4.1 Laws pertaining to manufacture and sale of drugs (Historical background)

In the beginning of the 20th century, the allopathic drug industry was nonexistent in India and pharmaceuticals were being imported from abroad. During and after World War I, India started to import cheap drugs in large volumes. Due to 'Swadeshi movement' Indian companies took initiative in manufacturing close substitutes to imported drugs, but due to the absence of quality control, the quality and the perfection were lost, to a considerable extent. Therefore, 'The Poisonous Act and Dangerous Drugs Acts were passed in 1919 and 1930. The Opium Act of 1878 was also amended. In 1931, a Drugs Enquiry Committee under the chairmanship of Lt. Col. R. N. Chopra was asked to make recommendations about the ways and means of 'controlling production and sale' in the interest of public health. Central Drugs Laboratory was set up to examine the quality and the utility of manufactured medicines. Licensing became mandatory to pharmacists and pharma producers. The Drugs and Cosmetics Act of 1940 was amended in 1955, 1960, 1962, 1964, 1972, 1982 and 1986. The drugs prices control order was passed in 1995. The Trade and Merchandise Act of 1958 and the Indian Patents and Design Act of 1970, were also passed.

State pharmacy councils were established and they were asked to maintain the register of the approved and duly qualified pharmacists. Cautions like 'poison', 'medicine only for external use' and 'medicine doses to be taken

59 Saket pharma handbook - Laws related to Mft. & sale of drugs - page 63 & 64.
strictly as per the registered doctor’s prescription’, became mandatory on the labels and containers of the drugs.\textsuperscript{60}

4.2 The Indian Patents Act of 1970

The Indian Patents Act has been drafted very carefully and precisely. It is as exhaustive, as the proposed ‘International Patents Act of 1995’ drafted by the WTO. The Indian Patents Act of 1970, consists of almost all the clauses and provisions of the WTO Patents Act. Therefore, India did not face serious difficulties in accepting and implementing WTO provisions of ‘TRIPS’.

The highlights of the Indian Patents Act of 1970 are as follows:
1) The aim of the act is to protect the interests and the rights of the inventors.
2) Any person claiming to be the true and first inventor of the invention can apply for a patent for that invention.
3) Every application for a patent shall be for one invention only and shall be made in the prescribed form and filed in the patent office.
4) Every specification shall describe the invention.
5) On acceptance, the controller shall give notice thereof to the applicant and shall advertise in the official gazette, the fact that it has been accepted and open to public inspection.
6) Within 4 months from the date of advertisement of the acceptance, any person interested may give notice to the controller, of opposition to the grant of the patent.
7) Hearing will be granted to both the inventor and the opponent before deciding the case.
8) No person, except under the authority of writer permit granted by the controller, can make application outside India to the grant for a patent.
9) Where a patent is granted to two or more persons, each of these persons shall be entitled to an equal share in the patent.
10) After granting the ‘patent’ it shall be sealed and entered in the register.
11) Patent will remain effective for a period of five years from the date of sealing or seven years from the date of patent.
12) The registered proprietor of the design shall have a copyright to a design for five years from the date of registration. It shall not be lawful for any person to apply the design or imitate for the purpose of sale.

\textsuperscript{60} Ibid - page 71
\textsuperscript{61} Saket pharma hand book - Laws related to pharma manufacture and sale - pages 91 to 94
Clinical trials
The World Medical Association (WMA) revised the rules and guidelines of 1964 Helsinki Declaration for clinical trials in developing countries. The WMA is an organization of physicians that searches to promote standards for ethical behaviour. Because of the comparative cost advantage, clinical trials are increasingly carried out in developing countries like India, Brazil, China on the basis of outsourcing of contracts given by western pharma giants.

Drug safety
The safety of drugs is heavily regulated and the health care workers have to understand, how their drugs can be safely used. In the case of production errors or contamination, unsafe production batches have to be withdrawn from the US market, the FDA of the US requires companies to strictly observe current “Good Manufacturing Practices” (GMP).

In March 2002, the WHO released the first list of pre-qualified manufactures for 30 medicines of international quality students. Indian generic manufacturers therefore have taken initiative to get their products, enlisted in the approved list of WHO, in order to capture the overseas markets.

Drug Promotion
In 1988, WHO published a set of ethical criteria for medicinal drug promotion. This code was again revised in 1994. After accepting the WTO membership, Indian pharma industry will have to abide by the norms set by the WTO.

In June 2004, Glaxosmithkline was accused of hiding research data about its anti depressant drug 'Paxil' which was unsafe for children and adolescents. Novartis had given exhorbitant fees to celebrities for promotion of its brand

Francis Weyzig - Sector Profile of the pharma industry - SOMO - Amsterdam Oct. - 2004 - P.28
Francis Weyzig - Sector Profile of the pharma industry - SOMO - Amsterdam Oct. - 2004 - P.28
Francis Weyzig - Sector Profile of the pharma industry - SOMO - Amsterdam Oct. - 2004 - P.29
Available at http://www.who.int/medicines/library/dap/ethical criteria
name drugs in TV programmes. Action was taken against them by the WHO.66

**Bribery, corruption and fraud**

Many pharma companies offer large gifts to doctors for promoting prescriptions of their products. They also give bribes to the purchase officials of government / semi-government, or private hospitals with a view to obtaining bulk / large scale orders for their products. Illegal payments are given to government officials to speed up the regulatory approvals of medicines. OECD adopted special provisions for prohibiting such irregular practices since 1997. Many companies have evaded taxes by under-invoicing. Indian pharma companies therefore are being regulated by the government, in recent era of "economic reforms"67

**Indigenous knowledge**

Traditional medicines are often subject to so called 'biopiracy'. For example, from time immemorial, Indians were in the know of the medicinal uses of *Tulsi, Hirada, Neem, Haldi (Tumeric) Sarpagadha, Shatawari* etc. Western MNCs manufactured drug made up of them and started obtaining their patents. This is a case of 'bio-piracy' and for prevention of these malpractices and protection of intellectual property rights of local knowledge and plants, the norms were made by the Convention on Biological Diversity. (CBD), which were adopted at the Earth Summit in 1992 and came into force since 199368

Access to essential medicines has been opened by patent flexibility, differential pricing and drug donations.

Systematic ratings of the pharma companies have commenced by the initiative of core ratings in developing countries69

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66 Ibid - Financial Times (June 3, 2004), GSK Faces pitzer suit over Paxil data.
67 Ibid - Somo octo - 2004 - p.30
69 Ibid
4.3 Indian patents: Amendment Act of 1999

After having sought membership of WTO, India had to make necessary amendments in Indian Patents Act of 1970. President of India promulgated the 'Patent Ordinance 1994 (No. 13)' Supplementing the Indian Patents Act 1970 and allowed the filing of 'product patent applications' for pharmaceuticals drugs and agrochemical products as required by sub-para (a) of article 70.8 of the TRIPS Agreement. The ordinance became effective on Jan. 1st, 1995. Then 'Patents Amendments Bill 1995' was passed by Loksabha in March 1996 but was not endorsed by Rajyasabha therefore it was referred to the 'select committee' Loksabha dissolved on 16th May, 1996 therefore the proposed patents bill 1995 lapsed. In the meanwhile, U.S. made a complaint to the 'Disputes Settlement Board' of WTO and after hearing both the sides, WTO directed India to satisfy all requirements under articles 70.8, 70.9 and 63 of TRIPS. Patents ordinance no. 3 of 1999 came into force on 8th Jan., 1999. Loksabha passed the 'Patents Amendments Bill (1999) in March 1999. Rajyasabha endorsed it and the act was published in the Gazette, Part II Section I in March, 1999. This act fulfilled the conditions of TRIPS.70

Elements of the Indian Patent Amendment Act 1999

1) Mail box provision for filing of product patents in drugs, pharmaceuticals and agrochemicals.

2) Process patents, with innovative original method of manufacture, will also be eligible.

3) Exclusive Marketing Rights (EMR) to the inventor

4) Applications for a product patent and EMR must be sent on or after 1st Jan., 1995. Application from a convention country is also acceptable.

5) Product patent will be qualified as 'patentable invention' under sections 3 and 4 of Indian Patents Act.71

TRIPS commitments

1) India will have to change the Patent Act and be fully TRIPS compliant including granting of product patents in all fields of technologies on or before 31st Dec., 2004.

2) Make other necessary changes such as modernise Trademark Act (1958), introduce Service Marks, update Design Registration Act of 1911 make term of patents of 20 years, introduce reversal of burden of proof for process patent infringements.

3) There should be legislations concerning 'trade secrets'.

4) 'Sui Generis' system of protection of new plant varieties.

5) Anti competitive practices in contractual license.

6) Simplified procedure for registration.

7) An appellate board for speedy disposal of appeals.

8) Enhanced punishment for patent offences.

9) Powers of courts to grant 'Ex-parte' injunctions.

10) Due amendments to Indian Copyright Act and Indian Designs Act.


4.4 TRIPS Agreement proposed by WTO

The agreement consists of 7 parts and 73 articles.

Part I

1. General provisions and basic principles (Articles 1 to 8)

2. Standards concerning TRIPS (Art. 9 to 40)

3. Enforcement of IPRS - (Art. 41 to 61)

4. Acquisition and maintenance of IPRs - Art. 62

5. Dispute prevention and settlement (Art. 63 to 64)

6. Transitional agreements - Art. 65 to 67

7. Institutional agreements - (Art. 68 to 73)

It protects rights of patent, EMR Design, trademarks, trade secrets, new plant variables, geographical indications and anticompetitive practices. The

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provisions bring uniform control of the trade related rights in all the member countries of WTO.

4.5 Controls on pharmaceutical industry after 1970s.

The Indian pharmaceutical industry.

The Indian pharmaceutical industry is undergoing revolutionary changes. The industry is witnessing a consolidation phase, with the companies increasingly looking to step up growth by acquiring companies/brands. With India inching towards the WTO norms, the consolidation/growth of pharmaceutical sector will increasingly become similar to that of the global trend.

In 1991 India announced a new industrial policy, promising to liberalize her economy. The country initiated reforms to reduce bureaucracy, restrict the use of industrial licensing, expand the private sector and perhaps, most important offer to foreign firms was “welcome foreign investment”. The government understood the relationship between foreign investment and technology transfer and agreed that firms providing this combination in high-priority industries be allowed an equity position of at least 51 percent, without any prior government approvals. High-priority industries were defined as those “requiring large investments and advanced technology”.

In the years that followed, foreign investment poured into India from the industrialized world. United States investors played a major role in this process and invested in such diverse sectors as “new power plants and telephone systems to ventures that will provide fresh choices in breakfast cereals, computers and soft drinks.” The United States was not alone; significant foreign investment was also made by NRIs (Non-Resident Indians), and firms from Great Britain, Switzerland, and Japan.

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73 Dr. P. Ganguli - Intellectual Property rights and pharma industry - Saket pharma handbook - p.99 and 98.
74 Indian Industrial Policy #24
75 Ibid # 25
76 John Burns India now winning US investment N. Y. Times Feb 1995- C1
77 Tata Econ. Consultancy Services - Statistical outline of India 1999.
A sector conspicuously ignored by this new foreign investment was the pharmaceutical industry. In addition to the reasons that made foreign investment in India difficult and unpopular for private firms prior to 1991, the pharmaceutical industry faced the additional problem that India did not offer patent protection for pharmaceutical products. The multinational pharmaceutical industry is unique in that it is largely organized and operated by privately owned companies, created to realize profits for its stockholders. The industry deals in life-and-death issues, and its products not only relieve illnesses, but also improve the quality of life. In addition to the life-giving aspect, the composition of products usually consists of highly toxic chemicals, which, when mixed indiscriminately, can cause serious health problems and even death. Since public health is of concern to all governments, the pharmaceutical industry is heavily regulated on the national level worldwide. This regulation takes the form of prior approval in order to market a new product, and in some countries, the establishment of a price for the product.

At the global level, the pharmaceutical industry is divided into two kinds of firms, the innovative firm and the producer of generic drugs. The first, the innovative or patent-protected firms, rely heavily on patent protection. These firms believe that in order to carry out the intensive research required to produce new products, patent protection is essential. As a result of the extensive research and cost to produce a patent-protected drug, patent-protected firms tend to be located in highly developed and industrialized countries.

However, not all research efforts are successful. It is only a small fraction that reaches the market. It is through the period of exclusivity provided under the patent, generally twenty years from the date of filing, that the firm can recoup its R&D costs to continue new and innovative research. Actually, the effective term of the patents is more, around 14 to 15 years due to delays in the patent approval process and in obtaining rights to market the new drug. These firms are dependent on patent protection and are reluctant to introduce new products in countries that deny such protection. Because the patent grant
provides a period of exclusivity, the patent-owning firm can establish a higher price for the product since no competition is allowed. This is true when patent protection exists, even in countries where the government regulates the price of the product.

The second, the generic pharmaceutical firm, manufactures and markets pharmaceutical products that are not subject to patent protection. In countries with patent protection, generic firms come into their own at the expiration of the patent. At such time, the technology is in the public domain and anyone is free to manufacture the product. Generic products are subject to some government regulation, and in the United States the manufacturer must demonstrate to the satisfaction of the Food and Drug Administration (FDA) that the generic version is the bio-chemical equivalent of the patented product before any sales can be made. Generally speaking, once the generic drug appears in the market, it will be available at a lower cost than the original patented version. Often, several generic products appear in the market within the same time frame, thus causing even larger price reductions.85

In countries lacking pharmaceutical patent protection, the entire industry could be said to be generic. In such countries, the profile of the industry will include firms that may manufacture internationally used drugs that are in the public domain in the country of origin. In such a case, the industry is similar to the generic firm in the United States. However, many firms in countries that do not recognize pharmaceutical product patents manufacture products that are still under patent protection in the country of origin, thus diluting the value of the patent. This practice is viewed negatively by the country providing patent protection and is often characterized as piracy or counterfeiting by the firm whose patent is not being recognized. Yet it is perfectly legitimate and legal in the country where the drug is being manufactured and sold.86

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85 Robert S. Tancer - The Pharma industry in India - Adopting to TRIPS. The Journal of World Industrial property 1999 Page 177 to 187
86 Robert S. Tancer - The Pharma industry in India - Adopting to TRIPS. The Journal of World Industrial property 1999 Page 177 to 187
Both, the patent-protected and generic industries are patent-driven. The former rely on strong, effective patent laws and extending patent protection as long as possible both, at home and abroad. The generic industry in the United States is eager to begin manufacturing the generic equivalent as quickly as possible, so as to gain market access at the earliest time, and is obviously opposed to any form of patent term extension. Each, however, is convinced that it is providing unique service to the public; the patent-protected firm by introducing the newest, breakthrough product, and the generic firm by offering quality products at lower costs. The 'Pharmaceutical Research Manufacturers Association' (PhRMA) located in Washington, DC, is a trade association representing the interests of the innovative or patent-protected manufacturers of pharmaceuticals. Its mission is to help the research-based pharmaceutical industry successfully meet its goal of discovering, developing, and bringing to market medicines to improve human health, patient satisfaction, and the quality of life around the world, as well as, to reduce the overall cost of health care.80

Currently, PhRMA membership consists substantially, of all the patent-protected pharmaceutical firms. A partial list of names and addresses of PhRMA member firms is provided in (Exhibit 2).

High on PhRMA's agenda is obtaining strong and effective patent protection in all countries where its members are active. In addition, PhRMA addresses such concerns as price control and generic competition, issues that could adversely affect the interests of its members domestically and abroad. On a global level, PhRMA keeps careful track of the availability and effectiveness of intellectual property protection throughout the world. Annually, it notifies the United States Trade Representative (USTR) of the outcome of its review and makes recommendations as to what action the United States government should take against countries believed to be deficient in meeting international standards. For years, India had been a problem country and high on PhRMA's

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80 PhAM Annual Report 1997 - 98
list because of failure to grant pharmaceutical product patents. As a result of the intellectual property environment in India, PhRMA members kept a low profile, and principally marketed drugs no longer protected by patent, as opposed to their premier, innovative products.

Global pharmaceutical firms watched developments in India closely after 1991. The situation in India may be changing. In 1995 India became a signatory of the Uruguay Round Agreement and Trade Related Aspects of Intellectual Property (TRIPS), thereby showing willingness to accept one of its requirements, the issuance of pharmaceutical product patents. India’s adherence to TRIPS would become effective in 2005 as a result of a provision of the Agreement granting developing countries an additional period if it is required “to extend patent protection to areas of technology not so protectable in its territory.” In an important first step towards full compliance, India acceded to the Paris Convention for Protection of Industrial Property (Paris Convention) and the Patent Co-operation Treaty (PCT).81

Adherence to the Paris Convention is required under the TRIPS, and membership in the PCT provided instant benefits to Indian firms seeking multiple country patent protection. As the year 2005 approached, the global pharmaceutical industry watched India with new interest and the Indian pharmaceutical industry positioned itself, for the first time, to face international competition82.

The pharmaceutical industry functions include manufacturing of basic drugs formulations, intravenous fluids, hospital disposable kits, capsules etc. In 1950 – industry in primitive stage involved in manufacturing of formulations only.

81 As first step towards full compliance, India accessed to the Paris Convention for Protection of Industrial Property (Paris Convention) and the Patent Co-operation Treaty (PCT)

82 RT Tancer - The Pharma Industry in India - Adopting to Trips 1999 - Page 198 to 191

Exempt from paying foreign licences fees and royalty, the Indian companies could now have to access the newest molecules from all over the world and reformulate them for sale in the domestic market. After seven years - 'Copying' was permitted legally. High tariffs of 80 percent on imports, also was beneficial for industrial progress.

Today domestic production dominates 70 percent of the bulk drug requirement. Many MNCs have opted out from Indian Market – Fera / (Investment of a Foreign Companies in India. Subjected not to exceed 40 percent ) Restriction indirectly helped to support Indian Pharma Industry.

The Pharma industry is among the most R & D intensive industry. The millennium of 2000 A.D. has ushered in new opportunities and prospects on the one hand and the disguised boon of the threats and challenges by accepting the WTO regime and the conditions of 'TRIPS' that is Patents; on the other.

83 Tancer - The Pharma Industry in India - Adopting to TRIPS Journal of World Intellectual property 1999 - Page 170 to 185
4.6 The Salient features of the Indian Pharma Industry

1. Very intense competition among about 24000 companies (large, medium and small) fighting for their own place in more then the Rs. 20,000 crores market.


3. Government price controls, eroding profits and a vanishing bottom line for survival.

4. Rigorous controls on formulations and international patent restrictions.

5. Growing health awareness and facilities of medical insurance.

6. Sixteen percent of world’s population, which accounts for one percent of global health care spending.

7. Per capita consumption of drugs per annum amounts to less than US $ 3 compared to U.S. $ 191.84.

8. India’s Medicare System covers only 3.7 percent of its population.

9. Average per capita income being very low, prices of medicines are to be maintained at an affordable level.

10. Indian medicines are among the cheapest few in the world, partly because of fierce competition among, the pharma companies. For example, ‘cipro floxacin’ when launched in 1989 cost Rs. 25,000 per kg., today it costs Rs. 4000 only and prices of its formulations have fallen from Rs. 14 per tablet in 1990, to as low as Rs. 2 today.

11. India, Egypt and Argentina have allowed only ‘process patent registration’. As a result, pharma R & D is monopolized by MNCs in U.S., Japan and Europe. These leading MNCs have captured a vast global market; hence they secure economies of scale, for their huge expenditure on R & D.

12. Procedure of ‘patent registration’ takes at least four to five years and the life of a new molecule patent’ generally lapses in a period.

84 Tancer - Ibid
of seven years. Thus Indian companies cannot afford to lose their money over a long period of time and they are unable to invest fabulous amount in their R & D.85

4.7 New trends in India's pharmaceutical market

India's pharmaceutical market currently stands ninth in the world with a 1.5 percent share. The market was valued at more than $3 billion in the year 1998. At its annual growth rate of 15 percent (almost double the world's 6% annual growth rate), this market is expected to reach $6 billion by 2001 and may be more than double viz. $13.3 billion in 2006. India's official OTC market currently stands at over $130 million, and the industry's heart disease sector is expected to grow from $90 million now to more than $350 million in 200586.

Current demand in the Indian pharmaceutical sector stands at about $4 to $5 billion, and is estimated to increase at an annual rate of 15 to 20 percent in the future. Nevertheless, average per capita expenditure on pharmaceuticals in India is only $3 -- compared to $412 in Japan, $222 in Germany and $191 in the US. This is partly due to the prevalence of alternative healing methods in India, such as Ayurvedic and Unani medicine and homeopathy, and partly because prices for drugs have been kept artificially low by the Indian government. In fact, India's pharmaceutical industry is one of the most severely regulated industries in the country. Price controls have a strong effect on profitability in the industry, and weak patent protection poses a long-term threat to investment in India's drug market. Foreign firms also find it difficult to operate in India due to arbitrary decisions of Bureau of Industrial Cost and Pricing (BICP) arbitrary local FDA decisions, high import duties (about 42%) and complex import procedures.87

However, while the pharmaceutical sector in India will, most likely, continue to be regulated in the short term, there are plans for its reform, which are in the offing, on account of new obligations undertaken by India under the WTO Agreements. These challenges require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug Policy 1986, as modified in 1994, so that policy inputs are directed more towards promoting accelerated growth of the pharmaceutical industry and towards making it more internationally competitive. The need for radically improving the policy framework for knowledge-based industry has also been acknowledged by the Government. The Prime Minister's Advisory Council on Trade and Industry has made important recommendations regarding knowledge-based industry. The pharmaceutical industry has been identified as one of the most important knowledge based industries in the process of liberalization set in motion in 1991, has considerably reduced the scope of industrial licensing and demolished many non-tariff barriers to imports. Important steps already taken in this regard are:

4.8 Reforms in pharma policy
1. 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.

2. Reservation of 5 drugs for manufacture by the public sector only, was abolished in Feb.1999, thus opening them up for manufacture by the private sector also. Foreign investment through automatic route was raised from 51 percent to 74 percent in March, 2000 and the same has been raised to 100 percent. 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.

3. 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 privatized.

4. Extending the facility of weighted deductions of 150 percent of the
expenditure on in-house research and development to cover as
eligible expenditure, which also include 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, inter-alia, provides for the extension in the life of a
patent to twenty years.

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. In 1999-2000, drugs and pharmaceutical exports
were Rs.6631 crores out of a total production of Rs.19,737 crores. However,
two major issues have surfaced on account of globalization and
implementation of our obligations under TRIPs which impact on long-term
competitiveness of Indian industry. These have been addressed in the
Pharmaceutical Policy-2002. A re-orientation of the objectives of the current
policy has also become necessary on account of these issues:-

The essentiality of improving incentives for research and development in the
Indian pharmaceutical industry was understood by policymakers. They also
adopted measures to enable the industry to achieve sustainable growth
particularly in view of the anticipated changes in the Patent Law; and the need for reducing further the rigours of price control particularly in view of the ongoing process of liberalization.

It is against this backdrop, that the Pharmaceutical Policy-2002 is being enunciated.

4.9 **Pharma policy 2002**

**Objectives**

The main objectives of this policy are:-

1) Ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption.

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 endemic or relevant to India by creating an environment conducive to channelise a higher level of investment into R&D in pharmaceuticals in India.

5) Creating an incentive framework for the pharmaceutical industry which promotes new investment into pharmaceutical industry and encourages the introduction of new technologies and new drugs.
Adopted approach
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 this department 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:
• Invest at least 5 percent of its turnover per annum in R&D,
• Invest at least Rs.10 Crore per annum in innovative research including new drug development, new delivery systems etc. in India,
• Employ at least 100 research scientists in R&D in India,
• Has been granted at least 10 patents for research done in India,
• Own and operate manufacturing facilities in India.

The recommendations of the PRDC in so far as they relate to the Pharmaceutical Policy have been taken into account while formulating the proposals on pricing aspects.

The Pharmaceutical R & D Committee has recommended in its report, submitted inter-alia, 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.

As far as the question of price control is concerned, 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 covering approximately 40 percent of the total market. The functioning of the Drugs (Price Control) Order, 1995, has brought to light some problems in the
administration of the price control mechanism for drugs and pharmaceuticals. In order to review the current drug price control mechanism, with the objective, inter-alia, of reducing the rigours of price control, where they have become counter-productive, a committee, called the Drugs Price Control Review Committee (DPCRC), under the Chairmanship of Secretary, Department of Chemicals and Petrochemicals was set up in 1999, which has given its report recently. The recommendations of DPCRC have been examined and taken into account while formulating the "Pharmaceutical Policy - 2002".

It has emerged that the domestic drugs and pharmaceuticals industry needs reorientation in order to meet the challenges and harness opportunities arising out of the liberalisation of the economy and the impending advent of the product patent regime. It has been decided that the span of price control over drugs and pharmaceuticals would be reduced substantially. However, keeping in view the interest of the weaker sections of the society, it is proposed that the Government will retain the power to intervene comprehensively in cases where prices behave abnormally.

In view of the steps already taken and in the light of the approach indicated in the foregoing paragraphs, the decisions of the Government are detailed below:

I. Industrial licensing

Industrial licensing for all bulk drugs was cleared by Drug Controller General (India), all their intermediates and formulations have been also abolished, subject to stipulations laid down from time to time in the Industrial Policy, except in the cases of bulk drugs produced by the use of recombinant DNA technology.
II. Foreign investment

Foreign investment upto 100 percent will be permitted, subject to stipulations laid down from time to time in the Industrial Policy, through the automatic route in the case of all bulk drugs cleared by the Drug Controller General (India), all their intermediates and formulations, except those, in mentioned under industrial licensing.

III. Foreign technology agreements

Automatic approval for Foreign Technology Agreements will be available in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those, mentioned under industrial licensing for which a special procedure prescribed by the Government would be followed.

IV. Imports

Imports of drugs and pharmaceuticals will be as per EXIM policy in force. A centralized system of registration will be introduced under the Drugs and Cosmetics Act and Rules made thereunder. Ministry of Health and Family Welfare will enforce strict regulatory processes for import of bulk drugs and formulations.

V. Encouragement for research and development (R&D)

(a) In principle approval to the 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 utilization of the PRDSF.

(b) With a view to encouraging generation of intellectual property and facilitating indigenous endeavours in pharma R&D, appropriate fiscal incentives would be provided.
VI. Pricing

(A) Span of Price Control

The guiding principle for identification of specific bulk drugs for price regulation would continue, as per DPCRC’s recommendation, as: (a) mass consumption nature of the drug and (b) absence of sufficient competition in such drugs. However, the DPCRC’s recommendation regarding the new criteria for ascertaining the mass consumption nature of a 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 source namely, "Retail Store Audit for Pharmaceutical Market in India" published by ORG-MARG, 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 products 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 / sources, viz.,

- Indian Pharmaceutical Guide (IPG)
- Current Index of Medical Specialities (CIMS),
- Monthly Index of Medical Specialities (MIMS),
- Drug Today
- Information provided by some manufacturers
- Label composition as indicated on market samples.
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, 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 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 in regard to composition of each brand, dosage form-wise and pack-wise may involve instances of omission / commission.

In view of above, it would be logical to conclude 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.

The department through NPPA, with the help of 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: -
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, there from of sera and vaccines, blood products, combinations etc. should form the total basket out of which selection of bulk drugs be made for price regulation.

The ORG-MARG data of March 2001 would form the basis for determining the span of price control as suggested by DPCRC\textsuperscript{91}. All formulations containing a bulk drug either individually or in combination with other bulk drugs, including those not identified for price control as bulk drug, will be under price control.

(B) **Maximum Allowable Post-manufacturing Expenses (MAPE)**

Maximum Allowable Post-manufacturing Expenses (MAPE) will be 100 percent for indigenously manufactured formulations.

(C) **Margin for imported formulations**

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.

(D) **Pricing of formulations**

(i) For scheduled formulations, prices shall be determined as per the present practice. 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 there under, 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 thereof in case of Scheduled 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.

(E) Ceiling prices

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.

(F) Exemptions

(i) 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.

(ii) 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 the patent.
from the date of the commencement of its commercial production in the country by the new patented process.

(iii) 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 its commercial production in the country till the expiry of the patent.

(iv) The DPCRC has suggested that the low cost drugs measured in terms of "cost per day per 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. All orders passed by the NPPA will be prospective in operation. Whenever the concerned formulator wishes to revise the price, he, before effecting any change in price, would be bound to inform NPPA and seek fresh exemption and in case the cost to consumer-patient, on the basis of the proposed revised price, exceeds beyond the limit of Rs. 2 per day, obtain the necessary price approval.

(G) **Pricing of scheduled bulk drugs**

For a Scheduled bulk drug, the rate of return in case of basic manufacture would be higher by 4 per cent over the existing 14 per cent on net worth or 22 per cent 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.

(H) Monitoring

(i) The DPCRC's recommendations to have effective monitoring and enforcement system and to move away from the "controlled regime" to a "monitoring regime" is in the present context an extremely important recommendation as imports will increasingly compete with local drugs and pharmaceuticals in the domestic market. A new system based on solely market prices data is required to be evolved and controls applied selectively only to cases where, either profiteering or monopoly profit seeking is noticed. The National Pharmaceutical Pricing Authority, set up in August, 1997, would need to be revamped and reoriented for this purpose. It will continue to be entrusted with the task of price fixation / price revision and other related matters, and would be empowered to take final decisions. It would also monitor the prices of decontrolled drugs and formulations and over-see the implementation of the drug prices control orders. The Government would have the power of review of the price fixation/and price revision orders/notifications of NPPA.  

(ii) Although the prices of some bulk drugs have been steadily decreasing, yet the same do not get reflected in the retail price of non-Scheduled formulations. Also, there is need to check high margin/commission offered to the trade by printing high prices on the labels of medicines to the detriment of the consumers. It is, therefore, proposed to strengthen the National Pharmaceutical Pricing Authority by providing appropriate powers under the DPCO which would make it mandatory for the
manufacturer to furnish all information as called for by NPPA and also to regulate such prices, wherever, required.

(iii) The other recommendations of DPCRC like giving powers to Drug Control Authorities to dispose off small and petty offences etc., will require an amendment to the Essential Commodities Act. This suggestion is considered not practicable. Monitoring price movement of drugs sold in the country as well as that of imported formulations will require developing appropriate mechanism in the NPPA.

(I) Drug Price Equalization Account (DPEA)

Provision would be made in the new Drugs (Prices Control) Order (DPCO) to ensure that amounts which have already accrued to the DPEA and those which are likely to accrue as a result of action in the past, are protected and used for the purpose stipulated in the existing DPCO.

(J) Quality Aspects

The Ministry of Health and Family Welfare would

(i) progressively benchmark the regulatory standards against the international standards for manufacturing,

(ii) progressively harmonize standards for clinical testing with international practices,

(iii) streamline the procedures and steps for quick evaluation and clearance of new drug applications, developed in India through indigenous R&D, and

(iv) set up a world class Central Drug Standard Control Organisation (CDSCO) by modernizing, restructuring and reforming the existing system and establish an effective network of drugs standards enforcement administrations in the States with the
CDSCO\textsuperscript{65} as a nodal center. This would ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals.

(K) **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 sciences and technologies, education and training. Through this institute, it will be the Government's endeavor to upgrade the standards of pharmacy education and R&D in India. Besides tackling problems of human resources development for academia and the indigenous pharmaceutical industry, the institute will make efforts to maximize collaborative research with the industry and other technical institutes in the area of drug discovery and pharma technology development.

4.10 **Intellectual Property Rights (IPR)**

The Indian regulatory system is nowhere close to the sophisticated regulatory systems of developed nations, and because the legislation is much weaker than internationally accepted norms, the entry barrier for developed nations into the Indian market is practically non-existent.

By joining the WTO, India has committed itself to alter its existing Patent Act to offer wider and stronger protection to intellectual property rights of any member nation. The time frame for complete transition to the new law allowed by the WTO is ten years. So far, the new law, although drafted and placed before the Indian Parliament, had been mired in controversy and inaction because most of the legislators regardless of their political affiliation were opposed to it in its present form.

As per the April 1998 agreement reached between the U.S. and India at Geneva, a Patent Amendment Bill has finally been passed by India's Lower
House of\textsuperscript{96} Parliament, enabling the country to meet the WTO's April deadline for complying with TRIPs. The Bill replaces the ordinance issued in February after the Lower House failed to pass a Patent Amendment Bill before the end of the parliamentary session. The Bill gives companies Exclusive Marketing Rights in India for patented pharmaceutical products and provides a legal framework for the "mailbox" provisions for new product patent applications, as required under TRIPs.

The introduction of full product patent protection now looks likely to be deferred until 2005, the latest date allowed under the TRIPs provisional arrangements. Although India has now taken the first step towards strengthening its intellectual property laws in line with WTO agreements, debates within the country show few signs of arriving at consensus. Opinions were sharply polarized between those who would like to see India adopt full product patent protection as soon as possible, with no strings attached, and those who argue that it should be delayed for as long as possible and that measures such as compulsory licensing should be retained to protect the domestic pharmaceutical industry. For the pharmaceutical industry, the new law, whatever be its final form, signifies a transition to product, rather than process patents. There is a very strong demand from developed countries that the importation of a patented product be considered on par with working the patent in the importing country, and generally to restrict compulsory licensing of the patent on this ground.

This means that Indian companies would no longer be in a position to introduce new products if they are not the original innovators of those products. However, they would enjoy the same protection in all member countries for new products that they develop.

This regression however, seems to be totally unfair from the point of view of Indian industry, with its limited capabilities with respect to new product

\textsuperscript{96} Loksabha - Patent Amendment Bill - 1998
development. The real impact of this provision for the pharmaceutical industry will, at best be marginal over a short or medium term.

The Agreement on Trade - Related Aspects of Intellectual Property Rights (TRIPS) provides for minimum norms and standards in respect of the following categories of intellectual property rights:

1. Copyrights and related rights
2. Trademarks
3. Geographical Indications
4. Industrial Designs
5. Patents
6. Lay out designs of integrated circuits
7. Protection of undisclosed information (trade secrets)

The agreement sets out minimum standards to be adopted by the parties, though they are free to provide higher standards of protection. A transition period of five years is available to all developing countries to give effect to the provisions of the TRIPS Agreement. This period ended on 1.1.2000. No transitional period is available, however, for grant of "national" treatment and "most-favoured-nation" treatment. Countries that did not provide product patents in certain areas of technology as on 1.1.1995, can delay the grant of product patents in those areas for another five years that is up to 1.1.2005.

Where a country does not make available patent protection for pharmaceutical and agricultural chemical products as on 1.1.1995, they have to provide means for accepting applications for such inventions (mailbox), apply applicable priority rights and provide 'Exclusive Marketing Rights' (EMRs) for such products. The EMRs have to be provided in India only if a set of conditions have been suitably met, that is where a patent application has been filed after 1.1.1995 by any WTO member, patent and marketing approval granted in that Member country, an application has been filed in the

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97 Ibid
mailbox in India and marketing approval obtained in India. The EMR is available for five years from grant or till the patent is granted or rejected, whichever is earlier. The Patent (Amendment) Act, 1999 was passed in March 1999 to provide for mailbox and EMR facility.

The state of India’s obligations under TRIPS arising as on 1.1.2000 in respect of the seven IPRs covered under TRIPS is briefly given below.

(a) **Copyrights and related rights**

In the area of copyright and related rights (i.e. rights of performers, producers of phonograms and broadcasting organizations), the Agreement requires compliance with the substantive provisions of the Berne Convention. Computer programmes are to be protected as literary works, the term of protection for copyrights and right of performers and producers of phonograms is to be no less than 50 years. In case of broadcasting organisations, however, the term of protection is to be at least 20 years. India is already a signatory to the Berne Convention and our laws conform to the provisions of the Convention. India’s Copyright law has been amended and in some ways exceeds the requirements of the TRIPS Agreement, for example, on the period for copyright protection (which is 60 years in India). The law was amended in December 1999 to grant 25-year term of protection for neighbouring rights.

(b) **Trademarks**

The Trade and Merchandise Marks Act, 1958 was, in its essential features, in accordance with TRIPS, except that it did not cover service marks in its scope. This has been done by replacing it with the Trademarks Act, 1999. We are now fully compliant with our TRIPS obligations.  

99 Government of India - Trademarks Act 1999
(c) **Geographical indication**

The Agreement contains a general obligation that parties shall provide the legal means for interested parties to prevent the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than true place of origin of the good. We currently provide protection to geographical indications through passing off action in courts or through certification marks. However, to provide better protection to geographical indications a new law "The Geographical Indication of Goods (Registration and Protection) Act, 1999 has since been enacted.

(d) **Industrial designs**

Obligations envisaged in respect of industrial designs are that independently created designs which are new or original shall be protected. There is an option to exclude from protection, designs dictated by technical or functional consideration, as against aesthetic consideration, which constitutes the coverage of industrial designs. The Bill to amend the Industrial Design Act was passed early this year.

(e) **Patents**

The basic obligation in the area of patents is that, inventions in all fields of technology whether products or processes shall be patentable if they meet the three tests of being "novel" involving an "inventive step" and being capable of "industrial application". In addition to the general security exception, which applies to the entire TRIPS Agreement, specific exclusions are permissible from the scope of patentability. These are available in the areas of inventions whose commercial exploitation is to be prevented to protect public order or morality, human, animal plant life or health or to avoid serious prejudice to the environment. In addition, they can exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of
humans and animals, plants and animals other than microorganisms, and essentially biological processes for the protection of plants and animals other than non-biological and micro biological processes.

To meet our TRIPS obligations as on 1.1.2000, the Patents (Second Amendment) Bill, 1999 has been introduced in the Parliament in December 1999 and was placed before the Joint Committee of the Houses.

In respect of plant varieties, there is an obligation to provide for protection either by patents or by an effective 'sui generis' system or by any combination thereof. The Agreement does not spell out the elements of an effective 'sui generis' system and it is left to each government to determine the elements, which could be deemed to be providing effective protection. A decision has been taken to put in place a sui generis system as it is perceived to be in our national interest. A Bill in this regard is before the Joint Committee of the Houses of the Parliament.

(f) **Layout designs of integrated circuits**

India is a signatory to the international agreement administered by WIPO on this subject known as the "Washington Treaty". The main obligations of the Washington Treaty are also incorporated in the TRIPS Agreement with some enhancement and cover the protection of intellectual property in respect of lay-out designs that are original in the sense of being the result of their creator's own intellectual efforts. The obligations include national treatment to foreign right holders and a term of protection for 10 years. A Bill in this regard was introduced in the Parliament in December 1999 and is awaiting passage.
(g) Protection of undisclosed information

The agreement provides in this area that natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by or used by others without their consent in a manner contrary to honest commercial practices. Further, parties are required to protect against unfair commercial uses, undisclosed or other data obtained as a condition of approving the marketing of pharmaceutical or agricultural chemical products.

In India we do not have a separate legislation dealing with trade secrets. Common law on the subject is evolving and the courts have provided relief where allegations of wrongful disclosure have been proven. It is not felt necessary to have a separate legislation on the subject.

4.11 History of price control

Since 1961, pharmaceuticals in India have fallen under heavy price regulation. Domestic drug prices in India are among the lowest in the world; the Organization of Pharmaceutical Producers of India (OPPI) says that year-on-year price increases of pharmaceuticals in the country are lower than the wholesale price index each year and considerably lower than the CPI. This applies to both controlled and decontrolled drugs, where increases were just 1.1 percent and 3.6 percent respectively for 1997 over 1996. This has severely affected the profitability of the industry, especially since the prices of basic raw materials and the costs of packing have shot up over the past five years.

Pharmaceutical manufacturers have also suffered from high transaction costs, including obstacles and difficulties associated with administrative processes.
dishonesty of public agents, delays in obtaining finance, and transportation bottlenecks.

Price controls are implemented under a Drug Price Control Orders (DPCO). Under Section 3 of the Essential Commodities Act, there have been four major revisions of DPCOs in 1970, 1979, 1987 and 1995\(^{102}\). In 1995, the DPCO was revised twice - once on January 6th and again on July 19th- to coordinate the price descriptions of controlled and decontrolled formulations. Drugs falling under DPCO are generally either of the following:

1) Those that have a minimum annual turnover of Rs 4 crore (US$1 million), and
2) Those of popular use in which there is a monopoly situation (a monopoly in India exists if for any bulk drug, with an annual turnover of US$250,000 or more, there is a single formulator with a market share of 90% or more).

For drugs where there is a "sufficient" market competition, that is where there are at least five bulk drug producers and at least 10 formulators, and where none has more than a 40 percent market share in retail trade, price control is not mandated by the government. Such drugs not falling under government price control are called "decontrolled" drugs.

Apart from lowering profitability and constraining the market, there are many administrative problems with DPCOs that have been worsening as the Indian drug industry expands. The government often fails to update the financial data on which it bases its criteria for inclusion, aggravated by the long time lag between the collection of data and announcement of new pricing policy. As a result, basic data for determining prices is at least three months old at the time of approval, and the price benchmarks used end up being historical instead of prospective.

\(^{102}\) Government of India - Drug Price Control Orders (DPCOs) 1970, 79, 87, & 1985
Furthermore, there are serious problems with the way the government calculates the fixed prices for many drugs. For example, it does not take raw material price volatility or exchange fluctuations into account when calculating prices. Also, the government determines drug prices solely upon cost, not quality, of production (no distinction in pricing is made, therefore, between a drug produced under Good Manufacturing Practices (GMP) and one that is not).

Until decisive reforms are made in the pricing of pharmaceuticals, foreign drug companies can continue to expect intense price competition from local manufacturers.

Apart from government price controls, foreign companies are at a disadvantage in the market due to significant import tariffs -- the government recently decided, for example, to impose an additional 8 percent import duty hike for foreign products - and retail pharmacy-driven distribution bottlenecks that can create 15 percent mark ups in drug prices (compared to just 5% in the U.S.).

4.12 Future of the drug price controls
Analysts believed that the drug price controls would remain in some form or the other. The government used the DPCO to protect against drastic price increases, which affect the affordability of drugs. Although both domestic and foreign companies lobbied hard against them, price controls would continue. The government planned to continue utilizing the DPCO after 2005 as price controls were not prohibited by the TRIPS.

I) Low R and D spending
Despite the large base of scientific manpower, India's pharmaceutical industry did not invest heavily in R&D. One of the major reasons for this was that there were no product patent laws in place for pharmaceutical products in India.
Without product patents, domestic Indian firms have developed their indigenous market through the creation of different processes. In 1999, Indian firms spent only 1.8 percent of sales in R&D. This trend, however, was changing with major players such as Ranbaxy, Dr. Reddy's, and Torrent, recognizing that to remain viable once product patent laws took effect, they must begin developing their own molecules to compete effectively in India and abroad.

II) Growth potential

By 1999, India’s pharmaceutical market was growing at 15 percent per year in terms of sales revenues, which was among one of the highest growth rates in the world. Senior industry analysts believed that the Indian pharmaceutical market could expand to $6 billion by 2001 assuming current exchange rates (1996). They attributed potential growth to the liberalization of the economy, easing of price controls, growth in the overall economy and personal spending, increases in health care spending and healthcare coverage, and the introduction of new products such as cancer drugs. According to late Dr. Parvinder Singh, erstwhile Chairman of Ranbaxy, one of India’s largest pharmaceutical companies, India’s pharmaceutical sales were expected to grow to $8 to $10 billion by the year 2005.

4.13 Controls at state level

1) Enforcing new drug legislation,
2) Granting approval to new drugs, and
3) Controlling the quality of imported drugs.

State FDAs, on the other hand, monitor the drug manufacture, sale, and testing by companies in their jurisdiction. There are also two main statutory bodies formed by the Parliament:
1) The Drugs Technical Advisory Board, whose technical experts advise the Central and State governments on special technical matters involving drug regulation, and

2) The Drugs Consultative Committee, where Central and State drug officials ensure that drug control measures are enforced uniformly in all states.

4.14 Current reforms: Maharashtra FDA

The most powerful state-FDA is located in the western state of Maharashtra, where the country's pharmaceutical industry has been concentrated for the past 46 years. Over 50 percent of manufactured drugs in India are currently produced in Maharashtra, and Maharashtra's FDA therefore plays a large role in determining the national policy on the import and local manufacture of pharmaceuticals in India. It monitors drug quality and safety through pre and post-licensing checks, as well as through periodic inspections and drawing drug samples from companies from time to time.

Maharashtra's FDA underwent some major changes over the past few years to improve its efficiency and raise its credibility. Under the present Commissioner, Anil Kumar Lakhina, the Indian FDA has revamped its structure, introduced a new drug management system, and instituted a new electronic drug renewal application procedure via its website. It has also started codifying all pharmacopoeia, patent and proprietary combinations of drugs - there are currently 50,000 drugs all licensed by the FDA and 4,300 of them have already been codified.\(^\text{103}\)

\(^{103}\) Government of Maharashtra - Recent Reforms in Food & Drug Authority (1995 Onwards) IDMA Bulletin H N XXIX(8)