KPMG

CII
Confederation of Indian Industry

Pharma Summit 2009

India Pharma Inc.: Overcoming Challenges to Maximise Potential

16 September 2009, Mumbai

AUDIT ▪ TAX ▪ ADVISORY

Pharma summit 2009
CII's 7th International Conference
16 September 2009•Inter Continental The Lalit•Mumbai

Acknowledgements

We would sincerely like to acknowledge and thank the following industry leaders for providing their valuable views for this report (in alphabetical order):

- Dr. Ferzaan N. Engineer, Ph.D., Chief Executive Officer, Quintiles Research (India) Private Ltd.
- Glenn Saldanha, Managing Director and CEO, Glenmark Pharmaceuticals Ltd.
- Jai Hiremath, Vice Chairman and Managing Director, Hikal Ltd.
- Dr. Kamal Sharma, Managing Director, Lupin Ltd.
- Dr. Rajesh Jain, Joint Managing Director, Panacea Biotec Ltd.
- Sahir Khatib, Vice Chairman, Medley Pharmaceuticals Ltd.
- Sucheth Rao Davuluri, CEO, Neuland Laboratories Ltd.

Foreword

Gaurav Khungar
Executive Director
Sector Head - Pharmaceuticals
KPMG in India

Jai Hiremath
Chairman, CII Pharma Summit 2009 and
Vice Chairman & Managing Director
Hikal Ltd.

Indian companies continue to strengthen their foothold in the global generics market, while also simultaneously leveraging their capabilities in penetrating other challenging business segments. These include contract research and manufacturing services, new drug discovery and biopharmaceuticals. India has made its presence felt in each of these business segments.

As a supplier of low cost, high quality pharma products and services, India is viewed as a serious competitor in the global generics and outsourcing markets by other emerging players. India is now increasingly considered by global pharma as an essential part of their global product development, manufacturing and supply value chain. The confidence of the global pharma industry in India is reiterated by the growing strategic alliances between Indian and foreign companies spanning the entire pharma value chain. Today, there is no doubt that India has an excellent potential to emerge as a 'global pharma hub', as it continues to evolve in building the requisite capabilities.

As the Indian Industry continues to make big strides forward to grow rapidly and build scale, it encounters various roadblocks at various stages of project execution. Overcoming these positively will likely determine the success of the Indian pharma companies in realising their true potential.

This report attempts to discuss and address some of the important issues and roadblocks faced by Indian companies as they aggressively enter new markets and business segments.

In years to come, the best-in-class companies in India will likely be those that demonstrate an understanding of how the future may unfold, and are agile enough to adapt to constant technology change. Creating shareholder wealth will likely depend on the ability of Indian businesses to create intellectual property, build market share and have the necessary financing available to get to the next value inflection point.

Companies should expect to be pulled in several different directions simultaneously, as they face the challenges of numerous regulatory hurdles; access to capital, competition and developing human resources.

We hope that this report, which contains valuable opinions of several senior executives in the Indian pharma industry, provides a better understanding of the foremost challenges in the industry today. We also hope that it provides a sense of direction to the Indian pharma industry and its various stakeholders to take coordinated steps forward.

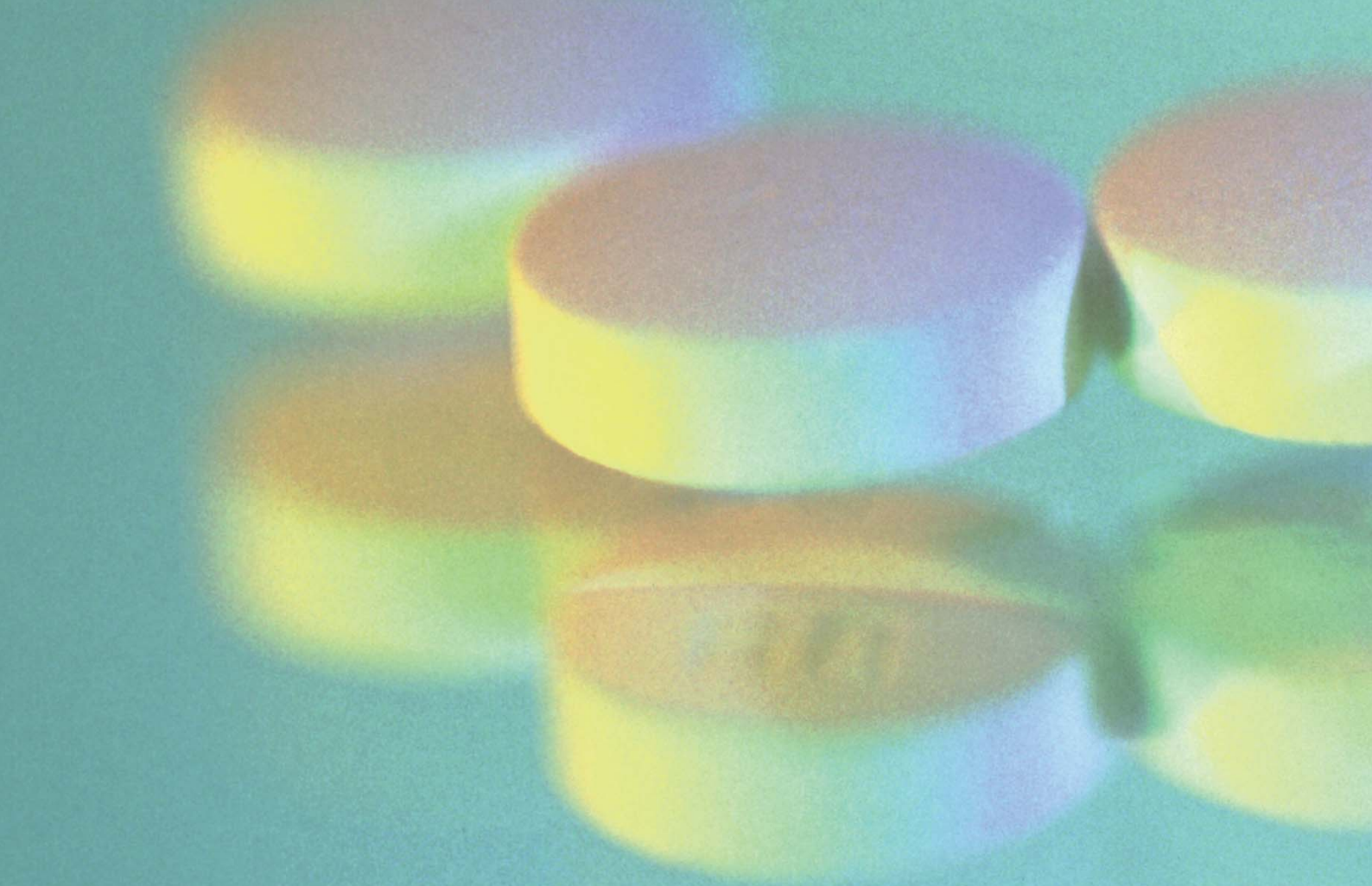
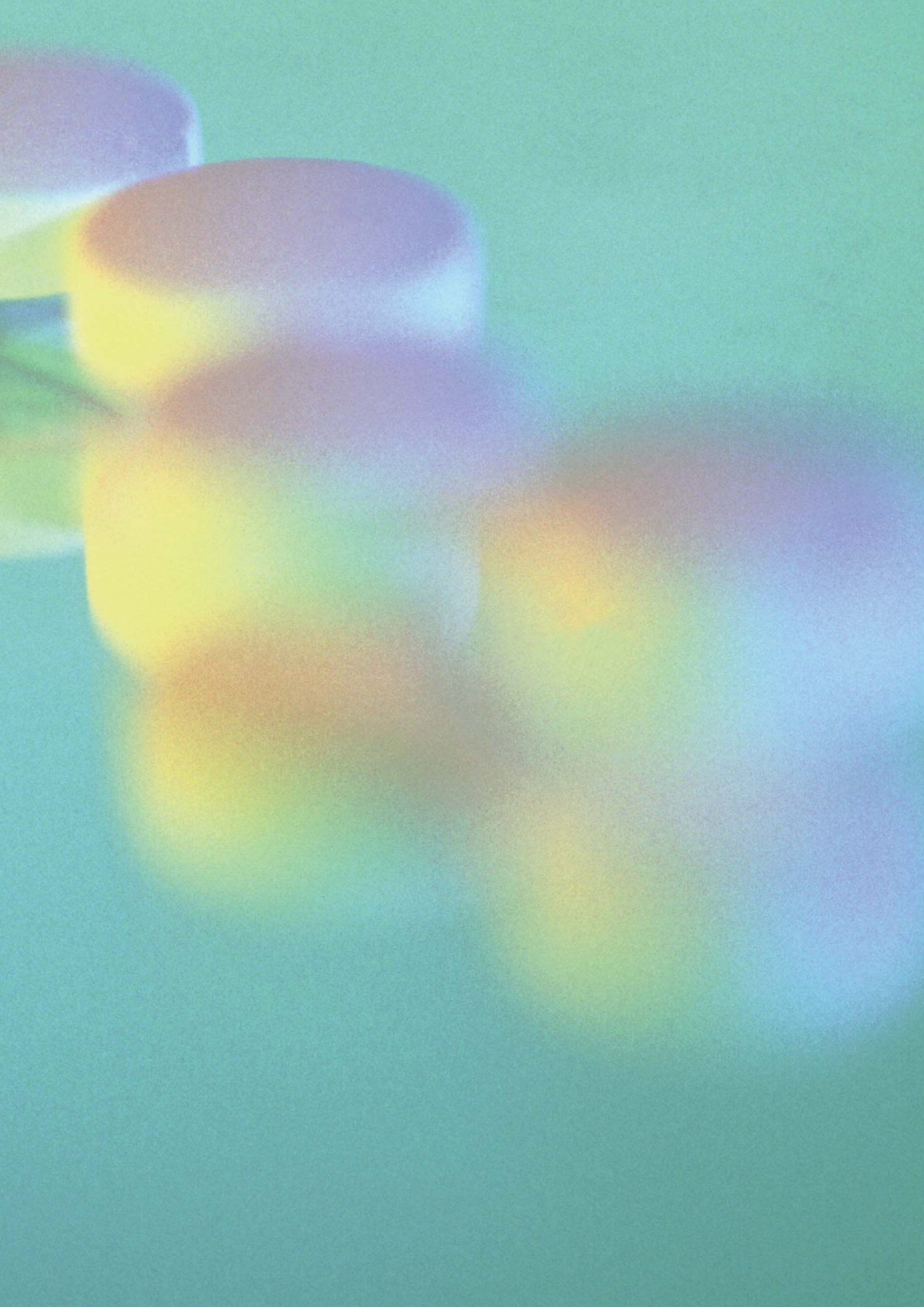


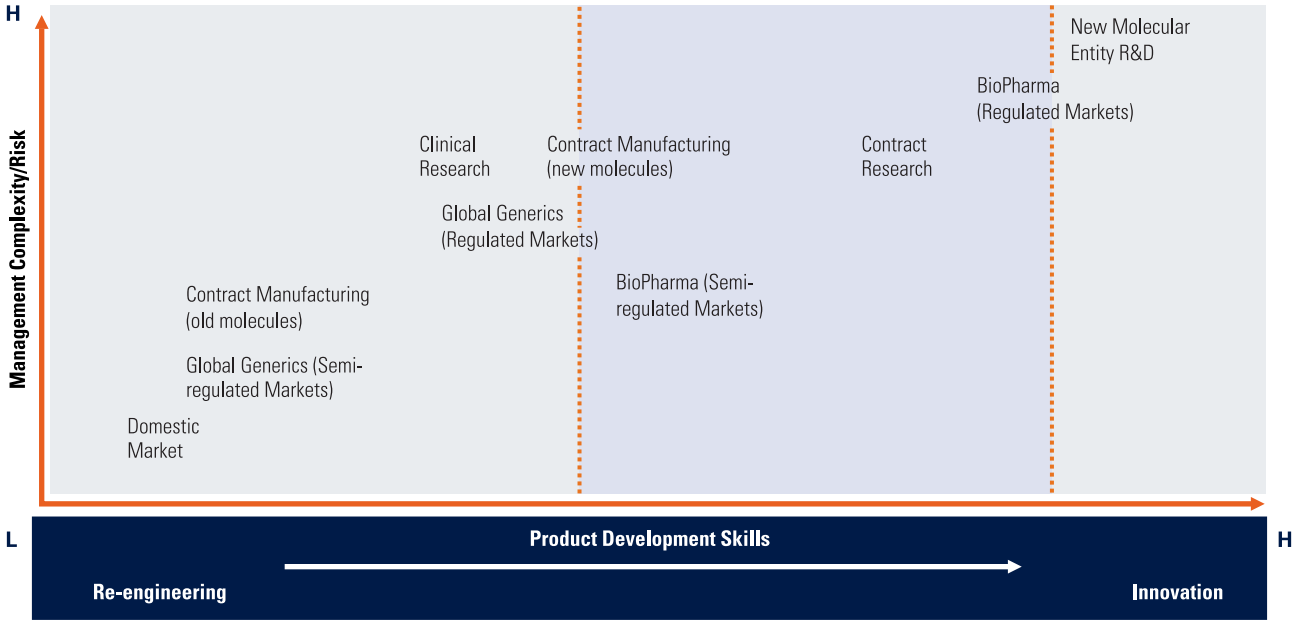
Table of Contents



Executive Summary

India has proven itself as a supplier of high quality, low cost generic drugs to the global market. In recent years it has also moved up the value chain into more challenging business segments such as drug discovery and development and biopharmaceuticals.

Figure 1: Indian Pharma: Moving up the value chain



Source: CII-KPMG Pharma Summit 2009

In the Pharma Summit Report 2008 titled 'India Pharma Inc. – An Emerging Global Pharma Hub', we showcased India's two-fold potential to emerge as:

- An integral part of the global drug development, manufacturing and supply chain
- A fast growing pharmaceutical market.

India's potential to emerge as the preferred hub for the global pharma market has already been established in numerous studies and reports published by consultancies, corporate houses, industry bodies and associations and equity houses.

However, India's share in the global pharma market for both products and services remains comparatively small. For example:

- The domestic pharma market ranks 4th in volume terms globally, but 13th in value terms[1]
- Until now, Indian companies have managed to capture only 3 percent of the global Contract Research and Manufacturing Services (CRAMS) market[2]
- India accounted for only 2 percent of the global clinical trials market in 2007[3].

The Pharma Summit Report 2009 titled "Indian Pharma Inc. – Overcoming Challenges to Maximise Potential" focuses on helping Indian pharma companies realise their potential by identifying and understanding the key execution challenges faced by them across the following business segments:

- Foreign generics markets
- Domestic pharma market
- Contract Research And Manufacturing Services
- Clinical research services
- New Chemical Entity (NCE) discovery and development
- Biopharmaceuticals.

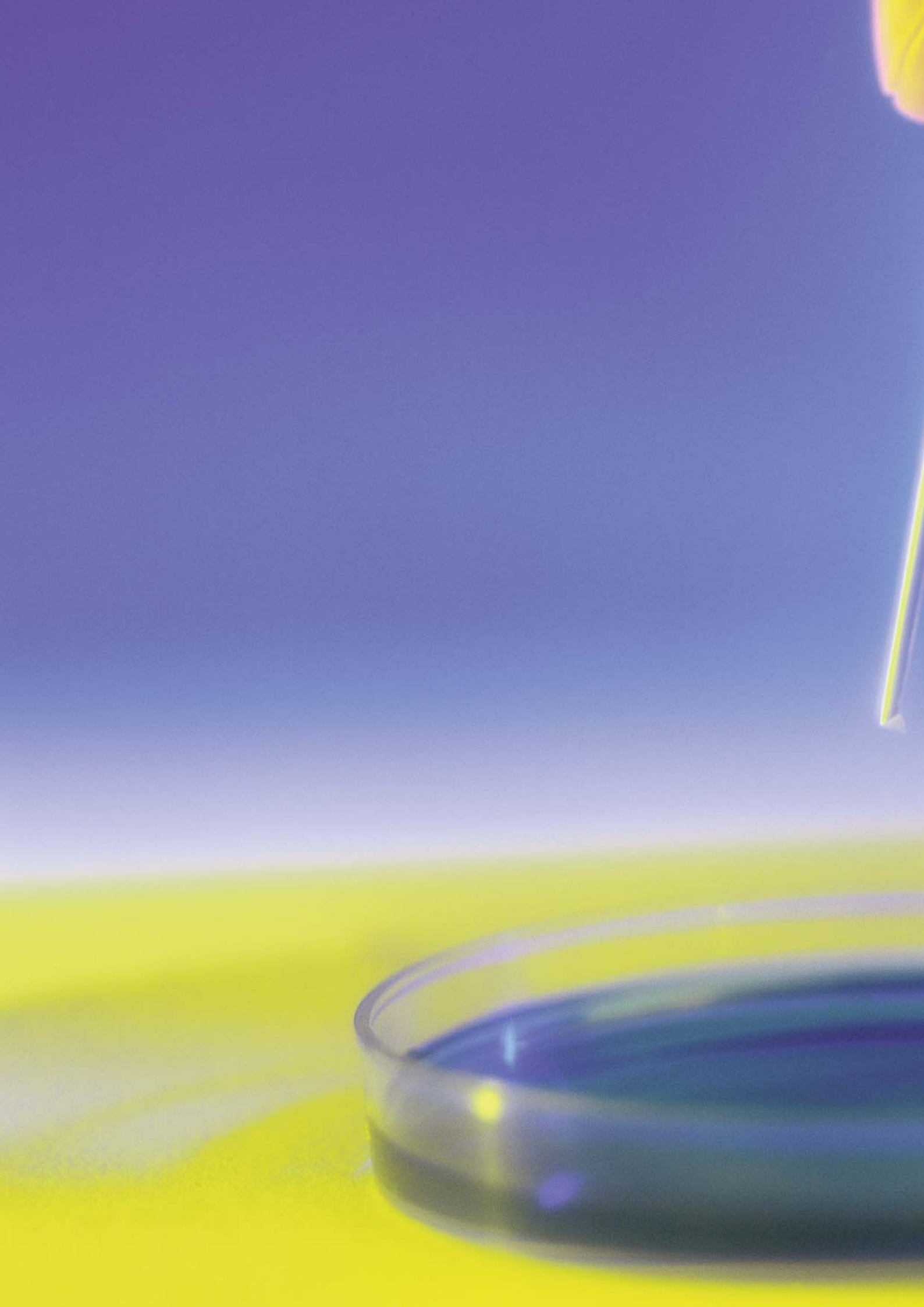
To achieve its potential and convert these opportunities into global success stories, the industry needs to undertake an integrated approach towards managing growth while being cognisant of the underlying risks. This approach requires the support and collaboration of all stakeholders including the government, academia and financial investors.

---

1 Pharmaceutical Outsourcing: Opportunity for India!, May 2009, http://www.asia-manufacturing.com/news-323-pharmaceuticalmarkets-pharmaceuticalsindia-formulation-api-news5.html

2 Reliance Money 'Indian Pharma CRAMS', July 15, 2008

3 RNCOS' 'Booming Clinical Trials Market in India', January 2009



Penetrating Foreign Generics Markets

Penetrating Foreign Generics Markets

Introduction

India's recognition of process patents for over three decades has played an important role in the development of the country's reverse engineering and chemical synthesis skills. This laid the foundation of India's capabilities in generics. Today, India is a leading supplier of high quality generic drugs. Its growing significance in the global value chain is evident in the strategic alliances between Indian companies and MNCs, which have chosen to partner with India to pursue their generics ambitions.

Figure 2: Recent alliances between Indian and foreign companies

Alliance	Rationale
Pfizer - Aurobindo	Pfizer acquired the rights to sell 75 drugs as pills and 12 injectable products of Aurobindo in US and Europe. This alliance is expected to strengthen Pfizer's generic product portfolio and reduce dependence on brand name prescription medicines.
Pfizer - Claris Lifesciences	Pfizer is expected to get marketing rights for 15 injectable products from Claris in therapeutic areas like anti-infectives and pain in order to broaden its generic drugs portfolio. Pfizer is expected to sell Claris' products in western markets under its own brand name.
GSK - Dr Reddy's	GSK is expected to gain exclusive access to Dr. Reddy's pipeline of over 100 branded products for sale in the emerging markets. This partnership is expected to strengthen GSK's portfolio in the emerging markets.

Source: Company Websites and Press Articles

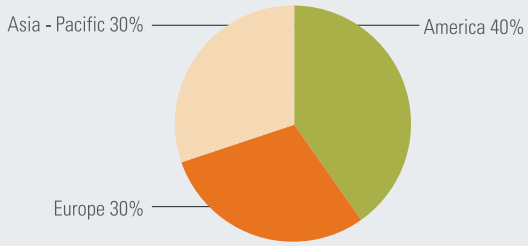
Generics sales – particularly to foreign markets - remain the largest business segment for Indian pharma companies.

The global generics market is expected to grow at a CAGR of about 10.5 percent between 2007 and 2012, outperforming the overall pharma market CAGR of about 5.5 percent in the same period.[1] This growth is expected to be driven by the following factors:

- The estimated USD 116 billion worth of drugs going off-patent over the next five years[2]
- Governments worldwide encouraging the use of generics to counter rising healthcare expenditure – particularly in countries with low generic penetration such as France, Spain, Italy and Japan
- The toughening macro-economic conditions leading to a greater shift towards generics usage.

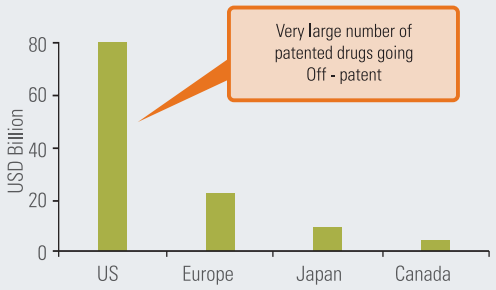
Figure 3: Global generics opportunity

Global generics market size



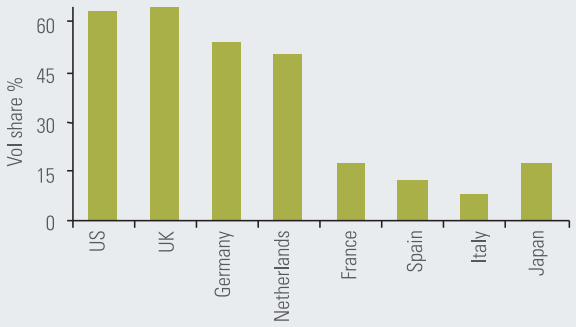
Source: Datamonitor

Annual sales of drugs going off-patent over next 5 yrs



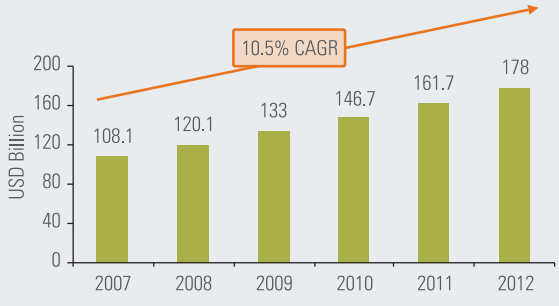
Source: India-Pharma IIFL Report 1Q 2009

Penetrating developed markets - An opportunity



Source: India-Pharma IIFL Report 1Q 2009

Global generics market forecast



Source: Datamonitor

Indian pharma companies continue to leverage their existing strengths to capture a greater share of this growing market. This section focuses on the challenges Indian companies face in entering and growing sales to foreign markets - in particular regulated markets.

[1] Datamonitor Report on Global Generics Industry Profile - August 2008, Piribo December 05, 2008

[2] India-Pharma IIFL Report 1Q2009

Key Industry Challenges

Understanding the complexities of regulated markets

Indian companies have already completed several big acquisitions and have entered into strategic alliances and partnerships in the developed pharma markets, particularly in the US and EU. This demonstrates the importance of regulated pharma markets to Indian players.

Some of the positive features and challenges associated with these markets are set out below.

Figure 4: Regulated markets: Positive features and challenges

Regulated Markets: Positive Features	Regulated Markets: Challenges
Large homogenous markets - easy to scale up due to easy replication of learnings	Fierce price competition from players from low cost locations clubbed with innovators aggressively delaying generic entry
Dealing with three agencies (US FDA, EMEA and Japan FDA) can give access to most developed markets	Stringent regulatory norms - involves greater time, money and scientific resources
Speedy market entry and faster market share gains if product and pricing are competitive	Stringent quality control norms - production and distribution is tougher and more expensive
Presence of incentives such as 180-day exclusivity for the first patent challenger in the US	Most large regulated markets are either already or moving towards becoming non-branded generics markets - provides limited scope for building brands
High paying capacity - overall market is several times larger than the emerging markets	High bargaining power of players such as insurance companies and government agencies

Source: IIFL Report 1Q 2009

A company that can understand and adapt to the various regulatory, pricing and supply complexities of regulated markets can build a sustainable presence.

Dr. Kamal Sharma says – "While fierce competition and shrinking margins are the key challenges that Indian companies face in international regulated markets, the sheer diversity in the business landscape for healthcare across the world is another element that needs careful thought, sound strategy and flawless execution. Different geographies call for their own unique business models, and this makes the process a dynamic one – while US is a fairly homogenous market with generics being the mainstay, EU as a market is a heterogeneous one. UK and Scandinavia are for example pure INN[3] markets whilst Southern Europe is a branded generics market. Japan, which is the second largest market for pharmaceuticals in the world, is a branded generics market where the influence of the doctor remains very high."

An effective way to manage these complexities is to assemble a strong resource pool with a good understanding of the local market conditions – Intellectual Property (IP), regulatory, pricing and reimbursement and marketing and distribution. This can be achieved in a number of different ways including:

- acquiring a local company with a well established presence
- entering into a partnership with a local entity
- setting up a local office with a human resource pool that has a good understanding of the local market conditions.

The preferred mode of entry depends on many factors including risk appetite, profitability expectations, size of investment, tax, speed of entry and rationale for entry.

Regulatory complexities

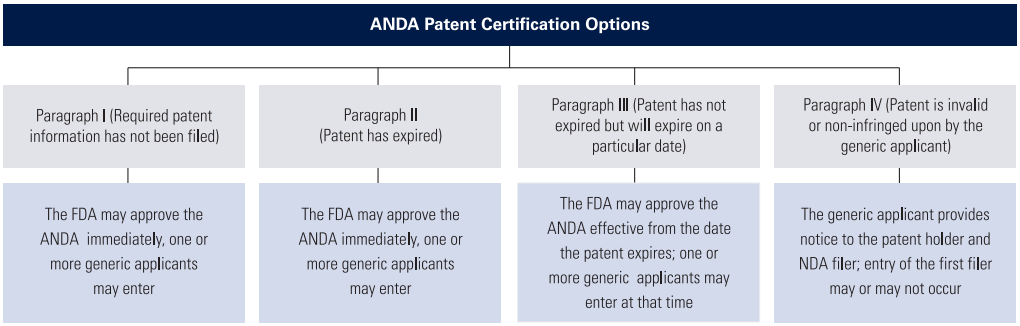
Each of the regulated markets, the largest ones being the US, EU and Japan, has its own clearly defined IP infrastructure and regulatory systems for quality control. Each market has its own regulatory authority and drug approval mechanism. A company penetrating into any of these markets needs to have a thorough understanding of the local framework to make a well planned entry.

In addition to this, the company also needs to closely monitor patent exclusivities, extensions and expiries, make ANDA / DMF submissions, address the queries of the regulatory authorities, and make the necessary amendments.

Indian companies have also been aggressively following the Para IV filing strategy, which can potentially give the company a 180-day period of exclusivity – a huge competitive advantage. This strategy, however, is considerably challenging to implement, given the regulatory and legal complexities it entails and the cost and risks involved in litigation.

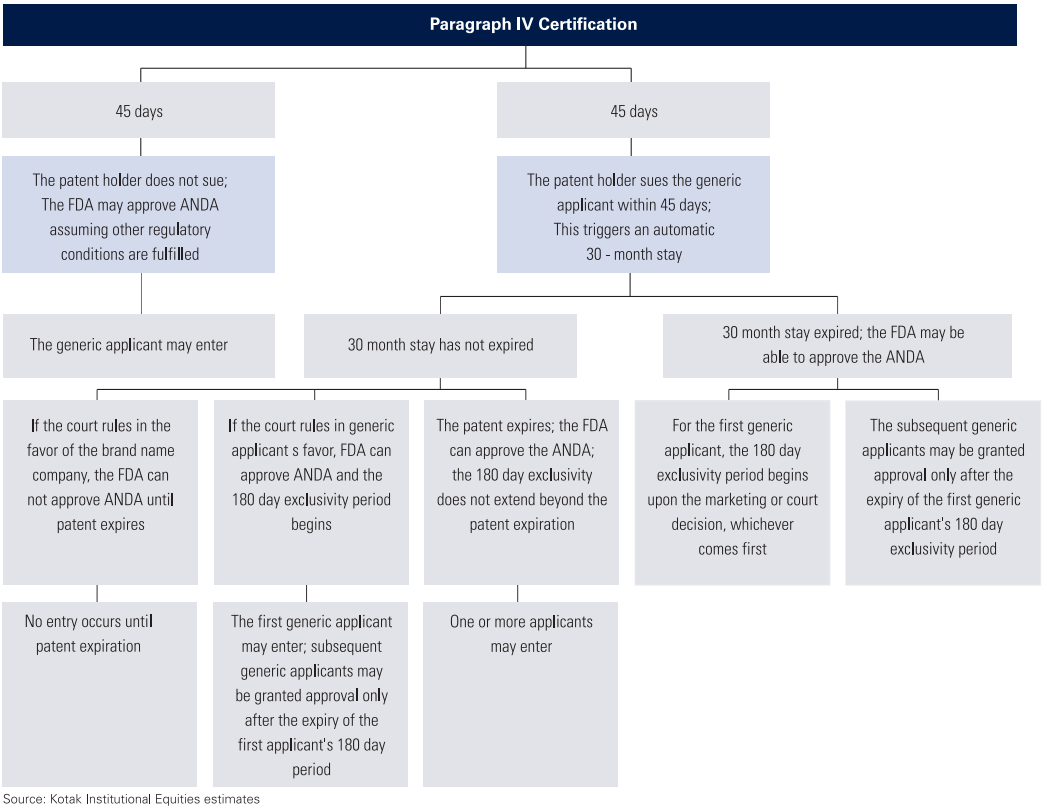
[3] International Nonproprietary Names

Figure 5: A sophisticated IPR system – US Healthcare Model



Source: IIFL Report 1Q2009,

Para IV Wins bring in windfall gains: The key is to understand the regulatory dynamics and develop capabilities to manage the associated risk: reward outcomes



Source: Kotak Institutional Equities estimates

Furthermore, there are high chances of the innovator company introducing an authorised generic manufacturer which can substantially limit market share and profits. For example, in 2003, Apotex received exclusivity for Paroxetine and estimated that it would likely generate revenues of USD 530-575 million during this period. However, the innovator company brought in an authorised generic player, limiting its revenues to USD 150-200 million.[4]

[4] Presentation by Lupin on 'Challenges in Generic Drug Development for Regulated Markets', Datamonitor Report 'Global Generics Guide: Part 2', June 2006, KPMG Research

Pricing complexities

As pharma markets worldwide are becoming increasingly cost conscious, pricing and reimbursement are increasingly playing important roles in determining profitability. It must also be understood that these factors are dynamic and will most likely change over time with market maturity and prevailing economic conditions.

Companies must have a strong understanding of the unique pricing dynamics of a market in order to set an 'acceptable' price that is competitive, profitable and adaptable. It is also necessary to have a sound understanding of the wider global market in order to consider the impact of issues such as reference pricing and parallel imports.

Some of the pricing mechanisms used in regulated markets are set out below:

Figure 6: Pricing complexities in regulated markets

Profit controls	• Used in the UK, under the Pharmaceutical Price Regulation Scheme agreement, which negotiates the prices of a range of pharma products with the companies taking into account generic intrusion and parallel trade • Companies and governments agree on the price of drugs for a fixed time duration
Reference pricing	• In Germany, reference pricing includes branded and generic pharma products to bring down price of branded drugs on patent expiry and to accelerate the generic impact on the market share - Internal reference pricing is used in France and Spain to lower the price of branded drugs once off-patent - External reference pricing - used by most EU countries - is where the drug price is based on the average of prices set in other countries
Price cuts, freezes and ceilings	• Price cuts are implemented on the reimbursement rates, reducing the profits of the companies over time • Japan reduces the price of drugs on its reimbursement lists every two years • In the EU, France and Italy use this to limit pharma expenditure, implementing cuts per annum
Discounts and rebates	• Companies offer rebates and discounts in the US and EU to governments and regional healthcare systems • Mandatory in some countries such as Germany
EU price	• Setting a single EU price across all EU countries is under consideration

Source: Datamonitor

Understanding reimbursement strategies is essential to help ensure inclusion of the drug in the formulary list. This needs to be done by demonstrating the ability of the company to consistently supply the product at the desired quality parameters within the cost-pricing considerations of the reimbursing authorities.

Product liability risk

Product liability risk is a critical consideration in developed, regulated markets. For example, in the US a significant number of product liability claims are governed by the doctrine of strict liability which is over and above those claims that are based on negligence and other fault-based theories.

Under the strict liability doctrine, sellers of faulty products are held responsible if the products they sell cause injury and without the requirement to establish negligence or other fault on the part of sellers. Factors that can be considered include failure to warn, design fault, manufacturing fault, inability to adhere to regulatory standards and techniques of product promotion.[5]

Companies have to mitigate this risk as best as they can through measures including stringent compliance programs with respect to product development and manufacturing, other regulatory and legal pre-requisites and marketing practices, maintaining product liability insurance and product recall insurance.

Supply chain management

Supply chain management in regulated markets is a complex process. Fierce competition among generic players often leads to a situation where 8-10 players are simultaneously approved to launch a generic product. With little differentiation among products, availability plays a key role in determining the market share of a product.

Dr. Kamal Sharma says – "Major regulated markets are also characterised by organised retail chains and wholesalers that wield considerable control over the supply of drugs, and for a company to be able to garner market share, these relationships need to be robust. It is imperative to ensure that service standards to retail giants like CVS, WalMart, Walgreen are of the highest degree and that fill rates are well maintained so that the supply of drugs is consistent and unobstructed. This calls for robust supply chain machinery that can manage inventory effectively, and can ensure that demand is adequately met."

[5] BioInsights, Biotechnology & Life Sciences Practice Group, August 2006

Managing different regulatory needs and simultaneous growth /penetration

It may be relatively easy to master the regulatory compliance requirements for a single market. However, many Indian pharma companies are focused on multiple markets penetration.

Managing multiple regulatory systems, patent exclusivities, extensions and expiries is challenging and this complexity increases with the number of foreign markets served. Furthermore, understanding different regulatory needs in terms of bioequivalence requirements, drug strengths and packaging norms and planning development strategies can also be very challenging.

Dr. Kamal Sharma says – "Being nimble, agile and relevant is key to any successful enterprise. To manage simultaneous growth in multiple markets calls for tightrope walking – ensuring protection of margins, market share along with growth, and reach. Strategy cannot be approached using the one-size-fits-all approach, rather a calculated and carefully crafted model that borrows from geographical diversities, and addresses their varied regulatory requirements."

Cultural challenges

Companies also need to be mindful of the challenge of managing cultural differences from market to market.

Dr. Kamal Sharma says – "One more challenge that we are increasingly being faced with is a cultural mix of philosophies – for example, the Japanese market is hugely different from a US market or an Indian market. To be able to understand, assimilate and adapt to these cultural differences is a skill that companies need to keep polishing and improving upon."

Forex management

Exposure to foreign exchange movement, particularly in relation to receivables and foreign currency loans, is a risk which must be considered by Indian companies. There are a number of high profile examples of significant foreign currency losses being made by Indian corporates recently.

Slowdown in new product approvals

Over the last few quarters there has been a slowdown in the approvals given by the US FDA / EMEA. One commonly cited reason is that the US FDA office is overburdened and is facing a shortage of manpower. It is also believed that the US FDA / EMEA, already considered among the toughest regulatory agencies globally, have become more stringent over quality and manufacturing standards.

There has also been a higher incidence of 483s[6] and warning letters issued to companies who breach the set quality norms. In such a scenario, in addition to ensuring the highest compliance to the established regulatory norms, companies also need to ensure satisfactory product development data submission (93 percent of ANDAs are not approved in the first cycle and 59 percent are not approved in the second cycle).[7]

Dr. Kamal Sharma says – "Recent years have seen an increase in the number of filings by various pharma players to the US FDA. We have been reading about the issues with lead in paints, melamine in milk, and the like which have prompted the US government to sit up and take notice. The FDA has therefore become a lot more vigilant – for growth to be exponential, responsible, quality healthcare must be maintained and this is a natural approach that is needed to ensure that drugs administered are of superior quality standards and safe.
All of these factors combined have caused an increase in the time taken by the US FDA to approve products. What used to take 10-12 months a few years ago, is now taking close to 18 months. This does not necessarily mean that there has been a 'slowdown' in the number of products being approved by the US FDA – but simply a ramp-up in vigilance, which is in fact, the need of the hour."

6 Form 482 is a 'Notice of Inspection' issued at the manufacturing site by the US FDA. A variation from the cGMP requirements invokes a Form 483 'Notice of Observation', which identifies the deviation. If not resolved by the company, it could lead to the issuance of a Warning Letter, which could be followed by more stringent action like seizures, product recall, not granting new approvals, fines and even prosecution.

7 Presentation by Lupin on 'Challenges in Generic Drug Development for Regulated Markets'

The economic downturn

Indian generic companies have been impacted by the ongoing economic slowdown. In markets where generics penetration is high – and these are important markets for Indian companies – the thrust is on further cutting down costs by implementing price cuts and other measures of price control. This is balanced to some extent from countries where generics penetration is relatively weak, where the thrust has largely been on encouraging the use of generics medicines to control healthcare expenditure.

Indian companies are also being adversely affected by tightened liquidity conditions, the weakening rupee, greater risk of realisation of receivables, and even an overall reduction in demand due to a lower inventory turnover ratio.

Companies need to re-look at their operating models from the perspective of higher fiscal prudence and efficiency through optimum resource utilisation and productivity improvement.

Acquisitions

Penetrating global markets through acquisitions has been a key strategy used by Indian companies. It is important that the risks involved are fully understood. Some important considerations include:

Strategic fit

Is the acquisition a 'strategic fit' to the overall business? What synergies can be derived out of the purchase in terms of product-line extension, new therapeutic segments, strengthening niche portfolios, acquiring new technologies, ready access to a well established distribution network, acquiring IP and marketing authorisations and strong regulatory expertise?

Funding

How will this acquisition be funded? Using existing cash reserves, raising debt to fund the buy-out or by diluting equity stake?

Acquisition size

Another important consideration is the size of the acquisition – is it preferable to acquire a large-sized company that can immediately provide a leading market position, or a small to medium- sized player? Whilst acquiring a larger player may provide a leading market position more quickly, it may also entail high risk. This is because there is the threat of changing market conditions (in terms of pricing, etc.) and fundamental structure changing (for example, from branded generics to commodity generics) in today's highly dynamic scenario, thereby disrupting the basic assumptions made at the time of purchase. On the other hand, if the company pursues the strategy of making a large number of small size acquisitions, it has to manage the acquisition, integration and management of more companies, which may be a more complex responsibility.

Synergies

The actual synergies derived from the transaction depends on the post-acquisition strategy implemented by the management.

Dr. Kamal Sharma says – "As one can imagine, there would be tremendous challenges faced whilst acquiring and integrating foreign companies. Firstly, there are cultural challenges to overcome. To be able to understand, assimilate and adapt to these cultural differences is a skill that companies need to keep polishing and improving upon.

Secondly, as a philosophy, the acquisition must fit into the company's overall strategic intent. We believe that bigger is not necessarily better. M&A should be part of a company's strategic tool kit and should be used judiciously to manage shareholder returns. The underlying theme should be to buy 'for a cost' and not 'at all costs'. Acquisitions should supplement the overall strategic model of the company. Size should not be the primary approach to any acquisition. It should be influenced by the value it can offer the company, in terms of either a chosen therapy segment or geographic market, or then for its technological edge.

Lastly, one must ensure operational synergies, in terms of both cost synergies as well as revenue synergies, are realised within the time frame envisaged."

Conclusion

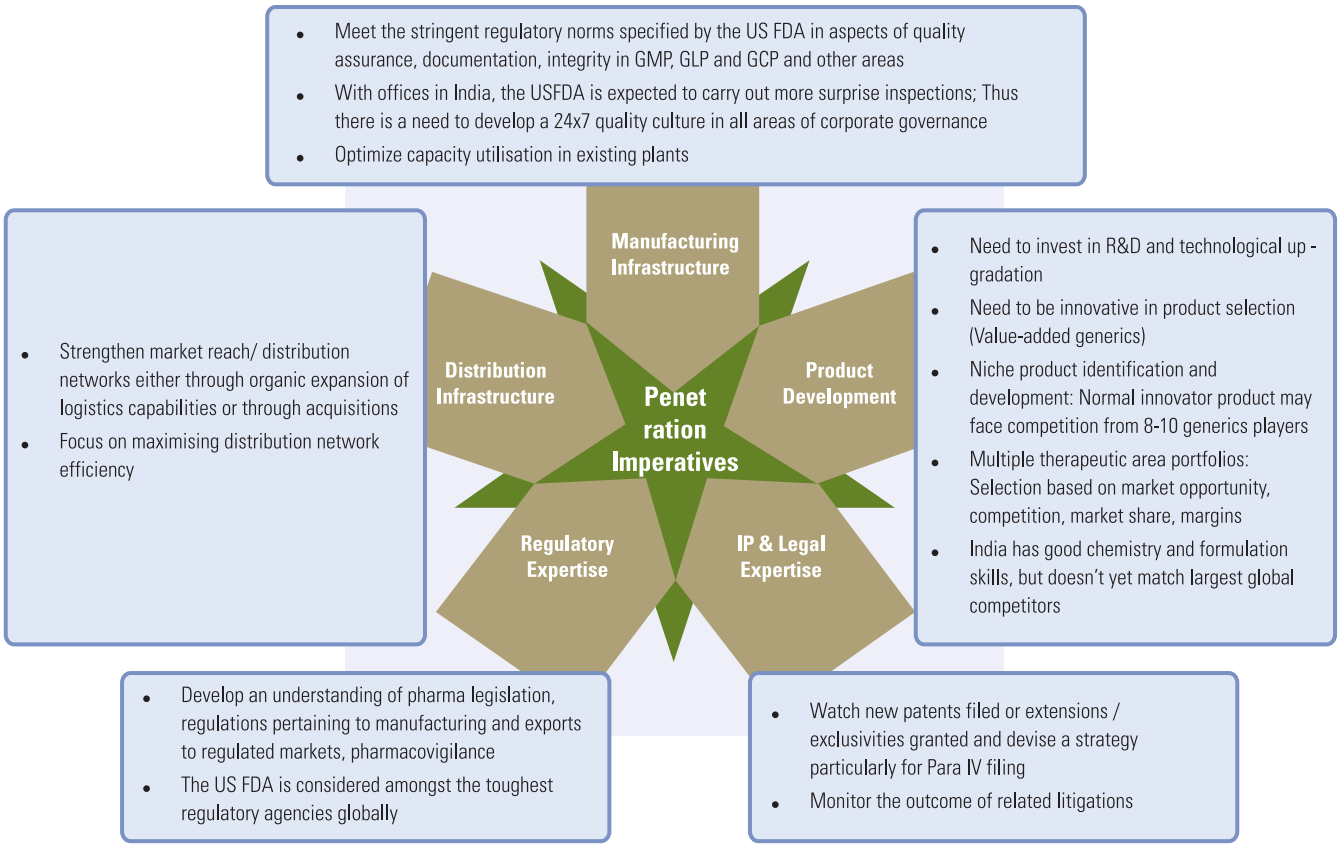
Competencies development

The imperative to succeed in the global generic markets means building strong competencies across the entire value chain and constantly realigning business focus and costs to changing market conditions.

Dr. Kamal Sharma says – "A company must constantly revisit, revise and renew its existing product offerings to assess where improvements can be made and how. This can help a company stay ahead of the curve, identify opportunities, latent needs and develop solutions to address them."

The illustration below highlights the key competencies any company needs to develop to achieve this:

Figure 7: Competencies development



Source: CRISIL Research, IIFL Report 1Q 2009, CII-KPMG Pharma Summit 2009

Dr. Kamal Sharma says – "Staying abreast with Current Good Manufacturing Practices (cGMP) and constantly revisiting and upgrading your existing processes, while simultaneously planning for future needs helps a company meet these challenges and gain both mind space and shelf space."

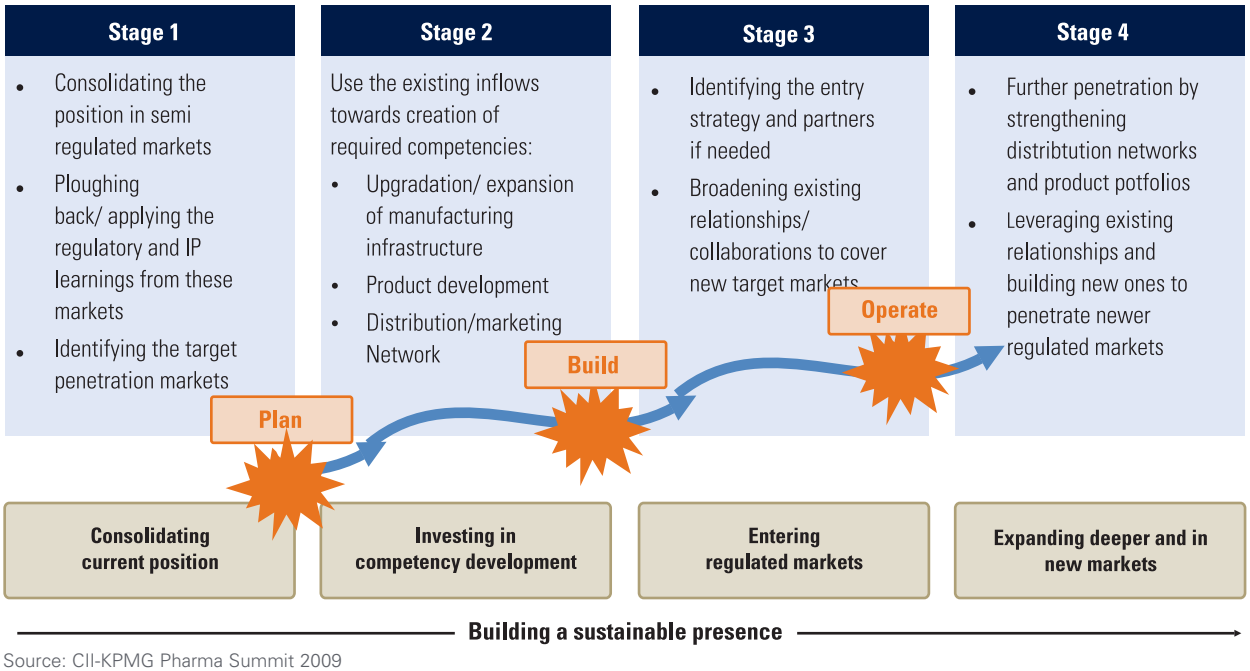
Based on the strength of its value chain, a company needs to decide on whether to span multiple markets or focus on penetrating a small number of selected markets. Further, a good mix of regulated and emerging markets can help mitigate risk.

Dr. Kamal Sharma says – "Geographical diversification in terms of regulated and emerging markets helps companies mitigate their risk exposures. Companies that are able to borrow best practices are those that have a consistent and balanced presence across all kinds of markets, and therefore can learn from the best minds across the worlds, in an environment that is conducive to growth and in a way that optimises business prospects."

Additionally, while developing new products, the company needs to perform a thorough cost-benefit analysis to evaluate the resource allocation for the development of a new product for one particular market or towards a product that can serve multiple markets.

The illustration below provides a roadmap to building a sustainable presence in regulated markets through consolidating the current position and building the right competencies before entering the regulated markets.

Figure 8: Roadmap to building a sustainable presence in regulated markets



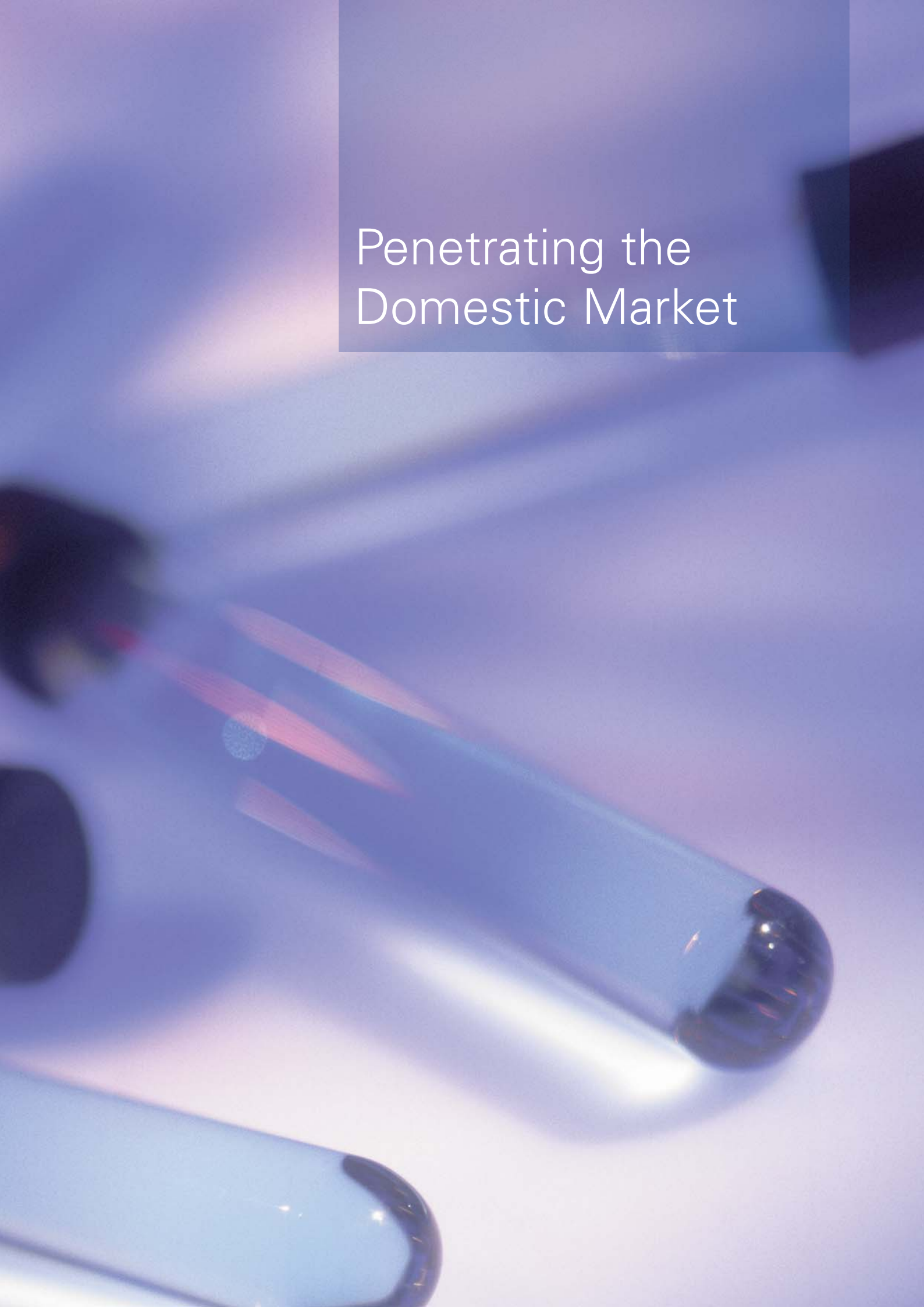
Source: CII-KPMG Pharma Summit 2009

Developing robust relationships with trade associations: Helps manage competition

Building strong relations with trade associations becomes extremely important in highly competitive regulated markets.

Dr. Kamal Sharma says – "Trade bodies will continue to play a pivotal role in drug demand and supply, especially in regulated markets, and strong service-based ties with these bodies along with retail chains will help companies protect their turf from competitive backlashes."

Penetrating the Domestic Market



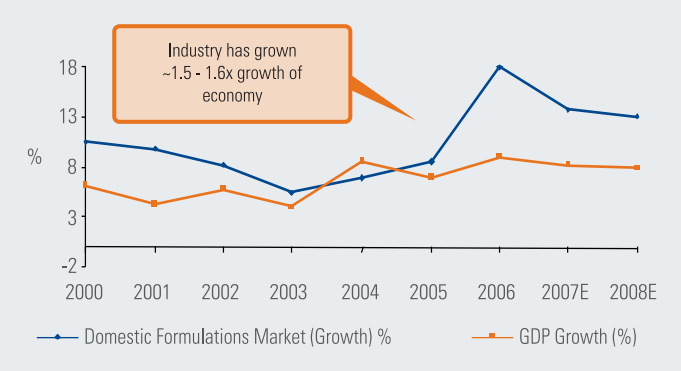
Penetrating the Domestic Market

Introduction

The domestic pharma industry has been typically growing at ~1.5-1.6 times the GDP growth.[1]

The growth rate of the Indian economy is expected to continue to outperform that of several developed and emerging economies, and the domestic drug market is expected to continue growing at a double-digit rate outperforming several other key pharma markets.

Figure 9: Growth trends in GDP and domestic formulations market



Source: CSO, IMS

Region	Market Size	Market Growth	Market Growth Forecast
	2008 (USD Billion)	CAGR 2003-2008	CAGR 2008-2013E
North America	311.8	5.7%	-1 - 2%
Europe	247.5	6.4%	3 - 6%
Japan	76.6	2.7%	1 - 4%
India*	**7.7**	**14.6%**	**12.2%**
Global Sales	773.2	6.6%	3 - 6%

*FY08-FY13

Source: IMS Health, Standard Chartered Capital Markets Research Equity Research - Pharmaceutical Sector Report July 2009, Crisil Research Report on Pharmaceuticals, December 2008

This growth is expected to be driven by socio-economic factors such as rising income levels, increasing affordability, gradual penetration of health insurance and organised retail chains, increasing healthcare awareness in rural markets, increased willingness to pay for treatment in rural areas and the increasing prevalence of chronic and lifestyle diseases.

[1] CSO, IMS

As a result of these high-growth expectations, the domestic market is being targeted both by Indian pharma companies - many of which have until recently been export-focused – and foreign companies who are keen to build a sustainable presence in India.

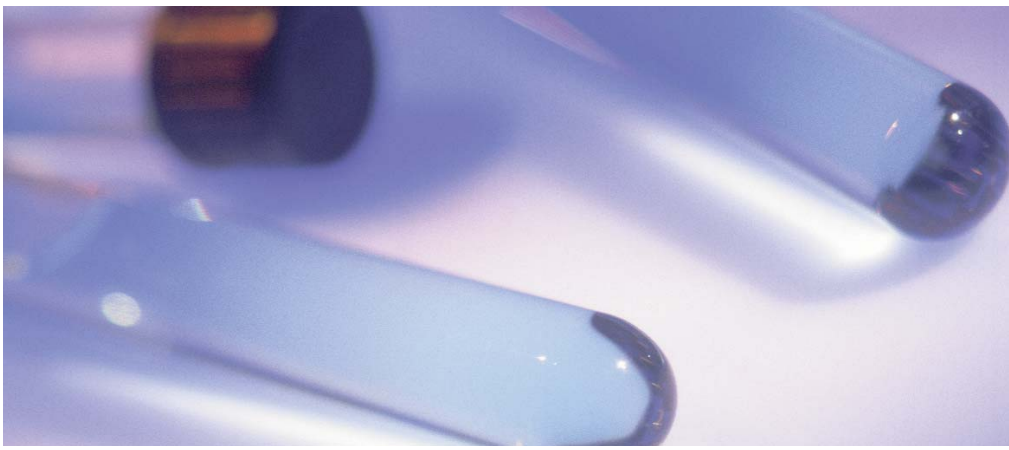
Foreign companies are making fresh investments in India by way of increased investment in existing subsidiaries, acquisition of Indian companies and strengthening of existing sales and distribution networks.

Figure 10: MNCs increase staff numbers in India

MNCs in India
• Pfizer India has increased its sales strength by 250 - a growth of over 20 percent
• In 2008, GSK India increased sales force and has grown its staff strength from 3,620, as of December 2007, to 3,722 by December 2008
• Aventis Pharma is reported to be recruiting 700-800 sales personnel over the next 2-3 years

Source: Avendus Research 'Lapping up India', April 2009

Whilst the opportunity to sell pharma products to Indian consumers is high, conversion into actual revenue flows is difficult because the domestic market - like foreign pharma markets - has its own set of challenges.

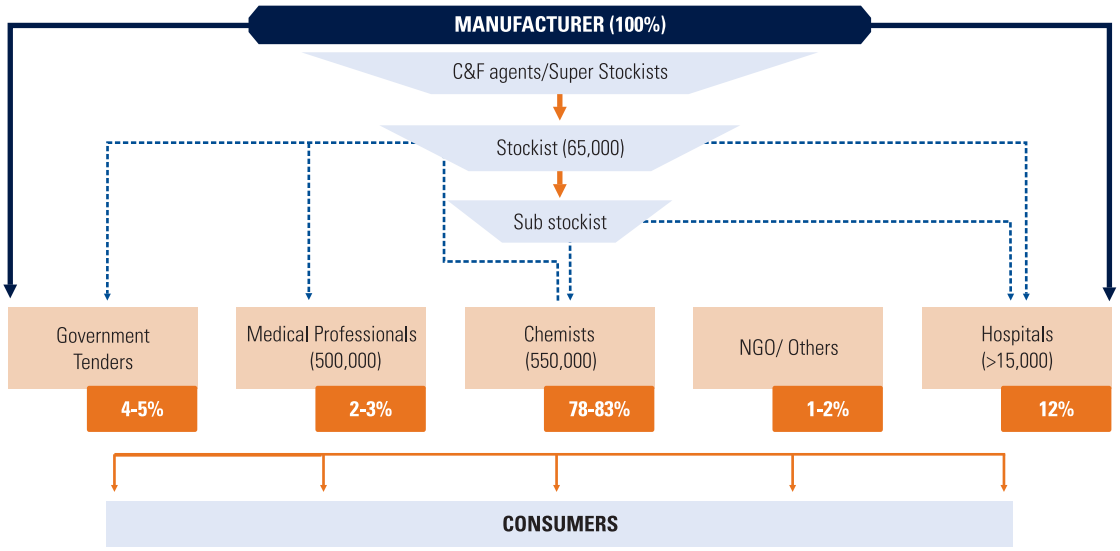


Key Industry Challenges

Complex distribution channel

The domestic drug distribution system is multi-layered, fragmented and controlled by strong industry unions. Over the years, the fragmentation of the distribution channel has increased. For example, the number of distributors has grown six-fold from 10,000 in 1978 to approximately 65,000 today whilst the number of retail pharmacies has grown four-fold from 125,000 in 1978 approximately 550,000 pharmacies today.[2]

Figure 11: Domestic distribution channel



Source: ORG IMS, Kotak Institutional Equity Research on Indian Pharmaceutical Industry, December 2007

This creates several challenges for the manufacturer to ensure effective and cost-efficient supply.

Inefficient utilisation of resources

The complex and inefficient distribution channel leads to pharma companies spending significant resources to help ensure adequate availability of their products across this geographically widely dispersed market. As a result, the industry faces high distribution costs, sub-scale distributor operations due to low average revenue per distributor and sub-optimal inventory management.

---

2 Indian Retail Druggists and Chemists Association, BioPharm International www.biopharminternational.com, 'Pharmaceutical Distribution in India', September 2008

Sales force management

The complex marketing and distribution channel also poses a challenge for managing the sales force. Pan-India penetration requires a well spread out, local territory educated and competent sales force to help ensure an optimum reach to pharmacies, medical practioners and hospitals. This demands higher investment and the need to track sales force performance to maintain high productivity. Further, the retention of sales staff can also be challenging with many competitors competing for high quality people.

Cost of distribution

As a result of these issues, the cost of distribution in India is much higher than that in other countries such as the US where the top three distributors are estimated to control 90-95 percent of the total sales.[3] The cost of supply chain management has been estimated at 4-6 percent of total revenues in India as compared to ~2 percent in the US or EU.[4]

Storage infrastructure and standards

Another problem of the distribution system is the inadequacy of cold storage infrastructure. This poses a major problem particularly in the distribution of biopharmaceutical products.

It is understood from discussions that, due to the limited control of manufacturers over the distribution channel, there are also issues of non-adherence to prescribed regulatory standards for transport and storage, spurious drug circulation in the market and unethical practices such as substitution of prescribed brands at the pharmacy level.

Increased penetration of organised retail players can bring about a significant transformation of the distribution network over a period of time and can help address the major problems.

Sahir Khatib says – "The pharma distribution still follows the archaic system. With the entry of organised players in other retail networks, it is hoped that the stranglehold of the associations in pharma distribution will be dented and the same revolution will take place in this network."

---

3 Kotak Institutional Equity Research on Indian Pharmaceutical Industry, December 2007

4 Indian Retail Druggists and Chemists Association, BioPharm International www.biopharminternational.com, 'Pharmaceutical Distribution in India', September 2008

Diverse market

There is a wide disparity in living standards and infrastructure development across India and demand scenario differs significantly from region to region, making it a very complex market to enter.

Dr. Kamal Sharma says – "The Indian pharma market is a very fragmented, widespread and complex market and more often than not, the outlook and awareness levels for healthcare, personal hygiene, diseases and drugs, differ across regions. This presents with a unique set of challenges that are present across levels – from the administrative to the individual. Catering to the demands of disparate regions in a rather vast country poses significant challenges."

Managing rural penetration

Another critical challenge for companies supplying to the domestic market, is penetration into rural markets, which are growing on account of the rising disposable incomes, affordability and awareness. The scale of the opportunity is evidenced by the fact that rural India accounts for over 70 percent of the total Indian population, but only 20 percent of total domestic pharma sales.[5] There are approximately 20 million middle class households spanned across 600,000 villages of rural areas.[6]

Given the geographically dispersed nature of the rural markets, the cost of distribution is higher than supplying to urban centres.

In addition, successful marketing to the rural consumer requires knowledge of the dynamics of the rural market, which are significantly different from urban markets. This is due to the lower education and literacy levels, poor healthcare infrastructure, lack of availability of adequate doctors who can prescribe appropriate medicines and poor distribution and storage infrastructure. The manufacturer has to break through these barriers to reach the consumer. This requires higher investment and a tailored marketing strategy.

Sahir Khatib says – "The major challenge shall be to rationalise the cost for penetrating such markets vis-à-vis the benefits of increase in the business."

---

5 Express Pharma Pulse 'Road to the village' September 2006, Kotak Institutional Equity Research on Indian Pharmaceutical Industry, December 2007

6 Express Pharma Pulse 'Road to the village' September 2006

Evolving regulatory infrastructure

Any company looking at launching a patented product in a new market first evaluates the regulatory infrastructure of that country to ensure that its IP is satisfactorily protected. The introduction of product patents in India in 2005 has opened up the market for patented launches. However, it is understood from discussions that foreign companies still believe that India's IP and regulatory system needs to be strengthened further.

Contrary to initial expectations, the launch of on-patent drugs in the domestic market has been relatively slow. Between January 2005 and March 2008, only 15 patented products were launched in India by 5 companies.[7] MNCs are awaiting the Indian government's resolution of certain regulatory loopholes and other ambiguities pertaining to matters including data exclusivity and pre-grant and post-grant opposition of patents.

In addition to the IP regulatory infrastructure, both domestic and foreign companies feel the need to have a centralised regulatory body. This can improve the process of getting the approvals and clearances for a drug launch.

Sahir Khatib says – "There is a need to centralise the regulatory authority which is present in most countries, whereby the interpretation or misinterpretation of the law by various states can be avoided."

Creating brand visibility

The domestic drug market is extremely competitive with often ten or more brands existing for the same molecule. In such a market, creating brand allegiance from doctors is not easy. Brand building and loyalty is therefore a critical and challenging exercise in India.

7 Crisil Research Report on Pharmaceuticals, December 2008

Shortage of new products

There has been a fall in the number of new launches in India which implies a scarcity of new products. During December 2008 (based on moving annual total data), the number of new products launched by the top 10 players, fell by less than 1 percent and the number of new products launched by the next 15 players fell by more than 8 percent.[8]

Sahir Khatib says – "The domestic companies are facing acute paucity of new products, which have been the major growth drivers in the earlier years. There is also a new breed of companies which are using unusual strategies for marketing which is causing disruption in the marketplace for established players. The market for domestic pharma appears to be in a transition and looking for direction and the steps taken by the large players may give it direction in the future."

Uncertainty of pricing policies

The government needs to make the final decision on the proposed pharmaceutical policy, which seeks to increase the scope of essential drugs under the purview of the Drug Prices Control Order (DPCO) from the current 74.[9] This is expected to bring more clarity on the pricing scenario for companies operating in this market.

Dr. Kamal Sharma says – "The pricing policies imposed by the government at various levels and bodies like NPPA is a dampening factor inhibiting consolidation and rapid growth of the industry. It is an unfortunate reality that for a country with a population of over a billion people, less than 5 percent enjoys access to quality healthcare. Pricing pressures for drug manufacturers in turn takes a toll on bottom lines, and reduces the share of R&D."

8 Crisil Research Pharmaceuticals, May 2009

9 Crisil Research Report on Pharmaceuticals, December 2008

Conclusion

Key success factors

In order to build a profitable business model for the domestic market, much depends on how these issues are tackled. The focus here needs to be on **ensuring an 'optimal reach' – capturing maximum population at minimal investment.** This can be done through comprehensive planning of all the different business functions – including development of tailored marketing strategies for rural markets, hospital market, optimisation of supply chain management and sales force management as set out in the table below.

Figure 12: Key focus areas to build a sustainable business model

Rural market focus	• Develop a unique marketing and distribution strategy for different rural markets including a pricing strategy • Due to inadequate availability of doctors, companies have to play the role of an educator as well • The company has to consider marketing options through community welfare programmes or by conducting healthcare workshops, roadshows, stalls at fairs, etc.
Hospital market focus	• India's healthcare landscape is set to change with the planned capacity addition and pan India expansion - Over 1 million beds need to be added to attain a ratio of 1.85 per thousand - Of this, about 8,96,500 beds are expected to be added by the private sector requiring an investment of USD 69.7 billion (Source: Fortis Healthcare Annual Report FY 08) • With this, the hospital segment can be expected to contribute a higher share to the total domestic market • Thus there is a need to increase focus on this segment
Optimize supply chain management	• Management of the entire value chain: An effective cost saving and revenue augmentation strategy • Ensure optimum utilisation of resources by integrating supply systems of manufacturer with the suppliers and customers, thereby increase competitiveness • This can facilitate in product development and approval cycles for new products, meet stringent regulatory requirements and also aid in reduction of inventory
Sales force management	• Clearly outline medical representatives' coverage areas • Ensure strong local market knowledge • Hire personnel with knowledge/experience of rural markets - contractual sales force is an option for rural markets • Set realistic yet challenging sales targets based on potential of each area

Source: CII-KPMG Pharma Summit 2009, Press Articles and Reports

Sahir Khatib says – "The benefits of an efficient supply network will translate into benefits to the consumer which will pave the way for healthy competition for all the companies keeping the end consumer in mind."

Other considerations

Need to combat spurious drug circulation

Spurious drug circulation is a major issue for the Indian pharma industry today. This issue needs to be addressed both by the industry and the government.

The government has initiated steps to address the issue. To combat adulterated and spurious drugs, the Ministry of Health and Family Welfare has newly notified an amendment to the Drugs and Cosmetics Act, 1940. The amendment made by the passage of the Drugs and Cosmetics (Amendment) Bill, 2008 strengthens the current law to help ensure bigger penalties for such offences. It has brought them under the classification of serious offences and in certain cases the penalty can be the life imprisonment.

The amendment provides for compensation to the victim of adulterated and spurious drugs. There will most likely be "special courts" to try such offences. Furthermore, the Ministry is also planning to put in place a "whistle blower" policy to reward people who inform authorities on the trade and source of spurious drugs.

Strengthening IP infrastructure

The government is already in the process of resolving the IP issues mentioned in the previous section.

One such step deserves a special mention here – the recently reported acceptance by the government of the revised Mashelkar Committee Report on Patent Law Issues. This report reportedly seeks to allow patenting of incremental innovation under Section 3(d) of the Indian Patent Act. This is provided the innovator can prove the enhanced efficacy through the incremental innovation. However, allowing patenting of incremental innovation also calls for careful evaluation to strictly discourage 'evergreening'.

On patenting of micro-organisms, the report is understood to state that excluding micro-organisms from patent protection would likely breach the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

To conclude, this report seeks to help ensure greater compliance with the TRIPS Agreement, which is a positive move in strengthening the IP infrastructure of the country and boosting the confidence of foreign companies in the Indian system.

Contract Research And Manufacturing Services: Capturing a Higher Market Share of the Global Opportunity

Contract Research And Manufacturing Services: Capturing a Higher Market Share of the Global Opportunity

Introduction

Big Pharma is under pressure due to a number of factors including growing patent expiries of major blockbuster drugs, price restrictions and a slowdown in new product approvals and launches. To add to these pressures, there has been a decline in R&D productivity, leading to a further deceleration in bringing new blockbuster drugs to the market leading to a difficulty in maintaining historic growth rates and revenue levels.

To deal with these issues, Big Pharma continues to work on optimising resource allocation and minimising the cost of taking products to the market and is increasingly outsourcing certain functions as part of its cost-cutting drive. The non-core functions within the product discovery to commercialisation value chain - particularly downstream product development and manufacturing - are being outsourced to low-cost geographies that have proved their credentials in these areas.

Figure 13: India's value proposition

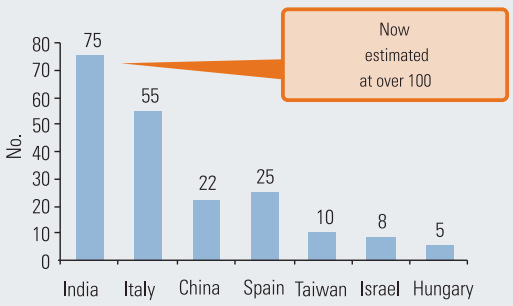
Strong Capabilities

- Historically strong chemistry and process re-engineering skills ...thanks to Patents Act
- Highly skilled technically qualified talent pool of English speaking manpower
- Recognition to Product Patents from 2005 increased confidence of global companies
- Adherence to international regulatory and quality standards like ISO, ICH, GLP, GCP

Source: CII-KPMG Pharma Summit 2009

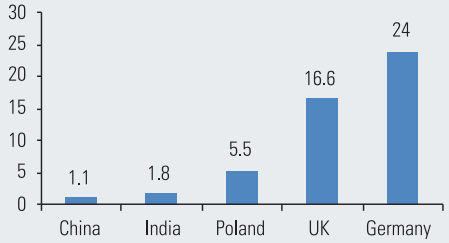
High Quality

No. of FDA approved plants outside US



Source: Merrill Lynch

Labour Cost Advantage



Source: Merrill Lynch

Lower Costs

Overall Cost Advantage

Cost of manufacturing in India and Europe v/s US

US	100
Europe	90
India	
US FDA	35-40
Others (Non US FDA)	25-30
China	20-25

Source: Crisil Research

India is at the forefront of this move towards outsourcing and has been steadily ramping up investment to create a sustainable presence and consistently generate a higher share of total revenues from the CRAMS business segment.

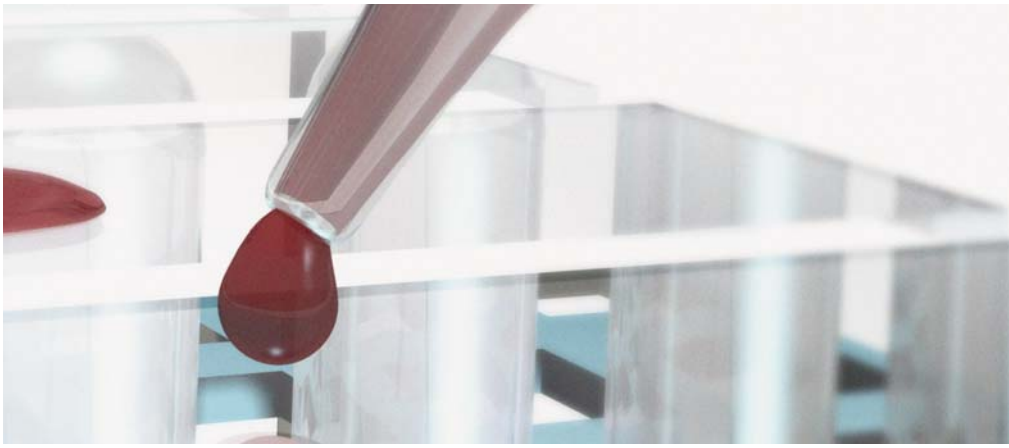
With strong credentials, India has already demonstrated its potential to emerge as the favoured destination in the global outsourcing market and has over the years progressed from being a 'Vendor of Choice' to being considered a 'Partner of Choice'.

India's value proposition has caught the attention of foreign companies. However, in spite of their potential, Indian companies have until now managed to capture only 3 percent of the global market.[1] It is evident that leveraging this value proposition to realise maximum potential and generate revenue streams is more difficult because of the challenges involved in executing the projects and in building scale.

"The inability to execute projects by maintaining timelines, lack of transparency with customers and quality issues raised by FDA with leading Indian generic companies have been some of the key deterrents for Indian companies in gaining a higher market share of the global opportunity." – says Jai Hiremath

All of these concerns and challenges need to first be clearly identified and then addressed by the industry and its various stakeholders together. Furthermore, this segment has not escaped the impact of the ongoing economic slowdown and growth has been affected.

"There has been a deceleration due to the economic slowdown and the M&A activities of the Big Pharma companies, which has put many decisions on hold." – says Jai Hiremath



[1] Reliance Money 'Indian Pharma CRAMS', July 15, 2008

Key Industry Challenges

Creating a reputation as a 'Reliable' partner: Managing quality and delivery timelines

'Reliability' is the fundamental requirement to successfully building a CRAMS business.

Sucheth Rao highlights – "To build long-term relationships, it is important to focus on reliability. A reliable company is one that delivers the product or service on time, within the defined parameters of quality and is responsive to the customers' changing needs. It is very easy to define reliability, but it is very difficult to function as a reliable company."

Reliability can be defined by two essential parameters – delivering the pre-defined quality at the pre-defined timeline. Successfully executing a project entails meeting these two parameters as promised.

Sucheth Rao says – "Quality of the final product and adherence to the specifications committed originally to the customer remains the key issue in the contract manufacturing segment. Delivery of the material as per the committed due date is another issue that many Indian companies are facing. One of the reasons why global pharmaceutical companies hesitate to outsource to India (and also China) is the fear of reliability of Indian companies to meet quality and delivery time consistently."

A company has to ensure that effective systems and processes are put in place through the entire supply chain in order to manage both these parameters.

Long gestation period

The gestation period in the CRAMS segment from the time a contract is assigned to the commencement of supplies is estimated to be 18-24 months[2]. This gap between contract award and revenue flow is primarily a result of the lengthy regulatory process involved. Further, when the relationship between the client and company is in the initial stages, the client takes more time to assign contracts of higher value. Therefore a company takes some time before it can generate a steady flow of revenues from this business segment and scale up.

Managing diverse segments

Indian companies are steadily expanding the scope of outsourced services offered in order to become integrated or one-stop-shop service providers. However, unlike other business segments, vertical integration across the value chain in the CRAMS segment is a more challenging task because the players need to regularly invest in technology in order to sustain their competitive advantage. As a company moves into multiple offerings, simultaneously managing each of these different segments can be a complex task.

"It is important that Indian companies expand their scope and technology in order to offer more value to their customers. This will definitely be a challenge as adopting new capabilities would require investments and more importantly recruiting scientific talent to manage these new areas." – says Sucheth Rao

For this reason, it is important that companies assess their ability to expand their offerings such that the quality of service is not adversely impacted by expansion.

Managing the IP of the client

Protecting the IP of the client is another critical factor for the success of a CRAMS business and trust plays the central role in the decision making process of the selection of an outsourcing partner or vendor. Indian companies must help ensure that highest standards of risk management and IP protection are in place and implement clear and stringent IP respecting/protecting and non-conflicting policies.

---

2 Reliance Money 'Indian Pharma CRAMS' Sector Report, July 2008

Ongoing economic slowdown

The CRAMS business segment has been affected by the economic slowdown in a number of ways as set out below.

Managing finance

The CRAMS business demands high investment towards building front-end infrastructure to create a strong client network. While many larger players in this segment are known to have already made this investment, new or smaller players may face a challenge in funding expansion.

"Given the slowdown in the world economy, companies have a challenging task to simultaneously manage capital expenditure and cost cutting to remain competitive." – says Jai Hiremath

The economic downturn has also adversely impacted working capital management and funding.

"Working capital funding during the October 08 - May 09 period and the volatility in the rupee have been some of the challenges faced by the companies in the contract manufacturing segment." – says Jai Hiremath

Lower inventory off-take and reduced orders

The tightened credit conditions coupled with an overall fall in demand due to a cut in healthcare spending have led pharma companies in several markets to adopt stringent working capital management strategies and rationalise inventory levels. This has led to reduced orders to CRAMS players.

"Customers are reducing inventory. So off-take will be affected for 6-9 months, but we expect bounce back by end of 2009. Conserving cash by deferring capital expenditure and intensive cost control programs are required to cope with these challenges in the ongoing economic slowdown." – says Jai Hiremath

Further, with the growing pressure of the ongoing economic downturn, foreign players have been forced to relook at their budget allocations for different functions leading to reduction in budgets for research projects, thereby affecting order flows.

Small and medium size biotech companies in the developed markets are facing a cash crunch because of the reduced fund flows. As a result, they have trimmed their project pipelines leading to reduced orders to CRAMS players.

"Lack of funding for biotech companies is also one of the reasons for the slow down in the contract research segment." – says Jai Hiremath

Indian companies have to cope with this short-term slowdown in orders from foreign players which directly affect their revenue flows.

Having made significant investments in capacity, Indian companies have to cope with working capital and cash flow implications of slight deceleration in order flows.

Impact on business development

Sucheth Rao highlights the indirect impact of the crisis – "The economic slowdown has definitely created a sense of caution and pessimism in the outsourcing environment. Ancillary activities like travel budgets, trade fair participation have seen signification reduction. Such changes have an indirect effect on development of new business opportunities."

Conclusion

The following factors have been identified as imperatives in building a sustainable CRAMS business model.

Building sustainable long-term relationships

It is important to focus on developing a strong long-term network of clients and partnerships – building sustainable relationships. This can be achieved by winning the confidence of the client by successfully executing big-ticket contracts

Jai Hiremath says – "Maintaining transparency, focusing on quality, cost management and adherence to delivery schedules are vital for building long-term sustainable client relationships."

Execution strategy

An effective execution strategy is one that focuses on improving the quality of service, adhering to the delivery timelines and improving the cost structures while offering value-added services.

Sucheth Rao says – "In order to cope up with the challenges of quality and reliability, a company must have quality systems in place that supersede operational priorities (sales, profit, costs, etc.). Also, supply chain and manufacturing controls need to be in place in order to meet committed deadlines."

High quality standards and strong technology platform

Technology and research play an important role in developing a successful CRAMS model. A company must work towards building capabilities in product and process innovation over time.

Sucheth Rao says – "In contract research, companies need to function as an extension of the customer's R&D department. Companies can develop various mechanisms to provide high levels of customer service in the contract research area. These could include innovative communication tools to provide regular updates on project progress, providing service level agreements in contracts, etc."

Regulatory adherence and ethical standards

Strictly adhering to the highest regulatory standards and processes and having a strong ethical foundation that maintains client confidentiality and respects his IP are key determinants of the success of any company in this business segment.

"Indian companies have the potential to grow by establishing wide product and customer portfolios, developing strong R&D capabilities, maintaining high EHS standards and strong regulatory and documentation capabilities." – says Jai Hiremath

The real challenge lies in building a strong culture within the company that focuses on each of the above stated imperatives for a successful business.

Government support

The government has an important role in maintaining and further developing India's credibility. The government needs to support the industry in preserving the Indian value proposition particularly given the competition from other attractive destinations.

"Government intervention to make India a desirable destination for pharma outsourcing has to increase. Many times the lead time for supply for Indian suppliers is amplified by the delays in transit and customs. The vendor's ability to supply on time is one of the key factors while making a choice for a customer." – says Sucheth Rao

BOROSILICATE GLASS
TEST TUBE

Clinical Research Services: Realising India's Potential on the Global Platform

Clinical Research Services: Realising India's Potential on the Global Platform

Introduction

India is amongst the preferred options for foreign companies struggling to cope with the pressures of rising R&D costs, declining productivity and approval of new product launches. However, the motivation to outsource drug development to India goes well beyond the cost consideration. Recognising the value proposition India can offer in clinical research, foreign companies have, in recent years, laid greater emphasis on making it an integral part of their drug development value chain. This is evident in the increased collaboration between Indian and foreign companies in the clinical development of drugs, the increasing number of multinational Clinical Research Organisations (CROs) setting up in India and the fast growing number of local CROs.

Figure 14: India clinical trial value proposition vis-à-vis other emerging markets

Source: World Economic Forum Annual Meeting 2008

Indian companies have built the foundations of a leading clinical trials services market by putting in place regulatory reforms, value-added services and ethical processes and have gained the trust of the global industry. However, there is a need to strengthen these foundations further.

Dr. Ferzaan N. Engineer says – "India has now become a major destination for the conduct of clinical trials. A large population, various unmet medical needs, a growing hospital infrastructure and a well established medical and scientific fraternity have contributed to the growth of this industry. It is important to identify the right hospital sites, offer appropriate GCP training to investigators and hospital staff and then strictly monitor compliance with standards and procedures, particularly those involving patient safety."

Despite demonstrating strong credentials in the global market and gaining the interest of foreign innovator companies including the Big Pharma, India managed to capture only a 2 percent market share of the global clinical trials market in 2007.[1] Although India has excellent potential to emerge as the preferred destination for conducting clinical trials globally, the success of Indian companies in developing a thriving industry depends on how best they address the key challenges they are faced with.

Key Industry Challenges

Building scale and credibility

The Indian clinical research services market is still in the stage of infancy. While Indian CROs are working on building scale, they appear to be facing a dilemma regarding their expansion plans.

Clinical research and development demands an extremely high level of commitment in terms of financial and time resources. It also demands the highest levels of safety, regulatory standards and quality processes. This means that the Indian CRO needs to build exceptionally high standards of credibility by demonstrating these skill-sets along with high standards of ethics to win the confidence of the sponsor to execute the contract. This is crucial in winning any contract. Only once this trust is built, the sponsor can award bigger and high value-added contracts to the CRO. However, to build the requisite expertise, the CRO must gain adequate experience, which in turn can be gained only by working on such large contracts.

[1] RNCOS' 'Booming Clinical Trials Market in India', January 2009

Shortage of trained and experienced clinical research personnel

A serious concern for CROs in India is the shortage of experienced clinical research personnel, particularly Good Clinical Practices (GCP) certified investigators.

It has been estimated that around 1,500-2,000 GCP trained investigators and about 50,000 clinical research professionals will likely be required over the next five years.[2]

Figure 15: Demand-Supply gap in human resources

Source: Netscribes Report titled Clinical Trials Market – India, July 2009

This demand-supply gap is likely to pose as a serious impediment to the plans of CROs in India to achieve scale. Thus an adequate talent pool must be created across each of these levels. In addition, India needs to build its strength in early stage clinical development.

[2] Netscribes Report titled Clinical Trials Market – India, July 2009

Physical infrastructure

CROs in India face an infrastructure challenge in terms of non-availability of:

- Sufficient GCP certified sites
- Infrastructure for central laboratory services
- Supportive medical infrastructure.

Further, equipment at the sites may not always be of the same standards as those of the western markets.

In addition to the challenge of inadequate infrastructure, a company also needs to regularly upgrade its existing infrastructure - such as diagnostic equipment, technology to maintain patient records and handling of investigational product - in order to maintain the highest standards of quality. This requires regular investment in the business to retain its competitive position.

Regulatory infrastructure

The government is a key stakeholder in realising the potential of the Indian clinical research market both in terms of potential benefits and obligations. It needs to:

- Build a strong regulatory and IP infrastructure in order to help win the confidence of the sponsor
- Address the concerns of CROs in India in terms of getting quick approvals and clearances and thereby contribute to savings in time and delivering the promised value.

The government has already taken several initiatives that have gone a long way in building India's credibility on the global platform.

Dr. Ferzaan N. Engineer says – "Clinical research represents a relatively new area in the country. The infrastructure and regulatory environment are evolving. This evolution is occurring relatively quickly (and with an emphasis on quality, safety and ethical standards) and is a strong indicator of the commitment to high quality, safe clinical research in the country. Significant progress has been made in terms of regulations governing clinical trials. Schedule Y has been amended to contemporary standards in many areas and various guidelines/initiatives have been rolled out to assure patient safety and compliance (by all stakeholders) with necessary standards."

However, several industry players have equivocally expressed the need to further strengthen the regulatory infrastructure on certain essential fronts. One of these is data exclusivity. Unlike the US and EU, India still does not provide data exclusivity for clinical trials conducted in India. A provision for data exclusivity is an important requirement to strengthen India's regulatory infrastructure.

Another important concern expressed by the industry is the delay in getting trial approvals. Although India is leading in comparison with other emerging destinations such as Brazil and China in terms of the average time taken for approval of clinical trials, it is still way behind the US and EU.[3] The Indian market can gain significantly if the government reduces the time taken to grant approvals.

The industry has also proposed a single window clearance system to speed up the process of seeking the various approvals and clearances required to conduct scientific protocols.

Managing patient recruitment and attrition

Delay in patient recruitment is a serious issue as it can directly lead to a considerable delay in the final product launch leading to higher product development costs as well as loss of revenues. This is why faster patient recruitment in India as compared to the US and EU is one of the biggest advantages of outsourcing clinical trials to India.

However, in India, CROs may possibly face difficulty in recruitment in areas of oncology, diabetology, cardiology and neuro-psychiatry. They also face a challenge in recruitment of children and pregnant women.

CROs in India, in order to maintain this competitive advantage must effectively manage patient recruitment and minimise the attrition rate once trials commence. Bringing transparency into the entire system between the patients and the investigators is an imperative to achieve this.

Further, as the clinical trials progress through the various stages of development, the prime responsibility of recruitment is on the investigator and his site team. This requires a well laid out strategy, comprehensive planning, and effective communication with patients to address their concerns.

[3] Ministry of HRD, Government of India (Anand Rathi Reserach, June 2008)

Conclusion

Building Credibility

Building credibility in the eyes of the sponsor is an important factor in building a sustainable CRO model. It is essential to build credibility in the following areas to cope with the above mentioned challenges:

- Credibility of the CRO to effectively and efficiently execute the assigned contract at the promised delivery quality and timeline

Dr. Ferzaan N. Engineer says – "Continuous improvement is very important, whether it is expanding the use of electronic data capture to reduce errors and improve efficiency, or going global to find the trained investigators and the numbers of patients needed in a timely manner."

- Credibility of the CRO to cope with challenges in order to build capacity

Dr. Ferzaan N. Engineer says – "Indian companies can build scale in the clinical research outsourcing business by training more investigators and fresh graduates who choose this industry. Technology services also represent an important area of opportunity."

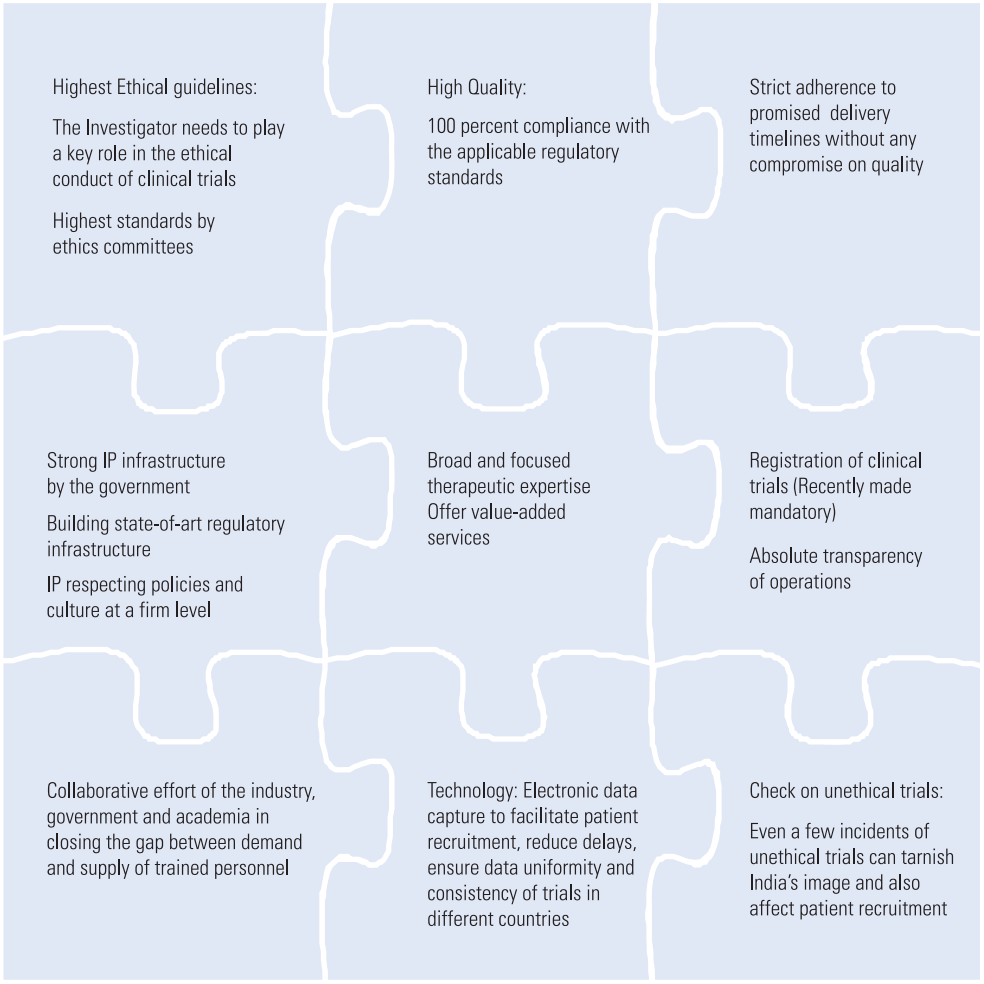
- Credibility of the CRO to realise India's value proposition – its cost and time advantage

Dr. Ferzaan N. Engineer says – "It is a given that CROs must be more efficient and find innovative ways to help customers show the value of their products and get them to the patient faster."

- Credibility in India's IP infrastructure

The following are the essential blocks to building credibility on all of the above parameters:

Figure 16: Essential Blocks in Building Credibility, Trust and Reliability



Source: CII-KPMG Pharma Summit 2009

However, it is not for companies alone to build credibility. The industry, government and academia have to make a coordinated effort in achieving this and building a sustainable growth model.

Building scale with a full range of clinical services

A global footprint and a broader range of service offerings can bring a tremendous advantage to the CRO.

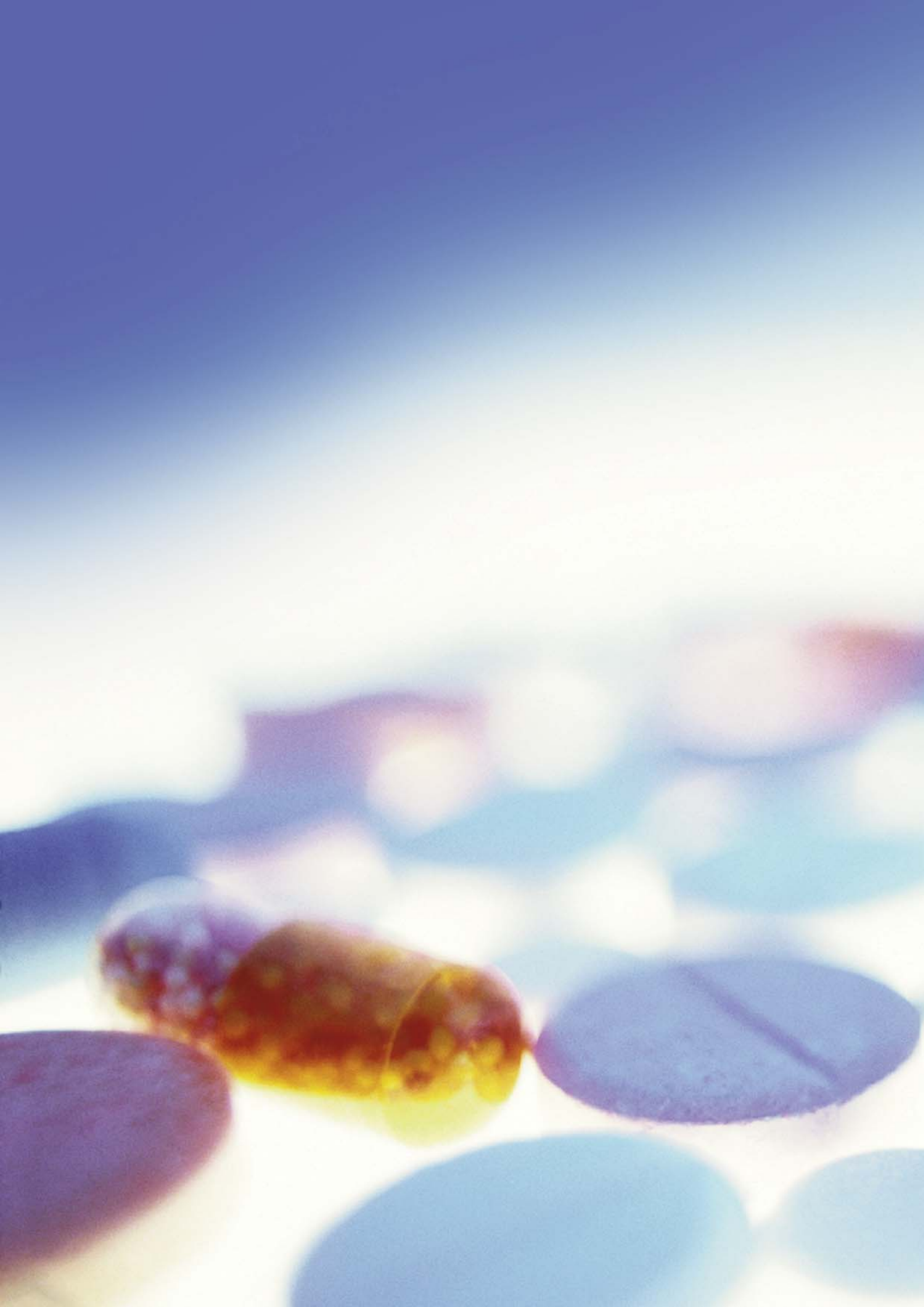
Dr. Ferzaan N. Engineer says – "CROs with a global footprint, a full range of clinical services and the ability to effectively partner pharma companies will have a competitive advantage."

- Having a presence in multiple geographies can help the CRO in realising greater efficiencies. This is viewed very favourably and can significantly facilitate in attracting clients.

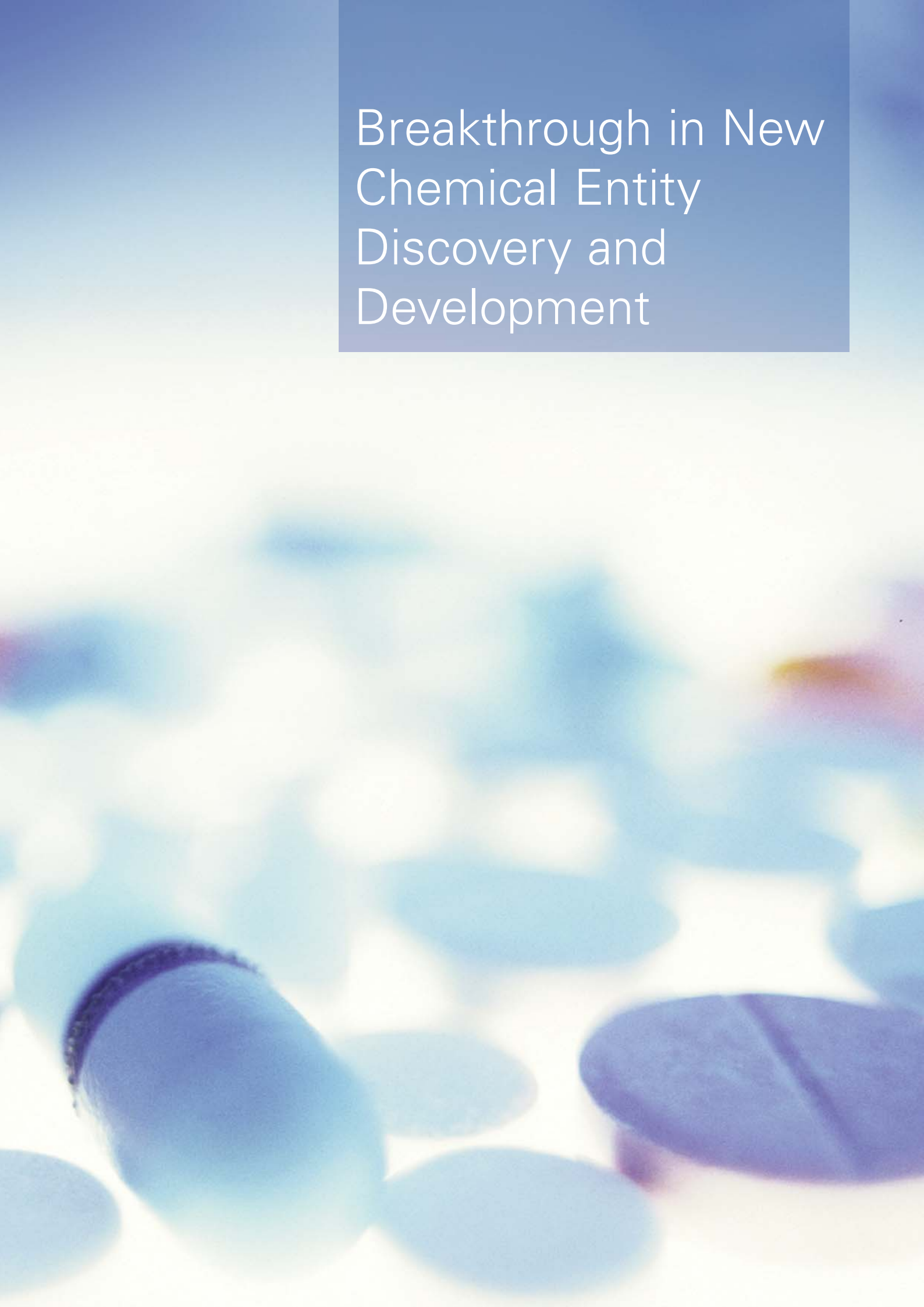
Dr. Ferzaan N. Engineer says – "Partnering with CROs with a strong global footprint allows sponsors an opportunity to leverage efficiencies across different geographic locations and services. The use of new technologies and processes, including adaptive design, enable sponsors to make better decisions sooner."

- How the company manages this broad range of services and multiple business segments is also crucial.

Dr. Ferzaan N. Engineer says – "Strong management always is important, particularly when a company has diverse business segments. It is important that all of the segments are aligned with the overall corporate strategy and working together to help customers respond to change. Technology platforms that integrate and synergise different services are also helpful."



Breakthrough in New Chemical Entity Discovery and Development



Breakthrough in New Chemical Entity Discovery and Development

Introduction

The absence of product patents in India for over three decades has laid the foundation of India's exceptional reverse engineering skills and strength in chemistry. Ironically, this has also been the primary reason for the absence of any indigenous new molecular entities. Indian companies have preferred to stay away from this business segment, which entails huge levels of investment in terms of money, time and other resources coupled with a very high risk of failure. As a result, Indian companies have less experience and a lower knowledge base in comparison with the Big Pharma, which has developed the resource pool of knowledge, talent, IP and finance.

However, with the changing market conditions and introduction of product patents in 2005, Indian pharma companies have commenced innovation-driven research aimed at launching proprietory products in order to create a long-term competitive edge and sustainability.

It is important to understand that the operating model of a pure generics company is completely different from the one required for having innovation-driven product development and commercialisation, which requires a long-term investment perspective, unique management skill-sets and commitment, higher funding levels, a strong scientific labour pool and IP development.

Glenn Saldanha says – "Innovation research is a totally different domain when compared to any other business area. If a molecule at an advanced stage fails, one cannot recover any part of the costs associated with the effort over the years, while the situation differs in regular ventures where much can be salvaged. In fact, true innovation is circumspect without the occasional failure... India has to create a culture for research, else it will be difficult for Indian companies to attain true success in discovery research."

Indian companies have made good progress by leveraging their strong chemistry skills and the Big Pharma is showing greater confidence in Indian companies as demonstrated by the increasing number of collaborative agreements, especially as the Big Pharma expands its existing scope of agreements or enters into multiple agreements with an Indian company for different therapeutic areas.

Indian companies have demonstrated good credentials by creating a strong research and innovation base. To what extent they can convert this potential into proprietory products and make a successful shift from the generics mindset to innovation depends upon how best they address the issues and challenges faced at the stage of execution.

Key Industry Challenges

Experience in developing IP

Being relatively new, Indian companies lack experience in developing their own molecules, especially the experience to take molecules through the advanced stages of development.

This is because, until now, very few molecules of Indian companies have progressed into the final stages of clinical trials. Hence, even though companies may have the mindset for this business segment and committed the requisite resources, lack of experience can be a serious constraint in the execution of the project.

Funding new drug discovery and development pipelines

NCE research is funded predominantly by internal funds generated by Indian companies from their generics business models. There is an absence of innovative funding models or private equity investment in this space. Given the high costs involved, high risk of failure and the long-term investment horizon, financial investors in India lack the experience and the risk appetite to invest in discovery research assets.

Glenn Saldanha – "One of the biggest challenges is early stage funding. Most venture capitalists and PE players are willing to consider funding at late stage 'development' rather than early stage 'research'. There are no or insignificant exemptions from government for innovation research separately."

Shortage of funds in taking the discovered molecules through advanced stages of development also pose a serious constraint for a company which has reached these stages. This is especially true in the current market scenario.

Availability of NCE R&D experienced talent pool

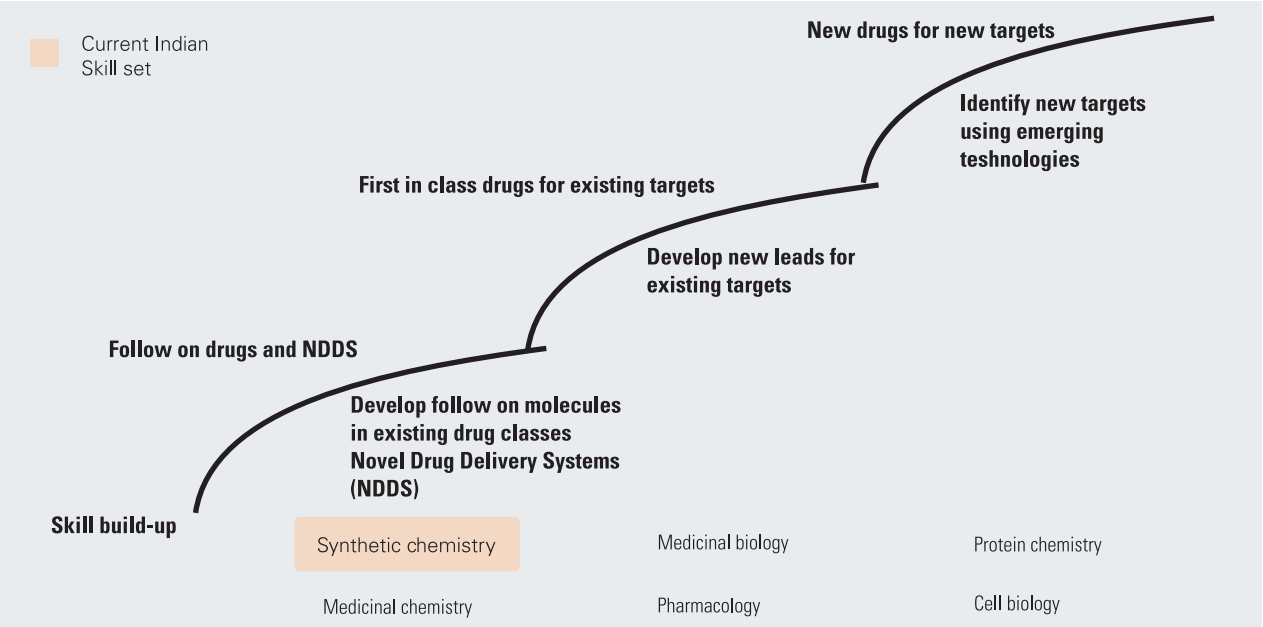
India's talent pool has excellent chemistry skills, which strengthens the potential of Indian companies to develop rich capabilities in new drug discovery and development. However, at present there is a lack of experienced scientific professionals who have carried out hands-on NCE R&D especially in the later stages of development. This challenge has eased to an extent as many US trained Indian scientists continue to return to India.

India is estimated to generate about 500,000 graduates in biological sciences, biotechnology and bioinformatics and about 250,000 postgraduates and 1,500 PhDs in the biosciences per annum.[1] However, the problem here as repeatedly highlighted by the industry is the wide gap between theoretical teaching and practical (on the job) experience.

India also lacks capabilities in terms of in medicinal chemistry, in vitro biology and efficacy related animal models.[1] Additionally, there is a need for more scientific leadership personnel to drive these programs.

Glenn Saldanha – "India has a huge talent pool when it comes to science graduates. However, the number of PhD graduates is insignificant as compared to the Science graduates… Even though we have good talent in chemistry or analytical chemistry, we have a dearth of experienced personnel in several other critical areas of discovery R&D."

Figure 17: Indian Pharma – Need to develop skill-sets for tapping NME/NCE opportunity



Source: Dr Reddy's Laboratories Presentation December 2005, Press Articles

[1] Pharma Focus Asia article tilted 'Drug Discovery and India' by JB Gupta Senior Vice President Collaborative Research, GVK Biosciences Pvt. Ltd. India

Limited infrastructure

Unlike developed markets such as the US, India needs to develop research centres and allied infrastructure that can be shared by the companies and the academic institutions or the government for a PPP programme. Development of such shared resources can facilitate significantly in optimum utilisation of the already limited resources.

"Infrastructure limits Indian companies' capabilities. Shared resources in the area of research are limited. The government must facilitate the establishment of shared resources that can be used both by the academia and the industry." – says Glenn Saldanha

Conclusion

Several Indian companies have consolidated their R&D assets under a special entity. This has resulted in increased focus and commitment, and ramping up investments in NCE discovery and research.

Funding options

Indian companies can typically consider the following options for funding its new drug discovery pipelines:

- Internal accruals - Divert a certain percentage of total earnings from other business segments, especially generics
- Licensing agreements – Provides financial backing of the partner and earnings generated through licensing agreements can be re-invested back into the business to strengthen the portfolio
- Raise capital - Through the equity markets or the private equity route
- Government support - By encouraging public-private partnerships.

The potential benefits and drawbacks of these funding options are set out below:

Figures 18: Evaluation of various funding models

	Key Positives for the Company	Key Negatives for the Company
Internal accruals	• Brings cautious and judicious approach towards funding based on the merit of the projects • No liability towards external partner if the project fails	• Ongoing assessment of risk/reward ratio throughout the life of project • Managing capital allocation among several internal business opportunities
Licensing agreements	• Monetization of risk • Upside potential in terms of milestones, royalties and co-marketing rights • Partner can bring complementary skill sets in clinical development, regulatory and marketing	• Dependence on the partner to undertake co-development and commercialization • Requires strong project management, communication and conflict resolution (if any) between partners
Capital raising through equity markets	• Funding provided by a group of informed investors who understand the potential upsides and risks involved in R&D • Provides liquidity to investors and enables smaller investors to participate in the funding	• PE funding for high risk basic research projects is not a feasible option yet • PE player may need certain assurances on potential performance which may be complex and onerous for the company
Private equity funding	• PE player understands the potential upsides and risks involved in the R&D • May help with potential alliances and commercialization efforts of the molecule	• Partnership discussion can be a bureaucratic and time consuming process • Government may have different priorities for research focus and spend that may not be in sync with the company
Government support (PPP)	• May provide both capital and scientific talent for the research projects • Company can benefit from the past research and IP as well as research infrastructure of the partner institution	• Partnership discussion can be a bureaucratic and time consuming process • Government may have different priorities for research focus and spend that may not be in sync with the company

At present, collaborative research is the most suitable and widely adopted business model…
However the industry has also expressed interest in PPPs…

Source: CII-KPMG Pharma Summit 2009

Collaborative research

The need for a collaborative approach goes well beyond addressing funding concerns. The level of experience and domain expertise the foreign player brings in is critical. As a result this collaborative model can mitigate the risk of failure, especially as the discovery program moves up the value chain.

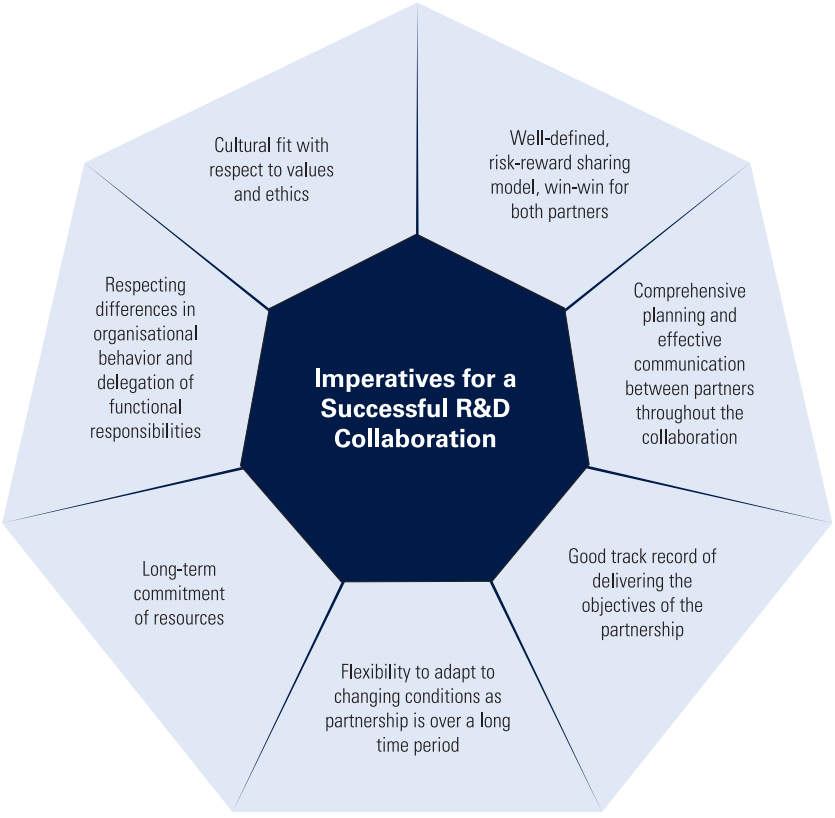
Big Pharma too potentially benefits from collaborative research because this mitigates some of the major issues they are facing such as rising R&D costs, declining productivity and new product approvals. Thus the collaborative strategy can benefit both parties.

"For Indian companies, for some time to come, collaborative research is the way to go. It helps both partners leverage key imperatives from the other's end. The risk is shared and the downside is limited. Monetising the research pipeline is of paramount importance, whether the R&D business is spun off into a separate entity, or otherwise. It becomes essential to generate substantial value from research in a very short time, out-license molecules and get a revenue stream." – says Glenn Saldanha

However the success of this model depends on how this collaborative agreement is executed.

As a molecule moves up the value chain, the prospects of commercialisation increase. Hence the foreign partner will most likely want to own the molecule at this stage. The cost of development also increases steeply and the Indian company may find it difficult to fund this phase of development. Thus, risk-reward sharing partnerships are typically entered into in the initial phases of development between identifying the drug candidate up to Phase II of clinical trials.

Figure 19: Imperatives for a Successful Collaboration



Source: CII-KPMG Pharma Summit 2009, Article on 'Conducting pharmaceutical R&D in India – Critical components of entry strategies' by Rajiv Gulati

Government and academic support

The government can play an instrumental role in collaborating with Indian companies in this field to build strong research capabilities and address each of the challenges mentioned above.

Although the government is already taking steps in this direction, it needs to further stress two important functions:

Strengthen the academic link with the industry

This can be done by increasing investments towards scientific research-based academic institutions to create a strong body of professionals in this field. In addition, academic institutions need to be encouraged and incentivised and to carry out basic research that the industry can leverage on and that can facilitate it to move to more high-end research.

Glenn Saldanha – "We need to strengthen our academic institutions engaged in scientific research. In the developed nations, the government provides grants to academic institutions engaged in scientific research. Institutions then sell their work or do collaborative research with pharmaceutical companies thus creating a win-win situation for both pharma companies and the institutions. This similar model should be encouraged in the country. It is difficult for pharma companies to invest time and resources in basic research. This is an area where academic institutions can play a big role."

Create substantial investment funds and incentivise R&D

The Technology Development Board of Department of Science and Technology and the New Millennium Indian Technology Leadership Initiative of Council of Scientific and Industrial Research have already invested in discovery research programs. Such initiatives and financial aid programmes can go a long way in contributing to the success of the sincere R&D efforts of Indian companies.

"The government needs to treat discovery R&D separately and incentivise organisations that are making progress in this area as the investment for taking a single molecule to market runs into hundreds of millions of dollars." – says Glenn Saldanha

The government and industry need to work together and consolidate their resource pool to complement each other and create an impact in the global environment. Indian companies too, need to make a conscious attempt towards aligning their R&D efforts with that of the government to be able to leverage the government's human and financial resource pool. Thus public-private partnership is critical in this business segment of the Indian pharma industry.

"One needs to have an appetite for risk when investing in discovery R&D in India. It is difficult getting external partners to part-fund your research efforts as the gestation period is long in this business. Secondly, if your efforts fail then you are left with virtually nothing. It is a high-risk, high-return and a very specialised area which could also be a deterrent for investors. Government initiatives encouraging public – private partnerships would be the ideal way to go." – says Glenn Saldanha


G.G.-17
250-m

Biotechnology: Building on the Indian Value Proposition

Biotechnology: Building on the Indian Value Proposition

Introduction

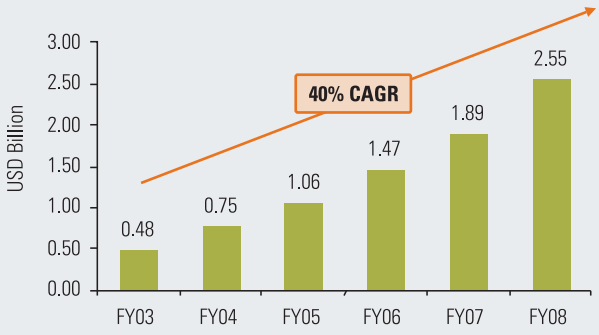
The Indian biotechnology industry is still small, but it has grown at a CAGR of 40 percent between FY03 and FY08.[1] Indian biotech players have made their presence felt in the global industry. Based on India's strong value proposition, the country's potential to emerge as a leading player globally has been well accepted not just in India, but also abroad.

Figure 20: India's value proposition has translated into rapid expansion of the biotech industry

India's Strengths

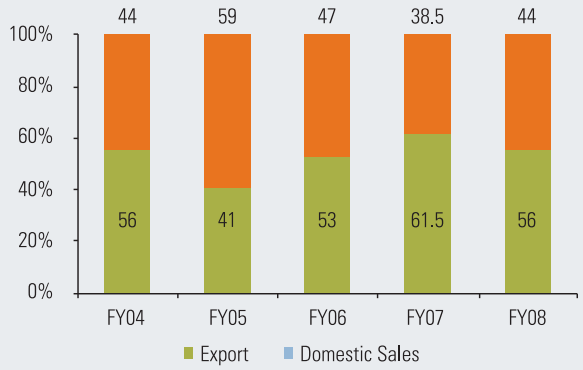
- Trained manpower and knowledge base at relatively low costs
- Academic resource: Good network of research laboratories
- Thriving base industries such as pharmaceuticals
- Extensive clinical trials and research access to vast and diverse diseases
- Bio-diversity: India's rich human gene pools and unique plant, animal and microbial diversity for genomic research
- Stem cells research: New valuable stem cell lines
- Government support: National Biotechnology Development Strategy and financial support to undertake research
- Emergence of Biotech Parks to provide specialised infrastructure

Biotech Industry Market Size



Source: Biospectrum Industry Overview

Export Vs Domestic Sales



Source: Biospectrum Industry Overview

Source: Biospectrum Industry Overview, Press Articles, CII-KPMG Pharma Summit 2009

However, the Indian biotech industry faces challenges that must be overcome to convert this potential into a reality, including the ongoing economic crisis which has impacted this segment and is considered one of the main reasons for growth decelerating to 18 percent in FY09.[2]

[1] Biospectrum Industry Overview July 2008

[2] http://biospectrumindia.ciol.com/content/CoverStory/10906091.asp

Dr. Rajesh Jain succinctly states – "There has been a slowdown in the growth rate primarily because:

- The biotech industry is export-driven
- It faces the challenge of market-to-market conditions
- VC firms prefer not to take the risk of investing in biotech ventures in the country
- Indian companies have been impacted by the credit squeeze."

Indian biotech companies have to cope with this economic slowdown and its implications. In addition, they also need to address regulatory, human resources management and funding issues to sustain their growth trajectory.

Key Industry Challenges

Challenges in product development and launch

Product development in biotechnology is a more challenging activity than developing a small molecule generic. This is because a biosimilar exhibits higher molecular complexity.

In recent times, there has also been a slowdown in the new product approvals. To add to these challenges in product development, it has been recently reported that the US Senate panel has approved the Healthcare Bill which provides the innovator biological product with 12-year data exclusivity.[3]

Dr. Rajesh Jain says "The important issues faced by companies operating in this industry are that:

- The industry has witnessed a considerable reduction in the number of new product approvals
- Safety standards for new drug approvals have become stricter as a result of the recent withdrawals and black-box warnings received by some high-profile drugs
- The cost new drug development has been steadily escalating
- The time taken for development of a new drug is increasing."

[3] FDAnews Drug Daily Bulletin, July 17, 2009, http://www.fdanews.com/newsletter/article?articleId=118822&issueId=12836

Funding concerns

Lack of adequate funding can be a serious growth inhibitor for any company and is particularly relevant to Indian biotechnology companies, many of which are relatively new start-ups.

Many companies have looked at venture capital for financing their business development. Venture Capitalists (VCs) too, have found biotech companies with good service offerings and management expertise an attractive investment option. However, during uncertain economic conditions, the risk appetite of financial investors including VCs shrinks substantially. They prefer to opt for low risk investment avenues. In such a scenario, VCs are likely to keep away from investment in biotech companies. This is primarily because:

- Biotech is a relatively new investment avenue for VCs
- Compared to many other industries, biotech companies have a longer-term investment horizon
- The regulatory framework in several key areas is still evolving. For instance, the biosimilars approval pathway in the US is still to be developed.

This can be a serious limitation in business development, product development and building marketing infrastructure particularly for a start-up venture.

Dr. Rajesh Jain says – "Companies with strong fundamentals and focused approach will get investor support, while others may not."

Funding constraints pose an even bigger challenge for a company having a presence in R&D.

Managing human resources

On the human resource front, several industry leaders have repeatedly expressed their concerns over:

- Poor linkage between industry and academia, that is, practical experience vis-à-vis theoretical teaching
- Shortfall of highly skilled and experienced scientists
- A significant disparity has been observed in the standards of biotech education and training across India
- The ability to scale up the skill base to match up with the rate of expansion.

Some companies even feel that the talent pool is already drying up. This can directly lead to an increase in the cost base.

Dr. Rajesh Jain says – "Although a large number of biotechnologists are available, it is difficult to recruit well trained persons with appropriate hands-on experience in molecular biology, cell biology and downstream process with respect to recombinant biotech products expressed in mammalian expression systems. There is dire lack of skilled and experienced 'critical mass' of biotechnologists."

Human resource management is even more challenging for fresh start-ups, who find it difficult to attract experienced personnel. This is because after a start-up invests time and money in developing talent, staff often leaves for larger companies and higher pay. To deal with this problem, start-ups may consider offering an equity stake in the company.

These concerns cannot be addressed by the industry or education institutions alone. There is a need for a collaborative effort by the all of these stakeholders including the government.

Penetrating regulated markets

The global biosimilars market appears to be very attractive, especially as the regulatory pathway has either already opened up in some of the biggest markets, or is in process of doing so. However, penetration into these highly regulated markets is challenging. Given the high regulatory standards and the overall market dynamics, launching a biosimilar in these markets is a complex process. It demands high-level capabilities at every stage from development to commercialisation.

Dr. Rajesh Jain states – "The primary issues while operating in regulated markets in product development are:

1 Understanding challenges associated with the product development pathway for many regulated markets, especially those in Europe and US

2 Absence of clear regulatory guidelines for the development of specific biosimilars

3 Long regulatory approval process."

Developing a biosimilar is a much more complex process than developing a small molecule generic. It requires the manufacturer to develop his unique manufacturing process, thereby making the process more expensive and time consuming. This calls for much more commitment and investment as compared with a small molecule generic. Additionally, proving bio-equivalence for a biosimilar is more difficult than it is for a small molecule generic.

Dr. Rajesh Jain states – "The challenges faced while operating in these markets in the area of brand building and supply and distribution are:

1 The need to generate clinical data in respective countries that is acceptable to the prescribers. This adds to the cost

2 Price reimbursement challenges – the ever increasing price pressures from 'payers'."

Successful marketing and distribution of a biosimilar requires aggressive strategies given the complex properties of the drug. In addition, innovator companies actively pursue strategies to discourage substitution of their products. In such a situation, for the company to crack the innovator's well-established marketing network and penetrate into the market is a highly challenging task.

The high costs and complexities involved in development, manufacturing and ultimate commercialisation necessitates strong financial support, managerial expertise and scientific capabilities.

India has successfully entered semi-regulated biosimilars markets. The regulatory standards in these markets are considered to be lower and thereby require lower investment commitment in comparison with Western Europe and the US.

However, it needs to make inroads into the highly regulated markets. To achieve this, an Indian company needs to build strong financial backing and well developed expertise in biotechnology product development, clinical research, regulatory compliance and marketing and distribution.

Conclusion

Biotechnology is a relatively new industry with a large number of start-ups. Hence, it is even more important for the government, education institutions and financial investors to collaborate closely with industry players to address the aforementioned challenges and build a strong industry base.

Figure 21: Imperatives for building a strong industry base through coordinated effort of all stakeholders

Source: CII-KPMG Pharma Summit 2009

Dr. Rajesh Jain says – "Companies can seek scientific advice, arrange meetings with regulatory agencies at an early stage and have the right manpower to manage the different regulatory needs and approval procedures of different markets."

The real challenge, however, lies in building these skills while retaining the low cost advantage.

Glossary

ANDA	Abbreviated New Drug Application
CAGR	Compounded Annual Growth Rate
CRAMS	Contract Research And Manufacturing Services
CROs	Clinical Research Organisations
DMF	Drug Master Files
DPCO	Drug Prices Control Order
EHS	Environmental, Health and Safety
EMEA	European Medicines Agency
EU	European Union
FDA	Food And Drug Administration
GCP	Good Clinical Practices
GDP	Gross Domestic Product
GLP	Good Laboratory Practices
GMP / cGMP	Current Good Manufacturing Practices
GSK	GlaxoSmithKline
ICH	International Conference on Harmonization
Indian Pharma	Pharma industry
INN	International Nonproprietary Names
IP	Intellectual Property
ISO	International Organization for Standardization
M&A	Mergers and Acquisitions
MNCs	Multinationals
NCE	New Chemical Entity
NDA	New Drug Application
NPPA	National Pharmaceutical Pricing Authority
Para IV	Paragraph IV
PE	Private Equity
PPP	Public-Private Partnerships
R&D	Research and Development
TRIPS	Trade-Related Aspects of Intellectual Property Rights
US	United States of America
US FDA	US Food And Drug Administration
VCs	Venture Capitalists

Profiles

Ferzaan N. Engineer, Ph.D.

Chief Executive Officer, Quintiles Research (I) Pvt. Ltd.

Ferzaan N Engineer, Ph.D., is Chief Executive Officer of Quintiles Research (India) Private Limited and Chairman of Quintiles Data Processing Centre (India) Private Limited. He is a member of the Asia-Pacific Management Board of Quintiles responsible for managing the India, SE Asia, China, ANZ and Japan geographies. He has contributed to establishing and growing the Quintiles organisation in India which currently employs over 1300 people at four locations: Ahmedabad, Bangalore, Mumbai and Delhi.

After obtaining his B.Pharm. in 1985 from the LM College of Pharmacy in Ahmedabad, Dr. Engineer completed his Ph.D. in Pharmaceutical Sciences in 1990, from the College of Pharmacy at the University of South Carolina, USA. He has attended management training programs at the Kenan-Flagler Business School (USA) and IIMA (India). He has also completed a 1 month management training program for senior executives at INSEAD (France).

From 1990-92, Dr. Engineer worked as Assistant Professor of Pharmaceutical Sciences in the United States at the College of Pharmacy, SDSU. On his return to India, he served as R&D Manager for Core Healthcare Limited from 1993-95; and subsequently as Vice President, R&D from 1995-96. After joining Quintiles in 1997, he focussed on establishing India's first international Contract Research Organisation (CRO).

Dr. Engineer has been associated with leading professional bodies such as the American Association of Pharmaceutical Scientists (AAPS), American Association of Colleges of Pharmacy (AACP) and the Rho Chi Honor Society (USA). He received the AACP New Investigator's Award in 1990 and also received research grants from the National Institutes of Health (NIH), USA. His research papers and abstracts have been published in leading international journals. He has been an invited speaker at international conferences and workshops in the field of pharmaceutical research. Currently, he is Member, CII National Committee on Drugs and Pharmaceuticals and is also Member, FICCI Pharmaceuticals and Biotechnology Committee in India. He serves on the Advisory Board of India Society of Clinical Research (ISCR). He also serves on the Board of Directors of Cenduit, a global JV between Quintiles and Thermo Fisher Biopharma Services.

Glenn Saldanha

Managing Director and CEO, Glenmark Pharmaceuticals Ltd.

As the MD & CEO of Glenmark Pharmaceuticals Limited, Glenn Saldanha oversees the entire operations of the organisation. Glenmark Pharmaceuticals Ltd which is a research-driven, global, fully integrated pharmaceutical company is a leader in the discovery of new molecules(NCEs and NBEs) and is focused in the areas of Inflammation [Asthma, COPD, Osteoarthritis, Multiple Sclerosis etc], Metabolic disorders [Diabetes, Obesity, etc] and Dermatology [Psoriasis, Pruritus, Atopic Dermatitis]. The company also has a significant presence in branded generics markets across emerging economies including India. It also has a fast growing and robust US generics business.

Glenn Saldanha holds a Bachelor's Degree in Pharmacy from Mumbai University and is an MBA from Leonard Stern School of Business, New York University. Prior to Glenmark, Glenn Saldanha has worked with Eli Lily, USA and Pricewaterhouse Coopers, USA.

In the last five years, Glenmark's sales have risen from Rs 324 crores to Rs 2010 crores; Net profit has risen from Rs. 42 crores to Rs. 631 crores; market capitalisation has risen from around Rs 300 crores to over Rs.5,000 crores. The company employs over 5500 people across its global operations in 95 countries. Glenmark was recently awarded by SCRIP, the largest selling and most respected pharmaceutical magazine in the world as the "Best Pharma company in the World – SME" and "Best company across Emerging markets" for 2008. Forbes, another leading international publication recognised Glenmark as the "Best Under a Billion Dollar companies in Asia" for 2008.

Jai Hiremath

Vice Chairman & Managing Director, Hikal Ltd.

Jai Hiremath is the Vice Chairman and Managing Director of Hikal Ltd. Hikal specializes in Contract Manufacturing in the areas of Crop protection chemicals, Active Pharmaceutical Ingredients and also Contract Research and development.

He was awarded "Chemtech Business Leader of the Year Award (Chemicals) 2005". He completed the "Owner President Management Program" at Harvard University, Boston, USA.

Jai Hiremath is currently holding the following positions :

- President of Indian Chemical Council (ICC).
- Chairman of FICCI's Chemicals Committee.
- Member of the National Committee on Drugs & Pharmaceuticals and National Committee on Chemicals & Petrochemicals of the Confederation of Indian Industries (CII).
- Member of CII's Western Regional Council.
- Board Member of the National Safety Council (NSC) of India.
- Board Member of the Novartis (India) Limited.

Dr. Kamal Sharma

Managing Director, Lupin Ltd.

Dr Sharma is a chemical engineer from Indian Institute of Technology (IIT), Kanpur, with a post-graduate diploma in industrial management from Jamnalal Bajaj Institute of Management Studies, Mumbai, and a Ph.D. in economics from IIT, Mumbai. He has also completed an advanced management programme from Harvard Business School, Boston.

In a successful career spanning more than three decades, Dr. Sharma has held a range of senior management positions managing operations, corporate development and general management in the pharmaceuticals and chemicals industries. He has been responsible for shaping and inking Lupin's stupendous success – one of the architects of Lupin having achieved global market leadership status in key markets and businesses globally - transforming it into one of the most profitable pharmaceutical companies in the Asia–Pacific region.

Dr. Sharma has been associated with the Lupin Group for over three decades now. He was the also the Managing Director of Lupin Chemicals (1991-95) which was later merged with Lupin Laboratories Limited. Thereafter, he joined RPG Life Sciences, as the President and Chief Executive Officer. Dr. Kamal Sharma is now the Managing Director of Lupin Ltd, having joined the company back in 2003-04.

Dr. Rajesh Jain

Joint Managing Director, Panacea Biotec Ltd.

Panacea Biotec Ltd., established in 1984, is a health management company involved in research, production and marketing of pharmaceuticals, vaccines and biotechnology products. Located in New Delhi, India, the Company employs an experienced, seasoned and dedicated workforce of 3,200 highly trained and skilled individuals who oversee, manage and facilitate its daily operations.

Dr. Jain serves a Joint Managing Director for Panacea Biotec Ltd. providing the strategic, visionary leadership, management and guidance, he is responsible for marketing and research and development.

Dr. Jain is also on the Board of Directors. His broad expanse of experience and qualifications in biotechnology enables him to efficiently handle his divergent duties.

Sharing ideas and techniques in an enthusiastic and persuasive manner, he provides the most practical and comprehensive solutions to keep the company out in front of the industry. Utilising outstanding analytical skills and an exceptional knowledge of science, he fortifies policies and strategies that contribute to the Company's overall record of success and maintain its superlative legacy of excellence.

Encouraging a culture which upholds the highest possible autarky, quality and transparency, he has gained the confidence and respect of his colleagues and peers and trust of clients in the services rendered by the Company.

A seasoned professional, Dr. Jain utilises expert judgment and creativity in the analysis of complex issues involving data from multiple sources and variables.

Reflecting professionalism, experience, integrity, commitment and perseverance, Dr. Jain plans to remain in his current role and continue growing and expanding with the company.

Sucheth Rao Davuluri

CEO, Neuland Laboratories Ltd.

Sucheth Rao Davuluri is the Chief Executive Officer (CEO) of Neuland Laboratories Limited. He joined Neuland Laboratories in the year 2002 and in his previous roles has been the VP – Operations and Chief Operating Officer (COO) of the company,

An MBA from the University of Notre Dame, USA and a Mechanical Engineer by qualification, prior to joining Neuland Sucheth Davuluri worked for Cummins Inc. USA in operations and as an expert in Six Sigma for projects.

Over the seven years that Sucheth Davuluri has been at Neuland, he has played a key role in strengthening the company's operations by expanding capacities as well as streamlining processes. Currently, the pharmaceutical industry lacks manufacturers who can supply APIs on committed due dates and with Sucheth Davuluri's efforts across the multiple functions- operations, research & development and marketing, Neuland is establishing a reputation for being extremely reliable.

Sucheth Davuluri has also played a key role in developing Neuland's presence in North America and Japan. He spent significant time understanding the markets and has been successful in establishing subsidiaries in both these markets.

Currently Neuland is growing at over 20% per annum over the past 5 years. The ability for Neuland to sustain this kind of growth has been largely due to Sucheth Davuluri's efforts. He strongly believes that systems play a stronger role than people in the long run. This is because in today's competitive environment, where organisations grow fast and people move quickly, a strong system will give stability. All his efforts at Neuland have been to bring in systems that reflect culture and operational excellence of the company.

When he is not at work, Sucheth Davuluri enjoys spending time with family and in outdoor activities. He plays soccer and golf very frequently and does not feel rested until he spends his daily quota of 90 minutes at the gym. He is also a keen reader of books on management and books on the Indian approach to spirituality.

About CII

The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the growth of industry in India, partnering industry and government alike through advisory and consultative processes.

CII is a non-government, not-for-profit, industry led and industry managed organisation, playing a proactive role in India's development process. Founded over 114 years ago, it is India's premier business association, with a direct membership of over 7800 organisations from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 90,000 companies from around 385 national and regional sectoral associations.

CII catalyses change by working closely with government on policy issues, enhancing efficiency, competitiveness and expanding business opportunities for industry through a range of specialised services and global linkages. It also provides a platform for sectoral consensus building and networking. Major emphasis is laid on projecting a positive image of business, assisting industry to identify and execute corporate citizenship programmes. Partnerships with over 120 NGOs across the country carry forward our initiatives in integrated and inclusive development, which include health, education, livelihood, diversity management, skill development and water, to name a few.

Complementing this vision, CII's theme for 2009-10 is 'India@75: Economy, Infrastructure and Governance.' Within the overarching agenda to facilitate India's transformation into an economically vital, technologically innovative, socially and ethically vibrant global leader by year 2022, CII's focus this year is on revival of the Economy, fast tracking Infrastructure and improved Governance.

With 64 offices in India, 9 overseas in Australia, Austria, China, France, Germany, Japan, Singapore, UK, and USA, and institutional partnerships with 213 counterpart organisations in 88 countries, CII serves as a reference point for Indian industry and the international business community.

About KPMG in India

KPMG is a global network of professional firms providing Audit, Tax and Advisory services. We operate in 140 countries and have 135,000 people working in member firms around the world. The independent member firms of the KPMG network are affiliated with KPMG International, a Swiss cooperative. Each KPMG firm is a legally distinct and separate entity and describes itself as such.

The Indian member firms affiliated with KPMG International were established in September 1993. As members of a cohesive business unit they respond to a client service environment by leveraging the resources of a global network of firms, providing detailed knowledge of local laws, regulations, markets and competition. We provide services to over 2,000 international and national clients, in India. KPMG has offices in India in Mumbai, Delhi, Bangalore, Chennai, Hyderabad, Kolkata, Pune and Kochi. The firms in India have access to more than 2000 Indian and expatriate professionals, many of whom are internationally trained. We strive to provide rapid, performance-based, industry-focused and technology-enabled services, which reflect a shared knowledge of global and local industries and our experience of the Indian business environment.

in.kpmg.com

KPMG in India

Mumbai
KPMG House, Kamala Mills Compound
448, Senapati Bapat Marg
Lower Parel, Mumbai 400 013
Tel: +91 22 3989 6000
Fax: +91 22 3983 6000

Delhi
DLF Building No. 10,
8th Floor, Tower B,
DLF Cyber City, Phase 2, Gurgaon 122 002
Tel: +91 124 307 4000
Fax: +91 124 254 9101

Bangalore
Solitaire
139/26, 3rd Floor, Inner Ring Road,
Koramangala, Bangalore 560 071
Tel: +91 80 3980 6000
Fax: +91 80 3980 6999

Chennai
No.10 Mahatma Gandhi Road
Nungambakkam, Chennai 600 034
Tel: +91 44 3914 5000
Fax: +91 44 3914 5999

Hyderabad
8-2-618/2, Reliance Humsafar, 4th Floor
Road No.11, Banjara Hills,
Hyderabad 500 034
Tel: +91 40 6630 5000
Fax: +91 40 6630 5299

Kolkata
Infinity Benchmark, Plot No. G-1
10th Floor, Block – EP & GP, Sector V
Salt Lake City, Kolkata 700 091
Tel: +91 33 44034000
Fax: +91 33 44034199

Pune
703, Godrej Castlemaine
Bund Garden, Pune 411 001
Tel: +91 20 305 85764/65
Fax: +91 20 305 85775

Kochi
4/F, Palal Towers
M. G. Road, Ravipuram,
Kochi 682 016
Tel: +91 484 309 4120
Fax: +91 484 309 4121

KPMG Contacts

Pradip Kanakia
Executive Director
Head - Markets
e-Mail: pkanakia@kpmg.com
Tel: +91 80 3980 6100

Yezdi Nagporewalla
Executive Director
Head – Industrial Markets
e-Mail: agporewalla@kpmg.com
Tel: +91 22 3983 5101

Gaurav Khungar
Executive Director
Head – Pharmaceutical
e-Mail: gkhungar@kpmg.com
Tel: +91 124 334 5006

Sanjay Singh
Associate Director
e-Mail: sanjaysingh@kpmg.com
Tel: +91 22 3983 5341

CII Contacts

Dev Ranjan Mukherjee
Head - Conference
105, Kakad Chambers,
132, Dr. Annie Besant Road,
Worli, Mumbai - 400 018.
Tel: + 91 22 2493 1790
Fax: + 91 22 2493 9463, + 91 22 2494 5831
e-Mail: dev.mukherjee@cii.in
Website: www.cii.in

Maah-Afreen Anklesaria
Executive
105, Kakad Chambers,
132, Dr. Annie Besant Road,
Worli, Mumbai - 400 018.
Tel: + 91 22 2493 1790
Fax: + 91 22 2493 9463, + 91 22 2494 5831
e-Mail: m.anklesaria@cii.in
Website: www.cii.in