The Indian PHARMACEUTICAL Industry
Changing Dynamics & The Road Ahead
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**TITLE**

The Indian Pharmaceutical Industry: Changing Dynamics & The Road Ahead

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Message

The Indian pharma companies have a wide variety of experience in manufacturing as per global standards. Through intensive competition in the Indian market, Indian companies are experienced in the manufacturing of a variety of formulations that makes them efficient and competitive in their operations. The Indian pharma market is mature with decades of experience in generics manufacturing, catering to the needs of the general population. We are entrusted with the responsibility of policy, planning, development and regulation of Pharmaceutical Industries across the nation.

I take this opportunity to invite all the stakeholders from the Pharmaceutical Industry to be a part of the Pharma Conclave 2015. Department of Pharmaceuticals, Ministry of Chemical and Fertilizer heartily thank ASSOCHAM for organizing this timely and meaningful conclave.

I compliment ASSOCHAM for organizing Pharma Conclave and hope that the deliberation will add to the efforts of stakeholder such as Government, Pharma Industry, Policy Makers, Scientists, Clinical Experts and Health sector.

(Dr.V.K.Subburaj)
The Indian Pharmaceutical Industry is the 3rd largest pharmaceutical market in terms of volume and 10th largest in terms of value, contributing towards 10% of global production. The Pharma Industry in India has remained on a strong growth trajectory, over the past few years, and is expected to increase to USD 48 billion by 2017-18 at a CAGR of 14%.

As tremendous opportunity opens up in the Generics space over the next 5 years, there will be an increase in bulk drug exports for off-patent products, which will drive overall exports. Contract Research and Manufacturing Services (CRAMS) is another sub-sector which is bound to experience strong momentum. Indian CRAMS companies are the most preferred players for global pharmaceutical companies, as their product mix consists of high-end research services, biologics, and complex technology services, all offered at a low cost. With externalization of research to emerging markets, India presents a strong case for outsourcing research and manufacturing.

The next few years will provide a dynamic environment for domestic and international players to work towards robust growth and enable better and affordable health outcomes. With support from the Government and the private sector, the India Pharmaceutical Industry will certainly grow exponentially and provide high-quality, technologically advanced, and affordable health solutions to India’s 1.25 billion citizens.

With the Pharma sector now poised for consolidation, many global ‘Big Pharma’ players are looking to acquire or forge JVs with Indian marquee companies to enter one of the biggest pharmaceutical markets. With strong political and economic stability, the Indian Pharmaceutical industry is bound to evolve and make India one of the leading pharma markets.

I am pleased to present the ASSOCHAM – YES BANK Knowledge Report ‘The Indian Pharmaceutical Industry: Changing Dynamics & The Road Ahead’ which highlights the key growth drivers of the Indian Pharmaceutical Industry and the steps that need to be taken to address the challenges faced by the sector. I am confident that the contents of the Knowledge Report will provide valuable insights into the Pharmaceutical Industry in India.

Thank you.
Sincerely,

[Signature]

Rana Kapoor
President ASSOCHAM
Managing Director & CEO YES BANK
Pharmaceutical Industry is a highly knowledge based industry, which has remained on a strong growth trajectory, over the past few years. Indian Pharma industry is ranked 3rd globally in volume and 13th in value, supplying 10% of global production. The size of Pharma industry in India is expected to increase to USD 48 billion by 2017-18, growing at a CAGR of 14%. The industry has a large part of its revenues coming from exports. India exports pharmaceutical products to more than 200 countries. The Government of India has come out with its policy document - ‘Pharma Vision 2020’, which aims to make India a global leader in end-to-end drug manufacture. Both the domestic and export market are set to witness high growth. The dynamics of the Indian Pharma Industry are set to change in the times to come.

ASSOCHAM is organizing the Pharma Summit, 2015 “Changing Dynamics the Road Ahead”. Through this summit, ASSOCHAM intends to bring together Government, Regulators, Pharmaceutical Companies, healthcare providers and all the stakeholders on a common platform to brainstorm on the road that lies ahead for the Drugs and Pharmaceuticals Industry in India. I extend my heartfelt gratitude to YES BANK, our knowledge partner for the summit for all the analysis and value addition.

ASSOCHAM also extends its gratitude to the Department of Pharmaceuticals & Ministry of Health and Family Welfare for making this programme meaningful.

Best wishes,

D.S. Rawat
Secretary General
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Overview
The Indian Pharmaceutical Industry, sized at USD 34 billion (including exports) in 2013-14, has remained on a strong growth trajectory, over the past few years. The industry size is expected to increase to USD 48 billion by 2017-18 at a CAGR of 14%. Indian Pharma industry is ranked 3rd globally in terms of volume and 10th in terms of value, supplying 10% of global production.

Of the USD 34 billion market, the domestic formulations market is about USD 10.9 billion (or INR 660.7 billion) and constituted around 1.1% of the global pharmaceutical market in value terms. This is because of lower drug prices and lesser penetration of healthcare, vis-a-vis developed markets, such as US and Europe. India spends only 3.5 - 4% of its total gross domestic product (GDP) on healthcare and hence, ranks amongst the lowest in this respect, globally. In contrast, developed countries spend about 10-13% of their GDP on healthcare.

The Indian Pharmaceutical Industry is highly fragmented with about 15,000 players, mostly in the unorganized sector. Out of these, about 300 - 400 are classified as belonging to medium & large organized sector. However, organised players dominate the formulations market, in terms of sales. In 2013-14, the top 10 formulations companies accounted for 42.3% of total formulation sales. MNC pharmaceutical companies have steadily gained a foothold in the Indian formulations market. As of March 2014, they enjoyed a market share of 20-24%. The key drivers are majorly knowledge, skills, low production costs, and quality. Due to this there is demand from both domestic as well as international markets.

The Key Segments in the Indian Pharmaceutical Industry are as follows:

A. API Manufacturers / Traders (Bulk Drugs)
B. Formulation Manufacturers
C. Contract Research and Manufacturing Services Companies
D. Biotechnology Companies

A. API Manufacturers / Traders (Bulk Drugs)

Bulk drug exports, constituting 80-90% of total bulk drugs production, accounted for about 33% of total sales in the pharmaceutical industry in 2013-14. The share of bulk drugs is higher in India as compared with developed countries, where bulk drugs are primarily manufactured for domestic consumption.
Bulk drug exports are estimated to have grown at a CAGR of about 18% between 2008-09 and 2013-14 to an estimated USD 11.9 billion in 2013-14. Of this, exports to regulated markets, which had a 49% share, grew at a CAGR of about 21% over the past 5 years.

In exports to regulated markets, exports of on-patent drugs are estimated to have surged at a 29% CAGR (on a low base), while that of off-patent drugs maintained a growth rate of 15% over the past 5 years upto 2013-14.

Exports to semi-regulated markets (the traditional export destinations for Indian players) also grew at a slow, but steady pace of a 15% CAGR.

**Future Outlook**

Bulk drug exports are likely to grow at a CAGR of 12-14% over 2013-14 to 2018-19, driven largely by exports to regulated markets as well as continued growth in the semi-regulated markets. Exports to the regulated markets would be driven primarily by three factors: a large value of drugs going off-patent in the next 5 years, the expected rise in penetration of Indian bulk drug players in regulated markets and the need of global pharmaceutical players to outsource API manufacturing to cut costs. We expect that major global innovators will not only extend existing deals with Indian players but will also look to increase sourcing of bulk drugs from Indian companies.

Indian bulk drug exports have shifted in favour of regulated markets. This is evident from the increase in the share of these markets to about 49% in 2013-14 from about 43% in 2008-09. We expect the share of regulated markets in Indian bulk drug exports to rise to about 51% by 2018-19, driven by Indian manufacturers’ better process chemistry skills, low manufacturing costs, a higher number of drug master filings (DMFs), the expected expansion of key generic markets and cost reduction initiatives by large global companies.

As a huge generic opportunity opens up over the next 5 years, we expect bulk drug exports for off-patent products to drive overall exports. Exports of bulk drugs used for manufacturing off-patent drugs will continue to grow at a 12-14 cent CAGR in the next 5 years till 2018-19. On the other hand, demand for API from on-patent drugs is expected to grow at a slower pace. This is mainly on account of the expected slowdown in the branded medicines market in both Europe and America. This coupled with pricing pressures is expected to impact pricing realisations for Indian API exporters. Nonetheless, strong growth in volumes is still expected in these markets as increasing competition from generics will lead to cost pressures on innovator companies.

**B. Formulation Manufacturers**

**I. Formulation (Domestic)**

In 2013-14, the domestic formulations market recorded the lowest growth rate in the last 5 years on account of the implementation of the Drug Price Control Order (DPCO). The order, announced in May 2013, led to sharp price revisions across several drugs that have been brought under price control. Around 348 molecules that cover close to 30% of the total domestic market have been brought within the ambit of this order.

The implementation of the drug price order in India lowered the prices of drugs and restricted the trade margins on these medicines from 10% and 20% to about 8% and 16% for wholesalers and retailers, respectively. Consequently, trade disruptions during the first half of the year coupled with the pricing impact of the notified drugs brought down the overall growth rate of the market.

To counter the impact of slower growth in volumes and pricing cuts on medicines, companies launched new products in the market which helped overall volumes in the domestic market grow by close to 4% during the
year compared to the usual 7% (approximately) seen in the past. This, coupled with a close to 2% pricing growth, mainly on account of price increases in non-DPCO drugs, helped the overall domestic pharmaceuticals market register close to 6% growth during the year.

**Future Outlook**

The growth story of the domestic formulations market is expected to remain strong, led by a rise in life-related diseases, better healthcare diagnostic infrastructure adding to increasing disease detection rate, new product introductions, volume growth driven by increasing penetration, and better access to healthcare. Domestic formulation sales are set to grow at a CAGR of 12-14% between 2013-14 and 2018-19, with the market size crossing USD 20 billion.

**II. Formulation (Exports)**

Formulation exports grew at 17% CAGR to an estimated USD 11.1 billion in 2013-14 from USD 5.2 billion in 2009-10. Growth was enabled by a 22% growth (CAGR) in exports to regulated markets. Exports to semi-regulated markets, which have grown at 13% over the same period, also supported growth in overall exports.

India’s overall exports grew by nearly 11% during 2013-14 to about USD 11.1 billion. The slowdown in exports was mainly on account of lower growth in the regulated markets compared to semi-regulated markets. Growth in exports to the semi-regulated markets sustained at nearly 12% during the year, while the exports to the regulated markets grew at a modest 10% compared to 18% growth seen last year. The slowdown was mainly on account of import alerts on Indian companies, slowdown of growth in Europe and increased competition during the year.

In the overall regulated markets, exports to the US grew at about 11% to USD 3.4 billion, lower than the close to 22% growth seen last year. On the other hand, exports to the European Union grew by just about 6% during the year to ~ USD 1.5 billion in exports. This was another consecutive year of slow growth, with 10% growth seen in 2012-13. Region-wise, the European Union market recorded an almost-flat growth in the leading markets of the UK, Germany, the Netherlands, Belgium and Spain during the year.

Exports to semi-regulated markets grew steadily by an estimated 12% y-o-y in 2013-14 led by exports to the African and Asian continent during the year. Exports to Asia and Africa grew by almost 17% to reach close to USD 4.5 billion in 2013-14 (about 78% of the total semi-regulated market exports), mainly led by growth in exports to the top 30 destinations out of the roughly 124 export destinations in these two continents put together. Exports to these 30 countries grew by nearly 20% and accounted for up to 79% (~ USD 3.5 billion) of the total Indian exports to these two continents in 2013-14.

**Future Outlook**

India’s formulation exports are expected to grow at a CAGR of 14-16% between 2013-14 and 2018-19. Steady growth is expected in exports to both regulated and semi-regulated markets over the next 5 years. During the period between 2012 and 2017, drugs generating annual sales of about USD 130 billion are likely to lose patent protection and will be exposed to generic competition. We therefore expect sales of generics to grow at a CAGR of 7-9% over the next 5 years, outperforming the overall global pharmaceutical market, whose growth is expected to be limited to 3-5%. Indian players are currently well placed to widen their presence in the generics market. This is reflected in the rising number of Indian players seeking Abbreviated New Drug Application (ANDA) approvals and tentative approvals from the US FDA (Food and Drug Administration). Additionally, mid-sized and small-sized Indian formulation manufacturers, who traditionally resorted to contract manufacturing, are also looking to tap the generic opportunity in regulated markets.
C. Contract Research and Manufacturing Services (CRAMS)

Contract Research and Manufacturing Services (CRAMS) is one of the fastest growing segments in the pharmaceutical and biotechnology industry. It pertains to outsourcing research services/manufacturing products to low-cost providers with world-class standards, in line with international regulatory norms such as USFDA, Australian-TGA, UKMHRA, and EMEA. Pharmaceutical multinationals have traditionally been outsourcing manufacture of intermediates, API’s and formulations. Since late 1990s, CRAMS has gained more importance, as MNCs have been coming under intense pressure to cut costs to maintain their profitability.

Indian CRAMS companies are the most preferred players for global pharmaceutical companies due to their product mix being skewed towards high-end research services, biologics and complex technology services, at low cost. India offers an abundant pool of professionals in the area of drug development and research chemistry with large number of pharmacists and chemistry post graduates qualifying every year. According to the Indian Government, by 2020, India would be one of the top five pharmaceutical innovation hubs with one out of every five to ten drugs discovered in India.

CRAMS as a segment constitutes of Contract Research Organization (CRO) & Contract Manufacturing Organization (CMO), of which CMO constitutes a major portion (>60%) of the overall business.

A Contract Research Organization (CRO) is an organization that provides support to the Pharmaceutical Industry, Biotechnology and Medical Device Industries in the form of Research Services Outsourcing on a contract basis. A CRO may provide such services as biopharmaceutical development, biologic assay development, commercialization, pre-clinical development, clinical research, clinical trials management, and Pharma co-vigilance. CROs also support foundations, research institutions, and universities, in addition to governmental organizations (such as the NIH, European Medicines Agency amongst others). Many CROs specifically provide clinical-study and clinical-trial support for drugs and/or medical devices. CROs range from large, international full-service organizations to small, niche specialty groups. CROs that specialize in clinical-trials services can offer their clients the expertise of moving a new drug or device from its conception to Food and Drug Administration/European Medicines Agency marketing approval, without the drug sponsor having to maintain a staff for these services.

A Contract Manufacturing Organization (CMO) is an organization that serves the pharmaceutical industry and provides clients with comprehensive services from drug development through to manufacturing. Outsourcing to a CMO allows the pharmaceutical client to expand its technical resources without increased overhead. The client can then manage its internal resources and costs by focusing on core competencies and high-value projects while reducing or not adding infrastructure or technical staff.

Key Growth Drivers – CRAMS

- MNCs have been coming under intense pressure to cut costs to maintain their profitability
- Our product mix being skewed towards high-end research services, biologics and complex technology services, at low cost
- Abundant pool of professionals in the area of drug development and research chemistry with large number of pharmacists and chemistry post graduates qualifying every year

Significance of CRAMS

With an increasing focus on managing costs and shortening time to market, many pharmaceutical companies now outsource their clinical trials to CROs. CROs are hired by pharmaceuticals companies and medical-device makers to provide research services such as overseeing discovery, preclinical and clinical testing. The CRO
industry has experienced double-digit annual growth in recent years and is increasingly relied on to perform clinical trials in countries with more diverse populations and less stringent regulations, including China and India, and nations throughout Central America. Such dramatic growth and consistent cash flows have recently drawn private equity investors to this niche industry.

Outsourcing to a CMO allows the pharmaceutical client to expand its technical resources without increased overhead. The client can then manage its internal resources and costs by focusing on core competencies and high-value projects while reducing or not adding infrastructure or technical staff. Virtual and specialty pharmaceutical companies are particularly well-suited to CMO partnerships, and big pharmaceutical companies are beginning to view relationships with CMOs as strategic rather than tactical.

D. Biotechnology Companies

Biotechnology refers to the application of scientific techniques using living organisms or their parts to make or modify plants, animals, micro organisms or environment to enhance their performance and values. In the recent years biotechnology has emerged as a major focal point for the developed as well as the developing nations. It has a greater vision to sectors such as human health, agriculture and environmental science for the future.

The Biotech Industry comprising Bio-Pharmaceuticals, Bio-Services, Bio- Agriculture, Bio-Industrial and Bio-Informatics is among the country's rising sector and is growing at CAGR of 20%. The market size of this sector was estimated at around USD 4 billion in 2013-14. India is among the top 12 biotech destinations in the world and ranks second in Asia, after China. The Indian biotechnology industry has evolved over the last three decades and the sector’s revenue has rapidly increased from USD 300 million in 2002-03 to USD 4 billion in 2013-14.

Biotech Industry Segmentation

The Indian Biotechnology sector is presently divided into five segments based on the products and services offered. These segments are Bio-Pharmaceuticals, Bio-Services, Bio- Agriculture, Bio-Industrial and Bio-Informatics. Bio-Pharma is the largest sector contributing to 62% of the total revenue followed by Bio-Services, Bio-Agri and Bio-Industrial sectors which contribute 18%, 15% and 4% respectively. Bio-Informatics is still at a nascent stage contributing to only 1% of the total revenue.

Bio-Pharmaceuticals

This constitutes the largest segment of the Indian biotech industry both in terms of domestic and export revenues. In 2013-14, bio-pharma generated revenues of USD 2.5 billion comprising approximately 62% of the domestic biotech industry. The Bio-Pharma sector includes vaccines, therapeutics and diagnostics. The highest growth was witnessed in the year 2003-04 when the growth crossed the 50% mark. The growth rate dwindled thereafter reaching a low of 12% in 2009-10. However in 2013-14, the growth saw positive signs and again increased to 18%.

Bio-Services

BioServices is the second largest sector of the Indian Biotechnology industry with revenues amounting to USD 600 million. The growth rate of this segment could be attributed to the fact that India has become a popular destination for clinical trial, contract research and manufacturing activities. The sector witnessed a growth of 16% in 2013-14. The highest growth of 104% was witnessed in the year 2003-04.
Key Growth Drivers: Indian Biotechnology

The global biotechnology industry is undergoing a transformation, thereby creating enabling factors that can lead to the growth of the Indian Biotech Industry.

- **Increasing cost of bringing a new drug to the market**: India can play a key role in reducing cost and time to market for new drug development through outsourcing of various components of the drug development process.
- **Top pharma companies spend a large part of their research for in licensing new modules**: There is an opportunity for R&D focused Indian biotech companies to enter into such alliances through collaborative development projects.
- **Inflammatory & Infectious disease segment high on agenda**: In the Indian context these are the two of the strongest disease segments with a huge domestic market.
- **Early stage deals are more common compared to the middle and late stage deals**: Indian companies with limited financial resources can optimize business models by partnering with larger companies for product development and licensing at an early stage.
Evolution of the Indian Pharmaceutical Industry
Evolution of the Indian Pharmaceutical Industry

The Indian pharmaceutical industry has grown rapidly over the last few decades. Prior to 2005, the Indian regulatory system recognised only process patents. This helped build a firm foundation for the strong and competitive domestic pharmaceutical industry. During this phase, the prevalent price control mechanisms helped companies deliver medicines at affordable prices, to patients across India. The different phases that the Indian pharmaceutical industry has gone through, during the pre-patent (till 2005) and post-patent (post 2005) regimes are as follows.

Pre-patent regime (Before 2005)

Process patents helped the Indian pharmaceutical sector flourish, amid a fast growing generics industry. During this regime, multinational companies (MNCs) were reluctant to directly introduce new products in India. Domestic companies leveraged this situation, by re-engineering these products and marketing them in India.

- **Indian Patent Act, 1970**
  The Indian Patent Act aimed at encouraging domestic players to manufacture drugs and ensure self-sufficiency in medicines. The Act granted patents, based on the process of manufacturing, as against the global practice of granting patents, based on the new drug alone. As a result, several Indian players began manufacturing products, based on the same bulk drug, yet through different processes. This strengthened domestic players’ process chemistry skills and increased their expertise in developing low-cost generic drugs.

- **Drug Price Control Order (DPCO), 1970**
  The DPCO governed prices of all bulk drugs and formulations, to ensure widespread availability of medicines, at reasonable prices. Together, the Indian Patent Act and the DPCO, significantly influenced the structure and growth pattern of the domestic pharmaceutical industry.

- **Decline in share of MNCs**
  Introduction of these regulations caused great dismay among MNCs, who were left with little incentive to introduce new products in India. They shifted their focus towards vitamins, cough preparations, NSAIDs (pain killers) and eventually built up a strong brand equity in these products. Hence, it is not surprising that the share of multinationals in total production of formulations began to decline after 1970.
Growth of small-scale units

At the same time, the number of domestic small-scale units increased rapidly, due to following reasons:

- Low-entry barriers
- Abundant availability of bulk drugs
- Numerous incentives, such as waiver of price control on drugs produced by them, offered to SSIs
- A vast, geographically dispersed market

Additionally, several large producers began outsourcing production to small units (under the loan licensing scheme) to contain costs, which further encouraged growth of SSIs.

Some of the major outcomes were:

- Spread of research know-how
- Bulk drug production increases
- Market share of multinationals continued to slide
- Indian players leveraged the opportunity to widen their exports
- Increased investments

Post-patent regime (Post 2005)

In line with its commitments to the WTO, the Indian Government passed an ordinance to introduce the product patent regime w.e.f. January 2005. This aided the integration of India into the global pharmaceutical market and rendered duplicating of post-1995 patented drugs illegal. While this discouraged process re-engineering of products patented post 1995, the amendment aimed at gradually enhancing confidence of large global players on Indian companies.

In 2005, the Indian pharmaceutical industry witnessed a series of regulatory developments, ranging from the implementation of value added tax (VAT), shift from excise duty levy to an MRP-based levy system and Schedule M implementation to recognise the product patent regime. While implementation of the VAT and shift in the excise duty regime had short-term implications, the implementation of Schedule M (compliance with tenets of cGMP) and adherence to the product patent regime will have medium and long-term implications, respectively.

Enactment of product patent regime

India entered the product patent regime on January 1, 2005. This marked the end of a protectionist era and better integrated India with the global pharmaceutical market.

While the earlier process patent regime helped the Indian pharmaceutical industry develop into a world-class generics industry, the product patent regime aimed at encouraging new drug discoveries over the long-term. Traditionally, Pharmaceutical MNCs had maintained a low-key presence in the Indian market, due to the absence of product-based patents and rigid price controls. Hence, the recognition of product patents will gradually boost confidence levels, placed by large global players on India.

From January 2005 till date, India has seen a handful of patented product launches. The launch of patented products in India has been slow as innovators are taking their time, to seek clarity on data protection, patenting of derivatives and pre- and post-grant opposition. While not much has changed on this front, MNCs’ approach towards the domestic market is slowly changing.
Rising focus on exports

India gained a foothold on the global arena, with innovatively-engineered generic drugs and active pharmaceutical ingredients (API). The country now seeks to become a major player in outsourced clinical research and the contract research and manufacturing services (CRAMS) segments. India has the highest number of manufacturing facilities (332 sites) approved by the US Food and Drug Administration (US FDA). Further, in 2011, one-third of all Abbreviated New Drug Applications (ANDA) approved by the US FDA, belonged to Indian companies.

Implementation of Schedule M

The mandate issued to small-scale pharmaceutical units, necessitated compliance with the Schedule M norms. Schedule M of the Drugs and Cosmetics Act outlines various requirements for manufacturing good quality drugs and pharmaceuticals, by applying cGMP.

Affixing of prices by NPPA

The Government fixed prices of nine commonly used drugs, in cases where it was noticed that companies have increased prices for no legitimate reason. As a result, pharmaceutical companies will no longer be able to increase medicine prices, at their discretion.

Major companies were asked to revise drug prices to levels fixed by the National Pharmaceutical Pricing Authority (NPPA). The regulator directed companies to make relevant changes in their maximum retail prices (MRPs). Drugs, which have come under the scanner, cater to major therapeutic areas, such as diabetes, cardiovascular, allergies and infections.

Drug law

In 2013, the Drug Controller General of India (DCGI) reviewed the rationality of fixed dose combinations (FDCs) available in the market. Based on the review, the regulator issued directives for withdrawal of certain FDCs. These norms, coupled with few others, point towards a more stringent drug regulatory environment, which could increase compliance and facility upgradation costs, for the industry, over the medium term.

New Drugs (Prices Control) Order (DPCO), 2013

Prior to the 2013 regime, the DPCO 1995 included 74 bulk medicines within its ambit and the pricing of the drugs were fixed on the basis of manufacturing costs declared by the drug manufacturers. The new DPCO 2013 empowers the National Pharmaceutical Pricing Authority (NPPA) to regulate prices of 348 essential drugs under the National List of Essential Medicines (NLEM) through market based pricing. The prices will be fixed at the weighted average price of brands that have more than 1% market share.
03

The Pharmaceutical Supply Value Chain
Bulk drugs or active pharmaceutical ingredients (APIs) are raw materials used to manufacture formulations, which are ready to use forms of bulk drugs (including capsules, tablets, syrups and injections) administered to patients.

Bulk drugs are manufactured by combining more than two chemicals or intermediaries. They directly influence the diagnosis, cure, mitigation, treatment or prevention of a disease.

Drug distribution in India has witnessed a paradigm shift. Before 1990, pharmaceutical companies established their own depots and warehouses. Now, they have been replaced by clearing and forwarding agents (CFAs).

- **CFAs**: These organizations are primarily responsible for maintaining, storage (stock) of the company’s products and forwarding drugs to the stockist on request. Most companies keep 1–3 CFAs in each Indian state. On an average, a company may work with a total of 25–35 CFAs. The CFAs are paid by the company yearly, once or twice, on the basis of the fixed percentage of total turnover of products.

- **Stockist**: is the distributor, who can simultaneously handle more than one company (usually 5–15 depending on the city area), and may go up to even 30–50 different manufacturers. They pay for the products directly in the name of the pharmaceutical company after 30 to 45 days.

- **The Retail Pharmacy**: obtains products from the stockist or substockist through whom it finally reaches the consumers (patients).
Regulatory Environment in India
The Pharmaceutical Industry is characterized by maintenance of high quality standards as it concerns the lives of people. Regulatory bodies impose regulations to ensure that drugs meet the safety and quality standards. Regulatory bodies not only ensure that pharmaceutical companies meet the set quality standards, but also ensure that the pharmaceutical companies do not charge unreasonable prices from consumers.

The stringency of regulatory procedures varies across countries. On the basis of established regulations and patent laws, the global pharmaceutical industry can be broadly classified into regulated and semi-regulated markets.

Regulated markets include the USA, EU and Japan that have established systems of patent laws and sophisticated regulatory systems for controlling drug quality. On the other hand, semi-regulated markets include countries such as China, India and South Africa, which have less stringent systems of patent laws and less sophisticated regulatory systems for drug quality control.

However, there is no single harmonized protocol for drug approval across countries. Countries have their own regulatory authorities and drug approval mechanisms.

List of Regulatory Authorities across Key Countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Regulatory authority</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>US Food &amp; Drug Administration</td>
<td>USFDA</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>UK Medicines and Healthcare Products Regulatory Agencies</td>
<td>MHRA</td>
</tr>
<tr>
<td>South Africa</td>
<td>Medicines Control Council of South Africa</td>
<td>MCC</td>
</tr>
<tr>
<td>India</td>
<td>Food &amp; Drug Administration</td>
<td>-</td>
</tr>
<tr>
<td>Brazil</td>
<td>National Health Surveillance Agency</td>
<td>ANVISA</td>
</tr>
<tr>
<td>Europe</td>
<td>The European Medicines Agency</td>
<td>EMEA</td>
</tr>
</tbody>
</table>
The Pharmaceutical regulatory environment in India comprises of the participants as displayed in the schematic arrangement below.

The Drugs and Cosmetics Act, 1940 (Drugs Act) and Drugs and Cosmetic Rules, 1945 (Drug rules) regulate the import, manufacture, distribution and sale of drugs in India.

Under the provisions of these Acts, the Centre appoints the Drugs Technical Advisory Board (DTAB) to advise the Central Government and the State Governments on technical matters. The responsibility to enforce the Drugs Act is entrusted with both the Central Government and the respective State Governments. Under the Drugs and Cosmetics Act, State authorities are responsible for regulating the manufacturing, sale and distribution of drugs, whereas the central authorities are responsible for approving new drugs and clinical trials, laying down the standards for drugs, controlling the quality of imported drugs, and co-ordinating the activities of State drug control organisations.

The Drugs Controller General of India (DCGI) is the central body that co-ordinates the activities of state drug control organisations, formulates policies and ensures uniform implementation of the Drugs Act throughout India. It is also responsible for approval of licenses of specified categories of drugs, such as blood and blood products, IV Fluids, Vaccine and Sera.

Indian Pharmaceuticals Industry is mainly regulated on the basis of patents, price and quality.
Patents

Before 2005, the regulatory system in India focused only on process patents. Indian pharmaceutical companies thrived during the process patent regime. They would re-engineer products of global innovator companies, which were unavailable in India, and launch them in the country as generics, as India did not recognise the product patents. In this manner, Indian companies gained process chemistry skills, but did not focus on R&D for new drug discovery.

In January 2005, India complied with the World Trade Organisation (WTO) to follow the product patent regime [sale of re-engineered products (for drugs patented after 1995) is restricted]. However, enterprises, which had made significant investments and were producing and marketing the concerned product prior to January 1, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent, are protected, and the patentee cannot institute infringement suits against them, but would be entitled to reasonable royalty.

Drug Prices

The Drug Price Control Order (DPCO) fixes the ceiling price of some APIs and formulations. APIs and formulations falling under the purview of the legislation are called scheduled drugs and scheduled formulations. The National Pharmaceutical Pricing Authority (NPPA) collects data and studies the pricing structure of APIs and formulations and accordingly makes recommendations to the Ministry of Chemicals and Fertilisers.

The new Pharmaceutical Policy, notified in 2012, intends to bring 348 essential drugs in the National List of Essential Medicines (NLEM), under the purview of the DPCO. With this policy, the market size of drugs under price control will increase from 15-20% of the domestic formulations market to 20-30%. The policy also introduces a radical change in the mechanism of control - shifting from the current cost-based control to a market-based price mechanism.

Under the policy, the ceiling price for each drug under control would be fixed as the simple average price of brands having more than 1% market share (by value) in the sales (MAT - Moving Annual Turnover) of that particular molecule. Thus, prices of brands which are higher than this ceiling will need to be lowered. The ceiling prices will be allowed an annual increase as per the Wholesale Price Index (WPI). Prices will be recalculated using MAT only once in five years or when the NLEM is updated.

Price of drugs that were part of the earlier policy, but do not come under the current policy, would be frozen for a year and, thereafter, allowed a maximum annual increase of 10%. A 10% increase would also be the limit for prices of drugs outside the Government’s price control.

Quality

No drug can be imported, manufactured, stocked, sold or distributed in India unless it meets the quality standards laid down in the Drugs Act. All companies have to comply with Schedule M of the Act, which outlines various requirements for manufacturing drugs and pharmaceuticals by applying cGMP (current Good Manufacturing Practice). cGMP has to be followed for control and management of manufacturing and quality control testing of drugs.
The India Advantage in the Lifesciences Industry
India has emerged as a pharmaceutical supplier in the international markets. This is not only because of a low-cost manufacturing, operations and research base but also a combination of additional factors such as process improvements in manufacturing API, faster recruitment for conducting clinical trials, availability of skilled manpower and developed regulatory skills.

In Contract Research Business, India is also an ideal location due to availability of skilled manpower and a large patient population which results in faster recruitment of patients. With low costs, highly competitive market and only process patents till recently, Indian companies have developed expertise in process innovation.

The above factors have resulted in India producing low cost high quality products, which have spurred exports of Indian products to international markets, especially to the higher regulated markets like USA and Western Europe. Of the main export varieties, formulation and API sales are the major portion. However, Contract Research has also grown into a significant contributor to total exports from the pharmaceutical market over the past few years.

Given the technical expertise of human resources in India, pharmaceutical exports have grown at a CAGR of 27% from 2007-14.
Indian companies have done well in the generics market internationally. This can be said to be because of competitiveness in some key areas which spell success in the generics space.

**Product Pipeline**

Most Indian pharma companies have significant competitive advantages in R&D to build a generic product pipeline. Indian advantages include high technical skill levels in the development of non-infringing processes, bio-equivalent formulations, and development of regulatory submissions, at lower cost.

**Geographical Breadth**

Indian companies in the recent past have ventured beyond partly regulated markets. Apart from servicing the markets of Africa, Eastern Asian countries, Russia and other CIS countries, Indian companies have made significant foray into highly regulated markets of Europe and North America as well as lesser accredited markets of Australia and South Africa. In recent years companies have also started setting up subsidiaries and registering products in Japan. The wide reach of companies ensures that using the same basket of products, a company can attain greater sales in markets with varying competitiveness and pricing pressures.

**Low Cost**

Labour costs in India are about 1/7th the levels in developed countries and offer an obvious cost advantage. Also, Indian companies are able to reduce the upfront capital cost of setting up a project by as much as 25-50% due to access to locally fabricated equipment and high quality local technology and engineering skills.

**API supply**

Most Indian companies entering the regulated markets have internal API manufacturing and development capabilities. Clearly, either strategically managed internal API development and manufacturing or strategic sourcing partnerships are essential to generics company success. American or European generics companies without API capabilities almost always have to source from India or China.
The US market is seeing the expiry of patents for many blockbuster drugs over the coming years. Patents for products in excess of USD 100 billion have expired over the past five-seven years, which has resulted in a number of new generic formulations entering the US market.

This leaves a large opportunity for a country like India where the companies are focused on higher revenue generation by sales to regulated markets and are prepared for the same. As a result it can be assumed that the exports by Indian companies will increase over the coming years.

**Patent Expirations**

The major event detailing the severity of patent expiration came in 2011 after Pfizer lost exclusivity of its blockbuster drug Lipitor. By 2011, Lipitor had generated revenue worth USD 115 billion since its release. The loss of exclusivity of Lipitor was a major dent in sales and profitability for Pfizer.
Patent cliffs have been one of the biggest opportunities for emerging markets like India. With expertise in process innovation and chemistry, Indian pharma companies are poised to take advantage of this patent cliff window. To put this in perspective, IMS Health, a health care information provider, predicts that by 2016 patent expirations will have caused a loss of USD 106 billion in sales from branded drugs over the previous five years, with the heaviest burden in 2012 and 2013.

**Opening of New Markets**

The developed pharma market has been known for its high regulatory standards as well as its high entry barriers. The market is prone to supporting ethical drugs because of the prevalent pharmaceutical system, where hospitals dispense medication and there are no incentives to doctors or patients from a lower priced generic. However, with rising medical costs resulting from an ageing population, the Government has modified its laws for generic medication and has thus enabled more companies to file DMFs and formulation dossiers in the country. A classical example has been the endorsement of Generics in “Obamacare”.

These developed economies intend to raise the share of generic drugs to 40% of the total pharma market in a bid to reduce healthcare costs. They have made a number of reforms to encourage generic drugs. Some of the key reforms are as follows:

- Generics substitution allowed
- Doctors are given incentive to prescribe medicines in Generic name rather than brand name
- Faster system to approve drugs
- Removal of obligation to manufacture locally

The success garnered by the French generics market is indeed a successful case-study for generics adoption. Faced with rising healthcare costs, the French Government set a target to increase contribution of generics to 23% of total expenditure, up from 3% seen in 2001. By 2004, the generics market in France had grown four-fold.

**Continued Growth in the European Markets**

The European generics market has been growing over the past years, and many Indian companies have created a strong foothold there.
Growth in the different pharma markets of Europe have seen varied but positive increase in the past years and the growth is expected to continue at a strong pace over the coming few years. Overall, the generics in European market are expected to grow at almost 10% CAGR.

**Biogenerics**

Biopharmaceuticals are defined as pharmaceuticals manufactured by biotechnology methods, with the products having biological sources, usually involving live organisms or their active components. Biopharmaceutical drugs (or biologics) address areas of clinical need that are unmet by conventional therapeutics (including many cancers and genetic diseases). Biosimilars/ Biogenerics are essentially generic versions of Biopharmaceuticals.

The introduction of similar biological medicinal products (biosimilars) into clinical practice presents new challenges that are not ordinarily presented by small-molecule generic medicines. This is because a biosimilar can only be proven to be similar and not identical to its reference product. In addition, all biotechnology products, including biosimilars have a potential to cause immunogenic events that are not caused by small-molecule products.

Some countries already have widely prevalent biogenerics in their pharma markets. China, Eastern Europe, India and South America already have biogenerics marketed along with other formulation generics.

Biogenerics already command high prices in many countries, especially the USA, and are expected to be potential sources of sizeable future income for the generics industry, with profit levels expected to be higher than those of traditional generics. Most biological drugs command a higher price than traditional formulations because of their difficult to make nature and high stress on quality.

The cost of entering into the Biosimilars market is considerably higher than that of generic pharma manufacturing. Apart from the inhibitory cost, the complexity of the product manufacturing and the sensitivity of the product ensures that competition is low.

Many Indian companies have already forayed into biogenerics manufacturing, for markets other than India. Besides Dr. Reddy’s, Wockhardt and Shantha Biotech, many other companies like Intas Bio, Zydus Cadila, and Emcure are developing various molecules in the biogeneric segment.

**Increasing share in ANDA fillings**

Dossier Filing to the US FDA is one of the best criteria to determine the focus of a company to enter the US generics market.

Over the years, the product pipeline (ANDA filings) of key Indian pharmaceutical players has grown, to become comparable to that of key global generic players. Product pipelines of Indian players such as Ranbaxy, Dr. Reddy’s, Aurobindo, and Sun Pharma are comparable with that of global generics giant.

Indian companies received final approval for 154 ANDAs during the year 2013 from US FDA and 38 tentative ANDAs approval during 2013. The US FDA has approved a total 400 final ANDAs during the year 2013 as against 476 in the previous year and it approved total 86 tentative ANDAs during 2013 as against 94 during 2012. Out of the total approvals, Indian companies grabbed 38.5% final approval during 2013 as against 37.4% in the previous year. Similarly, Indian companies received 44.2% of total tentative approvals as compared to 42% in the previous year.
ANDA Approvals for major Indian companies (2013)

Source: BioSpectrum India
Evolving Industry Trends
Indian Pharmaceutical players sharpen focus on regulated markets

Over the past few years, Indian pharmaceutical players have been increasingly tapping opportunities in global generics markets, especially the US and Europe. Meanwhile, mid-sized and small-sized players have targeted semi-regulated markets of Africa, Asia and Latin America to enhance their distribution network before exporting to regulated markets.

Buoyed by the above trends, Indian formulation exports recorded close to 17% CAGR between 2009-10 and 2013-14 (In dollar terms). The increase in growth was led by exports to both regulated markets, which grew by 22%, and also aided by exports to semi-regulated markets, which grew by 13% (CAGR) over the same period.

For bulk drugs manufacturers, a burgeoning generic market, and cost reduction measures by global pharmaceutical companies present a huge opportunity in regulated markets. Backed by cost-competitiveness, well-developed process chemistry skills and the largest number of drug master filings globally, India is well-placed to tap export opportunities in regulated markets.

Large players enjoy better profitability and undertake higher capital investments

Typically, large players (in both formulations and bulk drugs segments) have more profitable business models due to their wide base in regulated markets, which fetch higher realisations. Presence of strong brands in the domestic market further aids large formulation players. However, significant exposure to international markets also exposes these players to risks, such as volatility in currency rates, overall market performance and outsourcing plans of key players in the target destinations, regulatory risk amongst others.

In terms of capital expenditure too, large players score over smaller formulation and bulk drugs firms, as the latter have a fewer number of US FDA-approved plants, which significantly reduces their capex requirements.
India exports pharmaceutical products to more than 200 countries and the USA is its largest export market among all countries; being the world’s largest generic drug market. Exports to the USA are primarily driven by increased Abbreviated New Drug Applications (ANDAs) approvals by United States Food & Drugs Administration (USFDA), and Indian Pharma companies’ ability to produce high-quality medicines at competitive prices.

**Patent Cliff**

‘Patent Cliff’ is a term used to describe the phenomenon of drugs approaching their patent expiration date, resulting in steep decline in sales of the branded drug as generics enter the market place and undercut the price, thereby capturing the market share earlier served by the branded drugs. So there is a twin effect of steep fall in patented drugs prices as also flooding of market by generics.

**Impact:** Indian pharmaceutical companies have the opportunity to capitalize on the patent cliff and gain a greater share of the growing generics market. Currently, India accounts for nearly 40% of generic drugs and over-the-counter products and 10% of finished dosages used in the USA.

Indian companies’ share in the US generics market has grown rapidly on the back of aggressive ANDA filings and successful pursuit of Para-IV, capitalizing on the patent expiries of blockbuster drugs.

Under the US laws, ANDA filed with a Para-IV certification states that; the generic company which is the first-to-file a para IV, gets 'exclusive rights' to sell the generic version of a branded drug for 180 days, with only the patent holder as the other player in the market. Indian players with robust product portfolio, filings and necessary manufacturing infrastructure are well placed to capitalize on this upcoming opportunity.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Manufacturer</th>
<th>Market size 2012 (USD billion)</th>
<th>Therapeutic Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micardis</td>
<td>Boehringer Ingelheim</td>
<td>2.2</td>
<td>Arrhythmias</td>
</tr>
<tr>
<td>Nasonex</td>
<td>Merck &amp; Co</td>
<td>1.3</td>
<td>Rhinitis</td>
</tr>
<tr>
<td>Sandostatin LAR</td>
<td>Novartis</td>
<td>1.5</td>
<td>Cytoprotective and supportive care agents</td>
</tr>
<tr>
<td>Evista</td>
<td>Lilly</td>
<td>1</td>
<td>Bone Disorder</td>
</tr>
<tr>
<td>Nexium</td>
<td>AstraZeneca</td>
<td>3.9</td>
<td>Hyperacidity and Ulcers</td>
</tr>
<tr>
<td>Copaxone</td>
<td>Teva</td>
<td>4.3</td>
<td>Multiple sclerosis</td>
</tr>
<tr>
<td>Exforge</td>
<td>Novartis</td>
<td>1.3</td>
<td>Hypertension</td>
</tr>
</tbody>
</table>

*Source: Industry*

**Factors conducive to take on the opportunity**

a) Indian Companies hold strong Product Filing Pipeline

Indian companies have built a strong pipeline of products to be sold in the US. During 2013, Indian companies secured 39% of total 400 ANDA approvals from USFDA as against 37% of total 476 ANDA approvals during 2012.

Indian companies with strong generic portfolios have been successful in gaining a good foothold in the US pharmaceutical market. The large number of patent expiration in US presents interesting opportunities for Indian generic products manufacturers. Thus, generic manufacturers are leveraging this opportunity by increasing their ANDA filings.

b) Low-cost Manufacturing Base

Production cost in India is about 50%-60% lower as compared with developed countries, such as US and Europe, because of lower labour cost which is 50%-55% cheaper and capital cost of setting a production plant in India is 40% lower than in western countries. As a result, outside the US, India has the second-highest number of USFDA-approved plants after China. India is home to more than 523 USFDA approved drug manufacturing facilities as on March 31, 2014.

Estimated Market Size of Branded Drugs going off patent in US (USD billion)

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</tr>
</thead>
<tbody>
<tr>
<td>Value</td>
<td>47</td>
<td>33</td>
<td>37</td>
<td>22</td>
<td></td>
</tr>
</tbody>
</table>

*Source: YES BANK Analysis*

Relative cost of production with US cost as base

<table>
<thead>
<tr>
<th>Country</th>
<th>Cost Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>100</td>
</tr>
<tr>
<td>Europe</td>
<td>85</td>
</tr>
<tr>
<td>India</td>
<td>40</td>
</tr>
</tbody>
</table>

*Source: YES BANK Analysis*
c) US Healthcare Insurance Reform

The introduction of The Patient Protection and Affordable Care Act (PPACA) in US signed into law by President Barack Obama in March 2010, which aims at increasing the quality and affordability of health insurance marks a key development in US healthcare insurance reform. This has lead to increase in the proportion of the US population to be covered under medical insurance. As of May 31, 2014, approximately 20 million Americans had gained health insurance coverage under the PPACA and the percentage of uninsured Americans dropped from 18% in 2013 to 13.4% in May 2014. With the market largely catered by Indian companies, this reform is expected to further boost the demand for generic products in the US which will boost the prospects of Indian companies. Already, 86% of prescriptions in 2013 were for generic drugs in US, according to IMS Institute for Healthcare Informatics.

d) Rising M&A activities

The Indian Pharmaceutical Industry is witnessing increased M&A activities from domestic and international players which will help to boost R&D expenditure to achieve economies of scale and to strengthen the marketing network. As per the Department of Industrial Policy and Promotion (DIPP), the pharmaceutical sector attracted Foreign Direct Investments of USD 11.58 billion during April 2000 to February 2014. Since 2013, there have been 46 M&A deals (including announced and closed deals) in the pharma sector in India. Some of the key M&A deals were:

- Sun Pharma announced to acquire Ranbaxy in April, 2014 for USD 4 billion, which will make it the largest pharma company in India and 5th largest pharma company in the world
- Aurobindo Pharma acquired 100% stake in Andhra-Pradesh based Hyacinths Pharma and 25% stake in Silicon Life Sciences in September 2013
- Competition Commission of India (CCI) has approved Japanese firm Mitsui’s proposed takeover of 26.71% stake in Arch Pharmalabs Ltd. in January 2013
- Panacea Biotec Ltd. has entered into a strategic alliance with US-based Osmotica Pharmaceutical Corp to develop and market niche generic medicines for several markets including the US in September 2012

The outlook for the Indian Pharmaceutical industry remains positive on the back of patent expiries through which the country is expected to gain a larger foothold in the world’s generic market. However, as witnessed in the past, there has been an increase in the number of import alerts issued by the USFDA which has hampered the image of Indian Pharma companies and the supplies from such company’s units were banned. If this continues in the long term, it may hurt the profitability of Indian generic drug producers. Thus, the need of the hour is that Indian firms should make sure the quality standards are adequately met.

**Indian Pharma Companies Need To Evolve As Innovators (By 2020)**

Indian pharma firms need to diversify and focus on evolving as innovators as growth in generic market is expected to slow down over the next decade.

Revenues of large global pharma companies (innovators) depend on the performance of their novel, patented molecules. Hence, the R&D productivity of such players is of critical importance and accordingly, they invest heavily in R&D (about 20% of revenues excluding capitalised R&D expenditure).
Over the past few years, R&D activities by large global players have resulted in the innovation of only a handful of new and significant molecules. Meanwhile drug development costs have escalated. The cost for developing a New Molecular Entity (NME) has more than doubled to USD 1.5 billion over the past 5 years. During the same period, the number of NMEs approved by the US FDA continued to hover around 15-20 with an occasional rise to over 20 as seen in 2004 and 2008.

Low R&D productivity is further reflected by the decline in the number of NME applications with the US FDA. The year 2010 recorded the lowest number of NME applications in the past 15 years.

In addition to low R&D productivity, innovators’ returns from novel molecules have substantially declined over the last few years. None of the new drugs approved over the past 2-3 years have been blockbusters (with sales over USD 1 billion) or even sales greater than USD 750 million. This decline in sales is primarily due to the availability of substitutes (generic as well as patented) for existing diseases. Rising emphasis on usage of generics has also steadily reduced the prescription of patented molecules.

Over the last 40 years, since its inception, the Indian pharmaceutical industry has thrived on the generic model by leveraging on its process chemistry skills and low cost manufacturing advantage. This has enabled players to tap the huge generic opportunity abroad.

However, the R&D productivity of large global pharmaceutical players (innovators) has considerably slowed down over the past few years which is underscored by the declining number of NMEs being approved by the US FDA each year. Taking this trend forward, the lack of new drug launches between 2010 and 2015 onwards will mean that the generic opportunity set to open up in the next decade (post 2020) is likely to be significantly lower (assuming average age of 8-10 years of patent exclusivity).

These changes in the global pharmaceutical landscape could cause a slowdown in the generics segment and hence, the Indian pharma industry will be forced to look at newer avenues for growth.

**Contract Research and Manufacturing Service : 'The Indian Story'**

**Externalization of Research and Manufacturing**

India has achieved a leadership position in the segment and has established itself as a hub for CRAMS, as it offers a substantial cost advantage and high quality manufacturing capabilities. Big pharmaceutical companies from the developed markets are increasingly outsourcing their operations, in a strategic manner, to India to leverage on these advantages.

The global CRAMS market (excluding clinical trials) reached USD 75 billion in 2013, with the Indian sector being valued at USD 4 billion or a little over 5% of the total market. This indicates a vast growth opportunity, and the Indian CRAMS sector has been and is further projected to grow at a rate that is 3 times higher than that of the global market.

Outsourcing of activities such as manufacturing and R&D to low cost destinations such as India and China, leads to cost-arbitrage of more than 50% when compared to developed countries. As a result non-core activities such as manufacturing of APIs, dosage development, packaging, amongst others are increasingly being out-sourced.
Distinction between Contract Research and Contract Manufacturing

CRAMS can be divided into the following broader avenues:

1. Contract Manufacturing Segment (CMS)
2. Contract Research Segment (CRS)

Contract Manufacturing Segment (CMS) - Indian pharmaceutical manufacturing has come of age and an increasing number of generic companies are sourcing from India. Key advantages for Indian companies are process development, synthesis skills, quality, and cost-effective manufacturing facilities. The product range encompasses a wide variety of therapeutics and from pharmaceutical intermediates to finished dosage forms (formulations).

Contract Research Segment (CRS) is an end result of the discovery process being outsourced to cost-efficient destinations like India and China. The process is a mix of drug discovery, pre-clinical and final clinical development, leading to a new chemical entity. This being a time and capital consuming process is well aided by CROs across the globe.

Drug Discovery Funnel

Source: YES BANK Analysis
Contract Research & Custom Synthesis (CRS) - There is a clear realization that small volume intermediaries can be economically sourced from countries like India without any compromise in quality. This opportunity is expected to grow as the product patent regime has kicked in, giving significant comfort to big pharma with respect to IP protection.

Drug Discovery & Development (CRS) - As per industry estimates, the global outsourcing market for drug discovery services was pegged at USD 10 billion, and is expected to cross USD 15 billion by 2020. Drug discovery services include areas such as Analogue Research, Combinatorial Chemistry, Chiral Chemistry, New Drug Delivery Systems and Phyto-Medicine. Many of these areas also present themselves as contract services opportunities. These services include bioinformatics, lead discovery, generation and optimization, pharmacokinetics and pharmacodynamics (PKPD), and drug development services including clinical trials.

Chemistry Services (CRS) - These services include providing libraries of novel chemical compounds with high diversity to act as leads for the drug targets. Other services include combinatorial chemistry synthesis, compound purification and characterization and finally creation of different types of libraries of novel compounds.

Biology Services (CRS) - These services include i) identifying and characterizing targets involving genomics, proteomics, structural biology, computer modeling and protein functioning technologies ii) screening including assay development and iii) lead optimization for enhancing qualities of lead candidates using ADMET (absorption, distribution, metabolism, efficacy and toxicity) predictive techniques and structure activity relationship (SAR).

Clinical Research (CRS) - More than 40% of drug development costs are incurred in clinical trials, and India in addition to its vast and diverse genetic pool has a distinct cost advantage in the area. As per industry estimates, the cost of conducting clinical trials in India is between 40-60% of equivalent trials in US or Europe. Also, companies are potentially looking at undertaking quick small trials to lead to fast and cost effective go/no go decisions, especially for new indications.

Contract Manufacturing Services
- 18% CAGR till 2018
- Drugs going off-patent: Nexium, Cymbalta, Celebrex, Abilify, Gleevec and Crestor
- Highest USFDA approved plants outside US
- Moving up the value-chain and investing in technology

Contract Research Services
- 20% CAGR till 2018
- English speaking skilled manpower (Advantage compared to China and South East Asia)
- Outsourcing to Emerging economies; Joint search and development with Indian CROs
- Risk-reward joint development programs on the rise
- Opportunity in CRAMS
Clinical Research Industry: ’A Moderate Outlook’

The worldwide pharmaceutical sales reached USD 1.3 trillion in 2015 (~8% YoY increase) and are expected to reach USD 1.6 trillion by 2020. The emerging markets represent the fastest-growing segment of the global pharma industry. Sales in the four BRIC countries (Brazil, China, India and Russia) were up by 22.6% over the previous year, indicating that real surge in growth will come from the emerging markets. The Indian pharma industry is showing signs of healthy growth and is likely to be in the top 10 global markets by value by 2020. The major drivers of increase in revenues would be the branded generics segment and the emergence of the contract research and manufacturing services.

The process development and chemistry expertise that India acquired prior to signing the Trips agreement in 2005 has helped India become a leader in the contract manufacturing space. With regards to the contract research services, India has emerged as a favorable destination owing to its skilled scientific talent pool and the superior cost-arbitrage benefit. Contract research organizations (CROs) cater to services across the drug discovery and development value-chain.

The past decade has seen an increase in the number of clinical trials in Asia, these are largely cost-driven 'off-shoring' of patient enrollment, designed to take advantage of the region’s large population, diverse ethnic backgrounds and relatively low cost of clinical trials, rather than organically-driving innovation from within the region. With declining R&D productivity and increasing cost base, the pharma companies have adopted the strategy of ‘externalization of research’. This augurs well for developing markets like India.

India offers unique opportunities for conducting clinical trials due to a significant cost reduction and increased productivity of all R&D phases required to bring a safe and effective drug to market. This has been supported by large patient pool, well-GCP trained investigators, premier medical institutions and low per-patient trial cost.

India emerged as a global destination for clinical trials in 2005, the year in which it amended the intellectual property rights (IPR) law to recognise product patents. What helped the industry more than the change in IPR law was India’s decision to permit concurrent phase 2 (clinical studies to obtain preliminary data on the effectiveness of the drug for a particular disease in a few hundred patients) and phase 3 (large study on several thousand patients to know the risk-benefit ratio of the drug) global trials. Until 2005, MNCs were allowed to conduct trials in India only after they successfully completed each phase in developed countries. The change allowed companies to include Indian patients, too, in the global clinical trial map and use the resultant data to prove the safety and efficacy of potential drugs.

This policy change attracted global pharma majors to conduct clinical trials in India. In addition to this major global CROs like Quintiles, PPD, Parexel, Covance have set up full fledged Indian operations to encash the market attractiveness.
Clinical Trial Approval Flowchart

Introduction of NDAC
Has made CT approvals tedious

CT Application by Sponsor / Academic Investigator / Hospital to CDSCO

CT dossier and documents sent to NDAC

Review by CDSCO and NDAC

Meeting of Sponsor / Academic Investigator with CDSCO and NDAC
(Includes CT presentation and Q&A session)

Approval or rejection of CT

Overall Country Attractiveness Index

<table>
<thead>
<tr>
<th>Country</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>6.10</td>
</tr>
<tr>
<td>India</td>
<td>5.58</td>
</tr>
<tr>
<td>Russia</td>
<td>5.55</td>
</tr>
<tr>
<td>Brazil</td>
<td>5.26</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>5.00</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>5.00</td>
</tr>
<tr>
<td>Argentina</td>
<td>4.90</td>
</tr>
<tr>
<td>Poland</td>
<td>4.84</td>
</tr>
<tr>
<td>Hungary</td>
<td>4.81</td>
</tr>
<tr>
<td>Germany</td>
<td>4.69</td>
</tr>
<tr>
<td>South Africa</td>
<td>4.56</td>
</tr>
<tr>
<td>Taiwan</td>
<td>4.46</td>
</tr>
<tr>
<td>Israel</td>
<td>4.28</td>
</tr>
<tr>
<td>Singapore</td>
<td>4.27</td>
</tr>
<tr>
<td>Ireland</td>
<td>3.86</td>
</tr>
<tr>
<td>United States</td>
<td>6.88</td>
</tr>
</tbody>
</table>

Scale: 1 - 10

Patient pool  Cost efficiency  Regulatory conditions  Relevant expertise  Infrastructure and environment

Source: A.T. Kearney
Notes: Higher Scores indicate higher levels of attractiveness. The 15 countries analyzed were selected based on size, diversity and geographical distribution. The index is not meant to be comprehensive across all potential offshore locations.
Cost Advantage in Clinical Research Outsourcing to India

With adequate support from the Government, the clinical research industry would definitely witness greener pastures. The sector has significant cost advantage as compared to other geographies in the world. In addition to this, the diverse patient pool and highly skilled manpower will indeed make India into an attractive clinical research destination.

India by virtue of its cost effective human resource pool and currency, offers direct operational cost advantage in the conduct of clinical trials. A large part of the cost advantages also stem from the potential time saving by undertaking concurrent trials in India - aided by large patient population, better patient accruals, a reasonably good pool of ICH GCP aware clinical investigators, amongst others. We have brought out the cost advantages in various aspects of a study, vis-a-vis US / Western Europe, through an actual case study at a leading Indian CRO.

<table>
<thead>
<tr>
<th>Protocol No.</th>
<th>XXX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication</td>
<td>Metastatic Breast Cancer, Phase III</td>
</tr>
<tr>
<td>Sponsor</td>
<td>ABCD</td>
</tr>
<tr>
<td>Sample size</td>
<td>100 patients</td>
</tr>
<tr>
<td>Sites</td>
<td>10</td>
</tr>
<tr>
<td>Screening Period</td>
<td>1 month</td>
</tr>
<tr>
<td>Recruitment Period</td>
<td>8 months</td>
</tr>
<tr>
<td>Treatment Period</td>
<td>5 months</td>
</tr>
<tr>
<td>Follow-up Period</td>
<td>0 months</td>
</tr>
<tr>
<td>Total Clinical Duration</td>
<td>14 months</td>
</tr>
<tr>
<td>Stall Required</td>
<td>1 Project Manager, 3 Case RAs, 1 Regulatory Affairs, 1 Drug Safety Associate, 1 medical Manager, 1 Quality Assurance.</td>
</tr>
</tbody>
</table>
The inherent assumption in the above table is that the study in the US will also be completed in 8 months across 10 sites. However, in reality, this is a very unlikely scenario and the study in the US would probably need either 18-20 sites or the 10 sites would take 16-18 months to complete the trial, due to lower patient accrual. The cost estimates would thus favour India even more than indicated in the table above.

The number of clinical trials has decelerated in the last three years. From 500-odd trials approved in 2010 to 262 in 2012.

However, this downward spiral is a temporary phenomenon as the Government and DCGI are taking steps to streamline the regulatory framework. Clinical research in India, being an industry in its infancy, is bound to undergo such a transition period so as to harmonize its regulatory framework to International standards.

<table>
<thead>
<tr>
<th>Services</th>
<th>INDIA Expenses (Bench marking)</th>
<th>USA Expenses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start-up-Activities</td>
<td>100</td>
<td>150</td>
</tr>
<tr>
<td>Initiation Activities</td>
<td>100</td>
<td>138</td>
</tr>
<tr>
<td>Interim Activities</td>
<td>100</td>
<td>165</td>
</tr>
<tr>
<td>Site Management</td>
<td>100</td>
<td>187</td>
</tr>
<tr>
<td>Project Management</td>
<td>100</td>
<td>170</td>
</tr>
<tr>
<td>CTS Management</td>
<td>100</td>
<td>167</td>
</tr>
<tr>
<td>Medical Management</td>
<td>100</td>
<td>167</td>
</tr>
<tr>
<td>Quality Assurance Activities</td>
<td>100</td>
<td>167</td>
</tr>
<tr>
<td>Data Management</td>
<td>100</td>
<td>157</td>
</tr>
<tr>
<td>Biometrics &amp; Report</td>
<td>100</td>
<td>288</td>
</tr>
<tr>
<td><strong>Total Fees</strong></td>
<td><strong>100</strong></td>
<td><strong>167</strong></td>
</tr>
</tbody>
</table>

| Pass-through Costs           |                                |              |
|------------------------------|                                |              |
| Site Payments                | 100                            | 263          |
| Investigator Meeting         | 100                            | 147          |
| ICF Translation              | 100                            | 100          |
| Central Lab charges          | 100                            | 207          |
| Travel & Sustenance          | 100                            | 156          |
| **Total Fees**               | **100**                        | **227**      |
| **GRAND TOTAL**              | **100**                        | **198**      |

Source: Industry Sources
Investments in Pharmaceuticals

The recent deal between Sun Pharmaceuticals and Ranbaxy has paved the way for further consolidation and M&A in this sector. This highlights the importance of the Indian market in the global healthcare landscape. Earlier the focus was acquisitions of innovation-driven start-ups for technology platforms and early stage development product companies but now there is a renewed interest in larger market opportunities.

Some of the highlights of the Sun Pharma and Ranbaxy deal:

- Created world’s 5th largest specialty generic company
- No. 1 in India with leadership in 13 specialty segments
- No. 1 Indian Pharma company in US
- Operations in 65 countries and 47 manufacturing facilities
- 629 ANDAs; Combined T/O ~ USD 4 Billion with EBITDA ~ USD 1 Billion

Source: YES BANK Analysis

MNCs have been usually acquiring Indian pharmaceutical companies to experience the Indian advantage and have a strong footing in the ever-expanding market. They also leverage the acquired manufacturing sites to integrate vertically. The US-based Mylan, the most active of global players in India, has done about half a dozen major deals so far, investing around USD 3 billion in India alone. Japanese drugmaker Daiichi Sankyo bought Ranbaxy Laboratories in 2008 while American manufacturer Abbott purchased the domestic formulations business of Piramal Healthcare in 2010.

Even as this trend continues, the recent emerging trend has been that of Indian companies aggressively acquiring strategic local and foreign targets in a bid to expand inorganically. Cadila Healthcare’s purchase of Biochem Pharma in 2011, Torrent Pharma’s acquisition of domestic formulations business of Elder Pharma, Ipca Labs’ acquisition of 50% stake in Avik Pharma in 2013, Sun Pharma’s buyout of its larger rival Ranbaxy Labs in April 2014 and Shasun Pharma’s merger with Strides Arcolabs, reinforces the attractiveness of local targets for the ambitious and aggressive Indian drugmakers.
Snapshot of Acquisitions made by Indian companies

<table>
<thead>
<tr>
<th>Indian</th>
<th>International</th>
<th>USD Mn</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sun Pharma</td>
<td>Ranbaxy</td>
<td>USD 3,200</td>
<td>Acquired from Daiichi Sankyo (2014)</td>
</tr>
<tr>
<td>Piramal</td>
<td>DRG</td>
<td>USD 653</td>
<td>Purchased US Data company (2012)</td>
</tr>
<tr>
<td>Cipla</td>
<td>Cipla Medpro SA</td>
<td>USD 488</td>
<td>Acquired to strengthen presence in African market (2013)</td>
</tr>
<tr>
<td>Sun Pharma</td>
<td>DUSA</td>
<td>USD 230</td>
<td>Acquired US dermatology company (2012)</td>
</tr>
<tr>
<td>Piramal</td>
<td>Bayer Pharma</td>
<td>USD 200+</td>
<td>Acquired worldwide rights for Alzheimer’s drug (2012)</td>
</tr>
<tr>
<td>Lupin</td>
<td>Nanomi</td>
<td>Undisclosed</td>
<td>Netherlands based technology company (2014)</td>
</tr>
</tbody>
</table>

Increased Investments by MNCs

- The Indian pharma market is one of the fastest growing pharma markets in the world. This has led to increased investments by MNCs to gain a larger market share.
- MNCs are estimated to hold 35% of Indian Pharma market by 2017 as compared to the present level of 30%.
- MNCs are specifically developing India focused strategy in terms of product launches and pricing.
- MNCs compete with the domestic players through launch of patented drugs at relatively low price points than those in the global market.

Indian Pharma is the 5th largest recipient of FDI; accounted for ~5% of India’s FDI during April 2000-February 2014.

FDI in the Indian Pharma Sector (in USD million)

Source: Department of Industrial Policy & Promotion (DIPP)
Key Pharmaceutical Deals in 2013 and 2014

**Attractiveness of the Indian landscape**

With consolidation in the Pharma sector seeming a reality, many global Big Pharma are eyeing the Indian marquee companies. For example, the top 20 Japanese companies such as Takeda, Astellas, Mitsui and Mitsubishi Pharma are all seriously looking for opportunities in the Indian drug market.

**Major Indian Companies: Key Differentiators**

- **Cipla**
  - Strong in respiratory and anti-AIDS drugs
  - Strong in Emerging markets - Africa, West Asia, Australia
  - 50% revenue from India
  - Unique Partnership Models

- **Dr. Reddy’s**
  - Leading player in emerging markets like CIS and Russia
  - Strong product portfolio in Biosimilars
  - Very Sucessful in the US Market
  - Strong Custom Pharmaceutical Services

- **Lupin**
  - Largest Indian company in Japan
  - In Niche segments like oral contraceptives, ophthalmics and asthma
  - Strong in CIS, Africa, South-east Asia and Australia

- **Glenmark**
  - Strong in segments such as dermatology, respiratory and anti-infectives
  - Focus on low competition products in the US
  - Strong in Latin America, CIS and Africa region
Conclusion

India is one of the fastest growing economies of the world, and the Indian Pharmaceutical Industry has been an important constituent to the pharma sector worldwide due to the recent changes in patent laws, the rising use of generics, high cost competitiveness, and availability of large scientific research force in the country.

Strong GDP growth and significant cost advantages has resulted in the Indian Pharmaceutical Industry to grow significantly at CAGR of 20%. Participation of India pharma companies in the international pharmaceutical market has increased and with more generic products being introduced in developed economies, Indian formulation and bulk drug exports have grown significantly. Also, increasing cost pressures on innovators has resulted in significant growth in contract research business.

With downward pricing pressures in established markets, and at the same time increasing costs due to regulations, competition and innovation, the Pharma Industry is being forced to look for new models of efficiency and impact. This coupled with a weak pipeline of new molecules capable of showing major improvements in therapy, is bringing the ‘Blockbuster Model’ of the Pharmaceutical Industry into question. There are new risks, which exist not only in the development and market approval of drugs but can also be found in its entire lifecycle. Further, there is an increase in consumer activism, which is requiring an investment in tighter operating procedures, transparency and the maintenance of public trust.

Despite these concerns, India is fast emerging as the preferred R&D destination for many companies across the globe, outpacing cut-throat rival, China. Faced with increasing drug development costs and commercialization on one hand and drying pipeline on the other, global companies have now chalked out elaborate plans for India not just because of the low costs it has to offer but also due to faster and cheaper time-to-market opportunities, a larger and diverse patient pool, and the availability of a sizable number of skilled scientists. It has been estimated that the cost to conduct a trial in India is 50% lower than that of a developed market. Thus, India is definitely poised to become one of the leading Pharmaceutical markets in the world.
We would like to thank of the illustrious bodies with the help of whose publications we have been able to compile this report:

- Department of Pharmaceuticals, Government of India
- Ministry of Commerce, Government of India
- The Planning Commission, Government of India
- The Census Information of India
- Ministry of Finance, Government of India
- The Investment Commission of India
- The Ministry of Health and Family Welfare, India
- The World Health Organization
- Centre for Enquiry into Health and Allied Themes
- Centre for Studies in Ethics and Rights, India
- CRISIL Research
- Department of AYUSH
- NABH, NSDA, ASCI websites
- International Institute for Population Sciences
- YES BANK report on 'Healthcare Services in India'
- Euromonitor
- Datamonitor
- ISI Securities
- PWC Reports

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- The Hindu Business Line
- Silicon India
- Pharmabiz
- The Economic Times
- The Medical Travel Journal
- eHealth
- The Wall Street Journal
- The Economist
- Outlook Business Magazine
- Pitch Magazine
- Hindustan Times
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