## Chapter – 6
### Food & Drugs Policy

6.1 Food and drug industries in India “An Overview.”  175

6.2 Introducing India’s Food Industry.  175

6.2.1 Food processing industries in India - Regulatory Framework  178

6.2.2 There are various food laws applicable to food and related products in India.  179

6.2.3 Policies and Regulations  181

6.2.4 Food Parks  182

6.2.5 FDI in food sector  182

6.2.6 Fiscal policy & Taxation  183

6.2.7 Export Promotion  184

6.2.8 Custom clearance : Food items  184

6.2.9 New Opportunities in India.  185

6.3 Pharmaceutical Industry  187

6.3.1 Regulatory framework – Drugs section  187

6.3.2 Opportunities in Drugs sector  188

6.3.3 Manufacturing Innovation  190

6.3.4 National Pharmaceuticals Policy – 2006  190

1. Introduction

2. Past Approach

3. Experience Drawn from Pharmaceutical policies.

4. Important development after liberalization process in 1991 Industrial licensing
Foreign Direct Investment

Foreign Technology Agreement

Imports

Exports

Constitution of Pharmaceutical Export Promotion Council (Pharmexil)

Research & Development

Product Patent in Pharmaceuticals

Schedule M of Drugs and Cosmetics Act, 1940.

Introduction of value added tax (VAT)

Excise duty payable at MRP (Maximum Retail)

Key Policy Objectives

The National Common Minimum programme, as adopted by the government aims as follows.

New Policy initiatives

1. Strengthening of Drug Regulatory System

2. Intellectual property rights including data protection.

3. Clinical Trials and Drug development.

4. Public-Private Partnership Programme for Anti-Cancer and Anti-HIV/AIDS Drugs:
   = Anti Cancer Drugs
   = Anti-HIV/AIDS Medicines
   = Price of drugs for other life Threatening Diseases

6.3.5 Drugs (Price Control) Order, 1995
6.1 FOOD AND DRUG INDUSTRY IN INDIA “AN OVERVIEW”

The present Government policy, regulatory and business trends in food and pharmaceuticals Industry in India. These sectors of industry provide multifarious opportunities to potential investors in this Sector, both domestic and foreign. As several policy initiatives are undertaken by the Government of India since liberalization in August 1991, the industry sectors have witnessed unprecedented growth in most of the segments.

6.2 Introducing India’s Food Industry

The food industry is the complex, global collective of diverse businesses that together supply much of the food energy consumed by the world population.

The food processing industry is one of the largest industries in India. It is ranked fifth in terms of production, consumption, export and expected growth. Food Processing Industry is widely recognized as a ‘sunrise industry’ in India having huge potential for uplifting agricultural economy, creation of large scale processed food manufacturing and food chain facilities, and the resultant generation of employment and export earnings. India has enormous growth potential from its current status of being the world’s second largest food producer to be the world’s number one producer.

Food Processing Industry is of enormous significance for India’s development because of the vital linkages and synergies that it promotes between the two pillars of the economy, namely Industry and Agriculture. Food processing covers a spectrum of products from sub-sector comprising agriculture, horticulture, Plantation, animal husbandry and fisheries. Essentially, the food industry involves the commercial movement of food from field to fork.

While India has an abundant supply of food, the food processing industry is still nascent: only two per cent of fruit and vegetables; and 15 per
cent of milk produced are processed. Despite, of this the processed food industry ranks fifth in size in the country, representing 6.3 per cent of GDP. It accounts for 13 per cent of the country’s exports and 6 per cent of total industrial investment. The industry size is estimated at US$ 70 billion, including US$ 22 billion of value added products. This sector has been attracting FDI across different categories.

- One of the world’s largest food producers, India produces 600 million tonnes of food grains every year. Its granaries had a buffer stock of nearly 50 million tonnes of food grains (wheat and rice) in 2003-2004.

- The second largest exporter of rice and fifth largest exporter of wheat in the world, its agricultural exports account for nearly 14.2 percent of its total export figures.

- India ranks first in the world in production of cereals and milk. It is the second largest fruit and vegetable producer and is among the top five producers of rice, wheat, groundnuts, tea, coffee, tobacco, spices, sugar, and oilseeds.

- India is the seventh largest producer of fish in the world and is ranked second in inland fish production.

With the overwhelming success of the Green and White Revolution, India is now fervently poised for the Food Revolution that will ensure agricultural diversification and large investments in food processing. The entries of multinationals, aggressive rise of commodity branding and low cost of technology are changing the economics of the Indian food industry. The rise of aggressive regional players making forays into categories where entry barriers are low and a boom in Indian Fast Moving Consumer Goods (FMCG) markets and the rising need for these products are the key reasons for this growth in food business.

In Store…The Indian food market is approximately Rs 2, 50,000 crore ($69.4 billion), of which value-added food products comprise Rs 80,000 crore ($22.2 billion). Despite food production in the country is expected to double by
the year 2020. With food production expected to double by 2020, large investments are already going into food and food processing technologies, skills and equipment.

The Confederation of Indian Industry (CII) has estimated that the food processing sector has the potential of attracting Rs 1,50,000 crore (US$ 33 billion) of investment in 10 years and generate employment of 9 million persons. The Government has formulated and implemented several Plans and Schemes to provide financial assistance for setting up and modernizing of food processing units, creation of infrastructure, support for research and development and human resource development in addition to other promotional measures to encourage the growth of the processed food sector.

A Goldman Sachs report (‘Dreaming with BRICs: The Path to 2050’) states that among Brazil, Russia, India and China, India will grow the fastest over the next 30 to 50 years by leveraging its demographic advantages and through continued development. At its present rates of growth, the burgeoning market in the country “would be adding nearly one France every 3.5 years and one Australia every year”.

6.2.1 Food processing industries in India-Regulatory Framework

Different laws govern the food processing sector in India. The prevailing laws and standards adopted by the Government to verify the quality of food and drugs is one of the best in the world.

Multiple laws/regulations prescribe varied standards regarding food additives, contaminants, food colours, preservatives and labelling. In order to rationalize the multiplicity of food laws, a Group of Ministers (hereinafter referred as “GoM”) was recently set up to suggest legislative and other changes to formulate a modern, integrated food law, which will be a single reference point in relation to the regulation of food products. The food laws in India are enforced by the Director General of Health Services, Ministry of Health and Family Welfare, Government of India (GOI).
6.2.2 There are various food laws applicable to food and related products in India

- The Standards of Weights and Measures Act, 1976, and Standards of Weights and Measures (Packaged Commodities) Rules, 1977
- Agriculture Produce (Grading & Marking) Act (Ministry of Rural Development).
- Essential Commodities Act, 1955 (Ministry of Food & Consumer Affairs).
- Fruit Products Order (FPO), 1995.
- Meat Food Products Order, 1973 (MFPO).
- The Insecticide Act, 1968.
- Export (Quality Control and Inspection) Act, 1963.
- Pollution Control (Ministry of Environment and Forests).
- Industrial Licenses.
- SEO (Control) Order - 1967.
The Prevention of Food Adulteration Act (PFA), 1954 focuses primarily on the establishment of regulatory standards for primary food products, which constitute the bulk of the Indian diet. The Central Committee for Food Standards, chaired by the Director General of Health Services, is the decision making entity. The appeals process, however, is cumbersome and time consuming. All imported products must adhere to the rules as specified in the regulation, including the labeling and marking requirements.

The Standards of Weights and Measures Act, 1976 and Standards of Weights and Measures (Packaged Commodities) Rules, 1977 are legislative measures are designed to establish fair trade practices with respect to packaged commodities. The rules prescribe that the basic rights of consumers regarding vital information about the nature of the commodity, the name and address of the manufacturer, the net quantity, date of manufacture, and sale price are provided on the label. There are additional mandatory labeling requirements for food items covered under the PFA. The Department of Consumer Affairs in the Ministry of Consumer Affairs, Food, and Public Distribution is the regulatory authority and enforcement agency.

The fruit and vegetable processing sector is regulated by the Fruit Products Order, 1955 (FPO), which is administered by the Department of Food Processing Industries. The FPO contains specifications and quality control requirements on the production and marketing of processed fruits and vegetables, sweetened aerated water, vinegar, and synthetic syrups. All such processing units are required to obtain a licence under the FPO and periodic inspections are carried out. Processed fruit and vegetable products imported into the country must meet the FPO standards.

Meat Food Products Order, 1992 administers the permissible quantity of heavy metals, preservatives, and insecticide residues for meat products. This order is equally applicable to the domestic processors and importers of meat products. However, its implementation is weak due to unorganized production in the domestic market and fewer imports.
Milk and Milk Products Order, 1992 order regulates the production, distribution, and supply of milk products; establishes sanitary requirements for dairies, machinery, premises; and sets quality control standards for milk and milk products. Standards specified in the order are also equally applicable to imported milk products.

The Destructive Insects and Pests Act, 1914, and Plants, Fruits, and Seeds (Regulation of Import in India) Order, 1989 regulate imports of planting seeds into India, and prohibit imports of seeds for sowing and planting materials without a valid permit. The implementing agency is the Directorate of Plant Protection, Quarantine, and Storage under the Department of Agriculture and Cooperation, Ministry of Agriculture.

After the enactment of the proposed Food Safety and Standards Bill, 2005 in India, the food processing sector would be governed by only one law and one regulator, instead of presently applicable 15 different laws. With the simplified mechanism growth in the food-processing sector would kick-start, which is needed to ensure higher growth for the agriculture sector.

6.2.3 Policies and Regulations

Since liberalization several policy measures have been taken with regard to regulation & control, fiscal policy, export & import laws, taxation, exchange & interest rate control, export promotion and incentives to high priority industries. Food processing and agro industries have been accorded high priority with a number of important reliefs and incentives.

At present, no industrial license is required for almost all of the food & agro processing industries except for some items like: beer, potable alcohol & wines, cane sugar, hydrogenated animal fats & oils etc. and items reserved for exclusive manufacture in the small scale sector. Items reserved for Small Scale Industry (hereinafter referred as “SSI”) include pickles & chutneys, bread, confectionery (excluding chocolate, toffees and chewing-gum etc.), rapeseed, mustard, sesame & groundnut oils (except solvent extracted),
ground and processed spices other than spice oil and oleoresins, sweetened cashew nut products, tapioca sago and tapioca flour.

In order to boost the food processing sector, the Centre has permitted under the Income Tax Act a deduction of 100 per cent of profit for five years and 25 per cent of profit in the next five years in case of new agro processing industries set up to package and preserve fruits and vegetables. Excise Duty of 16 per cent on dairy machinery has been fully waived off and excise duty on meat, poultry and fish products has been reduced from 16 per cent to 8 per cent.

**6.2.4 Food Parks**

In a bid to boost the food sector, the Government is working on agrizones and the concept of mega food parks. Twenty such mega parks will come up across the country in various cities to attract Foreign Direct Investment (FDI) in the food processing sector. The Government approved 105 proposals between January 2002 and May 2005 from foreign industrialists to set up food processing industries in India involving Rs.643.47 crore (US$ 144 million). The ministry has released a total assistance of Rs.105.22 crore (US$ 23 million) to implement the Food Parks Scheme. It has so far approved 50 food parks for assistance across the country. The Centre also plans Rs.100 crore (US$ 22 billion) subsidy for mega food processing parks.

**6.2.5 FDI in Food Sector**

Actual FDI inflow in food processing sector in 2004-05 and 2005-06 (till November, 2005) was Rs.332.00 crore. Automatic approval is granted for foreign investment upto 51% in high priority industries which include all food processing industries (except milk food, malted foods and flour) and all items of packaging for food processing industries. Investors need to file an application with the Reserve Bank of India (RBI) in the prescribed format and approval is ordinarily granted within 15 days. For foreign investment higher than 51% and for investments in industries outside the high priority industries,
clearance has to be obtained from SIA. Applications are processed on a case by case basis on merit and usually SIA takes about 2 months for the process. Applications for setting up a 100% Export Oriented Unit is also required to be filed with the SIA. For setting up a unit in an Export Processing Zone (EPZ), application has to be filed with the Development Commissioner of the concerned EPZ. Foreign equity of upto 24% of the total shareholding is also being permitted in the small scale sector.

Under automatic procedures, foreign technology agreements are being permitted in respect of industries that are designated as high priority industries. The use of foreign brand names and / or trade mark of goods is also now being permitted freely. To provide access to international markets, majority foreign equity holding upto 51% equity is being permitted for international trading companies that are primarily engaged in export activities.

FDI in a company engaged in “cash and carry wholesale trading” is now permitted up to 100 % under automatic route. The present policy only permit FDI up to 100 % in Cash and carry wholesale trading, which is distinct from retail trading, involving sale to individual customers through normal retail outlets. Recently Government of India has allowed retail trading in single brand items. FDI is not allowed in any other agricultural sector / activity.

6.2.6 Fiscal Policy & Taxation

Wide ranging fiscal policy changes have been introduced progressively. Excise & Import duty rates have been reduced substantially. Many processed food items are totally exempt from excise duty. Custom duty rates have been substantially reduced on plant & equipments, as well as on raw materials and intermediates, especially for export Production. Corporate taxes have been reduced and there is a shift towards market related interest rates.

There are tax incentives for new manufacturing units for certain years, except for industries like: beer, wine, aerated water using flavouring concentrates, confectionery & chocolates etc. Indian currency (rupee) is now
fully convertible on current account and convertibility on capital account with unified exchange rate mechanism is foreseen in coming years. Repatriation of profits is freely permitted in many industries except for some, where there is an additional requirement of balancing the dividend payments through export earnings.

6.2.7 Export Promotion

- Food processing industry is one of the thrust areas identified for exports. Free trade zones (FTZ) and export processing zones (EPZ) have been set up with all necessary infrastructure. Also, setting up of 100% Export oriented units (EOU) is encouraged in other areas. They may import free of duty all types of goods, including capital foods.

- Capital goods, including spares upto 20% of the CIF value of the Capital goods may be imported at a concessional rate of Customs duty subject to certain export obligations under the EPCG scheme. Export linked duty free imports are also allowed.

- Units in EPZ/FTZ and 100% Export oriented units can retain 50% of foreign exchange receipts in foreign currency accounts.

- 50% of the production of EPZ/FTZ and 100% EOU units are saleable in domestic tariff area.

- All profits from export sales are completely free from corporate taxes. Profits from such exports are also exempt from Minimum Alternate Tax (MAT).

6.2.8 Custom clearance: Food items

Customs Department in India follows certain guidelines for custom clearance of food items which includes checks on the condition of the hold in which the products were transported, ensuring whether they meet the requirement of storage as per the nature of the products, and does not in any way cause deterioration or contamination of the products. Customs Department is also required to check the physical/visual appearance of goods
in terms of possible damage and its compliance with labeling requirements under the Prevention of Food Adulteration Rules and the Packaged Commodities Rules. In addition, any imported food item, at the time of its import, should have a valid shelf life of not less than 60% of original shelf life. The Customs Department ensures that the articles which do not meet this condition are not allowed clearance for home consumption.

Apart from the checks on all the consignments of edible/food products imported through Ports, Inland container Depots, Air Cargo Complexes, Container Freight Stations and Land Customs Station the samples of imported food products are required to be referred to the Port Health Officer for testing. For alleviating the difficulties of importers, it has been decided that pending receipt of the test report, such consignments be allowed to be stored in warehouses under Section 49 of the Customs Act, 1962.

6.2.9 New Opportunities: In India

In India the Food Processing Industry is relatively nascent and offers opportunities for FDI. It accounts for Rs 1,280 billion (US$29.4 billion), in a total estimated market of Rs 3,990 billion (US$91.66 billion). There is a rapidly increasing demand for processed food caused by rising urbanization and income levels. To meet this demand, the investment required is about US$28 billion. Food processing has been declared a priority sector.

The outlay in the Food Processing Sector has been increased from US$19.5 million in 2004-05 to US$41.35 million the next year, more than twice the earlier amount. The government is also considering investing US$22.97 million in at least 10 mega food parks in the country besides working towards offering 100 per cent foreign direct investment and income tax benefits in the sector.

The Government has recently established Special Economic Zones with the purpose of promoting exports and attracting FDI. These SEZs do not impose duty on imports of inputs and they enjoy simplified fiscal and foreign exchange procedures and allow 100% FDI.
The Government is also moving towards introducing an integrated food law, which is expected to help meet the requirements of international trade and make the Indian food industry competitive in the global market. To harness the value-creating potential of agro processing, superior market mechanism and infrastructure are required to be created. State governments have already begun to actively encourage the creation of aggregators by encouraging companies to engage in agriculture marketing. It is believed that this may provide the basis to jumpstart private investment into cold chain and other supply chain infrastructure.
6.3 Pharmaceutical Industry

The pharmaceutical industry has shown tremendous progress in terms of infrastructure development, technology base creation and a wide range of production. The country ranks fourth worldwide accounting for 8% of world’s production by volume and 1.5% by value. It ranks 17th in terms of export value of bulk actives and dosage forms. Indian exports are destined to more than 200 countries around the globe including highly regulated markets of US, Europe, Japan and Australia. During 1999-2000, production of bulk actives (APIs) is estimated at US $ 860 million and value of Dosage forms is estimated around $ 3 billion (growth + 15%). The country is also showing excellent performance on the export front with the exports touching $ 1.5 billion during 1999-2000 as per provisional statistics. 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.

India Patents Act of 1970 provided patenting of all processes and products in all areas excepting food, drugs and chemicals. Introduction of product patents in these three crucial areas indicates the sign of confidence and maturity of Indian industry particularly the emerging pharmaceutical industry. In fact, the new patent regime will help Indian pharma industry which has made large investments in drug research. It gives a chance to drug development by frontline companies with adequate safeguards to protect the interests of society.

6.3.1 Regulatory Framework-Drugs Sector

Under the current Indian legal and regulatory regime, the manufacture, sale, import, exports and clinical research of drugs and cosmetics is governed by the following laws

1. The Drugs and Cosmetics Act, 1940

2. The Pharmacy Act, 1948
3. The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

4. The Narcotic Drugs and Psychotropic Substances Act, 1985

5. The Medicinal and Toilet Preparations (Excise Duties) Act, 1956

6. The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act.

There are some other laws which have a bearing on the manufacture, distribution and sale of pharmaceutical products in India. The important ones being:

- The Industries (Development and Regulation) Act, 1951
- The Trade and Merchandise Marks Act, 1958.
- The Indian Patent and Design Act, 1970
- The Factories Act.

The Drugs and Cosmetics Act, 1940 is legislation brought in force to protect consumers interests. Provisions under this Act include punishments & fines for misbranding drugs, confiscating of such drugs (sec 14), prevention of the import of such drugs (sec10) etc. It prohibits the sale of such drugs under section 18. It also provides for the setting up of Central Drugs Laboratory for testing batches of drugs. The Act also prescribes strict standards that are to be followed by drug manufacturers and importers. It also clearly defines a misbranded drug under section 17. Section 13 clearly states that whoever contravenes any part of this Act will be punishable with imprisonment which may extend to one year, or with fine which may extend to five hundred rupees, or with both. If convicted again of the same offence then, in addition he shall be punishable with imprisonment, which may extend to two years, or with fine which may extend to one thousand rupees, or with both.

6.3.2 Opportunities in Drugs Sector

The Indian pharmaceutical market has been forecast to grow to as much as US$ 25 billion by 2010 as per Organization of Pharmaceutical
Producers of India (OPPI) estimates. However, Espicom’s market projections forecast more modest but stable annual market growth of around 7.2 per cent, putting the market at US$ 11.6 billion by 2009.

With such a large number of drugs going out of patent by 2005, the opportunity of Indian industry is becoming bigger and bigger and the future is certain.

As per Drugs policy – 1994, only five drugs have been reserved for public sector. Some drugs which involve use of recombinant DNA technology and those formulations which are targeted specifically at cells and tissues will require licence. Other drugs will not require any licence. Foreign companies will be allowed to hold upto 51% Shares. Existing companies will also be allowed to increase the foreign share-holding to 51%. Permission for holding above 51% will have to be obtained from “Foreign Investment Promotion board.” This will be decided on case to case. Basis on merits of each case.

Thus, the list covers only items which are sensitive either from defence point of view, security point of view of scarcity point of view.

Exemption from licensing to other industries – No industrial licensing is required if following conditions are fulfilled.

(a) Industry is not in Annexure I or II
(b) Product is not reserved for SSI.
(c) The project is not located within 25 kms. of the standard urban area limit of city having population of more than 10 lakhs as per 1991 census. There are now 30 such cities in India, having population over 10 lakhs. This restrictions of location is not applicable to electronics, computer software printing and other non-polluting industries as may be notified.
(d) These provisions are applicable to “substantial, expansion” as, which means increase in capacity by more than 25% of existing capacity.
(e) The location will, however, be subject to environment as restrictions and other regulation, if any
6.3.3 Manufacturing: Innovation

- Pharmaceutical Companies: High performers
- 1/3 of 2002 production of 5.2B exported.
- 1996-2001: 3 pharma companies in top 10 highest US patents by Indian company
- Average R&D intensity is 2%
- Joint R&D with MNCs, licensing, sponsored research, intl marketing
- Dr. Reddy's Laboratory
- R&D firm launched in 1992
- Invested Rs 1.12B over 8 yrs
- Filed 55 US patents, 19 granted, Total Revenue of $8M upto June 2001
- Licensed 3 molecules to foreign drug firms
- Others: Ranbaxy, Cipla, Wockhardt, Sun Pharma

6.3.4 National Pharmaceuticals Policy 2006

1.0 Introduction

Driven by the knowledge skills, growing enterprise, low costs, improved quality and demand (domestic and international) the pharmaceuticals 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 2004-2005. Exports have also grown very significantly to over Rs. 16700 crores during this period. India is today recognized as one of the leading global players in the manufacture of pharmaceuticals – it holds 4th position in terms of volume and 13th in terms of value of production. It is also recognized that the cost of drugs produced in India is amongst the lowest in the world. It is estimated that by the year 2010 industry has the potential to achieve Rs. 1,00,000 crores in formulations with bulk drug production going up from Rs. 8000 crores to Rs. 25,000 crores. 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 worldwide, after the US. However despite the impressive growth of the sector and low costs there are several concerns which need to be addressed. Some to these concerns pertain to accessibility and affordability of medicines by the common man particularly the vast segment of poor population, instituting standards of quality, particularly for units not conforming to standards of regulated markets, strengthening the fragmented regulatory system, sustaining growth of generics – the main forte of Indian Industry, meeting the challenge of product patent regime 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.

In the year 2002 Government had formulated a new Drug Policy but the same could not be implemented due to litigation involving it, hence the policy of 1994 still continues to be in force. The present Policy known as the National Pharmaceuticals Policy, 2005 has been necessitated due to several developments that have taken place during the course of last few years as well as to address some of the major concerns as highlighted above. Price regulation of the essential medicines is an important component of this policy. However several other matters having a close bearing on the pharmaceuticals sector have also been included in the policy.

2.0 Past Approach

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 policies and issued drug price control orders from time to time. The first price control order was issued under the Defence of India Act in 1963. Thereafter from 1970 onwards price control orders were issued under the Essential Commodities Act, 1955. Presently the Policy of 1994 is in existence and price control is being exercised through the Drugs Price Control Order, 1995 under which prices of 74 bulk drugs and their formulations are controlled. 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 the formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of 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 Department of Chemicals and Petrochemicals, Government of India, December 28, 2005 Health Administrator Vol : XX Number 1& 2 : 1-8 Pg. 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 categorized as essential medicines. Another important development that has recently taken place in India is the introduction of product patent regime in pharmaceuticals with effect from 1st January, 2005. Earlier with the enactment of The Patent Act, 1970 (which came into force in the year 1972) only process patent was made applicable for pharmaceuticals which played a very significant role in the development of the pharmaceutical industry in India. India emerged as a major producer and exporter of pharmaceuticals in the world. After India became a signatory to the WTO and TRIPS agreements it was obliged to introduce product patent on pharmaceuticals with effect from 1st January, 2005. Our 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 patented molecules without licence/payment of royalty to the innovator company. With this paradigm shift the Indian industry would now be required to focus much more on research and development.
2.1 Experience Drawn from Past

Pharmaceutical Policies

The first comprehensive Drug Policy of 1978 and thereafter the Drug Policy of 1986 together with the application of process patent under the Patent Act of 1970 successfully paved the way for development of indigenous pharmaceutical industry which went into the production of generic drugs in a big way. A conducive environment for success was provided by the then prevailing trade and economic policies. During the period from 1978 to 1990 indigenous industry acquired a respectable status in terms of product range and market share. R&D was confined to process development/innovation of existing molecules.

As regards pricing, the span of control, inclusion/exclusion of drugs under price control, methodologies adopted etc continued to be debated. The Government developed principles of selectivity, from time to time, to keep the price control manageable and focused, as would be observed from declining trend in number of drugs under price control. In 1970, almost all bulk drugs and their formulations were under price control. In keeping with the economic policies of the country the number got reduced to 347 bulk drugs in 1979, 142 in 1987 and finally to 74 in 1995. It would have got reduced further under the criteria adopted in the Pharmaceutical Policy 2002, however, the same could not be implemented due to litigation involving it.

3.0 Important Developments after liberalization process in 1991

Following are some of the important developments that have taken place in pharmaceutical sector after the process of liberalization of the Indian economy was initiated by the Government in the year 1991—

1. Industrial Licensing

Industrial licensing for all kinds of drugs has been abolished (it has recently been done for the last remaining 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). However the need for obtaining manufacturing licence under Drugs and Cosmetics Act, 1940 continues for all units whether organized or small scale. The State Drug Controllers are authorized to issue such licences in most cases.

2. **Foreign Direct Investment**

   FDI up to 100% is permitted, subject to stipulations laid down from time to time in the Industrial Policy, through the automatic route in case of all bulk drugs cleared by the Drug Controller General (India), all their intermediates and formulations. Recently bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids as the active principles and special cell/tissue targeted formulations have also been allowed this facility.

3. **Foreign Technology Agreement**

   Automatic approval for Foreign Technology Agreement (FTA) is already available in the case of all the bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids as the active principles, and specific cell/tissue targeted formulations.

4. **Imports**

   Imports of drugs and pharmaceuticals are regulated through EXIM Policy in force and presently all items except those requiring clearance under The Narcotics and Psychotropic Substances Act, 1985 are allowed under OGL. Further, a centralized system of registration has been introduced under the Drugs & Cosmetics Act and Rules made there under, administered by Ministry of Health and Family Welfare. These arrangements may continue to regulate imports of Drugs and Pharmaceuticals.
5. Exports

Exports are permitted in accordance with the Exim Policy and relevant procedures/rules formulated for the purpose by the Directorate General of Foreign Trade. Exports are also subject to laws prevalent in importing countries. Also, the exporters are allowed imports of inputs on duty free basis for export production. The industry has shown commendable export performance, the trade balance being positive. Over the last few years the compounded annual growth rate in exports has been 22.7 percent.

6. Constitution of Pharmaceutical Export Promotion Council (Pharmexil)

In order to provide a boost to pharma exports Government constituted a separate Export Promotion Council for Pharmaceuticals (Pharmexil) in the year 2004-05. This Council works closely with the Department of Commerce and the Export Promotion Cell in the Department of Chemicals and Petrochemicals to undertake activities such as promoting exports, preparing country-profiles, assessing export potential across the countries and to have greater degree of interaction internationally.

7. Research & Development

As recommended by the Mashelkar Committee in 1999 a Pharmaceutical Research and Development Support Fund (PRDSF) with the corpus of Rs. 150 crores has been set up under the administrative control of the Department of Science and Technology. A Drug Development Promotion Board (DDPB) to administer the utilization of PRDSF has also been set up.

8. Product Patent in Pharmaceuticals

Product patent in pharmaceuticals has been introduced in the country with effect from 1st January, 2005 by amending the Patents Act, 1970 in conformity with the TRIPS agreement. The physical infrastructure in the four patent offices in the country (Kolkata, Delhi, Chennai and Mumbai) has been substantially strengthened and computerization has been introduced. Steps
are now being taken to further augment and improve the software and human resources in these offices to enable them to deal with the new responsibilities.

9. **Schedule M of Drugs and Cosmetics Act, 1940**

The revised Schedule M of the Drugs and Cosmetics Act, 1940 related to Good Manufacturing Practices (GMP) has come into effect from 1st July 2005. This would in the long run strengthen the pharma industry as a producer of quality medicines.

10. **Introduction of Value Added Tax (VAT)**

VAT has been introduced in India with effect from 1st April, 2005. Already 22 States have implemented it. The remaining States are likely to implement it in the near future. VAT on medicines has been kept at 4%

11. **Excise Duty payable at MRP (Maximum Retail Price)**

A Notification was issued on 7th January, 2005 under which Excise duty became leviable on MRP with an abatement of 40%.

4.0 **Key Policy Objectives**

Following are the key objectives of the policy –

(a) To ensure availability at reasonable prices of good quality medicines within the country.

(b) To improve accessibility of essential medicines for common man particularly the poorer sections of the population.

(c) To facilitate higher investment for increased production of good quality medicines

(d) To promote greater research and development in the pharmaceuticals sector by providing suitable incentives in this regard
(e) To enable domestic pharma companies to become internationally competitive by implementing CGMP, GLP GCP and other established international guidelines

(f) To facilitate higher growth in exports of APIs and formulations by reducing the barriers to internationally trade in pharmaceuticals sector To develop India as the preferred global destination for pharma R&D and manufacturing To facilitate implementation of the Health Policy of the country

4.1 The National Common Minimum Programme, as adopted by the Government aims as follows

a) UPA Government will raise public spending on health to at least 2-3% of GDP over the next five years with focus on primary health care.

b) A national scheme for health insurance for poor families will be introduced.

c) The UPA will step up public investment in programmes to control all communicable diseases and also provide leadership to the national AIDS control effort.

d) The UPA Government will take all steps to ensure availability of life savings drugs at reasonable prices.

e) Special attention will be paid to the poorer sections in the matter of health care.

f) The feasibility of reviving public sector units set up for the manufacture of critical bulk drugs will be re-examined so as to bring down and keep a check on prices of drugs.

An issue of paramount importance in the Indian context is to increase the accessibility of drugs to the common man and in particular to the vulnerable and poorer segments of the population. Even though the prices of drugs as compared to most other countries and particularly the neighboring countries are one of the lowest yet these are important issued relevant to
India. A Committee set up by Government under the chairmanship of Joint Secretary (Pharmaceuticals) popularly known as the Sandhu Committee had made several recommendations in this regard. Thereafter the Task Force headed by Dr. Pronab Sen, Principal Adviser (PP), Planning Commission popularly known as the Sen Committee made several other wide ranging recommendations.

Some important recommendations were made by the National Manufacturing Competitiveness Council (NMCC). National Commission on Macroeconomics and Health Constituted by the Ministry of Health and Family Welfare in its report on ‘Access To Drugs and Medicine ‘ also made some valuable recommendations on issues relevant to the drug industry. The recommendations made by all these Committees have been examined by Government and there is a broad agreement on the implementation of several of the recommendations. Several suggestions were received from industry associations, voluntary bodies, States and other organizations. A Core Committee consisting of representatives of Department of Chemicals and Petrochemicals, NPPA, NIPER and Chief Executives of various public sector pharma undertakings was constituted to facilitate drafting of the policy based on the various/suggestions.

New Policy Initiatives

The new initiatives except for price control are enumerated in Part A of the report while Price control system is enumerated in Part B of the report (Part B has been prepared separately)

1. Strengthening of Drug Regulatory System

Drug regulatory system has a close bearing on the prices, availability and quality of drugs. Under the Drugs and Cosmetics Act, 1940 there is dual regulatory control over the drugs by Central and State governments. While regulation of manufacture, sale and distribution of drugs is primarily the responsibility of the State Authorities, the Central Authorities are responsible for approval of new drugs, clinical trials, laying down standards for drugs,
control over imported drugs, coordination of the activities of state drug control organizations. The Expert Committee set up by Government under the chairmanship of Dr R A Mashelkar, Director CSIR in its report submitted in 2003 has made comprehensive recommendations for strengthening the drug regulatory system including the problem of spurious drugs. It has made detailed recommendations to strengthen the existing regulatory organizations both at the Centre and the States.

The Task Force set up by Government to ‘Explore options other than Price control for achieving the objective of making available life saving drugs at reasonable level’ has recommended that in the long run both the functions of drug regulation and price control should be performed by the same agency and there should be an integrated regulatory system.

Keeping in view the recommendations of the two Committees it has been decided that –

a) As an immediate step an independent and autonomous body by the name of National Drug Authority would be constituted in place of the present Central Drugs Standard Control Organisation (CDSCO).

b) Several of the existing provisions of the Drugs and Cosmetics Act, 1940 would be amended to make the penalties more deterrent for various offences and in particular for spurious and sub-standard drugs. A bill in this regard has been introduced in the Parliament

c) In the long run the proposal of Task Force regarding merger of NPPA and NDA would be considered in the form of National Authority on Drugs and Therapeutics (NADT) which will lead to an integrated regulatory system in the country.

2. **Intellectual Property Rights including Data Protection**

   Government is committed to making the Indian laws and policies pertaining to Intellectual Property Rights fully compliant with the provisions of TRIPS. Significant progress has already been made in this regard. Product
patent in case of pharmaceuticals has been introduced with effect from 1st April, 2005 by amending the Patents Act, 1970. Under this Act both product as well as process patents can now be granted for pharmaceuticals. New Rules are being framed under this Act and would be notified soon. Under these rules it would be endeavour of the Government to simplify procedures and shorten the timelines for various approvals. Modernisation of Patent Offices in the country has been undertaken and the number of patent examiners has been augmented in these offices. Following action is contemplated towards further improving the working of the patent offices. Proper training to be imparted to the personal working in the four patent offices. Trainers from India and abroad would be utilized for this purpose.

a) The number of patent examiners to be further increased to match the increased workload

b) Full computerization would be undertaken so as to bring about greater transparency and convenience in the functioning of these offices.

c) All the pending patent applications to be made available on the website of the patent office

d) Electronic filing of patent applications to be introduced

e) An IP Cell to be set up in the Department of Chemicals and Petrochemicals to support innovator pharma SMEs in the patenting process, training in documentation and other areas of intellectual property. This would enable them to take advantage of the patent regime and in the process encourage greater R&D in their enterprises.

f) A Technical Expert Group has been constituted under the chairmanship of Dr R.A. Mashelkar, Director General, Council of Scientific and Industrial Research with the following terms of reference-

* Whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one of more inventive steps,
* Whether it would be TRIPS compatible to exclude micro-organisms from patenting. As regards Data Protection various options are being examined by the Inter-Ministerial Committee headed by Secretary, Department of Chemicals and Petrochemicals. The Committee has heard various viewpoints on the subject and is likely to submit its report soon. Suitable policy decision/action would be taken after receipt of the report of the Committee on this matter.

4. Clinical Trials and Drug Development

Clinical Trials are essential for drug development. Schedule Y of the Drugs and Cosmetics Rules, 1945 has been amended to allow for multicentric concurrent clinical trials in India. Under these rules clinical trials have been defined and it has been made mandatory to take approval for conducting any type of clinical trials in the country. Also Good Clinical Practices (GCP) guidelines have been published and made mandatory. It also addresses the protection of study subjects (patients/volunteers) and integration and quality and data. Following action is contemplated to facilitate and encourage clinical trials in India.

a) An early decision on data protection
   
   a) As improved regulatory infrastructure and some form of protection to undisclosed test data will increase the activity in this field.
   
   b) In order to facilitate pre-clinical trials National Toxicology Centre set up in NIPER to be made fully compliant with GLP norms
   
   c) Tax benefits available to R&D to be made applicable to for Clinical trials also
   
   d) Clinical trial samples being imported into India to be exempted from payment of import duty on the basis of authorization/licence issued by Drug Controller General of India
   
   f) To promote direct investment in the field of clinical development and data management exemption from service tax for a period of 10 years up to 2015
5. Public-Private Partnership Programme for Anti-Cancer and Anti-HIV/AIDS Drugs

For making available anti-cancer and anti-HIV/AIDS drug 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. Some of the steps proposed to be taken are as under

a) Anti Cancer Drugs

At any given point of time there are about 20 to 25 lac people suffering from cancer in the country who are affected by various types of cancer (lung cancer, blood cancer ect.) It is estimated that every year about 7 lac people are detected with different types of cancer. Most of them are unable to afford the cost of expensive anti-cancer medicines. Going by a conservative estimate of average cost of anticancer medicines per patient as Rs. 25,000 it would require medicines worth of Rs. 5,000 crores. As against this, the present turnover of this segment of medicines in India is estimated to be only Rs. 150 crores. The big gap indicates the near non-accessibility of the medicines to a vast majority of the affected population mainly because of the high cost of these medicines. In order to reach out to a larger number of cancer patients following steps would be taken –

1. Government would completely exempt anticancer drugs (bulk and formulations) from all types of Central taxes – excise duty, import duty etc and the benefit would be passed on to the consumers.
2. States would also be asked to exempt these medicines from all types of state and local levies
3. Industry and trade would be asked to reduce their margins – both profit and trade margins to the barest minimum level and pass on the benefit to the consumers.

4. A subsidy scheme for making cancer drugs affordable to the common man would be worked out with the help of concerned manufacturers and the Cancer hospitals. Under this scheme a subsidy on the sale of anti-cancer drugs would be made available to all the cancer hospitals who register under the scheme.

5. Subsidized anti-cancer medicines would be provided to all the cancer patients from the retail outlets of the cancer hospitals on the recommendations of the doctors of such hospitals. In order to take advantage of lower rates from bulk purchase a Rate Contract for the anticancer drugs would be worked out with the manufacturers for all the hospitals which join this scheme. All Government run hospitals with facilities for treatment of cancer would be eligible to become members of the scheme as also the private cancer hospitals. Efforts would be made to create drug banks in major cities where manufacturers would be encouraged to contribute to these drug banks which may be managed by hospitals and NGOs.

b) Anti-HIV/AIDS Medicines

India has the highest number of reported HIV/AIDS cases in the entire SOUTH Asian region. There are as many 5.1 million people affected by HIV/AIDS in India, about 85% of the South Asian total. In the world India has the second highest reported cases of HIV/AIDS, just below South Africa’s total of 5.3 million. There are presently 39 Anti-Retroviral Therapy (ART) Centres in the country located mostly in the medical colleges and major tertiary hospitals. These are located mostly in the six high prevalence states namely Karnataka, Tamil Nadu, Andhra Pradesh, Maharashtra, Manipur and Nagaland. 100 new centres have been identified to be opened in the near future and the number would go to 188 by the year 2010. It would be the endeavour of the Government to open atleast one or two centers in each state. The number of patients being provided free treatment through the ART centers is 16000.
(another 16000 patients are being treated by Railways and ESIC and 10000 by the private sector). The number of patients treated would be taken to 500,000 by the year 2010. Apart from the assistance available under the Global Fund for Aids, TB and Malaria-Round 4, additional funds would be provided to cover the entire AIDS affected population.

Presently anti-HIV/AIDS drugs that are being manufactured in India are mostly first generation which have developed resistance in many cases. Production of second generation drugs would be ensured in the country so as to provide an effective treatment on a continuous basis. Some of the measures envisaged to reduce the cost of ARV drugs and increase their availability are as follows:

a) Complete exemption of anti-HIV/AIDS drugs (bulk drugs as well as formulations) from the payment of excise duty, customs duty and other levies, if any. This benefit would be passed on to the patients.

b) Manufacturers and Trade to charge lower profit and trade margins on these drugs.

c) Most of the first generation drugs and some of the second generation drugs are presently being manufactured in India. All efforts would be made to ensure production of second generation drugs in the country in consonance with the provisions of Patent Act, 1970.

d) Incase of second generation drugs which are not manufactured in India these would be procured at prices which are negotiated with the concerned manufacturers. (In the case of AIDS cheaper and more easily available drugs have led to 80% decline in deaths between the period 1997 and 2003 – as reported by researchers from India and Rhode Island in the November 15 issue of Clinical Infectious Diseases. Government is running 39 testing and treatment centers where over 14400 patients are being treated – only those with CD 4 count below 200 per cubic ml of blood are treated. Railways and industry is treating another about 30,000 patients. At the same time the fact is that there are over 5 million HIV-positive cases in India which is 10% of the world’s population of people with HIV. Estimates of population
affected by HIV varies between 5 million to 7 million. Presently NACO is purchasing medicines and distributing these free of cost through its Centers and State Aids Control Societies Government would allocate larger funds for the purchase of these medicines particularly anti-AIDS through a centralized system)

4. Prices of Drugs for other Life Threatening Diseases

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.

6.3.5 Drugs (Price Control) Order, 1995

As per Drugs policy 1994, control over prices of drugs will be retained only if its total turnover exceeds Rs.4 crore per annum. However, it there are at least five bulk drug producer or 10 formulators with none of them having more than 40% market share, these will be out of price, control, even if turnover exceeds Rs.4 crore (5% drugs are covered under this criteria). Further, if there is only a single manufacturer with 90% market share in bulk drug, it will be considered as a monopoly situation. Such drugs will be brought under price control even if its turnover exceeds Rs.1 crore per annum (19 bulk drugs have been covered as per this criteria).

Sugar – Manufacturers of Sugar have to surrender fixed percentage of their production to Government for ‘public distribution system’ (PDS). Remaining sugar can be sold in open market. There is also control over movement of sugar, sugarcane etc.