INTRODUCTION TO INDIAN PHARMACEUTICAL INDUSTRY

Introduction

The Pharmaceutical industry is related to the manufacture and sale of pharmaceuticals. It involves the discovery, development, and manufacture of drugs and medications by public and private organisations. A drug is any chemical agent that affects the function of living things.

Historically, physicians prepared medicines. Today, drug development relies on the collaboration and effort of highly trained scientists at universities and private companies. The modern era of drug discovery and development originated in the 19th century when scientists learned how to isolate and purify medicinal compounds and developed large-scale manufacturing techniques. As understanding of biology and chemistry improved in the 20th century, the occurrence and severity of such diseases as typhoid fever, poliomyelitis, and syphilis were greatly reduced. While many drugs, such as quinine and morphine, are extracted from plant substances, others are discovered and synthesized by techniques of chemistry. The pharmaceutical industry has greatly aided medical progress, and many new drugs have been discovered and produced in industrial laboratories. Identifying new drug targets, attaining regulatory approval, and refining drug discovery processes are the most difficult tasks of the pharmaceutical industry. The current chapter introduces the Indian pharmaceutical industry. The role and importance of the industry to Indian economy is then highlighted. Finally a few suggestions are given at the end of the chapter to promote further growth of the industry.

Introduction to Indian pharmaceutical industry

1. The pharmaceutical industry in India can be divided in two parts: bulk drugs and formulations
2. The industry is split with over 20,000 companies, among which, 250 are in the organised sector, which control over 70% of the total market. There is not one company holding a market share greater than 10%
3. India constitutes 2% of the world market in value terms and 8% in volume terms.

4. The National Pharmaceutical Pricing Authority (NPPA) monitors the drug prices. The drug prices are controlled in India to ensure the availability of essential drugs to the society at affordable prices.

5. Drug prices in India are 1/6th of average world prices. But per capita consumption of drugs in India at US $ 3 is amongst the lowest in the world compared to Japan’s US $ 412, Germany’s US $ 222 and USA’s US $ 191.

6. Till recently, the Patent Act of 1970 was driving the Indian industry. This Act allowed Indian companies to manufacture patented drug molecules through reverse engineering the process of manufacture. Thus only the process of manufacture could be patented in India and not the product itself. This was allowed because India being a developing country could not afford to have patented drugs for its citizens. However, with pressure mounting from the World Trade Organisation (WTO), Patent (Amendments) Act was introduced in 2005. With the passage of this Act, it is now no longer possible for Indian pharmaceutical companies to reverse engineer drug molecules patented after 1995. The details of the Patent (Amendments) Act, 2005 and its impact on the Indian drug industry have been discussed in detail in chapter V of the study.

9. The Indian drug industry is a mature industry with strong manufacturing base. It has the capacity to produce quality drugs at relatively lower costs. Due to rising costs of R&D overseas, there is a greater tendency towards outsourcing and networking to India as R&D costs in India are much lower. India has maximum number of USFDA (United States Federal Drug Authority) approved plants (approximately 70) outside USA. Scientists here have successful experience in innovating new processes for manufacturing drugs.

10. Indian companies have huge competence in molecular biology, immunology and biotechnology. Companies like Biocon, Shantha Biotech etc. are relevant examples in the country.

11. There is very little R&D investment by private and public corporations. India shall have to cope-up with the rapidly changing new drug discovery technologies.
and processes at the global level to continue manufacturing drugs for the rest of the world.

**Role and Importance of Indian pharmaceutical industry**

The role and importance of the Indian pharmaceutical industry has been studied under two heads

a. On the basis of primary data

b. On the basis of secondary data

**Primary Data Results**

A primary data survey has been conducted to find out the opinions of respondents on the contribution of pharmaceutical industry to the economy. The results have been tabulated in Table 2.1

<table>
<thead>
<tr>
<th>Category</th>
<th>Provision of healthcare</th>
<th>Earning Foreign Exchange</th>
<th>Bringing Foreign Direct Investment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company Employees</td>
<td>100</td>
<td>97</td>
<td>97</td>
</tr>
<tr>
<td>Employed Doctors and Private Medical Practitioners</td>
<td>100</td>
<td>92</td>
<td>90</td>
</tr>
<tr>
<td>General Public</td>
<td>100</td>
<td>75</td>
<td>69</td>
</tr>
<tr>
<td>Chemists and Pharmaceutical Distributors</td>
<td>100</td>
<td>90</td>
<td>83</td>
</tr>
<tr>
<td>Patients</td>
<td>100</td>
<td>70</td>
<td>62</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td><strong>100</strong></td>
<td><strong>84.8</strong></td>
<td><strong>80.2</strong></td>
</tr>
</tbody>
</table>

(*More than one option has been ticked by respondents)

(Source: Field Investigation)
Table 2.1 (Graph 2.1) shows that all the respondents realize the importance of pharmaceutical industry in providing healthcare. They said that pharmaceutical industry not only saves the lives of the individuals but also helps build healthy citizens who can work for the upliftment of the country. This way it helps in nation building. Apart from this, 84.8% of the respondents said that pharmaceutical industry also contributed to the foreign exchange earnings of the country. 80.2% of the respondents feel that the industry attracts foreign direct investment in R&D because of its cost-effectiveness.

Table 2.2 (Graph 2.2) shows the opinion of respondents regarding the challenges facing the pharmaceutical industry of India. 81.2% of the total respondents feel that the sale of spurious drugs is a very big problem of the pharmaceutical industry. Majority of respondents feel that the government has not been able to control the manufacture and sale of spurious drugs. 8.4% of the respondents feel that there are other issues also that need to be addressed.
Table 2.2

Respondents' opinion on challenges facing pharmaceutical industry
(Figures in percentages*)

<table>
<thead>
<tr>
<th>Category</th>
<th>Spurious drugs</th>
<th>Any other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company Employees</td>
<td>93</td>
<td>12</td>
</tr>
<tr>
<td>Employed Doctors and Private Medical Practitioners</td>
<td>84</td>
<td>6</td>
</tr>
<tr>
<td>General Public</td>
<td>80</td>
<td>7</td>
</tr>
<tr>
<td>Chemists and Pharmaceutical Distributors</td>
<td>85</td>
<td>9</td>
</tr>
<tr>
<td>Patients</td>
<td>81</td>
<td>8</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td><strong>81.2</strong></td>
<td><strong>8.4</strong></td>
</tr>
</tbody>
</table>

(*More than one option has been ticked by respondents)
(Source: Field Investigation)

Graph 2.2

(Source: Table 2.2)
In this category of other issues the respondents have been given the following options:

a. issue of price control
b. issue of environmental pollution,
c. issue of safe clinical trials
d. issue of foreign trade
e. issue of R&D of new medicines
f. any other issues the respondents feel is important

The respondents have also given their suggestions to face the challenges of the industry. These have been incorporated in the study.

**Secondary Data Results**

The secondary data has been analysed in three parts:

1. Provision of healthcare
2. Contribution to the foreign exchange of the country
3. Attracting foreign investments

**Provision of healthcare**

The drugs and pharmaceutical sector has a direct link with the healthcare system. Drugs are used to protect, maintain and restore the health of the people. The pharmaceutical industry therefore plays an important role in the provision of healthcare. Moreover, the R&D work done in the industry either by private companies or by government organisations adds to the technology base of the country. The drugs and pharmaceutical sector is one of the largest components in the category of chemical industries. The Indian pharmaceutical industry meets over 95% of the country's pharmaceutical needs. This is a huge achievement for the Indian pharmaceutical industry because till 1970s, the multinational companies dominated the Indian market. The share of domestic companies was less than 25%. Because of the domination of foreign firms the prices of medicines were very high and out of the reach of many people as the government had no control over them. However, today the situation has changed. Now more than 70% of the Indian market is under the control of Indian firms. Because of the presence of a large number of Indian players in the industry, there is huge competition in the market and prices of...
medicines in India are some of the lowest in the world. The contribution of the pharmaceutical industry to provide healthcare can be gauged from the fact that India and Japan are the only two countries in the world where the western multinational companies do not dominate the pharmaceutical industry.

**Findings**

However the Indian drug industry faces lots of challenges like-

1. The Indian drug industry is badly facing the challenge of spurious drugs. These not only harm the image of the country but also ruin the health of its citizens. Through the Drugs and Cosmetics (Amendments) Bill, 2005 which was passed by the Parliament and became an Act in 2008, the government has made efforts to tighten the noose on those indulging in such malpractices. The Act makes the offence non-bailable with a minimum imprisonment of 10 years and a fine of Rs. one lakh. However the menace still prevails.

2. Over the years there has been a tie between the government and the pharmaceutical industry over price control of drugs. Drug prices are set by National Pharmaceutical Pricing Authority (NPPA) through Drugs Price Control Order (DPCO), 1995. However the industry feels that there should be no price control and the prices should be set through competition.

3. Although laws have been framed for waste water treatment by drug factories in the country, however a recent report in an esteemed newspaper indicates that the laws are being flouted openly leading to high levels of chemical in drinking water of nearby villages. The report indicates 100-30,000 times more chemicals than the levels considered safe for drinking. Such cases of law breaking are common in India as drug and environmental authorities are lethargic in taking action against such factories.

**Suggestions**

A. Issue of spurious drugs

The government has already taken steps that were required to strengthen the law to prevent manufacture and sale of spurious drugs in the country. Now efforts are needed to
bring awareness amongst all those who are directly or indirectly affected by this trade.

This should be done component wise-chemists and stockists, hospitals, state governments, pharmaceutical companies, allied industry and the consumers.

1. 40% of the respondents feel that the working of the chemists should be modernised.
   a. No person having any criminal background should be issued a licence for selling drugs.
   b. Maintaining information regarding the stocks, batch numbers of the drugs, expiry dates etc. should be made compulsory and computerized. Any failure on this regard should be seen as a non bailable offence.
   c. Chemists should not be allowed to sell any medicine without the prescription of a registered medical practitioner and without a cash memo. The cash memo should include the name and address of the patient, name and address of the prescribing doctor, name of the medicine, batch number and price charged.
   d. Any substitution of medicine prescribed by the doctor should be treated as an offence.

2. Hospitals dispensing medicines should purchase them directly from the companies or their authorised stockists only and not from open markets.

3. There should be a control on allied packaging industry such as labels manufacturer/ carton manufacturer. Any unauthorised printing leading to manufacture of spurious drugs should be considered a cognisable offense. Use of only printed capsules be permitted and un-printed capsules should not be permitted.

4. 20% of respondents feel that State governments need to take notice of the following issues.
   a. All vacancies in the state Drug Control Organisations should be filled with immediate effect. The number of inspectors should be sufficient to meet the work load and to monitor the quality of drugs. There should be one
inspector for every 25 manufacturing units and one for every 100 sales premises.

b. Each state should have an intelligence-cum-legal cell to monitor the quality of drugs coming in the market. At present only 10 States have the facility.

c. Drug Inspectors should make regular visits to their areas and pick up random samples of medicines from chemists, hospitals and stockists for testing them. Any drug official demanding and accepting bribe in this regard should be treated in same manner as a culprit who sells a spurious drug.

d. The state governments should make earnest efforts to set up proper testing laboratories in each and every district. At present only 15 of the 26 states of the country have well equipped testing laboratories of which only 7 are well staffed.

5. Pharmaceutical companies also need to take steps in this regard.

   a. Companies should use holograms, bar codes, special inks for printing; emboss logo on the tablets and capsules etc. to make it difficult for the spurious drug manufacturers to copy them.

   b. Month and year of manufacturing should be embossed on bottles also and not only on their labels. This shall help prevent their recycling.

   c. Companies should keep proper record of their stockists and keep testing their random samples to prevent mixing of spurious drugs in their stocks.

6. 20% of the respondents feel that consumers should be educated against the menace of spurious drugs. They should be taught to remain alert and vigilant while purchasing medicines. Some of the cautions they can follow are-

   a. To buy drugs from reputed chemists who issue cash memo for purchases.

   b. To check the batch number and the expiry date of the medicine on the label and cash memo.

   c. Do not buy if the packing is loose.
d. Do not buy if the price is lower than the routine price.
e. Do not buy if there is an additional mark on the name unless prescribed by the doctor like +, @, ! etc.
f. Avoid doctors who themselves dispense loose medicines and do not write a prescription.
g. Do not buy the medicine if the label looks old or is mutilated.
h. Illiterate patients should get the medicine checked by the doctor before consuming them.
i. Destroy the label and container of the medicine after using them.

B. Issue of price control

The issue of price control is very important to the pharmaceutical industry who feels that the industry has the right to fix prices. The industry’s plea is that since the companies invest in R&D of new drugs, they need to get this money from the consumer because it is finally the consumer who takes the benefit of a new developed drug. However the government wants that the prices of the drugs should be such that they are within the reach of the common man. In view of this situation, the following suggestions are made:

1. Companies give huge margins to dealers and chemists, samples and free gifts to doctors like foreign trips etc. to boost their sales. All these costs are charged from the consumers. The government should stop all these activities immediately. Instead of fixing the price of a drug the government should fix the
   a. maximum margin a manufacturer can charge on his basic cost price
   b. maximum margin a company can give to its dealer, carrying and forwarding agents, stockists and chemists.
   c. Maximum amount of free samples that a company can distribute of a drug
   d. All incentives to the doctors and other in the supply chain like free gifts, free trips etc. should be banned.

   Also this will lead to a reduction in the substitution of drugs by the doctors. It will also lead to a reduction in the total healthcare costs incurred by the patients.

2. The government should completely ban the combination of drugs in order to get the fair value of the basic cost of the drugs. Doctors should prescribe single drugs and not
combinations. This is because when a company sells a combination drug it increases the price unnecessarily.

3. Use of generic drugs should be thoroughly imposed as these do not involve unnecessary corrupt sales promotional activities to the medical professionals which lead to price rise which the patient has to bear at the end.

C. **Issue of environmental pollution**

The issue of environmental pollution is very serious especially in the wake of global warming. The government has already made laws and the administrative machinery required for implementation is also there. Still the problem of environmental pollution is huge because of corruption and carelessness. In this regard the following steps need to be taken

1. The general public and the media need to play a very important role. Wherever such cases of law breakage and environmental pollution are found the local public should bring them to the notice of media. The media should bring such cases in limelight. The administrative people in charge of that area should be booked and asked the reasons for their negligence. The media—newspapers, radio stations and news T.V. channels should telecast or print the names of such corrupt officials so that these people face social criticism. Already we have programmes like ‘Face the Nation’ on NDTV etc. These programmes should bring the culprits in peoples’ court. The owners of such drug factories should also be tried in people’s court.

2. The Central Drugs Control Department of India under the Ministry of Health and Family Welfare should create more awareness programmes for the pharmaceutical companies so that they realise the importance of environmental and social welfare.

3. The Ministry of Environment and Forests should also realise its responsibilities and create awareness among the local people regarding the hazards of environmental pollution. The awareness can be created in the form of programmes on T.V. and radio stations.
Advertisements regarding reward to persons who bring cases of such environmental pollution to the knowledge of government authorities.

Road shows, hoardings etc.

**Contribution to the foreign exchange of the country**

The industry contributes a lot to the foreign exchange of the country. Pharmaceutical exports which were just 0.55% of the value of the total Indian exports in 1970s have risen to 4.5% by the turn of the century. India’s share of the value of world pharmaceutical exports was just 0.4% in the 1970s. It rose to approximately 2% by 2008-year end. The Indian pharmaceutical industry, which depended solely on imported medicines and intermediates till 1970s, has now emerged as a leader amongst the developing countries.

Table 2.3 shows the foreign exchange contribution of the industry to the country from 2000-2008

**Table 2.3**

Foreign Exchange Earnings

*(Figures in crores of Rupees)*

<table>
<thead>
<tr>
<th>Foreign Exchange Earnings</th>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical Industry</td>
<td>10697</td>
</tr>
<tr>
<td>India</td>
<td>(42060)</td>
</tr>
</tbody>
</table>

*(Foreign Exchange Earnings = Exports – Imports)*

*(Source: DGCIS, Kolkata)*

Table 2.3 shows that the Foreign Exchange Earnings of the Indian pharmaceutical industry are positive. This means that the pharmaceutical industry is bringing foreign exchange in the country, which is actually very beneficial for the country. This is in contrast to the total foreign exchange earnings of the country where imports are
exceeding exports every year. Thus Table 2.3 very clearly explains the contribution of the pharmaceutical industry to the country’s economy.

It seems the Foreign Exchange Earnings of pharmaceutical industry will grow even more in the years to come. Hence, we have calculated the expected foreign exchange earnings by pharmaceutical industry in 2009 and 2010. For this purpose binomial method of extrapolation has been used.

\[(y-1)_n = \binom{n}{y} y^{y-1} n^{n-y} + \binom{n}{y-2} n(n-1)(n-2) y^{y-3} + \binom{n}{y-3} n(n-1)(n-2)(n-3) y^{y-4} \ldots \ldots \]

Where \( n \) is the number of known values of \( y \)

Substituting the values

\[ y_9 = 50740 \]
\[ y_{10} = 57765 \]

Hence foreign exchange earnings by the pharmaceutical industry in 2009 are expected to be Rs. 50740 crores and in 2010 are expected to be Rs.57765 crores. Thus, the pharmaceutical industry is expected to add to the country’s economic growth in the coming years also.

Findings

From the above calculation it is clear that contribution by pharmaceutical industry to foreign exchange shall continue in years to come. However the industry faces a lot of problems while exporting drugs like-

1. There are hurdles in the form of regulatory, non-tariff and trade barriers, which are hampering export growth prospects. It is estimated that service tax paid by the pharmaceutical sector on export-related activities constitutes nearly five percent of the freight-on-board value of consignments\(^6\).

2. Brazil and Mexico have increased the import tax to 14 per cent, prohibitive registration charges of about $20,000 for each product and a waiting period of 18 months, which are the major problems faced by exporters. In addition, these two countries, which used to have nominal import duties till last year, raised this
duty/import tax substantially without applying a similar duty hike on local manufacturers. Further, Nigeria has banned some specific drugs and formulations to protect the domestic pharmaceutical industry. This is similar to the complaint against Pakistan, as they have banned the import of Indian bulk drugs that are locally produced, though such restrictions do not apply to other exporting countries7.

3. On the European front, the major hurdle is in relation to the import of Hops (Humulus Lupulus Extract) by the European community. According to this legislation, Hops imported into Europe, which is not grown in Europe cannot be imported into the region, unless it is accompanied by an equivalence certificate, issued by the specified authorities of the exporting country. Exporters allege that India does not figure in the list of specified authorities for issue of equivalence certificate, while China is included7.

4. There is paucity of awareness about Indian pharmaceutical industry as a major manufacturing hub. A few countries like Argentina, Bangladesh, Egypt and Gulf countries do not recognise India as a major manufacturing hub8.

5. Besides these barriers, the counterfeit market is also a major hurdle. Even though India has the highest number of USFDA approved plants outside USA, the latter's administration has kept India under the '301 watch list' to monitor its pharmaceutical exports, because of the menace of spurious drugs, manufactured by unorganised pharmaceutical companies. WHO estimates that 10 percent of global pharmaceutical commerce or $21 billion involves counterfeit drugs and 35 percent of all detected counterfeit cases come from India. India's vision to become a major outsourcing hub could be deterred due to the above statistics. And this is also resulting in loss of brand equity, loss of reputation, and mistrust of customers, health officials and regulatory authorities9.

Suggestions

1. As per the provisions of Central Excise Rules read with CENVAT credit rules, credit of duty paid on inputs (including Bulk Drugs and APIs) used in the manufacture of finished drugs is not available. This adds to the cost of drugs
manufactured even in excise free zones. Further a custom duty of 7.7% is levied on the import of APIs in the country. The government should exempt the excise and customs duty on bulk drugs and APIs so that the cost of manufacture of drugs comes down. This shall greatly benefit the exporters from competing with low prices in the international market.

2. State levies and taxes such as Octroi, mandi tax, electricity duty etc., are not reimbursed to the exporters. The Government should examine a scheme to rebate/reimburse these taxes to exporters.

3. The Government should examine the feasibility of introducing zero duty EPCG Scheme replacing the present 3% concessional duty EPCG Scheme. This may be justified on account of continuous reduction in customs duty on import of capital goods.

4. The Government should examine whether incentives under Focus Product and Focus Market Schemes can be increased from the present level of 1.25% and 2.5% respectively. This will help exporters in tackling the adverse impact of rupee depreciation to a certain extent. The Government should include more markets under the Focus Market Scheme. At present no European country is included under this basket. The government should enter into dialogues with some more countries. This shall help in negating the effect of loss of exports to African countries like Brazil and Nigeria.

5. The Government should consider all ports notified by the customs for general import/export with valuation facilities to be treated as ports under Export Promotion Schemes. At present, only 108 out of 346 such ports are notified for Export Promotion Schemes.

6. The government should encourage the setting up of USFDA compliant plants by providing tax holidays for a specific period (as was given to Baddi (Himachal Pradesh)). This will help Indian companies to exploit the opportunity arising out of patented drugs and take up marketing of generics in developed countries like USA.

7. There has to be an increase in awareness by showcasing India as a major manufacturing hub for formulations and APIs through an apex export promotion
council like Pharmexcil. Such organisations should organise summits, conferences: seminars etc. or give advertisements in foreign countries about India being a big pharmaceutical business destination. Such programs need to be held in African third world countries because these are the countries that rely mostly on foreign drugs for their healthcare.

8. Suggestions related to control of spurious drugs have already been given above.

**Attracting foreign direct investment**

The pharmaceutical industry relies heavily on the research of new molecules or New Chemical Entities (NCEs). For a company to survive, it must keep inventing new drugs. However research and development of a drug is a very expensive process and failure rates are very high. Hence companies are looking out for cheaper options. One such option is to outsource this process to companies in countries where the same process can be carried out at much cheaper rates. Research and development in India is much cheaper than in regulated markets of USA and Europe. Also India has immense potential in terms of number of scientists, kind of diseases, and research facilities.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Approximate cost in USA and UK</th>
<th>Approximate cost in India</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discovery</td>
<td>10-20</td>
<td>7-14</td>
</tr>
<tr>
<td>Pre-clinical testing- Phase-I</td>
<td>4-5</td>
<td>1-1.5</td>
</tr>
<tr>
<td>Phase-II</td>
<td>3-6</td>
<td>1-5</td>
</tr>
<tr>
<td>Phase-III</td>
<td>20</td>
<td>15</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>150-200</strong></td>
<td><strong>90-140</strong></td>
</tr>
</tbody>
</table>

Hence a large number of foreign companies are coming to India to outsource their discovery process to Indian companies. In return of doing contract research for foreign companies, Indian companies are earning huge profits and also developing technical know-how. Table 2.5 shows the inflow of Foreign Direct Investment (FDI) for clinical research in the country. Figures prior to the year 2003 could not be made available as they were negligible. We can see that the business of clinical research outsourcing is increasing every year. This implies that multinational pharmaceutical companies are realizing the importance of making R&D investments in India.

Table 2.5
Clinical Research Outsourcing Market in India
(Figures in crores of Rupees)

<table>
<thead>
<tr>
<th>Years</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDI Inflow in India through clinical research outsourcing</td>
<td>68</td>
<td>77</td>
<td>95</td>
<td>118</td>
<td>144</td>
<td>176</td>
</tr>
<tr>
<td>Total FDI inflow in India</td>
<td>12117</td>
<td>17138</td>
<td>24613</td>
<td>70630</td>
<td>98664</td>
<td>122919</td>
</tr>
</tbody>
</table>


Looking at the increasing trend of FDI inflow in India from 2003 -2008, we have calculated the expected amount of FDI inflow for the years 2009 and 2010. For this purpose again binomial method of extrapolation has been used.

\[(y-I)_n = y_n - n y_{n-1} + n(n-1)y_{n-2} - \frac{n(n-1)(n-2)y_{n-3} + n(n-1)(n-2)(n-3)y_{n-4}}{2!} + \frac{n(n-1)(n-2)(n-3)y_{n-4}}{3!} \]

Substituting the values

\[y_6 = 234\]
\[y_7 = 284\]
Hence clinical research outsourcing to India in 2009 is expected to be Rs. 234 crores and in 2010 is expected to be Rs. 284 crores. Thus, the pharmaceutical industry is expected to add to the economic growth of the country in the coming years also.

**Findings**

However there are a few issues that need to be understood

1. The clinical trials business is relatively new to India. Hence the laws that have been framed lack a clear line of action and are quite vague. Further it is not wrong to say that in India laws are formulated but not implemented. Many a times companies conduct clinical trials without informing the government or the patients involved.

2. India being a developing country lacks adequate provision to healthcare. People here get into clinical trials for want of free healthcare without even knowing the real side-effects of the trial.

3. Laws governing clinical trials are there but not the machinery to implement them. Hence companies often get away easily after causing harm to the patients.

**Suggestions**

Conducting trials on human beings is crucial. The safety and welfare of the individuals participating in the clinical trial should be given utmost importance. The following measures are suggested in view of the current situation in the country-

2. The government has set up a National Biomedical Research Authority to look into the matters of clinical trials. But there are no state level organisations. Looking at the quantum of clinical trial business in India such state level organisations are very much needed. There should be a separate Biomedical Research Authority for every state. All state authorities should come directly under the purview of National Biomedical Research Authority. The structure of state authorities should be parallel to the national authority like-

   i. A chairperson - An eminent scientist to be appointed by the state government

   ii. Vice chairperson elected by members
iii. 6 eminent persons from basic sciences, clinical sciences, community health and behavioral and social science
iv. 2 persons representing NGO and social organizations
v. 1 eminent person from legal field

3. All clinical trials being conducted in the state should be routed through the state biomedical research authority. The organisation conducting the research in the state should give the committee complete information on the individuals under trial. Further the committee should conduct a meeting of all the volunteers in their area before the trial begins, informing them about the risks involved in the trial, the precautions to be taken care of etc.

4. The committee should ensure that all participants are provided with insurance cover in case of any mishap. The committees in all states of India should be connected through computers and other electronic media so that they remain in touch with each other.

5. Moreover the committee should also ensure that the participants are provided their due remuneration after the completion of the trial be it successful or unsuccessful. This is important because many times companies refuse to pay any remuneration in case the trial has failed.

6. The committee should also be empowered to decide on cases on clinical trials. This shall help in the speedy trial of such cases which keep pending for years or go unnoticed. Any party who wants to file against the decision of the state authority should go directly to the National Biomedical Research Authority. Any further hearing should be directly to the Supreme Court.

7. The laws regarding punishment on violation of rules or negligence on the part of companies and doctors conducting trials as formulated by the National Biomedical Research Authority is imprisonment upto 6 months or a penalty of Rupees 10,000 only. This is too less. Offences related to negligence on human subjects are quite dangerous. They can lead to deaths of individuals. Hence such crimes should be made non-bailable and imprisonment extended to life –term
Conclusion

The above analysis gives a picture of the Indian pharmaceutical industry. It shows the current status of the industry and its role and importance to the nation’s economy. Indian economy has progressed a lot after independence. Earlier India had to depend on foreign countries for drugs and medicines. Now the country is exporting medicines to other parts of the world. However, it does not mean that the Indian pharmaceutical industry is a completely mature industry. If the industry has strengths, it has weaknesses too. During the course of study many points came forward which show signs of the industry’s weaknesses and the threats that it faces from the outside world.
References


2 "Imperatives for Indian pharmaceutical industry in a changing world". Express Pharma. 16-31 January, 2008. pg.11.

3 http://commerce.nic.in


7 Problems put forward by the exporters to Commerce and Industry Minister Mr. Kamalnath, on release of Annual Supplement 2008 to Foreign Trade Policy 2004-09 (April 11, 2008).


10 The EPCG scheme allows import of capital goods for pre production, production and post production at 3% Customs duty subject to an export obligation equivalent to 8 times of duty saved on capital goods imported to be fulfilled over a period of 8 years reckoned from the date of issuance of the authorisation.

11 The objective of the Focus Market Scheme is to offset the high freight cost and other disabilities to select international markets with a view to enhance our export competitiveness to these countries. Exports of all products to the notified countries shall be entitled for duty credit scrip equivalent to 2.5% of the FOB value of exports for each licensing year commencing from 1st April, 2006. The scrip and the items imported against it would be freely transferable. The Focus Market scheme allows duty credit facility at 2.5 per cent of the free-on-board value of exports of all products to the notified countries.

12 www.eximkey.com/contents
The pharmaceutical industry wants only 62 drugs of the 354 drugs (663 formulations) in the National List of Essential Medicine (NLEM) 2003 to come under price monitoring mechanism. This view is reflected in the report of the joint committee on Draft National Pharmaceutical Policy headed by Ms Satwant Reddy, Secretary, Department of Chemicals and Petrochemicals. These 62 drugs are with 241 formulations. The drugs, which the industry did not want to be subjected to price control includes anti-cancer and anti-retroviral, formulations under public health programme, hospital supply products, and formulations having MRP below Rs 3 per unit. On these 62 drugs the industry has offered to roll back prices by six months from the date of the new DPCO order. It has also offered an additional 5 per cent reduction on the prices. Meanwhile, NPPA is of the view that the total number of drugs under price control should be 230 — this includes 44 drugs that are both part of the NLEM and DPCO 1995. The Government would like only those drugs that cost less than Re 1 per unit to stay out of the NLEM, as opposed to the Rs 3 per unit demand from pharma companies. The industry has also offered a rollback of prices by six months from the date when the new drug price control order comes into effect. To that they’ve offered to add a five per cent price reduction. The National Pharmaceutical Price Authority has suggested a 10 per cent reduction in prices. The Government would also like a three-year freeze of the 1995 Drug Price Control Order (DPCO). The industry is only willing to agree to a year’s extension. "The drugs under the DPCO have seen only an average price increase of one per cent. Also, some of the drugs in the list do not qualify under NLEM," says an industry representative. Even the number of formulations is under dispute, while the industry insists on only allowing 241 formulations to come under price control, the NPPA would like to see 391 formulations covered. (The Hindu Business Line, February 3, 2007, e-paper. The government has still not decided on the issue)