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INDIAN PHARMACEUTICAL INDUSTRY *(SAMPLE COPY, NOT FOR RESALE)*

Trends, Industry Participants, Product Overviews and Market Drivers

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1. Overview

1.1 Statement of Report

The pharmaceutical industry in India has evolved through three phases over the past 60 years. The first was the period prior to 1970, when the industry was relatively small in terms of production capacities. The second phase spanned from the early 1970s to 1990, a period during which the industry experienced policy-induced growth. In its third phase, from the beginning of the 1990s to the present, much of the regulatory structure that the government had imposed during the previous two decades was dismantled. The decade of the 1990s had been significant for India in terms of the changes in policy orientation directed at its economy. The policies adopted in 1991 sought to break down the walls of protection behind which Indian industry had developed in the past. The success that this industry experienced in the 1990s was, however, built on a foundation that was laid in the 1970s. This period witnessed the development of a viable domestic industry with adequate participation of Indian entrepreneurs.

The purpose of this study is to describe the specific segment of the pharmaceutical market sector called the Indian pharmaceutical industry. This sector includes all of the generally accepted pharmaceutical manufacturing activities that are currently used today, including the bulk drug industry, formulations and major therapeutic segments. It examines these clinical supplies as utilized in hospitals, clinics and doctor's offices. This report presents an overview of India's pharmaceutical industry and its evolution from almost non-existent to one of the world's suppliers of generic drugs. The Indian pharmaceutical industry was allowed to take off when India met its World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) obligations and amended its patent laws with the passage and implementation of the Patents (Amendments) Act 2005. When India re-instituted "product" patents, it effectively ended 36 years of protection for Indian companies and terminated legal reverse engineering or copying of patented foreign pharmaceutical drugs. To meet the shortfall in revenues many of India's leading pharmaceutical companies turned to foreign acquisitions and exports, especially to United States. Indian companies benefit from a greater acceptance of generic drugs among the U.S. public, tremendous pressure on healthcare providers to reduce costs, and impending expiration of patents on drugs with annual sales of \$50 billion. India's major pharmaceutical companies are positioning themselves to offer generic versions of these drugs and some have predicted that they will capture at least 30% of the U.S. generic replacement market.

The principal objectives of this analysis are to:

- Identify viable technology drivers through a comprehensive look at various platform technologies for the Indian pharmaceutical industry.
- Obtain a complete understanding of the Indian pharmaceutical industry practices from its basic principles to its applications.
- Discover feasible market opportunities via an identification of high-growth applications in different areas of the Indian pharmaceutical industry, with a focus on the biggest and expanding markets for the Indian pharmaceutical industry.
- Focus on global industry development through an in-depth analysis of the major world markets for pharmaceutical manufacturing, including forecasts for growth.
- Establish the essentials of the Indian pharmaceutical market including definitions, processes and trends.

Market figures regarding the current value of the Indian pharmaceutical industry market are taken from the most recently available data of the global medical products industry. This report will cover the following categories of the Indian pharmaceutical industry:

- Segmentation of the Indian pharmaceutical industry.
- Bulk drug industry.
- Formulations.
- Major therapeutic segments.
- Key players in the Indian pharmaceutical industry.
- Strategic groups.
- Critical success factors of the industry.

- Indian pharma exports.
- Policies and regulations.
- Marketing and distribution in the pharmaceutical industry.
- Future outlook for the Indian pharmaceutical industry.
- Emerging trends.
- Product patents.
- Clinical trials.
- Case histories.
- Competitive advantages.
- Generics players.

This examination includes the use of charts and graphs, measuring product growth and trends within the marketplace. In addition, a discussion of research into the Indian pharmaceutical industry provides the reader with a deeper understanding of the possibilities for future treatment and avenues for possible R&D budgets. Company-specific information, including sales figures, product pipeline status, and R&D trends is provided throughout the report. This study's aims are to:

- Assess the Indian pharmaceutical industry market drivers and bottlenecks, from the perspective of the medical and scientific communities.
- Discuss the potential benefits of the Indian pharmaceutical industry market for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the Indian pharmaceutical industry market and analyze the current size and growth of various segments.
- Provide current and forecasted market shares by company.
- Discuss profit/business opportunities by imaging segment.
- Provide strategic recommendations for near term business opportunities.
- Assess current commercial achievements of the Indian pharmaceutical industry market.
- Assess Indian pharmaceutical industry business models.

1.2 Scope of the Report

The emphasis in this analysis is on those companies that are actively developing and marketing technologies for Indian pharmaceutical industry. The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for a detailed understanding of the important individual market segments, which are related to the Indian pharmaceutical industry.

Emphasis is placed upon the Indian pharmaceutical industry market segment in important worldwide markets such as the U.S., Japan and Europe. It focuses primarily on products for the hospital market segment, and separately on a description of the pharmaceutical products marketed by major companies in this segment. The analysis discusses the market size, growth rates and market components for therapeutic products marketed by the Indian pharmaceutical industry.

This study discusses business trends, technology trends and developing areas of the Indian pharmaceutical industry and reviews the market for the Indian pharmaceutical industry products in the clinical hospital market. It defines the dollar volume of sales, both worldwide and in the U.S. of the market and analyzes the factors that influence the size and the growth of the market segments.

The report discusses activity and trends in the therapeutic pharmaceuticals in Indian manufacturing markets. The report goes on to discuss in detail the trends that have developed to stimulate this market. The review also comments in detail on the patterns of information processing and patent protection in the Indian pharmaceutical industry. It surveys most of the companies known to be marketing, manufacturing or developing the Indian pharmaceutical industry. Leading companies are discussed in depth with a section on the history of the company, the product line, business and marketing analysis, and a subjective commentary of the position of the company in its market.

1.3 Methodology

This study is based upon interviews with sales and marketing professionals of companies in the Indian pharmaceutical industry market. They were queried, some several times, about their companies' products and marketing strategies as well as their overall thoughts about their industry segment. Information was also obtained from interviews with founders, CEOs and vice presidents of some of the companies discussed. Descriptions of the hospital laboratories and nearby patient facilities were derived from interviews with laboratory directors and medical technologists in these areas.

Other sources of information included trade association publications and meetings, product brochures and catalogs, and company literature. We have also gathered statistical information from the U.S. government, the World Health Organization (WHO), and private foundations. Annual reports, 10k filings, and financial reports were used as the basis for data reported on publicly held companies. The author of this report is a PhD in biochemistry with years of experience in science writing and as senior researcher in the pharmaceutical industry with DuPont and Pzifer. The editor is an Indian national with a master's degree in botany and degrees in biotechnology and biochemical pharmacology.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information set forth in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information, omission or for the results obtained by the use of such information. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals with regard to commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects and Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark's research of the past three years as part of this data collection. We also extract qualified data feeds from e-questionnaire responses and primary research responses for this compilation.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government affiliated trade releases, and other published information as part of its secondary research materials.

The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations. The report conclusions are verified through intensive interviewing of top ranking companies in the industry.

TriMark Publications Report Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly available databases, proprietary databases, direct meetings and personal interviews with key personnel.
- Formulating a study outline with the assigned writer, including important items:
 - Market and product segment grouping and evaluating their relative significance.
 - Key competitor's evaluations including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.

- End-user research to evaluate analytical significance in market estimation.
- Supply chain research and analysis to identify any factors affecting the market.
- New technology platforms and cutting edge applications.
- Identifying the key technology and market trends that drive or affect these markets. Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.
- Launching a combination of primary research activities including two levels of questionnaires, executive-direct focused, company-specific, and region-specific communications to qualified and experienced senior executives worldwide.
- Completing a confirmatory primary research assessment of the report's findings with the assistance of Expert Panel Partners from the industry being analyzed.

1.4 Executive Summary

With an economy that is already the [REDACTED] largest globally, India ranks among the most important emerging markets in the world. From being a major importer of bulk drugs and formulations, the Indian pharmaceutical industry has today become a net exporter of pharmaceutical products. The trade balance of pharmaceutical import and export, which was negative for a long time, has shifted to the positive side with a net inflow of foreign exchange from [REDACTED] to [REDACTED]. Nearly [REDACTED]% of the domestic demand for pharmaceuticals is met through indigenous production. Presently, import of pharmaceuticals are limited to a few life-saving drugs like anti-cancer, cardio-vascular, anti-hypertension and newer drugs, which remain not cleared for indigenous production and marketing in the industry. At present, there are [REDACTED] to [REDACTED] pharma manufacturing units in the country, of which large-scale units are [REDACTED]. Of these, about [REDACTED] manufacturing units have an international presence. The Indian pharmaceutical industry today ranks [REDACTED] in terms of volume and [REDACTED] in terms of value. India amended its patent laws effective [REDACTED] to allow for pharmaceutical product patents on any product with a patent issued after [REDACTED] to meet obligations under the TRIPS. Further, the structure and dynamics of the Indian pharmaceutical industry are unique primarily because of the following facts:

- The process patent regime.
- Price controls.

Although the tight control of the government over the industry between [REDACTED] and [REDACTED] enabled the rapid growth of indigenous industry, most of the new introductions by the West took a very long time to be manufactured in India.

Exemptions to Small Scale Industries (SSIs)

The Indian Patents Act (IPA), 1970 was largely responsible for the change in structure in the Indian context. The IPA recognized "process patents" as against "product patents" which at present is prevalent in the developed world. As a result, for the first time, Indian manufacturers could produce internationally patented drugs within the country. This could have been made possible by developing an alternative process for the drug, after reverse engineering, using the relatively cheap and large manpower base of qualified pharmacists and scientists available in the country.

Presently, the Indian pharmaceutical industry is set to move up the value chain by overhauling its strategies to development and marketing of new drugs under the altered patent laws. At present, per capita annual consumption of drugs in India is about \$ [REDACTED] to \$ [REDACTED], one of the lowest in the world including developing countries.

Sourcing drug discovery development times, prolonged regulation-mandated testing, complex review processes, rapidly escalating R&D expenditures and competition are hurting the margins of pharmaceutical companies. In an attempt to improve falling revenues, the pharmaceutical industries in developed countries have resorted to outsourcing of high-end services such as drug discovery and development to in-expensive but highly skilled destinations in Asia. India has emerged as a preferred destination, owing to its low cost manufacturing, lower cost of R&D personnel, lower capital and operational costs for quality infrastructure of international standards.

The contract research business in India doubled from Rs. [REDACTED] (about \$ [REDACTED]) in [REDACTED] to Rs. [REDACTED] (about \$ [REDACTED]) in [REDACTED]. In [REDACTED], contract research in India was valued at \$ [REDACTED] to \$ [REDACTED] and growing at the rate of [REDACTED] % to [REDACTED] % each year. The current outsourced clinical trial activity in India is around Rs. [REDACTED] (about \$ [REDACTED]), and expected to grow at [REDACTED] % CAGR, hitting \$ [REDACTED] by the end of [REDACTED]. Currently, India holds nearly [REDACTED] the business of its nearest rival, [REDACTED] and [REDACTED] times as much as the next competitor, [REDACTED]. Consequently, the clinical research industry in India will witness a business of Rs. [REDACTED] (or \$ [REDACTED]) creating a demand of [REDACTED] professionals in the next [REDACTED] years. With a large native patient population pool, various disease profiles and robust infrastructure position, India is high on the outsourcing list. Today, nearly about [REDACTED] clinical trials are being conducted in India and GlaxoSmithKline, which is one among the world's top [REDACTED] global pharma majors, is currently carrying out the largest number of clinical trials in India. Apart from the development of vaccines, this company is conducting [REDACTED] drug trials in India for the treatment of diseases such as cancer, arthritis, epilepsy, heart diseases and constipation. AstraZeneca is outsourcing nine trials in India for schizophrenia, bipolar disorder, cancer, diabetes and testotoxicosis. Johnson & Johnson and Eli Lilly are conducting respectively eight studies in India and seven drug trials are conducted, one each for Pfizer, Sanofi-Aventis, Merck, Wyeth, Bristol-Myers Squibb and Roche.

Outsourcing clinical research to India allows the global pharma companies to trim costs considerably and it costs [REDACTED] % less than the average cost in the U.S. But more than cost, time is a crucial factor for pharma companies. When a drug is discovered and approved for clinical trials, nearly half the time is spent on clinical trials before marketing the drug. Clinical trials alone can last for up to [REDACTED] years. The best way to reduce time is to recruit patients quickly but it is increasingly difficult to achieve this in western countries, because health expenses are almost entirely covered by the government in Europe and in U.S. the patients are more often covered by health insurance policies. Therefore these patients are not financially compensated for their participation in clinical trials, whereas it is easy to recruit patients in countries with poor social security systems.

From [REDACTED] to [REDACTED], the U.S. based Pfizer has emerged as the biggest pharma patent applicant in India for pharma and agrochem inventions. Johnson & Johnson has emerged as the second largest applicant. Among Indian companies, Dr. Reddy's Labs with [REDACTED] mailbox submissions has been the most aggressive patent seeker. Its rival, Ranbaxy Laboratories has been a less aggressive user of the mailbox with just [REDACTED] filings. Among domestic firms, Delhi-based Panacea Biotech mailed in [REDACTED] applications, followed by bigger firms like Dabur India ([REDACTED]), Sun Pharma ([REDACTED]) and Cipla ([REDACTED]).

India has received [REDACTED] applications for patent of pharmaceutical products, becoming only the second country after U.S. to get a large number of such requests. The U.S., which topped the list, received [REDACTED] applications and Germany finished third with [REDACTED] applications. For the [REDACTED] position there was relatively close competition between U.K. and Switzerland, which received [REDACTED] and [REDACTED] applications, respectively. Japan secured the [REDACTED] place with [REDACTED] applications, Sweden [REDACTED] with [REDACTED], France [REDACTED] with [REDACTED], Denmark [REDACTED] with [REDACTED] and Belgium [REDACTED] with [REDACTED] applications. [REDACTED] countries including UAE, Chile, Egypt, Hawaii, Iran, Korea, Mexico, Russia, Saudi Arabia, Solomon Island had one application each. On [REDACTED], Pfizer cleared a big milestone in India and became the first to get patent protection for an acquired immunodeficiency syndrome (AIDS) drug. The new patent covers Celzentry or Maraviroc, a new human immuno virus (HIV) remedy that was already approved by U.S. Food and Drug Administration (FDA).

Generic drugs from India sparked a price war for anti-retrovirals (ARVs), which brought the annual price for triple therapy down from [REDACTED] to [REDACTED] in a single year. In Brazil, ARV prices plummeted by [REDACTED] % within five years after Brazil initiated local generic production (based primarily on API supply from India) and provided universal free HIV treatment to Brazilians who needed it.

The Indian pharmaceutical and biotechnology market was about \$ [REDACTED] during [REDACTED], \$ [REDACTED] in [REDACTED] and is expected to reach \$ [REDACTED] by [REDACTED]. Out of this, \$ [REDACTED] to \$ [REDACTED] will accrue from IT-related components such as bioinformatics, genomics/proteomics, data management for contract research, and remote sales and marketing. The Indian pharmaceutical industry is worth at least \$ [REDACTED] retail sales in domestic market, in addition to \$ [REDACTED] in exports. The industry accounts for [REDACTED] % of world's drug production by volume and [REDACTED] % by value. Indian exports are sent to more than [REDACTED] countries around the globe including highly regulated markets of U.S., Europe, Japan and Australia. The larger pharmaceutical unit's number is around [REDACTED] in addition to [REDACTED] small

and medium enterprises (SMEs) during [REDACTED] to [REDACTED]. Value of bulk drugs (Rs. [REDACTED]) and dosage forms produced (Rs. [REDACTED]) has grown by [REDACTED]%. Drug sales in India have grown at a [REDACTED]% compound annual growth rate since [REDACTED]. The total output of the Indian pharmaceutical industry was about Rs. [REDACTED], of which bulk drugs accounted for Rs. [REDACTED] ([REDACTED]%) and formulations Rs. [REDACTED] ([REDACTED]%). India's nascent but rapidly growing biotech industry earned revenues of \$ [REDACTED] in [REDACTED] and its share in global biotech market was [REDACTED]%.

R&D forms the lifeline of pharmaceutical industry. In [REDACTED], India's ten largest drug firms spent over \$ [REDACTED] on R&D, a figure that is expected to exceed \$ [REDACTED] by [REDACTED]. One of India's largest pharmaceutical drug companies, Ranbaxy has spent a cumulative \$ [REDACTED] on R&D since the beginning of its research efforts in [REDACTED] and expects to spend [REDACTED]% of sales on R&D going forward. There is likely to be a proliferation of research partnerships between Indian and western drug firms such as those with Novartis (Dr. Reddy's, Torrent), Novo Nordisk (Dr. Reddy's), GlaxoSmithKline (Ranbaxy) and Schwarz (Ranbaxy).

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