CHAPTER I
INTRODUCTION

1.1. Introduction

The underlying manifestation of the health transition that is sweeping through third world countries is the co-existence of a ‘double burden’ of disease. The heady cocktail of diseases – infectious and degenerative – is threatening to tear apart the fragile ‘healthy’ conditions of developing countries with a colossal loss of men and material. Although mortality in developing countries is declining\(^1\), the decline seems to have created other problems. As the population grows older with higher life expectancies, more and more in the old-age category are exposed to degenerative diseases raising morbidity levels\(^2\) to alarming proportions\(^3\). Despite 4-5 decades of planned development, communicable and tropical disease appears to still claim an enormous toll in post-colonial countries\(^4\). Behind this the single most widespread cause of ill-health is the problem of malnutrition\(^5\). Over half the deaths reported among children under the age of five occurs mainly due to diarrhoea. Their already vulnerable immune system is further weakened due to lack of nutrition – a direct consequence of poverty. The paucity of nutrition also takes its toll on pregnant and lactating mothers.

Adding to these woes, many developing countries are increasingly witnessing resurgent drug-resistant diseases such as malaria and tuberculosis.

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\(^1\) In effect, in a span of 3 decades, life expectancy at birth for demographically developing groups rose from 46 years in 1960 to 63 years in 1990. See World Bank (1993), p. 201.

\(^2\) Non-communicable diseases claims 59.8 percent of the total deaths in the world while communicable diseases, maternal and perinatal conditions and nutritional deficiencies together takes a toll of 31.1 percent and the rest of the deaths are caused by injuries, according to estimates made for 1999. See WHO (2000), pp.170-174.

\(^3\) Although, not in a strict sense, this phenomenon can be broadly termed as epidemiological transition. Epidemiological transition is said to occur when the burden of disease shifts from infectious to degenerative diseases, as mortality declines. India is witnessing a gradual decline in mortality over the years, but infectious disease still appear to be the major cause of death and disability eventhough the magnitude of degenerative disease is gradually rising in recent years.

\(^4\) In 1998, estimates for India (21.64 percent) and Africa (47.90 percent) suggests that the combined deaths from these countries due to infectious and parasitic diseases accounted for two-thirds of total communicable deaths in the world. See WHO (1999), pp. 98-103.

Unchecked, they are likely to put more pressure on the governments across developing economies. The emergence of new diseases like AIDS, Hepatitis etc., is further worsening the already damaged health profile of third world countries.

Rapid industrialisation and urbanisation have brought with them innumerable health problems. Unplanned industrialisation and increasing levels of trade have intensified migration and led to the extreme concentration of people in urban areas. Poor sanitation and inadequate availability of potable water in urban centres facilitates the easy and rapid spread of disease. The acceleration and expansion of geographic diffusion of communicable diseases in developing countries could be located in such a process. Newer forms of death and disability have been adding another dimension to health problems due to industrialisation and urbanisation such as industrial accidents, pollution and traffic accidents.\(^6\)

The 1930s and 1940s promised a radical departure from preventing and curing diseases with the innovation of antibiotics like penicillin. Modern medicine thus emerged by targeting germs by what is called the 'magic bullet'\(^7\) approach. The decisive role of vaccine in post-colonial era is remarkable in that public health immunisation programme were initiated and carried out in banishing killer infectious diseases like small pox. The other major crippling infant and childhood diseases such as, measles, tetanus, pertusis, poliomyelitis, diphtheria and tuberculosis were sought to be prevented through vaccination. Although initial success was made in combating these infant diseases, it could not be wiped out from the health map of developing world.

Despite evident gains against these diseases, it needs emphasis that much of this gain could be attributed to improvement in sanitation, nutrition and potable water\(^8\). For instance, communicable diseases like cholera, dysentery, typhoid and tuberculosis peaked and thinned out outside medical intervention in many

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\(^6\) Deaths due to injuries are the cause for roughly ten percent of total mortality in the world in 1998. See WHO (1999), pp. 98-103.

\(^7\) The term 'magic bullet' owes its origin to Paul Ehrlich in 1906. According to him, "substances able to exert their final action exclusively on the parasite harbored within the organism would represent, so to speak, magic bullets which seek their target of their own accord". Quoted in Tan (1988), p. 155.

\(^8\) For a thought-provoking empirical account on this subject, see Illich (1975) and Mc Keown (1979).
developed regions of the world in the 19th and early years of 20th century. It is during this period that developed economies underwent epidemiological transition, from infectious to non-communicable diseases. As developing countries are experiencing mortality decline and a consequent higher life expectancy, they inherit non-communicable diseases. Therefore, third world countries are essentially witnessing the prevalence of communicable and rising degenerative diseases. Tragically, such transition has left not only developing countries as a whole more vulnerable to both type of diseases, much of the burden unfortunately falls on world’s disadvantaged populations. It is this epidemiological polarisation that needs to be addressed immediately.

The period spanning the first half of twentieth century saw the introduction of life-saving vaccines and antibiotics. The initial advances in innovating ‘blockbuster’ drugs (in the therapeutic category of antibiotics) spurred further research and development. The imperative of medical intervention to prevent and cure life-style diseases added vital dimension to the nature of pharmaceutical research. Research priorities tended to shift its focus towards degenerative diseases. Gradually, drug development and marketing fell into the hands of giant multinational corporations. In order to retain their monopoly position, drug transnationals started drug promotion in a massive way and also began patenting their products. While a few industrialised market economies actually went in for strong patent protection, developing countries and many developed countries provided either a weak patent regime or no patent at all.

The drug industry has been under severe scrutiny among many countries of the world in the 1960s and 1970s – Kefauver Committee in the U.S, Sainsbury Committee in the U.K. and Hathi Committee in India – to name a few. Monopoly profits, sky-high prices, skewed production priorities, research predominantly inventing around ‘me-too’ drugs and many more issues have been the concern and were manifest in regulations and restrictions of the pharmaceutical industry.

The last two decades of the twentieth century have been witnessing major changes in the drug industry - both structural and policy-induced - changes which

are a direct challenge to the existence of the industry in developing countries, and on a broader level a cause for serious concern for the health care of society.

An unprecedented structural churning is sweeping through the pharmaceutical industry. This is the period of consolidations undertaken by drug multinationals. Mergers between companies, acquisitions of companies and brands, etc. are the *mantra* in the industry. Cost cutting, skill development, new modes of research and development of drugs (through molecular medicine, biotechnology, gene sequencing) are the emerging trends. The wheel of global capital finance has been spinning rapidly and savagely towards establishing private monopoly in drug production and research. The dynamics of global capital is such that it co-opts third world domestic capital in its side. This gives ample scope for transnational pharmaceutical corporations to position themselves and consolidate. Ultimately, in view of low cost labour, skill and infrastructure, production and research are shifted to developing countries. Contract production, contract research, marketing tie-up has gained currency in the new milieu. Another roadblock before drug multinational corporations\(^{10}\) has since been dismantled in the name of reducing trade restrictions. The transnational pharmaceutical corporations have successfully pushed through their agenda of strong patent protection in the field of drugs.

Apart from structural changes as depicted above, the industry is in the thick of a policy-based transformation. Many developing countries since the 1980s have been forced to undertake ‘economic reforms’ under the auspices of the IMF-World Bank. Since the early 1990s, the Indian economy has been subject to the trio of ‘globalisation’, ‘liberalisation’ and privatisation’ of the economy. Drug production licensing (mandated through The Drug Policy) which have been in place since 1978 have been dismantled completely. Price controls on essential drugs are also being withdrawn systematically and substantially. According to a recent government notification, the sectoral cap on the pharmaceutical industry is being lifted, with 100 percent foreign direct investment allowed in this sector. As public sector drug companies are being forced to bleed into red, disinvestment is carried

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\(^{10}\) Throughout this thesis, terms such as multinationals, transnationals and western pharmaceutical companies are used interchangeably entailing no distinction.
out enthusiastically. To cap it all, India was forced to sign and accept the treaty on intellectual property rights which makes it obligatory to offer strong patent protection to transnational drug companies.\textsuperscript{11, 12}

The return to market fundamentalism in an industry characterised by 'supplier-induced demand'\textsuperscript{13}, uncertain demand, oligopoly elements, in the backdrop of rising prices, monopoly profit, biased production in favour of inessentials, etc. does not augur well for a society swearing by the welfare state as its core principle. This will have far-reaching consequences on the health care of masses whose main problem lies in the lack of purchasing power, lack of access and knowledge of modern medicine.\textsuperscript{14} The expansionist agenda of the market has come to a full circle. The drug industry is only next to military-industrial complex in its size, operations and rent-seeking. The former is vying with the latter to attain a leading position disregarding health implications.

1.2 Concept of Health and its Significance

1.2.1 Definition of Health (Economic Aspects)

The concept of health has been defined variously by different authors\textsuperscript{15} and has undergone a metamorphic change over the years. Their perspective however differ. Grossman (1972) and Mushkin (1962) view health as an investment or more specifically as contributing to human capital formation. According to Mushkin (1962), "the concept of health capital formation through both education and health services rests on the twin notions that people as productive agents are improved by investment in these services and that the outlays made yield a

\textsuperscript{11} It must be noted that presently India follows 'process patents' as against 'product patents' being followed in other industrial countries. For a thorough account of the issues relating to patents, see Chapter VI of this thesis.

\textsuperscript{12} This section essentially intends to capture policy-based transformation in the drug industry. For a synoptic view of the development of Indian drug industry, see Section 1.5 of this Chapter.

\textsuperscript{13} Supplier-induced demand is a unique demand condition in the health care market. Unlike other markets where consumers 'decide' and 'choose', physicians exercise their 'choice' on behalf of patients in health care market.

\textsuperscript{14} It is disconcerting to note that despite the fact that in India drug prices are one of the lowest in the world in the post-1970 era, yet for an average Indian, essential medicines are unaffordable. This typically arises out of the problem of lack of purchasing power in India, whose annual per capita income is roughly around US $ 390. See OPPI (1999), p.50.

\textsuperscript{15} See WHO (1946), Mushkin (1962), Arrow (1963), Grossman (1972), Cropper (1977), etc.
continuing return in the future". This definition suggests that by investing in health programmes, the economy can hope to add more labourers in the working force by means of increased working hours and also enhances the quality of the labourers' product.

Taking a step forward, Grossman (1972) is more emphatic to assume "that individuals inherit an initial stock of health that depreciates over time - at an increasing rate, at least after some stage in the life-cycle and can be increased by investment". The central argument goes to show that health acts as a durable capital stock stimulating an output of healthy time. Moreover, Cropper (1977) emphasises that "individuals invest in health not to receive a monetary return but to avoid the disutility associated with being ill". But to cap it all, a more comprehensive definition is provided by WHO (1946), which states health as "a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity". This definition hardly needs any explanation as it is self-evident.

1.2.1.1. Sociological and Epidemiological Definition on Health

Apart from individual concerns relating to physical and mental well-being, the WHO definition brings in social aspect as well. The definition therefore, accommodates not only the concern with an individual but with the person as a member of living human groups. To extend the definition,

"the components of an individual (eg., blood, body, soul, spirit, shadow, name, etc.) are defined differently from one culture to the next. The death of the organism, however, is a biological constant which is taken into account conceptually in all cultures, and customs prescribe how the disposition of the corpse is to be arranged. Different components of the individual may be thought to depart from the presence of the living at

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16 See Mushkin (1962), p. 130
17 See Grossman (1972), p. 227:
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different times, and these various departures are marked by a series of ceremonies."

Epidemiologists regard illness as an interrelationship between various factors. In view of this, patients are treated considering them as total organisms in a complete setting. John Gordon, who pioneered this view displays the interplay of the host, the agent and the environment (which includes physical, biological and social) in the spread of both infectious and non-infectious diseases. Now, in this context, it is necessary to define what epidemiology means. According to Encyclopaedia Britannica,

"epidemiology may now be defined as that field of medical science concerned with the description of factors and conditions which are significantly associated with the occurrence of an infectious process, diseases or abnormal physiological state in a human community, with elucidation of the manner in which these factors and conditions operate in the causative complex."  

Therefore, the socio-cultural and epidemiological definition on health broadens the scope of the subject health to include and view health as an interaction between a person and his environment.

1.2.2 Significance of Health

On purely economic grounds, better health contributes significantly to further economic growth. This works in the following ways:

- Improved health curtails production losses caused by worker's illness. This happens through gains in labour productivity, increased availability of man-days to work; and longer working years. For instance, it is estimated that the prevention of 645,000 cases of deformity due to leprosy in India would have left the countries GNP increased by US $ 130 million in 1985.  

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21 This portion is heavily drawn from the World Bank (1993), pp. 18-20.
Education is complementary to health. Health improvement induces more number of school enrolments (more particularly female education) and increases ability to learn. A study conducted in Nepal reveals that the nutritionally stunted children have only five percent probability of attending schools while that for normal children is put at 27 percent.23

Better health enables people to harness natural resources, which were inaccessible earlier due to disease. Therefore, hiking health investments can enhance land productivity. In Sri Lanka, for instance, it is estimated that during 1947-77 the malaria eradication programme appears to have escalated national income by nine percent in 1977.24

The costs saved due to health improvement could be put to alternative uses. An estimate for America in polio eradication revealed that spending US $ 220 million over a 15 year period would prevent 222,000 cases and save between US $ 320 million and US $ 1.3 billion in annual treatment costs. After a 12 percent discount a year, the net return from the programme is put between US $ 18 million and US $ 480 million.25

Moreover, better health and nutrition leads to a dramatic increase in life expectancy at birth. Further, it also reduces the infant mortality rate considerably, which is an important health indicator.26

While the above outlined economic significance of being healthy, the following points essentially brings out non-economic significance of health.

Improved health results in higher literate rate and reduction in drop-outs from schools. This is likely to result in the development of matured citizens and a matured society which is needed for a community divided on religious and caste lines. This would also result indirectly in evolving a mature democracy.

23 ibid, p.18.
24 ibid, p.18.
25 ibid, p.19.
26 ibid, p.20.
• Better health is expected to reduce poverty substantially which in turn is supposed to reduce inequality – regional as well as inter-personal inequality.

• Healthy life arising out of clean environment (proper sewage, safe drinking water, reduced smoking) would lead to higher life expectancy;

• Community and individual campaigns to reduce substance abuse (like alcohol consumption, tobacco use and other drugs) improves not only the individual concerned, but helps to improve social life at broader level, such as, reduced drunk driving, fires, passive smoking and drug-related crime and violence.

• Health-related problems are common and substantial among old age population. In a society where nuclear family is thriving, improved health among old age population is certainly expected to reduce dependence on others and could aid them in managing their affairs on their own and reduce social conflict

1.3. Characteristics of the Health Care Market

Unlike other markets, the health care market is uniquely characterised, in view of the following:

1. **The Nature of Demand**: The demand for medical services\(^{27}\) is irregular and unpredictable.\(^{28}\) This is because medical services are demanded in the event of the risk of death, impairment and potential for loss of earning ability. A normal commodity gives instant satisfaction when demanded, while the demand for health care is made only in the event of ill-health.

2. **Supply Conditions**: In non-medical care markets, the supply of a good depends on the profit that it fetches. In view of the risk that the unfettered market provides to the public in general, health care market is restricted by licensing and bans. For instance, in the pharmaceutical market different categories of

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\(^{27}\) The usage of the words 'medical care' and 'medical services' are interchangeable here, though its distinction is made at appropriate places.

\(^{28}\) Although it must be emphasized that given the improvement in the availability of better data on incidence and prevalence of disease profile, it is becoming easier to estimate demand.
drugs are put under different restrictions, and in the case of an entry to the profession in this market is restricted by licensing. As far as medical education is concerned, the government provides students, a significant share in their cost, eventually expecting considerable social benefits.

3. **Price Determination**: Prices in the medical care market are not determined as done in any competitive market. Price in this market is characterised by price fixation, price discrimination and so on by the government in order to ensure that unaffordability and inaccessibility are not a hindrance to the underprivileged and poor.

4. **Physician’s Behaviour**: Unlike the non-health care market, where salesmen are guided by self-interest, the behaviour of physicians in the health care market is expected to be governed by a concern for the patients health.

5. **Supplier-Induced Demand**: Further, both the patient and the physician are aware of information asymmetry and in view of this the latter has an upper hand in deciding about the remedy to his patients, which is now widely recognised and termed as “supplier induced demand”.

1.4. Characteristics of the Global Pharmaceutical Market

The peculiarity of the pharmaceutical industry is well documented in the literature. It is estimated that the world pharmaceutical market is of the order of US $ 350 billion in 1998\(^{29}\). Not surprisingly, the top twenty companies accounted for US $ 244 billion of the total global sales. Compared poorly with this, the developing markets that inhabit 80 percent of the population accounts for only 20 percent of the total pharmaceutical market. Most studies\(^{30}\) have conceded the oligopolistic nature of the industry and its ability to earn supernormal profit. On the face of it, it may look as if there is wide polarisation between various market players. For instance, it is claimed that the top company’s market share seldom exceeds 5 percent and to be precise, of the top 20 global companies, 15 of them have shares less than 3 percent each in the global sale and the rest five companies

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\(^{30}\) See Lall (1974), Reekie (1978), Comanor (1986) and others.
have less than 5 percent of global sales. However, to claim that the industry is competitive based on this is tantamount to concealing the facts. Alternatively, one has to look into sub-market therapeutic categories for a better perspective. Competition in this industry is pursued not on the lines of price but by means of product differentiation. In view of the monopoly enjoyed by patent protected products, profit accruing to this industry is abnormally high. In fact, the abnormality of profits can be established when one compares the drug industry profits with the all-industry average.

The pharmaceutical industry the world over is highly research-oriented. It is claimed that the top drug companies sustain their market share by investing continuously in the Research and Development (R&D). Consequently, continuing research unleashes new products preceded by a high rate of obsolescence in drugs. It is worth mentioning that “nine out of ten drugs prescribed now were not known in the early 30s”. However, many studies have found, rather than inventing therapeutically new products, the drug industry is accused of trying to invent ‘in the neighbourhood’. This only encourages industries to pocket profit altogether neglecting social costs in the process.

Drug companies spend roughly 40-50 percent of their sales on selling costs or promotional expenses (advertising, salesmanship, etc.) to sustain their pre-eminence of monopoly power in their respective therapeutic categories. Big pharmaceutical firms, particularly transnational corporations till now have been successful in price discrimination in view of dependence of subsidiaries on inputs, technology and chemicals used in the drug manufacturing. One of the important factors that fetches high profits for the drug industry is the existence of brand names, as opposed to generic names, with the active aid of patent protection.

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31 See Matraves, Catherene (1999), pp. 188.
33 See for instance, Kefauver Committee Report (1962) and Lall (1974).
34 By incorporating minor and cosmetic changes in the already existing drugs, pharmaceutical companies market their product as if it is a new product. This is popularly called ‘me-too’ products or ‘inventing in the neighbourhood’ in the literature.
1.5 The Pharmaceutical Industry in India\textsuperscript{36}

The moderate Rs. 17,000 crore Indian pharmaceutical market is sharply polarised between a strong 300 large/medium-sized units on the one end, and a scattered tiny units of 8,000 small scale ones and a rest of 12,000 units in the unorganised category, on the other end.\textsuperscript{37} The Indian pharmaceutical industry which is considered to be one of the most advanced among developing countries can now boast of self-sufficiency in the formulations market, while nearly 70 percent of the domestic bulk drug requirement is catered to by the Indian drug industry. In addition, the growth rate of the industry is quite rapid, continuous and substantial. For instance, the value of the output of bulk drugs and formulations which stood at Rs. 550 crores and Rs. 3,150 crores respectively in 1988-89 sharply shot up to touch Rs. 2,623 crores and Rs. 12,068 crores respectively in 1997-98.\textsuperscript{38} Compare this situation with an abysmally low output of Rs. 10 crores in 1947. While bulk drugs were primarily imported during the 1950s, the formulation business was taken up in the domestic arena mainly by multinational corporations.

The 1950s belonged essentially to transnational corporations, who held sway over the domestic business. But with a modest beginning, the Indian Public sector was able to challenge the multinationals at least in the antibiotics sector. With the ushering in of the Patent Act of 1970, the Indian domestic private industry started to grow rapidly and significantly, is now in a position to check the mighty transnationals, and is able to export a considerable part of them\textsuperscript{39}. A mention of their relative shares is worth in place here. The organised sector (which consists of both Indian and foreign) accounted for 68 percent of the investment and 76 percent of the sales value of pharmaceuticals in 1952. Whereas, the public sector had a minuscule of six percent in terms of investment and nearly three percent in sales value. While the share of the small scale sector accounted for 25

\textsuperscript{36} For a comprehensive treatment of the growth and structure of the drug industry in India, see Chapter III.
\textsuperscript{37} These figures are for the financial year 1998-99. See OPPI (1999), p.50.
\textsuperscript{39} For a detailed analysis of how the Patents Act of 1970 aided the domestic pharmaceutical sector to grow, see Chapter VI.
percent and 20 percent respectively for the same period. Compared to this the public sector had staked its position to a high level to account for 26 percent of bulk drug production and seven percent of formulations in 1980-81.\footnote{The other major reason which is attributed for the phenomenal growth of public sector drug companies is the fact that much of the needed demand came directly from publically owned health institutions, like primary health centre, secondary referral services and tertiary-care services. The rapid and substantial growth of these institutions also resulted in higher demand for pharmaceutical products.} The share of organised sector, on the other hand, had undergone a slight downtrend accounting for 63 percent of bulk drug output and 66 percent of the formulations output. The share of the small-scale sector had also witnessed a quantum jump to 27 percent in 1980-81.\footnote{op. cit., Narayana, p.4} This phenomenal growth of the pharmaceutical industry has prompted the UNIDO to recognise and to categorise the Indian pharmaceutical industry in the category of self-sufficient ones having adequate production skill (both bulk drug and formulations) and process research.\footnote{See Narayana (1984), p.4.}

Equally vital is the role played by the growth of public health institutions over the years in pepping up the demand for drugs. The growth of public health infrastructure has been phenomenal in India during this period in a normative sense. The number of Primary Health Centre (PHCs) went up from 2,565 in 1961 to 23,179 in 1994; the number of dispensaries witnessed quantum jump from 9,540 in 1961 to 28,279 in 1994 and the number of hospitals also rose quite substantially from 3,334 to 14,867 for the same period.\footnote{See Health Information of India/Health Statistics India, various issues.} The growth of these institutions also provided the much-needed demand to the pharmaceutical industry to develop manifold. As essential pharmaceutical products became available - in adequate quantities and at affordable prices - the direct impact on the reduction in morbidity and mortality is perceptible.
1.6 Objectives of the Study

Given the issues involved as briefly discussed above, it becomes imperative to examine their implications in the light of changing policy environment. It is in this context that this thesis will make an attempt into the following:

1. A thorough analysis of growth and structure of the Indian pharmaceutical industry since the 1970s in the backdrop of drug policy changes;
2. An examination of the implications of Drug Control Price Orders on drug prices and profitability in India;
3. An analysis of trends and pattern in drug research over the years and to probe into the determinants of research and development in the drug industry in India;
4. A detailed investigation into the Indian Patents Act, 1970 vis-a-vis the pharmaceutical sector and the likely consequences of a change-over to new patent regime under TRIPS, WTO in India;
5. Finally the study will offer policy suggestions.

1.7 Methodology

1.7.1 Period of Study

A comprehensive package of policies relating to the pharmaceutical industry has been introduced since the 1970s. The late 1960s and early 1970s has been the watershed in Indian economic policy-making. Profound policy changes were sought to be introduced during this period. The economic landscape of the country underwent significant changes. The crisis on the political and economic
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front forced the then government to go in for a major policy regime change. Nationalisation of 14 private banks in 1969 and another six in 1980; introduction of Monopoly Restrictive Trade Practices (MRTP) Act and Foreign Exchange Regulation Act (FERA), in 1973 were the major policies put in place. The patent policy, drug price policy and drug policy all have been introduced in order to correct distortions in the market for drugs and to make drugs affordable and accessible at the right time. This was supposed to have a perceptible influence on the health care of people. The focus of the study would cover on the period immediately following these policies’ (last 30 years starting from the 1970s).

Although each of these policies underwent changes since the mid-1980s, looking back at their history would bring in insights and fresh evidence to review old policies and infuse new energy in future policy-making.

1.7.2. Data Sources

The major source of data that are being used in this thesis is secondary data derived from various government and non-governmental organisations, such as the following:

1. Various reports of the Centre for Monitoring Indian Economy (CMIE) which provides comprehensive data on financial indicators of the pharmaceutical industry. For instance, the PROWESS, 2000 database available in an electronic format, covers a wide array of financial variables for the 1990s. Different components of assets, liabilities, income and expenditure, costs, profit, sales, trade, dividends, equity, royalties, etc. are included in the database. The number of companies in the category of the pharmaceutical industry varies from year to year, with a maximum of 232 firms in 1997 and a minimum of 72 companies in 1990. Along with this CMIE’s annual reports of Trends in Industrial Production are of immense use in obtaining disaggregated data on drug and formulations production for a significant number of years from the 1980s. All these data would help us in analysing the changing structure of the pharmaceutical industry and would enable us to identify determinants of profitability and R&D over the years.
2. The other vital data on the drug industry is from the Operations Research Group (ORG). ORG provides data on the value of retail market sales – by top 300 companies, by leading 300 products (the number of companies and products varies from year to year) and by anatomical groups in a detailed sub-group level. Availability of ORG-Retail Audit Sales spans the period from the mid-1980s to the late 1990s.

3. The Monthly Index of Medical Specialties (MIMS India), spanning the period 1994-2000, is being used for obtaining price data on various retail price of formulations. Apart from price, MIMS India displays name of the company manufacturing the product, the generic name and other components of formulations along with its usage. In order to evaluate the changes in drug price policies and its impact on prices, MIMS India data would provide crucial input.

4. Annual Reports and other reports of Indian Drug Manufacturers’ Association (IDMA), and Organisation of Pharmaceutical Producer of India (OPPI) would also be considered to assess the growth, structure and policies of the drug industry.

5. Research and Development Statistics, issued by the Department of Science and Technology, Government of India, would provide the necessary link to assess Research and Development potential and trends in India, specifically in the pharmaceutical industry.

6. To probe into the question of the profitability aspect in the drug industry, various issues of Selected Financial Ratios of Public Limited Companies, Reserve Bank of India are being considered. These survey reports of RBI would be harnessed to compile and examine certain vital ratios of profitability relating to the pharmaceutical sector, such as: i) gross profit to total net assets; ii) gross profit to sales; iii) profit after tax to net worth and iv) dividends to net worth. To supplement the aspect of profitability in the public sector, various issues of Public Enterprises Survey, Department of Chemicals and Pharmaceuticals, Ministry of Industry, Government of India were made use of.
7. Patent statistics and pharmaceutical sector patent numbers were obtained from Annual Reports, various issues, Controller-General of Patents, Designs and Trade Marks, Government of India.

8. Various issues of World Health Reports, World Health Organisation provides vital macro health indicators over the years like different measures of mortality, morbidity, etc.

9. Relevant Annual Reports and other statistics issued by the Ministry of Petroleum and Chemicals, Government of India, which provides data on pharmaceutical production, consumption, import, etc.

1.8 Research Gaps and Relevance of the Study

Extensive research on the drug policy and its implications on health care have been eluding the attention of serious policy-makers and academia over the years. Although attempts have been made in the past to probe various policies and its consequence involving drug industry, such efforts were largely isolated in nature. An organic link that exists between drug policy, patent policy and health policy was seldom investigated into. A lacunae that needs to be bridged and addressed. Incidentally, as all these policies are undergoing tremendous transformation in contemporary India in the background of withdrawal of state and ushering in of market-based economy, it becomes crucial to probe into the weaknesses and strengths of the earlier state aided policy-based regime. The imperative of a reappraisal assumes vital import since health security comes under renewed threat in the market-economy.

1.9 Chapterisation Scheme

This thesis is organised in the following order: Chapter I of this thesis provided an outline on conceptual issues and characteristics relating to health and the pharmaceutical industry. It also included the scope of the study and its objectives apart from methodology. Relevant previous studies shall be examined in Chapter II. Chapter III will attempt to comprehensively capture the growth and structure of the drug industry in the backdrop of various drug policies. Peculiar
features, which are central to the pharmaceutical industry, such as, prices and profitability, would form the focus of Chapter IV. The fifth chapter would attempt to analyse and assess various issues relating to Research & Development activity in the Indian drug industry. This chapter shall also attempt to identify various determinants and the intensity of Research & Development in India. Chapter VI will evaluate the impact of patents and the changes that are being brought in the Indian Patent Act of 1970 on the structure of the pharmaceutical industry and prices. Summary, conclusions and policy suggestions shall be included in Chapter VII.