CHAPTER 3
Regulatory Framework - Drug Price Control Order & Indian Patent Act
3.1 Overview

Regulation is a very significant factor in pharmaceutical business. There are two reasons for that. First, since drugs affect the health and well being of the citizen, the government has an interest in assuring their adherence to medical standards and availability. Second, in light of the fact that patentable research can represent an important part of a given drug company’s cost structure, IP protection is essential to provide firms with incentives to develop new drugs.

With the objective of controlling prices of important drugs and making them available at reasonable rates to the consumer, the Government introduced the Drug Price Control Order (DCPO) in 1970. It specifies the maximum selling price of bulk drugs and formulations and the turnover ceiling for exemption from DPCO. At present DPCO fixes and monitors the prices of 74 bulk drugs, and all the formulations manufactured using any of these bulk drugs thus covering 50 percent of the pharmaceutical market. DPCO has been amended with three revisions in 1979, 1987 and 1995. The number of drugs under price control has been reduced with every revision.

The Government also enacted the Indian Patent Act (IPA) in 1970. Unlike the international norms, this Act provide for process patents, which recognized the process to manufacture a product and not the end product. This move was intended to develop the indigenous pharmaceutical industry. Indian companies took advantage of this policy and succeeded in producing molecules by reverse engineering, which were under patent protection elsewhere, at a cost that was a fraction of the original research cost. This cost advantage allowed Indian companies to price their products considerably lower as compared with their international counterparts. This scenario has undergone a substantial change as India being a member to the World Trade Organization (WTO) has introduced the product patent regime and provides legal protection to Trade Related Intellectual Property Rights (TRIPS) by 1st January 2005.

This ensures protection for new products and Indian industry would no longer be able to produce patented drugs and market them without license from the patentee.
3.1.1 (a) Government’s role

In India Government has been playing mainly two different kinds of roles with respect to pharmaceutical industry, namely

1. Regulatory role

2. Socialistic role.

3.1.1(b) Role in the Past

In the 50 years since independence, the Indian Government has played significant role for growth of domestic pharmaceutical industry. In earlier years, the multinationals had a near monopoly on the Indian pharmaceutical market. They imported and marketed low cost generics for masses and also few specialist formulations. Afterwards they had established formulation units in India due to pressure from the government against imports. In the 1960s, Indian Government has laid foundation of the domestic pharmaceutical industry by promoting HAL and IDPL. However MNCs maintained their lead due to their global R&D support.

In 1970 Indian government introduced The Indian Patent Act (IPA). Under IPA government allowed only process patents for substances used in foods and pharmaceuticals. Domestic manufacturers had started manufacturing bulk drugs developed by MNCs by doing modifications and then also stared manufacturing formulations. Foreign Exchange Regulation Act further compelled MNCs to curtail their operations because they had to bring down their holdings in Indian companies to 40% and give boost to domestic companies. In past government had also restricted entry of players to insurance sector, which hindered the development of market for healthcare insurance.

Indian government had also played another important role in the past with an aim to provide Indian public with medicines at affordable prices. In 1970, it introduced Drug Price Control Order (DPCO), which had put a ceiling on drug prices.

3.1 (b) Regulatory Role Today and in Future.

Regulatory role of Indian government was prohibitive in nature with respect to free trade in pharmaceutical industry. It has gradually made encouraging moves with
respect to free trade. India is one of the signatory countries to an agreement being implemented under WTO, which has been promoted to encourage free trade between member countries. According to this agreement India had been given time up to the year 2005 to amend its IPA to allow its product patent instead of process patent. So, new drugs introduced after this date will have to be accorded product patent in India.

India has adopted liberalized economic policy after year 1990 and at present is continuously doing so. Due to this, MNCs can enter freely into Indian market through various routes like 100% subsidiary, joint ventures etc. Similarly domestic companies can set up overseas subsidiaries, joint sectors etc in foreign countries. Government has now opened insurance sector for private players, which in turn increase the depth and breadth of the healthcare insurance market. DPCO still exist today, but number of drugs covered under DPCO has been reduced significantly from 370 in 1989 to 76 in 1995.

Socialistic Role

With an aim to provide medical facilities to the poor, Indian government or other legislative bodies are spending huge amount on creating medical treatment facilities, subsidizing medicines cost etc. It is estimated that government and municipal bodies are spending 33% of total expenditure on healthcare in India.

3.2 DPCO:

Introduction:

DPCO controls the domestic prices of major bulk drugs and their formulations with an aim to provide patients with medicines at affordable prices. DPCO ascertains, as per Drug Policy guidelines, the bulk drugs (and their formulations) to be kept under price control. Under DPCO, a bulk drug and formulation are defined as follows:

3. Bulk drug means any pharmaceutical-chemical, biological or plant product including its salts, derivatives etc used as such or as an ingredient in any formulation.

4. Formulation means any medicine processed out of or containing one or more bulk drug or drugs for internal or external use or for diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but shall not include any
medicine included in any bona fide Ayurvedic, Homeopathic or Unani system of medicine.

Thus, DPCO is applicable only to allopathic drugs. Ceiling prices for the DPCO bulk drugs and formulations are notified by the Government authorities and periodically revised. DPCO came into existence in 1970 and was thereafter revised in 1979, 1987 and 1995.

3.2(a) Dilution of Drug Policy and Drug Price Increase

Unlike consumer goods, drugs are not purchased by the preference of a person, but on a doctor’s prescription. Consumers have no choice of their own on this matter. Prices of drugs are increasing by leaps and bounds along with prices of other commodities in recent times. The drug manufacturers are flouting the Drug Price Control Order (DPCO). In 1970 when DPCO was introduced, most of the drugs were under control.

3.2.1 The New Drug Policy, 1995

The DPCO revised order was passed in Jan’95. Its basic structure remains same as the prior two orders of’79 and ‘87. However, it did liberalize the span of control considerably, from 143 drugs to just 76.

The minimum criterion for a drug to be included in the price control list under DPCO 1995 is that it should have an annual turnover of at least INR 40 million. A drug with a lower turnover can also be brought under price control if the drug has a turnover of more than INR 10 million and a single formulator has more than 90 percent of the market share. Similarly, a drug (irrespective of the turnover criteria) can be exempted from the price control if there are at least five manufacturers supplying it.

Under DPCO 1995, for arriving at a price for a particular drug or formulation the government has defined a formula. The maximum sales price of a bulk drug is fixed by the government to yield a post tax return of 14 percent on the net worth or 22 percent on the capital employed. Manufacturers can choose any of these two parameters. In the case of a new plant, an internal rate of return of 12 percent on long term marginal costing may be allowed. In case of imported bulk drugs, the landed cost (inclusive of import and custom duty) is the maximum permissible selling price.

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The government also determines the retail price for formulations (prepared from a bulk drug under price control). The rule allows the manufacturer to charge a markup of 100 percent as Maximum Allowable Post Manufacturing Expenses (MAPE) for scheduled formulations. MAPE includes all costs incurred from the ex-factory stage to retailing including margins for the manufacturer and retailers.

The price criteria for formulations is given by
\[
\text{Retail Price} = (\text{Material Cost} + \text{Conversion Cost} + \text{Packing material} + \text{Packing Cost}) \times (1 + \text{MAPE}) + \text{Excise Duty}.
\]

For imported formulations, the landed cost and the selling and distribution expenses, which would not exceed 50 percent of the landed price, form the basis of price.

Small-scale units were exempt from DPCO prior to 1995, but DPCO 1995 included small-scale units in its ambit. Moreover the DPCO also required pharmaceutical companies to maintain a ratio between the formulations and bulk drugs production which was removed by DPCO 1995.

DPCO has been successful in keeping drug prices among the lowest in India but price regulations have mainly affected the MNCs as Indian companies got into manufacturing drugs, which don’t fall under the purview of DPCO. According to an estimate, 50 to 75 percent of their products are under price control, while Indian companies having nearly 15 to 30 percent of their products under price control. The reason being, while MNCs have always been formulations-driven with focus only on domestic market, Indian companies were primarily bulk drug producers engaged in exports. Only recently they have started looking at the domestic market and for climbing up the value chain to enter the formulations business. This has led to restricted growth of the MNCs in India and limited investment in the industry and has encouraged the growth of the Indian companies especially in the small-scale sector. Moreover rigid price with inadequate revision in accordance with cost increases have adversely affected the profitability of the manufacturers. Another impact of the DPCO on the industry has been the low R&D spending in India. R&D spending accounts for 1.5 percent of the turnover compared to the international level of 15 percent.
The increased focus on exports those are exempt from DPCO, decreasing import tariffs under WTO obligations and rising competition among drugs under control have reduced the impact of the DPCO.

### 3.2.2 Drug Policy:

The Drug Policy decides the criteria to be used for selecting a bulk drug to be kept under price control. The modified criteria in the New Drug Policy were:

- Annual turnover calculation basis as on March 31, 1990.

5. Annual turnover calculation is including sales tax but excluding excise duty and other local taxes.

6. Inclusion of a bulk drug if turnover exceeds Rs. 40mn.

7. Inclusion of a bulk drug if turnover exceeds Rs 10mn, with any single formulator having a 90% plus market share.

8. Exclusion, if at least 5 bulk drug manufacturers and 10 formulation manufacturers exist, none having more than 40% market share.

9. Exclusion from price control for 5 year, for drugs developed indigenously for the first time.

#### Exhibit 3.1 Comparative Charts of Various Drug Price Control Orders (DPCO)

<table>
<thead>
<tr>
<th>Description</th>
<th>DPCO-1979</th>
<th>DPCO-1987</th>
<th>DPCO-1995</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs under price control</td>
<td>347</td>
<td>142</td>
<td>76</td>
</tr>
<tr>
<td>Categories for price control</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>*** Category I</td>
<td>40%</td>
<td>75%</td>
<td>100%</td>
</tr>
<tr>
<td>Category II</td>
<td>55%</td>
<td>100%</td>
<td>N.A.</td>
</tr>
<tr>
<td>Category III (single ingredient leaders)</td>
<td>100%</td>
<td>N.A.</td>
<td>N.A.</td>
</tr>
<tr>
<td>Category III (others)</td>
<td>60%</td>
<td>N.A.</td>
<td>N.A.</td>
</tr>
<tr>
<td>%age of market under DPCO</td>
<td>90%</td>
<td>70%</td>
<td>50%</td>
</tr>
</tbody>
</table>

Source: India Info line Research Report

Industrial Licensing has been abolished for all bulk drugs. There is no hindrance to capacity expansions. Supply is expected to rise to meet or exceed demand, resulting in competitive pressures.
Foreign investment up to 51% was permitted in case of all bulk drugs, their intermediates and formulations. Foreign investments above 51% were considered on a case-to-case basis, especially in manufacture of drugs from basic stage / using new technology.

3.3 National Pharmaceutical Pricing Authority (NPPA)

The NPPA was established in 1997, to improve the speed and transparency of the process of fixing the prices of bulk drugs and formulations. It is expected to reduce the time lag between price revisions, thereby providing stable margins for formulation, and revise the list of bulk drugs under price control within reasonable time.

3.4 The Indian Patent Act (IPA)

The IPA (1970) - the regulation defining the protection to intellectual property - does not provide for product patents. Instead it allows for manufacturing processes to be patented. This enabled the domestic pharmaceutical manufacturers to develop different processes and compete with international companies in the domestic markets.

But, India being a signatory to the GATT (now WTO) is obliged to ensure that IPA complies with TRIPS (Trade Related Intellectual Property Rights) agreement. Intellectual property rights are the rights of the originator of an innovative idea or product to hold sole international commercial rights over it for a period of time. Compliance with TRIPS would mean introducing product patents in India for pharmaceuticals for a uniform duration of 20 years for all products. India is entitled to a 10-year transitional period, making product patents applicable by January 1st 2005. However, companies that have filed patent applications from January 1st, 1995 will enjoy exclusive marketing rights.

The impact of the prospective transition from the current process patent regime to a product patent regime in 2005 is likely to be felt only gradually over the next few years and in a substantive measure only near to 2010.

Moreover the patent laws will protect only a small proportion of drugs as the patented drugs form only 10 to 12% of the domestic drug turnover.

The significant development which the pharmaceutical companies have recently started encashing is that many existing patented drugs will go off patent in next few years, opening up large generic markets for Indian manufacturers. The global pharmaceutical market is worth US$400bn; nonpatented drugs contribute to 70% of the

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same. In the next five years with the expiry of several patents, the non-patented segment is expected to grow to 75%. This would keep the drug prices from rising steeply.

In the long run, new patent regime and introduction of new patented products, would encourage domestic companies to invest substantially in R&D to take advantage of the abundant pool of scientific and technical resources available here. Even MNCs have recognized the opportunities of cost effective R&D in India and are planning to outsource R&D to India. Few of the MNCs like Novartis A.G., Astra Zeneca plc., Pfizer Inc. and Merck Kga have already set up 100 percent subsidiaries in India to support new research activities. Another long-term strategy that can be adopted by Indian companies would be to manufacture cost effective intermediates for foreign companies. Joint Ventures, technology collaborations and cross licensing arrangements can also be examined.

3.4.1 Indian Pharmaceutical Policy 2002

In order to strengthen the pharmaceutical industry's research and development capabilities, and to identify the support required by Indian pharmaceutical companies to undertake domestic R&D, a Committee was set up in 1999 by the name of Pharmaceutical Research and Development Committee (PRDC), under the Chairmanship of Director General of CSIR. To qualify as R&D intensive company in India, the PRDC has suggested following conditions (gold standards):

1. Invest at least 5% of its turnover per annum in R&D,
2. Invest at least Rs100mn per annum in innovative research including new drug development, new drug delivery systems etc. in India,
3. Employ at least 100 research scientist in R&D in India,
4. Company being granted at least 10 patents for research done in India,
5. Own and operate manufacturing facilities in India.

The new pharmaceutical policy has focused on liberalization by reducing number of drugs subject to price control and by further opening the market to foreign investment. This policy was released on February 15, 2002 and is based on recommendations made by Pharmaceutical Research and Development Committee (PRDC). The most significant change is the large reduction in the number of drugs under price control. 35 drugs will now be subject to price control, as against 76 drugs under the 1995 policy. The drugs in

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the new list are deemed essential, and include insulin, Rifampicin (for treatment of leprosy and tuberculosis, both of which are widespread in India) etc.

### 3.4.1(a) Budget FY04 and its impact

<table>
<thead>
<tr>
<th>Budget Measures</th>
<th>Impact of Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak custom duty reduced from 30% to 25%.</td>
<td>Overall the impact of budget is marginal on the pharmaceutical companies on account of rationalization of excise and customs tariff as well as initiatives to boost R&amp;D.</td>
</tr>
<tr>
<td>Custom duty on specified life savings drugs and specified life saving medical equipment reduced to 5%. The countervailing duty (CVD) on these items reduced to Nil by exempting them from excise duty.</td>
<td>The custom duty at the rate of 5% (without CVD) is likely to be positive for the consumers if it gets translated to lower prices of medicines.</td>
</tr>
<tr>
<td>All drugs and materials used in clinical trials are exempted under customs and excise duty.</td>
<td>Firms like Ranbaxy and Dr.Reddy's, who are focusing on research and development outsourcing are likely to benefit.</td>
</tr>
<tr>
<td>Larger number of life savings drugs under tax exemptions or concessional tax rates of 5%.</td>
<td>Custom duty exemption provided to drugs and materials used for clinical purposes is likely to augur well for the R&amp;D oriented Indian pharmaceutical companies as well as various multinational players who have identified India as a destination for conducting clinical trials.</td>
</tr>
<tr>
<td>Custom duty on Glucometers and Glucometric strips reduced to 5% from</td>
<td>The effort on part of the Government has been to create a structural support for</td>
</tr>
</tbody>
</table>

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development of the health care sector in the country. Both the announcements, launching of the insurance plan and incentive on lending hospitals are with a view to support the development of the required infrastructure.

<table>
<thead>
<tr>
<th>Specified pharmaceutical and biotechnology equipment for R&amp;D exempted from custom duty subject to their being registered with Department of Scientific and Industrial Research.</th>
<th>Traders fear that VT may increase retail prices of medicines by 4-5%. But DPCO puts caps on many prices.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surcharges on corporate Income Tax reduced from 5% to 2.5%</td>
<td></td>
</tr>
<tr>
<td>Dividend Distribution Tax at the rate of 12.5% imposed on the corporates.</td>
<td></td>
</tr>
<tr>
<td>Deduction of 100% of profits and gains for a period of 10 years is allowed to companies carrying out scientific R&amp;D.</td>
<td></td>
</tr>
<tr>
<td>An individual will get a health insurance cover of Rs 30,000 in case of hospitalization for a premium of just Rs 365 a year.</td>
<td></td>
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<tr>
<td>Concessions under the section 10 (23 G) to be granted to institutions lending to hospitals with more than 100 beds.</td>
<td></td>
</tr>
<tr>
<td>Depreciation rate on life saving medical instruments increased from 25% to 40%.</td>
<td></td>
</tr>
<tr>
<td>VAT to be introduced in all states.</td>
<td></td>
</tr>
<tr>
<td>Items under DPCO to be bought from 74 to 29.</td>
<td></td>
</tr>
</tbody>
</table>
3.4.1 (b) Budget 2007-Impact on Pharmaceutical Sector

The budget 2007-2008 has overarching importance to promote R& D. The salient features of the same are as under:

(1) Clinical trials exempted from the burden of service tax thereby boosting R&D and innovation.

(2) Increase focus on healthcare by increasing the budgetary allocation for healthcare by 22% to Rs 15,291 crores.

(3) Extension of weighted average deduction at 150% on in-house R&D expenditure by further 5 years.

(4) Exemption from service tax granted to Technology Business Incubators.

(5) R&D tax concessions extended to private research bodies.

(6) Exemption from service tax granted to Technology Business Incubators.

(7) R&D tax concessions extended to private research bodies.

(8) Concessional rate of 5% duty earlier available to public funded institutions have been extended to all research institutions.

(9) Import duty on 15 specified medical equipments has been reduced from 7.5 to 5%.

(10) Benefits of venture capital investment to be extended to biotech and new chemical entity (NCE) development.

(11) Full exemption of custom duty on selected life saving drugs that are attracting duty ranging from 5 to 12.5 per cent.

(12) Allocation for National Rural Health Mission increased from Rs 8,207 core to Rs 9,947 crores.

3.4.2 Objectives of IPA:

The main objectives of this policy are:

(1) Ensuring abundant availability of quality pharmaceutical products for mass consumption at reasonable prices within the country.

(2) Strengthening the indigenous capability for cost effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.
(3) Strengthening the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals.

(4) Encouraging R&D in the pharmaceutical sector in a manner compatible with the country’s needs and with particular focus on diseases relevant to India by creating an environment conducive to channelizing a higher level of investment into R&D activities.

(5) Creating an incentive framework for the pharmaceutical industry to promote new investment in the pharmaceutical industry and encourages the introduction of new technologies and new drugs.

3.4.3 Future Outlook

Indian companies are climbing the value chain by moving to developed markets and from bulk drugs to formulation exports. As a result, Indian companies are expected to produce six of the top 10 drugs that are scheduled to lose patent protection over the next five years. Indian companies are targeting opportunities arising in the regulated and unregulated markets.

Research focus of large companies has shifted towards discovery of New Chemical Entities in preparation of product patent era. For large players, there is a possibility of increased financial risks, because of uncertainty in income flows. In fact, the financial results of the players’ post 2005 depend largely on their ability to introduce new drugs.

The big players will speedup the launch of new products and will look a brand acquisition from relatively smaller players. The latter are under great threat of either closure or being taken over by the larger players. This would lead to further consolidation of fragmented pharmaceutical industry.

Product patent regime will hamper India’s drug exports, as countries will be forced to purchase from patent holders only. It is predicted that prices of drugs may go up significantly, and in some cases by as much as 5 to 10 times.

As more drugs are taken off the list, the importance of DPCO will reduce. The successful strategy of Indian companies in product patent regime would include:
(1) Attain right product-mix.
(2) Augment skills.
(3) Use M&A options for either companies or products.

The increasing importance of biotech industry, and its symbiotic relationship to pharmaceutical industry will be very relevant in this strategy. Some Indian companies will also manage to succeed in the fast growing over the counter medication market, which is based on traditional Indian medicine systems.

3.5 IMPACT OF IPA & DPCO ON MMNCs VS DOMESTIC PLAYERS

The IPA and the DPCO effectively curtailed the presence of MNCs in the pharmaceutical sector. The price controls deterred the MNCs from launching new products in India. In addition to the above legislation imposed by above two bodies, the implementation of the Foreign Exchange Regulation Act (FERA) in 1973 (now FEMA - Foreign Exchange Management Act, 1999 - a more relaxed and diluted version of FERA) compelled MNCs to reduce their equity holding in their Indian ventures to 40%. In order to retain a controlling 51% equity stake they had to comply with export obligations. As a result some MNCs abated their operations, which further strengthened the position of domestic pharmaceutical companies. The market share of MNCs has fallen from 75% in 1971 to around 20% at the current levels. It is generally accepted that pharmaceutical MNCs are at a disadvantage compared to local players. This is on account of the following factors:

- Greater DPCO coverage due to a more mature product range.
- Parent company's reluctance to launch new products because of the absence of patent protection, the threat of process piracy and the requirement to price the product lower in India because of the population's low purchasing power.
- Higher cost of manufacture due to parent company's insistence on stricter compliance of GMP (Good Manufacturing Practices).

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EXHIBIT 3.2 GROWTH DRIVERS IN 2002 MNC V/S INDIAN COMPANIES

<table>
<thead>
<tr>
<th></th>
<th>Volume</th>
<th>Price</th>
<th>New Introductions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indian</td>
<td>2.0%</td>
<td>1.8%</td>
<td>9.8</td>
</tr>
<tr>
<td>MNC</td>
<td>2.9%</td>
<td>3.2%</td>
<td>1.6%</td>
</tr>
</tbody>
</table>

Source: India Infoline Research Report

3.5.1 Key factors for greater profitability in the Indian market include:
- Presence in large, high growth therapeutic areas e.g. cardiology, diabetes, CNS, NSAIDs etc;
- Selection of new high potential molecules for launching in India;
- Backward integration into bulk drugs;
- Reverse engineering capability to pioneer new processes;
- Lower DPCO coverage - new product launches to reduce proportion of products under DPCO;
- Increasing franchisees among doctors;
- Distribution network in India; large number of well trained Medical Representatives (strength of the sales force);

3.5.2 Factors for greater profitability in Export Sales include:
- Development of products which have recently gone off-patent (generic drugs) or which are scheduled to do so;
- Entering the high potential US & European generics market;
- Seeking regulatory approvals viz. FDA/UK MCA approval for plants;
- Setting up Joint Ventures (JVs) / Wholly Owned Subsidiaries (WOS) or company acquisitions, marketing tie-up with overseas pharmaceutical companies in targeted markets;
- Franchisee manufacturing of formulations for overseas pharma MNCs;
- Own marketing network in other countries to develop brand equity for formulations.
Patent protected product exports to other unregulated developing/third world countries

Exhibit 3.3 REGION WISE EXPORTS-THE CHANGING EQUATION (RS MN)

Source: IDMA

3.6 NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

The NPPA was established in 1997, to improve the speed and transparency of the process of fixing the prices of bulk drugs and formulations. It is expected to reduce the time lag between price revisions, thereby providing stable margins for formulations, and revise the list of bulk drugs under price control within reasonable time.

With the product patent regime sets in from January 2005, the Indian companies have to develop their own drugs, which calls significant scaling up of investment of money, material and manpower in research and development (R&D). This discovery research also possesses a significant risk of failure. Despite this, the R&D has become the basic necessity of the pharmaceutical players to ensure their foothold in the new product patent era. Fortunately, India has an excellent base in basic biochemical process expertise, which is a prerequisite for all forms of drug development.

Further, to maintain and improve their competitiveness, the Indian pharmaceutical players have increased their thrust for R&D, viz. in respect of New Drug Development (NDD) and New Drug Delivery System (NDDS) shifting from reverse engineering. Indian pharma companies have already made their presence felt in the global arena by filling highest number of applications with USFDA in 2003. In fact, they have filed a
total of 126 Drug Master Files (DMFs) in 2003, accounting for 20% of all drugs coming into the US market, which is higher than Spain, Italy, Israel and China. Also the Indian filing for US patents has witnessed a tremendous growth by reporting 1700 fillings in 2003 from a mere 183 fillings in 1997.

With increasing importance of Indian R&D, various global companies are looking for collaborative research with domestic players. In the line, Reliance Life Sciences is recognized by the US National Institutes of Health for stem-cell research and Biocon’s subsidiary - Syngene International has entered into a contract research agreement with the Novartis Institutes for Biomedical Research to carry out research projects to support new drug discovery and development. Also, the Apollo Group of Hospitals has signed a MoU with the US-based University of Nebraska Medical Centre to conduct stem cell research on cancer. In fact, Quality, credibility, reliability and a very reasonable cost structure of Indian R&D has helped it to emerge as the R&D outsourcing destination of the world.

3.7 POLICY ISSUES BOGS DOWN MNCS’ R&D IN INDIA

While the domestic pharma companies are getting aggressive about introduction of new products, molecular research, developing NDDS and infusion of significant fund, the MNC pharma companies are quite hesitant towards R&D investments and launching of new drugs in India. The Pharma MNCs expect IPR and data protection to be in place through legislation, before scaling up their R & D activities in India. Nevertheless, the associates and subsidiaries of major Pharma companies like Glaxosmithkline Pharma, Pfizer do conduct research for their overseas parents. But to get the full benefit of India Advantage, the country has to address the genuine concerns of the MNC pharma companies in terms of IPR, data protection and some assurance that government will not overrule power patent laws without genuine national calamities etc.

In fact, the third amendment bill to the Indian Patent Act, 1970 is pending to be passed in the parliament, which will introduce a product patent regime for inventions in the fields of food, chemicals and pharmaceuticals from 1st Jan 05. But the approval of the bill is getting delayed due to certain contentious issues among the industry players and the policy makers, spreading confusion among the industry. The major issues are - nature
of 'invention' recognized by the Bill, scope of patents on microorganisms, data exclusivity etc.

So far as 'invention' is concerned, the old act says both 'inventions' and 'discoveries' are patentable, while the industry associations argue that patents should be granted only to products and must not to mere discoveries of existing products. Considering the scope of patents on micro-organisms, the domestic players expect the patent Bill must keep the definition of patents very conservative and do not admit micro-organisms (genes, DNA, cells or cell lines), nor allow patents on naturally occurring micro-organisms. Patents should be granted only for the particular function that constitutes the invention, so that the microorganism remains free for research and for others to create other inventions. Otherwise, many pharma experts believe that the overwhelming foreign patents would pose a threat for the domestic industry.

Among others, the stand of Government on "Data Exclusivity" has been keeping the pharma MNCs a bit away from the R&D initiatives in India. The MNCs are much more concerned about the amendments in data exclusivity provision rather than the patent law as a whole. Incidentally, data exclusivity is sought for a specified period. During this period, the test and clinical trial data of Innovator Company may not be relied upon by generic companies to obtain a marketing authorization of the same drug.

Thus the MNCs demand data exclusivity provision for a period of, at least, five years time since filling of the patents. Supporting their demand, they claim that more product introductions, research and development and clinical trials business will come to the country only if data exclusivity is in place. Some domestic pharma companies are also of the same view, in expectation of larger number of research contracts. On the contrary, some other domestic pharma players argue that the generic business is the growth driver of Indian industry in near future and the data exclusivity will hit it adversely. Seeing the ambiguous stand of domestic pharma players on data exclusivity, the government seems very uncertain about its move. So the decision of data exclusivity rests, largely, on what domestic pharma lobbies for.

3.8 INDIAN R&D SPENDING CROSSED RS 1000 CRORE IN FY04

In order to de-risk their business model in the post product patent period, the domestic pharma companies have increased their thrust towards molecular research and
scaled up the R&D investments accordingly. In the process, they have shifted from business-driven research to research-driven business.

According to a study, the R&D spend by 15 top Indian pharmaceutical companies reveal that the research expenditure has gone up by 56.6% to Rs 1,053 crore during FY04 over the previous year. This growth has boosted the R&D spending (as a % of turnover) to 6.85% in FY04, as against 5.29% in the previous year. In the race of R&D spending, on a standalone basis, Ranbaxy Laboratories topped with a revenue R & D expenditure of Rs 238.05 crore in the year ended Dec’03. Second in the list is Dr Reddys Laboratories, with revenue R & D expenditure of Rs 191.05 crore in the year ended Mar’04. But on a relative basis, as a % of gross turnover, Dr Reddy’s Laboratories topped the list with Revenue R & D expenditure at 11% of its gross turnover, followed by Ranbaxy Laboratories at 7.3% of its total turnover. Amongst others, Sun Pharmaceutical Industries, Cadila Healthcare, Cipla, Wockhardt, Lupin and Nicholas Piramal had recurred R & D investments in excess of Rs 30 crore in FY 2003-04. Inclusive of capital R & D expenditure, the aggregate R & D expenditure of 15 pharmaceutical companies zoomed by 48% to Rs 1117 crore in FY 04.

Of late, the Indian R&D is getting global to get the synergy benefit of their expertise with strength and benefits of other countries also. For instance, Three biotech firms are planning to set up research and development centers at the Frankfurt Innovation Center for Biotechnology (FIZ).
## EXHIBIT 3.4: TREND OF RESEARCH AND DEVELOPMENT (R&D) EXPENSES

<table>
<thead>
<tr>
<th></th>
<th>Revenue R&amp;D in FY04</th>
<th>% growth over FY03</th>
<th>Capital R&amp;D in FY04</th>
<th>% growth over FY03</th>
<th>Total R&amp;D in FY04</th>
<th>% growth over FY03</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranbaxy Labs.</td>
<td>238.05</td>
<td>41%</td>
<td>38.08</td>
<td>62%</td>
<td>276.13</td>
<td>44%</td>
</tr>
<tr>
<td>Dr Reddy's Labs.</td>
<td>191.05</td>
<td>38%</td>
<td>35</td>
<td>42%</td>
<td>226.05</td>
<td>38%</td>
</tr>
<tr>
<td>Sun Pharma</td>
<td>47.85</td>
<td>63%</td>
<td>59.83</td>
<td>65%</td>
<td>107.68</td>
<td>64%</td>
</tr>
<tr>
<td>Cadila Health</td>
<td>63.2</td>
<td>197%</td>
<td>25</td>
<td>47%</td>
<td>88.2</td>
<td>130%</td>
</tr>
<tr>
<td>Wockhardt</td>
<td>46.86</td>
<td>9%</td>
<td>13.55</td>
<td>301%</td>
<td>60.41</td>
<td>31%</td>
</tr>
<tr>
<td>Cipla</td>
<td>47.61</td>
<td>13%</td>
<td>8.89</td>
<td>-8%</td>
<td>56.5</td>
<td>9%</td>
</tr>
<tr>
<td>Nicholas Piramal</td>
<td>30.18</td>
<td>79%</td>
<td>25.68</td>
<td>1456%</td>
<td>55.86</td>
<td>202%</td>
</tr>
<tr>
<td>Aurobindo Pharma</td>
<td>27.32</td>
<td>88%</td>
<td>21.56</td>
<td>187%</td>
<td>48.88</td>
<td>122%</td>
</tr>
<tr>
<td>Lupin</td>
<td>42.98</td>
<td>48%</td>
<td>3.01</td>
<td>-57%</td>
<td>45.99</td>
<td>28%</td>
</tr>
<tr>
<td>Orchid Chemicals</td>
<td>12.59</td>
<td>2%</td>
<td>27.06</td>
<td>74%</td>
<td>39.65</td>
<td>42%</td>
</tr>
<tr>
<td>Glenmark Pharma</td>
<td>24.81</td>
<td>68%</td>
<td>12.35</td>
<td>-22%</td>
<td>37.16</td>
<td>21%</td>
</tr>
<tr>
<td>Biocon</td>
<td>14.34</td>
<td>79%</td>
<td>8.99</td>
<td>164%</td>
<td>23.33</td>
<td>105%</td>
</tr>
<tr>
<td>Pfizer</td>
<td>19.7</td>
<td>12%</td>
<td>1.48</td>
<td>56%</td>
<td>21.18</td>
<td>14%</td>
</tr>
<tr>
<td>Alembic</td>
<td>14.25</td>
<td>22%</td>
<td>5.33</td>
<td>-33%</td>
<td>19.58</td>
<td>0%</td>
</tr>
<tr>
<td>Shasun Chemicals</td>
<td>7.38</td>
<td>-5%</td>
<td>3.46</td>
<td>4%</td>
<td>10.84</td>
<td>-2%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>828.17</strong></td>
<td><strong>44%</strong></td>
<td><strong>289.27</strong></td>
<td><strong>63%</strong></td>
<td><strong>1117.44</strong></td>
<td><strong>48%</strong></td>
</tr>
</tbody>
</table>

Source: Capitaline Corporate Database
3.8.1 R&D EXPENDITURE IN Q2 FY05

The total R&D expenditure incurred by Sun Pharma, Dr Reddy and Nicholas Piramal in Q2 FY05 was Rs932mn up by 44% yoy, as against Rs650mn in Q2 FY04. Aurobindo Pharma also incurred a huge R&D expenditure of Rs210mn in the quarter. Market leader Ranbaxy increased its R&D expenditure to 7% of sales this year as against 6% of sales in the previous financial year.

Exhibit 3.5: HIGHER R&D EXPENDITURE IN Q2 FY05

![R&D Expenditure Chart]

Source: www.indiaifoline.com

3.9 R&D FINANCING

Any R&D activity in Pharmaceutical Sector is highly cost intensive and risky. As per the available estimates for the developed countries, the cost of discovering a single drug molecule and its further development representing a journey from mind to market place, ranges between US $ 250-500 million (Rs.1000-2000 crores) and takes about 10-12 years. Further, commercial success of a drug is somewhat uncertain. The rate of success can be as low as 1%. In India, the cost of discovering a drug could be as low as Rs.140 to 200 crores. This provides a great opportunity and competitive strength for drug discovery within the country.

Presently, the available financial resources for funding drug research include in house R&D inputs by industrial houses, government funding through publicly funded
R&D institutions and promotional funds set up by the government through Technology Development Board of DST as well as a special new drug development fund operated by DST. However, the total support available through all these financing routes is not adequate to meet the needs of the ambitious programmes that need to be launched.

Considering the size of the Indian companies and their financial resources, it may not be feasible for the industry to invest the required funds in high risk R&D projects. Further, with the risks being high, funding of R&D projects by financial institutions/banks in the country also becomes difficult. Innovative approaches to financing R&D therefore, need to be evolved. The Pharmaceutical Research & Development Committee (PRDC) considered the following ways of funding R&D in the pharma industry.

3.9.1 Venture Capital Funding - a new resource for Pharmaceutical R&D

Venture Capital Funds (VCFs) can provide seed capital for unproven ideas, products or start-ups. They can also be an important source of funds for companies, who are too young to raise capital through conventional routes such as term loans or public offers. The instruments used also vary - straightforward equity, quasi-equity (e.g. preference shares or convertible debentures), subordinated debt with varying swap and call options, and other financial derivatives.

Internationally, Venture Capital Funding has been a major resource facility to fund New Drug Discovery and Biotechnology Research. Basically, a Special Purpose Vehicle (SPV) is created by the Discoverers and Venture Capitalists, which then undertakes further research efforts and brings the product to the market. This SPV receives the proceeds, either in the form of royalties, dividends or contributions from the market players. The SPV then repays its various investors (both researchers and venture capitalists) their initial investment. If inflows exceed the total investment in the research efforts, the SPV realizes profits.

In India, however, there are bottlenecks in following this route. These have to be addressed if New Drug Discovery activity is to realize its potential by relying on this means of funding. The roadblocks are:
(1) Non-provision of free inflow and outflow of capital without going for separate approvals from the FIPB for the defined project and RBI for receipt or payment of funds.
(2) Non-provision of evaluation yard sticks and tax treatment on the lines applicable internationally.
(3) Inability to bring in new investors or their substitution into an existing SPV.

The following steps have to be immediately taken to overcome these roadblocks suggested by the Pharmaceutical Research & Development Committee (PRDC)

(1) Units undertaking New Drug Development Research (NDDR) and Novel Drugs Delivery System (NDDS) activities be registered with the DSIR.
(2) An automatic approval system for sourcing within defined limits of funds from both overseas and domestic sources to such approved units has to be evolved.
(3) Inflow/outflow (including repatriation) of funds should be permissible on the basis of quarterly returns to be submitted by the SPV.
(4) Tax treatment, as applicable to infrastructure and software industry, in the Income Tax Act as amended in the Finance Bill, 1998 be extended to cover any company or vehicle engaged in the NDDS Research, subject to necessary approvals from the Department of Scientific and Industrial Research (DSIR).
(5) No restriction should be applicable to such SPVs for expenditure undertaken overseas for the purpose of approved research activities.
(6) Modify SEBI's takeover code for VCFs. Just as the public financial institutions are excluded from the takeover code, so too should be the registered VCFs.

The venture capital assisted listed company should be allowed to purchase its stocks from its VCF without the 5% annual cap on creeping acquisitions. Moreover, like IDBI, ICICI and IFCI, a VCF should be allowed to sell its shareholding to a new promoter or acquirer at a negotiated price without triggering the 15% cap for an open offer. Provisions of the Indian Trust Act, 1898 should be modified to accommodate limited partnership and pass-through in line with the Venture Capital Trust Act of the UK. This will definitely attract larger investment to VCFs.

It should be appreciated that such SPVs would be engaged in the development activities consequent to discovery of New Chemical Entities (NCEs). The
development includes various phases of clinical trials which may extend up to 7 to 10 years. In the case of NDDS activity, the SPV would be required to finance its clinical research and bioequivalence studies, international registration etc., which may also involve a large amount of expenditure overseas.

A detailed note by Shri Omkar Goswami of Confederation of Indian Industries (CII) on "Financing Knowledge Based corporate Growth by galvanising Venture Capital Funds in India" which articulates the broader issues on Venture Capital Financing is at Annexure 5. Several of the ideas enunciated in this note need to be implemented if the Indian knowledge industry, of which drugs and pharmaceutical industry is only one player, has to take a leap forward.

3.10 Attracting R&D towards high cost-low return areas

It is often pointed out that stiff price control measures for the controlled drugs leave little scope to generate resources for R&D. On the other hand, outputs of R&D tend to remain out of the reach of common man due to high costs not matched by commensurate returns. In order to resolve the situation arising out of the above conflict of interests, the Pharmaceutical Research & Development Committee (PRDC) after careful examination of various aspects involved, considered a model to attract R&D towards high cost-low return areas. This model is narrated below:

1) A sur-charge of 1% of the Maximum Retail Price (MRP) of all formulations sold within the country could be collected by the concerned Central Excise or other authorities as mandatory contribution to a fund called "Pharmaceutical R&D Support Fund" (PRDSF). This fund could be expected to generate around Rs.100 crore annually.

2) A significant portion of the proceeds of Drug Price Equalisation Account (DPEA) created by the Drug Price Control Order (DPCO), 1979 when finally closed, may also be credited to PRDSF.

3) The high cost- low return areas of research required by the country may be identified and prioritised. For example, the highest priority could be possibly accorded to malaria, TB, filaria, leprosy, kalaazar and the like. The R&D support fund will be used for partially assisting the projects in those areas, where entire R&D
upto the final stage of Drug Development Promotion is undertaken within the country.

3.11 GOVERNMENT INITIATIVES FOR R&D INCENTIVES

The Pharmaceutical and Biotechnology Industry is eligible for weight deduction for R&D expense upto 150%. These R&D companies will also enjoy tax holiday for 10 years. A promotional research and development fund of Rs.150 crores is set up by the Government.

3.11.1 Tax holidays and concessions

Tax holidays and concessions will help an industrial unit retain its internal resource generation for specified purposes. Such a measure reduces the dependence on external resources as the ownership of retained earnings is with the retainer, there is an incentive for utilisation of the earmarked funds for the specified and required R&D activity.

(1) The Pharmaceutical Research & Development Committee (PRDC) also recommends that the following tax holidays and concessions be provided in respect of self-financed projects certified by DSIR.

(2) Treating royalty receipts, and other gains from R&D for the purpose of exempting them fully from Income tax.

(3) Permitting writing off R&D expenditure on consumables as well as equipment within a period of one year for the purposes of Income Tax.

(4) Exemption from the payment of import duty on chemical, bio-chemicals, special consumables, equipment and spares for R&D.

3.11.2 OUTRIGHT GRANTS AND SOFT LOANS

Despite the incentives suggested in the foregoing, there may still be areas of national importance where investment in R&D may not be forthcoming. The only way to stimulate focused pharmaceutical R&D in such areas could be through outright grants or soft loans. The PRDC committee recommends that such grants or loans may be given on a selective basis from Pharmaceutical Research & Development Support Fund (PRDSF).

3.11.3 USING PRICE CONTROL AS AN INCENTIVE FOR R&D

Presently DPCO 1995 provides various incentives to manufacturers by exempting specific drugs or drug delivery systems from price control. The Incentives are as follows:
(1) Bulk Drugs produced in India for the first time from basic stages by a process
developed through indigenous research and development for a period of five
years.

(2) Production of a bulk drug by a process, which is significantly different from a
known process and results in substantive cost reduction for a period of five years.

(3) Formulations manufactured by using a Novel Drug Delivery System which has
been approved and certified by the Drug Controller General of India for a period
of five years.

(4) A new drug, which has not been produced elsewhere, if developed through
indigenous research and development for a period of ten years.

(5) Genetically engineered drugs produced by recombinant DNA technology and
specific cell and tissue targeted drug formulations are exempted for five years
from the date of manufacture in India.

The PRDC committee recommends that these exemptions be continued and in
case of (3) and (4) above, they may be extended for the entire period of patent life. The
PRDC Committee further suggests that a company or a firm to qualify as R&D intensive
company in India for price benefits for the drugs under DPCO as recommended by the
Drug Price Control Review Committee should meet the following conditions:

(1) Invest at least Rs.10 crore per annum in innovative research including new drug
development, new delivery systems etc. in India,

(2) Employ at least 100 research scientists in R&D in India: A scientist as defined by
DSIR is a person having qualifications and training in science and engaged in basic or
applied R&D, non-routine testing and analysis, design engineering, R&D project
planning and control and intellectual property and technology management,

(3) Has been granted at least 10 patents for the research done in India before filing an
application for exemption from DPCO,

(4) Own and operate manufacturing facilities in India and has obtained a cGMP
approval.

The intention of setting the above 'gold standards' is to ensure that in India, we
will fuel the emergence of firms, who are deeply committed to innovation and
demonstrate this commitment by enhancing the financial inputs in R&D, switching over
to cutting edge and frontline innovative new drug development research, rather than just
imitative research creating significant employment opportunities for Indian scientists who
do not have such adequate challenging opportunities in R&D today, raising the Indian
standards of manufacture to contemporary international levels and creating a strong IPR
culture in the firms.

The PRDC committee recognises that none of the firms in India today meet all the
above criteria. However, it is hoped that by providing such stimuli it would be possible
for them to move on the path of becoming R&D intensive, quality conscious, indigenous
contenders to global players. In recognition of reaching their global status, the
government may eventually consider exempting such firms from the DPCO, subject to
sustainability of these indicators year after year.

3.12 MINISTRY OF SCIENCE AND TECHNOLOGY AND R & D
ORGANISATIONS IN INDIA
3.12.1 MINISTRY OF SCIENCE AND TECHNOLOGY

The formation of the Ministry of Science and Technology was announced through
a Presidential Notification dated January 4, 1985 (74/2/1/8.Cab.) contained in the 164th
Amendment of the Government of India (Allocation of Business) Rules, 1961; the
Department of Science and Technology (DST), the Department of Scientific and
industrial Research (DSIR), and the Department of Biotechnology (DBT) are the
departments under this ministry and the highlights of this ministry are:

1. 200 National laboratories.
2. About 1350 R&D Bodies in Industrial Sector.
3. 176 universities.
4. 39 deemed universities.
5. 11 premier institutions of national importance.
7. Outturn of S&T Personnel from Universities is around 2,30,000 per Year.
8. Indigenously designed PSLV-D3 was launched in March 1996.
9. Light Combat Aircraft (LCA) prototype has been successful.

(Source: http://mst.nic.in)
3.12.2 DEPARTMENT OF SCIENCE & TECHNOLOGY (DST)

Department of Science & Technology (DST) was established in May 1971 with the objective of promoting new areas of Science & Technology and to play the role of a nodal department for organising, coordinating and promoting S&T activities in the country.
(source: http://dst.gov.in/introduction.htm)

3.12.3 DEPARTMENT OF SCIENTIFIC & INDUSTRIAL RESEARCH [DSIR]

The Department of Scientific and Industrial Research (DSIR) is a part of the Ministry of Science and Technology, which was announced through a Presidential Notification, dated January 4, 1985 (74/2/1/8 Cab.) contained in the 164th Amendment of the Government of India (Allocation of Business) Rules, 1961. The Department of Scientific and Industrial Research (DSIR) has a mandate to carry out the activities relating to indigenous technology promotion, development, utilization and transfer.

The primary endeavour of DSIR is to promote R&D by the industries, support a larger cross section of small and medium industrial units to develop state-of-the art globally competitive technologies of high commercial potential, catalyze faster commercialization of lab-scale R&D, enhance the share of technology intensive exports in overall exports, strengthen industrial consultancy & technology management capabilities and establish user friendly information network to facilitate scientific and industrial research in the country. It also provides a link between scientific laboratories and industrial establishments for transfer of technologies through National Research Development Corporation (NRDC) and facilitates investment in R&D through Central Electronics Limited (CEL).

The above objectives are sought to be achieved through the following during Tenth Plan:

1. Technology Promotion, Development and Utilization (TPDU) Programmes
2. National Research Development Corporation (NRDC)
3. Central Electronics Limited (CEL)
4. Council of Scientific and Industrial Research (CSIR)
3.12.4 DEPARTMENT OF BIOTECHNOLOGY (DBT)

The setting up of a separate Department of Biotechnology (DBT), under the Ministry of Science and Technology in 1986 gave a new impetus to the development of the field of modern biology and biotechnology in India. In more than a decade of its existence, the department has promoted and accelerated the pace of development of biotechnology in the country. Through several R&D projects, demonstrations and creation of infrastructural facilities a clear visible impact of this field has been seen. The department has made significant achievements in the growth and application of biotechnology in the broad areas of agriculture, health care, animal sciences, environment, and industry.

The impact of the biotechnology related developments in agriculture, health care, environment and industry, has already been visible and the efforts are now culminating into products and processes. More than 5000 research publications, 4000 post-doctoral students, several technologies transferred to industries and patents filed including US patents, can be considered as a modest beginning. Department of Biotechnology (DBT) has been interacting with more than 5,000 scientists per year in order to utilise the existing expertise of the universities and other national laboratories. A very strong peer reviewing and monitoring mechanism has been developed. There has been close interaction with the State Governments particularly through State S & T Councils for developing biotechnology application projects, demonstration of proven technologies, and training of human resource in States and Union Territories. Programmes with the states of Gujarat, Rajasthan, Madhya Pradesh, Orissa, West Bengal, Haryana, Punjab, Jammu & Kashmir, Mizoram, Andhra Pradesh and Uttar Pradesh have been evolved. Biotechnology Application Centres in Madhya Pradesh and West Bengal have already been started.

(Source : http://dbtindia.nic.in/scholarships/studentsmain.html)

3.12.5 NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH (NIPER)

National Institute of Pharmaceutical Education and Research (NIPER) is the first national level institute in pharmaceutical sciences with a proclaimed objective of becoming a centre of excellence for advanced studies and research in pharmaceutical
sciences. The Government of India has declared NIPER as an 'Institute of National Importance'. It is an autonomous body set up under the aegis of Ministry of Chemicals and Fertilizers, Government of India. The Institute is conceived to provide leadership in pharmaceutical sciences and related areas not only within the country, but also to the countries in South East Asia, South Asia and Africa. NIPER is a member of Association of Indian Universities and Association of Commonwealth Universities. The Institute is located about 250 Km north of Delhi at S.A.S. Nagar (Mohali), Punjab on a total area of 130 acres.

The main objectives of the Institute are:

1) Toning up the level of pharmaceutical education and research by training the future teachers, research scientists and managers for the industry and profession.

2) Continuing education programmes

3) Creation of National Centres to cater to the needs of pharmaceutical industries and other research and teaching institutes

4) Collaboration with Indian industries to meet the global challenges – National / International collaborative research

5) Curriculum and media development

6) Study of sociological aspects of drug use and abuse, and rural pharmacy, etc.

7) Conducting programmes on drug surveillance, community pharmacy and pharmaceutical management

Source: www.niper.nic.in

3.13 Evolving Laws and Guidelines: An increasingly accommodating regulatory environment- Amendment of Schedule Y provided required acceleration

Schedule Y, which specifies the regulatory process of clinical trial permission, was amended in 2005. Earlier, only molecules developed in the country were permitted to undergo early stage clinical trials in India and there was a phase lag too (companies were
allowed to conduct trials at one phase lower than the trials carried out anywhere else in the world). However, post the amendment of Schedule Y, the domestic regulatory environment is gradually becoming more encouraging. Parallel Phase 2&3 trials can now be conducted in India.

Currently, Phase 1 trials of foreign companies are not allowed in India. After the amendment of Schedule Y, however, the government decided to allow it on a case to case basis. Phase 1 trials in India are part of the global trials by overseas drug companies, if the proposed drug is relevant to the Indian health concerns.

3.14 Regulatory Environment in India in context of CRAMS

The Drugs Controller General of India (DCGI) is responsible for regulatory approvals of clinical trials in India. The approval usually takes about 10-12 weeks. The Schedule Y of the Drugs and Cosmetics Act prescribes norms for clinical and pre-clinical studies for development of new drugs in the country. Before the enactment of Schedule Y, only molecules developed in the early stage are permitted to undertake early stage clinical trials in India and there was a phase lag for conducting trials for foreign investigational drugs.

The domestic regulatory environment has become more positive post the amendment of Schedule Y of the Drugs and cosmetics Act in 2005. Previously, the trials of foreign investigational drugs could be conducted only at one phase below the drug abroad. Now, parallel global clinical trials have been allowed. Concomitant Phase 2 & 3 clinical trials can now be conducted in India. Also, after the amendment the government has decided to allow, on a case to case basis, Phase 1 trials in India as part of the global trials by drug companies based abroad, if the proposed drug is relevant to Indian health concerns.

In India, New Chemical Entities (NCEs) cannot be administered to human subjects in a clinical trial without permission from the DCGI. An application for the clinical trial (CTA) must be submitted to DCGI for such permission. A CTA package must include a protocol for the study, a draft of the Informed Consent Document of human volunteers, a list of proposed investigators who will be participating in the study,
and background information about the drug in accordance with the Schedule Y of the Drugs and Cosmetics Rules. The DCGI generally gives permission in about 10-12 weeks.

A Test-Import license must be obtained if the clinical supplies have to be imported. However, there is no import duty on clinical supplies. Permission from the Directorate General of Foreign Trade (DGFT) must be obtained for exporting samples outside India.

3.14.1 Tax Incentives available to the CRAMS Industry

In a significant move, the government of India has slashed the tax levied on pharma products manufactured in the country by 50 percent, reduced the federal value added tax by two percent and extended tax concessions to the pharma and biotech research companies which take up outsourced research works. Some of these measures are likely to spur the growth of the Contract Research and Manufacturing Services (CRAMS) sector in India.

Most importantly industry experts, looking in hindsight predict that the budget 2008 will have a major impact on the manufacturing segment of the industry with reduction in excise duties, federal sales tax, and reduction of customs duty on life saving drugs. With the excise duty on all goods produced in the pharmaceutical sector reduced from 16 percent to 8 percent, pharma manufacturing units are sure to witness a positive impact in their productivity as this reduction of excise duty to 8 percent on all drugs and custom duty on life saving drugs to 5 percent should result in reduction of manufacturing costs and affordability of drugs. This may in turn spike the demand and may lead to higher growth for whole sector.

The Union Budget has a number of positives for the pharma biotech industry, mainly the reduction of Cenvat to 8.24 percent, the 125 percent weighted deduction to outsourced research, reduction in customs duty on raw materials for ELISA kits to 18.72 percent and select vaccines and select bio-therapeutics to 9.36 percent.

In addition to the above, the main incentives to the industry are listed below:

1. An exemption of “life-saving” vaccines from excise duty.
3. A reduction in duty for 15 specified types of equipment from 7.5% to 5% for pharma and biotech companies.

4. The introduction of a service tax exemption of 12.5% for conducting clinical trials of new drugs.

5. The introduction of R&D tax concessions of 5% duty, available to public funded research institutes, extended to private research bodies, and registered with the Directorate of Industrial and Scientific Research.

6. The application of pass-through status to venture capital funds with investments in biotechnology, nanotechnology, and R&D into new chemical entities in the pharmaceutical sector.