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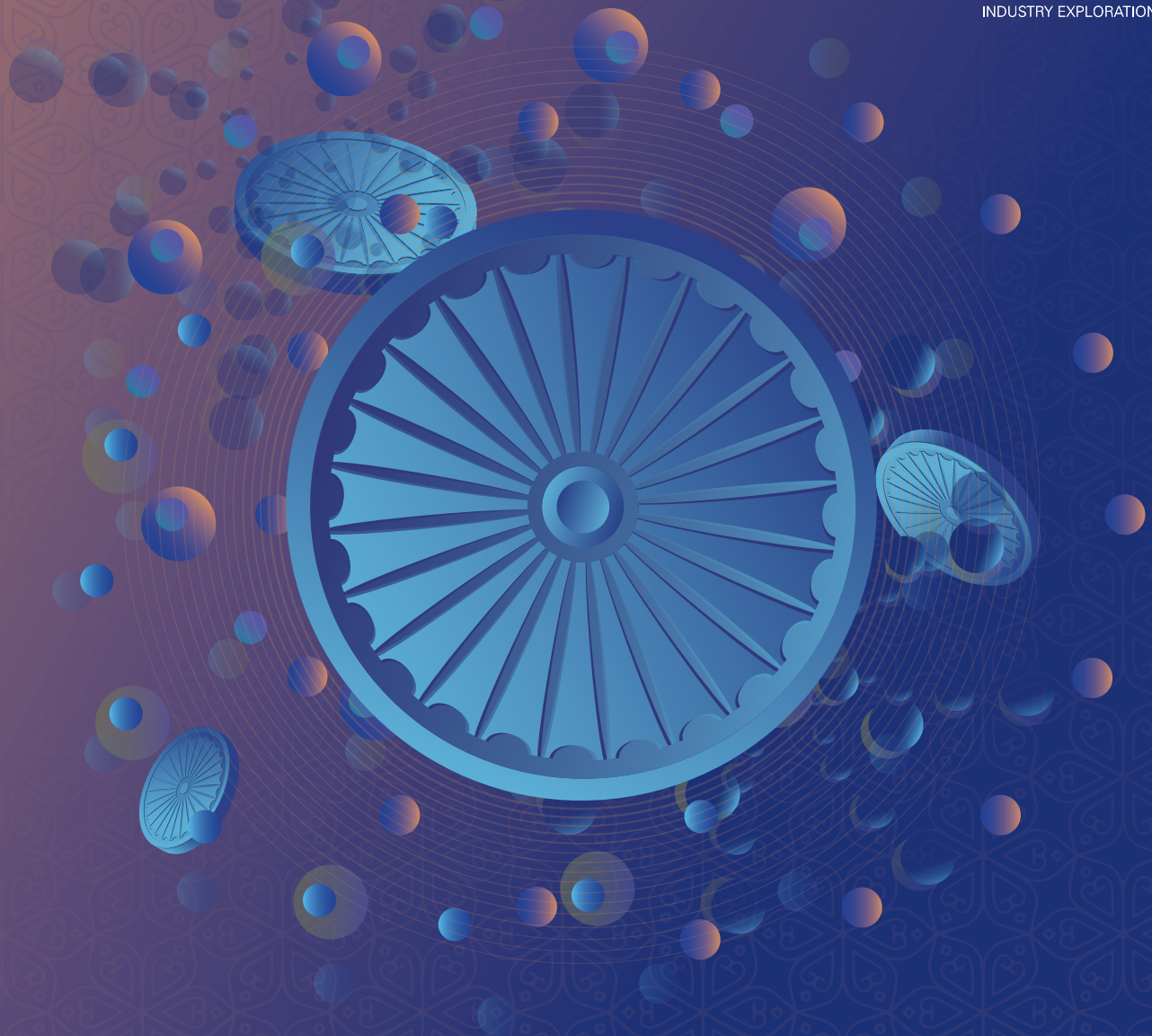

INDIA PHARMACEUTICALS 2019

Regulations and Markets - Geographic Clusters - Generics and Formulations - APIs, Excipients and Intermediates
Services and Equipment - Innovation and Specialization

Dear Reader,

Following the successful launch of the 2015 and 2017 reports, welcome to India Pharmaceuticals 2019, the third edition of a joint CPhI-GBR analysis to be launched at this year's CPhI Worldwide in November. This year, we visited Mumbai, Gujarat and Hyderabad where we spoke with industry leaders and representatives from across the value chain to understand their views concerning the state of India's vast pharmaceutical industry and how it has evolved in recent years.

With 2020 shortly upon us, India's pharmaceutical industry will be eagerly anticipating how many of India's Pharma Vision 2020 targets, whereby the Government committed to making India one of the world's leading destinations for end-to-end drug discovery and innovation by 2020, have been fulfilled. On the positive side, after many years of consistent growth, the pharmaceuticals industry will come within sight of the US$50 billion turnover target that the Vision set out. India has consolidated its position as the Pharmacy of the World, both by servicing its own huge domestic market as well as leading the world in the export of generic medicines all across the globe. The industry's champions continue to expand their reach and signify their ambition by various major acquisitions in Europe and the United States, amongst others, which have recently taken place.

On the other hand, the goal of becoming a leading destination for end-to-end drug discovery remains elusive and the country has yet to develop a significant roadmap to deliver a long-lasting novel drug development and delivery infrastructure. With significant advantages that include a vast domestic market, extensive pharmaceutical manufacturing experience, ample talent and knowledge developed across both industry and academia, the goal must eventually be achieved, but today India can not offer the scale and sophistication of the investments and developments that characterize the biotech hubs of the East and West coast in the United States and such as those emerging in Hong Kong and China.

With cost pressures increasing across the generics space due both to increased regulation and competition, India's pharmaceutical companies are exploring opportunity in specialty drugs, and companies that are willing to set up contract research or manufacturing for specialties can benefit. But they must be more ambitions and develop a taste for the large investments and lengthy development that creating novel drugs involves for India to fulfill its goal.

Thank you to the executives across the value chain that took the time to share their insights with us about the trajectory of India's pharmaceutical industry. On behalf of CPhI and GBR, we hope you enjoy the read, and we look forward to continuing to provide intelligence on this dynamic market for years to come.

Orhan Caglayan
Brand Director Pharma,
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INDIA PHARMACEUTICALS 2019
Industry Explorations
Global Business Reports

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Editorial Analysis

GBR journalists provide unique and first hand analysis and insights into all aspects of the India pharma industry after months on the ground

6, 16, 26, 44, 56...

Exclusive Interviews

Leading industry figures from pharma hubs across the country share their insights and their pipelines with GBR

11, 12, 14, 21, 23...

Data, Maps and Infographics

Maps, charts and graphs illustrate industry trends

8, 10, 19, 20, 53...

Industry Thoughts

The ideas shared with GBR during our encounters with the leading players in India pharma industry

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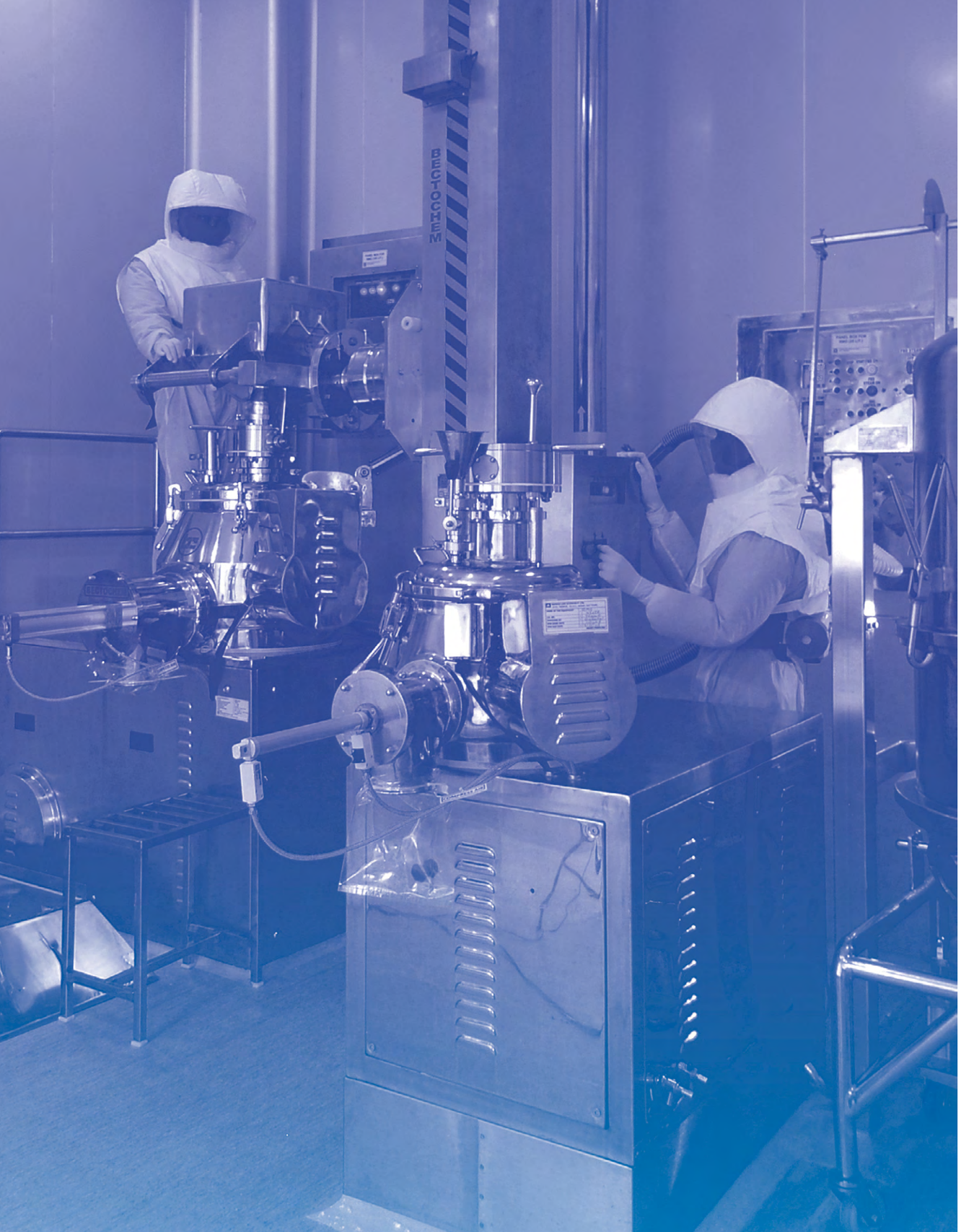


Introduction to India Pharmaceuticals

"India is burdened by high price controls, which means that the government shuns the maximum retail price without realizing the core value of the product. This system encourages counterfeits and the exploitation of loopholes. At the same time, 43% of India lives below the poverty line, which translates into little awareness and limited purchasing power. We need a holistic solution to share the value of the drugs between the consumer, manufacturer and retail stakeholders."

- Fredun Nariman Medhora,
Managing Director,
Fredun Pharmaceuticals

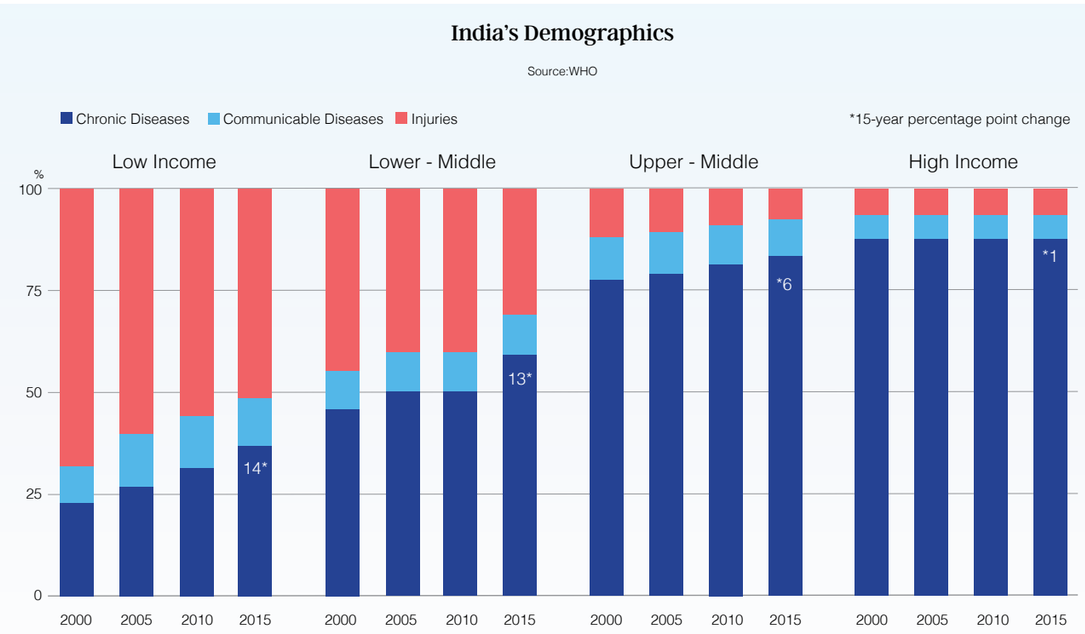
Image courtesy of Naprod Life Sciences

Introduction to India Pharmaceuticals

The 2020s: India's decade?

The 2010s have come to an end, fraught with global instability and uncertainty. Given the pace at which the world is changing, it would be futile to predict too far ahead into the next decade. There are, however, a few things that we can be certain about. India's population will surpass China's, most likely in 2022, as the largest globally and Narendra Modi will lead India into a new decade.

The often-divisive Prime Minister of India saw his Bharatiya Janata Party increase its majority in the Lok Sabha following the largest democratic exercise ever taken in the 2019 general election. While many will have strong views towards the Gujarati, a number of his visionary policies have shown demonstrable success in recent years. For example, the 'Make in India' initiative, set out by Modi in 2014 with government investment promises of US$240 billion, has drastically improved the rates of foreign direct investment in India. The country's 'Ease of Doing Business' Ranking in the World Bank's Doing Business Report 2019 has jumped to 77th, up from 100th in 2018 and 134th when the initiative began in 2014, and The World Economic Forum's 2018 Global Competitiveness Index has seen India place at 58th. Though the past decade will be written in the history books as one where India demonstrated clear economic progress, it is difficult to predict what fortunes the next will bring.



Pharma Vision 2020: From Imitation to Innovation?

With 2020 upon us, those in the pharmaceutical industry, both in India and globally, will be eagerly anticipating how many of India's Pharma Vision 2020 targets have been fulfilled. Although the government plan was laid out before Modi's tenure begun, his government's policies over the past six years have very much defined its successes and failures. Pharma Vision 2020 was a government commitment to make India into a global leader not only in the production of low-cost generic medicines but also end-to-end drug discovery and development. It also aimed to place India as one of the top five pharmaceutical innovation hubs, which would involve launching one out of every five to ten novel drugs, globally. This would help the pharma industry have a seismic impact on the country's growth, by adding significant value to the economy. Another aim was to meet the increasing demands brought

Image courtesy of Sai Life Sciences

on by a growing middle-class population and a faster-than-expected aging population that will continue adding pressures to India's healthcare system. To enable this, the government promised a multi-billion-dollar investment plan with a 50% public funding commitment through a public-private partnership model.

A quick observation of the numbers points to success. The pharma industry has seen continued growth throughout the decade, with turnover at US$37.2 billion, exports contributing US$19.14 billion – both in 2019 – and the domestic market in 2018 standing at US$18.12 billion. "At this rate, the Indian pharmaceutical industry is likely to touch the US$50 billion mark by the end of 2020, in line with the expectations of a compound annual growth rate (CAGR) of 22%," underlined Dr. Rao Vadlamudi, immediate past president of the Indian Pharmaceuticals Association and president of the Commonwealth Pharmacists Association.

Whilst there has been clear growth within the Indian pharma industry, this is almost exclusively rooted in the generics space. "[India] is the single largest provider of generic drugs globally, supplying over 50% of global demand for various vaccines, 40% of generic demand in the United States, 25% of all medicine in United Kingdom and extremely low-cost medicine to African nations," highlighted Daara B. Patel, secretary general of the Indian Drug Manufacturers Association.

The production of generic drugs remains India's bread and butter. However, the country has yet to develop a significant roadmap to deliver a long-lasting novel drug development and delivery infrastructure.

R&D, high-caliber academic institutions and capital funding are integral pillars towards the creation of novel drugs, given the high costs associated with their creation. In fact, a Tufts Center for the Study of Drug Development 2016 assessment put the cost of developing and having a drug approved at US$2.87 billion. The sheer capital and risk required to produce novel drugs makes it a completely different ball game to the manufacturing of generics. While there is some private capital in India's pharma space, it is not being directed into the production of innovative drug development. "The category of businesses typically in the fund's focus are SMEs who need funds to expand, to build larger factories, to develop and register generic products, to acquire different businesses or to launch products in different markets," remarked Hari Buggana, chairman of InvAscent, a company that provides private equity growth capital through three funds totaling over US$500 million in India.

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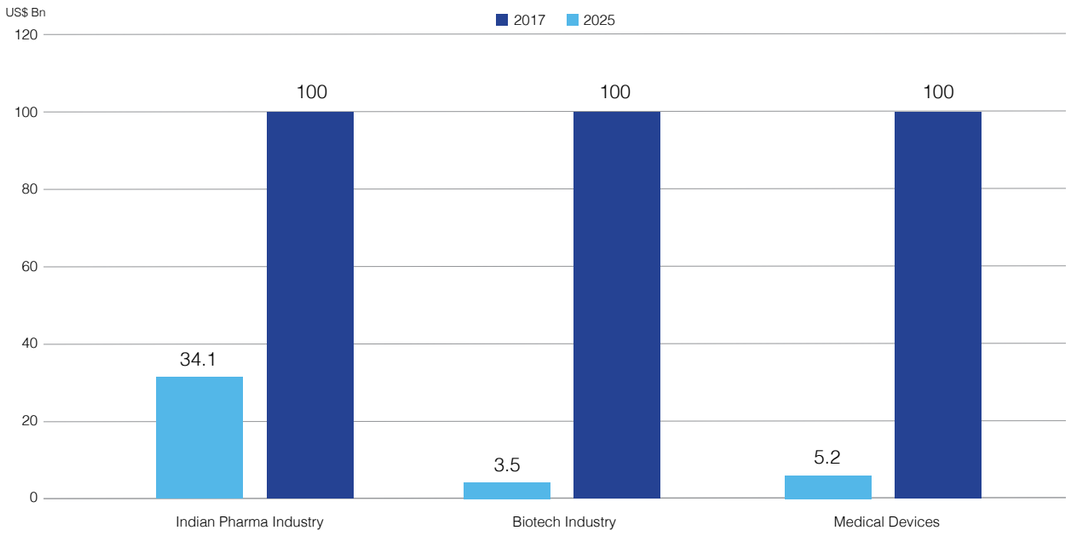
> The category of businesses typically in the fund's focus are SMEs who need funds to expand, to build larger factories, to develop and register generic products, to acquire different businesses or to launch products in different markets.
>
> - Hari Buggana, Chairman, InvAscent

Estimated Growth Projected in India by 2025

Source: IBEF, Make in India



Daara B. Patel

Secretary General,
IDMA

> The Indian Drug Manufacturing Association was formed in 1961 and consists of 1000 wholly-owned Indian large, medium and small companies in nine states. Besides organizing organizes seminars, training programmes and workshops, IDMA also works very closely with the Indian Pharmacopoeia Commission in compiling and bringing out the Indian Pharmacopoeia.

Could you highlight some of the activities of the IDMA?

IDMA contributes by guiding the industry in improving quality and efficacy through our annual Pharmaceutical Analyst Conventions, which have been held since 1997. Almost all leading regulatory agencies have attended the Convention in the past and assisted in resolving quality and regulatory related issues. IDMA also works towards the harmonization of various Pharmacopoeias. We also play an active role in policy discussions.

Since Narendra Modi came into power, there have been several changes to the nation's governance. How has this impacted the pharmaceuticals industry?

The Government of India has supported the pharmaceutical sector and has been working towards resolving long-standing issues. Industry specific schemes such as Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) have been initiated, but the best thing that has happened under the present government is implementation of the GST under a one nation, one tax, one market model. It has ensured that the burden of multiple taxes plaguing the pharmaceutical sector has been removed, and the introduction of Input Tax Credit under GST has largely worked towards eliminating the anomaly of inverted duty structure while also playing a significant role in supply chain management. Another landmark initiative of Shri Modi is the Ayushman Bharat Yojana, which is becoming the world's largest free healthcare scheme for providing free treatment up to Rs 5 lacs per year to approximately 500 million poor people in the country.

What are the repercussions of increased USFDA stringency and regulatory changes?

Wherever deficiencies have been identified following USFDA inspections, the Indian pharmaceutical industry has invariably carried out remedial measures to the satisfaction of the USFDA. According to USFDA data, 2018 witnessed only 4% inspections classified as Official Action Indicated (OAI) in contrast to 15% in 2017, reflecting improvement by Indian pharmaceutical companies in USFDA inspection outcomes. Moreover, these issues are not just limited to Indian pharmaceutical companies. Such aberrations are observed all across the world.

The frequent changes in regulatory guidelines create chaos in pharmaceutical development and manufacturing. While bad laboratory practices are usually at the root of the suspect data that inspectors are finding all over the world, in India, there have also been a couple of high-profile cases related to documentation that are bringing the manufacturing sector under particular scrutiny.

India is renowned as the largest producer of generic drugs; however the focus has been shifting towards increased R&D. How do you perceive these dynamics today?

Rising competition in the pure generics segment has led many of the top Indian pharmaceutical companies to focus increasingly on specialty and complex generics through higher R&D spending. Many companies are investing in complex injectables, complex oral solids, new drug delivery systems, new chemical entities and biosimilars, as well as looking to increase their presence globally in the therapeutic areas of oncology, dermatology, ophthalmology and respiratory, among others.

The Government of India is also supporting industry with tax incentives for R&D. The PTUAS is being implemented to encourage more SMEs to get WHO GMP and other international approvals. Industry Academia collaboration in R&D leading to manufacturing innovated products is a win-win situation for the better use of intellectual resources.

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

Stringent rules in clinical trials, environment clearance and the proposed stringent revision in Schedule M are some of the key challenges. In addition, high 'out of pocket' expenditure limiting access to medicines, changing disease patterns leading to increased healthcare expenditure, continuous pressure to make drug prices more affordable and facilitating fiscal and tax incentives required by the SMEs to help driving their growth are persistent challenges. Despite continuous growth of the Indian pharmaceutical market, quite a large number of small-scale pharmaceutical units have been compelled to shut their operations for not being able to adequately cope with the tough business challenges and competitive pressure. As the country moves ahead, these challenges, coupled with fierce competitive pressure, could further escalate, if not attended to with strategies by the individual companies and the support given by the Government's robust healthcare-reform oriented policy measures.■

Dr. Rao Vadlamudi

Immediate Past President,
INDIAN PHARMACEUTICALS ASSOCIATION

President,
COMMONWEALTH PHARMACISTS ASSOCIATION

The Indian Pharmaceutical Alliance (IPA) represents research-based National Pharmaceutical Companies, with a mission to make quality medicines available, accessible and affordable, as well as to disseminate knowledge and contribute to policy dialogues.

Could you tell us about the Indian Pharmaceuticals Association and its work within the industry?

The Indian Pharmaceutical Association (IPA) was established in 1939 when the pharmaceutical industry was almost non-existent in India, including pharmaceutical education programs. The progress of the IPA as a premier association of pharmaceutical professionals in India paralleled the development of the pharmaceutical industry, as well as pharmacy education in India. Many industry stalwarts were presidents of the IPA and worked relentlessly to lay foundations for the Indian pharmaceutical industry to flourish.

India is currently the largest producer of generics in the world. What improvements can be made in terms of production within India?

The Indian pharmaceutical industry must keep pace with global competitors to maintain its position as the world's largest generic drug supplier by improving regulatory compliance of manufacturing sites and developing cost-effective and high-quality manufacturing processes. To consolidate and sustain its global leadership position, India needs to reduce dependence on imports for APIs, key intermediates and starting materials. It is also necessary for the Indian industry to become fully compliant with the Track and Trace requirements being imposed by various regulatory agencies to ensure quality pharmaceutical imports and to prevent counterfeiting.

How have new governance and changes in the regulatory framework impacted the pharmaceuticals industry?

The Government of India introduced several initiatives intending to improve the health of India and strengthen its manufacturing industry. Pradhan Mantri Bharatiya Janaushadhi Pariyojana is a major initiative aimed at making quality medicines available to the public at affordable costs. The 'Make in India' campaign is aimed at creating the infrastructure necessary for making India the manufacturing destination of the world for all equipment, goods and commodities. In line with achieving this objective is the Skill India campaign implemented through the National Skill Development Corporation and its various sector skill development councils. The objective is to develop skills in people aspiring for industry jobs, as well as those who are already employed in various industries, to create employable human resources as well as to enhance the quality of production. In the field of pharmaceuticals, regulatory authorities such as the Central Drugs Standard Control Organization (CDSCO) and various state licensing authorities are expanding their headcount and operations as well as digitalizing their activities to build the efficiencies that are necessary to meet the needs of the rapidly growing pharmaceutical industry. SUGAM online portal of the CDSCO is for online applications, granting of permissions and to track the status of applications. The DAVA portal is meant for drug authentication and verification of batch number and manufacturer of that drug. CDSCO also came up with guidelines for biologics and biosimilars, medical devices and new guidelines for clinical trials.

Moving forward, what are the key objectives of the IPA?

IPA's current focus is to ensure that there are well-trained pharmacists in places where medicines are handled. To this end, IPA is involved in advocacy measures directed towards emphasizing the need and value of pharmacists. IPA believes that to provide quality health care services, pharmacists should be continuously trained. Through our pharmacy practice divisions (Community Pharmacy and Hospital Pharmacy), IPA is involved in organizing training programs to the community and hospital pharmacists all over the country. Areas of focus include rational use of medicines, containing antimicrobial resistance, building awareness towards detection of spurious and fake medicines, patient counseling, reduction of medication errors, good pharmacy practices and so on. IPA is also working towards convincing the government to make pharmacists an integral part of the healthcare initiatives and has been successful in demonstrating their value in detection and monitoring treatment goals of tuberculosis and AIDS. IPA also places a lot of emphasis on motivating and creating future leaders from the pharmacy students all over the country through the student forum (IPASF) platform. We also work closely with international organizations such as FIP, CPA, FAPA, and SEARPharm Forum to ensure that a well-trained pharmacist is behind each medicine prescribed to encourage better health outcomes. In conclusion, the key objective of IPA is to position pharmacists as one of the most important healthcare providers in our country.■

With a lack of public and private capital available and government tax incentives yet to have much effect, R&D has lagged behind. For example, India's R&D expense to GDP ratio stands at 0.6% for India compared to 2.1% for China. This is an unfortunate reality for a country with the human capital and academic depth to develop quality biotech hubs. "[I]nnovation is often thought to be synonymous with new drugs developed and launched," remarked Vadlamudi. "The Indian industry made attempts at new drug discovery and development, but successful launch of a new drug is a very long process. Given that, Indian efforts in the area of new drug discovery still fall below the industry averages. Expecting success in this domain at the current effort levels is unrealistic. A lot needs to be done in the area of innovation by the Indian industry and through Indian academic research. The focus on innovation must change towards finding effective solutions and treatments for country-specific diseases with particular focus in tropical and infectious diseases, targeted delivery of existing drugs to disease-specific sites to improve efficacy and safety and drug repurposing, to name a few."

The truth of the matter is, while India's pharma industry growth has been impressive, it has fallen short of fulfilling Pharma Vision 2020. There are clear examples where rising competition in pure generics globally has led a number of the top Indian pharma companies to focus on specialty and complex generics, including complex injectables and oral solids, new drug delivery systems and biosimilars. However, true innovation in the shape of an end-to-end drug delivery and development infrastructure is some way off. The human talent and academic system is in place, but R&D numbers need to increase. The Indian Pharmaceutical Alliance (IPA), which submitted its Vision 2030 in July 2019 underlining plans to make India into an innovation leader by building a strong innovation pipeline, has urged the government to set up a large fund to boost technological innovation in pharma, biotech and healthcare startups. But with capital funding missing, it is not likely to change any time soon as the capital intensity and high risks associated with the creation of novel molecules do not bode well in the current domestic and global economic climate.

> There are many global factors that affect growth, the primary factor being price erosion as the prices of generic formulations fall. The second is that most countries are creating policies to develop their own indigenous pharmaceutical industry.
>
> - Ravi Udaya Bhaskar, Director General, Pharmexcil

Economic Pressures at Home and Abroad

Analysts have predicted that India will become the third largest global economy by 2030, but the country's economic performance in 2019 will have raised some concerns over the possibility of this happening. At the time of writing, S&P had reduced India's growth projections from 6.3% for FY 2020, down from 7.1%. Alongside S&P's ratings, Moody downgraded India's GDP growth thrice during 2019. India's economy has clearly been faced with a number of old and new challenges. Private sector investment is at a 15-year low, the banking sector has slowly entered into crisis and the good and services tax (GST) – rolled out in 2017 – has seen slow rates of collection. India is also set to be impacted by a global economic downturn. OECD downgraded the economic forecasts for almost all countries it examined, reducing global growth projection for 2019 by 0.3% to 2.9%. Whilst Brexit and other political events are impacting this, the global trade wars – rooted in Donald

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Naresh T. Raisinghani

CEO and Executive Director
BMGI

BMGI India is the Indian division of the BMGI Global consulting company that provides management consulting services to companies based out of India and the Asia Pacific area.

What advice would you give to small and medium sized companies on their business models given the current environment in India?
I believe there is opportunity in specialty drugs, and companies who are willing to set up contract research or manufacturing for specialties rather than pre-existing high volume drugs would be more likely to benefit. I would also advise to strongly focus on reliable quality and being ahead of the curve on FDA requirements, to rapidly establish yourself. How can India's pharmaceutical companies adjust to cost pressures in the current market? Some of the core areas where in Pharma firms can work to reign in the costs include reducing and managing R&M costs via yields and efficient and alternate purchase options and manpower costs via focus on productivity and optimizing supply chain costs via focus on distribution and warehousing. Additionally, though an area not much focused on R&D productivity by targeting First Time Right Philosophy and Quality by Design with a focus on fast turnarounds / crashing lead times can reign in other anticipated R&D spends, which are likely to go up for firms pursuing that path.

How do you see BMGI progressing in the next three to five years?
There are major cost cutting opportunities and improving operational and supply chain efficiencies for the leading top Pharma firms engaged on such excellence programs, and they would continue to reap benefits in the years ahead. Likewise there are opportunities for accelerating new product introduction for Pharma firms wanting to get their drugs out in the market. This is a relative untapped area, ie, supporting R&D teams in releasing robust molecules by working on Quality by Design, accelerating FTF and ANDA cycles and likewise working on Innovation. We anticipate that in coming few years there would be interest in this area. Several mid and small size firms would require our support in their growth journey, and we look forward to helping them in making their next big leap. ■

Neha Ramani

Partner
LEXORBIS

LexOrbis is a comprehensive Intellectual Property law firm assisting Indian businesses to procure and protect IP rights across the globe.

What is your perspective on India's changing innovation landscape?
The innovation landscape is changing drastically and for the better. There is a definite shift in the trend and focus of the pharmaceutical industry in India and across the globe from development of pharmaceuticals to biopharmaceuticals. Despite the heavy costs, infrastructure for R&D and excess time required in the development of biologics, we have seen revamping of businesses, mergers and expansions to increase operational capabilities, as well as splitting, re-shaping and restructuring R&D by pharma companies to diversify into specialty medicine and biologics. It is an exciting time ahead, with a promise of evolution of biopharmaceuticals and breakthroughs in life-changing and life-saving drugs, like we have never seen before.

What is the top challenge you face when providing legal support to the pharmaceuticals industry?
Patent laws in India have few additional criteria for an invention to be patentable as compared to the United States, European Patent Office (EPO) and other major patent filing countries. Section 3 of the Patents Act, 1970 lists out what is not patentable in India. This list makes it difficult to patent any secondary uses of known compounds, methods of treatment, dosage forms etc. that maybe patentable in other countries.

What is your outlook moving forward for India's future as a pharmaceutical hub?
India is witnessing a rapid growth in the biotechnology and life science sector. With a clear shift in the pharmaceutical industry to biopharmaceuticals, in the agricultural industry to hybrids and green technology, in the energy industry to biofuels and with bioinformatics closing the gaps, India is a very attractive market for investment and R&D activities. Along with technological growth, India is also witnessing rapid evolution in laws, rules and practices related to corporate and commercial transactions. LexOrbis' future perspective is to evolve and adapt in this dynamic environment and render customized services to add value to our clients' businesses with due diligence, consciousness and promptness.■

Trump's belief that increasing global trade tariffs will positively impact U.S. growth and manufacturing – is the key reason. "There are many global factors that affect growth, the primary factor being price erosion as the prices of generic formulations fall," remarked Ravi Udaya Bhaskar, director general at Pharmexcil. "The second is that most countries are creating policies to develop their own indigenous pharmaceutical industry."
Indeed, a more insular, less globalized world is likely to heavily impact India's pharma industry and export numbers. This is even more pressing given the current geopolitical climate in key export markets for India's pharma industry – the United States and United Kingdom. With 147 FDA formulation sites approved compared to China's 45 sites and the highest number of FDA approved API plants in the world, India is likely to retain its title as the 'pharmacy of the world' for some time. Moreover, with an ever-increasing population that is getting older and richer, demand will continue to increase at home. However, the new decade is set to start with uncertainty for India and where the pharma industry will go. The most pressing concern for the industry will be that the CAGR continues above the 10% mark and for the industry's trade surplus to grow from the current US$11 billion as the geopolitical climate remains unstable. As the pharma industry is amongst the top five sectors contributing to the reduction of India's trade deficit, the country needs a secure pharmaceutical industry that will prevail over the coming years. When this happens and if both public and private capital can be brought into the industry, then India can realistically think about building the innovative drug delivery and development R&D ecosystem that will evolve the industry to the next level.■

> "India today has proven itself, but what we are doing is only "me too" products, instead of adventuring further. The business environment that holds to the government needs to be conducive to R&D through better grants and incentives. It shouldn't be the case that only large pharma companies can do research using their many years of profits. There are many small companies with big ideas, which is why I see this aspect as both a challenge, as well as an opportunity.
>
> - Mohal K Sarabhai, CEO, Asence"

Mapping India's Pharmaceutical Industry

"The pharmaceutical companies in India are globally competitive and relevant, which has created a core ecosystem for related industries, including CRO services, to grow. Secondly, India's pharmaceutical ecosystem benefits from a strong availability of a technically qualified talent pool which is well trained, English speaking and yet comparatively lower cost."

Mr. Ajay Tandon,
Executive Director,
Veeda Clinical Research

Image courtesy of Sai Life Sciences

Mapping India's Pharmaceutical Industry

The geographical hubs driving the nation's growth

With a territory spanning over three million square kilometers that are grouped into 29 states across seven union territories, India has the space and flexibility to develop multiple centers of industrial focus. Its pharmaceutical hubs stand out as geographical centers that have been nurtured by strategic investments to supply the necessary infrastructure, institutional support and human talent to sustain the country's position as a global pharmaceutical leader.

Generally demarcated by state or city, each of these hubs enjoys its own ecosystem featuring different strengths, weaknesses and particularities as a result of the interplay between the main companies present in the region and their relationship with the market and various stakeholders. Some hubs have been molded and defined by the features of their respective metropolis, such as the financially-driven Mumbai, while others have emerged through more inorganic means and strategic government initiatives, as is the case in the tech-savvy Hyderabad. A hub forms a web of cohesive and dynamic forces that attract further investments and key players whilst integrating the local economy, society and environment in a dialectical fashion. Together, they form the pull points around which segments of India's massive pharmaceutical industry gravitates.

The Role of Regional Authorities

India's federal state system allows regions to develop their own pulse and relationships with representative federal governments. Differentiation creates a sense of healthy competition between the different states, without undermining the strong sense of national identity that also drives the country's pharmaceutical industry. The impetus given by the "Make in India" initiative since 2014 propelled a proud resurgence of Indian goods and services, but within the broader billboard of this label, other taglines such as "Made in Gujarat" also surfaced with a complementary sense of pride: Maharashtra proudly boasts the most USFDA approved sites in India, whilst Gujarat touts itself as the first producer of contraceptive pills in the world.

The big decisions concerning the regulatory environment, harmonization with international standards and allocation of funds are taken at national level, but it is the regional governments with their delegated agencies that ensure implementation takes place; the Food and Drug Administration (FDA), or Food and Drug Control Administration (FDCA) are the government's designated agencies acting to implement the Drugs and Cosmetics Act of 1940 and the Drugs Price Control Order of 2013, amongst other legislative documents. What both Commissioner Dr. Pallavi Darade, from the Maharashtra FDA, and her counterpart in the Gujarat state, Dr. H.G. Koshia, have noticed is that their representing agencies cannot help close the gap between the regulatory text and on-the-ground implementation by simply acting as regulators or watchdogs; they both see a wider scope in the role regional authorities have to play in cultivating an enabling environment through bottom-up education. Extending this supporting arm from the regulators is particularly important for SMEs, who may lack the resources to follow the latest changes in regulation. "As a regulator, my job is to enforce the laws and regulations uniformly, throughout my area of jurisdiction, from multinationals to small companies. Whenever there is a change in regulation, I do mentoring and handholding for small and medium companies," confirmed Dr. Koshia.

However, there continues to be some dissatisfaction with the role played by local authorities in ensuring the highest quality of products when compared to the outside audits conducted by the United States' regulatory body, the USFDA. Known for its heavy hand in sanctioning non-compliance, poor marks from the USFDA can bring a company's line of production to a halt or even irrevocably damage an organization's reputation.

The perceived lenience of India's enforcement bodies when compared to their foreign equivalents has, according to some, done the industry no favors in preparing it for export markets. Karan Singh, managing director of Mumbai-based ACG, which offers manufacturing, packaging, research and development services to the industry, commented: "The Indian FDA is doing a good job in stepping up its game and inspecting our Indian facilities to ensure they comply with global standards. But when the USFDA intervenes to disqualify facilities and issue notices to pharma companies, it raises the question of why the Indian FDA is not taking this role. The government must take into account the loss gener-

ated every time Indian pharma facilities cannot supply into U.S. and European markets."

Mumbai: The HQ for Big Pharma

Mumbai embodies all the qualities of a modern metropolis, bursting with a population of over 22 million that live side by side in the city's luxury apartments and sprawling slums – a stark depiction of the nation's growing inequality problem. Formerly a constellation of seven constituting islands that were merged together under British colonial rule, a forceful urban push has continued to spread the boundaries of the city's outskirts into Navi Mumbai (New Mumbai), Thane, Pune and other emerging neighborhoods.

Mumbai is the site of the national headquarters for many of the country's big pharma companies, but it also serves as the home for several small and medium sized companies. Its industry residents include both indigenous players and multinationals, and it is the financial capital of India, as well as the designated capital for the pharmaceutical industry, given the sheer number of pharmaceutical companies that call the city home: over 2,000 manufacturers of drugs and cosmetics are located in the state of Maharashtra, many of whom are nesting in the city of Mumbai.

Across the value chain, a plethora of companies find their way in the crowd, with manufacturers of APIs and formulations, distributors, service providers and start-ups competing alongside the big multinationals and national Indian players. For multinationals like GSK or Roche, setting a base in Mumbai is a natural choice as the cosmopolitan gateway into the rest of the subcontinent. The Sahar International Airport serving the area is the second busiest in India by passenger traffic, and in Maharashtra, there are 18 colleges offering pharmacy courses.

While the commercial offices are conveniently located in the heart of the city, many of the manufacturing or laboratory facilities are moved further away into the state of Maharashtra, particularly in the face of skyrocketing real estate prices. In fact, many pharmaceutical companies tend to maintain their Mumbai-based corporate offices while keeping their manufacturing sites in other states, especially in the north-eastern region of the country where states offer incentives such as waivers on permissions related to registration fees or duties rebates.

In a market of over 1,500 competing API manufacturers, traders and exporters, finding the right place within the chain is crucial for a company's survival. For trading companies like Atman Pharmaceuticals, which sources APIs for formulators around the world, location is levied as a key advantage in their business model: "Because of the factory's geographic position, every order sent to a manufacturer can take up to a week for delivery. However, when an order is placed with Atman Pharmaceuticals, we dispatch the product within the same day, in a context where time is crucial for formulators," said Atman Parekh, director of the company.

In line with the international outlook of the city, the Mumbai pharmaceutical community is highly focused on opportunities in export markets. Drugs from Maharashtra hold the record for the most USFDA certifications, and Dr. Pallavi Darade, the FDA commissioner for the Government of Maharashtra, has made it a personal mission to make the state a leader in terms of pharmaceutical initiatives. Given the state's strong reputation in export markets, she has dedicated significant efforts into promoting investment for Mihan, an export park in Maharashtra.

However, the city is not without its challenges – the chaotic and saturated cityscape is an apt metaphor for the cut-throat competition facing industry players, and, at a more practical level, it points to the hurdles of traffic and space limitations. The price of rentals in Mumbai is 60% higher than in New Delhi, and real estate experiences the highest inflation rate in India at 18%. While the "city of dreams" remains compelling, the pay-offs of operating from Mumbai are questioned when balanced with other states that offer better tax incentives.

Nonetheless, Mumbai is an attractive place for entrepreneurs with a vision to break into the pharmaceutical industry. The wealthiest city in the country, its role as India's financial and commercial capital is owed to its high GDP ratio and the fact that the city is home to 70% of capital transactions in the national economy; in addition, the Bombay Stock Exchange, the Reserve Bank of India and the National Stock Exchange of India are all found in this vibrant city. A high-end destination by definition, the pharmaceutical industry is embedded into the broader cos-

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Top 10 Pharma companies in Mumbai:

GSK	Piramal
Cipla	Novartis
Bayer	Abbott
Sun Pharma	Lupin
Johnson&Johnson	Ipca

Source: Pharma Tips

Hon'ble Dr. Pallavi Darade

Comissioner
FOOD AND DRUG ADMINISTRATION (FDA) MAHARASHTRA

Food and Drug Administration Maharashtra State is the State's prime organization of consumer protection, in charge with upholding the highest safety standards. The Commissioner is the head of the Administration and Drug Control Laboratory.

What is the mandate of the FDA Maharashtra and what role does it play in protecting consumers as well as supporting the pharmaceutical industry?

The FDA is an important constituent of the Government of Maharashtra and is aligned to the Government of India to act as the implementing agency of the Drugs and Cosmetics Act, the Drug and Magic Remedies Act, the Drug Price Control Order, the Poison Act and more – all of which are applied across the manufacturing, sale and distribution of drugs.

The FDA has a multifaceted role to play, the first goal being to act as a leader in regulation in India ahead of other states; the second is to maintain the quality of the drugs, but also to work towards finding ways of improving quality even further; thirdly, we are looking for creative means to increase compliance, because the Act lays out the minimum benchmarks, which are not always the reality in practice. Reducing this gap through measures like workshops, self-compliance checklists, or through traditional inspections is a key focus for us.

Can you highlight your top priorities since taking office two years ago?

Last year, we focused on having the best pharmacies across Maharashtra, taking into account everything from optimal storage temperature to up-to-date inventories and availability of pharmacists. We realized that being a regulator in the field is not enough; we must also offer guidance.

Another initiative was to prepare manufacturers' checklist, covering the relevant schedules of the Drug and Cosmetics Act. The checklist included more than 100 points that manufacturers needed to go through to submit a report of self-compliance. There are around 2,000 manufacturers of drugs and cosmetics in Maharashtra, and each of them went through the different points, from air quality, to production processes, manpower, lab features, and all aspects that the Act regulates.

We have also tried to promote the pharma industry investments in MIHAN, which is a multi-modal export park in Maharashtra- a government project of exports in Nagpur.

Having implemented a system of self-compliance, have you seen an increase in manufacturers' commitment to higher quality?

The first response that we saw from manufacturers was appreciation of the fact that the FDA is also trying to educate and not only doing inspections and punishing. The approach shifted and it was well embraced, which is reflected in the level of compliance. Self-compliance is a long process and it cannot be done overnight, but awareness has enabled manufacturers to be ready for inspections by providing them with all the elements that the FDA will be looking for.

The online platform for WHO-approvals is a huge advantage for companies today. Can you tell us more about the benefits it brings and how it stimulates market growth?

This is a one of its kind tool to give WHO certifications, required by all WHO certified exporters. We have an online platform through which manufacturers can apply and obtain their licenses. Our portal was the first to be launched in India, setting a positive precedent for other states. We have a huge database that was created in 2010. The process is very quick; the timelines are defined by the government, so any enterprise that wishes to begin a business in the manufacturing sector will have their request processed within a specified time limit. Through the "Right to Service Act," it is stipulated that the government is under the obligation to deliver on certain services, and it has between 30 to 35 days to issue a permission.

Do you have a final message to share to our international readership and stakeholders in the industry and beyond?

Maharashtra is the future for pharmaceuticals in India and in the world, not only because it has the maximum of USFDA or WHO approved certifications, but because it is socially secure, and the climate here is pro-industry and pro-business. It is a stable and well-administered state. Investors around the world should think of Maharashtra as their prime destination because here, one can find a rare combination of good regulation and strong administration politically and socially, and this is what sets the future for the industry.■

Dr. H. G. Koshia

Comissioner
FDCA (FOOD AND DRUG CONTROL ADMINISTRATION)

The mission of FDCA Gujarat is to safeguard public health, boost consumer satisfaction, and create awareness in the areas of Food, Drugs and Cosmetics. The FDCA is the governing authority for the enforcement of two fundamental pieces of legislation, namely the Drugs & Cosmetics Act 1940 and Drugs (Price Control) Order 2013, together with other acts and rules.

Gujarat is considered the "pharma capital" of India. As the pharma industry grows, how will the state's FDCA grow with it?
The FDCA has been focused on training to strengthen our team and build capacity while continually updating our facilities with the latest science. Additional manpower is always a constraint for the government, but as a technocrat, I sought solutions in technology, whether it was advanced laboratory instruments, or empowering field officers with mobile devices such as spectometers, metal analyzers and NIR material analyzers to increase the productivity and competence of the team. When I joined FDCA in the 1980s, there were only two computers in the department, one belonging to the commissioner, and the other used by a statistician. Today, we have converted manual tasks into digital tools. If we compare the results from almost 10 years ago, only 6,836 samples were analyzed, out of which 381 failed the standard. Last year, we analyzed 13,616 – almost twice the size of the sample tested, with almost the same number of NSQ (not of standard quality). This shows our increased capabilities to monitor an ever larger sample, keeping in check the safety norms. Always open to new ideas, we listen to our stakeholders and to global organizations like USFDA, MHRA or the Bill Gates Foundation to modernize the regulatory system.

Gujarat absorbs up to 18% of investment in pharmaceuticals. What makes Gujarat an attractive destination for investors?
The four pillars of our government are transparency, speed, sensibility and development. We are a tough regulator, but we are also humans, and we are committed to promoting the wellbeing of society. In combination with quality, good infrastructure, continuous electric and water supply, political and civic harmony and the presence of soft skills and talent, Gujarat has become an important spot on the world map for pharmaceuticals. These factors make Gujarat a very logical choice for any investor. Gujarat has earned a reputation in pharmaceuticals to the extent that the name of the state is immediately associated with quality: when a product label says "Made in Gujarat," acceptance for that product increases.

How does the FDCA lend support to SMEs and companies that are vulnerable to changes in regulation and compliance standards?
As a regulator, my job is to enforce the laws and regulations of the land uniformly throughout my area of jurisdiction – from multinationals to small companies. Whenever there is a change in regulation, I provide mentoring and handholding to small and medium companies. For example, when I worked as a joint commissioner in 2005, there was a revamping of the GMP chapter in Indian regulation, with new provisions for the quality of water and quality of air, which required investment from manufacturers. About 200 micro units in Gujarat were at risk of seeing their business closed, because they were worried that they did not have the capital to adjust for the changes. The FDCA stepped in to provide these businesses with a clear understanding of the government requirements and facilitated the formation of clusters, which helped them share the costs of a consultant and buy in bulk to reduce costs. Almost all of these units survived, and many of them grew from local players to global ones. The compliance with stringer regulation eventually opened the doors to global markets, because the new systems were aligned with WHO standards.

Moving forward, what has the FDCA identified as a key area of improvement?
Our mission is to safeguard public health, and we have a great responsibility to do so by ensuring that the pool of pharmaceuticals is of safe quality. We are not limiting ourselves to the boundaries of Gujarat, because our products go beyond the borders, and thus we need to bear responsibility for the global population consuming the medicines manufactured here. Products from Gujarat are better than other parts of the nation because of our commitment to public health; in 2017-2018, 1.69% of our samples were NSQ, whilst the average of other states was at 4.62%. My ambition is to see zero NSQ in Gujarat.■

Bhagyesh Shah

Managing Director
UNISON PHARMACEUTICALS

Unison Pharmaceuticals Private Limited was established in 1981 with a vision to provide quality and affordable medicines across the nation. With more than 3 decades of medical service to the society, Unison is today one of the fastest growing company in Gujarat State.

Could you provide a brief introduction to Unison and highlight some recent milestones?
Unison was founded by my father in 1981 with the mission of providing high quality products at an affordable price. In India, the middle and lower middle socioeconomic strata constitute a majority of the population, so affordability plays a huge role in deciding the medication for any therapeutic condition. Our second facility was recently completed in 2017 and it is approved by the European Union. We have an R&D center with over 100 scientists, and all three facilities are located in Gujarat. Two years ago, we began working on a new portfolio of products with the aim of entering new markets globally. During 2020, we hope to file some dossiers within these markets.

Have you observed any changes in the India market as a result of the shift in environmental controls in China?
The large companies already have their own captive API facilities, however we are not at this scale. The eventual solution will be for India to manufacture its own APIs, and it will take a few years for Indian manufacturers to be able to offer the cost effectiveness that China was offering. When the price of certain imports from China soared, many Indian companies stopped their production of drugs that required those imports. We were one of the only companies to continue producing at a loss for the benefit of the consumer, which is why today we are in the top 80 companies in India in terms of revenue sales and top 40 in terms of volume sales. In Gujarat, we are number one by volume sales and sixth in revenue for 13 consecutive years.

How do you identify gaps in new markets that Unison can fill?
The products we have identified are not necessarily innovation driven; some are coming off their patents or are already off patent. Our strategy is to offer our price advantage to foreign markets and use our expertise of 38 years as manufacturers. We are in conversation with potential clients for whom we can manufacture in our EU-approved facility and provide a huge cost saving.
In addition to price, we can compete on technology. Prior to 2015, we had a small-scale R&D facility that was part of our manufacturing facility. We expanded to create a dedicated facility for R&D where we started exploring new technologies that can be more patient-friendly and compliant. We improvised our own formulations that provide incremental improvements to mouth dissolving products such as Vitamin B-12 mouth dissolving, for example, where we can compete on the taste, speed of dissolving and the effectiveness.■

mos of the Bombay metropolis, and there are benefits to be reaped from the city's ready accessibility to robust streams of economic and human capital.

Gujarat: The Home of Pharma Clusters

Located to the north of the Maharashtra state is Gujarat, which boasts the country's longest coastline. Its vast shore, up to 1,600 km, is punctuated by several key ports, making it an important region in the facilitation of trade. The capital city of Gandhinagar – named in honor of Mahatma Gandhi, who was born in the state – is a well-planned city with less than 300,000 inhabitants. While the region upholds a rich and distinctive cultural heritage, Gujarat has also made strides towards building new legacies in the industrial space. As the first state regulator to introduce the drug manufacturing license application software, the state has made particular strides in pharma e-governance and has been aptly recognized with the "E-Governance Gold Award."

Gujarat accounts for over 30% of the aggregate share of India's pharmaceutical industry, and it is home to 40% of CRAM companies, 40% of Indian pharmaceutical machineries and 28% of the country's exports. Today, over 52,000 people are employed in the pharmaceuticals industry in Gujarat, and there are over 3,500 manufacturing units in the state.

Rather than constructing its pharmaceutical ecosystem through a decentralized approach across various key cities, Gujarat has centralized its brand under the umbrella of the state, adopting the brand "Made in Gujarat" for its pharmaceutical products in homage to the national "Make in India" initiative. Dr. Koshia, the Commissioner of the FDCA, commented on the source of pride underpinning this expression: "[P]roducts from Gujarat are better than other parts of the nation because of our commitment to public health. In 2017-2018, 1.69% of our samples were NSQ (not of standard quality), whilst the average of other states was at 4.62%. My ambition is to see all zero NSQ in Gujarat."

The progress in quality has been built on a backbone of strong infrastructure, sustained reforms and incentives that gave rise to a friendly business climate. There are four pharmaceutical-dedicated special economic zones (SEZ), which are self-contained, duty-free enclaves aimed at facilitating foreign investment and integrating local firms into global value chains. In addition, a new Medical Device Parks is underway to accommodate and drive further growth for an already booming sector, as Gujarat is a national leader in medical device manufacturing. Rahul Maheshwari, managing director of DEFI Healthcare, commented on the advantages Gujarat's life sciences will enjoy upon the completion of the various parks: "Ahmedabad itself is surrounded by various industrial parks, and the Government is working on single window clearances in manufacturing zones, in and around the big hubs. Moreover, there are nearby ports which are not as congested as in Mumbai, for example. There is ease of access and plenty of infrastructure in terms of trucks, airplanes and vessels that can transport products quickly."

Four pharma clusters stand out within Gujarat as key driver's of the state's prominence in the industry: Ahmedabad, Vadodora, Bharuch and Ankleshwar. The heritage city of Ahmedabad alone hosts some of the largest pharmaceutical companies in the country, including Zydus Cadila, Torrent Pharmaceuticals, Dishman Pharma, Finecure, Claris, Lambda and Swiss Pharma, and Alembic, a multinational giant with over 100 years of experience, has made its headquarters in the neighboring cluster of Vadadora.

> Unique Biotech has been in the manufacturing of bulk cultures and customized formulations since 2001. We are continuously working on isolating new strains that have potential probiotic properties as well as antimicrobial properties against Methicillin-resistant bacteria. If we are able to isolate the strains with broad antibiotic-like substance producing capabilities, we will be able to work against the antibiotic resistance. However, biopharmaceuticals are highly capital intensive and regulations tend to take a lot of time.
>
> - Dr Ratna Sudha, Managing Director, Unique Biotech

However, the importance of these clusters is mostly felt by the state's SME sector, which has experienced substantial growth due to the assistance of subsidies of up to 50% for either installing Enterprise Resource Planning (ERP) systems or obtaining ISO or WHO GMP certifications. The subsidies are a welcome relief in the context of increasingly challenging conditions for SMEs, elaborated on by Daara Patel, secretary general of the Indian Drug Manufacturers' Association (IDMA): "Despite continuous growth of the Indian pharmaceutical market, quite a large number of small-scale pharmaceutical units have been compelled to shut their operations for not being able to adequately cope with the tough business challenges and competitive pressure. As the country moves ahead, these challenges, coupled with fierce competitive pressure, could further escalate, if not attended to with strategies by the individual companies and the support given by the Government's robust healthcare-reform oriented policy measures."

Gujarat absorbs 18% of India's total pharmaceutical investments, and at the Vibrant Gujarat Global Summit, 13 new companies have proposed further investment of more than Rs1 billion into Gujarat's pharmaceutical sector. Moving forward, Gujarat is on track for steady growth and development across its clusters, paving the way for the region to gain even greater prominence on national and international stages.

Hyderabad: A Robust Industrial Base

As a versatile hotspot with a cross-sector focus in IT, pharmaceuticals, textiles and tourism, a rich industrial ecosystem has sprung up in the city of Hyderabad, providing the ideal environment to promote a thriving pharmaceutical industry and incubate a burgeoning biopharmaceutical sector. Often known by the epithet of "The Pharma City," a name that will also be applied to the first-of-its kind industrial park that is being established near the city, another label frequently attached to Hyderabad is the "Genome Valley of India," which comes from another 600 square km science park of the same name being developed as a cluster for biomedical research, manufacturing and training. Top biopharma companies such as Dr. Reddys Laboratories, the largest Indian pharma company by market share, together with Suven Life Sciences, Piramal, Laurus Lab or GVK Bio are all based in Hyderabad, and between 35% to 40% of national pharmaceutical output is attributed to the state.

In the past 30 years, the success of bulk API production encouraged companies to venture into finished dosage products, prompting the development of a complete pharmaceutical ecosystem, and with many private colleges and universities mushrooming within the region, the subsequent talent pool has allowed the industry to flourish in the Telangana state. Ranked first in the Mercer's Quality of Living (India) 2019, Hyderabad is considered the best city to live in India for the fifth year in a row. The ranking alludes to the fact that Hyderabad is a city of balance – it scores high across complementary quality of life parameters, just as its emphasis on multiple industries helps it to achieve economic harmony.

The Telangana government has laid out ambitious plans to leverage the life sciences industry as a key driver of the region's growth, with the objective to augment its value to US$100 billion over the next decade. Different projects are underway in thrust of this expected growth, the largest being the Hyderabad Pharma City: a greenfield project that will cover a sprawling area of 19,000 acres. Located just 40 km from Hyderabad, the vision is to create the world's largest integrated pharma ecosystem. Genome Valley 2.0 is a continuation of the pharma-biotech cluster and the first of its kind in India, as well as one of the largest in Asia. Global players such as Novartis, GSK, Mylan, DuPont and the US Pharmacopeia are found the valley. Another project in the pipeline is a facility called the B-Hub, which will be focused on the scale-up R&D and manufacturing for the biopharma industry.

The construction of these industrial parks will go a long way towards helping companies to achieve efficiencies in their operations, as well as support efforts to make the industry more environmentally friendly. S. Murali Krishna, managing director of Smilax, which manufactures APIs, intermediates and NDDS/pellets for the generics market around the world, commented on the advantages of basing out of an industrial park: "Compared to other manufacturers in India, our facility is located within an industrial park developed by our group company, which offers unique facilities ranging from complete infrastructure to providing water treatment for waste that lends us a hassle-free operation."

Telangana enjoys the unique advantage of a government with the resources and will to create purpose-built clusters, artificially designing the ecosystem of the industry to recognize its full potential. If Hyderabad's entrepreneurial vision receives adequate investment and can attract enough interest from the large national and multinational players, it may just overcome Mumbai as the central hub for India's pharmaceutical market.■

The World's Pharmacy: India's Generic Drug Industry

"The long-term outlook for generic drugs is very robust, because many markets are yet intact. The higher numbers of people brought into the healthcare net will automatically drive the usage of medicines and consumables. The second factor is that the quest for quality healthcare will grow stronger together with rising household incomes in emerging markets. Overall, for the next ten years the macro climate is strong, but there will be many business models that need to be thought through."

- Hari Buggana,
Managing Director,
Invascent

Image courtesy of Ousa Chea

Global Business Reports
EDITORIAL

The World's Pharmacy: India's Generic Drug Industry

India must adapt to maintain its position as the world's largest supplier of generic formulations

Image courtesy of Naprod Life Sciences

The generic drugs industry continues to strengthen itself as a key pillar of India's burgeoning economy. As the largest provider of generics in the world, the sector contributes to 40% of the United States' generic demand with Indian companies receiving 304 Abbreviated New Drug Application approvals from the United States Food and Drug Administration (USFDA) in 2017. Moreover, the industry exports to almost every nation, and has significant footprints in all the highly-regulated developed markets.

The pharmaceutical industry in India, unlike the country's chemicals, petrochemicals, oil & gas and mining industries, is one of the most fragmented comprising of well over 10,000 companies. This is testament to the size of the market and country, as well as a pharma ecosystem that has collaborated very well over many years. "It is a matter of pride that many of the SMEs of yester years have become large-scale national companies now," underlined Daara B. Patel. "We regularly coordinate with the Government to support progress in our SME sector, and today, there are over 2,000 WHO GMP approved plants. It is estimated that another 1,000 SMEs will be WHO-GMP compliant in the next 3 to 4 years, which will add to the growing strength of the industry. Indian firms accounted for 35-40% of the global USFDA 971 approvals in 2018."

The Reign of India's Large National Players

Although the market continues to diversify with new players springing up from within India as well as internationally, a handful of national players continue to have a sizeable footprint in the domestic and international generics industry. Piramal, Torrent, Cipla, Sun Pharma, Aurobindo, Dr. Reddy's and Glenmark, to name a few, represent a number of the success stories in India's pharma industry landscape. With the biopharmaceutical industry rapidly evolving across the globe, inorganic growth has been an important part of company strategy for expanding footprints, retaining market share and moving into new areas of the value chain. For example, Torrent acquired Bio-Pharma Inc. (BPI) in early 2018 – its first acquisition of a manufacturing site outside of India – to diversify and strengthen its product pipeline. "Established in 1992, BPI has a proven track record in the research & development and manufacturing of oral solutions, suspensions and suppositories," underlined Jinesh Shah, director at Torrent Pharma.

Aurobindo has been particularly focused on cementing its global positioning in the market by preparing the acquisition of Sandoz's dermatology business and three manufacturing units in the United States for US$1 billion – the largest deal of its kind for an Indian pharma company if all goes through. "In terms of inorganic growth, this year we expect to complete two major acquisitions, Apotex's Europe business acquired in February 2019, and one involving Sandoz which may happen by the end of 2019," said Sanjeev Dani, COO and head of formulations at Aurobindo. "These acquisitions will help us not only to scale up, but also to expand into therapeutic areas (dermatology), access new markets (Eastern Europe) and sustain our future growth."

Indeed, a number of the larger players are looking at acquisitions in key markets across the globe. The generic landscape is rapidly changing with cost pressures slowing down domestic offtake, pricing pressures in developed markets such as the United States and Europe, as well as pricing pressures being introduced in India. Moreover, regulatory bodies are demanding stricter compliance, pushing up compliance costs. All these factors are making the larger Indian players conscious of how best to evolve from their current offering. "In the current market, there is opportunity in specialty drugs, and companies that are willing to set up contract research or manufacturing for specialties rather than pre-existing high-volume drugs would be more likely to benefit," underlined Naresh T. Raisinghani, CEO and executive director of BMGI India, a global consulting company that sees about 15% of revenue from its India operations coming from the pharmaceuticals industry. "I would also advise to focus strongly on reliable quality and being ahead of the curve on FDA requirements, to rapidly establish yourself," he continued.

A number of the pharma multinationals continue to increase their footprint in the Indian market as well. With a growing population and middle-class, as well as a rapidly increasing population of elderly people, the Indian market is full of opportunities for MNCs. GlaxoSmithKline, Roche, Bristol-Myers Squibb and Novartis are just a few of the international companies that bring their expertise to the Indian market. "Bringing global expertise and innovation to India assures the availability of innovative treatments and options for

"We regularly coordinate with the Government to support progress in our SME sector, and today, there are over 2,000 WHO GMP approved plants. It is estimated that another 1,000 SMEs will be WHO-GMP compliant in the next 3 to 4 years, which will add to the growing strength of the industry. Indian firms accounted for 35-40% of the global USFDA 971 approvals in 2018."

- Daara B. Patel, Secretary General, IDMA

better disease management and a better standard of care that would not be available otherwise," remarked Lara Yumi Tsuji Bezerra, managing director of Roche Pharma India. "With our local strategy in India we are able to focus on access to medicine and are able to bring diverse knowledge to support local stakeholders. This approach has helped us go beyond the traditional approach and helped impact more lives."

Slowing of Global Avenues: India's Exporters Change Tactics

While India's pharma exports grew by 11% in FY 2019 and appear to be promising, the industry is increasingly facing problems across its export markets. This has been underpinned by several changing global market dynamics as well as pressures faced at home in the domestic arena. Price erosion has made it more difficult for low-cost manufacturers in India to justify their margins as the price of generics formulations falls globally. Furthermore, efforts by Governments to promote the development of their own national pharmaceutical industries in key markets across Latin America, Sub-Saharan Africa and Southeast Asia have made the playing field more challenging as exporters encounter increasingly rigid regulatory policies. "The two major reasons for the cost pressures are slowing down of the domestic offtake and pricing pressures in developed markets such as the United States and Europe, in addition to some of the pricing pressures also being introduced in India in the domestic markets," commented Raisinghani. "This is further compounded by regulatory bodies demanding stricter compliance, which are leading to higher compliance costs," he added.

Indeed, the United States – a key destination for India's generic exports – has made it increasingly costly and time-consuming for generic producers across the globe. This is in part due to the prescription drug user fee act (PDUFA), which requires pharmaceutical companies to pay fees ranging from US$1.5 million to US$2.7 million when submitting a candidate for approval. The bottom line is that India's manufacturers are seeing slimmer margins and losing their global cost-competitiveness. Further to that, the challenges faced by Indian pharma companies in the United States are growing in other aspects as well. The United States recently ended India's Generalized System of Preferences Status (GSP) – a tariff reduction on imports – after President Trump determined that India did not adequately meet his trade demands.

The USFDA has been more critical whilst carrying out inspections of manufacturing facilities, giving warnings to a number of Indian national players. Moreover, companies exporting to the United States and Europe will need to become fully compliant with the track and trace requirements being imposed by various regulatory agencies to ensure quality pharmaceutical imports by preventing counterfeiting. Whilst the U.S. Drug Supply Chain Security Act (DSCSA) was enacted in Congress on November 27th 2013 with the aim of making drug products safer by creating a framework for enabling pharmaceutical product traceability, its implementation has been far slower than expected. Even though serialization has not been completely enforced yet, Indian players should be prepared for it in both the European and U.S. markets.

Despite the changing dynamics across the global industry, there is a lot to be positive about. India's export growth for FY 2019 was one of its highest growth rates in the last decade. While margins may be reducing due to the extra costs and regulatory fees, on average, Indian drugs cost 33% less in comparison to their U.S. counterparts, bringing much needed relief to the notoriously high healthcare prices in the United States and elsewhere. Moreover, the margins that Indian suppliers can earn in the United States are higher than those they can achieve in the more saturated Indian market. There are also ample opportunities presenting themselves across Asia for India's pharma players, especially as talks of a free-trade agreement (FTA) with the Eurasian Economic Union and Regional Comprehensive Economic Partnership in Asia progress.

As a protectionist tide sweeps across the globe, the Indian pharmaceutical industry needs to continue evolving. For the industry to retain its position as the largest generic drug supplier, it must continue improving regulatory compliance of manufacturing sites, as well as developing cost-effective and high-quality manufacturing processes. Reducing the industry's dependence on the imports of APIs, key intermediates and starting materials will be key to sustaining its global leadership position.■

Ravi Udaya Bhaskar

Director General
PHARMEXCIL

Pharmexcil is the Pharmaceutical Export Promotion Council of India, set up by Ministry of Commerce. The role of Council is to represent the government and other agencies in India, as well as assisting members in obtaining Market Access Incentives refunds, and organising seminars and trade delegations abroad.

Could you elaborate on Pharmexcil's mission, activities and contribution to the industry?

Pharmexcil was established by the Ministry of Commerce and Industry under Foreign Trade Policy to promote pharmaceutical exports as well as other commodities like APIs, Formulations Herbals, Ayush and Neutraceuticals. Through this process, Pharmexcil provides assistance to its current 4,300 member companies, which range from OEMs to SMEs. Pharmexil's activities include making representations to the government of India and other agencies to obtain amicable solutions to common industry problems. Pharmexcil also undertakes export promotional events and organizes trade delegations overseas.

Since we last met in 2017, how have you seen the industry change?

When we last met, India's exports were sluggish due to realization issues from the U.S. market. Generics prices went down in other markets, and the USFDA imposed the market user fee. However during the FY 19 India's exports growth were at nearly 11%, which is one of the best growth rates spread over the last six to seven years. During the last financial year, especially in the last three quarters, India had brisk exports. Price realization in the United States has since improved, though there is still scope for more improvement. Some of the top companies like Teva have withdrawn their ANDAs due to lower profits and costing being high, however India's exporters stood steadfast and could fill a part of this gap. India's industry has seen several accomplishments in the last few years. India's exporters stepped into a non biological complex molecule sector by getting "Glatiramer" USFDA's nod through a partner. India's exporters also had their biosimiars approved by USFDA. In fact "pegfilgrastim" of Biocon marketed by Mylan is the first biosimilar approved of the biologic Fulphila of Amgen. This is the second biosimilar of Biocon, an Indian company, to receive USFDA approval. Additionally, India's bulk drug exports are looking up.

How have USFDA audits impacted the Indian export market?

USFDA audits would certainly be on the rise as 12% (only second to United States, which owns 30% of the units supplying) of the manufacturing units supplying to United States from all over the world are situated in India. Almost 40% of generic market authorizations granted by USFDA in the calendar year 2018 are to Indian companies. These numbers speak volumes of India's manufacturers running their units at the high efficiency to meet ever increasing standards of regulatory agencies across the world.

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

Pharmexcil has been conducting many events under the flagship of International Knowledge Exchange Program and inviting Food & Drug Regulatory officials globally to exchange technical knowledge between countries for strengthening the regulatory framework. We have successfully
organized interactive meets with some of the drug regulators including UKMHRA, NAFDAC, PMDA, DAV, ANVISA, Food & PB Kenya, EDA (Egypt), FDA Ghana to name a few till date. In our Annual Meets, we propose to conduct International Regulators Meet, inviting regulators from top 50 export destinations of India during 19th-20th Sep 2019 in Hyderabad. Pharmexcil has been conducting training programs pan-India on the recent advancements in the regulations of overseas agencies. We feel this will increase the GMP levels almost every manufacturing unit in India.

What are the key priorities for Pharmexcil to drive the industry forward?

We work in Tandem with the Indian Government. We are always looking for ways and means to make bulk drugs a bigger sector, and we are in the process of marking out important KSMs and lower intermediates keeping in view the possible changing needs of the industry in the next decade. Many countries are leaning towards patented drugs, so Pharmexcil would like to explore new opportunities and study new markets, such as Australia, Japan, New Zealand, Cuba and other CIS & Latin American countries.■

Jinesh Shah

Director
TORRENT PHARMA

Torrent Pharmaceuticals Ltd, the flagship company of Torrent Group, is a pioneer in initiating the concept of niche marketing in India and today is ranked amongst the leaders in therapeutic segment of cardiovascular (CV), central nervous system (CNS), gastro-intestinal (GI) and women healthcare (WHC).

Torrent Pharma is one of the leading pharma companies in India and in the world. Could you introduce the business, highlighting its position in the global markets?

Torrent was a pioneer in initiating the concept of niche marketing in India and is ranked 8th in the Indian pharmaceuticals market. It is specialty-focused company with 75% of its revenue from chronic & sub-chronic therapies. Torrent's revenue is comprised by 60% from branded generics and 40% from generics. Currently, it is operating through 16 wholly owned subsidiaries around the world and seven state–of-the-art manufacturing facilities (six in India and one in United States) to cater the global demand.

Torrent ranks amongst the top 10 companies in the Indian and German markets and is also ranked first amongst the Indian companies in the Brazil market. In addition, we presently also have a footprint in over 40 other countries, which includes key markets such as the Philippines, Russia, Sri Lanka, Nepal, Malaysia, Myanmar and Kenya. In the United States, Torrent currently has 51 molecules and is ranked amongst the top three players in 30+ molecules. The Company has 34 ANDAs pending for approval and 11 Tentative Approvals as of June 30, 2019. In Germany, the Torrent is ranked 4th in the generic market and is first amongst the Indian companies, and in Brazil, Torrent is ranked 13th in the covered market and first amongst the Indian Companies. The Torrent's presence in Brazil is primarily in the CVD and CNS market, and the company currently has 34 products in Brazil and launched two products in the previous year. In all, more than 50% of our revenues are generated from our global operations.

Torrent stands out through its state-of-the-art R&D facilities. What are some of the key focus area as far as R&D is concerned?

Torrent has developed its own patent technology in generics that includes novel delivery forms or advanced generics, such as tablet in tablet, compact tablet technology, or sustained release formulations through which we can convert the three-times a day dose into one dose. For instance, Torrent is filing the marketing application for a topical dermal product delivered as a foam. Currently, the ointment version of the product in the market has limitations in terms of application convenience. The new foam formulation spreads with ease and is less oily and more hydrating in nature, thus improving the efficacy of the product.

We are also looking at acute pain solutions in post-operatory cases by developing a nasal spray to replace injectables and tablets. Unlike the frequent dose of four to six tablets a day or a painful injection, the patient can benefit from an early onset of effect through a simple application. In cases such as B12 deficiency, the nasal spray could prove revolutionary, replacing the painful injection and compensating for the limited bioavailability of the tablet, whilst also conferring autonomy to the patient, assuring the same therapeutic effect. In products with a psychiatric focus, sustained release injections can become indispensable to increase compliance and bring relief to patients and their families.

What are some of the therapeutic areas Torrent pays most attention to?

In terms of the therapeutic areas covered, Torrent ranks among the top five in cardiology, gastroenterology, psychiatry, neurology and Vitamins & Nutrients. We are also focusing on growing our presence in oncology, nephrology, rheumatology and hepatology. The upcoming facility, likely to be commissioned in the last quarter of the year, will focus on oral solid oncology, and it will later be transformed into injectable dosage forms for both the domestic and global markets. In the sizeable markets of Europe and Brazil, we have a strong field focus, because having one's own development pipeline is by far preferable.

Do you have a final message for our international audience?

Torrent continues to focus on its specialty driven business, brand building, productivity improvement, maintaining high quality manufacturing practices and investment into R&D for robust future pipeline. Torrent shall continue to gain market access across the globe and newer segments through organic & inorganic growth. We are building strategic alliances to increase our footprints in global markets. Our long-term commitment is to focus on value added generics, apart from the oral solid dosage forms.■

Rahul Maheshwari

Managing Director
DEFI HEALTHCARE

Director
DERREN HEALTHCARE

DEFI Healthcare Pvt. Ltd. is an Ahmedabad-based pharmaceutical manufacturing company involved in the manufacturing and supply of a wide range of avant-garde pharmaceuticals to semi-regulated and non-regulated markets across the globe.

Could you provide a brief introduction to DEFI and highlight its evolution since 2003?

DEFI began on a loan license manufacturing for various generic products, and we began marketing in Africa, Latin America, Central America and Russia, developing our own evaluation system for products to guarantee the highest standards of quality, at a time when Indian products did not enjoy the best reputation for quality globally. Initially, we exported to UNICEF and Red Cross through our partners in the United Kingdom and The Netherlands. DEFI has developed an in-house design studio to create our own mono cartons, labels and files. We procure good quality raw material by sea and we ensure that any product sent under the DEFI brand name is synonymous with quality.

What are some of the advantages of operating from Gujarat?

Gujarat is a manufacturing hub in India, such as Ahmedabad, Vadodara, Vapi and Ankleshwar. Ahmedabad itself is surrounded by various industrial parks, and the Government is working on single window clearances in manufacturing zones, in and around the big hubs. Companies such as Zydus, Torrent and Sun Pharma value their base in Gujarat because the Commissioner of Gujarat is proactive and industry-friendly; moreover, there are nearby ports that are not as congested as in Mumbai, for example. There is ease of access and plenty of infrastructure in terms of trucks, airplanes and vessels that can transport products quickly. The Government of Gujarat is supportive of entrepreneurs and has created free zones within the state. Gujarat also has the highest number of FDA approved facilities.

What motivated the start of the new company called Derren?

We are establishing a new manufacturing company, Derren Healthcare, which will incorporate new production systems with the aim of obtaining USFDA approval. This facility will manufacture products for export as well as the domestic market. In terms of our business model, we will be able to contract manufacture for big players and manufacture for DEFI as well. We have a foreign partner for whom we will manufacture high quality small volume parenteral drugs. ■

TK PC

Tushar A. Korday & Pradeep K. Chatuvedi

TK: Founder
EMIL PHARMACEUTICAL INDUSTRIES
PC: General Manager
MEDIBIOS LABORATORIES

How is Drug Price Control influencing competitiveness?
The selling price cap has been in place for the past 30 years. Initially, it was a very low-key affair, but gradually, the price control has been increasing, both at the top and bottom end of the market. Over time, many products came under ceiling price and we had to stop producing them altogether. To maximize the profitability, companies have used different strategies to reduce the impact of ceiling prices. Many manufacturers started developing combination products, nutraceuticals and new products to expand their topline and profitability, while others focused on exports, especially regulated markets. Overall the Indian pharmaceutical Industry has fared well despite ceiling prices. We have become more cost competitive, technologically more advanced and are meeting the global standards as well as bagging increasing market shares.

As an internationally focused company, how do you think a potential global slowdown may affect the pharmaceutical industry?
Global slowdown is by default going to impact all industries, but to some extent, the pharmaceutical industry is sheltered. The population is growing, demand for medicines is on the rise and the world cannot be without essential drugs like antibiotics. We believe it will be the lifestyle medicines or the nutraceuticals, which are expensive and optional, that are likely to feel the heat for some time. On the other hand, due to the price pressure, generic medicines will continue to grow, which is a big opportunity for Indian players who are well entrenched in this segment.■

Suresh Pattathil

CEO
FERRING PHARMACEUTICALS

Renowned for its focus on peptides, what is Ferring's current focus in terms of the molecules underway?
Peptides are still in our range of products, including our oral peptide for bed wetting in children and for nocturia in adults, but we have recognized that we must look beyond the peptide to meet unmet medical needs. Ferring has a gene therapy for bladder cancer in Phase 3 that is expected to launch early 2020, subject to approval by the USFDA, and we have entered into the space of Microbiome Replacement Therapy. Many of the antibiotics used today will be ineffective in the future due to heightened drug resistance, and to this end, Ferring acquired a company called Rebiotix Inc. in the United States; by 2021 we should have a product for clostridium difficile infections.

Could you provide insight into the challenges and advantages of India as an R&D destination?
India has the needed talent, but the country has always been in the re-engineering business, because we only had process patent, and no product patent until 2005. Up to that point, companies would dedicate their R&D spending to finding a different process in the manufacturing of the same product. Very few companies have attempted research that goes through the three phases of development to identify new molecules. Due to the lack of data exclusivity in India, a molecule without patent in India after completing an expensive phase 3 registration trial can see another 20 generics launched within a short time, and none of these generics have to do a registration trial. ■

Mehul Shah

Managing Director
ENCUBE ETHICALS

Could you elaborate on some of the innovations in Encube's R&D center and what proportion of revenue is spent on R&D?
Last year, Encube Ethicals invested upwards of 40% of its top line into R&D. This year, we are likely to continue on this journey and spend about 40% of the top line into R&D again. Typically, generic R&D centers around the world are focused on only formulation development. For topicals, we are trying to build expertise in In Vitro Release Testing (IVRT) models and the complete in-house characterization laboratory, which helps us solve some of the most complex development issues in the least time. We have a battery of high-tech instruments including XRD, LCMS and GCMS for polymorph identification and impurity identification.

How has the market for topical products evolved in India and what is the prospect for the future?
Over the last 10 years, the growth rate of topical products in India has been upwards of 13% consistently, while globally the focus has been more on OTC switches. Despite pricing pressures, regulatory challenges and competition, India is a large market and we are experiencing a strong return on investment. The Government has announced a new insurance scheme under which 500 million people will be insured, so that many more people will have access to topical products, which are quite reasonably priced. The growth potential in the Indian market for topicals is phenomenal. ■

SUN PHARMA

With global revenues of US$4 billion, Sun Pharma is the fifth largest specialty generic pharmaceutical company in the world. They provide high-quality, affordable medicines trusted by healthcare professionals and patients in over 150 countries worldwide. Sun Pharma is also India's largest and most trusted pharmaceutical company. Their global presence is supported by more than 40 manufacturing facilities across 6 continents. Sun Pharma is the leader in the generic dermatology segment In the U.S. market, which contributes a significant share of their revenues. The company has an established presence in Europe and key high-growth emerging markets like Russia, Romania, South Africa, Brazil and Mexico.

Founder And Managing Director
Dilip Shanghvi

Products
Sun Pharma produces a comprehensive, diverse and highly complementary portfolio of specialty and generic products targeting a wide spectrum of chronic and acute treatments. Their manufacturing capabilities span generics, branded generics, difficult-to-make technology intensive products, over-the-counter (OTC), anti-retrovirals (ARVs), Active Pharmaceutical Ingredients (APIs) and intermediates.
Sun Pharma's products have the hallmark of technology-based differentiation and cover the full range of dosage forms, including tablets, capsules, injectables, inhalers, ointments, creams and liquids. The therapeutic segments covered by their portfolio of over 2000 high quality molecules include psychiatry, anti-infectives, neurology, cardiology, orthopaedic, diabetology, gastroenterology, ophthalmology, nephrology, urology, dermatology, gynaecology, respiratory, oncology, dental and nutritionals. In several countries, Sun Pharma ranks among the leading companies in these therapy areas.

Research and Development
Sun Pharma has around 2000 research scientists working in multiple R&D centres equipped with cutting-edge enabling technologies for research. The scientists have expertise in developing generics, difficult to make technology intensive products, Active Pharmaceutical Ingredients (APIs), Novel Drug Delivery Systems (NDDS) and New Chemical Entities (NCEs). Their capabilities span the development of differentiated products, such as liposomal products, inhalers, lyophilised injections, nasal sprays, besides developing controlled release dosage forms.
Sun Pharma's scientists work closely with the business development team to generate innovative concepts and ideas, exploiting both market needs and synergies across therapeutic areas. They invest around 7-8% of their revenues annually in research. Their R&D productivity ranks among the highest for Indian generic companies and their R&D centres have been audited and approved by international regulatory authorities, including the USFDA and European authorities.

Corporate Social Responsibility
Sun Pharma believes in making good health affordable and accessible to the marginalized communities and society at large. With active fieldwork, dedicated research and recognition of the efforts of those who work behind the scenes to combat illness and disease, they help as many people as they can to ensure their right to good health.
Health, education, water, livelihood, environment and disaster relief are some of their key priorities in the area of corporate social responsibility (CSR). They also help conduct trainings in vocational skills for communities and undertake local-level community programmes that are need based.■

DR. REDDY'S

Dr. Reddy's commenced its generics business in India in 1986 and is today a trusted name in the healthcare industry consistently serving the needs of millions of patients with high quality, affordable and innovative medicines across therapy areas. Over the years, the company has significantly grown its portfolio of products across mass and specialty therapies. Seven of their brands are listed in "Top-300 of the Indian Pharma Market" and many others hold leadership positions in their respective categories.

Founder and Chairman
Dr. K. Anji Reddy

Leadership
Erez Israeli, CEO
M V Ramana, CEO, Branded Markets (India and Emerging Markets)

Primary Focus Areas
Today, Dr. Reddy's portfolio has over 200 products covering the whole spectrum of disease areas spanning gastroenterology, oncology, pain management, cardiovascular, dermatology, urology, nephrology, rheumatology and diabetes.

Research and Development
At the heart of Dr. Reddy's research and development organization is their state-of-the-art R&D centre spread over 300,000 sq. ft. The centre houses over 70 laboratories and has over 800 research scientists working on various projects. This R&D centre works in close conjunction with other centres across the United Kingdom and the Netherlands.

Work at the R&D centre results in a wide-ranging suite of capabilities and services—from synthetic organic chemistry to formulations development; intellectual property management to regulatory science; and polymorphism to bio-pharmaceutics. The company is also able to offer services and solutions for starting material, intermediates, active ingredients and finished-dosage forms to the industry customers.
Dr. Reddy's has over 170 ANDAs, over 500 DMFs and 86 patents filed in the last five years.

Corporate Social Responsibility
Dr. Reddy's is collaborating and building capabilities of social change agents and nurturing institutions that demonstrate new pathways of human development. The company has a strong focus on the inclusion of low-income communities into mainstream quality education and being sensitive to the community situations as well as to the constraints of social development systems.■

GLENMARK

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global and integrated pharmaceutical organization. It is ranked among the top 75 Pharma & Biotech companies in the world in terms of revenue (SCRIP 100 Rankings published in the year 2018). Glenmark is a leading player in the discovery of new molecules, including both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several molecules in various stages of clinical development and is focused in the areas of oncology, dermatology and respiratory.
The company has a significant presence in the branded generics markets across emerging economies, including India. Glenmark has 16 manufacturing facilities across five countries and has six R&D centers. Glenmark services the generics requirements of both the U.S. and Western European markets, and the API business sells its products in over 80 countries, including the United States, various countries in the EU, South America and India.

Founder and Chairman
Gracias Saldanha

Leadership
Glenn Saldanha, Chairman & Managing Director

Revenue and Growth
Glenmark's consolidated revenue raised 12.44% to Rs. 25,634.74 Mn. For Q4 FY 2018-19. Sales from the formulation business in India for the fourth quarter ended March 31, 2019 was at Rs. 6,677.94 Mn. (USD 94.90 Mn.) as against Rs. 6,086.70 Mn. (USD 94.70 Mn.) in the previous corresponding quarter, recording a growth of 9.71%.

Primary Focus Areas
Glenmark specializes in Dermatology, Respiratory, Oncology, Cardiology, Diabetes and Anti-infective.

Company Presence In India
Glenmark continues to be one of the fastest growing companies in the Indian pharmaceutical industry with most of its core therapy areas witnessing an increase in market share. As per IQVIA MAT Mar 2019, Glenmark is ranked 14th in the Indian pharmaceutical market with market share of 2.18%. The company has 9 brands among the 'Top 300 Brands in the Indian Pharmaceutical Market.'
In April 2019, Glenmark launched its novel, patent protected and globally researched sodium glucose co-transporter-2 (SGLT2) inhibitor Remogliflozin etabonate in India to become the first company in the world to launch Remogliflozin.
Glenmark's consumer care business continues to strengthen, growing in excess of 35% in the fourth quarter of FY 2018-19. The three major brands – Candid Powder, VWash Plus, and Scalpe+ registered strong growth, and the company launched new products under these brands.

Research And Development
Glenmark's R&D center in Navi Mumbai, India (NCE Research), spread over 1,25,000 sq. ft., has end-to-end capabilities for discovery and development of New Chemical Entities (NCEs) from target selection to clinical development. The research facility is equipped with state-of-the-art infrastructure required to carry out research activities like medicinal chemistry, process & analytical chemistry, in vitro & in vivo studies as well as project management.

Corporate Social Responsibility
In line with their CSR policy, Glenmark's social initiatives are focused on improving child health and making healthcare accessible to the most disadvantaged and vulnerable segments of society. They also focus on promoting swimming as a sport in India and encouraging inclusive development by providing artificial limbs to people with physical disabilities. As part of its global employee volunteering initiative, 'Glenmark Joy of Giving,' company employees around the world devote time and effort towards contributing to society by spreading cheer in the lives of the less fortunate.■

LUPIN

Lupin is a leading global pharmaceutical company, headquartered in Mumbai, India, offering a wide range of products. With a presence in over 100 countries, Lupin offers high-quality yet affordable medicines addressing unmet needs in many parts of the world. The company's world-class manufacturing facilities are spread across India, Japan, the United States, Mexico and Brazil. These 18 facilities benchmarked to international standards are set up to meet stringent quality standards, playing a critical role in achieving their global growth aspirations. All of Lupin's facilities are approved by international regulatory agencies like USFDA, UK MHRA, Japan's MHLW, TGA Australia, WHO and the MCC South Africa.

Founder
Desh Bandhu Gupta (8 February 1938 – 26 June 2017)

Leadership
Ms. Vinita Gupta, CEO
Mr. Nilesh Deshbandhu Gupta, Managing Director

Primary Focus Areas
Lupin is a significant player in the therapy areas of Gynaecology, Cardiovascular, Diabetology, Asthma, Paediatric, Central Nervous System (CNS), Gastro Intestinal (GI), Anti-Infective (AI) and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). Lupin holds a global leadership position in the Anti-TB and Cephalosporins segments.

Products
Generics – Lupin's generics business manufactures and markets branded and unbranded generics products across markets.
Complex generics - over the past few years, they have made strategic investments in capabilities and infrastructure to create development expertise across complex generics (in particular, across long-acting injectables, inhalation and biosimilars).
Specialty - the specialty business demands higher investment outlay as well as focused management bandwidth. Lupin is directing their efforts in a very targeted manner and intend to leverage this infrastructure across multiple products in their chosen therapeutic areas.
In addition to these three segments, Lupin has other activities, primarily the sale of Active Pharmaceutical Ingredients (API) to third parties in more than 50 countries worldwide and institutional sales of important anti-TB products.

Research And Development
Lupin's investments in Research and Development (R&D) have helped them gain a leadership position in differentiated product introductions and become a formidable player in the generics space. It forms the base for further successes as they emerge gradually as a specialty pharmaceutical player. These investments are calibrated for risks and appropriate returns and encompass not merely the developed markets like United States, Europe and Japan but also the emerging markets.
Lupin's solid highly skilled research team of more than 1,500 R&D personnel is dedicated to developing products that cater to the unique requirements of distinct markets. The company's technologists employed at state-of-the-art facilities in India and abroad. They are well on track to emerge as an innovation led transnational pharmaceutical powerhouse providing affordable healthcare solutions with uncompromising quality.■

Shravil Patel

Managing Director
ZYDUS CADILA

Zydus Cadila ranks 4th in the Indian pharmaceutical industry, with a strong global presence in the US, Europe, Latin America and South Africa, alongside 25 other emerging markets worldwide.

As one of the leading pharmaceutical companies in India, could you introduce Zydus Cadila's core strengths to our international audience?
Zydus has been strongly focused on generics with the aim of creating access and affordability. The value of the company was driven by our ability to meet both of these two objectives for India and in global markets. Today, we are one of the top five pharmaceutical companies in India and the sixth largest in the United States by prescription volume. We also boast a research center that conducts end-to-end research from Preclinical to Phase III and New Drug Application (NDA) approval. Additionally, we have important programs running in hepatology and anemia that have been filed with the United States Food and Drug Administration (FDA) for Phase II and other studies. Finally, our first New Chemical Entity (NCE) has gained approval in India and Mexico, following to be launched in other developed markets as well. In our biologics venture, we bring to market over 20 biosimilars of which 11 have been commercialized in India and other emerging markets. Eleven vaccines are approved for the public and private market and another eight are under development.

A generics-based company, Zydus is extending its focus to biosimilars, NCEs and vaccines. What potential for growth do you see in this space?
Over the past 15 to 20 years, we have expanded our focus from small molecule generics to NCEs, biosimilars and vaccines in addition to a portfolio of eight molecules that are incremental innovations for the United States market specifically. In India, we continue to introduce new NCEs and fixed dose combinations that help improve patient adherence. Our growth trajectory is governed by innovation and introducing technologies that are difficult to replicate.
Out the top ten molecules globally, eight of them are biologicals. Therapies such as oncology and autoimmune are becoming more relevant, and a large part of the discovery is happening with large molecules. Our strategy was to make biosimilars available to India, because many top selling products were never launched in India by the innovator. We saw an opportunity to bring these medications to markets where there is an issue with access or affordability. We launched products at one fifth of the global price and now we work actively to improve diagnostics and increase awareness for these diseases.■

Mitanshu Shah

Sr. VP Finance
ALEMBIC PHARMACEUTICALS

Alembic Pharmaceuticals Ltd is involved in the manufacture of pharmaceutical products, pharmaceutical substances and intermediates.

Can you explain how Alembic was able to navigate entry into regulated export markets successfully?
We forayed in regulated markets with a degree of skepticism; we had been cautioned that the market was overcrowded. However, we observed in the United States, for example, that once all the boxes are ticked, there is a still good opportunity to grab a large share of the market, the main boxes being an unblemished track record with the FDA and strong relationships with distributors. Of course, challenges remain; for example, three big distributors control 90% of the U.S. market. Another strategy has been to focus on backward integration, relying on our own APIs till date. As other players were vacating the market, Alembic saw an opportunity to create traction. Europe, on the other hand, is a very fragmented, tender-based market, where price is the biggest contender. Nonetheless, we have been able to win tenders in Europe consistently.

What makes India an attractive destination for investment, and how will this attractiveness evolve in coming years?
The industry's journey to annual revenues of about US$38 billion today can be attributed to world-class capabilities in formulation development, the entrepreneurial ability of its firms and the vision of the industry to establish India's footprint in large international markets. The Indian pharmaceutical industry has attracted more than US$2 billion in FDI inflows over the last three years, making it one of the top sectors attracting FDI. Middle class income is growing in India, and many Western companies wish to leverage this huge potential. More importantly, India with its capabilities can improve its global market share to ~7% by 2030 from current market share of 3.6% by value. It will also mean Indian pharmaceutical market will break into top five markets in the world from its current ranking of 11th market by value. Considering this and the massive export potential and domestic demand, significant investment is sure to continue.■

Mohan Jain

Director

NAPROD LIFE SCIENCES

Naprod Life Sciences, part of Naprod Group, is a well-established manufacturer of finished dosage forms, with a specialization in aseptic processing and high-tech injectable medicines.

Can you briefly introduce Naprod Life Sciences and how the company fits into the wider NMM Group structure in terms of its capabilities and objectives?

At present, we have three separate companies: Naprod Life Sciences works in finished dosage forms, including anticancer injectables, high-tech lyophilized products and anticancer tablets. The second company Mac-Chem is focused on APIs used for formulating the medicines. We have manufacturing facilities to produce oncology APIs in bulk, which are then marketed in India as well as 20 additional countries. The third business, Miracalus Pharma, manufactures the injectable formulations that are used in the hospital segment.

Naprod is focused in the therapeutic area of oncology. It was started in the 1990s when the opportunity was observed to develop a specialized and niche product segment. We began a freeze drying technology called lyophilization, which required significant investment in addition to the investment needed to establish a dedicated manufacturing facility. Those constraints help us to maintain our competitive edge. Oncology products were developed by our own R&D center, which has been approved by the Government of India's Department of Industry and for the past 20 years we have introduced various generic formulations in the domestic market as well as in the international markets.

In terms of export focus, where do you see the most opportunity to broaden your international presence and what is your strategy to accomplish this?

We are present in most of the major export markets. The fastest growing market is Southeast Asia, where we are present in almost all countries. Our plant was also recently audited by Malaysia, and we expect to begin business there in 2020. The Latin American market is the second most important market for us and we are currently looking to collaborate with a local partner in countries such as Mexico where the trade barriers are challenging due to the regulatory environment.

What does the ideal partner look like?

We are looking for partners in the chemotherapy and hospital segments. As the company has grown, we have developed a speciality in aseptic processing and high-tech injectable medicines. We broadened this segment to include the injectables and we now want to grow in hospital product segment. Companies with a presence in hospital products are traditionally operated through B2B procurement model as promotional activities are very different in the corporate hospital setting. By working with companies already active in these spheres, we can leverage their experience and connections with our portfolio of specialized oncology products.

How have you observed demand for the Group's contract services evolve in India?

In India, there is idle contract manufacturing capacity due to different factors and government policies but our facilities are fully occupied. We see very strong demand for the specialized oncology products and lyophilized products. Similarly in the case of APIs, our facilities are fully occupied and we are currently outsourcing much of our own manufacturing. Similarly for Naprod, the facilities are currently utilizing the entire capacity and we are entering an expansion phase to increase the capacity by double or triple over the next year.

Can you elaborate on how government policy has impacted this dynamic?

Government policy towards the pharma industry has been focused on integrating the entire supply chain, which has drastically altered distribution channels. Local distributors that were operating on a small scale model are finding the business no longer viable. The second factor is the introduction of the drug pricing controls which the government has introduced to promote more affordable medications. While this has opened the India market by providing affordable medicines to wider sections of the population, at the same time there is a disconnect between affordable medicine and the opportunities in the export market. Whoever is able to balance the two will find success.

What final message would you share about Naprod Life Sciences and its objectives in the years to come?

We have a responsibility to serve our society because incidence of cancer continues to increase every year. WHO statistics indicate that the global cancer burden is estimated to have risen to 18.1 million new cases and 9.6 million deaths in 2018. We are proud to be able to provide world class medicines at affordable prices thereby support needy patients from across the globe.■

Bharat Desai

CMD

BHARAT PARENTERALS

Bharat Parenterals Limited is a research driven and forward looking pharmaceutical company with a dedicated facility for antiretroviral drugs as well as a facility for general and B-lactam group of drugs.

Bharat Parenterals is a Gujarat-based pharmaceutical company established in 1992. Since our team last met you in 2017, how has the company evolved?

We have grown by 50% in turnover as a result of entering new markets in Southeast Asia and Latin America. We have a multi-dosage facility in India, and given the stringent regulatory requirements, we are not aiming to enter regulated markets in the next 2-3 years, maintaining our focus on semi-regulated markets. We were facing a key constraint due to having a common facility for Penicillins and Cephalosporins, which we have addressed, and from October 2019 our third plant will be commencing commercial production to separate them both.

What are some of the requirements in order to be able to comply with different regulatory frameworks around the world?

We have a WHO GMP certified plant and Indian regulation does not require a separate facility for Penicillins and Cephalosporins, however both need to be manufactured under a different campaign basis production plan. Other countries that are our partners, such as the Philippines, Thailand and Malaysia, are no longer accepting our plant because of evolving regulation requirements through membership of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) treaty. We will invite such partners for a fresh inspection of our new facilities, and it is advantageous for us to take action now rather than wait until it is too late. Our immediate goal is to fortify our presence in all the countries we supply to by adhering to the rules of the regulatory bodies that govern these countries and their pharmaceutical industries.

Could you elaborate on the shift in focus from contract manufacturing to a branded product offering?

Till 2015, 75% of our exports were generics and the remaining 25% were branded products. We realized that we wanted to focus more on our brand recognition and consequently put a halt to contract manufacturing services in order to utilize our facilities for our own brands. We have implemented this in Southeast Asia and registered our own brands in Myanmar, Cambodia, Vietnam, Philippines and Sri Lanka. We are marketing our products ethically using our own brand name for the last three years. In some African countries where the business model differs because the government buying is larger than private buying, we have a dual model where we participate through our local partners for the government tenders and also promote our own branded products.

What are some of Bharat's ongoing research and development (R&D) projects ?

We have an in-house R&D department with robust formulations, and our CEO Mr. Bhahim Desai, who specialized in the anesthesia segment, recently developed a temperature-controlled anesthesia product with unique packaging that indicates whether or not an anesthesia is suitable for use after being stored under various temperatures.

We are not involved in the development of New Chemical Entities (NCEs), however we do focus on developing new drug delivery systems and formulations with more nuanced technology.

What are your comments on being awarded 'Outstanding SME' in 2018?

We are grateful and honored to have received this award for the second year in a row. From the company's inception we have taken social responsibility seriously, treated our employees well and adhered to government taxes and policies. It is encouraging to see the rewards for years of dedication to this.

What is your vision for Bharat Parenterals over the next five years and do you have a final message for our readership?

In 2018, we achieved INR 240 crores (~US$35 million) in revenue. In the coming few years, we will be making some strategic investments and are aiming to cross the INR 500 crores (~US$70 million) turnover mark by 2022. Our first goal was to boost our production capacity, which we have achieved by setting up independent Penicillin and Cephalosporin Production Units. We will focus on increasing our penetration into three key markets-LATAM, CIS and Southeast Asian countries. The company has been debt-free since 2005 and we plan to keep it that way while focusing on our growth trajectory.■

Sanjeev Dani & N. Govindarajan

SD: COO & Head of Formulations
NG: Managing Director
AUROBINDO PHARMA

Could you begin by highlighting the focus of Aurobindo Pharma today?
SD: Aurobindo is among the top two most valuable pharma companies in India, and it is a company defined by its global outlook. More than 80% of our revenues stem from formulations, whilst the remaining come from APIs, but these numbers only tell part of the story, because 75% of our formulations are based on the internal API manufacturing. The strength of our formulations relies on the API supply, which is a mark of our backward integration. In the formulations space, almost half of our business is in U.S. market, nearly 35% is from Europe, and the remaining comes from emerging markets and ARV products. Our ARV (antiretroviral) business a sizeable segment, which is primarily focused on supplying Africa and Latin American markets.

How does a broader geographic spread help to minimize risks and potential shocks?
NG: Risk mitigation can be looked at from a geographical viewpoint, but the product range is another relevant angle. In the generics industry in the United States and the European markets, manufacturers filing a product understandably wish their product to become a "star," but this ambition is far from guaranteed. Having a larger portfolio reduces the dependency on new molecules, and continues to have a push-model driven by the base business. One cannot predict the breadth of opportunity opened by a new product, there are many surprises that can arise, and this is why we cannot revolve our business around one single molecule. In fact, 65% of our molecules have a top three market position in the U.S. market, but our top selling product in the United States represents at most 4% of the business, whilst 25 molecules represent up to 35%, which shows our focus is evenly divided. With a larger and deeper product portfolio, we can accommodate supply shocks and maintain a sustainable growth.

Can you highlight Aurobindo's R&D focus?
NG: From the outside, it is difficult to understand why the complexity of molecules is important. For the past five to 10 years, Aurobindo has been investing in complex molecules and their platforms. For example, by the beginning of next year we will be filing 70 oncological molecules from our subsidy Eugea. We have done R&D in terms of peptides, which have been forward integrated to develop depo injections-our depo injection will be filed by the next calendar year. Similarly, the acquisition of Sandoz is also bringing us a strong derma portfolio. We seek to make progress towards more complex products, not for the sake of complexity, but because the medical needs have become more complex.
SD: The focus in R&D is not limited to NDDS or one segment of complexity, but on overall complex products – products that are difficult to make. For instance, in the injectables supply, many players may have the approvals in hand, but they cannot scale-up their offering, or cannot meet the cost point or volume. This is a space where we can step in and meet those needs. Aurobindo has just started its program in biosimilars, and we are leapfrogging. As of the latest publicly available information, we had six biosimilar programs, with the first due to be commercialized by the end of 2021.

What is Aurobindo's strategy for growth moving forward?
SD: The strategic direction in Europe is driven by both organic and inorganic growth, having made key acquisitions and launching organically developed products. In terms of inorganic growth, this year we expect to complete two major acquisitions, Apotex's Europe business acquired in February 2019, and Sandoz', which may happen by the end of the year. These acquisitions will help us not only to scale up, but also to expand into therapeutic areas (dermatology), access new markets (Eastern Europe) and sustain our future growth.
NG: Before looking at other large acquisitions in India, it is crucial for us to integrate Sandoz's business in the next 18 months. Depth is very important to us, and we don't want to go overboard. Looking at our oncology, biologics, vaccines segments, these will all require between five to seven years before they are commercialized, and only after can we look at the next level of future investment. ■

Aurobindo is a fully integrated pharma company featuring among the top two companies in India in terms of consolidated revenues.

Lara Yumi Tsuji Bezerra

Managing Director
ROCHE INDIA

Roche was founded in 1986 in Switzerland and is now the world's largest biotech company, with 17 biopharmaceuticals on the market. Roche is also a market leader in cancer treatment.

What is the role of multinationals such as Roche in the Indian pharmaceuticals market?
Roche is an innovator drug company with the therapies and medicines that have been a result of years of research to create groundbreaking treatments. Oncology and cancer immunotherapy are two areas where we have discovered treatments for illnesses that often had no cure. Bringing global expertise and innovation to India assures the availability of innovative treatments options for better disease management and better standard of care. With our local strategy in India we are able to focus on access to medicine and bring diverse knowledge to support local stakeholders. This approach has helped us to go beyond the traditional approach and impact more lives.

What is the government's role to ensure healthy competition in India?
There is a huge opportunity in India because right now healthcare is in the focus of the government and the private sector. The question is, the challenges that we have right now were created by a health system that we had in the past; that will not be the health system of the future.
If we l work with these challenges right now, we might solve them, but we will not create the health system that is needed for the future. So we acknowledge the challenges that we have now, but we look at what is the health system that we would have in the next few years. Because by that time, India will be the third biggest economy in the world. We will be able to allocate resources to healthcare. And when we are going in this direction, how can we think about building the ecosystem in a way that it is ready when we arrive there? We need to then adapt and change to standards of care than are much better than we have today. If we go (ahead) thinking about universal healthcare, both public and private sector should work together to develop technology for better healthcare for patients, the best value and outcomes for patients. So that when we arrive there, the technology is almost ready, and we adapt it accordingly.■

Dr. Kunal Saxena

Managing Director
RUSAN PHARMA

Rusan Pharma is a fully integrated global pharmaceutical company specializing in the treatment of addiction and pain management.

Rusan Pharma has adopted a path towards backward integration. Could you elaborate on the strategy behind this decision?
Integration back to the opium crop has been a vision of Rusan, and we are one of the only private companies in India granted a trial cultivation license to legally cultivate the opium crop and extract the alkaloids that are used as starting material for the manufacture of the APIs for most of the pain and addiction treatment medications. This will enable Rusan to be integrated right from the crop to finished formulations and enabling us to tap the unmet potential of the emerging markets for pain and addiction treatment medications at affordable prices.

Drug Delivery Systems (DDS) have been a particular focus in Rusan Pharma's innovation efforts. Can you elaborate on why this has been the case?
Backward integration to the crop and API is not the only solution to growth; innovation of new platform technologies and new DDS holds the key to success. In 2016, we launched two independent companies namely: Quantys Clinical Pvt. Ltd, a 104 bed CRO and Navin Saxena Research & Technologies (NSRT) Pvt Ltd, which is a state-of-the-art R&D center where we focus on various novel platform technologies, like trans-dermal patches, implants and abuse-deterrent technology. The Center boasts of a from computer-aided drug design division, which focuses on NCEs for overdose deaths due to novel fentanyl analogues such as carfentanil (10,000 times more potent than morphine and 100 times more potent than fentanyl) and is now fueling the opioid crisis in the United States. NSRT also focuses on areas including Parkinson's, Alzheimers, schizophrenia, orphan drugs, zika, dengue, malaria and new technologies for needle-free deliveries. The delivery forms that we are working on are tailored to ensuring better patient compliance. For example, we are working on various opioid partial agonist or antagonist implants and depot injections capable of effectively managing drug and alcohol addiction for a period 1 to 6 months. We are already partnering with various U.S. based companies and funding agencies to co-develop such innovative sustained release products. ■

APIs, Intermediates and Excipients

"Up to 90% of India's raw materials were dependent on China. Nowadays, we have responded to external threats through backward integration, by making intermediates in-house to safeguarded ourselves from tumults in the global supply. Opportunities for backward integration are fruitful in India, because we benefit from a strong infrastructure and manpower. But our API industry needs to move away from its dependency on China, which makes us very keen to develop our advanced intermediates and basic raw materials."

- Ramesh Chodvadiya,
CEO,
Prudence Pharma Chem

Image courtesy of Sai Life Sciences

APIs, Intermediates and Excipients

India's API Industry: Exporting to the World

Image courtesy of Naprod Life Sciences

India's active pharmaceutical ingredients (API) industry has come a long way since the 1980s when the pharma industry was heavily reliant on API exports from Europe. The domestic consumption market for APIs is expected to have a CAGR of 10% between 2015 and 2022, with the industry expected to reach a size of US$18.8 billion by FY2022, according to RNCOS. In 2016, India's global generic API merchant market share was 7.2%, the third-largest when the last record was taken, according to the IBEF. Since then, India's share has significantly increased as a result of the country becoming a major exporter to all key markets, including China. "Three years ago, India was importing APIs from China and now, Indian companies are exporting to China," underlined Girish Chovatia, chairman and managing director of Ami Life Sciences – a generic API manufacturer. "One of the reasons for this reversed scenario the number of knowledgeable scientists and pharmacists in India. Furthermore, Chinese manufacturers have curtailed mass production due to environmental issues. With standardized and stringent global regulatory requirements, the same norms apply to all the producers in the world. In China, the pharmaceutical and chemical industry contributes 3% to its GDP, but accounts for 37% of overall pollution levels. Because of this, the Chinese government is focusing more on the engineering and digital industries. But in India, the pharmaceutical and chemical industry is focused on talent, raw material availability and the capacity to deliver."

Is China's Loss India's Gain?

Radical environmental policies have been implemented under Xi Jinping, the Chinese president, over the past five years, in an attempt to curb high levels of pollution in China. Thousands of manufacturing facilities across a number of industries have been shut down as a result of failing the required high environmental standards. This has left a vacuum of global supply given the reliance of so many countries on Chinese products. "Due to current environmental issues in China, the intermediates and even bulk drugs supply situation is completely disrupted," underlined Ravindra Jagtap, managing director at Aastrid Life Sciences. "To mitigate the risk of depending on China, a number of domestic as well as international manufacturers of pharmaceuticals are now looking for supplies from reliable Indian companies."

China's current situation has opened the door for India's API manufacturers to take a greater share of the global market and export to China. However, Indian pharma companies are still reliant on certain Chinese firms for APIs and the 25% to 30% increase in prices for Chinese APIs due to the reduction of supply has been felt by the industry.

India's Department of Pharmaceuticals (DoP) has tried to increase local supply and reduce the reliance on imports. A policy proposal released in August 2019 outlined plans for price controls and procurement programs that favor locally-made APIs so as to reduce a reliance on imported ingredients and intermediates. This also included a proposal for products made by local firms to be exempt from price caps for five years. The DoP's policy proposal, in line with the 'Make in India' initiative – which has prioritized the manufacturing of products within India – is another encouraging sign for an industry that has previously been so reliant on imports.

> These neighboring countries have recently set up formulations companies, but they continue to lack API manufacturers and thus they rely on India as a first destination to purchase APIs.
>
> - Yogin Majmudar, Managing Director, Bakul Group

Apart from the aforementioned opportunities, India is also seeing an increase of API exports to neighboring countries like Pakistan and Bangladesh. Although both

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Arun D. Joshi

Chairman and Managing Director
SURYA LIFE SCIENCES

Established in the year 2002, Surya Lifesciences has gained recognition worldwide as a manufacturer, exporter, and supplier of a wide assortment of highest quality bulk drug intermediates and fine API chemicals.

Could you introduce Surya to our global readership?

The word “Surya” means "sun" and it conveys omnipresence, which demarks our objective: to become global leaders in what we do. Growing at an accelerated rate of 30% yearly, Surya relies on four plants, with our newest operations at a fifth facility beginning in Indore. We also have a joint venture with a Japanese company to create an electronic molecule, currently supplied by only one manufacturer in the world. We have emphasized multidirectional progress spanning different verticals, including pharmaceuticals (API), nutraceuticals, electronic chemicals, speciality molecules and formulations so that market shifts do not shake us. Our ratio across sectors is very even, with about 20% to 25% in each of these sectors.

How has an emphasis on innovation allowed Surya to stay ahead of market trends over the past two decades?

Innovation has been the driving force of our business, having received the "Innovator of the year" award from the Chamber of Commerce (FICCI) for three years. This award was earned on the basis of our R&D acumen, flow chemistry and green chemistry. Flow chemistry is one of the latest concepts in the engineering of any chemical; we are able to manufacture a chemical in large quantities, as well as ensuring good quality and safety standards, using very compact and effective equipment.

Green chemistry is the second important concept. Through green chemistry, everything that is produced is relative to an adjustment of reactant and pollutant that needs to be filtered out in an environmentally friendly manner. If this basic concept is followed, the business is sustainable and viable in the future.

How does your commitment to R&D translate to good environmental practices?

The R&D underpinning our innovation and high-end capabilities is also aligned with supporting environmental goals. We are constantly working on our process developments with an angle on environmental safety, and we impose a strict control on our effluents. The government of India takes a very strict stance on environmental grounds, and we embrace this approach because it motivates us to undertake actions in creating new technology and to operate an effective R&D program that is recognized by the Department of Scientific and Industrial Research (DISR).

Our core focus is technology, and through unique processes and unique operations in every product that we make, we take great care of the details, from environmental aspects, to safety and quality. The latest innovation in the development process would be the addition of an ultrasonic reactor, and we utilize ultra microwave technology for the treatment of effluent, for which we have patent papers under review.

Can you elaborate on the scope of your product portfolio?

In the API business, we have ingredients in hypertension and diabetes treatment. Additionally, we make painkillers, anti-allergic, anti-depression, antitussives, xanthines, cardiovascular, anesthetics, aroma fine chemical and special electronic chemicals. Our plant has been recognized by Korea and Japan as destinations for supply. In the cosmetics field, many natural medicines are becoming popular with the realization that allopathic products risk harming the skin. This trend in demand galvanized our focus on herbal cosmetics and medicines and nutraceuticals. We also use our facility for contract manufacturing for international clients, offering scale-up services.

Surya is not just in the copy-paste business: when we take on a project, we fully engage in the development of that product. Our clients can expect from us to go the extra mile, and bring additional input. For instance, we use hydrogenation, a process many are reluctant to embrace due to its highly explosive nature, but Surya has a strong quality and safety system that is reassuring to our clients.

What are Surya’s priorities in the near future?

Surya is doing very well in India where we see both opportunities and hurdles, and we have already decided to cross the border to bring our name and fame worldwide. We are looking for ventures around the world, and we are open to importing technology as well as develop our own technology. In Oman, for example, we have joint ventures to provide medicines and formulations, and our next step after Oman will be expanding the business to Malta by setting a plant there. This represents a strategic geographical point of operation from where we can manoeuvre our exports to Africa.■

countries have fledgling pharmaceutical industries, they lack the adequate API manufacturers. “These neighboring countries have recently set up formulations companies, but they continue to lack API manufacturers and thus they rely on India as a first destination to purchase APIs,” remarked Yogin Majmudar, managing director at Bakul Group.

A lack of a substantial capital investment or subsidies for manufacturers has held India’s pharma industry back in previous years. With allocated special economic zones (SEZs) to support manufacturers and procurement programs in place to favor local firms, there should be added incentive for the local API industry to take full advantage of the window of opportunity being presented by the events happening in China.

A Move to Specialty and Green API Production

As India aims to increase its global share of the API market, manufacturers find themselves with an opportunity to add value to their portfolios. A core focus has been the shift to embrace green chemistry. R&D in the API space has seen the creation of novel synthetic routes to the creation of more efficient and environmentally friendly alternatives. The concepts of ‘flow chemistry’ and ‘green chemistry’ have also gained more significance as more sustainable approaches are being demanded by both market and regulations. “We are constantly working on our process developments with an angle on environmental safety, and we

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> The ‘Make in India’ initiative is one of the strongest programs that has been launched in the industrial development of pharmaceuticals. But what helped increase the country’s API business even further was the Chinese government’s implementation of restrictions on pollution. Many plants have now shut down in China because they could not comply with these new environmental regulations, and some of these Chinese companies came to Atman Pharmaceuticals to request products from the Indian market.
>
> **- Atman Parekh, Director, Atman Pharmaceuticals**

Ravindra Jagtap

Managing Director
AASTRID LIFE SCIENCES

Aastrid Life Sciences is a research-based manufacturer of intermediates and fine & speciality chemicals.

Could you provide a brief introduction to Aastrid Life Sciences and highlight your core product offering and key strategic markets?

Aastrid Life Sciences is an associate company of Aastrid International Pvt. Ltd., a pharmaceutical export business founded in 1997. We export APIs and bulk drugs to over 50 countries. In 2011, we decided to venture into the manufacturing of advanced pharmaceutical intermediates and launched Aastrid Life Sciences.

Initially, we set up our R&D Centre because we were keen to have R&D even before we started manufacturing. We see many small and medium size companies in India are struggling because they do not have their own R&D facility and depend on other companies for technology, and for this reason they cannot improve further process and remain competitive. In 2013, we acquired a sick unit and refurbished it completely to commence our manufacturing operations for advanced pharmaceutical intermediates. In 2014, we obtained approval from the DSIR (Department of Scientific & Industrial Research) and received recognition for our R&D Centre. We are also implementing the ISO 9001:2015 Quality Management Systems at both our sites. Recently we have also received GMP Certificate from TUV Nord India, a third party certification body.

What is your strategy to find clients in international markets?

Our office in China helps us identify opportunities and they study the potential of shortlisted products in terms of number of manufacturers for this product, their capacities, prices, current status and also prospective customers in India and worldwide.

We make use of this experience while selecting niche molecules where the supplies have been disrupted and thus customers are now looking for alternate vendors. With the help of our R&D, we develop niche molecules and then commercialize them. We make use of a large database of bulk drug manufacturers all over the world and contact our prospective customers for their requirements.

Could you elaborate on your commitment to R&D and highlight some of Aastrid Life Sciences' key activities for its clients?

We basically work on the process development for generics and use different routes of synthesis to try and make the process more viable and competitive. For example, we started to develop a molecule that was 100% exported from China to the rest of the world. Today Aastrid has become the number one manufacturer of this molecule in the world, and in fact Chinese factories have stopped producing it completely.

Our company has successfully developed and synthesized over 350 different molecules in the last six years. The success of Aastrid is based on R&D and our growth has been 60% to 70% year on year for the last three years. In CPhI 2018, Aastrid received a prestigious award for 'Make in India' Enablement category and thus our efforts for developing indigenous technologies and reducing dependence on China wee acknowledged by industry experts.

How has the change in regulatory framework over the last few years affected your business?

Since our inception, we have been conscientious about maintaining our QMS (Quality Management Systems). It was very challenging to implement a quality assurance at first as we made efforts to train our team and then implement the system. We are happy that over time we developed a robust system, and we have been benefited because of this initiative, which has helped us to develop business with the top pharma companies within a very short period.

What is your vision for Aastrid Life Sciences in the next three to five years?

We have already commissioned our greenfield project and plan to complete it in two phases. This will create additional capacities for us to grow our business. We want to take our revenues from US$40 million to US$55 million (INR 300 to INR 400 crores) in the next five years. We want to continue focusing on advanced intermediates and do not plan to enter APIs and formulations because we are very successful in this sphere.■

Image courtesy of Torrent Pharmaceuticals

impose a strict control on our effluents," highlighted Arun Doshi, chairman and managing director at Surya Lifesciences. "The government of India takes a very strict stance on environmental grounds and we embrace this strictness because it is motivating us to undertake actions to create new technologies and to operate an effective R&D that is recognized by the DISR (Department of Scientific and Industrial Research)."

There are ample opportunities presenting themselves in the API markets as manufacturers look to add value from green or specialized products. There has also been a trend of formulation companies venturing into API production and vice versa, which is set to ensure greater security across the industry. This move will most likely create more value within India's pharmaceutical sector and add to its vision of becoming a more specialized and customized industry.

> There are many opportunities for Indian companies, and the government has also been very supportive with Make in India initiative. I am sure the Chinese manufacturers will improve their systems and get back to the market aggressively in a few years, but in the meanwhile, we must look to grab the best opportunities and product openings which fit with our line of chemistry.
>
> - Gaurav Mohatta, Director, Benzo Chem Industries

India's Excipient Market Share Growing Exponentially

The continued growth of India's API sector, especially through increased exports, is set to benefit the country's producers of excipients and intermediates directly. India's excipients market is currently growing at 10% to 12%, according to Beroe, twice as fast as the global average.

The reasons for both Indian and global excipient market growth include the advancement of functional excipients, increasing uptake

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Prashant Nagre

CEO
FERMENTA BIOTECH

Fermenta Biotech Ltd. (FBL) is one of the top three producers of Vitamin D3 API in the world, as well as a provider of immobilized enzymes and enzyme technologies.

Fermenta Biotech Ltd (FBL) is one of the top three producers of Vitamin D3 API in the world, and the only one in India. What has propelled FBL to take this lead and how does it maintain its unique market position?

We have been in the active production of Vitamin D for over 50 years, which makes us one of the oldest continuous producers of this molecule in this world. Vitamin D is the only vitamin that the body produces on its own, and 20 minutes spent in the afternoon sun is the best way of getting this vitamin. The health value of Vitamin D has increased exponentially over the years, and 2005 to 2010 was a transformational period for Vitamin D research; until then, Vitamin D was considered to be beneficial to the bones, but intense medical scrutiny now established that Vitamin D deficiency is linked with a much broader range of health benefits, from prevention of diabetes, heart diseases, infertility and mental illness, along with being associated with immunity and general wellbeing.

Together with these findings, in the past 20 to 30 years we have seen an urban shift accompanied by lifestyle changes defined by less time spent outdoors, resulting in less exposure to the sun and lower Vitamin D production. In this scenario, food fortification and supplementation become key alternative sources. By 2017, Vitamin D became the second most researched vitamin, with more than 4,000 research publications coming out annually over the last few years. Demand for Vitamin D has been steadily growing, and we need to meet it by increasing capacities and capabilities. 10 years ago, we had a very small presence abroad, but today we export almost all over the world. We offer Vitamin D into the pharmaceutical, nutrition and dietary supplements, food, veterinary, animal feed and rodenticides sectors. In terms of turnover, around 80% of our business is in Vitamin D.

FBL is also active in the biotech space. What is your competitive advantage in this area?

The biotech division contributes less than 10% of the overall revenue of the company, but it remains a focus area with great potential, especially in green chemistry. In this very knowledge-intensive industry, having been in the business for over 30 years grants FBL a key advantage. Starting in 1987, we have improved the process from genetic engineering to fermentation purification enzymes. The last step is "immobilization," which means that you can reuse the enzyme from the first reaction into the second and third one, making the enzymatic reactions economical. If we are to replace traditional chemistry, the alternative has to be environmentally friendly, but also economical in order to be accepted by the industry.

We have also been at the forefront for enzymatic solutions for synthesis of penicillin G derivatives, and we have gradually carried that knowledge to the next level into first generation cephalosporin antibiotics. Currently, FBL is working with both Indian and foreign companies to demonstrate that there are friendlier ways to produce first generation antibiotics by enzymatic processes. Our heritage of working in this field for decades is a unique selling point.

FBL's sewage treatment plants also use biotechnology in an innovative way. How do you expect this aspect of your business to develop moving forward?

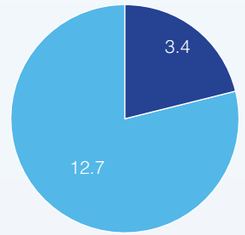
Today, regulation, together with accountability to your own customers, means that investment in waste streams is a must. In India, the drive to urbanization has made sewage a new problem that is being encountered. With our background of biotechnology, we had access to proprietary-consortium microorganisms, which are very efficient in degrading sewage. For the last 10 years, we have tried our hand in introducing this product, to improve the degradation process of domestic sewage.

The wastewater division is the third and smallest arm of the business, contributing 1% of total revenues, but we are expecting it will flourish in the future. Currently, we provide integrated solutions on wastewater for domestic purposes. We also work with industries that utilize an organic digestible ingredient, like the milk industry. Whilst small, this sector is very interesting because it represents a convergence of science, engineering and biotechnology.■

KEY STATISTICS (EXPORTS)

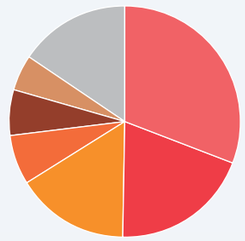
India's Export of Pharmaceuticals to World (US$ Billion)

Source: Food & Drugs Control Administration, Guajarat State



Top Geographic Areas of Export

Source: IBEF

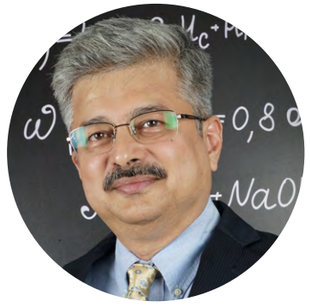


North America	31%
Africa	19.4%
EU	15.9%
ASEAN	15.3%
LAC	6.8%
Middle East	6.6%
Others	5.0%

"When we started in 2003, most iodine derivatives were imported because they could only be found in countries such as Chile and Japan, leaving India as a 100% importer. Today, India continues to be an importer and iodine derivatives continue to be a critical but rarely available material. While there were iodine derivative manufacturers for basic intermediates in India, the manufacturers for advanced intermediates were lacking. We identified this opportunity and started our business to create a niche segment in iodine chemistry.

- Sanjay Patel, Managing Director Infinium Pharmachem

of biologics and the rising adoption of orphan drugs. Many companies are focusing more on excipients to address issues such as segregation, low dissolution and poor bioavailability. Although the small global excipient market is dominated by the United States, Europe and Japan – contributing a combined 85% to the global market – India continues to be seen as increasingly attractive destination. Buoyed by the lower costs of raw materials and labor, domestic and global players have increased their footprint within the country through joint ventures and organic growth.■



Rahul Nachane

Managing Director
NGL FINE CHEM

NGL Fine Chem is a manufacturer of pharmaceuticals and intermediates for usage in the veterinary and human health.

NGL Fine Chem has been in the industry for 38 years. Could you give an overview of how the company has changed over the years?
The company started off as a human API company in 1981, with a single manufacturing unit in Navi Mumbai. In 1994, NGL Fine Chem went public, but the following years saw many ups and downs. This is when we had to shift our attention from mass scale production to small volume, higher value products. In parallel to this shift, we also moved towards veterinary products. Today, we are the second largest veterinary drug producer in this country.

What was behind this dramatic overhaul that took place in the 2000s, and how has the market evolved since?
I could not say that the transformation of the company in 2000 was a premeditated step, but what happened is that we came across a gap in veterinary products, and for the next 10 years we continued expanding our product range in this space.
It is worth keeping in mind that almost 70% of the products used in the veterinary business are human-health products, and thus have a dual use. However, there are certain products that are unique to veterinary application. For example, animals have a higher likelihood of ingesting worms, which attack tissues, lungs, intestines or the heart. We provide a wide range of products to meet this kind of disease and offer a variety of anthelmintics. Another important focus is in anti-protozoals, to protect farm animals from blood infection diseases transmitted by insects, pests, or mites. We retained a very small focus in human health, which contributes to around 5% of our sales. The rest of 95% of our business is veterinary.

How did the crackdown on pollution in impact your business and how do you see this dynamic playing out in the future?
The clampdown on pollution in China was not restricted to APIs but also to chemicals; in fact, it affected the chemicals industry more than pharma. The result has been a steep rise in prices for chemical compounds, which picked up in early 2017. Pharmaceutical companies were also affected and had to increase their prices. Some factories even closed down, which created an opportunity for Indian companies.
Before all of this happened, some Indian products were simply not competitive against Chinese-made products. The environmental restrictions in China eroded the price advantage China had, hence opening doors for India, not just in pharma, but also in chemicals and pesticides. Most importantly though, it created a shift in customer mentality, who are now thinking that it is not enough to have just two suppliers, but two suppliers in two different countries as insurance against policy and economic changes. Today, we talk about environmental laws, and tomorrow it could be a political upheaval; buyers need to plan to minimize risks.

NGL Fine Chem invested up to 2% of its profits in CSR activities in the past three years. How do you choose where to focus your CSR contribution?
For the past three years we have observed different projects, and based on their progress, we increased our involvement accordingly. For example, there is an eye hospital in Navi Mumbai that conducts free surgeries for patients from lower economic backgrounds; we started with small donations, but last year our contribution increased fivefold. CSR is not just about giving the check and closing your eyes – one needs to follow through to make sure the money gets into the right hands, and we have witnessed the great impact of our support.

This financial year, NGL Fine Chem enjoyed over 30% growth. How will you sustain this solid growth movng forward?
In the veterinary market, there are three segments by the target receivers: mammals, birds and fish. Currently, NGL Fine Chem is present in the mammals' space, but planning to launch products for the poultry market this year. The products that we have at this moment are essentially the bread and butter of the veterinary business, with an ample focus on farm animals and mammals. We also have a few phosphorous compounds to stimulate animal growth. With a strong product base, and having just commissioned an expansion, we hope to grow at least 20% every year. Additionally, we are creating a land bank with three parcels of land ready to be used to set up new plants.
growth. We have investment from the state, the City, key institutions and stakeholders to grow the industry. We are on the cusp of a breakthrough in becoming one of the most important hubs within the United States for biotech drug development. ■

Girish Chovatia

Chairman and Managing Director
AMI LIFESCIENCES

Ami Life Sciences is research driven generic API manufacturer as well as working on custom synthesis of New Chemical Entities.

Could you introduce Ami Lifesciences to our international audience, highlighting your most recent developments?
Ami Lifesciences started in 2006 in the API domain, and since then we have been growing year on year at a rate of around 25%. Our presence internationally spans to 52 countries, currently employing 900 people and relying on four factories in India. We are a generic API manufacturer, partnering with innovator companies like Sanofi, ABC Pharmaceutics, TRB and Dainippon in Japan. Our facility is EuGMP certified, and Ami Lifesciences focuses on targeting markets with high populations such as Japan, China, Brazil, Egypt, Iran and other EU countries. Ami Lifesciences is currently working in 11 therapeutic categories, with a major focus on anti-diabetic, pain management, CNS and respiratory. Ami Lifesciences emphasizes niche molecules rather than generic ones to create expertise in the complex generics where there are fewer players and greater demand in terms of technological advancement. An important milestone is that this year we will be adding our biological division, inoculating our focus on niche molecules.

What is Ami Lifesciences strategy when entering a new market?
To establish network in any of our key markets, we first need to create brand recognition and awareness of our presence in our target market. We do so by popularizing one product, say a simple molecule for cough and cold, which is a common disease. High sales from a single molecule spread the name of the company. Later, we follow with the introduction of more complex molecule in the same country, steadily building the reputation to cater to the needs of our customers.

China represents one of Ami's Lifesciences key export markets for APIs. How do you as an Indian manufacturer compete with Chinese products?
Before 1985, Europe was exporting APIs to India, but now this flow has reversed. Similarly, three years ago India was importing APIs from China, and now Indian companies are exporting to China. One of the reasons for this reversed scenario is the growing number of knowledgeable scientists and pharmacists in India. Furthermore, Chinese manufacturers have curtailed mass production due to environmental issues. In China, the pharmaceutical and chemical industry contributes 3% to their GDP, but account for 37% of pollution, and because of this proportion the Chinese government is focusing more on engineering and digital industries. However in India, pharmaceutical and chemical industry is focused because of concentrated talent, raw material availability and the capacity to deliver.

How does Ami Lifesciences embed environmental protection measures into its manufacturing practices?
Ami Lifesciences manufactures APIs based on enzymatic chemistry where there is less pollution and less solid waste. As a leader in the pharmaceutical company, we make advanced predictions for the future, thinking ten years ahead in every decision. We are ahead of the curve in our adoption of the latest technology, such as our soil-based water treatment technology, biological treatment, spray dryers and more. There is a common misunderstanding that waste water can only be processed using more (fresh) water, but we believe this is a waste in itself. To purify the wastewater, soil-based treatment is far preferred option. Environment is a top priority for us.

Due to the low barriers to entry, pharmaceuticals remains a competitive market in India. How does Ami Lifesciences utilize innovation to stay ahead in this market?
Our main strategy is to focus on the latest technological advancements and implementation of non-conventional technology, by adopting enzymatic and biological routes, as well automation and semi-automation in our processes. As long as we are selling good quality APIs at affordable prices and that benefit our patients, we don't concentrate on filing patents.

What is the vision for Ami Lifesciences in 10 years' time?
Our vision is simple: to be a billion-dollar company by 2024. We have been partnering with many multinational companies from North and Latin America, Asia, and Europe, and now we are focusing on targeting emerging markets.■

Services and Support

"What we notice now is that clients are very selective about their suppliers, demanding quality services, with arrangements such as fixing a system breakdown in less than 24 hours. Some companies will even want to take a look at the offices and lab, or even check the accounts of their suppliers."

- Akshay Charegaonkar,
Director,
Anchrom Enterprises

Image courtesy of Athena Drug Delivery Solutions

Services and Support

Contract services adapt to serve an increasingly quality-focused industry

The global pharma contract services industry, which includes contract development and manufacturing organizations (CDMO) and contract research organizations (CRO), has been growing exponentially over the past decade. As a result of the increased costs of developing and manufacturing new drugs, large pharma and biotechs outsourcing to contractors has become the norm. As large pharma, especially in the United States and Europe, look to increase margins whilst mitigating risks, the number of CDMOs across Asia has been steadily increasing. India, due to its talent pool and many WHO-GMP approved facilities has become a top destination. "Regulations in India have gradually become more transparent and comprehensive and, while ensuring the rights and safety of patients and volunteers on one hand, these are also supportive of the clinical research industry in India," said Ajay Tandon, executive director of Veeda Clinical Research, which has three clinical facilities to conduct studies ranging from bioequivalence in healthy volunteers to PK, PD and Clinical End point studies. "The new clinical trial rules released in March 2019 have helped compile and clarify the rules, which is very helpful for us as well as our sponsors who have come to expect clarity as they see in many other jurisdictions globally," he added.

"We see very strong demand for specialized oncology products and lyophilized products," remarked Mohan Jain, director at Naprod Life Sciences, a contract manufacturer headquartered in Mumbai. "Similarly, in the case of APIs, our facilities are fully occupied and we are currently outsourcing much of our own manufacturing. For Naprod, the facilities are currently utilizing the entire capacity and we are entering an expansion phase to increase the capacity by double or triple over the next year."

Naprod Life Sciences' story is a typical example of India's contract services segment as one of a number of SMEs that is seeing increasing demand, both in the domestic and international market, for its services by specializing in a specific therapeutic area. The substantially lower cost of operation and production has led a number of multinationals to both small and large Indian firms.

Similarly, Sai Life Sciences has seen growing demand for its service offering, which caters to innovative clients and the burgeoning client base in the biotech space, and quality and specialized services are fundamental to success. "Unquestionably, there is an increase in the demand for outsourcing services. But one should keep in mind the clear distinction that it is only a small share of the market, typically the top providers, who absorb this business," commented Krishna Kanumuri, CEO, continuing: "Growth in this area stems from building superior infrastructure, matched by world-class quality and safety systems. Our business is quintessentially driven by the quality of product we offer, in contrast to the low-cost model that India is otherwise known for."

Indeed, the contract research organizations (CROs) segment is forecasted to grow at 12% this year in India. With the ever-increasing number of biotechs, especially in the U.S. biotech superclusters, there will be an increasing demand on CROs. When asked to underpin factors for CRO growth in India, Mani Kantipudi, CEO at GVK Bio – a global contract research & development organization providing drug discovery and development services to the biopharma industry – said: "Global biotech funding continues to increase. To my knowledge, three new companies are being set up every week in Boston. These companies are usually virtual, originating in academic institutes like Harvard, MIT and others, and they look to outsource to CRO providers. Secondly, large pharma companies continue to outsource in more areas."

While the contract services market remains highly fragmented in India, this may begin to change in the coming decade. The global CDMO and CRO markets have become increasingly consolidated over the past five years. As of late-2018, the top five CDMOS – Lonza, Catalent, Patheon (acquired by Thermo Scientific in August 2017 for US$7.2 billion), Recipharm and Siegfried – accounted for 15% of overall market share, and the top five CROs controlled 70% of market share, according to Kurmann Partners. With compliance and international regulations becoming ever-more stringent globally, there will be more pressure on SMEs in India to evolve to changing standards in the contract services space.

In the meantime, leading providers in India are keeping pace with their counterparts around the globe and looking to expand their international presence through inorganic growth exercises. Ahmedabad-based Lambda Therapeutic Research, which provides a full spectrum drug development services to the global biopharmaceutical, innovator and generic drug industries with a special focus on late stage oncology studies, recently acquired Novum Pharmaceutical Research

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> The Government plays a pivotal role in the pharmaceutical industry. However, there are no substantial incentives in place to go green; it is up to the initiative and responsibility of individual companies to become more sustainable. Vishva is one of the few companies that is green on its own initiative and has in-house green architects & engineering team.
>
> - Vishu Bhoosnurmath, Managing Director, Vishva Protech

Krishna Kanumuri

CEO

SAI LIFE SCIENCES

Sai Life Sciences delivers advanced Discovery, Contract Development and Manufacturing Solutions, through a broad suite of expert capabilities across the molecular lifecycle.

Sai Life Sciences has been in existence for two decades now. What are some of the milestones that have marked the company's development over the years?

For a company that started in a small laboratory with two fume hoods, we've come a long way in our quest of bringing new medicines to life! Over the past two decades, we have supported several innovator pharma and biotech customers discover, develop and manufacture innovative new medicines, and make the lives of patients better. Sai Life Sciences is today one of the fastest growing contract research and manufacturing organizations. Over the past five to six years, we have grown consistently at CAGR of 15%. This is equally divided into three main segments, namely discovery, clinical development and commercial manufacturing. Today we focus on contract research and development, as well as manufacturing. We are on an upward growth trend, as illustrated by our clients, who are seven out of the top 10 pharma companies in the world. Our focus is entirely international, with the United States, Europe and Japan as the three main markets. Backed by our investors TPG Capital and HBM Partners, we are making significant investments in augmenting our R&D and manufacturing capabilities.

How does Sai Life Sciences maintain its strong track record in quality control?

Sai Life Sciences' core objective is to set benchmarks in two key aspects: quality and safety. 60% of our quality systems are online based, and hence paperless. The goal is to be have paperless manufacturing by the end of the year. Our plants are almost fully automated and thus very well documented. Our technology is latest generation. However, the biggest aspect that sets us apart is the training that we provide to our employees. It is our priority to make sure the attitude to quality is ingrained closely with the people on the shop floor. Finally, we take safety very seriously as well. To put it differently, Sai is doing things above and beyond what any Indian CDMO is doing.

What are the trends in the uptake of the biotech sector and what potential do you see in this space moving forward?

Services such as discovery to early phase development will be driven primarily by the biotech players, which is where innovators are crowding in. The uptake of the biotech sector is a very important trend in the market. Our entire Discovery business has been built around biotechs for the last 20 years, so we could say we are benefiting from this trend. However, mid stage and late stage development continue to be primarily pharma driven.

Sai is also committed to reducing green house emissions, or increasing the percentage of women workers. Could you elaborate on the company's alignment with social and environmental goals?

The reason why we have been able to achieve the scale we are at now and sustain the growth we've experienced is our long-term vision and our values, which we put above all else. We have stood by our commitment to integrity & transparency, publishing all data and making it available to public domain. Diversity is a very important part of our recruitment philosophy, and we seek to build diversity proactively, not only in terms of gender, but also in terms of regional representation. If we see too much of the same, we are concerned that we lose effectiveness as a company, which is why we choose not to be a bystander and take active steps to achieve our vision for the company.

What is your vision for the company's development in five years from now?

Sai Life Sciences is undergoing major transformation. Right now, we are playing with the big boys of global manufacturing. We used to be a niche player in the market, and now, just to place our growth on a scale, over the period from 2016 to 2020, our company is quadrupling in capacity. This capacity, combined with our proven track record and commitment to building long-term partnerships, will no doubt make Sai Life Sciences the partner of choice for large pharma and small biotechs in bringing new medicines to life.■

Services in Pittsburgh, Pennsylvania in the United States to strengthen its North American presence. "Since 1999, Lambda has been a pioneer in setting benchmarks in global Clinical Research, expanding organically and inorganically over the years," explained Bindi Chudgar, the company's managing director. "The size of operations, huge pool of international doctors and pharmacists as well as an outstanding regulatory track record has empowered us to service every market through our various facilities."

Embracing Pharma 4.0

Embracing the new technologies and approaches that have been brought on by the fourth industrial revolution will be of pressing relevance for a number of the Indian companies with international footprints. With some of India's main export destinations increasing their compliance standards and carrying out increasingly more stringent tests, margins will increasingly be squeezed. By implementing smart and/or continuous manufacturing, applying a cloud strategy, artificial intelligence and data analytics, companies across the pharma value chain will be able to increase efficiency and maximize yields. A number of the larger national players have already implemented a suite of the new technologies, but, in general, SMEs have been more hesitant. "Significant investment goes into Industry 4.0 - in our case 'Pharma 4.0', which entails continuous innovation through focus on technologies," underlined Karan Singh, managing director at ACG, a leading pharma solutions company headquartered in Mumbai that specializes in the manufacturing of empty hard-shell capsules. "In effect, these changes increase competitiveness in the long run while also ensuring regulatory compliance and documentation. We have already developed an internal platform for integration of all our facilities. We are now in the process of pursuing various use cases to see which models and platforms are most effective. Beyond this seamless internal integration, we aim to transform our entire supply chains and bring all facilities onto the platform and connect it all through a cloud network in order to truly harness the potential of Pharma 4.0."

A Turning Tide for India's Supply Chain?

India's supply chain and distribution channel is arguably the most complex of any, globally. The number of states and differing languages and cultures make it very difficult for companies, especially international, to navigate the perennial issues of connectivity and efficiency. As more of India develops and new opportunities emerge, streamlining the supply networks will become a necessity, especially given the pace at which India's pharma industry is hoping to expand at. "In India, the logistics and supply chain sectors have traditionally not been given as much importance and subsidization as drug formulation," highlighted Samir Gandhi, managing director and CEO at Ghandi Automations - a leading automation and loading bay equipment company. "However, since 2018 when the Goods and Services Tax (GST) was launched in India, we have found that logistics and warehousing have received infrastructure status in the country. Now, every company wants to have its own manufacturing unit and logistics park. In particular pharmaceutical cold storage, which is key in preserving medicines and ensuring they reach other parts of the country in their original condition, has gained traction."

While praise of the GST has been rather muted across India, it has had clear benefits within the logistics sector. The GST, which came into effect in June 2017, has been a key stepping stone to unifying the country into a single market by replacing numerous federal and state taxes. This will improve cross-border movement and taxation, especially for transport companies within the sector. Given the fragmented nature of India's pharma industry and especially its cold chain market, which has more than 3,500 companies across all industries, greater connectivity must be prioritized and the GST should only be the start. New technologies will be a solution to this. Advanced technologies, especially blockchain-based technologies and digitalization will enable a faster and smarter supply chain network.

Understanding India's complex supply chain was once a daunting prospect for both domestic and internationals companies. However, the GST, increased government spending on infrastructure and a slowly growing digital network will continue to open business opportunities across India.■

Image courtesy of Sai Life Sciences

Bindi Chudgar

Managing Director
LAMBDA THERAPEUTIC RESEARCH, INDIA

Lambda is a leading global CRO headquartered in Ahmedabad, with facilities and operations in Mumbai (India), Mehsana (India), Toronto (Canada), Warsaw (Poland), London (UK) and USA.

Lambda Therapeutic Research is a global clinical research organization with its headquarters in Ahmedabad. Could you please introduce Lambda to our readers?
We are a Multinational Clinical Research Organization, providing full spectrum drug development services to the global biopharmaceutical, innovator and generic drug industries. Our services include Early Phase I, First-in Human, BA/BE, DDI - Phase II to Phase IV Patient-based Clinical Trials; Bioanalytical services; Pharmacokinetics; Data Management; Medical Writing; Regulatory Affairs; Pharmacovigilance services; Large Molecule Assay services and Medical Imaging services. Our global infrastructure encompasses facilities and operations in India, Canada, Poland, the United Kingdom and the United States, employing more than 1,500 people.

Lambda most recently acquired Novum and extended its presence in North America. Could you speak about your plans in this region?
Novum Pharmaceutical Research Services is a marquee organization headquartered in Pittsburgh, Pennsylvania with operations in Fargo and Las Vegas. Established more than 40 years ago, Novum provides scientific leadership and full-service offerings to the pharmaceutical, biotechnology and medical device industries in the United States. As a stronger combined entity, we have multiple synergies to fuel our growth.

What are the advantages and challenges of conducting clinical research trials in India?
India continues to be one of top destinations for conducting clinical trials, especially the late phase, thanks to a huge treatment naïve population. The strong medical capability pool and English communication skills also play a role in its growth. Most importantly, India in particular offers a tremendous opportunity in contributing data for oncology trials due to genetic testing and high quality data generation. With the recent overhaul of the Indian regulatory guidelines, we expect the current upswing to continue for the next few years.

Based on Lambda's experience conducting operations around the globe, how do market requirements and dynamics differ?
Since 1999, Lambda has been a pioneer in setting benchmarks in global Clinical Research - expanding organically and inorganically over the years. The size of operations, huge pool of international doctors and pharmacists as well as an outstanding regulatory track record has empowered us to service every market through our various facilities.

In addition to its work in biosimilars, could you please provide insight into Lambda's bioanalytical services?
Lambda has created a new milestone in the field of biosimilars with the launch of the first biosimilar generic product in Europe. Considering our hands-on experience in conducting trials for USFDA/EMA/DCGI, our dedicated lab in India for biosimilars testing and an upcoming one in at our Canada facility, we continue to be very optimistic in this arena.
In the domain of small molecule bioanalytical services, Lambda has one of the largest footprints with more than 50 LCMS/MS, 1000 methods validated and a capacity to analyze more than 1,25,000 samples per month. This gives our clients an added advantage in terms of timeline and flexibility.

What are the main objectives for Lambda moving forward?
While our strategies might vary with regards to business lines overall, at Lambda we shall continue to focus on the late phase oncology studies, both in new entities as well as NDDS molecules, biosimilars and of course pharmacovigilance, as we continue to consolidate our undisputed leadership in the BA/BE segment. Business sustainability will be one of the key drivers for us as we move forward.
At Lambda, employee development is at the core. We work on a high collaboration quotient, with professional integrity and transparency, ensuring respect for individuals. These are our values, which we thrive upon and will continue to be our driving force.■

Ajay Tandon

Executive Director
VEEDA CLINICAL RESEARCH

Veeda Clinical Research is an independent CRO which offers a fully integrated package to its clients for studies ranging from bioequivalence in healthy volunteers to PK, PD and Clinical End point studies in patients for Generics, NCE and Biopharmaceuticals.

As one of the largest independent CROs in India, could you start with an overview of the company and your current service offering to customers in India and abroad?
In terms of infrastructure, Veeda benefits from three clinical facilities, representing over 500 beds in total, and one of the largest bioanalytical labs in India, which enable us to extend our services to a global clientele. As a young company, we have developed a full repertoire of competencies to meet all customer requirements. Veeda is known for its scientific capabilities to execute complete solutions for our customers, whether it is in the sphere of generics or more complex molecules. Over 90% of our submissions are to leading global regulatory authorities. We offer regular bioequivalence studies for generic drugs in healthy volunteers, pharmacokinetic and clinical endpoint studies for generic drugs in patient volunteers and bioanalytical work for NCE for innovators, and we are fast developing our capabilities in the large molecules and biosimilar space.

Demand for outsourcing services has been on the rise globally. What makes India a preferred destination for outsourcing for the international pharmaceutical industry?
While the clinical services provided by Veeda represent a significant part of that sphere, there is a lot of outsourcing work being done in the discovery, pre-clinical and post-clinical stages as well. In the CRO space, some people attribute India's competitiveness to its large availability of volunteers and low cost base, but this is an incomplete way of looking at it. The pharmaceutical companies in India are globally competitive and relevant, which has created a core ecosystem for related industries, including CRO services, to grow. Secondly, India's pharmaceutical ecosystem benefits from a strong availability of technically qualified talent pool that is well trained and English speaking, yet comparatively lower cost.

2018 saw the highest number of approvals in biosimilars by the USFDA. What is your expectation for how this market may develop in the future?
If we consider the quantum of the generics opportunity related to the molecules going off-patent in the next five years, a third of this number will be in the biosimilars space, with another third for complex generics, and the rest will be for simple generics. These proportions come in sharp contrast to previous years, when over 70% of the generics opportunity was for simple generics. Staying in tandem with the industry patterns and clients expectations, we see clear potential in CRO services for the development of biosimilars and complex generics. The demand for biosimilar development work currently tends to come more from Indian clients, while the European and U.S. biologics and biosimilar companies are not yet looking towards India in the same way. However, I think that it is a matter of time until the Indian biologics and biosimilars ecosystem also become globally relevant and the related CROs establish credentials in this space as well.

What is Veeda's strategy moving forward, and where do you identify most opportunities for growth?
Biosimilars, complex generics and patient-based clinical trials are the three core areas of growth where we are focused on strengthening our clinical and bioanalytical capabilities. We are also focus on deepening our presence in the European and U.S. markets where we already have strong relationships with leading pharmaceutical companies. Additionally, we are working actively to set up a base in China, which is the second largest pharmaceutical market globally and one in which our clients have increasing interest. Finally, we would like to complete our end-to-end service offering to our clients by acquiring pre-clinical services into our portfolio to support our clients' development programs in biosimilars and complex generics, besides NCEs.■

Mani Kantipudi

CEO
GVK BIO

GVK BIO is a global Contract Research & Development Organization (CRDO) providing Drug Discovery and Development services to the biopharma industry.

GVK Bio stands out as a pioneer in the CRDO model. What are some of the key distinguishing solutions that add value to the services offered by the company?
GVK BIO has uniquely branded itself as a Contract Research & Development Organisation (CRDOTM), looking to trademark the aforementioned term. The core purpose of GVK BIO is to "accelerate the research and development of its global customers," helping them bring better medicines to the healthcare market. Therefore, GVK BIO differs from other companies in two ways: The first distinction is that GVK BIO deals primarily and purely in services. Unlike many of our competitors, whose service offering is tertiary to their core business or are owned by larger pharmaceutical companies, GVK BIO has remained independent and entirely dedicated to its services. GVK BIO's main philosophy has always been to nurture partnerships with its customers. Secondly, up to 96% of the revenue comes from exports rather than local markets.
GVK BIO has designed a scalable company, as one of the few players that operates out of five sites, one of which is located in the United States. All of GVK BIO's sites run on the same operating systems, making information easily accessible across locations. Through the standardized Project Management Capability, newly branded XLrateTM, our Project Management Professionals (PMP) act as the 'voice of the customers' and the main point of contact with customers.

What are the core markets of operation and the profile of GVK BIO's clientele?
About 60% of GVK BIO's revenue comes from the United States, approximately 25% is sourced in Europe, 10-11% is based in APAC (Japan, Korea, Australia) and the remaining 4-5% revenue is domestic. In India, the market for innovators shall expand together with the IT culture, but the risks of undertaking research and development in an innovative molecule are strong deterrents in the domestic market at the moment.

What are the main drivers for growth for GVK BIO?
GVK BIO is poised to grow at a rate of more than 20% this year and is expecting to be around US$230-250 million in a few years. Our strength is in 'discovery' solutions, as the largest company in the country engaged in this service. The company shall continue to try and maintain this leadership status. Moving forward, the focus will fall on GVK BIO's Development business. GVK Bio's third growth vehicle is our Biologics division, which has grown at approximately 20% last year in San Francisco.

How are tensions between the United States and China playing out in India?
In the wake of the current trade war between the United States and China, the Finance Minister of India announced the largest tax cut in the corporate sector yet, going down from approximately 35% to approximately 25% (average). Also, any company coming into existence from October 1st, 2019 will have a 17% tax payable on the condition of a commencement of operations by the year 2023, a provision applicable for ten years. This move has been targeted at international companies, preparing the most favorable conditions for companies to choose India over other destinations. These developments illustrate the trajectory taken by India to capitalize on existing global dynamics.

What are the priorities of GVK BIO in exercising its Corporate Social Responsibility?
Every company in India is obliged to spend two percent of their profits on Corporate Social Responsibility, and our take on CSR is to re-invest this money in the sciences. Our scientists themselves are teaching in schools funded by GVK BIO. In the future, it is our vision to create a mobile laboratory (Lab on Wheels) that can be used to travel and teach Chemistry at different schools and institutions across India to increase the engagement in the sciences.■

Vinay Ranade

CEO
RELIANCE LIFE SCIENCES

Reliance Life Sciences is a research-driven organization developing opportunities in biotherapeutics, pharmaceuticals, clinical research services, regenerative medicine and molecular medicine.

Can you elaborate on your capabilities in the biopharmaceuticals space and highlight the competitive advantage that Reliance Life Sciences enjoys on the global playing field?
Reliance Life Sciences is fully integrated across the biopharmaceutical value chain and operates state-of-the-art facilities in the biopharmaceuticals domain. All products of Reliance Life Sciences have been researched, developed and manufactured in-house. Our flagship facility, the Dhirubhai Ambani Life Sciences Centre (DALC) in Navi Mumbai, is spread over 20 acres. DALC houses the R&D laboratories, an animal testing facility, quality control laboratories, clinical research facilities and manufacturing plants compliant with USFDA and EMA standards. Reliance Life Sciences operates the largest state-of-the-art, mammalian cell culture, biopharmaceutical manufacturing facility in India. Having these capabilities in-house allows us to collaborate closely with our teams across the entire spectrum, and we are also able to support this with a large workforce of people that receive training in the latest technologies.

How does Reliance Life Sciences balance achieving cost effectiveness and quality?
To be a strong global player, it is important to be cost-competitive by paying close attention to capital and operational costs. Reliance Life Sciences has invested carefully to build its state-of-the-art facilities this has helped to meet the global quality standards while achieving cost-effectiveness.

What is your final message to our readership about Reliance Life Sciences looking ahead to the next three to five years?
Biopharmaceuticals is one of the most promising sectors in India, and there are exciting times ahead for Reliance Life Sciences and the rest of the industry. For our company, we are aiming to gain more traction in terms of products and markets. While focusing on the domestic market, we plan to expand the geographical footprint by registering our products in various countries.■

SG

KG

Samir Gandhi & Kartik Gandhi

SG: Managing Director & CEO
KG: Director
GANDHI AUTOMATIONS

Ghandi Automations provides entrance automation and loading bay equipment to sectors including pharmaceuticals.

How does Ghandi Automations engage with clients that are less interested to incorporate automation into their operations?
We provide customized solution as per the specific needs of a particular sector e.g. pharmaceutical, chemical, automobile, food, cold storage etc. Each of these sectors has a unique material handling and warehousing requirement. Because of our expertise in this field, we understand and explain to the client how to make optimum use of technology. The customer acknowledges this as the greatest value addition in utilizing Gandhi Automations for a particular product. We design, manufacture, supply, install and maintain highly sophisticated products. To fulfill our objective of providing products that are technologically advanced, energy efficient and safe, we have a project engineering team that uses the latest design software combined with technologically advanced machinery to offer the customer a well-engineered product.

Could you provide an example of how Gandhi Automations' products help to raise safety standards?
Our solutions are innovative and centered on providing energy efficiency. We have a telescopic lip dock leveler that is used at loading bays to bridge the gap and height difference between the truck bed and the loading bay. The dock levelers land on the truck bed and become the platform, thus compensating for the height difference and gap. In pharmaceuticals, we see a lot of side loading, so a normal dock leveler is unable to cover the large gap. We have introduced a telescopic lip that goes one-meter deep, lands on the truck bed and becomes the platform. In India, we have plenty of hilly regions where the truck is unable to reach exactly near the loading bay, and our solution is extremely helpful in easing the loading problem. Further, the dock leveler holds the forklift and the palate preventing them from slipping off. The person operating also remains safe, which was not the case when conventional methods were used.■

Conclusion

"Innovation is the key to creating value; India has a huge potential because the country has high consumption and a large population. The major shift will take place once innovation takes off. The reverse-engineering of a product or the creation of similar products does not add sufficient value."

- Dr Vishal Rajgarhia,
Director,
Finecure Pharmaceuticals

Image courtesy of Sai Life Sciences

Conclusion

The Innovation Roadmap: India Pharma's Next Steps Forward

The Indian pharmaceutical industry is at a crossroads. Having cemented its status as the generics capital of the world over the past decade, the opportunities and challenges that it will face in the coming decade are set to change. As India continues to become more industrialized and technologically advanced, the pharmaceutical industry must also look to evolve. Despite India's sizeable global market share in generics, the overall size of its pharmaceutical industry is relatively small when compared to the United States, Japan, China and a handful of European countries. The next step will be for the government and industry to set out an innovation roadmap that takes India's pharmaceutical industry to a more advanced stage of development. This should be pinpointed around the opportunities presented by the 4th industrial revolution and pursuing opportunities in specialized areas such as nutraceuticals and veterinarian drugs, as well as building an R&D life sciences ecosystem that can regularly produce novel drug molecules, both large and small, for the global market.

Opportunity in Specialization

Traditionally, India's pharmaceutical industry has relied on a bulk manufacturing strategy – volume over value, to achieve economies of scale. However, increasingly companies are realizing that there is ample opportunity in speciality drugs and that focusing on quality is rewarded with stronger financial performance in the long run, not to mention the crackdown in audits from regulators at home and abroad. The nutraceuticals space is an area that has received particular attention in India in recent years. A rise in income and a growing middle class are trends accompanied by changing attitudes towards what constitutes a healthy lifestyle and increased interest in the physiological benefits afforded by natural supplements and vitamins. "The nutraceuticals sector is easily going to grow by 25%," said Vijay Rai, chairman of Akola Chemicals, which has a focus on providing food supplments that are suitable for athletes and sportsmen looking to gain mass. "Various lifestyle changes, together with the rise in the number of gyms are strong indicators. Keeping fit has become a very conscious part of people's lives, and supplements are part with this trend," he said.

Veterinary medicine is also a niche opportunity for companies looking for a differentiating factor in the face of a large and fragmented generics market. NGL Fine Chem receives 5% of its revenue from a small focus on human health, while the remaining 95% comes from its business in veterinary products. The company has found success in shifting focus from mass scale production to smaller volume and higher value products in the veterinary space. "It is worth keeping in mind that almost 30% 70% of the products used in the veterinary business are human-health products, and thus have a dual use," commented Rahul Nachane, managing director. "But there are certain products which are unique to veterinary application. For example, animals have a higher likelihood of ingesting worms, which in turn attack tissues, lungs, intestines, or the heart. We provide a wide range of products to meet this kind of disease and offer a variety of anthelmintics."

Nonetheless, for larger players it does make sense to adopt a hybrid approach as a mechanism for risk mitigation. "Having a larger portfolio reduces the dependency on new molecules, and continues to have a push-model driven by the base business. One cannot predict the breadth of opportunity opened by a new product, there are many surprises that can arise, and this is why we cannot revolve our business around one single molecule," explained N. Govindarajan, managing director of Aurobindo Pharma, which is a fully integrated pharmaceutical company among the top two companies in India in terms of consolidated revenues. He continued, "In fact, 65% of our molecules have a top three market position in the U.S. market, but our top selling product in the United States represents at most 4% of the business, whilst 25 molecules represent up to 35%, showing that our focus is evenly divided. With a larger and deeper product portfolio, we can accommodate supply shocks and maintain a sustainable growth."

Developing a Cohesive Life Sciences Ecosystem

As the global economy heads towards an inevitable slump in the coming years, governments should have learnt from the mistakes of the past and targeted industries that are less cyclical and volatile. The life sciences industry has proven to be the most resilient, globally, being the only industry to see continued growth throughout the global financial crisis of 2007-2008. The fortunes of the pharmaceutical and biotech industries are likely to remain positive in the future as the global population continues to grow and age. "The innovation landscape is changing drastically and for the better. Both small and big pharma companies are coming out with innovative products," said Neha Ramani, partner at LexOrbis, a law firm specialized in IP. In particular, she underlined the shift in focus in the pharmaceutical industry in India and across the globe to the development of biopharmaceuticals. "Despite the heavy costs, infrastructure for R&D and excess time required in the development of biologics, we have seen revamping of businesses, mergers and expansions to increase operational capabilities, as well as splitting, re-shaping and restructuring R&D by pharma companies to diversify into specialty medicine and biologics," she said.

India does have the ingredients to slowly develop a life sciences and biotech ecosystem that in the future may rival the mega-cluster biotech hubs of Boston-Cambridge and the Bay Area. This, however, will be a long process that needs meticulously drawn-out and followed plan. Looking at India's current situation, it has a number of high-performing universities – eight in the world's top 1000, including six technological universities – which form the bedrock to all the major biotech ecosystems. A good start – but this is where things become more difficult. For example, the Modi government has already announced plans to launch a national health insurance scheme – Rashtiya Swasthiya Bima Yojana, set to reach 40% of the population – but the government has yet to find a way to finance this scheme.

The need for capital investment, both from public and private funds, is essential in the development of a biotech ecosystem. "While these are some positives for the Indian Pharma Industry to move up on the innovation frame, India has a lot to change for "Building the Innovation DNA"," underlined Naresh T. Raisinghani CEO and executive director at BMGI, when discussing the potential for India's pharma industry to innovate. "While the Indian Pharmaceutical industry is concerned about Innovation and Government understands and desires innovation, reality bites as innovation research for the drug industry has long gestation time of 10-20 years, requires substantial large investment requirements and has risk of failure even in later stages of product development, leading to few takers for innovation research at a firm level."

India's larger national players that have dominated the generic market for so long could very much hold the key to advancing India's biotechnology ecosystem in the early years by contributing much needed capital and investment in academic research so that it can commercially develop within India.

However, the Indian government and the domestic pharma industry will need to implement an overall roadmap with a strategic plan to develop a long-lasting life sciences innovative ecosystem. This should include policies that encourage foreign investment, including R&D tax incentives. In relation to this, intellectual property rights will need to be aligned to those in Europe and the United States so that organizations undertaking high-capital R&D can do it in confidence. There also needs to be increased collaboration between academia and the pharma industry to fund scholarships and provide financial incentives for talent. Furthermore, a large fund must be rolled out to grow the pool of biotechs and encourage other VC funds and angel investors to look at India's biotech industry as a viable option.

The life sciences success stories across the world have been built by combining a solid academic foundation and successful industry players with consistent flow of capital funds. If India is able to keep growing consistently throughout the next decade, it should begin focusing on creating a long-lasting life sciences ecosystem. Building investor confidence with an ominous outlook for the global economy may put things on hold, for now.■

Vijay Rai

Chairman
AKOLA CHEMICALS

Akola Chemicals was established in 1981 and is producing hydrolysed proteins for the Agricultural, Animal Feed, Food, Nutraceutical and Cosmetics Industries.

Could you start with a brief overview of the company and the opportunity seen in the market when Akola Chemicals was started in 1981?
In the 1990s, Akola identified the opportunity in the nutraceutical area, primarily because of large imports of whey protein. A decade later, protein supplements became one of the fastest growing industries in India.
Akola Chemicals moved from supplying hydrolyzed protein solely to the agriculture industry into meeting the needs of animal feed, food and the nutraceutical Industries.

Could you walk us through the range of products on offer and how they cater to different demographic segments?
We offer two classes of products. First one are products based on gelatine, which is the source for collagen, a hydrolysed protein with the widest range of uses, as well as the largest number of amino acids.
Nonetheless, there are people who are not happy with the fact that gelatine is of animal origin. In response, we have products that are vegetarian, sourced from rice and soya.
There are formulas designed for different types of application; for example, Ako Pro has very high protein content made for body builders, whilst other products are for elderly people who struggle with digestion.

What would you comment about the way nutraceuticals are perceived today in India?
Nutraceuticals has developed as its own category; it has become a product and no longer an extension of a pill. A pill is for curing illnesses, whereas nutraceuticals are consumed by healthy people. The perception that one can live longer with proper nutrition has taken over, and nutraceuticals are connected to anti-ageing, living longer, better and healthier. As a result, the number of marketing companies in the field are increasing exponentially, and many manufacturers of food products are expanding into nutraceuticals.

We have discussed about the opportunities in the nutraceuticals market, but can you tell us more about the challenges you encounter as manufacturers in this sector?
Challenges are all from raw materials. Collagen is facing serious problems because of restrictions of all types; what's more, the price of raw materials has increased by at least 40%. There are political reasons underpinning these factors.
On the other hand, the prices of the other raw materials like rice and soya quite steady. The ability to make these into a high-protein product is not as easy as compared to collagen and the effectiveness is lower, yet the enhanced acceptability of the product: as a vegetarian product, makes it attractive. The demand both domestically and abroad is growing and will make it the choice ingredients for supplements future.

Akola Chemicals has a strong position in the market. How do you maintain this stronghold ahead of your competitors?
We are first in the market with new hydrolyzed proteins, and in some products we are still exclusive; for example, we are leaders in Amla and silk proteins. In Keratin we are unique with our costs. As a specialist company, we do not have the volume of the big companies, but in some products, we do enjoy monopoly.■

Akshay Charegaonkar

Director
ANCHROM ENTERPRISES

Anchrom Enterprises offers high-end analytical solutions together with technical expertise, acting as the exclusive distributors of Camag HPTLC.

In 2019, Anchrom celebrated its 41st anniversary. Could you give us a brief overview of how the company has evolved over the years?
Anchrom Enterprises was founded at a time when there were few instrument distributors operating on a scientific level; instruments were bought and sold without any expertise. In 1989, the company founded its laboratory, and as time passed, we focused on being the exclusive distributors of CAMAG HPTLC systems from Switzerland. We have given demonstrations, free training and analysis to students and government lab employees, and we have trained about 4,500 students and scientists in this manner. Out of the 5,000 square feet of our premises, half is dedicated to the laboratory, and the other half is used as a back office for other distributors' tasks. Fourteen people work for the laboratory team, which is the focus of our operations. We use it not as a commercial lab, but as a lab to promote the science and technology of HPTLC applications further.

To wrap-up the interview, could you share your vision of how the company may grow in coming years?
This is a very exciting time in the history of the company, because we are poised for a rapid period of growth across the various verticals we serve. Our team is also growing from 50 to about 70 people. In the medium term, we intend to get into more analytical partnerships with our customers. We also seek to become the supplier of choice for any customer who has an unsolved analytical question, for which we are developing the infrastructure around our team. Anchrom aims to make India the world leader in HP-TLC applications for routine use.■

Bhavin Bhagat

CFO
CORONA REMEDIES

Corona Remedies is a manufacturing and marketing pharmaceuticals company located in Ahmedabad.

Can you introduce Corona Remedies to our readers?
Today, we are the fastest growing pharmaceutical company in India, amongst the top 50 Pharmaceutical Companies, with a growth of 25%+ in the past few years. Furthermore, Corona is ranked number one in new prescription generation as per SMS-RC, which is an independent nodal agency that takes care of the prescriber's base. Starting with a team of five people, today our team is made of over 3,000 members. Our USP is "Ability to identify gaps in the market and strong capability to execute." There are three stages to this process - one, in the form of product, second in the form of people, and third in the form of science. In the promotion of our products, we always try to showcase ourselves from a science perspective. Patients' needs drive our strategy, and therefore costs are important indicators to us. If the patient doesn't feel a product is cost effective, they will not take it. Up to five years ago, we carried a portfolio of 65% Acute and 35% Chronic, but today these proportions are inversed. The Chronic segment is the upcoming segment, with growth in lifestyle medicines.

What are some of the differentiating products in your product portfolio?
One classic example of what we have right now is a brand named Rapifer, used in increasing the haemoglobin levels. We are the only company in India that is indigenously manufacturing this molecule, which is very challenging to stabilize. Doctors appreciate the product because it carries a cold chain end-to-end facility, from manufacturing to the last point.■

"Some dosage forms are more difficult to develop or to manufacture, which builds a barrier to manufacturers. Such molecules thus become more profitable, and we are determined to try to put more effort into them, rather than shying away from approaching molecules of more complexity. As most other API companies in India and China, we are looking at molecules which are going off-patent in the next 10 years, and we are looking to develop the processes in our R&D."

- Manish Doshi, MD, Amoli Organics/Umedica Labs

"The Excipient market is growing globally. Safe and multifunctional excipients are the need of the hour. With innovations in machine technology, excipients with superior performance to handle the rigors of the manufacturing process and in high demand. Hot melt extrusion, nanotechnology, implants and injectable deliveries are some areas where many excipient based innovations are being explored."

- Chitra Shah, Managing Director, Arihant Innochem

"We are expanding to other dosage forms such as tablets and ointments and extrapolating our soft gelatin manufacturing lines to other categories including vegetarian soft gels and cosmetic products. We want to specialize in core soft gels and be known for this in the market. Besides cosmetics, we will add a few more categories and widen our base for this dosage form while expanding to other lines that may not necessarily be manufactured in-house and could be outsourced".

-Bhavin Savla, Managing Director, Asoj Soft Caps

"Astral's products are mostly anti-infective, a drug category which does not lack demand. Global slowdown may translate into recession for other product categories, but our products are not affected. An edifying result of this success is our sustained growth rate at 14% year on year. For the future, we will invest in different molecules due to going off-patent."

- Dushyant Patel, Chairman and Managing Director & Ketan Naik, General Manager, Astral SteriTech

"Selection of product is the most difficult challenge we have faced. It is the lead question of all the investors, because the product one chooses depends on the long term life of the company. Either you choose a product because you believe in the product, or you have a good margin or a fast registration process with strong potential success in the market. In our field, which is oral solids, our product ranges in pain, gastro and specialty pharma, which has less innovative new products with a bigger requirement for new formulations."

- Alexandre Williams, Managing Director, Athena Drug Delivery

"It is very challenging these days to balance between cost and quality. Increasingly stringent regulations have been put in place, and we experience audits from many different places. However, we are committed to maintaining our facilities in this regard. India today is what we call is a pharmacy of the world –and rightly so. The industry has continued to improve and it is very quality-oriented."

- Paresh Mehta, Managing Director, Intermed

"There is a common assumption that the higher number of products, the higher the success rate. However, through our experience we have realized that only 20% of medications would actually make money for you. Chemo has always been selective about the products we invest in. We carry out intensive market research and competitor research to arrive at unique products like the vaginal rings, along with the traditional products."

- Dr Kumar Kurumaddali, Managing Director, Chemo

"The largest market for biosimilars, the US has a complex regulation, even though the market was opened five years ago. Pharmaceutical companies need to have the vision and the wherewithal to work towards and invest in the biologics business for the future."

- Jagdeep Shah, Director, Clinicare

"Up to five years ago, we carried a portfolio of 65% Acute and 35% Chronic, but today these proportions are inversed. Also, the domestic market has for a long time been our focus. But three years ago, we started to realize that if we want to move post 1000 crores Revenue, we need to adventure outside of India. We began filling dossiers in the CIS, South East Asia and Africa."

- Bhavin Bhagat, CFO, Corona Remedies

"Gestation period used to be about 18 months to make a company profitable, but today, it is nothing less than five years to make up for the investment before one can reap the benefit. It is a long process and it is becoming longer depending on the part of continent you want to cater."

- Anil Gidwani, Director, Dana Pharmaceuticals

"Multinationals have been focused on expensive modern analog insulin, which is unaffordable to large section of world population. This is where we come in to plug the unmet demand gap in the market. We are developing modern insulin at a much lower costs, and being affordable is where our competitive advantage lies."

- Amol Shah, Managing Director, MJ Biopharm

"There is plenty of opportunity and India has evolved to adopt global standards of compliance over the last few years, with measures being taken in drug formulation and marketing codes with doctors. Companies are adopting these measures and are redefining their approach to reach customers in a more holistic and compliant manner, which is beneficial for companies looking to grow globally and sustainably."

- Prashant Menon, Managing Director, Exeltis

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