

PHARMACEUTICAL MARKET INDIA 2014-2020

FORMULATIONS, ACTIVE
PHARMACEUTICAL INGREDIENTS
(APIs), CONTRACT RESEARCH &
MANUFACTURING SERVICES (CRAMS),
BIOSIMILARS, GENERICS & VACCINES



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1.0 Summary

“PHARMACEUTICAL MARKET INDIA 2014-2020, Formulations, Active Pharmaceutical Ingredients (APIs), Contract Research and Manufacturing Services (CRAMS), Biosimilars, Generics & Vaccines” by Kelly Scientific Publications is a comprehensive report on the pharmaceutical and biotechnology industry in India and its impact on international markets. This report scrutinises top Indian pharma companies and their battle within domestic and international therapeutic markets. The business environment in which they compete is analysed as are key drivers, constraints, challenges and opportunities.

The Indian pharmaceutical market is set to become the eighth largest pharma market globally by 2015. In 2012 it was worth \$ [REDACTED] according to the India Brand Equity Foundation (IBEF). It is forecast to reach at least \$ [REDACTED] by 2020 and increase its dominance as a leading player in Asia. It is predicted that the Indian pharma market will be a significant global competitor by 2020 with an expected worth of up to \$ [REDACTED]. This depends on the optimisation of the following submarkets: public health, generics, consumer healthcare drugs, biologics, vaccines and patented products.

This report describes the current therapeutics that are propelling the pharmaceutical and biotechnology markets in India. It examines the current economic climate and how India compares to other emerging markets and also evolved markets such as the US and Europe. Current developments relating to patent expirations, government funding, and regulations are discussed. The emerging trends that appear in key sub-markets such as generics, oncology, cardiovascular, diabetes and vaccines are elucidated and analysed.

This study reveals market figures of the overall Indian pharmaceutical market and sub-markets. Forecast projections and future growth rates are provided to give the reader a forthcoming perspective of this growing industry.

The study also provides a comprehensive financial and product review of key players in the biopharmaceutical industry in India. Strategic drivers and restraints of this market are revealed and market opportunities and challenges are identified.

In summary, the Indian biopharmaceutical market has huge opportunities for growth. This industry will significantly affect the international healthcare market and has enormous potential for investment.

1.1 Objectives of Report

The main objectives of this report are:

- To comprehensively summarize current developments in the Indian pharmaceutical and biotechnology industries.
- To identify emerging trends in key markets and sub-markets such as biogenerics, cardiology, oncology therapeutics, diabetic care, vaccines and anti-infective agents.
- To comprehensive review and analyse financial and product details of key players in the industry
- To present market figures of the current Indian biopharmaceutical market value and give forecast projections and growth rates
- To identify key drivers and restraints of the Indian biopharmaceutical market
- To report and analyse market opportunities and challenges
- To identify funding and government sponsorship issues

The reader of this report will gain:

- An in-depth understanding of the Indian pharmaceutical and biotechnology markets and environments
- Current market facts, figures and product lines of key players in the industry
- An insight into how generic therapeutics and vaccines will propagate the Indian biopharmaceutical market
- Knowledge of how the Indian biopharma market will integrate into the global healthcare market
- Information on key government policies
- Data on levels of private and publically funded biopharma studies in India
- Strategies on how to adapt and restructure current business models to this industry

1.2 Scope of Study

The Indian pharmaceutical market is the main driver of the country's healthcare industry. The Indian Pharmaceutical Industry (IPI) is divided into four main sectors:

- Active Pharmaceutical Ingredients (APIs)
- Contract Research and Manufacturing Services (CRAMS)
- Formulations
- Biosimilars

The study provides a comprehensive description of current companies with an interest in the Indian market and their financial and product portfolios. This paper also identifies key therapeutics that are driving the biopharma market in India and current restraints and challenges that may weaken this emerging industry.

1.3 Data Sources and Methodology

The project leader and author of this research obtained a Ph.D. in Medicine from the Royal College of Surgeons in Ireland, following completion of a M.Sc. in Biotechnology (NUIG) and an honours degree in Biochemistry from Trinity College Dublin. She has extensive experience in drug target discovery and vaccine research and development and conducted post-doctoral studies and lecturing in Trinity College Dublin. The author's career spans both industry and academia where she has worked with both start up biotech and multinational pharmaceutical companies. With many years of medical writing and publishing the author also has extensive experience and knowledge of genetics, molecular biology, immunology, bioinformatics and diagnostic testing. As a pharma/biotech industry analyst she has significant expertise in laboratory diagnostic testing and instrument and reagent development technology.

Sources of information for this report were collected and compiled from industry trade publications, academic journals, international scientific and medical research articles, investment research reports, trade and industry association reports, Government affiliated research reports. Key information from business literature was used to conduct interviews with business industry experts to determine commercial potential and market sizes. Graphical and numerical data have been referenced and sourced accordingly. Specific websites were consulted and referenced throughout the completion of this report including that of the World Health Organization (www.who.int) and European Medicines Agency (www.ema.europa.eu). Financial and business environment sources such as the World Trade Organization (www.WTO.org) and the International Monetary Fund (www.IMF.org) and other government agencies worldwide were also accessed. Kelly Scientific Publications has used the most recent statistical and numerical data available. The most reliable of data sources were used in the

production of this report, however we cannot guarantee complete accuracy or completeness from secondary information sources.

1.4 Key Findings and Observations

In 2012 the Indian pharmaceutical market (IPM) was worth \$ [REDACTED] and is forecast to reach \$ [REDACTED] by 2020 with a CAGR of [REDACTED]%. Globally it is the third largest with respect to volume and 13th in terms of value. Generic drugs make up the majority share ([REDACTED]%) of revenue, followed by over the counter (OTC) drugs ([REDACTED]%) and patented therapeutics ([REDACTED]%). Bio-pharmaceutical exports contribute greatly to India's successful pharma industry, with \$ [REDACTED] generated in 2013. This is a rise of [REDACTED]% CAGR since 2006. The fiscal year 2013-2014 generated export revenue of \$ [REDACTED], largely supported by US and UK sales. In the US, [REDACTED]% of generic and OTC agents are supplied by India. Export revenue is predicted to increase by a further [REDACTED]% in 2015, and is set to out-perform domestic sales.

Pharmaceutical sales are also on the increase in India and were calculated at \$ [REDACTED] in 2012. Industry experts forecast this to rise by over [REDACTED]% to \$ [REDACTED] by 2016. The most successful therapeutic area within the IPM is infectious disease, which commanded [REDACTED]% of the total market in 2013. Cardiovascular held [REDACTED]% of the market followed by gastrointestinal at [REDACTED]%. The vitamin/mineral and nutrient subsection demanded [REDACTED]% of the market in 2013, followed by respiratory ([REDACTED]%) and pain medication ([REDACTED]%).

The IPM is a significant player in emerging markets. This growth is fuelled by the significant level of chronic disease in the country which is estimated at 20% of the population. Over 50% of deaths are due to chronic diseases such as cancer, cardiovascular disease and diabetes in India. Therefore a market shift from acute therapeutics to chronic medications will occur in the coming years. Vaccine production and generic drug manufacturing are key products for the Indian market and Kelly Scientific Publications predict that international markets will be significantly penetrated with these products in the near future.

The government in India has identified biotechnology as a key area of growth and to that end has provided significant funding for opportunities within this area. India's Twelfth Five Year Plan (12th 5YP) will function to increase private investment in R&D and international collaborations. The overall aim is to position India as one of the top five scientific superpowers by 2020.

The Indian pharma market is fragmented and up to [REDACTED]% of it is dominated by a small number of players including Cipla, GSK, Sun Pharma, Ranbaxy and Piramal. The IPM is divided into four key areas - active pharmaceutical ingredients (APIs), contract research and manufacturing services (CRAMS), formulations and biosimilars. The market is currently controlled by acute therapy which demanded [REDACTED]% of total. This is forecast to decrease over the coming years as lifestyle and chronic disease increase further in prevalence.

1.5 Executive Summary

Today, India is the second largest country and is populated by more than 1.2 billion. By 2050, it is estimated that the population will have grown to between 1.6-1.8 billion and so key investments and strategies to exploit this growing market is paramount. India's potential as a key player in the pharma market is significant.

The population of India over 60 years old is forecast to reach 300 million by 2050. This is a 17% increase from 77 million in 2001. Noncommunicable diseases (NCDs) such as heart disease, stroke, cancer, chronic respiratory disease, diabetes, mental health issues, vision and hearing difficulties will all increase in incidence with this population growth and put pressure on health services. According to the World Health Organisation (WHO), 80% of adult deaths are due to NCDs in urban centres and 60% of deaths in rural areas.

Over 20% of the Indian population are currently suffering from a chronic disease and 10% have comorbidities. Chronic diseases cause 50% of all deaths in India. Infectious and parasitic diseases are a significant contributor, as are cardiovascular diseases, respiratory conditions, cancer and diabetes. According to a study by Patel et al in The Lancet, almost 75% of all deaths in India will be due to a chronic disease in 2030.

- Cancer fatalities will rise from 730,000 in 2004 to 1.5 million in 2030.
- Cardiovascular deaths will increase from 2.7 million in 2004 to 4 million in 2030.
- Coronary heart disease deaths will increase from 7.1 million in 2004 to 17.9 million in 2030.

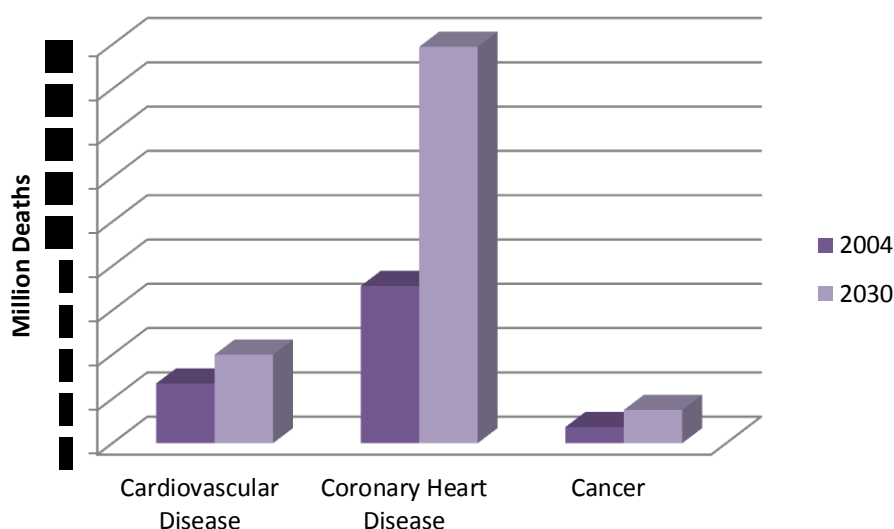
Today, the top causes of mortality in India are:

- Cardiovascular diseases
- Cancers
- Chronic Respiratory Disease
- Respiratory infections
- Perinatal Conditions
- Diarrhoeal diseases
- Digestive diseases
- HIV/AIDS
- Tuberculosis

Exhibit 1: Top Ten Causes of Mortality in India 2008-2030

	2008	2030
1	Cardiovascular diseases	Cardiovascular disease
2	Cancers	Cancers
3	Chronic Respiratory Disease	Chronic respiratory disease
4	Respiratory infections	Respiratory infections
5	Perinatal Conditions	Diabetes mellitus
6	Diarrhoeal diseases	Digestive disease
7	Digestive diseases	Perinatal conditions
8	HIV/AIDS	Neuropsychiatric disease
9	Tuberculosis	Genitourinary disease
10	Neuropsychiatric Non-communicable disease	HIV/AIDS
	Communicable disease	

Exhibit 2: Historic and Projected Death Rates Due to Cardiovascular and Cancer, India 2004-2030



India's Twelfth Five Year Plan (12th 5YP) aims to increase funding for six areas of scientific research and development until 2017. An investment of INR 1,204 billion (US \$24 billion) will increase Indian R&D and boost its credibility internationally. The plan also proposes to increase the output of scientific papers from 3% globally in 2012 to 5% in 2017. Biotechnology will receive significant funding and the following areas will expand over the coming years:

- Molecular and cell biology
- Structural biology
- Immunology
- Neurobiology
- Bioengineering
- Clinical and translational research
- Regulatory sciences
- Intellectual Property (IP) technology transfer
- Nanotechnology

The Indian Pharmaceutical market (IPM) is one of the most important emerging pharma markets and in 2012 was worth \$ [REDACTED]. It is forecast to potentially increase to \$ [REDACTED] by 2020 and increase its dominance as a leading player in Asia. This will depend on positive growth within the following submarkets: public health, patented products, vaccines, consumer healthcare and biologics.

The IPM is a significant driver of the domestic healthcare industry and is divided into four main sections:

- Active Pharmaceutical Ingredients (APIs)
- Contract Research and Manufacturing Services (CRAMS)
- Formulations
- Biosimilars

Over \$ [REDACTED] of Indian pharmaceutical products were exported during 2012-2013. The majority of exports are bulk drugs (including APIs) which contribute over [REDACTED]% share. Currently, Indian bulk drug exports demand [REDACTED]% of the global bulk drug market. India mainly exports to the US, which received [REDACTED]% of exported APIs in 2012. This was followed by the EU ([REDACTED]%) and Africa ([REDACTED]%).

The Indian formulations market exported \$ [REDACTED] during 2011-2012 and is set to reach \$ [REDACTED] by 2015. The domestic formulation market consumes [REDACTED]% of product manufactured and was worth almost \$ [REDACTED] in 2012. This will rise to \$ [REDACTED] by 2015.

Currently the Indian biosimilar market share is low at [REDACTED]% of the global market (\$ [REDACTED]). However between 2013-2015 it is forecast to grow strongly and demand [REDACTED]% of the global biosimilar market. By 2015, the global biosimilar market is expected to reach \$ [REDACTED].

The Indian Contract Research and Manufacturing Service (CRAMS) industry is currently worth \$ [REDACTED]. It is divided into manufacturing and research, with manufacturing services accounting for just over [REDACTED]% of Indian business. Between 2010 and 2012, the Indian CRAMS industry grew by [REDACTED]% due to a large increase in outsourcing. This growth rate is triple the global average of growth rate of [REDACTED]%. By 2015, it is forecast that the CRAMS industry in India will hit \$ [REDACTED], fuelled by the impending patent cliff and high requirement for generic manufacturing, biologics, and drug delivery technologies.

The Indian pharma market is fragmented and up to [REDACTED]% of it is dominated by a small number of players including:

- Cipla
- Dr Reddy's
- Sun Pharma

- Ranbaxy
- Piramal
- Zydus Cadila
- Mankind
- Lupin

Over the next number of years, it is expected that the IPM will continue to grow to as much as \$ [REDACTED] billion by 2020 with a CAGR of between [REDACTED]%. Therefore by 2020, the IPM will be comparable to other developed pharma markets (excluding the US and Japan) and also to the Chinese pharma market. Significant economic indicators that will propel the IPM in the near future include:

- India is one of the fastest growing economies globally with a [REDACTED]% growth increase in the pharmaceutical market 2012
- India's sovereign credit rating rose by [REDACTED]% during the period 2007-12
- Cumulative exports recorded during 2011-12 were \$ [REDACTED] - a growth of [REDACTED]%
- Imports in 2011-12 at \$ [REDACTED] – a growth of 29%

The Indian pharma market is currently dominated by the acute therapy market which demanded [REDACTED]% of total. This is forecast to decrease over the coming years as lifestyle and chronic disease increase further in prevalence. In 2012, the anti-infectives market held the premier position within the IPM, with [REDACTED]% share. The following therapeutic areas all hold significant market share within the IPM:

- Anti-infectives
- Cardiac
- Gastro Intestinal
- Respiratory
- Pain/Analgesics
- Vitamins/Minerals/Nutrients
- Anti-Diabetic
- Neuro/CNS
- Dermatology
- Gynaecology

Kelly Scientific Publications believes that chronic markets such as cardiovascular, diabetes and neurology/psychiatry will all contribute to market penetration within the next five years and will maintain a fast growth rate. A shift towards disease management and prevention will steadily cause a shift in the Indian pharma market from acute to chronic areas.

India's Twelfth Five Year Plan (12th 5YP) aims to increase funding for six areas of scientific research and development until 2017. The Indian Government has proposed an investment of INR 1,204 billion (US \$24 billion) to strategically increase the number of PhD graduates, researchers and essentially boost international recognition for Indian R&D.

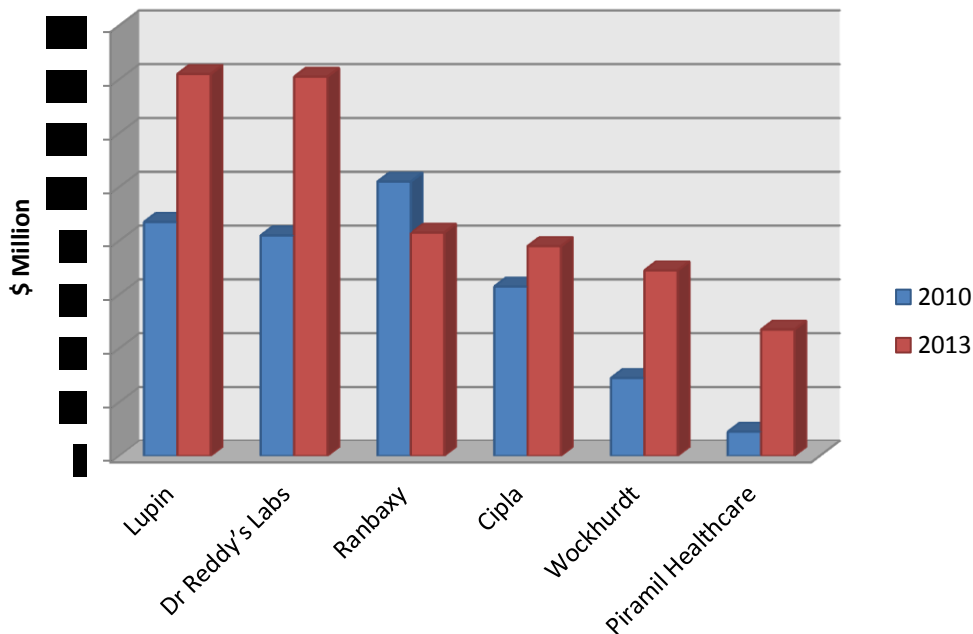
The 12th 5YP also proposes to increase the output of scientific papers from 3% globally in 2012 to 5% in 2017. The overall aim is to position India as one of the top five scientific superpowers by 2020. In order to do this information gathered from R&D must be commercialized and current pharma/biotech companies situated in India must increase their interests in R&D. By 2017, it is envisaged that the ratio of private: public share of investments is 50:50.

This report highlights a number of significant Indian pharma companies and gives details of their operations, products, financials and business strategy. The following companies were chosen for analysis as they have specific advantages that we believe will drive the pharmaceutical industry in India.

- Aurobindo Pharma
- Bharat Serums and Vaccines Ltd

- Biocon Biopharmaceuticals
- Cipla
- Divis Laboratories
- Dr Reddy's Laboratories
- Lupin
- Mankind Pharma
- Panacea Biotech
- Piramal Group
- Ranbaxy Laboratories
- Reliance Life Sciences
- Serum Institute of India
- Sun Pharmaceuticals
- Zydus Cadila

Exhibit 3: R&D Investment Comparison of Top Indian Pharmaco's 2010 Vs 2013



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