CHAPTER-V

THE PHARMACEUTICAL SECTOR
IN INDIA AND THE PATENT SYSTEM
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The Pharmaceutical Industry in India is one of the largest and most advanced among the developing countries. It has shown tremendous progress in terms of infrastructure development, technology base creation and a wide range of production. Even while undergoing restructuring, it has established its presence and determination to flourish in the changing environment. The industry now produces bulk drugs belonging to all major therapeutic groups. Strong scientific and technical manpower and pioneering work done in the process of development have contributed to this.\(^1\)

The industry’s contribution to the economy of the country is not only huge but it also provides drugs at affordable prices to different classes of the society. Almost the entire domestic demand is met by the industry’s indigenous production. Today India is amongst the top 15 pharmaceutical manufacturing countries in the World.

The industry began when the Bengal Chemicals and Pharmaceutical works was established in Calcutta in 1901. Subsequently in quick succession Institutes like Kings Institute of Preventive Medicine, Chennai; Pastures Institute at Coonor, Central Drug Institute, Kasauli and other Institutes were set-up. Post independence

saw setting up of public sector firms such as the Hindustan Antibiotics Ltd., IDPL (Indian Drugs and Pharmaceuticals Ltd.) and the like to reduce the import of important antibiotics and also to meet the country's demand by indigenous production. The industry was given its due by the successive governments in Five Year Plans, and the industry was promoted through direct investment, intellectual property, price regulation and above all the support for scientific research. Public investments in R & D, education and direct production have been more successful.

The pharmaceutical industry enjoys a special place since its knowledge based and research oriented. Scientific knowledge, research and innovations are considered as quintessential to public good. Pharmaceutical innovations are built upon and to integrate discoveries in biology, chemistry, medicine, botany, etc. Pharmaceuticals have provided opportunity for India, since it has a strong base in related scientific field. Added to this India is also a cheapest producer of drugs since it's labour cost is 50 to 55% less than the west, infrastructure cost is lower by at least 40%, it has a vast pool of talents and the Indian Patent Act, 1970 earlier accepted only process patent. Thus, with all these benefits, the industry was able to develop every drug at a fraction of cost that was being incurred by innovative company. ²

The Indian Drugs and Pharmaceutical industry has been playing a vital role by manufacturing and marketing a wide range of drugs within India and global markets. It is estimated that the drugs and pharmaceutical sectors worth US $5.5 billion growing faster at eight percent annually.

The industry is highly fragmented with more than 20,000 players, five central public sector units, about 300 large units, 700 medium units and 10,000 small-scale units. It is interesting to note that about 300 units control about 70% of the market, despite severe competition and price control by the Government of India.³

The industry meets about 70% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, oral and injectables. The industry provides almost every type of medicine from simple headache pills to sophisticated antibiotic and complex cardiac compounds. The industry with its rich scientific talents and research capabilities, supported by intellectual property protection regime (process patent for drugs) is well set to make its place as a 'sunrise industry' in global market.⁴

The industry provides excellent facilities. It has quality producers and many pharmaceutical units are approved by regulatory authorities in the U.S.A., and U.K. It has a pool of highly competent managerial, technical and skilled manpower. Its track record of development particularly in area of improved cost-

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⁴ Supra note 2.
beneficial chemical synthesis for various drugs molecules is excellent. It provides a wide variety of bulk drugs and exports sophisticated bulk drugs.5

Today the debate on intellectual property protection in the pharmaceutical sector has assumed significant importance because of its socio-economic relevance especially among developing economies. Realising that WTO regime is reality, at least some of the developing countries are looking for means to improve the competitive advantage of this industry within the WTO framework, since the future growth of pharmaceutical industry will be governed not only by the domestic business environment but will be shaped by the changing global scenario.6

5.1 Evolution of pharmaceutical industry in India

In India, modern system of medicine is a 20th century phenomena, though the traditional system of medicine has been in practice for many centuries. Therefore in discussing the evolution of the Indian pharmaceutical industry, three points of time are very relevant. These are 1900-1970, 1970-1990 and the decade after 1990s. The period 1900-1970 signifies the dominance of the multinationals in this field that were basically importing bulk drugs and formulations from abroad. Many domestic manufacturers were engaged in repacking the formulations produced by the multinationals and production was concentrated in

the hands of the multinationals. Production of modern medicine by indigenous units started with the setting up of Bengal Chemical and Pharmaceuticals Works in 1991, which was followed by the establishment of Alembic Chemical Works in 1907 and Bengal Immunity in 1919. At this point of time the Patents Act of 1911 was in practice, which facilitates for patenting all the known and possible processes of manufacturing of the said drug besides patenting the drug itself. Here the indigenous firms were legally prevented from manufacturing most of the drugs introduced by the Transnational Corporations (TNCs) during the life of the patent secured by the latter, i.e., for 16 years, which could be extended to a maximum of another 10 years if the working of the patent had not been sufficiently remunerative to the patentee. The domestic firms were also forbidden from processing a patented drug into formulations or importing it. However, the Second World War and the introduction of sulpha drugs and penicillin gave an impetus to the pharmaceutical industry. The policy instruments of independent India emphasised on creating a strong public sector unit. In the pharmaceutical front, specific areas of production were defined for the public, private and the domestic sector though the performance of the multinationals allowed them some leeway in the production of drugs reserved for other sectors also. The setting up of the public sector units and the technical institutes meant for creating technical skills in the country contributed to the growth of the domestic industry. By 1952, a few drugs like tetanus antitoxin, PAS and Indochlorhydroxyquimoline were produced in India from their basic stages. However, the import content of the basic drugs
was high due to which the prices of the pharmaceutical products of India were the highest in the world.  

The second period of 1970-1990 is very significant for the Indian Pharmaceutical Industry since a few important changes that had implications on the growth of Indian Pharmaceutical Industry took place during this time. The Patent Act of 1911 was amended in 1970, which came into force in 1972. The 1970 Patent Act provides protection for the processes of manufacturing of the drug for the seven years from the date of filing the application or five years from the date of the grant of the patent. Under this Act only one process that was used in the actual manufacturing could be patented. This change brought a renaissance to the pharmaceutical industry of India. More units bigger in size and capacity set up in the 1970s and 1980s started producing drugs, which were primarily imported till then. The technical institutes that were set up in the early 1950s and 1960s resulted in creating technical and engineering skills, which could easily adapt the technology developed elsewhere, proved to be very advantageous for the industry. By 1972, over 100 drugs covering a wide spectrum of therapeutic groups like antibiotics, antileprotic drugs, vitamins, tranquillisers and various other pharmaceutical chemicals were produced in India from basic stages, a significant increase in the production of bulk drugs and formulations is observed before and after 1970s.  

\[\text{1 Ibid.}\]
\[\text{8 Ibid.}\]
In the early 1970s the government introduced the Monopolies and Restrictive Trade Practices Act and the Foreign Exchange Regulation Act, which aimed at reducing the concentration of economic power with few units and controlling the flight of foreign exchange from the country. Basically units, which were not bringing in any new technology, were asked to reduce their foreign equity and renewal of their licence was also subject to their bringing in new technology. This resulted in dilution of foreign equity. As a strategy to protect the domestic industry from competition, the Foreign Exchange and Regulation Act (FERA) companies were also not permitted to produce list of drugs, which were licensed during the 1980s.9

In the 1990, several significant changes occurred in the pharmaceutical sector with the introduction of trade liberalisation measures. All those drugs, which were reserved for the production by the public sector, were delicensed in two stages.10 One immediate impact of delicensing of the drugs was that production increased manifold besides the increasing competition among the domestic firms and from foreign companies. The increased production had a positive impact on exports and on the balance of trade. Of the exported drugs, formulations account for higher percentage and in imports bulk drugs account for a larger share. Exports also spread over to developed and developing countries.

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9 Id., at p.3543.
10 Bulk Drugs produced by the use of recombinant DNA technology and bulk drugs requiring in vivo use of nucleic acids as the active principles and formulations based on use of specific cell or tissue targeted formulations shall continue to remain under compulsory licensing (Govt. of India 2000).
The government also increased the automatic approval limit for foreign direct investment in the pharmaceutical industry from 40 percent to 51 percent. This was subsequently increased to 74 percent in 1997. In 1994 government of India signed TRIPs Agreement.

The delicensing of the drugs and the policy of the government to allow subcontracting or loan licensing\(^{11}\) system resulted in an uneven growth of the domestic pharmaceutical industry. Though there are no official statistics that tells the exact volume of production by the loan licensees, according to the industry sources about 70 percent of the production in the pharmaceutical sector is contributed by loan licensees. As of 2000, it is estimated that the total number of units engaged in the production of pharmaceuticals is 24,000 (including that of loan licensees). Out of which, 1.25 percent or 300 belonged to the small and medium sector. Most of the firms were engaged in the production of finished formulations that are in the off patent segment. Lack of adequate funds for modernisation, increased competition from the private sector and high cost of production resulted in the decline of the public sector in the 1990s with the decline of the public sector, the investment in R & D, also declined from this sector. The R & D, as percentage of sales turnover was hardly 2 percent, which indicates that the per capita R & D expenditure by the firm is extremely low. Direct

\(^{11}\) Loan Licensing refers to the system of getting the product produced in a unit or units other than the parent unit. The parent unit provides the materials and sets the quality standards. This system enables the parent unit to cut down some of the establishment costs and for loan licensee it covers the overhead charges and saves the trouble of marketing.
employment provided by the organised industry and the small-scale sector is estimated at 2,90,000 and 1,70,000 respectively in 1999. The indirect employment created in the ancillary industry and in distribution trade is estimated to be 24,00,000. In production volume India account for 8 percent of world’s pharmaceutical production and is the fifth largest country in the world after the US, Japan, Europe and China in terms of volume of production.

The above paragraph in nutshell highlights the heterogeneous nature of the pharmaceutical firms where handful of firms are engaged in R & D. Thus we have a small percentage of manufacturers who have the capacity to invest in R & D, while majority of the firms are engaged in the production of off patent drugs and are functioning as contract manufacturers. A cursory glance over the growth of the Indian Pharmaceutical Industry demonstrates that much of the capacities in the Indian Pharmaceutical Industry have taken place after the amendment to the Patent Act was made in 1970.\textsuperscript{12}

The following table shows the significant increase in the bulk drugs and formulations after 1970s.

\textsuperscript{12} Supra note 5, pp 3543-44.
Table-1: Value of production of Bulk Drugs and Formulations (Rs. in crores).\textsuperscript{13}

<table>
<thead>
<tr>
<th>Year</th>
<th>Bulk Drugs</th>
<th>Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1950-51</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>1965-66</td>
<td>18</td>
<td>150</td>
</tr>
<tr>
<td>1975-76</td>
<td>113</td>
<td>544</td>
</tr>
<tr>
<td>1980-81</td>
<td>240</td>
<td>3148</td>
</tr>
<tr>
<td>1991-92</td>
<td>900</td>
<td>4800</td>
</tr>
<tr>
<td>1992-93</td>
<td>1150</td>
<td>6000</td>
</tr>
<tr>
<td>1993-94</td>
<td>1320</td>
<td>6900</td>
</tr>
<tr>
<td>1994-95</td>
<td>1518</td>
<td>7935</td>
</tr>
<tr>
<td>1995-96</td>
<td>1822</td>
<td>9125</td>
</tr>
<tr>
<td>1996-97</td>
<td>2186</td>
<td>10494</td>
</tr>
<tr>
<td>1997-98</td>
<td>2623</td>
<td>12068</td>
</tr>
<tr>
<td>1998-99</td>
<td>3148</td>
<td>13860</td>
</tr>
<tr>
<td>1999-2000</td>
<td>3777</td>
<td>15860</td>
</tr>
<tr>
<td>2000-2001</td>
<td>4344</td>
<td>17843</td>
</tr>
<tr>
<td>2001-2002</td>
<td>5439</td>
<td>21104</td>
</tr>
<tr>
<td>2002-2003</td>
<td>6529</td>
<td>24185</td>
</tr>
</tbody>
</table>

5.2 Production of drugs

The Drugs and Pharmaceutical sector in India has continued to maintain steady growth in terms of production.\textsuperscript{14} The pharmaceutical industry comprises

\textsuperscript{13} Estimated

\textsuperscript{14} \textit{Supra} note 1.
20,053 manufacturing units and provides employment to approximately 33 lakh people. The total production in the country in 1999-2000 was Rs.19,737 crores with formulations accounting for Rs.15,960 crores. The total capital investment in the pharmaceutical industry was Rs.2,500 crores with R & D expenditure being Rs.320 crores.15

During 2002-2003 several proposals for technology transfer including joint ventures, proposals for foreign direct investment, setting up of new undertakings expansion of existing units (manufactures of new articles in the existing units) have been received and processed. Following the delicensing of the pharmaceutical industry, a number of Industrial Entrepreneurial Memorandums (IEM) for manufacture of various bulk drugs/drug intermediates/formulations were received. The major items covered by the IEMs include a wide range of bulk drugs, intravenous fluids, formulations, etc.16

India is one of top five manufactures of bulk drugs in the world and is among the top 20 pharmaceutical exporters in the world. The industry manufactures almost entire range of therapeutic products and is capable of producing raw materials for manufacturing a wide range of bulk drugs from the basic stage.17 The Indian Patent Act 1970 was largely responsible for the change in structure in the Indian context. Indian Patent Act 1970 recognised “process

15 Ibid.
17 Supra note 1.
patents” as against “product patents” which is prevalent in the developed world. As a result, for the first time, Indian manufacturers could produce internationally patented drugs within the country. This has been made possible by developing an alternative process for the drugs, after reverse engineering, using relatively cheap and large manpower base of qualified pharmacists and scientists available in the country.18

5.3 Export of drugs

The industry has shown significant growth in export of drugs to developed and developing countries. The quality of drugs produced and exported has been of world-class standards. Exports form a vital component of the growth strategy of most Indian pharmaceutical companies. The industry has made rapid strides in this area in the last few years and export sales of companies such as Ranbaxy have been growing at a faster rate than their domestic sales. The compounded annual growth rate of pharmaceutical exports over the last five years has been more than 20 percent although in 1999-2000 exports grew by 11 percent.19

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18 Supra note 15.
The following table shows the export potential of the industry\textsuperscript{20}

\textbf{Table-II: Export of Drugs by the industry}

<table>
<thead>
<tr>
<th>Year</th>
<th>Exports (in Rs.crores)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994-95</td>
<td>2265.60</td>
</tr>
<tr>
<td>1995-96</td>
<td>3177.70</td>
</tr>
<tr>
<td>1996-97</td>
<td>4090.30</td>
</tr>
<tr>
<td>1997-98</td>
<td>5081.10</td>
</tr>
<tr>
<td>1998-99</td>
<td>5366.20</td>
</tr>
<tr>
<td>1999-2000</td>
<td>7230.16</td>
</tr>
<tr>
<td>2000-2001</td>
<td>8757.47</td>
</tr>
<tr>
<td>2001-2002</td>
<td>9834.7</td>
</tr>
<tr>
<td>2002-2003</td>
<td>11925.4</td>
</tr>
</tbody>
</table>


5.3.1 Export promotion cell

An Export Promotion Cell in the pharmaceutical division has been created with the objective of boosting pharmaceutical exports and to act as a nodal centre for all queries/issues regarding pharmaceutical exports.

The cell also undertakes promotional activities for acceleration of pharmaceutical exports and considers suggestions for medications in Exim policy from the industry. The cell has also been entrusted with the organisation of

\textsuperscript{20} Source: Organisation of Pharmaceutical Producers of India OPPI and Directorate General of Commercial Intelligence and Statistics – DGCIS.
seminars and workshops on standards quality control requirements etc. of important countries so as to prepare the domestic companies for exporting their products. Visits were undertaken to South Africa and other African countries and discussions were held on various aspects of pharma industry and ways and means of boosting exports to these countries. Database on the status of pharmaceutical industry in many counties is available in the cell for the benefit of Indian exporters.  

5.4 Import of pharmaceutical products

The following table shows the imports of the medicinal and pharmaceutical products:

<table>
<thead>
<tr>
<th>Year</th>
<th>Imports (in crores)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994-95</td>
<td>985.45</td>
</tr>
<tr>
<td>1995-96</td>
<td>1900.00</td>
</tr>
<tr>
<td>1996-97</td>
<td>2050.00</td>
</tr>
<tr>
<td>1997-98</td>
<td>2257.00</td>
</tr>
<tr>
<td>1998-99</td>
<td>2458.00</td>
</tr>
<tr>
<td>2000-2001</td>
<td>1701.47</td>
</tr>
<tr>
<td>2001-2002</td>
<td>2026.58</td>
</tr>
<tr>
<td>2002-2003</td>
<td>2717.82</td>
</tr>
</tbody>
</table>

There have been no reports of shortage in recent years. As already indicated the country is almost self sufficient in case of formulations required by

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22 Source: Organisation of Pharmaceutical Producers in Indian and Directorate General of Commercial Intelligence and Statistics.
the consumers. It may also be mentioned that industrial licensing for most of the
drugs and pharmaceutical products has been done away with. The manufacturers
are free to produce any drug duly approved by the Drug control authorities.

Imports of drugs and pharmaceuticals are allowed freely, except those in
the restricted list of import under an import licence. In view of these steps, no
shortage of medicines is likely to occur. Import can take place from any part of the
world, there being no general restrictions.

5.5 Research and Development

In a country where research and innovation have traditionally been
neglected by domestic industry, the pharmaceutical is now realising the
importance of R & D. The successes enjoyed by a few companies such as
Ranbaxy and Dr.Reddy’s in the R & D field have shown the way for others.
Several Indian pharmaceutical companies including Cipla, Lupin, Wockhardt,
Nicholas Piramal and Torrent are today engaged in R&D activities.

Investment in pharmaceutical R & D has been rising steadily. From Rs.220
crores in 1997-98 the R & D expenditure rose to Rs.260 crores in 1998-99 & to
Rs.320 crores in 1999-2000. This figure is projected to jump up to Rs.1500 crores.
At present R & D spending accounts for two percent of the pharmaceutical
industry’s turnover. This is estimated to rise to five percent.

Notwithstanding the increase in R & D expenditure, the R & D spends of
domestic industry will remain a fraction of the amount invested by Multinational
Companies (MNCs). Experts, however, point out that R & D costs in India are
much less than those in the developed world and it is possible to conduct both New Drug Discovery Research and Novel Drug Delivery System Programmes at competitive rates. The Investigational New Drug stage may cost 100 to 150 million overseas but costs only around Rs.40 to 60 crores in India, says the Mashalkar Committee Report. The report adds that while clinical trial cost approximately 300 to 350 million abroad they cost about Rs.100 crore in India.  

Apart from comparative cost advantage, Indian R & D efforts are also added by the presence of a well-established network of research laboratories and a skilled pool of scientific personnel. These need to be leveraged and utilised in an effective manner. Greater collaboration between industry, Government and academia in this area is required to achieve this. Most Indian companies realise that it will be difficult for them to commercialise their discoveries on an international basis on their own. Therefore they are entering into licensing deals and strategic alliances with international companies. This way their development costs get shared and returns will accrue faster.

The Department of Science and Technology has a dedicated programme for promoting R & D in the drugs and pharmaceutical sector. A two-tier structure exists to manage the programme, viz., an Apex Executive Committee at the secretariat level, chaired by the Secretary, Department of Science and Technology and Expert Committee at the operational level.

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23 Supra note 15.
24 Supra note 1.
To be globally viable in R & D high-level expertise and adequate human resources as also modern facilities in specific areas of drug development are required. It was therefore decided that the Department of Science and Technology Programme, besides assisting new drug development projects, should also support creation of facilities that are essential for new drug development. Government has taken several policy initiatives for strengthening Research and Development in pharma sector. The following table shows the R & D expenditure.

<table>
<thead>
<tr>
<th>Year</th>
<th>R &amp; D Expenditure (Rs.in crores)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994-95</td>
<td>140.00</td>
</tr>
<tr>
<td>1995-96</td>
<td>160.00</td>
</tr>
<tr>
<td>1996-97</td>
<td>185.00</td>
</tr>
<tr>
<td>1997-98</td>
<td>220.00</td>
</tr>
<tr>
<td>1998-99</td>
<td>260.00</td>
</tr>
<tr>
<td>1999-2000</td>
<td>320.00</td>
</tr>
</tbody>
</table>

5.6 Key Indian pharmaceutical companies

The Indian pharmaceutical industry comprises both MNCs domestics companies while at one time MNCS dominated the market; their market share has declined steadily from 75 percent in 1971 to about 35 percent. In order to boost the domestic industry, the government introduced process patents in the Indian Patent Act of 1970. Domestic pharma companies were quick to take advantage of

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25 *Infra* pp, 19-23.
26 Source: OPPI (Organisation of Pharmaceutical Producers in India)
this and developed expertise in process development and manufacturing of pharmaceuticals. As a result domestic companies had a robust pipeline of products, large therapeutic width and depth were able to provide masses with the low priced, quality pharmaceuticals.²⁷

According to a study on Indian pharmaceutical market by IMS Health, Glaxo-welcome, Ranbaxy Laboratories and Cipla topped the pharma sector in terms of domestic sales during 1998. The combined sales of these three companies accumulated for 14.4% of total formulation market. Cipla, Dr.Reddy’s and Glaxo were the three faster growing companies in 1998 with their respective sales increasing by Rs.146 crore, Rs.12 crore and Rs.108 crore respectively. In the formulation market the top 10 companies have nearly 31% market share. The market share in bulk drugs is difficult to estimate, since data is not freely available. The top 100 pharmaceuticals account for 26.65% market share.²⁸

²⁷ Supra note 16.
²⁸ Ibid.
The following table gives the list of top ten pharmaceutical companies operating in India

<table>
<thead>
<tr>
<th>Company</th>
<th>Finance year</th>
<th>Net Sale</th>
<th>PAT (Profit after paying tax)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranbaxy Laboratories</td>
<td>December 1999</td>
<td>1559</td>
<td>193.58</td>
</tr>
<tr>
<td>Glaxo Limited</td>
<td>December 1999</td>
<td>888.3</td>
<td>77.06</td>
</tr>
<tr>
<td>Wockhardt</td>
<td>December 1999</td>
<td>841.72</td>
<td>104.55</td>
</tr>
<tr>
<td>Novartis</td>
<td>March 2000</td>
<td>793.13</td>
<td>103.42</td>
</tr>
<tr>
<td>Cipla</td>
<td>March 2000</td>
<td>704.28</td>
<td>133.06</td>
</tr>
<tr>
<td>Aurobindo Pharma</td>
<td>March 2000</td>
<td>692.13</td>
<td>74.6</td>
</tr>
<tr>
<td>Lupin Laboratories</td>
<td>March 2000</td>
<td>485.23</td>
<td>30.62</td>
</tr>
<tr>
<td>Hoechest Marrion Roussel</td>
<td>March 2000</td>
<td>479.86</td>
<td>27.45</td>
</tr>
<tr>
<td>Cadila Health care</td>
<td>March 2000</td>
<td>447.86</td>
<td>27.45</td>
</tr>
<tr>
<td>Dr.Reddy’s Laboratories</td>
<td>March 2000</td>
<td>436.01</td>
<td>60.24</td>
</tr>
</tbody>
</table>

5.7 Pharmaceutical policy initiatives

India is a country of teeming millions, to provide quality life to all is a cherished goal. The policies of government are intended to benefit all strata of the society. One aspect of the governance is to make available quality medicines to all at affordable prices.

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29 Source: Prowess – CMIE
5.7.1 Pharmaceutical policy 2002

The drug and pharmaceutical industry is facing new challenges on account of liberalisation of the Indian economy, globalisation and the new obligations undertaken by India under the WTO agreements. These challenges require a change in emphasis. Therefore policy inputs are increasingly being directed towards promoting accelerated growth of the pharmaceutical industry while making it internationally competitive. The need for radically improving the policy framework for knowledge-based industry has been recognised by the government. Pharmaceutical industry has been identified as one of the important knowledge based industries in which India has a competitive advantage.

Two major issues have surfaced on account of globalisation and implementation of India’s obligation under the Trade Related aspects of Intellectual Property Rights (TRIPs), which have a great impact on long-term competitiveness of the Indian industry. The first is the reorientation of the objectives of the policy that had become necessary for improving incentives for research and development in the Indian pharmaceutical industry. Besides, it will enable the industry to achieve sustainable growth particularly in view of the changes in the Patent law. The second is the strong need felt for further reducing the rigours of price control, particularly in view of the on going processes of liberalisation. The pharmaceutical policy-2002 has been formulated against this background.\(^{31}\)

\(^{31}\text{Ibid.}\)
Objectives

The basic objectives of Government's policy relating to the drugs and pharmaceutical sector were enumerated in the Drug Policy of 1986. These basic objectives still remain largely valid. One of the main objectives of the pharmaceutical policy 2002 is to ensure abundant availability of good quality essential pharmaceutical products at reasonable prices within the country for mass consumption. Other objectives of the policy are as follows.

i) It aims at strengthening the indigenous capability for cost effective quality production and export of drugs by reducing barriers to trade in the pharmaceutical sector.

ii) The policy seeks to make quality an essential attribute of the Indian pharmaceutical industry. Also it will strengthen the system of quality control over drug and pharmaceutical production and distribution, which in turn may help, to promote rational use of pharmaceuticals.

iii) It will also help to create an environment conducive for channelising a higher level of investment in to R & D in pharmaceutical sector with a particular focus on diseases endemic to the country.

iv) An incentive framework will be created for the pharmaceutical industry to promote new investment into the industry besides encouraging the introducing of new drugs and technologies.

Keeping these objectives in view, the pharmaceutical policy-2002 lays down the action plan in industrial licensing, foreign investments and technology
agreements, encouragement to research and development, pricing, quality and pharma education and training.  

**Salient Features of the Policy**

The process of liberalisation set in motion in 1991, has considerably reduced the scope of industrial licensing and demolished many non-tariff barriers to imports. Many important steps have been taken by the government in this regard.

The impact of the policies enunciated from time to time by the Government has been salutary. It has enabled the pharmaceutical industry to meet almost entirely the country's demand for formulations and substantially for bulk drugs. In the process the pharmaceutical industry in India has achieved global recognition as a low cost producer and supplier of quality bulk drugs and formulations to the world. However, two major issues have surfaced on account of globalisation and implementation of India's obligations under TRIPs which impact on long-term

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32 Supra note 30.

33 Industrial licensing for the manufacture of all drugs and pharmaceuticals has been abolished except for bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids, and specific cell/tissue targeted formulations. Reservation of 5 drugs for manufacture by the public sector only was abolished in February 1999, thus opening them up for manufacture by the private sector also. Foreign investment through automatic route was raised from 51% to 74% in March, 2000 and the same has been raised to 100%. Automatic approval for Foreign Technology Agreements is being given in the case of all bulk drugs, their intermediates and formulations except those produced by the use of recombinant DNA technology, for which the procedure prescribed by the government would be followed. Drugs and pharmaceuticals manufacturing units in the public sector are being allowed to face competition including competition from imports. Wherever possible, these units are being privatised. Extending the facility of weighted deductions of 150% of the expenditure on filing patents, obtaining regulatory approvals and clinical trials besides R & D in biotechnology. Introduction of the Patents (Second Amendment) Bill in the Parliament. It inter alia, provides for the extension of in the life of a patent to 20 years.
competitiveness of Indian industry. These have been addressed in the pharmaceutical policy 2002.

**Industrial licensing**

Industrial licensing for all bulk drugs, their intermediates and formulations is abolished, subject to stipulations laid down from time to time except in the case of bulk drugs produced by the use of recombinant DNA technology, in vivo use of nucleic acids and specific cell tissue targeted formulations.

**Foreign Investment**

Under the Pharmaceutical Policy 2002 the foreign investment up to 100% is permitted, subject to stipulations laid down from time to time in industrial policy.

**Foreign Technology Agreements**

Automatic approval for Foreign Technology agreements is available in the case of bulk drugs cleared by Drug Controller General of India and their intermediates formulations except for those items kept under industrial licensing.

**Imports**

Regarding imports of drugs and pharmaceuticals the policy has provided that imports of drugs and pharmaceuticals will be governed by the Exim Policy in force. A centralised system of registration will be introduced under the Drugs and Cosmetics Act and Rules made there under.
Encouragement to Research and Development (R & D)

In order to encourage Research and Development (R & D) in the field of pharmaceuticals and to strengthen the pharmaceutical industry’s research and development capabilities the following measures have been adopted in the policy.

a) Establishment of the Pharmaceutical Research and Development Support Fund (PRDSF) under the administrative control of the Department of Science and Technology, which will also constitute a Drug Development Promotion Board (DDPB) on the lines of the Technology Development Board to administer the utilisation of the PRDSF.

b) With a view to encouraging generation of intellectual property and facilitating indigenous endeavours in pharma R & D, appropriate fiscal incentives have been provided. Standards enumerated by the pharmaceutical Research and Development Committee (PRDC) to qualify as R & D intensive company in India are:

(i) The company should invest at least 5% of its turnover per annum in R & D.
(ii) The company must invest at least Rs.10 crores per annum in innovative research including New Drug Development, New Drug Delivery System in India.
(iii) The Company has to employ at least 100 Research Scientists in R & D in India.

34 The Pharmaceutical Research and Development Committee has recommended in its Report, the setting up of a Drug Development Promotion Foundation (DDPF) and a Pharmaceutical Research and Development Support Fund (PRDSF). Necessary action in this regard has been initiated.
(iv) The Company must have been granted at least 10 patents for research done in India.

(v) The Company must own and operate manufacturing facilities with the approval of India.

Pricing

With respect to price control, the span of control has been gradually reduced since 1979. Presently under *DPCO 1995*, there are 74 bulk drugs and their formulations under price control. As per the industry calculations, while 22 bulk drugs may be coming under new price control regime under the first criteria, 6 drugs should come under the second criteria, taking the total to 28. Turnover wise 171 of the total bulk drug market will be under price control, from 38-40% earlier. The policy states that the guiding principle for identification of specific bulk drugs for price regulation should continue as per Drug Price Control Review Committee’s (DPCRC) recommendation. However, the DPCRC’s recommendations regarding the new criteria for ascertaining the mass consumption nature of bulk drug on the basis of the top selling brand is not acceptable as it gives rise to anomalies.

In this context, it may be noted that there is no tailor made data available for the purpose of ascertaining the mass consumption nature and absence of sufficient competition with reference to a particular bulk drug. There is only one

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35 The guiding principles are; (a) mass consumption nature of the drug and (b) absence of sufficient competition in such drugs.
source namely, "Retail Store Audit for pharmaceutical market in India" published by ORG-MARG,\(^\text{36}\) which lists out all major brands and their sale estimates on All India basis. This publication contains data for single ingredient as well as multi ingredient formulations. However, it does not give complete description of all the ingredients of the pharmaceutical product listed therein. Hence there is need to obtain information in regard to composition of each brand, dosage form wise and pack wise, from various other publications.\(^\text{37}\)

Though none of these sources can be said to be exhaustive and comprehensive in regard to market information, yet under the given circumstances, these are the best available. It has also been noted that the sale value of any combination formulation is not directly relatable to a single particular bulk drug forming part of the combination formulation. Combination formulations involve too many variables.\(^\text{38}\) In view of these facts, ORG-MARG sales data for combination formulations does not yield information in regard to mass consumption nature and absence of sufficient competition with reference to a particular bulk drug. Also, it is to be borne in mind that processing of such data, which requires cross checking with other publications and sources of information

\(^\text{36}\) ORG-MARG is India's Premium market surveillance and consulting firm, whose audits provide detailed product level information based on monthly retail sales.

\(^\text{37}\) Indian Pharmaceutical Guide (IPG), Current Index of Medical Specialties (CIMS), monthly Index of Medical Specialties (MIMS), Drug Today, Information provided by some manufacturers, label composition as indicated on market samples.

\(^\text{38}\) Viz strength of a particular bulk drug and its proportion with respect to other bulk drugs used in the combination formulation, price difference between bulk drugs used in combination formulation, pack sizes, dosage forms etc.
in regard to composition of each brand dosage form wise and pack wise may involve instances of omission/commission. In view of the above, it would be logical to state that although ORG-MARG sale estimates available in regard to all single ingredient formulations of a particular bulk drug would not yield the sale value of that bulk drug in the form of all its formulations yet it would adequately reflect the mass consumption nature of that bulk drug in the form of single ingredient formulations, which may be used as a practical indicator for formulating the policy.\textsuperscript{39}

The department through National Pharmaceutical Pricing Authority (NPPA), with the help of National Institute of Pharmaceutical Education and Research (NIPER) has developed the desired database for single ingredient formulations from the retail store audit data as published by ORG-MARG. On this basis, the department proposes to undertake the exercise of identifying the bulk drugs of mass consumption nature and having absence of sufficient competition according to the following methodology:

(i) The 279 items appearing in the alphabetical list of Essential drugs in the national Essential Drug list (1996) of the Ministry of health and Family Welfare and the 173 items which are considered important by that ministry from the point of view of their use in various health programmes, in emergency care etc., with the exclusion as in the past therefrom of sera and

vaccine, blood products combinations etc. should form the total basket out of which selection of bulk drugs be made for price regulation.

(ii) The ORG-MARG dated March 2001 would form the basis for determining the span of price control as suggested by Drugs Price Control Review Committee (DPCRC).\(^{40}\)

(iii) The Moving Annual Total (MAT) value for any formulator in respect of any bulk drug will be arrived at by adding the MAT values of all his single ingredient formulations of that bulk drug, it’s salts esters, stereo-isomers and derivatives, covering all the strengths dosage form and pack sizes listed against that formulator in all groups /categories of the ORG-MARG (March 2001).

(iv) The Moving Annual Turnover (MAT) value for all the formulators, as defined in sub para (iii) above, in respect of a particular bulk drug will be added to arrive at the total MAT value in the retail trade.

(v) The MAT value for an individual formulator, in respect of any bulk drug, as arrived at in sub para (iii) above, will be the basis for calculating the percentage share of that formulator in the total MAT value arrived at as in sub para (iv) in respect of that bulk drug.

\(^{40}\) In order to review the current drug price control mechanism with the objective of reducing the rigours of price control, where they have become a counter productive, a committee called the Drugs Price Control Review Committee under the Chairmanship of Secretary, Department of Chemicals and Petro-Chemicals was set up in 1999.
(vi) Bulk Drug will be kept under price regulation if the total MAT value arrived at as in sub-para (iv) above, in respect of any particular bulk drug is more than Rs.2500 lakhs (Rs.25 crore) and the percentage share, as defined in sub para (v) above, of any of the formulators is 50% or more. The total MAT value, arrived at as in sub para (iv) above, in respect of any particular bulk drug is less than Rs.2500 lakhs (Rs.25 crore) but more than Rs.1000 lakhs (Rs.10 crore) and the percentage share as defined in sub para (v) above, of any of the formulators is 90% or more.

(vii) All formulations containing a bulk drug as identified above, either individually or in combination with other bulk drugs, including those not identified for price control as bulk drug, will be under price control. The Government shall, however, retain the following over-riding powers:

In cases of drugs formulations listed by the ministry of Health and Family Welfare, mentioned in sub-para (i) above. And those presently under price control, having significant MAT value as per ORG-MARG but not covered under the criteria in sub-para (vi) above as a result of this proposal, the NPPA would specially monitor intensively their price movement and consumption pattern. If any unusual movement of prices is observed or brought to the notice of the NPPA, the Authority would work out the price in accordance with the relevant provisions of the price control order.
**Maximum Allowable Post-Manufacturing expenses (MAPE)**

Under the policy the Maximum Allowable Post-manufacturing Expenses (MAPE) is 100% for indigenously manufactured formulations.

**Margin for Imported formulations**

The policy with respect to imported formulation provides that for imported formulations, the margin to cover selling and distribution expenses including interest and importer’s profit shall not exceed fifty percent of the landed cost.

**Pricing of formulations**

So far as the pricing of formulations is concerned, the policy states that

(i) For scheduled formulations, prices shall be determined as per the present price. The time frame for granting price approvals will be two months from the date of the receipt of the complete prescribed information.

(ii) The present stipulation that a manufacturer, distributor or wholesaler shall sell a formulation to a retailer, unless otherwise permitted under the provisions of Drugs (Prices Control) Order or any other order made thereunder, at a price equal to the retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen percent therefore in case of schedule drugs, will continue.

(iii) The present provision of limiting profitability of pharmaceutical companies, as per the Third Schedule of the present Drugs (Prices Control) Order, 1995, would be done away with. However, if necessary so to do in
public interest, price of any formulation including a non-scheduled formulation would be fixed or revised by the Government.

**Ceiling Prices**

Regarding fixing of ceiling prices of formulations, the policy states that ceiling prices may be fixed for any formulation, from time to time, and it would be obligatory for all including small-scale units or those marketing under generic name, to follow the price so fixed.

**Exemptions**

The policy provides for exceptions from price control, they are:

A manufacturer producing a new drug patented under the Indian Patent Act, 1970- and not produced elsewhere, if developed through indigenous R & D, would be eligible for exemption from price control in respect of that drug for a period of 15 years from the date of the commencement of its commercial production in the country. A manufacturer producing a drug in the country by a process developed through indigenous R & D and patented under the Indian Patent Act 1970, would be eligible for exemption from price control in respect of that drug till the expiry of patent from the date of commencement of its commercial production in the country by the new patented process.

A formulation involving a new delivery system developed through indigenous R & D and patented under the Indian Patent Act 1970, for process patent for formulation involving new delivery system would be eligible for exemption from price control in favour of the patent holder formulator from the
date of the commencement of it’s commercial production in the country till the expiry of the patent. The DPCRC has suggested that the low cost drugs measured in terms of ‘cost per day medicine’ may be taken out of price control. Any formulator can represent to NPPA with proof of per day cost to consumer patient. NPPA will be authorised to exempt such formulation from price control if its cost to consumer patient does not exceed Rs.2/- per day, under intimation to the Government.

**Pricing of scheduled Bulk Drugs**

For a scheduled bulk drug, the rate of return in case of basic manufacture would be higher by 4 percent over the existing 14 percent on net worth or 22 percent on capital employed. The time frame for granting price approvals will be 4 months from the date of the receipt of the complete prescribed information.

The Government shall, however, retain the overriding power of fixing the maximum sale price of any bulk drug, in public interest. The table below gives the salient points of the new pricing policy and compares it with the previous policy.

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42 Supra note 35.
Table-IV: *Comparison between old and new Drug Policies*

<table>
<thead>
<tr>
<th>Criteria</th>
<th>New Policy</th>
<th>Old policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Span of control</td>
<td>17%</td>
<td>38%</td>
</tr>
<tr>
<td></td>
<td>Both Bulk Drugs &amp; Formulations</td>
<td>Both Bulk Drugs &amp; Formulations</td>
</tr>
<tr>
<td>1. Turnover</td>
<td>Rs.25 cores</td>
<td>Rs.4 cores</td>
</tr>
<tr>
<td>Market Share</td>
<td>50%</td>
<td>40%</td>
</tr>
<tr>
<td>2. Turnover</td>
<td>Rs.10 to 20 crores</td>
<td>Rs.1 to 4 crores</td>
</tr>
<tr>
<td>Market Share</td>
<td>90%</td>
<td>90%</td>
</tr>
</tbody>
</table>

**Quality Aspects**

The Ministry of Health and Family Welfare would progressively benchmark the regulatory standards against international standards for manufacturing, progressively harmonise standards for clinical testing with international practices, streamline the procedures and steps for quick evaluation and clearance of new drug applications, developed in India through indigenous R & D and set up a World Class Control Drug Standard Control Organisation (CDSCO) by modernising, restructuring and reforming the existing system and establish an effective system network of drugs standards enforcement administrations in the states with the CDSCO as a nodal center to ensure high standards of quality, safety and efficiency of drug and pharmaceuticals.

**Pharma Education and Training**

The National Institute of Pharmaceutical Education and Research (NIPER) has been set up by the Government of India as an institute of “national importance” to achieve excellence in pharmaceutical science and technologies, education and training. Through this institute, Governments endeavour will be to
upgrade the standards of pharmacy education and R & D. Besides tackling problems of human resources development for academia and the indigenous pharmaceutical industry, the institute will make efforts to maximise collaborative research with the industry and other technical institutes in the area of drug discovery and pharma technology development.

5.7.2 Critique of drug policy 2002

It has been criticised that the new pharmaceutical policy 2002 is a savage attack on health care in the country. Though it has been termed as a 'pharmaceutical policy', the new changes are only aimed at allowing a rise in drug prices. This has been done at the behest of pharmaceutical companies, who have been given further license to profiteer at the expense of the sick and ailing. All other elements in the policy are mere window dressing to justify the price hike.

It may be recalled that in 1995 the number of Drugs under price control had been slashed from 165 to 74. This had led to an immediate spiral in drug prices. The new policy has further reduced the number of drugs under price control to just.38

In the new policy, in one sweep, the volume of pharmaceuticals under price control has been reduced from an estimated 40% to 25% of the total drug market. There has been no attempt to provide even the semblance of justification for the decontrol of drug prices. Earlier studies have clearly shown that prices of drugs start rising as soon as controls are removed. This was evident in 1995-96, after the
last round of price decontrol effected through the Drug Price Control Order (DPCO) 1995.43

Further in almost all segments, the brand leader for a particular drug is usually one of the most expensive. This lies in the face of the argument that market forces and competition stabilises drug prices. If a more expensive brand sells more in the market than cheaper alternatives, it should be evident that the price of a drug does not determine its volume of sale.

This is so because market mechanisms are notoriously ineffective in stabilising prices of drugs, as there is no direct interaction between the consumer and the drug market. Companies are able to sell overpriced drugs through aggressive promotional strategies aimed at doctors and by providing lucrative margins to chemists. The government's claim, that market forces shall prevent price increase is not acceptable.44 Moreover the policy could not be implemented due to the stay order issued by the Karnataka High Court in Public Interest Litigation. (PIL)

5.7.3 The Draft National Pharmaceutical Policy 2006

Driven by the knowledge skill, growing enterprises, low costs, improved quality and demand the pharmaceutical sector has witnessed a tremendous growth over the past few years from a turnover of Rs.5000 crores in 1990 to over

Rs.50,000 crores during 2004-05. Exports have also grown very significantly during this period. India is today recognised as one of the leading global players in the manufacture of pharmaceuticals. It is also recognised that the cost of drugs produced in India is amongst lowest in the world. India’s rich human capital is believed to be the strongest asset for this knowledge-led industry. Various studies show that the scientific talent pool of 4 million Indians is the second largest English speaking group world wide, after the US.\textsuperscript{45}

However, despite the impressive growth of the sector there are several concerns, which need to be addressed. Some of these concerns pertain to accessibility and affordability of medicines by the common man particularly the vast segment of poor population, instituting standards of quality, strengthening the fragmented regulatory system, sustaining growth of generics the main forte of Indian industry, meeting the challenges of product patenting and so on. In order to find the right solutions and the right balance between various viewpoints almost a continuous debate goes on regarding some of these issues both within and outside government.

For meeting the requirements of medicines at reasonable prices as also for strengthening of the indigenous manufacturing capacity and capability, the government has, over the years, formulated polices and issued price control orders from time to time. In the year 2002 government had formulated a new drug policy

but the same could not be implemented due to litigation involving it, under the 2002 policy a new price control criteria was approved. However, before the same could be implemented it was stayed by Karnataka High Court. An SLP was filed in the Supreme Court against the order of Karnataka High Court. Supreme Court vide its interim order on 10th March 2003 stayed the order of Karnataka High Court. However it also ordered that, “the petitioner shall consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of the price control and to review the drugs which are essential and life saving in nature till 2nd may 2003”. Accordingly the Central Government reviewed the National Essential Drug List, 1996 and brought out a new list called the National List of Essential Medicines, 2003 which was made available to the Supreme Court. Under this list as many as 354 drugs have been categorised as essential medicines.46

Another important development that has recently taken place in India is the introduction of the product patent regime in pharmaceuticals. Earlier with the enactment of the Patent Act, 1970 only process patent was made applicable for pharmaceuticals, which played a very significant role in the development of pharmaceutical industry in India. Indian Patent Law has now been made TRIPs compliant by fulfilling various commitments under the TRIPs agreement. This has brought a new challenge to the Indian pharmaceutical industry as it would no longer be able to freely continue with the production of generics of the new

46 Ibid.
patented molecules without licence/payment of royalty to the innovated company. Thus Indian industry would now be required to focus much more on research and development. Further non-implementing of pharmaceutical policy 2002 led to the formulation of the National Pharmaceuticals Policy 2006.

**Features of the Draft Policy**

The Draft National Pharmaceutical Policy, 2006 aims to strengthen the drug Regulatory System and the patent office. It focuses on research and drugs development with clinical trials. The policy lays emphasis on developing human resources in pharmaceutical science by opening more institutions. The policy aims at providing a better access to anticancer and anti HIV/AIDS drugs to the patients.

The Draft National Pharmaceutical Policy, 2006 seeks to rationalise the excise duty on pharmaceuticals. It also seeks to streamline the system of bulk procurement of drugs by the government besides promoting the generic medicines. There would be a settlement commission for settling old dues under the Drug (Prices Control) Order 1979. Drug Price Monitoring Awareness and Accessibility Fund (DPMAA) would be set up along with pharma parks.

To the existing 74 drugs and their formulations, 354 drugs with specified strength as mentioned in the national list of Essential Medicines (NLEM) 2003 have also been patented.

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included in the Pharmaceutical policy. Some of the other provisions of the Draft Policy are as follows:

(a) The maximum allowable post manufacturing expenses (MAPE) presently 100 percent over the manufacturing cost, is proposed to be revised as 150% in general 50% additional MAPE for R & D intensive companies which fulfil the laid down standards. For existing 74 drugs under price control MAPE would continue to remain at 100% for one year in order to avoid a sudden increase in prices. It would be increased thereafter on the above patterns.

(b) For making available anti-cancer and anti HIV/AIDS drugs at reasonable prices to a much larger section of the population Government would evolve a public-private partnership programme with the concerned manufacturers and cancer hospitals in the country. All medicines pertaining to these categories whether under National List of Essential Medicines, 2003 or outside would be brought under this programme.

(c) Drugs for other life threatening diseases requiring life long treatment whether part of National List of Essential Medicines 2003 or outside it; would also be identified and brought under the public-private partnership model.

(d) The patented drugs (formulations under product patent) that are launched in India after 1\textsuperscript{st} January 2005 would be subjected to mandatory price negotiations before granting them marketing approval. Department of Chemicals and Petrochemicals in consultation with Department of Health would lay down necessary guidelines for determining the negotiated prices.
(e) One of the ways to make available cheaper drugs to people at large could be to promote the production of generic drugs in the country. The Draft Policy tries to do this in the following ways: public procurement and distribution of drugs through the public health system would preferably for generic drugs. Quality certification would be provided free of cost to generic drug manufacturers through an appropriate scheme. No control on prices of generic drugs (cost based or MRP based) would be specified. These would however, be kept under price monitoring. Only those drugs would be exempted from price control, which follow the prescribed norms.

(f) Review of all existing guidelines, norms and procedures followed by NPPA for fixing prices of bulk drugs and formulations by a committee to be set up by Department of Chemicals and Petrochemicals. Among others this Committee would include representatives of pharmaceuticals industry also.

(g) Some exemptions have been provided for certain drugs from the price control. New drugs developed in India through product patent, process patent and new drug deliver systems would be exempted from price control for 5 years. This will boost R & D in India. Simultaneously, vaccines and biotechnological drugs, drugs for sale to hospitals only whose MRP is Rs.1 per capsule/tablet and generic formulations fulfilling the prescribed norms would be exempted.49

49 Supra note 45.
A Critique of the Draft Policy

The Draft Policy is being criticised by some pharmaceutical industries saying that it may lead to drug shortage and increased costs contravening against the purported goals of accessibility and affordability. Union Health Ministry, one of the key decision makers with respect to the approval of pharmaceuticals, cautioned that increase in the span of price control may lead to companies discontinuing the production of such drugs thereby affecting its supply.

The other stakeholder, the union Ministry for commerce and industry too warned that any increase in the span of price control on drugs may affect the export of domestic pharmaceutical industry indirectly. The reduction in the prices of drugs in domestic market will compel several domestic pharmaceutical companies to quote low in export markets. Commerce ministry opines that drug companies had a tendency to discontinue the production of drugs under price control and embark on importing them, instead with the current Drug Price Control Order (DPCO) allowing a 50% mark up on the landed cost of imported medicines, it proved to be a better alternative for the companies.50

Arguing that the proposal is far more intrusive than required by the Apex Court, the finance ministry was next in line to come down heavily on the rationality of price controls. The availability and affordability of the essential drugs can be best ensured by competition in the market. “If an essential and life saving drug is not available in the market at a reasonable price only then the

government can intervene and fix a suitable price for the drug" the ministry said. \(^{51}\)

To top it all the Prime Minister’s Office (PMO) was the latest to sum up the government’s sentiments. PMO has asked the chemicals ministry to prepare separate cabinet note explaining how the issue of price control can be dealt with without increasing the span of control. It observed that adopting the entire national list of essential medicines as the list of drugs to be brought under price regulation is clearly inappropriate and asked to ensure that the list of price controlled drugs remain as short as possible. Not only the various ministries and allied departments but leading research institutions like Council of Scientific and Industrial Research (CSIR) also joined the growing army of dissent against Draft policy. Denying "reasonable margins" to the drug makers would adversely affect their ability to carryout research, which is crucial for the steady up keep of the industry, CSIR noted. The CSIR view assumes importance because its Chief Dr.R.A.Mashalkar’s Report on the pharma industry currently serves as the benchmark for many policy decisions and proposals. \(^{52}\)

However, the Ministry of Chemicals, vehemently countered these concerns. It argued that the span of control would not increase the prices to 50-70 % suggested by certain quarters. Nor would the prices of all drugs freshly brought under price control come down by 30-70%. It is not true that price control resulted in drug companies discontinuing production of controlled drugs neither

\(^{51}\) Ibid.

\(^{52}\) Ibid.
the shortage of medicines has been created. There was no availability problem for the drugs under price control”, the minister argued.53

5.7.4 The Drug (Price Control) Order, 1995

The Government of India in exercise of the powers under section 3 of the Essential Commodities Act, 1950 has passed the Drug (Price Control) Order 1995. The underlying object of the order is to apply transparent criteria across the board on all drugs with the minimum use of subjectivity for the purpose of listing of drugs and their categorisation for the purpose of price control. The instrument of price control is to be used to prevent and check market distortion and manipulation by vested interests. The drugs having adequate competition need not be kept under price control. However, ceiling prices have to be fixed for commonly marketed standard pack sizes of price-controlled formulation.

The order provides for a single list of price-controlled drugs and formulations with maximum allowable post manufacturing expenses (MAPE) of drugs to facilitate their production and availability. However genetically engineered drugs produced by recombinant DNA technology and specific cell/tissue targeted drug formulations will not be under price control for five years from the date of manufacture in India.

chemical, biological or plant product including its salts, esters, stereo-isomers and
derivatives, confirming to pharmaceutical or other standards specified in the
second schedule to the Drugs and Cosmetics Act and used as an ingredient in any
formulation. ‘Drug’ includes all medicines for internal or external use of human
being or animals and all substances intended to be used for or in the diagnosis,
treatment, mitigation, or prevention of any disease or disorder in human beings or
animals including preparations applied in human body for repelling insects like
mosquitoes. It also includes such substances, intended to affect the structure or
any function of the human or animal body and bulk drugs and formulations.
‘Formulation’ means a medicine processed out of or containing one or more bulk
drugs with or without the use of any pharmaceutical aids for internal or external
use or in the diagnosis, treatment, mitigation or prevention of diseases in human
beings or animals. It however does not include Ayurvedic, Sidha, Unani and
homeopathic system of medicines.

‘Non-scheduled bulk drug’ means a bulk drug not specified in the first
schedule of the order. ‘Non-scheduled formulation’ means a formulation not
containing any bulk drugs specified in the first schedule of the order. ‘Scheduled
formulation’ means of a formulation containing bulk drug specified in the first
schedule. ‘Scheduled bulk drug’ means a bulk drug specified in the first schedule.

Bulk drugs have been listed in two schedules. The First schedule lists bulk
drugs for important national health programmes and used in formulations
mentioned in category I of the third schedule. The second schedule has 139 items
of bulk drugs which are used in formulations appearing in the third schedule with some exceptions with a view to regulate the equitable distribution and increase supply of bulk drugs and making them available at fair prices, the Government has the power to fix from time to time by a notification in the official Gazette, after making an inquiry, a maximum sale price at which a bulk drugs is to be sold. In fixing the sale price there are certain options, which manufacturer or producers may choose. There is a different procedure for fixing the price of bulk drugs not listed in the schedule. The manufacturer is free to fix its price for such drugs. However, it has to indicate the details of the cost to the Government. Regarding price of formulations, DPCO empowers the Government to fix it on the basis of the formula.

The Government has also taken the power to fix a ceiling price of formulations specified in category I of the third schedule. No manufacturer or importer may market a new formulation or a new pack of his existing formulations specified in category I or in category II of the third schedule without obtaining the prior approval of it's price from the government. Duties have been imposed on

54 As per provision of sub paragraph (2) of paragraph 3 of DPCO 1995.
55 \[ R.P. = \frac{(M.C. + C.C. + P.M. + P.C.) x (1 + \frac{\text{MAPE}}{100}) + \text{E.D.}}{100} \]

Where “R.P.’ means Retail price,
“M.C.” means material cost,
“C.C.” means conversion cost worked out in accordance with established procedures.
“P.M.” means cost of packing materials etc.,
“P.C.” means packing charges.
“MAPE” means maximum allowable post-manufacturing expenses.
“E.D.” means Excise Duty.
Under the revised policy announced by the government on hundred percent of MAPE has been allowed for all categories on a uniform basis.
manufacturers or importers of bulk drugs to submit price list to the government every year within one month of introduction of Annual Finance Bill. Likewise every manufacturer, importer or distributor of a formulation is required to display on the label of the container the retail price with the words “retail price not to exceed” including local taxes.56

The National Pharmaceutical Pricing Authority (NPPA) an independent body of experts, has been set up and entrusted with the functions of price fixation/revision and other matter relating to updating the list of drugs under price control each year on the basis of the established criteria, the NPA has also been empowered to monitor the prices of decontrolled drugs and formulations.

The time frame for granting price approvals is two months for formulations and four months for bulk drugs from the date of receipt of the complete information. There have been complaints that the order has failed to achieve its objects. The prices of essential drugs as well as vitamins have been raised by unscrupulous manufacturers and distributors through various devices.

Under the DPCO all drugs are not subjected to price controls. There is list of essential drugs different from WHO’S list, which are subjected to price controls. Non-essential drugs are left to market forces. The number of essential drugs has varied. There are around 500 common bulk drugs. In 1995, mirroring

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reforms, the number under controls was reduced to 76 down from 145 in 1987. In 2002 this number has been further reduced to 38.

3.7.5 The Drugs and Cosmetics Act, 1949

Control over pharmaceutical trade is not only built into the Patents Act but restriction is also provided in the Drugs and Cosmetics Act, which is basically an Act, “to regulate the import, manufacture, distribution and sale of drugs and cosmetics”. The problem of adulterated, spurious and sub standard drugs led to the imposition of more stringent penalties and import controls in the amendment of the Act in 1982 but inadvertently it provided the government with ample provisions for regulating the importation of drugs. The Drugs and Cosmetics Act is a central Act, but its implementation depends upon both the centre as well as individual states. The Act lays down broad framework for governing the import, manufacture, distribution and sale of drugs, including those belonging to the Homeopathic, Ayurvedic, Siddha and Unani systems of medicine.57

The Drugs and Cosmetics Act is very important because it establishes the administrative set-up for the implementation of various provisions laid down under the Act and the Rules. It sets up advisory bodies such as the Drugs Technical Advisory Board and the Drugs Consultative Committee and also the Central Drugs Laboratory to carry out tests and analysis of Drugs. It also sets out

57 Monograph vol.II The Institute of Law and Ethics in Medicine, National Law School of India University, Bangalore, p.596.
the powers and functions of Drug Inspectors, who play an important role in the actual implementation of the Act and rules.

The Act empowers the central Government to issue notifications to prohibit the import of a given list of drugs and cosmetics including "any patent or proprietary medicine". The Central Government can further, in consultation with or at the recommendations of the Drugs Technical Advisory Board, make rules specifying classes of drugs for import, the licensing procedure for the importation of such drugs, places at which the drugs may or may not be imported and such other details for scrutinising procedure. The Central Government is also empowered to issue notifications to prohibit the import of drugs "in public interest".  

5.7.6 The Drugs (Control) Act 1950

Apart from control through import regulation, the Drugs (Control) Act of 1950 was passed "to ensure that certain essential imported drugs and medicine were sold at reasonable prices". The Act empowers the chief commissioner to fix by notification: (a) The maximum price which may be charged by a dealer or producer; (b) The maximum quantity which may at any one time be possessed by a dealer or a producer; (c) The maximum quantity, which may at any one transaction be sold to any person. The Act proceeds to lay down directives for dealers, producers and stockists to give effect to section 4 of the Act.  

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58 Ibid.  
59 Supra note 57, p.597.
5.7.7 National Pharmaceutical Pricing Authority

National Pharmaceutical Pricing Authority has been set up as a regulating authority for governing the pharma sector. The DPCO ensures the implementation of price control through the National Pharmaceutical Pricing Authority (NPPA), an independent body of experts established in 1997 under the aegis of the drug policy, 1994. The NPPA has the authority not only to fix and revise the prices of scheduled drugs and formulations but also to enforce the provisions of the DPCO. The NPPA addresses price fixation by notifying ceiling prices for some and non-ceiling prices for other controlled drugs.\(^{60}\)

It is also the authority’s responsibility to monitor the availability of drugs, identify shortages, if any, and to take remedial steps. It collects data on production, exports and imports, market share of individual companies, profitability of companies etc, for bulk drugs and formulations on an ongoing basis. NPPA is currently fixing prices on the basis of Drug Price Control Order (DPCO) 1995, which has separate methodology/ procedure for price fixation or revision of bulk drugs and formulations.\(^{61}\)

Other Functions of the National Pharmaceutical Pricing Authority are:

1) To implement and enforce the provisions of the Drug (Price Control) order in accordance with the powers delegated to it;

2) To deal with all legal matters arising out of the decisions of the Authority;

\(^{60}\) Supra note 1.

3) To undertake and /or sponsor relevant studies in respect of pricing of drugs/pharmaceuticals;

4) To recruit/appoint the offices and other staff members of the Authority, as per rules and procedure laid down by the Government;

5) To render advice to the Central Government on changes/ revisions in the drug policy;

6) To render assistance to the Central Government in the Parliamentary matters relating to the drug pricing.62

The prices of the bulk drugs are fixed /revised by the NPPA as per the provisions of para 3 of the Drugs (Price Control) order 95. Since inception NPPA has fixed /revised prices 184 bulk drugs (including derivations) and 2658 formulations. Further para 11 of the DPCO 95 stipulates that any manufacturer or importer of bulk drug or formulation fails to submit the application for price fixation / revision, as the case may be, to furnish information as required under this order, within the time specified therein, the Government may, on the basis of such information as may be available with it, by order fix the price in respect of such bulk drug or formulation. In case the required information is not furnished by the manufacturers NPPA fixes the prices of the bulk drugs under para 11 of DPCO 1995, based on available information. Since inception of NPPA in 1997, in about 34 cases of bulk drugs and in 1988 cases of formulations, prices have been fixed invoking para 11 of DPCO 95.

62 Ibid.
Whenever it comes to notice of NPPA, that the drug companies are charging prices higher than the notified prices of NPPA; necessary action under para 13 of DPCO 95, to recover over charged amount is taken. Till June 2005, an amount of around Rs.89 crores has been recovered as overcharged amount.63

Some of the actions/steps that have been taken by NPPA since its inception are:

(i) NPPA has asked the manufacturers of all the scheduled formulation pack sizes to work out the prices of different pack sizes of tablets and capsules of the same strength or composition packed in different strips or blisters on pro-rata basis of the latest ceiling price fixed. This was done to ensue that (a) manufacturers do not change their pack sizes in a bid to remain out of price control and (b) manufacturers are not forced to approach the government /NPPA frequently for price approvals for different pack sizes.

(ii) Revised/fixed the prices of 12 bulk drugs and 635 formulation packs.

(iii) Compiled the data on production and imports of bulk drugs for the year 1997-98.


(v) Fixed the prices of three commonly used Fluids by exercising the powers available under para 10 (b) of DPCO 1995. Their prices are lower by about 40% than the prices charged earlier by the companies from the consumers.

(vi) Kept a cheque on the prices of drugs, besides advising the state Govt. to enforce of scheduled formulations.

63 Ibid.
(vii) Set up an expert committee to review the norms of conversion cost (CC) packed charges (PC) and process Loss (PL). 64

5.7.8 National Drug Authority

It is envisaged that a National Drug Authority may be set up by a separate Act of Parliament to perform the following functions;

(i) Develop and define basic appropriate standards relating to the manufacture, import, supply, promotion and use of drugs.

(ii) To approve and register pharmaceutical products for use in the country only if (a) it meets real medical need, (b) it is therapeutically effective and (c) it is acceptable safe.

(iii) To enforce effectively appropriate quality standards of medicines and goods manufacturing practices, throughout the country, having full regard to the needs of public health and standardise dosage strengths and pack sizes of formulations with a view to check proliferation.

(iv) To monitor standard practices in drug promotion and use and to clearly identify those, which are acceptable and prohibit those, which are unethical, and against the consumer’s interest.

(v) To monitor the prescribing practices and to evaluate their appropriateness for the purpose of guiding the medical profession and for achieving the aim of rational prescribing.

64 Supra note 2.
(vi) To ensure that appropriate information about registered pharmaceuticals is made available for the guidance of consumers having regard to; (a) the adverse consequences of non-compliance by patients particularly in the case of antibiotics, steroids etc. (b) dangers of self-medication, and (c) the need to involve consumers as full partners in the health care system.

(vii) To prepare and publish national formulary and formularies relevant to various levels for the guidance of consumers as well as doctors.65

5.8 Drug policy and patented drugs

One of the main objectives of the pharmaceutical policy is to ensure availability of good quality essential pharmaceuticals at reasonable prices within the country for mass consumption. It will also help to create an environment conducive for channelising a higher level of investment into R & D in pharmaceutical sector with a particular focus on disease endemic to the country.

With a view to encouraging generation of intellectual property and facilitating indigenous endeavours in Pharma Research and Development (R & D), appropriate fiscal incentives have been provided in the policy. The pharmaceutical policy 2002 has allowed some exemptions from price control for new drugs patented under the Indian Patent Act.

(1) A manufacturer producing new drugs patented under the Indian Patent Act 1970 and not produced elsewhere, if developed through indigenous R & D, would be eligible for exemption from price control in respect of that drug for

65 Ibid.
a period of 15 years from the date of the commencement of its commercial production in the country.

(2) A manufacturer producing a drug in the country by a process developed through indigenous R& D and patented under the Indian Patent Act 1970 would be eligible for exemption from price control in respect of that drug till the expiry of patent from the date of commencement of its commercial production in the country.

(3) A formulation involving a new delivery system developed through indigenous R & D and patented under the Indian Patent Act 1970, for process patent for formulation involving new delivery system would be eligible for exemption from price control from the date of commencement of its commercial production in the country till the expiry of the patent. 66

These exemptions continue to exist in Draft Policy 2006.

Two major apprehensions of adopting the TRIPs Agreement in the pharmaceutical sector were regarding the higher prices of the patented products and their accessibility. By providing blanket exemption from price control the government is making the access to drugs difficult. It appears that 'who patents the product' matters more for the government than what is patented. It has been opined that rather than exempting drugs from price control, providing easy access to credit, promoting venture capital funds and stream lining the procedures would help in promoting innovations. 67

67 Supra note 35.
Price control measures are generally intended to ensure that consumers are not unfairly treated on the price front through charging excessive prices, not commensurate with the costs of supply or the benefits accrued. It is imperative that any pricing policy should ensure that the patients should receive their medicines at the lowest possible price and at the same time producers make adequate returns for his investments and efforts. None of the Drug Price control laws to date have been able to achieve these twin objectives of making drugs available at affordable price while ensuring profitable growth of the industry.

The pharmaceutical policy 2002 has attempted the price decontrol with the plea that this shall boost R & D expenditure in the pharmaceutical sector. When concerns were raised that amendment of the Indian Patent Act would result in rise in drug prices, the Ministry of Chemicals and Fertilisers had consistently claimed that any rise in prices would be kept in check through mechanisms in the DPCO. But nothing has been done so far. Price controls have already been diluted in the past decade and only 40% of the turnover of the industry was under price control. Any further dilution would mean virtual abandonment of price controls. If the Government considers this under grab of encouraging R & D, it will only substantiate earlier fears that a change in the Patent Act can only, lead to a spiralling rise in prices of drugs.68

In a new product patent regime (post TRIPs) patent protection on drugs and the bar on generic production can lead to abuse of dominant position by the drug companies that adversely impact consumer welfare. Therefore anticompetitive practices resulting from the new patent regime will also have to be addressed in the Draft Drug policy 2006, which is yet to come into force.

In other countries like South Africa, Public interest groups and patient organisation are beginning to approach competition commission to address anti competitive practice that seriously impact access to treatments. Countries like Canada, France, U.K, Japan Germany etc. have their own monitoring or controlling bodies as per their requirements. For example Canada’s patented medicines price Review Board, through negotiation sets maximum allowable price that pharmaceutical manufacturers may charge for patented medicines and any attempt to impose higher prices can result in significant fine for the manufacturer.

In U.K. local health care services are provided to the citizens under National Health Services.  

In India to take care of such a situation in future, there is proposal before the government that there should be a price negotiation mechanism for the new patented drugs prior to the grant of marketing approvals. It is suggested that the proposal should be concretised and enforced in the country expeditiously. Patent protection on drugs may lead to excessive pricing and refusal to voluntary license

69 Report of the Standing Committee on Chemicals and Fertilisers submitted to the speaker, New Delhi, September 27, 2005.
the patent in return for reasonable royalty. Therefore anticompetitive practices resulting from new patent regime will have to be tackled. The competition law is an important Act to address the abuse of monopoly resulting from a drug patent. In India however the amendments to the competition Act pre-date the Patent Act 2005 and therefore did not take into consideration anti-competitive practices arising out of patents. The competition Act needs to be reviewed by the government and if needed amendments that facilitate the usage of the Act vis-à-vis patents for drugs and resulting monopoly and dominant position should be introduced.

Some of the concerns regarding the competition law in India are:

(a) Crucial legislative synergy between patent and competition law is absent.
(b) Section 3 to 6 of the Act need to be reviewed keeping in mind anticompetitive practices arising out of abuse of dominant power by patent owner.\(^7^0\)
(c) Grant of compulsory license should be within the powers of competition commission.

5.9 Conclusion

Until early 1970s, Indian Patent Law was relatively strict, Drugs prices were amongst the highest in the world and only 30 percent of sales were manufactured domestically. In 1972, however, the Indian Patent Act 1970 came

\(^{70}\) Sec.3(5) (1) of the Act exempts patent holders from the applicability of the provision contained in sec.3 which aims to prohibit anticompetitive agreements, and section 4, 5 and 6 deals with regulation of combinations.
into force, loosing patent protection. Pharmaceutical processes but not products could be patented for seven years from the date of application.

In the next 20 years the industry flourished. By 2000, nearly 500,000 people were employed in a sector comprising 20,000 private enterprises, and domestically produced drugs accounted for over 70 percent of the market. India is the world’s fourteenth largest market for pharmaceutical products in value terms and the fourth largest market in unit terms. Exports of finished formulations rose considerably. Nearly 65 percent of the Indian export market is to the developed world. The larger companies both copied drugs and patented elsewhere-fostered R & D.

During this period prices fell significantly. By the 1990s, the cost of both patented and non-patented drugs in India was much lower than in the developed world, where health and income conditions were same but patent protection for pharmaceutical products had not been abolished.

The pharmaceutical industry in India is regulated by pharmaceutical policy 2002 and the Drug Price Control Order 1995. There are many other statutes and institutions which govern pharmaceutical industry. Inspite of this, it has been argued that drug prices are not effectively controlled and the government has failed to prevent the escalation of prices of drugs especially patented drugs.