CHAPTER – 5

REVIEW OF PRICING POLICY AND GOVERNMENT POLICY ON
PRICE CONTROL SOCIAL CONSEQUENCES STUDY

5.1: INTRODUCTION: -

In revising its drug pricing policies, the Government of India needs to balance its core responsibility to protect the health and welfare of the Indian people and the Nation’s interest in sustaining the continued development of an excellent Indian life sciences capability. It is vital that the citizens of India, particularly the common man, have access to affordable medicines for treating the most common and important disease conditions. This is a core mission for any government. India is a global competitor in the advanced life sciences. Our pharmaceutical industry is a world leader in international generics markets and has begun making serious inroads in innovative drug discovery. Indian scientists, doctors, and medical researchers have developed important, commercially successful treatments for disease, including biopharmaceutical inventions which have been patented in the United States and Europe. Indian scientists and researchers populate the laboratories of the major U.S. and European multinational drug companies, and increasingly are being drawn home by opportunities in our own country. Accordingly, any pharmaceutical pricing policy must also advance India’s capability to discover and develop advanced medicines. Our global competitiveness in the life sciences represents a long term national technological asset and a potential cornerstone of our Nation’s future economic prosperity.

The development of innovative pharmaceutical products plays a critical role in ensuring health gains and longevity through the provision of adequate amounts of effective drugs to treat the most important and common disease conditions. Governments play a vital role in encouraging development of new drugs though economic incentives like direct and indirect government funding, effective intellectual property laws and other policies that favour innovation. It
is the responsibility of the Government to ensure that consumers benefit both from technological breakthroughs and the competition that further innovation generates. The changes in the Patents Act of 1970 in India have now provided for the recognition of product patents and opened the door for a new era of advanced biopharmaceutical discovery, but such gains need to be nurtured through the creation of an enabling environment that would encourage research and development spending and new drug discovery. Even now, the investment in research and development by Indian firms is only a fraction of research and development spending by leading multinational companies, and this trend could pose a barrier to the emergence of a globally competitive Indian life sciences industry which can compete on an equal basis with leading U.S. and European research-based biopharmaceutical companies.

Given India’s unique circumstances as a developing country, which is globally competitive in the biopharmaceutical, area, these challenges can only, is addressed through a third way approach to drug pricing. Simply copying existing Western European price controls or the U.S. free market approach can not address India’s special role as both a developing country with tens of millions who lack adequate access to health care and as a future leader in global drug discovery. By formulating a new approach to pharmaceutical pricing, India can offer viable solutions to other developing countries that aspire to expand access to basic health for their rural and urban poor, avoid an uncontrolled expansion of government spending, and at the same time exploit the full economic potential of the 21st century life sciences.

In addition to providing the right incentives for innovations and advancements in pharmaceutical sector, the Drug Policy in a vastly populated developing country like India, also has a social dimension. The country is densely populated and the people below poverty line are still considerable. In addition access to proper health facilities and affordability of life saving drugs also are broader corners from the social welfare viewpoint. Hence in a country like India this social consideration also is vital in framing the Drug Policy. The Policy as it evolves in a private sector expanding pharmaceutical sector also
has to see that life saving drugs and the delivering of them reach that section of society which cannot afford costly never drugs sold under patented regime of price determination. These issues are broadly discussed in this chapter.

5.2: HISTORICAL REVIEW OF POLICY: -

Statutory controls on prices of drugs were imposed for the first time in India in the wake of Chinese aggression and declaration of emergency (1962). The Drugs Order, 1962, issued mainly to contain inflationary forces expected as a consequence of the war, required the manufactures, importers and distributors of drugs to publish price list of their products and the chemists dispensing them to display such price lists on their premises. The Drugs (Control of Prices) Order, 1963, was promulgated, freezing sale prices of drugs at the levels obtaining on 1st April 1963. Both these orders were issued under the Defence of India Act.1

The emergency ended in 1966 and since than the Government has issued following Orders under the Essential Commodities Act. Under section 3 of the Essential Commodities Act, the government has power to control production, supply, distribution and pricing of essential commodities. Under section 2 (a), drugs are considered to be an essential commodity.

1- Drugs Prices (Display and Control) Order, 1966
2- Drugs (Prices Control) Order, 1970
3- Drugs (Prices Control) Order, 1979
4- Drugs (Prices Control) Order, 1987
5- Drugs (Prices Control) Order, 1995
6- Drugs (Prices Control) Order, 2002
7- Drugs (Prices Control) Order, 2006 (Draft Policy)

These Orders classify drugs into bulk drugs and formulations. All these Orders attempted a three-tier control on bulk drug prices, formulation prices, and overall profitability. The first two Orders were introduced when India effectively had a product patent regime in pharmaceuticals under the Patents
and Designs Act 1911. In India, the 1911 Patent Act, was thoroughly revised and new patent Act was passed in 1970, and came into operation in 1972 which abolished product patent protection in drugs.

Control on drug prices, as an emergency measure, was continued after emergency ended in 1966. On 30th January 1966, the drugs (Display and Control) order was declared under the Essential Commodities Act. This order contained certain additional provisions, which did not form part of two separate orders, which it replaced. The additional provision of the new order was as fallow;

- Manufacturers had to secure prior approval of the Government before increasing the prices of any formulation in their lists as on 30th June 1966.
- Prices of new drugs had to be approved by the Government.
- Prices of drugs sold in loose were also regulated.
- Manufacturers were required to stamp the retail selling prices on the containers of drugs.

The amendments subsequently made to the above Order allowed for changes such as,

- Drugs with pharmaceutical names were exempted from price approval.
- Drugs, which had been evolved out of original research and marketed for the first time, were exempted from the price control. But the manufacturers had to furnish the relevant data to the Central Government. Government however reserved the powers to refuse approval of prices within a period of four months.

According to the manufacturers of drugs, the undesirable consequences of the price controls prevailing at that time were:

- The freeze on sales prices, without a similar control on the prices of raw materials hampered the long-term growth of the industry by reducing profitability of the units.
- The voluntary price reductions, which were regular feature before the introduction of price control may not materialize in future. Under the
Chapter 5

regime of price control, the consumer could be denied the benefits of lower prices, which flow as a result of competitive pressure, and economies of scale as manufacturer would be reluctant to make voluntary reductions in the price of the formulations.

In response to this criticism of the manufacturers a “Drug Advisory Committee” was constituted. In addition a mechanism for determining the price structure of drugs from the stage of manufacture to the point at which drugs are sold the consumers, as also a procedure for granting interim relief to compensate for increase in the prices of raw materials and for other reason.

The committee submitted a provisional report on 27th April, 1966. It recommended that as the pharmaceutical industry had been forced to hold the prices of drugs at the levels prevailing in April, 1963, the authorities should either evolve a scheme to supply imported and indigenous raw materials and packing materials to the actual manufacturers in required quantities at the prices prevailing in April, 1963. If the Government so desired the price control may be limited to “essential and life saving” drugs according to the committee suggestion.

In August 1966, the Tariff Commission was requested to study the cost structure of 18 specified drugs sold in bulk and ingredient formulations manufactured from these drugs. In view of this Government informed the “Drug Advisory Committee” that it need not submit the rest of the report.

During the interim period when the Commission was conducting the cost enquiry, Government appointed a committee consisting of representatives of the Department of Chemicals, the Drug Controller, the Ministry of Health, the Directorate General of Technical Development and chief cost Accounts Officer to scrutinize the price revision applications. For expeditious scrutiny the Development Council for Drugs and Pharmaceuticals suggested a mark-up of 150 to 200 percent over ex-factory cost. But it is reported that Government usually allowed a mark-up at the lower limit of 150 percent. Further compensation against cost escalations was usually limited to raw materials and
packing costs while the industry absorbed the increases in other elements of costs.  

5.3: TARIFF COMMISSION ENQUIRY:-

The Tariff Commission took the sample of 34 units producing 18 specified bulk drugs for detailed cost study and 39 single ingredient formulations using any one of the specified drug formulations each containing one or more of those bulk drugs. The general finding of the Tariff Commission on the domestic’s prices of bulk drugs and formulations are recapitulated here given below;

5.3.1: Bulk Drugs: -

The Commission conclusion in respect of bulk drugs was that the prices of the selected bulk drugs were generally very much lower in most cases in other countries. The reason for the high costs of domestically produced bulk drugs were,

- High cost of equipment intermediates and raw materials, a good part of which was imported.
- Plant size of domestic producers is small as compared to other countries and
- The patent law and related conditions for the transfer of know-how resulted in higher price.

5.3.2: Formulations: -

The Commission finding on the prices of formulations was that by and large, the prices in Indian market of formulations compare favorably with the prices of similar formulations in the domestic markets of other countries.

The Tariff Commission was requested to examine the feasibility of reducing the price of some specified essential formulations. Based on the recommendations of the Tariff Commission, the Drugs (Price Control) Order was passed in 1970. This had three main elements:

1. Prices of bulk drugs were controlled.
2. Prices of selected formulations were controlled.
3. A ceiling on overall profit was introduced.\textsuperscript{5}

\textbf{5.4: HATHI COMMITTEE: -}

A large expansion was envisaged in the production of pharmaceuticals during the Fifth Five Year Plan. The Task Force (Planning Commission) on Drugs and Pharmaceuticals, which was set up to draw up programmed for the Fifth Plan had estimated that the value of production of formulations would rise to about Rs.600 crore by 1978-79 as compared with the level of Rs.300 crore in 1971-72. A four-fold increase was envisaged in the production of bulk drugs during the above period. A high powered committee under the Chairmanship of Shri Jaisukhlal Hathi was appointed in 1974 to suggest a rational policy which would meet the growth needs of the industry outlined in the Fifth Plan. The major terms of reference of the committee were as follows.

- To enquire into the progress made by the industry and the status achieved by it.
- To recommend measures necessary to ensure that the public sector attains the leadership role in the manufacture of basic drugs and pharmaceuticals and in research development.
- To recommend measures for promoting a rapid growth of the industry particularly in medium and small-scale sectors.
- To examine the prevailing arrangements for the introduction of new technology into the industry and make suitable recommendations thereon.
- To examine measures taken so far to reduce the price of drugs and to recommended such measures as may be necessary to rationalize the prices of bulk drug and formulations.
- To recommend institutions and others arrangements to ensure equitable distribution of basic drugs and raw materials, especially to the small sector.
• To recommend measures, this will ensure the availability of essential drugs and common household remedies to the public especially in rural areas.  

**TABLE NO: 5.1**

**BUIK DRUGS UNDER PRICE CONTROL (1970 to 2006)**

<table>
<thead>
<tr>
<th>Year of Introduction of the Drug Price Control Order</th>
<th>No. of Drugs under Price Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970</td>
<td>347</td>
</tr>
<tr>
<td>1979</td>
<td>163</td>
</tr>
<tr>
<td>1987</td>
<td>145</td>
</tr>
<tr>
<td>1989</td>
<td>120</td>
</tr>
<tr>
<td>1995</td>
<td>74</td>
</tr>
<tr>
<td>2005</td>
<td>28</td>
</tr>
<tr>
<td>2006</td>
<td>354</td>
</tr>
</tbody>
</table>

*Source: Indian Pharmaceutical reference guide 2005-06, NEON*

5.5: PRICE REGULATIONS ON PHARMACEUTICAL PRODUCT IN INDIA:

Price controls for drugs and formulations have a long history in India. The first price control order was issued under the Defence of India Act in 1963. Price control orders have been issued under the Essential Commodities Act, from 1970 onwards. The Drug Price Control Order (DPCO) in 1970 was a measure to safeguard the interests of the consumer, while providing for a restricted but reasonable return to the producers. Simultaneously with the
negation of product patents in 1970, the measure brought about an era of cheaper medicines in India, albeit at the expense of diluting intellectual property rights. The drug price control order has been amended thrice since then, the last being in 1995. The drug price control order in 1995 has introduced three parameters to ensure proper market conditions: turnover, market monopoly and market competition. Under this, prices of 74 bulk drugs and their formulation are being controlled representing approximately 20 percent of the pharmaceutical market. Bulk drugs, with a turnover of over Rs.40 million, are under the purview of the drug price control order, excluding those drugs with sufficient market competition. Sufficient market competition is defined as the presence of at least five bulk producers and 10 formulations, with no producer’s market share exceeding 40 percent. In case a single producer controls about 90 percent of the market for a drug, which has a turnover in the range of Rs.10 to 40 million, the drug is considered to be under the purview of the price order.

Industrial licensing has been abolished for all drugs, formulations and drug intermediates except for the five drugs, which are reserved for public sector. Moreover, price controls have been waived for a period of five years for drugs which have been developed indigenously. The pricing methods for imported bulk drugs were based on the landed cost (inclusive of import and customs duty), which was the maximum permissible selling price. In case of a bulk drug manufactured locally, the price has been fixed based on the capacity and cost data of a particular production unit like post-tax returns or pre-taxed return on total capital employed or internal rate of return based on the long-term marginal cost.

In the case of pricing of imported formulations, the price has been fixed based on the landed cost and the selling and distribution expenses, which would not exceed 50 per cent of the landed price. In the case of locally produced formulations, the price has been determined using the retail price.
5.5.1: Calculation of retail price of formulation: -

The Government in accordance with the following formula calculates the retail price of formulation namely:

\[ R.P. = (M.C. + C.C. + P.M. + P.C.) \times (1 + \frac{MAPE}{100}) + E.D \]

1. “R.P.” where as retail price
2. “M.C.” where as material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any plus process loss there on specified as a norm from time to time by notification in the Official Gazette in this behalf;
3. “C.C.” where as conversion cost worked out in accordance with established producers of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;
4. “P.M.” where as cost of the packing material used in packing of concerned formulation, including process loss, and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;
5. “P.C.” where as packaging charges worked out in accordance with established producers of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;
6. “MAPE” (Maximum Allowable Post – Manufacturing Expenses) where as all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed one hundred percent for indigenously manufactured scheduled formulations;
7. “E.D.” where as excise duty:

Provided that in the case of an imported formulation, the landed cost form the basis for fixing its price along with margin to cover selling and distribution expenses including interest and importers profit which not exceed Fifty percent of landed cost, landed cost means the cost of import of formulation inclusive of customs duty and clearing charges.

It implies that the drug price control order (DPCO) monitors and fixes the price of 74 bulk drugs and all the formulations, which uses these bulk drugs.
Therefore, the government controls under drug price control order 50 per cent of the pharmaceutical market in India. The impact of prices of drugs during post drug price control order (1995) period evaluated by the ORG (1996) found that there had been a 4.6 percent increase in drug prices in the 12 months following the announcement of the 1995 drug price control order compared to an increase in the Consumer Price Index (CPI) of 9.8 percent for the same period. The study also showed that the index of prices on products that had moved from the controlled to the decontrolled category under the drug price control order had also registered around 10.7 percent increase. Though there is a price controls under drug price control order, still a majority of drugs in the market are not regulated and the price rise during this period is still considered to be minimal. In short, while the drug price control order has evolved in a step-by-step ad hoc fashion, it has managed to strike a rough balance between regulating prices to ensure adequate access to essential medicines for the rural and urban poor, while allowing the emergence of a globally competitive Indian domestic drug industry.

5.6: HISTORY OF DRUG PRICE CONTROL ORDER: -

Drugs and formulations have been subjected to price control for more than three decades now. The economic reforms initiated by the Government of India in July 1991, trickled down to the Pharmaceutical Industry only in 1994 and that too partially. Price control in a large number of industries has already been abolished.

The main objectives of the Drug Policy after the modifications in the Policy of 1986 announced in September 1994 are to ensure availability, at reasonable prices of essential and life saving and prophylactic medicines of good quality; strengthening the system of quality control over drug production and promoting the rational use of drugs in the country; creating an environment conducive to channeling new investment into the pharmaceutical industry to encourage cost effective production with economic sizes and introducing new
technologies and new drugs; and strengthening the indigenous capability for production of drugs.

The Drugs Price Control Order (DPCO), 1995 is an order issued by the Government of India under Section 3 of the Essential Commodities Act, 1955 to regulate the prices of drugs. The Order inter alia provides the list of price-controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by Government and penalties for contravention of provisions among other things. For the purpose of implementing provisions of drug price control order, powers of the Government have been vested in the National Pharmaceutical Pricing Authority (NPPA). Drugs are essential for health of the society. Drugs have been declared as essential and accordingly put under the Essential Commodities Act. Only 74 out of 500 commonly used bulk drugs are kept under statutory price control. All formulations containing these bulk drugs either in a single or combination form fall under the price control category. However, the prices of other drugs can be regulated, if warranted in public interest.

The National Pharmaceutical Pricing Authority was established on 29th August 1997 as an independent body of experts following the Cabinet Committee’s decision in September 1994 while reviewing the Drug Policy. The Authority, inter alia, has been entrusted with the task of fixation/revision of prices of pharmaceutical products (bulk drugs and formulations), enforcement of provisions of the Drugs (Prices Control) Order and monitoring the prices of controlled and decontrolled drugs in the country.9

5.6.1: THE PATENT ACT 1970: -

The introduction of the Patent act 1970 was perhaps the single most significant policy initiative taken by the government that laid the foundation of the modern pharmaceutical industry. The British government in 1856 first introduced the patent system, primarily in order to defend the proprietary rights of British patent holders. The 1856 Act was replaced by the Industrial Patent and Design Act 1911 the previous Act although the main clauses remained the
This Act provided exclusive right to the patent holder for a period of 14 years. This act conferred monopolistic advantages to multinational companies as they were the main patent holders. With a view to breaking their monopolies and encouraging the Indian pharmaceutical industry, the Government introduced a new system of patents through the Patent Act 1970. This Act, which is prevalent until date, does not allow product patents on medicines, agricultural products and atomic energy. For these, only process patents can be registered. The basic philosophy has been to disallow monopoly and encourage research to help in overall growth in these sectors. In general, India provides patent protection only for 14 years, but in case of food, chemicals, pharmaceuticals and agro chemicals, the patent period is only 5 years from the date of sealing or 7 years from the date of patent, whichever is lesser. The patent act also has provisions relating to compulsory licensing. On the completion of 3 years from the date of sealing, any person interested in working the patented invention may apply for compulsory license with respect to the invention on the grounds of public benefit. The controller of patents may direct the patent holder to grant such a license upon the terms as may be deemed fit. In addition, the Patent act 1970 includes a provision of ‘license of right’ where the central government can after the expiry of three years of the sealing of patent apply for compulsory licensing on the grounds of public benefits. This act enabled Indian companies to develop skills in reverse engineering and to produce alternate processes for drugs. Exempt from paying for licenses and royalties, Indian companies could now access the newest molecules from all over the world and reformulate them for sale in the domestic market. As a result, after 1970, many new drug firms were set up. These companies developed research and development base, which was later, leveraged by them to move up the research and development value chain.

5.6.2: DRUGS (PRICES CONTROL) ORDER, 1970: -

Price controls in Indian pharmaceutical industry were introduced in 1962 when Drug (Display of prices) Order 1962 came into force. Later these controls
were modified through Drugs (control of prices) Order 1963, and Drugs (Display and Control) order 1966. In 1966, the government requested the Tariff Commission to examine the prices of 18 bulk drugs and their single ingredient formulation. Following the submission of the Tariff Commission Report in 1968, the government introduced a price regulatory policy better known as the Drug Price Control Order 1970. The objective was to protect the interests of consumers and ensure a restricted but reasonable return to producers. The government brought 18 essential bulk drugs under the purview of drug price control order 1970. These drugs accounted for less than 9 percent of total value of drugs marketed. The sale prices of other bulk drugs were frozen at the level prevailing immediately before the issue of the order. The policy was subsequently revised in 1979, 1987 and 1995.

5.6.3: DRUGS (PRICES CONTROL) ORDER, 1979: -

In the mid 1970s, the government appointed a Parliamentary committee better known as the Hathi Committee. This committee reported that in the year 1976-77 there were 45 foreign drug companies operating in India accounting for roughly 42 percent of the total production. The committee examined various aspects of foreign and domestic companies’ functioning. It was observed that foreign companies had far lower ratio of bulk drugs to formulations than their local counterparts. Moreover, they also thwarted attempts by indigenous units to produce bulk drugs by means of import dumping and filing patent suits. On the basis of the report of this committee, the government formulated a comprehensive drug policy. It was introduced in 1978, which was subsequently modified in 1986. It sought to develop a strong pharmaceutical sector deepen the production base of domestic industry, channelize the activities of foreign companies in accordance with “national objectives”, encourage research and development and provide drugs at reasonable prices. To achieve these objectives, public sector was assigned a leading role. In contrast, stringent guidelines were issued for control on foreign companies. Foreign companies were directed to bring down their equity first to
40 percent and then further reduce it to 26 percent. Higher levels were permissible for firms producing bulk drugs though. Small sector was prohibited for foreign firms. The policy stipulated a 1:10 bulk drugs to formulation ratio for Indian manufacturers with 30 percent supply to other formulators and allowed formulations to be produced with a ratio parameter of 2:1 indigenous to imported bulk drugs. However, foreign manufacturers had to follow a 1:5 bulk drug to formulation ratio and had to supply 50 percent of their production of bulk drug to other formulators. Moreover, foreign companies had to indigenously manufacture bulk drugs and intermediates required for their formulations within a stipulated period. It was also compulsory for foreign companies to set up research and development facilities in the country and spend at least four percent of their turnover annually as recurring expenditure on research and development facilities.

Following the recommendations of the Hathi Committee Report, the drug price control order 1970 was also revised in 1979. The government extended the coverage of drug price control order to 347 drugs which accounted for 90 percent of the industry. All the drugs were clubbed under four categories: life saving, essential, less essential, non essential/simple remedies. Of these, the first three categories were subjected to price controls. In fixing the price, the Government continued to advocate profitability ceiling. In case of bulk drugs, this was through a limit on the company’s return on net worth or capital employed. In case of formulations, retail prices of controlled products were decided by applying the concept of MAPE (Maximum Allowable Post manufacturing Expenses) which is akin to a mark-up on ex-factory costs provided to cover all selling and distribution costs including trade margins. The policy allowed the mark up of 40 percent, 55 percent and 100 percent for the life saving, essential and less essential drugs respectively. Non-essential drugs were kept out of the purview of price controls. Besides, all drugs manufactured by small-scale units were also exempted from price controls. Finally, new bulk drugs developed through local research and development were also kept outside the ambit of price controls. The multinational companies were badly hit
by these controls. Profitability fell steeply, new investments in the sector dwindled and multinational companies discontinued many products the policy however consolidated the growth patterns in the indigenous sector.

5.6.4: DRUGS (PRICES CONTROL) ORDER, 1987: -

The drug policy was revised in 1986. The new policy titled ‘Measures for Rationalizations, Quality Control and growth of Drugs and Pharmaceuticals industry in India’ emphasized among other things creating an environment conducive to channelising new investment to encourage cost effective production with economic sizes and to introduce new technologies and new drugs. These policies resulted in the dilution of price controls, relaxation of restrictions on the inflows of foreign investment and foreign technology, reduction in trade barriers and relaxed licensing requirements. Following the drug policy 1987, drug price control order was also revised in 1987. In the revised version of drug price control order, the number of drugs under price control was reduced significantly from 370 to 143. Moreover, it categorized drugs into two lists with different Maximum Allowable Post manufacturing Expenses: drugs required for National Health Programme (category I) with 75 percent mark up and others with 100 percent mark up. Trade polices also underwent significant changes with the pruning of the Negative list for imports.

5.6.5: DRUGS (PRICES CONTROL) ORDER, 1995:-

In 1995, the drug price control order was revised twice. Its basic structure remains same as the prior two orders of 1979 and 1987. But, it did liberalize the span of control considerably. Only 74 out of 500 (down from 163) commonly used bulk drugs are kept under statutory price control. All formulations containing these bulk drugs in either a single or combination form fall under the price control category. The prices of other drugs can be regulated, if warranted in public interest. Moreover, the policy stipulated a single list of drugs under the price control with a Maximum Allowable Post Manufacture Expenses of 100 percent. Small-scale firms are no longer free of
price control. Finally, exemption period for new drugs produced by indigenous research and development has increased from 5 years to 10 years. Under drug price control order 1995, the government claims that 40 percent of market is now covered by price control, down from about 70 percent under the old order. In addition to controls on drug prices, maximum returns on manufacturing (except basic manufacturing) are fixed at 14 percent and 22 percent respectively\(\text{1}\). No producers come close to these ceilings so this part of the drug price control order is currently not binding. The National Pharmaceutical Pricing Authority was established on 29th August 1997 as an independent body of experts following the Cabinet Committee’s decision in September 1994 while reviewing the Drug Policy. The Authority, inter alia, has been entrusted with the task of fixation/revision of prices of pharmaceutical products (bulk drugs and formulations), enforcement of provisions of the Drugs (Prices Control) Order and monitoring the prices of controlled drugs.\(\text{1}\)

5.6.6: DRUGS (PRICES CONTROL) ORDER, 2002:--

The basic objectives of Government’s Policy relating to the drugs and pharmaceutical sector were enumerated in the Drug Policy of 1986. These basic objectives remain largely valid. However, the drug and pharmaceutical industry in the country today faces new challenges because of liberalization of the Indian economy, the globalization of the world economy and because of new obligations undertaken by India under the world trade organisation 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 which India has a comparative advantage. 

5.7: SOCIAL ASPECTS OF DRUG PRICING POLICY: PRICE CONTROL ON PHARMACEUTICAL PRODUCT AND PROVISION OF HEALTH CARE SYSTEM OF GOVERNMENT AND PRIVATE SECTOR: -

The negative consequences of price controls on pharmaceutical products are related to the health system administration and level of market size of the pharmaceutical industries in respective countries. Therefore, it is imperative to review the existing healthcare system and its compatibility with the proposed price controls on pharmaceutical products in India.

The healthcare system in India consists of primary, secondary and tertiary care institutions and managed by medical and paramedical personnel at different levels of the State government. There are also specialized institutions and hospitals set up by the Central government in different parts of the country. The on-going health programs are managed at the Central, State, and district levels. The process of public sector funding to health care commences from the Central Ministry of Finance based on recommendations from the Planning Commission and flows to the Ministry of Health and Family Welfare at the Central level and in turn to the respective State governments. The Central Health and Family Welfare Ministry plays a major role in allocation of funds to various programs to the States, as they are responsible for implementation of family welfare, and public health programmes.

Table No 5.2 gives details about pattern of investment and expenditure on health and family welfare, public sector investment and expenditure was compared to private sector investment and expenditure. Private sector expenditure increased from Rs.7.5 billion in first five year plans (1951-52) to Rs.7500 billion in tenth five-year plans (2002-2007). However, public sector investments and expenditure has also been low from Rs.0.65 billion in first five-year plan to Rs. 589.2 billion in tenth five-year plan. The Government of
## TABLE NO: 5.2
PATTERN OF INVESTMENT AND EXPENDITURE ON HEALTH AND FAMILY WELFARE
AND SELECTED HEALTH OUTCOMES

(Rs. in billion)

<table>
<thead>
<tr>
<th>Plan Period</th>
<th>Public Health Investment &amp; Expenditure</th>
<th>Private Health</th>
<th>Total Health</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>1951-56</td>
<td>0.65</td>
<td>3.33</td>
<td>2.27</td>
</tr>
<tr>
<td>1956-61</td>
<td>1.46</td>
<td>3.12</td>
<td>3.93</td>
</tr>
<tr>
<td>1961-66</td>
<td>2.51</td>
<td>2.92</td>
<td>6.68</td>
</tr>
<tr>
<td>1966-69(Annual)</td>
<td>2.11</td>
<td>3.18</td>
<td>6.84</td>
</tr>
<tr>
<td>1969-74</td>
<td>6.14</td>
<td>3.89</td>
<td>19.91</td>
</tr>
<tr>
<td>1974-79</td>
<td>12.53</td>
<td>3.18</td>
<td>34.33</td>
</tr>
<tr>
<td>1979-80(Annual)</td>
<td>3.84</td>
<td>3.3</td>
<td>11.29</td>
</tr>
<tr>
<td>1980-85</td>
<td>34.12</td>
<td>3.12</td>
<td>95.72</td>
</tr>
<tr>
<td>1985-90</td>
<td>68.09</td>
<td>3.11</td>
<td>-</td>
</tr>
<tr>
<td>1990-92(Annual)</td>
<td>37.71</td>
<td>3.06</td>
<td>109.95</td>
</tr>
<tr>
<td>1992-97</td>
<td>141.1</td>
<td>2.9</td>
<td>434.34</td>
</tr>
<tr>
<td>1997-2002</td>
<td>299.96</td>
<td>3.19</td>
<td>847.69</td>
</tr>
<tr>
<td>2002-07(draft outlay)</td>
<td>589.2</td>
<td>3.86</td>
<td>1785</td>
</tr>
</tbody>
</table>

**Source:**
1. Indian Planning Experience – A Statistical Profile; Planning Commission, GOI, New Delhi, 2000; 2. Ninth Five-Year Plan, Planning Commission, GOI, New Delhi, 1998; 3. Draft Tenth Five – Year Plan, [www.planningcommission.nic.in](http://www.planningcommission.nic.in); for total public health expenditure (ministries of health and family welfare: 1. Up to 1986—combined finance & revenue accounts, respective years, GOI, New Delhi; 2. finance accounts of states & Union government, respective years; & RBI -- finance of states government, respective years, RBI, Mumbai; for private health expenditures & GDP data—national accounts statistics; CSO, 2003; for health outcomes—Registrar General of India, respective years, (Coated by, price control on pharmaceutical product in India, S. Narayan, ISAS Working Paper, No.20, Date: 19 March 2007)

1 - Public health & FW plan expenditure  
2 - Public health & FW plan as % of plan  
3 - Public health & FW expenditure plan + non plan  
4 - % of health & FW of total Govt expenditure  
5 - % of health & FW of GDP  
6 - % of plan H & FW expenditure  
7 - Private Health % as GDP  
8 - Private Health as % of GDP  
9 - Total Health expenditure  
10 - Public as % of total Health
India spending on health was hardly 0.9 percent of gross domestic product in 1999-2000. Health being a predominantly a State subject, 81 percent of total health expenditure is borne by the respective States and the balance 19 percent by the Central government through its own funds or through external assistance. It is interesting to note that health expenditure has always hovered around 3 percent of the plan allocations and it is only in the tenth plan that there is an effort to increase it to nearly 4 percent. The significant growths in private health expenditure, particularly after the 90s, is indicative of alternates to public health being available and affordable for a larger section of the population. Based on the National Sample Survey Organisation (NSSO) 52nd survey round data, the total health expenditure of the country was around Rs.26, 281 crore out of which the public sector accounted for only 21 percent and the balance by the private sector.

Table No. 5.3 gives the nature of health expenditure in terms of revenue expenditure and capital expenditure. It clearly illustrates the low capital formation that is taking place. Total public health expenditure in terms revenue expenditure and capital expenditure has been very low. In 1975-76 total public health expenditure.

Price controls benefit health delivery in countries that have a well-regulated public health delivery system. Public health expenditures in India continue to be low; there is a large private sector and unorganized access to medicines. In these circumstances, price control would lead to market distortions, excessive regulation and the development of market. Prices should be considered in the context of the total regime of the treatment, where several alternatives may be available, that could be as effective as any measure of cost control.

The pharmaceutical industry is a lifeline industry has played a significant role in raising the general health standard of the nation. In India a large segment of the population being poor, the reach of the health coverage being inadequate, non-availability of appropriate medical insurance coverage, price
### TABLE NO: 5.3
**TOTAL PUBLIC HEALTH EXPENDITURE (REVENUE+CAPITAL)**
**TRENDS 1975 TO 2003 AND SELECTED RATIOS**
(Values in Rs. crores)

<table>
<thead>
<tr>
<th>Year</th>
<th>Percent of GDP</th>
<th>% of total govt expenditure</th>
<th>Per capita (rupees)</th>
<th>Capita as ratio to revenue expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1975-76</td>
<td>0.9</td>
<td>3.13</td>
<td>11.16</td>
<td>0.11</td>
</tr>
<tr>
<td>1980-81</td>
<td>0.99</td>
<td>2.96</td>
<td>18.94</td>
<td>0.08</td>
</tr>
<tr>
<td>1985-86</td>
<td>1.19</td>
<td>3.29</td>
<td>39.28</td>
<td>0.09</td>
</tr>
<tr>
<td>1991-92</td>
<td>0.96</td>
<td>2.96</td>
<td>65.89</td>
<td>0.08</td>
</tr>
<tr>
<td>1992-93</td>
<td>0.74</td>
<td>2.71</td>
<td>74.13</td>
<td>0.04</td>
</tr>
<tr>
<td>1993-94</td>
<td>0.98</td>
<td>2.89</td>
<td>86.21</td>
<td>0.04</td>
</tr>
<tr>
<td>1994-95</td>
<td>0.93</td>
<td>2.33</td>
<td>94.33</td>
<td>0.05</td>
</tr>
<tr>
<td>1995-96</td>
<td>0.89</td>
<td>2.47</td>
<td>103.57</td>
<td>0.04</td>
</tr>
<tr>
<td>1996-97</td>
<td>0.88</td>
<td>2.43</td>
<td>115.96</td>
<td>0.04</td>
</tr>
<tr>
<td>1997-98</td>
<td>0.92</td>
<td>2.5</td>
<td>132.65</td>
<td>0.05</td>
</tr>
<tr>
<td>1998-99</td>
<td>0.94</td>
<td>2.66</td>
<td>155.01</td>
<td>0.04</td>
</tr>
<tr>
<td>1999-00</td>
<td>0.96</td>
<td>2.61</td>
<td>173.72</td>
<td>0.05</td>
</tr>
<tr>
<td>2000-01</td>
<td>0.98</td>
<td>2.69</td>
<td>182.66</td>
<td>0.04</td>
</tr>
<tr>
<td>2001-02</td>
<td>1.02</td>
<td>2.72</td>
<td>203.53</td>
<td>0.05</td>
</tr>
<tr>
<td>2002-03</td>
<td>1</td>
<td>2.6</td>
<td>208.54</td>
<td>0.05</td>
</tr>
</tbody>
</table>


Coated by, price control on pharmaceutical product in India, S. Narayan, ISAS Working Paper, No.20, Date: 19 March 2007,

inelastic demand, market imperfections and inadequate consumer awareness. It is necessary to continue formal regulation of the price of pharmaceutical products and medicines for some more time until public expenditure of health
care for those who cannot afford to increased and an alternative system developed for others. The pharmaceutical industry is a knowledge based and highly technology oriented manufacturing industry in the country, which is under formal price control regime. This is mainly because the financial provision in the budgets of central and state governments are too inadequate to cater to needs of the ailing people the budgetary provision should be raised. Further, there is an urgent need to expand public health care, supply of essential drugs and health insurance cover both by the governmental and nongovernmental organizations.

The government should strengthen the public health infrastructure to ensure that rural and urban poor people have universal access to treatments for basic medical needs. Such a system should be built around government bulk purchases of low-cost generic medicines. While such medicines are older and may not incorporate some of the latest advances, they provide a low-cost solution to expanding access to basic medical treatment, and are often quite effective in treating disease. Accordingly, instead of seeking to provide the latest state-of-the-art treatments for the rural and urban poor, the focus should be on the low-cost delivery of high quality, essential care for all. By keeping drug costs low, more care can be provided to more people, providing hope and help to the common person. Such an approach would facilitate a dramatic expansion of public access, particularly for low income workers, subsistence farmers, and the unemployed, and rural and urban poor.

The government should aim to facilitate the continued evolution of private health care markets, including private hospitals, private insurance, and high-cost patented drugs. Further, there are various systems of ensuring reasonable health cover either by the public funded programme or through the private companies in the health and insurance sectors. India already has an extensive system of private hospitals. Creating a separate private market would ensure that India’s expanding middle-class, which now comprises roughly 200-300 million people, would have access to sophisticated world class health care. It would also ensure that the cost of such advanced care would be borne by
middle-income households who can afford private insurance or out-of-pocket payments, and would not have to be subsidized by the public treasury.

The regulation of the drug prices is considered necessary to contain public expenditure due to government’s role in funding social health and insurance scheme that cover hospital. The price regulations are used as an instrument to keep their health budgets in the reasonable limits. In India, population should cover public health and health insurance scheme. As a result, the consumers are not affected directly by the high price of drugs or costs of medical service, but are made to pay for the increased prices through high insurance premium. As opposed to this, a substantial proportion of the population in India is market dependent and has to meet all their expenses out of their own pocket on this account making price regulation of pharmaceutical products in the market unavoidable.15

5.8: CONCLUSION: 

The Drug price Control Order (DPCO) controls consumer prices of several drugs in India. The scope of drug price control order has been decreasing over the last few years. However, there could be significant changes in the functioning of drug price control order in the product patent era. Price monitoring and control in the Indian pharmaceutical industry would continue to evolve as the dynamics of the industry change in the coming years. These developments need review and critical study to access their impact on the industry and the economy as a whole.
References :-

1 - Annual Reports of Organisation of Pharmaceutical Producer of India: Memorandum to the Committee on “Drugs and Pharmaceutical Industry: 2nd September 1974 Chairman of that Committee Shri Jaisukhlal Hathi

2 - Chaudhuri Sudip, (2005), The WTO and Indian Pharmaceutical Industry: Patent Protection, TRIPS and Developing Countries, Oxford University Press. p.no.247

3 - Indian Patents as Competitive Instruments Dream and Reality, Amiya Kumar Bagchi & Uttam Kumar Bhattacharya, Economic and Political Weekly 24th June 1995, Vol.XXX, No.25, pp.1501to1511


5 – Ibid, pn.132

6 – Ibid, pn. 57

8 - Drug Price In India Order The Gazette of India-Extraordinary PART-II
Section 3 Sub-Section (11) Ministry of Chemicals and Fertilizers Department

9 - National Pharmaceutical Pricing Authority, www.nppaindia.nic.in for the
text of DPCO

10 - Amiya Kumar Bagchi & Uttam Kumar Bhattacharya Indian Patents as
Competitive Instruments Dream and Reality, Economic and Political Weekly
24th June 1995, Vol.XXX, No.25,pp.1501to1511

11 - Kumar,N. and Pradhana, J.P. 2002. ‘Economic Reforms, WTO and Indian
Drugs and Pharmaceuticals Industry: Implications of Emerging Trends’ CMDR
MONOGRAPH Series No.-42, the Centre for Multidisciplinary Development
Research, Dharwad.

12 - India 1995, a reference annual, Ministry of Information and Broadcasting,
Government of India, edited research, reference and training division,
pp.561to563

13 - The modifications in Drug Policy, 1986, Department of Chemicals and
Petrochemicals, New Delhi, 1994 accessed from www.nppaindia.nic.in, see
also press Note dated 7 January 1995, issued by the Department of Chemicals
and Petrochemicals.
14 - Drug Policy 2002

http://envfor.nic.in/divisions/csurv/biosafety/Files/2002.PDF
