CHAPTER I

INTRODUCTION AND DESIGN OF THE STUDY

1.1 INTRODUCTION

Medicine was born the day man was born or even earlier, because even animals have the instinct and the “know-how” for curing ailments. The greatest urge in human beings, or as a matter of fact in any living organism, is the love for one’s own life. It is this urge which has kept medicine or science and art of healing alive since ages and has enriched and advanced medicine day by day. In the pre-historic era, disease was considered to be due to the influence of evil spirits or curse from God. The only way to cure was to combat these influences or please God.

The birth of Ayurveda (the knowledge of life) dates back to the Vedic period (about 5000 BC). Dhanvantri, who was known as the God of Medicine, brought one pot full of immortal spirit (amrit kalash) with Him which served as a cure for all known ailments. The Vedas were believed to be a document of God’s own versions. Ayurveda was a part of Rig-Veda. Atharvaveda contained, besides names of certain diseases and mantras for obtaining relief from evil spirits, the names of different organs of the body.
and treatment schedules for certain disease conditions. The “tridosa” theory for causation of human ailments originated from Ayurveda itself. Description of certain disease is also given in the Upanishads. Pointing references of such conditions as tukman (coryza and cough), phthisis, jaundice and ascites are also available in the Vedas. After the Vedic period, several classified documents (the Samhitas) were added to the subject of medicine in due course of time.

Modern medicine, however, originated from the teaching of Hippocrates (460-370 BC). Hippocrates after examination of the human body and after due recognition of signs and symptoms of several diseases, gave their clinical descriptions. Hippocrates also evolved a code of conduct for the medical men in the form of the Hippocratic oath. For these reasons, Hippocrates has been called “the Father of medicine”.

From ancient times, two systems of medicine were in India. Firstly there was Ayurvedic medicine, which dates back to the Vedic period. Ayurvedic medicine depends largely on the combination of various herbs, minerals and metals like gold, copper, etc. Secondly there was the Arabian system of medicine. Innumerable invasions had brought the Arabian system
into India. In contrast to these, two other systems of medicine, namely, Allopathic and Homeopathic, were in vogue in the western part of the world.

Despite being a very advanced indigenous system of medicine, Ayurveda has not really become popular enough, probably because of a very long British rule and the consequent development of educational system including medical education based on a typical British model. As Allopathic or modern medicine started taking root in India, all the research and development activities the world over fuelled its growth in India as well. Conversely, there was hardly any research and development activity in the area of Ayurvedic medicine. Though the Government has been making some efforts to promote Ayurvedic medicine, its development seems to be a long way off. It is still popular in rural areas, may be because modern medicine cannot reach there. In urban areas, it is yet to gain importance. So far as the prescription drug market is concerned, the inclination of Allopathic doctors towards prescribing an Ayurvedic medicine is very low indeed.

Of late, however, the attitude of consumers towards Ayurvedic medicine seems to be increasingly favourable. Some of the pharmaceutical companies are planning to diversify into Ayurvedic drugs Preparations.
1.2 INDIAN PHARMACEUTICAL INDUSTRY

The Indian pharmaceuticals industry has come a long way from its humble beginnings in 1910 when the first pharmaceutical company Bengal Chemical and Pharmaceutical works commenced its operations. At the time of Independence, the domestic industry had a turnover of Rs.10 crores.

By 1941 industry took up the manufacture of new drugs like iodochloro-hydroxy quinoline as well as a number of alkaloids like ephedrine and codeine. Besides this, the industry made a beginning in the production of chemotherapeutic drugs like arsenicals, anti-leprotic drugs and colloidal preparations of calcium, silver, manganese and iodine. The production of glandular products like, liver-extracts was also undertaken. The production of several formulations based on imported bulk drugs also showed a significant expansion during the period.

(i) Post-Independence Era

Immediately after independence, the Government addressed itself to the task of achieving a high rate of economic progress with special emphasis on speedy industrialization. When the Government of Independent India
embarked on a planned economic expansion about four decades ago, the development of the Indian pharmaceutical industry was not commensurate with the size of the country and the growing needs of its population. Since then, the progress of the pharmaceutical industry in the country has been substantial and many-sided, and can best be described as dramatic\(^1\).

(ii) Dramatic Progress

From a mere Rs.10 crore (production value) in 1947 to a whopping Rs.22401 crore in 2005, the Pharmaceutical Industry in India has come a long way. Today India manufactures over 400 bulk drugs and around 60,000 formulations. The number of pharmaceutical units too has increased from 1752 in 1955 to over 23,000 in 2002. Furthermore, in the UNIDO classification of developing countries, according to the “state-of-art” in the pharmaceutical sector, India is ranked among the top.

However, the industry grew at an infinitesimal pace from 1947 to about 1970 due to lack of incentives and a clear regulatory framework. During 1970, the Indian Patents Act (IPA) and the Drug Price Control Order

\(^1\)Subba Rao Chaganti, Pharmaceutical Marketing in India, GIFT – Excel Series, New Delhi, 2005, pp.3-5.
(DPCO) were passed. Although, the DPCO acted as a buffer against Pharmaceutical Companies by making free pricing illegal, it fulfilled the goal of providing quality drugs to the public at reasonable rates. The introduction of the Indian Patents Act (IPA) provided a major thrust to the Indian Pharmaceuticals Industry and Indian companies, who through the process of reverse engineering and synthesis, began to produce bulk drugs and formulations at lower costs. This led to high fragmentation in the Indian Pharmaceutical Industry due to the emergence of a number of small Indian firms.

Today the Indian Pharmaceutical Industry is in the front rank due to science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. A highly organized sector, the Indian Pharma Industry is estimated to be worth Rs.22401 crores, growing at about 7 per cent annually. Indian Pharma market is ranked 15th in the world\(^2\). It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously.

\(^2\) ORG – IMS, August 2005.
Indian Pharmaceutical is playing a key role in promoting and sustaining development in the vital field of medicines. And, it has excellent quality producers and many units approved by regulatory authorities in USA and UK. International companies associated with this sector have stimulated, assisted and spearheaded this dynamic development in the past 53 years and helped to put India on the pharmaceutical map of the globe.

Following the de-licensing of the pharmaceutical industry, industrial licensing for most of the drugs and pharmaceutical products has been done away with. Manufacturers are free to produce any drug duly approved by the Drug Control Authority. Technologically strong and totally self-reliant, the Pharmaceutical Industry in India has low costs of production, low R&D costs, innovative scientific manpower, strength of national laboratories and an increasing balance of trade. The Pharmaceutical Industry, with its rich scientific talents and research capabilities, supported by Intellectual Property Protection regime is well set to take on the international market.
(iii) Indian Pharmaceutical Industry Structure

The pharmaceutical industry is very aptly described as a “life-line” industry. It plays a vital role in alleviating the suffering of millions of people and controlling various ailments that afflict human beings. Recognizing this, the planners of Indian economic development after independence have rightly included this industry in the core sector.

Today, the industry is broadly classified into the Organized and Unorganized sectors.

(iv) Organized Sector

There are about 250 manufacturing and formulation units in the organized sector, which account for over 70 per cent of total sales. The organized sector can be classified into multinational companies and Indian companies on the basis of management control. The multinational corporations, which had dominated the industry till 1970, began to lose market share following the introduction of the Indian Patent Act (which did not recognize product patents). Consequently, the market share of Indian companies increased steadily from low levels of about 10 per cent in 1970
to over 62 per cent in the year 2000. The Multinational companies accounted for about 37 per cent of the Indian pharmaceutical market in the year 2000 and the balance was the share of the public sector\(^3\).

**(v) Unorganized Sector**

The unorganized sector is made up of over 20,000 manufacturing units, which contribute to about 30 per cent of total sales. Government policy as well as the regulatory framework has been the primary reason for this high level of fragmentation. The combined effect of the Indian Patents Act (1970) and the Drug Price Control Order of 1970 (DPCO) resulted in a highly fragmented industry structure. The lack of product patents enabled manufacturers to produce existing drugs through alternate processes, which required minimal capital investment, thus significantly reducing the entry barriers. Moreover, the small-scale units were exempted from Drug Price Control Order (DPCO) and payment of excise duty, which led to their further proliferation. In addition, the government provided several subsidies to small-scale units, which helped them in lowering their production cost. As a result, the large players in the organized sector started outsourcing their

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requirements from small-sized companies through loan-licensing arrangements, thus boosting their growth.

The pharmaceutical industry in India meets around 80 per cent of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectables. These 20,000 manufacturing units produce the complete range of pharmaceutical formulations, that is medicines ready for consumption by patients and about 350 bulk drugs, that is chemicals having therapeutic value and used for production of pharmaceutical formulations.

1.2.1 Geographical Location

With respect to location, the industry is geographically concentrated in four main states viz. Maharashtra, Gujarat, Andhra Pradesh and Tamil nadu. Maharashtra accounts for a majority of the formulations produced while Andhra Pradesh accounts for over 50 per cent of the total bulk drugs produced in India.

Geographical concentration is expected to continue over the next few years. This is mainly due to the existence of related infrastructure (such as
presence of chemical feedstock manufacturers) in these states. Also, Maharashtra is in close proximity with Gujarat and Andhra Pradesh, which facilitates easy transportation of bulk drugs to Maharashtra for the manufacture of formulations.

Currently the government policy is to promote the states like Utaranchal and Himachal by offering zero per cent excise duty for those, who manufacture their products at Utaranchal State. Because of this, most of the Pharmaceutical companies have been shifting their manufacturing units to Utaranchal to utilize zero per cent excise duty. All the pharmaceuticals companies are attracted by this state. Now Himachal and Utaranchal will have more manufacturing units of pharmaceuticals.

(i) Domestic Pharmaceutical Market

The Indian Pharmaceutical industry is currently in a state of flux with several trends emerging, which are changing the shape of the industry. Domestic players are pursuing various strategies to sustain their businesses by consolidating through mergers and acquisitions, introducing new products to hold their shrinking market shares and looking at alliances to further their growth.
More than 85 per cent of the formulation in the country is sold in the domestic market. India is largely self-sufficient to their domestic demand. However some life saving drugs and new generation drugs under patent formulation continue to be imported or marketed by Multinational companies in India.

**FIGURE 1.1**

**INDIAN PHARMACEUTICAL MARKET – THERAPEUTIC SEGMENT WISE AS ON AUGUST -2011**

Source: ORG-IMS, August 2011.
Moreover to protect their falling market shares, large pharma companies launched new products, which enjoy higher price-realizations compared to their aged substitutes. New product launches also helped companies diversify their existing product portfolio and realize higher margins by gaining entry into high-growth segments such as Cardiovascular, Diabetes, Central nerves system and Dermatology.

**TABLE 1.1**

**TOP 10 PHARMACEUTICAL COMPANIES IN INDIA**

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>IPM</th>
<th>Value (in crores)</th>
<th>Value (in Market Share %)</th>
<th>Value in Growth (%)</th>
<th>Volume in Growth (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total IPM</strong></td>
<td>22401</td>
<td>100</td>
<td>7</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Glaxosmithkline</td>
<td>1290</td>
<td>6</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>2.</td>
<td>Cipla</td>
<td>1153</td>
<td>5</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>3.</td>
<td>Ranbaxy</td>
<td>1043</td>
<td>5</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>4.</td>
<td>Nicholas Piramal</td>
<td>962</td>
<td>4</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>5.</td>
<td>Zydus Cadila</td>
<td>808</td>
<td>4</td>
<td>4</td>
<td>-1</td>
</tr>
<tr>
<td>6.</td>
<td>Dr. Reddys</td>
<td>780</td>
<td>3</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>7.</td>
<td>Sun Pharma</td>
<td>735</td>
<td>3</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>8.</td>
<td>Pfizer</td>
<td>610</td>
<td>3</td>
<td>0</td>
<td>-6</td>
</tr>
<tr>
<td>9.</td>
<td>Sanofi Aventis</td>
<td>566</td>
<td>3</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>10.</td>
<td>Alkem</td>
<td>563</td>
<td>3</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8512</td>
<td>38</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: ORG-IMS August 2011.

*Indian Pharmaceutical Markets.
From the above table, it is clear that Indian pharmaceutical market grew by 7 per cent in the terms of value growth and grew by 6 per cent in the terms of volume growth and surpassed 22,401 crores and Indian pharma market is ranked 15th in the world in the terms of value and occupy top 3 position in the world in the term of units consumption.

The 10 leading pharmaceutical companies in India are holding together 38 per cent of market share and value by Rs.8512 crores. In this Glaxosmithkline is at number one place in terms of sales and followed by Cipla with 8 per cent growth volume, Ranbaxy by 6 per cent growth volume and sales by Rs.1043 crores. Moreover Nicholas Pirama grew by 10 per cent and Sun Pharma grew by 13 per cent in term of value growth. Whereas Pfizer did not grow in term of value and volume wise degrew and improved by 6 per cent due to price change in certain products.

1.3 EXPORT AND IMPORT MARKET OF PHARMACEUTICAL PRODUCTS IN INDIA

At the time of Independence, there were no exports of pharmaceuticals from India. The total value of exports of pharmaceuticals was a mere Rs.3 crore in 1965-66. During the last few years, the Indian

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4CMARK-CPR-July-October-2005- Stiefel Corporate Over View.
Pharmaceutical Industry has achieved commendable progress on the export front. The industry’s total exports were valued at $ 3177.3 millions in the year 2004.

TABLE 1.2

VALUE OF EXPORTS AND IMPORTS OF DRUGS AND PHARMACEUTICALS IN INDIA

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Exports</th>
<th>Total Imports</th>
<th>Total Balance (Col 2 – Col 3)</th>
<th>Trade Balance as per cent of Exports</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999-2000</td>
<td>486.2</td>
<td>371.1</td>
<td>115.1</td>
<td>23.7</td>
</tr>
<tr>
<td>2000-01</td>
<td>567.9</td>
<td>459.1</td>
<td>108.8</td>
<td>19.2</td>
</tr>
<tr>
<td>2001-02</td>
<td>694.0</td>
<td>486.3</td>
<td>207.7</td>
<td>29.9</td>
</tr>
<tr>
<td>2002-03</td>
<td>698.7</td>
<td>558.1</td>
<td>140.5</td>
<td>20.1</td>
</tr>
<tr>
<td>2003-04</td>
<td>1152.1</td>
<td>664.2</td>
<td>487.9</td>
<td>42.3</td>
</tr>
<tr>
<td>2004-05</td>
<td>1458.1</td>
<td>729.5</td>
<td>728.6</td>
<td>50.0</td>
</tr>
<tr>
<td>2005-06</td>
<td>1462.3</td>
<td>724.3</td>
<td>738.0</td>
<td>50.5</td>
</tr>
<tr>
<td>2006-07</td>
<td>1668.5</td>
<td>346.6</td>
<td>1321.9</td>
<td>79.2</td>
</tr>
<tr>
<td>2007-08</td>
<td>1910.9</td>
<td>444.9</td>
<td>1466.0</td>
<td>76.7</td>
</tr>
<tr>
<td>2008-09</td>
<td>2196.6</td>
<td>541.2</td>
<td>1655.3</td>
<td>75.4</td>
</tr>
<tr>
<td>2009-10</td>
<td>2464.1</td>
<td>227.8</td>
<td>2236.3</td>
<td>90.8</td>
</tr>
<tr>
<td>2010-11</td>
<td>3177.3</td>
<td>686.7</td>
<td>2490.6</td>
<td>78.4</td>
</tr>
</tbody>
</table>

Source: IDMA, Annual Publication (various years) for export and import figures in rupees. These have been converted to $ figures by using the average exchange rates for the relevant financial years obtained from Reserve Bank of India, Handbook of Statistics on Indian Economy, 2010-11 (accessed from www.rbi.org.in). - The WTO and India’s Pharmaceuticals Industry by Sudip Chaudhuri Pulis: Oxford: 2011, p.45
Research and Development

With India becoming a signatory to WTO and TRIPS, the threat of product patents loomed large over the Indian industry. Very soon, it became evident that only those companies, which have a strong research orientation, can expect to stay competitive in the post-2011 era. Companies have realized the importance of research as the key future driver of growth and have started focusing on R&D. Some of the leading domestic players such as Ranbaxy Laboratories and Dr. Reddy's Laboratories have taken the first few successful steps by foraying into international markets and generating revenues from their existing R&D pipelines.

Currently, the average R&D expenditure by Indian Pharma Industry is around 2 per cent of the turnover as compared to global average of 15 per cent. However, this is changing rapidly and by 2011, R&D expenditure of major players is expected to touch 5 per cent of their turnover.\(^5\)

\(^5\) Pharma Pulse, December 2011.
New Product

The Indian Pharmaceutical market due to prevalent government policies and regulations have been fiercely competitive with a multitude of brands available for the same molecule. Companies are adopting various strategies to achieve their target growth rates and are actively looking at introduction of new products to stay ahead of competition. The last two years have witnessed a phenomenal increase in new product launches in the domestic market owing to various competitive pressures. In the year 2010-11 (Nov 10-Oct-10), Indian pharmaceutical industry have launched 12733 new products in just one year.
FIGURE 1.2
NEW PRODUCT LAUNCHES

The Indian pharmaceutical industry is therefore looking for further strengthening of their presence in the international markets. Companies like Ranbaxy have ensured that a better part of their revenue comes in from global operations. While generics still hold a significant promise of Indian companies globally, it is the pursuit of new molecule discoveries that will help to earn its rightful place in the world market. Given its highly skilled manpower and cost effectiveness, it looks like a distinct possibility. Rather, new chemical entity (NCE) research would be detrimental to companies' survival a few years hence\(^6\).

1.4 REVIEW OF LITERATURE

This section presents a review of literature on the past research studies and concepts used, thorough voluminous literature is available in these areas, only a few important related works are received here. Such a review would facilitate the researcher to have a comprehensive knowledge on the concepts and in earlier studies and enable researcher to adopt, modify and formulate an improved conceptual framework for the use of the present study and draw meaningful conclusions.

\(^6\) www.chemtech.com
According to Dr. Webber, “Because of Globalization, the world is drinking Colombian Coffee, using Japanese Cameras, driving American Cars, wearing clothes made in Asia and using Finnish mobile phones”\(^7\).

According to Dr. Suman Sahai “there is some reason to have consensus on the need to protect anything in the Patent Act that would impact on indigenous system of medicine”\(^8\).

According to Hoang Tran and Brian H. Kleiner “Globalization is inevitable in most industries, and the pharmaceutical industry is no exception. To expand product mix and enhance distribution channels as well as the marketing sales forces, pharmaceutical companies have found that acquiring international, smaller companies or merging with another pharmaceutical company is the best strategy to compete in the extreme rivalry between competitors.

In order to adapt to these new strategies, management needs to understand the cultures as well as the norms from the target countries to


successfully conduct acquisitions or mergers. Moreover, such operations require cultural change, restatement of goals and the mission statement, and proper motivation.

They further conclude saying that the pharmaceutical industry has many traits in common with other industries: however high capital investment in the long term, along with the associated high risks of research, requires focused decision making, the ability to produce high quality products to deliver to patients and comply with the government agencies and essential social welfare awareness in keeping with the nature of the business. Such qualities distinguish effective management in the pharmaceutical industry”9.

According to Ms. Anjana Kak, “In Pharmaceutical Industry the basic research and development decides the future of the organization. In her study both the organizations have core competence on the front of research and development. With the help of core competencies, the organizations are capable of achieving objectives and executing strategies effectively. The

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core competencies play an important during the technology acquisition, assimilation and implementation process. The study has provided an insight that core competence is responsible for generating a competitive advantage, which in turn leads to corporate success.\textsuperscript{10}

According to Dr. APJ Abdul Kalam, "India is suffering badly from loss and under-utilization of Intellectual Property Rights from Indian Research and Development effort. This is happening in every sector but is most prominent in Pharmaceutical and Biotechnology. Most of the newly discovered pharmaceutical molecules by the Indian R & D organizations and pharmaceutical industries were sold to multinationals abroad for further development into drugs, adding that the benefit of value addition goes to companies abroad. "On intellectual property rights (IPRs) Dr. Kalam said, that" in order to make sure that the country does not lose out on any of the IPR issues, it was necessary to properly document research work and to put in claims for patents at the right time."\textsuperscript{11}


\textsuperscript{11}Dr. APJ Abdul Kalam, \textit{India Daily}, Nov 19, 2004, p.3.
According to H.Richard Friman, “Globalization has influenced immigrant and other migrant participation in the drug distribution networks of advanced industrial countries, by opening new sources of supply, expanding potential niche markets and pipelines with home countries, as well as by facilitating linkages between migrants and organized groups based in their home countries. However the nature of migrant participation in the lucrative distribution networks for drugs within advanced industrial countries is not easily captured by marginalization arguments that posit a native/migrant ethnic division of labour. Nor is this participation easily captured by breakout arguments that posit a post-Taylorist empowerment of those on the margins by the forces of globalization.\footnote{H.Richard Friman, : “The Great Escape ? Globalization, immigrant Entrepreneurship and the Criminal Economy”, \textit{Review of International Political Economy}, Vol.11, No.1, February 2004, pp.98-131.}

According to Mary E Hunt, HIV/AIDS has changed from a disease of white gay men in the United States to a pandemic that largely involves women and dependant children in developing countries. Many theologies of disease are necessary to cope with the variety of expressions of this pandemic. Among the ethical issues that shape future useful conversations are globalized economics and resource sharing, the mortality and economics
of pharmaceutical Industry, and the need for sex education and access to reproductive choice\textsuperscript{13}.

According to Isabelle Schuiling and Giles Moss “The differences identified in the branding strategies between both industries are more linked to the fact that the Pharmaceutical Industry is several year’s behind FMCG in terms of brand development than to major structural differences. This shows that the Pharmaceutical Industry will benefit from a good understanding of the FMCG experience to guide future development successfully”\textsuperscript{14}.

Changes in the International Pharmaceutical Industry are being brought on by continued technological innovations and an increased dissemination of information. In the future, companies may get away from the development of blockbuster drugs for specific diseases. Instead, they may develop a series of smaller products for one ailment, each designed for people with a different genetic makeup. Human genome research is likely to


change the development time-frame for new drugs. As a result Pharmaceutical companies need to be in a position to launch new products in key markets faster in order to recoup R & D Costs sooner, and gain market leadership and brand name recognition. A thorough analysis of foreign markets and the use of conceptual framework for international market entry strategy may enhance the ability of pharmaceutical companies to capitalize on these new mark”15.

According to John Abraham, “The Pharmaceutical Industry has produced many drugs that have benefited man. Political frameworks designed to govern the industry must maintain these benefits. However regulation needs to be sufficiently robust to protect public health from drugs that are unsafe, ineffective, or unnecessary. He concludes the present drug regulatory systems are insufficiently robust in their political relations with the Pharmaceutical Industry, because they prevent proper public accountability, are highly vulnerable to industrial capture, and permit the Industries scientific experts to have extensive conflicts of interest while providing their expert advice. A regulatory system capable of delivery of

publicly defensible assessments, which are uncompromisingly in the interest of public health, is needed. First, all countries should move towards the public rights of access to regulatory information that exists in the USA. Second, regulatory agencies should identify a few key tests for each new drug application which their own scientists could undertake independently of the manufacturer. The cost of these studies would be borne by the companies, but the regulatory agencies would control, own, and publish the data. To avoid wasteful duplication of effort, the data could be passed to other regulatory agencies before publication. Third, the state should reassert some responsibility for funding regulatory review so that agencies do not have to compete with each other for industry fees to survive”\textsuperscript{16}.

According to C.R.Coile “Pharmaceutical Companies may launch 50 to 100 new drugs yearly, which is a 200 per cent to 400 per cent increase over the dozen new medications typically approved by the FDA. It is foreseen that more knowledgeable patients and Physicians might also

increase their demand for new genetic-based drugs and diagnostics (e.g. gene testing is growing at a 20 per cent)\textsuperscript{17}.

According to Terry Belcher and Lance Nail, “Integration Problems and turnaround strategies in a cross-border merger - A clinical examination of Pharmacia-Upjohn merger, concludes” with the increasing globalization brought about by consolidation, cross border mergers are growing increasingly popular as means of rapidly achieving size-related economies of scale and scope as well as global reach. However integration issues such as culture clashes, which are problematic in domestic mergers, are often more severe when the merging companies are headquartered in separate countries with widely differing social mores\textsuperscript{18}.

According to Rajshekr G. Javalgi and Robert F. Wright, “The global pharmaceutical market will continue to evolve and healthcare costs will continue to rise. The result will be increased pressure to have harmonization standards and mutual recognition agreements. The acceptance

\textsuperscript{17} C.R. Coile, “Impact of the New Science of Genomics”, \textit{Journal of Health Care Management}, Vol.46, No.6, November-December 2001, pp.365-368,

of international standards by governments will not only help to decrease rising healthcare costs, but will also enhance pharmaceutical companies abilities to globally brand and market products.

The three strategic decisions which pharmaceutical companies need to evaluate are:

1. Foreign Market Analysis
2. Consumer and Governmental Obstacles
3. The method of Market Entry.

The conceptual framework for international pharmaceutical market entry and the market analysis model may help companies to evaluate both the obstacles to foreign market entry and the various methods of market entry, prior to deciding to enter the market. Currently pharmaceutical companies appear to be rushing to position themselves, whether through mergers and acquisitions or by establishing joint ventures, to take advantage of the rapidly changing international market place, without a thorough analysis and consideration of the long term consequences of these strategic decisions.
According to S.V.R. Subba Rao, “The relationship between patent protection and the Pharmaceutical Industry is closest and most direct in Research and Development”\textsuperscript{19}.

1.5 STATEMENT OF THE PROBLEM

Since relationship marketing is seen as the new marketing paradigm, it is imperative to gain an understanding of how physicians perceive the pharmaceutical sales representative and what components impact those perceptions. If there are certain characteristics, that will improve a representative's chances of being effective in the physician's office, then it is critical that pharmaceutical companies develop the means by which to install this characteristic in their sales people. With the implementation of new Pharmaceuticals Research and Manufacturers of America (PhRMA) gift giving guidelines in USA and the number of field forces growing day by day in INDIA and more competitions among pharma companies, reduce the Physicians' interview time with field forces drastically, leading to pharmaceutical field force not able to build a good rapport with their physicians. In this context, pharmaceutical companies have been adapting a

\textsuperscript{19}S.V.R. Subba Rao, “Game Plans for Post Gatt Era”, p.147.
lot of marketing strategies to build a good relationship with physicians. However still they are finding a lot of difficulties to understand which factors really influence physician (according to their potential) to have relationship with pharma companies. If any pharma companies are not able to build the relationship with the physician, they are not able to communicate the worth goodness of their product as well as scientific benefits to the physicians which results in good products and good scientific advancement benefits failing to reach the patient community. Thereby the entire human society will suffer. So it will be more critical than ever for pharmaceutical companies who continue to use sales representatives, to focus on how these representatives are perceived in the physician's office. Research in this area is needed so that perspective guidelines for pharmaceutical companies can be developed in the areas of ethics training, hiring practices, image management and corporate communications and marketing strategies to the physician community. In addition, research into how corporate and personal values impact physician's perceptions of pharmaceutical companies, may provide these companies with a sustainable competitive advantage.
Relationship marketing is commonly seen as a fundamentally new paradigm of the function and role of marketing. It is one of the prime drivers of sales in the pharmaceutical industry. These relationships can be understood to exist between the organization and other firms and stakeholders. Consequently, it is important to determine how physicians perceive pharmaceutical sales representatives, relationship marketing is the focus of marketing activities on establishing, developing and maintaining co-operative, long-term relationships, sales people play a key role in the formation of long-term buyer seller relationships especially in those that have close, interactive dynamic interfaces. In this study, the researcher has made an attempt to assess the role of medical representatives in co-ordinating company, wholesalers, doctors and pharmacies.
1.6 OBJECTIVE OF THE STUDY

The specific objectives are:

(i) To explore the relationship marketing in terms of doctors and medical representatives with pharmaceutical company.

(ii) To measure and compare dimension-wise Doctors and Medical representatives perceptions on relationship with pharmaceuticals company;

(iii) To identify the factors which influence the relationship between Doctors and pharmaceuticals company;

(iv) To examine the relationship between characteristic features of Medical representatives and their perception level;

(v) To identify the factors which influence the Doctors relationship in the view of Medical Representatives; and

(vi) To offer suitable suggestions based on the findings of the study.


1.7 METHODOLOGY

The study is an empirical study based on survey method. Both primary and secondary data have been used in this study. Primary data have been collected from the Medical representatives and Doctors in Tamil Nadu with the help of an interview schedule. Secondary data have been collected from the books, reports and Journals.

Construction Tools

A structural interview schedule has been used to collect primary data from the selected Medical representatives and Doctors (vide Appendix 1 and Appendix 2). Based on the previous studies and in consultation with experts, a comprehensive list of all possible variable and perception factors are identified, distributed to the experts both academicians, physicians and managers in pharma industry. Based upon the suggestions, 46 perception factors under seven dimensions have been identified by the researcher. The interview schedule is pre-tested with 30 Medical representatives and 30 Doctors. In the light of the experience gained by the researcher, two
different interview schedules for Medical representatives and Doctors respectively are prepared and improved.

**Sample Design**

For the purpose of selecting 300 Medical representatives for the present study from five important district headquarters namely Chennai, Coimbatore, Madurai, Salem and Trichy, simple random sampling technique has been adopted. Equal weightage was given for each district (60 respondents in each district) for selecting medical representatives. For the purpose of analysis, 300 respondents were post-stratified into three categories namely top volume sales, high volume sales and medium volume sales based on their sales during survey period. Total of 250 sample Doctors, 50 each from five districts, sample doctors were post stratified into three categories namely, Top Volume Contributor, High Volume Contributor and Medium Volume Contributor. Doctors who are having 50 patients and above per day were grouped as Top volume contributor; those who are having 20 to 49 patients per day were classified as High volume contributor and those who are having less than 20 were termed as Medium volume contributor.
**Period of Study**

The survey was conducted during the period from August 2010 to July 2011. The reference period of the survey refers to 2010-2011.

**Frame work of Analysis**

Perception on doctors relationship with pharma company has been measured with the help of 46 statements. The scoring of perception level is based upon 'Likert method', to secure the total perception score of doctors and Medical representatives. Five points are given for 'Always', four for 'frequently', three points for 'some times', two points for 'Rarely' and one points for 'Never' response. Thus the total perception score of respondents was obtained by adding up the score of all the 46 statements.

The dimension-wise comparison of doctors relationship among doctors and Medical representatives, spearman's Rank correlation co-efficient has been computed by using the formula

\[
\rho = 1 - \frac{6 \sum d^2}{N (N^2 - 1)}
\]
In order to examine the relationship between the characteristics of physicians and volume of contributors, Chi-Square test has been employed. It is calculated by adopting the following formula:

\[
\text{Chi-Square } (\chi^2) = \sum \frac{(O - E)^2}{E} \quad \text{with } (r-1)(c-1) \text{ degrees of freedom}
\]

where

\( O = \) Observed frequency
\( E = \) Expected frequency
\( E = \) Row Total \times Column total / Grand total
\( c = \) Number of columns
\( r = \) Number of Rows

The calculated value of chi-square is compared with the table value of chi-square for a given degrees of freedom at 5 per cent levels of significance. If at the stated level, calculated value (C.V) is greater than the table value (T.V), there is a relationship between the attributors. Otherwise it is rejected.

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The technique adopted to identify and analyse the important factors on the Doctors relationship with Medical representatives and pharma industry is Factor Analysis. The principal factor analysis method is mathematically satisfying because it yields a mathematically unique solution to a factor problem. Its major solution feature is the extraction of maximum amount of variation as each factor is calculated. In other words, the first extracts the most variance and so on.

Most of the analytic methods produce results in a form that is difficult or impossible to interpret. Thurstone argued that it was necessary to rotate factor matrices if one wanted to interpret them adequately.

He pointed out that original factor matrices are arbitrary in the sense that an infinite number of reference frames (axes) can be found to reproduce any given 'R' matrix.

In order to move the axes from the arbitrary location determined by the method of extraction to some position useful for interpretation of the factors for comparison with other studies, the axes are rotated. A major goal of rotation is to obtain meaningful factors that are as consistent as possible from analysis to analysis.
There are several methods available for factor analysis. But the principal factor method with orthogonal varimax rotation is mostly used and widely available in factor analysis computer programme.

Further orthogonal rotations maintain the independence of factors, that is, the angles between the axes are kept at 90 degrees. One of the final outcomes of a factor analysis is called Rotated Factor Matrix, a table of coefficients that express the ratios between the variable and the factors have been prepared. The sum of squares of the factor loadings of variable is called communalities ($h^2$).

The communality of a factor is its common factor variance. The factors with factor loadings of 0.50 or greater are consider as significant factors. This limit is chosen because it had been judged that factors with less than 50 per cent common variation with the rotated factor pattern are too weak to report.

In the present study, principal factor analysis method with Orthogonal Varimax Rotation is used to identify the significant set of quality system factors.
Factor Analysis used to condense and analyse medical representatives perception on doctors relationship with pharma company. The principal factor method with orthogonal varimax rotation is mostly used and widely available in factor analytic computer programme. One of the final outcomes of factor analysis is called Rotated factor matrix, a table of co-efficients that express the ratios between the perception variables and the underlying factors. The perception variables with factor loading of 0.50 or greater are considered as significant factors.

1.8 LIMITATIONS

1. This study was done only for Tamil Nadu which cannot be generalized for all segments.

2. Primary data collection is confined to a particular point of time that is one year from Sep-2010 to Aug 2011.

3. In order to avoid bias responses, cross check has been carried out.

4. The study was conducted only in Tamil Nadu and it cannot be generalized in all over India.
1.9 SCHEME OF WORK

A report of the present work on “A STUDY ON THE ROLE OF MEDICAL REPRESENTATIVES IN CO-ORDINATING WITH THE COMPANY, WHOLESALERS, DOCTORS AND PHARMACIES” has been organized and presented in six chapters. They are:

Chapter I introduces the subject, Indian pharmaceutical industry, Export and import market of pharmaceutical products in India, review of literature, statement of the problem, objective of the study, methodology, limitations and scheme of work.

Chapter II presents the origin of the Indian pharmaceutical industry and general scenario of Abroad pharmaceutical industry.

Chapter III discusses the relationship marketing, organizational prospective from the doctors, doctors prospective from the pharmaceutical company, relationship between medical representatives and doctors, relationship between senior managers and doctors, and dimension-wise comparison between doctors and medical representatives.
Chapter IV identifies the factors influencing the doctors relationship with pharma industry. Further, it examines the relationship between the characteristic of medical representatives and volume of sales.

Chapter V discusses the role of medical representatives to promote doctors relationship with pharma industry. Further, it identifies the perception of medical representatives on doctors relationship.

Chapter VI presents a summary of findings along with conclusion and suggestions and scope for further research.