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THE POLITICAL ECONOMY OF THE INDIAN DRUGS AND PHARMACEUTICAL SECTOR: A PRELIMINARY ENQUIRY

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MASTER OF PHILOSOPHY

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This dissertation entitled ***"The Political Economy of the Indian Drugs and Pharmaceutical Sector: A Preliminary Enquiry"***, is submitted in partial fulfilment of six credits for the Degree of **Master of Philosophy** of this University. This dissertation has not been submitted for any other degree of this University or any other university and is my original work.

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SL.No. CONTENTS Page No.

Chapter I

Introduction

Chapter II

The Growth and Evolution of the Indian Drugs and Pharmaceutical Industry

Chapter III

Political Economy of Policy Decisions and Its Impact on the Indian Drugs and Pharmaceutical Sector

Sl. No.	List of Tables	Page No.
	Chapter I	
1.1	Geographical Concentration of Global Drug Production	7
	Chapter II	
2.1	Patents Held by Indians and Foreigners in India 1856-1970	51
2.2	Structural Details of Indian Drugs and Pharmaceutical Industry in 1954	55
2.3	India's Share in the Total Foreign Sales of 12 Drug Transnationals in 1977	58
	Chapter III	
3.1	The Various Categories of Drugs and their Mark-Ups, DPCO, 1979	93
3.2	Production Details of Controlled Drugs from 1978 to 1980	93
3.3	Growth Rate of Companies during the Period 1979-84	100
3.4	Comparison of Consumer Price Indices of All Commodities and Drugs	101
3.5	Sector-wise Value of Production for Bulk Drugs and Formulations during the Period 1974-84	102
3.6	Profit & Loss of Public Sector Undertakings	102
3.7	Value of Export of Drugs	103
	Chapter IV	
4.1	Pre- Tax profit of MNCs in India	119
4.2	The Financial Performance of the PSUs During 1999-2001 (Rupees crores)	128
4.3	Differences in Prices of Medicines, May 1999	132
4.4	Number of Drugs and Pharmaceutical Units in the Last Four Decades	137
4.5	Production of Bulk Drugs and Formulations during 1980-2000	139
4.6	Capital Investments in the Drugs and Pharmaceutical Industry from 1973	140
4.7	Financial Details of the Top Pharmaceutical Companies of Indian Private Sector	140
4.8	Export Composition of Drugs and Pharmaceuticals	142
4.9	Import Composition of Drugs and Pharmaceutical Products	143

CHAPTER-I

CHAPTER 1

Introduction

1.1. Introduction:

Over the years, both the curative and preventive elements of medical care have become indispensable parts of the health care system. The profession of medicine as well as medical industry is growing at a faster pace. Today, the global pharmaceutical market alone is worth more than 310 billion U.S dollars and it is estimated that the annual market growth rate is in the range of seven per cent to eight per cent. In the wake of liberalisation and globalisation, the health care systems throughout the world are undergoing a critical scrutiny. The issues of accessibility and availability of health care in the changing economic and political contexts are being discussed at length both in academic and non-academic levels.

In the developing countries like India, most of the major health problems arise from poverty and poor environmental conditions. In fact, most of these health problems can be prevented by better nutrition, safe drinking water, and proper sanitation. This indirectly reveals the fact that drugs and pharmaceuticals are only necessary and effective to a very small area of health intervention. Moreover, it has been estimated that barely 20 per cent of the medicines available in the market today are necessary to treat over 80 per cent of the prevailing diseases (AIDAN and VHAI: 1986). In spite of this fact, today, drugs and pharmaceuticals have become an important component of health care. The curative-oriented model of health care, which fosters dependence on drugs and pharmaceuticals, has contributed to the increase of burden of disease, especially to the poor. Thus, today we are faced with

1. AIDAN and VHAI (1986), *A Rational Drug Policy,* AIDAN and VHAI, New Delhi, p.2.

a paradoxical situation where flourishing drug market as well as high mortality and morbidity are co-existing side by side.

The developing countries have been experiencing innumerable problems in relation to the drugs and pharmaceuticals. One of the major problems is that essential drugs are not available/accessible to the people, while worthless, irrational, and harmful drugs are plenty in the market. Another serious issue is that of high share of drugs in the health care costs that limit people from getting quality health care. Apart from this, the lack of proper drug control, misleading advertisements and claims of therapeutic drugs also contribute to many other problems (Koivusalo and Ollila: 1997). According to the AIDAN (All India Drug Action Network) and VHAI (Voluntary Health Association of India) 20 per cent of the drugs in India have been found to be substandard and of this, more than fifty per cent were manufactured by the MNCs (AIDAN and VHAI: 1986). When we look at the issues and problems in the Indian drugs and pharmaceutical sector, we begin to grapple with a lot of politically burdened questions. Can we solve these problems by enforcing control measures on drugs and pharmaceutical industry alone? What are the historical origins of the problems? Are these problems symbiotically related to the problems of the larger social system? Who is benefiting by perpetrating these problems? Why do the instruments of the state singularly and systematically fail to check these problems?

In the latter part of the 20th century, especially during the 1960s and 1970s, there were attempts to build up indigenous industries, nationalise the existing drugs

2. Koivusalo, Meri and Ollila, Eeva(1997), *Making a Healthy World: Agencies, Actors & Policies in International Health*, Stakes, Helsinki and Zed Books Ltd., London, p.163.
3. AIDAN and VHAI (1986), *op cit*, p.103.

and pharmaceutical industries and to rationalise the production and consumption of drugs and pharmaceuticals in the developing countries like India and Bangladesh. However most of these efforts faced serious opposition from the multinational capital and later did not find its objective in the changed political and economic conditions. It has been a widely acknowledged fact that growth and development of drugs and pharmaceutical industries in most of the Third World countries have been merely through imitation of its western counterpart. Therefore a brief account of the history and characteristics of modern drugs and pharmaceutical industry would be helpful for one to have a better understanding of the issues and problems of the industry.

1.2. A Brief History of Growth and Evolution of Modern Pharmaceutical Industry

The history of the therapeutic use of medicinal plants and minerals can be traced back to the ancient Greek, Egyptian, Indian, and Chinese civilisations. In the 14th century B.C., Hippocrates taught the value of plants in treating diseases in ancient Greece. It is reported that out of those 400 herbs used by Hippocrates, nearly half of them are still in use. *Historia Plantasum*, written by Theophrastus (a disciple of Aristotle) in 300 B.C is considered to be the earliest publication on herbals. Galen, a Greek physician who practiced in Rome in 200 A.D classified a variety of herbs and developed the art of extracting their essential principles (Government of India: 1954).

During the 16th century AD, once so-called western medicine began to recover from the stagnation it suffered in the Middle Ages, pharmaceutical practice began to develop to its new form. For example, the first pharmacopoeia appeared in Germany in 1546. Later, in 1617 the establishment of the Society of Apothecaries in London led to

4. Government of India (1954), *Report of the Pharmaceutical Enquiry Committee*, Ministry of Commerce and Industry, New Delhi, p.11.

the emergence of the profession of pharmacy. Thereafter, King James I introduced legislation that separated apothecaries from grocers and which also stated that only a member of the Society of Apothecaries could keep a shop and make or sell pharmaceutical preparations. This helped the profession of pharmacy to grow with distinction in the later period.

When Edward Jenner discovered cowpox vaccination in 1790s, for the first time ever in history, it demonstrated man's mastery over a disease. The development of medical profession and specialist sciences of modern medicine and the evolution of bacteriology together took the allopathic medicine far ahead of any other system of medicine. It should be noted that, Louis Pasteur and Robert Koch made significant contributions to the development of bacteriology, especially during the period between the 1860s and the 1880s (Arnold: 1989). With the development of bacteriology there started a new era of drug therapy in which "snake oil" types of medications were substituted by chemicals, biological products, vaccines, sera etc. (Klass: 1975). According to Davis, the changes in the structure of science and in the organisation of medicine during the Industrial Revolution provided the essential foundations for the modern pharmaceutical sector (Davis: 1997). Besides this, the 19th century witnessed a growth spurt in the number of pharmaceuticals as a huge number of chemicals were purified from natural sources. Anaesthetics like morphine (1806), ether (1842), chloroform (1847), and cocaine (1860) and other therapeutic substances such as strychnine (1817), quinine (1820), and nicotine (1828) were introduced to medical care. In 1865 when Joseph Lister used phenol (carbolic acid) to prevent infections, it paved

5. Arnold, David (1989), *Imperial Medicine and Indigenous Societies*, OUP, Delhi, p.12.
6. Klass, Alan (1975), *There's Gold in Them Thar Pills*, Penguin Books, London, p.35.
7. Davis, Peter (1997), *Managing Medicine- Public Policy and Therapeutic Drugs*, Open University Press, Buckingham.

the way for the modern era of antiseptic surgery in England. In other words, these developments took the allopathic medicine to an age of "curative confidence."

According to Ivan Illich the age of new drugs began with the entry of therapeutic usage of aspirin in 1899. Before this only a few substances - opium, smallpox vaccine, quinine for malaria, ipecac for dysentery - were used safely and effectively. Since 1899 there had been a flood of new drugs in the next five to six decades, of which a few were considered to be effective, safe, and comparatively cheap (Illich: 1976).

From the very beginning of 20th century, the medical sciences and modern allopathic therapy began to move to new heights. This consequently gave an impetus to the pharmaceutical industry. In 1935, Dr.Gerhard Domagk, a German scientist, discovered "Prontosil" while conducting experiments related to the germs-killing properties of red dyestuffs. Subsequently, medical practitioners started using prontosil effectively against many diseases such as pneumonia, urinary infection, childbed fever, and scarlet fever. Later, research related to the prontosil led to the development of sulpha-drugs, which thereafter became crucial to the treatment of infectious diseases (Chaturvedi: 1990). With the discovery of penicillin by Alexander Fleming in 1928 the era of antibiotics began. The commercial production of penicillin was initiated by Flory & Chain along with other US companies on a small scale in 1941 and later on a large scale in 1944. When Selman.A.Waksman discovered streptomycin in 1943, it became a watershed in the treatment of tuberculosis. Thereafter, there was an array of

8. Illich, Ivan (1976), *Limits to Medicine-Medical Nemesis: The Expropriation of Health*, Penguin Books, London, p.82.
9. Chaturvedi, Harivansh (1990), *Drug Industry, Social Responsibility and the Multinationals*, Commonwealth Publishers, New Delhi, pp.10-11.

discoveries as chloramphenicol and neomycin in 1949, oxytetracycline in 1950, reserpine in 1952, and tetracycline in 1953.

After 1950 there was a shift in the focus of R&D in the drugs and pharmaceutical industry. The R&D of the pharmaceutical companies started focusing on mainly mental, heart and cardio vascular diseases. In other words, treatment of lifestyle diseases became the focus of pharmaceutical companies. As a result, more and more antidepressants, diuretics, and antihistamines found their place in the market. In the 1960s well-known tranquilisers such as valium and librium were introduced by Swiss companies. The production of contraceptives was yet another area where companies invested more time and energy (Chaturvedi: 1990).

Over the time there has been a fundamental change in the therapeutic classes in the markets. A few decades back it was antibiotics that dominated the markets. Whereas, nowadays the therapeutic classes driving growth in the world markets are anti-depressants, atypical anti-psychotics, cytostatics, anti-diabetics, erectile dysfunction preparations, and anti-obesity preparations. Therefore one important point to be noted here is that drugs for life style diseases are taking the centre stage of world drug production and the drugs for the treatment of so-called 'tropical diseases' are not the top priority in the world market.

1.3. Characteristics of the Drugs and Pharmaceutical Industry

1.3.1 Concentration

There are two forms of concentrations: geographical concentration and structural concentration. According to Sanjaya Lall, geographical concentration shows

10. *Ibid, p.11.*

how drug production is dispersed between the developed and less developed worlds and structural concentration gives an indication of the supremacy of the MNCs in international drug production (Lall: 1981). According to UNIDO, the world's largest and sophisticated pharmaceuticals are from the developed market economies. They accounted for a share of 67.2 per cent in 1975 and 73.0 percent in 1990 in global drug production, whereas the share of developing countries was 22.6 per cent in 1975 and merely 18.4 per cent in 1990. This shows that the share of production in the developing countries has decreased over the years, while the developing countries registered a high growth rate (see table1.1 below). Therefore the industry is geographically concentrated in developing countries. Within this group, countries like US, UK, Japan, Switzerland, Germany, and France are the leading producers.

Table1.1. Geographical Concentration of Global Drug Production.

Country Group	Percentage Share in Worlds Total Production		Growth Rate(percentage) 1975-1990
	1975	1990	
Eastern European countries and USSR	10.2	8.6	4.0
Developed Market Economies	67.2	73.0	5.8
Developing countries	22.6	18.4	3.8
World	100%	100%	5.2

Source: UNIDO, 1992

In the case of structural concentration, the data provided by IMS Health Inc., shows that the top ten MNCs enjoy the market share of 38.2 per cent in 1999 and the top

11. Lall, Sanjaya (1981),"Economic Considerations in the Provision and Use of Medicine" in Blur, Richard et.al (ed), *Pharmaceuticals and Health Policy*, Groom Helm, London, p.187.

20 MNCs have the market share of 59.1 percent in 1999 (OPPI, 1999). This structural concentration has been consistentently present for a long time. According to Sanjaya Lall, 30 leading firms had a market share of 52.0 per cent in 1974 (Lall: 1981).

While discussing the production structure of the industry in developed countries Lall argues, " the pharmaceutical market is extremely heterogeneous and comprises a number of sub-markets within which firms have tended to specialise. This has led to concentration within the product classes which is high both in degree and stability"(Lall: 1974:1949). In the product classes the therapeutic categories show a higher level of concentration than that of the pharmaceutical market as a whole (Lall: 1981).

Unlike other manufacturing industries, pharmaceutical industry does not enjoy economies of scale.* Therefore large firms have no special advantage over the small firms. While discussing the economies of scale, Lall comments, " the fact that bigness has succeeded is due to an entirely different set of reasons"(Lall: 1974:1949). In fact, this study makes an attempt to understand this complexity in the Indian context.

1.3.2 Technology- Research and Development

Since the drugs and pharmaceutical industry is a knowledge-based industry, it is highly research intensive. Compared to other non-military industries, this industry shows a high ratio of research expenditure to sales (Lall: 1974). The task of chalking

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12. OPPI (1999), *Global Pharmaceutical Growth Opportunities in the New Millennium*, OPPI, Bombay, p.12.
13. Lall, Sanjaya (1981), *op cit*, pp. 186-87.
14. Lall, Sanjaya (1974), "International Pharmaceutical Industry and Less-Developed Countries- I- Oligopolistic Power of Leading Firms," *Economic and Political Weekly*, Vol.IX, No.47, p.1949.
15. Lall, Sanjaya (1981), *op cit*, p.187.

* This concept is used to explain the predominance of large firms in the world economy. Economies of scale refers to the factors that cause the average cost of production of a commodity to fall as output of the commodity rises.

16. Lall, Sanjaya (1974), *op cit*, p.1949.
17. *Ibid*, p.1949.

out the exact amount of financial input for research and development activities of a pharmaceutical firm is a difficult one. According to Alan Klass the word research is used in three different ways in the industrial world.

1) To an accountant "research" category is a mechanism to avail tax deduction from the government.
2) To sales departments "research" means market testing of a new product to determine its acceptability.
3) Lastly, to the scientific division of the firm, research means "the trial of certain chemicals or biological products in perhaps hundreds, if not thousands, of combinations and formulations to develop a specific drug that may be an improvement over existing treatment" (Klass: 1975:24).

Under these circumstances the figures that are produced by the firms may be misleading. According to Chowdhury, over the years, R&D spending, supposedly for the development of new drugs, has grown to unbelievable levels, from less than US $ 20 million in the 1970s to over US $ 30 billion in the 1990s (Chowdhury: 1995). It is reported that UK companies spent as high as 50.5 per cent of its domestic sales on R&D (Chowdhury: 1995). According to Chowdhury, most often these exaggerated research costs are used as an argument to prolong patent rights period as long as 15 to 20 years. Lall, discussing the R&D aspects of the drugs and pharmaceutical industry, summarises, "the structure of private research and development in the pharmaceutical industry and its

18. Klass, Alan (1975), *op cit*, p.24.
19. Chowdhury, Zafrullah (1995), *The Politics of Essentials Drugs*, Vistaar Publications, New Delhi, p.12.
20. *Ibid*, p.13.

supporting base of patent laws, leads to heavy and not necessarily efficient concentration on R&D in large firms, to a great deal of wasteful expenditure on competitive patenting, and to granting patent protection which can lead to 'excessive' profits" (Lall: 1974:1952). Therefore it could be argued that the drugs and pharmaceutical industrial firms use the exaggerated figures of research spending to realise or maximise profit, through tax deductions and this is done at the cost of original research for new, cheaper, and quality drugs.

1.3.3 Marketing Practices

Historically the pharmaceutical industry is known for its notorious marketing practices. Unlike any other commodity market, "there is a complete separation of identity between the purchaser (the patient) and the choicemaker (the doctor) in the pharmaceutical market"(Lall: 1974:1952). Illich has also discussed the particular characteristic of pharmaceutical products. He observes, "as commodities, prescription drugs...are products that ultimate consumer rarely selects for himself" (Illich: 1976:80). Therefore, in effect, the doctor becomes the effective purchaser rather than the patient. As a result, there is no direct pressure on the doctor to economise the purchase by prescribing drugs according to the income of the patients. Usually, the doctors prefer to prescribe drugs under its brand name. In this state of affairs, the pharmaceutical companies concentrate their marketing and promotion strategies into persuading doctors to prescribe their brand names. Medical representatives play an important role here as they make use of many tactics to persuade the doctors. Lall observes " not only do their visits save the trouble of having to read, but their conversations are unrecorded, they use

21. Lall, Sanjaya (1974), "International Pharmaceutical Industry and Less-Developed Countries- I- Oligopolistic Power of Leading Firms," *EPW*, Vol.IX, No.47, p.1952.
22. *Ibid*, p.1952.
23. Illich, Ivan (1976), *op cit*, p.80.

such tactics as gifts and fast talk gimmicks to win over nurses and receptionists, they sometimes gain access to confidential files to discover doctors' prescribing practice, and they subject recalcitrant doctors to 'concentrated sales assaults' to win them over to their products" (Lall: 1974:1953). In the industrialised market economies, pharmaceutical companies spend huge amounts for drug promotion on doctors. It varies from 2,665 US dollars in Canada, 3,065 dollars in New Zealand to around 8,000 dollars in the UK and the USA per doctor per annum (Chowdhury: 1997). Another important point to be noted down is that of false campaigns and misinformation as a part of marketing. There are many cases of excessive claims, or suppression of side effects and failure to mention the contra-indications in the materials and advertisements used for the drug promotion (Lall: 1974). Major companies like Smith Kline and Eli Lilly had been punished many times for covering up adverse reactions and severe side effects in developed countries like the USA and the UK (Braithwalt: 1986).

Thus, the peculiarity of the pharmaceutical market and the marketing practices has helped the industry to have highly abnormal levels of profit.

1.3.4 Profitability

The United States Task Force on prescription drugs (1968) reported, "in a free enterprise system it is obvious that a company must make a profit. Unless it achieves this primary objective it cannot stay in business. Ample evidence is available to demonstrate that the drug industry has been able to stay in business. It has maintained annual profit based upon net worth which is substantially above that of the average

24. Lall, Sanjaya (1974), *op cit*, p.1953.
25. Chowdhury, Zafrullah (1995), *op cit.*
26. Lall, Sanjaya (1974), *op cit.*
27. Braithwalte, John (1986), "The Corrupt Industry", *New Internationalist*, Issue-165, November, 1986.

major American industry" (Klass: 1975:74). Historically, the profits accruing from the drug industry have been substantially higher than any other industry in both the developed and less developed countries (Lall: 1981).

According to Lall, there are some problems about determining the economically correct rate of profit in the drug industry. This is because there is difficulty in calculating the original R&D expenses, capital base, transfer of prices and the allowance for risk (Lall: 1981). This leaves a lot of scope for manipulation in the accounts. Therefore, it is difficult to come up with exact figures of profit of pharmaceutical firms. As mentioned earlier, pharmaceutical firms make use of different methods to reap high rates of profit. Of these, transfer pricing is the most widely used financial manipulation method. According to Chowdhury, transfer pricing refers to "a method of financial manipulation to shift profits clandestinely from one area of operation to another with a view to depriving the governments of both the host country and the TNC's home country of legitimate tax revenue"(Choudhury: 1995:17-18). Transfer pricing is practiced in both the developed and developing countries. Usually transfer pricing is done through either overpricing of imports or over invoicing. For example, the Puerto Rican subsidiary of Eli Lilly is supplied with the raw materials to produce Darvon, a painkiller, at an artificially and extremely low price. Then subsidiary sells the finished products back to Eli Lilly at an artificially and extremely high price. Therefore, on record, the profit of the Eli Lilly is very low and hence is subjected to very low taxation. The subsidiary, on the other hand, shows a very high profit, which helps the company to pay only low tax according to the Puerto Rican rules. As a result these high profits are again repatriated

28. Klass, Alan (1975), *op cit*, p.74.
29. Lall,Sanjaya (1981), *op cit.*
30. *Ibid.*
31. Chowdhury, Zafrullah (1995), *op cit*, pp.17-18.

back to the parent company i.e., Eli Lilly (Bodenheimer: 1984). On the other hand, over invoicing is done by transferring of old equipments (with nil book value) from one third-world country to another, where they show current market price or even more of the equipment. For example, Pfizer (Bangladesh) imported most of its machinery from its factory in India (Chowdhury: 1995).

The drugs and pharmaceutical industry is known for many other dubious characteristics also. It is corrupt as well as powerful. Australian criminologist Professor John Braithwalte has shown that it has a shoddier record of bribery and corruption than any other industry. His research on corruption found evidence of substantial bribery by 19 out of the 20 largest American pharmaceutical companies. There is concrete evidence of bribes being paid to political authorities as high as cabinet ministers to get drugs approved for marketing and of bribes being paid to social security bureaucrats who are in charge of fixing drug price, quality standards and of subsidisation. In fact, this corruption system embraces health inspectors, tax assessors, political parties, customs officials, hospital authorities, and others (Braithwalte: 1986). It is said that some American pharmaceutical companies have recruited vice presidents whose one of the main functions is to go to jail for the crimes the companies are committing. Their prime responsibility is to act as a scapegoat for the corporate crime and thus to protect the chief executive of the corporation (Braithwalte: 1986).

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32. Bodenheimer, S. Thomas (1984), "The Transnational Pharmaceutical Industry and the Health of the Worlds People" in Mc Kinlay, B. John(ed), *Issues in the Political Economy of Health Care*, Tavistock Publications, New York.
33. Chowdhury, Zafrullah (1995), *op cit.*
34. Braithwalte, John (1986), *op cit.*
35. *Ibid.*

1.3.5 Major Targets of the Drugs and Pharmaceutical Industry

Women, children and the elderly population, who cover at least two-thirds of the world's population, are the major targets of pharmaceutical companies. The pharmaceutical companies view these groups as the most vulnerable sections of the population. Bodenheimer has discussed sexism of the industry. He argues "the very real stresses facing women, particularly working class women, under capitalism are celebrated by the drug industry as a profitable market for the sale of drugs- whether tranquilizers, antidepressants, hormones, or contraceptives"(Bodenheimer: 1984: 206). The industry, to target doctors, makes use of constant and unrelenting publications and advertisements; which portray women as neurotic, depressive, weak, and needing unending varieties of pills to lead a normal life (Bodenheimer: 1984). Incidentally, a disparity has been observed in the prescription for men and women as the latter very often receives more than twice as many prescriptions as the former (Bodenheimer: 1984). In India, Sandoz, one of the leading multinational companies, recommends giving women with anxiety thioridazine, an antipsychotic drug, which is usually reserved for the treatment of severe psychoses such as schizophrenia (Chetley: 1995). Hormone therapy is yet another area where pharmaceutical companies make profit by targeting women. Apart from this, women are the targets for invasive and dangerous contraceptive treatments. As a result, women are at the receiving end of a huge load of contraceptive technology and other reproduction-related drugs (Chetley:

36. Bodenheimer, S.Thomas (1984), *op cit*, p.206.
37. *Ibid.*
38. *Ibid.*
39. Chetley, Andrew (1995), " Pill Pushers, Drug Dealers," *New Internationalist*, Issue No. 272.

1995). Therefore, it could be argued that the drugs and pharmaceutical industry has been sexist in its nature.

As a part of natural process of building up immunity, usually, children frequently fall ill. In most of the cases these are not very serious illnesses. Therefore, in most of the cases drugs are not required for the treatment. According to the WHO, two-thirds of all drugs used by children may be of little or no value (Chetley: 1995). A study conducted in Brazil in 1992 among 6,000 children aged between three to four years revealed the fact that nearly 60 per cent had used one or more drugs in the previous two weeks and nearly 10 per cent had been given medicine daily for a month or more. The medicines were used basically to cure the problem of "loss of appetite." Chetley also points out that pharmaceutical companies have used measures such as free samples, promotional toys and children's clubs to directly target children in countries like Malaysia and the Philippines. Chetley argues that the rationale behind selling unnecessary drugs for children is to shore up a habit of a lifetime (Chetley: 1995).

It is true that the prevalence of health problems is high among the elderly. One out of every six people in the US is over 60 and they consume one out of every two sleeping pills, two out of every three antihypertensives, one out of every three antidepressants and two out of every five gastrointestinal drugs. In the case of the elderly people, the over prescription for senility related ailments is a significant problem. Doctors over-prescribe without recognising the fact that old people metabolise drugs differently and their problems are diverse (Chetley: 1995).

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40. *Ibid.*
41. *Ibid.*
42. *Ibid.*
43. *Ibid.*

1.4. Drugs and Pharmaceutical Subsystem in the Larger Social System

The Cartesian-Newtonian dualistic-mechanistic paradigm had its impact on the very concept of "health" and "disease." The reductionism advocated by this model conceives the human body as a sum total of its mechanistic parts and further, disease is conceived as malfunctioning of these parts that could be repaired like any other machine. According to this paradigm, hospitals are workshops for the repair of malfunctioning human body. Furthermore, the drugs and other pharmaceuticals are considered as the spares and tools to repair the human body. With the ascendance of this mechanistic-technocratic paradigm, the holistic conception of human body and health lost its significance and became sidelined. Therefore the mechanistic- technocratic paradigm, being a mainstream paradigm, provides for an unwarranted importance to drugs and pharmaceuticals in the health care, which itself is a very complex system.

Health care system is a part or subsystem of a larger social system. The other parts or subsystems like social, ecological, economic, and political have profound influence on the health care system. According to Banerji " both the health problems and health practices of a community are deeply embedded within the ecological, social, economic and political systems" (Banerji: 1985:3). The drugs and pharmaceutical sector has been an indispensable part or subsystem of the larger health care system. Therefore social, economic, and political forces also profoundly influence it. Since these systems and sub systems are interrelated, a crisis in the larger system can also lead to a crisis in the sub system and the changes in the larger system has its impact on subsystems.

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44. Banerji, D (1985), *Health and Family Planning Services in India,* Lok Paksh, New Delhi, p.3.

Navarro has focused on the crisis of medicine in his book *Crisis, Health and Medicine- A Social Critique.* According to him, the crisis of medicine, which is characterised by continuously rising health costs and ever-growing health expenditure, accompanied by a relative ineffectiveness of those health care interventions, relates to the crisis of capitalism. Medicine being a part of the whole, i.e. capitalist society, is not free from crisis. Therefore, Navarro writes, "the crisis of medicine under capitalism is the crisis of capitalism in medicine"(Navarro: 1986:2). He further builds up his argument based on the premise that the sectoral crises are sectoral realisation of the overall societal crisis. Therefore internal contradictions in the different parts of a whole are interrelated. However, this does not mean that whatever happens in medicine is just a reflection of the whole or other outside forces. Medicine being a part has an opacity of its own. Therefore the relationships between the whole and its parts are not wholly deterministic. In the early decade of this 20th century, Gramsci has indicated, " it is precisely in the periods of crisis that the relationships between the parts and the whole appears most clearly."*

Ivan Illich has also discussed the complex relationships of the drug industry and the structure of society. Illich uses the concept "iatrogenesis" to explain the damage that has been perpetrated by allopathic medicine. Illich argues that the crisis of over prescription and over consumption are consistent with the ideology of the society oriented towards open-ended enrichment, regardless of whether its industrial product is meant for distribution by the presumption of planners or by the forces of market (Illich: 1976).

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45. Navarro, Vicente (1986), *Crisis, Health, and Medicine: A Social Critique,* Tavistock Publications, New York, and p.2.

* As quoted by Navarro, Vicente (1986), *ibid,* p.2.

46. Illich, Ivan (1976), *Limits to Medicine-Medical Nemesis: The Expropriation of Health,* Penguin Books, London.

A book published by WHO in 1997 notes that "pharmaceutical policy reform must be viewed in the broader context of socio-economic change, changes in the political ideology, health sector reform and trends towards globalisation"(Bennett et.al: 1997:88). This itself reveals the relationship between the drugs and pharmaceutical system and broader political and economic systems.

1.5. Objectives of the Study

This study attempts modestly to study the above complexity of factors by first tracing the evolution and growth of the Indian drugs and pharmaceuticals sector, and identifying the factors outside and within the system contouring its growth. By reviewing the literature and policy documents relating to the drugs and pharmaceutical sector, the issues and problems of Indian drugs and pharmaceutical sector are contextualised in the wider contours of national and global political economy.

Given the broad objectives of the study above, some of the specific research problems that the present study attempts to answer are the following:

- India has been known for its abundant raw materials for drug production. In such a background what hindered the natural growth of indigenous drug production in India during colonial rule?
- The indigenous production of drugs and pharmaceuticals started in the first decade of 20th century. However it did not grow as it ought to or might have. Even after Independence the multinational corporations enjoyed monopolistic market

47. Bennette, Sara et.al (1997), *Public- Private Roles in the Pharmaceutical Sector: Implications of Equitable Access and Rational Drug Use* , World Health Organization, Geneva, p.88.

structure and import based production structure in India. In these circumstances why did Indian drugs and pharmaceutical sector remain unprotected and underdeveloped?

- Why did the Indian government fail to bring in a new patent policy that favours drugs and pharmaceutical industry immediately after the independence and what was the political economy of the New Patent Act of 1970?
- What was the political economy of policy level changes during the 1970s? And what made the Indian government to announce a national drug policy in 1978? And what was the impact of these policy level decisions?
- What made India opt for liberalisation in the drugs and pharmaceutical sector? And what would be the impact of TRIPS in Indian drugs and pharmaceutical sector?
- What has been the role of the state in providing cheaper and quality drugs to the people?

1.6. Period of the study

As is evident, this present study covers a wide time period starting from the early decades of 19th century to the present decade. The study covers the examination of Indian drugs and pharmaceutical sector in three different phases of capitalist growth in India, viz. the colonial period, the early decades of post-Independence and during the period of globalisation. During these different historical stages there have been many fundamental changes in the economic and political systems in India. Governmental policies ever since the colonial rule have been influencing the growth and evolution of

Indian drugs and pharmaceutical sector. However, the study is more focused on the post-1970 period of Indian drugs and pharmaceutical sector.

1.7. Sources of Data

The present study is largely based on secondary data sources, although some primary data such as Annual Reports of the Ministry of Chemicals and Fertilizers have also been perused. Annual Reports of the governmental and non-governmental organisations, and the reports of various committees and study groups constituted by the government are basically used as the sources of data. In addition, the study has also analysed the work of various scholars of the Indian drugs and pharmaceutical industry over this period. Following are the details of the data sources:

- Bhore Committee Report (1945).
- Chopra Committee Report (1948)
- Report of the Pharmaceutical Enquiry Committee (1954)
- Report of Health Survey and Development Committee (1962)
- Report of the Hathi Committee (1975)
- Report of the ICSSR-ICMR Study Group for Health for All (1981)
- NCAER report on Problems and Perspectives of Indian Drug Industry (1984)
- Annual reports of Ministry of Chemicals and Petrochemicals
- Annual reports of Organisation of Pharmaceutical Producers of India (OPPI) and Indian Drug Manufacturers' Association (IDMA)
- Indian Pharmaceutical Guide published by Pamposhak

1.8. Chapterisation

The study is divided into five chapters. The first chapter basically gives an introduction to the drugs and pharmaceutical industry in which it discusses the history and the characteristics of the industry. The chapter also makes an attempt to locate the drugs and pharmaceutical sector in the larger social system. The last part of the chapter presents the methodology of the study. The second chapter outlines the history of Indian drugs and pharmaceutical industry during the colonial rule and immediately after the Independence. The discussion in this chapter includes different aspects of the sector such as the patent policy, the structure of the industry, and role of the state in the drugs and pharmaceuticals sector. The third chapter deals with the political economy of policy changes during the 1970s and early 1980s and its impact on the Indian drugs and pharmaceutical sector. The fourth chapter attempts to understand the political economy of liberalisation and drugs and pharmaceutical sector. The last chapter provides a brief summary and conclusion of the study.

CHAPTER-II

CHAPTER II

The Growth and Evolution of the Indian Drugs and Pharmaceutical Industry

2.1. Introduction

The development of the Indian drugs and pharmaceutical sector, compared to its international counterpart, does not have a very long historical background. Moreover the steady growth of Indian national sector has only a short history of 25-30 years. This chapter makes an attempt to trace the factors that influenced the drugs and pharmaceutical sector during the colonial period and early decades of post-independence in the broader political and economic environment. At the same time, with the purpose of understanding the policy level interventions of the government and their impact, the chapter makes a brief review of important government documents and literature on the drugs understanding the policy level interventions and pharmaceutical sector.

2.2. The Backdrop

Any discussion on developmental issues would be incomplete without understanding the colonial background of India. It is a widely acknowledged fact that, under colonial rule India experienced fundamental transformation. According to Bipan Chandra " from the mid-18th century and in particular, from the beginning of the 19th century, India had been gradually integrated into the world of modern capitalism although in a subordinate or colonial position"(Chandra: 1975:2-3).

1. Chandra, Bipan (1975), *Nationalism and Colonialism in Modern India*, Orient Longman, New Delhi, p. 2-3.

Consequently, this integration paved the way for the "development of underdevelopment" in India.

Patnaik in his book *Whatever Happened to Imperialism* has discussed at length about the colonial Indian economy. According to him, the European capital extracted surplus from the colonies, particularly in the form of commodities that was required for the industrial expansion in Europe (Patnaik: 1995). In fact, the colonial policies were drafted in such way that it would lead to the construction of a new structure, which again would make the surplus capital extraction process more effortless and smooth. Moreover, it was this same colonial rule which made the Indian economy an unequal member of the international economy. Patnaik uses the phrase "network of unequal interdependence" to denote this relationship between colonial countries and its masters (Patnaik: 1995). The policies and colonial structure have done an irreparable damage to Indian economy basically in three ways: 1) it destroyed the traditional industries and rural crafts, 2) it led to forced production of primary commodities for exports, 3) it suppressed the native bourgeoisie (Patnaik: 1995). Therefore, India could not enjoy any of the benefits of so-called fruits of capitalism even after it was integrated into the international capitalist economy.

The two World Wars and the Great Depression had its impact on Indian economy. Foreign trade, the great engine of development, and the inflow of the foreign capital were reduced or interrupted drastically during these years. "The process of British capital imports was temporarily slackened"; notes Chandra

2. Patnaik,Prabhat (1995), *Whatever Happened to Imperialism and Other Essays*, Tulika, New Delhi, p.63.
3. *Ibid*, p.63.
4. *Ibid.*

(Chandra: 1975:8). Consequently, the domestic market, which was then extremely limited, became available to Indian indigenous industries. Apart from this, another important point to be noted is that the colonial government was compelled to purchase more goods from local producers to meet war-time needs. Apparently, this gave an impetus to Indian capitalist development. Under these circumstances Indian capitalists could make huge profits. These new developments helped Indian economy to loosen its economic ties with the metropolitan capital. This resulted in the strengthening of the financial base of Indian capitalist class (Chandra: 1975).

During this period, simultaneously, the Nationalist Movement was at its threshold. The Non-Cooperation Movement with its swadeshi and boycott programmes weakened the link between Indian economy and the world capitalist economy. However, later, once the international economy revived from its stagnation during the Great Depression, the gains that were made by Indian capitalists during the World War I and the Depression period was seriously threatened. At this crucial juncture, the Indian capitalist class — the Birlas, the Dalmiya-Jains, the Singhanias, the Thapars and others — extended their whole hearted support to the National Movement. Similar to the World War I experience, during the World War II Indian capitalists made huge profits as they could expand their business in the new economic and political conditions where no fresh British capital entered then Indian soil. In the mean time, Indian capitalist class could subsidise the financial base of the British capital (Chandra: 1975).

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5. Chandra, Bipan (1975), *op cit*, p.8.
6. *Ibid*, p. 12-15.
7. *Ibid*, p.8.

Since the 1930's onwards, empowered Indian capitalist class had been intervening in the national politics in a significant way. They thwarted Nehru's attempt to evolve a left political alternative to the Gandhian leadership by supporting the right wing political leaders in the Congress Party. According to Chandra "...supporting the right wing in the Congress also played an important role in first containing him (Nehru) and then moulding him so that, by 1947, the capitalist class was ready to accept him as the prime minister of independent India and to cooperate with him in the task of building up its economy along the capitalist path"(Chandra: 1975:202-03).

The alliance of Indian capitalist class and the right wing leaders of the Congress Party was instrumental in pushing through the capitalist agenda. For example, the Bombay Plan, which visualised planning as an aid to capitalist development, introduced a blue print for development in which the imperial hegemony would be taken over by domestic bourgeoisie. The Mahalanobis developmental model that glorified the "trickle down" approach for the Five Year Plan also contributed to these efforts.

The government implemented developmental activities through Five Year Plans (FYPs) from 1951 onwards. As a result, during the period 1950-65, India experienced laudable industrial growth. This, in fact, helped the state to become the single biggest capitalist in the country, with a 60 per cent share of the investment made in the public sector. However, a series of tragedies such as Indo- China war (1962), Indo-Pak war (1965) and drought and famine of 1965 together put the progress in a reverse gear. The rising expenditure of defence, lack of buoyancy in the government revenue, lack of effective demand in the home market and legal

8. *Ibid*, pp.202-203.

barriers in using product patented technology for industrial purposes altogether contributed to the industrial slow down in the post- Nehruvian period. The National Planning Commission faced attack from different sides. At this crucial juncture, when India approached the World Bank and United States Agency for International Development (USAID) for aid, they presented a package of economic reforms which broadly aimed 1) to get the Indian Government to reorient its national priorities in favour of agriculture to generate demand for chemical fertilizers and other agricultural inputs supplied by the MNCs; 2) to get the industrial licensing and controls (including import controls) liberalised for allowing a greater role to private capital; and 3) to force devaluation of rupees to increase foreign investors' command over Indian economy(Swamy:1994). Thereafter, by accepting this package, the public sector, the engine of industrial growth and the industries across the board got into the phase of stagnation.

From the very beginning, capitalist development in India has been facing serious contradictions. The state has to perform two mutually mismatched roles: the first one is that it has to keep expanding its investment as the chief means of stimulating growth. The second is to serve as an instrument for the primary (or primitive) accumulation of capital by the capitalist class and landlord class. At the same time, the Indian capitalist class is noted to be prone to and compromise and collaborate with the imperialism even while confronting it. The very amorphousness

9. Swamy, Dalip Singh (1994), *The Political Economy of Industrialisation*, Sage Publishers, New Delhi, p.76.

of the ruling class alliance robbed the state of the ability to enforce any degree of discipline upon any section of this alliance (Patnaik: 2000).

2.3. Indian Drugs and Pharmaceutical Sector during the Colonial Period

The allopathic system of medicine entered Indian soil during the period of colonialism. According to Arnold, allopathic medicine "..forged new and powerful links between the imperial capitals and distant colonial domains" like India(Arnold:1989:13). He argues that even in the latter part of the nineteenth century, the segregation of lepers and lunatics and vaccination were among the few medical services provided. Later, there had been significant level of involvement of colonial regime in the "indigenous health care." There were several imperatives behind this increased involvement (Arnold: 1989). One of them comes from the understanding that the health of the civilians and the European military could not be achieved through the measures targeting their health alone. Moreover, their increased vulnerability to the so-called 'tropical diseases' also compelled them to take measures to contain these deadly diseases. Another important point to be noted here is that the mortality and morbidity rates among the colonial working class slackened the efficiency and the profitability of production in plantations, mines and factories and therefore of the commercial and industrial enterprises. The colonial regime thus had to intervene in colonial health, especially of the productive section of the colony. According to David Arnold "..while the mine compounds, the plantations, barracks and the main urban centres were favored there was a general neglect of the rural population and of the health of the women and children. In effect,

10. Patnaik, Prabhat (2000),"The State in India's Economic Development" in Hassan, Zoya (ed), *Politics and the State in India*, Sage, New Delhi.
11. Arnold, David (1989), *Imperial Medicine and Indigenous Societies*, OUP, Delhi, p.13.
12. *Ibid*, p.15.

this led to the growth and development of study of tropical medicine"(Arnold: 1989:15).

The production of modern drugs in India was first started in the public sector by the British government. The British government established factories to process opium and cinchona bark in 1870 and 1871 respectively. In the last quarter of 19th century the British government also started the Government Medical Stores Depots which later turned into the production centres for drugs and pharmaceuticals, for the supply and storage of medicine (Government of India: 1954). With the aim of developing the allopathic system of medicine in India, the British set up a teaching institution in Calcutta in 1935 to impart knowledge about medicine and trained medical practitioners (Banerji: 1986). Before the 20th century, pharmacology and chemotherapy were not much developed as only a limited number of chemical raw materials were being used for the therapeutic purposes. According to Ramachadran and Rangarao: "The pharamacopeas and materia medicas* of those days contained mainly galenicals# and inorganic chemical preparations. The raw materials Cinchona Bark, Nux Vomica seeds, Poppy seeds etc. were shipped from India to England and returned as extracts or tinctures for the physician's use" (Ramachandran and Rangarao: 1972). In fact, India was just a periphery for the supply of raw materials for British industry.

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13. *Ibid*, p.15.
14. Government of India (1954), *Report of the Pharmaceutical Enquiry Committee*, Ministry of Commerce & Industry, New Delhi, p. 434.
15. Banerji, D (1985), *Health And Family Planning Services In India*, Lok Paksh, New Delhi.

* The term *materia medica* generally refers to the drugs of vegetable and animal origin.

\# Galen, the Greek physician who practiced in Rome in A.D 200, classified a large variety of herbs and also developed the techniques of extracting them. Therefore, the products derived from such herbs are generally known as galenicals.

16. Ramachandran, P.K and Rangarao,B.V (1972)," The Pharmaceutical Industry in India", *Economic and Political Weekly*, Vol.VII, No.9, p.M-27.

No single Indian enterprise existed in the drugs and pharmaceutical sector until Acharya Prafulla Chandra Roy, a firm nationalist, in 1901 established the Bengal Chemical and Pharmaceutical Works in Calcutta. Thus, it has the distinction of being the first Indian owned drug factory in the history of Indian drugs and pharmaceutical sector. Likewise, the other notable efforts in this area was that of Messers T.K. Gajjar, B.D. Amin and Koti Bhaskar,[♣] which had influenced the setting up of small units for the production of galenicals and other simple drugs (Government of India: 1975). Even though, "the indigenous production of allopathic medicine made a fledgling start only in the first quarter of twentieth century after which it grew at a snail's pace" (Kumar: 2001: 356). Through the biased policies the British controlled and monopolised the Indian market. The policies of the British government did not entertain the idea of drug substitution in India. They rejected the proposals for the indigenous private manufacture of alkaloids such as morphine, heroine, codeine, and denonin. The government continued old practice of importation, which shrunk the possibility of development of a strong indigenous drugs and pharmaceutical sector (Kumar: 2001).

With the dawn of the 20th century the germ theory started establishing its presence in epidemiology. As a result, it strengthened the practice of chemotherapy and prophylaxis. Therefore the further development of Indian sector should be analysed in this background.

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17. ♣Gajjar T, Amin B.D.and Kodi Bhasker together started Alembic Chemical Works in 1901.
18. Government of India, (1975), *Report of the Committee on Drugs and Pharmaceutical industry*, Ministry of Petroleum and Chemicals, New Delhi.
19. Kumar, Anil (2001), "The Indian Drug Industry under the Raj, 1860-1920," in Pati, Bismoy and Harrison, Mark (ed), *Health, Medicine and Empire*, Orient Longman, New Delhi, p.356.
20. *Ibid*, p.366-367.

A serious attempt of state involvement in the drugs and pharmaceutical sector could be traced back to the establishment of Haffkine Institute at Bombay in 1904.* This and other research institutions mainly engaged in the research related to "tropical diseases." As research progressed, information about the epidemiology of diseases also developed. For example, Ronald Ross identified the anopheles mosquito as the vector of malaria, a disease that caused a huge mortality load among the British military personnel. Short and Swaminthan identified the sand fly as the vector of Kala Azar. Apart from these, the different types of sera and vaccine that were produced also had been used extensively to control the killer diseases like cholera, small pox, and typhoid (Ramachandran And Rangarao: 1972). However they hardly succeed in this task primarily because the colonial state was unwilling to make the financial commitment necessary. At the same time, according to Arnold, there had been opposition and apathy towards vaccination and other measures like inoculation due to the "ambivalent or hesitant attitude" of the colonial state and other factors like the divided nature of medical opinion on diseases and their treatment (Arnold: 1993).

2.3.1. The Impact of the World Wars

During the World War I, research on chemotherapy reached into new heights. Consequently, the use of chemicals in the treatment of diseases became more effective and thereby popular also. Here the contributions of some of the individual efforts are worthy of mentioning. Paul Ehrlich and Gerhard Domagk are the two individuals who made a significant contribution to chemotherapy and the industry. The chemical and

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* During the first decade of 20th century, the British Government established 1) Haffkine Institute at Bombay (1904), King Institute of Preventive Medicine at Madras (1904), Pasteur Institute at Conoor (1907) and the control Research Institute at Kasauli (1905).

21. Ramachandran and Rangarao, B.V (1972), *op cit*, p. M-27.
22. Arnold, David (1993), *Colonising the Body*, OUP, New Delhi.

dyestuff industry could enter into the field of pharmaceuticals because discoveries of Paul Ehrlich and Gerhard Domagk have replaced the role of animal and vegetable substance by chemical and synthetic substance in the therapeutic usage. Furthermore, it was in this period that the synthesis of the active constituents and studying their action became a main research area of organic chemists. The use of aspirin – the wonder drug, acetanilide, barbital, and adrenalin etc, are the result of that sort of research (Government of India: 1975).

Meanwhile, in India the cessation of imports during the First World War years gave impetus to the industry to produce medicines locally. Moreover, the withdrawal of German chemical industries posed a big threat to the pharmaceutical sector (Government of India: 1975). With the First World War experience, for the first time in the history, the colonial government realised the fact that raw materials and drugs should be made into medicine where they are naturally available. Thus cutting off of earlier sources of supply and imposition of tariff on imported manufacture boosted local production. The value of drugs exported increased from Rs.15.5 lakhs in 1908-09 to Rs.41.6 lakhs in 1928-29(Kumar: 2001). During this period there had been many important research and development activities (Government of India: 1975). Through local R & D activity, a new compound, urea-stibamine was developed. It was then quite useful for the treatment of Kala–Azar. Another useful effort was that of manufacturing caffeine from tea waste. The increased research and development had its impact on industrial production. The industry undertook the production of the biological products like sera and vaccines, anaesthetics like ether and chloroform, and coal tar distillation

23. Government of India (1975), *op cit*, p.16.
24. *Ibid*, p.16.
25. Kumar, Anil (2001), *op cit*, p.380.
26. Government of India (1975), *op cit*, p.16.

products such as naphthalene, cresol etc (Government of India:1954). According to the Hathi Committee "in spite of such development, the progress was far from being satisfactory"(Government of India: 1975:16). Immediately after the World War I, the imports that were stopped during the war years resumed again. Therefore, the industry in its infancy received a setback as no restrictions were imposed on import, which resulted in unfair competition (Government of India: 1954).

It should be noted that the lack of dependable pharmacological knowledge and the apprehensions of failing to compete with imported drugs desisted major Indian industrial and commercial classes from drug production. Those who ventured into the drug production were mostly professional chemists. For example, in 1935, Khwaja Abdul Hamied, a western educated chemist, set up The Chemical, Industrial & Pharmaceutical Laboratories, which came to be popularly known as Cipla and started drug production using patent and proprietary formulas. Cipla later became India's leading drug manufacturing company in the private sector.

By 1939, the indigenous producers met 13 per cent of the total medical requirements of the country (Government of India: 1954). Till the start of World War II the British government kept India as its exclusive preserve for unloading drugs produced in its home country. British manufacturers marketed drugs basically through those British trading companies that were established in India. Therefore, even though there had been entrepreneurial efforts from Indians, it hardly made any significant impact in the sector. However it was a beginning of a new period, though short.

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27. Government of India (1954), *op cit*, p.17.
28. Government of India, (1975), *op cit*, p.16.
29. Government of India (1954), *op cit*, p.17.
30. *Ibid*, p.18.

During the war years, especially during World War II, British India faced a severe shortage of imported medicaments. This resulted in the mushrooming of small manufacturing units. They produced those products that found a ready market (Ramachandran and Rangarao, 1972). During the first half of 1940's, the country almost became self-sufficient in the production of sera and vaccines. According to the Report of the Pharmaceutical Enquiry Committee, both the production and demand also increased during the early phase of 1940's. The Indian producers who were producing only 13 per cent of the total requirements in 1939 were in a matured position to meet up to 70 per cent of the requirements of the country by 1943. Another notable point is that the Government demand also had increased during this period for meeting the requirements of the armed forces in West Asia and the Far East. (Government of India: 1954).

The major discoveries and large-scale production in the pharmaceutical industry occurred during the post – Great Depression period, more specifically 1940-1965. Large-scale production of penicillin was started in 1944 in USA, streptomycin, which is effective against T.B., in 1943; chloramphenicol and neomycin in 1949, oxytetracycline in 1950; reserpine in 1952 and tetracycline in 1953. In 1960's the tranquilisers-librium and valium*- were introduced to the world market by Swiss companies (Chaturvedi: 1990). These discoveries and industrial production of drugs contributed to the growth spurt in the world drugs and pharmaceutical industry.♣ In this process the US and Swiss manufacturing companies took the lead.

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31. Ramachandran and Rangarao, B.V (1972), *op cit.*
32. Government of India (1954), *op cit.*

* The sale of librium and valium helped Roche, a Swiss company, to amass huge profit.

33. Chaturvedi, Harivansh (1990), *Drug Industry, Social Responsibility and the Multinationals*, Commonwealth Publishers, New Delhi.

♣ See OECD Report, March 1968, pp. 22-23, OPPI (1971) p. 10.

The drugs and pharmaceutical market, especially of developed market economies, got enriched with diverse products as a result of increased R&D activities and marketing. Consequently, as the logic of capitalism demands, pharmaceutical companies and their products began to move horizontally across geographical boundaries. This movement, basically, was from European and American countries to the third world countries of Asia, Africa and Latin America. These pharmaceutical TNCs with the advantage of having huge monetary capital, technology and effective marketing techniques started yielding profit from so-called third world countries.

Under the above mentioned circumstances the Indian units were at disadvantage in competing with foreign companies in the production and marketing of the drugs and pharmaceutical products. As a result, a number of Indian manufacturers gave up even the little production and jointed the ranks of formulators (Rangarao: 1975). Therefore, the Indian drug sector after an infantile rapid growth during World War II entered the phase of retardation. These efforts, especially during World War period, however small, contributed to the development of a sense of nationalism, like in many other industrial sectors, in the Indian pharmaceutical industry (Mazumdar: 1986).

2.4. The Bhore Committee Recommendations on Drugs and Pharmaceutical Sector

The Government of India appointed the Health Survey and Development Committee in 1943 under the chairmanship of Joseph Bhore. The setting up of Beveridge Committee in UK and the developments in USSR had its influence on the

34. Rangarao, B.V (1975), "Indian Drug Industry: Status and Perspective," *Mainstream*, March 1, p.16.
35. Mazumdar, J.S (1986), "Background Paper" in Sengupta, Amit(ed), *Drug Industry and the Indian People*, Delhi Science Forum and F.M.R.A.I, New Delhi, p.8.

Bhore Committee (Banerji: 1985). The Bhore Committee comprised experts from different walks of life and was appointed basically to make:

I. A broad survey of existing position in regard to health conditions and health organization in British India.

II. Recommendations for future developments.

After surveying the health condition and health organisation in India, the Committee submitted its report in 1946. The most salient guiding principles adopted by the Committee were: 1) No individual should be denied adequate medical care because of inability to pay for it; 2) the health programme must, form the beginning, lay special emphasis on preventive work; 3) the health services should be located as close to the people as possible to ensure the maximum benefit to the communities served; 4) Medical relief and preventive health care must be urgently provided to as early as possible to the vast rural population of the country (Government of India:1946). Besides this, the Committee highlighted the need for social orientation of medical practice and people's participation.

On the basis of the above mentioned principles the Committee made two types of recommendations: 1) a comprehensive blue print for the long term development; and 2) a short term scheme covering two five year plans. According to the long-term plan, the smallest service unit was to be a Primary Health Unit, serving a population of 10,000 to 20,000. Apart from this, the Committee recommended a few more institutional mechanisms such as a District Health Organisation in each district

36. Banerji. D, (1985), *Health and Family Planning Services in India,* Lok Paksh, new Delhi, p. 18.
37. Government of India. (1946), *Health Survey and Development Committee (Bhore Committee): Report*, Vol.1, Manager of Publications, Delhi.

headquarters to address the health issues of the people. Under the short term scheme the stress would be on the establishment of 30-bed hospitals, one for every two Primary Health Units. To elicit the active participation of the people in the health programmes, the Committee recommended the setting up of village Health Committee.

The Committee had its specific recommendations to offer about the different specific areas of the health care. In the report, the Bhore Committee noted the importance of the therapeutic substances and medical appliances without which doctors and public health workers generally may be reduced to a state of virtual impotency in the practical exercise of their profession (Government of India: 1946). Thus the committee was mindful about the importance of the therapeutic substances and medical appliances.

The Bhore Committee registered its apprehension over the supply structure, price structure, monopoly character of the industry and control mechanisms that existed in the country. They called for immediate attention and remedy. The Committee warned about the "human greed and the world causes" that would limit or interrupt the bulk of poor people's accessibility to cheap and effective medical supplies (Government of India: 1946).

After exploring the conditions of Indian drugs and pharmaceutical sector the Committee realised that only an organised effort could lead the country to self-sufficiency in the matter of drugs and medical requirements. For developing the national sector to a self sufficient one, the Committee emphasised both the need of exploration and exploitation of natural resources, and research and development. The Committee also stood for promoting and encouraging private enterprises in drug production that

38. Government of India. (1946), *ibid*, p.448.
39. *Ibid*, p.450.

they thought would contribute to self-sufficiency in the country. However, there was a strong voice of opposition from Mr. N.M. Joshi, one of the committee members, who argued that the production and distribution of drugs and other medical requirements should be undertaken solely by the state and not be left to private enterprises (Government of India: 1946). As against this argument, the Committee clearly recognised the need for a private sector in the manufacture of drugs. At the same time, they were clear that the state should be solely responsible for the production of prophylactic sera and vaccines for mass use (Government of India: 1946).

"The patents are prima-face to be deprecated if the people's health is our first consideration"- this was the view of the Bhore committee on patents (Government of India: 1946). The Committee also made recommendations for developing organisational mechanism for the sector. They recommended that a committee should be appointed to monitor and control the drug and pharmaceuticals supply. Moreover, to protect the general public from hazardous supply and use of therapeutic substances, the Committee recommended that the profession of pharmaceutical should be reserved for pharmacists (Government of India: 1946).

The Bhore Committee set a vision for the development of health in India as its recommendations gave a comprehensive blueprint for health development in India. As mentioned earlier, the Committee had been very much influenced by the Beveridge Committee of Britain and the developments of erstwhile USSR. The elements of "welfarist" and "socialist" ideology were visible in the committee's recommendations

40. *Ibid*, pp.450-452.
41. *Ibid*, p. 450.
42. *Ibid*, p.450.
43. *Ibid*, p.462.

(Government of India: 1946). However, most of these recommendations were neglected or discarded silently by the government in the changing political and economic conditions.

During the time of Independence, the Indian drugs and pharmaceutical industry was the monopoly of the multinational corporations (MNCs). This naturally helped them to charge high prices for the drugs. Since most of the drug production depended on imported raw materials, the MNCs justified exorbitant drug prices. Apart from this, the indigenous drugs and pharmaceutical industry was not adequately developed. The committee was able to understand this situation to a great extent. It is because of this reason, the recommendations of the Committee addressed the issues such as accessibility and self-sufficiency. However, in this situation the government could not control the monopoly of the MNCs in India. Consequently, as the Committee apprehended earlier, the drug prices went very high, which limited or prevented the poor masses from accessing quality medical care. According to the Report of the Kefauver Committee of the USA (1961), drug prices in India during that period were among the highest in the world. Moreover, as against the committee recommendation, the government could not introduce any price control mechanisms with immediate effect. With regard to the issue of patents and drugs, the government took twenty-four years to enact a favourable patent act. Therefore, in practice, most of the crucial recommendations of the Committee were neglected by the government.

2.5. The Pharmaceutical Enquiry Committee

In 1953, the Government of India set up the Pharmaceutical Enquiry Committee to study the working of the existing pharmaceuticals manufacturing

44. *Ibid*, p. 448-50.

concerns in India with particular reference to the demand for the drugs, the quality of the drugs and the cost of production, the efficiency of the process, basic raw materials, and chemicals. The Pharmaceutical Enquiry Committee submitted its Report in 1954, making a detailed enquiry into the various aspects of drugs and pharmaceutical sector in India.

According to the Committee, when compared to with the drugs and pharmaceutical industry of developed countries like USA and UK, the Indian counterpart may be considered almost nonexistent (Government of India: 1954). The committee noted that the drug industry in India was dependent on imports. Therefore, most of the recommendations of the committee aimed at the development of self-sufficient indigenous drugs and pharmaceutical industry.

The most important recommendation of the Committee was that each manufacturer of pharmaceuticals "..should endeavor to produce as many of the basic drugs as many of the fine chemicals and drugs as possible starting from basic chemicals and/or intermediates as close to the basic chemicals as practicable..."(Government of India:1954:14). Thus, the Pharmaceutical Enquiry Committee showed its concern over the production of drugs from its basic stages, which is very central to the development of drug industry in any country. The Committee studied the operations of both the foreign and Indian undertakings. It recommended "no new foreign concerns should be allowed to set up factories unless they undertake to manufacture products which have not been manufactured in adequate quantities by other factories, starting from basic chemicals and or

45. Government of India (1954), *Report of the Pharmaceutical Enquiry Committee*, Ministry of Commerce and Industry, New Delhi.
46. *Ibid*, p.14.

intermediates as near to the basic chemicals as possible within a reasonable time"(Government of India: 1954:64).

The Committee also found out that the Indian sector was finding it difficult to compete with multinational units, which have both monetary capital and sophisticated technology. Therefore the Pharmaceutical Enquiry Committee strongly recommended that the state should not encourage foreign tie-ups at the cost of Indian sector, though it was a small sector (Government of India: 1954).

Like the Bhore committee, the Pharmaceutical Enquiry Committee also called on the government to encourage the private sector to meet the increasing demands of drugs like penicillin, streptomycin and the insecticides like DDT. The Committee was also of the opinion that the small-scale concerns should be pooled together. However little progress has been made in this direction.

Since the Research and Development activities are sine quo non to pharmaceutical industry, the Committee suggested enhanced state investment in state-owned research laboratories. It specifically pointed out that penicillin factory at Pimpri and the Haffkine Institute should be given more research facilities for future growth.

As regards patents, the Committee observed: "The patent laws of the country should be amended to secure effective utilization of all developments in the field of science and medicine, wherever necessary, in the interest of the country"(Government of India: 1954:65). Since under the colonial Patent Act drugs and pharmaceutical products enjoyed patent protection, the local producers could not manufacture those

47. *Ibid.*p.64.
48. *Ibid.*
49. *Ibid*, p.65.

patent protected drugs. But the irony was that it took 16 more years to amend the Patent Act of 1911, which had been crippling the Indian sector for more than half of a century.

Most of the recommendations of the Pharmaceutical Enquiry Committee had a "Swadeshi" colour as it used a very tough language against the foreign manufacturing units. It is interesting to note that in 1953, the FICCI (Federation of Indian Chambers of Commerce and Industry) also had passed a "Swadeshi Resolution" against the government's liberal policies towards foreign capital in its 16th Annual meeting (Chenoy: 1985).

In fact, the Pharmaceutical Enquiry Committee made a thorough study of the different aspects like structure, strengths and weaknesses of the drugs and pharmaceutical industry in India. It made very significant recommendations that were aimed at a self-sufficient indigenous industry.

2.6. The Mudaliar Committee Recommendations

To survey the progress made in the field of health since the submission of the Bhore Committee Report and to provide guidelines for the national health planning, the Government of India appointed the Health Survey and Planning Committee (popularly known as the Mudaliar Committee) in 1962. After surveying the progress made in the health sector, the Committee made its recommendation for future development and expansion of health services in India. The Mudaliar Committee found the quality of health services provided by the Primary Health Centres (PHC) inadequate. Therefore it advised the government to strengthen the existing primary health centres before new centres were set up. The salient recommendations of the committee were: 1) Consolidation of the progress made in the first two five year plans; 2) Strengthening of

50. Chenoy K.M (1985), " Industrial Policy and Multinationals in India", *Social Scientist*, Vol.13, No.3, New Delhi pp.15-31.

district hospital with specialist services to serve as the central base of regional services; 3) Each PHC not to serve more than 40,000 population; 4) Integration of health services as recommended by the Bhore committee; 5) Constitution of All India Health Services on the pattern of Indian Administrative Services. As part of the report; the Committee made its observations and recommendations about drugs and medical supplies in India.

According to the Mudaliar Committee the following were the major developments that have taken place before it was set up.

1. Enforcement of Drug Act and the establishment of machinery at the Central and the State levels for supervision and control of drug manufacture, distribution, and sale.

2. Passing of the Pharmacy Act and the setting up of the All India and State Pharmacy Councils.

3. The passing of the Drug and Magic Remedies Act.

4. The setting up of a Central Drug Laboratory.

5. Establishment under the public sector plants for the manufacture of penicillin and DDT with the assistance of UNICEF.

6. Increase in the production of drugs by indigenous manufacturers.

7. Grant of licenses to certain foreign drug houses for the progressive manufacture of their product by themselves within the country or in collaboration with the local counterpart.

8. Finalisation of a scheme with the Government of USSR for the setting up of four plants for the manufacture of antibiotics, phytochemicals, synthetic drugs and surgical instruments.

The Committee discussed the issues and problems in drugs and medical supplies under the following headings (Government of India: 1962). (1) Drug industry (2) Drug control (3) Patent law (4)Instruments and appliances (5) Standardization (6) Medical Store Depot Organization (7) Research and cultivation of medicinal plants.

The committee made visits to several manufacturing units and observed numerous problems directly from the field. The deficient quality control facilities or absence of quality control facilities in the medium and small manufactures was one among such problems. Therefore, the Committee emphasised the need of active role of the Drug Control Organization in ensuring the better quality (Government of India: 1962).

The Committee observed that the pharmaceutical industry has to contend with competent know-how, big capital, worldwide sales and competent organization, on the one hand, while on the other hand, it has to face unfair competition from mushrooming units producing quality products (Government of India: 1962).

With the objective of avoiding complex procedures of dual control,* the Committee recommended that the licensing for drugs manufacture, then done by the Ministry of Commerce and Industry, should be the function of the Ministry of Health (Government of India: 1962). This is a very important recommendation because it gave

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51. Government of India (1962), *Health Survey and Planning Committee (Mudaliar Committee) Report*, Ministry of Health, New Delhi, p.418.
52. *Ibid*, pp.423-425.
53. *Ibid*, p. 423.
* Both the Drugs Act and IDRA have provisions for Drugs Control.
54. *Ibid*, p.427.

the message that drug and pharmaceutical industry is not a mere industry that works according to the logic of market but more importantly, must be in consonance with the health needs of the country.

To control the market and to save the nation during the emergency situations the committee suggested the expansion and modernisation of Medical Store Depots. During that time there were five medical stores -- Bombay, Madras, Calcutta, Kirnal and Hyderabad. Therefore, according to the Committee, the ultimate target should be one depot for each of the states.

Like many other committees did in the past, the Mudaliar Committee also made its remarks on patent policy. The Committee was totally against product patents and held the view that patents should cover only process. It also supported the recommendation of Ayyangar that the period covered by the patents should be reduced to 5 to 10 years (Government of India: 1962).

The Mudaliar committee was able to comprehend the problems and issues of the drugs and pharmaceutical industry in India. The Committee could figure out the role of multinational companies in keeping drug prices high. However, the Committee did not recommend any comprehensive strategy to deal with the problems posed by multinationals. At the same time, the Committee's recommendations to establish more Medical Store Depots and to bring the licensing of drugs under the Ministry of Health were very forward looking.

It should be noted that, even after the 14 years of independence, the MNCs enjoyed many benefits such as patent protection for drugs, import based production structure, which helped them to maintain monopoly in the market. Such a hegemonic

55. *Ibid.* p. 431.

presence of the MNCs was detrimental to the health sector as well as to the drugs and pharmaceutical industry. To be more precise, it was detrimental to the health sector because the MNCs charged high prices for drugs, which eventually limited the accessibility of the poor people to medical care. At the same time, with the protection of patent rules and competent capital base and technical know how, the multinationals were indirectly causing stagnation to the growth of indigenous drugs and pharmaceutical industry. Further, once the import substitution became a reality, patent protection, in fact, became an impediment to the growth of Indian indigenous sector. Actually, there were strong waves of dissent against the policy level impediments, which thwarted the growth of both the Indian private and public sector.

2.7. Patent Policy and the Drugs and Pharmaceutical Sector

"A patent is intended to protect a particular product or a process that is the result of inventive thought. The patent permits the holder to forbid commercial exploitation (use, sale, manufacture) of the protected product or process by others in the country or countries where the patent is granted for a limited period (normally 17- 20 years, but the period varies by country and product)"(Belcher and Hawtin: 1994: 267). Generally there would be three specific conditions of eligibility for patents.

1. Novelty –The invention must be new.

2. Utility - It must be useful.

56. Belcher, Brian and Hawtin, Geoffrey (1994), "A Patent Life: Ownership of Plant and Animal Research" in Nair, K.R.G and Kumar, Ashok (ed) *Intellectual Property Rights*, Allied Publishers, p. 267.

3. Inventiveness (or non-obviousness) – It must represent a real advance that might not have been reached without the inventor's creative insight (Belcher and Hawtin: 1994).

The modern patent system directly traces back to a statute from the Republic of Venice in 1474(Belcher and Hawtin: 1994). In India, the first patent legislation was the 'Act for Granting Exclusive Privileges to Inventor's Act (XV of) 1859 which required "Exclusive privileges" to have some utility later. This legislation was brought in so that British patent holders could attain a right to manufacture and market in India. Later, the Inventions and Designs Act, 1888 protected designs and inventions. In 1911, the colonial government enacted the Indian Patents and Designs Act, 1911. The Act set pre-set time limits for processing applications, for providing a time bound framework for objections and for better administrative arrangements. This Act had been amended many times. Of these, the 1930 Amendment extended the life of patents from fourteen to sixteen years (Dhawan et.al: 1991).

Since the colonial patent act had become obsolete and undesirable, the Government of India took many steps to review the working of the patent system in India so that a new patent legislation could be brought in. As early as in 1948, with the objective of reviewing the working of patents in India, the Government of India constituted the Patents Enquiry Committee under the headship of Justice Bakshi Tek Chand. The Patent Enquiry Committee in its interim report pointed out: "The Indian patent system has failed in its main purpose, namely to stimulate invention among Indians and to encourage the development and exploitation of new inventions for

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57. *Ibid.*
58. *Ibid*, p. 266.
59. Dhavan, Rajeev et.al (1991), "Power Without Responsibility on Aspects of the Indian Patents Legislation," *Journal of Indian Law Institute*. Vol. 33 No.1, pp.2-4.

industrial purposes in the country, so as to secure benefits thereof to the largest section of the public"(Government of India: 1948:166-167). The committee recommended substitutes prepared or produced by chemical processes should not be patentable except when made by the invented processes or their obvious equivalent. According to the Patents Enquiry Committee the novelty should be determined on the basis of prior knowledge or prior uses in India. In addition to this, the Committee also recommended that the government must amend the sections in the Patents And Designs Act, 1911 that dealt with compulsory licensing so that the government would be empowered with the special provision to issue compulsory licenses for food, drugs, insecticides, and other curative devices (Government of India: 1948). Some of the recommendations of the Committee were incorporated into the Indian Patents And Designs (Amendment) Act of 1950 and 1952, whereas vital and decisive recommendations of the Committee were spared in the enactment. Later in 1953, a bill regarding the patent issues was introduced in the Lok Sabha. However, this lapsed on the dissolution of the Lok Sabha (Dhavan et.al: 1991).

Efforts have thus been made to bring in a favorable patent act since the very inception of independent India. However, there has been consistent pressure from foreign capital against the moves of the Government to amend the Patent and Designs Act, 1911 as it helped the multinational corporations to establish and continue its monopoly.

The direct intervention of the Prime Minister, Jawaharlal Nehru, in the matters of technical collaboration in the public sector and the Patent Act amendment gave a new

60. Government of India (1949), *Interim Report of the Patents Enquiry Committee*, Ministry of Commerce and Industry, New Delhi, pp.166-167.
61. *Ibid.*
62. Dhavan, Rajeev et.al (1991), *op cit.*

direction to patent politics in India in the early 1950s. According to Tyabji, "it was through his direct experience with the problems posed by the penicillin project that, ...Nehru insisted that steps must be taken to modify the Act to ensure that India's industrialization effort was not needlessly entrapped in frivolous claims to priority in developing manufacturing processes"(Tyabji: 2002:32-33).

The Government of India appointed Justice Rajagopal Ayyangar in 1957 to make a fresh review of the patent policy in India. Justice Ayyangar, after a comprehensive study of the working of patents in India, submitted a report in 1959. The report encompassed far-reaching recommendations to revamp the Indian patent policy. The major findings of Justice Ayyangar were that 1) the patent system was being used by foreigners to establish monopoly in the market and most of the goods are imported at extremely high charges; 2) Since the Patents And Designs Act, 1911 had a provision of right to importation, the country was denied the right to obtain goods for its fundamental and essential requirements from competitive sources in the international market; 3) foreigners held the 80-90 per cent of the patents and of these, 90 per cent of the patents were not being worked in India (Keayla: 1994).

But the irony was that it took six more years to bring a bill that was based on the recommendations of the Ayyangar Report, to the Lok Sabha for the enactment. The Joint Select Committees of the Parliament and members of both the houses of the Parliament examined the bill and eventually, extensive debate took place on this issue. Simultaneously, the bill was subjected to intense lobbying by many firms and

63. Tyabji, Nasir (2002), " Acquiring Know-Why Vs Licensed Manufacture: Penicillin In Nehru's India", Paper presented at the Conference on Shifting Centres and Emerging Peripheries: Global patterns in Twentieth Century Chemistry, Organised by the Commission on History of Modern Chemistry During the XXI International Congress of History of Science, Mexico, 2001, p.32-33.
64. Keayla, B.K (1994)," Patent Protection and the Pharmaceutical Industry"in in Nair, K.R.G and Kumar, Ashok (ed) *Intellectual Property Rights*, Allied Publishers, p.152.

individuals. More significantly, the bill came under vehement criticism from multinational corporations (Kapoor: 1990). Incidentally, as it happened in 1953, this bill also lapsed with the dissolution of the Government in March 1967. Thereafter, in 1968 the Government introduced a few more amendments to the Patents And Designs Act, 1911. At last, in 1970 a new comprehensive patent act was enacted (Dhavan et.al: 1991).

The enactment of the Indian Patent Act of 1970 was a radical step. According to the new legislation, patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay. The Act further envisaged that patents should not be a source of monopoly for the importation of the patented article (Government of India: 1970).

Under the Indian Patents and Designs Act of 1970, there are two kinds of patents - product and process patents- that have a life of fourteen years. The important provision of the Act is that process patents used for food, medicine or drug have a term of only five years from the date of sealing of the patents or seven years from the date of the patent whichever is shorter (Government of India: 1970). It should be noted that earlier this was 16 years as per the Patents and Designs (Amendment) Act 1950.

The act gave a wide definition to 'medicine and drugs'. It includes:

1. All medicine for internal or external use of human beings or animals.

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65. Kapoor, Jyothi (1990)," The Role of the Public Sector Drugs And Pharmaceutical Industry in Meeting the Health Needs of the Indian People: An Analysis and Perspective", Unpublished M.Phil Dissertation, Centre of social Medicine And Community Health, JNU, pp.116-117.
66. Dhavan, Rajeev et.al (1991), *op cit*, pp.2-4.
67. Government of India (1970), *Indian Patents Act*, 1970, section 83.
68. *Ibid.*

2. All substances intended to be used in prevention of disease in human beings or animals.

3. All substances intended to be used for or in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals.

4. Insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection of and preservation of plants.

5. All chemical substances which are ordinarily used as intermediates in the preparations or manufacture of any of the medicines or substances above referred to.

The 1970 Act made a few more provisions favourable to drugs and pharmaceutical industry. The important provisions are:

1. Government of India retained its right to use compulsory license system,* if it is against public interest or the prices are not reasonable.
2. Mere import of patent protected products does not come under the definition of a working of patent, as novelty is determined on the basis of prior knowledge or prior usage in India.

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* Under the Section 84(1) of the Patent Act, 1970 a patentee is given exclusivity of his patents for a period of three years after the sealing of the patent. After these three years, any person may apply to the Controller of Patents for a compulsory license. The grounds for granting compulsory license may be any one or more of the following: 1) Public interest needs. 2) The patented invention is not being worked completely on a commercial scale or not being worked on its fullest extent. 3) The demand for the patented product is not being met on reasonable terms or it is being met to a substantial extent by import from out side.4) by default of the patent owner or by reason of his refusal to grant a licenses on reasonable terms.

3. In the case of violation of patent rule, the burden of proof would fall on the complainant.

According to IDMA's Legal Advisor, N.B. Zaveri "The Patent Act of 1970 has struck a correct balance between national objectives, priorities and interests on the one hand and the rights and benefits to be granted to the genuine inventors and for their contributions, research work and establishing production in the country. There is mutuality that has promoted the all-round and speedy growth of the indigenous drug industry"(Zaveri: 1998:58). According to Zaveri the Indian pharmaceutical manufactures:

a) Enabled the nation to save valuable foreign exchange in excess of US $ 500 million per year.*

b) Brought life saving drugs and medicines of standard quality within the reach of the common man.

c) Enabled the nation to become self reliant in the drugs and pharmaceutical sector, as an indispensable part of health care (Zaveri: 1998).

Table 2.1 Patents Held by Indians and Foreigners in India 1856-1970

Year	Patent applications By Indians		Patent applications By foreigners	
	(Number)	(Percentage)	(Number)	(Percentage)
1856	0	Nil	33	100
1900	44	9	448	91
1920	99	19	938	90
1940	213	29	528	71
1947	220	9	2150	91
1960	662	15	3841	85
1970	1,116	22	4,026	78

Source: Keayla, B.K., Patents Regime: Indian Experience and Options Available, National Working Group on Patent Laws, New Delhi, 1992.

69. Zaveri N.B (1998), *Patents for Medicine*, Indian Drug Manufacturers' Association, Mumbai, p. 58.

* Introduction of product patent with 20 year term could have caused an overburden of around Rs. 5,000 crores or more every year to the nation and thus to the consumers.

70. Zaveri N.B (1998), *op cit*, pp.16-17.

Before 1970's the Indian patent system was being exploited by the foreign firms for monopolistic control of the market. Foreign firms imported goods from abroad at extremely higher prices than the prevailing market rates, which helped them to manipulate the accounts so as to make high profit. In fact, more than 90 per cent of the patents registered by foreigners in India were not used for any production purposes (details of patent applications are given in table 2.1) (Keayla: 1994). With the enactment of the Patent Act of 1970, these conditions changed totally.

It is true that 1970 Act has a lot of provisions that are crucial to the people's health. At the same time, it is also true that most of these provisions remained unused or under-utilised. For example, the provisions such as compulsory licensing have been rarely used by the government of India during the last three decades. According to Rajeev Dhawan et.al, foreign patent holders are using the provisions of the Indian Patent Act, 1970 to a greater extent than the Indians (Dhawan: 1991).

2.8. Structure Of Indian Drugs And Pharmaceutical Industry

The pharmaceutical industry during the first three decades after the Independence can be divided into four distinct categories based on their ownership and size. These are:

1) Government factories;
2) Large scale private enterprises under foreign control and /or collaboration (MNCs);
3) Large scale private companies under Indian management; and

71. Keayla, B.K (1994), *op cit*, p.152.
72. Dhawan, Rajeev et.al (1991), *op cit*, p.56.

4) Small scale private enterprises.

The first three come under the broad category of the organised sector and the remaining comes under the unorganised sector. Large scale private enterprises under foreign control or multinational corporations had a clear edge, both in the matter of capital investment and sales out put, over other players of the industry ever since its inception. As mentioned earlier, in the 1950s they imported huge quantities of raw materials at high cost and they employed a small work force compared to other sectors. Though numerically small-scale private industries constituted the biggest group, in sales out put they were far behind the Indian large-scale private producers (refer table 2.2 below). Therefore it is clearly evident that private sector, especially MNCs, dominated the industry.

2.8.1 Multinational Corporations in Indian Drugs and Pharmaceutical Sector

The term 'Multinational Corporation' ("MNCs") was first used and defined by David E. Hibenthal as "Corporations which have their home in one country but operate and lie under the laws and customs of other countries as well"(as quoted by Singh: 1985:10). By 'operating' what he meant was that industrial and commercial operation abroad which directly involve management responsibility.

There are more than 10,000 drugs manufacturing companies in the world. However, it is important to note that, of these companies, only about 100 multinational corporations rule the pharmaceutical industry (Chaturvedi: 1990). They are the keen players of international pharmaceutical politics. In India also MNCs have been playing an important role in the drugs and pharmaceutical sector for the last six decades.

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73. As cited in Singh, Satwinder (1985), *Multinational Corporations and Indian Drug Industry*, Criterion publications, New Delhi, p. 10.
74. Chaturvedi, Harivansh (1990), *op cit*, p.23.

The All India Congress Committee's Economic Programme Committee, chaired by Pandit Jawaharlal Nehru, submitted its report in 1948. It categorically stated, "The place of foreign capital should be examined so as to ensure that the economic controls remain with the nationals of the country." But the very next year, Nehru's statement on foreign investment in India totally discarded the earlier Congress policy of strict regulation of foreign capital. Nehru now argued: "The stress on the need to regulate, in the national interest, the scope and manner of foreign capital arose from past association of foreign capital and control with foreign domination of the economy of the country. But the circumstances today are quite different. The object of our regulation should therefore be the utilization of foreign capital in a manner most advantageous to the country. Indian capital needs to be supplemented by foreign capital not only because our national savings will not be enough for the rapid development of the country on the scale we wish, but also because in many cases scientific, technical and industrial knowledge and capital equipment can best be secured along with foreign capital."* Thus the first Industrial Policy, in fact, explicitly assured foreign investors that foreign investment would be treated on par with similar Indian enterprises. It also conveyed that government would not object to foreign capital having control of a concern for a limited period, if it is found in the national interest to earn profits, subject only to regulation common to all (Chenoy: 1985). Thus the political environment in the country immediately after the independence was conducive for MNCs to enter and establish their business in India.

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* Nehru (1949) as quoted in Chenoy, K.M (1985), " Industrial Policy and Multinationals in India", *Social Scientist*, Vol.13, No.3, New Delhi, p.16.

75. Chenoy, K.M (1985), *Ibid.*

Table2.2 Structural Details of Indian Drugs and Pharmaceutical Industry in 1954

Type	Total No. of Factories	No.of Factories out of Col.2 regd. Under the Industries (D&R) Act	Present Capital Invested	Sale Value of Products made in 1952	Value of Raw Materials Consumed in 1952		Labour Employed	
					Indigenous	Imported	Technical	Non-Technical
1	2	3	4	5	6	7	8	9
Major Government factories	11	7	1,48,14,900	1,16,35,200	45,74,700	14,70,000	181	1,492
Large scale private enterprises under foreign control and /or collaboration	28	14	6,90,38,390	13,13,49,310	59,72,300	4,17,15,850	354	3,126
Large scale private enterprise under Indian management	54*	54*	9,25,86,050	13,38,29,473	1,73,05,882	2,23,54,850	1,076	15,896
Small Scale private enterprises	1,550	---	6,00,00,000	7,00,00,000	2,50,00,000	70,00,000	1,700	8,300
Total	1,643	75	23,64,39,340	34,68,13,983	5,28,52,882	7,25,40,700	3,311	28,814

* Includes four factories with foreign collaboration

Source: Government of India (1954), Report of the Pharmaceutical Enquiry Committee,p.21

On the other hand, some sections of the Indian capitalists represented by the FICCI vehemently criticised the government's liberal policy towards foreign capital. After the 1952-53 recession and deflationary crisis of the Indian economy, FICCI sharpened its criticism and adopted a 'Swadeshi Resolution' at its 16th Annual meeting. However in 1954, there was a change in the sluggish nature of the economy. In 1955, a FICCI sub-committee (including B.M. Birla, J.R.D. Tata and Tulsidas Kilachand and others) "generally welcomed the flow of foreign capital into India.... (including) in the consumer's industries like textiles, cement, papers where India had already established itself"(as quoted by Chenoy: 1985:17). Furthermore it is this same Indian bourgeoisie who compelled the government to initiate measures for further liberalisation (Chenoy: 1985). Hence the Indian bourgeoisies gave a red-carpet welcome to the MNCs.

Multinational corporations from Britain, the USA, West Germany, and Switzerland established their trading concerns in India. In due course, they dominated the Indian market. If we analyse the structural concentration of the Indian drugs and pharmaceutical industry, it is clearly evident that the multinational corporations dominated the industry in relation to Indian private and public undertakings. With meagre investment, they amassed huge profits and enjoyed many privileges. The figures produced by the Hathi committee reveal the fact that most of these firms, which have foreign equity, amassed huge reserve compared to its original equity (Government of India: 1975). According to Chaturvedi: "Within two decades of their business foreign companies accumulated vast reserves thousand time more

76. *Ibid*, p.17.
77. *Ibid*, pp.15-17.
78. Government of India (1975), *op cit*, pp. 108-109.

than original equities"(Chaturvedi: 1990:15). The MNCs harvested a good profit by using money-spinner formulations. Annexure II of chapter V in the Hathi Committee report contains the list of these 360 money-spinner formulations (Government of India: 1975). They were mostly cough mixtures, gripe mixtures, multi-vitamins, laxatives, tonics, digestives, ointments for burns, piles and for skin diseases, which had a ready market. Since the MNCs concentrated on the production of formulations, the production of bulk drugs lagged behind the former in both its tempo and magnitude. In fact, effective production of bulk drugs by MNCs started only in 1950's and it entered its take-off stage in 1960's (Choudhury: 1986). Details of India's share in total foreign sales is given in the table.2.3.

In this profit making process, MNCs did not even take care of the epidemiological factors as it deliberately neglected the presence of most of the killer diseases. As a result, the production of antibiotics, anti-malarial, anti-diabetic and anti-leprotic were started only in the early 1960s. Therefore, it is clearly evident that the prime motive of the MNCs was huge profit from meagre investment. However, it is argued that there were many other hidden motives as it was a period of cold war. To be more specific, there was a deliberate attempt to keep the Soviets away from India. Once the 1956 Industrial Policy Resolution envisaged a leading role for the public sector in drug manufacturing, the Soviet Union had offered the free technological support for the project.

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79. Chaturvedi, Harivansh (1990), *op cit*, p.15.
80. Government of India (1975), *op cit*, pp. 110-120.
81. Chaudhury, Sudip (1986), " Licensing Policies and Growth of Drug TNCs in India" in Sengupta, Amit (ed) *op cit*, p.246.

Table.2. 3 India's Share in the Total Foreign Sales of 12 Drug Transnationals in 1977.

Sl.no.	Company	Domicile	Total sales	Foreign sales	5 as % of 4	Sales in India	7 as % of 5
1	2	3	4	5	6	7	8
1	Cyanamid	USA	484.0	164.56	34.00	21.80	13.25
2	German Remedies	FRG	734.6	506.87	69.00	11.69	2.31
3	Glaxo	UK	594.3	364.90	61.40	62.71	17.19
4	Hoechst	FRG	1572.9	1053.84	67.00	35.27	3.35
5	Organon	NLD	441.5	387.20	87.70	6.20	1.60
6	Parke Davis	USA	1024.8	443.74	43.30	28.37	6.39
7	Pfizer	USA	1016.0	518.16	51.00	42.23	8.15
8	Richardson Hindustan	USA	234.8	113.64	48.40	12.51	11.01
9	Roche	SWIZ	1145.0	1030.50	90.00	13.74	1.30
10	Sandoz	SWIZ	934.8	888.06	95.00	34.65	3.90
11	Symbiotics	USA	668.4	220.57	33.00	6.89	3.12
12	Wyeth Labs	USA	1116.0	348.19	31.20	6.29	1.81
Total			9967.1	6040.23	59.25	282.35	4.67

Source: Singh, Satwinder (1985), *Multinational Corporations and Indian Drug Industry*, Criterion Publications, New Delhi p.129.

When Merck, one of the largest multinational corporations based in US, entered the Indian soil in 1958; a leading American journal, *Chemical and Engineering News* reported, "Merck's entry in Indian pharmaceutical makes friends, future profits and helps sideswipe Soviets...." (as quoted by Mazumdar:1986:9). Later, the efforts of Merck and American

82. Mazumdar, J.S (1986), *op cit*, p.9.

Home Products ensured that Indian pharmaceutical market would not be a government monopoly. Since then multinational corporations have been a significant player of pharma-politics in India. They formed an association named Organisation of Pharmaceutical Producers of India (OPPI), which represents the interests of MNCs in India.

2.9. Role of the State in Drugs and Pharmaceuticals

According to V.R. Krishna Iyer, a retired Judge of Supreme Court, "The democracy of medical remedies and the equal opportunity for health for all citizens, are imperatives implicit in our Constitution. The Preamble plus Arts. 14 & 21 mandate this equal right to healthy life reinforced by the directive principles laid down in Arts.39 (e) and (f) as well as Art. 47"(Iyer: 1986:266). He also argues that democratic concern for the poor and a socialistic assurances of medical facilities for those who need, is fundamental in the governance of the country so that the state can ensure better health of the people (Iyer: 1986).

The Indian state intervenes in the drugs and pharmaceutical sector in many ways. In fact, the prime responsibility of the state is of providing drugs and pharmaceutical products at reasonable prices i.e. without putting any burden on the poorest of the poor. Since there are public sector as well as private sector, controlling of the sector is one of the major functions of the state.

The state has the responsibility of controlling both prices and quality as well as of licensing. From 1962-63 onwards, the government of India started controlling drug prices through the Drug Price Control Orders (DPCO). It was in the same year that the

83. Iyer, Krishna (1986), "A New Nationalist Drug Policy" in Sengupta,Amit (ed), *op cit*,p.266.
84. *Ibid*, p.266.

Government of India brought in first Drug (Display of Prices) Order. Today, there are about 500 bulk drugs that are consumed in the country. Out of this, about 350 bulk drugs are Indian made and the rest are imported ones.

The state, both during the colonial rule and after independence, has been instrumental in bringing in legislation relating to manufacture and sale of drugs in India. It is also the responsibility of the state to frame rules under the provisions of Acts enacted. Apart from this, the state took up the responsibility of establishing institutions like IDPL (Indian Drugs & Pharmaceutical Limited) and HAL (Hindustan Antibiotics Limited) etc to engage directly into the production of drugs and pharmaceutical products.

2.9.1. Entry of the State into Large Scale Drug Manufacture

In the earlier periods of development of the industry in India, most of pharmaceutical concerns were mainly interested in making and marketing formulations rather than in making drugs. As a result, there had been tremendous pressure on the government to develop a public sector so that this could be ensured that the Indian sector became self reliant. According to Tyabji, " as early as 1946,a year before Independence, the Government of India began to explore the possibilities of the manufacture of pharmaceutical products, particularly those related to the prevention and treatment of communicable diseases"(Tyabji: 2002). With this purpose, technical teams visited many plants in Western Europe and North America in 1946 and 1948 and recommended the production of a few most important drugs like penicillin, paludrin and

85. Tyabji, Nasir (2002), *op cit*, p.1.

three sulpha drugs. Considering this recommendation, the government decided to establish a public sector company to manufacture drugs and pharmaceutical products (Tyabji: 2002). The public sector undertakings like HAL (1955) & IDPL (1968) are products of this effort of the state to make the nation self reliant in drugs and pharmaceuticals.

HAL (Hindustan Antibiotics Limited) was established in 1955 with technical assistance from WHO and UNICEF. This unit had a paid-up capital of Rs. 24.7 Million and in total capital employed in 1972, was Rs. 75.5 Million. In 1972, HAL had a turnover of Rs. 76.1 million. Later, with the purpose of producing semi-synthetic penicillin in India, the HAL made a collaboration agreement with the American Home Product Corporation (Rangarao:1975).

The IDPL, which was incorporated as a company under the Companies Act, has five plants.* It has also three subsidiaries set up in association with State Industrial Department Corporations in Rajasthan, Uttar Pradesh and Orissa. IDPL was established with an initial issued capital of Rs. 8 million and authorised capital of Rs. 150 million. IDPL had a paid-up capital of 337 million and authorised capital of 400 million in 1973. In the initial period of its establishment, IDPL faced a problem of severe loss. The establishment of an antibiotic plant in which huge capital was invested was the main reason for this severe loss (Rangarao: 1975).

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86. *Ibid.*
87. Rangarao, B.V (1975), *op cit*, pp. 19-20.
* IDPL- Rishikesh for the manufacture of Antibiotics, Hyderabad for Synthetic Drugs, Madras for Surgical instruments and formulations; Gurgaon for formulations and at Muzaffarpur for Drugs and Chemical intermediate.
88. Rangarao, B.V (1975), *op cit*, p. 19.

A strong and healthy public sector is one of the means of ensuring that production and prices in this essential industry are not governed solely by the profit motive. The Committee on Public Undertakings noted in their 22nd report, "The setting up of the drug manufacturing units and surgical instruments factory in the public sector was intended to serve the triple objectives, namely to bring down the prices by large scale production of high quality life-saving drugs, to provide facilities for medical relief to the people on mass scale in consonance with the declared objectives of the Government in this regard and finally, not only to achieve self sufficiency but also to produce an exportable surplus and earn foreign exchange"(as quoted by Government of India:1975:54). In fact, Indian public sector was successful in achieving almost all the three objectives set by the Committee on Public Undertaking. For example, both the IDPL and HAL, account for the large per cent of the penicillin production in India. They brought down the penicillin price remarkably within a few years. It is these two undertakings that compelled the MNCs operating in India to take up the effective production of bulk drugs in India,

2.10. Summary and Conclusion

The colonial regime of nearly 200 years brought in fundamental changes in the socio-economic and political spheres in India. With the colonial invasion India was integrated into the global capitalism. During the British regime, India was made to a typical colony where raw materials were exported and finished goods were returned to the local markets. Apart from the colonial plundering, the British regime hindered the natural growth of indigenous capitalism through biased policies which restricted the growth of local

89. Government of India (1975), *op cit*, p. 54.

industries and the trade activities of artisans. It was during this period that the allopathic system of medicine entered India.

Not only did the British, especially the military, bear the burden of a huge load of preventable morbidity and mortality due to so-called tropical diseases, it was soon realised that the health of the British people could not be achieved by delivering healthcare measures targeting them alone. Moreover, the high morbidity and mortality rate of indigenous people working in the plantations and mines slackened the efficiency and thus profitability also. These factors compelled the Government to intervene in the "indigenous health," however tardily and ineffectually.

In the latter half of 19th century, the British government had established many public sector production units that engaged in the processing and production of galenicals and inorganic chemical preparations. The government also established the Medical Store Depots for the distribution of drugs. The Indian entrepreneurial efforts in the drugs and pharmaceutical industry began with the establishment of Bengal Chemicals And Pharmaceuticals Works by Acharya P.C.Ray in the beginning of the 20th century. Thereafter, a few more small-scale firms also came into the field of drug production. Large scale production was almost absent in India. In fact, the Indian drugs and pharmaceutical sector during the colonial period and immediately after the colonial period, does not have a glorious history of production and distribution. It would not be incorrect to argue that Indian national sector was almost virtually nonexistent during this period. The only bright spot in the history is that, by the early years of 1940s, Indian sector was able to meet the 70 per cent of the total medical requirements and also engaged in export of drugs to the armed

forces in West Asia and Far East. However, after a very short span of time this also collapsed. The main reasons for this were the end of the World War II, the therapeutic revolution in the West, and the entry of foreign firms with huge capital and technology. Another important point is that none of the national capitalists ventured into drug production though it was one of the most profitable industries. During the pre-1970 period, the Indian Patents Act, 1911 had caused a long lasting damage to the Indian sector. Moreover, the Indian state's industrial policies, which were considerably liberal to foreign capital, also retarded the growth of the Indian sector during this period. Another important point is that the dominance of MNCs kept drug prices high in the country. The irony is that the State took twenty-two years more to come up with a mechanism for controlling the prices of basic drugs.

CHAPTER-III

CHAPTER III

Political Economy of Policy Decisions and Its Impact on the Indian Drugs and Pharmaceutical Sector

3.1.Introduction

The government's decisions on policies such as the industrial policy, foreign exchange policy, drug policy, and pricing policy have its impact on the drugs and pharmaceutical industry. The evolution and the implementation of these policies are basically a political process. Usually before taking any decisive moves on these regards, the government constitutes different committees and study groups to look in to the issues and problems. Therefore, this chapter attempts to understand this complex processes. Specifically, the chapter makes an attempt to analyse the political economy of the policy level decisions and its impact on the drugs and pharmaceutical sector during 1970s and early 1980s. As part of policy analysis, basically, this chapter looks into documents on FERA, National Drug Policy, and Price policy. The first section deals with the global and national economic and political background in which these policy decisions and changes are made. It also makes an in-depth analysis of recommendations of the Committee on Drugs and Pharmaceutical Industry (The Hathi Committee) as it has been considered very central to the policy level changes during 1970s. In fact, the Hathi Committee Report is still considered as the most comprehensive document on the Indian drugs and pharmaceutical industry. Therefore, this section is the main focus of the chapter as it tries to provide details of how and why the policy level decisions were ushered in. Further, the chapter makes an analysis of the drug policy and price policy documents to show that how the Hathi Committee recommendations were diluted or neglected. Then, the chapter presents a brief review of

the recommendations of ICMR - ICSSR Study Group on the drugs and pharmaceutical sector. Apart from this, the chapter deals briefly with the concept of "essential drugs." The last section of the chapter gives an overview of the Indian drugs and pharmaceutical industry and analyses the significant changes.

The establishment of public sector undertakings and the enactment of the Patents And Designs Act of 1970 eventuated a new era for Indian drugs and pharmaceutical sector. Once the public sector undertakings entered the sphere of production and marketing of bulk drugs and formulations, with the objective of taking the nation to the state of self-sufficiency, it triggered of a new political-economic situation in the sector. To quote J.S. Mazumdar, "Out of fear losing a lucrative market, multinational companies started establishing factories in collaboration with their partners or converted their trading houses as subsidiaries. But even this time they did not contribute much towards production of pharmaceuticals from basic stages"(Mazumdar: 1986:9).

Meanwhile, the national private sector began to scale new heights with the support of the new Patent Act of 1970. In fact, most of the front runners in this sector were those traders, distributors and business associates who had close links with the MNCs. It is not surprising, therefore, that these firms adopted the same market behaviour of the MNCs. "Being closely associated with the MNCs", J.S. Mazumdar writes, "they learnt the art of marketing practices of the MNCs in the drug industry and started challenging the monopoly control of multinationals in the drug market. The experiences gained by the technicians in the factories of multinationals also helped them

1. Mazumdar, J.S (1986)," Background Paper" in Sengupta, Amit (ed), *Drug Industry and the Indian People*, Delhi Science Forum and F.M.R.A.I, New Delhi, p.9.

immensely"(Mazumdar: 1986:10). Guha also attests to the same argument and adds that marketing techniques were not employed till the industrial development took place in the field of drugs and pharmaceuticals. As noted by Boyd and Westfall (1950), "Selling effort is very limited among Indian wholesalers. The travelling salesman scarcely exists ....."(Guha: 1986:220).

India has been a safe haven for the MNCs. It has been offering whatever MNCs want, i.e. both huge quantum of diseases and a lucrative market. According to Lypson and Lamaunt, "the knowledge that 5 per cent of India's 520 million of 26 million people have income that give them the buying power of the average American should suggest to marketers that it is imperative for them to get early in India's industrialisation and market development, such a market size in fact represents an affluent market that is just a little larger than the Canadian market"(Chaudhuri: 1986:245). Even though India's share in the global market was comparatively low, MNCs had foreseen a glorious future in the coming decades.

Except two small units; Ethanor and Indian Schering, almost all the other MNCs started the production of bulk drugs only in the late 1970's. The companies like Glaxo, Parke Davis, Boots etc. were using their plants just to prepare profit spinning formulations from imported drugs and intermediaries (Guha: 1986). This particular production pattern wreaked damage to Indian sector in many ways: 1) it helped MNCs to charge higher rates for medicine; 2) it prevented technology transfer as the MNCs

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2. *Ibid*, p.10.
3. As quoted by Guha, Amitava (1986), "Marketing of Medicine: Parasitology of Profit" in Sengupta, Amit(ed), *op cit*, p. 220.
4. Chaudhuri, Sudip (1986)," Licensing Policies and Growth of Drug TNCs in India" in Sengupta, Amit(ed), *ibid*, pp. 245-46.
5. As quoted by Guha, Amitava. (1986), "Marketing of Medicine: Parasitology of Profit" in Sengupta, Amit (ed), *ibid*, p. 220.

focused on import based production; 3) it led to the stagnation among local raw material producers; and 4) it caused drain of foreign exchange.

Under these conditions, policy level changes were inevitable in the sector. In fact, the political and economic climate both of international level and in India was conducive for that.

3.2. Global Political and Economic Situation

During the 1970s and early 80s, there had been many strong and massive movements - labour, civil rights, feminist, and ecological movements-against the dominant ideology of capitalism (Navarro: 1986). Moreover, at the same time, the Keynesian welfarism, which many people saw as the most human friendly face of capitalism, was under severe attack from the ultra-liberal economic theologians like Hayek and Friedman (Hobsbawm: 1996). According to Cornia et al "in the 1950s growth maximisation was the dominant philosophy of development. However, it became clear in the subsequent two decades that trickle down growth was often limited and that increasing poverty, defined in terms of numbers of people below a poverty line, often accompanied growth because of deteriorating income distribution - partly due to high levels of unemployment and often due to a process of growing inequality built into the political economy of national development. Consequently, emphasis was put on poverty eradication, employment and income distribution and subsequently on basic services and basic needs"(Cornia et.al: 1987:6).

During the 1970's, "all developing countries lacking indigenous oil reserves, felt the double shock of declining commodity prices (and therefore, of declining export

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6. Navarro, Vicente (1986), *Crisis, Health, and Medicine- A Social Critique*, Tavistock Publications, New York, p.9.
7. Hobsbawm, Eric (1996), *The Age of Extremes*, Vintage Books, New York, pp.409-410.
8. Cornia, G.A. et al (1987), *Adjustment With A Human Face*, Vol.1, Clarenton Press, NewYork, p.6.

prices) and rising import prices. They needed balance of payments (BOP) support in addition to development finance."(Ghosh: 1994:1930). Therefore, there was a genuine need to solve the BOP problem. In this economic crisis most of the Third World countries experienced many other economic and political consequences. In this process India also was not spared.

According to Hobsbawm, the "Second World" of the "centrally planned economies" also were undermined by the crisis of 1970s. Both the post-Maoist China and Brezhnev's USSR badly needed economic reforms as their economies were showed severe regression. The uncontrollable movements and the unpredictable fluctuations of the transnational economy compelled the socialist countries to resort to a few fundamental changes, which had a significant impact in the global political economy. To quote Hobsbawm, " the massive entry of the U.S.S.R on the international grain market, and the impact of the oil crises of the 1970s dramatised the ending of the "socialist camp" as a virtually self-contained regional economy protected from the vagaries of the world economy"(Hobsbawm: 1996:418). The decade of 1970s witnessed many other crucial incidents in the global politics. For example, in 1976, the whole world witnessed the first ever military defeat of USA at the hands of Socialist Republic of Vietnam. This is often seen as the symbolic victory of the Third World over the developed capitalist world. According to Chowdhury, this victory led to calls for pro-people policy reforms in Afro Asia, especially in South and Southeast Asia (Chowdhury: 1995). Thus the global economic recession and financial crisis that started in 1970's did have its influence on policies in the national level. In the later

9. Ghosh, Arun (1994), "Ideoloques and Ideology of Privatisation of Public Enterprises," *Economic and Political Weekly*,Vol. XXIX No.30, p.1930.
10. Hobsbawm, Eric (1996), *The Age of Extremes,* Vintage Books, New York, p. 418.
11. Chowdhury, Zafrullah (1995), *The Politics of Essential Drugs*, Vistaar Publications, New Delhi, p.26.

years of 1970's, the ideas of 'poverty alleviation' and 'basic needs approach' became very dominant in the development discourse. One of the main reasons for such a change was the economic crisis of the 1970's.

At the same time, the whole world witnessed laudable developments in the field of health and education in the countries such as Chile, Mozambique, Costa Rica, and Sri Lanka, under socialist regimes; which remained as an alternative to the capitalist model of development. Thus the values of 'equitable distribution' and 'universality' became more and more acceptable.

3.3. Political and Economic Situation in India during 1970s

In India, the 1970s could be noted as a decade of economic and political turmoil and instability. Since the very inception of global economic crisis India has been facing BOP crisis and a series of adverse balance of trade or trade deficit*. According to the Industrial Policy Statement of 1977:

> The growth of per capita national income during the last 10 years has been about 1.5 per cent per annum and is clearly inadequate to meet the needs of a developing economy. Unemployment has increased, rural-urban disparities have widened and the rate of real investment has stagnated. The growth of industrial output in the last decade has been no more than 3 to 4 per cent per annum on an average. The incidence of industrial sickness has become widespread and some of the major industries are the worst affected. The pattern of industrial costs and prices has tended to be distorted; and dispersal of industrial activity away from the larger urban concentrations has been very slow (Government of India: 1977).

At the same time, most of the multinational corporations in India were making huge profits in the market through foreign equity participation or technological collaboration. A study of 30 American companies in India has shown that the average

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* By the year of 1981-82, trade deficit of India reached as high as Rs. 5,849.58 crores.

12. Government of India (1977), *Statement on Industrial Policy*, Ministry of Commerce and Industry, 23rd,December, 1977,New Delhi, p.1.

rate of return of their total assets increased by 16 percent during the period between 1976-80 (Bhambri: 1991). In

order to prevent outward mobility of finance, the government initiated many policy level changes, so that it could keep a decent level of foreign exchange. Therefore, the policy level decisions and changes should be analysed in the aforementioned wider backdrop.

As regards the political sphere, in 1974, India tried to demonstrate its might to the developed world by detonating its first nuclear bomb, which changed the direction of both the national politics and of the South-Asian power politics. Immediately after that, India experienced the most coercive face of the State in the form National Emergency from 1975 to 1977. During this period, with a mistaken notion of associative relationship between development and population control, the state came with the most extreme form of coercive strategy to control population. Consequently, the political leadership of the state; the Prime Minister Indira Gandhi, was thrown out of the power in the general election of 1977 and it led the way for Janata Party regime headed by Prime Minister Morarji Desai. Within a short span of time, Morarji Desai Government initiated a number of changes but could not carry it forward as the Government was fell due to internal conflicts in August 1979. Thereafter, a caretaker government came into power headed by Prime Minister Charan Singh. Later, in 1980 once the general elections were held, Indira Gandhi was sworn into power for her second term.

13. Bhambri, C.P (1991) *Political Process in India*, Vikas Publishing House, New Delhi, p.160.

3.4. Industrial Policies and FERA

The Monopolies Inquiry Commission of 1965 and the Industrial Licensing Policy Enquiry Committee of 1966 have pointed out the severe shortcomings in the industrial policies followed by the government. They indicated the failure of the industrial licensing to prevent the concentration of economic power in the hands of a few big business houses and recommended the Government to reformulate its industrial policies. As a result, the Government came with a new Industrial policy in 1970. According to this new policy, the foreign companies would be treated at par with the large and monopoly business houses of Indian origin. It also implied that foreign companies could be allowed to expand only in "the core sector," which consists of those industries that involved high technology or were capital intensive or were mainly export oriented. This was done basically to attract foreign capital. In 1973, the government again revised its industrial policy, which stated "Foreign concerns and subsidiaries, and branches of foreign companies will be eligible to participate in the industries specified in Appendix-I along with other applicants but will ordinarily be excluded from the industries not included in this list. They will also be entitled as at present to invest in industries where production is predominantly for exports. Their investments will be subject as hitherto to the "guidelines on the dilution of foreign equity" and will be examined with special reference to technological aspects, exports possibilities and the over-all effect on the balance of payments"(Government of India: 1973: 2).

The drugs and pharmaceutical industry was also included in the list of 19 core industries given in the appendix-I of the policy. The specified areas of the industry were:

1) Drug intermediaries from basic stage of production of high technology bulk drugs.

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14. Government of India (1973), *Industrial Policy-Government Decisions*, 2.February 1973, New Delhi, p.2.

2) High technology drugs from basic stage and formulations based thereon with an over all ratio of bulk drug consumption (from own manufacture) to formulation from all sources of 1:5(Government of India: 1973).

The industrial policies of the government relaxed the restrictions on multinational corporations so that they would be able to expand their business in India. In effect, industrial policy could not do much to contain the MNCs as they were allowed entry into core industries. Therefore, the industrial policies completely failed to find a solution to long-standing problem of outward movement of finance through MNCs.

Once the economy got into the serious economic crisis due to BOP problems, the government had to take some bold steps to mitigate the crisis. The Foreign Exchange Regulation Act,1973 (F.E.R.A) originated from such a necessity. The Act affirmed that all companies, except shipping and airlines, were to be converted into Indian companies "on selective basis with the overall condition that all their branches and subsidiaries have a minimum 26 percent Indian equity participation." However the Act allowed 74 percent equity to those foreign companies that were engaged in the production activities specified in the appendix-I of the Industrial Policy statement of 1973 and industries that were predominantly export oriented. Under this provision, therefore, most MNCs in the drugs and pharmaceutical industry in India were able to insulate themselves from the foreign equity reduction. According to Dinesh Abrol et.al, "the organised private sector comprises about 200 units. After the introduction of FERA 1973, there are now only 8 units in drug industry in the foreign sector....ex-FERA units are still, in our view, essentially foreign controlled firms"(Abrol: 1986:126). The MNCs

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15. Ibid.

16. Abrol, Dinesh and Guha, Amitava (1986), "Production and Price Controls: the Achilles Heel of National Drug Policy" in Sengupta, Amit(ed) *op cit*, p.126.

or Ex-FERA companies were able to retain more than 40 per cent of equity shares as against the policy decision and enjoyed all the benefits at par with their Indian counterparts.

The Industrial Policy statement of 1977 also had many provisions that favoured foreign capital. In fact, the government was compelled to favour foreign interests, as there was stagnation in the industrial development. Under these circumstances, it stated that foreign investment and foreign technology were necessary for industrial development in India. Further, it stated "for all approved foreign investments, there will be complete freedom for remittance of profits, royalties, and dividends as well as repatriation of capital subject, of course, to rules and regulations common to all"(Government of India: 1977:6). Therefore, the industrial policies of the different governments during 1970s were in support of foreign capital.

3.5. Drugs Policy – The Role of WHO and the Global Experiments

Dr.Halfdan Mahler, who was appointed as the Director General of WHO in 1973 had a special interest in the issue of essential drugs. Under his leadership, there was a qualitative change in the WHO's role in making quality essential drugs widely available at reasonable cost (Chowdhury: 1995). A report presented by WHO at the 28th World Health Assembly (WHA) in 1975 described the main problems encountered by developing countries in ensuring adequate supplies of safe, effective and good quality drugs to all those who need them at prices they could afford. Later, in 1976 WHO convened an informal consultation on a model essential drugs list with five representatives of the International Federation of Pharmaceutical Manufacturer's

17. Government of India (1977), *Statement on Industrial Policy*, 23,December, 1977, New Delhi, p.6.
18. Chowdhury, Zafrullah (1995), *The Politics of Essential Drugs*, Vistaar Publications, New Delhi, pp. 40-41.

Associations (IFPMA). Based on the above-mentioned report and consultation, WHO published an 'Essential Drug List' in 1977 (Balasubrahmanyam: 1996). According to Chowdhury "this book was a bombshell for the drug industry"(Chowdhury: 1995:42). The WHO's efforts were subjected to severe criticism by the US Pharmaceutical Manufacturers Association (PMA) and the association stated " the medical and economic arguments presented by WHO as justification for an essential drug list are fallacious and ...adoption of this recommendation could result in sub optimal medical care and might reduce health standards already attained" (Chowdhury: 1995). Later, through intense lobbying, pharmaceutical association could dilute the spirit of the WHO efforts and they could literally purchase the main people behind WHO's essential drug list (Chowdhury: 1995).

In 1981, WHO set up an Action Programme on Essential Drugs (APED) to provide operational support to a number of member states to develop rational drug policies, which aimed at developing an institutional mechanism to provide good quality and cheaper drugs to the needy people. This programme is also known as Drug Action Programme (DAP). According to Balasubrahmanyam, "the programme has been very successful in increasing global awareness of the concept of essential drugs" (Balasubrahmanyam: 1996:133).

During the 35th World Health Assembly (WHA),1986, the Health Action International (HAI) team - a network of activists and organisers – mooted a strong resolution on rational drug use. But the US delegation guided by Heritage Foundation (a right wing think tank) threatened to withdraw its 25-percentage budget support to

19. Chowdhury, Zafrullah (1995), *op cit*, p.42.
20. *Ibid*, p.42.
21. *Ibid*, p.42.
22. Balasubrahmanyam, Kumariah (1996), *op cit*, p.133.

WHO. In 1986-87 the US withheld its contribution to the WHO budget, allegedly because it disapproved of WHO's policies on breast milk substitutes and essential drugs (Werner and Sanders: 1998). Since then the role WHO in international drug politics has been very marginal.

3.5.1. Global Experiments on Drug Policies

Dr. Salvador Allende, a physician and a Marxist, could be named as the first national leader to come up with a rational drug policy (in 1971) in Chile, which covered the procurement, manufacture, and promotion of essential drugs. It introduced restrictions on imports, sale and prescription of useless and irrational drugs. Meanwhile, he took many bold steps to curtail the growth of MNCs.* However, Dr. Salvador Allende's regime did not last too many years. He was ousted from power in a coup and was murdered. ITT and other transnationals were involved in this heinous crime, with the covert support of the USA. (Chowdhury: 1995)

In 1972, when Sri Lanka implemented policy measures to eradicate all unsafe and cost ineffective drugs from its private market, the total number of imported drugs fell down to just 600 from 2100. In this radical step, the role of Prof. Bibile Senanayake, who earlier published Ceylon Hospital Formulary in 1959,* has been highly distinguished (Phadke: 1998, Chowdhury: 1995).

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23. Werner,D and Sanders,D(1997),*Questioning the Solution: The Politics of Primary Health Care and Child Survival*, Health Wright, Palo Alto,p.96-97.

* It is shocking to note that, during the same period investigations revealed that Pfizer had been involving in drug smuggling in Chile.

24. Chowdhury, Zafrullah (1995), *op cit*, p.38.

* Ceylon Hospital Formulary became the de facto list from which public health institutions ordered drugs.

25. Phadke, Anand (1998), *Drug Supply and Use- Towards a Rational Policy in India*, Sage Publications, New Delhi p. 48.

26. Chowdhury, Zafrullah (1995), *op cit*, p.75.

In Mozambique, the Government headed by FRELIMO (The Front for the Liberation of Mozambique) introduced a comprehensive health development programme in 1975, i.e. immediately after the end of colonial rule of the Portuguese. They brought in many radical changes in the drug sector also. As part of this, the Government introduced a new law (which was based on the concept of essential drugs), which made the re-registration of all products compulsory. Through this Government was able to control non-essential drugs in the market. Apparently the number of formulations in the market was reduced to just 2600 from 13,000(Phadke: 1998).

In most of the above cases political will had played an important role in bringing about people-friendly policies in the sector. For example, Finance Minister, Dr. N.M. Perera, who belonged to Sri Lanka Communist Party and Industries and Scientific Affairs Minister, T.B. Subasinghe of Sri Lanka Sama (Socialist) Samaj Party had played an important role in the implementation of the rational pharmaceutical policy in Srilanka. Here, it is important to note that these policy level changes had been introduced as a part of broader comprehensive and holistic development policies, which were essentially based on the socialist principles of equitable distribution and universality.

3.6. The Indian Effort

As mentioned earlier, there had been a strong wave against the multinational corporations and their functioning in India. Many questions were raised in the Indian Parliament about the oligopolistic nature of pharmaceutical industries and about the performance of the public sector undertakings (Government of India: 1975). Based on

27. Phadke, Anand (1998), *op cit*, p.48.
28. Government of India (1975), *The Report of the Committee on Drugs and Pharmaceutical Industry in India*, Ministry of Petroleum & Chemicals, New Delhi, p.1.

a suggestion made in the Parliament, the Government of India in the Ministry of Petroleum and Chemicals, set up a committee by the resolution No.3 (26)/73-Ch III dated the 8th February, 1974. This committee is popularly known as the Hathi Committee.

3.6.1. The Committee on Drugs and Pharmaceutical Industry (The Hathi Committee)

The Committee, headed by Jaisukhlal Hathi, was constituted with a view to study the issues and problems in the drugs and pharmaceutical industry in India and to suggest ways and means of developing the drugs and pharmaceuticals industry to meet the growing requirements of the country (Government of India: 1975). The fifteen-member committee comprised people from the different walks of life like politics, research, bureaucracy and academics.

The Government of India appointed the above committee to go into the various facets of the drug industry in India with a view to:

(1) promote growth of the drug industry particularly of the Indian and small scale sectors;

(2) improve technological development;

(3) take effective quality control measures on drugs as well as rationalise the price structure;

(4) provide essential drugs throughout the country;

(5) make available raw materials to the industry particularly to the small-scale sector etc.

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29. *Ibid*, p.1.

The Fifth Five Year Plan envisaged a large-scale expansion and thereby rapid growth of the drug and pharmaceutical industries. The terms of reference of the Committee were as stated below:

1. To enquire into the progress made by the industry and the status achieved by it;
2. To recommend measures necessary for ensuring that the public sector attains a leadership role in the manufacture of basic drugs and formulations, and in research and development;
3. To make recommendations for promoting the rapid growth of the drugs industry and, particularly, of the Indian and small scale industries sector. In making its recommendations the Committee will keep in view the need for a balanced regional dispersal of the industry;
4. To examine the present arrangements for the flow of new technology into the industry and make recommendations thereof;
5. To recommend measures for effective quality control of drugs, and for rendering assistance to small-scale units in this regard;
6. To examine the measures taken so far to reduce the prices of drugs for the consumer, and to recommend such further measures as may be necessary to rationalise the price of basic drugs and formulations;
7. To recommend measures for providing essential drugs and common household remedies to the general public, especially to the rural areas;
8. To recommend institutional and other arrangements to ensure equitable distribution of basic drugs and raw materials especially in the rural areas.

With the view of studying the issues and problems, in the industry, the Committee constituted two sub-committees (1) sub-committee to examine the questions of issues of permission/no objection letters and C.O.B. Licences by the Government (2)

sub-committee to recommend measures for effective quality control of drugs and rendering assistance to the small-scale units in this regard. Finally, in April 1975, the Hathi Committee after studying the Indian drug sector submitted its report, which carried more than 200 recommendations.

3.6.1.1. Findings and Recommendations of the Hathi Committee

The Hathi Committee observed that the "drug needs of the country are diverse and the industry has to meet all such demands. This industry has an important role to play in maintaining the health of the nation and has the responsibility of meeting the expanding needs of the country ..."(Government of India: 1975:16). The task before this industry therefore, is not only to produce more medicine and provide them in the required quantities but also to ensure that the medicines produced are of the right quality and which would relieve the suffering millions of their illness at low cost. By stating this, the Committee acknowledged the complexity of the industry and emphasised its need to have a social concern. As a result, the Committee held the view that the trade aspects of the industry should not work according to the logic of market, which is based on the profit motive (Government of India: 1975). The Committee, after analysing the production and import data of the drugs observed: "the progress attained so far is not commensurate with the increasing needs of the country particularly in respect of bulk drugs. It also found that even for a number of items which were then produced within the country, substantial imports are being made" (Government of India: 1975:20).

According to the Committee, the production achieved by the sector was much below the approved capacities. The delay in the procurement of equipments, raw-

30. *Ibid*, p.16.
31. *Ibid*, p.66.
32. *Ibid*, p.20.

materials, poor technology, management problem, uneconomic production etc. were the reasons for such non-implementation or under-implementation of proposals/capacities. The role of small-scale units, according to the Committee, was one of the most important in the production of bulk drugs. Therefore, the Committee felt that it was necessary to provide adequate incentives and assistance to this sector for its growth, particularly in the field of basic manufacture (Government of India: 1975).

After studying the distribution pattern of drugs, the Committee realised that about 22 percent of the market share was enjoyed by unessentials like vitamins, tonics and health restorers and haematinics, while about 20 percent was shared by the antibiotics. The Committee also found that the share of sulphonomides and anti-T.B. preparations were very low. It is interesting to note that the Committee, without analysing the gravity of the problems, ended up with the conclusion that "this low percentage in respect of sulphonomids and anti-T.B. preparations could be due to the fact that such preparations are made available in large quantities to the consumers through the hospitals and other governmental agencies" (Government of India: 1975:25).

3.6.1.2. The Public Sector

After realising the harsh realities of drugs and pharmaceutical sector, the Committee recommended many "measures necessary for ensuring that the public sector attains a leadership role in the manufacture of basic drugs and formulations and in research and development" (Government of India: 1975:54).

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33. *Ibid*, p.20.
34. *Ibid*, p.25.
35. *Ibid*, p.54.

To engage in the production of drugs with high degree of specialisation and sophistication, the Committee recommended that there should be division of responsibilities for the production of individual items within the different public sector units. It also held the view that public sector units like IDPL should utilise its maximum capacity for drug production, especially the production of essential drugs (Government of India: 1975).

The Committee made it clear that if the technology for the production of essential drugs is found not to conform to economic working, such technology should be imported by the concerned public sector unit on priority basis (Government of India: 1975). In order to develop the R & D laboratories in the public sector units, the Committee recommended the reasonable and liberal allocation of men, equipment and material. This recommendation was based on the realisation that "a sound R & D base is the best insurance for the growth of the drugs and pharmaceutical industry"(Government of India: 1975:64).

Since the Committee was concerned about the production as well as distribution of drugs, it stated, "distribution systems in the public sector should make use of unconventional agencies such as primary health centers, panchayat dispensaries, post offices, petrol and kerosene sale depots etc. for the distribution of household remedies"(Government of India: 1975: 66).

With a view of protecting public sector units from their private counterparts, the Committee suggested that items which are part of the approved production programme

36. *Ibid*, pp.58-59.
37. *Ibid*, p.62.
38. *Ibid*, p.64.
39. *Ibid*, p.66.

of public sector unit or items in respect of which public sector has the capacity to produce should ordinarily not be licensed to private sector units.

3.6.1.3. Multinationals and Indian Private Sector

According to the Committee, a "more liberal policy is necessary in order to encourage the Indian companies to make this contribution to the production of bulk drugs and formulations"(Government of India: 1975:90). The Committee vehemently criticised multinational firms 1) on their monopolistic nature of business; 2) on distorted production pattern of drugs; and 3) for charging exorbitant drug prices. While discussing about the 'takeover' of multinational firms in the Committee, there emerged different views and opinions. There were three views on this issue. One view was that the multinational units should be taken over by the Government and managed by the proposed National Drug Authority (Government of India: 1975). As against this, another view was placed. "The question of taking over of multinational units clearly has political overtones. The economic case for takeover of drugs and pharmaceutical units, however, has to be based on the advantages accruing to the community from such a step, and in this, it is difficult to make a distinction between foreign and Indian companies. If there is a case for nationalisation of drugs and pharmaceutical firms, the arrangement would be equally applicable to units in the Indian sector, above a certain size. There is no case for limiting the take over to a segment of the industry namely the multinational units and no persuasive case has been made out in favour of nationalisation of the whole industry"(Government Of India: 1975:98). The third view almost supported the second view and added that "the size of the wholly Indian units to

40. *Ibid*, p.90.
41. *Ibid*, p.97.
42. *Ibid*, p.98.

be nationalised be at least with an annual turnover of Rs.2 crores and above and those which are determined as sick units need not be nationalised and paid unnecessary compensation" (Government of India: 1975:98).

Here, once the Committee deliberates into the political questions like "Does the drug industry, as it has developed, fulfil the socio-economic needs of the country? If not how should its development be oriented?"*, it comes out with different politically burdened views and alternative solutions. In fact, these different views represent the different political ideologies. This particular instance itself shows the fact that the Committee comprised nominees of different interest groups. It varied from private interests to national interests.

Since the majority was in favour of the first view, the Committee came up with the recommendation that the multinational firms should be taken over forthwith. Apart from this, the Committee made a few more recommendations, which insisted that where foreign undertakings were producing drug formulations using imported bulk drugs, they would start and complete manufacture from the basic stage within the period of three years, failing in which they should not be allowed to continue marketing of the formulation after the said period (Government of India: 1975). Another important recommendation was that foreign firms should be directed to bring down their equity to 40 per cent forthwith and further reduce it progressively to 26 percent. With a purpose to protect this plan, the Committee strictly made it clear that equity reduction should not take the form of dispersed holding of the shares by large number of Indian nationals. The Committee stated: "It would be desirable for Government to purchase these shares

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43. *Ibid*, p.98.
* *Ibid*, p.95.
44. *Ibid*, p.99.

either by public sector undertakings ... or by public financial instructions or by Government itself'(Government of India: 1975:98).

However, these radical recommendations did not apparently find favour even from the Government. On 27th May 1975, i.e. nearly one month after the submission of Hathi Committee Report, the Minister of Petroleum and Chemicals, K.D. Malaviya said that there would be no doctrinaire approach to the question of takeover of the foreign firms and that they would be allowed to continue in business. When the issue was raised in the Parliament, Minister of Chemicals and Fertilizers, P.C. Sethi responded, "the question is a complex one." (Gupta: 1976:71)

As against the recommendations of the Hathi Committee, the multinational companies reduced the equity share in the form of dispersed holdings of the shares by large number of Indian nationals. The government policies could not do much to avert this crisis. Therefore, once again, the nation witnessed an instance where the Indian Government succumbed to the interests of the multinationals. This is a clear example of the contradiction of the Indian state. Primarily, it has to function as an instrument for accumulation of capital and, on the other hand, it has to cater to the needs of the people. But during the time of crisis, it always buttressed capitalist class.

3.61.4. Drug Control

The Committee proposed the constitution of the National Drug Authority (NDA). According to the Committee, the function related to the control and distribution of drugs would be undertaken by NDA. The Committee recommended that the NDA should review the norms for the payment of research contributions, technical know-how

45. *Ibid*, p.98.
46. Gupta, Meena (1976), "Prescription, But No Cure," *Social Scientist*, Vol.4, No.6, Jan. 1976, p.71.

fees etc. by foreign companies. It also entrusted to the NDA the functions of maintaining a comprehensive drug information service, monitoring of licenses etc. (Government of India: 1975). The Committee acknowledged the fact that the operation of price control so far had certainly helped in preventing the emergence of very large or excessive profit by the drug and pharmaceutical industry. At the same time the committee pointed out that the price control measures did not appear to have contributed materially to the emergence of a product or price pattern which was more in consonance with social needs or national objective (Government of India: 1975). Therefore the Committee argued that more selectivity in the system of price regulation with a view to ensuring fair prices in respect of drugs and formulations would be desirable rather than on all drugs and formulation irrespective of their importance (Government of India: 1975). The Committee made recommendations to fix the prices on the basis of post-tax return of 12-14 per cent on equity or 8-10 per cent profit on sales. (Government of India: 1975). Whereas, price control of formulations was recommended to be done on the basis of selectivity in terms of size of the units, the selection of items and in terms of controlling prices only of market leaders in particular products for which price control is contemplated. Apart from this, the committee recommended an increase in profitability ceiling from 6-11 per cent to 8-13 per cent on sales turnover of formulations. This was done in the light of the subsequent changes that have taken place in the economy due to oil crisis and unbridled increase in the cost of inputs and the increase in the bank rates (Government of India: 1975).

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47. Government of India (1975), *The Report of the Committee on Drugs and Pharmaceutical Industry in India*, Ministry of Petroleum & Chemicals, New Delhi, p.106.
48. *Ibid*, p.178.
49. *Ibid*, p.182.
50. *Ibid*, p.181.
51. *Ibid*, pp.182-184.

However, the Committee expressed its apprehension that the range of products that come under direct price control would be limited, and the manufacturer would therefore have much more freedom to adjust the prices of other products according to market conditions and would thus increase profits. In fact, just as the Committee foresaw the problem, the multinational companies reduced their production of drugs under price control, went in for the production of decontrolled drugs, and amassed huge profits (Sengupta: 1994).

3.6.1.5. Brand Names

The Committee trenchantly critiqued the concept of "brand names." According to the Committee, "effective competition is often vitiated by the prevalence of brand names"(Government of India: 1975:182). Therefore, the Committee initiated attempts to introduce phased abolition of brand names. In respect of formulations based on thirteen drugs, the Committee recommended that the brand names should be abolished (Government of India: 1975). It stated that the drugs, which were to be exported, may be allowed to bear brand names and new drugs should not be allowed to be marketed under brand names, when first introduced into this country (Government of India: 1975). The Committee's recommendation to abolish brand names aroused uneasiness from different corners.

According to Meena Gupta, this suggestion has not found support from doctors, manufacturers and policy makers (Gupta: 1976). There has not been any wholehearted attempt from the Government to abolish brand names in the last 25 years. Even though

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52. Sengupta, Amit (1994), "New Drug Policy: Prescription for Mortgaging Drug Industry," *Economic and Political Weekly*, Vol.29, No.39, pp.2526-27.
53. Government of India (1975), *op cit*, p.182.
54. *Ibid*, p. 182.
55. *Ibid*, p. 257.
56. Gupta, Meena, (1976), *op cit*, pp.71.

in 1981, legislation was introduced insisting companies to display generic names more prominently than brand names, this attempt was sabotaged by German and U.S. MNCs by obtaining a stay order from the court (Chowdhury: 1995). Thus, the abolition of brand names still remains as an uncherished dream.

6.3.1.6. R & D and Technology

In order to reduce dependence on import of technology, the Committee made recommendations to equip the laboratories for more specialised and sophisticated research. It entrusted the NDA to plan and supervise the development of indigenous know-how of natural products by utilising the relevant national laboratories, educational institutions etc. on an economic scale (Government of India: 1975).

In the political debate, the issue of Hathi Committee recommendations got sidelined because of other issues like Emergency, population control programme etc. during the period between 1975 and 1977. In 1977, the Janata Party again took up the issue of drug policy and the Hathi Committee recommendations. During its short tenure the Janata Party Government had pursued many people friendly policies. But as mentioned earlier, the Government was dissolved due to inner conflicts and thus, could not carry the policies forward. Thereafter, in the new political and economic climate, the Hathi Committee recommendations found little place.

3.6.2. The National Drug Policy 1978

The recommendations of the Hathi Committee did not see its place in the policy decisions until 1978, when the new Janata Party Government announced its Drug Policy. In fact, the Government in announcing the new Drug Policy of 1978 diluted the

57. Chowdhury, Zafrullah (1995), *op cit*, p.37.
58. Government of India (1975), *op cit*, p.162.

most significant recommendations of the Hathi Committee although it stated its intention to bring the operation and control of multinational drug companies in line with national needs and to follow the recommendation of the Hathi Committee (Chaturvedi: 1990).

The Drug Policy, as recommended by the Hathi Committee, insisted that foreign companies dilute their foreign equity to 40 per cent and thus, in a sense, nationalise themselves. However, contrary to the recommendations of the Hathi Committee, the Policy stipulated that remaining 60 per cent equity should be widely dispersed (of this 66 percent to public financial institutions and 34 per cent to Indian investors (Kapoor: 1990).

The Drug Policy reserved the production and distribution of 25 bulk drugs only to the public sector and 23 bulk drugs to the private sector. The remaining 66 bulk drugs were left out of reservations (Kapoor: 1990). It should be noted that some of the provisions of the policy were ambiguous and thus provided ample scope for manipulations. For example, according to one of the provisions, foreign companies manufacturing bulk drugs involving high technology were allowed to retain foreign equity exceeding 40 per cent to a maximum of 74 per cent depending on the proportion of the total turn over evolved in the production of such high technology drugs and activities, related to appendix – I or the 'core-sector' of the industrial licensing policy of 1973. The ambiguity involved in the very concept of 'high technology' was not sorted out by the policy.

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59. Chaturvedi, Harivansh (1990), *Drug Industry, Social Responsibility and the Multinationals*, Commonwealth Publishers, New Delhi, p.38.
60. Kapoor, Jyothi (1990), "The Role of the Public Sector Drugs and Pharmaceutical Industry in Meeting the Health Needs of the Indian People: An Analysis and Perspectives", Unpublished M.phil Dissertation, Centre for Social Medicine & Community Health, JNU, p.128.
61. *Ibid*, p.128.

In April 1978, a committee was appointed under the chairmanship of Mr.K.V. Ramanathan to identify the companies, which were involved in the high-technology bulk production. The committee identified 22 out of 31 companies as producing high technology bulk drugs and of the remaining nine companies, seven were formulators. Ultimately, the committee declared the remaining two companies as producing bulk drugs not involving high technology (Kapoor: 1990). Therefore in effect the majority of the MNCs retained their foreign equity and enjoyed all the privileges and concessions of an Indian company. This is one of the best examples for twisting or diluting the Hathi Committee recommendations in favour of foreign capital. In a way, the provisions of the Foreign Exchange Regulation Act, 1973 (FERA) also were indirectly harmful to the Hathi Committee recommendation that MNCs should be fully nationalised. According to the provisions of this Act: "All foreign companies, except shipping and airlines companies, were to be converted into Indian companies on a selective basis with the overall condition that all their branches and subsidiaries have a minimum 26 per cent Indian equity participation"(Chaturvedi: 1990:38).

The Policy stated that new licenses and regularisation of existing capacity for the manufacture of high technology bulk drugs and formulations in foreign companies could be considered only if they supply 50 per cent of their bulk drug production to non-associated formulators. At the same time, foreign companies were required to maintain the ratio of 1:5 between their bulk drug consumption from own manufacturer and formulation production from all sources (Kapoor: 1990).

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62. *Ibid*, p.128.
63. Chaturvedi, Harivansh (1990), *op cit*, p.38.
64. Kapoor, Jyothi (1990), *op cit*, p.131.

After diluting the basic recommendations of the Hathi Committee regarding multinationals, the policy then regulated the remaining companies under FERA (Kapoor: 1990). Apart from this, there were other lacunae in the policy as in the case of issuing licenses for bulk drugs or formulations where capacities had not been specified.

The policy document categorically stated that the regularisation of excess production in household remedies, foreign companies would not be permitted. But in practice, it went in a diametrically opposite direction. The policy document simply ignored and rejected the Hathi Committee proposals to establish a National Drug Authority (NDA) with the justification that it was not feasible. The Hathi Committee proposed the NDA with a purpose of monitoring, co-ordinating and streamlining of drugs and pharmaceutical sector in India. Therefore, by neglecting the Hathi Committee recommendation to establish the NDA, the 1978 Policy sabotaged the very idea to introduce a mechanism to control the sector.

As regards the issue of public sector, the Policy envisaged a leading role for the public sector in the drugs and pharmaceutical industry in India. However, it failed to make very specific recommendations on various issues such as financial outlays, technological support. This in effect diluted the whole issue.

The Hathi Committee's recommendation to abolish the brand names found little place in the Policy. However, for the purpose of introducing abolition of brand names, the Policy identified a list of five essential drugs, as against the Committee's list of 13 essential drugs. Apart from this, the Policy progressively accepted the Committee's recommendation of introducing all new single ingredient formulations under generic name.

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65. *Ibid*, pp.123-29.

3.7. Drug Price Control Order (DPCO) 1979

According to the Industrial policy of 1977:

> a sound price policy has to aim at a reasonable degree of price stability.... There has been a tendency to regulate prices of industrial products which are vital to the needs of development in a manner which made their production less attractive than production catering to the needs of the elite. It will be the policy of Government to ensure that in cases where there is price control, the controlled price will include an adequate return to the investor.... By the same token, Government cannot permit exorbitant profits being made by industries which are operating well below their capacity or by units which operate in a monopolistic environment (Government of India: 1977:8).

This gives the general idea of government's approach to the issue of industrial pricing. It has been a widely acknowledged fact that the drug companies are charging exorbitant prices. Almost all the committees have pointed out this fact in their reports. However, no systematic effort had been initiated until 1979 to address this issue. The issue of overpricing is a serious one, precisely because, exorbitant drug price limits or even blocks poor people's access to drugs. Therefore price control is crucial to medical care.

The DPCO, 1979, which was meant to control the prices of drugs was based on the recommendations of the Hathi Committee; but only partially. According to Sengupta, "for the first time comprehensive price control was introduced in the drug industry (through some price control measures had been in force since 1970)"(Sengupta: 1994:2527). The DPCO 1979 categorised drugs into four categories (1) Life Saving (II) Essential (III) Less essential (IV) Non essential/Simple remedies. It

66. Government of India (1977), *Statement on Industrial Policy*, 23rd December1977, New Delhi, p.8, para.32.
67. Sengupta, Amit (1994), *op cit*, p.2527.

also fixed different mark-ups (profit on cost of production) for the categories (Details are given below in Table 3.1).

Table.3.1 The Various Categories of Drugs and their Mark-Ups, DPCO, 1979.

Category	Mark-ups
Life saving	40
Essential	55
Less essential	75
Non-essential/ simple remedies	No control on price

Source: Government of India (1979), Drugs (Prices Control) Order, 1979

The idea behind this categorisation was to make life saving and essential drugs cheaper so that poor people can afford it. But even this was effort was substantially sabotaged by the MNCs and the Indian private companies as they focused more on the production of last two categories in which they have huge profits (Refer table.3.2 below).

Table.3.2 Production Details of Controlled Drugs from 1978 to 1980.

Category	1978	1979	1980
Life saving	4.5	4.2	3.6
Essential	16.7	14.8	13.2
Less essential	67.1	67	68.6
Non-essential/ simple remedies	11.7	13.2	14.6

Source: Reproduced by Phadke, Anant (1998) p.30 from P.L.Narayana (1984), *The Indian Pharmaceutical Industry: Problems and Prospects* ,NCAER, New Delhi.

The Order also stated that for bulk drugs which are manufactured indigenously or even imported, the government will fix: 1) Retention price for individual manufacturers, importers or distributors of such bulk drugs II) a pooled price for the sale of such bulk drugs with the aim of promoting indigenous technology. The price policy allowed price control exemption for a period of five years if the drugs are developed

through indigenous technology and which have not been developed elsewhere (Government of India: 1979).

There had been strong belligerent noises against Drug Policy, 1978 and price policy of 1979. A study conducted by NCAER under the sponsorship of OPPI came to the flawed conclusion that drug policy and price policy of the Government were causing heavy loss to the industry. Therefore, it argued for the modification of the policy decisions. With the support of this study report, the industry led by the MNCs, argued that the drug production was becoming unprofitable. According to Sengupta "In this campaign, they were joined by large companies in the Indian private sector which had by now consolidated their position in the industry" (Sengupta: 1994:2528).

Historically this has been a typical trait of the Indian capitalist class. This class; argues Bagchi "behave like short-sighted merchants even when they control large factories. The few who try to behave industrial capitalist and exploit the home market for increasing output and making productivity gains are all the time hobbled by myopic government policies following collaboration with foreign capital on unequal terms. There is plenty of evidence from Eastern India in areas such as drugs and pharmaceuticals, engineering, ceramics and metallurgy that the more progressive and more nationally oriented from of Industrial capital have been again and again overwhelmed by the less progressive and more collaborationist forms. This situation applies to many other parts of India"(Bagchi: 1991:17-18). At the same time, it should be noted that the large Indian private companies could develop themselves only after import substitution became a reality. In fact, this import – substitution was carried out

68. Government of India (1979), *Drug Price Control Order, 1979*, Ministry of Petroleum and Chemicals, New Delhi.
69. Sengupta, Amit (1994), *op cit*, p.2528.
70. Bagchi, Amiya Kumar (1991), "Reflections on the Nature of the Indian Bourgeoisie," *Social Scientist*, Vol.19, Nos. 3-4, pp.17-18.

with foreign technology, foreign capital and foreign 'aid' (Patnaik: 2001). In fact, this symbiotic relationship, which is essentially a relationship of unequals between the foreign multinational capital and the Indian capitalist class, has played a very crucial role in curbing the power of the State over them. Thus, the fight against the Government control over pricing is a classic example of the unholy alliance between foreign multinational capital and national private capital, which was grown with state protection and support.

3.8. ICSSR-ICMR Study Group Recommendations: The Drugs and Pharmaceutical Sector

In 1978, the International Conference on Primary Health Care, popularly known as the Alma Ata Conference, which was organised by the World Health Organisation (WHO) in collaboration with the UNICEF, came up with a declaration on health. The declaration was based on the fact that malnutrition and ill health among the poor are biological manifestations of a socio-economic factors like 1) foreign debt 2) exploitation of the primary (agricultural) sector 3) international and national income maldistribution 4) the commoditisation of agriculture 5) overt or hidden under-employment or unemployment 6) illiteracy particularly female illiteracy (Balasubrahmanyam: 1996). Based on this understanding it proclaimed that the PHC (Primary Health Care) was the key to achieve Health For All by the year of 2000. According to the Declaration, "Primary Health Care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that

71. Patnaik, Prabhat (2001), "The State in India's Economic Development" in Hasan, Zoya (ed), *Politics and the State in India*, Sage Publications, New Delhi, p.68.
72. Balasubrahmanyam, Kumariah (1996), *op cit*, p.14.

community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination"(WHO: 1978:1). The declaration also pointed that the provision of essential drugs and immunisation against the major infectious diseases are important components of the PHC (WHO: 1978).

Being a signatory of the declaration, India was also committed to the cause of Health for All by the year of 2000. Therefore the very formation and recommendations of the ICSSR-ICMR Study Group should be analysed in this background.

In 1981, ICSSR and ICMR jointly set up a study group with the aim of bringing health practitioners and social scientists together to study the social aspects of medicine with a view to suggest reforms which would lead to the improvement of the health status of the people and thus reach the state of Heath for All. The study group made an analysis of drugs and pharmaceutical sector and made recommendations also.

According to the study group, the pharmaceutical industry in India is the result, in essential sense, not of the indigenous development of the industry, but of the development of the industry in the western world (ICSSR-ICMR: 1981). Therefore, the pattern of drug production in India has been always influenced by the western counterpart. Since there are essential epidemiological differences between India and the west, the product pattern trends tend to be unsuitable for the needs of this country. In this background the committee strongly recommended that "the pattern of drug production in the country should be oriented closely to the disease pattern"(ICSSR-ICMR: 1981:125).

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73. WHO (1978), *Primary Health Care: Report of the International Conference on Primary Health Care*, Alma Ata,USSR, September 6-12, Geneva, World Health Organisation, p.1.
74. *Ibid*, p.2.
75. ICSSR & ICMR (1981), *Health for All: An Alternative Strategy- Report of a Study Group Set up jointly by ICSSR and ICMR*, Indian Institute of Education, Pune, p.124.
76. *Ibid*, p.125.

The report severely criticised the drug policy for its idea of producing drugs in 'abundance'. The report states that the excessive production has its own dangers like over-medicalisation.

The study group report realised the fact that the small-scale sector can play a very important role in taking the indigenous sector to self-sufficiency. In fact, even in 1981, India imported 40 per cent of its bulk drug requirement from abroad (ICSSR-ICMR:1981). By developing the small-scale sector, the study group thought that there would be a change in the current status of dependence.

With regard to the price control, like the Hathi Committee, it also came up with a lot of recommendations. Apart from this, it made a lot of recommendations to control the quality, to develop the Indian private sector, and to develop R&D and technology (ICSSR-ICMR: 1981). However these recommendations almost sounded like the Hathi Committee recommendations.

In fact, the Study group prescriptions for the illnesses of the drugs and pharmaceutical sector was a complete failure in its curative function due to various policy decisions. A detailed discussion of this is given in the next chapter.

3.9. The Concept of Essential Drugs

Theoretically, the concept of essential drugs is located where generic drug needs are unmet because of the drug demands created by market forces. According to Shiva, "the concept of essentiality is universal and is based on the following principles and criteria: (1) Therapeutic needs (2) Efficacy (3) Safety (4) Value for money" (Shiva: 2000:2).

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77. *Ibid*, p.126.
78. *Ibid*, pp. 126-127.
79. Shiva, Mira (2000), *Medicines, Medical Care and Drug Policy*, Voluntary Health Association of India, New Delhi, p. 2.

During the "stagflation" years of 1970's, most of the developing countries and under-developing countries were facing a resource crunch. In this background, the WHO guidelines came out, which said, " for the optimal use of limited finances the available drugs must be restricted to those proven to be therapeutically effective, to have acceptable safety and to satisfy the health needs of the population. The selected drugs are here called 'essential drugs', indicating that they are of the utmost importance, and are basic indispensable and necessary for the health needs of the population"(Shiva: 1986:69). The ICSSR-ICMR Study Group also suggested that the list of basic essential drugs should be calculated on the basis of the prevailing disease patterns (ICSSR-ICMR: 1980).

The concept of "essential drugs" should be differentiated from "rational drugs" and "priority drug list". The "rational drugs" are those drugs which are accepted worldwide and included in the standard textbooks of medicine and pharmacology, and "essential drugs" are those related to each country according to health needs of its people based on well defined criteria, whereas 'priority drug list' is drawn from among the essential drug list to give priority to drug production, distribution and availability for use in diseases having greater mortality, greater morbidity, severe sequelae and communicability.

According to UNCTAD, the small number of drug which suffice for almost all health needs and which may be called essential drugs, must be identified and listed.* It also stated that unless essential drugs are used in the private as well as in the public sector, an essential drug policy would not succeed. In 1975, the Hathi Committee also

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80. As quoted by Shiva, Mira (1986), "Essential Drugs: Concept, Need and Implementation" in Sengupta, Amit (1986), *op cit*, p 69.
81. ICSSR-ICMR (1981), *op cit*, p. 125.

* UNCTAD Guidelines – Annexure 2.1 in "A Rational Drug Policy" by AIDAN.

had recommended an essential drug list, which consists of 116 drugs. Later WHO also published a list of essential drugs consisting 200 drugs.

Even though there were many prescriptions on essential drugs, the government did not show any political will to implement the essential drug policy in its full spirit. The National Drugs and Pharmaceutical Development Council introduced an 'essential drug list' containing only 95 drugs. To an extent this was an eyewash. Since the Government was serving private interests, it simply discounted the 'essentiality' for a less significant cause of minimising the size of price controlled drug market. Unlike India, countries like Chile, Sri Lanka, Mozambique, Iran and Bangladesh are some of the countries that could do something substantially in the case of essential drug list.

3.10. An Overview of Indian Drugs and Pharmaceutical Industry

3.10.1. Structure of the Industry

The policy level changes had brought in itself changes in the structure of the industry. In 1983, there were about 9000 licensed drug manufacturers in India. Out of these, the majority were small-scale producers, ie. about 8750 units; the large scale units accounted for 250(Abrol and Guha:1986). The total capital investment in the industry had grown from Rs. 225 crores in 1973 to Rs. 600 crores in 1982.* Abrol and Guha point out that of this " one third is estimated to be in the public sector units which account for about ten per cent of the total formulation market and about sixteen per cent of the bulk drugs output reported in the country in 1983-84"(Abrol and Guha:1986:127).

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82. Abrol, Dinesh and Guha, Amitava (1986), in Sengupta, *op cit*, p.127.
83. *Data reproduced from *Indian Pharmaceutical Guide* (1997) published by Pamposhak, NewDelhi, p.3.
84. Abrol, Dinesh and Guha, Amitava (1986), *op cit*, p.127.

During the period 1979-84, quite a number of Indian companies have shown higher growth rate than that of the international companies. Details of the largest three national and international companies are given below in the table 3.3.

The provisions under the Patent Act of 1970 and the preferences and priorities enjoyed under the Drug Policy in the form of sectorial reservation also helped the indigenous private drug sector to expand themselves. The Indian private firms could produce those drugs of which the patent was not working in India. This helped the companies to sell drugs at cheaper and more competitive price than the MNCs. The drug policy facilitated the indigenous private sector to make rapid progress due to restrictions on the MNCs and protection to the Indian sector through the sectoral reservation in respect of licensing, production of bulk drugs and formulations.

Table.3.3 Growth Rate of Companies during the Period 1979-84

Name of the companies	Growth rate %
Indian	
Cadilla	192.60
Ranbaxy	168.91
Cipla	246.91
International	
Glaxo	55.41
Pfizer	40.51
Hoechst	90.03

Source: Jayaraman, K (1986), "Distortions Inherent in Drug Policy,"*EPW*, August 2, p.1381.

It should be noted that these companies achieved this growth rate under price-controlled marketing. An analysis of the All India Consumer Price Index given below(in table 3.4) would the evidence of the impact of price control. The consumer price index

of all the commodities has gone up by more than 300 per cent whereas the consumer price index of the drugs and medicines registered a hike as low as 89 percent.

Table 3.4. Comparison of Consumer Price Indices of All Commodities and Drugs.

Year	All commodities	Drugs and medicines
Base 1970-71	100	100
1980-81	270	137.5
1983-84	321.7	189.2

Source: Singh, Parvinder (1990), *Seminar*, p.44.

3.10.2. Production of Bulk Drugs and Formulations

The value of total bulk drugs production had grown from Rs.99 crores in 1974-75 to Rs.377 crores in 1984- 85. The sector wise value of the production of bulk drugs and formulations is given below in detail. Likewise, there had been tremendous growth in the production of formulations as the value of production had grown from Rs. 400 crores to Rs.1827 crores in the same time period.

Both the public sector and Indian private companies have contributed to the increased production in the sector. The main reason for the increased production in the public sector is that many new projects and plants were commissioned during the late 1970s like IDPL and HAL. Moreover, many plants could utilise its capacity to produce in a much better way. Since the PSUs spent a lot of money in establishing new plants and projects it faced a severe financial crunch. Moreover, mismanagement of units became a big problem to the public sector. As a result it incurred loss in their revenue. Details of the loss is given below in the table(3.6).

Table.3.5. Sector-wise Value of Production for Bulk Drugs and Formulations during the Period 1974-84

Sector	1974-75	1975-76	1976-77	1977-78	1978-79	1979-80	1980-81	1983-84
Bulk drugs (Total)	99	130	150	164	200	226	240	355
Public sector	33	43	48	47	49	59	62	61
Foreign sector	34	52	63	105*	56	53	56	65
(Percentage)	37.2	40	42	64	28	23.4	22.1	20.3
Indian private sector	23*	25	29	-	75	90	95	155
Small scale sector	-	10	10	12	20	24	27	74
Formulations total	400	560	700	900	1050	1150	1200*	1760*
Public sector	25	35	47	53	60	72		
Foreign sector	203	300	292	697	460	778		
Percentage	50.8	53.6	41.7	77.4	44.0	67.7		
Indian private sector	172	225	241	_	340	_		
Small scale sector	_	_	120	150	190	300		

*Break up data not available

Source: Abrol and (1986) in Amit Sengupta, ed. (1986), p.140

Table 3.6. Profit & Loss of Public Sector Undertakings

Name	Net Profit(+)/Net loss(-) Rs.in Lakhs		
	1982-83	1983-84	1984-85
IDPL	(-)2401	(-)1943	(-)2628
HAL	(-)23.87	(-)171.41	(-)498.00

Source: Maitra, Shambu (1986), "Actual Drug Needs: Facts and Fallacies," in Sengupta, A (ed), *op cit*, p.66.

With regard to the export of drugs, Indian sector achieved a substantial growth. The total value of export grew from Rs.3.05 crores in 1965-66 to Rs. 79 crores in 1983-84. Details of export are given below in the table(3.7).

Table 3.7. Value of Export of Drugs

Year	Finished formulations	Bulk drugs including quinine salts	Total (In Crores)
1965-66	1.16	1.89	3.05
1980-81	35.10	11.28	46.38
1981-82	69.34	15.45	84.79
1982-83	54.60	11.34	65.94
1983-84	61.46	18.46	79.92

Source: *Indian Pharmaceutical Guide* (1997), p.8

3.11. Summary and Conclusion

The decade of 1970s is known for the economic and political crisis all over the world. At the same time the decade also witnessed a few progressive changes in the many parts of the world, especially in the former socialist countries. The oil embargo implemented by the Arab world and subsequent economic crisis devastated the Third World economies. Most of the third world countries experienced severe BOP problem due to the skewed the international trade. Saving the foreign exchange reserve became the prime concern of the Government so as to protect the economy from further damage.

India under its unstable political leaderships initiated many efforts to control the MNCs and to save the local industries. However, in effect all the policy decisions including FERA ended up favouring the interests of the MNCs as there were loopholes in the policies. With regard to the drugs and pharmaceutical industry, there has been a lot of criticism against the MNCs as they charged exorbitant drug prices and were instrumental in the outward drain of wealth from India. The committees like the Hathi committee recommended the enhanced intervention of public sector in the drug production and stressed the need to develop the national private sector. Even though many of the recommendations were diluted with the National Drug policy of 1978 and

DPCO of 1979, the new policy brought in a new graded system of drug price control, which was essentially done to control the price of essential drugs. Besides this, some of the policy recommendations such as sectoral reservation and licensing priorities were beneficial to the Indian private sector. Therefore, with help of government policies and many other factors, the Indian drug industry started growing and started establishing its role in the market. However, the ICSSR-ICMR study group found out that the production pattern of the drugs in India was not oriented to the disease pattern of this country. According to the Study Report the main reason for this mal-orientation was that the Indian sector was essentially a result of the development of the industry in the west. Therefore, to reorient the Indian sector according to the needs of this country, the Report stressed the need for high level R&D. Another important point discussed is that of essential drugs. The many committees ever since the Bhore Committee have been recommending that the government take necessary steps to announce the essential drug list. But till date no serious effort has been made by the government. It should be noted that there has been severe pressure from the industry against the very concept of essential drugs. The industry, especially MNCs fears that an essential drug list would decrease their profit. The analysis of industry reveals that even though the production and sale of multinationals did not decelerate; it could not reach to the pace of Indian private sector. But both of them realised a potential threat in the market from the public sector and it became a common enemy to these two. Thus it paved the way for new political economy in the Indian drugs and pharmaceutical sector.

CHAPTER-IV

CHAPTER IV

Liberalisation and Drugs and Pharmaceutical Sector

4.1. Introduction

This chapter attempts to understand the changes that are taking place in the drugs and pharmaceutical sector under the liberalisation regime which was started in the mid-1980's. This chapter is divided into four parts. The first part of the chapter discusses the global economic and political scene since 1980. The second part of the chapter discusses the political economy of development in India since early 80's. The third part starts with a discussion of the National Health Policy of 1983 and moves on to discuss the NCAER report, which is an important document as far as the liberalisation of Indian drugs and pharmaceutical sector is concerned. This chapter also makes an attempt to understand the changes that have been taking place during the last two decades. The fourth part of the chapter presents an overview of Indian drugs and pharmaceutical industry during the last two decades.

4.2. Global Political and Economic Scene Since 1980

4.2.1. Debt Trap

As mentioned in the last chapter, the stagflation of 1970's paved a way for a new political economy in the world. Most of the developing countries faced BOP problems which subsequently led to much more devastating problems of massive external indebtedness. According to Arun Ghosh, during the 1970's there was a glut of finance availability in the form of petro-dollars and many commercial banks lent large sums of capital unwisely, especially to South American countries. But, these loans misfired; and in the early 80's, many borrowing countries around the world, particularly those in Latin America, faced problem of massive external debt- contracted at high

interest rates (Ghosh: 1994). At this point of time it became a matter of serious concern for the so-called "Paris Club," with the support of IMF, to support the sinking commercial banks of developed countries. This helped the IMF and the World Bank to take up a new role in the international political economy. This has been observed and well documented by academicians of developing countries. To quote Ghosh, "the IMF and the World Bank stepped in to lend the indebted countries, provided they did not renege on the debt contracted by them from commercial banks. Debt-servicing and debt-repayment thus became a first charge and a condition for assistance from the IMF and the World Bank. Debt –equity swap, all to the advantage of foolish and greedy lender to poor countries, became the order of the day. The Milton Friedman approach informed the IMF lending conditions; while the Hayek-ian approach of "minimum government" became the credo of the World Bank, even in regard to development financing" (Ghosh: 1994:1930).[2] As a result, debt repayment became an important consideration or the main driving force of the economic policies of the developing world.

4.2.2. Rise of Neo-liberalism

There have been many attempts of theoretical edification so as to justify the words and deeds of the World Bank and the IMF, more specifically, of metropolitan capital. The theories of new right wing economic liberals like Hayek and Friedman served the purpose of such theoretical edification. Their ideas of free-market and minimal state, which obtained more or less unquestioned acceptance in the developed countries, especially in the USA and UK, is broadly branded as neo-liberalism.

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1. Ghosh, Arun (1994)," Ideologues and Ideology of Privatisation of Public Enterprises", *Economic and Political Weekly*, Vol.XXIX, No.30, p. 1930.
2. Ghosh, Arun (1994), *ibid*, p.1930.

As an ideology, neo-liberalism influenced both Margaret Thatcher and Ronald Reagan, who could be considered as the political guardians of metropolitan capital during the 1980's. As a result, they implemented neo-liberal policy reforms in their respective countries. Moreover, Reagan impelled the IMF and the World Bank to assiduously pursue neo-liberal policies for developing countries, in regard to financing the balance of payment disequilibria and of the capital needs of development of hitherto underdeveloped countries around the world (Ghosh: 1994). Both Thatcherism and Reagonomics, which glorified the virtues of the free market and private economic interest, aggravated problems like economic recession unemployment and poverty in their respective countries (Tombs: 1996; Woolhandler et.al: 1993)

4.2.3. The Recession of the 1980's and its Impact

Most of the industrial market economies faced a serious deceleration in economic growth during the first half of the 1980's. One of the major factors for the deceleration was the tough monetarist policies - which consisted of tight restrictions on domestic monetary and credit expansion, cut backs in government expenditure and in ODA- adopted by developed capitalist countries such as United States, the United Kingdom, and increase in the real rate of interest. Furthermore, these policies had strong contradictory effects both in the countries implementing them and in those countries which are linked to them through trade and financial relations (Cornia et.al: 1987). According to Cornia et.al, through the mechanisms of trade, capital flows and aid; the

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3. Ghosh, Arun (1994), *ibid*, p.1930.
4. Tombs, S (1996), "Politics of Occupational Safety Regulation", *International Journal of Health Services*, Vol.26, No.2, p.311-12.
5. Woolhandler et.al (1993), "High Noon for US Health Care," *I.J.H.S.*, Vol.26, No. 2, p. 197.
6. Cornia et al (1987), *Adjustment With A Human Face*, Vol.1, Clarendon Press, New York, p.13.

economic crises was transmitted to the developing countries from industrial market countries (Cornia et.al: 1987).

Later, the stringent monetarist policies adopted by the U.S.A. helped its economy to rejuvenate from the recession. Consequently, the U.S. trade linkages and import structure have become the main determining factor for the development of the other countries (Cornia et.al: 1987). Thus the USA became a magnet of attracting capital flows from all over the world. Therefore this could be marked as the beginning of a new US –centered world order.

The global financial relations based on the asymmetric international trade and import structure consequently aggravated problems in the developing countries. However, a few South and East Asian countries like India, Indonesia, Pakistan, Sri Lanka suffered only a minor decline when compared to African and Latin American countries. According to Cornia et.al: "The sustained growth of agriculture production, the fruit of extensive investment, and of rapid technological improvement over the last ten years were the contributing factors which helped these countries from severe economic crisis whereas, most Latin American and African Countries suffered financial crisis in the form of indebtedness, poor growth rate etc." (Cornia et.al: 1987:19). In addition to this, there has been a substantial increase in the net outflow of resources from the developing/under-developed countries of the poor south to the developed capitalist countries of the rich north. The estimates provided by UNICEF show that the total outflow amounts to 60 billion dollars per annum (Rao and Loewenson: 2001).

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7. *Ibid*, p.16.
8. *Ibid*, p.16.
9. *Ibid*, p.19.
10. Rao, Mohan and Loewenson, Rene (2001), "The Political Economy of the Assault on Health", *Background Paper*, Peoples Health Assembly, Dhaka, p.6.

Therefore, the debt crisis and the economic recession of 1980's devastated the underdeveloped countries.

With the purpose of rescuing the Northern Banks, the IMF and the WB lent money and prescribed Structural Adjustment Policies (SAP) to the borrowing countries as ostensibly a way out. Based on neo-liberalist ideology, these policies are meant to help third world nations not default in loan repayment. The SAPs, basically consisted of the three pronged strategy of liberalization, privatisation and globalisation. In fact, to qualify the IMF and W.B loans these countries had to implement SAP, which ensured serving of their foreign debt and complying with the requirements of the Northern system (Werner & Sanders: 1997). Analysing this macro level political and economic process Chossudovsky comments, " A 'parallel government', which bypasses civil society, is established by the international financial institutions (IFIs). Coutries which do not conform to the IMF's 'performance targets' are blacklisted"(Chossudovsky: 1991:2527).

In order to assert hegemonic power, the developed countries of the North especially USA, made use of international organizations like GATT and the World Bank. These organizations were used to re-commercialise merit goods and services, which had been de-commercialised by Keynesian welfarism. It included health, education, and other social services. In fact, "the state involvement in the public health had been at the heart of the strategy to stabilise the economies, in a move to help capital

11. Werner, D and Sanders, D (1997), *Questioning The Solution: The Politics of Primary Health Care and Chlid Survival*, HealthWright, Palo Alto, p.83.
12. Chossudovsky, Michel (1991), "Global Poverty and New World Economic Order," *Economic and Political Weekly*, Vol.XXVI, No.44, p.2527.

growth and technological change."(Rao and Loewenson: 2001:3). In the changed political and economic conditions, liberalisation of the trade policies through tariff elimination and restrictions on imports became one of the major agendas of international negotiations. The W.B. had its own prescriptions and proscriptions to offer. The World Bank's *World Development Report, 1993,Investing in Health*, which clearly stated that the health is a commercial good. It called for more privatisation of health services.

GATT is the other organization which is being utilised by the rich countries to assert their hegemonic power over poor ones. The Uruguay round of negotiations of the GATT, which stated in 1987, was basically on trade related aspects of intellectual property rights; in which historically the GATT played only a peripheral role (Patel: 1989). The Uruguay Round, the longest round of multilateral trade negotiations held under the aegis of GATT made trade agreements which covered, for the first time in history, not only services but also agriculture, investments as intellectual property rights as patents, trademarks and copyrights. Later these agreements culminated in the establishment of the WTO (World Trade Organization) in 1994. The agreements that come under the WTO could be broadly classified into six broad categories.

- Multilateral Agreement on Trade in goods.
- General Agreement on Trade in Services (GATS).
- Agreement on Trade Related aspects of Intellectual Property Rights (TRIPs).

13. Rao, Mohan and Loewenson, Rene (2001), *op cit*, p.3.
14. Patel, S.J. (1989),"Inellectual Property Rights in the Uruguay Round: A Disaster for the South",*EPW*, Vol.XXI, No.21, May 6,p.28.

- Understanding on rules and procedures governing the settlement of disputes (DSV).
- Trade Policy Review Mechanism (TPRM)
- Plurilateral Trade Agreements.

By means of these agreements, especially GATS and TRIPs, multinational and transnational corporations, more specifically pharmaceutical, insurance, and health care companies, are making efforts to reap more and more profits (Sexton: 2001). According to Sarah Sexton: "International trade in commercial services was worth US $ 1.35 Trillion in 1999- about one quarter of the global trade in goods- up from some $ 400 billion in 1985 and from $1.2 trillion in 1995. This trade is firmly in the grip of the industrialized countries, which exported nearly 71 per cent of services traded internationally in 1997 and imported 67 per cent" (Sexton: 2001:3). Therefore it is clearly evident that the agreements of WTO have started aggravating the asymmetry in the global trade. It should be noted that the trade policies have a substantial influence on health. It is in this context that Sexton argues that "the World Trade Organization, not, the World Health Organization, is according to some, the international agency with the greatest impact on health"(Sexton: 2001:26).

In the beginning of the last decade the whole world witnessed the collapse of socialist project in the erstwhile USSR and other East European countries. This, too in away strengthened the neo-liberal ideology and thus, private enterprises got a big boost

15. Sexton, Sarah (2001), *GATS and Health Services*, Corner House, Briefing 23: Trade and Health Care, July 2001,p. 28.
16. *Ibid*, p.3.
17. *Ibid*, p.26.

(Ghosh: 1994). Moreover the economic reforms adopted by China and other communist countries in Asia and East European present the most "striking evidence of the global reach of free markets and private enterprises"(Ghai: 1997:29-32). Therefore, it appears that in a way everything under the sun went in favour of metropolitan capital.

In the whole process of neo-liberalization along with the globalisation of finance capital, a globalisation of poverty and insecurity are also taking place. In fact, the maintenance of global poverty and underdevelopment, especially of the Third World, constitutes the foundation upon which the national and world relative surplus populations are reproduced and sustained (Chossudovsky: 1991). In this process, the worst affected are the working class population of the entire world. Even the small and medium sized enterprises are suffering in the national and international scramble for profit. The only winner in this process is a group of big corporate, owners of capital and professional, technical and managerial personnel (Ghai: 1997).

In the globalised economic and political situation, most of the Third World countries have been victims of free moving capital. In effect, the Third World countries were trapped in a vicious cycle of low capital for initiating development, borrowing, devaluation, and less capital (Rao and Loewenson: 2001). Here, India also committed the same mistake, without learning from the experiences of Latin American and Africa.

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18. Ghosh, Arun (1994), *op cit*, p. 1930.
19. Ghai, Dharam (1997),"Globalisation, Change and human Security" in Lindberg, S and Sverrisson, A (ed) *Social Movements in Development*, Macmillan Press Ltd, London, pp. 29-32.
20. Chossudovsky, Michel (1991), "Global Poverty and New World Economic Order," *EPW*, Vol.XXVI, No.44, p.2536.
21. Ghai, Dharam(1997), *op cit* ,pp. 29-32.
22. Rao, Mohan and Loewenson, Rene (2001), *op cit*, p.6.

Sacrificing the needs and interests of the suffering millions of the country India also has been pursuing the neo-liberal reforms as directed by the IMF and the World Bank.

4.3. Economic and Political Scenario In India Since Early 1980s.

The contradictions of capitalist development in India reached its worst period during the 1980's after the stagnation of 1970's. In order to resolve the contradictions, the government lowered the tempo of public investment with the purpose controlling recessive inflation. The government adopted deficit budgeting also in these years. Moreover, by the end of the1980's Indian Government commenced borrowing from abroad. In fact, this eventually aggravated many other problems in the Indian economy. According to Prabhat Patnaik: "As the Indian economy piled up debt, a crash in the form of a collapse of creditor's confidence that dries up further loans and leads to a capital flight became inevitable". He adds, "this crash came in 1991, paving the way for the IMF (International Monetary fund) to come in with its liberalization-cum-structural adjustment package" (Patnaik: 2000:149).

Vanaik has argued that the cause of the balance of payment deficit and associated fiscal deficit can be attributed to the irresponsible manner in which the economy had been liberalised in the latter half of the 1980's (Vanaik: 2000). The import liberalization, inadequate growth in exports, poor taxation, etc led to greater economic crisis. The interest paid by the Government on debt increased from 10 per cent in 1980-81 to 19 per cent to 1990-91. Likewise, the total external debt (excluding short-term debt) and defence debt rose from $3.8 billion in 1980-81 to $ 62.3 billion by

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23. Patnaik P. (2000), "The State in India's Economic Development " in Hasan ,Zoya (ed), *op cit*, p.149.
24. Vanaik, Achin (2000), "The Social Character of the Indian State" in Hasan ,Zoya (ed), *ibid*, p.104.

1990-91(Vanaik: 2000). Consequently, the debt service burden nearly doubled during this period.

At this juncture of crucial macro-economic imbalance, the GOI approached the IMF/WB for loans. "These loans came with strings attached," notes Vanaik (Vanaik: 2000:104). Like many other third world countries India also accepted the Stabililisation and Structural Adjustment Programme (SSAP). The NEP (New Economic policy) implemented by the Narasimha Rao government showed its commitment to SSAP. This standard IMF/WB policy package gave impetus to liberalization process; which GOI pursued in 1980's in a cautious and careful manner. As a result, the foreign private investment in India registered a massive increase. It reached over $2 billion by 1996-97 from $ 208 million in 1986-87 (Vanaik: 2000).

The introduction of SSAP led to many fundamental changes. Of these, the most notable change is that there has been a gradual rolling back of state capitalism, where state had a role of both the producer and investor. In the changed economic and political conditions, the state took a new role of buttressing the position of large capital. In other words the state has been supporting large capital in general against the proletariat, the petty bourgeois and the small capitalists (Patnaik: 2000). Apart from this there is a fundamental change in the class configuration. Prabhat Patnaik observes "from a situation dominated by the domestic monopoly bourgeoisie in alliance with landlords, engaged in carving out a space for itself in opposition to metropolitan capital (even which collaborating with it), and for that reason enlisting the support of other classes

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25. *Ibid*, p.104.
26. *Ibid*, p.104.
27. *Ibid*, p.104.
28. Patnaik, Prabhat (2000), *op cit*, p.149.

(notwithstanding the fact that its aggrandizement perpetuate the misery of the poor), there is a transition to an alliance between the ruling classes and metropolitan capital, notably finance capital, under the hegemony of the latter which arrays itself against the other domestic classes"(Patnaik: 2000). As against the interest of the millions of people, and ignoring the domestic opposition, the government of India is still not ready to give up the liberalisation process, even which it has experienced all the negative signs of growth and development.

Indicative of this new ideological vision, and important in view of its great bearing on the drug and pharmaceutical sector, is a study report of the NCAER which prepares the ground for foreign private investment in these sectors. This report is thus analysed in some detail.

4.4. The NCAER Study: A Representation Of Foreign Private Interest In India

In January 1984, the National Council of Applied Economic Research (NCAER) published a study report, "The Indian Pharmaceutical Industry: Problems And Prospects". In fact, this study was sponsored by OPPI, which represents multinational companies' interests in India. This study covered aspects such as investment, trends in bulk drug production, trends in exports, technology, licensing policies, analysis of profitability, analysis of policy instrument of the government and so on. (Narayana: 1984).

Since most of companies refused to furnish information regarding the drug production, cost profitability etc, the study never claimed its findings represented the

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29. *Ibid*, p.151.
30. Narayana P.L. (1984), *The Indian Pharmaceutical Industry: Problems and Prospects*, NCAER, New Delhi, pp.23-24.

entire Indian pharmaceutical industry. However, despite this limitation, the study came up with dangerous conclusions. It vehemently attacked the government policies, especially of 1978 pertaining to the drug sector. It stated "the polices adopted by the government of India during the past decade were conducive neither to the import of modern-technology nor for its development in India. The policies were vitiated by ad-hocism, prejudice against larger business houses and foreign companies arising from political and ideological considerations....the cumulative effect of all these measures is the present stagnation in the pharmaceutical industry"(Narayana: 1984:126).

The NCAER study argued for the deregulation and liberalization of many policy restrictions and this argument was made in favour of multinational corporations. This is clearly evident when it says, "the present restrictions on larger business houses should be relaxed and mergers should be encouraged in order to enable Indian companies to face international competition" (Narayana: 1984:127).

The NCAER study vociferously argued for more profitability for the industry. According to Narayana, because of the price control measures that were introduced in 1979 through DPCO, the pharmaceutical companies were incurring losses. As a result, policy restriction was considered damaging for the industry. He observes, "the total effect of all these halting and restrictive measures was comparable to what the cultural revolution did to China's economy" (Narayana: 1984:96).

According to Narayana, the radical amendment through Indian Patent Act 1970 has completely failed to produce any tangible results (Narayana: 1984). He attributed the

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31. *Ibid*, p.126.
32. *Ibid*, p.127.
33. *Ibid*, p.96.
34. *Ibid*, p.127.

diversified growth of Indian drugs and pharmaceutical sector to the governmental policies which allowed liberal import of technology from overseas and the licensing policies which permitted the manufacturing units to diversify and grow (Narayana: 1984).

While discussing production capacity, the study glorified the role of multinational firms and severely criticized the public sector (Narayana.:1984). According to the study the public sector undertakings were bedevilled by technological obsolescence from the very beginning as the choice of technology was governed by political and ideological considerations instead of business principles. It should be noted that throughout the study Narayana used the logic of business principles and pragmatism to analyse the issues of an important sector like pharmaceuticals, which is one of the central aspects of health care.

As regards to the brand names, the Report stated, "The abolition of brand names for new drugs will prove a strong deterrent to their introduction into the country. The generic policy is likely to benefit only mushroom manufacturers and the traders"(Narayana: 1984:127). The Report also "warns" that the abolition of brand names would pave the entry for substandard and spurious drugs. Actually, these statements are based on the assumption that brand names carry quality assurance and purity. The Report also assumes that only large firms could produce quality drugs, which past experience has amply proved wrong.

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35. *Ibid*, p.43.
36. *Ibid*, p.51-52.
37. *Ibid*, p.127.

Apart from this, the report has some more ill-conceived notions of development, drug consumption and health. According to the statistics produced by the Report, value of per capita drug consumption in India was Rs. 0.41 in 1951-52. This has grown to Rs.19 in 1982-83. Compared to this, in 1982-83 the value Japan's per capita drug consumption was as high as Rs.1000. The Report stated, "the rise in per capita drug consumption may appear impressive. But a comparison of the domestic rates of consumption's with the some of the developed and developing countries shows a wide gap that is yet to be bridged"(Narayana: 1984:66). This statement is a negation of the complexities involved in the whole issue of accessibility and consumption of drugs. The very assumption that increased drug consumption would lead to a healthy society itself is highly questionable.

In order to solve the problems of the industry the report suggested the government to take up pragmatic polices which is based on business principles. To put it in Narayana's own words: "If the industry is to come out of the woods and meet the rising needs of the vast population, a more pragmatic growth oriented policy should be evolved by the government"(Narayana: 1984:126).

It is a widely acknowledged fact that the NCAER study report was not based on reliable and valid data. Its argument that drug companies were incurring losses after the 1979 DCPO has been proven false by both newspaper reports and academic studies. For example, *The Economic Times* (30 July 1984) reports, "the financial performance of 33 pharmaceutical companies substantially improved during 1982-83. The net sales, income gross profits and net profits of these companies increased during the year"(as

38. *Ibid*, p.66.
39. *Ibid*, p.126.

quoted by Mazumdar: 1984:16).According to Guha, the 1983-84 balance sheets of six multinational companies showed an earning of 21 to 70 per cent profit on the capital employed (Phadke A: 1998). A brief account of the financial performance of a few companies is given below in the table.4.1. It is clearly evident from these that drug companies were not in fact incurring losses.

Table 4.1 Pre- Tax profit of MNCs in India

Company	Financial Year	Pre Tax Profit
Hoechst	1984	2.23
Pfizer	1984	5.56
May & Baker	1984	4.01
Glaxo labs	1984	11.29
E. Merck	1985	1.85
Abbot	1985	0.62
Eskayef	1985	9.23

Source: Mazumdar (1986) in Sengupta, A. (ed.), p. 17.

The OPPI, which sponsored the NCAER study, used the study report, which clearly represented their interest, to pressurise the government. They launched an intensive campaign for the revision of DPCO 1979. "In the campaign" argues Amit Sengupta "they were joined by large companies in the Indian private sector which has by now consolidated their position in the industry" (Sengupta: 1994:2528). As an immediate outcome of this pressure, in March 1985 the central government delicensed 94 bulk drugs by making the policy of reservation of drug licenses almost infructuous

40. Phadke, Anant (1998), *Drug Supply and Use: Towards A Rational Policy in India*, Sage Publications, New Delhi p. 30.
41. Sengupta, Amit (1994)," New Drug Policy-Prescription for Mortgaging Drug Industry," *Economic and Political Weekly*, Vol.XXIX, No.39, 24 Sept., p.2528.

(Rane: 1996). Apart from this, in 1986, a new modification in NDP was brought in which was drafted according to the "pragmatism" and "business principles" that the NCAER study suggested earlier.

4.5. Drug Policy Measures in the Liberalization Era:

4.5.1. 1986 NDP Modification And Its Impact

As noted above, under severe pressure from the industry, the government came up with new measures for the industry, effectively subverting the NDP 1978. In 1986 the government announced "The Measures for Rationalization, Quality Control and Growth of Drug and Pharmaceutical Industry." The four major aims of the new measures is as follows:

1. To ensure abundant availability of essential drugs at reasonable prices.
2. To strengthen the system of quality control over drug production and promote the rational use of the drugs in the country.
3. To create an environment more conducive to channeling new investment into the pharmaceutical industry.
4. To strengthen indigenous capability of production of drugs (Government Of India: 1986:3).

The 1986 policy reduced the number of drugs under price control as enunciated by DPCO 1979. With the new policy, the number of price controlled drugs came down to only 166 bulk drugs from 347 in DPCO 1979. With regard to the reduction of price-

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42. Rane, Vishvas (1996), "Analysis of Drug Prices: 1980 to1995," *EPW*, Vol.XXXI, No.34, Aug 24th, 1996,p.2331.
43. Government of India (1986), "The Measures for Rationalization, Quality Control and Growth of Drug and Pharmaceutical Industry, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi, p.3.

controlled formulations, the new policy reduced it to 40 per cent as against 85 per cent in the DPCO 1979.

In order to liberalise the profitability measures the policy attacked the graded system of price control, which was introduced through the DPCO (1979) in which there were four categories of price-controlled drugs on the basis of MAPE (Maximum Available Post-manufacturing Expenses). The new policy decreased the number of controlled categories to just two and furthermore, it allowed higher MAPE. Thus for Category I, Essential Drugs, the MAPE allowed was 75 per cent and for Category II, the MAPE allowed was 100 per cent.

The 1986 policy was for the liberalisation of import restrictions on technology and bulk drugs and intermediates. With this, restricted drugs started coming into the Indian market under the provision of Open General License (OGL). It should be remembered that the earlier drug policy, based on the Hathi Committee recommendation, had restricted the importation of technology, bulk drugs, and intermediaries with the aim of developing a self-reliant national sector. Therefore, the policy level change with regard to the importation shows yet another instance of neglect of national interest.

With regard to brand names, the 1986 policy completely subverted the NDP,1978 decision. It allowed the companies to sell new single ingredient formulation under brand names on condition that the generic names shall be displayed in double size as the brand names.

The new policy document almost discounted the importance of the public sector. The public sector is no more expected to take up the leadership role, as recommended by the Halthi committee. Its role was restricted to the production of bulk

drugs for national health programmes. Thus the 1986 policy decisions and price order had a devastating impact on the public sector. It paved the way for the industry "to proliferate increasingly into the production of non-essential, irrational drugs and formulations which were already flooding the market" (Kapoor: 1990:154). Besides this, the lack of production control also led the companies to concentrate on low-technology areas, which produced irrational and non-essential drugs (Sengupta: 1994).

A study conducted by Vishvas Rane in 1996 showed that " there has been an overall price rise of 196.58 per cent which means that the drug prices have nearly trebled during 1980 to 1995" (Rane: 1996:2331). Likewise, the new price control system also created greater anarchy in production. According to Sengupta " the implementation of the DPCO of 1987, based on the 1986 policy led to an immediate hike in the drug prices" (Sengupta: 1994:2528). Another study conducted on the market share and production of 58 monitored bulk drugs after the implementation of the 1986 policy revealed that 1) In the case of 14 drugs, main production is in the small-scale sector; 2) Top 20 MNCs which account for 31.5 per cent share in eight drugs; over 25 per cent in four drugs and over 10 percent in five drugs of the eight drugs in which they have a major share, one is totally inessential, viz. Vitamin E. and one is hazardous, viz. Baralgan; 3) 40 top companies, which account for 63 per cent of the formulations market, have over 50 per cent share in only 17 out of 58 drugs (Sengupta :1999).

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44. Kapoor, Jyothi (1990), *op cit*, p.154.
45. Sengupta, Amit (1994), *op cit*, p.2528.
46. Rane, Vishvas (1996), *op cit*, p.2331.
47. Sengupta, Amit (1994), *op cit*, p.2528.
48. Sengupta, A(1999),"Infrastructure Development in Healthcare and the Pharmaceutical Industry: Implications of the *World Development Report, 1993*"in Rao,Mohan(ed), *Disinvesting in Health*, Sage Publication, New Delhi,p.159.

Therefore lack of production control helped the drug companies to concentrate their production on those drugs which were more profitable, irrespective of their therapeutic and epidemiological significance. One should note that whatever the multinationals wanted -- and whatever the NCAER study report suggested -- received its place in the 1986 policy. The logic of the market became the only criteria with which the government approached the drugs and pharmaceutical needs of the millions.

4.5.2. The Drug Policy 1994 and DPCO 1995

On 15 September 1994, the Government introduced a new drug policy. On the lines of the 1986 policy, this too was concerned with issues of deregulation and decontrol. The DPCO 1995, which was based on the drug policy of 1994, liberalised the span of control to an even greater extent. The number of controlled drugs came down to just 76 from 143 (Government of India: 1995:16).

The criteria for the selection of bulk drugs to be brought under the price control was modified (Government of India: 1994:14). The new criteria of including drugs under price control and other details are as follows:

1. A minimum annual turnover of Rs. 400 lakhs was considered as the criterion of including drugs under price control.

2. Drugs of popular use, in which there was a monopoly situation, were kept under price control. For this purpose, if for any bulk drug, having an annual turn over of Rs. 100 lakhs or more (or If there is a single formulator having 90 per cent or more

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49. Government of India (1995), *Drugs (Prices Control) Order, 1995*, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Petrochemicals, New Delhi.p.16.
50. Government of India (1994), *Modifications in Drug Policy, 1986*, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Petrochemicals, New Delhi, p.14.

market share in the Retail Trade (as per ORG)) a monopoly situation was considered as existing.

3. Drugs in which there was sufficient market competition viz. at least 5 bulk drug producers and at least 10 formulators and none having more man than the 40 per cent market share in the retail trade (as per ORG) were kept outside the price control.

4. Annual turnover was calculated on the basis of data up to 31st March 1990.

5. Genetically engineered drugs produced by recombinant DNA technology and specific cell/ tissue targeted drug formulation was kept out of price control for 5 years from the date of manufacture in India.

Apart from this, "a new drug which has not been produced elsewhere if developed through indigenous R&D would be put outside the price control for a period of 10 years from the date of commercial production in favour of the company who undertake the R &D" (Government of India: 1994:13).

The policy allowed a greater rate of return in case of bulk drug production in order to assist companies garner greater profit. The rate of return was increased by 4 per cent over the existing 14 per cent on net worth or 22 per cent on capital employed (Government of India: 1994).

The policy document clearly revealed its neglect of the public sector and thus the appeasement of multinational companies. The number of drugs reserved for the public sector was further reduced to just five (Government of India: 1994). On the other

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51. *Ibid*, p.13.
52. *Ibid*, p.15.
53. *Ibid*, p.12.

hand, the MNCs got a warm treatment. The policy permitted foreign investment up to 51 per cent in the case of all bulk drugs, their intermediates and formulations. It also decided to consider foreign investment above 51 per cent on a case by case basis in areas where investment is otherwise not forthcoming. (Government of India: 1994).

Thus, the 1994 NDP may be seen as surrender to private interest at the cost of sacrificing the needs of millions of poor people. In fact, the pharmaceutical sector is moving towards laissez-faire.

4.5.3. Pharmaceutical Policy –2002

The pharmaceutical policy 2002 reinstated the objectives of 1986 drug policy as it states that the objectives of 1986 policy remain still valid. In the introduction, the Policy stated: "the drug and pharmaceutical industry in the country today faces new challenges on account of liberalization of the Indian economy, the globalization of the world economy and on account of new obligations undertaken by India under the WTO agreements. These challenges require a change 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 pharmaceutical industry and towards making it more internationally competitive" (Government of India: 2002:1). Therefore in the changed political and economic conditions, a change in the policy decisions became inevitable. As in the case of drug polices of 1986 and 1994, the new policy also has many provisions of deregulation and delicensing.

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54. *Ibid*, p.12.
55. Government of India (2002), *Pharmaceutical Policy, 2002*, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Petrochemicals, New Delhi, p.1.

According to the new policy, industrial licensing for all bulk drugs cleared by Drug Controller General of India, all their intermediates and formulations will be abolished. But there exist some conditions and exceptions (Government of India: 2002). The new policy also permits up to 100 per cent foreign investment in the pharmaceutical industry. Besides this, it also relaxed regulations on foreign technology agreements (Government of India: 2002). Therefore like the previous two drug polices, the new policy also served the interest of foreign multinational companies.

With regard to the price control, the new policy introduced new criteria. According to the first criteria, in the case of bulk drugs, price control will be applied to 1) drugs which have annual sales of Rs. 2500 lakhs (25 crores) 2) drugs which have at least 50 percent of market share of any of its formulators. According to the second criteria, in the case of any particular bulk drug, price control will be applicable 1) if the annual sale of a drug is less than Rs. 25 crores but more than Rs. 10 crores; 2) if the percentage of market share of any of its formulators is at least 90 percent or more (Government of India: 2002). According to new criteria, there will be only 35 drugs under price control, ie. 23 drugs under first criteria and 12 drugs under second one. According to R. Rama Chandran "In 1995, the 74 drugs and their formulations that were under price control constituted about 40 per cent of the total market. In the present policy the span of control has been reduced to 22 per cent" (Rama Chandran: 2002:80).

The present policy has almost neglected the public sector undertakings. The policy does not have anything to offer to rejuvenate the PSUs. This is a clear signal of

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56. *Ibid*, p.4.
57. *Ibid*, p.4.
58. *Ibid*, p.6.
59. Ramachandran,R (2002),"Unhealthy Policy," *Frontline*, March 15,p.80.

withdrawal of the state from the role of investor and producer in the drugs and pharmaceutical industry. Over the years, there has been a complete role reversal of the state with regard to the issue of pharmaceutical PSUs. It should be remembered that, in 1956, the government through the Industrial Policy Resolution declared that the public sector would play a dominant role and that the private sector would play a subsidiary role (Ganguly: 1984). In 1976, the Hathi committee also strongly argued for the leading role of the public sector in pharmaceuticals. But as mentioned earlier in this chapter, by the 1980's the whole approach to public sector had changed. According to the Prime Minister, Rajiv Gandhi, the public sector had overstepped itself and therefore he encouraged the private sector to play a more active role in the industry (Ganguly: 1986). In a way it would not be incorrect to say that since then the denigration of public sector got more gravity and velocity.

While 1984 policy discounted the importance of public sector, the 1994 policy almost dismissed the role of public sector undertaking in pharmaceutical sector. The 1994 policy stated: "Many of the drugs reserved for the public sector undertaking have lost relevance vis-à-vis production programme of these units. Therefore, there is need to prune the list of items reserved for the public sector to only a few select items"(Government of India: 1994:3). According to Sengupta, deliberate neglect, mismanagement, corruption and sabotage at various levels led the public sector to the present dismal situation (Sengupta: 1994). Nowadays, almost all the PSUs are incurring huge losses every year, as revealed in Table 4.2.

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60. Ganguly.P.K (1984),"The Drug Policy: A Part of the Economic Policy of the Government" in Sengupta, Amit (ed), *op cit*, p.301.
61. *Ibid*, p.301.
62. Government of India (1994), *op cit*, p.3.
63. Sengupta, Amit (1994), *op cit*, p.2531.

Table 4.2 The Financial Performance Of The PSUs During 1999-2001 (Rupees crores)

Name of PSU	Production			Sales			Loss		
	1999-2000	2000-01	200-02	1999-2000	2000-01	2000-02	1999	2000	2001
IDPL	7.85	7.92	2.35	9.49	7.17	2.43	209.29	246.59	133.05
HAL	125.01	130.94	64.19	124.14	131.83	61.33	7.47	4.98	1.66
BCPL	43.39	45.01	21.99	36.35	33.82	18.92	3.87	7.02	1.54
BL	1.91	2.19	0.29	1.40	1.98	0.49	14.18	15.41	7.50
SSPL	3.21	5.36	2.35	2.44	4.11	2.43	6.68	9.79	133.05

Source: Compiled from the Annul Reports of Department of Chemicals and Petrochemicals, Ministry of Chemicals and Petrochemicals, of the years 2000-2001 and 2001-2002

In august 1992, the Bureau for Industrial and Financial Restructuring (BIFR) formally declared IDPL as a sick unit. In the mean time, there had been many half-hearted attempts to revive these units. But these efforts hardly succeeded in refurbishing the abysmal state of affairs. On 8th March 2001 BIFR issued a show cause notice to all the parties concerned for winding up of the IDPL. Now, they are working out strategies for speedy privatisation. At present the operations of IDPL have almost ceased except for marginal production in some of the units. The wages and salaries of the employees are being paid through non-plan assistance (loans) (Government of India: 2002).

As in the case of IDPL many other public sector unit like HAL, in 1997 (Hindustan Antibiotics Ltd.), Bengal Chemicals and Pharmaceutical Ltd.(BCPL) in 1993, BIL (Bengal Immunity Ltd.) in 1993, Smith Stanistreet Pharmaceutical Ltd.(SSPL) in 1992, have been declared sick due to the poor performance and loss.

64. Government of India (2002)-" Annual Report 2001-2002", Department of Chemicals and Petrochemicals, Ministry of Chemicals and Petrochemicals, New Delhi.

(Government of India: 2002). With regard to HAL, the penicillin plant has been handed over to private companies and the streptomycin plant has been leased out to another private company for the production of some other drugs

This has been the case of most of the Pharmaceutical PSUs. The BCPL has, however, started showing positive signs of recovery. The company's net loss per annum is coming down significantly. Besides this, BCPL obtained WHO GMP (WHO-good manufacturing practice) for manufacturing of tablets, capsules, and obtained ISO 9002 license for tablets and capsules.

In the case of joint sector undertakings, except Rajastan Drug and Pharmaceutical Ltd. (RDPL) and Karnataka Antibiotic & Pharmaceutical Ltd. (KAPL) all the other units are incurring losses (Government of India: 2002). Thus most of the PSUs are faced with serious problems including imminent closures. It should be noted that the Government's only interest in these units is that of handing over these units to private companies as early as possible.

Considering the above-mentioned facts, the Pharmaceutical Policy should have looked into the issues of pharmaceutical PSUs. But the policy neglected these issues and silently discounted the cause of PSUs, undermining their critical role in the production and distribution of cheap and quality drugs.

The Pharmaceutical policy, instead of bringing more essential drugs under price control, chose to bring only those drugs that are of mass use under price control. The new policy completely fails to suggest serious and systematic measures to control the increasing drug prices in the wake of liberalisation. It should be noted that India is a

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65. *Ibid.*
66. *Ibid.*

country where the burden of treatment is higher for the poor and mere hospitalisation or treatment can aggravate the intensity of poverty (Krishnan: 1999). In fact, a major chunk of the treatment expenditure is on the purchase of drugs. Another point to be noted is that the policy has taken a serious and dangerous decision to allow 100 percent FDI in the drugs and pharmaceutical industry in India. This undue importance to the MNCs is given at the cost of national private and public sector interests. Thus principles of self-sufficiency and self-reliance are completely discounted for the cause of 'free trade.' This is clearly an anti – people policy as it shrinks the scope of access of people to essential drugs. It would not be incorrect to say that the drug policy measures during the liberalisation period are drafted with the rationale of the neo-liberal market regime. It clearly spells out, indeed glorifies, the ethos of liberalisation and the retreat of the state.

4.6. TRIPs and Indian Drugs and Pharmaceutical Sector

As mentioned in the earlier part of this chapter, the Uruguay Round served as a framework for the negotiation of intellectual property rights, widely known as TRIPs (Trade Related Intellectual Property Rights). In fact, in the pre-Uruguay Round negotiation there had been strong opposition from developing countries to the inclusion of IPRs (intellectual property rights) in the new GATT treaty. The inclusion of IPRs in the GATT treaty was suggested by the developed countries. However, later in a changed political and economic context, where developing countries surrendered issues of economic sovereignty, their protest against exploitation by developed countries became weak and fractured. This eventually helped the developed countries to pursue their

67. Krishnan, T.N (1999)," Access to Health and the Burden of Treatment in India" in Rao, Mohan(ed), *op cit*, pp.221-27.

agenda in the GATT negotiations (Mishra: 2001). Thereafter the GATT negotiations culminated into the formation of the WTO (World Trade Organization) in 1995, which included TRIPs as its main component.

By signing the WTO agreement, the members, whether it is developed or developing countries, are committed to the new patent regime designed by the WTO. Thus those countries, which followed process patent regime, must provide for product patents of twenty years duration by January 2005. This particular shift has become a potential threat to the pharmaceutical industries of the developing countries and thus to their people.

In the developing countries, especially in India, the process patent regime for pharmaceuticals ensured the availability of drugs at relatively low prices. By January 2005 the production and sale of the drugs using process patent will become an illegal affair. Consequently the prices of drugs are expected to shoot up. Even immediately after the India's entry to the WTO there has been remarkable increase in the price of drugs (Shiva: 2000). Given below in the table 4.3 are the details of differences in prices of medicines in different countries. It should be noted that except India all other countries have been following product patent regime. It is clearly evident from the table (4.3) that there is a huge difference in the price of medicines; which is primarily due to the difference in patent regime. This is only an example of potential problems. Therefore, under the product patent regime there would be substantial increase in the

68. Mishra, Veena (2001),"TRIPS Review: Basic Right Must Be Restored," *EPW*, Vol. XXXVI, No.31, Aug.2001, p.4464.
69. Shiva, Mira (2000), *Medicines, Medical Care and Drug Policy*, VHAI, New Delhi p.22.

drug prices. This would adversely affect the millions of poor people in India in accessing and availing quality medical care.

The developed nations justify this anti-poor policy on the grounds that "high prices are necessary to ensure the delivery of new medical treatment in the future." But as Mishra argues, "In the case of "poor country" diseases such as malaria and T.B., stronger intellectual property protection, while necessary, may not, by itself, be sufficient to induce new improved and affordable medical treatments for these ailments" (Mishra: 2001:4464).

If we consider the present market structure, the situation of international and national pharmaceutical industry, the balance of payments, consumer habits, the legal environment and the country's pharmaceutical policy, it is an inevitable reality that the developing countries, especially India; are on the losing side.

Table 4.3 Differences in Prices of Medicines, May 1999

(Prices in Indian Rupees)

Drugs/ brands	Company	India	Pakistan	Indonesia	UK	USA
Ranitidine(Zantac) 150 mg x 10s	Glaxo	7.16	195.35	178.35	316.20	739.60
Times costlier			(27.30)	(24.90)	(44.16)	(163.30)
Diclotenic(Voltaren) 50 mg x 10s	Ciba Geigy	5.64	106.74	59.95	123.76	505.68
Times costlier			(18.93)	(10.63)	(21.94)	(89.66)
Piroxicam Dolonex/ Feldene 20mgx 10s	Pfizer	24.64	149.58	75.65	236.64	1210.88
Times costlier			(6.07)	(2.49)	(9.60)	(49.14)

Source: Shiva,Mira(2000), *Medicines, Medical Care and Drug Policy*,VHAI, p.13

70. Mishra, Veena (2001), *op cit*, p.4464.

Gorman Velasquez and Paseule Boulet in a book published by WHO have come to the conclusion that "because the geographical distribution of know-how is concentrated in industrialized countries this harmonization is likely to strengthen their existing economic superiority, in particular by prohibiting developing countries from copying a new product by reverse engineering and thereby developing their own technology" (Velasqnez and Boulet: 1999). This fatal situation was even mentioned in the *WDR 1997* which noted: "poor countries often lose out because the rules of the game are biased against them particularly those relating to international trade. The Uruguay round hardly changed the picture" (World Bank: 1997).

Recently, with the Declaration on the TRIPS Agreement and Public Health, the Third World countries have started seeing a ray of hope in the case of the patent regime. The Declaration recognised "the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics"(WTO: 2001:1). The discussion on TRIPS and public health came into the general understanding that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. The declaration also stated that the TRIPS can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. Another most important point is that the Declaration also stated: "Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted"(WTO:

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71. Velasques, Gorman and Boulet, Pasculc(2000), *Globalisation and Access to Drugs: Implications of the WTO/TRIPs Agreement*, WHO, Geneva, p.40.
72. World Trade Organisation (2001), *Declaration on the TRIPS Agreement and Public Health*, Adopted at Doha Ministerial Conference, p.1, para1.

2001:1). The declaration further specified that each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. Besides this, the least developed countries benefited more as the declaration agreed to extend the transition period until January 1, 2016 for the implementation of new patent regime in compliance with the WTO obligations.

Most of legal experts see the Declaration as a turning point in the patent politics and consider this as a victory of the Third World countries. However, the benefits of the Declaration can be enjoyed only if there are sufficient provisions in the patent legislation at the national level. Moreover, in the present economic and political context, it is less likely that the political leadership will exploit the provisions of the declaration to benefit the common people with regard to the issues of public health. For example, the present incidence of tuberculosis cases itself is more than sufficient condition to declare it as a national emergency. But the priority of the present government is different. Therefore the argument is that there should be political will to exploit the benefits of the Declaration. Only then will the motto of access to medicine to all be realised.

4.7. Amendment of the Patent Act

In is a widely accepted fact that the TRIPs agreement in a product of lobbying of multinational pharmaceutical companies and pressure tactics of the other and US

73. *Ibid*, p.1, para. 5.b.

developed countries (Agrawal P. & Saibaba, P: 2001). Ever since the enactment of the patent Act of 1970, India has been a target of multinational and the US attack. The US had been exerting pressure using special 301 provisions of the US Trade Act which put pharmaceuticals and other Indian industries on the watch list (Sathish: 1991, Keayla: 1994). According to the US Trade Representative, Mrs. Carla Hills: "India had been targeted because it provided an inadequate level of patent protection including too short a period of protection and overly broad compulsory licensing provision. As a result of total lack of protection, certain classes of inventions, particularly in the pharmaceutical industry, in 1995 the total loss (to the US) due to unfair patent laws was between $ 123 and 244 million per year" (as quoted by Sathish: 1991:104). However many economists like Dr. Surendra. J. Patel, a former director of the UNCTAD, has disputed these exaggerated figures (Sathish: 1991).

Succumbing to US pressure, India had to comply with the provisions under TRIPs from Jan. 1 1999, as it became a member of the WTO. With the purpose of amending the existing Patent Act, 1970, a bill was introduced in the Lok Sabha in March 1995. The Bill had the provisions to meet the WTO obligations. However, it did not obtain the approval of Lok Sabha. Later the bill was passed in the Rajya Sabha in December 1998. Even after this, the government could not pass the bill in the Lok Sabha due to the strong resistance from the opposition.

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74. Agrawal P. & Saibaba, P (2001),"TRIPs and India's pharmaceutical industry", *EPW*, Vol. XXXVI, No.39, Sept.29, 2001.
75. Sathish.V.M (1991),"Special 301 and the Indian Pharmaceutical Industry", *Man & Development*, December, p.104.
76. Keayla, B.K (1994),"Patent Protection and the Pharmaceutical Industry"in Nair, K.R.G and Kumar, Ashok (ed), *Intellectual Property Rights*, Allied Publishers, New Delhi, p.156.
77. Sathish.V.M (1991), *op cit*, p.104.
78. *Ibid*, p.104.

Since the US had lodged a compliant against India in the WTO, India was bound to amend the Patent Law in line with WTO provisions by April 1999. Therefore in order to satisfy this obligation, the government finally resorted to the introduction of the Patent (Amendment) Ordinance on 8th Jan. 1999. This new ordinance has provision for:

1. Filing of applications for product patents in the field of agro-chemical, and pharmaceuticals.
2. Grant of EMRs (exclusive marketing rights) for the applicant after a set of condition is fulfilled.

At last, in the midst protests and pressures, the Parliament passed the Patent (Second Amendment) Bill, 1999 in June 2002. The provisions of the Act are in compliance with the provisions of the WTO. Thus the new enactment has ushered in new patent regime in India.

Therefore, in the new political and economic atmosphere where measures taken for public health is regarded as a trade barrier, the interests of the millions have been sidelined or neglected and thus, national interest was discounted in favour of new globalised multinational capital. It is in this context that Sexton notes, "the use and promotion of TRIPs encourage shifting money from the sick and the poor to corporate shareholders" (Sexton: 2001:26).

4.8. An Overview of Indian Drugs and Pharmaceutical Industries

There have been many changes in the structure and composition of the Indian pharmaceutical industry over the years. Over 20,000 pharmaceutical producers;

79. Sexton, Sarah (2001), *GATS and Health services*, Corner House, Briefing 23: Trade and Health Care, July 2001,p.26.

including small-scale sector producers, exist in India. Of these, around 250 units are on the list of Director General of Technical Development. They are known as the organised sector and are responsible for around 40 percent of the total production. As in the case of number of producers, there has been a significant improvement in the number of formulations also. According to Shiva "...Indian markets are flooded with over 80,000 formations"(Shiva: 2000:1).

Table 4.4. Number of Drugs and Pharmaceutical Units in the Last Four Decades.

Year	No. of units
1969-70	2,257
1979-80	5,156
1989-90	16.000
1999-2000	20,053

Source: OPPI : 33rd Annual Report-2000

The size of the industry is expanding day by day as it registered a significant growth rate of 11 percent in 2000. It has done a business of Rs.20,000 crores in 2000 and Rs.23,000 in 2001.* The total capital invested in the industry also registered a high growth (see table 4.6 below). In 1952 it was only Rs.24 crores and it was Rs.600 crores and Rs. 2500 crores in 1982 and 1999 respectively.

The *Annual Report*, 2002 of Ministry of Chemicals and Petrochemicals claims that " today, India is in a position to meet 70 per cent of the country's requirement of bulk drugs and almost all the demands for formulations"(Government of India: 2002:3).

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80. Shiva, Mira (2000), *op cit*, p.1.

*Reproduced from *The Economic Times*, March 1,2001 and 2002.

81. Government of India (2002), *Annual Report 2001-2002*, Department of Chemicals and

82. Petrochemicals, Ministry of Chemicals and Petrochemicals, New Delhi, p.3.

According to OPPI, over 60 per cent of the bulk drugs produced is exported and rest is sold to the other formulators. The total value of production of bulk drugs has skyrocketed from Rs.240 crores in 1980-81 to Rs.3,777 crores in1999-2000. Likewise, the production of formulations also increased very markedly from Rs.12000 in 1980-81 to Rs.15960 crores in 1999-2000(see table (4.5) below for more details).

However, one should note the fact that import of bulk drugs is also increasing. This is a potential danger to the domestic bulk drug producers. Since liberalised import measures are in favour of MNCs, they do not produce drugs from its basic stage. In other words MNCs are more interested and engaged in the production of formulations. If the present situation continues there would be steep hike in the prices in the near future itself.

The total capital investment in the industry has increased substantially. It was only Rs. 225 crores in1973. Within 20 years it reached a figure as high as Rs.1,060 crores. Especially during the last decade capital investment has registered an astonishing growth. It should be noted that many of the private pharmaceutical company shares come under the blue chip category in the share market and therefore attract investors.

Table 4.5. Production of Bulk Drugs and Formulations during 1980-2000

Years	Value of Bulk Drugs (Rs. crores)	Value of Formulations (Rs. crores)
1980-81	240	1,200
1981-82	289	1,434
1982-83	345	1,660
1983-84	355	1,760
1984-85	377	1,827
1985-86	416	1,945
1986-87	458	2,140
1987-88	480	2,350
1988-89	550	3,150
1989-90	640	3,420
1990-91	730	3,840
1991-92	900	4,800
1992-93	1,150	6,000
1993-94	1,320	6,900
1994-95	1,518	7,935
1995-96	1,822	9,125
1996-97	2,186	10,494
1997-98	2,623	12,068
1998-99	3,148	13,878
1999-00	3,777	15,960

Source:OPPI, 2001

Table 4.6 Capital Investments in the Drugs and Pharmaceutical Industry from 1973

Years	Capital Investments (Rs. crores)
1973	225
1977	450
1979	500
1982	600
1985	650
1988	800
1993	1,060
1994	1,200
1995	1,380
1996	1,600
1997	1,840
1998	2,150
1999	2,500

Source:OPPI 33rd Annual Report-2000

Both the MNCs and Indian domestic producers in the private sector have shown significant growth. They have been reaping substantial profits from the business. Indian domestic giants like Ranbaxy, Cipla, Dr. Reddy's Lab etc. have been incurring huge profits (refer table 4.7). This shows that Indian companies are still benefiting from the patent policy and drug control policies. However, in this whole process, public sector units are nowhere in the scene. They have lost the battle almost completely.

Table 4.7. Financial Details of the Top Pharmaceutical Companies of Indian Private Sector

Name of the company	Sales		Net profit	
	Dec,2000	Dec,2001	Dec,2000	Dec,2001
Dr.Reddy's Lab	471.41	1200.47	81.01	358.47
Cipla	---	1034.49	--	167.48
Pfizer	327(Nov)	277.4(Aug)	39.47(Nov)	36.1(Aug)
Novartis	541.53	377.35	52.39	46.1
Ranbaxy	475.50	1996.73	53.1	182.23
Glaxo	934.62	--	70.54	--

Source: compiled from the *Economic Times*, Friday, 1st March 2002

Over the years both export and import have also been increased. According to the Annual Report, 2002, of the Ministry of Chemicals and Petrochemical, the exports have clocked a growth rate of 15.54 per cent in 1998-99, 15.57 per cent in 1999-2000 and 20.73 per cent in 2000-2001(provisional)(GOI: 2002). According to the Report, India exported drugs, pharmaceuticals and fine chemicals of Rs.6256.06 crores in 1998-99,of Rs. 7230.16 in 1999-2000, of 8729 in 2000-2001(provisional).* It should be noted that it was only Rs.46.38 crores in 1980-81(refer table 4.8. below for more details.). Over the years there has been a substantial increase in the export of the bulk drugs. This could be because the Indian companies were able to sell their bulk drugs at a cheap and competitive price in the international market.

Likewise, import has also increased to a great extent. In 1980-81, the total imported medical and pharmaceutical products worth Rs.112.54 crores (refer table 4.9 for more details). The latest figures shows that in 2001-2002 financial year, India imported medical and pharmaceutical products worth Rs.1701.46 crores (GOI: 2002). During the last decade import have increased significantly. This is because of the relaxation of import restrictions that came as a part of the liberalisation package. It should be noted that in the latter half of the last decade there is a substantial increase in the import especially in the import of bulk drugs. One of the reasons for the growing rate of drug prices during the last few years could be this. The growing amount of import is not a healthy sign for both the indigenous industries and the people as far as the question of self-sufficiency is concerned. During the time of

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83. Government of India (2002), *op cit*, p.3.

* The OPPI data does not tally with the data provided by the Government of India for the years 1998-99 and 1999-2000

84. Government of India (2002), *op cit*, p.4.

emergencies it might lead to problems in both availability and accessibility to the people.

Table 4.8. Export Composition of Drugs and Pharmaceuticals

Year	Finished Formulations	% of Total	Bulk Drugs Including Quinine Salts	% of Total	Total
1980-81	35.10	(76)	11.28	(24)	46.38
1981-82	69.34	(82)	15.45	(18)	84.79
1982-83	54.60	(83)	11.34	(17)	65.94
1983-84	61.46	(77)	18.46	(23)	79.92
1984-85	99.50	(77)	29.25	(23)	128.75
1985-86	106.59	(76)	33.36	(24)	139.95
1986-87	102.12	(54)	87.16	(46)	189.28
1987-88	88.25	(39)	139.71	(61)	227.96
1988-89	157.29	(39)	242.87	(61)	400.16
1989-90	314.20	(47)	350.50	(53)	664.70
1990-91	371.40	(47)	413.40	(53)	784.80
1991-92	558.50	(44)	722.60	(56)	1,281.10
1992-93	965.50	(70)	409.50	(30)	1,375.00
1993-94	1,310.80	(71)	530.80	(29)	1,841.60
1994-95	1,505.50	(66)	760.10	(34)	2,265.60
1995-96	2,044.80	(64)	1,132.90	(36)	3,177.70
1996-97	2,509.20	(61)	1,581.10	(39)	4,090.30
1997-98	3,180.00	(59)	2,173.00	(41)	5,353.00
1998-99	3,194.90	(54)	2,764.10	(46)	5,959.00
1999-00	-	-	-	-	6,631.00

*Excluding medicinal caster oil

Source:OPPI,2001.

Table 4.9 Import Composition of Drugs and Pharmaceutical Products.

Years	Bulk Drugs	Formulations	Intermediates, Chemicals, Solvents & others	Total
1980-81	87.24	9.62	15.68	112.54
1981-82	105.06	1.93	29.34	136.33
1982-83	115.55	5.41	27.52	148.48
1983-84	123.06	3.43	36.85	163.34
1984-85	178.41	10.17	27.05	215.63
1985-86	208.13	15.82	43.44	267.39
1986-87	207.49	21.84	58.26	287.59
1987-88	234.13	21.44	93.87	349.44
1988-89	328.35	35.43	83.13	446.91
1989-90	425.64	55.09	171.39	652.12
1990-91	322.57	84.94	196.49	604.00
1991-92	458.51	96.12	252.75	807.38
1992-93	508.39	119.51	509.48	1,137.38
1993-94	612.74	138.33	415.46	1,166.53
1994-95	811.43	173.02	384.27	1,368.72
1995-96	1,630.00	270.00	505.00	2,405.00
1996-97	1,705.00	345.00	555.50	2,605.50
1997-98	1,827.00	430.00	611.00	2,868.00
1998-99	1,918.00	540.00	670.00	3,128.00
1999-00	2,025.00	680.00	736.00	3,441.00

Source:OPPI, 2001

4.9. Summary and Conclusion

The oil embargo and subsequent 'stagflation' of 1970s resulted in many fundamental changes in the global political economy. During this global crisis developing countries suffered most as problems such as poverty and unemployment became very rampant. The BOP problem, precipitated through the skewed trade, later contributed to the mounting of external debt. In the meantime, the World Bank stepped in to assist the affected countries by loan on the basis of a few conditions. Eventually, most of these countries were entangled in the trap set by the World Bank by accepting the package of Structural Adjustment And Stabilisation Programme. Another point is that with the economic crisis of 1970s, the golden era of Keynesian welfare state ended.

As a fall out of this whole process a new US centered world economic order came into existence, where developed capitalist countries have a clear edge over the developing countries in international politics and trade. India being a part of global capitalist system had to undergo the crisis, which subsequently put India into a debt trap. Thereafter, by adopting and implementing the Structural Adjustment and Stabilisation package offered by the World Bank, India indirectly submitted its economic sovereignty to multinational capital. In this juncture the state monopoly capitalism started taking back steps and the state began to withdraw itself from the role of investor and producer in the economy. These changes had its impact on the drugs and pharmaceutical sector in India. In the wake of liberalisation along with globalisation and privatisation, the principles of pragmatism in the form of delicensing, decontrol, and deregulation have become part and parcel of the pharmaceutical policies. From the mid-eighties onwards there were many efforts to protect the interests of the MNCs at different levels. The study report brought out by the NCAER in 1984 is an example of such an effort. In fact, the NCAER study, which was sponsored by the OPPI, was not based on accurate data. In spite of this weakness, the Report argued that drug companies were incurring heavy losses due to government policies. However this argument has been proven false by both newspaper reports and academic studies. Later, the OPPI used the study report, which clearly represented MNC interest, to pressurise the government and campaigned vigorously for the revision of DPCO of 1979. In the changed political and economic conditions the government began its liberalisation of control measures in the industry. The government first reduced the number of drugs under price control from 347 to 166 with the modification of NDP in 1986. Later, this was again brought down to 76 and 35 in 1995 and 2002 respectively through policy level changes. The drug policies starting from 1986 discounted the importance of the Public Sector Undertakings (PSUs) in drug

production. As a result, almost all the pharmaceutical PSUs are facing potential closure and some of them are in the process of disinvestment. On the other hand , MNCs received a warm treatment as the government has decided to allow 100 percent foreign direct investment in the Indian drugs and pharmaceutical industry.

The enactment of the Patent Act of 1970 had invited a lot of criticism and displeasure from the developed world as it did not have product patent regime for agricultural products and pharmaceutical products. But the GATT negotiations and the resultant TRIPS agreement came as a serious blow to the Indian Patent Act once India signed WTO. In fact, India was compelled to amend its Patent Act in compliance with the provisions of WTO, which provides product patent regime for drugs and pharmaceuticals. The product patent regime according to TRIPS would lead to problems of accessibility and availability of drugs for the poor people. Moreover, this patent regime would destroy the Indian indigenous drugs and pharmaceutical industry, especially the small-scale sector.

Over the years the capital investment in drugs and pharmaceutical industry and production of the drugs also have been increased substantially. The export and import of drugs also have been increasing. The point to be noted is that the increase in the import of bulk drugs should be viewed with suspicion as it can take the industry back to the 1950s- a period of monopoly and high prices. Another important point is that a few Indian private companies have shown laudable growth during the past few years.

CHAPTER-V

CHAPTER V

Summary and Conclusion

This study is an attempt to contextualise and to understand the Indian drugs and pharmaceutical sector in the broader contours of international and national political economy. The study also traces the growth and evolution of drugs and pharmaceutical industry in India. Besides this, the study also reviews a few policy documents and committee reports that were crucial to the Indian drugs and pharmaceuticals. The first chapter of the present study deals with the historical background and the characteristics of the global drugs and pharmaceutical industry. The second chapter basically focuses on the development of the Indian drugs and pharmaceutical sector during colonial rule and immediately after the Independence. The third chapter analyses the policies that were decisive to the development of Indian drugs and pharmaceutical industry in 1970s and early 1980s. In the next chapter the issue of political economy of the liberalisation and drugs and pharmaceutical industry are briefly dealt with. What follows is a brief summary and the conclusions of the study.

The colonial regime of nearly 200 years brought in fundamental changes in socio-economic and political spheres in India. With colonisation the Indian economy was integrated into the modern international capitalist economy. During the British regime, India was a typical colony where raw materials were exported and finished goods were returned to the local markets. Apart from colonial plundering, the British regime hindered the natural growth of indigenous capitalism through biased policies, which restricted the growth of local industries and the trade activities of artisans. It was during this period that the allopathic system of medicine, which many people consider as a "tool of empire", entered India.

Not only did the British, especially the military, bear the burden of a huge load of preventable morbidity and mortality due to so-called tropical diseases, it was soon realised that the health of the British people could not be achieved by delivering healthcare measures targeting them alone. Moreover, the high morbidity and mortality rate of indigenous people working in the plantations and mines slackened efficiency and thus profitability also. These factors compelled the Government to intervene in the "indigenous health", however tardily and ineffectually.

In the latter half of 19th century, the British government established many public sector production units that engaged in the processing and production of galenicals and inorganic chemical preparations. The government also established the Medical Store Depots for the distribution of drugs. As it happened in the case of most of the other industries, India served as a typical colonial periphery from where raw materials for drug production were exported and later, finished drugs and pharmaceutical goods, were imported. Indeed the basis for so-called western medicine, the raw materials, were largely derived from the colonies and their medical practices. Moreover, the British controlled and monopolised the Indian drugs and pharmaceutical market and the proposals for drug substitution and indigenous private manufacture of drugs were not entertained during colonial rule, especially in the 19th century. The Indian entrepreneurial efforts in the drugs and pharmaceutical industry began with the establishment of Bengal Chemicals And Pharmaceuticals Works by Acharya P.C.Ray in the beginning of the 20th century. Thereafter, a few more small-scale firms also came in to the field of drug production. Large-scale production was almost absent in India. In fact, the Indian drugs and pharmaceutical sector during the colonial period and immediately after, does not have a glorious history of production and distribution. It would not be incorrect to argue that Indian national sector was almost virtually non-

existent during this period. The only bright spot in the history is that, by the early years of 1940s, Indian sector was able to meet about 70 per cent of the total medical requirements and also engaged in export of drugs to the armed forces in West Asia and the Far East. However, after a very short span of time this also collapsed. The main reasons for this were the end of the World War II, the therapeutic revolution in the West, and the entry of foreign firms to the local market with huge capital and technology. Another important point is that none of the national capitalists ventured into drug production though it was one of the most profitable industries. During the pre-1970 period, the Indian Patents Act, 1911, had caused lasting damage to the Indian sector. Moreover, the Indian state's industrial policies, which were considerably liberal to foreign capital, also retarded the growth of the Indian sector during this period. Another important point is that the dominance of MNCs kept drug prices high in the country. The irony is that the State took twenty-two years more to come up with a mechanism for controlling the prices of basic drugs.

The decade of 1970s is known for the economic and political crisis all over the world. At the same time, the decade also witnessed a few progressive changes in many parts of the world, especially in the countries which were having moderate socialist regimes. The oil embargo implemented by the Arab world and subsequent 'stagflation' of 1970s devastated the Third World economies. This resulted in many fundamental changes in the global political economy. During this global crisis, developing countries suffered the most. Most of the third world countries experienced severe BOP problem due to the skewed international trade. Saving foreign exchange reserves became the prime concern of governments so as to protect the economy from further damage.

India under its unstable political leaderships initiated many efforts to control the MNCs and to save local industries. However, in effect all the policy decisions including

FERA ended up favouring the interests of the MNCs as there were loopholes in the policies. With regard to the drugs and pharmaceutical industry, there has been a lot of criticism against the MNCs as they charged exorbitant drug prices and were instrumental in the outward drain of wealth from India. Committees like the Hathi committee recommended the enhanced intervention of public sector in drug production and stressed the need to develop the national private sector. Even though many of the recommendations were diluted with the National Drug Policy of 1978 and Drug Price Control Order (DPCO) of 1979, the new policy brought in a new graded system of drug price control, which was essentially done to control the price of essential drugs. Besides this, some of the policy recommendations such as sectoral reservation and licensing priorities were beneficial to the Indian private sector. Therefore, with help of government policies and many other factors, the Indian drug industry started growing and started establishing its role in the market. However, the ICSSR-ICMR Study Group found that the production pattern of the drugs in India was not oriented to the disease pattern of this country. According to the Study Report the main reason for this mal-orientation was that the Indian sector was essentially a result of the development of the industry in the west. Therefore, to reorient the Indian sector according to the needs of this country, the Report stressed the need for high level R&D. Another important point discussed is that of essential drugs. Many committees, commencing with the Bhore Committee, have been recommending that the government take necessary steps to announce the essential drug list. But till date no serious effort has been made by the government. It should be noted that there has been severe pressure from the industry against the very concept of essential drugs. The industry, especially MNCs, fears that an essential drug list would decrease their profit.

The analysis of the industry reveals that even though the production and sale of multinationals did not decelerate, it could not reach the pace of Indian private sector. But both of them realised a potential threat in the market from the public sector which became thus their common enemy. This then paved the way for a new political economy in the Indian drugs and pharmaceutical sector.

As mentioned earlier, the BOP problem, which was precipitated through the skewed trade, later contributed to the mounting of external debt in the third world countries. In the meantime, the World Bank stepped in to assist the affected countries by loan on the basis of a few conditions. Eventually, most of these countries were entangled in the trap set by the World Bank by accepting the package of Structural Adjustment And Stabilisation Programme. Another point is that with the economic crisis of 1970s, the golden era of Keynesian welfare state ended. As a fall out of this whole process a new US-centered world economic order came into existence, where developed capitalist countries have a clear edge over the developing countries in international politics and trade. India being a part of global capitalist system was also embroiled in this crisis, which subsequently put India into a debt trap. Thereafter, by adopting and implementing the Structural Adjustment and Stabilisation package offered by the World Bank, India submitted its economic sovereignty to multinational capital. In this juncture, the state monopoly capitalism started taking backsteps and the state began to withdraw from the role of investor and producer in the economy. These changes had their impact on the drugs and pharmaceutical sector in India. In the wake of liberalisation, along with globalisation and privatisation, the principles of pragmatism in the form of de-licensing, decontrol, and deregulation have become part and parcel of the pharmaceutical policies. From the mid–eighties onwards there were many efforts to protect the interests of the MNCs at different levels. The study report brought out by the

NCAER in 1984 is an example of such an effort. In fact, the NCAER study, which was sponsored by the OPPI, was not based on accurate data. In spite of this weakness, the Report argued that drug companies were incurring heavy losses due to government policies. However this argument is undoubtedly false as revealed by both newspaper reports and academic studies. Later, the OPPI used the study report, which clearly represented MNC interest, to pressurise the government and campaigned vigorously for the revision of DPCO of 1979. In the changed political and economic conditions, the government began its liberalisation of control measures in the industry.

The government first reduced the number of drugs under price control from 347 to 166 with the modification of NDP in 1986. Later, this was again brought down to 76 and 35 in 1995 and 2002 respectively through policy level changes. The drug policies starting from 1986 discounted the importance of the Public Sector Undertakings (PSUs) in drug production. As a result, almost all the pharmaceutical PSUs are facing potential closure and some of them are in the process of disinvestment. On the other hand, MNCs received a warm treatment as the government has decided to allow 100 percent foreign direct investment in the Indian drugs and pharmaceutical industry.

The enactment of the Patent Act of 1970 had invited a lot of criticism and displeasure from the developed world as it did not have product patent regime for agricultural products and pharmaceutical products. But the GATT negotiations and the resultant TRIPS agreement came as a serious blow to the Indian Patent Act once India signed WTO. In fact, India was compelled to amend its Patent Act in compliance with the provisions of WTO, which provide product patent regime for drugs and pharmaceuticals. The product patent regime based on TRIPS would lead to problems of accessibility and availability of drugs for the poor people. Already the drug prices have gone up since the latter half of the 1990s. In addition to this, the new patent regime

would destroy the Indian indigenous drugs and pharmaceutical industry, especially the small-scale sector.

Over the years capital investment in drugs and pharmaceutical industry, and the production of the drugs have also have increased substantially. The export and import of drugs also have been increasing. The point to be noted is that the increase in the import of bulk drugs should be viewed with suspicion as it can take the industry back to the 1950s- a period of monopoly and high prices. Another important point is that a few Indian private companies have shown laudable growth during the past few years. They have emerged as strong competitors to multinational corporations both in the Indian market and in other Third World markets.

Historically, it has been observed that the major players in the pharmaceutical politics have included MNCs, the indigenous private sector, the state and finally the consumers. In the Indian situation, multinational corporations have enjoyed a clear edge over other contenders with a huge capital base and patent protected technology ever since the colonial regime. The suppression of indigenous private manufacture of drugs and pharmaceuticals by the colonial government directly helped the multinationals to establish their hegemony over others. It also led to the stagnation of indigenous growth of the industry even after the Independence. During the World War years and the Depression, the Indian economy isolated itself from global capitalist system. This isolation had helped the indigenous private manufacturers of the drugs and pharmaceuticals to develop themselves to a greater level when compared to the previous years. However, when the economy was again reintegrated to the global capitalist system, these developments took a reverse step. Besides this, lack of sufficient effective demand in the native population could also be considered as one of the contributing factors for the retardation of the indigenous sector.

The indigenous drugs and pharmaceutical industry even after the Independence did not grow sufficiently to meet the drug needs of the country. Both the private and public manufacturers faced problems such as lack of infrastructural facilities, technology and R&D and capital investment to establish a self-reliant national sector. The patent policy implemented by the colonial government continued to handicap the indigenous drugs and pharmaceutical industry. The country's industrial and financial conditions, even political conditions, were not conducive to enact a new patent act that would favour the growth of indigenous industries. The collaborationist relationship that developed between the national capitalists and the multinational capital has actually shrunk the scope the Indian industrial sector. The dependency over the MNCs for the technology and capital investment compelled both the state and the private manufacturers to compromise in many ways. With this dependent relationship the MNCs could ensure that the drugs and pharmaceutical industry in India would not be a monopoly of the state. Besides this, the MNCs could continue their monopoly in the Indian market and it also helped them to carry forward their import based production structure, which helped them to levy exorbitant drug prices. However, with the policy level changes of the 1970s these situations changed, albeit to a small but significant extent. In fact, even these policies were implemented basically because of economic necessity.

The contradiction of the state in the pharmaceutical politics is clearly evident from the very beginning of the Independence to the present decade. The state has been performing mutually contradictory roles in the drugs and pharmaceutical sector. Primarily it has to facilitate for the primitive accumulation of private capital in the sector, where as on the other hand, it has to take necessary steps to satisfy the drug needs of the common people. Today it has been evident that the state has been

withdrawing from the role of investor and producer of drugs and pharmaceuticals. This should be understood in the backdrop of the rolling back of state capitalism, with India's initiation of neo-liberal reforms. Moreover there has been a right-ward shift in policies, including the new patent policy. It should be noted that none of these policies are of benefit to poor people in any form.

The return of multinational monopoly, high drug prices, and the import based production structure due to the policy level changes would take Indian drugs and pharmaceutical sector back to the era of colonialism, perhaps to worse than that. Only the functional entities in the free-market would enjoy the accessibility and availability of the drugs in the changed state of affairs. Thus in the changed political and economic conditions, the poor people are at the receiving end of the burden. This would imply the poor people would continue to suffer from unnecessary and unconscionable morbidity and mortality due to inaccessibility of medical care. This may also lead to wide spread re-emergence of communicable diseases, which are otherwise curable with medical care, in the near future.

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