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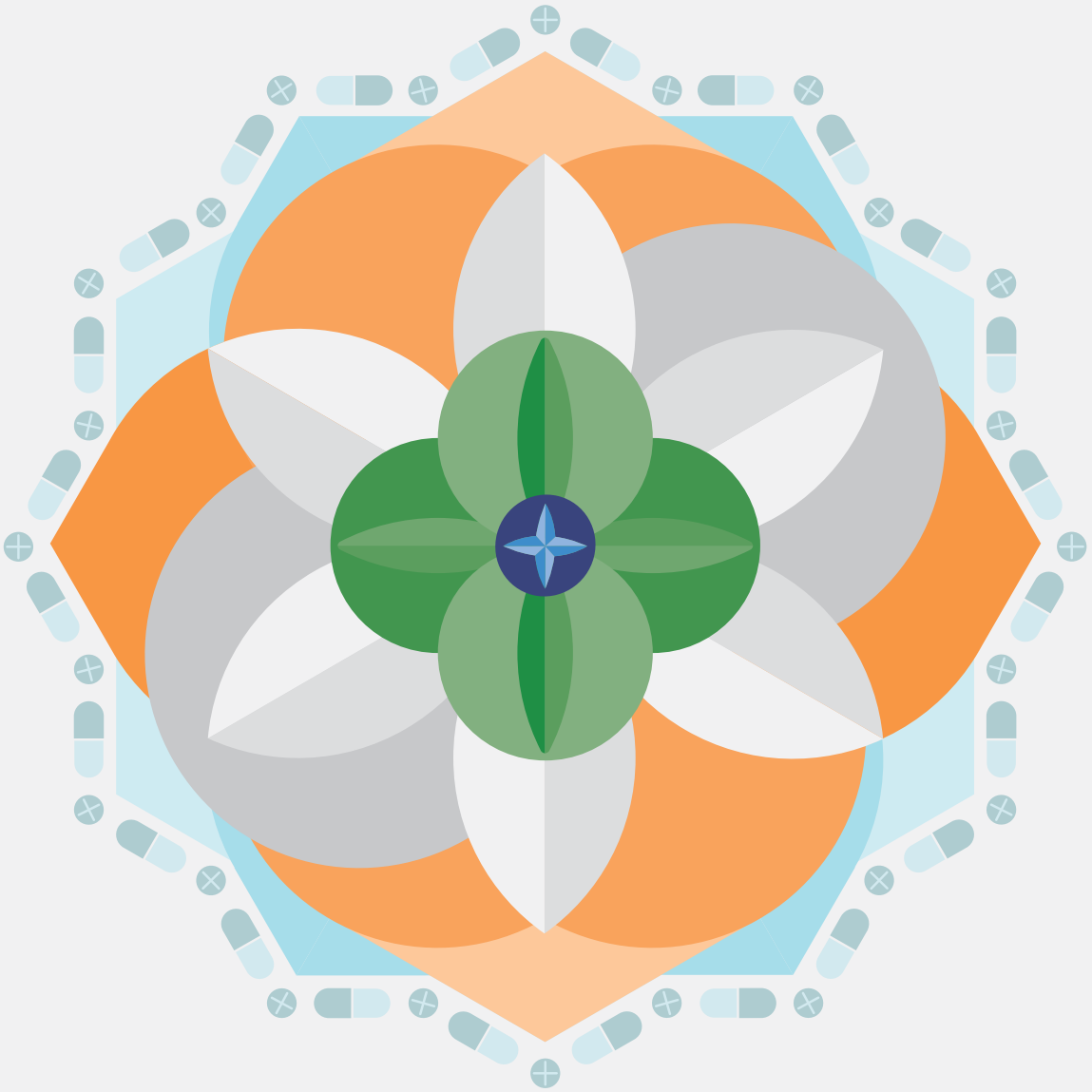


INDUSTRY EXPLORATIONS

INDIA PHARMACEUTICALS 2015

Manufacturing | Regulatory Framework | Patents | Foreign Direct Investment | Export
Biotechnology | Ayurveda | Contract Manufacturing | Research and Development

Dear distinguished readers,

First of all, a warm thank you for being part of the #cphifamily, which this year celebrates 25 years on the forefront of the pharmaceutical industry. We truly believe that by sharing knowledge the industry moves forward and develops faster, reaching better outcomes.

CPhI is proud to announce research partnership with Global Business Reports (GBR), which aims to produce top-notch market reports on relevant topics for our industry. This collaboration was born with the Turkey market report and now continues with "CPhI India Pharmaceuticals 2015 – Industry Explorations". The present study reveals a wealth of information on this strategic global pharma hub. In-depth discussions, holistic market analysis as well as facts & figures about the Indian pharmaceutical industry. Furthermore, this study presents valuable insights into local growth strategies on domestic and international lookout and exclusive interviews with top C-level industry leaders.

The report bestows thought-provoking perspectives and forward-looking commentaries examining the actual and future potentials of this burgeoning market. The collaboration between CPhI and Global Business Report (GBR) to produce the first country market report has proved to be hugely successful. Combining CPhI's pharmaceutical contacts worldwide with GBR's extensive research capabilities has resulted in an authoritative analytical report that covers all areas of the pharma market in India.

GBR has also collated the findings of our contributors to provide a series of articles examining the bigger picture and focusing on major facets of the Indian pharma industry. These include:

- "Creating Synergies: Government Support for Indian Pharmaceuticals"
- "Attracting Capital While Avoiding Dependency: Foreign Direct Investment in India"
- "Growth Through Innovation: Small and Medium-Sized Enterprises in India"
- "The Next Booming Segment? Contract Research and Manufacturing Services in India"

The respected consultancy firm, McKinsey & Company has predicted that the market value for India will reach a staggering US$45 billion by 2020. India has assumed a major role in the global pharmaceutical landscape and has entered a new political era with the current Government increasingly seeking to tie regulators and Government initiatives. API development, finished dosage forms and biosimilars, are all major contributors to India's continual growth.

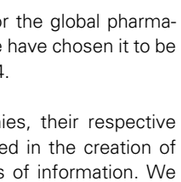
It is clear how strategic this market is for the global pharmaceutical industry and that is the reason we have chosen it to be the last market intelligence report of 2014.

We would like to thank all the companies, their respective CEOs and partnering associations involved in the creation of this report which were essential sources of information. We would like to show appreciation to our illustrious partners IBEF, Pharmexcil, the Ministry of Commerce and IDMA for the support to this research.

This report will be distributed to more than 130,000 pharmaceutical executives worldwide. We would encourage you to take some time exploring the in-depth, thought-leadership content within. On behalf of UBM Live and GBR, we wish you much success at #CPhIIndia 2014 and throughout 2015.

With kind regards,

Rutger Oudejans,
Brand Director Pharma,
UBM



Agostina Da Cunha,
General Manager,
Global Business Reports

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UBM

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This research has been conducted by Alice Pascoletti, Neha Premjee, Karl Reilly, and Jan Schmidt-Whitley
Edited by John V. Bowlus
Graphic design by Gonzalo Da Cunha

A Global Business Reports Publication
For updated industry news from our on-the-ground teams around the world, please visit our website at gbreports.com, subscribe to our newsletter by signing up to our VIP list through our website, or follow us on Twitter: @GBReports.

Exclusive Interviews
Leading figures in India's pharmaceuticals industry the government, associations, and private companies, big and small, discuss their business and organizational strategies and the state of the industry.

10, 11, 16, 47, 54, 65, 79, 96

Editorial Analysis
Global Business Reports' journalists gather first-hand accounts from industry leaders and conduct independent research to present a careful analysis of what the industry is doing and where it is heading.

20, 24, 30, 38, 50, 60, 62, 66, 76, 90, 100

Company Profiles
An industry is only as strong as its companies, and GBR provides additional information on how the key players are shaping both the domestic market in India and export markets abroad.

28, 40, 41, 42, 44, 80, 92, 94, 98, 102

Gujarat
Gujarat is the undisputed pharmaceutical manufacturing hub of India and the hometown of Prime Minister Modi. GBR devotes a special section to explaining Gujarat's unique success.

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Final Thoughts
The future of the Indian pharmaceuticals industry starts today. Company leaders provide further insight into their specific industries and future strategies.

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The Pharmacy of the World?

An Introduction to India and its Pharmaceuticals Industry

"Our strategy has always been to look at a product category rather than a therapeutic segment because most of the research that is undertaken on chemicals is common across multiple sectors. We wanted to focus on a very large number of chemicals rather than in one area that may have a limited number of chemicals. While we do have a vast portfolio of chemicals that we can supply, the fact is that most of these chemicals are derivatives of a much smaller number of basic chemicals that we use."

- Vijay Kumar Ambati, President and CEO, and Biren Parekh, Strategy Director, Clearsynth

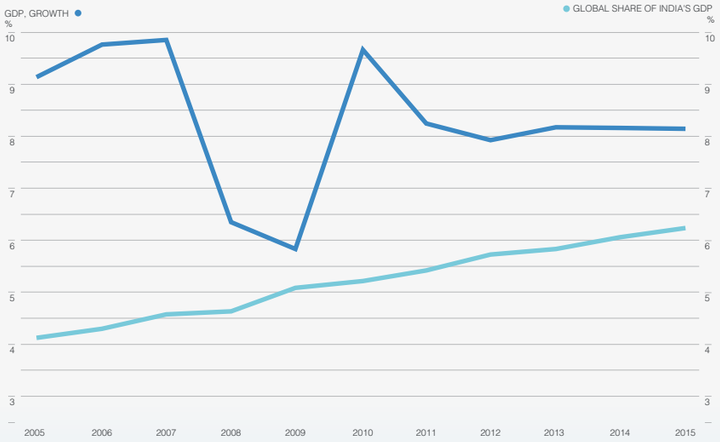
Image: Biocon

Introducing India

A Brief Political and Economic Overview

INDIA'S GROWING GDP

Source: International Monetary Fund



India conjures up fascination for outsiders, who are in awe of its ancient civilization, cuisine, unique caste system, and the bustling activity of the streets of its major cities. In recent years, however, fascination has given way to admiration. One of the original BRIC countries, India is not only a massive market for imports, but also continues to surge as an exporter to emerging and developed markets. In no other industry is India's growth more apparent than in pharmaceuticals.

The landslide electoral victory of Narendra Modi and Bharatiya Janata Party (BJP) in May 2014 was a defining moment for the country and has the business community brimming with optimism. The pro-business BJP had been in opposition since 2004 but won a convincing 282 seats out of 543 possible in India's lower house, and, with its coalition allies, now controls more than 340 seats. The most apparent consequence of the election will be an end to India's fractious politics, which had succumbed to turpitude under weak ruling coalitions. Modi's mandate is not only evident from the number of seats that the BJP leads but by the fact that so many Indians voted during the historic election, which ran for over one month, from 7 April to 12 May. Moreover, the electorate swelled to 814.5 million registered voters, 100 million more than in 2009, as the result of an ambitious campaign to register Indians.

Modi's election was a good omen for the Indian pharmaceuticals industry, not least because he grew up in Gujarat, a state known as a pharmaceuticals and industrial hub of India (see pages 74 to 87 of this report). In his first five months in office, Modi has not initiated a series of market reforms, as some may have hoped, but has instead focused on modernizing and strengthening the power of the government. These efforts could pay dividends down the road when market reforms are initiated and a more capable bureaucracy can nourish them. To be fair, Prime Minister Modi has taken decisive steps to streamline the economy, including dismantling the Planning Commission, a remnant of former central planning, and replacing it with a think tank headed by pro-market thinkers. In any case, it appears that Modi is building India for the long-term, which is the same philosophy that the leaders of the pharmaceuticals industry are currently taking.

Modi also sees trade as the best way to smooth relations with foreign countries and has expressed admiration for China's economic model and success. Instead of the Look East policy, which cultivated relations with Southeast Asian countries as a check against a growing China, Modi will seek to integrate economically with China and take its place alongside China in forging the Asian Century.

The cornerstone of India's rise is its people, and the growth of the middle class, both recently and in forecasts, is impressive and speaks to the sustainability of the country's trajectory. India has revolutionized the pharmaceuticals industry by increasing accessibility in ways never before imagined, and, in the process, has helped improve the planet's health and wealth. Now, it is beginning to leverage its position as a global leader in pharmaceuticals to advance the industry to new heights. India is no longer an object of fascination. It is force to be reckoned with. •

$1.67 trillion
GDP
Expenditure-Based 2013
Source: CIA World Factbook

3.2%
GROWTH RATE
2013
Source: CIA World Factbook

$4,000
GDP PER CAPITA
2013
Source: CIA World Factbook

INDIA AT A GLANCE

Source: CIA World Factbook

Population: 1,236,344,631 (July 2014 est.)
Capital: New Delhi
Chief of State: President Pranab Mukherjee (since 22 July 2012)
Growth Domestic Product: $1.67 trillion (2013 est.)
Growth Rate: 3.2% (2013 est.)
GDP per Capita: $4,000 (2013 est.)
Economic Sector Breakdown:
Exports: $467.5 billion (2013 est.): petroleum products, precious stones, machinery, iron and steel, chemicals, vehicles, apparel.
Imports: $99.55 billion (2013 est.): crude oil, precious stones, machinery, fertilizer, iron and steel, chemicals.
Major International Trade Partners: China, United States, Singapore, Saudi Arabia, United Arab Emirates.

Shri Sudhanshu Pandey

Joint Secretary
MINISTRY OF COMMERCE & INDUSTRY, GOVERNMENT OF INDIA

India is seen as one of the major hubs of the global pharmaceuticals industry and is now ranked third in the world in terms of volume. What are India's strengths in this field?
India has inherent strengths in the pharmaceutical sector. One of the biggest strengths is the vast pool of qualified and scientific manpower. Manpower is a very important area, as it is a basic requirement for a successful pharmaceutical industry. The second success driver has been the demand factor in the country. India has a strong demand and the socio-economic profile of the population itself is a very strong driving force to produce good quality, affordable medicine for our own consumption. This is what has been the fundamental factor driving the growth of the pharma industry.

What role does the government play in the pharmaceutical industry here in India?
Government started with large public sector undertakings in the 1970s. This laid the foundation of the pharmaceutical industry in India. Later on, the private sector picked up and grew on its own. As a country with one of the largest populations in the world, the government felt that it was important for India to be self-sufficient in pharmaceuticals, so when the private sector took off, the government was there to help support them to grow.

What do you see for the future of the pharmaceuticals industry in India?
There are a significant amount of developments that are taking place especially on the research and development (R&D) side. By 2018, a substantial amount of patented drugs are also going to come off their patent. This means that the generic drug industry is going to be very important, and India will continue to play an important role in this sector. India will also continue to play a role because of its expertise. It is not possible for any other country to have such a large base of scientific manpower and industrial facilities. India has the largest number of U.S. FDA and EDQM-approved plants. In 2014, Argentina has also included India in the list of the countries from which imports are allowed.
India is also trying to focus on the new opportunities that are available in two areas. The first area is bio-pharmaceuticals, which is going to be the future of the pharmaceuticals industry. The other area is phyto-pharmaceuticals, as people are moving more to natural products and away from chemical intakes, which can create side effects and problems. Through phyto-pharmaceuticals, efficacy and safety issues are being addressed. This medicine provides a holistic approach to healthcare.

What government initiatives are going to take place in the future to help promote this industry?
The new government's entire focus is to remove infrastructural bottlenecks and deficiencies that exist. These problems have resulted in the Indian industry not having a level playing field, as the infrastructure available is not on par with the rest of the competing world. Therefore, you have to have good infrastructure and this is what government is committing to do. Secondly, the government wants to remove the red tape and ease the process of doing business. The industry feels that if these two aspects are addressed, there is hardly any need for financial incentives. If a good enabling environment and infrastructure is there, the industry would be able to compete with the rest, on their own terms. The success of a good infrastructure has been proven by the success of Gujarat.

Why is the entrepreneurial spirit so prevalent in Gujarat, a significant amount more so than in the rest of the country?
In terms of Gujarat, the state has had a very good industrial culture. Gujarat has good power and industrial services, which facilitates business. Gujarat developed very good industrial infrastructure, which was important for the pharmaceuticals industry. Gujarat also has an enabling environment, which leads to the entrepreneurial culture being very strong in this state. Gujarat has been a trading community for centuries. This has been in its history and in the DNA of the people of Gujarat.

Do you have a final message for the international investment community looking to India?
India does not treat pharmaceuticals as only one of the commodities. Trust is very important between the pharmaceuticals industry and the people to whom it is going to serve. The sense of responsibility has to be at a different level altogether and so should the bonding and trust. Consideration for profitability also has to be at a different level. •

Dr. P V Appaji

Director General
PHARMEXCIL

Can you please provide us with a brief overview of the background of Pharmexcil?
The Pharmaceutical Export Promotional council of India or Pharmexcil is a government agency whose task is to promote pharmaceutical exports from India. It was formally a part of the Chemexcil agency, however the pharmaceutical industry took up this issue with the government explaining that they needed a separate agency for the purposes of promotion. Their argument was that because pharma was a knowledge-based industry it required a separate agency. This was agreed with the Ministry of Commerce and Industry in May 2004 and the headquarters was set up in Hyderabad with additional offices established in Mumbai, New Delhi and Ahmedabad. When we first started, we focused primarily on APIs, intermediates and formulations, but now we have branched out into other areas such as vaccines, biosimilars and even medical devices.

Today the Indian pharmaceuticals industry represents about 1.4% of the value of the international market and about 10% of the global volume. How do you see these figures evolving in the coming years?
It is difficult to get statistics that accurately reflect India's contribution to the global pharmaceutical industry as the numbers are constantly changing. I have seen data that suggests that India's contribution to international pharmaceuticals could be as high as 3% in terms of value and 14% in terms of volume. The fact is that India's contribution is much higher than any of these statistics. If you look at the value of the global pharmaceutical market, it was about $750 billion in 2013. From this about $230 billion came from the generics market. Out of this $230-billion generics market, India contributed about $15 billion. This is a much more accurate reflection of India's contribution to the global pharmaceuticals market. One must also realize that developing countries do not always have the resources to create new pharmaceuticals, so when a drug goes off patent, we only get about 5% of the initial value that the drug had when it was under patent. Furthermore, a lot of the large international players use India as a hub for producing pharmaceuticals and can add up to 50% to the value after they are exported. So even the figure of $15 billion, as an export value, is greatly undervalued. At the end of the day this is business, but there is no doubt that India's role has not been accurately reflected in the statistics.

While India may not play a large role in developing new molecules for the pharmaceuticals sector, it does seem to play an innovative role. Can you talk to me about this?
Once a drug goes off patent, companies in India can begin to start developing biosimilars, generics, super generics and even new innovative processes to administer such drugs. As these pharmaceuticals will be manufactured in India the cost is greatly reduced. As a result of this 85% of drugs that are administered by NGOs in developing nations are sourced from India. In Africa today there are many people who now have access to HIV drugs that have been manufactured in India and even the United States has benefitted from a $250 billion saving from Indian generics. The reality is that the biosimilars, generics and super-generics that are developed here in India bring a huge benefit to the international community.

Can you describe your organization's relationship with the government?
Pharmexcil has a very healthy relationship with the government. It has been very supportive of our work to increase pharmaceutical exports. In fact, about 90% the requests that we make to the government are cleared. The levels of support are spread throughout the world where exporters can go to their local Indian embassy and obtain subsidies to help encourage their growth. The government is also keen to provide confidence to local regulators and if there are any issues they are quick to rectify any issues. The government recognizes that the pharmaceutical industry is a huge strength of the Indian economy and supports it accordingly. •

Can India Become the Pharmacy of the World?

India, the largest democracy and the tenth largest economy in the world, has seen growth rates over the last decade that many of its Western counterparts would envy. While these figures have taken a dip in recent years, the most recent information shows that India's economy grew 5.7% in the second quarter of 2014 compared to the same period last year. These figures are the highest in two years and represent a new era of hope that has engulfed the country since the electorate replaced the former government with the National Democratic Alliance, a coalition of centre-right parties that is led by the Bharatiya Janata Party (BJP) under the leadership of Narendra Modi.

The May 2014 election was judged by some as the most significant since India won independence from Britain in 1947, as the new prime minister represents a drastic change from previous governments in his strong emphasis on business and turning India into a global manufacturing hub. In September 2014, after a few months in office, Modi declared: "We will create world-class infrastructure that India badly needs to accelerate growth and meet people's basic needs. We will make our cities and towns habitable, sustainable and smart; and we will make our villages the new engines of economic transformation… 'Make in India' is our commitment - and an invitation to all - to turn India into a new global manufacturing hub. We will do what it takes to make it a reality."

Over the last fifty years, the pharmaceutical industry has also witnessed major evolutions. Foreign companies initially dominated the sector, but in recent decades domestic companies have triumphed and conquered the market. This was seen with Ranbaxy Laboratories, which was originally bought out by the Japanese pharmaceutical company Daiichi Sankyo and then acquired again by an Indian company, Sun Pharmaceuticals, for $4 billion in 2014. With the market estimated to have been at $6 billion in 2005, a threefold increase was seen in just seven years as the sector expanded to $18 billion in 2012. This now accounts for approximately 1.4% of the global pharmaceutical industry in value terms and about 10% in terms of volume. Projections for growth by McKinsey & Company are equally impressive, with the consensus that the Indian pharmaceutical market will reach $45 billion by 2020.

This growth has been driven primarily by the manufacture of Active Pharmaceutical Ingredients (APIs). Once the patents expire on these APIs, it makes economic sense for foreign companies to shift their focus to acquiring such chemicals from countries that can offer a cost advantage while still maintaining strict international standards. With the highest number of U.S. FDA-approved facilities outside of the United States and low manufacturing costs, India has proved itself to be the ideal hub in recent years for the production of these APIs.

With a large number of drugs coming off patent in the coming years, including $90 billion in 2015, and becoming available to international players, it is expected that more Indian companies will have income to start increasing their investment in research and development (R&D). Industry experts say that the amount of expenditures on R&D by thirty of the top pharmaceutical companies in India rose by 19.7% in the financial year leading up to March 2013. This research and development has been focused primarily on developing areas such as Novel Drug Delivery Systems (NDDS) and to a lesser extent on drug discovery. This is due to the high costs associated with drug discovery and the lengthy process period, which requires companies to have a long-term vision rather than meeting the demands of shareholders who are more interested in short-term dividends.

This has recently been the case with Piramal, which closed down an R&D facility and let go of 200 employees in Mumbai due to increasing pressure from shareholders. Despite the growing acceptance of the need to invest in R&D, India has seen little return in terms of patentable molecules or NDDS. This has led many of the major local pharmaceutical companies to form R&D partnerships with multinationals such as Biocon did with Mylan, Sun Pharma did with Merck, and Panacea did with Osmotica Pharmaceutical. In some cases companies are starting to put more emphasis on their R&D programs being based outside of India and have instead focused on moving such departments to Western countries, where it is felt that technology and expertise can compensate for higher costs. Lupin has recently invested in setting up two R&D plants in the United States, while Cipla Ltd. has said that it would invest $166 million for research and clinical trials to develop drugs for respiratory and oncology-related diseases. Ironically at the same time, an increasing number of Western companies are starting to look to India to take financial advantage of India's Contract Research and Manufacturing Services (CRAMS) in a sector that is forecasted to be worth $8 billion by the end of 2015.

It is too early to evaluate the extent of the role that the current government has played in the establishment of India as one of the world's major pharmaceutical manufacturers, but the decisions made by previous government have certainly played a contributing role. With the establishment of Pharma Vision 2020 by the Department of Pharmaceuticals, the government is aiming to establish India as a major hub for end-to-end drug discovery. There has also been a reduction in approval times for new facilities as well as collaborations with leading organisations such as the USFDA,

REVENUE SHARE OF INDIAN PHARMACEUTICAL SUB-SEGMENTS

With 72 per cent of market share (in terms of revenues), generic drugs form the largest segment of the Indian pharmaceutical sector.

Source: IBEF

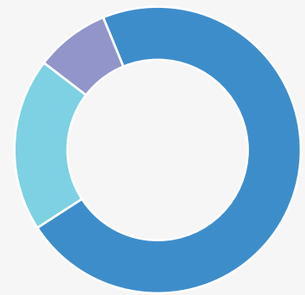


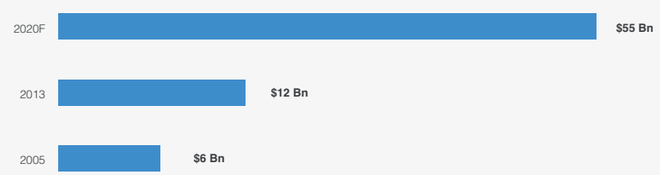
Image: Intas Pharma

Image: Megafine

REVENUE OF INDIAN PHARMACEUTICAL INDUSTRY

Source: IBEF

The Indian pharmaceuticals market is expected to expand at a CAGR of 23.9 per cent to reach US$ 55 billion by 2020.



WHO and Health Canada. Furthermore, the government has increased support for the pharmaceutical sector by relaxing FDI practices in the industry and removing duties on technology upgrades through the Export Promotion Capital Goods (EPCG) scheme.

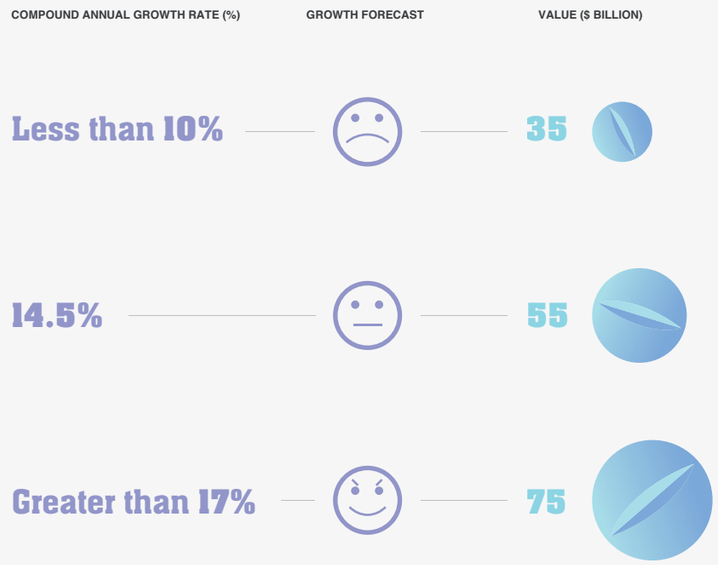
The biotechnology sector has also seen significant growth in recent years, with turnover in 2013 estimated to be roughly $4.3 billion, representing a growth of 15.1% over the previous year. Over the course of nine years from 2005 to 2013, the industry had an impressive Compound Annual Growth Rate (CAGR) of 22.2%. Biotechnology exports, valued at $2.2 billion and making up 51% of the total market also performed particularly well during this same nine year period, registering a CAGR of 25.1%. There are some issues of concern, however, such as the lack of private funding available, which has prompted the Indian government to increase their investment from $1.1 billion to $3.7 billion with a $2.2 billion venture fund to support new drug discovery in the sector. They have also increased the number of PhD fellowships in this sector to two hundred per year, which demonstrates their long-term commitment to the sector.

The Indian pharmaceutical market does face a number of current obstacles. The primary hurdle currently faced by the industry is the wave of FDA sanctions that have been filed against major Indian companies for inadequacies in their quality control, including Sun Pharma, Ranbaxy and Wockhardt. The knock on effect of these sanctions has seen export growth, which stood at 23% in 2012, to fall to 2.6% in March 2014. Further to this is the unresolved issue of what constitutes intellectual property (IP) in modern day India and whether India should put the needs of its people before the IP entitlements of major pharmaceutical companies?

India is the "Pharmacy of the World" is a phrase that can be heard in many circles around the pharmaceuticals industry in India. It is challenging for some to balance such a statement when considerations of the relatively limited scale of R&D and in particular new drug discovery in the Indian market are taken into account. Moreover, many Indian companies themselves are now either closing existing research operations or transferring them to Western countries. However, it is important to bear in mind that India does contribute to global innovation, even it this is on behalf of Western companies through their CRAMS sector. Furthermore, it plays a pivotal role in the development of existing APIs as well as being a major manufacturer and distributor of affordable drugs that has increased accessibility for millions. If the sector is to flourish beyond the expectations of 2020, the government needs to address the quality concerns expressed by the FDA as the drastic falls in export growth can only be addressed by rebuilding confidence in India as a supplier of generic drugs through proper quality management. Regarding the more long-term issue of India's role in research and new drug discovery, it is entirely understandable and commendable if one country wants to focus on being self-sufficient and increasing millions of people's access to low-cost generics. The question is whether it is sustainable for the industry to have one of its biggest players focus on replicating molecules that have passed their patent expiration date, without making a more substantial contribution? •

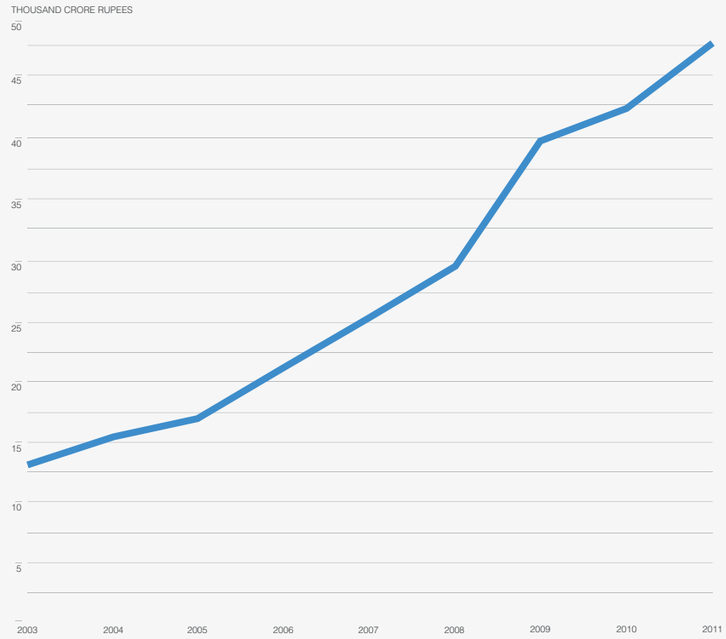
PROJECTED SIZE OF THE INDIAN PHARMACEUTICALS MARKET (2020)

Source: McKinsey&Company



EXPORT VALUE OF PHARMACEUTICALS AND FINE CHEMICALS (2003 TO 2011)

Source: Government of India, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals



In 2011, The Hindu estimated 10,000 Crore Rupees as "over $2 billion."

Daara B. Patel

Secretary General
INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

Indian Drug Manufacturers' Association (IDMA) was formed in 1961, what has been its role since?

IDMA was formed 53 years ago to support the industry. At that time, in the late 1950s and early 1960s, the profile of the companies was very different. India was a major importer of pharmaceuticals. Now, India has acquired a dominant position in the global industry and a leading exporter of APIs as well as formulations to developed nations. Thanks to our late Prime Minister Indira Gandhi, the industry received the support it needed. The government at that time ensured Pharmaceutical manufacturers could enter the patent market by having a process patent law in India. Any change in the process allowed us to manufacture the products, this is how the industry grew and people could afford to buy quality medicine. The treaty on Product Patent in 2005 was a key driver in the growth of the generics market in particular. Changes in Indian patent legislation should lead to industrial change. Now the pipeline is drying up and many companies are starting to increase their expenditures on research and development (R&D). We do expect some new molecules in the next couple of years.

What have been your main achievements in the past few years?

Should the government come up with new regulations or amendments related to our activity, they always make a point to discuss the same with IDMA. IDMA has 20 Sub Committees headed by experts in various streams. IDMA has always supported the government in bringing about pragmatic changes to meet national and international standards; however we have always kept in mind the interest of the patients and the manufacturers.

India is one of the world's main pharmaceutical products manufacturers, but is still lagging behind when it comes to value. How is it evolving?

We are trying to improve. We are working together with the government to set a vision of making India the largest global provider of safe and efficacious quality medicines at reasonable prices by 2020. We are also jointly aiming at narrowing the volume-value gap of India from third in volume and 14th in value to second in volume and eighth in value. In order to reach these goals, the industry needs to develop new products as well as have value-added generics.

We need to confront and overcome a few hurdles, such as the TRIPS Plus non-trade barriers in exports being imposed by multinationals, their efforts to impose data exclusivity, the contentious issue of SLA-Approved FDCs, the problem of the medical representatives' union wanting to have fixed hours timing for medical representatives, the stringent Code of Pharma Marketing Practices, and extending the validity period of COPP.

India is a global player, how is your competition?

Countries like Italy and China with a good base in API manufacturing will continue to be tough competitors. The Chinese API manufacturers with huge capacities and great government support have gone far ahead of us as far as API manufacturing is concerned, resulting in closure of several Indian API plants. It is unfortunate that Indian manufacturers of formulations import their APIs from China. On the other hand, we are already exporting to more than 200 countries globally. We want our members to increase their share in exports and are supporting them to enter the United States, China, Japan, and the UAE. The government is also supporting the industry to access ASEAN + some other regional countries through Regional Comprehensive Economic Partnership. We have already entered into an MOU with the CPIA (China), OPMA (Japan), UL (USA) and Dubiotech (Dubai). This will help our members to understand the regulatory requirements in those countries better and facilitate visits to manufacturing plants and exchange of information.

And what is the government answer to your concerns?

The government has started getting responsive and become a good listener. They had asked us to prepare a White Paper mentioning the problems faced by the Industry and the support required by the government. We have prepared a detailed document, "Journey towards Pharma Vision 2020 and Beyond." This document has been printed and distributed to all our members, all the Ministries, the members of the Parliament of both the houses, NGOs etc. I have pleasure in providing a copy of the same for your perusal and records.

What message would you like to convey?

We are enlightening our members that, after ensuring affordable and quality generics globally and promoting the growth of CRAMS, they need to focus on the next wave of growth through R&D and Innovation. We want our members from small and medium-sized enterprises to be progressive in their outlook. We will do everything possible to get them the required finance, marketing support and manufacturing facility upgrade. In return we want them to consistently supply safe, efficacious medicines at affordable prices with consistent good quality matching global standards. We also want to eradicate the general perception that IDMA does not support patents. IDMA supports genuine patents and would like the innovator to be remunerated suitably, but not at the cost of creating a monopoly. For us, it is always "Patients First, Patents Next." •

Aparna Dutt Sharma

CEO
IBEF

India Brand Equity Foundation (IBEF) is celebrating its 10th anniversary, a decade of multiple objectives and important achievements. What do you think has been IBEF's most crucial contribution to the Indian economy?

First, the most unique and substantive contribution that IBEF has made was establishing a connection for the nation's brands across markets and regions and becoming the reference point for information on branding India. Secondly, we have raised the level of awareness about branding, not only at the national level but also into branding specific sectors. We have raised the banner and stature for the specific sectors in which India thrives.

Today, IBEF is a one-stop shop for information that is available at the click of a button. Over the last 10 years, we have produced more than 434 sector reports that have covered all states in India. Through this process, we have started driving thought leadership. We are steadily moving into a thought leadership role, becoming the first organization in the country which has spoken about the contribution of entrepreneurship in brand building and its impact on the nation's overall branding.

Investing in a brand is quite a sophisticated and costly effort for small and medium-sized enterprises (SMEs), which make up much of India's business fabric. How do you convince these players that branding is important and has to be at the forefront of their efforts?

Over the last ten years there has been a dynamic change in India's profile. Today, Indian multinationals have become part of the general lexicon and are convinced of the value of brand projection. Having seen this, the rest of the Indian companies are approaching IBEF to discuss these issues. We are even starting to see a change with the SMEs, whose older generations used to rely on reputation to retain clients.

In the pharmaceutical sector, we are engaged with Pharmexcil, which gathers most of the exporting companies and is 80% to 90%-comprised of SMEs. We have convinced companies of the value of branding and changed the way that they project themselves globally. Today they are taking the most prominent spaces in established international exhibitions like CPhI.

That being said, this is not an achievement that we can stop investing in. Branding is not a one-off exercise but a sustained one. Over the years we have witnessed the results, with companies noticing that the branding efforts and the commitment that the Department of Commerce has taken up is making a difference to India's international image.

Do you believe that branding has been a key factor in the emergence of businesses such as the Mittals, Tatas and Reliance?

The success stories have always been there, and IBEF cannot take the credit for what the companies have achieved. But IBEF certainly takes credit for communicating those achievements to the world. India can win innovation awards and produce at low cost. Our "Indovations" are not only coming from the scientific labs. We are applying creative solutions to develop product and process-based innovations that are touching people's lives. We as a nation excel at "thinking out of the box," which can be considered our unique brand identity. IBEF's main contribution is to communicate this unique brand identity of our companies and our sectors to the world.

When it comes to pharmaceuticals, the brand being put forward is India as the "Pharmacy of the World." Can you explain what you are trying to convey with this message?

When people think of our pharmaceutical sector, the first brand recognition that comes to mind is that India has been the supplier of affordable medicines to the world. Through its generic portfolio, India has become the pharmacy of the world by providing credible, affordable, and sustainable solutions. This was the first stage of our campaign. Today we are launching the second stage, which has added the term "Responsible Care."

India takes responsibility for the safety and quality of the drugs that it provides. We want to emphasize that affordable healthcare can still be done under the more stringent quality standards. The world needs to cope with a growing and aging population and governments have realized that they need affordable quality healthcare solutions in which generic drugs play a major role. This will continue to be the role that India plays globally, but at the same time we have very important advances taking place in other fields like molecular science and biosimilars. Just as the Indian IT sector started as the back-end office of the world, today it has moved up the value chain and is providing design and technology for Boeings and Ferraris.

Would you like to leave us with a final message about the recent political developments in India?

There is a great sense of dynamism and confidence in the economy. The Modi Dividend is a reality. We do expect changes to happen, and companies will grow. The administration has identified five main strands for India: tradition, talent, tourism, technology, and trade. These are the five dimensions that guide us and can certainly vouch for my final message: India means business! •

Getting to Production: Regulations, IP, and FDI in India Pharma

"The industry now really understands that it needs to take care of all the regulations and is moving forward. Still, this is not enough, as everyone is not on the same page at the moment. If people move from industry to industry, there should not be any variation in their thinking. The government and industry are investing money to support organizations and experts to give the people the proper training… Pharmexcil wants to make sure that the players in the industry follow one set of regulations."

- Madan Mohan Reddy, Vice Chairman, Pharmexcil

Image: Cipla

Creating Synergies

Government Support for Indian Pharmaceuticals

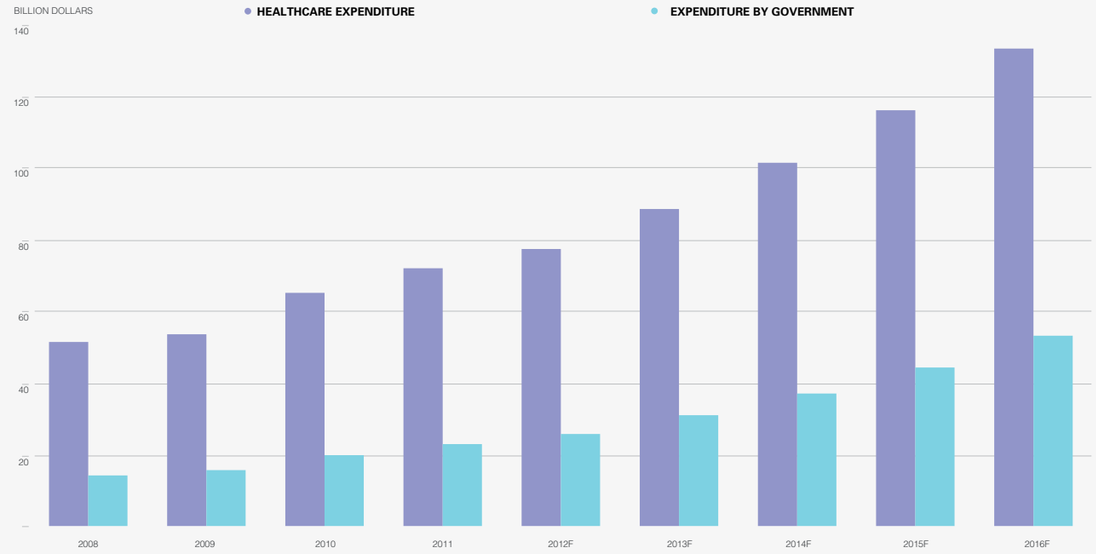
It is only in recent years that the Indian government has begun to realize the massive potential of the country's pharmaceuticals industry, to prioritize it in policymaking, and to help it grow into what it is today. The slow start of the industry was partly due to the fact that the industry's concerns and interests were lumped together with those of the chemicals industry and advocated for by one association, Chemexcil. In 2004, a new association was created, the Pharmaceutical Export Promotion Council of India (Pharmexcil), to deal exclusively with the concerns and interests of the Indian pharmaceuticals industry. Then, in the wake of the WTO and TRIPS ratification in 2005, India modified its patent law to be more in line with western standards. Only off-patent and generic versions of drugs would be allowed on the Indian market, which forced companies to shift their business development strategy and helped nurture the development of research and development (R&D) in the NCE (New Chemical Entity) segment. In parallel, many companies started investing into NDDR (New Drug Delivery Research) once again in order to diversify their offer.

Now, under the guidance of Prime Minister Narendra Modi, the industry is set for even further growth and expansion. The private and public sectors praise Modi for his eagerness to promote Indian business and the sector specifically, but the government is also signaling a renewed commitment to tighten regulations and improve good manufacturing practices, so that there is no difference between India's regulatory standards and those of the United States and Europe. The government

Image: Cipla

RISING SHARE OF GOVERNMENT EXPENDITURE

Source: IBEF



is also building India's reputation on a global level for manufacturing quality pharmaceuticals. The Indian Brand Equity foundation was established by the Department of Commerce to promote the industry abroad and give voice to its smaller players, as Indian's large players have already carved about considerable market share, most notably in the United States. The government, in other words, is not content to rest of past success and is looking to create new synergies between the private and public sectors to strengthen the industry.

Although India is a market driven economy, pharmaceutical companies still benefit from government intervention in order to protect their market and help them develop their activities, both in India and abroad. Government initiatives are numerous in an effort to establish a business friendly environment and to foster R&D expenditures by Indian companies. For smaller companies, the Indian government is able to offer competitive land prices, tax exemptions and loans to initiate activity. To foster research, companies are eligible for weighted tax deduction at 150% for their R&D expenditures. Large companies such as Lupin, Dr. Reddy's Laboratories, or Cipla are the largest spenders on R&D, but smaller companies need to be encouraged to join them, and steps have been taken to streamline procedures covering the development of new drug molecules and clinical research.

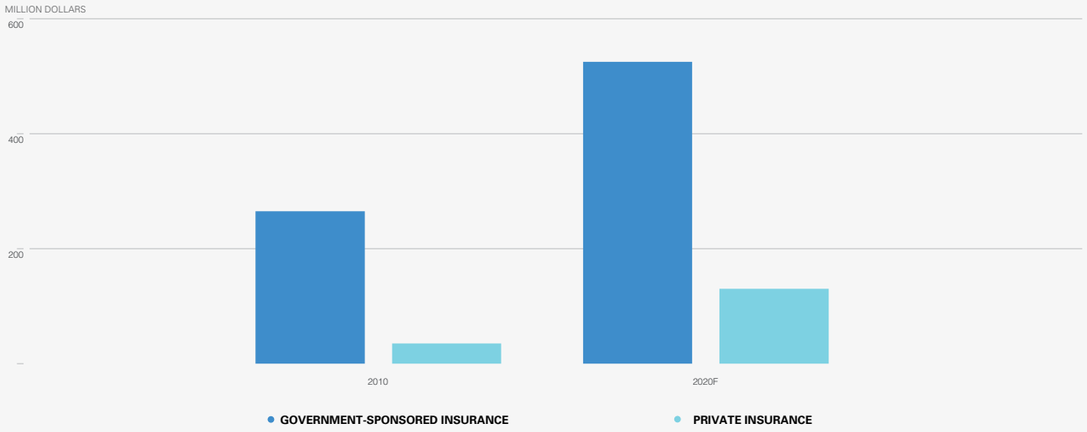
In parallel with governmental initiatives, manufacturers have also set up their own organizations, the most central being the Indian Drug Manufacturers' Association (IDMA), which conveys the messages of the industry to the government. Daara Patel, secretary general of IDMA, explained: "The IDMA was formed 53 years ago to support the Indian Pharmaceutical Industry. At that time, the profile of the companies was really different. India was a major importer of pharmaceuticals. Now, after over five decades, the complexion of the Industry is distinctly Indian, and India has acquired a dominant position in the sector. From depending on importers of finished formulations from the West, India has emerged as a leading exporter of APIs as well as formulations to developed nations in competition with the might of MNCs."

Most recently, the government established the Responsible Healthcare Trust, which comprises some of Indian's major stakeholders in the industry, including the Pharmexcil, IBEF, IDMA, the Indian Pharmaceutical Alliance (IPA), and the Bulk Drug Manufacturers Association (BDMA), Association of Biotechnology Led Enterprises (ABLE). The Trust aims to combine resources towards a common agenda aimed at creating better awareness and develop an informed perspective about Brand India Pharma in both the domestic and global markets.

The vast majority of the industry continues to meet or exceed regulatory standards and together industry, the regulator and Government is helping to move forward the knowledge base to its small and medium-sized enterprises (SMEs). In 2012, the Ministry of Micro, Small and Medium Enterprises (MSME) began promoting the development of clusters to foster the growth of the industry by enhancing the competitiveness and productivity of the companies involved. Clusters are also intended to foster Indian research and innovation in the sector. One of the best-known clusters is located at Genome Valley, in the vicinity of Hyderabad, the pharma capital in southern India. Genome Val-

POPULATION COVERED BY HEALTH INSURANCE

Source: Mckinsey estimates, Aranca Research



ley extends over 600 square kilometers and is defined as a cluster for research, including biomedical. The dozens of companies that have been established cover a broad spectrum of complementary activities. In June 2014, the Indian government expressed its will to open pharmaceutical industrial parks in China too. Among many benefits, companies in clusters can claim incentives including tax holidays, capital subsidies, and energy concessions. The aim is to reduce the cost of production by around 20% and ultimately help Indian companies to produce better products at even more competitive prices.

These initiatives are geared towards securing the future of India's pharmaceutical industry, and, by 2020, India has the goal of being involved in the discovery of 10% to 15% of new drugs around the world. The private sector has been responsive and Dharmesh Shah, chairman and managing director of BDR, demonstrates this trend: "The major focus and long-term target for BDR is to create a bank of intellectual properties, and we are trying to develop molecules that are more cost effective and accessible. In my opinion, the pharmaceutical industry is a game of right identification and selection and deploying research and resources on those identifications." One area of government action that has been a source of concern for industry's players is its strengthening of price controls. In 2012, the Indian government introduced the NPPP (National Pharmaceutical Pricing Policy) to regulate the prices of 348 drugs that are in the National List of Essential Medicines (NLEM). Margins on the said products went from 20% to 16%. Many fear this increased weight on the Indian market will negatively impact the industry. In 2013, the NPPP revised and fixed prices for 10 drug formulations and, in July 2014, added commonly used diabetes and heart disease drugs to the list of price controlled medicines to the dismay of the industry. Srinivasan, Managing Director of Srikem Laboratories Pvt. Ltd explained: "The industry is doing well, but there is a significant amount of variations happening due to the price control situation. In 2014, there is more improvement than in 2013, as the government insisted on maximum price regulation, which involves retrieving the product from the market and then relabeling the MRP." The 50 molecules initially targeted by the regulator in July 2014 have sales that represent 6% of India's drugs market. The NPPP has also decided to benchmark the price of new medicines to the most expensive brand in a particular therapeutic segment, in order to ensure that the price of the new drug does not exceed the most expensive brand in the market.

The Indian government has the difficult task of finding the right balance between the needs of its growing and still largely poor population and the aspirations of the Indian pharmaceutical industry, which employs 4.5 million people across the country and provides revenues through its massive and ever growing exports. Moreover, it must actively increase the number of graduates in pharmaceuticals, as only a strong talent pool in the pipeline can ensure its success. When speaking with the relevant associations, government agencies and leaders of the private companies that make up the industry during our research, the mood was generally confident that a healthy balance will be achieved and that India's pharmaceutical industry can continue to fulfill the dual role of energizing the Indian economy, while also providing a huge domestic population and a global one desperate to reduce healthcare expenditures, with the low-cost, high-quality drugs that they require. •

Dr. Rao V.S.V. Vadlamudi

President
INDIAN PHARMACEUTICAL ASSOCIATION (IPA)

Can you give a brief overview of your background?

I am a pharmacy graduate with a Ph.D. in pharmacology. Once I graduated I started teaching pharmacy courses at the University in Mumbai. After a few years I moved to the industry and started working in research, particularly in the area of discovery and development of new drugs. Over the past 30 years, I worked for several pharmaceutical companies while simultaneously teaching in academic institutions. I am currently the director of the St. Peter's Institute of Pharmaceutical Sciences in Warangal and work between academic and industry.

What is the mission and goals of the Indian Pharmaceutical Association (IPA)?

For the last 75 years, the Indian Pharmaceutical Association (IPA) has worked for the pharmaceutical profession and has supported pharmacists. The association does not represent any group of companies, as it is different from the IDMA. IPA is an association of individuals in any facet of pharmacy profession. IPA looks at problem areas for the pharmacy profession and strives to address them. IPA publishes peer reviewed research articles in its journal, the Indian Journal of Pharmaceutical Sciences, and has an official magazine, the Pharma Times, which is highly informative and often publishes theme-based issues alongside news of the association.

IPA also works through five divisions: the industrial pharmacy, regulatory affairs , community pharmacy, education and hospital pharmacy. We are trying to promote awareness of responsible and rational use of medicines to the public and patients as well as at primary health centers and to the pharmacists. IPA continuously works towards building a better health care system in the country and wants to help the pharmaceutical industry to build quality consciousness.

Why do you think the Indian pharma market has seen such big growth in the recent years?

Growth is very natural and actually started in the middle of the 1970s, as the Indian pharma industry is built on the objective that they have to produce quality medicines and make these medicines accessible to each and every person in the country. In a way we have not reached that target yet as there are still places where essential medicines are not accessible. As companies were building capacity and confidence to develop quality medicines, they were looking at opportunities to expand their markets. When new entrant companies could not find a foothold in the Indian market, they looked at niche market opportunities outside India. In 1995 when India became a member of the WTO the companies were challenged to bring new molecules into the market. Initially, Indian companies were able to produce large quantities of APIs at very competitive prices, which gave a platform for the API industry to grow. Afterwards, formulation and drug discovery and development capabilities started developing.

As the capabilities in the industry were developing, capacities also were built simultaneously to generate quality medicines that the companies could confidently enter into different markets. However, in the area of drug discovery and development, the same expected growth did not come as it requires a much longer and much more focused attempt to succeed. The future for the Indian pharmaceuticals industry is in APIs and generic formulations rather than in research and development (R&D). If India keeps the quality of medicines high and the prices low, the industry will keep growing. There is also a shift in the industry into protein therapeutics and although many of the protein therapeutics are currently patented, they will become generic one day. These generic opportunities would lead to the development of biosimilars. In my opinion the Indian industry will be able to handle this challenge as its growth is based on its ability to overcome complex problems. The Indian industry is predominantly knowledge-based but not necessarily volume-based.

What role do you think do small entities play in the pharmaceutical market?

Smaller companies always come and look at how they can enter the market. Their approaches are somewhat highly based on out of the box thinking, and several have had very high growth curve by looking at opportunities that are left aside by the big players.

In terms of regulations, what do you see for the future of the Indian pharma companies being in the regulated and non-regulated markets?

Many Indian companies are in regulated and semi-regulated markets. If one looks at the facilities that are certified by any global regulatory organization, more than 1,000 facilities in India are certified. The primary challenge that the industry poses for global investors is that it may be considered as having very high competition. As India has such a huge market share in global generics, to sustain market share through sustaining quality becomes a huge challenge. IPA would like to handle this challenge by taking a look at how to build a culture of continuous compliance in the quality of the products.This must be built right from the academic level. We are trying to build a synergy between academics, industry and regulators. IPA is trying to develop focus groups, which could leverage on its members' diversity to develop strategies to bring about this synergy. •

Image: Megafine

Investing in Intellectual Property

Patents, Pricing and Compulsory Licensing in India

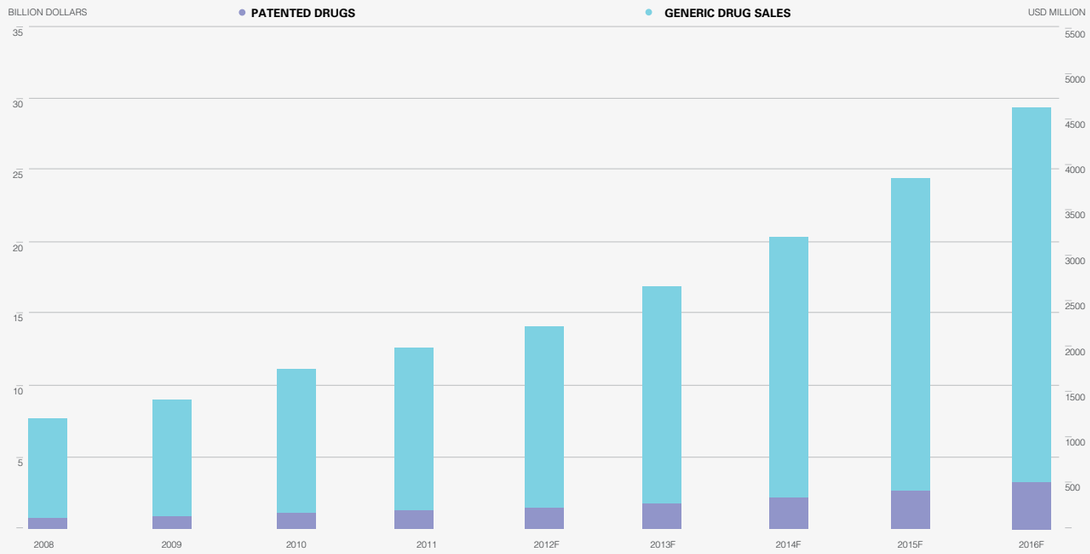
The question of intellectual property in the Indian pharmaceutical industry has been debated since the Indian government signed the Patents Act of 1970 into law. This change of policy recognized only process patent and not product patents, thus allowing pharmaceutical companies in India to replicate patented drugs that were manufactured through a different process. Without the burden of investing in the initial research that was required to develop the molecule or the excessive amounts spent on marketing and promotion of the drugs, the generic formulation can be sold for a fraction of the cost of its branded counterpart. The question remains as to whether a country has the right to ignore a patent holder's right to exclusivity in order to drive down the costs to increase accessibility and potentially save millions of lives.

The Patents Act of 1970 was adopted into law as a means of promoting the country's domestic pharmaceutical industry and ending the MNCs monopoly of the market. Furthermore, with the eradication of the monopoly, local pharmaceutical companies could offer generics at a fraction of the price that was previously dictated by the MNCs, therefore increasing accessibility and self-sufficiency. This was all achieved through Section 3(d) of the Patents Act (1970) which dictated that the following was not considered to be an invention within the meaning of this act: "the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant…" This meant that India would no longer recognize a new substance as being patentable, but rather just the process that was required to develop the substance. This allowed local manufacturers to produce identical generics of existing patented molecules, as long as they did so through a unique process. In most cases, these newly re-engineered processes proved to be more efficient than the original patented process. As a result local industries thrived whilst the MNCs were gradually pushed out. Today all of the top players in the Indian pharmaceutical market are domestic companies, which were either established after the change in policy or did not come to major prominence until such time.

In the United States, AIDS-related deaths peaked in 1995, shortly before the FDA approved antiretrovirals (ARVs) as a standard treatment in 1996. Due to the prevalence of health insurance, the adoption of expensive yet accessible ARVs as a treatment for HIV/AIDS had an immediate effect in reducing the number of deaths. However in Africa, the numbers continued to swell, as local people simply could not afford the ARV price tag that could be up to $15,000 per year. Despite being the continent worst affected by HIV/AIDS, Africa represented just 1% of the ARV market. Despite treatment being available, it was inaccessible and as a result millions of people continued to die. In 2001 Yusuf Hamied, the chairman of Cipla, announced that his company would start supplying a combination ARV, of which he had been a pioneer of, to developing countries for just a $1 a day. Today such ARVs can be purchased in developing countries for an incredible $60 per year. Yusuf Hamied was seen as

SHARE OF PATENTED AND GENERIC DRUGS IN OVERALL MARKET

Source: Ministry of Energy and Natural Resources, General Directorate of Mining Affairs



been a prominent force in the fight for increased access to medications, arguing that it was immoral that there should be monopolies in the area of life-saving pharmaceuticals. His reasoning eventually led the way to India's Patent Act of 1970. Today 40% of patients taking ARVs for HIV/AIDS consume Cipla drugs with 80% of the global consumption of ARVs being manufactured in India. Cipla continues this message of accessibility with the CEO Mr. Subhanu Saxena stating: "Access is our mission and every decision we make we screen it against that mission. Cipla strives to bring high quality medicines at the right affordable access level so that we can ensure that more patients get the benefit of these therapies."

> "GSK's position is that intellectual property should be protected, but pricing is a different discussion. We believe that patenting is a good thing, but pricing is completely different and you should not link the two. In our opinion one must be in the position to decide on how you want to price your products".
>
> - Dr. H.B. Joshipura, Managing Director, GSK

If the story ended here, most reasonable people would agree that the increased accessibility of life-saving drugs must be prioritized over the pharmaceutical companies' interests to protect their intellectual property. However, Professors Ernst R. Bendt and Ian M. Cockburn argue that this increased accessibility by generic companies is in fact restricting the availability of newer and more effective medications. In their study of 184 new medications that were approved by the FDA between 2000 and 2009, only 50% of them of them were available in India after five years. Furthermore after ten years of being released into the U.S. market, just under a quarter of them were still not available in the Indian market. They found that generic manufacturers copied half of the innovative drugs that were released into the Indian market within one year, while 85% were copied within three years. They argued that the delay in new drugs reaching the Indian market was because there was no incentive for Western drug companies to launch their new drugs in India due to the relaxed patents laws that allowed generic companies to replicate them at a greatly reduced cost. Whilst their findings are not in question, it would seem that such new branded drugs would still be too expensive for the majority of people in developing countries such as India. Whilst they may become available at an earlier date if India had a tighter IP regime, it is likely that their price tag would still keep them inaccessible. Unfortunately this study did not seem to specifically differentiate between availability and accessibility, which are two very different things.

Regardless of the arguments that could be made either way, the Indian government recognized that they would have to address the country's patent issue in order to enter the World Trade Organization (WTO). Having joined the organization in 1995, India committed itself to making its patent laws compliant with the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) within the next ten years. Amendments were made in 1995 and 2002 with the third and final amendment coming into effect in 2005 with the Indian Patents (Amendment)

Act, 2005. This marked a new era in intellectual property recognition in India for all drugs patented after its implementation. Most significantly, Section 3(d) was amended to declare that the following would not be considered inventions within the meaning of the Act: "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."

This amendment allowed for genuinely innovative drugs to be patented but stopped short of allowing pharmaceutical companies to continuously patent similar molecules in a process known as evergreening, unless such derivatives could be demonstrated as having a higher "efficacy." Whilst this new policy fell within the perimeters of what was required by TRIPS on paper, the reality would rest on how it was applied in subsequent years.

> The company lost a patent challenge in the US and we have a liability, which emerged from it. How it works is that you challenge a patent and then you get sued and a jury decides whether your challenge is valid or not. In India the patent situation is somewhat different from other countries. The Indian government has gone through affordability and accessibility very carefully based on which they came up with the Indian patent act which is now in force. From that perspective, India now respects patents and the patent laws in India are pretty well defined by the government.
>
> - Mr. Glenn Saldanha, Chairman and Managing Director, Glenmark

Following the Patents (Amendment) Act 2005, Novartis decided to seek a patent for their cancer medication Gleevec (also marketed as Glivec). Gleevec was the branded name for matinib mesylate, which was the salt form of an existing medicine, imatinib. When their initial patent was denied on the grounds that it was simple a derivative of an existing medicine, Novartis challenged the ruling all the way to the Indian Supreme Court, arguing that Gleevec had an increased efficacy of 30% to its predecessor and as a result had been patented in forty other countries. In 2013, after six lengthy years, the Supreme Court ruled that Gleevec was an example of a drug that had gone through an evergreening process and upheld the decision to deny it a patent. As a result, the drug, which was being sold at $2,600 per month, was now available to be manufactured by the Indian generic companies for less than $200 a month.

Another noteworthy case occurred between the German multinational giant, Bayer and the Indian generic company, Natco over the drug sorafenib, which was branded by Bayer as Nexavar for the treatment of liver and kidney cancer. The branded drug by Bayer was priced at $96,000 per year, which meant that it would require a person on an average Indian salary to work for three and a half years to purchase a single month's supply. As a result of the drug's inaccessibility in India, Natco requested Bayer for a voluntary lice to produce a generic version of the drug. When this was denied, Natco filed an application with the Controller of Patents Court in order to be granted a compulsory license. On the 9th March 2012 the Indian Controller of Patents granted the first compulsory license in India, allowing Natco to replicate the patented drug, providing that they pay Bayer a royalty of 6%. The judgment was reached because Bayer was obliged by their Indian patent, which was granted in 2008, to fulfill Section 84(1)(a) Reasonable Requirements of the Public and Section 84(1)(b) Reasonable Affordable Price. With an extremely limited amount of the drugs available at exorbitant prices, Bayer was found to be non-compliant with the terms of their patent and Natco commenced production of sorafenib for a greatly reduced cost of just $2,800 per year. Bayer subsequently appealed the decision but the Intellectual Property Appellate Board (IPAB) upheld the decision in 2013, however they did increase the royalty from 6% to 7%. The CEO of Bayer, Marijn Dekkers, later sparked outrage when he commented that 'We did not develop this medicine for Indians. We developed it for western patients who can afford it.' While there have been a number of patent infringement lawsuits, the general path for most Indian pharmaceutical companies today is to wait for a product to go off patent before distribution of a generic to avoid any such infringements. Dr Appaji, the director-general of Pharmexcil explains: "Once a drug goes off patent, companies in India can begin to start developing bio-similars, generics, super generics and even new innovative processes to administer such drugs. As these pharmaceuticals will be manufactured in India the cost is greatly reduced. As a result of this 85% of drugs that are administered by NGOs in developing nations are sourced from India."

The expectation of global compliance on issues such as intellectual property could be seen as being unrealistic, when one considers the vast economic and social differences that exist between countries. Western developed countries that benefit from social healthcare and health insurance cannot expect less fortunate developing countries to play by the same rules. This is made explicitly clear by the TRIPS agreement, which allows each country to introduce a patent regime that is more suited to its socio-economic context. On the other hand the work of innovators in the field of pharmaceuticals need to be recognized in order to ensure the incentive for future research. Without such recognition, there is a fear that the pipeline of future innovation may dry up. The solution seems to be that the pharmaceutical giants need to adopt a tiered price that allows their drugs to penetrate developed and developing markets with maximum accessibility, whilst still earning a fair profit. In the words of Cipla's CEO, Mr. Subhanu Saxena, "What Cipla has learnt over the years is that it is possible to drive access and get a decent return." •

Hasit. B. Joshipura

Managing Director
GSK

GSK is one of the oldest pharmaceutical companies in India. What has been the strategy for success for GSK since 1924?

The three companies that constitute GSK have been in India for almost 90 years. Early on, each company had developed a unique India specific model including pricing products that were appropriate to the country and focusing on local manufacturing. This along with the coming together of all the three companies resulted in an entity called GSK.

Given the success on GSK in India, GSK Plc, which earlier had 50.7% stake in its Indian pharmaceuticals division increased it to 75%. GSK Pharmaceuticals India is completely focused on local manufacturing, marketing and supply. The company does not export any of its products, instead focusing 100% on the domestic market.

GSK has a number of products in its product basket. What are the most popular products in the basket?

The GSK India product portfolio includes prescription medicines and vaccines. Our prescription medicines range across therapeutic areas such as anti-infectives, dermatology, gynaecology, diabetes, oncology, cardiovascular disease and respiratory diseases. GSK enjoys the privilege of being the only company to have about 20 brands in the top 300 list with Augmentin (an antibiotic) being the number one brand in the pharmaceutical industry.

GSK had been internationally regarded as a company with a strong focus on innovation, demonstrated recently with the establishment of the $5 million Innovation Challenge Fund to advance bioelectronics medicines research. Can you elaborate on the role of R&D here in India?

GSK has one manufacturing unit in India, located at Nashik in Maharshtra. The plant at Nashik makes formulations and also has a vaccines filling facility. Besides, GSK has a clinical development centre for vaccines in Bangalore. All our research and discovery is carried out centrally in state-of-the-art laboratories. We have major research centres in the UK, USA, Europe and China.

The corporate responsibility of the global company has been ranked first place twice in the last four years. Can you elaborate on the local corporate responsibility of GSK?

GSK's medicines are some of the most widely distributed medicines in India. We follow a country specific pricing policy and price our products as best suited for the country to help make our medicines and vaccines more affordable and accessible for more people in the country. The wide distribution of our products is a measure of the access pricing that we have adopted in India.

We have a tiered pricing approach and therefore some of our cancer medications, which the company introduced from 2008 onwards, are at significantly lower prices compared to some of the other markets. That is true for vaccines as well. The focus for GSK has been to provide access to our medicines.

From a CSR standpoint, access is very important to the company. GSK has other CSR projects as well. The company has a focus on underserved and underprivileged women and children and we also focus on healthcare and education. Since 2007 the company has been investing a part of our profits into these projects.

Do you have an opinion about intellectual property in the pharmaceutical sector in India versus the need for increased accessibility?

GSK's position is that intellectual property should be protected, but pricing is a different discussion. We believe that patenting is a good thing, but pricing is completely different and the two should not be linked.

India is a major player in pharmaceuticals with optimistic growth forecasted at up to 17% in the coming years. What do you think India's role is in the pharmaceutical industry going forward?

I think that there is headroom for growth as healthcare access improves. In India there is room for growth as we have a large underserved population with respect to healthcare. The Indian pharmaceutical industry is a very challenging market. It is a branded generic market and for every molecule there are hundreds of brands, thus making it a very competitive environment.

What role do you think the government plays in the pharmaceutical industry of India?

The government in India plays the same role as in any other country. Pharma and healthcare are a highly regulated industry everywhere in the world and I do not see that changing. It is a highly regulated market with quality approvals, clinical trials and pricing being key areas. The government plays an important role in all elements of the industry.

As one of the most established pharmaceutical companies in the country, can you talk to us about the future of the company going forward?

GSK India is very important for GSK Plc. The parent company owns 75% of GSK India. The recent Novartis deal with GSK will positively impact GSK in India as our vaccines portfolio will grow bigger. GSK will continue to remain a key contributor to meeting the healthcare needs of the country. •

Cipla Ltd.

FOUNDER
Dr. K.A. Hamid (1898 – 1972)

LEADERSHIP
Dr. Y.K. Hamid, Chairman, and
Mr. Subhanu Saxena, Managing Director

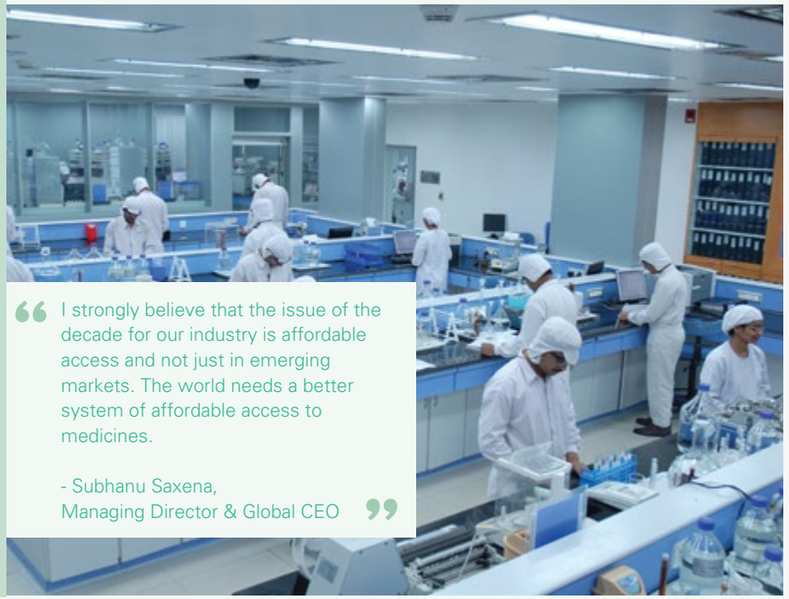
REVENUE AND GROWTH
Cipla's revenue from operations on a consolidated basis during the financial year 2013-14 amounted to Rs. 10,218 crore against Rs. 8,388 crore in the previous year, recording a growth of 21.8%. The income from operations for domestic business increased by 14.7% to Rs. 4,094 crore in the financial year under review.

EXPORTS
Total exports increased by 25.0% during the year to Rs. 5,659 crore.
Product Portfolio: Cipla's basket includes includes 2000 products in 65 therapeutic categories with one quality standard globally.

R&D FOCUS AND APPROVALS
Cipla's research and development focuses on developing innovative products and drug delivery systems and has given India and the world many 'firsts'. In a tightly regulated environment, the company's manufacturing facilities have approvals from regulators, including USFDA, UKMHRA, WHO, MCC, ANVISA, and PMDA.

COMPANY PRESENCE IN INDIA AND PRODUCT GROWTH
In 2014, Cipla's domestic branded generics business revenues grew 15.5% versus industry growth of 9%. Over the last six months the market share for Cipla's branded generics grew 5.3%, rising steadily from the previously recorded 4.7%. Cipla continues to maintain its leadership in respiratory, paediatric and urology therapies. The progressive product portfolio grew 23%, while the share of new product launches increased from 1.5% in Q1, 2012 to 2013 to 3.5% in Q4, 2013 to 2014.

UPCOMING PRODUCTS
Cipla recently entered into a strategic alliance to market MSD's HIV drug, raltegravir. Raltegravir is an important part of the third-line salvage regimen for HIV patients and should be available to patients in mid-2015.

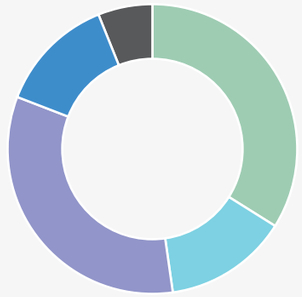


> "I strongly believe that the issue of the decade for our industry is affordable access and not just in emerging markets. The world needs a better system of affordable access to medicines."
>
> - Subhanu Saxena, Managing Director & Global CEO

ANNUAL MANUFACTURING CAPACITIES
Source: Cipla Brochure, 4 January 2013

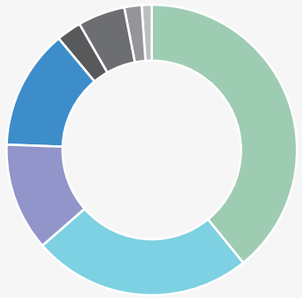
	MILLION UNITS
Tablet and Capsules	17,300
Aerosols mPDI	100
Respules	400
Lyophilised Injection	20
Prefilled Syringers	45
FFS Eye drops	75
Oral Liquids	35
APIs	800 *Tons*

CIPLA'S EXPORTS BY DESTINATION
Source: Cipla, Seventy-Seventh Annual Report, 2012-2013



North, Central, and South America	34%
Europe	14%
Africa	33%
Australasia	13%
Middle East	6%

DISTRIBUTION OF REVENUE
Source: Cipla, Seventy-Seventh Annual Report, 2012-2013



Material Cost	39%
Other Expenses	24%
Retained Earnings	12%
Employee Cost	13%
Depreciation	3%
Taxation	5%
Divided (including divided tax)	2%
Excise Duty	1%

Subhanu Saxena

Managing Director & Global CEO
CIPLA LTD.

You joined Cipla in 2013 but before that you have had significant experience in the international pharmaceutical field. How does Cipla compare to your previous experience?
Joining Cipla felt like coming home as the company's calling is true to my own calling. Cipla is a company that has one of the clearest higher purposes of any company that I have been involved with. The mission of the company has always been to put patients first and to assure that people get access to affordable medicines. Cipla helped make India self-reliant in healthcare. When the company goes into other markets, our mission and mandate is to work with government to make them self-reliant in healthcare and have access to affordable medicines. The founder of Cipla was a follower of Gandhi and the invitation that was given to me was come and help take Gandhi's message to the world and put Cipla on the global stage and do something good for India.

Cipla has recently been in the news with regards to its decision to change its global strategy. Can you elaborate on this new global strategy?
It has actually been an evolution of an existing strategy over the last number of years, rather than a completely new strategy. Every company has different priorities and objectives at different phases. Cipla was there at the birth of the Indian pharmaceutical industry and therefore it is quite natural that the company was focusing on India for a number of years. I strongly believe that the issue of the decade for our industry is affordable access and not just in emerging markets. The world needs a better system of affordable access to medicines. It has been in Cipla's DNA for decades and it is the right time for the company to come forward and take its place on the world stage. We want to lead the fight for access and build a strategy that gives us more of a global footprint.
The evolution is to build a basis in India and then expand where it makes sense globally. It is important not to forget the importance of our domestic business. The Indian market is 45% of our total income and Cipla has an unparalleled strength in the Indian market. The company's strategy in India is very simple which is to reach every Indian with Cipla medicines. If we can drive our regional presence throughout the whole country, we will double our business within the next four years. What Cipla has started doing more systematically is to partner with other companies to launch their products through our infrastructure with the idea of driving access.
The core strategy outside of India is to put our flag in key markets and be the main presence. We will achieve this goal through three means. Firstly, where we find the right platform, we will make an acquisition. Secondly is to have strategic partnerships with our existing partners who have built an on the ground presence and going into joint ventures with them. And lastly will be to build our own foundations and enter the markets directly.

How important is theme of access to Cipla and for its distribution?
Access is our mission and every decision we make we screen it against that mission. What Cipla has learnt over the years is that it is possible to drive access and get a decent return. Profit is not all about price, but one has to invest in education as well. Cipla has a commitment to high science and good medicine as well as bringing educational tools and approaches to help improve treatment for patients. Cipla strives to bring high quality medicines at the right affordable access level so that we can ensure that more patients get the benefit of these therapies.

Can you elaborate on the innovation and R&D that Cipla does?
Cipla is a company that is committed to innovative affordable access. There are still many unmet needs in curing diseases as current formulations and medicines are not patient friendly as there are still many side effects. Cipla has developed a capability in the field of nano technology where we can work on a molecule, reduce the dose and maintain the efficacy without side effects. In the respiratory field, there is a significant amount of innovation around the device as you need the technologies to also marry with the molecule. Cipla can bring therapeutic solutions with the right delivery of the right drug in the right way for the patient.

Can you talk about the role of CSR in the company?
It is very difficult to distinguish CSR as a separate activity because when our staff comes to work, they come because of the impact they want to have on society. Cipla trains doctors to treat TB and we are very involved in palliative care as we have an institution in Pune. The company has learnt a significant amount about how to support other therapies through some of the techniques that we use at the institution. Currently the company feels that we should be expanding our activities around palliative care and we are looking at how best we can do that. Here at Cipla, we cannot extinguish our day job from CSR because of the higher purpose that the company has.

What is the role of India in the global pharmaceutical industry?
The Indian pharma industry can be a major driver of economic growth in India. About 40% of medicines in the US come from Indian pharma companies. A vast majority are high quality well made products that are meeting a health need as well as an economic need. The Indian pharma industry must lead the way in the debate on access and bringing high quality medicines to the rest of the world. •

Image: Biocon

Attracting Capital, Avoiding Dependency

Foreign Direct Investment in India

Foreign Direct Investment (FDI) plays a pivotal role in the economy of any country, with such a generalization not being truer than for developing nations. An influx of FDI into any sector of a developing country will generally result in radical reforms that will help bring it up to international standards. Apart from the capital involved, an industry in a developing country can benefit immensely from FDI through the transfer of technology, management and organizational skills as well as financing tools that can greatly increase efficiency. In most cases, such an array of benefits can easily be correlated with increased revenues of the sector, which can have the spin-off effect of amplified taxes and an improved standard of living for the host country.

In the last couple of decades, India has certainly proved itself not to be naïve to the importance of integrating FDI into its economy. In the early 1990s, the then finance minister and subsequent prime minister Manmohan Singh introduced FDI to India with the New Industrial Policy 1991. Later in the decade, the Foreign Exchange Regulation Act of 1973 (FERA) was repealed and replaced by the Foreign Exchange Management Act of 1999 (FEMA), which allowed for FDI up to 100% in a range of sectors, including the pharmaceutical sector through the automatic route. The current situation in India allows FDI in the pharmaceutical sector up to 100% through the automatic route in cases of greenfield investment. In the case of a brownfield investment, the application must go through the government route and be approved by the Foreign Investment Promotion Board (FIPB).

Apart from a relaxed FDI system that is actively seeking investment, it is clear why India is attractive to investors. Chief among these are the country's impressive growth rates in the past and forecasts for Compound Annual Growth Rate (CAGR) of 14% to 17% in the five years leading up to 2016. Apart from growth, the industry has proven itself to be dedicated to rigorous training to maintain high quality control standards, cemented by the fact that India currently has the highest number of FDA-approved facilities in the world outside of the United States. Furthermore, with a mammoth talent pool of English-speaking graduates and a low cost of labor, there are few countries that can compete with what India has to offer to the international investor.

There is little doubt that FDI is big business in India, and total FDI inflows for 2013 to 2014 increase 8% from the previous year and totaled $36.4 billion dollars, with $24.3 billion in FDI equity inflows. However, it may be a surprise to see that the number one investor in India is actually Mauritius, which has contributed to 36% of India's total inflows over the last fifteen years. This is due to a process known as the Mauritius Route, which is a channel that is used by foreign investors to invest in India, whilst taking advantage of India's Double Taxation Avoidance Agreement (DTAA) with Mauritius, where capital gains tax stands at just 3%. The list of top 5 countries with respect to FDI inflows is completed with Singapore at 12%, the United Kingdom at 10%, Japan at 8% and the United States at 6%. The key sectors where this investment takes place are in the services sector with 18%, construction with 11%, telecommunications with 7%, information technology with 6% and pharmaceuticals with 5%.

In the first year following the New Industrial Policy of 1991, FDI contributed $4.63 million into the Indian pharmaceutical sector making up 2.77% of the overall FDI. Two years later this figure had risen to $50.47 million, which increased the share of overall FDI to 7.7%. In 2012, FDI into the Indian pharmaceutical industry was at $3.232 billion, representing a 9.2% share of investments coming into the country. Although such figures seem to represent a case of rapid growth of FDI inflows to India, the case is somewhat more complex.

The reality paints a picture of turbulent growth, which is illustrated by a series of steep peaks and valleys over the last couple of decades. Whilst there has certainly been an overall growth in the amount of investment since the early 1990s, there have also been plummets. Whilst investment did reach $3.232 billion in 2012, it plummeted to $1.123 billion in 2013 bringing foreign investments in the sector down to just over 5%. However, this dramatic drop of 58.8% did not compare to the nosedive in FDI that occurred in 2010. The year prior to this, FDI had peaked at almost $4.247 billion, with a 13.53% share. The following year this has dwindled to just $213 million representing a 0.82% share of all FDI.

A strong argument can be put forward that such turbulence can be associated with India's stance on intellectual property. In what appears to be a form of anticipation to India's agreement to amend its patent laws to be TRIPS-compliant by 2005, a period of increased growth occurred from 2002 to 2005. The spectacular fall in FDI in 2010 took place as the Indian Pharmaceutical Alliance decided to challenge eighty-one patents that had been issued by India's patent office over the previous five years, whilst the fall in 2013 correlated to Novartis losing their landmark case to file a patent for Gleevac. It would appear that 2014 has been a more stable year with the most recent data showing growth in FDI of 13.9% in the Indian pharmaceutical sector with $1.279 billion being invested from overseas.

Over the last decade there have been a number of acquisitions of major Indian pharmaceutical companies by Multinational Corporations (MNCs), which have included Ranbaxy (recently acquired again by Sun Pharma), Shantha, Paras, Orchid, Dabur, Piramal and Agila. The benefits of FDI going into such acquisitions can be clearly demonstrated by the increased innovation that the pharmaceutical sector has experienced with 341 new formulations being collectively released into the domestic market by these companies between May 2009 and November 2013.

Furthermore such investments can play an important role in helping companies to correct their balance sheet and diversify their portfolio. Mr. Vivek Sharma, CEO of Piramel Enterprise's critical care unit spoke of how Abbott's acquisition of Piramel's domestic formulations business in 2010 for $3.72 billion impacted the company: "after addressing the company's debt, the remaining funds

> "India is the best place to innovate as the cost of innovation and the cost of failure is affordable. In India we can afford to take the risk as a country as even if it fails it is still affordable."
>
> - Ms. Kiran Mazumdar-Shaw, Chairperson & Managing Director, Biocon

were invested into a diverse portfolio of industries including communication and travel but we remained most committed to the healthcare industry. Our primary goal was to invest the money on the basis that our shareholders got the best possible return on their investment in us."

Such an acquisition seems to have finally paid off for the Piramal Group conglomerate, which showed consolidated annual growth, across its sectors of pharmaceuticals, healthcare information, management and financial services, of 27.5% in 2014. Its primary business focus of pharmaceutical solutions showed growth levels of 14.2%, with critical care and OTC & Ophthalmology showing growth rates of 16.9% and 21% respectively.

While it is clear that companies usually benefit from the FDI that they receive through such mergers and acquisitions, it is unclear how the industry and the wider population share in these benefits. There are no doubt, many case studies where FDI contributions to various sectors correlate to very high standards of living, such as the case with Hong Kong, Singapore and Ireland. However, the situation with the Indian pharmaceutical industry is completely different, as this industry's success over the last number of decades has been based on its ability to become domestically controlled.

When India started to become self-sufficient in this sector, the nation and developing countries across the world, greatly benefitted from the fractional costs associated with Indian generic medications. In 2013 the Department of Industry Policy and Promotion (DIPP) estimated that 28% of India's pharmaceutical market is currently controlled by MNCs. This share could increase to 41% if another pharmaceutical company in the top three tier was acquired, with this share possibly rising to 55% if another acquisition of a company in the top eight tier took place. It is a sobering thought that a country that fought so hard to make its industry self-sufficient and in doing so revolutionized the generics industry and increased accessibility for millions, could revert to being controlled by MNCs. This is a strong possibility, as 96% of all FDI into this sector been targeted at brownfield investments, worth approximately $2.2 billion, with only 4% of FDI investments have been invested into the greenfield operations of the Indian pharmaceutical industry.

The government has certainly considered such recommendations with proposals to make the industry more self-sufficient brownfield production. The suggestion by the DIPP was that FDI that is invested in critical drugs via brownfield projects should be curbed at 49% with FDI up to 100% being permitted through greenfield projects, however this was rejected by the Ministry of Commerce and Industry. It was a gamble that could eventually increase the cost of life-saving generics that have gone off patent to both developing and developed markets, as foreign companies seek to increase their margins.

While these investments are vital to future research and development, India needs to weigh its responsibility as the pharmacy of the world and consider keeping a controlling interest. The Department of Pharmaceuticals (DoP) seems to disagree, stating in 2013, that 70.8% of the medications produced by the six major pharmaceutical companies that have been acquired in recent years, have not changed their prices in the domestic market since 2010. Furthermore, increases have been relatively modest over this timeframe, with 6.8% of products experiencing a price increase of up to 5% and with 2.9% of pharmaceuticals experiencing an increase greater than 15%. FDI is no doubt critically important to most sectors of the Indian economy. However, India has demonstrated its ability to not only be self-sufficient in pharmaceuticals, but to increase the developing world's accessibility to such medications.

A strong argument can be made that the true cost of FDI could lead to a scenario that could complete a cycle of dependence on foreign industries to self-sufficiency and back to dependence again. This scenario has not yet unfolded, but it should be a concern to India's model of being a global supplier of inexpensive generic drugs, as MNCs will undoubtedly prioritize their margins over accessibility. The role of the government today is get the balance right between whatever FDI may be required and the autonomy of the industry as a whole. In the words of Mr. K.V. Subramanian, CEO & President of Reliance Life Sciences: "the end result of any FDI has to be in enabling the multiplier effect of the investment to both industry and society, and not being restricted to the benefit for a limited set of investing organizations." •

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Liberalization of the politics had the result that there was a significant amount of foreign investments into India. The Indian industry experienced great growth as there is a huge local demand. In India there has always been a good balance between the supply and demand.

- Mr. Bhavin Mehta, Director of Business Development, Kilitch Drugs

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Megafine's main markets are in the United States and Europe. Japan is a market that we entered almost five years ago and in which we now have a significant presence. The Japanese market is difficult but very interesting, and Megafine already has some approvals and is in the process of gaining more drug master files in 2015.

- Shailesh Sanghvi, Director, Business Development, Megafine Pharma Ltd.

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Kavita Mehrotra, Ph.D.

Global Strategic Relationships Head
UL LIFE AND HEALTH

As a major international safety consulting and certification company, can you talk to about the role that UL plays in the pharmaceutical industry here in India?

UL works with a diverse international array of companies and stakeholders every day to make the world safer and provide quality assurance. We work with more than two-dozen pharma companies in India, ranging from the ten largest in the world to smaller startups. Our vision for UL Eduneering in India is to expand that presence in the area of quality and regulatory compliance learning in keeping with our company's vision of working for a safer world. We aim to provide a good example of corporate citizenship and social responsibility by partnering with Pharma, government agencies, and medical devices companies to promote safe and effective regulatory standards.

How has this helped pharmaceuticals companies to comply with the recent domestic regulations and reach out to regulated markets?

UL Eduneering has a 15-year learning partnership with the U.S. FDA, which includes global commitment to consistent GMP standards. By using and offering content authored by FDA, we bring a high level of consistency and credibility to a globally applicable standard for regulatory and compliance training. We prepare companies not only to have standardized processes, but also an audit readiness while demonstrating superior compliance practices.

Our expertise in systemic and content leadership, our FDA-authored library of more than 200 courses, our 700+ course library, including recent topics such as sunshine Act, and our multilingualism and global approach all enable us to help companies comply with domestic and global regulations.

Can you talk to us about the primary problems that you encounter in a typical Indian company inspection and how these problems may differ to problems encountered in Western companies?

The biggest challenge in India today is a mindset issue on quality. What will make us succeed will be companies not looking at quality from the point of view of regulation alone. Any inspection should reveal consistent quality. It is, after all, a patient safety issue, not an Indian or a U.S. issue. The common thread is the lack of a consistent approach to quality processes and implementation.

The second challenge is the lack of a robust training ecosystem to bring professionals across various functions up to speed on compliance processes. There is very poor management of training records for employees. The industry lacks a systematic way of monitoring the levels of individual preparedness for compliance. Let me also share another cultural interpretation of compliance, which can use a re-visit. I am privy to closed door meetings with industry leaders and have found that sometimes, an absence of records is also a function of unwillingness to share what may be "incomplete" records, as opposed to seeing that as a work in progress. Ironically enough, it is a cultural focus on academic excellence rather than misrepresentation of data that drives this, but with unpleasant consequences. The challenge is not so much of intent but of globally shared perception of records, knowledge and awareness.

So what can we do about this?

According to our recent annual survey, The Product Mindset, globalization is a core business reality that is increasing in importance and influencing priorities. The supply chain is a significant priority and increasingly global. 48% of manufacturers state they will increase global sourcing over the next five years.

Consumers globally are well-informed about the complexities of the supply chain. They understand manufacturers are sourcing pieces and parts globally and want visibility and insight into that. We saw in our study that supply chain transparency is a rising priority among consumers and manufacturers. It was also an area of disconnect between manufacturers and consumers. 84 percent of manufacturers agree that stakeholders are increasingly demanding supply chain transparency. Yet, 42 percent of consumers believe that manufacturers do not provide sufficient transparency into their supply chains.

To compete globally, many companies must adopt a "quality first" culture. This starts with regulatory knowledge, then moves to more rigorous production systems, and a top-down quality mind-set. Often, this investment into quality is surrounded by education, quality-based compensation incentives and governance policies. The rollout of the Affordable Care Act and increased cost of healthcare in the United States will lead to additional pressures in production costs globally.

India is currently the third largest manufacturer of pharmaceuticals. What is your opinion of India's role in the global market?

Our customers face challenges in navigating regulatory requirements and ensuring that their products perform as expected, are safe and meet market demands. Technology helps businesses and consumers better understand and enhance supply chain visibility can be a competitive advantage for businesses.

As I have mentioned earlier, our offering to R&D, product realization, packaging etc., is driven by the larger goal of providing the right training to the right people at the right time. Hence, we provide learning solutions globally as a one stop shop, where we have over 700 courses, a validated Learning Management System, an audit readiness for training records, a 2i cfr 11 chapter 21 compliant system easily accessible over the Internet while being fully secure and complying with FDA's electronic signature governance requirements. •

Vivek Sharma

CEO Pharma Solutions & Critical Care
PIRAMAL ENTERPRISES LTD.

Can you describe the current situation for Piramal Enterprises Ltd.?
We sold to Abbott our India based branded generics formulations business in 2010 so that was a changing year for the company. This sale gave us the leverage to not just broaden our range in existing businesses, but also to enter into new ones. We acquired a number of new companies in the healthcare sector including the molecular imaging research and development (R&D) pipeline of Bayer Pharma AG in Germany. We've also focused more on our critical care business in the United States and gained a significant market share. Today, our overall healthcare portfolio has expanded and become more prominent. We are looking at expanding our presence in our current markets.

In terms of pharmaceuticals, what market do you primarily focus on?
Ninety percent of our revenues come from the regulated markets of Europe and the United States. This is also the area for the biggest growth for us, as this happens to be where all of the largest pharmaceuticals companies are based. Whilst there is also growth in Japan and China, our presence in the Asian market is limited but we are making good inroads here.

R&D is a challenging area to invest in even for large corporations like Piramal Enterprises Ltd. What is your opinion?
We invested heavily into R&D & new chemical entity (NCE) research over a number of years here at Piramal Enterprises Ltd. but one has to keep in mind the challenging environment of maintaining significant R&D operations for a company like ours. We still continue to invest in R&D, but it is true to say that we have shifted our focus to our existing pharmaceutical products and doing R&D-related work for our customers rather than invest in our own pipeline of NCEs. We just did not feel that the resources that we were initially putting into it were justified and felt it could be better used in other areas. We had to change our strategy after observing the situation for over a decade.

With over 12,000 pharmaceutical units in the country, how do you analyze the situation here in India in 2014?
Many of the larger pharmaceutical companies are very well established and have a global presence. Today they have deeper pockets and so can take part in international acquisitions and play the same game as any other multinational corporations. However there is still some uncertainty regarding the smaller companies and how they can contribute to the industry and grow. The changes in the Drug Pricing Policy have also significantly shaken up the domestic industry.

The Abbott deal in 2010 that you mentioned earlier allowed Piramal Group Ltd. to pay off a lot of debt. What else you did with the remaining funds?
The remaining funds were invested into a diverse portfolio of industries including communication and information services, but we remained most committed to the healthcare industry. Our primary goal was to invest the money on the basis that our shareholders got the best possible return on their investment in us. As a listed company Piramal Enterprises Ltd. has to evolve in a complex economical environment.

How competitive is the pharmaceutical market for a company such as Piramal Enterprises Ltd.?
Piramal Enterprises Ltd. has a range of values that is the driving force of its success. The company is very focused on encouraging its staff to be innovative and act in an entrepreneurial manner. Our company is very much a global company that recruits its staff based solely on their skills. Piramal Enterprises Ltd. is also a very professionally run company. Unlike many other companies in India, the influence of the family owners is non-existent. Piramal Enterprises Ltd. is operated like any other professionally managed corporation in the world. This is our strength.
We are present across the drug life cycle for API and formulations with facilities in North America, Europe & India. Our R&D and manufacturing facilities are world class. Moreover, we are continuously investing in new technologies such as Continuous Flow Chemistry, Bio and Chemo catalysis in order to enhance our offerings.

Looking to the future will the pharmaceutical sector remain an important part of the Piramal Enterprises Ltd?
The pharmaceutical segment is the largest component today and will continue to remain an important part of Piramal Enterprises going forward. With the increased resources that we now have we can look at expanding our portfolio and investing into a range of different sectors but we remain committed to pharmaceuticals and it will remain a key component of the group. We are investing significantly in our existing healthcare businesses, and investments worth more than $70 million are at various stages of execution. We are also aggressively looking at potential inorganic growth opportunities in our focus areas. •

Capturing Global Market Share: India's Major Pharmaceutical Companies

"The government has been doing a lot of work to promote the Indian pharmaceuticals sector. It is promoting the sector at the CPhI event in Mumbai and at similar events around the world in the United States, Russia, Africa, Europe and Japan. During my tenure as President of the IDMA, I saw firsthand how much the government did to help and promote the sector. Of course, there is always more to do."

- Manish Doshi, Managing Director, Amoli Organics

Image: Glenmark

Dethroning the MNCs

The Emergence of the Global Indian Pharmaceutical Companies

Few industries experience the revolution that the Indian pharmaceutical industry has undergone in the last number of decades, whereby small domestic companies have been able to grow into global players in a sector that was previously monopolized by multinational giants. While this revolution is still very much a work in progress, there is little doubt that a clear blueprint has been drawn up as to the direction that this industry will continue to move towards.

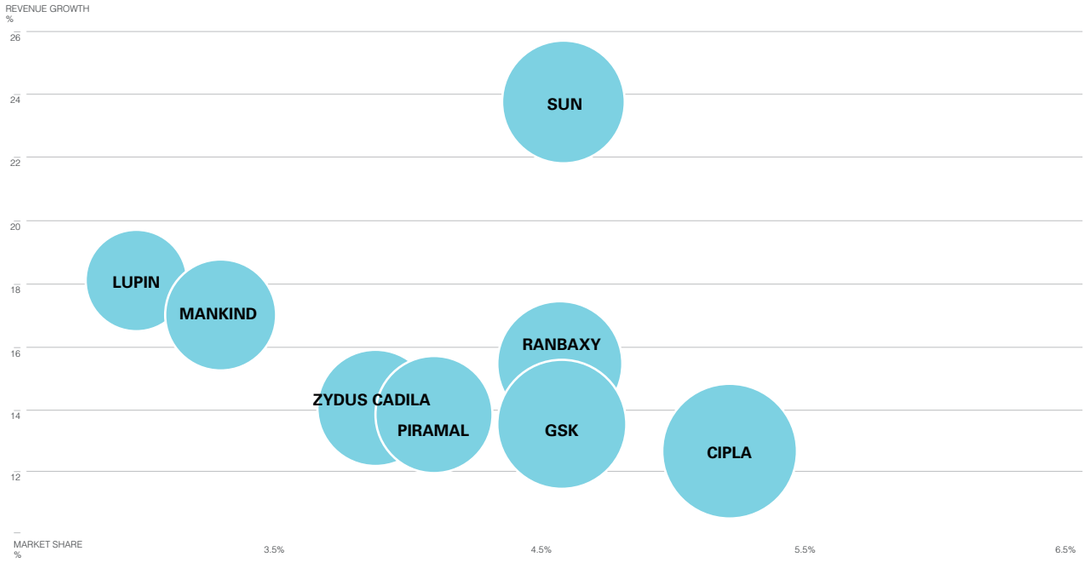
Previously, foreign multinational corporations (MNCs) dominated the Indian pharmaceutical industry. In its determination to curb this monopoly and promote a domestic infrastructure to the sector, the Indian government passed the Patents Act of 1970. This reform of intellectual property law was seen as being a game-changer for the industry, as it allowed local companies to develop their own unique processes to manufacture drugs that were still under patent. In many cases, local Indian companies, in their quest for a new process, were often able to identify processes that were considered superior to the patented processes.

While the Patents Act of 1970 could be seen as the fundamental catalyst in transforming the industry to where it is today, the reality is that India always had a number of factors working in its favor, which only became exposed with the change in intellectual property (IP) policy. Most importantly, India could offer reduced production costs because of the lower cost of labor. However, this advantage was only possible because India has a vast talent pool of English-speaking graduates specialized in pharmaceuticals. Executive Director of Micro Labs S.M. Mudda argues: "it

Image: Glenmark

REVENUE GROWTH AND MARKET SHARE, INDIA'S LARGEST COMPANIES (2011-2012)

Source: Revenue Growth and Market Share, India's Largest Companies, 2011-2012



is not difficult to find skilled people in India, as we have a vast pool of qualified people with exceptional abilities, which is one of the country's strengths. India prides itself in having technical expertise at a much lower cost than the global market." Saaryu Pareek, Managing Director at Ideal Cures, agrees: "If you take into the consideration the availability of the pharmaceutical industry's manpower and talent, we have a huge advantage over many countries."

The government also addressed the bureaucracy and red tape that stood in the way of India reaching its full potential by introducing the New Drug Policy of 1978. This policy was further revised into the New Drug Policy in 1986 and greatly reduced the regulation that private domestic companies would have to go through, while still being somewhat restrictive for larger MNCs. Thereafter, the share of MNCs dropped to just 50% by the late 1980s. The stage was set for the small domestic players to overtake the industry.

The industry, fueled by a more liberalized market, experienced growth in the Active Pharmaceutical Ingredient (API) and formulation sectors at rates of up to 20% from 1995 onwards. Mr. Harish Shah, CEO of Signet, spoke of the reforms of the 1991 budget as being instrumental in this growth, "the government introduced a revolutionary budget that liberalized the Indian economy and is seen by many as India's second independence day. This resulted in the dismantling of many import duties, which had a very positive effect on the whole of the economy, including the pharmaceutical sector." The number of manufacturing units also dramatically increased from 1,752 in the post-independence era of India (1953) to an estimated 20,053 by the dawn of the new millennium. India had transformed from complete reliance on foreign owned companies to being self-sufficient and growing into a hub for the global pharmaceutical market.

While the evolution of the Indian pharmaceutical market could serve as a template for any country wishing to become self-sufficient in a particular sector through regulatory reform, it would be wrong to claim that the transition's smoothness equaled its success. While many international companies could enjoy up to twenty years of international exclusivity on their patented molecules prior to clinical trials, Indian companies could simply engineer a different process to develop an identical generic without having to invest huge sums in research or clinical trials. The Indian government has tried to negotiate this sore spot with their peers in the Western world with a new patent law that was adopted in 2005. While this policy does edge closer to product patents, rather than process patents, the reality is that even today, MNCs are still losing patent infringement cases that they bring against domestic companies in Indian courts. The issue was even a point of contention during Narendra Modi's

> "The Ranbaxy acquisition gives us access to a portfolio of products of which we are not traditionally strong in as it is the acute care segment of the business and Sun Pharma has always been a chronic disease player.
>
> - Abhay Gandhi, CEO India, Sun Pharma"

Aurobindo Pharma Ltd.

Aurobindo leverages its large manufacturing infrastructure for APIs and formulations and possesses a wide and diversified product basket.

FOUNDERS
PV Ramaprasad Reddy and K. Nityananda Reddy

LEADERSHIP
N. Govindarajan, Managing Director and M. Madan Mohan Reddy, Fulltime Director

2014 REVENUE
2911.1 Crores

MANUFACTURING UNITS
Nine for APIs/intermediates and seven for formulations.

INTERNATIONAL OPERATIONS
Aurobindo exports to over 125 countries, with 70% of revenue derived from international operations. Exports go to China, Brazil, Japan, Netherlands, South Africa, Thailand, UK, the United States, and Russia, among others.

KEY THERAPEUTIC SEGMENTS
Neurosciences, Cardiovascular, Anti-Retrovirals, Anti-Diabetics, Gastroenterology, Cephalosporins

APPROVALS AND KEY PRODUCTS FOR 2014
Following approvals in USA (194 cumulative approvals including 29 tentative by USFDA), Australia (49 cumulative approvals by TGA), South Africa (73 cumulative approvals by MCC-SA) and Canada (53 cumulative approvals by Health Canada) were received during the quarter ending 30 June 2014.

Source: Aurobindo

recent historic visit to the United States. Despite such disagreements with the international community over their interpretation of international IP laws, there is little disagreement over how India is now a global pharmaceutical player. India accounts for 10% of the global industry in terms of volume, with a forecast that the industry will expand at a CAGR of 12.1% during the period 2012-2020, reaching $45 billion. APIs make up the largest segment of the industry, which is forecasted to be the third largest in terms of volume by 2016, with a 7.2% global share. Incredibly, pharmaceutical companies from India filed 49% of all Drug Master Filings (DMF) in the United States in 2012. Formulations have also been a very successful segment of the market with India now deemed to the world's largest exporter of formulations in terms of volume, with a 14% market share and a forecast that is looking at double-digit growth over the next five years. Contract Research and Manufacturing Services (CRAMS) constitute another major sector, which is estimated to reach $8 billion by 2015, doubling up on it $4 billion valuation in 2012. Biosimilars make up the final major segment of the Indian pharmaceutical industry, which is expected to reach $1.4 billion by 2016. Whilst this figure might not seem impressive in relation to other segments, the growth rates are impressive when one considers that the industry was worth only $482 million in 2011. Furthermore the government remains committed to promoting this industry with plans to invest $70 million for local players to develop such pharmaceuticals.

Sun Pharma, which acquired Ranbaxy this year, is now the largest such company by market capitalization with a $15.6 billion valuation. Founded in 1983 with just five products to treat psychiatric ailments by Mr. Dilip Shanghvi, Sun Pharma is today the largest chronic prescription company in India with an annual revenue of $2.7 billion in 2014 and a market leader in the areas of psychiatry, neurology, cardiology, orthopedics, ophthalmology, gastroenterology and nephrology. Its primary focus has been on exports, which accounts for 72% of its sales. The United States is its biggest market, responsible for 60% of revenues.

> Aurobindo's rapid growth occurred after it entered the regulated market. It closed on $1.3 billion in 2013 without acquisition. Approximately 65% of Aurobindo's sales come from formulation and 35% from APIs. Out of the 65%, the majority still comes from the United States, which alone contributed approximately $580 million, while Europe contributed $110 million. ARV contributed $140 million and the remaining sales came from APIs.
>
> - N. Govindarajan, Managing Director, Aurobindo

> In the next five years we would like to be one of the top five generic players in the world in terms of size and market capitalization. We are currently the seventh by market capitalization and eleventh by size. We have the building blocks in place in terms of the people, the skill sets and the passion to succeed, so we are hoping to reach this goal by 2020.
>
> - Ramesh Swaminathan, CFO, Lupin

Dr. Reddy's is another major player that was set up in 1984 with a focus on APIs, but branched out into formulations in 1987 before going into international exports in 1991. Today, its major markets are the domestic market, the United States, Russia and Europe. In recent years, the company's operations have extended to the Indian countryside as part of its corporate social responsibility of increasing the accessibility of drugs. The company now has annual revenues of $2.2 billion with growth rates of 14%.

Lupin was founded by Dr. Desh Bandhu in 1968, with the goal of manufacturing drugs of the highest social priority. The company first received global recognition when they became one of the world's largest manufacturers of drugs developed to fight against tuberculosis. Today, its drugs are available in over a hundred countries, and the company is the fifth largest prescription drug company in the United States. It is the second largest company by market capitalization with revenues of $1.83 billion.

Dr. Reddy's Laboratories Ltd.

Dr. Reddy's Laboratories Ltd. is an integrated, global pharmaceuticals company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - pharmaceutical services and active ingredients, global generics and proprietary products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars, differentiated formulations and NCEs. Therapeutic focus is on gastro-intestinal, cardiovascular, diabetology, oncology, pain management, anti-infective and pediatrics. Major markets include India, the United States, Russia and CIS, Germany, UK, Venezuela, S. Africa, Romania, and New Zealand.

LEADERSHIP
Dr. Satish Reddy, and Dr. GV Prasad, Chairman and Managing Director

NUMBER OF MANUFACTURING FACILITIES
Nine API manufacturing units

NUMBER OF FDA APPROVED PLANTS
Six

NUMBER OF FINISHED DOSAGE UNITS
11

INTERNATIONAL PRESENCE
20 countries

EMPLOYEES
20,000 worldwide

PRODUCTS AND MARKETS
North America: Revenues from North America at 16.5 billion, year-on-year growth of 51%. Sustained performance from limited competition launches namely decitabine, azacitadine, zoledronic acid injection 5mg/100mL, donepezil 23mg and divalproex ER. Progress on market share expansion of key base molecules namely metoprolol succinate and ziprasidone. Four new products were launched during the quarter.
Emerging Markets: Revenues from emerging markets at 7.1 billion, year-on-year growth of 19%. Revenues from Russia at 4.2 billion, year-on-year growth of 18% in local currency, largely driven by higher volumes in the OTC segment and certain key products in prescription segment. Emerging Markets (Ex-Russia) at 2.9 billion recorded year-on-year growth of 25% primarily driven by Venezuela Market.
India: Revenues from India at 4.0 billion, year-on-year growth of 15%.
Source: drreddys.com

Cipla is a company that has played a prominent role in increasing accessibility both in India and on a global scale. Its goal is to make sure that no patient is denied access to high quality and affordable medicine and support. Founded in 1935 by Dr. Khwaja Abdul Hamied, the company today has a turnover of $1.7 billion and a market capitalization of $8.4 billion. With a global market of 170 countries, they are a major player in the field of antiretroviral therapy, with approximately 40% of HIV/AIDS patients undergoing some form of Cipla's therapy.

Aurobindo was established in 1986 by Mr. P.V. Ramaprasad Reddy. Mr. K. Nityanada Reddy and a small group of professionals with a single unit manufacturing semi-synthetic penicillan (SSP). Today it is a truly international company, exporting 70% of its drugs, across an array of therapeutic areas, to 125 countries. By 2016, they are forecasted to earn $2 billion in revenues.

Glenmark was established in 1977 by Gracias Saldanha. With a global market, they are primarily focused on the API and generic formulation markets as well as investing in their own high-end drug discovery research. They are a great example of a company that has enjoyed recent success with their sales exploding from $32 million in 2000 to $1 billion in 2013. They continue to outperform the industry average with current growth rates of 20%.

> Glenmark had a turnover of $ 18 million in 1988 and in 2000 we were $ 32 million strong. In 2013 we closed sales at $ 1 billion.
>
> - Glenn Saldanha, Chairman and Managing Director, Glenmark

The Indian pharmaceutical industry is a textbook case study of a country's determination to overcome the foreign monopolies that controlled its industry and fully exploit its vast talent pool, whilst increasing accessibility of drugs that were out of the reach of millions. Whilst questions may arise about the means of how this was achieved, there is little doubt that from a current standpoint, the Indian pharmaceutical industry has provided immense benefits to the international community through affordable, high quality generics. It remains to be seen whether these benefits will be counteracted by constrained investments in future research, resulting in a dried up pipeline of innovation. For now, at least, India can declare itself as the Pharmacy of the World. •

Sun Pharma

Sun Pharma is India's top specialty pharmaceuticals company. Its primary markets are India and the United States, which combined comprise 79% of total sales, but the company also sells its production in forty other countries. Overall, international sales account for 62% of its revenue. Annual turnover recently crossed the $2 billion mark in the financial year ending in 2013.

Forbes lists Sun Pharma as the 38th most innovative company in the world. The company pioneers drugs in niche areas like psychiatry, neurology, cardiology, diabetology, gastroenterology, orthopedics and ophthalmology. It has a product basket of over 600 products, but five, core therapy areas account for 75% of domestic prescription sales.

In India, its market share is currently 4.7%. It has a commanding presence in the U.S. generics market, with revenues reaching $730 million. Sun Pharmaceuticals is also among the leading companies to invest in research and development (R&D), with over $550 million ploughed into R&D to date, with the company typically reinvesting 6% of its revenues each year. It has filed 645 patents and received 304.

Sun Pharma manufactures products across 24 plants, 15 of which are approved by U.S. FDA or European authorities. Eight plants produce APIs and a range of solid oral dosage forms, while injectables are manufactured at fifteen plants, of which three are in the United States and one is in Canada.

Sun Pharma is renowned for its joint ventures and acquisitions. Recently, the company made headlines with its merger with Ranbaxy, a former leader in the Indian pharmaceuticals industry. The companies look forward to merging resources, penetrating new and emerging markets, and strengthening their presence in India.

INTERVIEW

Abhay Gandhi

CEO India
SUN PHARMA

What are the values make Sun Pharma the company that it is today?

The main focus of the company has been on delivering value to our customers. Sun Pharma adds value through introducing new products and staying true to its therapeutic focus. Its main focus has always been chronic disease and within the different therapeutic segments, it has been offering its customers a bouquet of products that meets patient needs. Sun Pharma tries to achieve excellence by sticking to science.

Can you elaborate on the role of research and development (R&D) in Sun Pharma?

The company has two areas in which it works: developing products for the U.S. market and Abbreviated New Drug Application (ANDA) products, which involve trying to improve the existing profile of existing products. Sun Pharma has launched quite a few ANDAs in India and in emerging markets and subsequently, for some of these products, it is trying to get them into Western European and U.S. markets. The company has more than 800 scientists working on projects with different areas of focus, as there are various roles within R&D.

What is Sun Pharma's growth strategy and approach to acquisitions?

In terms of acquisitions, Sun Parma looks if for a company that has a strategic fit for us. We also focus on developing our generic product basket. If there are generic products registered by a company and we do not have these and believe there is value in them, we will explore it. The Ranbaxy acquisition gives us access to a portfolio of products in which we are not traditionally strong, as it is the acute care segment of the business, and Sun Pharma has always been a chronic disease player. Also, Ranbaxy's strength in certain markets complements Sun Pharma's strength in other markets.

If the markets are put together, the degree of overlap is minimal. To be able to leverage our strengths in markets where we are strong with the products of Ranbaxy is one opportunity and visa versa. Essentially, there has to be a strategic fit either in terms of therapy and products or geographical relevance. Financial discipline is also an important area to look at.

Can you elaborate on the role of Sun Pharma in making India the strong global player that it is today?

Every company ends up shaping the industry. This is not part of the decision making process but rather an outcome of achievements and the good things that are executed. Sun Pharma is seen as committed to the chronic care segment and as a company that is very close to its customer. The company is also seen as being fair to its own team and grooming internal talent. We are also known to be cautious in terms of our finances and are focused on the productivity of our employees. Productivity is achieved through setting goals, measuring them and incentivizing them.

What does Sun Pharma do in terms of corporate social responsibility (CSR)?

CSR is something that Sun Pharma is just launching, and we have been working on it as a project for the last six months. The company does a significant amount of CSR without calling it CSR. For example, we have an anti-patient fund, which we have been involved in for over a decade. We invest very heavily in various camps. These were always done with doctors without any proclivity to prescribe our brands, but rather to increase the rate of detection, the rate to compliance to therapy, and the knowledge base of patients.

What does the government need to do in order to continue enabling the pharmaceuticals sector to grow at its current rate?

The new leadership has instilled a vision in different areas. Over time, the execution of those visions will come to actual deliverables, actions and plans that can be used as a basis of investment. The industry needs more clarity about the regulatory processes, what should comprise an essential drug list, and the pricing policy. The industry also thrives on innovation, and unless one encourages innovation, the industry would not be able to migrate to the next level. If we want to be a global player and have patented products and technologies, the government can do a significant amount more to encourage innovation.

Hoe does Sun Pharma attract the right talent?

Firstly the company tries to retain the talent that we already have. Sun Pharma also focuses on training and grooming our employees for the next higher level of assignments. Learning is driven and supported by the company. There is also the attitude that one is allowed to fail, as this is an important part of learning and risk taking.

Sun Pharma has growth aspirations and sometimes the internal talent alone is not enough. The company will then look outside and work very closely with educational institutes. We have very robust summer training programs as well as senior manager driven programs. With these programs, we try to build talent from the ground up. For specific assignments, we select people from the industry.

What is the vision for Sun Pharma for the next five years?

Currently the domestic market is about 23% of our business. The United States contributes about 60% to our business and the remaining is from emerging markets. With the Ranbaxy acquisition, we are among the top five global generic players. Our main goal will always be to be good at what we are doing. The company would also like to do well in R&D and develop meaningful scale in each market that we enter. Sun Pharma also strives for high quality products at an affordable cost. •

INDIA BRANDED GENERICS

Neuro-Psychiatry	26%
Cardiology	19%
Diabetology	11%
Gastroenterology	14%
Gynecology & Urology	8%
Musculo-Skeletal & Pain	5%
Antiasthamatic & Antiallerci	4%
Opthalmology	5%
Other	7%

Lupin

FOUNDER AND CHAIRMAN
Dr. Desh Bandhu Gupta

LEADERSHIP
Dr. Kamal Sharma, Vice Chairman, Vinita Gupta, CEO, and Nilesh Gupta, Managing Director

GLOBAL REVENUE
$1.83 billion.

GROWTH
Currently, 23.4% CAGR. Lupin is the fifth largest generics company in the United States by prescriptions and seventh largest by market capitalization.

SPECIALIZATION AS PERCENTAGE OF REVENUE
APIs = 10%
Domestic formulations = 22%
Emerging Markets Formulations = 21%
Advanced Markets Formulations = 47%

EXPORTS
75% of Lupin's revenues come from exports, both in regulated and emerging markets. Their products reach over 100 countries, including key markets such as the USA, India, Japan, Europe, South Africa, Phillipeans and Australia.

PRODUCT AREAS
Lupin specializes in the cardiovascular, diabetology, asthama, pediatric, CNS, GI, anti-infective and NSAID space. The company holds a global leadership position in Anti-TB and Cephalosporin segment.

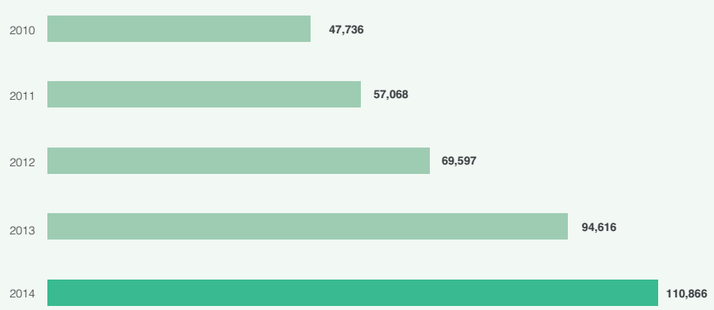
RESEARCH AND DEVELOPMENT
Lupin spends 8.6% of it's net sales into R&D. Rs. 37,358 million is the amount spent cumulatively over R&D in the last seven years. This has helped the company attain its 1,762 patents. The company employs over 1,400 scienctists at the Lupin Research Park in Pune, and other facilities in India, Japan and the United States.

CORPORATE SOCIAL RESPONSIBILITY
Lupin is a responsible company that has touched 2.08 million lives through its CSR initiatves. The company's prime initiative is the Lupin Human Welfare and Research Foundation (LHWRF) that was aimed at uplifting rural families. The reach is as vast as 3,100 villages with Rs. 500 million spent by the LFWRF. Lupin has eight locations where CSR is carried out in the fields of agriculture, animal husbandry, rural industrial development and financial inclusion.

Lupin's social development is targeted towards issues of women's empowerment, health and education. The company also works in natural resource management, infrastructure development, and post disaster response as part of their corporate social responsibility initiatives.

Source: Lupin

NET SALES (Rupees million)
Source: Lupin



INTERVIEW

Ramesh Swaminathan

CFO
LUPIN

Lupin is seen as being an example of a great Indian pharmaceutical success story. Can you talk to us about Lupin's journey from its inception in 1968 to where it is now?
Lupin Limited is a USD 1.83 billion, innovation led transnational pharmaceutical company developing and producing a wide range of quality, affordable generic and branded formulations, APIs and biotechnology products for the developed and developing markets of the world.
Dr. Desh Bandhu Gupta's vision and dream to fight life threatening infectious diseases and to manufacture drugs of the highest social priority led to the formation of Lupin in the year 1968. Lupin started out with an emphasis on making anti-TB medication more accessible to the Indian market. This was because foreign companies in India at the time controlled the cost of such medication and as a result it was too expensive. Whilst we still remain committed to our social responsibilities, there has been a great shift in our focus in recent years. India now makes up only about 22% of our turnover whilst the United States makes up about 44% with Japan at about 12%. In the United States we are now the fifth largest generic pharmaceutical company by prescriptions. We are also working on building our presence in emerging markets such as Mexico, Brazil and South Africa as well as the Philippines and certain parts of Europe. Our focus on APIs has also shifted dramatically from 45% of our turnover close to 9 years back to just 10% today. As a result about 90% of our business comes from value-added formulations which are being sold in over 80 countries across the globe.

You just mentioned that Japan is one of your major markets. We have heard a lot of people talking about the potential of the Japanese market to the Indian pharmaceutical industry but not many companies have yet chosen to explore this market. How do you view this situation?
India is the 3rd largest manufacturer of drugs in the world yet it is true that no Indian pharmaceutical companies have chosen to focus on what is potentially a very important market for the future. Japan as you might be aware is the 2nd largest pharma market in the world. Currently the presence of generics is only 34% of the Japanese market by volume and only 8% in terms of value. This is because the Japanese consumer has always equated low cost with low quality. However the Japanese government has been working hard on changing this perception over the last 8 years by taking strong measures to increase generic penetration. What has made it more critical for the government is the fact that Japan has one of the largest aging populations globally and they are trying to bring down the healthcare expenditure which has been increasing steadily. Their current healthcare expenditure stands at 9% of GDP and is set to rise. Therefore the government is keen to reduce the country's dependence on expensive branded medications and promote similar high quality generics that are more affordable. Their plan is to increase the volume of generics in the Japanese market to 60% over the next five years which is an ambitious goal. Japan is a market of strategic focus for the Company and I am happy to note that Lupin has emerged as the 8th largest generic pharmaceutical company in Japan.

The United States continues to be your top market with 44% of Lupin's turnover coming from this particular market. Can you talk about Lupin's role in this market?
The United States is the most important and the largest market for Lupin. We entered the US market just over a decade ago and have clearly surprised everybody by building a business with revenues in excess of USD 800 million in just 10 years. Your readers would be happy to note that Lupin is the 5th largest generic pharmaceutical company in the United States (5.4 % market share by prescriptions – IMS health data). We have been particularly successful in the United States due to the kind of products that we chose to develop & market. This backed by the fact that we were heavily vertically integrated for these products has been helpful in having control over our supply chain metrics not to mention reduced costs and hence higher profitability. We are now expanding into newer niche therapy areas in the United States such as oral contraception, dermatology, complex injectables and the inhalation & respiratory segemnts. Due to this expansion into new therapy areas, the United States will remain our most important market in the years to come.

You mentioned that part of Lupin's success has been its vertical integration strategy. Can you talk to us about Lupin's various strategies that are in place today?
Vertical Integration helps us in being the last man standing when it comes to cost, in a situation where the prices are eroding and the cost of production is rising. It also helps us in terms of supply chain metrics, which are extremely important from a channel point of view. When you look at the major retailers in the United States, the last thing they want is for a customer to request a product that they are unable to supply. So for Lupin, as a manufacturer, supply chain optimization is very important for us to meet the needs of such retailers.

In most cases Lupin tries to take an organic growth strategy, however there are some exceptions to this. When we are deciding on a strategy we usually look at the geography of the location, the brands of existing medications in that location and the technology associated with that medication. Recently Lupin took an inorganic growth strategy and acquired the Netherlands-based injectable company Nanomi, because we felt that they had a significant amount of technology in this complex field.

Can you talk to us about the role of the government in the Indian pharmaceutical market?
The government plays an important role in the pharmaceutical industry in India. When you look at the healthcare system of a country like India, you should focus on the areas of awareness, availability, accessibility and affordability. I think the government has been particularly successful at making drugs available and affordable, however my submission to the government is that they now need to focus on increasing awareness and accessibility to these drugs. The government also needs to do more with regards to reaching out to the masses as 60% of India's population lives in rural communities. The industry could also be incentivized more in terms of research, as this will make more drugs become available and increase access to treatments.

You said earlier that despite Lupin shifting its focus in recent years, it still remains committed to its social responsibilities. Can you talk to us about Lupin's current approach to CSR?
Lupin was founded with a very strong sense of social responsibility in that the drugs that we would manufacture would be for social priority instead of commercial priority. Today we continue that focus on social responsibility through the Lupin Human Welfare and Research Foundation. The mission of this foundation is to provide assistance to rural households that are living under the poverty line. We started this project in 1988 with 25 communities but this has since grown exponentially. Today Lupin donates 2% of its profits to this foundation to fund projects in social development, economic development, healthcare development and infrastructure development in rural areas.

Where would you like to see Lupin in five years time?
We would like to be one of the top five generic players in the world in terms of size and market capitalization. We are currently the seventh by market capitalization and 10th by size. We have the building blocks in place in terms of the people, the skill sets and the passion to succeed, so we are hoping to reach this goal by 2020. •

N. Govindarajan

Managing Director
AUROBINDO

Can you give a background of how Aurobindo started and what where the major milestones?
Aurobindo originally started as semi-synthetic, penicillin bulk manufacturer with its first plant in Pondicherry. The company first focused on bulk products but in 2001 to 2002 Aurobindo started moving to finished products. Aurobindo's major regulatory shipments started only in the last 13 years, as prior to that the company was more focused on the domestic market and non-regulated markets, including Latin America and South East Asia. Aurobindo also moved into anti-retroviral (ARV) and started manufacturing both APIs and the finished dosages and supplying to major funders. Aurobindo is one of the largest dossiers in terms of its particular rehabilitation suppliers across the globe. Aurobindo's rapid growth occurred after it entered the regulated market. It closed on $1.3 billion in 2013 without acquisition. Approximately 65% of Aurobindo's sales come from formulation and 35% from APIs. Out of the 65%, the majority still comes from the United States, which alone contributed approximately $580 million, while Europe contributed $110 million. ARV contributed $140 million and the remaining sales came from APIs.

What were the drivers for growth at that point of time?
Aurobindo experienced some growth as the company started relationships with two key promoters, one based in Europe and the other in the United States. One of Aurobindo's main manufacturing units is Aurolife, which is a facility that we acquired in 2008. There is control substance approval, which means that if you want to supply to the U.S. government, you have to do the final stage manufacturing in the United States. Today the Aurolife asset is turning out approximately $800 million annually. When Aurobindo started ascending in the regulated market, one of the key aspects was the number of filings. In the U.S. market, we have filled approximately 355 ANDAs and out of that, 155 were approved and 45 more tentatively approved. In addition to the number of filings, Aurobindo has the advantage of being much more differentiated. The first level of differentiation that Aurobindo achieved was moving into injectables. The second level was acquiring a company in 2013 to support more work in oncological steriles. We also started peptides and are looking into some new platform technologies.

Is there any segment that Aurobindo feels has a better growth potential?
We expect that peptides and microsphere will be the least crowded when it gets commercialize because the chemistry of acid peptide is very complex. The greatest advantage that Aurobindo has is that t is in the top three in the world in terms of our capability and competency. Aurobindo only started developing microsphere technology in the last six months of 2014 and is about two years away from commercializing the products.

The Indian pharmaceuticals market is very complex. How does Aurobindo position itself within this market?
Aurobindo is a multinational company and is not focused only on the Indian market but is penetrating global markets. The company was started by a set of promoters that is still enrolled in the business. I joined Aurobindo in October 2010. Many companies in this industry are looking at Japan at the moment. Japan is part of Aurobindo's strategy for APIs and not for finished products. Aurobindo has registered about 16 products and commercially is supplying about 22 products. Every year we register about 67 products in Japan. In the regulated markets of the United States, Europe and Japan, Japan is the fastest growing market for Aurobindo. Aurobindo is moving very cautiously to where we want to be and sets achievable goals. Aurobindo is focusing on a sustainable market and achieving sustainable growth.

Aurobindo is a research and development (R&D)-focused company that requires a long-term vision, but this is not the case for many companies in India. What is Aurobindo's position on this?
Aurobindo has an innovation forum, which the senior management is part of. On a quarterly basis we keep evaluating in terms of what technologies we wanted to be in and also complex chemistry. Aurobindo is very proactive about hiring the best talent in the world to get the particular technology. In the innovation forum, Aurobindo lists the technologies that it would like to acquire and evaluates if it can acquire them or if it has to set up its own. If we cannot acquire the technologies, we hire the right talent to set them up.

Where does Aurobindo's competition lie?
Competition is different for every segment of the business. In terms of Aurobindo's finished product business in solids, there is competition both globally and locally. The top ten generic companies are our competition in solids.

How do you see Aurobindo evolving in the coming years?
From a global perspective, Aurobindo would like to de-risk itself by not entirely depending on any single market. The United States is Aurobindo's largest market, but we do not want it to be the largest market for the company in perpetuity. Aurobindo feels that Europe is a great opportunity from a market perspective. •

Mr. Glenn Saldanha

Chairman and Managing Director
GLENMARK

Glenmark is a leading company in the discovery of new molecules. It has a significant presence in branded generics markets across numerous emerging countries and employs over 10,400 people in over 80 countries.

Number of manufacturing facilities: 14
Number of R&D centers: 6

Glenmark is one of the real success stories in India, with much of that success being in the last decade. Can you talk us through the company's history and its rapid growth in recent years?
The company was founded in 1977 by my father and he named it after me and my brother. I received my MBA in the United States and returned back to India in 1998. In 2000 my father retired and I took over as the CEO of Glenmark and I have been running the company for 14 years. In terms of our turnover, the company had a turnover of $18 million in 1988 and in 2000 we were $32 million strong. In 2013 we closed sales at $1 billion. It has been a phenomenal run for Glenmark in terms of growth. We are consistently growing 20% per year and are consistently outperforming the Indian industry.
Glenmark has three main businesses. The first is a broad innovation platform, where we do high-end drug discovery research. We have a site in Switzerland with about 80 scientists, one in India with about 300 scientists, and one in the UK with about 15 scientists, all of which are working on innovation. Glenmark also has a generics business, which is mainly in the United States and Europe. We have over 90 products and sell $350 million in the U.S. market. Our sales in Europe are $120 million. The third line of business is in emerging markets in Latin America, India, Africa, Asia and Russia.

Can you elaborate on the values of Glenmark?
Glenmark's key driver is innovation, which will differentiate itself in the Indian market. Currently, it has six molecules in clinical development and we have biological compounds in both phase one and two.

Accessibility is a major theme in India. What role does it play in Glenmark?
Low cost medicines are critical today. Given the pressure on most governments to reduce healthcare costs, accessibility and cost of medicines are critical aspects for a generics business. Nonetheless, we want to transform Glenmark from a branded generic company into an innovative one.

There have been problems regarding intellectual property between Indian generics companies that want to increase accessibility and foreign companies that originally filed patents. Can you talk about these issues?
Glenmark is not having a problem with patent infringements, but the company lost a patent challenge in the United States and has a liability as a result. A company can challenge a patent, which leads to a lawsuit and a jury decides the validity of the challenge. In India the patent situation is somewhat different from other countries. The government has gone through affordability and accessibility very carefully and created the Indian patent act. Now, the patent laws in India are well defined.

Can you elaborate on the U.S. market and whether you have seen slowed growth as a result of sanctions?
The United States is Glenmark's largest market, and we are still investing in it. Glenmark has a new facility in Monroe, North Carolina. Currently the U.S. market is challenging because of the slowdown in approvals. Recent consolidation has also driven down prices and margins. In terms of compliance, Glenmark has an impeccable track record. The company continues to get product approvals and sell products in the U.S. market.

What is the strategy for Glenmark going forward?
Glenmark's basic strategy is to build a broad footprint in the markets to which we sell. The company has a good reach and distribution network and tries to leverage it to sell new and innovative products to gain scale. Although we have a broad footprint across numerous markets, our primary focus is on eight key markets, which are the United States, Europe, India, Brazil, Mexico, Russia, South Africa and Venezuela. These drive performance and sales.

What are the opportunities and challenges in the Indian pharmaceutical market for global investors?
India continues to be an excellent market, as it offers low costs for manufacturing and research with a high quality of work. India is the pharmacy of the world, and exports levels from India are massive. Pharmaceuticals companies view India as a market that they must be in and one that can serve as a base. The government also supports the industry and has made substantial progress on generics and exports, but can do more to promote innovation.

Can you elaborate on Glenmark's CSR?
Glenmark does a significant amount of CSR and most of our CSR is in the child health and sustainable livelihood areas. Our initiatives are mostly rural based and we also have a global program running in Kenya. We choose Kenya as we have a presence in the country. •

Casting a Wide Net: India's Variegated Pharmaceutical Sectors

"The formulation business only started four years ago and not only on contract manufacturing, but MSN has some of its own branded products in the Indian and emerging markets. The formulation business is different from APIs, as you need different expertise in the different segments. Currently MSN's API segment is much larger than its formulation segment, but it is confident that the formulation segment will grow in the future.

- Dr. MSN Reddy,
CEO and Managing Director,
MSN Laboratories

Image: Neuland

Growth Through Innovation

Small and Medium-Sized Enterprises in India

If the top four Indian pharmaceutical companies account for 20% of the national market and the largest 200 command a 70% share, most of the companies in the pharmacy field in India are small and medium-sized enterprises (SMEs). In 2013, SMEs accounted for 40% of India's pharmaceutical production and they make up for the vast majority of the 24,000 pharmaceuticals businesses scattered across the country. Satish W. Wagh, chairman and managing director of Supriya Lifescience, an Indian company manufacturing APIs and intermediates since 1993, said: "India has grown not only because of the large industries, but also through small-scale industry units that have become medium-scale units. Roughly 62% of the industry's strength belongs to this category. These smaller operations are giving many employment opportunities and are doing quality work, but most do not know how to export."

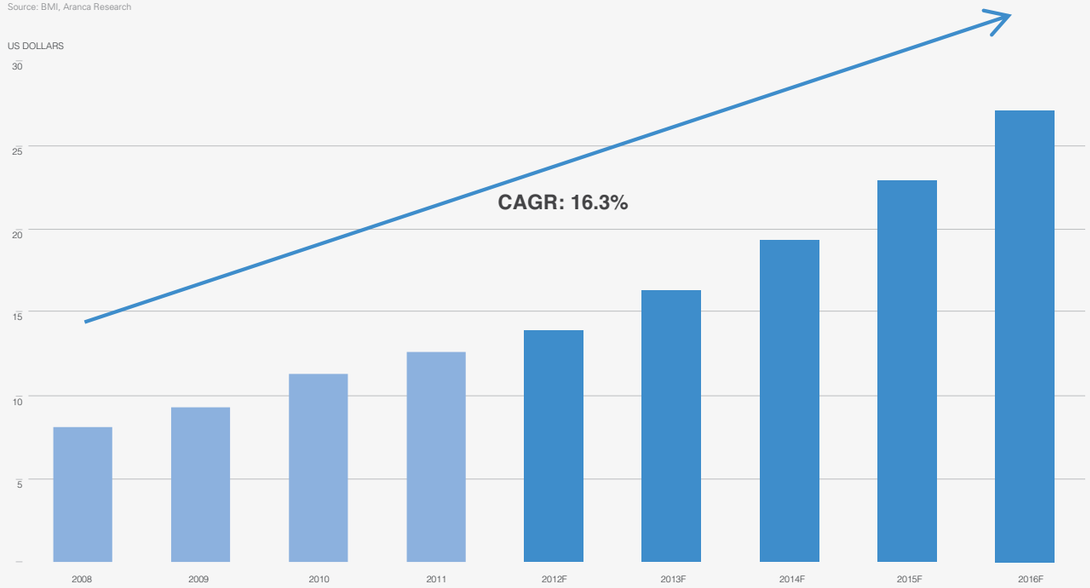
Indeed, many SMEs are focused on the local market and only the more adventurous have decided to try their luck in exports. Traditionally Indian companies tended to rely on the generic local market, but many believe that India can do better, as Dr. S.K. Yadav, CEO of Olax, a young company specialized in API impurities, metabolites, degradation products and secondary reference standards, underlined: "I feel Indian companies are too shy when it comes to broadening their vision. I would like to see more companies looking for challenges. I know it requires time and money. Still I think India could make a difference with more innovative companies."

By providing guidance and organizing workshops, Pharmexcil helps support

Image: Cogent

PER CAPITA SALES OF PHARMACEUTICALS

Source: BMI, Aranca Research



PER CAPITA SALES OF PHARMACEUTICALS

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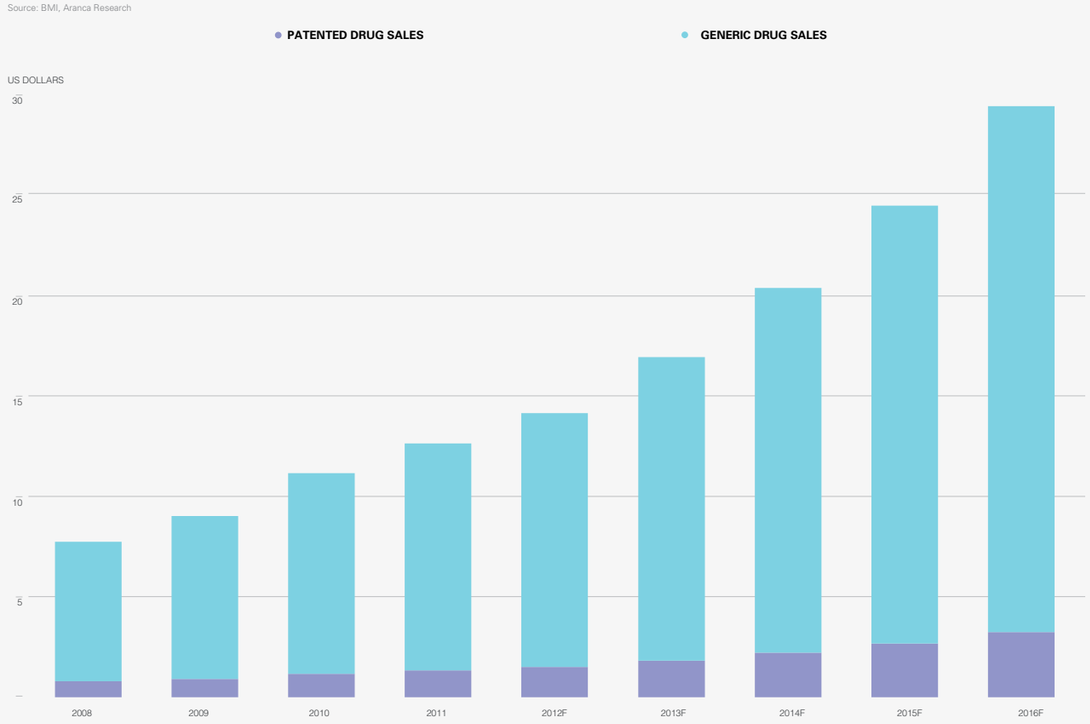
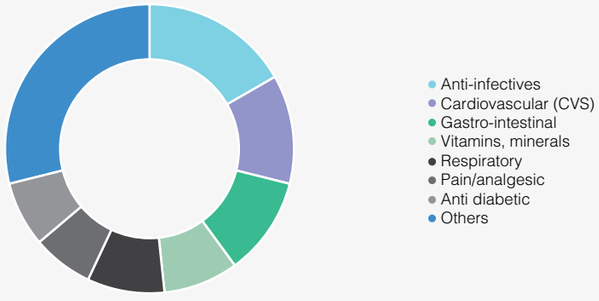


Image: Intas Pharma

INDIAN PHARMACEUTICAL MARKET SEGMENTS BY VALUE

Source: IBEF



> In terms of our own approach, I believe that we have been so successful because we greatly value each and every relationship that we have with our customers and are eager to adapt to their needs. We like to provide a very high level of service and to conduct business in a very transparent manner. As a result of our approach we have won the Best Supplier Award from Abbott India for the past three years in a row.
>
> - Piyush Ajmera, CEO, Parth Antibiotics Pvt. Ltd

We currently have over 300 products in our basket with the most successful being antibiotics followed by vitamins. We also have a number of medications in the oncology area, including hormones and steroids, which have been very successful. We are currently in discussions with companies in the regulated markets to supply them with raw materials for certain projects, and our goal is to enter these markets by 2015 to 2016.

- Gaurav M. Rupani, Managing Director, Parth Antibiotics Pvt. Ltd.

We are very optimistic about the outlook for small and medium-sized enterprises like ours. The fact is that companies operating in larger industries need supporting suppliers. A company that is making formulations will need an API supplier, and a company making the API will need an intermediate supplier. Everybody is interrelated.

- Vijay Agrawal, Chairman and Managing Director, Survival Technologies Pvt. Ltd.

small and medium-sized companies to expand their presence in regulated, developed markets as well as less regulated, emerging markets. Only companies that obtain from the proper regulatory agencies all needed permissions can export. These validation processes are long and costly, but for many, part of the troubles experienced by Indian companies abroad are more a matter of mentalities than anything else, as M Madan Mohan Reddy, vice chairman of Pharmexcil and director at Aurodindo Pharma, explained: "The industry needs regulatory understanding to move forward. Today in India there is a lack of understanding of the regulations. Through Pharmexcil we want to make sure that the players in the industry follow regulations and achieve good practice."

The Indian market is still greater in value than its exports and is on the verge of significant changes, due to the size and spending power of the burgeoning middle class. The Indian population exceeds 1.2 billion people and in 2007, the middle class was estimated to contain 250 million; a figure that is projected to reach 600 million by 2030. In 2005, the Indian population spent less than 7% of its available income on health care; this figure is expected to double by 2025. According to the WHO, the per capita expenditure in 2012 was $54, a fraction of the expenditure of countries such as China and Brazil. But that figure will soon change.

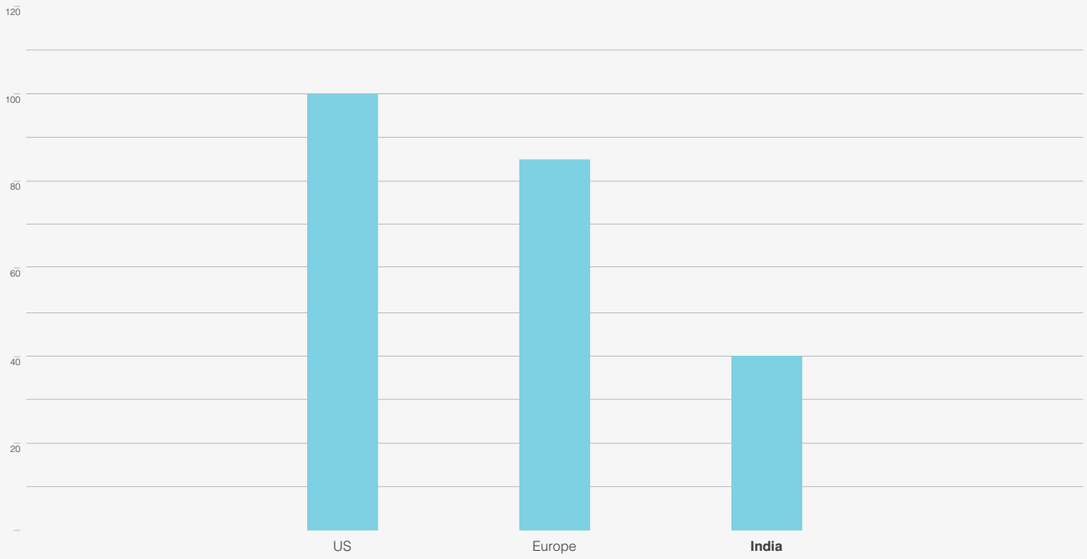
The government is investing heavily in the field of health care, with the aim of covering 600 million Indians so that conservative estimates project that the Indian domestic market will account for $50 billion in 2020. Much of the needs of the Indian population will be covered by generics manufactured by Indian companies. Most of these companies are large groups, yet it is possible for smaller companies to take advantage of the growth and by adapting a niche strategy, Indian small and medium-sized enterprises can be successful quickly.

For now, large, multinational Indian companies have an advantage over SMEs in navigating both export and domestic regulations due to their large scale of operations, but the history of India's pharmaceuticals industry indicates that India's current SMEs can make the leap into global players, just as their predecessors did. Attention to quality, a flexible and ambitious management that can uncover niche opportunities and carefully leveraging India's strengths has proved a successful formula for many Indian SMEs that have grown to join the ranks of big pharma. The scale of growth may not be the same as in generics, but the path can be forged. Two thirds of India's pharma industry is still coming from SMEs and with these companies increasingly growing into international markets we are going the next few years promises to see a more mature and globally dominant Indian pharma industry. •

> The industry is doing well, but there is a significant amount of variations happening due to the price control situation. In 2014, there is more improvement than in 2013, as the government insisted on maximum price regulation, which involves retrieving the product from the market and then relabeling the MRP.
>
> - S. Srinivasan, Director, Srikem Laboratories Pvt. Ltd.

RELATIVE COST OF PRODUCTION WITH US COST AS BASE

Source: Frost and Sullivan report on Indian Generic Pharmaceuticals Market, BMI, Financial Express, Aranca Research



Satish W. Wagh

Chairman & Managing Director
SUPRIYA LIFESCIENCE

Can you give us an overview of your career background and what led you to found Supriya Lifescience in 1993?
After experience in government starting in 1978, I founded my first company in 1986 with a small amount of investment. With this working capital I established a factory in a heavy chemical zone to manufacture surfactants. Our first product was a surfactant used in the local textile industry as a wetting agent. The textile market was very big in India at that time and we were able to offer a lower price to the market than a larger surfactant company that had been dominating the industry. When union action closed the textile industry in Mumbai, the sector moved to remote areas and receiving timely payments from customers became a very large problem. It became very difficult to obtain raw materials without this cash flow and we began to look for new products to manufacture.
By partnering with academia, we started to explore new products and markets and decided to begin manufacturing an anti-allergy cough syrup. Because there were many European multinationals making this product already, as well as a very large manufacturer based in Hyderabad, we decided to focus on export markets. In 1992, we made our first contact with companies in Southeast Asia. We began selling 500 kilos a month to the local market and eventually got our first international order from Thailand with a government institution called GPO. Within six months we had already grown internationally.

What size and scale of operations has Supriya Lifescience achieved today?
Today Supriya Lifescience manufactures and markets nearly 27 products that are APIs and drug intermediates. We now produce 50,000 kilos a month of our original product. At our U.S. FDA approved facility near Mumbai we manufacture APIs for therapeutic segments like anti-asthmatics, antihistamines, anti-allergics and anesthetics. We export our products to over 65 countries, including regulated markets and China.
We are working on starting up two new factories that will be focused in a new area that we are working in, phytochemicals for APIs. They are located close to our existing factory and will bring our factory space up to 36,000 square meters.

What are the main markets for Supriya Lifescience today?
Our main markets today are the United States, Europe, Latin America, and Southeast Asia. We are now entering into new areas such as African markets and Russia. We see opportunities in every part of the world, both traditional regulated markets and developing markets. Supriya Lifescience is also developing a partnership with many Multinationals in India for product approval.

What is the role that small-scale manufacturers play within India's pharmaceutical sector and what steps is the government taking to better support them?
India has grown not only because of the large industries, but also through small-scale industry units that have become medium-scale units. Roughly 62% of the industry's strength belongs to this category. These smaller operations are giving many employment opportunities and are doing quality work, but most do not know how to export. For this reason the government gives a lot of money to take these entrepreneurs to the international forum.

How do you see your activity developing over the next three years?
In the next year we plan to reach $30 million as we introduce two new products and two new factories. Over three years our goal is to reach $80 million. Supriya Lifescience is also looking for good partners that want to take use of our 80,000 square feet of manufacturing capacity that is USFDA approved.

Apart from being the Chairman and Managing Director of Supriya Lifescience, you are also the Chairman of Chemexcil. In that context what is your outlook for the chemical sector in India as a whole in the medium term?
India has a great future. We are seeing chemical businesses booming across the country, compared to before when chemical activity was limited to very few areas. Now we are seeing states are fighting for chemical business. In the next two years we will see a stronger industry with more exposure.

Do you have a final message for our readers about Supriya Lifescience and India's pharmaceutical industry?
As an industry we have good political leadership, good growth and large markets. The government of India offers a lot of incentives to the industry to promote our products. As for Supriya Lifescience, we have grown very much in the last 26 years and we expect to grow much more in the future. By 2016/17 we expect to have a turnover of US$ 80 million. •

Image: Neuland

B.G Bairy

CMD
BELOORBAYIR BIOTECH LTD.

Can you give a brief overview of BeloorBayir and your role in the pharmaceuticals industry?

BeloorBayir was established in 1981 with the intention of becoming a critical player in the global fine chemicals and intermediates arena for bulk drugs. In its 35-year history, Bayir has evolved from a manufacturer to a life-sciences solution company. The transformation in our vision has seen us progress from manufacturing to an in-depth research & development organization with additional focus on the global food & dietary segment.

With this focus, the company has strategically expanded its Glucosamine facilities with recent European Union, Mexican and Brazilian GMP status. Furthermore, Bayir in 2007 expanded into formulation production, which was a logical initiative in its endeavor to achieve end-to-end customer value addition.

Currently, Bayir has nine facilities across India with its corporate office located in Bangalore. The multiple areas of expertise, with dedicated manufacturing units include APIs, Glucosamine, Botanical Extracts, Finished Dosage Formulations and Nano Materials.

What is the importance of the pharmaceuticals industry in a company like Bayir?

Over the years Bayir's focus has been to stay relevant in the Global Pharma Industry and therefore has invested into research and development (R&D), which will help it remain relevant in the years to come. For example, our glucosamine product is considered both a pharmaceutical and a neutraceutical product. Pharmaceutical APIs have contributed significantly to the total export revenue at Bayir. Bayir has no intention of developing totally new molecules, but our area of interest is to add value by increasing productivity, cost effectiveness and quality of molecules.

Which markets is Bayir catering to?

The company has a global focus. The United States, Europe and Japan are our primary markets with further expansion into Latin America, Russia & Commonwealth of Independent States (CIS), and Asia. Africa, Australia and the Middle East are in an exploratory phase with a clear objective to develop them into potential high growth areas for Bayir in the long-term.

What differentiates Bayir from companies manufacturing only APIs?

Bayir is definitely different from companies that are involved purely with APIs. The company's approach is to stay close to nature while isolating actives from their natural origin. We intend to be at the forefront of the revolution in healthcare with the 'biosimilars' concept.

How do you position yourself in the pharma industry in India?

Today Bayir turns over $25 million. The company has every intention to expand its market in India by positioning itself as a reliable natural ingredient-based solution provider in addition to its ongoing pharmaceuticals business, and thereby grow to a $50-million company by 2017, when 15% of its turnover contribution will be from the sub continent.

What is your opinion about the pharmaceuticals industry in India?

The Indian pharmaceuticals industry will change the way healthcare is delivered. Our wealth and knowledge of natural medicine will be a major driver of change. The current focus on bio-actives will replace synthetic medicaments and therefore pave the way for a major role for Indian companies in the global market.

Oftentimes a company does not want to put a significant amount of resources into R&D. Why did Bayir decide to focus so heavily on R&D?

R&D defines the culture and longitivity of a company. It ensures that a business remains relevant in a constantly changing environment. Coming from a pure science background and having grown as a technocrat, I know and understand that apart from personal satisfaction, innovative research drives growth and creates new opportunities by breaking barriers to success. In simple terms, it is the ability to constantly surprise and satisfy our customers.

Where do you see opportunities in the coming years for a company like Bayir?

As stated earlier, biosimilars will be our success factor in the actives market. This will be our opportunity in the coming years. Additionally, formulation manufacturing of nutraceuticals, which is our specialization, will also contribute to this growth.

Do you have a final message for our international readership about Bayir and the company's activities?

BeloorBayir represents a revolution. By investing in new ideas, we believe that we can bring about a change, which results in choice. The aim is to provide affordable, unique and high technology products and solutions to the global health market. As an approachable company, our facilities are always open to customized production. Moreover, we are focused on our goal are becoming among the largest manufacturers of natural medicine in the world by 2020. •

Global Business Reports

Dharmesh Shah

Chairman and Managing Director
BDR

Can you give a brief overview of BDR and how you managed to go from HIV into API manufacturing?

BDR is the result of years of experience in the pharmaceuticals industry. I started the enterprise myself with a focus on the oncological sector as my father suffered from cancer and I saw a gap in the market. I decided to use my knowledge and resources to research and develop cheaper generics that could help a significant amount of people in terms of affordability and accessibility. That is how BDR gained its focus on oncology, critical care, gynecology and neurology. BDR was the first to bring in an antifungal for the intensive care unit and to launch a generic drug for prostate cancer, both of which made us a market leader. One of BDR's areas of expertise is the identification of new molecules in order to make medicines more affordable and available to the people of India. BDR got its own ethical marketing division that is highly specialized in oncology and intensive care and is expanding into gynecology and neurology. It set up a state-of-the-art anti-cancer facility, which will be completed in 2015, to deal with the Indian and emerging markets. BDR will be entering the United States and Europe in 2015 once it is accredited, its facilities are ready and it is geared up for inspections.

I am a chemical engineer gold medalist from one of the most renowned universities in India. In 1985 I started as an entrepreneur and manufactured lubricants for the pharmaceutical industry. In 1987 I became one of the leaders in raw materials and my major customers were all the MNCs. In 1989, some pharmaceutical companies forced ciprofloxacin into use, and I became a key partner with them, manufacturing one of the key raw materials in intermediates, piperazine salt. This changed my business from lubricants to tablet manufacturing and from multivitamin based raw materials to a high-ended game. In 1993 in partnership with Dr. Bandi Parthasaradhi Reddy, I promoted a company called Hetero. From 1993 to 2003, I was in charge of business development, marketing and new product identification, and in 1996 I joined hands with the Brazilian government and was one of the first people to introduce new antiretrovirals into Brazil. In 2003, I started BDR.

In India, there are some big companies catering to the regulated markets and others to the non-regulated markets. For a company like BDR, what strategy do you think is most effective?

BDR generates molecules that are going to patented and regulated markets from 2016 to 2025. BDR is preparing to set up infrastructure that will qualify with all the regulatory requirements. BDR's strategy is to enter first into the Indian market in order to help the people of the country and start generating the data with which we will enter the regulated market. The share of the split between the local market and the export market in terms of the turnover of the company is 50% international and 50% domestic. There is more growth potential in international markets, but the Indian market is also growing. BDR is entering into international markets with strong local players and does not have plans to set up offices internationally.

What is your view of the state of the Indian pharmaceuticals industry today?

Worldwide, the pharmaceuticals industry has to consolidate, which is happening at the moment. Fewer players are better because many need support, especially from the government. The Indian industry is growing by the virtue of the skills of the companies. BDR positions itself in a segment of niche players and its expertise area is complicated chemistry, cost effectiveness, and challenging chemistry. The major focus and long-term target for BDR is to create a bank of intellectual properties, and we are trying to develop molecules that are more cost effective and accessible. The pharmaceutical industry is a game of right identification and selection and deploying research and resources on those identifications.

Do you have a final message for our international readership?

My message to my colleagues in the Indian market and to the international market is that we do not have to be commodity player. We need to identify our strengths and be a leader in our strengths. We need to continue to improve our costs so that medicines can be made more affordable worldwide. The industry needs to identify its expertise, focus, and grow in a scientific manner. There is plenty of space for everyone to grow in the pharmaceuticals market. •

Global Business Reports

Industry Explorations

Image: Biocon

Building Blocks

Excipients and Raw Materials in India

Whilst the last couple of decades have seen a surge in the demand for Active Pharmaceutical Ingredients (API) and formulations from India, a separate industry has thrived from its success. The increasing market for excipients and other raw materials could be seen as an inevitability, bearing in mind that they usually make up the bulk of a formulation. Harish Shah, CEO of Signet Chemical Corp., comments on this growth with regard to their first partner's sales: "It was shortly after the budget of 1991 that we got our first fully committed partnership with one company in the United States. This one company at the time was selling approximately thirty metric tons (mt) a year of one excipient to international corporations here in India. Today that same company sells seven thousand mt of the same excipient to pharma companies here in India."

The role of excipients in the pharmaceutical industry is quite broad ranging. Primarily they are used as a carrier for the API, however they can also be used to help enhance the bioavailability of some APIs, which may not be readily absorbed by the human body. Excipients can also be used to bulk up a formulation with a very potent API in order to allow convenient handling of the medication and accurate dosage. Furthermore excipients can also be used for:

- Lubricants and Anti-Adherents: To prevent the tablets from sticking to the plastic packaging. A commonly used lubricant is magnesium stearate.
- Binders: Helps to keep all the ingredients together and include saccharides and their derivatives.
- Colors: Used to help create a consistent color to the formulation and improve its appearance.
- Coatings: Helps to preserve the tablet by reducing deterioration that may occur from moisture in the air. Can also make large or unpleasant tasting tablets easier to swallow. Most common type of coating is hydroxypropyl methylcellulose. An enteric coating can also control the rate at which an API is released into the body. Examples of such enteric coatings include fatty acids, waxes, plastics and plant fibers.
- Disintegrants: Expand and dissolve when they come into contact with water, which causes the tablet to disintegrate in the gastrointestinal tract.
- Flavors & Sweeteners: Used to help mask a strong or unpleasant taste to ensure that a patient will continue to take the medication.

Despite the big demand for excipients from Indian pharmaceutical companies, the industry is still somewhat niche with only a small number of players in relation to the much larger number of API and formulation manufacturers. One of the largest Indian companies that focus purely on excipients is Signet. At Signet, the emphasis for their customers is on the regulated market, so in order to meet the stringent regulations in such markets, they import their excipients from such markets and distribute them in India to be used for formulations that will be exported back into the regulated markets. Harish Shah, CEO of Signet, explains: "By importing such excipients from these regulated markets to India, the manufacturers that export to the regulated markets can be safe in the knowledge that the excipients that they are using have already met all necessary requirements for this market. We have a number of partners across North America, Europe and Japan who work closely with us on providing these excipients to our clients here in India."

Another major Indian corporation that works in the field of excipients is Godrej. Specialized in the area of chemicals, Godrej are a multi-billion dollar business as well as a household name that approximately 600 million Indians come into contact with on a daily basis. Managing Director of Godrej Industries, Nadir Godrej, says: "We supply a product called refined glycerin to the pharmaceutical market, which is used as an excipient for cough syrups, which meets all the stringent requirements necessary for the pharmaceutical industry…Apart from refined glycerin we also provide our fatty alcohols and stearic acid to the pharma industry. Looking forward, we are keen to expand in this sector through the export of our pharmaceutical grade fatty alcohols to foreign companies in the pharma sector."

Looking to the future, the demand for excipients is unlikely to slow down. It is forecasted that with the aging population and the increasing use of pharmaceuticals, excipient use will exceed $5.2 billion globally by 2020, according to Grand View Research, with a current valuation of the United States, European, Indian and Chinese markets being collectively worth $2.3 billion, with each region using approximately 100,000 mt of excipients annually. Kline & Company predicts that the Oral Solid Dosage Form (OSDF) excipient market will continue to expand at a very healthy rate of 7.4% per year until 2018. It would seem that as long as the pharmaceutical market continues to thrive, the excipient industry could expect to continue to flourish. •

> "We are very excited about a material that we are ready to launch at CPHI this year that is composed of about 35% solids. We never thought that such high-content solid material could be used in the coating industry. It has not yet been unveiled so I cannot share the name with you but its code name is SLS 35 and it has been patented. We expect it to come out in products that require immediate release such as paracetamol in 2015. It is expected that it will save 60% to 70% of manufacturing time and capital costs. It will be the first product of its kind in the world and we expect it to be a major success considering the amount of technology that went into it."
>
> - Suresh Pareek, Managing Director, Ideal Cures Pvt. Ltd.

Nadir B. Godrej

Managing Director
GODREJ GROUP

Everyday it is estimated that six hundred million Indians come into contact with one of your products. What are Godrej's major areas of business and can you talk about its rich history?

Established in 1897, Godrej Group enjoys patronage across various businesses, such as consumer goods, real estate, agriculture and appliances and makes a wide range of B2B and B2C products. The group also makes chemical equipment, rocket engines, and even the injector for the Mars satellite, which the Prime Minister commented on, saying it was "30 million dollars cheaper than the movie Gravity."

Godrej began in 1897 making locks and what followed was legendary. In 1920, we began a small soap company and launched the first soap in the world made without animal fat. Gradually, we made several products such as Almirah (cupboard), safes (lockers), refrigerators and entered several other businesses. We went into oleo chemicals and oil seed processing in the 1960s and then into animal feeds, agricultural chemicals and eventually founded the palm oil business. We are currently India's largest producer of palm oil and one of the largest producers of oleo chemicals. My grandfather wrote his thesis on creating soap from fatty acids. In the 1960s, we built India's first modern fatty-acid plant, where we also produced stearic acid. In the 1990s, we began manufacturing fatty alcohols, lauryl alcohol derivatives, and surfactants. We were also the first in India to produce alpha olefin sulfonate.

The real growth came in 2000, when we separated our consumer products division into a new company. We had bought a household insecticide business, merged it with Sara Lee, later buying Sara Lee's share. It is now the largest Indian owned consumer products business in the country.

Did the liberalization of the economy in the 1980s affect the price of these commodities?

The liberalization helped considerably and had a dual effect; on the one hand we were exposed to competition, but on the other hand we had more freedom. The exposure to competition was bad in the short term but made us more efficient in the long-term. We set up joint ventures with GE and Proctor & Gamble as well as with Sara Lee for household insecticides. Most of these partnerships have ended, but we still work with Tyson in the chicken business.

Your family business is very prominent in India. Can you talk about the responsibility that this brings?

We have had responsible and ethical business practices since day one, when my granduncle, a lawyer at the time, admitted that he had to lie to win a case in Zanzibar. After that day, he quit law. He also liked investing in difficult businesses. He once told Mahatma Gandhi: "we have independence but no industry." Gandhi replied: "what are you going to do about it?" After that, he studied science and invented a fireproof safe as well as a vegetable soap through his own research and scientific experiments. Self-education is a necessity in India, and now is a great time for such initiatives. Our future looks bright due to our demographic dividend.

Godrej is heavily involved in the chemical sector. What are your operations in this area?

In the chemical sector, we are mainly a B2B business. We export oleo chemicals and surfactants to over 82 countries, catering to a range of sectors including pharmaceuticals, cosmetics, and plastics. In terms of value, approximately 30% of what we manufacture is for the international market and 70% is for the domestic market, however our international exports are increasing.

We supply a product called refined glycerin to the pharmaceuticals market, which is used as an excipient for cough syrups. Due to the quality of our refined glycerin, many Indian manufacturers prefer to source this excipient from Godrej as opposed to importing it. It is currently the top chemical that we supply. Apart from refined glycerin, we also provide fatty alcohols and stearic acid. Looking forward, we are keen to expand in this sector through the export of our pharmaceutical grade fatty alcohols to foreign companies.

In 1999, Godrej & Boyce entered into a joint venture with the Portuguese company Efacec. Can you talk about the storage solutions you provide to companies such as those in the pharmaceutical sector?

As is the case with many large companies, pharmaceutical companies normally require large amounts of storage in their warehouses. With Efacec, we provided storage systems, which greatly increased the efficiency that such companies with very large inventories could operate. Apart from increasing the vertical storage capacity of warehouses, we provided a fully automated system that requires no manual intervention.

Can you talk about the growth in the last few years at Godrej?

The chemical business has been growing about 6% to 8% per annum, which is on a par with the sector's growth, however our growth in the speciality sector is higher. By global standards, we are not a big oleo-chemical-player, but being in India gives us acess to produce high erucic acid rapeseed oil. We are a leader in rapeseed-based oleo chemicals such as erucic acid and others. •

Harish Shah

Managing Director
SIGNET CHEMICAL CORPORATION PVT. LTD.

When Signet was first established during the 1980's, the pharmaceutical environment was much different. Can you talk to us about these early days?

Signet was established in 1986. The scenario of the Indian Pharmaceutical Industry then was very different. The US drug patents were highly robust and foreign MNCs played a dominant role. Besides these issues, another challenging factor was the gigantic import duties levied on raw materials.

A decade down the line, the Indian Patent Act was implemented which liberalized the market and domestic companies expanded operations. Import duties reduced drastically and the Pharma sector developed as one of the top 5 segments globally. During the same time, Signet received its first formal distributorship from a leading global player of the US. This was followed by partnerships with 29 other principal-partners from USA, Europe and Japan in the subsequent years. Today Signet successfully distributes around 400 quality products covering almost every excipient application. Thus, beginning life in the pre-liberalisation era of India, Signet has grown rapidly over the last 3 decades achieving a commendable & consistent level of growth.

Can you please explain to the role of Signet in the pharmaceuticals market?

Signet is India's largest distributing company supplying quality excipients to almost the entire Indian pharmaceutical industry. We not only trade our products to the pharmaceuticals companies but also offer varied solutions to formulators for almost every application and dosage form. Signet's team of 85 employees is a blend of commercial and technical experts who bring with them the skills and requisite market knowledge that has greatly contributed to creating Signet as the "First recall name in Excipients." Signet has a large portfolio of specialty products and a logistics infrastructure that is maintained very well. 30 principal partners from USA, Europe and Japan continue to put their faith in Signet's abilities to grow their business in India. Signet's strategy can be summarised in just two words, "Creating Value," which means selling based on value over price.

One aspect of Signet that makes it different from other companies that we have seen in the pharmaceutical industry here in India is the fact that you import your products from abroad. Can you talk to us about this?

Signet believes in providing quality products to its customers. The Indian pharmaceutical market, as you know, is characterized by the domestic and export segment.

With the expiry of a majority of U.S. patents in the past five years and with multinationals looking at India as a podium for manufacturing their products for the global market, the current need of the Indian pharmaceuticals industry is high quality and products that comply with international regulatory standards. Most of our principal partners are innovators of their own products and all of them provide the requisite regulatory documentation, which would aid the formulators in registering their products in the United States, Europe, Japan and rest of the world. Our partnership with these global excipient manufacturers in the United States, Europe and Japan has facilitated us to create a distinctive edge over other distributors. •

The Science of Life

Ayurvedic Medicine in India

Ayurveda originates from the Sanskrit words ayus (life) and veda (science) and can be translated as meaning the Science of Life. Dating back five thousand years, it is considered to be one of the world's oldest holistic healing systems. Ayurveda is founded on the principle that the correct balance between mind, body and spirit dictates health and wellness. The focus of ayurveda is therefore more preventative, but treatments are very much prescribed for a range of illnesses.

According to the ancient ayurvedic texts, every person is made up of five basic elements that exist in the universe: earth, water, fire, air and ether. Each element combines in the body to form three distinct life forces that are called doshas, with each person having his own unique balance of doshas. The combination of ether and air creates vata dosha, which is responsible for the most basic of bodily functions such as heart function, blood flow, breathing, and mind. Fire and water combine in the body to form pitta dosha, which controls appetite, metabolism and digestion. Finally water and earth combine to create kapha dosha, which controls strength, weight and the immune system. The ayurvedic philosophy states that the unique balance of these energies in the body determines whether someone will get ill.

A visit to a practitioner of ayurvedic medicine is very different from that of a general practitioner. The initial examination usually consists of three parts: observation, touch and questioning. In a process known as darshan, the practitioner makes an overall assessment by observing skin color, hair, nails, eyes, lips as well as body movements, body contour and facial lines. Following this, the practitioner will apply touch to the body in a process known as sparsha, which focuses on the patients' pulse, tongue, speech and nails. Finally, the practitioner will ask about the patient's symptoms and personal life, in a process called prashna. Through these processes the practitioner establishes possible dosha imbalances that the patient is suffering from and prescribes an appropriate treatment to address them.

Ayurvedic therapies are based not only on symptoms, but also on the person as a whole, based on his prakriti, or unique psychsamatic temperament. These therapies are tailored specifically to a patient's needs and can include massage, diet and nutrition adjustments. Other therapies include shirodhara, where medicated oil is dripped onto a patient's forehead. A detoxification process known as panchakarma or prescriptions of one of the 850 herbs are also used to treat ailments.

While ayurvedic medicine has large support in India, the international community remains undecided, with warnings from western governmental health agencies that such therapies should not replace conventional medicines. The U.S. National Centre for Complementary and Alternative Medicine (NCCAM) cautions people that although there is some indication that some treatments may be effective, most clinical trials "have been small, had problems with research designs, or lacked appropriate control groups, potentially affecting research results". Furthermore, it argues that ayurvedic treatments do not have to meet the same standards as conventional medicines, stating that 21% of some 193 ayurvedic products tested positive for high levels of lead, mercury or arsenic.

The prevalence of ayurveda in Indian cannot be underestimated, with the majority of its population using it exclusively or combined with conventional medicines. The fact that ayurveda is seen as a way of life means that people will take daily supplements as a preventative approach. With growth rates forecasted from 10% to 15% in the next ten years, it is clear that this industry has a strong foundation of cultural acceptance and trust. •

EXPERT OPINION

Ayurveda

Patel Janmejay
Director,
Nej Biotec

Ayurveda is the oldest medical science in the history of mankind and is widely popular in India. The ayurvedic philosophy maintains that prevention is always better than a cure. People visit ayurvedic specialists for their illnesses, and doctors prescribe ayurvedic medicines. The ayurvedic medicines manufacturing industry is developing very quickly in India. There are colleges providing ayurvedic knowledge and education all over India that offer bachelors, masters and Ph.D. programs.

Companies that manufacture ayurvedic medicines are divided in three categories – large, medium, and small. Norms and regulations are very similar to the pharmaceuticals companies and in some respects even more stringent. Companies that manufacture ayurvedic medicines are accredited with good manufacturing practices (GMP), and use the utmost care and strict controls to generate highly standardized finished products.

Ayurvedic products have attracted worldwide attention. India is the fastest growing exporter of ayurvedic herbal medicines, standardized herbal extracts, and phytochemicals. Diversified herbal flora are available all over India, and the country is mostly self sufficient for its own supply of herbs from the vast wild lands on the Indian subcontinent. As a result, Indian manufacturers produce premium quality ayurvedic medicines and are ready to supply the world, for the betterment of mankind. •

K. Shyam Prasad

Founder & Managing Director
VIDYA HERBS

Can you tell us how Vidya Herbs started and what was your initial focus?

Vidya Herbs was started because I was working in a pharmaceutical company but wanted to do something with natural products. My background is in natural products chemistry, and I started as a one-man company. Then I met up with a German customer who bought a product, paid in advance money and then I thought there was a big potential. Then I started selling to Japan. I was buying and selling, Japanese customers are very demanding and require a quality manufacturing facility and quality controls. So, I started doing herbal extracts in my home. It was a very small thing and hard work in a humble way. Business is not a shortcut; it is a long-term project. I was always thinking of innovative ideas. Now we are thinking in terms of value added products, not just extracts. And we go deep into the chemistry of a particular herbal molecule to analyze all the secondary metabolites of it and provide the customer with all kinds of data, documentation, traceability programs, and sustainability. Then, we work with the farmers to procure the raw materials.

And how does it work?

We have a render program. We select farmers to cultivate the area and will work with an agent of those farmers, since one farmer is not able to supply us with the quantity that we need. In addition to the agent, we also have a person to monitor the crops. Farmers are told which pesticide has to be put and not to use hard pesticides. We have the pesticides checked out in our laboratory, we will check all of the extracts, do all types of toxin studies, and determine what types of toxins are in the extracts.

To what extent do you work with the pharmaceutical industry today?

With the pharmaceutical industry we have been very forward thinking on that, we want to synthesize through fermentation. We recently acquired a company in Pondicherry, which focuses on carotenoids and biomass cultivation. We work with carotenoid and beta-keratin, glutens, glycopenes, Zanthin, Zeaxanthin. Apart from that we have a concept of fermentation. What do you synthesize in chemical synthesis, we can do the same thing in fermentation. Naturally. We also do it with as few toxins as possible. And it will be very effective, so we are thinking about anti-cancer molecules. We have already read a lot of studies on that. We want to really come out with such kind of molecules in a very short time. We want to introduce those products. It's a very neat and safe process. So instead of using very hazardous chemical reactions, we want to do it naturally. Vidya Herbs concept is natural; we want to think natural. See, nature has its own chemistry. A plant molecule has a chemical molecule with this much growth in them. Whatever is, for example the algae extract in Astaxanthin. So the big structure of chemistry is there in the natural molecule. We identify it and take it out naturally.

What are the challenges in opening new markets in Europe or the United States?

Europe is challenging because it requires a lot of documents and paperwork. When we do extraction, we need to have a system that we can track. We must track records of what herbs have gone and document it. The U.S. inspectors have come and inspected our facilities, which we are very proud of. Even the Japanese have commented that we have reached the standards of Japan. They have said that the quality of our facilities matches theirs. •

The Next Booming Segment?

Contract Research and Manufacturing Services in India

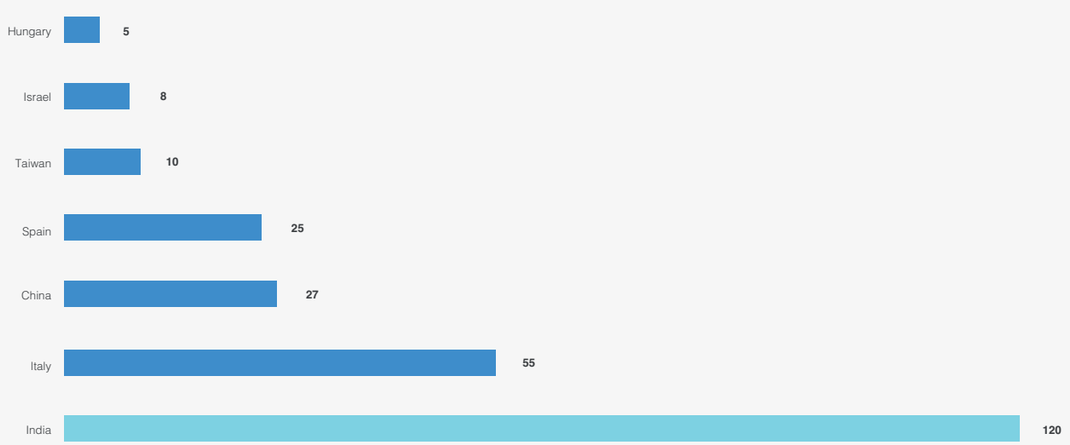
The success of the Indian pharmaceutical industry in the international market comes down to its very unique model, which addresses the two primary concerns of consumers regarding product: quality and price. The pharmaceutical industry has always been one of the most regulated sectors of the regulated market as governments realize the devastating effects that a low quality pharmaceutical product can have if it becomes available on the mass market. However, in an era of growing austerity, it is becoming increasingly difficult for governments and consumers to afford expensive medications. India has become the pharmacy of the world because it recognized the need in the global market for access to high quality and affordable medication. Fortunately for India, it is a distinctive model that cannot be easily replicated by other countries due to India's unique mix of being a low cost country, while having a vast talent pool of highly qualified, English-speaking pharmaceutical graduates. This scenario led to the inevitability of Contract Research And Manufacturing Services (CRAMS), which allowed pharmaceutical companies in regulated markets to outsource their expensive research and manufacturing requirements to India. As a result of this set-up, companies in regulated markets could expect the same high quality for a fraction of the cost.

The CRAMS industry has two main segments, Contract Manufacturing Services (CMS), which account for more than 60% of the industry, and Contract Research Services (CRS), which accounts for the remaining 40%. CRAMs consists of outsourcing various services, including R&D and manufacturing, to low cost countries which meet international regulatory standards like the European Union, USFDA or UKMCA. Typically,

> Granules India is among very few companies in the world that can supply six metric tons of pharmaceutical formulation intermediates (PFI) in one single batch. It has been able to predict global market requirements well in advance and can accordingly adjust batch sizes and install capacity to cater to them.
>
> - Dr. Prasada Raju, Vice President, Corporate Strategy, New Business, Granules India Ltd.

NUMBER OF U.S. FDA-APPROVED FACILITIES IN DIFFERENT COUNTRIES

Source: BMI, Aranca Research



only MNCs outsourced formulations, intermediates and API manufacturing, but the economical crisis has forced the majority of businesses in this sector to seek out all possible cost saving measures.

Suven Life Sciences were one of the pioneers of CRAMS and started providing the service in 1995. Since the inception of the service, which covers the process from research to execution, they have worked on over 700 CRAMS projects. In the final quarter of 2014, they were working on a total of 99 active CRAMS projects, with pre-launch quantities of three New Chemical Entities (NCE's) supplied for the financial year of 2014. Venkat Jasti, Chairman and CEO of Suven, spoke of his company's decision to develop this field: "In 1995, we innovated a new business model by coining the term CRAMS (Contract Research And Manufacturing Services) and with that business model worked alongside innovators in the supply chain during the clinical phase of their NCE drug development by supplying intermediates. We are the only company that has adhered to CRAMS focusing on the NCE supply chain since the company's inception and we have worked on more than 700 such projects involving NCEs."

Today the CRAMS market in India is somewhat fragmented with over a thousand different Contract Development and Manufacturing Organizations (CDMOs) offering their outsourcing services. While the Indian pharmaceutical market is still being sustained by the Active Pharmaceutical Ingredients (APIs) and formulations segments, CRAMS is emerging as a fast growing major player. In 2012 the market was worth just over $4 billion, by the end of 2015, it is forecasted that the CRAMS market will be worth $8 billion.

Such growth is hardly surprising when one considers that the cost of conducting phase I/II/III drug trials in the United States is around $20/$50/$100 million respectively, whereas the cost of similar trials could cost as little as half this amount in India. Furthermore, India has the distinction of being the country with the most FDA approved facilities outside of the United States. With 584 approved facilities, India has built a solid reputation, which has been recognized by one of the strictest regulatory bodies in the world.

> We would now like to get into international market for formulations. Today, we have already covered semi-regulated markets and in the coming years our focus will be on regulated markets like the United States, Europe, Canada, Australia and South Africa.
>
> - S.D. Sawant, Managing Director, Centaur Pharmaceuticals Pvt. Ltd.

However, there is a cautionary side to this tale of pharmaceutical success and growth. While India does have the most FDA approved facilities, the past year could prove to be a threat to this accolade of excellence and quality. Within the past couple of years, a number of major generic companies such as Sun Pharma, Ranbaxy and Wockhardt have been sanctioned by the FDA due to lapses in production quality. These sanctions have been deeply felt by the Indian pharmaceutical market, which recorded growth in exports in March of 2014 of just 2.6%, down from 23% in 2012.

Whilst India continues to retain the title of a low cost market to outsource CRAMS, their reputation for high quality has now come into serious question since the FDA sanctions. The future success of India as a destination to outsource research and manufacturing services rests on the Indian pharmaceutical industry being able to salvage this reputation. India has been capable of addressing such concerns in the past and has proved to be a master at addressing international concerns. With a global CRAMS market forecasted to be worth $375 billion by 2018, the Indian pharmaceutical industry cannot afford to lose the potential of this market over the coming years. There is little doubt that India has the resources and initiative to overcome this hurdle, but for the sake of the pharmaceutical industry as a whole, the timing for action must be now. •

Dr. S.K. Yadav Ph.D

CEO
OLAX PHARMA

Could you tell us a little bit more about yourself, what is your background and how you decided to start Olax?

I am from India and I did my graduation and post graduation in Organic Chemistry and then Ph.D. into synthetic-organic chemistry from Rajasthan University Jaipur. I started my career as a scientist and worked for 7 years with different CRO companies. I used to do custom synthesis on FTE model. After that I changed my field a bit and went into APIs. I joined a company where we started to work on impurities and metabolites synthesis, which were used for API manufacturing. I worked there for 3 years then decided to start my own business in the same area and started OLAX 2 years ago. At OLAX we deal into API Impurities (equivalent to BP/EP/JP Impurities, USP Impurities, In-house Impurities), metabolites, degradation products and secondary Reference standards. We synthesize the impurities using retro-synthetic and purification techniques (including flash and preparative HPLC). Sometime we do degradation of APIs and isolate the impurities. All impurities will be characterized using analytical techniques including NMR (1H, 13C, 2D NMR), Mass and HPLC & GC purities.

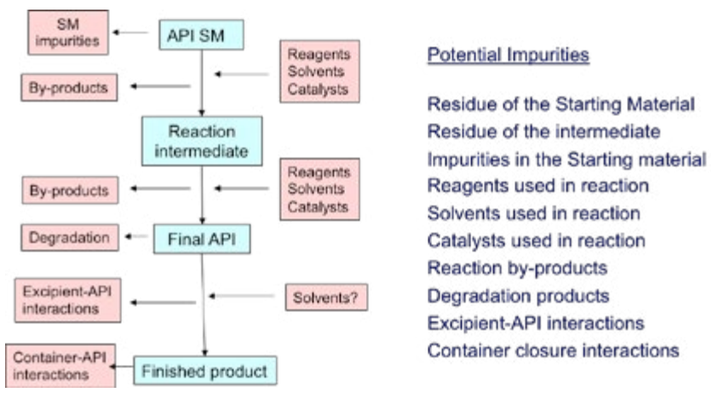
How do you see the growth of the Indian pharmaceutical market?

The Indian pharmaceutical market is growing at an average of 10 to 15% on an annual base. Whenever Indian companies need to increase their operations, there is an opportunity for a company like OLAX. Generics are representing a big business and the API industry is doing well. Sometimes I feel Indian companies are too shy when it comes to broadening their vision. I would like to see more companies looking for challenges. I know it requires times and money. Still I think India could make a difference with more innovative companies.

What are your plans for the coming years?

We are planning to expand our work globally. We are in touch with some big players and expecting the fruits in coming future. The company has started its operation 2 years ago and serving all big clients in India and targeting small formulation and API companies also. And as far as our competition is concerned, in India there are very few companies who are purely into manufacturing of Impurities and Metabolites. Olax is a team of young talents and experienced chemists. Every day we synthesize a new impurity using latest chemistry skills and our team is ready to face the new challenges. This is where OLAX is truly unique. We will be coming up with ISO 9001:2008, ISO 17025 and USP guide 34 certifications in coming future to make our standards more authentic. We want to set a mark in Pharma industry where people recognize OLAX synonym to highest purity standards available in market. We are happy to share our expertise with all the companies meeting the pharmacopeial requirements by providing them all sorts of impurity standards. •

CHART SHOWING POTENTIAL IMPURITIES IN API AND FINISHED PRODUCT (FP).



Frederic Barbier & Sardar Akshay Singh

FB: Managing Director
SAS: President Conversion
COGENT GLASS LTD

FB

Can you give an overview of why Cogent Glass started activity in India, what potential did you see in the market and what is the stage of the company today?

AS: The reason behind starting Cogent Glass Limited was that most of the pharmaceutical companies from the regulated markets were getting more and more contract manufacturing done in India. These companies wanted the Indian manufactured products to be at European and American levels.

In order to have such controls on the final products, the Indian contract manufacturing companies were importing glass vials from Europe or the USA. The Indian Pharmaceutical companies producing generic drugs were also following the same strategy. This was both very expensive and would come with high lead time.

The promoters of Aurobindo decided to build a brand new glass company in India to control their supply and insure high quality while also cutting down on delivery time and cost. This is the vision that started Cogent Glass.

At this time there were two existing moulded glass companies in India. European and American Pharmaceutical companies largely preferred to get supplied in Europe for reasons including quality and supply risk.

The Cogent Glass project was built with the vision to take it to European level, especially for quality levels and regulations.

Cogent Glass produces both moulded and tubular glass packaging, using the best machines available worldwide.

Cogent Glass produced its first moulded vials in February 2013.

FB: The owner of SGD Group entered in a JV with Cogent Glass Limited in April 2013. SGD Group is the world leading manufacturer of moulded glass bottles for the perfumery and pharmacy industries. SGD Group is owned by Oaktree Capital Management. Oaktree Capital Management is a leading investment firm managing over $80 billion in assets, with a global portfolio of companies and, in particular, with several investments in the packaging sector. Oaktree owns both SGD and 74% of Cogent Glass Limited.

SGD signed a cooperation agreement with Cogent that provides for technology sharing as well as marketing and management support.

The next step is that Cogent will at some point join the SGD Group and will become the 11th plant of SGD.

What advantages does a company such as Cogent Glass have in the Indian market?

FB: Cogent Glass produce moulded and tubular vials of European quality, made in India. This is quite unique as you have both quality and price.

This joint effort has proved so far to be very successful. Thanks to the cooperation between SGD and Cogent team, Cogent glass is now serving more than 80 clients after less than two years of operation. We are now starting to export.

This is a very fast sales ramp up in the packaging world.

It would not be possible without a strong technical ramp up established by the Cogent team, with the help of SGD Group expertise.

Was Cogent glass targeting regulated markets from the beginning?

AS: Cogent glass is following a three steps strategy. First step was to go through the technical ramp up and start selling in India. This has been successfully implemented. Second step is to export to non-regulated and semi-regulated markets to build credibility. This is starting, with the support of SGD Group international network.

The third step is to sell to regulated markets, again with the support of SGD Group. We want to show the international market that there is something much better than before coming from India.

How supportive have the Indian authorities been to Cogent' initiative to develop its activities here?

FB: Very supportive. For instance, the Chief Minister of Telangana was the guest of honor at the recent inauguration of Cogent glass' plant. He decided to announce his upcoming new policy that is pro-entrepreneur and pro-implementation of investment. He said that he will create a fast-track channel for investors at a certain level to make it easier to invest in Telangana.

He was quite happy with our strategy and is encouraging us to continue to create local employment and to raise the skills sets of our employees. More than 80% of our employees are from Telangana and the rest is among the best expertise you can find in India in our industry. Cogent glass has a very strong training program which we call the Saraswati program (the Indian goddess of knowledge) and we offer 1500 hours of training every month to about 500 employees.

In terms of the India pharma industry, how would Cogent glass analyze the state of the industry today?

AS: Exports are enabling growth in the market as India is the second country in the world, after the USA, with the most FDA approved plants. India is a very large genetic provider and the growth is about 15 to 17% per year. As Cogent Glass is providing the highest quality level pharmaceutical packaging, our growth is significantly higher than that.

Does Cogent glass have plans to expand in terms of manufacturing units?

FB: Yes definitely. Cogent glass targets to double capacity and see another 200% growth in the company within the next three years. It would create 300 to 500 new jobs in the next three years.

The key growth factor is to export our products and support Indian generic companies who export their products. •

Quality Systems Approach for Good Manufacturing Practices Implementation: From Philosophy to Practice

S.M. Mudda
Executive Director, Technical & Operations
Micro Labs Ltd.

The basic responsibility of the pharmaceuticals manufacturer is to provide high quality, safe and effective drugs. The only way to ensure consistent quality is to adhere to good manufacturing practices (GMP).

The Indian pharmaceuticals industry has made remarkable progress in the global market and is the third largest manufacturer in the world, with an estimated 40% share of generic drugs sold in the United States. India has the highest number of GMP-approved facilities by MHRA and U.S. FDA outside of the United States and UK. The industry has grown in the last ten years by creating state-of-the-art facilities, comprehensive systems and controls.

Despite these accomplishments, serious lapses in GMP compliance have occurred among some of India's leading companies. The industry should use this as an opportunity to expand its capacity to deal with increasing cost and regulatory pressures as well as and to deliver even higher quality medicines.

Understanding GMPs

The Indian pharmaceuticals industry has been complying with the requirements of GMP specified in Schedule M of the Drugs and Cosmetics Act. As exports have increased, leading players voluntarily raised their GMP compliance standards to meet those of the UK MHRA, European Union, and U.S. FDA.

However, an excessive emphasis is placed on inspections, which is producing a risk-averse, inspection-oriented approach rather than a quality, system-based, holistic approach. Invariably, an announcement of a regulatory audit is the trigger for companies to review their compliance with GMP, but this should be an ongoing process. Moreover, while adherence to GMP should result in consistency of practices, due to a lack of uniform understanding and implementation of the GMPs, good practices are consistently inconsistent.

Therefore, it is time to look beyond mere practices and understand the concepts behind a quality management system (QMS).

Understanding Product Quality:

Quality cannot be determined by testing alone; it must be built into the product. Finished products are generally tested for quality by assessing whether they meet regulatory standards without looking into compliance with Quality-by-Design (QbD) requirements. Emphasizing GMP over design impacts the assessment of the product quality before filing the product dossier and has widened the gap of quality parameters between development and scale-up. GMP without product quality is futile; by the same token, a well-designed product can be ruined, if GMP is not followed. Assurance of product quality is built on the solid foundation of product design. In other words, even before manufacture, the safety, efficacy and stability of a product must be unambiguously established, which can only be achieved by adopting a QbD approach. QbD approach lays a solid foundation for achievement of product quality through the life cycle of the product and is even more important in view of the recent U.S. FDA guideline that has a provision to issue a RTR (Refuse-to-Receive) letter if the application is deficient in development aspects.

Adoption of Quality Systems Approach:

The industry needs to respond with a paradigm shift in its approach towards GMP compliance and product quality and adopt quality system-based and risk-based approaches for implementation of GMPs. This calls for creating a formally documented quality management system (QMS) for consistent implementation of GMPs through out the product lifecycle.

The FDA and ICH support the QMS approach. The FDA's 2006 "Quality System Approach for Pharmaceutical CGMP Regulations" document emphasized management responsibility for quality systems and key concepts such as design, quality risk management, change control, corrective and preventive actions (CAPA), quality unit, and a six-system model. Similarly, the ICH Q10 Guideline describes the model for an effective quality management system for the pharmaceutical industry, referred to as the Pharmaceutical Quality System (PQS). The PQS recommends a focus on achieving quality throughout the product lifecycle and also emphasizes management review of performance and product quality.

PQS - Regulatory Expectations:

Recent regulatory deficiencies are indicative of the lack of adoption of QMS approach by the industry. Companies' focus on inspection causes them to react when things go wrong or change under pressure. It is expected that the companies investigate the failures with a view to find a root cause rather than building arguments for release of the products. The benchmark of investigations performed has not been found to be of required standards, with particular reference to complaints, rejects, deviations and out-of- specification data. Detailed root-cause analysis invariably leads to inadequate CAPA.

The Management Responsibility:

"Quality is too important to be left to the Quality Controllers alone." This statement underlines the importance of the quality function and expects it to be a management function driven by the commitment of the top management.

The Pharmaceutical Quality System (ICH Q10) places the responsibility for quality on senior management, which must provide company leadership to establish and maintain a commitment to quality and adopt intelligent systems and processes to establish a best-practice PQS. Senior management should conduct periodic reviews of PQS, encourage transparency in reporting of deviations, and implement CAPA. Best-practice PQS should improve the competitive edge of the company, as each member of the organization understands his responsibility for quality. Best-practice PQS also leads to an increase in process capability, investigation free lots, compliance risk reduction, internal audit performance, and a decrease in product complaints and product recalls. Finally, it reduces costs by investing in prevention rather than paying more heavily for internal or external failures. •

Kairus Dadachanji

Managing Director
SCHOTT KAISHA

Can you give a brief overview of the history of Kaisha in India?

The company started in 1991 with a very small plant under the name Shakai. In 1996 we opened another plant and the company merged Shakai into Kaisha. Kaisha also started very small with only four machines for ampoules. At that time the volume was about 30 million ampoules annually and the company had a turnover of about $80,000. In 2008, Kaisha entered a 50/50 joint venture partnership with Schott, which is the largest manufacturer of pharmaceutical glass and packaging worldwide. Schott Kaisha has since grown and currently we produce 2.5 billion pieces annually with a turnover of about $54 million in 2013. The Schott group has about 15 packaging plants worldwide which produces around 9 billion pieces per annum. The company in India produces 2.5 billion pieces per annum.

Prior to 2008, what attracted Kaisha and Schott to enter into a joint venture partnership?

Before the joint venture, Kaisha made a significant niche for itself as a quality player in the pharmaceuticals industry. In India we have many manufacturers for primary packaging. Kaisha decided that we had to change the concept of packaging to one of very high quality. It was quite a challenge, but we were very successful in achieving this goal. The good recognition of the market helped us to grow and Kaisha then started to import a significant amount of equipment from Europe for manufacturing. The company completely revolutionized manufacturing for ampoules and vials in India and with this equipment in place, improved our quality levels. Kaisha then started exporting about 30% of our products outside of the country. Thereafter, a joint venture was formed with the leading global player Schott for packaging in India under the name of Schott Kaisha. The benefit of the joint venture is that Schott, being the global leader in this business, can provide us with good quality raw materials as well as technical knowhow for our products, whereas Kaisha can provide Schott with knowledge of the Indian market as well as our market presence.

In 2010 you said your dream was to have a facility that supersedes international standards and in 2012 the dream was realized. Can you elaborate on this facility?

Many Indian companies were starting to enter the export markets, but this required a high level of quality, which was missing. These companies had to import materials from other markets like Europe in order to meet quality standards. Schott Kaisha decided to open a facility in India to cater to the needs of these companies. Schott Kaisha invested €35 million into 20 acres of land in Jambusar as this was logistically efficient. This facility has 36 lines that are all running well. Since the company has opened the facility, our capacity has increased by 50%. The goal of this facility is to produce big volumes of high quality glass and packaging that is consistent with International Standards. Schott Kaisha has already created a strong reputation of reliability and credibility in the Indian pharma market so it's important to maintain and live up to that expectation.

What is the role of research and development (R&D) in the facility?

Schott Kaisha is a pro-active company and we have always tried to have something before its time. However now that we have the joint venture with Schott, there is a large amount of innovation coming from them. Therefore R&D is not necessary at this facility currently.

What is the relationship of Schott Kaisha with Sovereign?

When Schott Kaisha joined up with Schott as a partner, we had the tubing and the packaging. I was advised a while back, that one should also make headway into contract manufacturing for pharma companies. The company decided to enter the contract manufacturing market under the name of Sovereign Pharma, which is a contract manufacturing company for injectables. Today the injectable manufacturing company is producing 300 million ampoules annually.

There are 4 manufacturing lines currently at Sovereign Parma; 3 for ampoules and 1 for vials along with freeze drying facility.

Where do you see Schott Kaisha in five years' time?

The goal is continuous growth. The market will decide how the company needs to move, as it is the driver of growth. Schott Kaisha makes it a point to grow more than the market and to take care of its customers' needs and requirements We are currently exploring the next module at the new plant, which will significantly increase our capacity further. With additional capacity the company will also look to expand our exports, but the first preference will always be supplies to India. Schott Kaisha will also look at significant pre-fillable syringe expansion in India, as we see this market as the market for the future. •

The Jewel of the West: Gujarat and Pharmaceuticals Manufacturing

"Gujarat is responsible for 45% of total finished dosage production in the industry. The reason for this huge contribution is that the state is very supportive of the industry and there is a very good setup both for the active ingredients and the finished dosage form. The government supports the industry through fast decision making and an excellent Food and Drug Administration."

- J.R. Vyas, Chairman and Managing Director, Dishman Pharmaceuticals & Chemicals Ltd.

Image: Cadila Healthcare

Introducing Gujarat

India's Pharma Hub

Known as the Jewel of the West, the state of Gujarat is a major industrial hub of India that caters to a broad range of industries. Gujarat's entrepreneurial spirit and hard working population of sixty million have produced Compound Annual Growth Rates (CAGR) of 13.4% during the tenure of the current Prime Minister, Narendra Modi, compared to national GDP growth rates of 7.8% during the same period.

Situated in the northwest of India, its 1600-km coastline is the longest of any state in India, allowing for good connections with the international trade routes that link with North America, Europe, Australia, the Persian Gulf, the Far East and Africa. In addition to Sardar Vallabhbhai International Airport in Ahmedabad, there are a further nine domestic airports spread across the state. Gujarat has an extensive road and rail network that is vastly superior to other transport networks across the country. It is also power sufficient and rarely suffers from power outages, a common problem in other states. Furthermore, it is the only Indian state that has an integrated statewide gas grid. When it comes to infrastructure, Gujarat is in a league of its own. Forbes predicted that Ahmedabad, the business capital of Gujarat, would become the world's third fastest growing city of this decade.

While Gujarat appears to have the Midas touch when it comes to all of the industries it has taken on, few industries can match the levels of success of the pharmaceutical sector. Incredibly, despite only containing 5% of the country's population, Gujarat is responsible for 33% of the overall output of national pharmaceutical production and 28% of India's global exports in the sector, having peaked at 42% prior to the introduction of a ten-year tax holiday that encouraged some businesses to move to less developed states. However, with the end of this tax incentive in sight, Gujarat is expecting a further surge in the coming years.

The state is also home to 40% of India's Contract Research Organizations (CRO) and had manufacturing licenses for some 3,637 units in 2013 with some 63,000 employees. In common with the rest of the country, Gujarat owes its strong presence in the pharmaceutical industry to a large range of the big players, including Zydus Cadila, Torrent, Alembic, Intas, Sun Pharma, Dishman and Claris Laboratories, who form the backbone of the state's pharmaceutical industry. The biotechnology sector has also being successfully integrated into the Gujarati industrial model and had enjoyed annual turnovers of up to $175 million, with some $1.2 billion estimated to have been invested into the sector in recent years.

The reasoning behind Gujarat's success goes beyond its excellent infrastructural network and self-sufficiency in power, gas and water. What drives the pharmaceutical industry in Gujarat is no different than what drives every other industry that Gujarat has successfully promoted over the years; it is simply in the DNA of the Gujarati people to make their state as business-friendly as possible. Like many Western states, they realize that by cutting down on corruption and red tape, the state and its people can reap rewards. Apart from a transparent and efficient style of doing business, the people themselves are very business minded with a large number of people oriented towards setting up their own businesses. It would be impossible to discuss Gujarat and its success in the pharmaceutical sector without discussing the contribution that education has played in guiding this entrepreneurial spirit towards pharmaceuticals, which all began with the opening of the India's first pharmacy college in 1947, L.M. Pharmacy College.

While the state clearly has some of the best business minds in the country, it has also produced some of the best political minds, including Mahatma Gandhi and the recently elected Prime Minister, Narendra Modi, who has been credited with greatly improving his home state when he was Chief Minister of Gujarat. Whilst there is little doubt that Gujarat will continue to prosper and grow, it remains to be seen if Prime Minister Narendra Modi can replicate his success in Gujarat on the much broader scale of the nation or whether Gujarat's success is an achievement that belongs solely to the Gujarati people. •

> "The number of manufacturers in Gujarat grew from 117 in 1962 to more than 900 in 1985 with a major share in the country's pharmaceutical production. During the last decade, Gujarat's pharmaceutical companies like Sun Pharma, ZydusCadila, Torrent and Dishman have been expanding their global footprint through acquisitions, mergers and alliances with international companies and setting up subsidiaries and marketing offices overseas. Gujarat's pharma companies have also been increasingly working towards getting their facilities approved by U.S. FDA, MHRA, and TGA to augment their market presence across regulated and semi-regulated markets.
>
> - Bharat R. Desai, Managing Director, Bharat Parenterals Ltd."

Dr. H.G. Koshia

Commissioner
FOOD AND DRUGS CONTROL ADMINISTRATION (FDCA) GUJARAT STATE

What is the role of the Food and Drugs Control Administration (FDCA) in Gujarat?

The FDCA's primary role is to monitor the quality of the food and pharmaceuticals moving across Gujarat State. We have a team of FDC officers and facility inspectors who controls the quality of food and pharmaceuticals. We also have strong powers for regulating the food and drug industries. Any licensing must happen under the regulating act to improve public health by providing quality food and pharmaceuticals in the country. The FDCA is strongly supported by the government, which invests a significant amount of money into this department for public health.

What is your role as commissioner and what exactly do you do?

As the FDCA commissioner, my main function is to manage the team of FDCA officers and act as a controlling authority to ensure the quality of food and pharmaceuticals manufactured or sold in Gujarat State. There are roughly 1,350 personnel working with me. I have to ensure that implementation of the Drug and Cosmetic Act and the Food Safety & Standard Act is uniform through the state. I also manage the FDCA's 25 provincial offices and make sure that they use their authority within the framework of laws and regulations. I am also responsible for ensuring the smooth functioning of the Food & Drug Testing Laboratories under FDCA and therefore making sure that these facilities have the necessary equipment, manpower and chemicals. I am an administrator, regulator, and controlling authority.

Gujarat represents only 5% of the population of India. What is the pharmaceuticals turnover of Gujarat?

Since the early days, Gujarat has had a strong presence in the pharmaceuticals industry and a strong and efficient administration system. Gujarat has only 60 million people, which is small compared to India's overall population of 1.2 billion. However, Gujarat produces 33% of India's pharmaceuticals and accounts for 28% of its pharmaceuticals exports. Gujarat exports to roughly 150 countries, including the European Union and United States. Gujarat has emerged as a strong brand in India and overseas partly because the pharmaceuticals industry abides the law and the FDCA provides effective regulation.

Can you talk about the talent pool in Gujarat and how the FDCA is helping to increase it?

The FDCA is continually working on increasing the talent pool in Gujarat to improve the technical manpower of pharmaceutical facilities. There are a significant amount of direct and indirect jobs. In Gujarat there are about 3000 licensed manufacturers, and each company needs a minimum of five to ten people to run a very small unit. There is a substantial amount of medium scale and large scale manufacturing units in Gujarat. Production is one area that creates jobs, but indirect jobs like marketing the products also increases the amount of people employed by the pharmaceuticals industry.

Much has been done in recent years to develop the skills of Gujarat's workers. Thirty years ago there were only about three pharmaceutical colleges, and now there are eighty. For capacity building, FDCA organizes trainings for industry representatives and FDCA officers at regular intervals or various seminars under the banner of Vibrant Gujarat events. These events increase the efficiency of the FDCA and improve industry compliances in Gujarat.

Can you please elaborate on Gujarat's international exposure?

As a regulator, my primary function is to safeguard public health by providing quality food and pharmaceuticals. Gujarat tries to raise its capabilities to international standards and share its practices with top global regulators. The FDCA has a significant amount of interaction with the U.S. FDA offices and MHRA. They have helped train newly recruited FDCA drug inspectors. Through this interaction, the FDCA is gaining insight and knowledge into regulations in the global pharmaceuticals industry.

Whilst Gujarat is a pharmaceuticals hub, some feel that the state needs to invest more into research and development (R&D). What role does R&D play in the state?

Out of more than 3,000 licensed manufacturers, a few top companies, universities, and research companies are doing significant in-house R&D. The process of discovering new molecule entities is, however, very expensive, time consuming, and risky. Very few will have blockbuster entities. Therefore, many companies are involved in NDDS, formulation & development and ANDA submission to regulated market. In Gujarat, a significant number of products are currently in the pipeline.

Where do you see Gujarat in the future?

Gujarat experiences significant growth every year and, with strong support from the government, it is able to apply good practices and e-governance. FDCA is the first state in India to start e-governance in licensing systems, which began in 2007. Many states are starting to move to the Gujarat model; so far ten states have replicated the model. I see a bright future for the pharmaceuticals industry not only in Gujarat but also around the world. Gujarat also has a very professional approach to business, which helps it attract investors. As a result, Gujarat will lead India's pharmaceuticals sector and gain considerable brand equity in the international level too. •

Ashok Modi

Executive Director
TORRENT PHARMACEUTICALS LTD.

Could you start by giving us some information about Torrent's backstory?
Shri U.N. Mehta founded torrent in 1959. At this point, there were very few, truly Indian companies involved in the domestic pharmaceutical scene; production was dominated by multinationals. The company began to develop serious momentum in the 1970s and since that time we have moved from strength to strength.

What are the core values behind Torrent's success?
The Torrent Group comprises several companies with diverse interests. Broadly speaking, our operations can be divided into two units: power generation and transmission and pharmaceuticals. We have generation plants at three locations and exclusive distribution rights in four cities. We aim to impart strong values across all our companies. Integrity is of paramount importance, and we always strive to work in a way that demonstrates respect for other human beings. As a generics manufacturer, ensuring a greater level of accessibility to our products must always be a key driver for us.

How would you characterize Torrent's role in India's pharmaceutical sector? What role do overseas markets play in your sales mix?
Almost 60% of our turnover comes from overseas. Our three main markets are the United States, Brazil, and Germany. It is very important to know your markets and adapt accordingly. The U.S market is not driven by one particular therapeutic area, but by whatever product happens to be going off patent. Success in the United States becomes a race to be the first to file for a generic product. Brazil is more of a brand-driven market, where it is important to build up a name in certain therapeutic areas and meet with doctors on the ground. In Germany, on the other hand, it is more a case of working together with the insurance companies. Japan could be a great opportunity but so far the market has proved to be very difficult to penetrate, not only for Indian firms but all foreign companies. As such, we have no particular plans to enter Japan.

In the wake of your recent acquisition of Elder Pharmaceuticals, could you explain Torrent's growth strategy?
For most of Torrent's history we have pursued a strategy of organic growth. However, in June 2014, Torrent acquired the branded domestic formulations business of Elder Pharmaceuticals in India. This move was driven predominantly by growing demand in the Indian and U.S markets. The acquisition allows us to move into segments in which we did not previously participate, such as gynecology, vitamins and pain management. In the current scenario it is quite rare to see an Indian company take over another Indian company because there is likely to be up to 50% of overlap between the two companies.

What role does Torrent's research and development (R&D) department play in India?
Our focus is more on development than pure research, although we have invested some of our U.S budget in new drug discoveries, which has resulted in a number of patents being filed. All such products are currently at the trial stage. Our main thrust is in diabetology.

Gujarat is responsible for approximately 42% of India's total pharmaceutical output. What are the reasons behind the state's status as a pharmaceutical hub?
Gujarat has been a major center for pharmaceutical production for many years. The government has always enacted business-friendly policies, developing world-class infrastructure and aiding growth of young industries. As a result, Gujarat has consistently outperformed most other states. In the beginning, the state steered clear from heavy enforcement of patents, which allowed the nascent pharmaceutical sector to find its feet and build up a core level of expertise and technical capabilities. Now, we are going to see much more stringent enforcement of patent laws. This will undoubtedly affect the way that Indian companies do business but we doubt that it will have an unduly negative impact on growth.

We have heard of certain companies leaving Gujarat in order to benefit from tax incentives in other states. Do you see this as a problem for the region?
Some companies left Gujarat for a period of ten years in order to benefit from tax breaks in other states. This is to be expected in a country the size of India. The central government wants to see more balanced development across the country so it tres to encourage businesses to set up in other, less developed regions. Although we do not like to see companies leaving Gujarat, the overall impact is positive for the industry and positive for the country.

How do you hope to see Torrent progress in the coming years?
Over the past four years we have seen very pleasing growth rates and hope to see even better results in coming years. We plan to concentrate on our existing markets rather than entering news ones. There is great potential to increase our footprint in Mexico and the Philippines and possibly in Romania. Today, our portfolio is primarily based around oral solid dosages but we would like to expand our scope and move into injectables and newer, more sophisticated delivery mechanisms. •

Binish Chudgar

Vice Chairman & Managing Director
INTAS PHARMACEUTICALS LTD.

Can you give a brief background of Intas Pharmaceuticals?
My father laid the foundation of Intas three decades ago. When I joined Intas, in the late 1980s, the company had an annual turnover of less than $1 million, but today we are on target to cross $850 million. Intas has been able to maintain a 25% compound annual growth rate (CAGR) on its revenue over the last ten years. The CAGR over the same period on net profits has been from 35% to 45%. From being 100% domestic-focused at inception, Intas' products are now sold in more than 70 countries.

Could you describe Intas' business?
Intas has divided its sales and marketing operations into three major geographical segments: India, Europe, and the United States. We have sold to Europe for nine years and the United States for five. Intas also operates in South East Asia, Africa, Latin America, Australia and New Zealand, but these areas contribute less than 10% to total turnover. Intas is growing faster internationally than domestically, with 55% of current year revenue targeted from international operations and 45% from domestic operations. Intas' international presence is particularly strong in oncology, with a wide basket of anti-cancer drugs, and hospital-based healthcare in select geographies. We also have a very strong and wide solid oral basket. The third growth driver is our portfolio of drugs based on our novel delivery platform, which we have been developing for six years.
Finally, Intas is a leader in biosimilars. With seven biosimilars commercialized and two to be launched in the next few months, Intas has the largest number of indigenously developed biosimilars in India. Intas is also the first Indian company to market a biosimilar in Europe. The company has a very rich pipeline that will ensure that at least two to three new launches are made annually. The current turnover from biosimilars is about $25 million, and the area holds big promise for the future.

Please elaborate on where you have invested in terms of R&D?
As a percentage of our turnover, Intas spends around 6.5% to 7% on research and development (R&D). In addition to the normal focus on developing generics, we have also focused on more innovative areas. For the last 15 years, we invested in and have now mastered R&D for biosimilars, culminating in several products and a rich pipeline of molecules. We are also focusing on novel drug delivery solutions that can improve the efficacy or safety profile of existing generic drugs, thereby adding value to them. The company also has a couple of new chemical entities (NCEs) in development, one of which is an antimetabolite of the anti-cancer drug, tamoxifen citrate. The antimetabolite is called antoxifen and is patented by Intas worldwide. The product is currently in phase two clinical trials. The research part of our NCE operations are U.S.-based but in India, we undertake the development of the molecule, i.e. process and scale up.

How does Intas maintain its impressive growth?
The company has enhanced its market intelligence, particularly in identifying demand-supply gaps and filling them rapidly. Intas also has access to Temasek, a highly reputed global private equity player, as an investor holding 10.16% stake in the company. This access further solidifies our capability to raise growth capital. In addition, we are expanding geographically and in product offering. Our R&D efforts also play a major role. While, the company does not have joint ventures, we actively pursue collaborative efforts and have formed many marketing alliances worldwide.

Why do you think Gujarat has been so successful in pharmaceuticals?
The first pharmacy collage of India was started in Ahmedabad about 45 years ago, and most of the first generation entrepreneurs, who now head the big pharmaceutical companies, were educated there. The college essentially germinated the Indian pharmaceutical industry. If one looks across any business sector, one finds people from Gujarat, either as entrepreneurs or at senor and influential positions. They are well known for their business acumen. Additionally, the Government of Gujarat has been very proactive and transparent, which has promoted the industry, and has invested in infrastructure, which helps attract investment.

Does Intas plan to branch out beyond Europe and the United States?
Intas already has a manufacturing plant in Mexico and a packaging line and a small manufacturing setup in the UK, which is currently being expanded. To be successful on the global front, a company's entire supply chain must be dynamic, robust and highly responsive. Intas is the first Indian company to have a pan European footprint. We have been able to consistently maintain the highest level of quality and delivery standards, which are key ingredients of our success. As we expand further, we are constantly scouting for opportunities to expand existing operations or acquire products, markets or manufacturing capabilities.

Do you have a final message?
Intas' present and future is full of promise, potential and continued commitment. We are likely to maintain a 25% CAGR for the next several years, just organically. In addition, we are actively looking for in-organic growth opportunities. The past growth has been phenomenal, but the best is yet to come. •

Zydus Cadila

FOUNDER
Late Ramanbhai Patel

LEADERSHIP
Mr. Pankaj Patel, Chairman and Managing Director

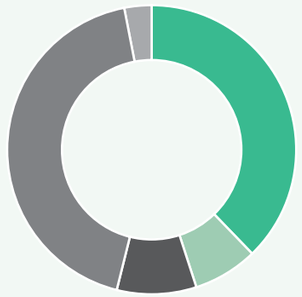
SALES
Gross revenue grew by 15% to Rs. 72,083 in 2014. Sales growth was driven primarily by the US formulations business, which registered growth of 44%.

NET WORTH
The consolidated net worth increased to Rs. 34,390 at the end of March 2014, up by 17% from Rs. 29,445 at the end of March 2013.

PRODUCTS AND MARKETS 2014
India: Launched Lipaglyn (Saroglitazar), the first New Chemical Entity (NCE), maintained strong leadership positions in the represented markets of cardiology, gynaecology, gastro intestinals and respiratory therapy areas. Launched over 75 new products (including over 45 line extensions) in India, of which 19 were first in India. Overall, the formulations business in India registered a growth of 6.1%, higher than the overall market growth and posted sales of Rs. 24,644.
United States: Filed a record 50 ANDAs with the U.S. FDA during the year, taking the cumulative ANDA filings to 227. The U.S. business posted sales of Rs. 21,704.
Mexico: Commenced commercial operations in June 2013 with launch of seven products. Posted sales of Rs.109.
Europe: Consolidated the business in France by restructuring the product portfolio and customer base. Launched eight new products in the French generic market. Overall, the European business posted sales of Rs. 3,902.
Emerging Markets: Launched more than 35 new products in the key markets of Asia Pacific, Africa and Middle East in 2014. Posted sales of Rs. 3,592 during the year, up by 15%.
API: Filed 10 DMFs with the USFDA, taking the cumulative U.S. DMF filings to 117. API business grew by 13% and posted sales of Rs. 3,497.

CADILA'S FISCAL YEAR 2011 REVENUES

Source: ICRA Limited



India Formulations	38%
India Consumer Business	7%
APIs	9%
Export Formulations	43%
Other	3%

Image: Cadila Healthcare

Pankaj Patel

Chairman and Managing Director
ZYDUS CADILA

Can you tell us briefly about the history of Cadila?
Established in 1952 as Cadila Laboratories, our group's association with the industry spans over five decades. Founded by my father, the Late Mr. Ramanbhai B. Patel, Cadila grew to become the second largest Indian pharmaceutical company in the 1990s. In 1995, we restructured our operations and emerged with a new identity under the aegis of Zydus group as Cadila Healthcare Ltd. Since then, it has been a process of rebuilding the organisation, growing the business, exploring newer avenues, building strengths and enhancing capabilities. Mr. Ramanbhai Patel had started with a vision to create innovative therapies and this is the spirit that guides our journey of innovation even today.

Could you tell us more about your business strategies and journey of growth?
When we restructured our operations in 1995, we decided to focus on our core area. Initially, we dedicated ourselves to growing in the domestic market and became one of the top ten grossing companies domestically in 1996. Subsequently, we decided to start to look at markets beyond India and targeted very specific territories. Many of our moves were unusual; for instance, we were the first Indian company to move into France. We then went to Spain, and then to the United States, Brazil, and elsewhere. We selected those where we believed that the market would expand if we entered, and that there was enough for everybody to share.
Another part of the business that we developed focuses on capability building. If we want to compete globally and offer a basket of quality products, we must focus on building the internal capabilities of the organization. We created several verticals on which our business has developed. Of course, originally, formulation was our first vertical. Thereafter, we developed a biological vertical, a vaccine vertical, and some specialized product verticals.
We have also focused on talent management. We constantly make an effort to hire and retain good talent. We have also created a culture that is very unique to our organization. We instill our values in our people and they are encouraged to, in effect, think differently and create something unique.
Classically, companies have grown many-fold because of acquisitions. We have of course made some acquisitions but they have been strategic in nature. When we wanted to understand a new market, we acquired a company to help us understand it and acquire the capability to market products in a particular country. Most of our acquisitions have been small.
Collaborations have been key for us and are integral to the pharmaceuticals industry. Everybody is competing and partnering at some level. At Zydus, we have a number of successful alliances that continue to grow. We have added value through partnerships in manufacturing, development, supply, and marketing. Zydus may not yet have a pipeline, but the partner can bring the pipeline: when it comes to an innovation partner, they have a pipeline, and we have the capability to help them bring that pipeline to India, and hence it is an interesting proposal for both companies to grow their businesses.

We would like to know more about Zydus' innovation journey
We have been on the path to innovation since 1995. We planned 20 years ago to become a research-driven company by 2020. In 2000, we invested in a basic research facility, and created a center where we could focus on doing novel molecule research and related activities. We have built up a capability where we can do everything from conceptualizing a target, to developing and actually testing it—and we can do all of it in-house. We can do our own in-silico molecule design, our own chemistry, our own biology, our own pre-clinical studies; we can create INDs, we can do Phase I studies.
Last year, we achieved a major milestone, as we launched our own, patented NCE, Lipaglyn, which is the world's first drug to be approved for the treatment of diabetic dyslipidemia. The discovery of Lipaglyn is an important milestone for the entire healthcare fraternity in India and the world of drug discovery. Lipaglyn is the first NCE discovered and developed indigenously by an Indian pharma company.
Discovering new medicines is the dream of any pharma company because, ultimately, the goal is to improve health and provide people with the means to improve their wellbeing. Our maxim is "Dedicated to life." Indian companies can do more of this. India has the resources and its costs are significantly lower than in the West, except, of course, in the late stage of development, when we conduct trials around the world. For that stage, costs would be comparable. In this space, we again have a very focused strategy. We are focused on certain therapeutic areas and highly selective targets. If things go well, many Indian companies can follow suit and do what we have done.

What is India's contribution to the global pharmaceuticals industry?
The message is that whatever good was done from the policy initiatives of the government has made us rich here. I hope the government will continue the support. The world is looking at India, and trying to copy what Indians have achieved in terms of building up this platform. •

Arjun Handa

Managing Director and CEO
CLARIS LIFESCIENCES LTD.

Claris is one of the major producers of injectable pharmaceuticals. Could you provide us with some information about the company's background?

Claris was initially established to cater to the injectables segment. We produce finished formulation injectables in the fields of anesthesia, nutrition and infusions. At the time of the company's founding, we felt that there was a gap in the Indian market for a high quality, affordable injectables manufacturer. Historically, Indian manufacturers tended to focus on the production of older molecules and compete primarily on price. From the outset, we wanted to deliver newer molecules that better addressed the needs of patients. We started off with the production of propofol, which is now the most popular anesthetic on the market and offers patients a much faster post-operation recovery time. We also offer a range of amino acids and lipids that can cut down this time, thus reducing bed usage and healthcare bills.

What would you say are the main values behind Claris' corporate philosophy?

Our primary concern is quality. Injectables are difficult to manufacture and, as the product is going directly into the bloodstream, there is no margin for error. Unlike orally administered drugs, injections bypass the body's immune system. All of our plants are world class and numerous inspections, including from the U.S. FDA, have confirmed this. After quality, affordability and accessibility are our driving forces. To ensure that our products reach as many patients as possible, we operate a large distribution network, with close to 1,000 outlets stocking our products across India. On a global scale, we export to 95 countries and work with 100 distributors.

Claris is involved with several joint ventures with Japanese companies such as Mitsui and Otsuka. How difficult has it been to enter the Japanese market?

To clarify, the Claris Group is divided into two separate companies: Claris Injectables and Claris Otsuka. Claris Otsuka works with relatively commonplace infusions, such as dextrose or saline. Although these are produced in joint venture with the Japanese company, Otsuka, they are sold in India and other emerging markets. Claris Injectables produces generic injectable molecules that are mostly exported to the United States and Europe. In terms of revenue, both companies contribute approximately the same amount. We have not yet attempted to move in Japan. It offers great potential but is difficult because of its strict demands on packaging and quality. It is necessary to have a strong local partner. The joint venture is more about bringing Japanese products to India than exporting Indian products to Japan.

What strategies are you adopting to develop Claris' business in the medium-term?

Our main strategy is to broaden our product offering; over the next three years we plan to roll out 48 new products on a global level. Our research and development (R&D) department is constantly looking to develop new generic formulations. We prefer to develop products that are not widely manufactured. We do not research new molecules but work on new ways to deliver our products. Within injectables there are many associated technologies: suspensions, emulsions, powders, prefilled syringes, which we always try to make more efficient. Claris is currently the only company in India to deliver drugs in bags, rather than the typical bottle or vial. This has the advantage of being far easier to sterilize.

The Claris Group recently inaugurated its fifth manufacturing facility, which will help boost total production capacity. We have many products filed in the United States and Europe, as western countries are looking to bring down healthcare costs. We are already present in the main healthcare markets, but in the case of infusions and other more affordable products we are targeting new opportunities in Africa, Latin America, and the CIS countries.

What factors do you believe have led to Gujarat's dominant position in India's pharmaceutical production landscape?

There are several reasons for Gujarat becoming a pharmaceutical and industrial hub. It offers quality infrastructure, surplus power, and abundant skilled labor with a low level of unionization. Government policy is very industry-friendly, it is relatively easy to set up a new business, and bureaucracy is not as onerous as in other states. Of course, there is room for improvement. A discharge network to take care of plant effluent would be a great boost. This is already present in various industrial clusters but on a regional level these individual treatment plants do not link up.

Where do you hope to see Claris in five years?

If all goes to plan, we will be an important player in regulated markets, particularly in the United States. Because of the breadth of our product portfolio we could become a key supplier to new markets. As for the infusions business, we plan to expand to reach an even greater number of patients in emerging markets. We hope to move into more production of general injectables that will cover a larger range of therapeutic segments. Anesthesia and renal treatments will continue to be our main drivers but there is potential to broaden our portfolio to other areas such as pain management. •

Claris Lifesciences Ltd.

MANUFACTURING AND RESEARCH AND DEVELOPMENT (R&D) FACILITIES
ISO 9001-2000 and WHO GMP certified

THE STATE-OF-THE-ART LABORATORY SET-UP
World-class machines, including:
DRO from Christ, Switzerland
WFI from Stilmas, Italy
Vessel from Diesel, Germany
Bomer (Bag Printing Machine), Germany
Bosch (Ampoule washing Machine), Germany

REGULATORY APPROVALS
United States, United Kingdom, European Union, Australia, New Zealand, Gulf Cooperation Council, Brazil, Columbia, Tanzania, Uganda, Oman, Ethiopia, Egypt, India

QUALITY PHILOSOPHY
Commitment to achieve a level of perfection that matches the highest international pharmacopoeial standards.

Our final test for quality is a very simple question that we ask ourselves without fail: "Would we use it to treat our dearest ones?" If the answer is an unhesitant "Yes," then the product has passed our final quality test. We call this "Emotional Pharmacopoeia."

AWARDS:
- Claris Inc. in India Innovation Top-100 List (2013)
- Merit Award (2011)
- Best Supplier Award (2010)
- Greentech HR Excellence Award (2010)
- IMEA Award (2009)
- IDMA Quality Excellence Award (2009)
- India's Best Company to Work Award (2010-2013)

KEY PRODUCTS IN THE UNITED STATES

Source: Claris

MOLECULE	ANDAS	GLASS VIALS	BAGS
Ciprofloxacin	2	YES	YES
Fluconazole	3	YES	YES
Furosemide	1	YES	
Levofloxacin	2	YES	YES
Metoprolol	1	YES	
Metronidazole	1		YES
Norepinephrine	1	YES	
Ondansetron	2	YES	
Total	13		

Kalpesh Patel & Satyam Pandya

KP: Executive Director
SP: Product Executive
NIRMA LTD.
(NIRLIFE HEALTHCARE)

KP

Could you begin with a brief history of Nirma's activities in India and the company's transition to pharmaceutical production?

Nirma was established in 1969 by Dr. Karsanbhai Patel to produce innovative and cost-effective detergents. At the time, detergents were considered a luxury far beyond the means of the average Indian consumer, commanding a price tag of around 13 to 14 rupees per kilo. Dr. Patel was able to produce his formula and sell it at just three rupees per kilo, allowing a whole new section of society to gain access to detergents. At its peak, Nirma achieved market share of approximately 80% but it was becoming increasingly difficult to secure materials at competitive prices. it therefore decided to take advantage of its size and invest in plants to produce all the inputs for soaps and detergents. This process of backward integration opened up many new options.

We have always focused on products for mass consumption, and healthcare was one of the most rapidly growing sectors in the Indian economy. In 2006 we took the decision to move into pharmaceutical production by acquiring Core Healthcare Ltd, which operated a 550-acre manufacturing base for injectables and infusions. The facility was quite run down when we acquired it so it was necessary to carry out a lot of work before commencing production.

How did Nirma manage the process of moving into the pharmaceutical sector?

As pharmaceuticals require longer development periods than other chemical products, we started slowly and worked on building up our expertise and capabilities. We began by producing infusions but did not want to limit ourselves to one market, particularly as infusions are regulated by governmental price controls. The majority of our customers are hospitals, which require a diverse array of different pharmaceuticals and medical products, so it made sense to enter a wider range of segments. Today we produce over 1,000 different healthcare products, from nutraceuticals to medical equipment. Our main focus remains semi-regulated markets, such as India, but ultimately we aim to move into more highly regulated countries and eventually would like to distribute our products in the United States.

Since 2008, Nirlife has achieved 27% to 28% year-on-year growth, which is almost double the industry average. Looking forward we hope to see growth rates of 15% off the back of new product lines.

What is the balance between domestic and overseas sales for Nirma?

Less than 20% of our sales are overseas, largely because registering pharmaceutical products abroad is a very lengthy process. Nevertheless, we aim to boost our participation in new markets, and today our products are registered in over 50 countries. Next year we plan to introduce some of our products to European countries.

Gujarat is responsible for approximately 42% of India's total pharmaceutical output. What are the reasons behind the state's status as a pharmaceutical hub?

Since the time of independence, Gujarat has always been a region of entrepreneurs. Approximately 20% of India's GDP is generated within the state despite it only holding some 5% of the total population. The state's position on India's west coast is advantageous because it allows easy access to fast-growing markets in the western part of the country. In the past we have seen heavy investment in oil and petrochemical production, ensuring continuous supply of basic input materials for chemical and pharmaceutical manufacturing. This, in turn, attracted downstream producers to build production bases nearby, creating an industrial hub.

How do you evaluate the government's role in Gujarat's industrial development?

We are fortunate in that the government positions itself as pro-industry and pro-growth. There are seven major State Owned Enterprises (SOEs) here in Gujarat, such as Gujarat State Fertilizers and Chemicals Ltd., which are highly professional and extremely well managed. The strength of these public bodies has served as a powerful incentive for investment and a strong foundation upon which private enterprise was able to thrive. The government recognizes that demand for industrially produced goods is growing rapidly and that ideally India should meet this demand through local production. To this end, the state government organizes a biennial investment promotion summit known as Vibrant Gujarat, which has proved instrumental in attracting new business to the region.

How do you see Nirlife advancing in the coming years?

Nirlife has only one possible path open to it: growth. We will continue to follow new opportunities and create new products to better attend to our customers' needs. In tandem with this, we plan to move into contract manufacturing, allowing well-established players to make use of our production facilities. This business is still nascent, but we are already seeing considerable interest from producers across India that do not have spare capacity. The future is very bright for Indian pharmaceuticals. The world's population is aging and beyond a certain age, medication becomes a part of daily life. India is well positioned to help meet this growing demand. Not only do we have the manufacturing infrastructure in place, we also have a vast pool of skilled labor and huge potential to expand. •

Nirma University

Dr. Karsanbhai K. Patel, chairman of the Nirma Group, is also president of Nirma University. This socially responsible educational institution is based in Ahmedabad and is one of India's leading institutions accredited by the National Assessment and Accreditation Council (NAAC). It is also a member of the Association of Indian Universities (AIU) and the Association of Commonwealth Universities (ACU).

Numerous Indian corporations are playing an active role in giving back to the community. The university was established with the aim of shaping a better future by developing effective and ethical individuals and organizations.

The university has six institutes that cover the areas of technology, management, pharmacy, law, science and architecture. The institute possesses the capabilities of conducting cutting edge research, strong academic programs, and a quality learning process.

Nirma University's mission is to produce good professionals and worthy citizens of a great country. It therefore provides a holistic education. It recognizes that each student has unique potential and should receive the best preparation and training for achieving his or her career ambitions and life goals.

The objectives of the university are:
To provide certificate/diploma, undergraduate, postgraduate and doctoral degree programs and to maintain a high standard of education and its applications, to create capabilities for upgrading science and technology, dental, medical, paramedical, physiotherapy, pharmacy, commerce, management, education and the humanities;
To disseminate, create, and preserve knowledge and understanding by teaching research, training and extension activities by effective demonstration and influence of its corporate life on society in general; and
To establish close linkage with the industry to make teaching, research and training at the university relevant to the needs of the economy, at national and global level.

The mission is fulfilled through various practices such as academic development, outcome based education, a unique grading system and different research centers. Additionally, the university specializes in value added courses, skill development and modular classes, enrichment and humanities courses in addition to the regular curriculum. Being a pharmaceuticals company that also excels in providing education, Nirma University demonstrates good corporate social responsibility practices. •

Investing for the Future: Biotechnologies and R&D in India

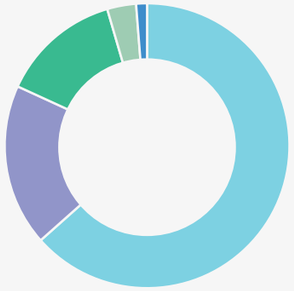
"“The success of our customers at clinical trials is our success. CRAMS is very important for us, and we are investing 80% of revenues into our drug discovery program. In drug discovery until Phase 1, we can support ourselves, but when it comes to Phase 2 clinical trials, which can cost from $15 to $25 million, we need to get support either from strategic partners or we need to raise funds from the market… Everyone knows that in Central Nervous System (CNS) diseases there is a high, unmet need and even then there is no support for the research. We are the only one from India focusing on these diseases and hope to achieve success soon so that there will be validation, monetization, and easier fundraising.”

- Venkat Jasti, Chairman & CEO, Suven Life Sciences Ltd."

Image: Reliance Life Sciences Pvt. Ltd.

EXPORT SHARE OF MAJOR SEGMENTS (2013)

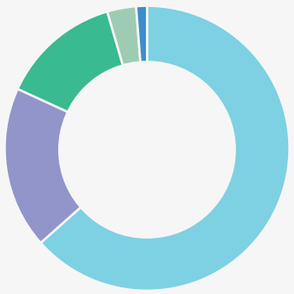
Source: ABLE - Biospectrum Industry Survey, June 2013, Aranca Research



- Bio-pharma 64.6%
- Bio-services 31.7%
- Bio-agri 1.1%
- Bio-industrial 1.7%
- Bio-informatics 0.9%

MARKET BREAK-UP BY REVENUE (2013)

Source: ABLE - Biospectrum Industry Survey, June 2013, Aranca Research



- Bio-pharma 64%
- Bio-services 18%
- Bio-agri 14%
- Bio-industrial 3%
- Bio-informatics 1%

The Next Wave

Biotechnology in India

For countless millennia, human societies have had a close relationship with some form of biotechnology, primarily seen in the manufacturing of foods such as bread and alcoholic beverages such as beer that must go through a process of fermentation. While humans have exploited the beneficial effects of using biological agents, the parameters have been radically refined in recent years, with biotechnology playing an increasingly greater role in the pharmaceutical sector. As the pharmacy of the world, India is certainly playing its part in exploring the relevant biotechnology sectors, which have seen rapid growth in recent years.

Biocon, India's first biotechnology firm was established in 1978 by Ms. Kiran Mazumdar-Shaw, paving the way for what was to become a multi-billion dollar industry. This was followed by the founding of the Centre of Cellular and Molecular Biology in 1981 and the Institute for Microbial Technology in 1984. The sector got official recognition from the Indian government in 1986, with the establishment of the Department of Biotechnology (DBT).

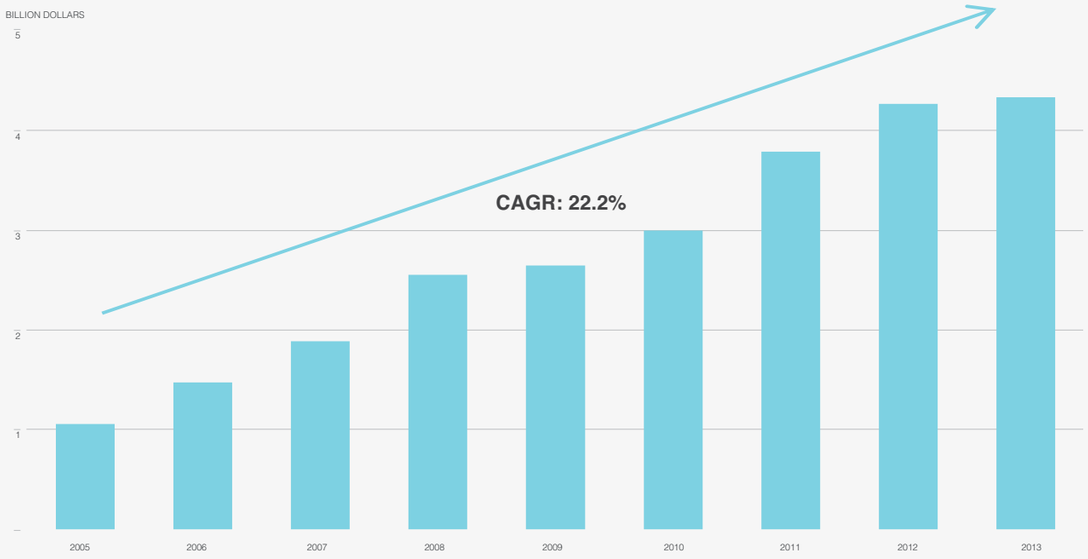
Today, Indian biotechnology is a fast growing, robust industry with total turnover for the 2013 financial year estimated to be at $4.3 billion, representing a growth of 15.1% compared to the previous year and a Compound Annual Growth Rate (CAGR) of 22.2% over the previous nine years. Exports faired particularly well during this same nine-year period with a CAGR of 25.1%, with exports growing from just $400 million in 2005 to $2.2 billion in 2013, representing 51% of the industry's total revenues.

It is fair to say that Biotechnology has had a great decade, but the best years appear ahead of it, with the sector forecasted to reach $11.6 billion in turnover by 2017. This projection may seem overly optimistic, but it is feasible when one considers what India has to offer the global biotechnology community in terms of cost-efficiency and expertise. Dr. Ratna Sudha, Managing Director of Unique Biotech says: "India has considerable manufacturing expertise. Partnering with Indian companies cuts costs and reduces time to market. Clinical trials can also be conducted more cost effectively." Furthermore the increasing global and domestic demand for biotechnology, the heavy investment that has been put into R&D and most importantly, the generous government initiatives that have been put in place to promote the industry, all

> "India has an enormous opportunity to play a big role in making an impact on global healthcare. There are many companies in India that have excellent quality systems and good respect for IP. India is uniquely positioned to leverage its cost advantage and talent to deliver affordable innovation. A renewed thrust on innovation in India can position it to be the next destination for good quality research as that is the future for India."
>
> - Kiran Mazumdar-Shaw, Chairperson & Managing Director, Biocon

MARKET SIZE

Source: ABLE - Biospectrum Industry Survey, June 2013, Aranca Research



EXPORTS OF BIOTECHNOLOGY PRODUCTS

Source: ABLE-Biospectrum Industry Survey, June 2013, Aranca Research

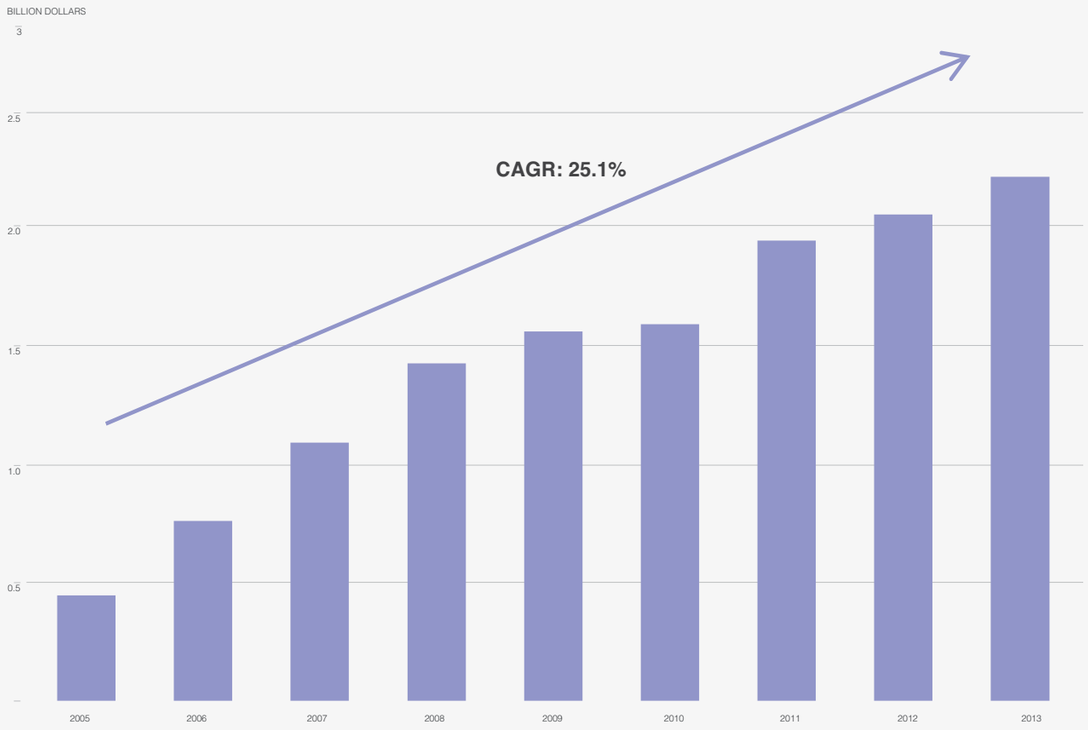


Image: Neuland

make the forecast of $11.6 billion very likely.

The Indian government's commitment to the biotechnology sector has be unwavering, with investment rising from $1.1 billion in their 11th Five Year Plan to $3.7 billion in their 12th Five Year Plan, corresponding to an incredible growth rate of 336.3%. The government also announced a venture fund of $2.2 billion to support new drug discovery in the sector as well as infrastructure development, which is seen as crucial to the growth of the industry due to the limited funds that are available. Apart from public funding, the biotechnology sector has benefited from initiatives such as 100% FDI investment through the automatic route. This FDI friendly environment has enticed global pharmaceutical companies that work in biotechnology, including Lonza, which plans to invest $150 million to establish a manufacturing base in Hyderabad.

The government has also set up a number of agencies to promote the industry and allocate funding. These include the Biotechnology Industry Research Assistance Council (BIRAC) whose role is to promote innovation and research in the field and provide funding for technology and product development. The DBT also put forward the National Biotechnology Development Strategy (NBDS) to support the industries' infrastructure whilst promoting growth and trade. As part of this promotion the government allotted 30% of the DBT's budget to be invested in public-private partnership in order to promote R&D. The government is also planning to set up a National Biotechnology Regulatory Authority (NBRA) in order to streamline the drug approval process, which should greatly increase the efficiency of the system. Apart from existing biotechnological clusters that exist today such as the Genome Valley, the government is further planning the commissioning of new bioclusters at Faridabad, Mohali Kalyani and Hyderabad.

While the government have put forward a number of initiatives, there is a strong argument that they are not putting enough financial emphasis on the biopharmaceutical market, which accounts for 64% of the total biotechnology sector. Despite being the largest and fastest growing segment of the biotechnology sector, growing at a rate of 17.7% in 2013, with exports increasing by 25% in the same year to $1.4 billion, the government only earmarked 26% of its 12th Five Year Plan towards medical biotech.

From a starting point of a single entrepreneur who founded her company, Biocon, in the garage of a rented house, India's biotechnology sector has exploded to become the 12th largest such sector in the world and second largest in Asia (after China) in a matter of just a few decades. With proven achievements such as being the world's largest producer of the recombinant Hepatitis B vaccine and current growth rates of 17.7%, India has secured its role as a global biotechnology hub. However, as with any young industry, it will be up to the government to follow through on their ambitious initiatives to foster the staggering growth that this sector has already experienced. •

> "We set up here in the Genome Valley in 1997. At that time this area was just a barren land. There weren't any roads or electricity. So when we first started here we had to use a generator. We initially got an investment of $3.5 million from the government of India, the Technological Development Board and the Industrial Development Bank of India. By 1999 the area had been named the Genome Valley and it began to attract other knowledge based biotech companies. Today the area is a cluster of more than 150 different companies, which I believe has greatly benefitted India.
>
> - Krishna Ella, Founder, Bharat Biotech International Ltd and Ella Foundation"

Kiran Mazumdar-Shaw

Chairperson & Managing Director
BIOCON

Can you give a brief background of Biocon and your role in the Indian pharmaceuticals industry?

India has proved to be a high-quality, low-cost producer of generics and vaccines, and Biocon started its business in this context. In 2000, Biocon decided to look into bio-pharmaceuticals, which was still an untapped field. We felt that we could leverage what we had done as a biotech company in the area of industrial and pharmaceutical enzymes. What led Biocon's strategy at that time was our technology base. Biocon had very good fermentation technology and thus looked at fungal fermentation-based products, bacterial fermentation-based products and recombinant technologies. Through fungal fermentation, statins are produced, and Biocon started producing statins rather than enzymes, starting with a product called Lovastatin.

What are the cost advantages to working on enzymes rather than in traditional pharmaceuticals?

The big difference in costs between industrial enzymes and pharmaceutical APIs was that the regulatory processes were very different. Biocon could develop an enzyme and bring it to the market in less than a year, but that was not the case with pharmaceuticals. I had to learn how to take products through regulations and then to the market. We leveraged our existing strengths in fermentation technologies for pharmaceuticals, which gave us a huge differentiation from other companies. Lovastatin was developed on Biocon's own unique fermentation platform, which was based on solid-state fermentation and not deep-tank fermentation. Biocon was the only company in the world making Lovastatin on solid-state fermentation, for which we also obtained approval from the U.S. FDA.

Besides Lovastatin, in what other areas has Biocon been involved?

Biocon started looking at other fermentation-based products and got interested in recombinant human insulin. Biocon had a very clear strategy in terms of its market positioning and product differentiation as well as a sense of purpose. When every Indian company was developing generic drugs Biocon looked at where we could make a global impact and that was in biopharmaceuticals.

Biocon had a proprietary fermentation technology based on a Pichia expression system, which was very high yielding and thus we used this technology to produce insulin. Ten years ago the price of insulin in India was much higher than today, as the country was dependent on imports. When Biocon's indigenously developed insulin came into the market at an affordable price, the price collapsed. Biocon thus made a huge difference to diabetes management in the country and successfully expanded access to insulin to a much larger patient pool by making it affordable. Biocon is currently the largest Indian insulin player and the fourth largest insulin producer in the world. Biocon's recombinant human insulin is registered in over 55 countries and we are supplying insulin to several markets across the globe thus making a difference to global health by providing high quality yet affordable insulin to diabetic patients in these countries.

Why did you decide to enter these markets?

Biocon realized that there were problems with access and affordability in terms of expensive biopharmaceuticals including monoclonal antibodies. We wanted to make a difference and started a program based on novel antibodies. We licensed some very early-stage antibodies from a Cuban research institute and developed them further. One antibody was for head and neck cancer – a type of cancer that is highly prevalent in India – and was developed by Biocon and launched in India as BIOMAb EGFR. As Biocon improved its expertise in antibodies development, we decided to create a pipeline of biosimilar antibodies.

What place do you see India playing in this arena?

After generics, biosimilars are going to disrupt the pharmaceuticals market, which is why manufacturing in India is becoming very important in the pharmaceutical space. India provides a high-quality, low-cost manufacturing base for biosimilars. This competitive advantage opens up the market and provides greater access to this very important class of drugs. I think that biosimilars present a very attractive opportunity for India and for Biocon, which is ahead of the other players in this exciting space. Our proven scientific expertise in the biologics and biosimilars space positions Biocon to capitalize on this opportunity and expand further into the market even though it is a very expensive process. The research model of Big Pharma is under immense pressure, as it has created huge research engines that are expensive to sustain. What is happening now is that they are shrinking their research budgets and focusing on outsourcing research and investing in developing products and taking them to the market. This augurs well for India's contract research services sector.

How do you see the Indian pharmaceuticals industry doing in the next five to ten years?

India has an enormous opportunity to play a big role in making an impact on global healthcare. There are many companies in India that have excellent quality systems and good respect for IP and that can help the industry to grow. India is uniquely positioned to leverage its cost arbitrage and quality talent to deliver affordable innovation. A renewed thrust on innovation in India can position it to be the next destination for good quality research as that is the future for India.

Can you elaborate on Biocon's pipeline?

Biocon has a very diversified pipeline that includes novel biologics, biosimilars, and differentiated generic formulations.

Our core fermentation capabilities allow us to manufacture small molecule APIs — Statins and Immunosuppressants as well as difficult-to-make specialty molecules. Capitalizing on our existing strengths in the API business, we have forward integrated to develop generic formulations. We are building a robust pipeline of difficult-to-make, technology-intensive molecules which can be commercialized in several global markets including the US.

In the biosimilars space, we are developing a portfolio of generic insulins, biosimilar monoclonal antibodies and other biologics. We have introduced the world's most affordable trastuzumab for the treatment of HER2-positive breast cancer in India in the early part of 2014 and our other biosimilar MAb programs, which are partnered with Mylan, are also making good progress.

We also have a very robust novel molecules pipeline, which includes the oral insulin program. This is a huge breakthrough for Biocon and will potentially revolutionize the treatment of diabetes mellitus. Furthermore, we have initiated the groundwork for trials to expand the label indications of Itolizumab, our novel anti-CD6 monoclonal antibody, which has been launched in India for the treatment of chronic plaque psoriasis. Itolizumab holds promise in treating diseases like rheumatoid arthritis, multiple sclerosis and several other autoimmune diseases.

It seems that a lot of Biocon's projects are breakthrough projects?

I am proud to say that Biocon has taken the lead in harnessing the power of biotechnology to find novel solutions for numerous healthcare challenges in chronic areas where patients' needs are relatively unmet.

We have a large and diverse portfolio of innovative therapeutics, including two novel biologics for patients in India: BIOMAb EGFR® (an anti-EGFR monoclonal antibody) for head & neck cancer and ALZUMAb™ (an anti-CD6 monoclonal antibody) for psoriasis. We are also pursuing the development of the world's first oral insulin as a tablet.

We realized early on at Biocon that without affordability driving innovation, it would serve no purpose. Which is why our products – from patented enzymes to statins and insulin, and from antibody drugs to novel molecules – help doctors and patients access cutting-edge and high quality drugs at treatment costs that are affordable.

India provides the ideal environment for concentrating on breakthrough products because the cost of innovation and the cost of failure here is affordable. Scientists at Biocon also feel invested in the company, as they love the challenge of working on exciting programs.

Biocon is also involved in corporate social responsibility activities. Can you elaborate on the Biocon Academy?

The biggest challenge that India faces is in finding skilled people to expand the pharmaceutical sector. The newer generation of talent does not have the same expertise and experience that the older generation has and now we have to help the younger generation build these skills. Biocon thus started Biocon Academy as an advanced learning center in applied biosciences to develop industry-ready, high-end talent. The academy acts as a finishing school for bioscientists soon after they graduate from college by equipping them with skills that enhance their employability. In the Biocon Academy, students are trained in a very well designed, intense and compressed program, which takes 16 weeks. Biocon wants to train 100 students a year not just for Biocon but for the whole industry. By collaborating with leading academic institutions globally, Biocon Academy aims to bring world-class training programs for biotech students in India and thus develop a new cadre of life sciences professionals with specialized skills. The academy will focus on developing the spirit of experimentation, application of knowledge and innovation skills among bioscientists in India. It will enable them to unlock their potential and foster excellence in the biotech sector. •

Reliance Life Sciences Pvt. Ltd.

Reliance Life Sciences is part of the Reliance Group of companies. Reliance Life Sciences participates primarily in medical biotechnology business opportunities; with key initiatives in biopharmaceuticals, pharmaceuticals, clinical research services, regenerative medicine and molecular medicine services.

Reliance Life Sciences has launched three of the world's first biosimilars and has the highest number of biosimilars under development globally. It has the distinction of being the first manufacturer of plasma proteins in South Asia. Reliance Life Sciences has catalyzed the emergence of regenerative medicine in the country and has the highest experience with stem cell transplants in India. RLS is one of the few centres in the world offering a specialized range of tests in molecular medicine.

Reliance Life Sciences operates state-of-the-art facilities in the life sciences domain. The flagship facility is the Dhirubhai Ambani Life Sciences Centre (DALC) in Navi Mumbai, India. Spread over 20 acres, DALC is among the most diverse and integrated life sciences campuses in the world; housing world-scale and world-class manufacturing facilities approved by Indian and international regulatory agencies. A second facility is in Bengaluru, India, for clinical data management and biometrics.

Today Reliance Life Sciences is a fully-integrated life sciences industry player with in-house capabilities in research, pre-clinical and clinical development, process development, commercial-scale manufacturing and marketing. •

"As a general policy, we never depend on the incentives of the government. Whenever we require government support in specific instances, we prefer to meet and seek support from all the concerned officials. This support permits a faster pace of approval, given that Reliance Life Sciences' development of molecules is bound by stringent regulations and longer procedures in comparison to smaller molecules. In the context of contract manufacturing, government support can provide a quick approval process, but it depends on the quality of documentation submitted and the scheduling of reviews, audits and reports."

- K.V. Subramanian,
CEO & President

K.V. Subramaniam

President & CEO
RELIANCE LIFE SCIENCES PVT. LTD.

"Currently, the Indian pharmaceuticals industry is disproportionately driven by small molecule generics and limited to India and Rest of World (RoW) markets. India will have a future when it graduates from this mindset and moves i) to being competitive, ii) being able to participate in developed country markets, and iii) engaging with more scientifically and technologically challenging projects, as well as novel molecules."

As a fully integrated industry player, Reliance Life Sciences was established to develop business opportunities in medical biotechnology. What have been your biggest achievements so far?

Reliance Group ventured into biotechnology under the auspices of Reliance Life Sciences in response to a conviction that biotechnology would be a major opportunity in the 21st century with a strong social sector dimension.

Reliance Life Sciences explored three opportunities of biotechnology: medical, plant and industrial. Three years back, Reliance Life Sciences decided to focus only on medical biotechnology, given its strong contribution to society in terms of (i) addressing unmet medical needs, (ii) enabling traditionally high cost bio-therapeutics at competitive prices without compromising on quality, safety and efficacy, and (iii) addressing medical product domains where India faces chronic and periodical shortages.

The Industrial Biotechnology group of Reliance Life Sciences has since been integrated with Reliance Technology Group of Reliance Industries Limited, given its relevance in biopolymer and biochemical context. The Plant Biotechnology has been integrated with Reliance Foundation as part of its rural transformation engagement.

The biggest endeavor so far has been to develop, entirely in-house, a wide range of biosimilar products, leading to the largest number of biosimilar products marketed in India as well as, probably, the largest pipeline globally. In addition, Reliance Life Sciences has been the first manufacturer of plasma proteins in South Asia. It has been consistently supplying and significantly meeting the Indian needs of plasma proteins. Reliance Life Sciences has been able to grow the market in terms of its developmental focus and consistent supplies at consistent prices.

Reliance Life Sciences sees its end game in catering to patient needs and all its integrated components, from several areas of laboratory research, pre-clinical research, clinical research, manufacturing, regulatory and quality management to marketing.

Reliance Life Sciences is a relatively new entrant in the global pharmaceutical context. It has remained focused on differentiated products used in critical care of patients in hospital settings. All other players, some of whom are competitors, have been in the larger frame of business for nearly four to five decades, whereas Reliance Life Sciences has only one decade of experience. Reliance Life Sciences is working on global engagement based on a model of partnership.

How is the government supporting the pharmaceuticals industry and what could be done to improve the market presence of the Indian companies?

The government is supporting the industry by bringing more clarity to the regulatory approval process, particularly for biosimilars, and supporting research initiatives through soft loans and grants. However, such loans and grants should be limited to specific, mission-driven areas, instead of spreading them to a number of products and compromising on the level of support. The government's role is to enable an environment for competitive industry without compromising quality, safety and efficacy, and to prevent non-tariff barriers such as ever-greening of patents, market access and regulatory barriers.

However, stepping up the level of manufacturing and investments in research and development (R&D) in India is an imperative. Unless the government promotes this, it would be very difficult to have oversight of product quality, safety and efficacy. The end result of any foreign direct investment (FDI) has to be in enabling the multiplier effect of the investment to both industry and society, and not being restricted to the benefit for a limited set of investing organizations.

What challenges and development is the industry today facing and what has been done to ensure that India is going to be one of the main players in this highly competitive market?

The most important challenge would be addressing the dearth of talent and competency development. While India has a strong pipeline of educated talent pool in biotechnology and engineering, they need to be groomed and molded to be competent professionals in several aspects of the value chain from laboratory research to marketing.

Currently, the Indian pharmaceuticals industry is disproportionately driven by small molecule generic, and limited to India and ROW markets. Unless India graduates from this mindset and moves to being competitive and, equally, being able to participate in developed country markets, and engaging with more science and technology challenging projects, as well as novel molecules, only then will the industry have a future.

As exports increase and the local market grows, where is the best potential for growth in the Indian pharmaceuticals industry?

The best potential of growth lies within the industry, in terms of not being a highly fragmented industry, being more quality-focused and developing competent resources. This essentially means that there has to be a transformation both structure and content. •

Dr. M. Ratna Sudha & M. Jawahar Babu

RS: Managing Director
JB: Director
UNIQUE BIOTECH

Can you elaborate on the range of products that Unique Biotech is manufacturing and to what markets are you supplying?

Unique Biotech (UB) is one of the leading manufacturers of probiotics, enzymes and nutraceuticals in India. Indiscriminate use of antibiotics leading to emergence of multidrug resistant bacteria has led to an increase in gastrointestinal and metabolic disorders. This is where probiotics can step in, as they replenish the gut flora and help in the prevention of diseases. UB has been manufacturing naturally beneficial probiotic strains from 2001 onwards and provides premium probiotic solutions in different health categories like Immunity, Inflammation, Women's Health and Digestive health including diarrhea and irritable bowel syndrome. UB manufactures and markets bulk probiotic strains (APIs), customized pre/probiotic blends and finished products in different dosage forms via capsules, sachets, tablets and enteric-coated pellets. UB has been marketing its products to more than thirty countries including the United States, Europe, Japan and South Africa besides its strong presence in India.

Unique Biotech is specialized into probiotics, but legislations are different across the world. In India, probiotics are considered as drugs, and UB manufactures and markets high quality and stable probiotics under the drug category with its state of art WHO GMP-approved manufacturing facility. Currently, different regulatory bodies across the globe consider probiotics under several categories, such as biologics, drugs, foods, nutritional supplements, and are regulated by different guidelines depending upon their regulatory category. An effective regulatory framework in operation and harmonization of guidelines is required to maintain high quality, safety, stability, and efficacy of probiotic formulations during the entire processing, production and storage chain. As no proper standardization parameters are present for probiotics, lack of standardization is becoming a major challenge. Probiotic products that claim specific nutritional, functional or therapeutic characteristics are on the boundaries of being food, dietary supplements or medicine, so they pose challenges for regulators. Considering the rapid growth in probiotics worldwide, there is an urgent need of globally accepted, uniform regulatory guidelines.

Unique Biotech specializes in quite a broad product range. How challenging was it to represent yourself in different markets?

UB manufactures many probiotic strains, formulations, and blends, each with their own distinct properties and applications. It has been a challenge to represent these in different markets but a very rewarding task nonetheless. In India, it has been especially challenging, as there is still low consumer awareness on the benefits of probiotics. There is lack of proper labeling. The effects of probiotics are strain-specific. Lack of proper distribution and cold chain facilities are other challenges. Unique Biotech has been meeting these challenges through its well-documented and clinically proven strains. UB labels its products according to regulatory guidelines and provides technical information so that the consumer can make informed choices. Cold chain facilities problems have been circumvented in many cases through the introduction of spore forming bacteria like the Bacillus species, which are stable at room temperature.

As probiotics do not come under drugs in many other countries, health claims are not allowed. The European Food Safety Authority (EFSA) has disallowed hundreds of submitted probiotic health claims. Exporting probiotics as food supplements has not posed an issue, as probiotics are registered as food supplements and come under the GRAS (Generally Regarded as Safe) category. UB has been demonstrating efficacy and educating doctors and other personnel in the medical field about the importance of probiotics. The probiotic needs of different population groups are also being explored in order to meet the various challenges posed in the market.

How important is the role of research and development (R&D) at Unique Biotech?

Unique Biotech's Department of Scientific and Industrial Research (DSIR)-recognized R&D plays a very important and vital role in its success. Its dedicated R&D department is continuously researching and developing new and innovative products in different health segments. UB focuses on developing innovative probiotic solutions through fermentation technology leading to improvements in yields and robustness. The R&D team ensures purity, viability and potency throughout the entire process from isolation, fermentation and final delivery of the product. Unique Biotech's R&D started with the isolation of a single probiotic strain in 2001. It has come a long way and can now boast of its repository of twenty eight different, well characterized probiotic strains, customized blends, and disease specific probiotic formulations for diarrhea, irritable bowel syndrome, cholesterol reduction, bacterial vaginosis, and immune health. Roughly 5% to 6% of Unique Biotech's revenue is reinvested in R&D.

Where does Biotech source its machinery and what role does it play in the company?

Most of the equipment, we would say with pride, is indigenous. With its in-house process engineering knowledge, UB has built state of the art, R&D driven large scale fermentation facility and is well positioned to handle the growing market needs.

What role does India play in the global pharmaceutical industry?

India plays a major role, as high R&D costs, fewer new drugs, and increasing pressure for reduced health care costs have prompted global companies to partner with Indian companies. Areas of partnership include manufacturing, R&D and clinical trials. India has considerable manufacturing expertise, an English-speaking workforce, and technically qualified personnel, which provide a source of research talent. India competes global in biotech in some key areas, but is a potential partner in others. Partnering with Indian companies cuts costs and reduces time to market. Clinical trials can also be conducted more cost effectively. The government has made healthcare one of its top priorities and has launched new policies and programs to boost access and affordability to quality healthcare. The challenges for the industry is meeting global standards and complying with global regulatory requirements.

Does Unique Biotech have plans to be more environmentally friendly in how it conducts business?

Unique Biotech uses a solar thermal water heating system as part of its program to be environmental friendly. In the next couple of months, UB plans to set up a solar power plant for captive consumption.

What is the future for Unique Biotech over the next five years?

UB sees itself as a major global player in probiotic and other nutraceutical segments including enzymes. It has been exporting bulk probiotic strains, serratiopeptidase and ready to fill customized blends. UB has just launched its own brands of finished products (well documented and researched) in different health categories like diarrhea, immunity, inflammation, bacterial vaginosis and irritable bowel syndrome. These products are in the process of registration in many countries. More products are in the anvil, as R&D is focusing on offering probiotic solutions for other diseases. Unique Biotech also intends to foray into other nutraceuticals besides probiotics and enzymes. •

A Drying Pipeline?

R&D in India Pharma

For many years now, India has had a reputation as a generics player with very little expenditure on research and development (R&D). Throughout the thirty-five year history of the Patents Act of 1970, the idea of R&D in Indian pharmaceutical circles meant trying to replicate a known patented drug through a unique process that would allow the domestic companies to avoid any infringement issues.

Today, levels of spending on R&D for a market as big as India's still fall short of its international peers. In 2012, Dr. Reddy's spent the largest amount on R&D, totaling approximately $130 million, up from $82 million in 2010. Lupin was a close second with $124 million in R&D, up from $87 million two years previously. In total, R&D expenditure in 2012 from seven of the top companies; Dr. Reddy's, Lupin, Ranbaxy, Cipla, Wockhart, Piramal Healthcare and Orchid Chemicals, stood at $533 million, which represented about 2% of these companies' annual revenues.

The real issue, however, is not how much money that these companies invested, but rather how much is invested into the area of new drug discoveries, as the development of new processes to administer existing drugs is not seen as being particularly beneficial to the sector. Furthermore, there have been issues recently with some R&D facilities closing down, such as is the case with Piramal Healthcare, whose CEO, Mr. Vivek Sharma, explained the situation: "We still continue to invest in R&D but it is true to say that we have shifted our focus to our existing pharmaceutical products and doing R&D related work for our customers rather than investing in our own pipeline of NCEs. 90% of our revenues come from the United States."

Nonetheless, there is a lot of room for optimism with one of the fastest growing segments of the Indian pharmaceutical market being Contract Research and Manufacturing Services (CRAMS), which is estimated by the Indian Brand Equity Foundation (IBEF) to hit $8 billion in 2015, up from $4 million in 2012. Suven Life Sciences were a pioneer in this new area of research and their CEO and Chairman, Mr. Venkat Jasti spoke of the success they have had with it: "In 1995, we have innovated a new business model by coining the term CRAMS and worked alongside innovators in the supply chain during the clinical phase of their New Chemical Entity (NCE) drug development by supplying intermediates. We are the only company that has adhered to CRAMS focusing on the NCE supply chain since the company's inception. There are more than 700 projects that we have worked on for NCEs. We were successful with three of the innovator molecules, which will give us continual business over the life of the patent period of those molecules."

Furthermore, there are an increasing number of large pharmaceutical companies that are collaborating with domestic companies for R&D in order to reduce their overall costs. Such examples include the alliances between Biocon & Mylan and Sun Pharma & Merck. If such collaborations with domestic Indian companies become a staple for some of the large global pharmaceutical companies it could dramatically change the direction that R&D is taking in India. The government is promoting this area with an ambitious plan called "Pharma Vision 2020," which plans to make India one of the premiere locations for end-

R&D SPENDING BY TOP SIX PHARMA GIANTS

Source: Deloitte, PWC, Aranca Research

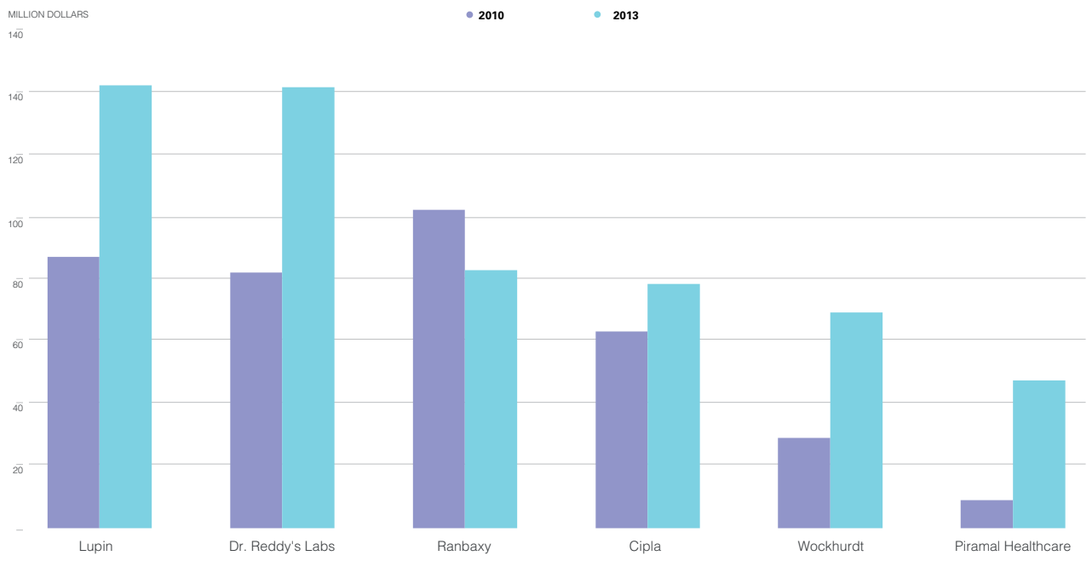


Image: Biocon

to-end drug discovery and innovation. Apart from providing world-class infrastructure and scientific competences, the government will offer up to 50% public funding through a public-private partnership in order to fully exploit India's innovation capabilities. Further incentives will include providing a weighted tax reduction of up 150% for R&D expenditure.

However, despite the tax incentives, the government still has more work to do in terms of its communication with the industry, according to Mr. Shekhar Khanolkar, Managing Director of Navin Fluorine International Limited: "The government has been giving tax incentives for R&D…and has allocated money for development activities for research, but getting the money to reach the right industries is challenging. Communication between industry and government needs to improve….India is very competent in terms of knowledge and expertise…There is, however, still a gap between what the industry expects from science students and what they actually study."

Looking forward, India considerable work so that its new drug discoveries gain a commensurate level of international recognition as the industry. While the government has put some strong incentives forward, it needs to work harder to remove the obstacles that will prevent funding from reaching the right projects and be more communicative with the industry. With the right system in place, there should be optimism that companies will see the benefits of research, hopefully before the pipeline dries up. •

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The facilities in India are on par with every other country in the regulated world. Our hardware being the same, the people are the core reason why multinationals are flocking to India. There is trust. People believe the value of our word: whether it is our factory or processes and there is strong regulatory compliance in India.

India received a major boost when it was recognized for its process for patents. With this recognition, the segment has been able to invest substantial resources in basic research, which drove growth and made India among the top finished dosage manufacturing countries in the world. In the past, R&D was centered on reverse engineering of existing drugs, and this still continues to drive the Indian domestic Industry, but now more pharmaceuticals companies are developing their capacities or investing in the following areas.

Anil Jain, Director,
S.A. Pharmachem Pvt. Ltd

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Dr. Ashok Alate

CMD
FERRING THERAPEUTICS PVT. LTD.

Ferring is a unique company. Could you please explain what it does?

Ferring is in a very niche area of therapeutic treatment that is used to treat a large range of conditions such as female healthcare, fertility, oncology, urology, and gastroenterology. At Ferring, we say that we treat the body on its own terms, which we do through the use of peptide hormones, an area in which we have been a global pioneer and leader. While other drugs can be effective, they can create side effects, but natural peptide hormones or their derivatives do not have these side effects. Furthermore, we have a unique delivery system whereby the treatment can be injected and slowly released into the body over an extended period of time.

Could you please explain your background and activities in India and internationally?

We established a liaison office in India in 1996, which was converted into a legal entity known as Ferring Pharmaceuticals Ltd. in 1997. Initially this company was only used to market imported Ferring brands. However, since these early days, we steadily increased our locally produced product basket. In 2007, we decided to harness the scientific and technical strengths of India and opened up an research and development (R&D) center in Thane, just outside Mumbai. At this specialized facility, we have about forty scientists, ten of which are Ph.D.-accredited. Further afield, we have several major research facilities in Denmark, Israel, China, Scotland and the United States and a new development center in New Jersey. Apart from our main headquarters in Switzerland, we also have additional manufacturing facilities in locations such as Germany, Sweden, Denmark, Scotland, Czech Republic, Israel, China and South America.

Can you please describe the role of Ferring India?

Ferring has a marketing presence in a total of 72 countries. While many of these markets have similarities, the Indian market is somewhat distinguished because of its size and annual growth rate of 10% to 12%. It is forecasted that India will enter the top ten in terms of its global presence by 2015. Since our first year, we have had double-digit growth and are also always adding new products to our basket and new people to our team.

For many years many people in the pharmaceutical industry had a biased vision against the use of peptides as a form of treatment. What is your competition today?

When it comes to high quality peptide treatments for humans, Ferring is somewhat unique as we are one of the oldest and biggest players in the industry. We are also the most innovative, as we were the first company to develop peptide drugs that could be consumed orally as a tablet, which has been very successful in our pediatric area of treatments.

It is estimated that Ferring will have annual revenue of $3 billion by 2020, with 35% of it coming from the United States. What role will India play in this expansion?

Ferring India is planning to grow in three areas. Firstly, we plan to increase our sales and marketing to maintain our consistent, double-digit growth. Recently a dynamic management team has been recruited to achieve this goal. Secondly, we are looking at increasing our development activities on New Drug Delivery Systems (NDDS) at our center in Thane. Finally, we are looking at manufacturing. Based on the trials that we conduct here in India for future products we are looking at getting approval from the U.S. FDA and manufacturing novel products.

There are a variety of peptide-based products on the market. Can you talk about one of your products and how it compares to conventional treatment?

Two of our most successful products worldwide are for treatments for prostate cancer called Firmagon® and Menopur® for in-vitro fertility procedures. Most patients who suffer from prostate cancer will choose either surgery or agonists with lifelong therapy. The latter being more prevalent in developed countries. The problem with agonists is that they are known to have side effects. At Ferring we came up with a solution to this problem that blocks the receptors on the prostate gland itself. It is currently available as a one-month depot injectable but will soon be available as a three-month depot injectable.

Ferring states that it is driven by science and not by profit and uniquely it is still a privately owned company. Do you believe this gives you a competitive edge?

Yes. Dr. Frederik Paulsen Sr., whose primary area of interest was peptide research established Ferring in Sweden in 1951. Ferring has always believed in power of research and is passionate about science. We work with the body's own endocrine system to restore our patients' balance and good health. We have used our knowledge to drive into other therapy areas and other, non-peptide, treatments. Our philosophy dictates providing a high quality product and the best information to our customers. We are privately owned. The son of Dr. Paulsen Sr., Frederik Paulsen is the chairman and has kept Ferring's focus firmly on research into therapeutic solutions to satisfy patient's needs, and the needs of their treating physicians. •

Lambda Therapeutic Research Ltd.

Lambda Therapeutic Research Limited is India's leading global Clinical Research Organization (CRO) with facilities and operations in Mumbai (India), Toronto (Canada), Warsaw (Poland), London (UK) and the United States.

Over the last decade, Lambda has been one of the preferred partners for leading pharmaceutical corporations across the world. It has till date worked with 200+ domestic and international sponsors, delivering Clinical Research Services to biopharmaceutical, generic and OTC companies. Lambda's services spread across the spectrum of clinical development are:

1. Phase I studies – DDI / FDI / SAD / MAD studies
2. Bioavailability / Bioequivalence Studies
3. Bioanalytical + Pathology lab Services
4. Late Phase Studies
5. Biostatistics & Data management
6. Medical Imaging
7. Pharmacovigilance

The company is powered by futuristic technologies, world-class infrastructure and a team of approximately 800 professionals working round the clock, around the world. Lambda has conducted more than 5,000 BA/BE Studies and has major experience with 20+ TC's viz. CVS, CNS, GI, Musculo-skeletal, Endocrinology, Dermatology and other segments, with more than 750 validated research methods across different matrices. Lambda has been the pioneer in adopting 21 CFR-compliant U.S. FDA electronic data capture platforms across various phases of clinical trials, seamlessly bridging globally scattered sites and labs.

Lambda has been audited by some of the world's top regulatory agencies, with no critical observations been made in any of their reports. Lambda has successfully imbibed software technology as an infrastructural necessity and raised its prominence in the field of clinical research v/s competition.

People are the backbone of Lambda's success. Its inspirational managing director, Bindi Chudgar believes that an engaging and empowering work culture is 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. Lambda strives to inculcate strong beliefs, and capabilities that help challenge conventional things and expedite trials for its clients.

Lambda has harnessed its strengths of ultramodern infrastructure, cutting edge software technology and human capital of more than 500 scientists across the clinical development hierarchy to carve a niche for itself and become the undisputable leader in the Indian CRO space. The early phase deliverables from Lambda are path breaking while the late phase deliverables are in the space of NDDS & biosimilars. On both fronts, Lambda is a step above the rest. •

> "We are proud to be a global CRO and one of the preferred clinical research partners for leading pharmaceutical companies across the world. The crux of our success as a CRO has been our resolute aim to continually augment our infrastructure, technologies as well as workforce potential."
>
> - Bindi Chudgar, Managing Director, Lambda Therapeutic Research Ltd.

Into the Future:
Final Thoughts and Company Index

"There are lots of medium-sized Indian pharmaceuticals companies that want to expand and are interested in pursuing opportunities in the United States as well as in India and other smaller countries. Formulations play a larger role than APIs, and the main driver of growth is inexpensive labor. The cost to manufacture in India is approximately three to five times lower than in the United States or Europe. The talent pool is another important factor. Our Prime Minister's focus is on the under-35 age population and its capacity to become a global workforce."

- Dr. Prasad Panzade,
Vice President/Head, Corporate Analytical Services (R&D and Quality),
Aditya Birla Science & Technology Co. Ltd.

Image: Cipla

Global Business Reports

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If you look at India’s export figures more than 50% are going towards the regulated markets. Pharmexcil tries to help the small and medium companies to expand their markets and look for new opportunities. Obviously there is a global demand for generics, and we want as many Indian companies as possible to participate in that market, but generics are not the only drivers for growth. The government and Pharmexcil are also looking to promote Ayurveda products alongside food supplements. We foresee interesting potential in these areas.

- Raghuveer Kini, Executive Director,
Pharmexcil

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European and American countries are now looking at India in a way that they did not previously in terms of pharmaceuticals. If we want to serve them, we have to invest in R&D now, which will also help sow the seeds for a growing industry in the future.

- Nilay Shah, Manager, Business Development, and Piyush Shah, Director,
Aurochem

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Drug delivery systems can play an important role in growth, and Galpha focuses on changing the technology in drug delivery systems. It has gone into pellets technology, where the drug delivery is considerably faster than powder technology. Galpha is now developing most of its products in pellet form. It is also working on paper technology and sustained release technology, and has been present most in the anti-infectant and general physician ranges, where the drug delivery system is very important.

- JPN Singh, Director,
Galpha Laboratories

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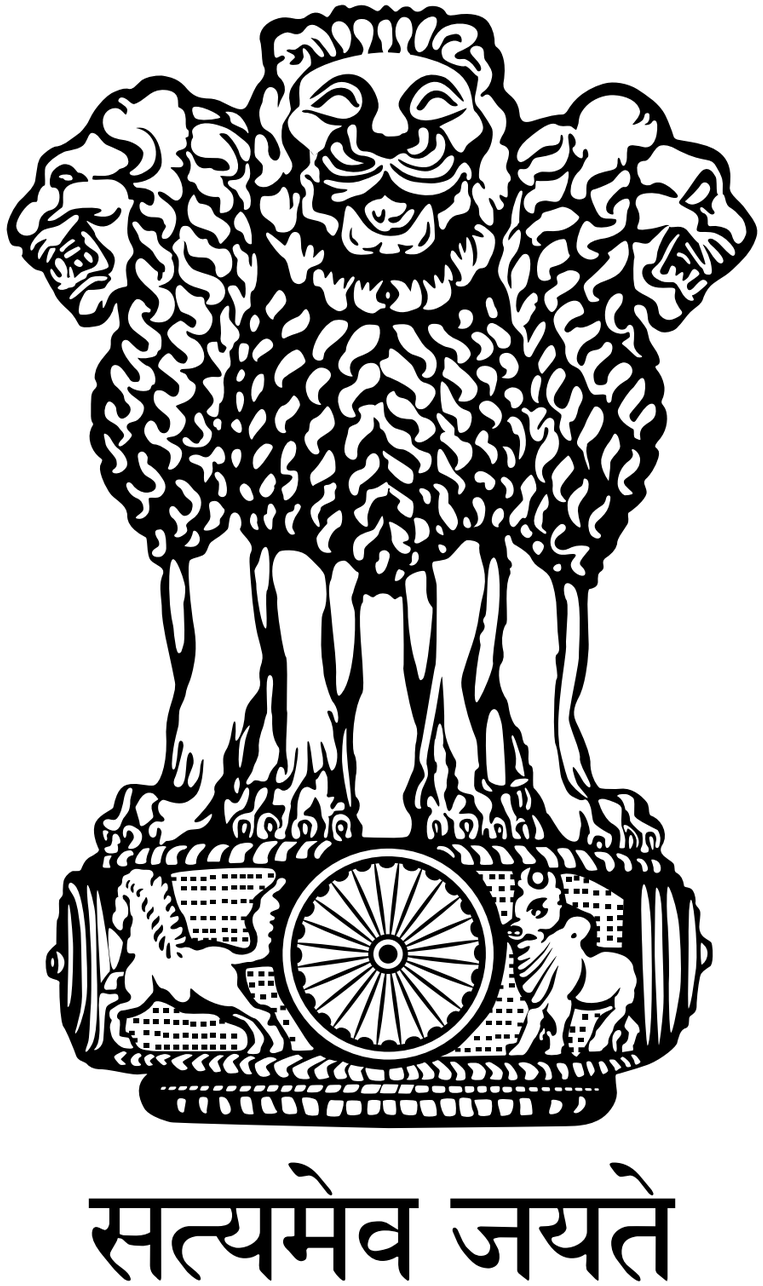
Biotechnologies are the future, and we are looking at a specific support for this. We do have available products and will have more in coming years. Hopefully India will be a leader in this specific market within 5 years. As far as vaccines are concerned, we are already a preferred partner.

- Ashutosh Gupta, Chairman,
Pharmexcil



Ideally, consultants would audit a facility and identify compliance issues before the FDA-regulator arrives. As consultant, we help companies prepare for a successful FDA audit. At times we have been contacted following an FDA audit to help correct issues identified by the regulator. However, generally we identify problems and provide suggestions, but it is up to the company to make the corrections.

- Jose Hernandez, Consultant,
5 W’s Consulting

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Our Hepatitis B vaccine has been very successful. As I mentioned earlier, the most important principal of modern biotech with regards to vaccines is that you come up with a unique process that will not cause any patent infringement issues. Our unique process for this particular vaccine was to use ultra-cell diffusers for the purposes of purifications rather than cesium chloride, which was being used by all the other manufacturers. This unique process gives us a yield that was five times higher than that of our competitors. So far we have managed to distribute 600 million doses to over 90 countries.

- Krishna Ella, Founder,
Bharat Biotech International Ltd and Ella Foundation

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Within a very short span, the company has started our R&D business and we have come up with a couple of new products which include our excipient portfolio. Apart from that, the company is also looking for API manufacturing.

- Manoj Patel, CEO,
Accent Microcell Private Ltd.

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There are certain areas in India, which are tax benefit areas. Alembic has been one of the first companies to play this strategy of manufacturing in tax free zones. It makes sense for a company to operate in such an area if they have big domestic operations.

- Ish K. Bansal, Vice President, International Business (API),
Alembic Pharmaceuticals Ltd.

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Industry Explorations

Europe is our most successful market, followed by the United States. We have been doing business in Japan for ten years and established an office six years ago.

- D.R. Rao, Chairman and Managing Director, Neuland

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BEC Chemicals is not a marketing driven company; instead, it is a research and customer driven company that primarily focuses on process development research. With this in our mind we are focusing on understanding prospective customer requirements and are working on meeting those requirements.

- Manish Kothari, CEO, BEC Chemicals

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Finance is very easily available, as the banks in India are always ready to support companies. Micro Orgo Chem also has funds readily available in terms of family finance.

- Vinod O. Ranka, Managing Director, Micro Orgo Chem

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In a majority of cases large companies such as Ranbaxxy and Dr. Reddy's will outsource their development of new formulations to us. A number of companies that work in the deodorant market also outsource their formulations to us.

- Sangithaa Gupta, Managing Director, MidasCare Pharmaceuticals Pvt. Ltd.

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Our main products are linked to life style's diseases like anti-hypertensives, anti-ulceratives, cardiovasculars or anti-depressants. These markets are growing for us; our own growth is around 15% to 20% annually.

- S. Murali Krishna, Managing Director, Smilax Laboratories Ltd.

We are open to companies coming to India for manufacturing. Some time back, Rusan was in discussion with Pfizer and they were interested in some of our products for the European market.

- Ajay Saxena, Director, Bulk Drug Operation, Rusan Pharma Ltd.

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We want to enter the markets on the basis of our strengths in quality and technology of the machines that we produce. What differentiates us is that we honor the needs and requirements of the market and our customers.

- Mahesh Mevada, Director, Brothers Pharmamach Pvt. Ltd.

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The Indian chemical industry ranks third in Asia in volume and its global rank is around 12. India's share in the global chemical business is around 3%, while the country represents 17% of the world population. In terms of these figures, this share can be considered as low. It should be higher indeed, and the government is attentive to this situation.

- Rajeev Pandia, Director, Business Development, Asia, Chemical Search

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As a supplier of the industry we are benefiting this growth, our customer base is constantly expending. We are happy to serve companies with big plans. Another good thing for us is that middle-sized companies that are numerous in India constitute most of our market.

- N. Lenin Babu, Managing Director, Omega Scientific Instruments Pvt. Ltd.

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Most of our competition comes from Western countries. Here in India and Asia in general, this is very much an untouched market. Most of the companies that operate in the pharmaceutical market here in India are focused on producing APIs, intermediates and formulations. As a result we have very limited competition in this field in India.

- Vijay Kumar Ambati, President and CEO, and Biren Parekh, Strategy Director, Clearsynth

This list contains those companies interviewed during the course of research for this publication and as such represents only a limited selection of the companies operating in the pharmaceutical industry of India. It should not be considered a comprehensive guide. GBR holds an exclusive and extensive pharmaceutical database for India and the wider region. For further information on database access packages, please contact info@gbreports.com or call +44 20 7812 4511.

EDITORIAL AND MANAGEMENT TEAM

Project Director: Alice Pascoletti (apascoletti@gbreports.com)
Journalists: Karl Reilly (kreilly@gbreports.com)
Project Coordinator: Neha Premjee (npremjee@gbreports.com)

General Manager: Agostina Da Cunha (agostina@gbreports.com)
Executive Editor: John V. Bowlus (jbowlus@gbreports.com)
Graphic Designer: Gonzalo Da Cunha (gdc@d-signa.com)

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Additional copies of this book can be ordered through Elif Ozturk (elif@gbreports.com).

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