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Indian Pharmaceutical Industry, Strategies and Challenges in India, Comparison of Post Reform and Pre-Reform Period

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***Abstract*- The pharmaceutical manufacturing, especially in countries like India, is in addition to playing an important economic and social role directly related to many health related issues. It is a science-based industry, a symbol of development of science, technology or information, provides service chance for different population levels and has supply significantly to the overall growth of the Indian industryThe principle of this study is to examine presentation and future trends of the Indian pharmaceutical industry in the period before and after the reform. By analyzing data from the pharmaceutical industry, you can understand market trends, the new and emerging companies in the industry and the industry's expenses and profitability. The analysis of such data provides guidance for monitoring market environment, which in turn can help future investment decisions. In addition, it also helps to track different developments related to certain diseases (such as cardiovascular, anti allergic, etc.).In addition, psychiatry also highlights the legal aspects (patent law) or rations related to the commerce. The study also suggests discussing a specific area within the pharmaceutical industry, the therapeutic area. Therefore, the proposed research includes recognized pharmaceutical manufacturing activities currently in use, including the API industry, formulations, and important therapeutic areas. The researchers outlined the Indian pharmaceutical industry and its evolution from almost non-existent to one of the global generic drug suppliers.**

***Keywords*- pharmaceutical, legal aspects, analyzing data, etc.**

I.INTRODUCTION

The pharmaceutical manufacturing, especially in countries like India, is in addition to playing an important economic and social role directly related to many health related issues.It is a science-based industry, a symbol of develo pment of science, technology or information, provides service chance for different population levels and has supply significantly to the overall growth of the Indian industry.Over the years,the Indian pharmaceutical industry has become a producer of approximately all types of house hold medicines and the imports from developed countries are very small. (Kiran Vallecha (Kiran Vallecha, 2008))

In the last few years, expansion rate of the pharmaceutical industry has been 1.5-1.6 times the economic growth. Currently, India has become one of preferred purpose for Contract Research and Manufacturing Services (CRAMS) with its inherent competitive advantages. (Kiran Vallecha, 2008) Global opportunities for production and outsourcing are estimated at $ 20 billion and are predictable to reach $ 31 billion by 2010. (Kiran Vallecha, 2008)

Indian planners have recognized their key role and have included the industry in the core industry of aid. Through various initiatives taken by the government and a proa ctive attitude, the pharmaceutical industry has been for the last 25 and half years.Given its amazing growth and future, this work presents research on the performance and prospects of the pharmaceutical industry. expect. Taking into account the relevance of these aspects at national and global level, the historical aspects have been examined, affecting demand or provide factors in the pharmaceutical industry, drug prices, policies and regulations, R&D trends or some outsourcing challenges. This research emphasizes the following aspects.

1. Some economic aspects or quantitative expansion in phar maceutical industry: "According to McKinsey's research (2007), pharmaceutical industry in Asia is expected to reach $ 25 billion by 2010, while India's domestic market can more than triple by 2015, When 20 billion. Dollars and will be one of important pharmac eutical markets in next decade "(BVS Prasad and K Gowri Shankar, 2007). It is significant to note that in last three decades, the Indian pharmaceutical industry has undergone dramatic structural and quantitative changes.

From a pure processing manufacturing to today, it has become an manufacturing with advanced manufacture tech nology, present equipment and strict quality manage. It has also made important progress in transportation development and production of various products. As declare above, we intend to examine the micro- and macr oeconomic aspects of industry, such as demand, supply,

price behavior, service, etc. This is useful from point of view of policy makers or researchers. Below are other feature that are just as important or discussed for us.The discovery, progress or division of pharmaceutical industry:

The pharmaceutical industry is world's largest manuf acturing due to its global turnover of approx. $ 2.8 trillion. The pharmaceutical industry has Significant modify have taken place in current years, and new demands have been made on payers, providers or producers. Now customers are asking the pharmaceutical industry to offer the same options and conveniences as other market segments. (Saurabh Kumar Saxena, 2005)

Driven by many factors, Indian pharmaceutical industry is expected to achieve sustained and stable growth over the next few years, including unresolved intellectual property rights, a strict regulatory environment, increased consumer awareness and threats to the biopharmaceutical industry. The pharmaceutical industry is a knowledge-based indu stry that is heavily dependent on investigate or expansion of new products or expansion. However, basic research (discovery of new molecules) is a time-consuming or exclusive procedure or is conquered by large multinational companies. (Saurabh Kumar Saxena, 2005)

Due to the high cost of innovation for the development of new molecules, Indian pharmaceutical industry is hesitant to enter this field. though, some of dominant tropical diseases in mounting countries have not received the attention of the developed countries because they cannot generate profits. Therefore, developing countries like India need to invest in research and development of such diseases. Cost-benefit aspect of the industry: It can be sharp out from outset that measuring the benefits of such industries to society will produce a lot.

Therefore, the treatment of complications is beyond scope of this study. Benefits can be social benefits, financial benefits, or a combination of the two that require thorough income inference processes and methods.

There may also be different fees. They are probably the result of cost, not the cost of buying an existing drug or discovering a new drug. Any attempt to measure benefits is hampered because identifying and estimating benefits is a difficult task and the benefits are determined, so it may not be possible to determine the share of revenue from operations in the pharmaceutical industry.Therefore, we estimate neither the cost nor benefits of this huge manufacturing. though, we do involve some significant connected aspects. If they intend to take on the task of estimation costs or benefits of the manufacturing, they may be able to provide future guidance to researchers and future business investors. That is why we try to strive for goals.

2. Background and problems of the pharmaceutical industry: A review of some early studies shows that feature such as demand, supply, marketing, discovery process or other connected question have become very important in the research of this industry, namely pharma ceutical industry. The pharmaceutical industry is known as one of leading manufacturing sectors in the country. The results of its general research or progress are sold worldwide or have enhanced lifespan or quality of life of countless persons. At the same time, though, industry has been criticized for its marketing or pricing practices and even its R&D focus(Comanor,1986; Kane, 1997), showing that the industry has been very profitable or great R&D expenses. And marketing that promotes censorship and criticism.(Schweitzerand Comanor,2001)pointed out that indemnity coverage of medicines compared to other medical services is lower combined with the increased possibility that people suffer catastrophic costs due to prescription medicines, which has increased people's dissatisfaction with the industry.

Another factor that received criticism from commerce is occasional discovery of hazards in prescribed pits that have not been discovered before. The mainly current example is risk of COX-2 arthritis medications such as Vioxx and Celebrex. People are confused because it is not clear if defect is due to manufacturer or Food and Drug Administration (FDA) that first accepted product. How can we praise and criticize an industry at the same time? The answer lies in the conflict between roles or responsibilities that the industry faces. The pharmaceutical market sets it apart from other markets and brings this sense of contradiction to industry. Unhappily, we are not able to get much research on the industry, but we often mention some important studies, and we found that in this type of research, the method used by several researchers is standard economic study.

Their research involves the supply of medicines, the study of several mechanism of industry or its various functions, including R&D,production and marketing, and market demand.On demand side,it is not one party but the four parties concerned in consumer decision making: doctors, patients,pharmacists and more and more insurance comp anies.Market results include pricing of medicines and the transnational nature of the market. Various studies have also examined the regulatory issues that separate the drug market from other markets, raising some key issues. (National Center for Health Statistics, 2005)

The basis of pharmaceutical industry is its research and development (R&D). Medicine is one of the models of technical or economic success in the 20th century. The plan to subsidize non-commercial feasibility studies also proposes a model that enables R&D to solve problems in increasing countries, where occurrence or prevalence of diseases are rare in industrialized countries and malaria can be huge. But income of the torturers is so low that profitable market is small. The pharmaceutical manufactu ring also differs from other industries through marketing

labors.The marketing of instruction drugs is different from the marketing of most other products because the unique relationship between consumer and agent characterizes Medical needs.Traditionally,physicianschoose prescription drugs on behalf of patients, and their role in product selection is passive. By definition, patients must purchase prescription drugs to obtain physician approval.The company competes fiercely in many of more popular therapeutic markets, such as cardiovascular, palliative, or digestive systems.In recent years, another category of drug marketing has emerged: ads targeting end users, patients This is called direct-to-consumer(DTC) advertising.

These media and television commercials encourage patients to tell their doctors that they want to try a meticulous creation.Do consumers respond to this type of advertising? Will the doctor put pressure on them to prescribe inappropriate drugs? We provide direct evidence of extent to which DTC advertising has led to unnecessary use of new or exclusive drugs and a reduction in the number of patients not receiving suitable drugs. (Schw eitzer O Stuart, 2007).

II. FINANCIAL INCENTIVES FOR RESEARCH AND DEVELOPMENT

1. Financial incentives listed in the"2006 National Drug Policy Draft" Financial incentives for R&D activities:

- 150% weighted tax-free income (according to income tax section 35 (2AB) The 1961 Act lasts until March 2015.
- This extension will include the depreciation of inves tment in land and buildings for dedicated research facilities and expenses incurred to obtain the service Approvals and patent applications from foreign regulators and costs of clinical trials in India.
- The reference standard (the tested sample) is exempt from import duty.
- Reference books imported into R and D are excluded.
- At present, there are 101 designated tools (List 28) required for F and D purposes that are exempt from import duty.

All other new instruments certified by the Department of Science and Industrial Research (DSIR) are also exempt from import duties.

2. R & D-intensive companies:

Some drug development companies meet certain cond itions and should grant certain price concessions for drugs under the "Drug Price Control Order" (DPCO);

- Use at least 3% of annual sales for R & D activities or 500 million rupees per year (average 3 years), which is the highest in research facilities.
- Hire at least 200 researchers in India (at least one year for master's or PhD)
- Owning and operating production facilities in India approved by at least two foreign regulators (USA, Europe, Japan, Canada, Australia, Israel, South Africa, etc.)
- According to research conducted in India, at least 10 patent applications have been filed in India. Companies that meet the above specifications are eligible to enjoy the benefits of a 200% weighted deduction under 35 (2AB) by March 31, 2015

3. Pharmaceutical Research and Development Support Fund (PRDSF):

At present,PRDSF has a1billion rupees company(of which only interest income can be used for expenditure), which is used to fund research and development projects from national scientific research institutions and industries. It is not enough to meet the current and new needs in this market segment.It has been decided to convert to a subsidy of 1.5 billion rupees per year. If malaria, tuberculosis, hepatitis B HIV AIDS and other specific diseases in India prioritize research and development.

4. Development of orphan medicinal products:

The Central Pharmaceutical Research Institute (CDRI) has previously developed many drug technologies that cannot be produced and sold commercially. These technologies can be perfected to enable them to enter the market. The new policy draft also has two new initiatives. they are:

- Cancellation of industrial licenses for bulk medicines, intermediates and preparations and
- Automatic approval of foreign technology agreements through Reserve Bank India.

Table 1. Foreign and Indian Patent Granted To CSIR and Other Government Laboratories Engaged In Drug Research 2003-04.

	India	Foreign
CDRI	7	5
CIMAP	7	29
IICP	4	5
IICT	24	39
Total for 4 above	42	78
Total for CSIR	275	212

5. Scientific Research Institutes:

The research and development costs associated with the Indian pharmaceutical industry require about two-thirds of the industry's operating costs. The Central Medical Center requires a large portion of the new small drugs produced by Indian manufacturers. CDRI is considered one of the

few state-owned enterprises in the world to have its own drug development infrastructure.Over the years, it has produced ten new drugs and licensed them to other companies in the private sector. Of course, most of them have to face fierce competition from multinational comp anies.In addition to CDRI, CSIR authorities have other laboratories involved in this type of drug research.

Four of this research institutes under CDRI camp have contributed to above one Fourth of patents obtained by CSIR laboratories till 2003-04. (Prasad BVS, 2008)

6. The Emerging Research and Development Collabo rative Opportunity:

Major pharmaceutical companies began to become involved in drug research in 1997. Dr. The Reddy Research Foundation began conducting medical chemistry research in Hyderabad in the late 1990s. Throughout the screening and goal discovery process,Reddy's Thera peutics, headquartered in the United States, has a high market share. Another Reddy group was involved in early research in proteomics for drug discovery. Molecular compound is the research area for bioinformatics. (Mani Sunil, 2006) Pharmaceutical specialty companies such as Nicholas Piramal have invested $ 20 million in research and development facilities,and the company has conducted three contract studies. (Mani Sunil, 2006) Ranbaxy collaborates with GlaxoSmithKline in drug discovery and development. The company also signed an ant malarial drug development agreement with (MMV) Geneva.

7.Strategies of Drug Discovery Adopted by Indian Companies:

Despite the high cost of conducting research, Indian companies do not have the scope or resources to engage in groundbreaking research involving all phases of drug discovery India's prices are lwer due to the availability of cheaper scientific labor. (B Rajesh Kumar and SM Satish, 2007) The goal of Indian companies is to pursue two basic strategies in simulation reearch and licensing to optimize costs and risks. In the analogy strategy, the company will not seek to find a new family of drugs. The research will focus on finding new dugs in existing families that have been discovered. This strategy is called a similar strategy because it involves finding compounds similar to those already discovered (BRajesh Kumar and SM Satish, 2007).

The significance of a smilar strategy is that it can reduce costs.By focusing on established protein targets and deve loping new drugs in families that have undergone exten sive research, the uncertinty surrounding drug research can be greatly reduced. But the downside is that as the first drug in the new family, the new drug developed using this method will not become a huge blockbuster. But there are exceptions to the trend.Pfizer'sCholesterol-Lowering Drug Lipitor is not the first drug of its kind to hit the market, but the best drug selling. Japanese medicine has used a similar strategy very successfully industry.

The outsourcing licensing strategy involves licensing pro mising connections to a multinational company.An Indian company identified many new compounds that may be working in a family and took them on for preclinical testing. Thereafter, the compound is licensed to a multi national company for further development, provided that if the multinational company succeeds,it will have the exclusive right to sell the substance.

Multinational companies will have to bear test fee. When a compound crosses every step of clinical development, multinational companies also have to pay certain miles tone payments to composite discoverers.(B Rajesh Kumar and SM Satish, 2007)The reason why multinational com panies tend to obtain composite licenses from Indian companies can be attributed to serious errors in the development of new areas of resistance. For every 1,000 connections identified by the company, only 30 cross barriers. On average, only three compounds passed the first round of clinical trials and finally reached the goal.

Table 2. Drug Discovery Status.

Company	Category	No. of Promising Compounds	Stage of Development
Dr. Reddy's	Cardiovascular diseases, Diabetes and cancer	37	9 in Phases I and II
Ranbaxy	infectious respiratory and urinary diseases and diabetes	11	2 in Phase I
Orchid	Inflammatory and infectious diseases, cancer and diabetes	8	3 in Phases I and II
Glenmark	Respiratory and inflammatory diseases, diabetes and	6	4 in Phases I and II
Source: Businessworld, Junel9th, 2006.			

Therefore, the concept of licensing has received increasing attention. In addition to the compounds they develop, multinational companies also look for promising compo unds developed by other companies in the therapeutic field and then use these compounds in clinical trials. (B Rajesh

Kumar and SM Satish, 2007) The following shows some of the drugs discovered by leading Indian pharmaceutical companies and their developmental status.

8. Clinical Trials in India:

India is fast becoming a hub for clinical research. Clinical Research Organization (CRO) revenue doubled from US $ 5 billion in 1997 to US $ 10 One billion dollars in 2002. (B Rajesh Kumar and SM Satish, 2007), by 2010, revenue is expected to reach $ 50 billion. Clinical testing has great potential as a world leader. Pharmaceutical companies will focus on multi-billion dollar industries.

It is estimated that the production value of the global clinical research industry by2010 will reach US$10billion. According to estimates by McKinsey & cCompany,by 2010major global researchers will spend as much as $ 1.5 billion on drug trials in India.(BRajesh Kumar, SM Satish, 2007) A report by Rabobank India said that India has the most patients in many types of diseases such as cancer and diabetes. The study also believes that the biggest benefit is cost. For example, the cost of testing a standard drug in the United States can be as high as $ 150 million, while the cost of testing the same drug in India is less than half. (B Rajesh Kumar and S M Satish, 2007)

The increase in medical trials will have a greater impact on the medical system in India. Improve record keeping in Indian hospitals, especially patient records. Indian medical institutions will rely on the discovery of new drugs to report their findings in internationally recognized medical journals and in doing so will gain international recog nition.Patients with incurable disease can choose treatment options

With the latest drugs,it often takes years to enter the market.From a strategic point of view, providing professi onal medical research companies will reduce the cost of commercial drug development, which will help Indian companies continue to develop their drug patent strategies. For competitors like China, the clinical treatment methods in West India are the same.Since it was discovered and approved by a medical examination, the patent is only 20 years old. Since the trial ended and the drug was placed on the market, more than half of the time has passed. Accurate medical testing can last up to ten years. In Western countries, it is difficult to collect patients quickly.

There is no financial compensation for patients participa ting in medical examinations. Medical expenses are almost entirely borne by the European government. Similarly, patients in the United States are protected by a health insurance policy. Most of the clinical trials of emerging economics are the study of multiple websites.

9. Worldwide Clinical Trials-A Perspective:

Rising research and development costs are forcing multina tional companies to increasingly consider offering low-cost options for outsourcing clinical research indeveloping countries and emerging economies.(B Rajesh Kumar and SM Satish, 2007) In the United States, 8.9% of clinical trials recorded in the US healthcare sector were conducted in new Asian countries,7.4% were conducted in Latin America, and 7.1% were conducted in Central - and East Asia. Central Asia performed 1.6%. Africa. Mexico has 429 clinical trials and is the most attractive destination for clinical trials, followed by Taiwan's 402 trials and Poland's 200 trials. Lebanon and Brazil conducted 193 and 161 trials, respectively.(BRajesh Kumar and SM Satish, 2007)

10. Drug Discovery Service: Contract Research and Manufacturing segmentation:

Services that actually support the process of discovering new drugs and testing their effectiveness are called outso urcing of drug discovery research.Contract research Org anize preparatory appointments that handle all complex aspects of clinical trials; recruit investigators, form ethics committees, monitor projects and manage databases. In the last decade, the Indian industry has witnessed an increase in the amount of clinical trial data. (B Rajesh Kumar and S M Satish, 2007) The aging population of the West has strained health budgets. Therefore, governments in the United States and European countries are looking for cheaper generic drugs and cheap drugs. In addition, due to the expensive nature of new drug development, pharmaceutical companies will not be able to sustain large R&D expenses unless new and cheaper blockbusters are developed. In this case, Indian outsourcing and CRAMS are well suited to global conditions. (B Rajesh Kumar, SM Satish, 2007)

11. Contract manufacturing-Growth perspective:

Many Indian companies have turned to contract manufa cturing to use their expertise in process research and development (mainly reverse engineering) to sustain high growth. In connection with large investments in discovery research, this strategic choice of contract manufacturing seems possible. Together with contract research, this appr oach will ensure that these companies are able to exploit their research and production opportunities and expand their activities in India and abroad. contract Manufacturin g, also known as third party manufacturing or tolls, is not a new activity for the Indian pharmaceutical industry. Most large Indian companies.

It is forbidden to produce a large number of"active ingred ients" and formulas for third parties (mainly small entities) in order to circumvent strict orders for the control of drug prices. (B Rajesh Kumar, SM Satish, 2007) In the last few decades, the trend of multinational pharmaceutical giants outsourced drugs such as bulk medicine, pharmaceutical intermediates and preparations has evolved. Due to the shift in focus to advanced value-added services such as marketing, the company has transferred the less profitable production tasks to external staff. Some companies Active outsourcing of US household products Bristol Myers

Squibb, Glaxo Wellcome, Merck and Hearst work for local subsidiaries such as GlaxoSmithKline.

Glaxo Wellcome produces ranitidine in bulk and the bulk manufacturing industry moves from Western Europe to The latest trends from the US to India and China are their inherent benefits, such as cheap manufacturing, easy access to skilled labor and relaxed environmental laws, which help to invest in these two countries. From 1970 to 2001 it was 18.5%. (B Rajesh Kumar and SM Satish, 2007)

The increase in R & D expenditure for the pharmaceutical industry has an impact on its net profit. Dr. Reddy's net profit fell by 40% from 592 million rupees, from 592 million rupees to 40 million rupees, and R & D investment increased by 705 million rupees from 5.16 billion rupees in 2006.

Ranbaxy's R & D expenditure doubled from 565 million rupees in October 2003 to 26 million US dollars in 2004. This is a decrease of Rs 1,565 crore from Rs 1,758 crore the previous year. Lupine has

Table 3. Global Outsourcing Opportunity.

Specification	Global Market Size (bn $)	Potential Global Market (size bn $)
Global outsourcing opportunity for pharma & biotech industry	100	168
Contract manufacturing services for prescription drugs	26.2	43.9
Contract manufacturing services for over the counter drugs (OTQ	71.2	100
Contract research services	14.5	21.9
Drug discovery outsourcing	4.1	7
Clinical research outsourcing	9.57	Not Available
Source: ET Pharma Survey, ET Finance, September 29th, 2006.		

12.Research and development costs for Indian medicines:

The company India's total annual R&D expenditure is 3.15 billion.USD,which is lower than the annual R & D budgets of companies such as Ford (US $ 7.4 billion) and GM (US $ 6.2 billion). India currently spends only 0.8% of GDP on research and development.(BRajesh Kumar andSM Satish, 2007) Compared to the Global Pharmaceutical Industry; India's R & D expenditure is still insignificant and can have a negative impact in the long run, especially in an era of patent enforcement.

Compared to 12-15% of global revenue, most Indian comp anies spend 6-7% of their revenue on R&D. In 2001, global research-based pharmaceutical companies invested DKK 30.5 billion. Dollars in R&D, an increase of 18.7% compared to 2000. Usually, one of the four NCEs that go into clinical trials will eventually be commercialized. In addition, only 30% of NCE's market can exceed or exceed the minimum development cost of US $ 200 million. In the last ten and a half years, the cost of developing new drugs has tripled to more than $ 700 million. Globally for the last thirty years

Table 4. Top R&D Spenders In Domestic Pharma Industry .

Rs cr		
Company	R&D Spend on Current Account:	R&D as Per of Sales
Ranbaxy's Lab	492.5	9.49
Dr. Reddy'sLab	234.1	9.45
Sun Pharma	155.1	8.94
Cipla	120.5	3.87
Lupin	98.9	5.65
Cadila Healthcare	81.7	5.42
Wockhardt	79.8	5.65
Nicholas Piramal	77.5	4.59
Torrent Pharma	56.4	5.47
Aurobindo Pharma	39.8	2.35
Total	1436.2	
Source: ET Pharma Survey, ET Finance, September 29th, 2006.		

Wockhardt, a pharmacy, has increased its R&D costs to $ 1,250 billion since April 2005. This will amount to 8.5% to 9% of total sales. The company will spend money on new drug discovery, new drug delivery systems and on-going engineering processes. During the 2004-05 business year, these 177 companies spent R&D costs of approximately 850 crore and total sales of 2.88 crore. (B Rajesh Kumar, SM Satish, 2007) Strides Arcolab Specialty pharmaceuticals have Strides special technology and research centers to accommodate the research sites of their foreign colleagues, with a variety of evidence proving that the process is not exclusion and delivery of new drug Research system

In the table up to 1999-2000:5.6 R and D activities are increasing.Beginning in 2001, it suddenly dropped in 2001 and then began to rise again in 2003-04. This is related to changes in Indian patent law and the World Trade Organ ization's insistence on recognizing patent laws in devel oped countries. The resurgence of R&D activities from 2003-04 can be attributed to the fact that the industry's

innovation skills circumvented the WTO's insistence on patent law restrictions. In the developmental age, inputs to R and D are expected to be uneven, so high changes as shown in the standard deviation graph are expected to be normal. We expect fewer changes before the reform and more changes after the reform. The standard deviation figures in Table 5.6 prove this.

Table 5. R And D Spend By Major Pharmaceutical Companies In India.

Year	USD m
1976-77	10.15
1978-79	12
1979-80	14.75
1981-82	29.3
1983-84	40
1984-85	48
1986-87	50
1991-92	80
1992-93	95
1993-94	125
1994-95	140
1995-96	160
1996-97	185
1997-98	220
1998-99	260
2001-02	97.77
2001-02	130.51
2002-03	175.3
2003-04	280.01
2004-05	392.37
2005-06	495.19
2006-07	1430
2008-09	930.22
Average (76-2009)	234.80
Std Deviation (76-2009)	323.78
Average (2001-9)	491.42
Std Deviation (2001-9)	434.9

13. Challenges in the drug development process:

As mentioned earlier, drug development is a difficult pro cess.From conception to launch, the drug will cost approximately $400 million ($1,682),of which $80 million ($ 3.4 billion) will be used for discovery and $ 320 million will be used for clinical trials. However, the average income for each drug throughout its life cycle is only $ 265 million. More than 90% of the new drugs have sales of less than $ 180 million. About 2/3 never get any return on investment. It takes about 13 years after applying for a patent to bring the drug to market. (B Rajesh Kumar, S M Satish, 2007) Traditionally, this process takes many years and no results can be guaranteed because most new compounds fail the screening process.

Now pioneers like Dr.ReddysLab andDr.Ranbaxy invested in new drug development for about ten years. But the Indian company does not have a new medicine. On a global scale, about one in ten of the substances studied will see light, while 179

It takes about 10 to 15 years. It is generally expected that the drug may fail. There can be several reasons for failure. This may be due to strong side effects or existing better alternatives.

The potential market size may not justify the resources required to develop the drug. Therefore, there is no single reason why the drug failed. In the next three to four years, it is not expected that Indian companies will have new drugs on the market. The number of new drugs approved by the USFDA has dropped from 53 in 1996-1997 to 21 in 2003-04. Hence the global situation

It's not that attractive either.(BRajesh Kumar and SM Satish, 2007). According to an estimate, almost 30% of the drugs sold by large multinational companies are licensed. In the preclinical stage, the global failure rate was slightly higher than 40%, increased to 50% in the first phase, 70% in the second phase and decreased to approx. 47% in the third phase. (B Rajesh Kumar and S M Satish, 2007) Due to the huge development costs, drug development and drug development are prerogatives for large companies in developed countries.According to a clinical trial conducted by McKinsey Quarterlyf in August 2004 it has been observed that the cost of obtaining a licensed compound is much lower compared to the company's internal develo pment of the compound.

The cost savings are approx. 1 to 9 million US dollars. Compared to the internally developed compound, it was found that the licensed compound was successful twice in clinical trials. The R&D expenditure of large pharmac eutical companies has grown steadily every year, from DKK 2 billion. $ (880 billion Rs.) In 1980 to more than 30 billion. $ (122 billion Rs.) Per year. The study estimates that the pre-tax cost of developing a new drug is US $ 800 million, a sixfold increase in 25 years. According to a survey, three out of ten

Drugs can recover nearly $ 500 million (22 billion rupees) in R&D spending after tax. (B Rajesh Kumar and S M Satish, 2007)

14. Future Innovations in Drug Discovery:

These three groundbreaking innovations are expected to radically reduce the duration of the drug discovery process and improve the quality of production. (B Rajesh Kumar and SM Satish, 2007) These are genomics, combinatorial chemistry and high

Screening throughput (HTS). Genomics aims to establish the relationship between genes and disease. These efforts have reached the genetic response to obesity and breast cancer. Combined chemistry allows chemists to start with known basic chemicals and then produce thousands of combinations quickly and easily at thousands of prices. HTS is the result of advances in molecular biology and can help in the detection of new compounds for drug purposes. International companies are now able to identify targeted targets and receive ads, drug delivery systems, product information and compliance plans tailored to the specific patient market needs of patients.

The pharmaceutical company monitors all molecules that enter thousands of molecules to test their biological activity, which is expensive. But the focus now is on so-called real drug discovery.In this way,research has focused on molecules, often proteins, that can be targets of drugs in the body. Modeling molecules and other techniques allows researchers to see if a specific resistor can attack the target. Work hard and develop strategies to increase success rates,

Use common and modern combination techniques for intelligent synthetics, and then identify the source of these combinations. Similarly, plants, micro-organisms, fungi, insects and various poisons are also sources of various chemical sources, so new combinations of these mines can also be explored.

Another reliable source is the drug, which is often used by doctors to treat certain ailments but is known to have serious side effects.They can also be difficult to synt hesize, separate and clean. Some of the medicinal value of these drugs can be improved by using the basic compo nents of the system as a base, having biological functions and modifying or replacing related systems that cause side effects, or can be studied from the point of view of chemists and engineers.

Similarly, toxic substances may be the source of new drugs. By modifying and transporting it to the desired location in the biological process, the dosage and toxicity can be reduced.

A revolution in large companies is conducting research into drug discovery. Regardless of animal experiments, humans react completely differently. The four properties of the drug are being tested in humans. It consists of ways of absorption, distribution, degradation or metabolism and ultimately excretion. Pharmaceutical companies refer to research as ADME (absorption, distribution, metabolism and excretion).ADME research is later than traditional methods. Now, pharmaceutical companies are examining drug metabolism in drug history at the same time as drug efficacy and animal toxicity testing. During animal experiments, molecular biologists learned to use genetic engineering techniques and clone receptors in animal models.

15. Status of Drug Discovery in India:

It is estimated that Indian companies have so far invested only $ 450 million in new drug research. Reddy has spent approximately $57 million promoting his first batch of new connections to the preclinical stage.(B Rajesh Kumar, SM Satish,2007)In India,at least a dozen Indian companies have participated in the development of new drugs. An estimated 60 new compounds are in various stages of development and testing. Compared to the world standards for GlaxoSmithKline and Pfizer (contains about 143 and 140 connections respectively) this figure is actually very small. It is gratifying,

However, the Indian pharmaceutical industry has started to develop from mere imitators to find the original medici nes.So far, medicines produced by the Indian pharma ceutical industry have been a recurring generic drug found by international companies. Every step in the process of drug design will make a big difference. Indian pharmac eutical companies need to spend millions of dollars to deal with this change. The map of the human genome consists of 3 billion life maps in pairs. Only 1 in 500 people will make a change. For couples, even the letters are not the same. The pairs form a spiral staircase. For most people, 3 billion pairs of four letters are the same. In fact, it is estimated that there is only 0.1% inequality in people. However, most of these 3 billion couples don't matter. There are 30,000 to 50,000 genes that work in the human body. If you describe the genes that control the production of various proteins in the body,

Then the associated disease can be clearly identified. But it turns out that there are very few diseases in a single plant, such as cystic fibrosis or Huntington's disease. Most others are difficult.(BRajesh Kumar and S M Satish, 2007)

Companies such as Sequenom, Orchid Biosciences, Millen nium Pharmaceuticals,and Nanogen are studying the techn ology to identify and classify the various important genes. If Indian companies(such asHIV, tuberculosis and malaria) do research and development on tropical and global diseases, they will benefit greatly because Western comp anies do not have to worry about it.

An international pharmaceutical company has also established a partnership with the National Chemical Labo ratory in Pune, India,the National Institute of Immunology in New Delhi, the Indian Institute of Science in Bangalore and the Center for Cellular and Molecular Biology in Hyderabad.(B Rajesh Kumar and SM Satish, 2007). Some companies have research facilities in India for this purpose.

16. The changing global R&D landscape:

New drugs for future chronic illness may include protein, genetics,cell therapy,vaccines,monoclonal antibiotics, new molecular gas(NME) and other biological drugs.Thus, the focus will shift from chemistry to molecular biology, mole cular therapy and receptor pharmacology.Learn. From new chemical industry (NCE) to new molecular organization (NME). Although the first batch of protein-related patents (such as HGH, TPA, insulin, interferon and CSF) has been completed,the regulatory system and standard biopharmac eutical standards may still last five years. This makes the growth of large biotech companies (such as Amgen, Biogen,Genentech,Chiron, Serono, and Novo) a challenge. (B Rajesh Kumar and S M Satish, 2007)

Finding drugs is a complex science that requires a lot of scientific infrastructure. Recent advances in molecular biology and genetic engineering have improved people's basic understanding of human physiology and the effects of drugs on receptors and proteins. New drug discovery tools, such as combinatorial chemistry, molecular design, and advanced testing, have revolutionized the drug process. (B Rajesh Kumar and S M Satish, 2007)

III. RESEARCH AND DEVELOPMENT

Having discussed pricing policies or system of the Indian and global pharmaceutical industry, we are now discussing R&D issues in this area. This chapter introduces and is based on analysis, reviews development mechanism and nature of drug research and the process of drug discovery. The research and development of Indian pharmaceutical companies includes collaborative research, important drug discovery and progress, and contract services. (B Rajesh Kumar and S M Satish, 2007 Due to the increased cost of increasing new drugs or the risks occupied in this process, the company is trying to mitigate the risks involved. This kind of research and development costs in India and globally and their changes have been discussed.

The second section of this section introduces the area or procedure of drug discovery and the nature of drug research in the second section. Section 5 introduces new R & D activities, Section 6 introduces clinical trials in India, and Section7 introduces contract manufacturing. Section 8 refers to research and development expenditure.The summary describes nine major challenges in drug develo pment.The third and fourth parts focus on India's position in research or development and take the pharmaceutical market as a global perspective. Development factors and trends in the Indian pharmaceutical industry were also converse. Finally, the political framework is summarized.

1. Area and Process of Research and Development (R and D):

Basic research occupy discovering/inventing a new me dically effective chemical substance. Compared to process research, basic research involves more time and cost. In addition, patents and new drug approval rules (NDAs) for pharmaceutical preparations are other typical skin texture of pharmaceutical industry. Hundreds of molecules must be analyzed to determine possible effect of the drug. (B Rajesh Kumar and SM Satish, 2007) After such laboratory tests, clinical trials will be conducted to determine the efficacy of the drug in patients. Therefore, the process takes about 12-15 years. The cost of the new chemical department is estimated at $ 350-400 million. The R&D Process is the molecular engineering that is repeated by modifying its processes. In India, Indian drug regulators must manage the approval of new drugs. In general, the clinical trial of drugs consists of three stages: (B Rajesh Kumar and SM Satish, 2007)

- Animal traits (animal tests);
- Experiment with selected volunteers and
- Take a lot of tests at the hospital / institution.

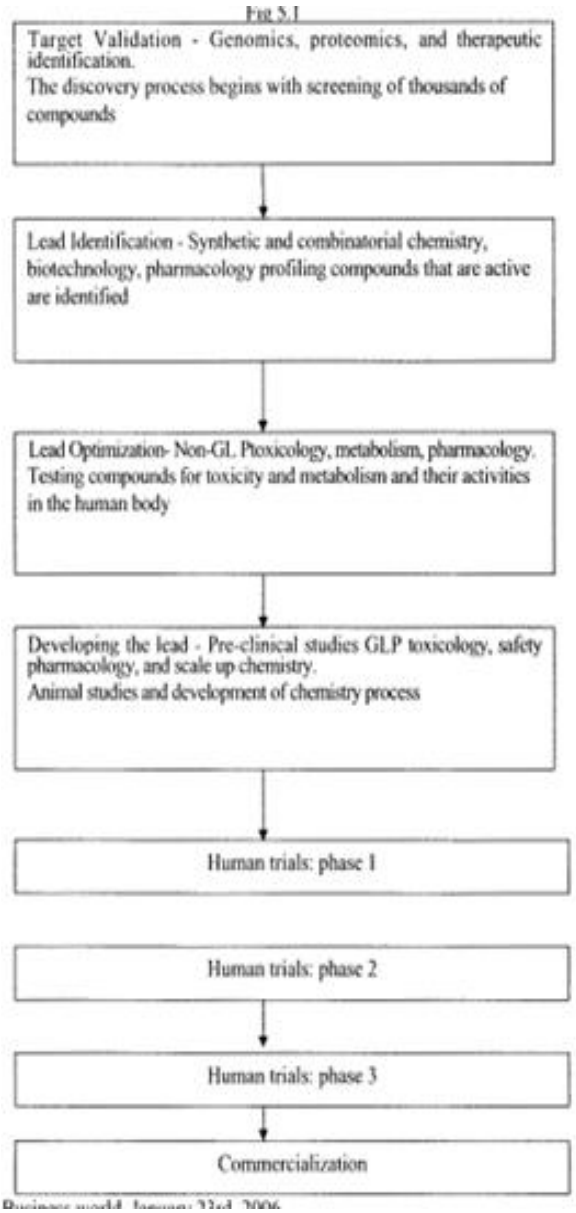

Fig 1.The stages of the drug discovery process.

Research companies are engaged in research, general drug promotion and new drug delivery systems(NDDS).To promote research,companies often focus on specific treat ment areas, such as anti-ulcer, anti-cancer, etc. The major diseases that are being treated regularly with new global medicines are AIDS,Alzheimer's disease, gout, cancer, depression, diabetes,heart disease, osteoporosis. and blood vessels.In today's context, drug research is a blood transfusion activity

These include the design and development of composite materials, biological processes, screening, toxin analysis, drug testing, bioavailability, etc. It therefore requires exp ertise in the fields of medical chemistry, molecular mod

eling, biochemistry, microbes, toxins and pharmaceut icals. (B Rajesh Kumar and SM Satish, 2007)

2. The Discovery Process:
The new drug development process is a knowledge-inten sive, time-consuming and uncertain process. The develop ment process can be roughly divided into two main phases, namely preclinical and clinical.The purpose of pre clinical research is to propose a molecule that is effective against disease vectors and is safe in animal experiments. This phase is called the research level (IND). this phase

The study can take 3 to 5 years and the overseas expenses are between 10-150 million dollars and the expenses in India are around 400-600 million rupees. (B Rajesh Kumar and S M Satish, 2007) After the preclinical research has been completed, the IND file will be submitted to the Regulatory Body (General Administration of Medicines of India) so that it can conduct clinical trials with Phase I, II and III humans to ensure efficacy and safety. (B Rajesh Kumar and SM Satish, 2007)If the new research drug undergoes all these clinical trials,the compound will become a marketable drug.

Clinical research usually takes 5 to 8 years, and it is estim ated that the cost of foreign and rupees is around 30-350 million US dollars. India billion.(B Rajesh Kumar, SM Satish 2007) Clinical trials require facilities that comply with clinical practice GCPand expertise from clinicians, cl inical pharmacologists, toxicologists, and analytical chemi sts.

3. Drug Development Process:
The first step is to identify the patient to be cured. The purpose is to determine the model of the human genome shared by these individuals.(BRajesh Kumar and SM Satish, 2007) The purpose of targeted drugs is to detect the biological activity of these patterns and to identify microbial proteins. Improving lead can detect chemical molecules that inhibit disease-causing proteins. Drug testing requires a determination of whether chemical molecules can be extracted. Medical tests require testing of the efficacy and side effects of the drug To the people. Of course, the drug in the medical examination is ready for treatment. (B Rajesh Kumar and S M Satish, 2007)

4. The nature of drug research:
The pharmaceutical industry has deep roots in science and technology. The discovery and development of drugs and economic considerations are the leading factors for drug development. (B Rajesh Kumar and S M Satish, 2007)

In the past, most substances were discovered through the separation of active ingredients from traditional substances or accidental discovery. Modern biotechnology usually focuses on understanding the metabolic pathways related to disease states or pathogens and using molecular biology or biochemistry to manipulate these pathways. Much of the results discovered in the early stages came from the traditional knowledge of herbal medicine and other commonly used things. (B Rajesh Kumar and S M Satish, 2007)

Establishing the physico-chemical properties of a new chemical entity (NCE) also requires drug development, the stability and solubility of its chemical composition. These Characteristics will determine its suitability for use as capsules, tablets, aerosols, intramuscular or subcutaneous injections. These processes are called CMC (chemistry, manufacturing and control) in preclinical development. After NCE first started clinical trials in humans, its long-term toxicity and effects on various systems (fertility, reproductive immune system, etc.) were determined If the compound is isolated from tests with acceptable toxicity and safety and can be further demonstrated to have the desired effect in clinical trials, it can be sent to each country/region where it will be sold for marketing authorization. However, most NCEs fail during drug development due to high toxicity or adverse clinical trial results. (B Rajesh Kumar and S M Satish, 2007)

IV. STATUS OF RESEARCH AND DEVELOPMENT IN INDIA

The research has become the focus of Indian pharmac eutical companies.An Indian company started its drug research program in1990,with Dr.Reddy and Dr. Ranbaxy. (B Rajesh Kumar and SM Satish, 2007). Initially, Indian companies participated in the identification of lead molecules and obtained permission from some of them in preclinical processes.

Nowadays, Indian companies are using drugs alone for medical tests. With the completion of human genome iden tification projects,functional genomics and systems, proteo mics, genetics, bioinformatics, and other disciplines are relevant to the search for new drugs. (B Rajesh Kumar and S M Satish, 2007)

A report entitled "New World View of Medicines" by the IBM Global Business Services Department of the IBM Group also said that the cost of research in India is 40% lower than in the United States, and the cost of producing new drugs is only one-tenth that of the United States. Western countries.For India, this is a great time.The report also points out that by 2035, emerging countries such as Brazil, Russia, India and China are expected to account for 25% of the global drug market. In India, the cost of research on life-threatening diseases is very low.If a country wants to have a global leadership position, it must focus on research and development. (B Rajesh Kumar and SM Satish, 2007)
India can become a distant place for research and devel opment. The Confederation of Indian Industries (CII) believes that Indian companies with weaker R&D should entrust development work to partners in many countries

who are knowledgeable in management, clinical trials and registration procedures.

According to the International Strategy and Management Consultant, India will soon be the center of a global R & D network for international pharmaceutical companies.For multinational companies in all industries,India is one of the countries with the best R & D costs. Research conducted by global strategy analysts Booz, Allen, Hamilton and French Business School shows that more than three-quarters of R&D centers to be built in the next three years are in India or China.(B Rajesh Kumar and S M Satish, 2007)

Since India established a new patent system in the mid-1990s, it has started investing in research on domestic events. One-third of the rejected research and development will be used in drug research. The rest will be used for research, development and publication of special events in 2007, aimed at potential market and commercial profits.

1. Basic R and D:
This means finding new molecules in the cell. It should avoid the side effects of many trials and tribulations so that you know exactly what drugs can do. For products from pharmaceutical companies, the average product price is 7-10 years and $ 350-500. Statistics have already said that. (B Rajesh Kumar and SM Satish, 2007)

2. Repeated research and completion of engineering:
This requires reviewing the process of drug production and modification of its process. the molecule of 2005. (B Rajesh Kumar and SM Satish, 2007) Simulate the release of a simulator or research obtained by the country on a new patent for a new molecule, modifying the molecule containing t molecules containing t molekiy va commerc ial. Biotechnology research on gas producers.

3. Introducing conventional medicine:
The introduction of spiritual medicine into the market requires the same experience as existing products on the market. New Drugs).

4. NDDS Research:
NDDS (New Drug Delivery System) has released new dru gs. Latin America, a new image of the NDDS, if improved it could gain special rights for 3years in the United States. It has already been proven that the fish process I like is 40% -50% priced compared to developed countries.The attractiveness of investing in India as an R&D destination

In the pharmaceutical and pharmaceutical field,100% of foreign equity investments are made automatically,and more than 74% of cases depend on specific circumstances.

- Quick customs clearance for foreign direct investment.
- Depreciation allowance for factories and machines established based on local technology.
- Exemption from customs duties on goods imported for state-funded research and development projects.
- Exemption from customs duties and excise duties on recognized scientific and industrial research organizations (SIROs).
- A weighted tax reduction on R&D expenditure of 150%.
- Patented products are exempt from consumption tax for three years.
- 100% discount on own R&D expenses,
- If the research is signed in a publicly funded research institution, 125% is returned. (B Rajesh Kumar, SM Satish 2007)

V. PHARMACEUTICAL MARKET: (GLOBAL PERSPECTIVE)

Drugs have two main components-the active drug (API) or multi-drug and the preparation, the latter being the last possible form of dosage. Generally, APIs are produced by synthetic chemicals of plants,animals or biological origins. (Prasad BVS, 2008) Patents are an important aspect of the development and sale of drugs. New drug molecules, new patent molecular instructions or patents on new drug delivery systems for existing products. Generally, the life span of product patents in all countries/regions is 20 years. With the 10 years of drug promotion and market approval, the pharmaceutical industry needs 10 years of preparation. (Prasad BVS, 2008)

The cost of drug production forces the price of the drug to stay high, and the drug is protected by patents. Not all projects generate revenue from marketable products, so a successful product must be able to guarantee the cost of a failed project. In 2006, the current global drug market was worth more than US $ 60.8 million (Prasad BVS, 2008).

The major contributing regions are the United States, Japan and Europe.The price of drugs varies from country to country.Citizens of developing countries cannot afford expensive patents. National Companies (MNCs) must choose to sell products at low prices in these countries / regions, otherwise they will face the challenge of piracy or neighboringtrade.Of course, different types of medications are needed to treat these disorders.Drug application. The products developed by the research are obviously expens ive and may not be easy to sell in poor countries in the market. This may be one of the reasons why multinational companies are reluctant to produce new products.

1. Trends towards Research and Development:
The global pharmaceutical market is around US $ 50-600 million, and R&D investment in developed countries is around 18-20% The Indian pharmacy market is estimated at $ 400-600 million. Total R&D costs range from 1.5% to 2% of total sales, which is very low compared to international standards, and the total amount of R&D available also small (Prasad BVS, 2008). This is reflected

in the number of new molecules found in developed countries.

India is working hard to develop modern technology in the pharmaceutical industry. The main task is to promote research and development comparable to that of other developed countries. The necessary conditions for the development of the pharmaceutical industry are capital, infrastructure, R&D management and human resources.

The Indian government encourages the private sector, the public and foreign investors to increase their investment in research and development.

- In recent years, the Indian government has taken positive steps, including: (Prasad BVS, 2008)
- Be recognized as an industry based on knowledge of the pharmaceutical sector.
- Reduce export rates
- Tax exemption on R&D expenses.
- Reduce drug price control.

The Indian Pharmaceutical Industry (IPI) industry, which is trying to take full advantage of government benefits, has allocated funds to the R&D department.Development of drug discovery, biotechnology drug deli very system and bioinformatics. The company reviews its strengths and focuses on products Profitable separation for business. Many companies are developing their investment portfo lios to focus on specific areas of care. (Prasad BVS, 2008)

Drug sales are also changing rapidly, and companies are selling cautiously. Companies such as Sun Pharma, Nich olas Piramal and Reddy's Lab have opted to buy brands/ companies to expand their medical and market segmenta tion.This special ability will make it difficult for interna tional companies to enter. Another perspective is that companies with strong business potential may be attracted to the acquisition. Many pharmaceutical companies have developed business plans. For example, the Hoechst Mar ions agreement with Nicholas Piramal and the agreement between Ranbaxy and Cipla and Cipla. Nicholas Piramal (Nicholas Piramal) got Roche products, which are usually in diagnostic products, and Zydus Cadila (Zydus Cadila) acquired German remedies in India. (Prasad BVS, 2008)

VI. CONCLUSION

This study examined the Indian pharmaceutical industry and attempted to compare it with the global pharmaceuti cal industry. In it we hope to inform the public (investors, decision makers,managers,corporate employees) of current developments.Their main purpose is to analyze the current situation,the biggest challenges and the vision of the pharmaceutical industry.Unlike many other studies, he tries to compare and analyze his methods and results.

The study is also trying to determine the position of Indian pharmaceutical companies in the global pharmaceutical industry and indicate the time to further strengthen their position. Through a detailed analysis of various factors related to the pharmaceutical industry, we have obtained data necessary for marketing and obtained the value of import and export of articles and publications marina. There is almost no data on each industry as they will reveal their future policies and strategies.

1. Research constraints:

Only because the management of the pharmaceutical company maintains a high degree of confidentiality, it is necessary to collect large amounts of data from secondary sources. As large The proportion of the analysis is based on data collected from the other public source, which places some restrictions on the research. In this study, vve analyzed the policies of the sample companies based on some qualitative analyzes or quantitative indicators. Eg. Is the entire financial policy area analyzed on the basis of relevant key figures. Using this method, we can analyze the design after the policy is implemented, rather than its actual plan. Sometimes certain broad performance indic ators indicate that planned policies and policies can vary significantly.

Similarly, the planned targets for growth and profitability may be very different from the actual growth and profit ability calculated on the basis of the sales and profit figures in the company's annual report. Because we rely on help data sources in many places, we are not able to reflect on the specific policies of all companies. As far as the policy analyzed is concerned, it is impossible to include.

Research and development policy, social policy and personnel policy. Although R&D expenditure is reported in the annual report of some companies, this information alone is not sufficient to comment on this aspect of behavior. Another limitation of the investigation is that it did not discuss the impact of the parent company's policies on its subsidiaries. The impact on management skills and technical knowledge transfer can be This is important for many companies. Sometimes state or regional research and proper data collection is not possible. Using the information and data provided, we tried to study the topic. The study is divided into seven chapters as described below.

It can be seen that the Indian industry has developed tremendously in the production of generic medicines over the years, but in order to maintain its comp etitiveness, it must energetically carry out research and development. Leading companies are moving slowly and steadily forward
Destination, because the funds for this activity are limited, the main goal must be generic drugs. Further research is needed to explore different fields to understand the correct trends to be followed in the future.

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