



# Evolving Landscape And Emerging Trends Across India's Healthcare Continuum

**Pharma, Biotech, Devices, Diagnostics & Delivery**

**MEDCON 2016**





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## **Pharma, Biotech, Devices, Diagnostics & Delivery**

**MEDCON 2016**







शमीमा सिद्दिकी  
SHAMIMA SIDDIQUI

भारत के राष्ट्रपति की उप प्रेस सचिव  
Deputy Press Secretary  
to the President of India



राष्ट्रपति सचिवालय,  
राष्ट्रपति भवन,  
नई दिल्ली-110004.  
PRESIDENT'S SECRETARIAT,  
RASHTRAPATI BHAVAN,  
NEW DELHI - 110004.

### MESSAGE

The President of India, Shri Pranab Mukherjee, is happy to know that the Associated Chambers of Commerce and Industry of India (ASSOCHAM) is organising the MEDCON-2016 "Congress-cum-Awards on Diagnostics, Medicines and Medical Devices" on March 10, 2016 at New Delhi.

The President extends his warm greetings and felicitations to the organisers and participants and sends his best wishes for the success of the event.

Deputy Press Secretary to the President



हंसराज गंगाराम अहिर  
HANSRAJ GANGARAM AHIR



29<sup>th</sup> February, 2016.

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भारत सरकार  
नई दिल्ली - 110001  
Minister of State  
Chemicals & Fertilizers  
Government of India  
New Delhi - 110001

**MESSAGE**

I am glad to know that The Associated Chambers of Commerce and Industry of India (ASSOCHAM) is organizing the MEDCON-2016, Congress-cum-Awards on Diagnostics, Medicines & Medical Devices: Rethinking Healthcare Delivery on 10<sup>th</sup> March 2016 at New Delhi.

I compliment ASSOCHAM for organizing MEDCON-2016 and participants of this conference and wish the event a great success.

  
(HANSRAJ GANGARAM AHIR)







## **ACKNOWLEDGEMENT**

It gives me immense pleasure that ASSOCHAM is organizing its flagship healthcare summit namely MEDCON 2016.

The pace with which healthcare sector is evolving is unparalleled. Alongside the emergence of better quality of life and awareness among the population, the disease patterns are also shifting from communicable diseases to non-communicable diseases. Today India is one of the youngest nations in the world but however by 2050 more than 20% of its population will be aged above 65 years, which will further increase the burden of non-communicable diseases and geriatric disorders.

The major pillars of healthcare which are required to fulfill the healthcare requirements of the country are diagnostics industry, pharmaceutical industry, medical equipments industry, doctors, and hospitals which are closely interlinked to each other. At MEDCON we are putting together all these segments of this industry, to initiate a holistic development and success.

I extend my heartiest thanks to all the stakeholders including ICMR, NABH, Apeejay Svrans Group, Dr. Lal Path Labs, OncQuest, SRL, Environics, Krishna & Saurastri Associates, Sun Pharma, Nutas and others, for lending their support to this summit. I would also like to thank our Knowledge Partner of this summit "Sathguru Group" for its wonderful efforts in putting up this comprehensive report on all the subjects pertaining to the Indian Healthcare Industry.

I also acknowledge the efforts put in by Sandeep Kochhar, Deputy Director and Head-ASSOCHAM Healthcare & Pharma Division and his team members Shagun Ahlawat, Karanveer Singh and Anshul Gupta for the organizing these Conferences.

I not only wish this congress a great success but also assume that ASSOCHAM shall continue to organize such programs for larger public benefits with a great degree of excellence.

**D S Rawat**  
**Secretary General**  
**ASSOCHAM**



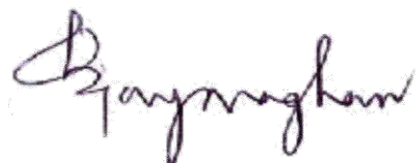
## ACKNOWLEDGMENT

This knowledge report on “**Evolving landscape and emerging trends across India’s healthcare continuum**” has been prepared by Sathguru Management Consultants as a part of ASSOCHAM MEDCON 2016.

The research has been conducted by studying various reports, recent publications and substantiated with sectorial know-how of our technical team in order to understand current trends, future focus areas, regulatory aspects and market scenario across pharma, biotech, devices, diagnostics & delivery.

I would like to acknowledge the contribution of Ms. Pushpa Vijayaraghavan, Dr. Hridayesh Dixit, Dr. Abhishek Joshi, Mr. Dhruv Arora and Ms. Shruti Singh towards, development of this knowledge report.

Yours sincerely

A handwritten signature in black ink, appearing to read 'K Vijayaraghavan', written in a cursive style.

K Vijayaraghavan

Chairman and Director

Sathguru Management Consultants



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## Table of Contents

|  |    |
|--|----|
| Executive Summary.....   | 5  |
| Introduction .....   | 11 |
| Section A – Pharmaceutical Industry .....  | 17 |
| I. India Pharma Market- Current Landscape and Emerging Trends.....                 | 17 |
| Market Dynamics and Commercial Trends.....   | 17 |
| Key Industry Trends .....  | 20 |
| Technology and Innovation Adoption.....  | 24 |
| Policy and Regulatory Framework .....  | 26 |
| II. Growth Drivers and Challenges for Pharmaceutical Industry.....                 | 28 |
| III. Segment Outlook .....   | 29 |
| Section B – Medical Devices and Diagnostics Industry.....                          | 33 |
| I. India- Current Landscape & Emerging Trends .....                                | 33 |
| Market Dynamics and Commercial Trends.....   | 33 |
| Key Industry Trends .....  | 37 |
| Technology and Innovation Adoption.....  | 39 |
| Policy and Regulatory Framework .....  | 42 |
| II. Growth Drivers and Challenges.....   | 43 |
| III. Segment Outlook .....   | 44 |
| Section C - Healthcare Delivery Industry .....                                     | 47 |
| I. Healthcare delivery – Overview of Current Landscape .....                       | 47 |
| II. Market Dynamics and Commercial Trends.....                                     | 48 |
| Market Dynamics and Evolving Business Models (including home healthcare etc.)..... | 48 |
| Expanding Healthcare Access .....  | 51 |
| Improving Quality of Care .....  | 52 |
| III. Growth Drivers and Challenges.....  | 54 |
| IV. Segment Outlook.....   | 54 |





# Executive Summary





## Executive Summary

The pace with which healthcare sector is evolving is unparalleled. Alongside the emergence of better quality of life and awareness among the population, the disease patterns are also shifting from communicable diseases to non-communicable diseases such as cardiovascular, cancers, diabetes etc. Today India is one of the youngest nations in the world but by 2050 more than 20% of India's population will be aged above 65 years. This will further increase the burden of non-communicable diseases and geriatric disorders.

There is currently great momentum in India around innovations in healthcare and their adoption, and this is further strengthened by the evolving startup culture. Government grants and schemes have further fueled innovators to come up with novel products and are thus enabling better quality healthcare and greater access. Several Government units such as the DBT funded BIRAC, C-CAMP and THSTI, international and philanthropic funders such as the Wellcome Trust and Gates Foundation and many such organizations have contributed to nurturing building blocks in the healthcare innovation ecosystem and have seeded this current wave of innovation led development.

**Pharmaceutical Industry:** The relatively mature Indian pharmaceutical industry stands on a strong foundation of domestic and global success in small molecule generics. Domestic and export revenue was close to US\$30 billion in 2015 and it is anticipated the industry will continue its present double digit growth rate provided it prioritizes focus on quality and is supported by robust regulatory and export policies. However, the industry is aware of the need to enhance competitive advantage to sustain the growth. This is reflected in the current trend of focusing on more complex formulations, alternative route of administration and rapidly expanding beyond small molecules into biosimilar and peptides. While there has been an overall increase in R&D spending by large companies, the risk appetite has been lean and thrust on new drug discovery and development is insignificant. While there have been few success stories on new drug development and some of the leading CROs have built an internal pipeline of new chemical entities, these developments are not reflective of a broader trend. While several young ventures have been seeded, even today there is dearth of VC capital and other sources of scale up funding required for the ventures to emerge as a stable source of innovation for the industry. There is a need to bolster the innovation eco-system to empower the industry to sustain global leadership in the long term horizon.

The future of this industry is quite promising because of expanding healthcare access, improved medical infrastructure, higher insurance penetration and purchasing power. This is expected to boost the industry forward and support the country's goals for improved health outcomes.

**Medical devices and diagnostics industry:** The Indian medical devices and equipment industry contributes to 6% of India's US\$40 billion healthcare sector. The industry is growing at a CAGR of 15%. Medical supplies and disposables market is dominated primarily by



domestic Indian manufacturers, whereas high-end medical equipment and devices are largely imported into the country by large multinationals. The industry is influenced by not only country's GDP but also by overall public expenditure on healthcare, disease incidence, public awareness of diagnosis and treatment options, regulatory environment, health insurance etc. Dearth of localized and competitively priced products in high end medical devices continues to be a large concern. The industry is gearing up in several ways to address the current gaps and interest from existing players to expand is at its peak. Several new players are aspiring to enter the industry given the growth potential that emanates from current unmet needs and amateur industry structure.

Historical skewed landscape dominated by international products being imported into India without customization for local requirements has now created scope for new product development. Both multinational companies and domestic players are working towards developing differentiated products suited for Indian needs. Emergence of seed funding opportunities has given rise to many ventures focused on innovation in this sector as well. Ventures emerging have relatively greater support from venture capital and private equity funds compared to pharmaceuticals given the shorter product development cycles and glaring gaps in the market. Small to mid-sized companies have attracted great acquisition interest from global companies eyeing the Indian market and we anticipate that several strategic partnerships will also emerge in the near future. The government has taken several steps to develop the market and foreign direct investments have been specifically allowed in the sector, more specific regulations are underway and new medical technology parks are being planned. Within the healthcare landscape, the devices and diagnostics segment stands out with highest potential for growth, innovation adoption and overall market development.

**Healthcare delivery industry:** Healthcare delivery sector includes hospitals and clinics. Unlike many other countries, Indian hospital sector is serviced by both public sector and private groups. The sector has been growing at a fast rate and attracting substantial investments, not only from financial investors but from strategic investors as well. Many large private hospital groups have built world class advanced medical facilities and are now expanding their services to remote locations through various hub and spoke models. Several new business models in healthcare are emerging and gaining popularity such as public-private partnerships, single specialty focus hospitals, Tier II & Tier III focused plush hospitals, home healthcare, digital transformation and more. Excellent medical infrastructure and services offered by various private hospital at globally competitive prices has attracted medical tourism. However, only limited potential has been exploited given lack of aggressive promotion and facilitation of medical tourism by the Government.

Healthcare delivery especially in peripheral city locations, Tier III cities and rural locations is largely catered by government due to far lower financial returns. Government has been securing healthcare services for underprivileged population along with government employees and expanding healthcare access through various schemes and insurances.



Schemes like Rashtriya Swasthaya Bima Yojana, Aarogyasri scheme, NRHM are few indicative examples which have expanded healthcare access to many underprivileged population segments. Recent announcements to establish many new medical colleges, new AIIMS, furnishing existing institutions with advanced digital technologies such as telemedicine are encouraging. Compared to government insurance coverage, coverage by private health insurance players is small today but has been witnessing double digit growth in recent past. Private insurance sector is also poised to grow with recent increase in foreign direct investment limits.

Expanding middle class population with increased willingness to pay for quality healthcare has also fueled emergence of new business models. There is clear trend of evolving upgradation from basic medical services to quality and convenience. Companies like PRACTO. Portea, 'Healthcare at Home' are providing health services at patient's door step with quality and convenience. There is also significant momentum around adopting institution-wide quality practices, leveraging technology to leapfrog healthcare delivery possibilities to remotest of populations and improving processes, operations and efficiency in existing hospitals. The segment's growth and thrust on expanding access is accompanied by a strong determination to achieve globally commendable clinical outcomes in the country's leading institutions some of which have developed innovative processes and clinical practices to accomplish this. Despite daunting challenges, the current trends in the healthcare delivery segment offer great promise and reflect potential to have significant impact on India's health outcomes in the medium term horizon.





# Introduction





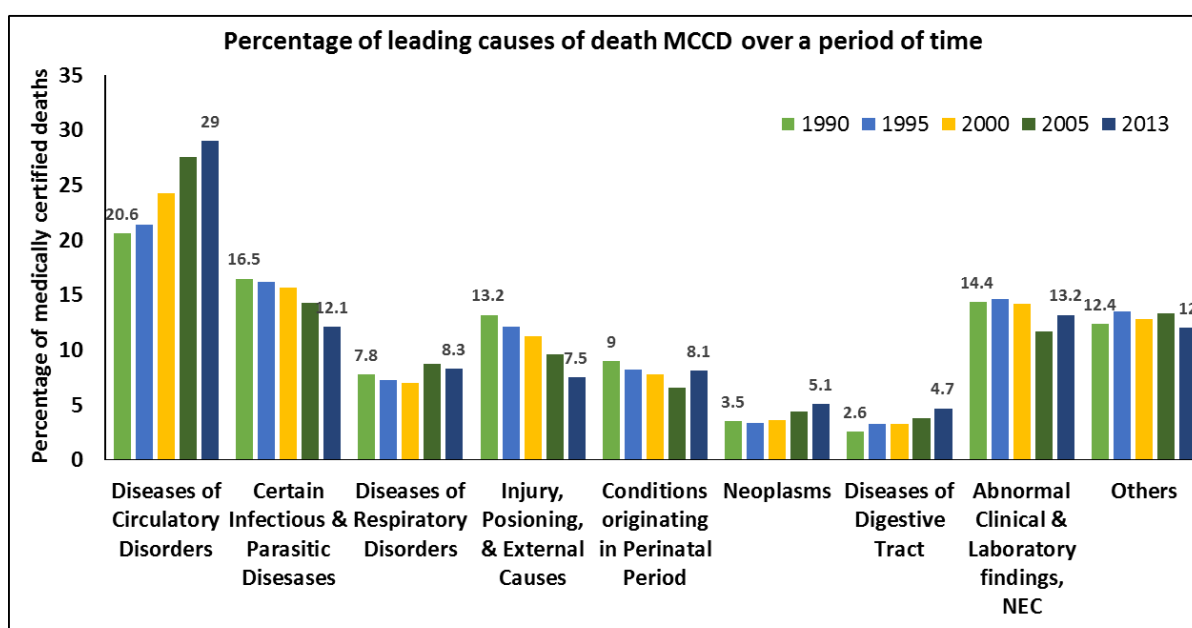
## Introduction

India is one of the most populated and fastest growing countries in the world driven by the availability of skilled younger generation. India will be youngest nation in next five years. However, by 2050 20% of India’s population will be aged (>65 years). The fast growing middle income strata with higher willingness to pay has been a driver of significant economic growth but has suffered the unfortunate impact of increasing lifestyle diseases and chronic diseases. At the other end, rural India still remains underprivileged for fundamental personal hygiene and access to healthcare within their affordability and reach. Timely diagnosis is a dream yet to be realized in the underprivileged segments and this further compounds the healthcare access problem.

## Evolving disease profile

### Communicable diseases continue to remain a large problem but are now better managed:

Communicable diseases which were earlier the dominant problem in Indian healthcare landscape are now better managed but new lifestyle diseases have emerged as national threats. Communicable diseases accounted for 16.5% of deaths during early 1990s but have now reduced to 12.1% of deaths.<sup>1</sup>



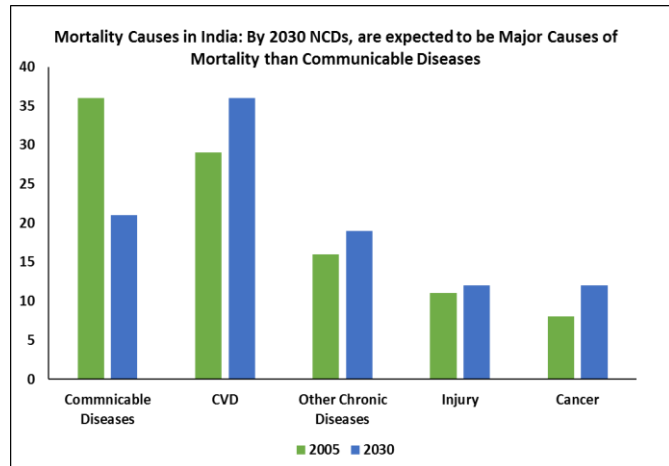
Source: Report on Medical Certifications of causes of Death 2013, Office of the Registrar General, India

<sup>1</sup> Report on Medical Certifications of causes of Death 2013, Office of the Registrar General, India.



**Non-communicable diseases (NCD) are bulging as causes of mortality:**

Cardiovascular diseases have emerged as the most common causes of death and accounted for 29% of deaths in 2013 compared to 20% in 1990. It is also anticipated that by 2030, cardiovascular diseases alone will be responsible for 36% of deaths. Cancers and other NCDs are also leading causes of deaths. Diabetes accounts for 80.7% of all endocrine, nutritional and metabolic diseases and looms as one of the largest burdens of chronic disease that India has to deal with.



Source: Report on Medical Certifications of causes of Death 2013, Office of the Registrar General, India

**Rising Insurance Penetration and Willingness to Pay will drive industry expansion and growth**

In India, health insurance achieved can be classified into 3 ways. Group health insurance (Other than Government Sponsored), Government Sponsored health insurance and Individual health insurance. In past five years, amount spent on health insurance has been significantly increasing. In terms of health insurance premium paid, the industry has doubled in size from 2010-11 to 2014-15. The sector is growing at CAGR of 16.1%. Reasons for low penetration of health insurance are affordability and lack of awareness.

About 29 crore Indians are covered under health insurance by one or the other way. Government insurance/schemes cover approximately 75% of these people, about 17% are covered under group health insurance programs while remaining 8% opt for retail insurance. Number of retail health insurance policies bought by individuals has declined over past five years, while number of government and group insurances policies has been growing consistently.

The recent increase in foreign direct investments (FDI) limit from 26% to 49% in insurance sector will further promote growth in this sector.

In addition to expanding insurance coverage, economic growth and increasing willingness to pay are expected to be continuing drivers of healthcare industry expansion and growth. India still largely remains an out-of-pocket market. Consequently, the market largely remains more value driven but also offers a complex market landscape with several customer segments with varying purchasing power. At one end, these market segments create pricing challenges with differential pricing being a debatable concept in healthcare globally. At the other end, they



offer potential for business model innovation to leverage willingness to pay in mid to high income segments that are willing to reward convenience and quality.

### **Innovation as an Enabler**

There can be no better enabler for healthcare than innovation. Technology upgradation grants by Gates Foundation has allowed detection and treatment of more than 6.1 million TB patients. Welcome Trust have been funding various public health, translational, and biomedical research programs. Government has been proactive to provide necessary thrust to nurture startups and innovation in this sector. Government bodies such as BIRAC (DBT) are today sharing investments risks with innovator firms to accelerate introduction of affordable solutions in the country and several novel initiatives taken by the National Health Systems Resource Center such as the National Healthcare Innovations Portal are fostering increased adoption of innovation in healthcare delivery across the public and private sectors.

The recently announced Government Startup India Policy 2016 could provide further fillip to the innovation momentum. It reflects the intent to address the current capital access challenge for product development and innovation advancement, includes a special focus on startups in Biotechnology sector, provides for easier secretarial compliances and exit, envisions new Innovation centers at national institutes and also provides for tax exemptions.

Several building blocks in the innovation ecosystem have been put together and with continued thrust from the Government and industry, there is great potential for innovation led growth and expansion in India's healthcare sector. Greater innovation engagement and adoption could be the key facilitators in the next decade for not only expanding healthcare access but also improving health outcomes and achieving the country's overall healthcare goals.





# Pharmaceutical Industry





## Section A – Pharmaceutical Industry

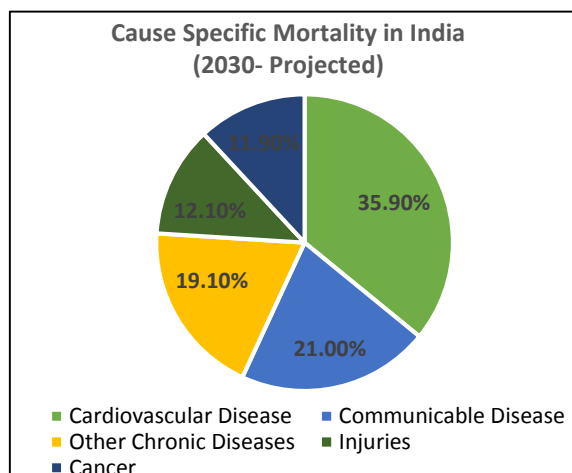
### I. India Pharma Market- Current Landscape and Emerging Trends

India accounts for 15% of the world’s population, but 20% of the global disease burden. India has a triple disease burden<sup>2</sup>- diseases prevalent in developing countries (communicable and nutritional diseases), diseases usually seen in the developed world (lifestyle diseases, cancer), and globally prevalent diseases (pandemics, orphan diseases).

Sustained efforts in controlling communicable diseases and increased longevity and lifestyle changes driven by health improvements and economic prosperity are leading to increase in non-communicable diseases (NCDs).

As a consequence, lucrative opportunities have emerged, particularly in treatments for Obesity, Diabetes and other lifestyle diseases in the Indian market. Initially, MNCs benefitted from this as they were able to import and market premium drugs into India

to address these therapeutic areas. However, Indian pharmaceutical majors have greatly benefitted from the synergy of these therapies with global treatment profiles, allowing them to develop and market these drugs for both the Indian and Global regulated markets. In the next 10-15 years, NCDs and chronic diseases such as diabetes are expected to be major reasons for mortality in India, creating a large, sustained market for drugs aimed at these therapeutic areas.



Source: Chronic Non-Communicable Diseases in India- PHFI (2011)

### Market Dynamics and Commercial Trends

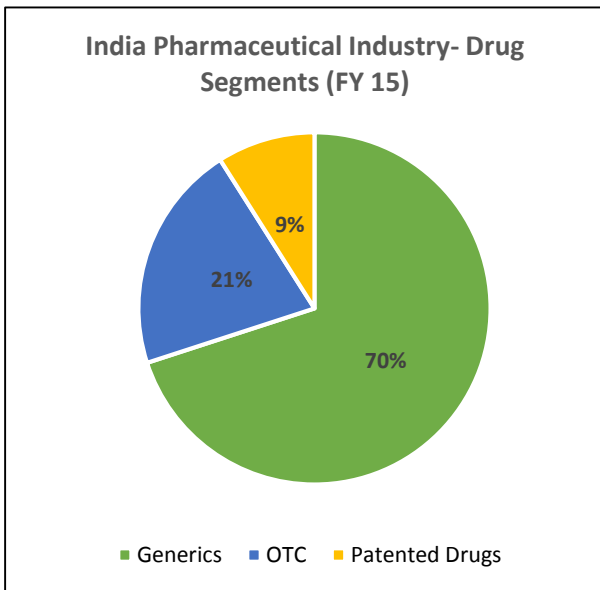
The Indian Pharmaceutical Market has been growing at a CAGR of 17.46% to US\$ 30 billion in 2015 over US\$ 6 billion in 2005 and is expected to reach US\$ 55 billion by 2020 at a CAGR of 12.89%<sup>3</sup>. 70% of the market consists of generic products with a further 21% attributed to OTC products and remaining 9% to patented drugs<sup>3</sup>. In terms of therapeutic focus, anti-infectives, CVS and GI drugs dominate the market with 40% share combined in FY '15. The anti-diabetic, respiratory and urology segments grew significantly over last year at 32.9%, 27.8% and 29.5% respectively<sup>4</sup>. Significant growth is also expected in these segments for the next 5 years, along with growth in dermatology, gastrointestinal and cardiovascular segments. Immuno-oncology is also gaining a lot of importance, with development of several biosimilars and NCEs in that area.

<sup>2</sup>“Economics of Non-Communicable Diseases in India”- World Economic Forum and Harvard School of Public Health- Nov 2014

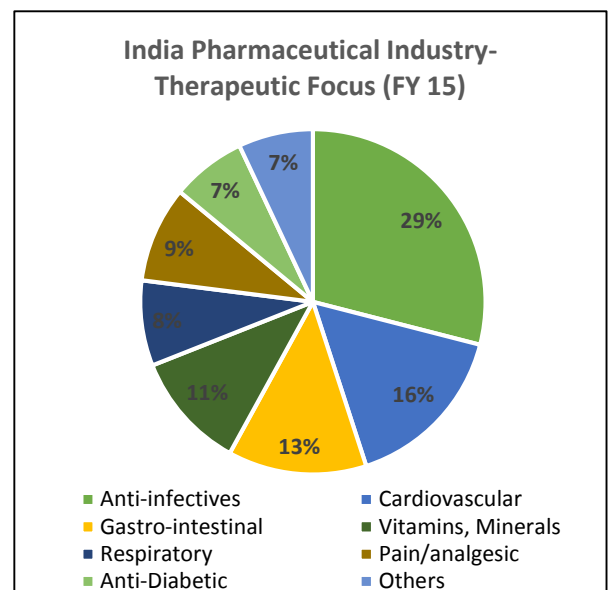
<sup>3</sup> India Brand Equity Foundation (IBEF) Sector Report on Pharmaceuticals- January 2016

<sup>4</sup> All Indian Origin Chemists & Distributors (AIOCD) Analysis

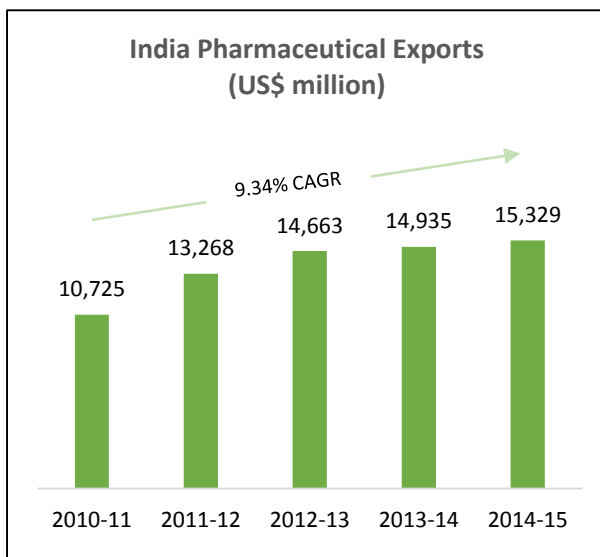




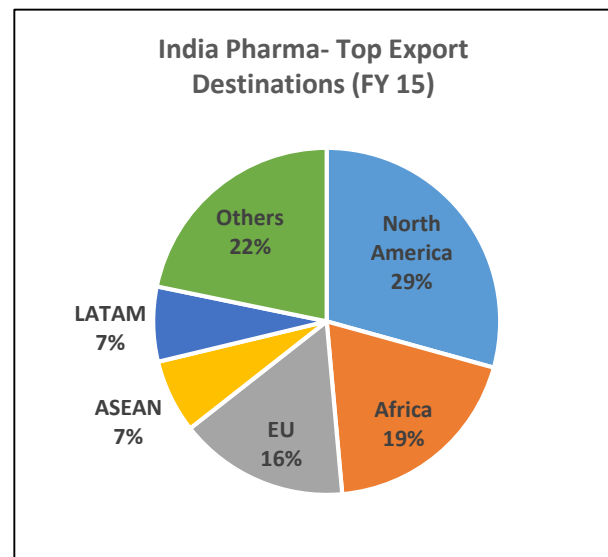
Source: IBEF Sector Report on Pharmaceuticals- January 2016



Source: All Indian Origin Chemists & Distributors (AIOCD) Analysis



Source: Pharmexcil Annual Report- 2014-15



Source: Pharmexcil Annual Report- 2014-15

Export has been a major driver for growth for domestic pharmaceutical companies, accounting for US\$ 15.33 billion of industry revenue<sup>5</sup>. On the global stage, India is the world's largest supplier of generic drugs, accounting for 20% of the world's generic drug exports in terms of volume<sup>6</sup>, with the largest supplies aimed at the US (29% of the total pharma exports). Penetration of Indian products into other regulated and semi-regulated markets has also increased manifold owing to the cost advantage offered by manufacturing in India. Exports in

<sup>5</sup> Pharmaceuticals Export Promotion Council of India (Pharmexcil)- Annual Report 2014-15

<sup>6</sup> Pharmexcil- Statistics on India Pharmaceutical Exports

FY 15 to countries such as Brazil, Myanmar, Thailand, Turkey, Kenya and Venezuela have recorded growth in excess of 15% over FY 14.

**APIs:** API is the largest segment in the Indian pharmaceuticals sector, with a 7.2% market share in the global generic API market. India's API export to regulated markets constitutes roughly 48% of its total API exports, out of which 29% of exports were to generic formulators and 19% to on-patent innovator formulators<sup>7,8</sup>. The Indian pharmaceutical industry is also the world's leader in Drug Master Files (DMFs) applications with the US.

**Formulations:** At a domestic market size valued at US \$ 11.2 billion in 2016, formulations are expected to grow in excess of 10% over the next 5 years. India is also the largest exporter of formulations in terms of volume, with a global market share of 14%<sup>9</sup>

**Contract Research and Manufacturing Services (CRAMS):** Expected to grow at over 18% to approximately US\$ 18 billion by 2018, the CRAMS segment has emerged as an important component of the pharmaceutical market in India, with several global and Indian majors outsourcing discovery and clinical work to over 1,000 players<sup>9</sup>.

**Biopharmaceuticals:** The Biotechnology industry has set an ambitious goal for itself of a US\$ 100 billion market by 2025. Discounting the Bio-agriculture and the Bio-services aspect of this vision, the biopharmaceuticals sectors is expected to grow manifold, due to the emerging global acceptance of biosimilars and their rise in India, along with strong global leadership in vaccines from Indian majors.

- **Biosimilars:** With multiple products introduced in this segment, and several in pipeline, it is expected to touch US\$ 1.4 billion by end 2016, growing annually at a rate of 30% in India<sup>9</sup>, with immuno-oncology a high demand therapeutic area. Despite this high expected growth, a number of challenges remain. Primarily, the limited penetration of biosimilars in the Indian market, and a nascent eco-system of CROs and CMOs in India for biosimilars.
- **Vaccines:** Indian companies enjoy global leadership in this segment, with 1 in 3 vaccines globally being manufactured by Indian companies. Having successfully tapped the public health supply markets (GAVI, WHO, PAHO), vaccine manufacturers are looking at supply to ROW (non-GAVI) markets. In addition to sustained global growth, recently introduced changes in the Indian UIP are expected to drive growth in the domestic segment.

**OTCs:** Currently, the Indian OTC drugs market ranks 11<sup>th</sup> in terms of value globally, and is expected to grow at a CAGR of 16.3 per cent to US\$ 6.6 billion over 2008–16<sup>9</sup>. Increasing

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<sup>7</sup> CRISIL Database 2014-15

<sup>8</sup> OPPI Annual Report 2014-15

<sup>9</sup> India Brand Equity Foundation (IBEF) Sector Report on Pharmaceuticals- January 2016

incidence of lifestyle factors along with increased promotion of nutraceutical products are expected to contribute to the growth of this market in India.

### Key Industry Trends

Building on global leadership in generics and exploring future avenues to maintain global competitive advantage

#### **1. Enhancing formulation complexity of their generics portfolio itself (injectables, liposomal, transdermal, inhalation et al)**

The complex generics market accounts for around 50% of the US generics market and is valued at \$25 billion, with the potential to outperform the growth rate of the overall market by at least two times<sup>10</sup>. However, at present, domestic drug makers get less than 15% of their US revenue from sales of complex generics in the US. Given the lure of higher growth and relatively leaner competition, Indian pharma majors are looking to increase their presence in this segment and enhancing formulation complexity of their generics portfolio. They are increasingly focusing on building capabilities in alternative drug delivery forms including complex injectables, controlled release dosage forms and inhalation platforms. Most of the top 10 pharmaceutical companies in India with focus on regulated markets have made several efforts in this direction and are strategically exploring all possibilities including building in-house expertise, in-licensing technologies and even acquiring companies. For instance, Lupin Pharma has been aggressively purchasing companies with complex generics' pipelines such as Nanomi, and also recently opened an R&D center for inhalation products in the US. Dr. Reddy's acquired OctoPlus to get access to PLGA technology for formulation of liposomal and microsphere injectables, and is investing in technology platforms to develop complex APIs.

#### **2. Aggressive focus on peptides and biosimilars**

Leading Indian generic companies are aspiring to extend their global presence in generics beyond small molecules to now include peptides and biosimilars that offer significantly higher margins. This is also critical for long term sustenance of their generics business given the increasing share of peptides and biologics in new product approvals globally. The Indian biosimilar sector is expected to touch US\$ 1.4 billion in 2016 and is expected to grow at 30% CAGR<sup>11</sup>. Several Indian firms have made significant investments in these areas and are building strong pipelines for Indian as well as global markets. Companies with deep engagement include Dr Reddy's, Intas, Biocon, Cadila, Torrent, Aurobindo, Lupin etc. In biosimilars, Monoclonal Antibodies (mAbs) offer the largest opportunity and dominate the pipelines of these companies, with oncology being a key focus area.

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<sup>10</sup> Financial Express Article- "[Pharma Companies Eye US Complex Generics Market](#)". Accessed on 15<sup>th</sup> February 2016.

<sup>11</sup> India Brand Equity Foundation (IBEF) Sector Report on Pharmaceuticals- January 2016

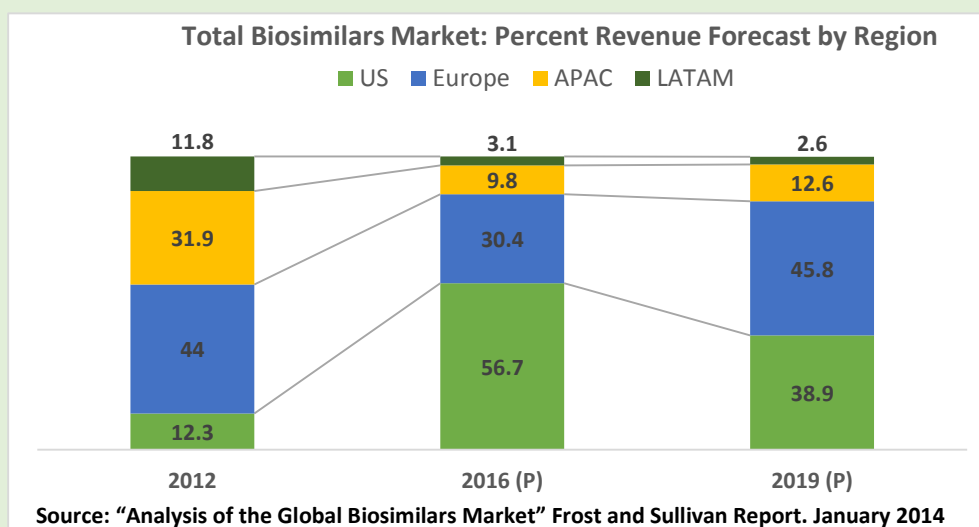


Additionally, small and medium sized companies are targeting amino acid supply and biosimilar API for India and less regulated markets.

However, companies continue to deal with challenges such as dearth of technical expertise in India in biologics and peptide synthesis, regulatory uncertainty, negligent CROs and CMOs capability in the area and lastly, high cost of clinical validation that serves as a commercial deterrent to most companies. Despite the recent introduction of biosimilar development guidelines, a coherent and streamlined mechanism for approval of biosimilars is also evolving in India. Globally too, several aspects of product approval and reimbursement are still taking shape.

### Biosimilars - Global Market Opportunity

- Patent Cliff- Patent expiry of blockbuster biologics worth US\$ 100 billion by 2020
- Highly concentrated market- Top 3 players constitute ~70- 80% market share
- Global biosimilars/follow-on-biologics market accounted for US\$ 2.5 billion in 2014 and it is anticipated to grow to US\$ 20-35 billion by 2020<sup>12</sup>



### Peptides - Global Market Opportunity

- The global peptide therapeutic market is expected to be worth US\$ 23.7 billion by 2020, growing at a CAGR of 2.8% from 2014-2020<sup>13</sup>
- The global peptide market is dominated by the US and EU, accounting for ~60% of the total revenue.

<sup>12</sup> "World Bio-similars/Follow-on-Biologics Market - Opportunities and Forecasts, 2014 - 2020"- Market Research Reports Inc. 2015

<sup>13</sup> Peptide Therapeutics Market-- Global Industry Analysis, Size, Share, Growth, Trends and Forecast 2014 – 2020". Transparency Market Research. 2015

### **3. Going beyond generics- climbing the innovation ladder in a gradual manner**

The current engagement in novel drug discovery and development in large Indian pharmaceutical companies is not intense and has rather been cut back in the recent past. Commercialization successes that stand out in this landscape include Ranbaxy's (now Sun Pharma) Synriam<sup>®</sup>, a novel drug for treatment of uncomplicated Plasmodium falciparum malaria, Zydus Cadila with Lipaglyn<sup>®</sup>, an indigenously developed drug for diabetic dyslipidemia and Glenmark that is pursuing regulatory approval for Crofelemer, a natural product derived drug for HIV associated diarrhea. Despite the relatively lean investments on NCE/NBE development, the focus on moving up the innovation ladder continues albeit in a gradual manner with lower near term risk being shouldered. Several companies have articulated a near term focus on building a proprietary portfolio of re-formulating and re-purposed drugs. These include Cipla, Lupin and Dr Reddy's which have a focus on CNS/oncology, pediatrics and CNS/dermatology respectively. This middle ground of assets less risky than completely novel products provides the opportunity for cash rich pharmaceutical majors in the country to vet their risk appetite and gradually progress to NCEs and NBEs in the long term.

### **4. Building a proprietary portfolio and front-end market presence in high- value markets- Specialty pharma**

In addition to strengthening product portfolios beyond generics, leading Indian pharmaceutical companies are now strategically focusing on building front end sales capability in regulated markets. There is significant aspiration and intent to go beyond the current mold of supplying substitutable generic formulations to pharmacies. They are building their own sales force as well as considering acquisition opportunities to build this front end strength in high value regulated markets. In the current nascent stage, these sales forces are oriented towards specific therapeutic areas and are combined with efforts to build proprietary product portfolios as discussed above. Lupin has built its own front end sales force in pediatrics in the US to promote its proprietary portfolio of branded drugs such as Alinia<sup>®</sup> and Locoid<sup>®</sup> Lotion. Dr. Reddy's is similarly promoting its developed and acquired dermatology portfolio in the US and other regulated markets through its US specialty pharma subsidiary Promius Pharma.

#### **Consolidating and Expanding Geographic Presence in International Markets**

Mid-sized to large Indian pharmaceutical companies have been aggressively pursuing international acquisition opportunities to strengthen market presence across developed and emerging markets and get a foothold in markets they are not currently strong in. With large transactions such as Aurobindo's acquisition of Western European operations of Actavis and Lupin's acquisition of US generics firm Gavis, Indian companies have been able to establish themselves as active buyers in the cross-border M&A landscape in the pharmaceuticals sector.

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**Indicative transactions –**

**Frontend markets focused outbound M&A by Indian Pharma Majors**

- Cipla has entered into an agreement to acquire two US based pharmaceutical companies InvaGen Pharmaceuticals Inc., and Exelan Pharmaceuticals Inc. for US\$ 500 million to get traction in the US generics market across a wide product portfolio
- Panacea Biotec entered into a strategic alliance with Canadian firm Apotex for research, development, license and supply of two drug delivery based generic products to US, Canada, Australia and New Zealand markets.
- Cadila Healthcare is in late-stage talks to acquire USA's Claris Lifesciences which makes specialty generics including blood products and anti-infectives, as well as delivery systems for these products, with sales across 70 emerging markets including Russia and Brazil.
- Lupin acquired US generics firm Gavis Pharmaceuticals LLC and Novel Laboratories Inc. for US\$ 880 Mn, the largest acquisition by an Indian pharma company in the US. This is expected to help Lupin access manufacturing and marketing in the US, and accelerate its presence in niche areas such as controlled substances and dermatology.

While the US and Europe remain largest markets of focus in terms of impact on revenue, pharmaceutical companies are also aggressively seeking M&A opportunities in key emerging markets such as LATAM, Russia & CIS, South Africa and South East Asia.

In addition to market expansions in these geographies, several large companies have also acquired and invested in local manufacturing and research assets in these geographies.

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**Indicative transactions –**

**Manufacturing assets focused outbound M&A and investments by Indian Pharma Majors**

- Cipla, the largest supplier of anti-malarial drugs to Africa, set up a US\$ 32 billion plant in Africa for the production of anti-retroviral and anti-malarial drugs
- In 2015, Lupin opened a research and development centre for inhalation products in Florida, US

Domestic market expansion due to increased healthcare access and pharma penetration in Tier 2, 3 and rural markets

Increase in disease incidence, disease diagnostics and drug accessibility coupled with increasing health insurance penetration, increased government expenditure on healthcare and an increase in purchasing power is expected to drive significant growth in the pharmaceutical sector in India. The demand for generic medicines in rural markets and Tier 2 & 3 cities has seen a sharp rise, as a result of which several companies are investing in distribution networks in these areas. Additionally, increase in lifestyle diseases and

consequent demand for effective therapeutics (including several novel and patented drugs) is expected to expand the value of the Indian pharmaceutical market.

### Technology and Innovation Adoption

#### Foundation for a holistic innovation ecosystem – surge of young ventures

The last decade has been transformational for the biotech and pharmaceutical innovation in India. Transformational, not with respect to traditional metrics of drugs commercialized or advanced, but with respect to efforts made to bridge the most significant gap – the overall ecosystem for innovation in life sciences. A concerted effort has been made to nurture various layers of this ecosystem, foster applied research in institutions and nurture innovation driven entrepreneurship. There has been a surge of new ventures with varying levels of innovation engagement. Non-dilutive grants are more easily available to allow for technology de-risking and incubation infrastructure has been bolstered. This is prompted both globally experienced people of Indian origin and experienced scientists from industry to take the entrepreneurial plunge in India. These startups have been largely funded through innovation grants, with limited participation from VCs. BIRAC, setup by the Department of Biotechnology to promote new ventures in this space has funded over 400 start-ups through grants, with the Department of Science and Technology (DST), Govt. of India and other public bodies also contributing.

| Indicative Indian startups in biotech and pharmaceuticals |   |
|---|---|
| <b>Connexios</b>  | Early stage drug discovery and development company pursuing several programs for metabolic disease and diseases related to NASH and Fibrosis. Recently out-licensed a set of its anti-diabetes molecules to German pharma major Boehringer Ingelheim. |
| <b>Vitas Pharma</b>                                       | Focused on identifying and developing novel therapies for infectious diseases, particularly, multi-drug resistant nosocomial infections   |
| <b>Curadev</b>  | Focused on pre-clinical research to develop and out-license pre-IND assets and IND packages for drug development. Recently signed an agreement with Roche to develop and commercialize IDO1 and TDO inhibitors applied in the immune-oncology space.  |
| <b>Navya Biologicals</b>                                  | Biologicals development company with novel integrated bioprocess platform and multiple product pipeline including biosimilars, bio-betters, novel biologics and cell therapies  |
| <b>Aten Porus Lifesciences</b>                            | Developing unique cyclodextrin-based nanoparticle platforms as biodegradable long-circulating MRI contrast agents and lipid mobilizing agents for the treatment of lysosomal storage disorders  |
| <b>Bugworks</b>   | Focused on discovering and developing novel biopharmaceutical assets for treatment of antibiotic resistant bacterial infections   |

### Strong and underrated pipeline built by leading CROs

Leading Clinical Research Organizations (CROs) in India have evolved beyond toxicity studies and now have integrated discovery expertise involving in-silico modelling, medicinal chemistry, animal models, genomics, screening and lead optimization. Their discovery infrastructure and expertise is comparable to global standards with several CROs having a successful track record of delivering IND molecules to International clients. Many of these CROs started engaging in risk-sharing models to go beyond fee for service and participate in the upside of their discovery effort. Some of them have gone even beyond risk-sharing into building their own proprietary pipeline of molecules and have even tasted success in out-licensing the molecules. Within the overall Indian life-sciences landscape, the CROs' proprietary pipelines represent the most valuable but underrated cluster of drug assets that have potential for global advancement.

### Gradual increase in innovation investments by larger companies

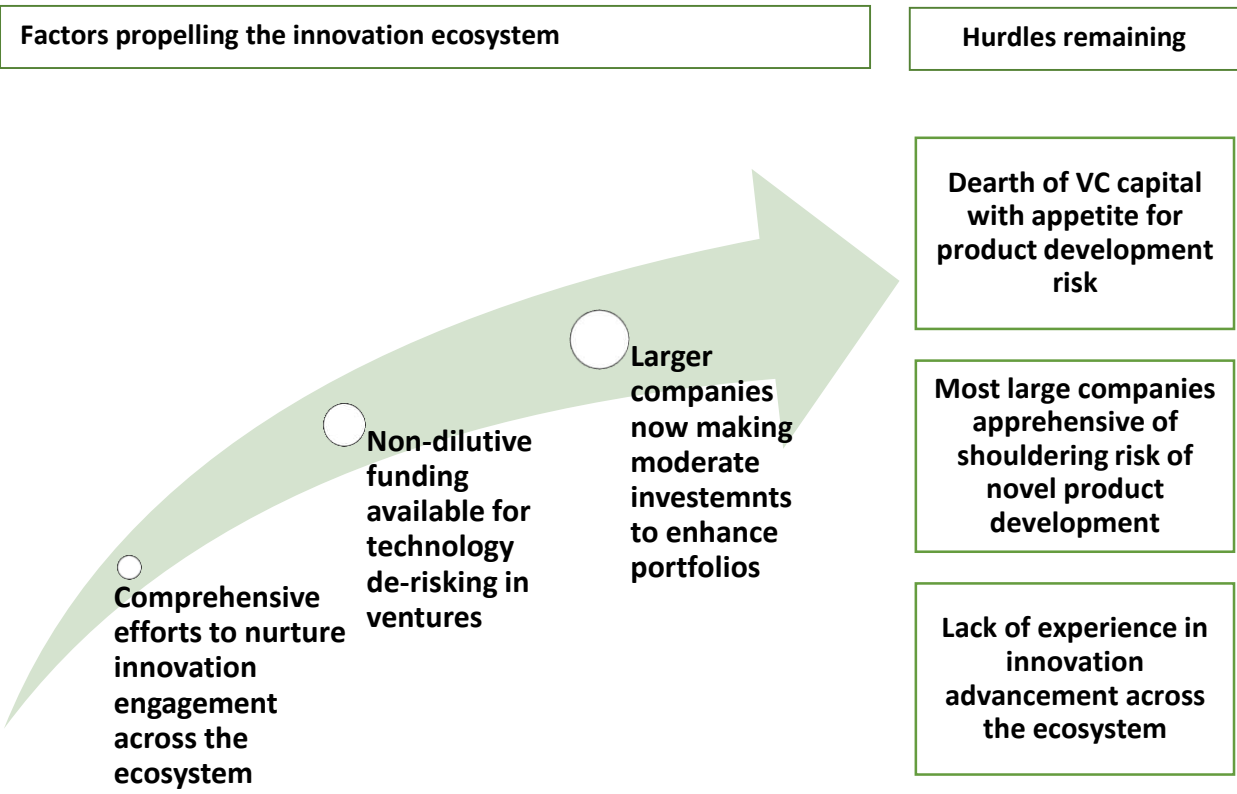
Several of the Indian pioneers to invest in drug discovery and development such as Dr Reddy's, Wockhardt and Piramal have significantly curtailed their engagement in novel drug discovery and development and have taken to a more paced out approach. Only a handful of large companies such as Glenmark, Biocon and Zydus Cadila continue to have deep engagement in discovery and development of novel drugs.

Most of the large and mid-size pharmaceutical companies are primarily focused on a gradual transition to go beyond generics. They have expanded formulation capabilities into areas of complexity such as liposomal drug delivery and inhalation platforms and are expanding their portfolios beyond small molecules to include peptides and biosimilars. Additionally, many of them are focused on developed reformulated/repurposed drugs for regulated markets. Oncology and metabolism are emerging as key therapeutic areas where the most R&D efforts are being concentrated. Infectious diseases, inflammation and pain are other areas seeing significant research investment from Indian pharmaceutical companies. Several companies are also investing in developing nutraceuticals and increasingly pursuing therapeutic applications through the prescription pathway to gain greater clinical acceptance and expand markets. Lastly, they are beginning to harbor appetite for moderate investments in young ventures developing novel therapeutics and vaccines.

### **Indicative Examples - large Indian pharmaceutical companies investing in young ventures**

- Cipla invested in Stempeutics, a Bangalore based venture developing a portfolio of stem-cell based applications across oncology, dermatology et al
- Alembic Pharma invested in Incozen therapeutics, a Hyderabad based venture developing a portfolio of NCEs
- Aurobindo Pharma invested in Tergene Biotech, a Hyderabad based venture developing a novel Pneumococcal Conjugate Vaccine (PCV) candidate offering wider immunity than vaccine currently marketed by MNCs

Summary and way forward



Overall, the Indian pharmaceutical innovation eco-system is at unique crossroads, with fragmented end-to-end capability, pledged support from the government, infrastructure to support young ventures, proven success in the discovery outsourcing industry and maturity of allied services. For these propellants to drive India into an enviable position on the global pharma innovation map, the remaining hurdles need to urgently be bridged. Today, venture capital chases proven products but has negligent appetite for technology or product risk. The large companies are still trading with caution and widespread innovation investments are yet to be made. The current Government’s initiatives under Startup India offer great promise for the biotech and pharmaceutical innovation ecosystem, especially given the proposed fund of funds. If given wings, the current surge in innovation engagement could expand impact of Indian industry on healthcare in India and the world and will expand the horizons for what is ‘Made in India’.

**Policy and Regulatory Framework**

Global pricing pressure implies continued opportunity for Indian generics industry

Globally, there is a sustained pressure on drug pricing, with drug prices stagnating in most developed markets. In the US, which has been an outlier from regulated pricing and where the drug prices have been rising at an annual rate of 10% since 2010, there has been recent outcry on the price premiums levied on certain life-saving drugs. As proposals to reduce drug

costs are put forward, regulated markets in particular are expected to procure and promote cheaper imported drugs. Additionally, the adoption of biosimilar guidelines by the US FDA, following the EMEA are expected to further drive exports from cost competitive markets such as India.

#### Drug approval and regulatory pathway

Within India, while there is fairly good clarity on framework on drugs, the process has been frayed with delays and lack of transparency. In the recent past, there is significant change with better accessibility to regulators and engagement with them. However, industry is still seeking greater transparency in the process and more efficiency in drug approval process.

#### Price control and measures to widen access

From the introduction of the New Drug Pricing Control Order by the Directorate of Food and Drugs in India in 2014, the net for drugs under price control has further widened. With the compulsory licensing history and expanding net of price control even beyond drugs, there is the persistent question on whether these are the best mechanism to widen access to healthcare. Industry is keen to draw attention of policymakers to the need to for balancing this intent with industry interest as wider price control could be a deterrent to development and launch of newer and innovative products and formulations. Additionally, imbalanced pricing for imported and locally produced products, such as in the case of insulin, has invited criticism from the industry.

#### Pharmaceutical sales and related practices

The Uniform Code of Pharmaceutical Marketing Practices (UCPMP) has been through a trial and has been recommended for voluntary compliance by the Department of Pharmaceuticals (DoP) in 2015 to curb unethical drug marketing practices. While the policy is under review, it is expected to be made mandatory for all pharmaceutical companies, forcing them to keep detailed listings of marketing expenses, putting strict control on sponsorship of medical conferences and prohibiting medical representatives from paying or giving gifts to healthcare practitioners.

#### Overall healthcare spending

Providing impetus to the health care sector, the National Health Policy Draft 2015 has proposed raising public health expenditure to 2.5% from the present 1.2% of GDP in the next 5 years. Increased expenditure by the government, along with the passage of the insurance bill which raised the foreign investment cap in the insurance sector from 26% to 49% is expected to boost the penetration of medical services and pharmaceuticals in the country.

#### Pharmaceutical trade and exports

Additionally, the Foreign Trade Policy 2015-20, unveiled last year aims at fast-tracking growth of pharmaceutical exports from India by addressing issues related to non-trade barriers and regulations faced by Indian pharmaceutical firms abroad. Through this, the non-tariff barriers in Japan and regulatory hurdles faced by Indian drug makers in China will be addressed. The



Government will also implement a 'track and trace' policy which would limit the chances of genuine drugs being considered spurious or counterfeit.

## II. Growth Drivers and Challenges for Pharmaceutical Industry

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### Key Growth Drivers:

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- Increase healthcare access due to increasing health insurance penetration, increased government expenditure on healthcare and an increase in drug purchasing power
  - Increase in disease incidence and disease diagnostics expected to increase overall drug sales and access
  - Increased penetration into tier 2, 3 cities and rural markets of pharmaceutical sales forces to widen market presence
  - Ongoing pricing pressures, particularly in the regulated markets, will ensure strong export presence of Indian majors who can keep costs down without compromising on drug quality.
  - Portfolio strength of domestic manufacturers to drive export into less regulated emerging markets
  - Successful development of peptides and biosimilars, expected to further drive growth promote development of advanced drug discovery and manufacturing capabilities locally
  - India's global vaccine leadership to facilitate foray into previously untapped ROW markets, and further transition into higher value, premium vaccine markets
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### Key Challenges:

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- Quality violations and increased scrutiny by the US FDA on manufacturing facilities of several Indian pharmaceutical majors threatening to cause global erosion of trust in Indian drugs, and prompting allocation of resources towards improving systems, controls and standards
  - Complex, less transparent and ambiguous regulatory mechanism improving at a slower pace than desired, with persisting need for efficiency and transparency
  - Low risk appetite of VCs and investors, and overall lack of patient capital limiting development of innovation eco-system, with small, innovator companies struggling to get access to capital to scale.
  - Nascent innovation eco-system and lack of commercialization-ready technology is prompting manufacturers to look for technologies outside of India, often at premium cost.
  - Increasing dependence of manufacturers on intermediate and bulk imports from Asian countries is posing threat to local intermediate manufacturers and limiting control of formulators on the quality of inputs
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### III. Segment Outlook

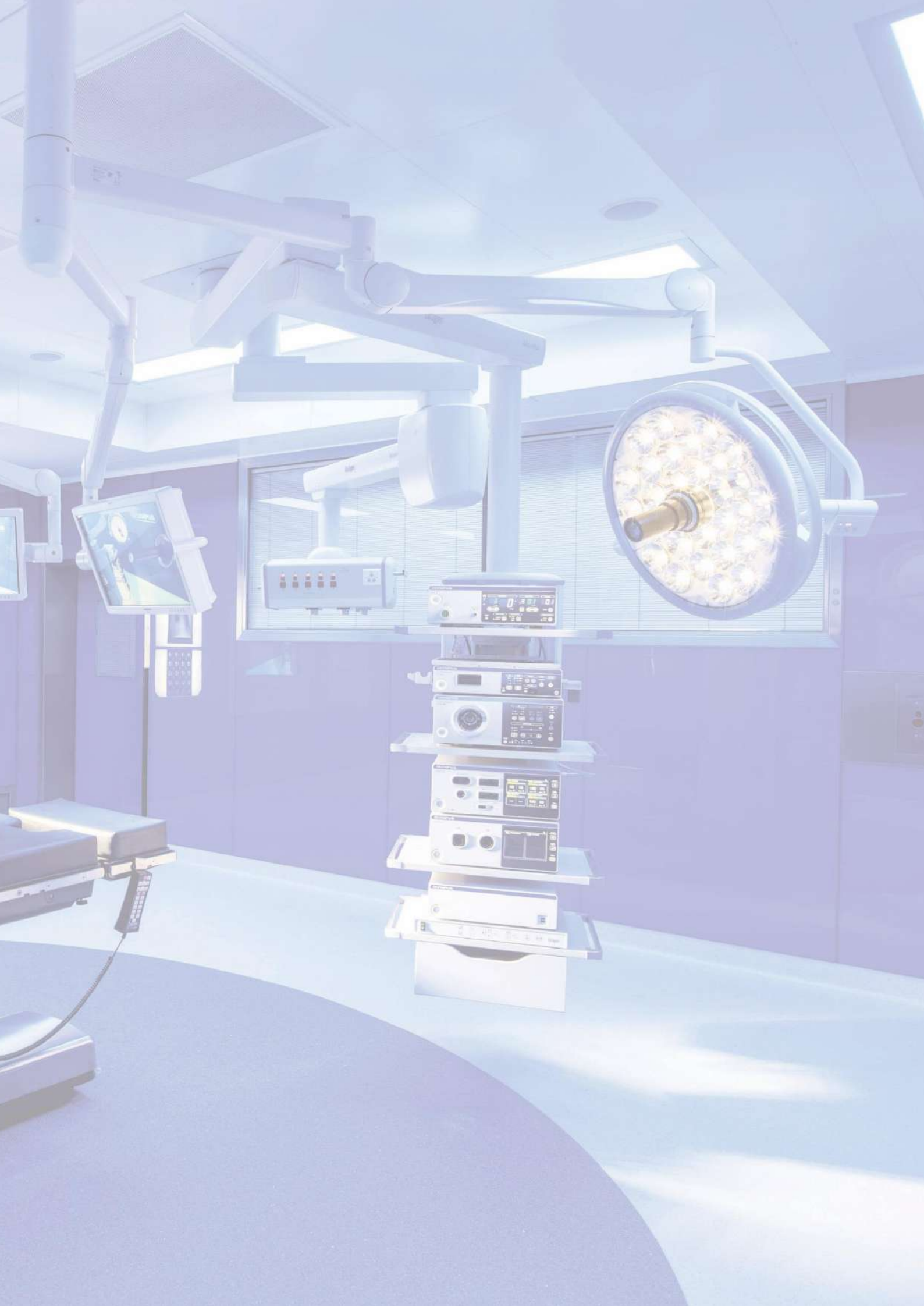
The Indian pharmaceutical industry has most of the ingredients required to sustain double digit growth for several years to come, provided it is supported by robust regulatory and export policies. Incentivizing new drug discovery and development, and further nurturing the innovation eco-system will be critical to empower India to deal with its burgeoning burden of disease. This coupled with increased healthcare access, improved medical infrastructure, higher insurance penetration and purchasing power is expected to boost the industry forward and support the country's goals for improved health outcomes.





# Medical Devices and Diagnostics Industry

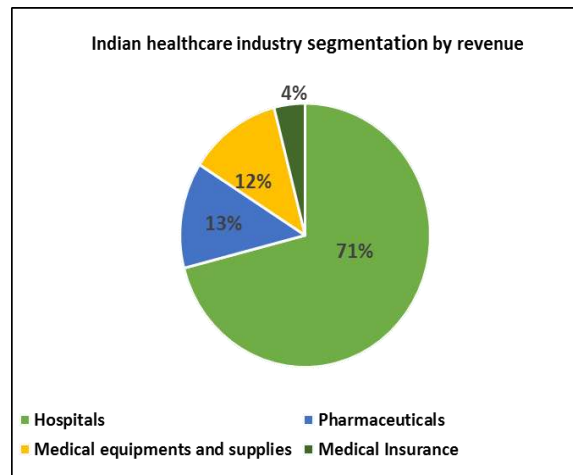




## Section B – Medical Devices and Diagnostics Industry

### I. India- Current Landscape & Emerging Trends

The Indian Medical devices and equipment industry contributes to 6% of India’s US\$40 billion healthcare sector, close to US\$2.5 billion. The industry is growing at a compounded annual rate of 15%<sup>14</sup>. Medical supplies and disposables market is dominated primarily by domestic Indian manufacturers, whereas high end medical equipment and devices are primarily imported into the country by large multinationals. The latter segment of imported high-end devices is anticipated to contribute to almost 75% of



Source: IBEF

total market share. A rise in the number of hospitals and diagnostic centers, increase in disease burden and transition from communicable to non-communicable diseases (NCDs) and increasing Government support for healthcare have driven growth for the industry and have exposed the need to urgently bridge gaps in India’s devices and diagnostics landscape.

Dearth of localized and competitively priced products in high end medical devices continues to be a large concern. The industry is gearing up several ways to address the current gaps and these developments are outlined in greater details in the section below. Interest from current players to expand is at its peak and new players are eyeing the industry given the growth potential that emanates from current unmet needs and amateur industry structure. This growth intent further fueled by investor appetite and recent innovation initiatives place the industry at the beginning of a decade of unprecedented growth.

### Market Dynamics and Commercial Trends

The diagnostics industry is classified into two segments- diagnostic services market and diagnostics devices and supplies market, each at different stages of growth.

#### Diagnostic Services

The diagnostics service industry has traditionally been fragmented and unorganized. However, large PE funded reference lab networks have significantly expanded presence across the country and are representative of the ongoing shift from unorganized, non-branded service providers to organized and branded diagnostic chains for higher quality and reliability. National chains such as Super Religare Laboratories (SRL), Dr. Lal Pathlabs, and Metropolis led this trend and regional/niche players have now followed. While Thyrocare and Oncquest represent niche players focused on specific therapeutic areas, regional players

<sup>14</sup> The Medical Devices and equipment Industry- FICCI

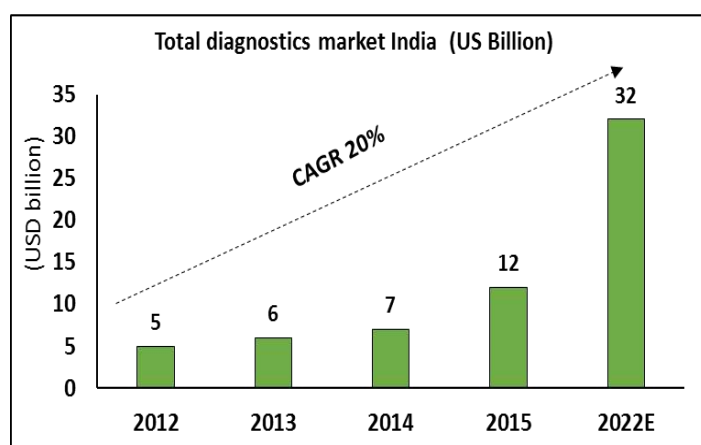


have also emerged such as Vijaya Diagnostics in the South. While consolidation and competitive advantage was earlier largely driven by quality assurance and pricing, the leading reference labs are now focused on expanding the portfolio of tests to offer more contemporary diagnostic tests to Indian population. They have also expanded their footprint beyond India and are able to service markets such as the Middle East through their reference lab model.

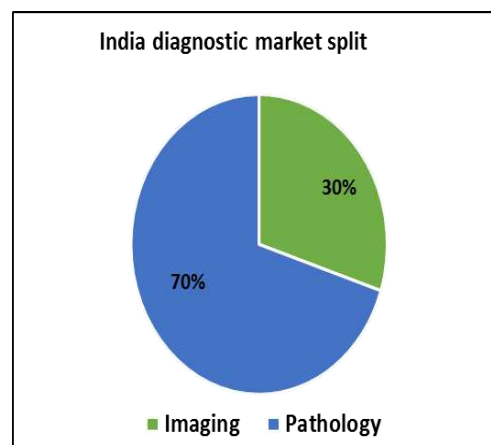
| Diagnostic Laboratory chains | Number of labs   | Countries of operation  |
|------------------------------|--|---|
| <b>Metropolis</b>            | 130 diagnostic laboratories, 1000 collection centers   | India, Sri Lanka, South Africa, Kenya, Mauritius, Ghana, UAE  |
| <b>SRL Laboratories</b>      | 275 laboratories with 12 Reference Labs, 4 Centers of Excellence, 19 radiology/imaging centers, over 5700+ collection points | Nepal, Dubai, Malawi, Nigeria, Bangladesh, Malaysia, Sri Lanka, Maldives, Zambia, Tanzania, Bahrain, Kuwait, Qatar, Oman, Kenya, Sudan, Afghanistan, Ethiopia |
| <b>Dr. Lal Path labs</b>     | 150 laboratories, 2000 diagnostic centers  | Saudi Arabia, Oman, Qatar, Kuwait, UAE, Tanzania, Nigeria, Bangladesh, Nepal, Bhutan, Sri Lanka, Myanmar, Malaysia  |
| <b>Thyrocare Lab</b>         | 1 central lab, several regional labs, 630 collection centers, 22,000+ collection points                                      | India, Middle East, South East Asian countries  |

### Diagnostic Devices

The Indian in-vitro diagnostics market (IVD) is valued more than US\$500 million and expected to cross US\$1.5 billion by 2018 with a compounded annual growth rate (CAGR) of 20%. The attributed reasons for growth can be accounted to increased healthcare awareness, preventive health checkups, and shift from manual to semi-automated and automated



Source: Apollo investor presentation, IBEF 2016



Source: IBEF, 2016

equipment amongst others<sup>15</sup>. Major players in IVD segment include Transasia, Meril, Roche, and Backman Coulter amongst others. The IVD market is majorly classified based on platforms.

**Table: IVD market segments, key players and industry trends<sup>16</sup>**

| IVD segments                 | Key players   | CAGR (%) | Industry trends   |
|------------------------------|---|----------|---|
| <b>Biochemistry</b>          | Thyrocare, Transasia  | 15       | <ul style="list-style-type: none"> <li>○ Automation with increased throughputs</li> <li>○ Increased complexity of tests</li> </ul>  |
| <b>Hematology</b>            | Sysmex, Beckman Coulter, Abbott, Mindray, Transasia                               | 5.2      | <ul style="list-style-type: none"> <li>○ Automation to reduce turnaround time</li> <li>○ Adoption of digital imaging to generate more information</li> </ul>  |
| <b>Histopathology</b>        | Dako, Abbott, Roche Diagnostics, BioMerieux                                       | -2       | <ul style="list-style-type: none"> <li>○ Major industry slowdown</li> <li>○ Automation and workflow integration</li> <li>○ Information management</li> </ul>  |
| <b>Microbiology</b>          | Hi-Media, BioMerieux, BD India, Tulip Diagnostics, Beckman Coulter, Thermo Fisher | 13       | <ul style="list-style-type: none"> <li>○ Automated and rapid microbial testing</li> <li>○ Real time monitoring</li> </ul>   |
| <b>Hemostasis</b>            | Transasia, Sysmex, Siemens, Rapid Diagnostics                                     | 7        | <ul style="list-style-type: none"> <li>○ Two modalities- laboratory and point-of-care testing</li> <li>○ Increase in cardiovascular disease incidence- major driver</li> <li>○ Trending shift towards fully automated instruments from semi-automated ones</li> </ul> |
| <b>Urinalysis</b>            | Bayer Diagnostics, Roche diagnostics, Rapha, Accurex                              | 7.6      | <ul style="list-style-type: none"> <li>○ Priority to chemical analysis and urine microscopy</li> <li>○ Automatic urine analyzers picking trend</li> </ul>   |
| <b>Molecular diagnostics</b> | Bayer Diagnostics, Roche diagnostics, Abbott, Chiron                              | 25       | <ul style="list-style-type: none"> <li>○ Dominated by infectious disease diagnostics E.g. Tuberculosis, HIV, HPV etc.</li> <li>○ Point-of-care diagnostics major trend</li> <li>○ Personalized healthcare targeted</li> </ul>   |

<sup>15</sup> <http://www.marketreportsonline.com/294372.html>

<sup>16</sup> Medical buyer reports 2013-15



**Table: Imaging equipment market, key players and industry trends<sup>17</sup>**

| Imaging equipment market                    | Key players  | Industry trends  |
|---|--|--|
| <b>MRI Systems</b>                          | GE Healthcare, Philips, Siemens, Toshiba, Hitachi                    | <ul style="list-style-type: none"> <li>○ Use of digital scanners and user-friendly machines</li> <li>○ Rise in 3T MRI equipment sales</li> <li>○ Increased usage in coronary angiography and oncology</li> </ul>               |
| <b>Ultrasound Systems</b>                   | GE Healthcare, Philips, Siemens, Toshiba                             | <ul style="list-style-type: none"> <li>○ Smaller, higher image quality, power efficient systems</li> <li>○ Advancements in volumetric and portable color ultrasound</li> <li>○ Color Doppler major contributor</li> </ul>      |
| <b>X-ray Systems</b>                        | GE Healthcare, Philips, Siemens                                      | <ul style="list-style-type: none"> <li>○ Price sensitive market</li> <li>○ Digital X-ray to drive future market</li> <li>○ Lack of standardization in low end equipment, high end equipment have FDA or UL approval</li> </ul> |
| <b>Computed Tomography (CT) Systems</b>     | GE Healthcare, Philips, Siemens                                      | <ul style="list-style-type: none"> <li>○ Increased usage in cardiovascular and cancer screening</li> <li>○ Trend towards more quantification and direct diagnosis</li> </ul>   |
| <b>Nuclear Imaging Systems (SPECT, PET)</b> | GE Healthcare, Philips, Siemens, Toshiba                             | <ul style="list-style-type: none"> <li>○ Sharp decline in standalone SPECT and PET systems</li> <li>○ Increased integration in multimodality systems</li> </ul>  |
| <b>Multimodality Systems</b>                | GE Healthcare, Philips, Siemens, Trivitron                           | <ul style="list-style-type: none"> <li>○ PET/CT and SPECT/CT usage on rise- no more standalone PET, CT and SPECT are done</li> <li>○ High usage in oncology segment examinations</li> </ul>                                    |
| <b>Interventional Imaging Systems</b>       | GE Healthcare, Philips, Siemens, Perfint Healthcare, Panacea Medical | <ul style="list-style-type: none"> <li>○ Rise in usage of Cath labs for real time cardiac interventions</li> <li>○ Shift towards robotic assisted and portable, therapeutic ultrasound</li> </ul>                              |

The ex-vivo diagnostics devices market is dominated by multinational companies such as GE, Philips, Siemens and others. Most of these multinational companies (MNC's) have marketed and sold products from their global portfolio in India, often even manufactured outside. More recently Indian companies have been aggressively get a foothold in the market with innovative products as well as assembled products.

<sup>17</sup> Medical buyer reports 2013-15

## Key Industry Trends

Healthcare delivery's focus on quality and increase in sophistication driving aggressive and sustainable demand

Indian healthcare providers and hospital chains play a crucial role in the domestic medical device industry. In the last decade, corporate hospital chains have penetrated Tier 2 and Tier 3 cities. Also, independent hospitals have developed into centers of excellence for specialty treatments. These hospitals compete not only on skilled physicians but also on quality of service and costs to the patients. Medical device manufacturers have targeted and collaborated with these hospitals to identify the right target patient population, price products competitively and to strategically establish and strengthen their alliance with healthcare providers to maximize their revenue. This strategic move in collaboration with healthcare providers combined with the overall growth in the healthcare delivery market due to increased healthcare spending and insurance coverage is driving sustainable growth and demand for diagnostics and medical devices in the country.

Highly skewed competitive landscape creates significant scope for new products and an attractive commercial opportunity

The historical context of MNCs selling imported high end devices and Indian companies selling less complex devices and equipment presents a highly skewed competitive landscape and opportunities for both segments of companies. Indian medical device and diagnostics companies are engaging in product development and are targeting both Indian domestic market as well as exports. The product gap in India is very significant gap since MNCs largely sold limited part of their global product portfolio in India. Indian companies are filling the gap by reverse engineering products at affordable prices and developing products customized to Indian needs. For example, Transasia Bio-medicals has developed *in-vitro* diagnostic equipment through its R&D base in Mumbai. The Sushrut Adler Group has developed an external fixator for the Indian market. Forus Health's "3nethra" device is a portal, mass eye-screening, affordable device for cataract, diabetic retinopathy and cornea related problems developed for rural Indian market. Another example of affordable medical device is Perfint Healthcare's "Maxio" and "Robio" robotic system to assist in faster, more accurate targeting and tumor ablation.

On the other hand, encouraged by increased demand and growth potential for medical devices in the domestic market, multinational companies have started tailoring their product portfolio to suit local needs. For example, Johnson and Johnson has developed a reusable stapler for use in surgeries at price points which are amenable to the Indian market. Roche Diagnostics has developed a screening device for cardio-vascular diseases, which is suitable for use in rural settings. GE Healthcare has developed a low cost ECG machine and a low cost Ultrasound machine for the Indian market. GE Healthcare launched Discovery IQ, a PET/CT molecular imaging system designed in India and is claimed to be 40% more affordable. Toshiba Medical Systems has introduced Vantage Elan MRI system with optional power-

saving mode and compact design (compact design yielding in reduced foot print which is important for hospitals who don't have large floor spaces).

Continued P/E and VC funding in healthcare diagnostic chains and medical device start-ups  
 The emergence of seed funding opportunities has given rise to many ventures focused on innovation in Indian medical technology sector. Some of these ventures have successfully raised venture capital (VC) for scale up and private equity (PE) to drive commercial expansion. Forus Healthcare and Perfint are two examples of VC fund raising success stories while several companies such as Sutures India, Trivitron, Skanray, Prognosys Medical Systems and others have raised PE funding for growth. The number of investments in Indian medical device and diagnostics space has risen considerably in the last few years and ventures have been able to scale up and commercialize their products with VC support. Given the shorter product development cycles and relatively lower capital need for product validation, the venture capital community has had more appetite for investments in the medical devices and diagnostics segment as compared drug discovery and development.

**Table: Indicative transactions - PE/VC funding in Medical device and diagnostics industry<sup>18</sup>**

| Venture Capital           |                          |                  |
|---------------------------|--------------------------|------------------|
| Investor                  | Company                  | Amount (US\$ Mn) |
| VentureEast               | OneBreath                | 3                |
| IDG Ventures              | Forus                    | 5                |
| GSF India & Insitor Fund  | Biosense Technologies    | 0.5              |
| Villgro Innovations       | Windmill Health          | Undisclosed      |
| Private Equity            |                          |                  |
| Investor                  | Company                  | Amount (US\$ Mn) |
| Somerset Indus Capital    | Prognosys                | 3.32             |
| Peepul Capital            | Cura Healthcare          | 9                |
| India Value Fund Advisors | Trivitron                | 24.6             |
| Samara Capital            | Lotus Surgical           | 24               |
| Goldman Sachs             | BPL Medical technologies | 20               |
| TPG Capital               | Sutures India            | 22.9             |
| Ascent Capital            | Skanray Technologies     | 14.7             |
| Norwest Venture Partners  | Perfint Healthcare       | 11               |

Market focused small and mid-sized players emerging as attractive acquisition targets for global companies seeking to build market presence in India

India is emerging as an important target market for mid-sized to large international medical device and diagnostics companies. They are aggressively eyeing Indian acquisitions to set foot in the Indian market as well as to enhance their product portfolio. With larger acquisition targets being far and few in India, the small and mid-sized companies are attracting great

<sup>18</sup> Grant Thornton Deal tracker 2012-15. Accessed February 15<sup>th</sup>.

acquisition interest. For example, Terumo, a Japanese company recently acquired remaining stake in PenPol, a Kerala based blood Bag Company. Similarly, Piramal diagnostics was acquired by DiaSys Diagnostics Systems a German company. With this acquisition, DiaSys aims to develop a new R&D center to launch international activities based out of India and strengthen its presence in lab diagnostics and point-of-care products. Arkray, a leading Japanese diagnostics manufacturer has acquired Span Diagnostics In-vitro diagnostics segment for an estimated deal size of INR 100 crores. This deal allows Arkray Healthcare to be a leader in Indian IVD market.

## Technology and Innovation Adoption

### Emergence of Product Development Engagement in India

#### 1. Emergence of small ventures with innovation suited to Indian needs

Historically, the Indian device and diagnostics industry has primarily been dominated by multinationals and has had limited product development engagement. During the past decade, there has been emergence of new ventures focused on developing devices and diagnostics suited to Indian needs changing the landscape of product development in India. Many young and innovative ventures are developing products of varied complexities. This trend is supported by various critical drivers such as emergence of seed funding, medtech product development expertise nurtured by product development centers of various MNCs in India and translational capability in public research system. Innovation funding platforms such as the SBIRI and BIPP created by DBT and TDB by DST, Grand Challenges Canada et al have received several applications for development of affordable devices and diagnostics that are relevant for the country. Examples of small ventures receiving such funds include Bigtec labs, Achira Labs, Perfint Healthcare and Wrig Nanosystems amongst others. The other contributing factor driving product innovation in Indian landscape is emergence of technical collaborators in public research systems. For example, Stanford Biodesign program, RBCCPS/IISc, IIT Chennai’s HTIC’s efforts with companies to develop the second generation an ophthalmic diagnostic device and a neonatal incubator is a great example of such collaborative possibilities.

**Table: Product development engagement in India across small ventures**

| Domestic innovations       |   |
|----------------------------|---|
| <b>Aravind Eye Care</b>    | <ul style="list-style-type: none"> <li>○ Low cost intraocular lenses manufactured by AuroLab</li> <li>○ Cost- US \$2 as compared to international costs of US \$70</li> <li>○ Holds 7% of intraocular lenses market globally</li> </ul> |
| <b>SRL Diagnostics</b>     | <ul style="list-style-type: none"> <li>○ CLIMS Cloud Application for information management in diagnostics industry</li> </ul>  |
| <b>Sushrut Adler Group</b> | <ul style="list-style-type: none"> <li>○ External fixator developed for Indian market</li> </ul>  |
| <b>Skarray</b>             | <ul style="list-style-type: none"> <li>○ World-class high-frequency X-Ray machines at half the price global product</li> </ul>  |

**2. Emergence of product development in established companies moving up the value chain**

R&D focused companies with product innovation make up a small part on Indian diagnostics and devices industry. Medium and large Indian diagnostics and devices companies with a strong manufacturing and/or distribution network are moving up the value chain and are getting involved in product development to drive sustainable growth. These companies have had limited or no R&D engagement in past. However, a gradual shift is being observed towards building their R&D capabilities and effecting new development to transition from distribution and contract manufacturing to own-brand development. The R&D engagement seen in these relatively larger manufacturing/marketing entities is not as deep as the R&D driven ventures. However, their existing market reach and down-streaming potential implies relatively higher and sooner commercialization impact. Additionally, these companies are also emerging as potential partner for emerging ventures. An example of such a collaboration is MolBio, a joint venture between Tulip Diagnostics and Bigtec.

#### Case Study: Trivitron

- Trivitron- major player in medical device and diagnostics industry in India
- Teamed up with IIT, Chennai to set up Trivitron Innovation Center for R&D acceleration in medical technology
- Area of focus for research- cardiology, critical care, ophthalmology, clinical diagnostics
- Developed products include cardiac positioning system, mobile retinal screening, wireless ECG systems, syringe pumps
- Acquired Labsystems Diagnostics in Finland to accelerate product development for global market

Emergence of transnational research engagement in public institutions and creation of product pipeline supporting industry's innovation trend

Country's leading research, clinical and engineering institutions are acting as cradles for medical technology product development and innovation. They are also fostering innovation suited to country's need at affordable prices. A structural gap in public research capacity in India for medical technologies is the lack of institutions that house both teaching hospitals and engineering schools. With this gap bridged through well conceptualized and structured initiatives such as the Stanford India Biodesign (AIIMS, IIT Delhi and Stanford University) and the National Biodesign Alliance, there is a strong pipeline in the public research system and a fertile ground for public-private partnerships

IIT Chennai has collaborated with Shankar Netralaya, a clinical institution engaged in ophthalmic outreach in rural areas for the development of a mobile ophthalmic van. IIT Chennai has further collaborations with smaller companies such as Forus and Phoenix on their ophthalmic diagnostic and neonatal incubator respectively.

**Table: Translational research engagement in public institutions across India**

| Collaborations for medical device and diagnostics innovations | Area of focus                              | Partner institutions  |
|---|--|---|
| <b>Stanford-India Biodesign</b>                               | Medical devices & Implants                 | AIIMS - Delhi, IIT-Delhi & Stanford University - USA                          |
| <b>Center for Biodesign &amp; In-vitro diagnostics</b>        | In-vitro diagnostics                       | THSTI - Gurgaon, ICGEB - Delhi, AIIMS - Delhi & University of Turku - Finland |
| <b>DBT-IITM Center for Health Technology Innovation</b>       | Health Technology                          | IIT - Chennai   |
| <b>Biodesign-Bioengineering Initiatives</b>                   | Medical devices, Implants & Bioengineering | IISc – Bangalore  |

Emergence of medical technology parks in India to boost innovation and product development ecosystem

Many state governments have announced medical technology parks to boost innovation and indigenous product development in medical diagnostics and devices. The plans when implemented aim to reduce India’s dependency on imports and promote domestic manufacturing under India’s “Make In India” plan. A table enlisting a few medical technology parks announced in India is as follows.

| Park Name                         | Location | Status    |
|-----------------------------------|----------|-----------|
| Medical Technology Park           | Vizag    | Announced |
| Trivitron Medical Technology Park | Chennai  | Completed |
| Gujarat Medical Devices Park      | Gujarat  | Announced |
| HTIC (IIT Chennai)                | Chennai  | Completed |

Diagnostics- increasing engagement in molecular diagnostics, genomics and computer aided testing and automation

Molecular diagnostics is universally acknowledged as highest growing segment in pathology. With the wide range of available genetic tests with extremely high sensitivity and specificity of these tests are driving the growth. Molecular diagnostic segment is primarily applicable for infectious diseases, and cancers. Genetic tests are becoming common for diagnosing prenatal and postnatal anomalies

There is significant leverage of PCR based diagnostic platforms for product development efforts by companies. These localized development efforts are focused in infectious disease diagnostics such as “QDxInstaLab” integrated PCR developed by Piramal Enterprises, “I Amp” PCR developed by Bhat Biotech and “TrueLab” PCR developed by Bigtec Labs amongst a few.



Earlier there were only a few laboratories and institutes such as Centre for DNA Fingerprinting and Diagnostics (CDFD); ICMR Labs; Kasturba Medical College Manipal; Department of Pediatrics, AIIMS etc. providing advanced genetic testing, biochemical and prenatal diagnostics. Today, private labs such as SRL Diagnostics, Datar Genetics and companies such as MedGenome, Strand Lifesciences, Mapmygenome etc. are working towards bridging this gap.

### Policy and Regulatory Framework

The Indian medical device sector is expected to grow in near future owing to demographic changes such as increasing burden of chronic diseases, increasing demand for quality of care resulting in increased demand for accurate comprehensive disease diagnosis, expanding advanced healthcare to tier 2 and Tier 3 cities etc. currently, the Indian medical device industry is import driven, contributing to approximately 75% of the market (reference to be added).

#### Lack of standardization and ambiguity on regulatory standards

Currently, the manufacture, sales and distribution of medical devices in the country is regulated under Drugs and Cosmetics Act, 1940; and Rules, 1945. There is lack of standardization and ambiguity on regulatory standards with no separate section on medical devices. At present only fourteen medical devices have obtained regulatory approvals from CDSCO and some of the notable ones are heart valves, scalp vein set, orthopedic implants etc. While most other medical devices are not regulated by Indian regulatory body. Some of the devices come under the concerned State Drug Licensing Authority only and include disposable syringes, perfusion sets, in-vitro diagnostic devices etc. In the absence of robust medical device regulations in India, market expectations at the high end of the market has become CE marking and hence most reputed players obtain CE marking prior to commercialization in India.

#### Government's "Make in India" initiative strengthening medical device innovation ecosystem

With the government encouraging medical device industry, "Make in India" drive is pushing towards industrial growth. India's engineering talent, experience in IT innovation and the Modi government's 'Make in India' focuses to underscore the importance of government and industry to work toward creating the proper ecosystem for medical device innovation. NHRSC and WHO India office have formulated two technical documents; "Electrical and Electronic Medical devices testing Laboratory" and "Biomaterial and Biocompatibility Testing Laboratory" for establishment of medical device testing laboratories. Under "Make in India" campaign, an increase in basic custom duty by 2.5%, removal of SAD Special Additional Duty exemption of 4% and reduction of import duty by 2.5% on import of raw material, accessories, and components required by local manufacturers have been implemented.



The Government has, recently, clarified that medical devices with universal labeling (i.e., non-India specific labeling) will not be permitted to enter the territory of India effective September 2014.

Government approval on 100% Foreign Direct Investment (FDI) in medical device industry to enhance growth

Government has also mandated 100% Foreign Direct Investment (FDI) in medical device sector under the automatic route, thereby eliminating the requirement to seek permission of Foreign Investment Promotion Board (FIPB) to acquire an existing company or set up a new manufacturing unit in the medical devices sector. The government of India has further approved ten proposals of FDI amounting to INR 2857.83 crore approximately. Approval has been sought for amalgamation of M/s Alere Medical Private Limited and M/s SD Bio Standard Diagnostics Pvt. Ltd., two diagnostics companies. Allowing 100% FDI in the medical devices sector will enhance and promote local manufacturing of medical devices and diagnostics and reduce further dependence on imports.

## II. Growth Drivers and Challenges

### Key Growth Drivers

- Higher disposable incomes due to higher economic growth leading to higher spending on healthcare
- Increased market penetration due to expansion in Tier 2 and Tier 3 cities
- Increased investments from PE/VC funds in medical device, diagnostics and hospitals
- Evolution of public-private partnership models promoting innovation ecosystem
- Evolution of India as a medical tourism hub leading to demand for world class equipment and diagnostics
- Increasing incidence of lifestyle/ non communicable diseases

### Key challenges

- Archaic and nascent regulatory standards
- Lack of quality benchmark leading to inadequate quality standards tarnishing the image of Indian made products
- Low indigenous product manufacturing due to high import dependency
- Lack of proper infrastructure for device and diagnostics product development
- Market flooding with Chinese and Taiwanese medical device and diagnostic products with false CE marking

### III. Segment Outlook

The Indian medical device and diagnostics contributes about 6% of the total healthcare sector and the industry has witnessed tremendous double digit growth of 15% year on year. The industry is influenced by not only country's GDP but also by overall public expenditure on healthcare, disease incidence, public awareness of diagnosis and treatment options, regulatory environment, health insurance etc. The diagnostics services industry has historically been fragmented and unorganized. However, over the last ten years there has been a high growth spurt and consolidation in the urban markets. The diagnostic devices market, at the other end, has been and is still dominated by multinational companies (MNCs) such as GE, Philips, and Siemens. Most of the MNCs that operate in the Indian market have sold products developed globally and there has been very limited country specific product development. The diagnostic supplies market includes in vitro diagnostics (IVD) companies, who are involved in producing kits, reagents and laboratory processing devices.

The Indian diagnostics and devices market has opened up for new entrants and several joint ventures, agreements and loan licensing procedures have influenced the market. The government has also taken several reforms to develop the market by regulating it to bring out more transparencies and by allowing foreign investments in the industry.

Despite of many challenges, the Indian medical device and diagnostics market shows a huge potential in coming decade.



# Healthcare Delivery Industry





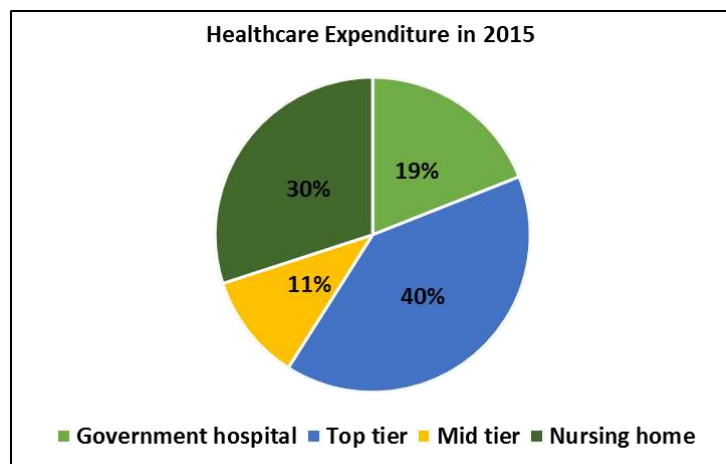


## Section C - Healthcare Delivery Industry

### I. Healthcare delivery – Overview of Current Landscape

Indian healthcare delivery industry mainly comprises of hospitals and clinics providing treatment and patient care. This sector is densely crowded with different ranges of players and layers of medical infrastructure such as government hospitals, private hospital chains, private nursing homes, and private clinics. Total Indian healthcare delivery market (excluding stand-alone consultation clinics) is estimated about USD 70 billion as of year 2015 and is growing at a CAGR of 17%.<sup>19</sup>

Government run hospitals accounted for 40 % share of medical infrastructure whereas private players and individual clinics accounted for the rest. However, in value terms leading private players like Apollo Hospitals, Fortis Healthcare, Narayana Hrudayalaya, Max Healthcare and other big hospital chains accounted for 40% of India’s total healthcare



Source: IBEF, Healthcare Report, August 2015

expenditure during the same year. Share of government run hospitals as a percentage of healthcare expenditure has been continuously shrinking from 40% in year 2005 to just 19% a decade later. Healthcare spending at boutique nursing homes has risen to approximately 30% whereas midsize hospitals accounted for only around 11% of healthcare expenditures. This shift between share of public and private hospitals has been widened by the growing middle class and their willingness to spend on quality of healthcare. In terms of payers of healthcare services in India, ‘out of pocket’ expenses contribute to about 58%, government spending to about 32%, insurance to only 3-4% and NGOs and others contribute to the rest.<sup>16</sup>

<sup>19</sup> IBEF, healthcare report August 2015

## II. Market Dynamics and Commercial Trends

### Market Dynamics and Evolving Business Models (including home healthcare etc.)

Growth in healthcare delivery supported by continued private equity interest; gets further fillip with public markets beginning to demonstrate appetite

Demand led growth in healthcare delivery in India has been aptly supported and encouraged by interest in the segment from the private equity community. The investment appetite from private equity funds has only increased with high unmet need remaining and resulting in significant market opportunity to explore. During past one year, more than 57 investment transactions have been closed in the sector.<sup>20</sup> This trend has also spurred regional and national growth of branded healthcare delivery providers who have been able to put together building blocks for successful scale-up and drive quality and standardization across centers.

Few indicative recent deals are highlighted below:

**Table: Indicative investment deals in healthcare delivery sector during past one year**

| Hospital group       | Initial Public Offerings | Deal size (in USD Mn) |
|----------------------|--------------------------|-----------------------|
| Narayana Hrudayalaya | IPO                      | 90                    |
| HCG Oncology         | IPO                      | Expected soon         |

| Hospital group             | PE Investor & Strategic Acquisition   | Deal size (in USD Mn) |
|----------------------------|---|-----------------------|
| CARE Hyderabad             | ABRAAJ Group  | 248                   |
| Narayana Hrudayalaya       | CDC group   | 48                    |
| Manipal Health Enterprises | TPG Capita  | 150                   |
| Medanta Medicity           | Temasek   | 113.5                 |
| Cloudnine                  | India Value Fund Advisors (IVFA)  | In progress           |
| Practo                     | Sofina, Google Capital, Altimeter Capital, Sequoia Capital Global Equities, Yuri Milner, Sequoia Capital, Matrix Partners                     | 120                   |
| Portea Medical             | Accel Partners, with participation from International Finance Corp. (IFC), a member of the World Bank Group, Qualcomm Ventures and Ventureast | 37.5                  |
| Global Hospitals           | IHH Healthcare ( <b>Strategic Acquisition</b> )   | 195                   |

<sup>20</sup> Yourstory.com Article: "With \$277M in funding and 57 deals in 2015, here's what to expect from healthcare in 2016" by Sindhu Kashyap, December 2015. Accessed on 15<sup>th</sup> February 2016.



The investment appetite from foreign institutional investments (FII) has also been high and recent exits (such as Care hospitals) attracted significant interest from international strategic investors as well. The secondary markets have been active as well in 2015 and recent IPOs include Narayana Hrudayalaya's that was well received and oversubscribed. It has now joined the cluster of other publicly traded hospital groups including Apollo Hospitals and Fortis Healthcare. HCG Global, an oncology chain has also received a nod for its IPO recently. The confirmed interest from international strategic investors as well as the IPO market in second half of 2015 receiving healthcare IPOs with tremendous warmth has provided high level of comfort on exit to PE investors and has further enhanced investor appetite.

Investments will continue to grow in this sector largely driven by significant potential for organized healthcare and quality healthcare services. According to World Bank, India does not even have 1bed/1000 population against global norm of 3bed/1000.<sup>21</sup> According to CRISIL, reaching this global norm will require further investments of USD 204 billion<sup>22</sup>.

#### Expansion of Private healthcare Delivery into Tier II & III

Number of physicians in India is estimated about 0.7 for every 1000 people which drastically drops to about 1/30000 people in rural areas. These numbers are below the WHO standard of 3 physicians/ 1000 as a global average<sup>23</sup> and 1 physician/ 1000 population for rural areas<sup>24</sup>. India also suffers by widening gap in terms of availability of specialist clinicians across metro cities and non-metro cities predominantly due to far lesser provisions of financial and non-financial incentives to clinicians in non-metro cities. Few healthcare groups have started exploring non-metro locations in well-organized manner and are now enabling comparable medical services in Tier II & Tier III cities. With increasing income per capita and willingness to spend on quality healthcare, Tier II & III cities are the new focus for ventures. Few such indicative hospital ventures include Vaastsalya Healthcare, Glocal Healthcare, Premia Healthcare group etc. Many Hospital groups with strong presence in metro cities such as Apollo, HCG, and LVPEI etc. are expanding their reach to patients from distant cities in a hub and spoke model of outreach by building satellite centers, smaller clinics and by deploying mobile-health vans.

#### Continued thrust on Single Specialty Hospitals

The existing single specialty hospital groups are growing geographically and newer groups are fast emerging. Single specialty hospitals are operationally more efficient, lean with advanced care focus, capital efficient and hence are becoming attractive targets for investors. Patients prefer these hospitals over multispecialty hospitals for obtaining treatment for chronic diseases as well as critical illnesses and find them less inundating overall. Therapeutic areas that have been popular for single specialty hospitals include obstetrics and gynecology, ophthalmology, oncology and dental and emerging areas of focus include pediatrics,

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<sup>21</sup> World Bank Databank. Accessed on 15<sup>th</sup> February 2016.

<sup>22</sup> Economic Times Article- "Dubai-based Abraaj Group buys 72% holding in CARE Hospitals". Accessed on 15<sup>th</sup> February 2016.

<sup>23</sup> WHO Global Health Observatory (GHO) data. Accessed on 15<sup>th</sup> February 2016.

<sup>24</sup> IBEF Healthcare report, August 2015

orthopedics, and neurology. While investor interest continues to be very high, it will be critical that hospitals steer away from a star doctor culture, build scalability with respect to standardization of procedures and clinical practices and successfully nurture quality associations with their brand. Lastly, despite the relatively asset light model, it will be important that single specialty hospitals exercise caution on pace of scale-up to avoid financial feasibility being marred by aggressive assumptions on timelines for break-even of individual centers.

#### Medical Tourism - Limited potential exploited due to lack of concerted national effort

Medical tourism still remains a relatively untapped segment of healthcare delivery in India. Countries like Malaysia, Singapore, Thailand, have been making aggressive efforts to promote medical tourism and have now emerged as top medical tourism destinations globally. On the contrary, several Indian hospitals in tier 1 cities have built state of art infrastructure and latest modalities but are still lagging behind in a strong cohesive effort to globally promote medical tourism opportunities in India. Out of total foreign tourist arrivals in the country, only 2.4% account for medical visa travel<sup>25</sup> despite the fact that India has 21 JCI accredited hospitals, next only to Thailand. While several of the individual hospitals have been making intentional marketing efforts, at a national level the impact is negligible. If concerted effort is made by the Government and the industry, and aggressive branding, global promotions and facilitation of accelerated visa processing by Indian government are accomplished, there is great potential for the medical tourist to expand multifold in the coming decade and have significant economic impact.

#### Emergence of organized home health care models complemented by innovative e-commerce and m-commerce

With the proliferation of technology led service models, an interesting phenomenon of extending medical services to patients directly to their homes is emerging. E-commerce and m-commerce platforms have allowed digital connectivity of patients with clinical community and have provided a platform to seek and pay for healthcare services. Several novel business models are now emerging and evolving. Today doctors and other medical professionals such as nurses and physiotherapists are available 24x7 through on-line portals, doctor reviews are available online, diagnostic test prices can be compared and home diagnostic and health monitoring services can be subscribed to. Almost all telecom companies now offer value added services such as 'Ask a Doctor by Vodafone', 'Mediphone helpline by Airtel' enabling doctor consultations over phone at very low costs. There has also been significant debate in the recent past on the online pharmacies that have emerged and this has drawn attention to the need for regulations that apply meaningfully to these evolving business models.

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<sup>25</sup> "India Tourism Statistics 2014" Ministry of Tourism India. Accessed on 15<sup>th</sup> February 2016.

Last couple of years have only experienced the beginning of this trend in healthcare delivery and a surge in more such asset-light and technology driven models is anticipated over the next five years.



### Expanding Healthcare Access

Several initiatives from Central and State Governments expand access to healthcare delivery for lower income sections of society

Government initiatives are facilitating affordable healthcare access to existing public & private medical centers for range of populations segments including low income strata. Central and state governments have rolled out number of schemes to provide healthcare access for underprivileged. Central government’s Rashtriya Swasthaya Bima Yojana (RSBY) facilitates healthcare access to ‘Below Poverty Line (BPL)’ population, which accounts for about 40% of Indian population. Government has approved list of private hospitals in addition to all government managed hospitals for obtaining health benefits under these schemes. Andhra Pradesh government launched Aarogyasri insurance scheme in partnerships with private hospitals to facilitate expanded healthcare access.

Government has proposed new AIIMS and medical colleges to bring improved quality of care with expanded reach. Central government scheme, National Rural Health Mission (NRHM), has extended accessibility of healthcare to even remote villages. NHRM scheme has enabled upgradation of community health centers, primary health centers, referral units, and promoted speedy referral services like Janani Express which are providing medical services at many hard to reach remote areas. Various other state governments’ run schemes include ‘Ladli Lakshmi Yojana’, ‘Mukhyamantri Bal Hriday Upchar Yojana’, etc. In order to reduce dependence on ‘out of pocket’ expenditures, government has increased the limit of FDI to

100% in insurance sector which will strengthen accessibility of healthcare to larger population pool.

#### Continuing growth of innovative access models

Private players are leveraging modern technologies to expand healthcare services till hard to reach remote locations and connecting these with reference hospitals. Few hospital groups such as Apollo, Fortis, Sankara Nethralaya are now implementing telemedicine centers to provide video consultations for remotely located patients. Indian government has also stepped into telemedicine by starting a green field project on National Medical College Network (NMCN), interlinking medical colleges across the country with the purpose of e-Education and National Rural Telemedicine Network for remote consultations by inducting telemedicine centers in 150 medical colleges across the country. Few other government eHealth initiatives include 'Mother and Child Tracking System (MCTS)' and 'Mother and Child Tracking Facilitation Centre (MCTFC)'. All of these efforts have been instrumental in expanding access to healthcare through innovative models and addressing the current infrastructure limitations in India.

#### Public Private Partnership Initiatives continue – accelerate capacity building and enhance service quality

Asha Jyoti, a joint effort of PGIMER and Philips India becomes a role model for various pre-screening related to women health such as breast cancer, osteoporosis and cervical cancer in outreach areas of Chandigarh. GE Healthcare, has partnered with various state governments to upgrade diagnostic service centers within government run hospitals<sup>26</sup>. SRL Diagnostics has begun managing all diagnostics for public hospitals for three state governments. We envision that several such partnerships will be forged in the next five years and will be instrumental in addressing current capacity constraints, accelerating capacity building in the public healthcare facilities and improving quality of healthcare.

### Improving Quality of Care

#### Sophistication of Infrastructure

Indian hospitals are increasingly becoming more sophisticated by building state of art medical facilities, investing in advanced medical equipment, and adopting modern, technological driven healthcare processes. At present there are 26 IBM Watson (best known device for artificial intelligence) operating in India and around 147 trained surgeons in advanced robotic surgery – a number which is expected to rise to 300 by 2020<sup>27</sup>. Tier 1 hospitals are often comparable to global best standards in infrastructure. Contemporary infrastructure and quality of devices has resulted in sophistication in procedures and overall healthcare delivery comparable to high global benchmarks.

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<sup>26</sup> Economic Times Article- "PPP Model in Healthcare" June 2015. Accessed on 15<sup>th</sup> February 2016.

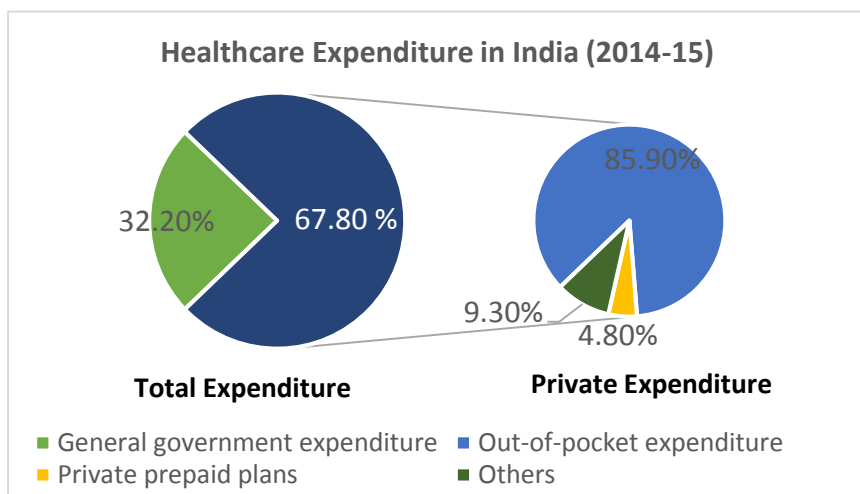
<sup>27</sup> The Hindu Article- "Surgical robots to become ubiquitous in Indian hospitals" September 2015. Accessed on 15<sup>th</sup> February 2016.

High level of focus on improving clinical outcome comparable to global standards and improved clinical practices

Some of the established Indian hospital groups have been successful in delivering medical services at-par or above global standards in terms of treatment success rates while accommodating massive patient turnout each day. Narayana Hrudayalaya has very high success rates of cardiac surgeries that is comparable and even better than several globally known hospitals.<sup>28</sup> Hospitals have developed their own set of best practices and have adopted from global peers as well. . There is an ardent focus on clinical outcomes and measures to improve it are pursued with strategic focus. Additionally, operations and supply chain are being streamlined to optimize the overall organizational elements. While digitization of hospital management is now common across most known hospitals in India, Institutions like Narayana Hrudayalaya, Aravind Eye Hospitals have innovatively leveraged their cloud based digital platforms (HIS) to improve their operational and clinical efficiency and many more to follow the suit.<sup>29</sup>

Greater appetite for adoption of innovation and new technologies in public healthcare delivery

Public hospitals have historically been slow adopters of new technologies. This is changing, albeit in a gradual manner. Newer technologies are now being adopted public hospitals and initiatives and large patient populations will benefit from greater



transparency and speed in patient care. Many state government run hospitals are increasing being connected through digital platforms and now connecting with far located community centers into their network. ASHA workers in rural areas are getting empowered through mobile health apps for consolidating health parameters, clinical data and relevant information of patients<sup>30</sup>. Most railway stations now have AED and CPR machines to save lives at time of emergency<sup>31</sup>. A truly innovative that deserves a mention is the National Healthcare Innovations Portal (NHInP) run by the National Health Mission, Mistry of Health and Family

<sup>28</sup> Narayana Hrudayalaya Hospitals Website. Accessed on 15<sup>th</sup> February 2016.

<sup>29</sup> Dataquest Article- “Dr Agarwal’s Eye Hospital adopts cloud-based healthcare solution from Dell”. Accessed on 15<sup>th</sup> Feb 2016

<sup>30</sup> Economic Times Article- “App launched to aid ASHA workers in maternal, child healthcare duties” – April 2015. Accessed on 15<sup>th</sup> Feb 2016.

<sup>31</sup> The Hindu Article- “Heart revival machine to be set up at Kannur railway station”- July ’15

Welfare. Inventors or companies with novel products can submit innovations on the NHInP and if approved, the Central Government will provide funding support for procurement of such devices for public hospitals.

### III. Growth Drivers and Challenges

#### Key Growth Drivers:

- Expanding middle income strata with increasing willingness to pay
- Increasing penetration of health insurance coverage
- Growth in public Infrastructure and expanded access to healthcare for poorer segments of society under government schemes
- Continued interest from investors:- PE funds, banks, hire - purchase, Non-Banking Finance Companies, Device companies
- Appetite for new models of health care delivery - mhealth, digital health, various form of home healthcare

#### Key Challenges:

- Improved financial matrix under infrastructure expansion are yet to be proven - critical for sustained growth
- Dependence on imported medical equipment that drives up cost and shrinks options
- Standardization of clinical practices challenge for scale up & growth
- Sustainable model still evolving for access to rural communities and Tier III cities
- Infrastructure, Human Resources, & Affordability still need to go far

### IV. Segment Outlook

Healthcare delivery sector has significant scope for growth and reaching closer to global healthcare delivery standards. Underprivileged rural population, burgeoning middle class with increased willingness to pay, shortage of physicians and hospital beds indicates, there is a lot to achieve yet. This is being realized by the private equity (PE) investors and other institutional investors who are heavily investing in this sector. Few major hospital groups have gone public with successful IPOs. Government is making efforts by implementing forward looking policies, which are easier for investors and aggressive growth seekers in the market resulting in expansion of better healthcare delivery to Indian masses. However cautioned growth plans by hospital groups shall be implemented to avoid financial deadlocks, and impaired sustainability.



Accessibility of healthcare to masses is an important imperative beyond metro cities. With the launch of government schemes like RSBY, NRHM these dreams can be realized. Public Private Partnership models are allowing advancements in quality of medical services and associated technology innovations. Primary access of health at the bottom of pyramid can largely be achieved by government support as there are concerns around financial feasibility for private players. Private players are not yet able to break even their investments made towards rural healthcare projects. Despite all that, few newer hospital groups are now targeting non-metro cities. Many of the established hospital group are expanding their reach to non-metro cities through hub and spoke models.

Today, corporate hospitals have completely transformed infrastructure compared to decade old picture of typical Indian hospital. They have state of art architecture, modern medical devices, and high-end technologies to make medical intervention a very pleasant experience. The veterans of healthcare industry have realized that newer models such as telemedicine, mHealth, e-commerce, increasing insurance coverage, increasing demand for patient convenience additional to quality of medical care are emerging sector trends. Increasing investments, adoption to newer models are yielding in improved quality of healthcare and increased access. This emerging state of art infrastructure at lower costs is all poised to cater global patients however government's active engagement to promote medical tourism in India is highly desirable.

Perhaps, golden era of Indian healthcare delivery sector has begun. Private players, government, institutional investors, emerging startups are all indispensable industry players to take it further. This golden era of healthcare delivery will not only fulfil the masses in need of quality medical services but will significantly boost the economy of our country.



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# Sathguru Management Consultants

## About Sathguru

Sathguru Management Consultants (Sathguru) is a multidisciplinary advisory firm providing strategy, innovation and policy advisory to public and private sector entities in life science sector covering a broad spectrum of disciplines such as agriculture, food, animal sciences, human health care and industrial biotechnology. Sathguru provides a one stop solutions to all stakeholders in the life sciences sector ranging from researchers conceptualizing their next big idea to large corporates acquiring cutting edge technologies or finding growth avenues to multinational exploring growth opportunities in developing world to public sector developing policies, creating sector development platforms or creating life science infrastructure.

Since its formation in 1985, Sathguru has strived towards professional excellence and has grown to be the largest Indian strategic and technology management firm and a leader in life science sector. With offices in India (Hyderabad and New Delhi), the United States (Boston) and East Africa (Malawi) and strategic partners across regions including Asia, Latin America, Europe and Israel, Sathguru is well entrenched in the global innovation ecosystem and leverages business opportunities across regions globally. Sathguru engages over 200 highly qualified full time techno-commercial professional with varied background and experience across life sciences including doctorates and business professionals. Sathguru's deep understanding of global market, competition and trends (technology and business) coupled with its network of global partners allowing Sathguru to access modern technologies and develop winning business strategies for its clients.

## Services:

- Innovation Advisory
- Corporate Strategy
- Executive Education and Leadership Development
- Policy and Regulatory Advisory
- Corporate Finance and Transaction Advisory
- International Development and Project Management

## Indicative partners & clients:

**North America:** Cornell University, University of Florida, Stanford Research Institute, Pfizer, Merck, Boehringer Ingelheim, CURE Innovation Connecticut

**EU and MENA:** University of Sheffield – Fraunhofer – Yissum (Israel) – GSK – Novartis – DSM Ventures – JPMed (Israel)

**Asia:** Dong A, LG Lifesciences, Shin Poong Pharma (Korea), Johnson & Johnson (Singapore), World bank





## **THE KNOWLEDGE ARCHITECT OF CORPORATE INDIA**

### **EVOLUTION OF VALUE CREATOR**

ASSOCHAM initiated its endeavor of value creation for Indian industry in 1920. Having in its fold more than 400 Chambers and Trade Associations, and serving more than 4,50,000 members from all over India. It has witnessed upswings as well as upheavals of Indian Economy, and contributed significantly by playing a catalytic role in shaping up the Trade, Commerce and Industrial environment of the country.

Today, ASSOCHAM has emerged as the fountainhead of Knowledge for Indian industry, which is all set to redefine the dynamics of growth and development in the technology driven cyber age of 'Knowledge Based Economy'.

ASSOCHAM is seen as a forceful, proactive, forward looking institution equipping itself to meet the aspirations of corporate India in the new world of business. ASSOCHAM is working towards creating a conducive environment of India business to compete globally.

ASSOCHAM derives its strength from its Promoter Chambers and other Industry/Regional Chambers/Associations spread all over the country.

### **VISION**

Empower Indian enterprise by inculcating knowledge that will be the catalyst of growth in the barrierless technology driven global market and help them upscale, align and emerge as formidable player in respective business segments.

### **MISSION**

As a representative organ of Corporate India, ASSOCHAM articulates the genuine, legitimate needs and interests of its members. Its mission is to impact the policy and legislative environment so as to foster balanced economic, industrial and social development. We believe Education, IT, BT, Health, Corporate Social responsibility and Environment to be the critical success factors.

### **MEMBERS – OUR STRENGTH**

ASSOCHAM represents the interests of more than 4, 50,000 direct and indirect members across the country. Through its heterogeneous membership, ASSOCHAM combines the entrepreneurial spirit and business acumen of owners with management skills and expertise of professionals to set itself apart as a Chamber with a difference.

Currently, ASSOCHAM has more than 100 National Councils covering the entire gamut of economic activities in India. It has been especially acknowledged as a significant voice of Indian industry in the field of Corporate Social Responsibility, Environment & Safety, HR & Labour Affairs, Corporate Governance, Information Technology, Biotechnology, Telecom, Banking & Finance, Company Law, Corporate Finance, Economic and International Affairs, Mergers & Acquisitions, Tourism, Civil Aviation, Infrastructure, Energy & Power, Education, Legal Reforms, Real Estate and Rural Development, Competency Building & Skill Development to mention a few.

## **INSIGHT INTO ‘NEW BUSINESS MODELS’**

ASSOCHAM has been a significant contributory factor in the emergence of new-age Indian Corporates, characterized by a new mindset and global ambition for dominating the International business. The Chamber has addressed itself to the key areas like India as Investment Destination, Achieving International Competitiveness, Promoting International Trade, Corporate Strategies for Enhancing Stakeholders Value, Government Policies in sustaining India’s Development, Infrastructure Development for enhancing India’s Competitiveness, Building Indian MNCs, Role of Financial Sector the Catalyst for India’s Transformation.

ASSOCHAM derives its strengths from the following Promoter Chambers: Bombay Chamber of Commerce & Industry, Mumbai; Cochin Chambers of Commerce & Industry, Cochin; Indian Merchant’s Chamber, Mumbai; The Madras Chamber of Commerce and Industry, Chennai; PHD Chamber of Commerce and Industry, New Delhi.

Together, we can make a significant difference to the burden that our nation carries and bring in a bright, new tomorrow for our nation.



### **The Associated Chambers of Commerce and Industry of India**

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**Email:** [assochem@nic.in](mailto:assochem@nic.in) • **Website:** [www.assochem.org](http://www.assochem.org)



# ASSOCHAM's REGIONAL & OVERSEAS OFFICES

## ASSOCHAM REGIONAL OFFICES

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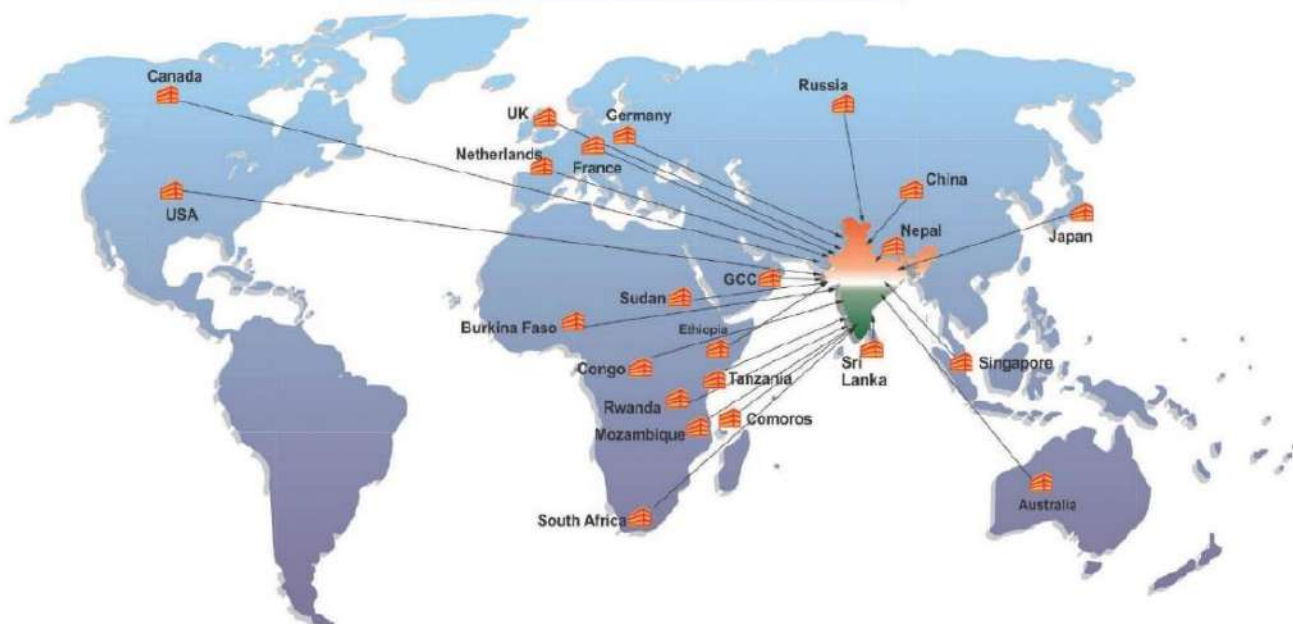
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## ASSOCHAM OVERSEAS OFFICES







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