International Journal of Scientific Research & Engineering Trends
Volume 7, Issue 1, Jan-Feb-2021, ISSN (Online): 2395-566X

Literature Review on Pharmaceutical Industry in India Comparison of Post Reform and Pre Reform Period and Policy

Ph.D. Scholar Vinod Kumar Gupta, Professor Dr. Rajesh Gupta
Sai Nath University, Ranchi

***Abstract*- The extant literature dealing with the impact of TRIPS agreement on Indian pharmaceutical industry takes the whole country as a unit of analysis, but the present study is unique in the sense that it takes into account the regional aspects of Indian pharmaceutical industry, based on various reports and unit-level data of Annual Survey of Industries since 1991 to 2011. In the year 2005, Indian pharmaceutical industry came under the obligation of Trade-Related Aspects of Intellectual Property Rights (TRIPS); Simultaneously, Indian pharmaceutical firms were also required to comply with Good Manufacturing Practices of World Health Organisation (WHO-GMP). The descriptive evidences depicted that with the introduction of TRIPS and WHO-GMP number of firms and man-days employed declined across the states during the introductory period of TRIPS; whereas net value added and gross capital formation remained constant for the same period. But in the post-TRIPS period most of the states reported greater performance, especially in terms of net value added and gross capital formation.**

***Keywords*- Pharmaceuticals, TRIPS, WHO-GMP, Growth Rates, Stakes, States.**

I.INTRODUCTION

Indian pharmaceutical industry is a knowledge based industry, emerged as one of the major producers of drugs across the world over the period of time. Indian pharma ceutical industry occu-pies a significant place in the international pharmaceutical market, standing at third and fourteenth place in terms of volume and value,the differ ence between value and volume, attributes to its low cost of production in India ranging from 5 to 50 per cent lesser to the developed countries (OPPI, 2012). Indian pharma ceutical industry has a transforming history, renovated from multinational corporations (MNCs) dominated indus try to the net exporting industry.

Before 1970, this industry was dominated by MNCs and those MNCs were mainly engaged in the production of formulations with the hell of imported bulk drugs and other inter-mediate products from their home countries (Lalitha, 2002; Kumar & Pradhan,2003;Joseph,2012). The dominant role played by MNCs before 1970, was compl etely unfavorable for the existence of Indian pharma ceutical industry, because the manufacturing of formul ation does not require many plants for production, research and development (R&D) and much capital investment. This was the reason that before 1970 the industry was not having many units of pharmaceuticals and low level of R&D activities (Chaudhuri, 1997).

In order to improve the state of Indian pharmaceutical industry, Indian government effected many policies during 1970s, viz.,Monopoly Restricted Trade Practices Act (MR TP,1969),Foreign Exchange Regulation Act(FERA, 1973), New Drugs Policy(NDP,1978, 1986) and most importantly the amendment of Patent Act (1911) in the year 1970. In 1990s,Indian pharmaceutical industry had been grown continuously,where domestic firms dominated the industry due to their stronger capabilityties in process development. For instance, in1991 domestic firms accounted between 70 and 80 per cent market shares in the case of bulk drugs and formulation, respectively(Lanjouw,1998).

The process patent regime led to the technological change in the Indian pharmaceutical industry through improve ment in production process,raw materials and intermediate inputs.Starting of the twenty first century witnessed a change in patent regime, where the product patent regime was re-introduced. Now,Indian pharmaceutical firms are required to invest more in R & D so that they could compete with their foreign competitors. This trend is visible for Indian firms as some of them have taken steps to improve R&D intensity and developing new molecules. While some firms decided to pursue joint R&D with foreign firms or entering into contract manufacture-ring (Pradhan, 2006).

Indian pharmaceutical industry faced a wide range of policy changes which have been conducive to the industry. Over the period of time, Indian pharmaceutical companies have been producing a large amount of formulation and bulk drugs and the industry is growing at a good pace due to the policies adopted by Indian government (Lalitha, 2002; Jha, 2007).

© 2021 IJSRET

Indian pharmaceutical industry like other industries in India has concentrated in few states namely, Maharashtra, Gujarat, Andhra Pradesh, and Tamil Nadu. These states have been the major sources behind the growth of Indian pharmaceutical industry over the last few decades. Apart from these well-established states, there are other states viz. Himachal Pradesh and Uttarakhand, emerging as the new sources of the growth of Indian pharmaceutical industry during the last decade.

Indian pharmaceutical industry has grown at a rapid pace after the introduction of economic reforms by Indian government (Joseph, 2012). The growth rates achieved by Indian pharmaceutical industry either in terms of number of factories, output, profitability or employment are positively affected by the economic reforms in India. Due to the introduction of economic reforms, firms get benefited indirectly from competitive pressure and directly through access to funds and outsourcing activities. But this does not ensure that these reforms would have affected all the regions in same fashion to the regional pharmaceutical industry. This is very likely, that different regions of India should have respond differently to the economic reforms and did not contribute to the growth story of Indian pharmaceutical industry.So,this becomes a great matter of concern whether, all the regions contributed equally to the growth of Indian pharmaceutical industry or has it been contributed by few regions and states? Whether dominated regions/states maintained consistent growth? Is there any regional transformation? The next section of the study deals with the policy aspect related to pharmaceutical industry, while the third section deals with the data issues and methodology. The fourth section deals with the trends and pattern by different states of India; whereas fifth section deals with the Theoretical background and sixth section reveals policy implication drawn from the study and last section concludes the study.

1.Indian Pharmaceutical Industry and Policy Regimes:
The 1970s has witnessed wide changes in Indian policies to trim down the role of dominant foreign firms and to increase the participation of domestic firms in the Indian pharmaceutical industry, these policies/Acts were MRTP (1969), FERA (1973), NDP (1978, 1986) and most impo rtantly the amendment of Patent Act (1911) in the year 1970.The MRTP act was aimed to reduce the concen tration power of few firms in an Industry. This policy was formulated to increase the competition in industrial sector and to increase the participation rate of medium and small firms.

Similarly, FERA was introduced to reduce the equity participation rate of foreign firms in India. It was laid down in Section-29 that FERA companies, i.e., foreign companies with an equity holding of more than 40 per cent and engaged in the production of only formulation products or bulk drugs not involving 'high-technology', should reduce their equity holding to 40 per cent or below.

The NDP was introduced in 1978 and the main aim of this policy was to promote the domestic production of drugs from the very basic stages.

Apart from these policies Government of India in the year 1970, introduced the process patent regime through the Patent Act(1970),where only the process of manufacturing of drug was protected. This Act was based on preferential policy treatment of Indian firms and adaptation of process patent regime. This has contributed to significant accumulation of domestic skills in cost effective process development and rapid growth of the industry during 1980s;domestic enterprises based on large-scale reverse-engineering and process innova-tion achieved near self-sufficiency in the technology and production of bulk drugs belonging to several major therapeutic groups and devel oped manufacturing facilities for all dosage forms like tablets, capsules, liquids, orals and injectables (Pradhan, 2010).

The era of 1990s witnessed a historical reform period in Indian economy,where liberalization, privatization and globalisation were widely accepted. The introduction of economic reforms in India during 1990s allowed Indian pharmaceutical firms to participate in the international market without much restriction,as a result higher numbers of firms entered the export market over the last two decades. The openness of economy during 1990s through economic reform and specially the trade policy reforms intensified the growth of export of Indian pharmaceutical firms (Joseph, 2012).

Economic reforms in India, on the one hand, forced Indian pharmaceutical firms to participate in export market due to globalization; on the other hand,policies were also formulated to help Indian firms in the process of internatio nalization.

In mid-1990s,a new institution called,World Trade Organ isation(WTO) was established to deal with the world trade in a more formal fashion, replacing the earlier informal institution General Agreement on Trade and Tariff (GATT). WTO brought in many new rules and regulations related to the protection of innovation and invention in the spheres of intellectual property rights. India as a founder member of WTO and signatory to Trade-Related Intellect ual Property Rights (TRIPS) had to amend the existing patent laws to comply with TRIPS.

In respect to the Patent Act (1970), three amendments had been carried out by Indian Government in the span of six years viz. March 1999, June 2002 and April 2005. The TRIPS agreement came into force to provide a protective environment to the innovation and invention, with the help of product patent regime. The TRIPS agreement states clearly, that the patent will be granted to any inventions either product, process or involve an inventive step and it must be capable of industrial application. The duration of

© 2021 IJSRET

patent was also increased to 20 years from the date of application. This product patent regime has significant implications for the developing countries, especially for India. In India there are mix kinds of opinions about the implications of product patent regime on the growth of Indian pharmaceuticscal industry. Some of the experts believed that the introduction of product patent will bring the foreign firms directly in competition with domestic firms, which might lead to the closure of many small pharmaceutical units, affecting growth of Indian pharma ceutical industry adversely in respect of out-put, employ ment etc.

On the other hand, some of the economists speculated that the introduction of product patent will increase the R&D expenditure, bring in new investment, innovation and drugs in the Indian market. Recently, the trends of the Contract Research and Manufacturing Services (CRAMS) have been increasing in Indian pharmaceutical industry. In addition to this, the number of merger and acquisition of Indian pharmaceutical industry has also been increased; many Indian pharmaceutical firms are being taken over by the foreign firms over the last few years, e.g. Ranbaxy Laboratories was taken over by Daiichi Sankyo Co. Ltd. of Japan in 2008, similarly, Shanta Bio-tech, Dabur Pharma, and Paras Pharmaceuticals etc.,were taken over by different foreign firms.

The quality of manufacturing practices in Indian pharma ceutical industry has always been a matter of concern. In India, The Drugs and Cosmetics Act, (1940) and Rules, (1945) regulates the drug regulatory affairs. This act and rules have been amended from time to time in India to comply with the standard manufacturing practices across the globe. In December 2001, the Schedule M of the rules has amended to comply with the Good Manufacturing Practices of World Health Organisation (WHO-GMP).

Hence, those firms which are unable to comply with the WHO-GMP are not allowed to get license from State Drug Control Administration. While, if the established firms fail to comply with WHO-GMP their license will be repealed and will be discontinued from the manufacture-ring of drugs and medicines. With the introduction of WHO-GMP,many pharmaceutical firms upgraded their manufa cturing practices. Still, there were some small firms, failed to upgrade their manufacturing practices due to the inadequate funds (to comply with the WHO-GMP, firms are requi-red more than 2.5 crores). Apart from inadequate funds, many firms were also afraid of losing their MSME status, as the investment limit of SSI at that time was1 crore.

As a result many units were closed down in various states and more importantly the dominant regions, Maharashtra, Gujarat and Andhra Pradesh witnessed a large number of closures of pharmaceutical units. So the present study is an attempt in the con-text of examining the growth of Indian pharmaceutical industry at regional and state level keeping the above policies into consideration.

II. PHASES OF POLICY CHANGES

Evolution of Indian pharmaceutical industry has been categorized into three: Phases after the 1990s based on the changing patent regime in India, shown in Box-1. The first phase covers two periods viz., 1991-95 and 1996-00, these two periodsof Indian pharmaceutical industry were mainly governed under the process patent regime i.e. pre-TRIPS phases. The second phase cover the period of 2001-05, this was the period when the introduction of patent regime was under process in India (product patent regime in India was introduced during the period of March 1999 to April 2005) i.e.introducing-TRIPS phase.The third phase cover the period of 2006-11when the product patent regime was completely introduced in India, i.e. post-TRIPS phase.

1. Methodology and Data Issues:

To reveal the growth of Indian pharmaceutical industry at regional/state level simple annual average growth rates have been calculated. In case of Net Value Added (NVA) growth rates are calculated from the constant values derived from the whole sale price index of drugs and pharmaceutical products.The growth picture of Indian pharma-ceutical industry at state/regional level is shown, basically in the three periods of time viz. pre-TRIPS, intro ducing-TRIPS post-TRIPS.

Table 1. Categorization of Time Periods Based on Patent Regime.

Phases	Time Periods	Patent Regimes
Pre-TRIPS	1991-1995 and 1996-2000	Process patent
Introducing-TRIPS	2001-2005	Introducing product patent
Post-TRIPS	2006-2011	Product patent

The proposed study is based on secondary data. The principle source of data is the Annual Survey of Industries (ASI) released by Central Statistical Organization (CSO), under the Ministry of Statistics and Programmed Impleme ntation, from where the data on Indian pharmaceutical industry (Manufacture of Pharmaceuticals, Medicinal Che micals and Botanical Products) is taken. The present study also deals with the Unit-level data during the period of 1998-99 to 2007-08, because of non-availability of publi shed data at state level, during the same period. Data has been taken at three digit level on the basis of NIC-1987 code i.e. 304 during the period of 1991-92 to 1997-98 and

© 2021 IJSRET

at four digit level according to the NIC-2008 code i.e. 2100 during the period of 2008-09 to 2010-11.

2. Trends and Patterns by Indian States:

India is a country with various sub-national entities, where huge disparities existing terms of various economic indicators such as, income, output employment and manu facturing units, over the period of time. Similarly, most of the manufacturing activities in India have concentrated in few states namely, Maharashtra, Gujarat, Andhra Pradesh, and Tamil Naduetc.,due to favorable business environment in the res pective states and positive complementarities provided through different policy reforms by Indian government. So it is very likely that Indian pharmaceutical industry concen trates in few states of India and responded differently to the various policy reforms in India.

3.Regional Trends and Patterns of Pharmaceutical Units:

The trends in Indian pharmaceutical industry at national, regional and state level has responded quickly to the changes in patent regimes. Table-1 reveals that the number of Indian pharmaceutical firms have increased by two times during the last two decades, with the constant numbers of firms during the period of introducing-TRIPS. This phenomenon can be explained by the annual average growth rates(AAGR) calculated for the respective periods. reveals that during the period of 2002-06 Indian pharma ceutical firms reported almost zero per cent growth rates; whereas, during the period of 1992-01 (pre-TRIPS) and 2007-11 (post-TRIPS) phases Indian pharmaceutical ind ustry had reported significantly higher

AAGRs in terms of number firms. Indian pharmaceutical industry by majority of states had also remained sluggish during the introducing-TRIPS phase and grown significantly in the pre-TRIPS and post-TRIPS phases. But there were some exceptional states which have grown significantly during the introducing-TRIPS phase and some states which were neither grown in introducing-TRIPS phase nor in the post-TRIPS phase. The states which have shown healthy growth rates during 2002-06 were Uttarakhand, Himachal Pradesh, Jammu and Kash mir (J&K), Pondicherry, Chandigarh, Daman and Tamil Nadu in terms of number of units.

The states of Himachal Pradesh and Uttarakhand reported higher AAGRs due to the concessions and incentives provided by central government in the year 2003 i.e. 'New Industrial Policy and other concessions for the state of Uttaranchal and the state of Himachal Pradesh.' Tamil Nadu has reported healthy AAGR during the introducing-TRIPS period, due to the conducive business environment and conducive government policies by the state gover nment.

Gujarat and Maharashtra are the two most dominated states of every time have reported very marginal or even negative growth rates in the last two periods (viz. 2002-06 and2007-11); despite witnessing the AAGRs of around ten and above ten in the early two periods (viz. 1992-96 and 1997-01).The declining growth rates in the states of Maharashtra and Gujarat were reported due to the closure of many small units in these states; as those small units could not complied with WHO-GMP.As a result the shares of these states declined drastically during the post-TRIPS period. Other major states and union territories like, Andhra Pradesh,Karnataka,Kerala,Uttar Pradesh and Delhi revealed the trends similar to India, i.e. lower AAGRs during the period of 2002-06 and higher in pre-TRIPS and post-TRIPS periods. Indian pharmaceutical industry was dominated by the West and South India before the introduction of TRIPS agreement, but after TRIPS North India has also emerged as a new hub for Indian pharma ceutical industry.The negative impact of TRIPS agreement can be clearly seen in the West that in the post-TRIPS period, most of the states have reported high investment per unit, implying to compete with the large foreign enterprises and domestic firms started making huge amount of investment.

This phenomenon also reveals that only inefficient and financially weak firms were shut down across the states after the introduction of TRIPS and WHO-GMP.Indian region, as this region reported a declining share by five percentage points in the

III. THEORETICAL BACKGROUND

The phenomena of industrial districts, agglomeration, and concentration etc., have long been studied in the industrial and regional economics. These theories explain that how a region becomes the suitable location for higher number of firms, belonging to the same industry; and how the firms of the same industry leave the region either in search of profit or serving the different regions. These two opposite forces are called 'centripetal and centrifugal forces.' If the centripetal forces are vigorous enough to offset the centrif ugal forces,region will be subjected to the agglomeration economies.

Marshall(1920) propounded the concept of industrial district,explaining that how few regions become the specialized producers or suppliers of few goods,even with out having the advantageous of specific natural resou rces.The concentration in a particular region starts due to some historical

Events in the past, when firms follow the existing located firms in a region(Scott,1988;Becattini,1992). The new eco nomic geographical literature propounded by Krugman(19 91)explained the emergence of large-scale economies in a region with the help of increasing returns and trans portat ion cost.In the new economic geographical literature, low transportation cost and increasing returns play the role as centripetal forces;whereas the increasing landrents, prices,

© 2021 IJSRET

congestion and incentives provided by other regions play the role of centrifugal forces.Before the literature of new economic geography there were many economists explain ed the concentration of specialized firms in a region on the one hand, and leaving a concentrated region on the other.

These include Ohlin(1933),explaining the role of trans portation cost and other factors in determining the concent ration of firms in a region; Hoover (1948), the interaction of different firms and industries determine the pattern of location in different regions; Hirschman (1963), backward and forward linkages play the vital role in concentration of firms in a region; Myrdal (1957), backwash effects lead to the locational advantageous due to the concentration of quality labour in a region.

IV. POLICY IMPLICATIONS

Introduction of TRIPS agreement in the year 2005 brought in the regime of product patent, now the reverse engineering is no more allowed in India to produce the generic drugs. Numbers of papers dealt with the positive and negative impacts of TRIPS on Indian pharmaceutical industry, majority of them revealed that the introduction of TRIPS did not affect much to this industry. The present study also revealed that the implementation of product patent did not affect pharmaceutical industry at national level in terms of units, employment and value added, but the industry at regional and state level was not free of shocks created by amendment of the Patent Act in the year 2005. The two most dominated states namely, Maharashtra and Gujarat are affected adversely in terms of number of units and employment in pharmaceuticals, as the highest number of closure has been reported in these two states due to inability of firms to comply with the WHO-GMP.

On the other hand, the states of Himachal Pradesh and Uttarakhand reported drastic improvement in terms of number of units, employment and value added, during the period of 2005-11, due to the introduction of 'New Industrial Policy' and other concessions for the state of Uttaranchal and the state of Himachal Pradesh' in the year 2003.

1. Marketing strategy for the Indian pharmaceutical market:

What distinguishes drug marketing is the interaction with the end customer (patient) through the intermediary client (the doctor who advises the end customer through the medication). The U.S. pharmaceutical industry has spent $15.7 billion promoting its products through literature, magazine advertisements, samples and DTC ads, accoun ting for about 14% of of all income. Approximately 50% of the total expenditure is spent on promotional activities through medical representatives. (Krishnaphani Kesiraju, 2003). This is the most common way of promoting drugs. But in India, the sale of drugs through the media is not possible, which is not suitable for many products in any situation. A conversation with a doctor is common. For this purpose, the pharmaceutical company needs more field workers to meet regularly with existing and existing customers and to promote the company's products. As a result, local business representatives have become the main link between companies and doctors, and are often referred to as "ambassadors" of companies in this field. The distribution network of pharmaceutical companies is organized by region or product. Often the entire market is divided into different.

Areas designated by agents/dealers/distributorsand dealers. However, sometimes as a precautionary measure, compan ies will assign agents / distributors / distributors to each product category to cover multiple areas. For companies with limited products, the second strategy is appropriate. Distribution networks support network marketing through a centralized/C & F interface covering the entire market.

Marketing of medicines includes marketing of raw materials and preparations. The sale of APIs is completely different from the sale of preparations. For bulk medicine, the number of buyers is small and the manufacturer establishes and maintains a good relationship with some of the customers he regularly supplies. In terms of marketing formulas, the company needs to have a network of trained medical representatives to sell its products.Moreover, beca use of the market. Recipes are very diverse and brand choices should be made. This makes API trading relatively simple compared to design marketing.(Krishnaphani Kesi raju, 2003).

Traditional marketing methods combined with customized strategies for non physicians and patient segregation provide excellent barriers to product delivery and mark eting. However, the downside depends on a series of ongoing events, i.e. the company expands its sales mix to a specific audience and distributes resources based on attracting these viewers or expecting to respond accordi ngly. these attendees are expected. The problem is that the results often do not go according to plan

In today's complex trading world, wise business decisions require a complete understanding of market issues. Before launching a new product it is necessary to evaluate the product concept, analyze the potential market, analyze the use of the product and placement strategy, while Indian companies need to develop and improve competition with through innovation and strong marketing responsibility. Compared to the new marketing methods of Western pharmaceutical companies, now is the time for Indian oil companies to gather better intelligence, predict the market (including the results of each market segment in new drugs), and to design, quantify and evaluate the impact of various marketing strategies. All of these initiatives allow companies to decide which marketing tools will be deployed and where resources will be distributed before they begin. (Krishnaphani Kesiraju, 2003).

© 2021 IJSRET

India's pharmaceutical industry enjoys 70% of the co untry's demand for Hulk drugs, pharmaceutical inter mediates, pharmaceutical preparations, chemicals, tablets, capsules, oral and oral contraceptives. There are about 250 large sizes and 8,000 seals of small seals, which are central to the Indian pharmaceutical industry (including the5 middle sector bodies). These components can be fully productive the preparation of medicines, that is, medicines for patients to eat and about 350 ingredients, i.e. chemicals with healthy values, is used to make medicines. (Drugs and manufacturers) The regulatory framework has played an important role in the competitive environment of the Indian pharmaceutical industry. The WTO TRIPS solution will be implemented gradually in developing countries in 2005 and will be implemented gradually in developing countries by 2015. This agreement gives Indian companies legal rights. to sell standard and patented drugs. The table above shows Indian companies, such as C'ipla. Ranbaxv, Lupine, etc. are the most expensive producers, and they see the potential as driver growth.

Most home-based businesses have started investing heavily in research and development. Some Indian education companies with strong R&D time may be able to produce new products to increase profits. According to traditional methods, the main reasons for the success of the pharmaceutical industry are the reverse engineering and low production. Various forces have changed the Indian industrial trade dynamics. The WTO solution in TRIPS provides a patented product system, which was implemented in the process in 2005. Implemented in 2015 in developing and underdeveloped countries.

An amendment to another patent was passed in 2002, which gave Indian companies the legal right to sell medicines in general to poor countries / regions after 2005. The spread among those was rapid. these are countries, and profits are expected to be very low. The sound will be loudnCheck the income of Indian companies. Indian companies such as Cipla, Aurobindo, Lupine, etc. It has been approved by the USFDA and is the most expensive manufacturer. But, most home-based businesses have started investing heavily in R and D, and that is an increase of $ 2.2 billion. Rupees (1997-98) to 75 billion rupees. (2002-2003). It is estimated to rise to 15 billion rupees. (Kaushesh Anshul 2003)

Indian companies are testing new companies (NCEs) at all stages of the clinic. Some well-known Indian companies are focusing more on the research and development of the 1MCE New Drug Delivery System (NDDS). Some Indian companies with strong R&D time may be able to produce new products, so that they can increase profits and profits. Indian companies have also done more tactical research.

2. Target of drug market:

Although facts have proven that DPCO (1970) and 1PA (1970) are not good for multinational companies and allow domestic companies to grow under government protection, the new policy recommends only controlling the prices of medicines with a high concentration of market power. The government has opened 100% of foreign-funded pharma ceutical companies through automatic approval. 100% fore ign participation will increase India's opportunities for technology transfer from pharmaceutical multinational companies (Anshul Kaushesh, 2003).Another advantage is that India can automatically approve foreign direct investment. This policy can stimulate the investment of multinational companies in establishing cheap research bases in the country.

To consolidate their position, Indian companies are increasingly considering merger and acquisition options for companies or products. This will help compensate for the loss of new product opportunities, thereby improving its research and development efforts, improving its product portfolio and improving its distribution coverage to cover markets with greater geographic coverage. India is not only a huge market for infectious drugs and vaccines but is also becoming a market for lifestyle diseases. The growth of traditional therapies (such as antibiotics) has stagnated and competition is increasing. The price war is so fierce that the company began promoting unlabeled formulas to its own brand formulas to achieve growth. (Kaushesh Anshul 2003)

Therefore, in the last few years, companies have been paying more and more attention to lifestyle areas such as cardiovascular, antidiabetic and ulcer. Therefore, the devel opment in these areas is very fast. Therefore, most companies have very high potentials.Afraid to launch products in these market segments. The future growth of domestic sales will depend on the company's ability to launch products in the relatively fast growing therapeutic field. The growing markets for generic drugs and strong statistics have attracted more Indian pharmaceutical companies to the United States and European countries. For Indian generic pharmaceutical companies, although the United States will still be the first in terms of growth opportunities,Europe is fast emerging as an equally important international market.

Given the benefits of low cost and high quality, contract research and contract manufacturing have gained new momentum. Indian companies are expected to benefit from contract research business on behalf of multinational companies. In India, the potential for outsourcing research, clinical trials and creating registers for drugs or synthetic data is enormous. Out sourcing of patented drugs is a very profitable market.On a global scale, such as bulk drugs and Over the past decade,the giant drug strategy of inter national medicine has become popular.(Kaushesh Anshul 2003)Companies that have multiple production facilities and have received approval from regulatory agencies in developed countries have begun API production and outdated preparations. Many large Indian companies.

© 2021 IJSRET

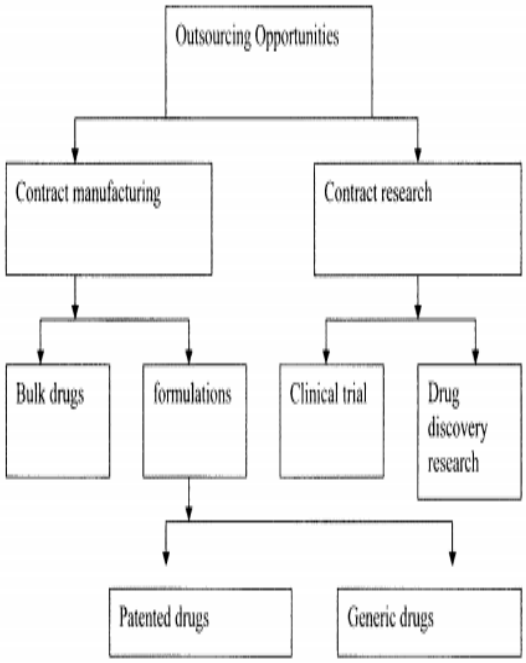

Fig 1. Pharmacy Marketing Emerging Trends.

The company began to enter into contract production. Ohg Ranbaxy-EliLilly and Lupine-Cynamid are the first major contractors for contract production. Nicholas Piramal has taken positive steps to become an international out sourcing center favored by pharmaceutical companies. It could be used as a base manufacturing company in the future. (Kaushesh Anshul, 2003) Higher R&D prices make less expensive places like India a better option. Due to the large number of patients and various diseases, the role of Indian companies is increasing in testing, making it a viable option for clinical examination, reliability and reliability as well as infrastructure that must also be considered. Indian hospitals and doctors have a good reputation in the international market. With a large number of patients, the presence of almost all diseases, a well-trained English-speaking entrepreneur, and the ethics of accepting medical examinations in line with inter nationally compliant standards, India is an attractive clinical trial site.

Elli Lilly from India completed the agreed time. Pfizer has completed 20 tests (Kaushesh Anshul, 2003), Astra Seneca also plans to conduct clinical trials. Novartis, Glaxo and Roche are currently setting up clinical research depart ments. Despite the turmoil caused by the simplification of the airport and the new patent system since 1990, the Indian pharmaceutical industry has made progress and is ready to compete in a constantly changing environment. For Indian companies, the biggest moment is huge technical reserves. They can contribute to the research and development of clinical chains in the chain to help deliver faster results. It is said that Indian chemical research is a global standard and has a global perspective.

The pharmaceutical company signs a research agreement and a license agreement to develop new drugs and event ually sell them. (Kaushesh Anshul,2003).Contract research and contract production have become a new force. Given the benefits of low and high prices, Indian companies are ready to take advantage of research companies on contracting on behalf of international companies.

In India, foreign research, clinical trials, registered drugs or synthetic data have great potential.Outsourcing patented drugs is a lucrative market. Globally, the huge growth in foreign medicine is the release of external drugs such as bulk drugs, drug intermediaries and preparations have become available in the last decade. After a discussion of the needs and structure of the pharmaceutical industry market, we will discuss the prices and other policies related to the industry in the next chapter. Introduction of this new industrial policy by central government nullify the negative impact of TRIPS and WHO-GMP on the pharmaceutical industry in the states of Himachal Pradesh and. Thus the central as well as state governments need to provide special attention to the pharmaceutical industry at state level.

The negative impact of changing business environment at international level can be minimized by providing various incentives and concessions to the local firms, by regional governments.The continuous poor performance of pharma ceutical industry in the states of Uttar Pradesh,West Bengal, Orissa, Madhya Pradesh and Rajasthan can also be improved by providing various incentives and conces sions to the firms already located in these states and to the new firms planning to setup business, as shown by the performance of Himachal Pradesh and Uttarakhand.

IV. LITERATURE REVIEW ON PHARMACEUTICAL INDUSTRY

70 editions were reviewed; 43 publications directly related to drug quality, while 37 publications related to general quality practices. The satisfied of the following basis was examine or following topics were identified:

Alka Chadha (2008) examined impact of a strict patent system on the patent action of Indian pharmaceutical companies or found that after the signing of TRIP, the patent action of these companies increased. This study was conducted in 65 pharmaceutical companies from 1991 to 2004 using a semi-parametric statistical data model. The model results of the various data points show that the introduction of stronger patents will have a positive and significant impact on patent action. In addition, the results show that there is a two-year difference between R&D costs and patent applications.

Beena,S (2006) this article attempts to address size, nature or impact of recent emergence of merger strategies,

© 2021 IJSRET

particularly in the form of mergers and acquisitions followed by Indian pharmaceutical companies. The study found that various companies are employ these strategies in the globalization environment, especially to overcome the fierce competition caused by market reforms and to strengthen their market portfolios. The study concluded that merger strategy followed by the company allows them to reduce the cost of expenditure, and the consolidated company is able to do better than the non-consolidation company in the industrial sector.

Chadda (2006) tried to show in his paper that Indian companies spend a lot of resources to protect their patents from going abroad. After employing developing countries, they attempt to enter developed countries through the General Declaration Form (DMF) to provide more active ingredients and develop new application summaries (AND As) for drafting.

Chadha (2005) has a more rigorous patent system that stimulates patent activity in the Indian pharmaceutical industry.

Chaturvedi and Chataway(2006) described in their study that lesser drugs may not survive in the market without these sources. Indian companies are accustomed to altering environment, in the post-TRIP situation, R&D is considered as a "livelihood". The newspaper pointed out that Indian companies are not only investing in research and development, not only in discovering new drugs, but also in developing the ability to receive and use foreign knowledge. They also position themselves as the preferred partners of powerful technology and multinational corporations.

Chaudhuri (2007) observed that after the rise of TRIPS the share of R&D expenditure of Indian pharmaceutical industry has increased significantly.Not only has R&D costs increased, but also the construction of R&D activities of Indian companies has undergone significant changes. Initially, they were involved in developing new processes in drug production, and now they are also occupied in the development of new chemical compounds (NCE). In the post-TRIPS era the Indian pharmaceutical industry is having an exciting time.

An analysis provided by **Dhar & Gopakumar (2006)** shows that with the changes in the patent system required by the TRIPS agreement, the effectiveness of the Indian pharmaceutical industry is also reflected. Research shows that the R&D costs of some leading companies, especially those of Ranbaxy and Drs. Reddy, showed an increase in the post-TRIPS era. As a result, R&D strength has improved significantly.

Dinar Kale & Steve Little (2007) The definition of the Indian pharmaceutical industry has become a common supplier of medicines to increasing countries. The change in Indian pharmaceutical industry following the R&D chain marks a significant shift from importers to drug manufacturers. Indian government policy and technology as well as changes in intellectual property laws and reg ulations have played an important role in shaping R&D capabilities. This article uses the "skills creation model" to discuss the learning process or process involved in the rapid accumulation of technical skills. Studies show that Indian pharmacies From mass drugs to creative drug manu facturers, entire industry is moving towards a chain of drug research and development. Finally, due to changes in patent law, industry is learning to expand new R&D skills.

Basic and moderate technical skills gained from simu lation learning give these companies a solid founda tion for developing new R&D skills. These findings have suggestion for government policies and the strategies of other countries around the world, although there are some limitations as the World Trade Organization promotes the integration of laws on the patent.

Grace(2004)stated that the prospect of altering intellectual property in the pharmaceutical sector is very beneficial to the future of Indians. Studies show that one-third of FDA function in 2003 came from India, and that number is expected to reach half of 2004. International companies are interested in cooperating with Indian companies. For a long time, which attracts the low price structure.
Gupta (2007) Indian companies increase their quarterly DMF delivery rate. Indian oil companies are also growing their participation in emerging markets, especially the US market. In the period after TRIPS, YOUR demand for USFDAs also increased.

Haritha Saranga, BV Phani (2008) Beginning in 2005, the Indian Industrial Procurement Industry(IPI) model will change significantly as the existing patent system replaces the patent system of products to comply with intellectual property system related to trading Agreement TRIPS).As a result, the IPI, which has more than 20,000 participants, is graduallymerging into mergers,acquisitions or agreements; and prepare to adapt to the new world. In such an active environment, it is necessary to verify whether there are common factors in the business sector that contribute to the survival and growth of the business.Because almost all companies will not be able to control their impact on the industry as a whole, this is important. This is especially true if change leads to change and not the political change of each government. To achieve this goal, we conducted a data envelope(DEA) survey of 44 companies that survived at least ten years ago to determine the best practices in the Indian pharmaceutical industry. Analyze the DEA results And the annual growth rate (CAGR) to determine if there is a correlation between the internal efficiency or growth rate of the Indian pharmaceutical industry. We also used regression analysis to determine relationship between different inputs/outputs or growth rates. Various DEA models, such as Return to Level (CCR), Return to Rate

© 2021 IJSRET

(BCC), and Secure Guarantee (AR), can be used to verify the results obtained.

In this paper, **Jaya Prakash Pradhan (2003)** attempts to honestly test the impact of economic liberalization on the R&D behavior of Indian pharmaceutical companies that control the impact of corporate behavior many of which include the size of the company. Tobit's analysis of company samples from 1989-90 to 2000-01 showed that competitive pressures caused by liberalization played an important role in 2006.

Jaya Prakash Pradhan (2006) What are trends in global competition of The Indian Pharmaceutical Industry? How the industry stands evaluate to the rest of the world Partners in additional drugs, production, R&D and trade shows? What new strategies are being put in place by Indian pharmaceutical companies to become global players? These issues are addressed in this article. Seems strategic Government policy has been the main factor in changing the status of the Indian pharmaceutical industry from mere drug importers and distributors. Medicine, has become a manufacturer of innovative, effective, high-quality drugs. India has become one of fastest growing pharmaceutical industries in the world, with rising prices. Export. However, government policy needs to address some limitations, such as low production and low R&D levels. Recently, a number of competitive strategies have become popular among Indian pharmaceutical companies, such as direct investment in rice fields, overseas acquisit ions, strategic contracts and production contracts.

Jaya Prakash Pradhan,(2007) This paper inspect impact of strengthening intellectual property protection on techno logy exports similar to countries such as India. India's experience in drug trafficking can contribute to existing literature, otherwise they are limited to knowledge of OE CD countries or United States. Official psychiatry shows that even exports such as developing countries do not necessarily have a negative impact on the strengthening of the patent system on a global scale. However, in the case of pharmaceuticals, this research is unlikely to apply to other sectors of the Indian economy, and in general to the impact of a stronger patent system on total exports. Indian economy should be based on other research.

Jayashree Dubey, Rajesh Dubey The World Trade Orga nization (WTO) has developed a law governing inter national trade to give consumers the greatest benefit. One of its goals is to eliminate trade barriers to international competition. The association is based on principle of free trade; foresight through sealing and transparency; national treatment (equality of foreigners or locals); most popular treatment; the elimination of trade barriers, such as the removal of quotas and price constraints and the promotion of fair competition. Meanwhile, developed countries have used their power in negotiating trade laws, which have become a major challenge for increasing countries. It can be said that the way these rules are developed gives people the opportunity to provide services to customers in WTO countries.Only competitively viable companies can survive on a global scale,and this also applies to the Indian industry. Because the WTO forbids the use of aid and other security measures, the economy will change.This requires a major change in Indian business system.Under this system textile,food processing or leather industries will benefit. Despite the confusion among Indian pharma ceutical com panies, India can also take advantage of this opportunity to develop in this field. Madhya Pradesh| These companies need to create a warm atmosphere. This article presents the current economy in Madhya Pradesh and discusses the reasons for the decline.Compare the potential of the pharmaceutical industry in Madhya Pradesh with other residential countries in India.

Kubo (2004) It appears that the R&D rate and the patent R&D rate have increased since 1995.

Lanjouw (1996) believes that manufacture technology is well controlled, thus eliminating the long interval among release of new products in its primary market and India, or in some cases it can be delayed for two years. Previous literature has highlighted that companies in developing countries are competing for production skills,and producti vity is available from other sources, and it is strengthened through it.'concepts related to simple knowledge infrastru cture towards technical skills in between;Bell and Pavitt, 1995) With signing of the WTO, in particular the signing of the TRIPS in 1994, it is expected that the industry and market structure will change. Many Indian pharmaceutical companies are not only doing well in domestic market, but are also able to gain a foothold in the overseas market. Despite the confront posed by the WTO system, the sector continues to grow (Exim Bank, 2007).

Nair (2007) pointed out that the future of Indian pharma ceutical companies focused on vision strategies is bright. Drug discovery, Article IV document, focuses on the production of high-quality and high-quality generic drugs, strengthens the production of APIs/intermediaries in drugs, releases multi-industry production infrastructure to standard and the U.S. Food and Drug Administration (USFDA) funding for medical assistance services. In the long run, diagnostic services, diagnostic testing services, data management services and clinical research work will help India develop and compete with the world's leading pharmaceutical companies.

Pradhan(2006) examines impact of a stronger intellectual property security system on the export of fake techno logical countries India. Empirical analysis provided by the study shows that in terms of medicine, India will benefit from market expansion.

Pradhan,Jaya Prakash(2006),"Global competition in the pharmaceutical industry in India: trends or strategies."

© 2021 IJSRET

What are the trends in global competition in Indian phar maceutical industry? Compared to its global counterparts, where is the drug, manufacturing, R&D and marketing industry?What new strategies are being put in place by Indian pharmaceutical companies to become global players?These issues are addressed in this article. It appears that the policy of the strategic government is the main reason for changing the status of the Indian pharma ceutical industry from importers and distributors of medicines and pharmaceuticals to high quality pharma ceutical manufacturers. India has become one of fastest growing pharmaceutical industries in world, with rising prices or export.

However, government policy needs to address some limitations, such as low production and low R&D levels. Many competitive strategies, uch as underdeveloped direct investment, overseas acquisitions,strategic agreements and contract production,have become popular among Indians. Pradhan,JayaPrakashandAlakshendra,Abhinav(2006)Forei gn M&A and Investment in Greenfield:What is the appropriate international education strategy for Indian pharmaceutical companies?

Recently,overseas acquisitions and foreign investment have become two major ways of promoting the Indian pharmaceutical industry.This study examines the advanta ges and disadvantages of these strategies, and given the nature of profitability for Indian pharmaceutical compani es, presents one of the two most effective international dev elopment strategies as of Indian pharmaceutical compani es. The analysis was conducted in three stages.

First, the process of developing the Indian pharmaceutical industry is entrenched in four levels of theory, highlighting the existence of various international models, such as internal investment, import, export, investment in in rice fields, foreign purchases and internal business strategies.

Second,there was a theological perspective on the different ways in which Greenfield invested and obtained abroad profits from pharmaceutical companies and/ or strengthen ed its competitive position.

Third, a survey was conducted at Ranbaxy Lab to formally evaluate their experience with overseas access. Studies show that the growth and globalization of India.

Pharmaceutical companies rely heavily on previously targeted government policies. India's experience has provided many political lessons for other developing countries wishing to build internal facilities for the pharma ceutical industry. The theoretical understanding shows that compared to Greenfield investment, acquisitions are a more effective international strategy, because the former not only gives all the benefits to the latter, but also gives the key to success the company in the global market. Another important advantage of competition. Ranbaxy's experience shows that overseas acquisition has expanded its intangible assets to integrate distribution networks and markets and provided time to enter existing markets.

Raveendra Chittoor, MB Sarkar, Sougata Ray, and Preet S.Aulakh (2008) discuss the imitation of emerging international companies in their article:institutional change and change in the Indian pharmaceutical industry. The relentless system has undergone organizational changes due to environmental changes caused by economic liberali zation and intellectual property reform. Globalizing the market for resources and products is a big part of transfo rming local businesses into emerging economies. Using the long-term data of206 Indian pharmaceutical companies from 1995 to 2004, we find that the company's access to international technology and resources has boosted the market' the product to be international. In addition, we receive theoretical support and support our assumption that the relationship between international resources and the market is limited by time and group of companies, and the globalization of the product market. will have an impact on financial performance.Thus, the theories and practices related to the dynamics of emerging economic enterprises and transforming them into competing inter national companies have implications.

Raveendra Chittoor, Sougata Ray, Preet S. Aulakh, M.B. Sarkar(2008) examines the strategic response of the Indian pharmaceutical industry to the institutional change caused by the economic liberalization of the Indian econo my and the intellectual property system provided the WTO.An analysis of the growth status and growth of Indian companies associated with foreign international companies,the transformation of the resources and capabili ties of these companies, and the analysis of its scope.

Ravinder Jha (2007) With reversal of strong patent laws, Indian oil companies are quickly shifting their focus to the drug market in developed countries.However,despite India becoming an effective drug exporter, its dependence on the importation of active drugs has grown steadily over the past 10years. As for the branches of international pharma ceutical companies in India, their role in drug packaging and preparation is declining, and their choice of "inves tment" has turned into financial security. The process of investing through mergers and acquisitions continues, in addition to increasing market focus, it is always a key strategic element for companies to achieve business opportunities. areas of internal and external market value. In the field of research and development, no Indian pharmaceutical company has the potential to develop the drug from the possible investment process to the final market design process.Therefore, cooperation with international companies is the norm. Thus, the choice of treatment area is biased towards life style-related illnesses.

Sampath (2005) categorized companies in the Indian phar maceutical industry into 3 main categories based on the

© 2021 IJSRET

data collected, and identified the main strategies and factors for each of the 3 business categories. A survey of 103companies high lighted that Indian companies are adjusting their mix of collaboration and competition stra tegies to suit and take advantage of the times set by the changing patent system.There is a significant link between the intensity of Indian pharmaceutical industry exports and R&D investment. In addition, companies

V. CONCLUSION

Indian pharmaceutical industry has undergone wide policy changes, assumed to have direct effects on performance of this industry at national as well regional level. This industry performed well after the introduction of new economic reforms in India in the early 1990s till the early 2000s, i.e. before the introduction of product patent in India. But as the Indian pharmaceutical industry experienced the product patent regime in the early 2000s, its performance had declined at national as well as state level for the period of 2002-06.

Although most of the states recovered and showed signs of comparatively better performance, during the latter period of 2007-11, but Maharashtra and Gujarat could not recover and reported consistent declining stakes and growth rates in terms of number of units, man days employees, value added and capital formation. On the other hand, Himachal Pradesh and Uttarakhand reported a drastic rise in their stakes and growth rates in the latter period of 2007-11. The states like Andhra Pradesh, Karnataka, Kerala and Tamil Nadu revealed fluctuating stakes and growth rates in the last two decades; whereas the states like Uttar Pradesh, West Ben-gal, Orissa and Rajasthan reported consistently declining stakes and growth rates over the last two decades.

REFERENCES

[1] Becattini, G. (1992) Competitiveness of Regions from an Evolutionary Perspective, Regional Studies, 38:9,
[2] Chaudhuri,S.(2002) Economic Reforms and Industrial Structure in India, Economic and Political Weekly, 37:2,
[3] Government of India, (2011-12) Organisation of Phar maceutical Producers in India (2011-12), 46th Annual Report,Ministry of Chemicals and Fertilizers, Depart ment of Pharmaceuticals : New Delhi.
[4] Hirschman,A.(1963) The Strategy of Economic Devel opment, New Haven : Yale University Press.
[5] Hoover, E.(1948) The Location of Economic Activity, New York : McGraw-Hill.
[6] Jha,R.(2007)Options for Indian Pharmaceutical Indu stry in the Changing Environment, Economic and Political Weekly, 42:39,.
[7] Joseph, R.K.(2012)Policy Reforms in the Indian Pharmaceutical Sector Since 1994:Impact on Export and Import, Economic and Political Weekly, 47:18,.
[8] Krugman, P.(1991) Increasing Returns and Economic Geography, Journal of Political Economy, 99:3, pp. 483-499.
[9] Kumar, N.& Pradhan, J.P. (2003) Economic Reforms, WTO and Indian Drugs and Pharmaceuticals Industry :Implications of Emerging Trends,CMDR Monograph Series,
[10] Lalitha,N.(2002)Indian Pharmaceutical Industry in WTO Regime:A SWOT Analysis, Economic and Political Weekly, 37:34, pp. 3342-3555.
[11] Lall, S.V.& Chakravorty, S.(2005) Industrial Location and Spatial Inequality : Theory and Evidence from India, Review of Development Economics, 9:1.
[12] Lanjouw, J.O.(1998) The Introduction of Phar-maceutical Product Patents in India:Heartless Explo itation of the Poor and Suffering? NBER Working Paper, No. 6366, Cam-bridge, MA: National Bureau of Economic Research.
[13] Marshall, A.(1920), Principle of Economics,8th edition Myrdal, G.(1957) Economics Theory and Under-developed Regions, London : Duckworth.
[14] Ohlin, B. (1933) Interregional and InternationalTrade, Cambridge : Harvard UniversityPress.
[15] Pradhan, J.P.(2007) New Policy Regime and Small Pharmaceutical Firms in India, ISID Working Paper No: 2007/02.
[16] Pradhan,J.P.(2010) Strategic Asset-Seeking Activities of Emerging Multinationals : Perspectives on Foreign Acquisitions by Indian Pharmaceutical MNES, Organisations and Markets in Emerging Economies, 2:2,
[17] Pradhan, J.P.& Alakshendra, A.(2006) Over-seas Acq uisition versus Greenfield Foreign Investment: Which Interna tionalization Strategy is Better for Indian Pharmaceuti-cal Enterprises?,ISID Working Paper, No. WP2006/07.
[18] Pradhan,J.P.& Sahu,P.P. (2008) Transnationa- lization of Indian pharmaceutical SMEs, New Delhi: Book well. Scott,
[19] A.J.(1988),New Industrial Spaces, London : UK Pion.
[20] Singhi, M.C. (2012) Report on the Role of Incentives in the Development of Indus-trially Backward States/ UTs, Office of the Economic Advisor, Ministry of Commerce and Industry
[21] Chaganti Subba Rao, (2007); ”Pharma Marketing in India - Concepts Strategy Cases ”
[22] Chaganti Subba Rao,(2007);"P/?arma Marketing in India Concepts Strategy Cases”;
[23] Clarkson K, 1993;Intangible capital and profitability measures.effects of research and promotion on rates of retum;Amcrican Enterprise Institute Conference on Competitive strategies in the Pharmaceutical lndustry; Oetober
[24] ComanorWS,(1986);The political economy of the pha rmaceutical indstry; Journal of economic Literature 24
[25] Comanor WS Schweitzer SO,(1994); The pharma ceutical industry; In Adam W and Brock J (eds); The structure ofAmerican Industry; 9th ed; Macmillan

© 2021 IJSRET