct dosage forms. Consumers are increasingly demanding more variety and benefits from delivery methods beyond traditional capsule and tablet technologies, and meeting these demands will be a challenge for companies moving forward. Increasing bioavailability for lower doses is another area of focus but can be difficult to execute. Sarv Biolabs has sought to address this challenge in its extraction of curcumin, which has strong antibiotic, antiarthritic, nonsteroidal anti-inflammatory



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drug (NSAID), pain relief and anti-cancer properties. “Although curcumin is not water soluble, generally making the bioavailability for this material very low, Sarv scientists have made a complex of curcumin which has increased its bioavailability by 85%,” highlighted Mishra. “As a result, patients that would normally take a 500mg tablet of curcumin can now take a smaller dose and receive the same therapeutic benefits.”

Being able to innovate and deliver in a cost effective manner lies at the crux of success in this space. Moving forward, prospects in India look promising due to the abundant availability of herbs, favorable labor prices and rapidly evolving infrastructure that is becoming increasingly conducive to innovation. —

Sarv Biolabs
PHYTOCHEMICALS & STANDARDIZED HERBAL EXTRACTS MANUFACTURE

- Thicolchicoside (PYP/EP)
(Filed DMF in USA & Canada and EU Written Confirmation)
- Colchicine USP/EP/IEP
(Filed DMF in USA & Canada and EU Written Confirmation)
- Taxol Derivative (TD-GMS II, Paclitaxel, Docetaxel)

Plot no.2, Triokpur Rd, Behind IIT College of Engineering, Kala Amb, HP
Tel: +91 11 4111 7652 Mob: +91 98917 10088
Email: hertato@sarvbiolabs.com www.sarvbiolabs.com

Gaurav Aggarwal

Director
LASONS INDIA

Lasons is one of the leading producers of Vitamin B3 (Niacin & Niacinamide).

Could you briefly introduce the company and outline its evolution?

Lasons is a privately owned company founded in 1979. In 1983, the company ventured into pharmaceuticals and had its first commercial production of Niacinamide in 1984. After adding a few more pharmaceutical products in the late 1980s and early 1990s, it was realized that the focus of the company should be in Niacin and Niacinamide because of its growth potential.

With that shift in focus, Lasons built a new manufacturing setup for Niacin and Niacinamide and continued to grow in quantity expansion and global reach. Subsequently, the company began manufactur-

ing its own raw material for Niacinamide and added a few more key raw materials for specialty chemicals. When capacities were expanded and a new plant was built for specialty chemical manufacturing, Lasons picked products that are mostly imported into India from China. As the number of Indian producers was very limited and supply consistency from China wasn't very consistent, this plant gave Lasons an edge. Indian companies would rather purchase locally. This year, Lasons launched its nutraceutical brand for nutrition, wellness and beauty. Since the company already manufactures vitamins and supplies APIs to almost every known brand across the globe, nutrition and wellness were natural verticals to add. Beauty will be the second phase of this new brand selection.

Lasons has several customers worldwide. How is the base segmented geographically?

Lasons has customers spread over 90 countries but North America remains the company's largest consumer, as they are largest user of vitamins in the world. China is very close behind the United States in vitamin consumption and will most likely become the largest global vitamin user in the next coming years.

What gives Lasons a competitive advantage over Chinese suppliers?

Chinese suppliers are more volume-driven and have a macro approach. The Indian manufacturers largely are micro-based and focus on yields and other manufacturing costs. Furthermore, Lasons has been in the industry for over 30 years, while most Chinese companies are relatively new. Quality also presents a big competitive advantage because nutraceuticals are open-priced while pharmaceuticals are largely controlled. Although more expensive, consumers are more likely to seek out higher quality even if the price is elevated.

Will the distribution for Lasons's nutraceutical brand mirror the company's current geographical scope?

Lasons' nutritional brand is a completely different vertical and will follow a completely different model to the pharmaceutical division. Lasons' nutraceuticals are marketed as preventive products. We are seeing huge demand for the mul-

tivitamins, fish oils and children's health products. Although there is a lot of hesitation surrounding children's nutraceuticals, the demand and need remains tremendous. Nutraceutical popularity is dependent on education and awareness; now, people are becoming more aware of the deficiencies we all face today. For example, most Indians are vitamin D3 deficient. Doctors are also becoming more pro-nutraceuticals as preventive products and they play a large role in promotion. Usage will grow with the rising awareness of the need for nutraceuticals.

In terms of R&D, are there any new products in the pipeline?

Lasons is currently focused on multivitamins, fish oils and weight-loss-management products, heart health, bone health amongst others. Moving forward, the company has formulated a product for diabetes, liver, sports nutrition range etc. Cardiology is another major area of focus. Additional areas of interest are hair growth, general well-being and pre- and probiotics. Our R&D plans are vast and the products and formulations will gradually roll out according to how the market dynamics change.

What is the strategy for entering countries such as China?

In countries like China, it is important to have local representation. Many countries are very community-driven. For example, in India one must have a local presence and representative because business is still conducted based on relationships, PR and one-on-one interactions, not to mention the difficulty of doing business in the region.

What are the main objectives of the company over the next few years?

We are aiming at 40% top line growth for the company this year itself. Moving forward, the focus will largely be on expanding Lasons' customer base in the API segment, developing vitamin APIs in the nutraceutical segment and specifically targeting regions where there is a lot of scope for work and need for nutraceutical products. Although we have received many export inquiries, sales will be focused on India for the time being. Exports will be planned for the near future. —



Chandrakant Rathi

Managing Director
ADVANCED ENZYME TECHNOLOGIES

Advanced Enzyme Technologies was incorporated in 1989 and today sits in the top 15 global enzyme companies, with a market share of around 0.9%.

What are the focus areas of the company today?

90% of Advanced Enzyme Technologies' business focuses on nutraceuticals and animal feed. Consumers purchase nutraceuticals primarily based on their belief systems rather than efficacy and very few people understand the role of enzymes and their therapeutic value for the body. All drugs that are administered to the human body are predominantly used to delay or enhance enzyme reactions. They are completely safe and can therefore directly progress to Phase 3 and 4 without undergoing pre-clinical and clinical trials. Also, nutraceuticals are complementary to all therapies and include traditional, Ayurve-

da, allopathy, arthropathy, and Afghani/Chinese medication. Advanced Enzyme Technologies is focused on oral dosage forms and will not be venturing into injectables. Several diseases have no remedial action available, such as pulmonary fibrosis, and Advanced's products have provided good results to patients as they are safe to take throughout their lifetime. The company's product line is also useful for lactose intolerance and food allergies. Additionally, Advanced also focuses on animal feed for monogastric animals.

The global nutraceuticals market is growing but currently the United States, Europe, and Japan collectively account for 93% of the market. Do you expect to see the dynamics of India's nutraceutical industry evolving at all?

Although income is rising in India, the nutraceutical industry is very nascent because price points are much lower than in Europe and the United States. In the more developed markets, the cost of enzyme medication is much higher as consumers are willing to pay more. It is therefore a big challenge to grow this market in a country like India. In India, there is a blurred line between the pharmaceutical and nutraceutical sectors; many Indian pharma companies have a range of hard-core pharmaceutical products and another range of nutraceutical products that are sold under a pharma brand. Several food companies have also started to claim that their products have various health benefits. These factors make working in the Indian pharmaceutical industry very challenging.

Advanced Enzyme Technologies has a number of subsidiaries and operates out of India and the United States. How extensive is its geographic reach?

Unregulated markets are generally high volume and low-value. Also, in Asia, those who are willing to spend more on their health usually purchase nutraceuticals through doctors' prescriptions. Therefore, there is not much opportunity for Advanced to grow in these markets. On the other hand, there is a large demand for products with fewer or no additives because additives must now be declared. The

regulatory pressure on label declaration in Europe, the United States, Japan and other parts of the world is forcing these countries to adopt enzyme technology. Therefore, the biggest opportunity for Advanced lies in the highly regulated markets such as the United States and Europe.

In November 2016, Advanced Enzyme Technologies received an award for Best Nutraceutical Company of the Year. What differentiates the company from others in the market?

Advanced is the only company specialized solely in enzyme nutraceuticals in the world. The company also has a clear plan to predominantly focus on non-GMO products when moving into the food chain for human healthcare. Our USP is completely natural enzymes from vegetable sources. Animal-originating enzymes are avoided in our products to provide an alternative for many people who require vegan-based supplements.

Advanced Enzyme Technologies has five research labs in India and two in Germany. Could you elaborate on some areas of R&D focus?

One of the German labs has the technology to completely engineer novel enzymes that are not available in nature. The other R&D focus is creating novel carbohydrates. Two have been developed so far – one for diabetic care, which eliminates sugar spikes in the body, and the other is a low-calorie sweetener made from an enzymatic process. More than 400 enzymes are available at the acquired German company to take care of biocatalysts and API synthesis. APIs are now required to have high purity, which is achievable through using enzymes as the reaction pathway in green chemistry.

What are the objectives for the company over the next few years?

We aim to exceed Rs. 1,000 crores in a few years' time, and Europe and the United States will be our main focuses for future geographic expansion. In the next five years, we predict business to mostly be gained from the enzyme-food industry in the form of biocatalysts. —



CONCLUSION



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 concerning. 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. —

“The Indian industry has grown a great deal on its own steam. Now that the government support is there and countries such as Japan and many in Europe with ageing populations have budget constraints when it comes to healthcare, they have no choice but to look forward to India to get supply of medicines. They must work closely with our regulators and companies to construct a mutually-beneficial relationship and think of India as a strong business partner.”

- Daara B. Patel,
Secretary General,
Indian Drug Manufacturers’ Association

“Recently, the Indian government drafted the new National Pharma Policy, currently being discussed by industry participants to understand its implications and deliberate over its implementation. The market will likely continue to be under pressure, with more consolidation, but it should all ultimately bode well for larger organizations. More than 70% of the market will remain focused on the branded generic segment, which is Lupin’s target for growth of at least 12% to 14% over the next five years.”

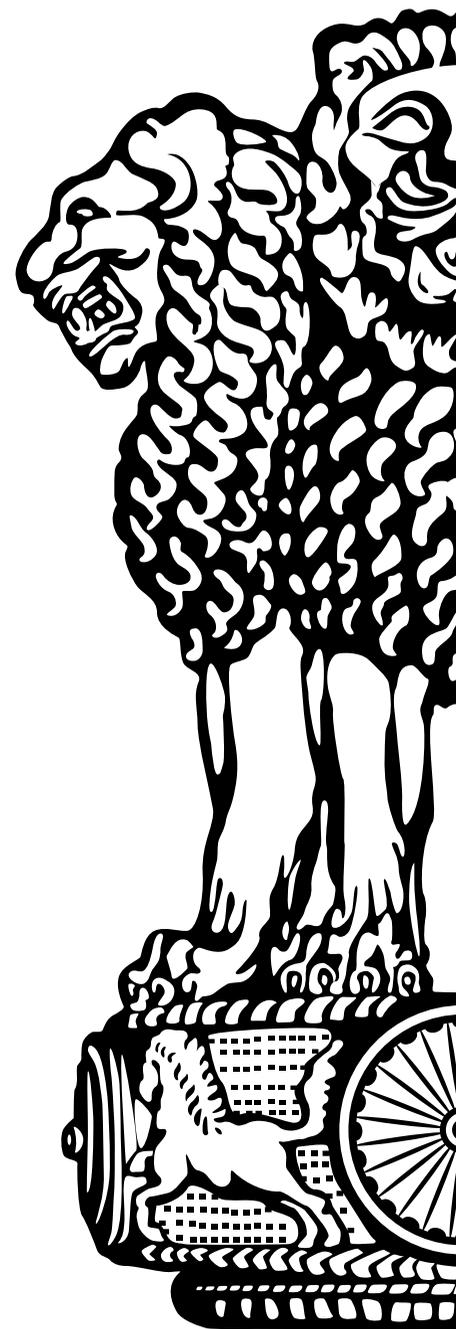
- Lupin Spokesperson

“The government must collaboratively engage with pharma companies through regulations that encourage business transactions in India. Getting the western industry familiar with the quality of science, innovation investments, and the focus on quality that exists in India will also be of big help to the Indian life science industry, in them being able to meet the mandatory quality requirements and achieving greater levels of accessibility. Providing the Indian regulatory authorities with the training that may be needed to keep the local agencies on par with the west will also assist in improving local quality standards. Higher transparency from the government agencies will also help the business community.”

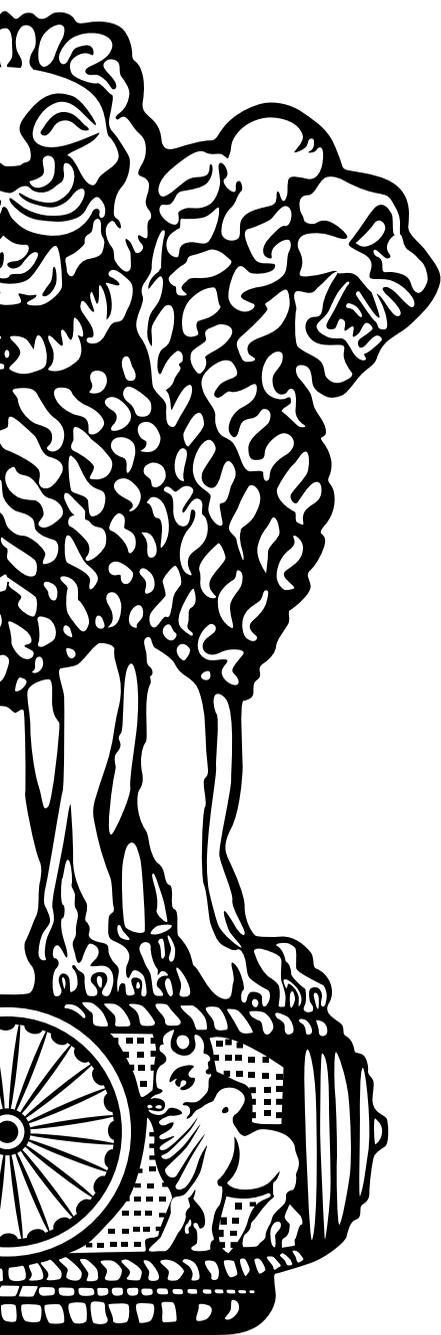
- Vivek Sharma,
CEO,
Piramal Healthcare

“BDMA is working towards getting drug controllers to harmonize their way of thinking and will potentially enter into an agreement with USP and EP to establish a globally-accepted uniform regulatory mechanism for agency approval. This would be a positive method to ensure safety and quality medical care. A message to the government is to nurture the existing domestic manufacturers, ensure they are being taken care of, pay attention to their requests and give them what they need and deserve.”

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



सत्यमेव



व जयते

“We need to improve quickly or else we will lose the opportunity to capture the global market. India has become the 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.”

- Ketan Shah,
Managing Director,
Eskay Speciality Chemicals and Eskay Fine Chemicals

“7 out of every 10 products approved in the U.S. generic market are either made in India, made by Indian companies, or contain raw materials that come from India. Therefore, India's prominence in the U.S. generic business remains strong. As for the regulatory issues, the expectations of regulators has risen over the years, and companies are now becoming more attuned to these new expectations.”

- Rajeev Nannapaneni,
Vice Chairman & CEO,
NATCO

“India is unlikely to become the research hub of the world, particularly as China is very competitively positioned here. China has, to an extent, better infrastructure than India and is viewed by the pharmaceutical sector as more open to innovation and IP. India, on the other hand, is viewed as an environment in which companies will shortcut innovation and IP regulations – the government has made exceptions to patent protection in the past – in favor of affordable generics. Other markets such as the United States and Europe will also maintain strengths in this area.”

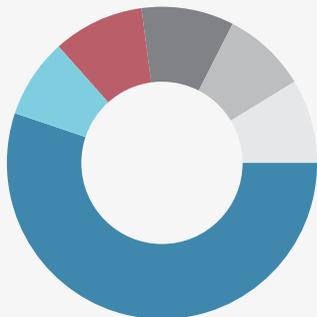
- Manni Kantipudi,
CEO,
GVK Biosciences

“Due to the patent cliff, India's pharmaceutical industry which is mainly in generics is facing large price pressures due to a substantially lower number of molecules to pursue. As a result, Indian firms are moving towards specialty generics and improving their work in this area. There may not be new innovator products emerging in India at this time but there are many examples of CRO and speciality drugs being attempted.”

- Naresh Raisinghani,
CEO & Executive Director,
BMGI India

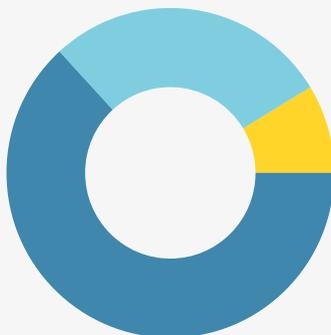
INFORMATION ABOUT YOUR COMPANY

Please indicate the type of company you represent within the pharmaceutical industry



- Manufacturer
- APIs, excipients and specialty chemicals
- Distribution and Logistics
- Biotechnology
- Services and Equipment
- Medical Devices
- Manufacturer, Distributor
- Technology solution provider
- Professional Association

The main sector in which you operate has a positive outlook



- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

INDUSTRY CHALLENGES

There are limited resources available to support R&D efforts and innovation



- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Does your company serve only the national market?



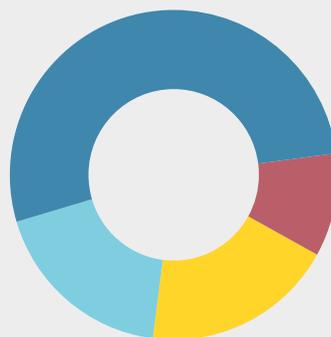
- Yes
- No

If no, what other markets does your company serve?



- Other countries in Asia
- North America
- South America
- Europe
- Australia
- Africa

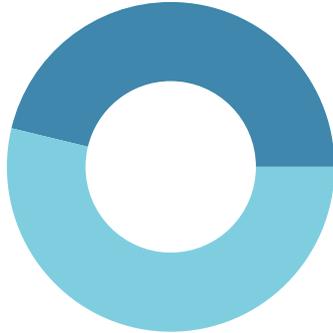
More could be done to support companies in export endeavors



- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

INDIA'S PHARMACEUTICAL INDUSTRY

The sector has extensive capabilities and the potential to remain an international leader in generics



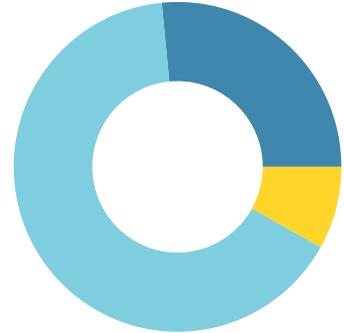
- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

The presence of prominent multinationals is beneficial to the surrounding industry



- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Relatively low operating costs give India's pharmaceutical sector a strong competitive advantage



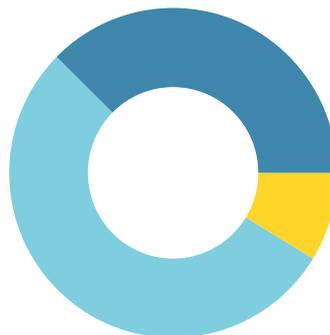
- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Companies within the pharmaceutical industry are well supported by the local and national governments



- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

One of the key benefits of operating in India is the access to skilled labor



- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

India's pharmaceutical industry is very well regarded internationally



- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

COMPANY / INSTITUTION

Website

MANUFACTURING

Aarti Drugs	http://www.aartidrugs.co.in/
Apex Drug House	http://www.apexdrugs.com/
Athena Drug Delivery Solutions	http://athenadds.com/
Aurobindo	http://www.aurobindo.com/
Alves Group	http://www.alvesgroup.com/#
BDR Pharmaceuticals	http://www.bdrpharma.com/contact/
BELCO	http://www.belcopharma.com/
Bharat Parentrals	http://bplindia.in/
Biocon	https://www.biocon.com/
Canton Laboratories	http://www.cantonindia.com/
Cipla	http://www.cipla.com/
Ciron	http://www.cironpharma.com/
Concept Pharma	http://conceptpharma.com/
Cooper Pharma	https://www.cooperpharma.com/
Espee	http://www.espeeusa.com/index.htm
Gepach	www.gepach.com
Glaxo Smith Kline	http://india-pharma.gsk.com/
Glenmark	http://www.glenmarkpharma.com/
Gufic Group	http://gufic.com/
Hemmo Pharmaceuticals Ltd	http://hemmopharma.com/
IND SWIFT	http://www.indswifttd.com/
KA Malle	http://kamalle.com/
Kilitch Drugs	http://www.kilitch.com/
Lasons India Pvt	http://lasons.com/
Lupin	http://www.lupin.com
Mac Chem Products	http://macchemgroup.com/
Nirlife	http://nirlifehealthcare.com/
Parth Antibiotics	http://www.parthantibiotics.com/
Prudence Pharma Chem	http://prudencepharma.com/
RA Chem Pharma	www.rachempharma.com
Reliance Life Science	http://www.rellife.com/
Rusan Pharma	http://rusanpharma.com/
S.A Pharmachem	http://www.sapharmachem.com/
Saga Laboratories	http://sagalabs.com/
Samarth Life Sciences	http://samarthlifesciences.com/
Sarv Bio Labs	http://www.sarvbiolabs.com/
SciTech Specialities	http://scitech.net.in/



This list intends to include just a representative sample of companies operating in the Indian Pharmaceutical sector, and as such it should not be considered a guide to take investment decisions.

COMPANY / INSTITUTION

WEBSITE

Signet Chemicals	http://signetchem.com/
Srikem Laboratories	http://srikem.com/
Sun Pharmaceutical	http://www.sunpharma.com/
Supriya Lifesciences	http://supriyalifescience.com/
Suyog Life science	http://suyoginc.com/
Synthoke Labs	http://www.synthokelabs.com/home.html
Taurian Pharma	http://www.taurianpharma.com/
Troikaa Pharma	http://www.troikaa.com/
Vigor Pharma	http://www.vigortd.in/
Wanbury	http://wanbury.com/
Zim Laboratories	http://zimlab.in/
Chempifine Group of Companies	www.chempifine.com/
Themis Medicare	www.themismedicare.com/
Advanced Enzyme Technologies	http://advancedenzymes.com/
Intas	www.intaspharma.com/
Arihant Innochem Pvt Ltd	http://arihantinnocem.com/
Chempro Pharma	http://www.chemprogroup.com/
Premier Intermediates	http://www.premierindia.co.in/
Ademar Pharma	www.ademarpharma.com/
Coral Drugs	www.coraldrugs.com/
Biophore	biophore.com/
Himedia	http://www.himedialabs.com/
Natco	www.natcopharma.co.in/
Micro Labs	http://www.microlabsltd.com/
Dr Reddys	http://www.drreddys.com/

CONTRACT SERVICES

Accutest Global	accutestglobal.com/
Lambda Therapeutic Research	www.lambda-cro.com/
Piramal Healthcare	http://piramal.com/
GVK BIO	https://www.gvkbio.com/

CHEMICALS

Benzo Chem	http://bcipl.com/
Eskay Fine chemicals	http://sk1932.com/eskay.htm
Godrej Industries	http://godrejindustries.com/
Sajjan India Limited	http://sajjan.com
Sharda Chem	http://shardacropchem.com/



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PACKAGING

ACG	http://www.acg-world.com/
P.R. Packagings Ltd.	http://www.prpac.net/
Sergusa Solutions Pvt Ltd	http://www.sergusasolutions.com/
SGD Pharma	https://www.sgd-pharma.com/

SERVICES AND EQUIPMENT

Albia Biocare	http://www.albia.in/
BMGI India	www.bmgindia.com/
CI Precision	http://www.ciprecision.com/en/
Fablab Engineering	http://fablabindia.com/
Federal Equipment Company	http://fedequip.com/
Gandhi Automations	http://www.geapl.co.in/
Infionic	http://infionic.com/
Innovexia	http://www.innovexia.in/
Kirloskar Pneumatic co Ltd	http://www.kirloskarkpcl.com/
Mack Pharmatech	www.mackpharmatech.com
Polmon	http://www.polmon.com/
Transasia Bio-Medicals Ltd.	http://transasia.co.in/
Valfit Engineers Pvt Ltd	http://www.valfitengineers.com/

GOVERNMENTS AND ASSOCIATIONS

BDMA	http://bdmai.org/
Chemexcil	https://chemexcil.in
CIPI	http://www.cipi.in/
Government of Telangana	http://www.telangana.gov.in/
Gujarat Food and Drug Control Administration	http://dmla.guj.nic.in/mfg/myaccount/Home.aspx
IDMA	http://idma-assn.org/
IPA	http://www.ipapharma.org
Pharmexcil	http://pharmexcil.com/

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THANK YOU

We would also like to sincerely thank all governmental bodies and associations that took time to share insights into the market, as well as their experience and knowledge.

Food & Drugs Control Administration Of Gujarat State

fdca.guj.nic.in/myaccount/frmfdcahome.aspx

Ministry Of Commerce & Industry Government Of India

commerce.nic.in/moc/index.asp

Government of Telangana

www.telangana.gov.in

Pharmexcil

www.pharmexcil.com

IBEF

www.ibef.org

Chemexcil

chemexcil.in

Indian Drug Manufacturers' Association (IDMA)

www.idma-assn.org

The Bulk Drug Manufacturers Association Of India (BDMA)

www.bdmai.org

Indian Pharmaceutical Association (IPA)

www.ipapharma.org

Confederation Of Indian Pharmaceutical Industry (CIPI)

cipi.in



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