# The Role Of The Public Sector Drugs And Pharmaceutical Industry In Meeting The Health Needs Of The Indian People. : An Analysis And Perspective.

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## SUPERVISOR'S CERTIFICATE

Certified that the dissertation entitled "The Role of the Public Sector Drugs and Pharmaceutical Industry in meeting the health needs of the Indian people - An Analysis and Perspective" submitted Miss Jyoti Kapoor is in partial fulfilment of six credits for the degree of Master of Philosophy of this University. This dissertation has not been submitted for any degree of this University or to any other University, and is her own work.

I recommend that this dissertation be placed before the examiners for evaluation.

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# TABLE OF CONTENTS

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# INTRODUCTION

# I N T R O D U C T I O N

The Indian national leadership that formed the Government in independent India inherited from its British predecessors an economy ravaged by unmitigated exploitation (inherent to its status as a colony of the British Empire), mirrored in the large scale suffering and poverty of its masses. Geared to subserve imperialist interests the Indian economy had been reduced to a state of abject dependence and subsistence by the British, who behind a facade of liassez faire used their state political power for purposes of economic drain deindustrialisation and inhibition of indigenous industrialisation.[1]

The basic challenge before the new Government which took over the administration of this ravaged economy, especially in view of the poor socio-economic profile of the people was the alleviation of human suffering by rejuvenating the economy through effective resource mobilisation and investment in the direction of socio-economic development involving all sections of the Indian people.

Based on their understanding of the economic problems facing the country the Government of India opted for a process of planned economic development and set itself the aim of establishing a more just and egalitarian social order, adopting the 'socialist pattern of society'

as a national objective.[2] The attainment of the above was envisaged through progressively increasing active state intervention as stated in its social and economic policy embodied in the Industrial Policy Resolutions of 1948 and 1956.[3 & 4] The resolutions postulated accelerated socio-economic development through the tenets of what is commonly known as the 'mixed economy'. A pattern of development that visualises a place for both private and public or state promoted sector was created as a major instrument of state control designed to countervail and check the operation of free market forces, preventing monopolistic tendencies and the concentration of power in private hands and, by their dominance, determining the nature of growth in consonance with broader socio-economic needs and goals of the society at large. Consistent with the social orientation of this Sector the public sector was expected to develop such industries which the private sector would not be able to take up due to financial and technological considerations or because of their long gestational periods and low profitability.[5]

Within the chosen fram work of socio-economic development, the importance of the welfare sectors of the economy was also realised and the Directive Principles of State Policy committed the state to,

"Strive to promote the welfare of the people by securing and protecting as effectively as it may a social order in which justice, social-economic and political shall inform all institutions of national life"[6].

Imbued with the above ideals of a welfare state the Government of India assumed responsibility for the elimination of poverty ignorance and ill-health from the country.

HEALTH SITUATION AT INDEPENDENCE AND POWER

The health situation of the Indian masses at independence mirrored the exploitation and subjugation inherent to their status as colonial subjects. The expectation of life at birth was only 26.91 years for the male and 26.51 for the female (1921-1930 figures) the death rate was as high as 22.4 (1934 figures) while the infant mortality stood at an enormous 162 (1937 figures)[8]. A major cause of the mortality was large scale epidemics of cholera, typhoid, plague, influenza and malaria which repeatedly ravaged the population especially affecting infants and children who accounted for 22.4% of the deaths occuring annually[9].

In context of the above scenario of rampant morbidity and mortality, independence from the colonial yoke and the transfer of power to the Indian leadership, was expected to bring about a radical change in policy and major

improvements in the health status of the people. In fact, as early as 1940 many years before the country actually gained independence the Sub-Committee on National Health of the National Planning Committee (1948)[10] had envisaged a peoples oriented health service system. The committee saw the State as responsible for the peoples health and proposed a decentralised integrated system of health care based in relevant research and adequate trained manpower, the corner stone of which was a community health worker. The Committee further proposed an integration of the indigenous systems of medicines into the health service system developed and stressed the need for socio-economic changes in improving the health status of the people.

Another committee whose vision regarding the nature of the health care delivery system to be developed in India is considered valid to date was the Health Survey and Development Committee (1946) the Bhore Committee as it was commonly called visualised the development of a health care delivery system located close to the people, with a rural base, a preventive bias, and with the primary health care unit as its pivotal structure from which all health care activities emanated.

Based on the recommendations of the Health Survey and Development Committee and the aspirations of the people the Government of India pledged itself to the provision of basic health services to all sections of

the people irrespective of their ability to pay for it and made health planning a part of the overall development planning process.

In addition to its recommendations related to the pattern of health services to be developed in the country the committee also addressed itself to questions related to medical pre-requisites. It stated,

"the final responsibility should in our view rest with the Government for seeing that the essential needs of the country with respect of all important medical pre-requisites are met and the responsibility should be interpreted as covering the necessity for ensuring that these requirements are met satisfactorily in regard to quantity, quality and price."[12]

The Indian drugs and pharmaceutical industry at independence, especially, in relation to the drugs and pharmaceutical industries in Europe and U.S.A. was only in its primordial stages of development though beginning had been made in the field of drug manufacture in the private sector by pioneers like Acharya P.C. Ray (who set up Bengal Chemical and Pharmaceutical Works in 1892) Messers T.K. Gajjar, B.D. Amin and Koti Bhaskar (sho started Alembic Chemical Works in 1901) and leading physicians like Nilratan Sircar, Kailash Chandra Bose, Bidhan Chandra Roy and others (who established Bengal

Immunity in 1919)[13] and in the State owned sector by the Haffkine Institute, which after the second world war was not only producing sera and vaccines but had also diversified into the production of synthetic drugs like sulphathiazole, sulphamerazine, sulphadiazine, atrebin, and had developed processess for the manufacture of pencillin and vitamin A.[14] The Pharmaceutical Enquiry Committee was constrained to note that in relation to its western counters parts, the

"drug industry in India may be considered non-existent."[15]

Further the team of Soviet experts who visited India in 1956 also stated,

"the pharmaceutical factories in India are mainly occupied in processing preparations of mixtures, tablets and injections etc. They are not being produced in this country but are imported from outside in bulk."[16]

After taking into account the state of the Indian drug and pharmaceutical industry and its commitment to a mixed pattern of economic growth. It was decided by the Government to develop the drugs and pharmaceutical industry under a certain degree of state regulation and control. Essential drugs and pharmaceuticals were thus placed in Schedule B of the Industrial Policy Resolution (1956). The 2nd Schedule consisted of those industries

which were to be progressively state owned and in which the state would generally take the initiative in establishing new undertakings, but in which private enterprise would also be expected to supplement the effort of the state.

THE PUBLIC SECTOR UNITS IN THE DRUGS AND PHARMACEUTICAL INDUSTRY.

In 1951 the Government of India entered into a collaboration with WHO and UNICEF to set up a pencillin factory at Pimpri near Poona. This was called Hindustan Antibiotics Limited. HAL started production of Pencillin with indigenous technology in 1954. In 1961 the 2nd public sector undertaking Indian Drugs and Pharmaceuticals was established in collaboration with M/s Technoexport of USSR. The undertaking initially consisted of three plants an antibiotics plant at Rishikesh or Synthetic Drugs Plant at Hyderabad and surgical instruments plant at Nandambakkam in Madras. Subsequently a new plant was established at Bela, Muzzaffarpur, in Bihar in 1978 for the manufacture of Niacinamide & some bulk chemicals. At the same time a formulations unit was set up at Dundahera at Gurgaon, Haryana and a formulation unit was also added to the surgical instruments plant at Madras.

17

In addition to the state promoted units the three sick units were taken over and nationalised at different points of time and today from a part of the public sector.

These include Smith Stanistreet Pharmaceutical Limited (1977), Bengal Chemical and Pharmaceutical Works (1980) and Bengal Immunity (1984) respectively.[18]

The rationale behind setting up public sector undertakings in the drugs and pharmaceutical industry was clearly stated in the 22nd report of the Committee on public Undertakings,

"the setting up of drug manufacturing units and surgical instruments factories in the public sector was intended to serve the triple objectives, namely to bring down the prices by large scale production of high quality drugs, to provide for medical relief to the people on a 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 exportable foreign exchange."[19]

In addition to the creation of public undertakings in the Drugs and Pharmaceutical Sector, in order to bring about a balance between the logic of the market place and the needs of the people especially in relation to the composition of output and the structure of prices in this sector the drugs and pharmaceutical industry was brought under direct Government regulation and planning. These regulations directed mainly towards private enterprise manifested themselves in the form of

policy measures on licencing, foreign capitals investment, pricing, and legislation related to drug quality control. Thus while the drug and pharmaceutical industry was brought under the industries (Development and Regulation) Act of 1951 right from the first five year plan, drug prices were controlled by the Government from 1962-63 onwards.

In 1978 the Government declared its first explicit Drug Policy. Based on the recommendations of the committee on the Drugs and Pharmaceutical Industry (1975),[20] the policy aimed at developing self-reliance in drug technology, providing a leadership role to the public sector, quick self sufficiency in the output of drugs with a view to reducing the quantum of imports, fostering and encouraging the growth of the Indian Sector, ensuring that drugs are available in abundance in the country to meet the health needs of the people, making drugs available at reasonable price, keeping careful watch on the quantity of production, offering special incentives for research and providing other parameters to control regulate and rejuvenate the industry as a whole with particular reference to containing and channelising the activity of foreign companies in accordance with national objectives and policies.[21]

In 1986 the Government brought out new measures based on the recommendations of the Steering Committee of

the National Drugs and Pharmaceuticals Development Council set up by the Ministry of Chemicals and Fertilizers (1984). The measures aimed at ensuring abundant availability at reasonable prices of essential life saving and prophylactic medicines of good quality, strengthening the system of quality control over drug production and promoting the rational use of drugs in the country, creating an environment conducive to channelizing new investment into the pharmaceutical industry, to encouraging cost effective production with economic size and to introducing new technologies and new drugs while strengthening the indigenous capability for production of drugs. The major areas of implementation of the new policy were pricing, licencing, quality control and the rational use of drugs.[22]

## THE DRUG AND PHARMACEUTICAL INDUSTRY; STATUS ( 1987-88) AND ORIENTATION.

The drugs and pharmaceutical industry has shown tremendous growth over the past four decades. It consists of over 350 units in the organised sector including five Central Government Public Sector Undertakings, seven Central and State Government Joint ventures, viz. Joint venture of HAL with the Government of Karnataka and Maharashtra and I D P L with the State Government Undertakings viz. Bihar and West Bengal[23] and a strong presence of the transnational corporations

(there are 31 direct foreign equity holding companies operating in this sector) (Table-1 Appendix-1). Additionally there are more than 8000 small scale units in the drug and pharmaceutical industry (of which not more than 1500 are active at any one time).[24]

The industry today is capable of producing 350 bulk drugs while the total number of formulations vary anywhere between 45,000 and 50,000.[25] The magnitude of growth in this sector is further substantiated by the fact that the total investment in this sector has increased from a mere Rs.24 crores in 1952 to Rs. 750 crores in 1987-88.[26] The value of output has similarly increased from a mere 35 crores in 1952 to 2830 crores for the year 1987-88 (Table-2 Appendix-1).[27] The industry whose successful operation is a function of technological innovation has made great strides in research and development (Table-3 Appendix-1).[28] In fact UNIDO in its classification of the pharmaceutical industries of the less developed countries placed India in Group V, the most advanced stage indicating near self-sufficiency in raw materials for production of drugs from basic stages and a wide variety in therapeutic groups of drugs produced.[29] Further the country is exporting a large number of formulations and bulk drugs, the figures for 1988-89 being Rs.350 crores about 10 - 15% of production.[30]

While there is no undermining the quantum of growth shown by this industry in the decades following independence the pattern and direction of growth of the industry has not been in consonance with the felt needs of the people or national priorities. The ICSSR-ICMR Joint-Group putting the above picture in perspective stated in their report,

"It is not enough to see that drugs are produced by Indians and in abundance. It is even more important to see what drugs are produced and for whom".[31]

Thus, despite the labyrinthine nature of regulatory statutes under which the drugs and pharmaceutical industry has operated, less than 20% of the Indian population today has access to modern drugs. The total insensitivity of the industry to the drug needs of the people may be seen from the fact that while the disease profile of the country continues to be one associated with poverty, lack of environmental, sanitation and hygine and the absence of a potable water supply for large sections of the people, with undernutrition and communi cable diseases like cholera, typhoid, dysentery, malaria, leprosy and filaria continuing to be major causes of morbidity and mortality (Table-4 Appendix-1) the production of drugs and pharmaceutical is geared towards non-essential irrational and sometimes even hazardous drugs.[32] These in the guise of nutritional

supplements, vitamin and mineral preparations (including tonics growth elixirs, appetite stimulants, multi-vitamin capsules and vitamin injections) fixed dose combinations (including antipain combinations antibiotic combinations etc.)[33] and cough and cold preparations, flood the markets while the production of essential drugs used to combat malaria, filaria, tuberculosis, diarrhoeal diseases kalazar and leprozy continue to fall short of estimated demands so that short falls have to be made good through imports. (Table-5 Appendix-1).[34] Not only is the production of drugs geared towards non-essentials but the industry through massive promotional compaigns and high pressure sales tactics is also successful in determining the pattern of sales so that even these show the same trends. (Table-6 Appendix-1).[35] The fact that an over whelming majority of drugs in the Indian market are sold under brand names as against generic or chemical names has further strengthened the hands of the industry which uses brand names to create brand loyalities among physicians resulting in the generation of a strong product competition as against price competition.[36] In effect then a producer in this sector may through suitable sales promotion succeed in maintaining a high sales volume despite a higher sales price. In view of the price in elasticity of demand thus created it is not surprising

that drug prices have remained high, escalating enormously every year. The drug price index calculated on the basis of 'B' age old and static drugs rose by 41.9 points in 1970-71 with 1961-62 as the base year.[37] Between 1970-71 and 1980 it rose by 35 points between 1980-86 with the same base year.[38] The unreasonable nature of drug prices is further substantiated by the fact that despite less than 20% of the people having access to modern drugs and a considerably large percentage of the population lying below the poverty line the per capita expenditure of drugs worked out to, 2.2 US $ ( 1985 figures)[39] which is no mean expenditure in consideration of the above facts.

Further, as against the dominant role envisaged for the public sector, the drug market, in the country is controlled by a few large firms in the private sector most of which had considerable foreign equity holdings. According to the Retail Store Audit of the Operations Research Group (1984-85) the top ten firms including six direct foreign equity holding companies controlled about 37% of the entire market for drugs.[40] Additionally while these firms have consistently (both in the past and present) been able to make considerable profits[41, 42] the public sector with its onus of social responsibility stands on the side lines fighting for its very survival. All five public sector undertakings

are running for considerable losses for over a decade (Table-7 Appendix-1).[43] The dismal condition of the public sector may be gauged from the fact that out of the already meagre outlay of Rs.144.9 crores for the sixth plan the public sector expenditure was only Rs.87.59 crores on account of "non-generation of internal resources.[44] The continuing losses of the public sector have infact come in for a lot of flak both in the Parliament and in the Press with their present profile being attributed to mismanagement, poor capacity utilisation, low production levels, stagnant sales and general inefficiency.[45 & 46] Many have even accused the public sector of joining hands with the multi-nationals in the collective loot of the consumer. One such critic has stated,

"If multinationals have exploited customers in their business interests one wonders whether the public sector has defrauded them by making them pay for their own mis-management, poor efficiency and dismal performance.[47]

Dr P.N. Dhar, a noted Economist delivering the 4th V.T. Krishnamachari memorial lecture on "Constraints on Growth Reflections on the Indian experience" described the public sector as a "public liability" suggesting that public sector investment during the 8th plan

should be restricted to existing limits for improving their performance.[48]

The increasing disillusionment with public enterprises has not been restricted to those outside the Government, it has even found expression in statements made by representatives of the Indian State itself the former Prime Minister Shri Rajiv Gandhi for example has stated,

"we were unable to achieve socialism since we laid emphasis on one aspect ignoring the conditions of the poor, we concentrated on the role of the public sector to achieve socialism. Can we afford socialism where the public sector instead of generating wealth is absorbing and sucking the wealth of the people."[49]

An increasingly felt trend infact is in the direction of the liberalisation of the Indian Economy through the dilution of state controls resulting in the opening up of the economy to competitive market forces as against focus on public sector growth and dominance, in meeting the drug and pharmaceutical requirements of the Indian people. The 1986 policy statement is bearing testimony to this trend. The policy while failing to identify a clear role for the public sector, except in terms of the need for the existing public sector undertakings to function at

optimum level of efficiency in production and marketing, focuses mainly on the increased availability of drugs through liberalization in licencing and price regulations.[50]

The overt shift in Government policy today towards increasing liberalizations, sidelining the public sector an important instrument of public policy, is in considerable contrast to post independence beginnings which envisaged a dominant role for public undertakings in the Indian economic experience. It also makes the present attempt at understanding the role played by the public sector drugs and pharmaceutical industry in meeting the health needs of the Indian people relevant. The need for wider understanding of the role played by this sector in the past and its future becomes even more meaningful at this stage when the Government has only recently reiterated its committment to the provision of basic health care to all its people by becoming a signatory to the Alma Ata declaration, aiming at Health for All by the year 2000 A.D.

## AIMS AND OBJECTIVES OF THE PRESENT STUDY

Within the larger canvas of the social, political and technological forces which have shaped the growth of the Indian economy, the present dissertation aims at obtaining a more holistic understanding of the use of the public sector, and its growth and present status

with reference to the drug and pharmaceutical industry and to analyse within the same perspective their role in meeting the health needs of the Indian people.

SPECIFIC OBJECTIVES

1. Tracing the historical growth of the drug and pharmaceutical industry in India with special emphasis on the growth of the public sector.

2. Examining specific Government policies affecting sectoral growth with special reference to their impact on the growth of the public sector i.e.

- the official Drug policy (1978, 1986)
- the official Policy on Patents (Patent Act 1911, Amendment of Patents Act of 1911 in 1950) and Patents Act 1970)
- the official Policy towards foreign capital (before and after FERA)
- Industrial Licencing Policy
- the official pricing Policy (Drugs (Display of Prices) Order 1962, the Drugs (Control of Prices) Order 1963, the Drug (Display and Control), Order 1966, the Drugs price Control Order 1970, Drugs Price Control Order 1979, Drugs Price Control Order 1987).

3. Studying the nature of interaction between different sectors of the industry and their impact on the growth

and performance of the public sector.

4. A comparative analysis of the different sectors in context of

- their pattern of drug production
- market strategy
- research and development
- product quality

with special reference to their consonance with the health needs of the people.

## CHAPTERIZATION

### Chapter - I

It was in the colonial period that the foundations of the present day Drugs and Pharmaceutical industry were laid. It shall therefore trace the historical evolution of the industry prior to independence and attempt to assimilate historically the social, economic and political determinants of the post independence economic policy of the Indian Government.

### Chapter - II

Government Policy to a large extent determines the nature extent and type of state control on an industry directing its growth Chapter-II shall attempt to trace the growth of the Indian drug and pharmaceutical

industry in relation to changing government policy in key areas including pricing, licencing, import and export of drugs & patents over time as affected by the changing social, economic and political mileu of factors affecting key policy decisions, special emphasis shall be laid on the implications for the public sector.

Chapter - III

This Chapter shall profile the major public sector units in the country and discuss the internal contradictions and constraints faced by the public sector and the nature of its interaction with the other sectors of the industry.

Chapter - IV

Officially the discussion chapter, it attempts to interlink the issues raised through chapters I, II & III with the present status of the public sector and questions the present trends in the industry in context of stated government goals and objectives.

Chapter - V

The penultimate chapter highlights conclusions arrived at on the basis of analysis in the previous chapters.

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# CHAPTER - I

# BRITISH LEGACY

## CHAPTER - I

## SECTION - I

### BRITISH LEGACY

As the Indian colonial experience is considered a factor of major historical importance in influencing both the pre and post independence pattern of Indian industrial growth and development, it is but appropriate that the present attempt at recounting the historical evolution and growth of the Indian drugs and pharmaceutical industry and the rise of the public sector within should begin, from coordinates located within the framework of the above experience.

### THE EARLY PHASE OF BRITISH DOMINANCE

With colonial policies and priorities being directed largely towards the interests of the British Crown, initial developments associated with the growth of the Drugs and Pharmaceutical sector were apparently patchy, and prompted more often than not by crisis situations which either undermined British Military and political dominance in India or affected smooth trading operations.

The often quoted concern of both the Company and later the British Government, for the health and welfare of the British Army, was also infact wrought by the realisation of the instrumental role the army had to play in the Companies political consolidation in India and in the continuing security of its "eastern possessions"[1]. Medical Officers initially employed by the Company were few in

number and their social status extremely low. It was only in the middle of the eighteen centary with the out-break of war between England & France in 1745, and battles of similar intensity being fought at the same time between the French and English Companies, on the Indian soil of Mysore that the Company first felt the need to employ surgeons with its troops and at its factories.[2] The period between 1745 and 1760 then saw an increasing recruitment of medical officers by the Company leading in 1764 to the institution of the Indian Medical Service (IMS).[3] The service, in view of the increasing number of wars fought throughout the 18th and early 19th century grew considerably in importance.[4]

Surgeons serving the Company were equipped with medical accessories including drugs. These were largely imported. The East India Company infact had a long history of imports from the Society of Apothecaries at London.[5] Interestingly the weakest link of the allopathic system at this stage of its developmental history was therapy. Pharmacology was still in its infancy and practice continued to be dominated by such therapeutic procedures as blood-letting and purging.[6] Effective drugs were few and consisted mainly of extracts and tinctures of Animal and vegetable origin.[7] In the above context, it is not surprising that the indigenous systems of medicine aroused considerable interest among the Companies surgeons who were not averse to employing native Indian doctors in the IMS.[8]

It was within the above framework that Education in the Allopathic system was first introduced in 1822 at Calcutta. Classes were initially held in combination with classes in the Ayurvedic and Unani Systems.[9] The colonial policy towards the indigenous systems was extractive as against supportive and growth oriented.[10] Not surprisingly, therefore, with the establishment of the first medical college in 1835 and the IMS reaching its full strength the same year, classes in the indigenous systems of medicine were abolished from the official curriculum while courses in Allopathic medicine lengthened and teaching conducted completely in English. The years that followed were marked by the establishment of medical colleges at Madras, Bombay and Lahore and the setting up of medical schools in different parts of the country. Allopathic medical education was thus well established by the latter half of the 19th century.[11]

The impact of state patronage and the propogation of Allopathic medical education was manifold. Not only did it give a death blow to the already stagnating indigenous systems but also marked the beginning of the gradual ascendence of the Allopathic system to a position of dominance. The clientile of the indigenous systems started slowly shifting to the Allopathic system.[12] The need for Allopathic medicinal preparations, as an obvious corollary to the latter, further brought into focus both the possibility of their indigenous manufacture and the creation of a market for their sale. The former especially in context of the limitations in therapeutic arsenal, the stability

(at that early stage) of pharmaceutical technology and elementary structure of the industry which was restricted to small scale laboratories of retail pharmacists even in Europe,[13] under extended state patronage should not have posted problems of great enormity. The British Government however, despite the above conditions prevailing at that point of time preferred to continue to import required medicinal preparations from Great Britain, France and Germany as against their indigenous manufacture.[14] The lack of state interest was further substantiated by the fact that no recognised courses were organised in Pharmacy before 1896 while an Act requiring a degree of knowledge in Pharmacy was passed much before.[15] Even indigenous enterpreneurs did not take the initiative of setting up nascent production units since they did not see sufficient profit in this. The possibilities of making higher rates of profit through money lending, land ownership and trading, acted as effective deterents to private investments in drug manufacturing activities and no drug manufacturing unit came up in India before the last decade of the 19th century.[16]

A market for allopathic medicinal preparations, (although initially limited by the poor access of the general populace to the practioners of this system, the considerable competition faced from practioners of the indigenous systems and the inherent limitations of available therapy in the allopathic system at this stage of its developmental history,) was, however created. Druggists stores

started sprouting in areas where the allopathic system had started taking roots. The earliest historical evidence of the establishment of such a store being dated back to 1811 when a scot by the name of Bathgate came to India with the East India Company and started a Chemist Shop in Calcutta.[17]

While the initial period of British dominance thus did not result in the establishment of an indigenous manufacturing industry and the market for allpathic preparations remained limited, certain developments of considerable historical importance did arise from the framework of priorities followed by the British much before the terminal decade of the 19th century. Firstly opium processing factories were set up by the Company at Ghazipur and Patna (1820) as a consequence of the Companies flourishing monopoly trade in opium with China.[18] Opium trade itself being developed by the Company to solve remittance problems which surfaced as a result of the decline of traditional exports of cotton and silk manufactures from India due to Manchester competition.[19] Further inconsonance with the traditional British aim of developing India as a market for British manufactured goods in view of her raw materials, India was developed as a source of raw-materials to the British Drugs and Pharmaceutical Industry.[20] The Government encouraged, with a liberality beyond procedure the cultivation of medicinal plants suited to India, and even the experimental cultivation of those proved to be unsuitable for growth on the Indian soil, only, so that they could be exported to drugs and pharmaceuticals manufacturing countries like Germany, France and Great Britain and then be reimported from Britain as extracts and tinctures at much higher prices.

Nux Vomica, Sandal Wood, Indian hemps, Cinchona, Chiretta, castor and croton oil seeds, Linseeds, Seasame and Groundnut oil, Kino, Ginger, Capsicum, Senna, Catechu, Tea waste, Tea dust and many others were thus exported by India.[21] The British benefitted doubly from this Policy. While economic dependency was thrust upon India as she became an exclusive preserve for unloading of British pharmaceutical products on one hand, Indian export surpluses with countries other than Britain, as the principle/sole supplier of some of the above raw-materials on the other hand contributed towards settling British balance of payment problems with these nations.[22]

## POST MUTINY PHASE

The mid 19th century marked a major watershed in the colonial health policy and changes in the drugs and pharmaceutical sector too. The considerable enhancement in the numbers of British troops stationed in India following the mutiny of 1857 coupled with the findings of the Royal Sanitory Commission (1859) which stated that the high mortality among the European troops was not due to the wars they fought but mainly due to diseases including fevers, dysentry, diarrhoea, liver diseases and cholera, made it essential for the British to undertake certain measures to reduce mortality and morbidity in the British Army.[23] It was as a part of these measures that the British decided to introduce Cinchona (the bark of which plant is

the source of the anti-malarial alkaloid quinine) as a public health measure, in Darjeeling and the Nilgiris in 1861.[24] Factories were started in Naduvattum in the Nilgiris and Mungpoo in Darjeeling District for the extraction of total alkaloids in 1871. Qunine Sulphate was first manufactured near Darjeeling in 1887 while the factory in the Nilgiris followed suit in 1890.[25]

An interesting development that occured in 1870 was the introduction of Medical Stores Depots by the British Government. Introduced in some important cities in the country with the primary objective of ensuring the supply of drugs instruments and appliances of uniform quality and pattern for the army in India, the Depots in the course of time extended their sphere of activity to Civil Medical Departments of Local Governments, municipalities, District boards and some princely States. The importance of these Depots was further enhanced when the Depots at Madras and Bombay gradually commenced the preparation of chemicals serving as major competitors of initial indigenous private entrepreneurs in Drug manufacture.[26]

Another trend that emerged at about the same time as the introduction of medical Store Depots by the British Government was, the establishment of Research Institutes for the study of communicable diseases in India. The spread of the germ theory of disease by Louis Pasteur (1822-1895) and the identification of pathogenic becteria as the cause of many communicable diseases, at a stage when India was

being repeatedly ravaged by epidemics of communicable diseases like Plague (1896-1918) Malaria, Smallpox and Cholera, to the extent of effecting trade dislocation, resulted in a number of eminent scientists being invited to India to conduct research on these diseases.[27] To facilitate these efforts early state enterprises in the Drug and Pharmaceutical sector were established these included the Kings Institute of Preventable Medicine (1904) the present Haffkine's Institute (1896) the Pasteur Institute Coonor (1907) and the Drug Research Institute, Kasauli (1905).[28]

INDIGENOUS ENTREPRENEURSHIP

Initial inroads by indigenous entrepreneurs in the directions of drug manufacture were made only in the last decade of the 19th century. This was a stage at which the developing chemical basis of pharmacology coupled with advances in pathology was ushering in the pharmacological revolution in Europe, while a growing national awakening among the middle class educated intelligensia found expression in an economic critique of foreign rule in India and on that basis in an increasing stress by national leaders on indigenous industrialization along capitalist lines.[29] Scientists and nationalist entrepreneurs like Acharya P C Roy, B D Amin, Captain Narendranath Dutt and many others in response to the above call launched small drug manufacturing units in different parts of India.

P C Roy an eminent chemist launched Bengal Chemical and Pharmaceutical Works (BCPW) on the outskirts of Calcutta in 1892. Roy who was haunted by the problem of

middle class unemployment used the observation that raw materials locally available in India were being exported from the country only to be imported as finished products at such higher costs to establish B.C.P.W. as an Institution where the genius of the young would find full play for creation and organisation. Starting with import substitutions, the firm set up a research laboratory and developed many vital drugs, producing them from basic stages without any foreign help and with mainly indigenous raw materials. It also revived the image of some potent indigenous drugs and fought for their inclusion in the British Pharmacopoeias.[30]

In Western India T K Gajjar another renowned chemist inspired his student A S Koti Bhaskar and B D Amin to set up a small factory manufacturing drugs and toilet preparations. A spirits factory was established at Baroda in 1905 and Alembic Chemical Works incorporated in 1907.[31] Calcutta Chemicals was similarly founded by Rajendra Nath Sen, Birendra Nath Maitra and Khagendra Chandra Dasgupta (distinguished students and teachers of Science at the Bengal Engineering College, Shibbpur) in the beginning of 1916. The establishment of Bengal Immunity 3 years later was another notable event. In 1919 a group of leading physicans and scientists Nilratan, Sircar, Kailash Chandra Bose, Bidhan Chandra Roy and others set up this firm. Starting initially with the manufacture of Sera and vaccines the firm had the objective of attaining self-sufficiency in the field of medicine.[32]

It is of considerable importance at this stage to characterise the above industrializing group, and to distinguish them from the big business groups who continued to remain aloof from these changes in view of the policy of free trade followed by the British Government which when coupled with the environment of mass poverty made investments in domestic industry, for supply of home markets, unprofitable. These pioneers did not have a back ground of family business, they were genuine entrepreneurs, belonging to the middle class intelligensia who started out with a modest capital and nationalistic ideals in a negative environment charged with public prejudice, lack of Government patronage, foreign competition etc. with the aim of achieving self-sufficiency through economic nationalism leading eventualy to economic and political freedom. The establishment of this character of the initial industrializing group is important at this stage as the anti-imperialist pro-nationalist quality of the pioneers has been repeatedly used as we shall see later for the benefit of the profit oriented indigenous industry both prior to and after independence.

## THE WARS - THEIR IMPLICATIONS

The first stimulus for domestic manufacture came through the chaos created by the first World War. The cutting off of earlier sources of supply and the impositions of tariffs on imported manufactures boosted production. The production of caffein from tea dust and surgical dressings was established during this period in addition to an increased manufacture of galenicals.[33]

The Medical Store Depots of the Government also played a major role in drug manufacture during the war, meeting demands for medical stores both internally and externally (as in the case of war torn East Africa, Mesopotamia and Egypt). These Stores were at this stage often able to produce drugs at much lower costs than local manufacturers, (a situation interestingly, which made local manufacturers to feel threatened, to an extent that they eventually protested against government involvement in manufacturing activity to the Drug Enquiry Committee in 1930).[34]

The considerable impetus to the growth of the indigenous Drugs and Pharmaceutical Industry received during the war, could not be maintained during the interwar phase. This was despite the fact that the economic and political crises faced by British imperialism during this period resulted in a new twist to the Indo-British dependency equation, whereby the British Government decided to follow a policy of guided industrialization and granted several concessions to Indian industry.[35] Factors that may may be identified as causative in the condradictory impact on the drug and pharmaceutical industry are discussed below.

Firstly, not only did the war give an impetus to the growth of the Indian Drug and Pharmaceutical Industry but also to the British and American Drugs and Pharmaceutical sectors. Both countries prior to the war were dependent on Germany for their requirements of complex organic

chemicals. The temporary withdrawal of the German Chemical Industry during the war brought home the problems associated with reliance on one supplier for materials critical to national welfare. Both USA and Britain thus included chemicals in their policy of key industry duties on imports, allowing local firms to achieve substantial growth within their home markets.[36] Secondly the modern drugs and Pharmaceutical industry developed largely as a subsidiary of the fine chemical industry. Direct Government support and the chemical basis of the Drug Industry in these advanced countries allowed the industry to take great strides during the war. The industry undertook the manufacture of organic arsenicals, barbiturates, aspirin, phenacetin, etc. Not only, was development more rapid but occured from the basic stages of drug development in contrast to India where the developments were restricted to the final stages of drug formulation and where no direct Government support was forthcoming. Further, while the industry in the West continued to be protected during the post war phase (with the first major break through of the therapeutic revolution occuring in 1935 and the development of sulpha drugs and a variety of chemotherapeutic drugs and vitamins being discovered during this period,[37] restrictions that had been placed on imports through higher tariffs during the war period. The local industry faced increasing competition from Companies abroad, a number of whom established their offices in India in the early 20th century.[38] It was not surprising therefore that the Indian industry was unable to continue developing

at the same pace in the interwar period as it did during the war.

In the face of increasing competition from abroad the Congress Party in support of the industry, in the year 1930, took the decision to bycott all drugs manufactured by foreign companies. The British Government reacted to this move by establishing the Drugs Enquiry Committee with the specific purpose of enquiry into the extent to which impure and defective drugs were being imported, manufactured or sold in the country and to recommend measures to control such imports, manufacture or sale. The timing of the appointment of the Committee according to the Committee itself was such that, "the motives of the Government were questioned and the Committee itself was viewed with considerable suspicion ....." The distrust found expression in columns of a section of the press .....". "The fact that it was constituted soon after the inauguration of the campaign to boycott British drugs, the delay of about 3 years in giving effect to the Resolution of the Council of State, and the alleged absence of any attempt on the part of the Government to develop or encourage the drug industry in India in the past, were relied on in support of this view. The intention to stifle the indigenous drug industry of India and to restrict the Indian market to British drugs to the exclusion of those of other foreign countries was openly attributed to the Government. The financial stringency and supposed unrepresentative character of the legislatives were stressed

to show that the appointment of the Committee at this junction was highly inopportune and ill-advised".[39]

The Drugs Enquiry Committee also known as the Chopra Committee as it was chaired by Col. R N Chopra recommended the following: (i) Central legislation to control drugs and pharmacy (ii) establishment of test laboratories in all States for the purpose of controlling the quality of imported drugs and also to act as an expert body in disputes between States arising from their analysis of samples (iii) prescription of minimum qualification and setting up training courses for the pharmacists and (iv) compulsory registration of all patent and proprietory medicines of undisclosed formula whether imported or manufactured in the country.[40]

It was ten years after the Chopra Committee submitted its report that the Drugs and Cosmetics Act was enacted in 1940 to regulate the import, manufacture, distribution and sale of drugs and pharmaceutical in the country. The Rules to implement the provisions of the Act took another five years to frame and the Act and Rules came into force only in 1947 after the new Government came to power.[41]

Despite the problems faced by the industry in the interwar period by the time the second world war broke out India was producing 13% of its total drug demand. Drugs were being produced by several indigenous manufacturers e.g. Zandu Pharmaceutical Works, Calcutta Chemicals, Standard Pharmaceuticals, Chemical Industrial and Pharmaceuticals Laboratories and the East India Pharmaceuticals

etc. The private sector was manufacturing synthetic drugs of plant origin, drugs of animal origin, Sera and vaccines at this stage. Progress was however not uniform. In view of the small number of drugs, the role of seras and vaccines was even more important. The private sector produced a variety of sera including diptheria Antitoxin, Anti-meningococcus, Tetanus Antitoxin, Gas gangrene, Anti-toxin and vaccines for Cholera, Typhoid, Whooping Cough etc. Indigenous firms further continued to extract various Aurvedic and Western drugs for example Ephedrine Hydrochloride, Kurchi, Bismuthous Iodide, Caffiene, Strychine, Tannic acid, Gallic Acid etc. Manufacture of bulk drugs included Liver extract, Pitutary extract, Abrenaline etc.[42] In the 1930's efforts were made in the direction of manufacturing Synthetic bulk drugs which however lagged behind other categories of drugs. Ether, Chloroform, Naphthaline and Cresol were among those manufactured. The bulk drugs produced and imported were processed into various formulations i.e. tablets, syrups, injections, ointments etc.[43]

The outbreak of second world war gave the much needed second impetus to the drugs and pharmaceutical industry, the manufacture of a number of alkaloids like ephedrine, santonin, strychnine, morphine, emetine, atropine and codeine was undertaken during this period. Chemotherapeutic drugs such as arsenicals, anti-dysenteric, anti-leprotic drugs, colloidal preparations of calcium, silver manganese, iodine etc. were made in the country. The Shark

liver oil industry came into existence and the manufacture of certain glandular products was also undertaken. Many new firms came into existence including India Pharma, Unichem, Chemopharma, and the Indian Process Chemical Laboratory etc. Production increased to meet 70% requirements by 1943.[44]

Even after the end of hostalities, the world shortage of pharmaceuticals continued and the tempo of development of the pharmaceutical industry was maintained and export markets for galenicals, alkaloids etc. were developed. BCPM in 1947 developed processes for manufacture of 20 synthetic drugs and a number of related formulations including Thiarsin, Ambiarsin, Mepacrine-Hydrochloride, Phenacetin, 2 Compounds of the Sulphagroup etc. During the war years East India Pharmaceuticals diversified to manufacture Sulphacetamide, Quinidochlor, Nikethamide. Bengal immunity diversified from production of Sera's and vaccines and took on the production of p-aminobenzene, Sulphonamide and Atebrin.[45] In the State owned sector the Haffkine Institute played a major role in bringing down the prices of Sulphathiazole which had sky rocketted after the war to 1/3rd the earlier price, by starting its manufacture on a semi-commercial basis from 1948. The new process patented by the Institute was based on the use of acetamide, chlorosuphonic acid, vinyl acetate and thiourea as starting materials and avoided the costly and scarce pyridine.[46] The Institute also developed a process for the synthesis of

Paludrine a synthetic anti-malarial. Experimental production at the pilot plant stage revealed that the drug could be supplied at 1/5th the prevailing market price. The Institute was however initially, unable to undertake its production commercially as the patent for the drug was held by a multi-national M/s Imperial Chemical Industry. Eventually Haffkine's Institute entered into an agreement with the concerned multi-national for the production of paludrine. Vitamin A was also produced at the Laboratory on a small scale from Shark liver oil at a price much lower than the market price. Experiments to scale up, improve existing processes and to develop new processes for the manufacture of penicillin were also undertaken by the Laboratory. But the time the country became independent, the Institute had developed processes to manufacture numerous sulphonamides including sulphamerazine, sulphadiazine their intermediates, atebrin etc.[47]

THE POST SECOND WORLD WAR PERIOD

The interest of the British Government with regard to to the domestic production of new drugs and fine chemicals in India was aroused after the second world war and in 1945, the Government of India in the Department of Planning & Development set up a Panel on Fine Chemicals Drugs and Pharmaceuticals[48] under the chairman ship of Colonel R N Chopra to enquire into and indicate to the Government the drugs to be produced in the next five years and necessary steps to be taken for the same. The Panel submitted its Report in 1946. The major recommendations of the Panel included the undertaking of the domestic manufacture of Antibiotics like

Pencillin and Streptomycin, anti-malarial and synthetic and Sulpha drugs. Government assistance was recommended to the indigenous industry especially in setting up pilot plants for the manufacture of new drugs while at the same time measures for training of technical manpower required by the Industry were also recommended.[49] Focus on the recommendations of the above Panel however did not occur till after the country attained independence.

The post war period also saw considerable activities in the camp of the big Indian businessmen. With large international companies and cartels already beginning to dominate world capitalism and the industry becoming more technology intensive[50] the Indian big bourgeoisie recognised the wisdom of foreign collaboration for plant design, process knowhow as well as use of licences and patents. Tata & Birla infact in the year 1945 led an Indian business delegation to Britain & America. Agreements were concluded during that year between Birla and Nuffield and Tata and Imperial Chemicals.[51] While the big bourgeois leaders thus hunted for collaborative efforts to move into a new phase of import substitution, the pioneering smaller enterpreneurs with their nationalist attitudes found competition from other countries with better established and well-known pharmaceutical products their bane.[52] Further, the nature of development for Indian industry was confined viz. to processing and manufacture of compounded preparations not extending

rapidly to their production from basic chemicals. The rapid development in the field of pharmacology and medicine and increased rate at which new drugs both chemotherapeutic and antibiotic entered the market made the Indian industry and its products due to its slow pace of development obsolete.

The many small firms that had entered the industry during the war boom now abondoned even the little production of synthetic drugs that had been undertaken during and immediately after the war, as this is found uneconomical at existing prices in the market.[53]

## PROFILE AT INDEPENDENCE

The Indian drugs and Pharmaceutical industry consisted largely of a dependent industrial initiative dominated by the private sector with the exception of a few Government Research Institutes undertaking the production of basic drugs on a semi-commercial basis. The initiative in the private sector was largely limited to formulations. Bulk drugs were imported from the advanced capitalist countries in the absence of a basic chemical industry capable of supplying raw materials needed for the manufacture and use of sophisticated technological and research inputs required for independent development. In context of the above colonial legacy any attempt at growth of the industry in the direction of self-reliance during the post independence period would require considerable imports of expensive technology and knowhow and therefore large initial capital

investment in the development of the base plant of the industry i.e. the production of bulk drugs of this Chapter shall study the way in which the new Government in independent India faced this challenge and the factors affecting their decisions.

While the nature and pattern of industrial development in the Drugs and Pharmaceuticals sector did form an important determinant of post independence economic policy, there were in addition numerous other important social economic and political factors and vested interests that gave final shape to the Economic policy in independent India. Immediately after independence the following section shall attempt to explore the 2 key factors among these, emphasising the nature of the Indian National Movement and the Keynesyian Revolution in capitalist economies which resulted in the very acceptance of planning and the mixed pattern of economy leading to the creation of public sector.

## SECTION - II

## PREINDEPENDENCE DETERMINANTS OF POST INDEPENDENCE ECONOMIC POLICY.

### THE BIG BUSINESS AND THE INDIAN NATIONAL MOVEMENT

The Character of the political leadership, their class bais and affiliations are important factors in determining the nature of policies and their pattern of implementation by the State.[54]

Since the Indian national leadership emerged from the national movement for Indian independence, the class bias of this group may be ascertained by the study of the nature of this movement. We start here from the post first world war period, as it was at about this stage that the Indian National Congress, which had began as an elitist organisation representing largely the interests of the middle class intelligensia, slowly started assuming the form of a mass organization representing larger Indian interests.[55]

War time oppression through mass recruitment, heavy taxation and a sharp rise in prices succeeded in focusing on the inherent contradiction between British Political and economic dominance and the Indian national interest, causing considerable dissatisfaction among the masses. The above scenario created by the war coupled with an increasing strength of Indian capitalism during the same period may be directly related to the extension of the Indian National Movement to the Indian bourgeoisie and

large sections of the Indian peasentry.

The take over of the leadership of the Congress by Mr M K Gandhi with his perspective of controlled mass participation, his message of rejuvenation of Khadi, village reconstruction and his aura of personal simplicity, was also of considerable importance in the roping in of these major sections of the Indian people, into the Congress.[57]

The Indian progressive bourgeoisie were an extremely class aware group which in the years that followed showed considerable accumen for conscious manipulation of economic and political forces to serve their interests.[58] Never directly joining the movement, the farsighted sections of the Indian big business, through a policy of qualified and consciously calculated support for the Congress policies and of those within the Congress supporting the interests of Indian capitalism, was infact successful in establishing a hegemony of the 'Right' over the Congress, despite an overt bent of the Congress leadership during this time frame towards 'Left' policies and socialistic ideals.[59] The Left challenge within the Congress led by Jawaharlal Nehru himself (who later went on to become Prime Minister of independent India) as seen from his presidential address at the Lucknow Congress (1935).

"I must frankly confess that I am a Socialist and Republican and am no believer in Kings and Princes ....."[60] was effectively squashed by the machinations of the Indian bourgeoisie who working through the right wing in the

Congress aided by Gandhi" curbed disciplined and tamed the fire eating Nehru of the Lucknow Session".[61]

The Left outside the Congress on the other hand in an attempt to build up a united and anti-imperialist front tried to work within the nationalist mainstream even while criticising the Congress leadership for its many compromises with imperialism and was therefore unable to offer effective alternative to the Congress.[62]

The maintainence of the hegemony of the Right over the Congress was of considerable importance as it resulted in the actual involvement of the Indian capitalist class in the process of economic planning in India and thus in the determination of the economic policies of the State in the post independence period.[63] The Indian big business groups and their representatives thus formed important members of the National Planning Committee set up at the initiative of Subhas Chandra Bose under the chairmanship of Jawaharlal Nehru in 1938. Birla, Lala Shri Ram and M Visvesvaraya (who was responsible for the first ever effort at Economic Planning for India) were infact invited to the Congress Industries Ministers Conference which set up the National Planning Committee.[64]

The effort of the above Committee did not lead to conclusions as the Second World War broke out in the midst of the deliberations of the 29 Sub-Committees into which the main Committee was divided and Jawaharlal Nehru the Chairman of the Committee and several of the members were arrested resulting in a decreasing interest in the work of the Committee.[65]

The work started by the members of the Committee was then taken over by a section of the big business including J.R.D. Tata and G.D. Birla who in brought out in 1944 what was commonly known as the Bombay Plan.[66] 'The Bombay Plan' became a landmark in the history of Indian Economic Planning. It resulted not only in considerable discussion on the plan itself but also opened floodgates to other efforts at providing alternative direction to planned economic development in India. Two major efforts among these included "the Peoples Plan" of the Indian Federation of Labour headed by M N Roy[67] and the "Gandhian Plan" by Shriman Narayan Aggarwal.

Before discussing the above Plans, it is first important at this point to comment on the acceptance of the very concept of 'Economic planning' in the capitalist world which till then was advocating the principle of 'liassez faire'.

## ECONOMIC PLANNING IN INDIA

The acceptance of the concept of economic planning in the country was largely an outcome of the inspiration received by the Indian National leadership from the sucess of the Soviet experiment at planned economic development, through State Five Year Plans.[68] The fact that the Soviet Economy continued to prosper and grow even through the depressions of the late 20's and early 30's which shook the capitalist world resulted in considerable rethinking on the role of the State in the economic development of a Nation. The final blow to classical 'liassez faire' political

economy came as a result of the above rethinking and effort towards understanding the crises of world capitalism, and was brought about by the publication in 1936 of "the General Theory on Employment Interest and Money" by J.M. Keynes.[69] The theory successfully refuted "the Say's Law" and its assumption - that the capitalist economic system automatically adjusts the various forces and factors working with it. According to Keynes the crises in the capitalist system was due to and imbalance created by a growing tendancy towards accumulation of capital, to the extent that no successful profitable investment could be made by it. Keynes therefore emphasised the use of State intervention to promote capital investment and control the growing tendency of capitalism towards accumulation of capital. State intervention in this context took the form of economic planning.[70]

Visvesvaraya's Effort

The first attempt at planning for the Indian economy by M Visvesvaraya, an elder statesman and administrator of the princely state of Mysore, was an outcome of the inspiration he derived from the Soviet experiment and his own experience of dealing with problems of India's development. This attempt called "Planned Economy for India" was published a couple of years before Keynes published his Theory.[71] Visvesvaraya saw British control over Indian State machinery as the greatest obstacle to Indian economic development. The essence of planning for Visvesvarya was industrialization. His plan was extremely ambitious and proposed doubling of

the National Income over a period of ten years with an increase of only Rs. 500 crores in agricultural production as against an increase in industrial production from Rs.400 crores to Rs.2000 crores. Simultaneously the total population supported by agriculture was to reduce by 50 million.[72] In addition to his economic projections he gave considerable thought to the nature of the planning machinery and suggested active cooperation of the business interests not only in implementation but also formulation of plans.[73]

On the nature of development he stated,

"it is safe for this country to proceed along lines practised in such capitalistic countries as France and the United States of America .....we have yet to build up some measure of moderate industrial prosperity, and for the present, Capitalism is best suited for that purpose".[74] The role of the State was more or less confined to coordination of the activities of private individuals and firms as well as giving subsidies. All industries, agricultural and other projects were to be in the private sector.[75]

The Bombay Plan

The perspective behind the formulation of the Bombay Plan was more or less similar to the earlier effort by Visvesvaraya.

With the limits of import substitution in the consumer goods being reached on one hand and the obvious unacceptability to the Indian bourgeoisie and leadership of the alternatives of either widening the market for consumer goods through developments in the rural sectors (the

unacceptability of this option arising from the requirement of wide ranging structural changes in the rural sector) or the development of an intermediate capitalist goods market (this proposition became unattractive as it required a heavy initial investment, technical knowhow, and a readiness to accept low initial profits) left very few options regarding the pattern of economic development possible. The first option being the encouragement of investments of the India limited type, while the second was the acceptance in consonance with the recently propounded Keynesian Economic Theory of a degree of State regulation, planning, and public investments in basic industries to create a favourable infrastructure for their own growth. The Indian big business which prepared the Bombay Plan opted for the second alternative emphasising industrialization and proposing the quintupling of industrial production in 15 years. In some respects the methods envisaged anticipated those of the Three Five Year Plans.[76]

Production of power and capital goods was to have priority, but to avoid hardship, prevent inflation, produce employment and economise capital resources the fullest possible use was to be made of small scale and cottage industries in the production of consumer goods.

Regarding the role of the State the plan felt that State control as against ownership or management was fully adequate in mobilizing all available means of production and directing them towards socially desirable goals. Even

in such cases where State ownership became essential in view of public welfare or security it was stated that,

"if later on private finance is prepared to take over these industries State ownership may be replaced by private ownership"[77].

State control was recommended over public utilities, basic industries, monopoly industries using or producing scarce natural resources and industries receiving State aid. Such control was however to be exercised without unduly hampering the initiative of the management[78].

The Bombay plan also laid stress on rapid industrialization wanting to invest Rs.4480 crores on industry in the course of 15 years[79].

The People Plan

"The peoples Plan" too, like the Bombay laid utmost emphasis on rapid industrilization wanting to invest Rs.5,600/- crores in industry[80] in ten years. The similarities between the two Plans were however not many and the People's Plan could be distinguished from the Bombay Plan by its considerable emphasis on agricultural growth. The peoples plan based itself on the Soviet experience and advocated the collective control of the Nation over all its resources,

- the control of the State over heavy industries and banks;
- the entitlement of cultivators to hold land without any disability, subject to the payment of a Unitary Land Tax, and the freedom of small cultivators from taxation except at local rates;

- the promotion by the State of cooperatives in agriculture;
- the provision of an irreducible standard of living for all labouring in fields, factories, mines, transport, offices and schools guaranteed through minimum wages.[81]

Despite the fact that the peoples plan did not envisage any really radical policy measures it definately saw the desirability of socialism and was concerned about the expansion of the public sector of the economy at the expense of the private and proposed stringent controls over private industry during the tranisitional period.[82]

The Gandhian Plan

This Plan by Shriman Narayan Aggarwal was full of the typical Gandhian dislike for the large scale & centralised in all fields of human endeavour, therefore, the author said regarding the earlier plans,

"I feel that these plans have not taken into account the special cultural and sociological foundation on which our economic planning in India must be based".[83] Despite his predilection for simplicity and decentralization Mr Aggarwal was constrained to produce a long list of 'basic' industries and to allocate them a sum of Rs.1000 crores out of a capital budget of Rs.3,500 crores. Further, he also proposed many new functions for the Central Government, including the running of public utilities, the acquiring of all private industrial enterprises and during the'transition' the

exercise of rigid control and supervision over them. The plan was however quiet on how the above was to accomplished.[84]

While, the above individual efforts at planning were of no immediate consequence, they did influence the nature of Government effort in the direction of economic planning prior to independence and of economic policy in independent India. With Jawaharlal Nehru at the helm of affairs and his distinctly radical stance from the late thirties the preindependence efforts made by the Congress were atleast apparently in the direction of increasing State control and nationalisation of the economy. However, since the Congress was a conglomeration of disparate class and interest groups the extent to which these were converted to policy was determined largely by the relative dominance of the various groups within that party. The hegemony of the right in this context played an important role in determing the direction of Government economic policy.

Government Efforts

In 1941 the Government of India appointed a Committee for planning, this was replaced in 1943 by the Reconstruction Committee of the Executive Council with the Governor General himself in chair. In June, 1944 a Planning and Development Department was brought into existence and simultaneously State and Provincial governments were requested to set up and establish their own planning organisation. The Central and State departments were to draw up their own five year plans. To provide general guidance the Reconstruction Committee

published its second Report on Planning & Reconstruction (1945).[85]

The above document was extremely bold and advocated not only the need for ownership of large scale industry by the State but ownership also of new and necessary enterprises "for which private capital may not be forthcoming". The industrial policy statement of 1945 gave greater precision to the principles of industrial reconstruction embodied in the Committee Report. 20 major industries were to be brought under the control of the Central Government while other basic industries of National importance were to be nationalised if adequate private capital for their development was not available. Aircrafts, automobiles, tractors, chemicals, dyes, iron and steel, prime movers, electrical machinery, machine tools, electro chemicals and non-ferrous metals were mentioned specifically as potential candidates for such treatment.[86] The Report of the economic programme committee established in 1947 which submitted its report in 1948 were similar in context. The Report however came under considerable opposition from the big business and conservative elements in the Congress Party. The industrial policies statement that came three months later therefore perhaps opted for a softer approach.[87]

The nature of Government policies in the post independence period and their implications for the public section are discussed in the following chapter.

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# CHAPTER - II

## EVOLUTION OF A POLICY AND ITS IMPLICATIONS FOR THE DRUGS AND PHARMACEUTICAL INDUSTRY

# CHAPTER II

## EVOLUTION OF POLICY AND ITS IMPLICATION FOR THE DRUGS AND PHARMACEUTICAL INDUSTRY

State regulation and control has formed an important feature of Indian economic planning. Manifested mainly in the form of social and economic policies, it is a powerful tool in harmonizing the pattern of economic growth and development with national priorities and socio-economic objectives, embodied in the State's Five year Plans.

As already stated a major objective of Indian economic planning has been the "the socialist pattern of society"[1] to be attained through a progressive widening of the role of the public sector, a reorientation of the private sector to the needs of a planned economy and lastly through the prevention of monopoly and concentration of economic power in the hands of a few.[2]

The drugs and pharmaceutical industry was brought within the purview of State regulation and planning directed towards the above objectives of social and economic policy through the very first Resolution on Industrial Policy (1948).[3] The first explicit statement of policy specific to this sector was however evolved only in 1978.[4] The delineation of policy prior to 1978 in the following Chapter is, therefore, based on the assumption that the nature of state regulation and control in specific areas

including licencing, foreign capital investment import and export of raw materials, drugs and technology, pricing and patent legislation and its implications for the growth of the industry as a whole and its specific components is a reflection of Government policy for the concerned industry.

Since the 1978 policy was an outcome of the recommendations of the Report of the committee on the Drugs and Pharmaceutical Industry appointed in 1974 by the Indian Government a major watershed in the direction of developing a comprehensive policy for the Drugs and Pharmaceutical Section, we have divided this Chapter into 2 Sections the Ist Dealing with the 1948 - 1974 time frame and the 2nd with the post 1974 period.

Further, since the present effort is concerned, mainly with the public sector, which was created to serve the objectives of public policy, in a situation where the field was largely governed by the free play of market forces, our review of policy shall emphasise the extent to which Government policy has helped this sector in facing the two basic challenges of expansion and deomination over private enterprise envisaged for it.

## SECTION - 1

## IMPLICIT POLICY DELINEATED

### INDUSTRIAL LICENCING AND ATTITUDE TOWARDS FOREIGN CAPITAL (1947 - 1974 )

#### The Initial Years(1947 - 1956)

The Industrial Policy Resolution of 1948 was influenced by at least two basic factors, the need on one hand to assuage to a greater or lessor extent, the aspirations of ideologically and socially disparate interest groups that had during the struggle for independence alligned themselves with the Congress, and the fact that through skillful manouevres combining pressures with concessions the Right was able to preserve its hegemony over the national movement during the later phases of the independence struggle.[5]

Announced on the 6th of April, 1948[6] the Resolution combined socialist ideology at the level of policy objectives with Keynesian economic theory as the corner-stone ofpolicy. Thus, while rendering socialist rhetoric envisaging the establishment of a more just and egalitarial social order through progressively active state intervention, the Resolution on the other hand negated the need for State ownership of the means of production. It restricted, infact, the area of economic activity exclusively

for the state to three industries while new undertakings in six others were to be set up by the State. The rest of the field was left open to private enterprise, which in the case of 18 industries identified to be of basic national importance including the Drugs & Pharmaceutical industry, whose location was governed by economic factors of all India import/that required heavy initial investments/high degree of technological skill, were to be subject to Central Regulation and Control. The growth of private enterprise was to be facilitated through removal of transport difficulties, facilitating unfair import of essential raw materials, imposing tariffs to prevent unfair foreign competition and by reviewing the system of taxation to encourage saving and productive investment. The takeover of private enterprise in State reserved areas was further delayed for a period of ten years.

Regarding foreign capital investment too, the Resolution was able to maintain a degree of ambivalence. Thus, while on one hand, foreign investment was to be restricted as a rule, to those cases where control remained national, enough room was made on the other hand for foreign control on grounds of 'national interest'. The trend towards the encouragement of foreign investment was confirmed by the Prime Minister's statement at the

Constituent Assembly (Legislative) in 1949.[7] The statement offered assurance to foreign investors that the Indian Government would treat foreign capital at par with Indian capital. Foreign firms were to be allowed to remit profits or withdraw capital subject to foreign exchange considerations. Further provision was also made for fair and equitable compensation in conditions of compulsory takeover.

The first Five Year plan taking its cue from the Industrial Policy Resolution, encourage foreign capital investment especially in fields,

"when new lines of production are to be developed or where special types of experience and skill are required or where the volume of domestic production is small in relation to the domestic demand and the indigenous industry is not likely to expand at a sufficiently rapid pace".[8]

As regards the nature of foreign investments it said,

"from the point of view of industrial development it would be best if foreign investment in the country take the form of equity capital.[9]"

The private entrepreneurs in the drugs and pharmaceutical sector made full use of the above directions of

policy and the period between 1948 and 1956 saw rapid expansion of both indigenous and foreign controlled private enterprise in this industry. Foreign collaborations too were recognised to have marketing advantages and became the fashion of private producers. The pattern of investment of foreign capital however did not always confirm to the specifications laid down in the first plan. The Pharmaceutical Enquiry Committee that submitted its Report in 1954 stated that the total number of firms in the large scale private sector were 75, while 1568 firms were operating in the small scale sector.[10] Of these firms 28 were under foreign control with a capital investment of 6.9 crores (Table-1 Appendix-2).[11] While another 18 had entered into foreign collaborations.

As against the stated policy the Committee found that foreign collaborations were allowed in many cases,

"on non-essential items such as tooth pastes, face creams, balms, laxatives, cough syrups etc. which certainly do not call for foreign collaboration for manufacture in India."[12] Despite stated policy therefore there seemed no guiding principles governing the approval of such agreements or the grant of licences against them e g. the same Company was allowed to enter into collaboration with two firms for the same product. (M/s Atul entered into collaboration with both M/s. American Cynamide Co. USA & M/s. Ciba Ltd.

Basle, Switzerland for the manufacture of Sulphathiazole).[13]

Similarly, royalty payments as high as 12 to 15% for periods between 1 to 20 years were allowed for the provision of 'processing' as against 'manufacturing' knowhow. Even where agreements included manufacture of pharmaceutical from basic chemicals actual knowhow stopped very often at a stage converting the penultimate into the final product. Further, in some cases royalties were stipulated for distribution rights of finished products in India while others made the purchase of raw materials from foreign principles and integral part of agreements. Royalty was doubled if the above conditions were not adhered to.[14]

The approval of such obviously disadvantageous terms of technology transfer regardless of the drain of foreign exchange and the direction of growth of the industry resulted in the private sector both indigenous and foreign dominating investment (68%) and sales (76%) in this industry.[15]

In view of the above aspects of the industry the pharmaceutical Enquiry Committee (1954)[16] made specific recommendations to the Indian Government regarding its policy towards foreign participation. These included (i) the preference for equity participation in tie ups with foreign firms as against tie ups with no foreign participation in capital. The limitation of foreign

capital do not more than 49%. (ii) permission for new foreign concerns to set up factories to be given only if the product they undertook to manufacture was being manufactured inadequately in the country, that too only if they started from basic chemicals and/or intermediates as near to the basic chemicals as possible within a reasonable period of time. The Committee further provided guidelines for permitting collaboration with foreign firms. It emphasised that no foreign collaborations with respect of non-essential items should be entertained e.g. tooth pastes, shaving creams etc.. Foreign collaboration was only to be allowed if the firm agreed to manufacture at least few of the basic drugs from primary raw materials. Permission for the manufacture formulations of selected drugs was only to be given on the basis of essentiality provided the firm agreed to complete its programme of manufacture of basic drugs in a stipulated time period. Schemes for licencing were to be evolved which would not give monopoly to any one firm but keep competition alive.[17] A preference order for such foreign collaborations was to be evolved which manufactured maximum raw materials indigenously.[18]

In 1952 the Industrial (Development and Regulations) Act (IDRA) came into effect.[19] As per the Act existing, producers were required to register themselves with the

Government and receive registration certificates. These certificates were extremely embiguous merely listing manufacturers, as producers of 'Drugs & Pharmaceuticals'. No reference was made to product lines or capacity limitations in these certificates. Although very few of the pre 1952 manufacturers are in existence today the impact of such blanket licencing is felt even today. Many manufacturers today state that they acquired the business of old companies and thus obtained a blanket right to 'manufacture drugs.', e.g. the Indian subsidiary of the American giant pfizer for instance acquired Dumex, a firm with such a certificate, and now justifies its hugely expanded capacity to manufacture 'Becosules' on the grounds that the Dumex registration certificate had no stated capacity.[20]

Thus, State policies between 1948 and 1956 were extremely conducive to the expansion of private enterprise. The same however, did not hold true for the expansion of the public sector. The State did not conform to its own policy of "progressively active State intervention" into economic activity of basic national importance.[21] In fact when the need for the development of an integrated drugs and pharmaceutical industry as a State concern came up in the parliament in 1959. It was rejected on the ground that, "this is not a line where we can put all the eggs in one basket".[22] The growth

of the public sector drug and pharmaceutical industry was negligible being restricted to a single factory set up at Pimpri near Poona with an initial product mix of only one antibiotic "Penicillin". In fact, even in the establishment of this factory the Government revealed an active preference for foreign technology despite the availability of viable indigenously developed technology. Dr. S.S. Sokhey and Dr. K. Ganpathi, eminent Indian Scientists from the Haffkine Institute developed a process for the manufacture of Pencillin and submitted a project report of the same to the Government of India for setting up of a Pencillin factory. The Government, however, rejected this proposal and went ahead with a collaboration agreement with M/sm Karnobolaget of Sweden in 1949. It was only later that difficulties in the transfer of technology, due to M/s Karnobolaget entering into another agreement with Merck of USA, to avail themselves of more advanced technical processes, of secret nature for the manufacture of Pencillin, were used by Dr. S.S. Sokhey to make the Government shift its earlier position and accept the indigenous technology. Dr. S.S. Sokhey who was now the Assistant Director-General of WHO was able to get financial and technological assistance from WHO and UNICEF for the project resulting in its being offered to the Indian Government through these agencies making it

difficult for the Government to refuse. Hindustan Anti biotics was thus set up in collaboration with WHO & UNICEF using indigenous technology.[23]

The negligible State initiative in the public sector, despite the facts that the Indian Drugs & Pharmaceutical Industry was in its primordial stages of development, with most producers restricting themselves to processing activity as against bulk manufacture from basic stages, (most vitamins, antibiotics, sulphase, hormones, and other chemotherapeutic products were being imported), and the country losing increasing sums of scarce foreign exchange through imports (which increased from Rs. 7,8996 crores in 1949-50 to Rs. 10,5150 crores in 1950-51 and were as high as Rs. 15.6 crores in 1951-52)[24], in the backdrop of increasing foreign and private control over the industry, gave a clear indication of the opposition between espoused policy objectives and the actually prevailing policy.

Induatrial Spread (1956 - 1974)

In the year 1956, the Indian Government brought out a second Industrial Policy Resolution.[25] This Resolution showed a distinct shift from the 1948 Resolution. The shift was however not in the direction of regulating the burgeoning private enterprise or limiting its role, it was in the significant enlargement envisaged in the role of the State promoted sector in economic activity.

of the State promoted sector in economic activity. Considerably diluting the impact of this shift was the fact that this enlargement was to be restricted to those areas of industry in which private enterprise on account of their low profitability, had so far shown an obvious lack of interest in.

Disguising itself in the garb of socialist ideals, given weight by the acceptance of "the socialist pattern of society" as an objective of social and economic policy by the Parliament,[26] the Resolution actually, was only, a clearer ennunciation of the States concept of the mixed pattern of economic development, than found in the 1948 Resolution. Thus, as against concerning itself with the imposition of social discipline on private enterprise as the 1948 Resolution had done the 1956 Resolution set about outlining a more positive role of the State in relation to the private sector. Not only was the State to develop transport, power and other basic facilities for this sector but it was also to provide fiscal and other concessions towards the development of private enterprise. The resolution further eliminated the threat of nationalisation, while explicity promising private enterprise, the freedom to expand and emphasising the supplementary and complementary nature of the two sectors of industry. Incomplete contrast was the States stand towards the public sector, which, as against being

supportive was distinctively unsupportive especially where the public enterprise was pitted against the private sector. The Resolution stated,

"when there exist in the same industry both privately and publicaly owned units it would continue to be the policy of the State to give a fair and non-discriminatory treatment to both of them.[27]

This "non-discriminatory" attitude when viewed in context of the inherent contradiction of purpose (social versus individual) between the two sectors, placed the public sector at a distinct disadvantage to private enterprise and can only be construed as unsupportive.

The committment of the Resolution to State led industrialisation did, howeverm lead to an increased investment in the public sector (the investment doubled in 1957 from very low levels in the preceding years and trebled in 1958, showing afresh spurt in the third plan after which it fell off)[28]. Hopes of progressively widening State initiative in securing a dominant position for the public sector in the drugs and pharmaceutical industry, at the same time, were greatly belied. The setting up of IDPL was infact delayed over ten years so that the plants were completed only in 1967-68. The 22nd Report of the Committee on Public Undertakings

(1966) on the Indian Drugs and Pharmaceuticals Limited stated,

"the committee regrets to observe that the Government of India took ten years to put through proposals for establishment of projects which were thought of in 1956 for implementation in the 2nd Five Year Plan. The projects were thought of because pharmaceutical factories in India were producing only negligible quantities of drugs. Most of these factories processed the drugs imported from abroad. Apart from the heavy drain of foreign exchange for their import these drugs were costly and the availability was limited owing to import restrictions. The position was aggravated by the fact that the biggest plants depended for raw materials on foreign firms who used their monopoly position to maintain high selling prices. It was with the view to make available drugs and surgical instruments on a mass scale that the establishment of these projects was thought of".[29]

Further as against opting for setting up an integrated public sector industry, in the field of drugs and pharmaceuticals, the Governmentopted for the separate growth of Hindustan Antibiotic limited and Indian Drugs and pharmaceuticals Limited, despite receiving an all encompassing offer from U.S.S.R., for the integrated

State led development of this industry. In 1956 as a result of preliminary negotiations conducted by Indian teams that visited USSR in 1953 and 1954-55 the team of Soviet experts came to India and after making an in depth study of the Drug industry in the country submitted a proposal to the Indian Government for setting up of four integrated totally self-sufficient plants manufacturing antibiotics, vitamins, synthetic drugs, drug intermediates and hormones and the extension of the already existing plant for antibiotics manufactured at Pimpri at a cost of Rs. 36 crores.[30] In view of the foreign exchange crisis, the Soviets even agreed to offer a long term loan of 80 million roubles (Rs. 9.52 crores) for the project.[31] As against approving the project especially in context of the integrated character, the Government opted for delaying tactics and started negotiations with Merck Sharp Dohme of USA and Bayer a German multinational for the expansion of H.A.L. through setting up of a plant for the manufacture of 45 mm of Streptomycin (the Soviet proposal for expansion had included Aureomycin, other new antibiotics, vitamin $D_2$ and vitamin $B_{12}$ in addition to Streptomycin) and for the manufacture of only six intermediate chemicals (the Soviet proposal had a much wider scope) respectively.[32] The agreements with these two firms were signed desoite the Government agreeing that terms of royalty and

interest payment of these firms were more onerous,

"..... the terms quoted by the German firm were very onerous, 7½% interest and 10% payment immediately on signing of the agreement in addition to continuous payment of royalties. As against this the Russians t terms were 2½% interest only ....."33

It was only once these agreements were signed that the Government of India sent a second team of experts in 1958 to Russia with a freshly formulated proposal for the establishmentof a unit in the public sector. The new proposal obviously omitted the extension of HAL and the intermediate chemicals plant. It additionally omitted the hormones extraction plant. Instead of these, plants for the manufacture of surgical instruments and phyto chemicals were substituted. Further the product mix of the synthetic drugs plant was reduced from 52 in the earlier proposal to a mere 16. The 32 deleted products interestingly, being those which the private sector had already been given licences to manufacture (competition from the public sector was obviously not considered desirable ! ) irrespective of the fact that these producers were more likely to import penultimates as against manufacturing from basic stages.[34, 35] The piece meal implementation of the project eventually in the form of the new proposal had major repercussions

on the pattern of growth and the present profile of the public sector.

Interesingly the Neria mangalam project at Kerala for phyto cehmicals was abandoned (at a loss of Rs. 33.02 lacs of which the Kerala Government lost 19.96 lacs)[36], while the Surgical instruments plant at Madras was unable to find a market for its range of General, Gynaecological Opthalmic, ENT, Dental and Neuro-Surgery instruments, in view of fact that the doctors found them heavier and some had specification different from what the Indian Doctors were used to.[37] The Antibiotics plant also faced several problems to the extent that the Chairman of IDPL was forced to say that the collaborators were experimenting with the particular project of IDPL to get round patents.[38]

The product mix chosen for the Antibiotic and Synthetic drugs plant, and installed capacities in these plants were further not in consonance with the needs and demand profile in the country. Let us take the case of Tetracycline as an example - the country had a requirement for the antibiotic of 10 tonnes. The collaboration however resulted in the creation of the capacity of 120 tonnes. The relevant committee on public undertakings infact noted

"The committee are unable to understand how the

capacity of the Tetracycline group of antibiotic was fixed at 120 tonnes when the actual consumption in India at that time was only 10 tonnes. It is surprising that although Government had demanded a capacity of 50 tonnes for Tetracycline, the capacity was raised to 120 tonnes in the final discussion".[39] Of the product mix of the antibiotic plant Dihydrostreptomycin Sulphate was dropped due to no demand. Chlorotetracycline for which the capacity of 70 tonnes was created was found obsolete and eventually dropped.[40] Further, India itself had the technology for production of at least pencillin and HAL had offered to undertake the designing and commissioning of the Antibiotic plant. Despite this offer, however, the Government had thought it fit to collaborate with the Russians for the plant.[41]

In the case of the Synthetic drugs plant, similarly, of the 16 bulk drugs mentioned initially in the detailed project report the production of 5 had to be dropped or restricted. Acetazolamide was dropped in September 1965 on account of obsolescence and marketing difficulties. INH was deferred due to the high cost of production. The introduction of Diethyl Carbamazine Citrate had to be stopped as the plant could not compete with the other manufacturers who were producing the drug at a lower cost by importing a later intermediate. The production

of Sodium Sulphacetamide was restricted because of limited demand and the capacity of Piperazine Adipate which became idle due to availability of imported stocks in the market was partially used for production of other piperazine salts.[42]

In the case Phenacetin, Analgin, Nicotinamide Sodium Sulphacetamide, Piperazine, Hexahydrate, Ditrazine Citrate and Phenobarbitone modifications in technology provided by the USSR had to be done to get the drug of required purity. In the case of phenacetin this seriously affected the credibility of IDPL to produce quality drugs. A denigrading compaign was undertaken by some manufacturers regarding the quality of phenocetin produced by the company, despite the fact that it was the Government which was at fault as it had accepted technology for a product which did not conform to Indian Pharmacopoecial standards.[43-44]. Of considerable consequence here is the fact that when agreements with the USSR were made they were made in such areas where the Kane Committee had specifically said that Russian Technology was not upto the mark, e.g. Antibiotics.

While one must admire the manner in which the pharmaceuticals and drugs industries have been developed

in the USSR, it must be admitted that in the Antibiotics field the techniques employed in Western Europe and USA are more advanced and yields higher. A similar position exists with respect to some of the vitamins, since the cost of production of a drug will depend to a great extent on yields obtained. In each process it would appear desirable to explore other sources of collaboration in these fields before taking final decisions"45.

The setting up of two different public sector units with two different segments where there could have been one made the two units competitors instead of collaborators especially in view of the considerable overlap in their product mix. At an interview official source at IDPL stated that the company faced serious marketing problems because of the overlap in the product range of the two companies. IDPL is for e.g. forced to produce both Ampicillin and Amoxycillin, both products are identical in their therapeutic spectrum, because it faces competition from HAL which is marketing Ampicillin IDPL makes good its losses in the Ampicillin market by pushing Amoxycillin.[46]

A major factor in the rejection of the earlier proposal was considered to be oppsition of the trans-national industry to it.[47]

Thus while the public sector was fragmented by the

very state it was supposed to represent, the private sector gained fresh impetus through the establishment of public undertakings in different sectors of the economy.

The industrial Licencing Policy inspite of the already mentioned recommendations of the Pharmaceutical Enquiry Committee (1954) continued in the same direction as specific policy guidelines were absent.[48] It is not surprising that during the period between 1956 and 1966, against 184 licences being granted to the private sector for the manufacture of bulk drugs only 15 were given to the public sector. Similarly while 344 licences were given to private enterprise duringthe same period for formulation activity only one licence was given to the public sector.[49]

The earlier pattern of industrial licencing in the post 1956 period in fact became even more accentuated with the crunch due to the foreign exchange crisis being felt as early as 1957. Saddled with the heavy industrialization strategy of the second plan the Government, in a time when uncertainties of foreign exchange gripped the nation opted for increasing dependence on foreign firms for accomplishment of its plan objectives, rejecting again the most suitable option of conservation of foreign exchange emphasis on import substitution.[41] The increasing dependence on foreign aid also served towards

increasing policy liberalization by making the Government more vulnerable to pressures from the World Bank, International Monetary Fund and the Aid India Consortium in this direction.[50] (foreign aid rose from 9.1% of the plan outlay to 34% of the total outlay in the second plan)[51] Schedule A & B industries were both opened to private investment from the latter half of 1957. The Report of the Industrial Licencing Policy Enquiry Committee (1969)[52] in fact stated, that in both the grant of licences and in the approval of foreign collaboration the Government preferred those applicants who could not ensure that their requirements of imports of capital goods, as well as other initial foreign exchange payments such as technical fees would be met from the equity contributed by the foreign collaborating party and loans and credits provided by them or through their support. The above liberalisation of policy resulted in numerous multi-nationals including pfizer/Dumex (USA), Johnson & Johnson (USA), Roche (USA), Lepelit (Italy), Bayers (FRG) and Merck (USA) entering the Indian market for the manufacture of various products including Sutures, Dressings, Antibiotics, Vitamins and intermediate chemicals.[53]

The accentuation of uncertainities regarding the availability of foreign exchange in the wake of increasing

defence demands, in the period starting from 1962 only enhanced the tendency towards the liberalization of industrial policy. Infact, according to the Report of the Industrial Licencing Policy Enquiry Committee (1969),

"A pragmatic approach was developed of undertaking whatever could be undertaken, which would not immediately burden the country with foreign exchange payments."[54]

As a result of the recommendations of the Industries Development Procedures Committee commonly known as the Swaminathan Committee priority in licencing was given to 8 industries mostly in Schedule B. Again in 1966 as a result of the recommendation of the above Committee (reconstituted in 1965) 11 more industries mainly from Schedule A & B were delicenced.[55]

From 1962 onwards the Government issued permission letters and no objection certificates to a number of firms. These only increased the possibilities for exploiting ambiguity. As in the case of the registration certificates these permission letters and no objection certificates did not contain any statement on capacities licenced or product lines. These licences were given mainly to multi-national firms and a few large Indian private firms,[56] resulting in a massive unauthorised growth of the industry which made a mockery of pharmaceutical licencing.[57]

Another rather dubious development in policy during this period was related to the Government decision to allow, during the post devaluation period a diversification upto 25% of the licence capacity on the existing licences, subject to the condition that such additional capacity would not entail the installation of new plant machinery other than that available in India.[58] These facilities for diversification were however withdrawn in 1970 in view of their likely misuse by large business houses, as a result of the enactment of the MRTP Act (1969) based on the recommendations of the Monopolies Enquiry Commission and the submission of the Report of the Industrial Licencing Policy Enquiry Committee (1969). At the same time, any diversification that have already occured under the scheme was regularised through the issue of "Carry on Business Licences". These were issued to 12 foreign and 5 Indian companies and covered 215 formulations and 20 bulk drugs (Table-2 Appendix -2), in complete contravention of the very purpose behind the withdrawal of the diversification scheme. Further, of the firms that were issued these licences only three (M/s Merck Sharp & Dohme, Hoechst and East India) had in accordance with the scheme notified the Directorate General of Technical Development regarding details of expansion undertaken by them.[59]

In 1970 as a result of the reports of various

committees and commissions indicating the failure of industrial licencing in preventing the concentration of economic power in the hands of a few certain changes in industrial licencing policy were affected. These changes however were only superficial and as against resulting in a focus on the public sector only attempted to shift preference from the large scale to the small scale sector. when it was necessary to develop to a minimum economic level which would ensure greater cost efficiency (the possibilities for exploiting ambiguity thus remaining). In 1972 the small and medium scale sector were allowed expansion upto 100% of their capacity. Large scale firms too, could apply for similar expansion within the purview of the above condition.[60]

In 1973 with a view to conserve foreign exchange the Government of India enacted the Foreign Exchange Regulation Act. A section of the Act concerned itself with companies with foreign equity of more than 40%. Such firms had certain restrictions placed on their expansion. The impact of the Act was however not felt in the drugs and pharmaceutical industry as its implementation in this industry was made to await the recommendations of the Report of the Committee on the Drugs & Pharmaceutical Industry (1975)[61] set up in 1974 under considerable pressure from the unsatisfied masses.

In additional to industrial licencing import an important control determining the direction of licencing is also industrial growth, despite self reliance being a policy goal, import licencing as industrial licencing followed a pattern which did not discriminate favourably with regard to those manufacturers who through import substitution produced the drug indigenously from basic stages. This resulted in considerable unfair competition by those who ventured into basic production and those who either imported the bulk drug only to formulate or imported a penultimate intermediate thus being able to lower production cost. Since, the public sector was obligation bound to produce drugs from basic stages, this sector suffered most as a result of the difference between the prices of indigenously produced bulk and imported bulk.[62] The lack of Government interest in this context may be seen from the following example: IDPL was producing Diethyl Carbamazine Citrate from basic stages and had stocks of about 7845.8 Kgs lying in the plant for disposal in 1974. Despite the market for the product being limited the Indian Government supplied licences to private manufacturers to produce the same drug from penultimate stages obviously at a much lower cost, cutting into IDPL's market for the drug considerably (the two firms included Unichem and Burroughs Wellcome). It was only when IDPL took up the

matter with the Government that the import of Diethyl Carbamyl Chloride (the penultimate intermediate used by Unichem and Barroughs Wellcome for manufacture of Diethyl Carbamazine Citrate) persistantly pusuing the matter from 1971 itself, that the item was placed in the banned list from 1972-73 onwards.[63]

## PRICE CONTROLS (1962 - 1974 )

Drugs and pharmaceuticals are essential tools of health care in the existing health service system of the country. In view of their social utility, appropriate production of drugs in consonance with the needs of the community becomes even more relevant. With regard to drug prices, the Report of the Committee on the Drugs and pharmaceutical industry (1975) stated,

"the concern for drug prices, .... arises from the fact that many of them (drugs) are essential for the health and welfare of the community and that there is no justification for the drug industry charging prices and having a production pattern which is not based on the needs of the community but on aggressive marketing tactics and created demands ..... The main objective of policy has to be to secure better convergence of Commercial considerations and community needs and priorities. The emphasis has to be on increasing the social utility of

the industry particularly in the context of extreme poverty and the urgent need for extending as rapidly as possible certain minimum facilities in terms of preventive and curative medicine to the large mass of people both rural and urban.[64]

Drug (Display of Prices) Order (1962) & Drug (Control of Prices Order) 1963

The first attempt at controlling the drug prices in India came only in 1962 in the wake of the Chinese aggression and the declaration of emergency. An anti-inflationary war measure, the Drug (Display of Prices) Order, 1962 required drug manufacturers, importers and distributors to publish price lists of their products, while the chemists dispensing these drugs were to display, on their premises, the above lists. Following on the heals of this order on the first of April, 1962 the Government brought out another order, the Drug (Control of Prices ) Order, 1963. The Orders together had the effect of freezing the prices of drugs on levels as on the first of April, 1963.[65]

Interestingly the absence of price control or any other form of State regulation on drug prices prior to 1962 was despite the fact that drug prices in India during this period were among the highest in the world (the Kefauver Committee of USA (1961) infact stated that

India had borne the cost of research of new drugs in USA for the past decade),[66] and the pharmaceuticals Enquiry Committee (1954) had recommended the need for the fixation of fair selling prices of drugs in order to prevent undue inflation of prices at times of shortage and to give the public a sense of security as also stability regarding the prices of drugs. The Committee had also recommended that traders must be made to sell at prices so fixed, and any deviation should entail the cancellation of their licence.[67] These recommendations however, were not implemented at all before 1962 as already stated.

The price freeze brought about by the 1962 - 1963 Orders came under severe criticism from the industry on grounds of increasing raw material costs and other input costs. These protests of the industry were however unwarranted, as while increases in raw material costs did occur, the industry was in a position to absorb them comfortably. A study by Hazari and Lakhani (1967) infact showed that drug companies in Maharashtra earned cash profits during 1964, of an order, that would bring back their investment between 2 to 4 years[68]! Further, the industry was able to circumvent the very objective of the price freeze by increasingly introducing new products, which had been exempted from the freeze, into the market. The number of new products jumped from 61

in 1962-63 to 91 in 1965-66.[69] Not only was private enterprise unaffected by this first attempt at price control, but in certain ways it even worked in their favour. For example, as a result of the freeze in prices the drug industry did not have to bring about compulsory reduction in price associated with the later stages of a products life in this industry.

Drug (Price Control) Order 1966

The Government decided to continue with price controls after the war and promulgated a new Drug (Price Control) Order, 1966 under the Essential Commodities Act.[70] In the light of the protests of the industry against the price freeze affected by the earlier order, a system of selective price increases was introduced. Manufacturers could now increase prices of drugs, however, this required prior Government approval. New Drugs and drugs sold loose were also brought under the purview of this Order. The Government identified at this stage a group of 18 essential drugs which it submitted to the Tariff Commission for examination of their costs structure and recommendation of fair selling prices.

In order to scrutinize applications for price revision a Committee was set up consisting of

representatives of Department of Chemicals, the Drug Controller, the Ministry of Health, D G T D and Chief Accounts Officer. Guidelines evolved by the Development Council for Drugs and Pharmaceuticals allowed exfactory mark ups of 150 to 200% on cost to the industry while implementing the Order.[71]

As a result of the Order, new drugs introduced in the market, which had reached a peak prior to the order, now under the purview of price control fell to a mere 22 in number for the period 1966-67.[72] The Organization of Pharmaceuticals producers (OPPI) a representative of dominant foreign control companies continued its agitation against price control, even after the new order warning the Government that price control "must eventually lead to the withdrawal of some essential drugs from the market".[73]

Succumbing once again to the demands of private enterprise the Government offered to amend the 1966 Order in September, 1977 the Amendment which came into effect in August, 1968 exempted new drugs and drugs sold under generic names from price control. This move had a positive implication for the public sector also as this sector sold its products under generic names and was thus able to regulate their prices between 1968 and 1970. Private manufacturers benefited as they could again introduce new drugs into the market without

prior price approval by the Government. The power to revise prices fixed by these manufacturers was however retained by the Government and it could do so within four months of the fixation of the new price.[74]

Giving further insight into the Governments conscious protection of private interest, through policy, was the introduction of certain liberalizations in import duties, at almost the same time as the introduction of the Order, making it possible for formulators to import bulk drugs at much lower costs and therefore maintain profits. The impact of the continuing price freeze on old drugs was thus negated. It did not worry the Government, despite its policy objective of widening the role and scope of the public sector, that as a result of the above measures, thepublic sector was likely to face unfair competition and a further reduction in its market for both bulk drugs and formulations.[75]

Between the first of November, 1967 and the 31st December, 1969, 521 applications were received for price revision, which were granted price increases of varying degrees, interestingly only 6% of the applications emanated from foreign own and controlled companies, most of them appeared to be reluctant to submit their cost figures for scrutiny and to prefer the lesser evil of a continuing price freeze despite the much espoused escalation in costs.[76]

The 1966 Drug price control order therefore as its predecessor made no attempt at the reduction of drug prices, while on the other hand, in a number of cases prices were revised to a higher level.[77]

In 1968 the Tariff Commission submitted its Report Its basic conclusions included,

- the domestic prices of selected drugs are generally very much lower in most cases in other countries;
- by and large the prices in the Indian market of formulations compare favourably with the prices of similar formulations in the domestic markets of other countries.[78]

The Commission felt that the higher prices of essential bulk drugs in India as compared to other countries was due to the higher costs, intermediates and raw materials and good part of which was imported, the small size and lower capacities of production as compared to other countries, and the patent Law and related conditions for the transfer of knowhow. Taking the above factors into account, the Commission recommended the fixation of a pooled price based on a weighted average of the prices of different manufacturers in order to arrive at a fair ex-works price. Regarding

formulatons, the Commission felt that the prices could bear some reduction even after allowing for all costs and reasonable return on investment. The selling expenses of most companies were found to be "rather on the high side" which the Commission reduced to 15%. The recommended selling prices included a 15% mark up on cost of sales.[79]

Drug (Price Control) Order 1970

Instead of immediately acting on the recommendations of the Tariff Commission, the Government opted to negotiate with the industry.[80] These negotiations lasted for a period of two years during which the country continued to experience shortages of essential drugs, import increasing amount of drugs, and the consumer continued to pay high prices for drugs while the industry, especially the foreign owned/controlled sector, continued to make large profits as may be seen from the remittances to their principles (Table -2 Appendix 2)[81] In 1970. over 2 years after the Commission submitted the report based on the recommendations of the Tariff Commission, the Goverment announced the Drug Price Control Order 1970[82] on the 16th of May of that year, aimed at -

- bringing down prices of essential drugs wherever high;
- providing sufficient incentive to the industry to maintain/facilitate its growth from the basic stages and to develop research facilities and its expansion in planned manner;
- promoting, diversification of enterpreneurship in further development of the industry and thereby providing better opportunities for Indian personnel with requisite technical qualifications and ;
- curbing excessive profits.

The new Price Control Order thus did not attempt to relate the reasonableness of drug prices or the pattern of drug production to the health needs of the people and social objectives of the Government and national priorities. It is not, therefore, surprising then that the public sector which was created to serve the needs of public policy took the back seat here also (as shall be seen in the ensuing details).

The Order, fixed the selling prices of 17 essential bulk drugs accounting for the tariff Commission recommendations. Prices of all other bulk drugs were fixed at the same level as before the commencement of the order, with the Government retaining the power to fix the price of any imported drug after calling for information from the manufacturer. Formulation prices

were to be fixed by manufacturers in accordance with prescribed formulae. Two schemes of pricing were provided, a general scheme and an alternative scheme. In the general scheme the retail prices of formulations were to be worked out based on material costs, conversion costs, packaging costs and an adequate mark up which covered the manufacturers margin, promotional expenses, outward freight, distribution costs and the trade commission. This mark up was 75% in the case of all formulations except new ones developed through appreciable indigenous product development work and those containing as an active ingredient the new drug which was developed as a original research in India. For such formulations the mark up was 100 & 150% respectively to be reduced to 75% in three and five years, respectively. The alternative scheme was more flexible and allowed prices to be so fixed as to let the manufacturers get a 15% pre-tax return on the sales turn over for the year. Any profit in excess of this limit was to be earmarked for purposes other than the payment of dividend.[83] The new prices came into effect from the Ist of August, 1970. By allowing manufacturers the freedom to recalculate prices the Government gave the manufacturers and excellent opportunity "to make hay

while the sunshine lasted". Drug prices (by the Ministers own admission) especially in the case of anti TB drugs, antibiotics and other drugs of day to day use were increased by 2 to 3 times.[84] The drug price Index showed an all time annual increase of 12 points in 1970-71.[85] The parliament was in an uproar over the increase in prices.[86]

On the other hand the drug companies, many foreign owned, brought out advertisements in national dailies claiming reductions in prices brought about by them as per the provisions of the DPCO 1970. Retail prices of over 1100 drugs were claimed to have been reduced including vitamins, antidiabetics, sulphate, antibiotics etc., in order to "demonstrate the industries cooperation with the government". (A stance in total contradiction with the industries earlier battle against price control).[87]

The fact that prices had increased could however not be hidden and on the 19th of August the Minister of petroleum and Chemicals was forced to retreat from his stand of 'trusting' drug companies to recalculate prices in a disciplined manner and prices of all drugs were frozen at levels before May 15, 1970.[88] The order was amended over 21 times in the period that followed so that by January, 1971, the latest amendment order made it compulsory for manufacturers to obtain prior

approval of all price increases and price fixation for new formulations and new packs of the same drug introduced in the market.[89]

The Minister claimed that the order would benefit the community to the extent of Rs. 20 to 25 crores out of a total turnover of Rs. 250 crores. Further the government brought out a pamphlet "Aims and achievements of drug price control, which similarly emphasised price reductions claiming maximum reductions upto 82.53% in antibiotic preparations, 50.1% in anti T.B. preparation, 54.6% in Tonics and vitamin preparations, 63.8% in Sulphas and 68% in the case of corticosteriods etc.[90] The profitability of drug firms was said to have reduced as a result of the order. In the case of 34 firms having foreign equity of more than 50% profitability on sales turnover was stated to have declined from 18.80% in 1969 to 11.10% in 1971.[91] The above statement however did not present the true picture as gross profits in 1972 were much higher than in 1969-70 in the case of 38 foreign equity majority firms increasing by more than 100% in just 2 years.[92] This could perhaps be explained by the fact out of 76 formulating units only 13 opted for the general scheme while the rest for the alternative scheme which left considerable scope for the manufacturers

to show profits by diversification into production of consumer goods such as cosmetics and foods thus contravening the very essence of the order.[93]

The attitude of the industry in this context was extremely interesting, while on one hand it continued to complain about the rigours of price control and its consequences for growth of production and the introduction of new drugs, on the other hand spokesmen of the industry admitted in private that the DPCO (1970) had not been successful in bringing down prices of essential drugs.[94]

Thus while price control upto 1970 was not even able to control successfully the direction of diversification of the industry or its extreme profits on one hand, on the other it had very little to offer specifically to the public sector either.

The public sector drugs and pharmaceutical industries were also brought under the purview of price control through the new DPCO. But the policy directives here in context of the social objectives of this sector directed public undertakings (dated 15th June, 1970) not to make any upward revision in the prices of the formulations while at the same time reducing the drug prices of those formulations where as per the Drug price

Control Order 1970 prices were to be reduced. Thus while IDPL and HAL brought about voluntary reductions in the prices of several drugs, no increase in the prices of the formulations produced by these companies occured. As a result of the continuation at existing prices IDPL was put to an estimated loss of 1.98 crores during 1970-71 alone.[95]

Similarly in the case of bulk drugs, since most of the bulk drugs produced by HAL, all antibiotic produced by the Antibiotics plant at Rishikesh and some of the drugs produced at a synthetic drugs plant at Hyderabad were classified as 'essential drugs'. The prices of these drugs were fixed with effect from 18th May, 1970 on the basis of the recommendations of the Tariff Commission. The Tariff Commission's recommendations being based on cost studies conducted on the cost of production of these drugs in units in production in 1965-66 and 66-67, when the Antibiotics plant at Rishi Kesh had not commenced commercial production and the Synthetic drugs plant was still in the process of rationalising its prices in relation to the costs of production, placed IDPL at a distinct disadvantage as its actual production costs were not considered in the price fixation by the Commission.[96] Further the delay

of over 2 years that took place between the submission of the report and the implementation of its recommendations only added to the woes of the indigeneous producers of essential drugs (mainly in the public sector). Since costs of production had escalated considerably during this period. The cost of production of both IDPL and HAL thus often exceeded the prices by the Government based on the Tariff Commission recommendations. In view of the disadvantageous nature of price fixations for bulk drug that occured as a result of the DPCO, IDPL approached the Government for a fair fixations of prices for bulk drugs based on costs of production. As a result of such representations the Government on the 11th of September, 1970 set up a working group under the Bureau of Industrial costs and prices to examine the cost structure of bulk drugs and to review the norms for conversion costs and packaging costs, and to recommend the extent to which they require modification having regard to the representations received regarding escalations in costs of production since the submission of the Tariff Commission report and the objectives of DPCO 1970.[97]

Despite the working group submitting its recommendations in October, 1973, it was in April, 1974, when the situation became critical as the oil crisis looked

up that the Government allowed revisions in the prices of certain bulk drugs in the product mix of the synthetic Drugs plant.[98] Requests made for the increases in the selling prices of essential bulk drugs were however only acceeded to in 1975-76 when the prices of drugs at both HAL and IDPL under went increases.[99,100] In the mean time in July, 1974 the Government made revisions in the prices of formulations (made mainly by the private sector) to the extent of the enhancement of the costs of raw materials.[101]

The Drug price control Order (1970) did however offer one extremely progressive scheme. It introduced a system of pooled prices and canalization based on recommendations of the Tariff Commission for certain bulk drugs with effect from the 1st of April, 1970.[102] The system of pooled prices was introduced to safeguard the interest of the users and producers of indigenous raw material against unfair price competition, which resulted from the import of the same product at cheaper prices from abroad. 'Pooled Prices ' were to be determined by taking a weighted average of prices allowed to indigenous manufacturers and the price of imported material, inclusive of CIF price, customs and clearance charges, commission paid to the State Trading Organisation (STC) and allowance for warehousing handling

and financing charges.[103] The reimbursement of differences between the price notified by the Government for indigenous producers and the pooled price to the indigenous manufactures.[104]

The public sector specially IDPL which had, prior to fixing of 'pooled prices ' suffered considerably on account of prevailing dual prices of drugs (one the CIF price and the other based on the costs of production of the indigenous producer) was a major beneficiary of the scheme.[105]

The scheme for canalization, further had a positive impact on IDPL's performance. As a part of this scheme the government canalised theimports initially of 11 bulk drugs (increased 24 in 1971-72 and 36 in 1973-74) through STC and appointed IDPL as canalising agency for 10 of these drugs which were in its production range. The company made a gross profit of 63.66 lacs during 1970-71 (September 1970 to 31st March 1971) and Rs. 169-32 lakhs during 1971-72 on trading in bulk imported drugs. The profit on the same activity increased to Rs. 219.26 lakhs in 1972-73.[106] The company was however not able to take full advantage of the above scheme. While canalization was introduced in 1970 the Government did not bring out any order banning the import of canalized drugs through other agencies. The result was that imported raw materials

were freely available in the open market, trickling into the country against valid licences issued to actual users. Further licences already issued, prior to the introduction of the scheme, were not immediately withdrawn.[107] It is interesting to note that as a result of Government laxity in implementation of this positive measure the public sector was unable to achieve a greater surplus through canalization while private manufacturers were able to used the same laxity to their advantage.

Price Controls therefore, as industrial licencing, instead of regulating the prices of drug manufacturers in such a fashion as to direct production towards increasing import substitution and essential bulk drug manufacture, in consonance with national priorities, seemed only to limit itself to preventing extremes of profit made by these companies and in general succumbing to the requests for increasing prices of drugs produced. The Hathi Committee (1975) commenting on the contribution of Drug price control stated, "the operation of price control so far .... does not appear to have contributed materially to the emergence of a production or price pattern which is more in consonance with social needs or national objectives. For instance, inspite of the fact that the industry has been under some form of price control for over a decade, there are still wide variations in the

prices charged by different units for same or similar formulations, even more disturbing however is the fact that the structure of product pricing appears to have a bias in favour of greater profitability in respect of less essential formulations which are consumed by more affluent sections.[108]

## PATENT LEGISLATION (1856 - 1974)

A patent is a statutory grant by the Government to the inventors and to other persons drawing powers from the inventors, that confers on them, for a limited duration the rightto exclude others from manufacturering and selling the patented articles or using or initiating the patented process or vending the resulting product.[109] The legal basis of patent grant arises from the concept that the inventor is entitled to enjoy the fruits of his invention which resulted from the exercise of his brain and skills. This right of the inventor, however, is not without restrictions, which arise from the need to counter balance private ownership/individual benefits and creation of monopolies, with public interest and social benefits, and to provide a proper climate for a balance between technological self-reliance and import substitution, as against import of technology and goods. Each country

thus evolves a patent system suited to its national interests at a particular point of time inconsonance with its social goals economic status and systems, science and technology policies and political aspirations.[110]

Importance of Patents for the Drug Industry in the Developing World

At the stage at which the west was experiencing a boom in basic research and development in the Drugs and Pharmaceutical industry, the industry in developing countries like India was in its primordial stages of development, restricted in activity mainly to the final stages of drug manufacture i.e. formulating activity. Technological knowhow was thus largely concentrated in a few developed countries which made use of patent laws to maintain monopoly privelages. Over 90 per cent of world patents even today belong to the developed countries and almost 85% of patents are still foreign owned.[111] Even in these countries it is few trans national corporations that control most of the technology. Interestingly, of the patents held very few are actually worked, most being there to create monopolies for the importation from the patentee at prices dictated by them. Since the continuance of such monopoly privileges is in the interest of these companies, it is argued by them

that restrictive patent protection laws are essential to finance further discoveries and the development of new products in the industry.[112] In developing countries on the other hand which have a very limited history of indigenous scientific technical or manufacturing effort and often virtually no infrastructure of supportive integrative industries, the need is for a patent law which allows maximum access to technology but which at the same time is not detrimental to furthering relevant research and development in accordance with national oriorities and requirements.[113]

The following pages shall attempt to study the extent to which the changing patent legislation in India has been able to further the national objective of self-reliance in technology through effective backward integration. Further, since the effectiveness of any legislation is a function not only of its content but also of the nature of interpretation and implementation each of the nature of interpretation and implementation each of these aspects shall be touched upon emphasising implications for the development of the public sector drugs industry.

Patent Acts (1856 - 1970)

The origins of the Indian patents system dates back to the 1856 Act for granting Exclusive privileges for protection of certain inventions in India.[114] After several revisions and amendments this act was finally replaced by the patents and Designs Act of 1911.[115] which was in force in 1942 when the country attained independence. The latter Act was extremely ambiguous in content and largely served the interest of the British Crown. The ratio of the number of patents granted to Indian and foreign countries was about 1:9 between 1930 and 1937[116] Even after the attainment of Independence and the opening of more institutions for scientific education, post-graduate training and national laboratories this ratio remained the same upto 1958.[117] The ratio was even lower if one took into account the economic or industrial importance of inventions. In the area of antibiotic production for example of a total of 195 patents in force in April 1959 only 5 were Indian, a clear indication of the bias of the existing law against indigenous enterpreneurs.[118]

The problems with the Act of 1911 included the fact that it did not even categories what was patentable and what was not. The patent Office when left to interpret the Act assumed that all new drugs and new

processes for manufacture of a drug were patentable. The above coupled with the fact that the term of the patent was initially 16 years extenable to another 10 years if the working of the patent had not been sufficiently remunerated, meant that trans national corporations holding these patents were able to develop a virtual monopoly over both product and process patents in the country. The impact for the Indian industry was obviously negative. Even where indigenous firms both in the private and public sector attempted to develop process technology they were often prevented by trans nationals from commercial manufacture, through the institution of legal proceedings under the guise of infringement of patent protection. On interesting example involves the Hindustan Antibiotics Limited. This public sector company as early as 1958-59, through completely indigenous research developed a process for the manufacture of Oxytetracycline HCL and Chlorotetracycline and decided to set up a plant to manufacture the same.[119] The plant went into production in 1961. At about the same time M/s pfizer began the manufacture of the same drug. This multinational immediately instituted proceedings against the public undertaking on grounds of infringement of patent rights and Hindustan Antibiotics Limited, in view of its own

patent pending in the patent office was forced to suspend production without prejudice to their right to dispute the pfizer claim.[120]

Similarly, although provision for compulsory licencing were made under the 1911 Act these were so worded that they were totally in effective and not a single compulsory licence was granted under the Act prior to Independence.[121] The nature of the Act in fact pressurised the Government into accepting technology for the establishment of Public Sector Undertakings that was "second best". Representative of the Ministry of Petroleum and Chemicals when questionned about the decision to go into collaboration with the USSR despite the Kane Committee's (the Indian Pharmaceutical Delegation 1956) recommendations advising against collaboration with the USSR for antibiotics and vitamins stated.

"In deciding to develop the production of these drugs in the Public Sector, Government look into account the possibility of the technical assistance available from various countries and the terms on which that would be available such as royalties, patent rights and financial assistance for launching the projects. As there did not appear to be any prospect of technical or financials collaboration becoming available from

other sources at suitable terms, the conclusion that emerged was that the most suitable collaboration would be with the USSR though there technology was "second best"."[122]

"The Secretary of the Ministry also stated that the Kane Committee had also referred in their report to the problem, that would be faced over the patents. The problem could be of an onerous 'nature in respect of payments that would have to be made as a result of patent problem."[123]

Since the Soviet on the other hand did not have any patents of their own "Indian Drugs and Pharmaceutical Ltd suffered considerably on account of the fact that in order to by pass existing patents and to evolve new procedures the Russian had to repeatedly modify the design of the plant",[124] the Chairman of IDPL infact said to the Committee on Public Undertakings "it was right to say that the collaborators were experimenting with the particular project of IDPL to get round patents"125.

Recognising the need for a comprehensive revision of the Act 1911 the Indian Government established the patents Enquiry Committee (1950). The Committee presided over by Dr. Bakshi Tek Chand submitted an interim report in 1949. This stated,

"The Indian patent system has failed in its purpose, namely to stimulate invention among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to secure the benefits thereof to the largest section of the public."[126]

The interim report also recommended the amendment of Sections 22, 23 and 23A to 23G of the Indian Patents and Designs Act, 1911, regarding the issue of compulsory licences, which were accepted by the Government and enacted (vide Act 32 of 1950).[127] The amendments resulted in the introduction of an entirely new section (23 CC) including drugs, foods insecticides germicides, fungicides, surgical or curative devices. Under the section the Controller was empowered to grant a compulsory licence to any applicant at any time after the expiry of three years of the patent unless there were good reasons for refusing. Despite this amendment however, foreign firms by using delaying tactics like asking absurdly high royalities or refusing to negotiate reasonable terms for grant of the licence were able to prevent compulsory licencing. The Halfkinee institute, a Government research institute worked out a process for manufacture of paludrine (a bulk drug). Experimental production in a pilot plant revealed that the drug could be supplied at 1/5 of

the prevailing cost. In order to produce the drug commercially the institute tried to obtain a compulsory licence from imperial chemicals ltd who held the patent for the drug. The firm while agreeing to provide the licence voluntarily took 4 years negotiating time to bring down the royalty from an absurdly high 25% to 10% which was still 5% higher than the value stipulated by the reserve bank of India. By that time the Halfkine Institute decided to give up negotiations.[128]

The patents Enquiry Committee (1950) submitted its final report in April 1950. A bill based on the recommendations of this committee, for revamping of the patent laws was introduced in the parliament by Shri T.T. Krishnamachari in the Lok Sabha (Bill No. 59 of 1953) in 1953. The Bill was however not proceeded with and lapsed with the dessolution of the 1st Lok Sabha. Instead of the Bill being broughtup again before the 2nd Lok Sabha, the Government appointed in 1957 Mr Justice Raja Gopal Ayyangar to examine a fresh and review the patents law in India and advise the Government of changes necessary. The Report on the Revision of the Law in India Relating to Patents for Inventions (1959) was submitted by Justice Ayyangar in 1959.[129] The Report made comprehensive and far reaching recommendations regarding the varied aspects of the patent laws in India covering issues like the terms

of the patent, to the revocation of the patent and the nature of possible legal proceedings.

A Bill based on the recommendations of the Ayyangar Committee Report (1959) was however, introduced in the Parliament only in 1965.[130] The Bill incorporates some changes in the lightof examinations made with particular reference to patents for food and drugs. The Bill unlike the initial assertions of Mr. Shastri in the 3rd March edition of the Financial Express of the same year, to introduce the Amendment of 1911 Act "In the current session" was, in the face to vigorous controversy delayed and referred to a Joint Committee of the Parliament on 25th November, 1965.[131] This was more inconsonance with a later statement made in the Economic Times of the 1st of May, 1965 by the then Minister of Petroleum and Chemicals in his speech which said, "It was a ticklish issue. Any extreme position would be against national interest. Abolition of patents would harm even a country like India. All factors like the good of the country and the scientists and technologists would be taken into consideration. All parties would have an opportunity to offer suggestions when the amending bill would be introduced in the Parliament. On an issue like this the attempt should not be isolate national interest from the scientific interest of the world. In fact national interest must not though against scientific interest".[132]

In view of the fact that the Indian Government has always been vulnerable to pressures from abroad and the fact that the bill came under considerable flak from trans national corporations the world over[133] the elusion of the Minister to the need to take into account both 'national' and 'scientific' interest while at the same time asserting that national interest must not go against scientific interest, was not surprising.

The Joint Committee of the Parliament adopted a number of amendments and reported back to the Lok Sabha 1st of November, 1966. The report was however, not unanimous and contained notes of dissent by some Members of Parliament who considered that the Amendments proposed in the majority report resulted in the purpose of the bill, which was to stimulate inventions amongst citizens of India and to encourage the development and exploitation of newinventions for industrial progress and the free flow of technology from abroad, not being achieved.[134] The fact that the hearings of the Joint Committee were attended by a number of representatives of big American Export Organisations and also Japanese, German and British observers, pressurizing the Indian Government against passing the Bill may have influenced the fact that the Bill was not proceeded with even in the 3rd Lok Sabha.[135]

A new patents Bill was introduced in the Parliament in August, 1967 to consolidate and amend the law relating to patents. The Bill was again referred to a Joint Committee of the Parliament in 1968. The Committee submitted its Report only in 1970. This time, in view of favourable political circumstances the Bill was passed, and the New Indian Patents Act (1970) came into being.[136] The passing of the Patent Bill occured at a stage of Congress history when the party led by the Prime Minister Mrs. Indira Gandhi was fighting against considerable criticism from the Right wingers and in the need of proving its Socialiest bonafides to the people. To quote from the Press, "After a decade of concerted opposition to the Ayyangar Reports recommendations by TNC's as well as Sections of Indian capital Indira Gandhi's minority government which was then dependent on the left for crucial support, and in the wake of a near scandal over drug pricing presided over the passage of the bill in the Parliament."[137]

This view of the press is further substantiated by the following extract of the speech made by the Mrs. Gandhi at the Bankers Club New Delhi on the 28th of August, 1969,

"Social tension was growingin this country because of the disparities because of the sense of injustice amongst many of our people and therefore any move that can be made or any step which can be taken to help in easing this tension is a move for stability and security of all of us"[138]

SUMMARY

The study of different aspects of Government regulation and control between 1948 and 1974 clearly indicate a bias if the Government towards the growth of private industry. Where the public sector has gained from policy it is largely secondary to the gains of private enterprise. Section II shall discuss the twists and terms of Overt policy and its implications for the public sector.

## SECTION - II

## FROM THE HATHI COMMITTEE TO THE MEASURES FOR RATIONALIZATION, QUALITY CONTROL AND GROWTH OF THE DRUGS AND PHARMACEUTICAL INDUSTRY. (1974 - 1986)

The growing dominance of foreign capital in the drug industry, the increasing influence that this begetted it on matters related to policy, and the obviously negative repercussion of the above on the pattern of both drug production and pricing were issues of Central focus between 1973 - 1974 and were discussed extensively at various forums including the press and Parliament.[139] The Government was assailed for its neglect of the public sector and demands were made for the nationalization of the drug industry. Support for this demand came not only from radical groups and left parties but also from within the Congress Party.[140] As Union Minister of State for Petroleum and Chemicals, K.R. Ganesh had the courage and conviction to mobilize many aminent scholars and technologists to fight against antipeople activists of the drug industry. Indeed this generated sufficient momentum to establish an organization called Association for economic independence and prespective of the drug industry, to counter the propoganda barrage of the powerful drug industry, at a national convention held in the above convention.[141]

## HATHI COMMITTEE (1975)

It was in response to this debate that the Hathi Committee or the Committee on the Drugs & Pharmaceutical Industry was appointed in February 1974 with Jaisukhlal Hathi as its Chairman.[142] The major terms of reference of the Committee included,

- 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;
- to make recommendations 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 balance regional dispersal of the industry;
- to examine measures so far taken to reduce the prices of drugs for the consumer and to recommend further measures as may be necessary to rationalize the prices of basic drugs and formulations;
- to recommend measures for providing essential drugs and common household remedies to the general public especially in rural areas.

The committee after an indepth study of the working of the industry submitted its report to the Government

in April, 1975. The Report was tabled in both Houses of Parliament during the same year. The Committee Report which was the first attempt made in India towards a comprehensive explicit drug policy made about 226 recommendations, the most important of them being directed towards provision of a leadership role to the public sector, strengthening the indigenous private sector and restraining the growth of multinationals. The major among these included,

- the Committee in appreciation of the socio-economic implications of the health felt that in a welfare State such as India the production and distribution of drugs should constitute an important social responsibility of the State. It further was of the opinion that trade aspects of this vital industry should be separated from the accepted principles of trade and profit, influencing the industry only to the extent of allowing it to generate adequate resources for its own growth and expansion, through R & D, where necessary to meet the increasing needs of the nation. It was in this context, the Committee felt that the public sector should be given a leadership role in the production, distribution and R & D functions of the industry. The Committee in this direction recommended a large scale expansion of

public sector production facilities so that they covered the production of almost all essential drugs, identified by the Committee, and certain non-essential, but drugs nonetheless of growing importance for the health of the people. The production where possible of bulk intermediate by the public sector was also recommended. In view of the overlap in product profilesof the two state promoted units, a change in product mix was recommended. With regard to R & D it recommended a minimum initial increment of at least 5% by the public sector in R & D expenditure which was to be directed towards diseases of national importance. The use in this direction of the all relevant sections of the patents Act of 1970 in order to provide technology to this sector was also recommended. The need for a better balance between bulk production and formulation activity in the public sector was also realised and the Committee recommended that this sector should be allowed to formulate at least 60% of the bulk that it produced.[143]

- With regard to multinationals, the Committee recommended by majority view that they should be

takenover forthwith, it was however not able to come to any unanimous decision in this direction. It did however unanimously recommended that foreign undertakings should be directed to bring down their equity to 40% forthwith and further reduce it progressively to 26% : this reduction in equity, the Committee further recommendedshould not take the form of dispersed holdings. The Government, public financial institutions or public sector undertakings related directly or indirectly to the manufacture of drugs/chemicals should purchase their shares. The Committee further recommended that having regard to the present stage of theindustry for purpose of FERA guidelines thisindustry should not be eligible for preferential treatment given to items specified in Appendix -1 of the Industrial Secrecy Policy of 1973.[144]

- Price regulation according to the Committee should be directed towards securing a better convergence between commercial considerations and social needs and priorities. In this direction, the Committee recommended higher returns on capital employed for a manufacturer than available for formulations for the industry as a whole (a 12 to 14% post tax return being the recommended figure for basis of

price fixation), Formulation prices were to be regulated on the principle of selectivity in terms of the size of the units, the selection of items and in terms of controlling prices only of market traders. A profitability ceiling of 8 to 13% on sales turn over for formulations was also recommended. Generic products were to be free from price regulation.[145]

- The phased abolition of brand names starting with a list of 13 drugs specified by the Committee (table 3 Appendix 2) formed a major recommendation of the Committee. Further all new products were to be introduced under generic names.[146]

- With a view to streamlining operations and achieving the above basic objectives aimed at producing and distributing essential drugs to the largest number of people, as economically as possible, the Committee recommended the establishment of a National Drug Authority which would be responsible for all matters relating to the laying down, coordinating and implementing policies in consonance with the health needs of the people and disease profile of the country.[147]

The Government though outwardly accepting the general approach of the Committee did not takeany action regarding

implementation of its recommendations.[148] That the Government was not ready, infact, to accept any of the major recommendations of the Committee was best articulated by K.D. Malaviya who stated "A doctrinaire position on nationalization was contrary to the spirit of the new economic environment as it would cause uncertainity in the private sector.[149] K.R. Ganesh who was instrumental in the setting up of the Committee and regarded as a major threat to interests of multinationals was forced to resign. Though his resignation came on grounds of absence of support in the Ministry and Cabinet it was welcomed by the representatives of the multinational.[150] To prepare ground for the rejection of the Report a Cabinet Sub-Committee was reappointed to deal with the Report. The fact that this coincided with the revival of the Indo-US Business Council led some members to suspect that the Government put the Report in a showcase because of pressure from the Indo-US Buiness Council.[151]

The negative attitude of the Government towards the report was confirmed by Mr. H.N. Bahuguna who stated, based on the recommendations of the Sub-Committee and Minutes of Cabinet meetings, that the Government "were not willing to go to any length with the Hathi Committee except on minor matters."[152]

The period between 1975 and 1977 was in fact characterised by a liberalization of economic control, In October, 1975, 21 industries were exempted from licencing and 31 other foreign companies and many Indian Companies were allowed unlimited expansion beyond licenced capacity these included among others basic drugs and chemicals.[153] Further by an order of 31st December, 1976 a large number of drugs were placed under open general licence list in order to ensure that manufacturers could import such drugs without any quantity or value restrictions. In early 1977 the import trade policy allowed large scale REP imports by export houses directly for banned restricted and canalised items of drugs for sale of such imported bulk drugs to actual users in the country.[154] The liberalizations granted resulted in large scale imports of canalised restricted and banned items of bulk drugs resulting in indigenous production getting adversely affected due to price of indigenous bulk drugs being higher than the import prices.[155] Major price revisions were also affected during this period based on the guidelines for price revision issued in July, 1974.[156] It was only after thefall of the ruling Government in 1977 that the Hathi Committee Report was reopened for considerations by the new Government.

## DRUG POLICY ( 1978)

Despite considerable criticism of the policy framed by the earlier Government, especially in context of the delay in implementing the recommendations of the Hathi Committee (1975), the Drug Policy which was eventuating announced by the new Janata Government on the 28th of May, 1978 was not in the same inspired mould as the recommendations of the Committee. While the policy did attempt to restrain the otherwise unrestrained growth of the multi-national sector and visualised a wider role for the public sector, providing, at the same time a considerable boost to the Indian sector of the industry, it infact did not implement a number of major recommendations of the Hathi Committee, diluting considerably even those that were implemented.[157]

### Multinationals

The policy, as against nationalising foreign companies or even directing all foreign equity companies in this sector to reduce their equity to 40% forthwith and further reduce it progressively to 26%, while making the industry ineligible for preferential treatment given to items specified in Appendix - 1 of the Industrial Licencing Policy of 1973,[158] (as

recommended by the Hathi Committee), opted instead for a redefination of, "drugs and pharmaceuticals" listed in Appendix-1 of the Industrial Licencing Policy of 1973 to ,

"(a) Drug intermediates from basic stages for production of high technology bulk drugs and

(b) high technology bulk drugs from basic stage and formulations based thereon with an overall ratio of bulk drug consumption (from own manufacture), to formulations from all sources of 1:5.[159]

The reduction of foreign equity was thus linked to the ill defined issue of 'high technology'. The result was that only those multi-nationals which were not producing high technology bulk drugs were required to reduce their equity to below 40% (this would make them eligible for all concessions available to Indian Companies). Foreign Companies producing bulk drugs involving high technology were allowed to retain foreign equity exceeding 40% to a maximum of 74% depending on the proportion of the total turnover evolved in the production of such high technology drugs and activities related to Appendix -1 or the core sector of the Industrial Licencing Policy of 1973.

In order to identify foreign companies engaged in the manufacture of bulk drugs "not involving high technology" the Government appointed a high level committee in April, 1978 under the Chairmanship of K.V. Ramanathan.[160]

The Committee submitted its report in October, 1979 the main criteria adopted by the Committee for categorising the processes involving high technology were extremely general including e.g.

"the steps of operation involved in a chemical synthesis" or

"the use of toxic material"

or

"purification and separation by different type of sophisticated technologies" (Table-4 Appendix 2)[161]. Of the 31 foreign drug companies with direct foreign equity exceeding 40%) in 1978, 22 were declared as producing high technology bulk drugs. Of the remaining 9 companies 7 were pure formulators. Only 2 firms therefore declared as producing bulk drugs not involving high technology.[162]

The Committee further confined to itself to technological aspects of processes. Important linkages including the extent of imports, the stage of manufacture itself (basic stages or penultimate stages) and the

stage of manufacture relative to the stage from which indigenous manufacturers were producing the drugs did not form a part of the criteria for assessing high technology.[163]

Of the 22 firms thus detected as producing high technology drugs, 3 were to be allowed to retain 74% foreign equity, 3 between 52% and 73%, 6 companies were allowed to retain 51% equity, 2 firms between 40% and 50%, while 5 firms offered to bring down foreign equity to 40%. (Table - 5 Appendix - 2).[164]

The dilution of equity further according to the policy was to occur in such a way that 66% of the balance equity (beyond allowed levels) was to be disinvested in the favour of Government financial or public sector institution and the rest in favour of Indian investors, preference in the latter case being given to Indian employees of such Companies. The above clause shows how the recommendations of the Hathi Committee were twisted in favour of foreign companies, as even in the extreme case where foreign investment constituted 100% equity and the Company was forced to dilute to 40% equity, a take over of 66% of the balance equity would still constitute only 39.6% of total equity. Since in most cases dilution would not occur from 100% equity, the share of the public sector/Government financial institutions

would be still lower and the multi-national though declared Indian would in actual fact remain foreign in its strategies (in the eventual implementation of the policy even these safeguards were not adhered to, let alone complete takeover of balance foreign equity by the Government as recommended by the Hathi Committee).[165]

After dilutingthe basic recommendations of the Hathi Committee regarding multinationals in the above manner the policy then regulated the remaining companies under FERA. With regard to licences for bulk drugs or formulations where capacities had not been specified it was stated that these would be fixed on the basis of the highest production achieved in any one year during three years ending 31st March, 1977.[166]

New licences and the regularisation of expanded capacities on old licences for bulk drug manufacture were made subject to the condition that 50% of the production (as against 40% for the public sector and 30% for the Indian sector) was to be supplied to non-associated formulators, and that they restricted their overall ratio of bulk drugs to formulations (from all sources) to 1:5. The formulations licences were further linked to the production of bulk drugs from basic stages. These companies were also compelled to have R & D

facilities and quality control facilities. Firms with a turn over more than Rs. 5 crores per annum were directed to have R & D facilities in the country on which capital investment was not less than 20% of their nett block. Further, they were to spend atleast 4 % of their sales turnover on recurring R & D expenditure.[167]

Public Sector

Though the 1978 Drug Policy accepted in general the need to provide a leading role to the public sector through expansion in the direction of meeting the needs of the public health services, adequate financial outlays and technological support, specific recommendations of the committee directed towards providing the public sector with such a leadership role were either evaded/rejected/ or diluted.

Thus, while the Hathi Committee had envisaged the expansion of the public sector into the manufacture of not only essential drgus identified by the committee, but also certain non-essential drugs of increasing therapeutic value, the policy statement restricted the line of production for the public sector to the production of only 25 drugs most of which were already in the production range of the sector.[168]

The Hathi Committee had also recommended that public sector units should be allowed to use the patents/

inventions as permissible under section 99 and 100 of the Patents Act (1970). The Government chose not to take any stand on the recommendation. Discussed in detail under the section on patents. Similarly the committee had also recommended that the existing overlap in the product mix of HAL and the Antibiotics plant of IDPL at Rishikesh should be removed leading to better economic working, and allowing the units to concentrate and specialise in a given line of products. The Government again chose to ignore this recommendation.[169] Discussed in Chapter III.

The National Drug Authority which had been envisaged as the central body coordinatingand streamlining operations of the public sector specifically, and of the industry in general, was not considered feasible by the Government and outrightly rejected.[170]

Similarly, recommendations made in relation to, top priority to be given, to the manufacture of essential drugs, through special assistance schemes, priority in power supply and other incentives being made available to the manufacturers of such drugs were also omitted in the policy statement.

The recommendation regarding the phased abolition of brand names was also diluted so that as against 13

essential drugs identified by the committee, the policy implemented the recommendationsin the case of only 5 drugs (since a large percentage of the production by the public sector was sold under generic names, they faced unfair competition from branded products).[171] The Policy however did accept the recommendations envisaging the introduction of all new single ingredient formulations under generic names.[172]

The 1978 Drug Policy did offer certain positive measures for the growth of public sector also. It tried to encourage the use of indigenously produced bulk drugs by linking the sanction of formulation capacity to a formulation turnover based on a ratio of 2:1 between consumption of indigenous bulk drugs and imported/canalised drugs. It was further stated that equal, in view of the leadership role envisaged for the public sector, preference would be given to public sector undertakings in the procurement of drugs for Government purchases of the same.[173]

Indian Sector

The Policy also gave a considerable boost to Indian Sector of the industry by allowing them formulations licences upto ten times the value of their drugs production. Further in the grant of industrial licences preference would be given to Indian Companies over MRTP Companies and FERA Companies. The Policy

also established priorities in the pattern of capacity regularization and expansion. Thus, while FERA Companies were to be allowed to expand in high technology areas, the regularization and expansion of capacities in the Indian, public sector and MRTP Companies was based on the condition that they made available 30, 40 and 50% of their production to non-associated producers.[174]

Pricing Policy - Drug (Price Control) Order 1979

Based on the recommendations of the Hathi Committee, the policy controlled theprices of formulations on a selective basis. Formulations were divided into four categories. Categories I, II, and III were to be controlled while category IV was not subject to price fixation. Mark ups of 40, 55 and 100% on ex-factory costs were provided for categories I, II and III respectively. Further the policy for the first time also provided for a differential permissible pattern of pre-tax return on sales turn over linked to the magnitude of turn over, the contribution ofthe firm to bulk drug production and research and development liability. For category I & II drugs, a ceiling price was also

to be notified, on the basis of the prices of major efficient producers called 'leader prices'.[175]

For category III formulations, prices were to be calculated on an individual basis, however even here leadership prices would be established wherever possible.[176]

All bulk drugs used in the production of price controlled formulations were further brought under price control. While a post tax return on nett worth of 14% was allowed for category I and II drugs, a return of 12% on nett worth was allowed for all other bulk drugs.[177]

A very significant development in the Drug Price Control Order (1979) was the introduction ofa Drug Price Equalization Account (DPEA) and the introduction of the concept of retention prices.[178] Retention prices of different manufacturing units, based on their costs and actual yields, were to be fixed by the Government while the bulk drug was to be supplied for use in formulations at a common selling price. Where a manufacturer or formulator used in his formulations any bulk drug, either from his own production or procured by him from any other sources, the price of such a bulk drug being lower than the price allowed to him in the

price of his formulation, the excess was to be credited to the D P E A. The excess of common sale price or the pooled price over the retention price fixed by the manufacturer was to be paid by the manufacturer into this account to be used to pay the manufacturer, importer or distributor, the shortfall between his returntion price and the common sale price of the relevant bulk drug. The DPEA was to be maintained also by funds so deposited by manufacturers. The system was of considerable benefit to indigenous producers especially in the public sector whose cost of production was generally higher than the cost of production of either imported bulk drugs or the cost of production of those who manufactured the bulk drug in the country from imported penultimate compounds.

## IMPLEMENTATION OF THE 1978 POLICY AND TRENDS TOWARDS POLICY LIBERALIZATION

Even such pheripheral reforms as were envisaged in the 1978 Drug Policy were not tolerated by the multinationals which dominated the drug industry. Through systematic campaigns misleading newspaper advertisements, creating an artificial shortage of essential and life saving drugs and resorting to legal machinery in the country, the multi nationals represented

by the Organization of Pharmaceutical Producers (OPPI)[179] and the Indian sector (successfully roped in by the OPPI) tried to make the 1978 Drug Policy and the 1979 Drug Price Control Order unoperative.[180]

The 22 multinational identified by the Ramanathan Committee (1979) created a big hue and cry over the reduction of foreign equity based on the percentage turnover involved in high technology bulk drug production. The industry further by a deliberate cut in production created an artificial shortage of essential and life saving drugs in category I and II.[181] The production of essential drugs fell from 21.2% in 1978 to 16.8% in 1980 with the situation becoming worse after 1980.[182] Regarding the issue of phased abolition of 'Brand Names', the companies challenged the notification of the Ministry of Health and Family Welfare of January 1981 and obtained stay orders from the Delhi High Court (the companies included were Hoechst, Cynamid, and Pfizer).[183] Further, as a part of the implementation of the 1978 Policy the Drug Controller of India had issued a notification banning the manufacture and sale of 18 fixed dose combinations of drugs from 30th September, 1982 and Ist April, 1983 respectively. Boehringer Knoll obtained a stay order from the Bombay High Court while Organon obtained a similar stay order from the Calcutta High Court.[184] Some of these companies refused to

comply with prices of bulk drugs fixed by the Government based on Bureau of Industrial Costs and Prices (BICP) studies obtaining stay orders against Government prices from the Delhi High Court. Hoechst for example sold Balargan Ketone at Rs. 24735 Kg. as against a Government fixed price of Rs. 1,810/- per kg. Glaxo similarly sold Beta methasone 17 valarate at Rs. 220000/- per kg. and Betamethasone Disodium Phasphate at Rs. 1,26,230/- against Government selling prices of Rs. 1,05,850/- and Rs. 1,26,230/- per Kg.[185] The campaign for a review of the 1978 Drug Policy was stepped up in 1980 with the fall of the Janata Government and the re-election of the Congress-I Government. The OPPI launched a Rs. 2 lakh advertising campaign spread over 15 publications criticising the previous Government Policy.[186]

The lack of cooperation of the industry coupled with the tendency of the Indian Government to succumb to pressure by multinationals (seen from independence onwards) led to a progressive liberalization of the Drug Policy between 1978 and 1986. Theimpact of even those reforms that the policy had attempted was not felt to any significant degree.

In the reduction of foreign equity for e.g. the Government did not implement even the limited safeguards provided for in the 1978 policy, whereby equity dilution occured in a dispersed fashion (as had been feared by the Hathi Committee). Most firms continued to have a major say in the decision making of the company. In the absence of any such safeguards it was notsurprising that a number of firms found it to their advantage to dilute equity holding to 40% voluntarily. (Table 6 Appendix 2)

## LICENCING POLICY REVERSAL

While the 1978 Drug Policy had decided to freeze capacities of those companies with unlimited/unauthorised capacities through permission letters registration certificates and carry on business licences at the highest levels achieved in any year during the 3 years period preceeding 31st March, 1977, the campaign against the policy by representatives of the industry and the vulnerability shown through out by the Government towards pressure from the industry worked towards the reversal of the earlier decision. In August, 1980, the Government, brought out a new scheme for capacity regularization in 34 industries includingthe drugs and pharmaceutical industry whereby regularization was to be based on recognised installed capacities as on the first of

September, 1980 (clearly contraducting the March 1978 Drug Policy).[187]

In April, 1982 the Department of Chemicals and Ferlizers was reported to have designed a new regularization schem, 1982 being declared the year of producitivity. The scheme envisaged re-endorsement capacities indicated in the industrial licences with reference to thehighest production achieved in any of the previous five years and 1/3rd thereof, provided this is more than the licenced capacity and 25%.[188]

The scheme remained in operation till the 31st of March, 1985 and 358 industrial units took advantage of the schem. The scheme was reintroduced in the 7th Five Year Plan after further liberalization. The facility of re-endorsement was now to be made available to all units which had achieved 80% capacity utilization during any of the 3 years ending 31st March, 1985. In order to encourage production, it was further stated that the industries where the production exceeded reendorsed capacity, would be re-eligible for further re-endorsement to the extent already achieved plus 1/3rd thereof.[189] In the case of FERA Companies in a complete Shift from the restriction of expansion of these companies to high technology areas, stated that they would be eligible for

re-endorsement of capacity for all drugs and pharmaceuticals, in regard to licences issued prior to May 1978 and the existing entry in Appendix - 1 of the industrial licencing policy was to be applied only in respect of licences issued to FERA companies from May 1978 onwards.[190]

In the direction of liberalizing policy further, the industrial policy statement July, 1980 announced a scheme for the automatic growth of the drug industry. In pursuance of this statement the Government allowed growth in the case of 30 industries including the drugs and pharmaceutical industry to the extent of 5% annually with a maximum of 25% in 5 years, in one or more stages. FERA companies were initially allowed this facility in High Technology areas only. The scope of this decision was however enlarged in favour of the multinationals in March, 1981. The Government decided to allow automatic growth of these companies in the case of drugs and pharmaceuticals other than those under item no. 14 of Part - A relating to the expansion of FERA companies in 'high technology' areas.[191]

Reviewing the above policy decision in May 1982 its scope was further enlarged to allow automatic growth to a unit in the private sector in respect a drug which under the 1978 Drug Policy was reserved for licencing to the public sector, , if the unit was making drug in

question under a valid licence on March 31, 1978. The question of a leadership role to the public sector being conveniently forgotten.[192]

The pattern of industrial licencing between 1978-79 and 1984-85 further showed a clear bent towards the growth of the Indian private sector as against the public sector (Table 7 Appendix 2)[193] which the Government had stated would be given a leadership role. Out of a total number of 292 licences granted between 1978 and 1983, 23 were granted to the multi-national sector, 172 to the Indian private sector and 53 to the public sector. The number of licences granted to the public sector declined throughout this period.

In 1982 the Government in a move towards restricting the scope of the public sector reviewed the lists of indicative lines of production for the Indian and public sector. Out of a list of 25 drugs reserved for the public sector 8 were deleted from this list including Erythromycin, Griseofulvin, Piperazine, Ampicillin, Doxycycline, Sulphacetamide, Metronidazole and Amidopyrin was removed as it was banned by the Drug Controller, while it was stated that Ampicillin, Doxycycline, Sulphacetamide and metronidazole were already present in the Indian Sector list. No reasons were given for

the deletion of Erythromycin, Griseofulvin and Piperazine. Phenacetin banned by the Drug Controller was deleted from the list for the Indian sector while two drugs Phthalyl, Sulphathiazole and Tolbutamide were shifted to the Indian sector, (As the concerned multinational had diluted equity to 40% and thus became eligible for protection under Government Policy) from the open list.[194] Further the last move in this direction by the Indian Government was the further removal, through the new Drug Policy 1986, of Penicillin and Polio vaccine from the reserved list for the public sector. Interstingly, the decision to dereserve pencillin was taken after the Government allowed both HAL and IDPL to modernize their plants in reddiness to meet the projected demand for the drug in 1989-90.[195] The CMD IDPL stated clearly in reply to the Committee on public undertakings regarding the reasons for the step. "15 Indian firms with foreign tie up hence approached for Ministry for manufacture of Pencillin. It seems that the Dutch Company which is refusing to talk to us on technology is wanting to come with collaborator here to start production in India"[196]

Further the Government did not ever consider it fit to consult IDPL or HAL before finalizing the new Drug Policy, the committee was constrained to state in this regard,

"the committee are shocked over the grave ignorance of the ministry about the capability of their own unit especially when they have themselves agreed to the proposal of IDPL to modernize the Rishikesh Plant for increasing Pencillin production. The committee see no reason for deserving the production ofpencillin which will not only permit all sectors to manufacture pencillin but will also enable the multinationals who are not prepared to share technology with IDPL to enter the field from the back door by collaboration with small units"[197].

"The committee deprecate the casual manner in which the question of deresefvation of penicillin has been decided by the Government without consultation with their own undertakings"[198], while the Government had promised preference to public sector undertakings in the purchase of medicines and drugs by the Government in view of the leadership role envisaged for this sector the little preference that this sector had so far received was also withdrawn in 1978-79.

As per the 1970 Drug Price Control Order, IDPL had been chosen as distribution a certain canalised drugs in its production range. In 1978-79 based on the recommendation of a committee set up under the Chairmanship of Shri K.S. Chavda, M.P. which was constituted to

look into the prices of Drugs imported through the State Chemicals and Pharmaceuticals Corporation of India Ltd. (C P C) and distributed through both C P C and I D P L, the Government withdraw Streptomycin Sulphate from the list of canalised drugs distributed by the Company (the Committee had criticised certain pricing decisions of IDPL).[199] In 1979-80 the Government further withdraw 5 other drugs distributed by the Company. This was also based on the recommendations of the Chavda Committee which stated that a manufacturer should not be appointed as distributor of the same drug because the manufacturer may try to adjust his losses on production from imports.[200] The decision was not surprising in context of the fact that the Government had made canalization through IDPL virtually in effective much before 1978-79. This was affected through the considerable liberalization of import policy permitting the import of canalised restricted and banned items of bulk drugs upto certain limits against registered exporters policy licences (REP licences).

When representation were made by the company to the Government regarding the Indiscriminate issue of such licences, the Chief Controller of imports and exports was requested by the Ministry to link the

facility to the export of specified bulk drugs contained in the concerned formulations.[201]

Since the linkage was however brought about only with effect from September, 1977 in the respect of Drugs and Pharmaceuticals, there was only partial relief at best; The Times of India as late on 1983 reported

"Indiscriminate and clandestine of drugs have dealt a crippling blow to the Indian Drugs and Pharmaceuticals HAL's Rishikesh plant .... "..... Inquiries reveal that IDPL had drawn the attention of the Government, several times to the danger involved in the indiscriminate imports of basic drugs and intermediates in response some steps including confiscation have been taken to curb import of drugs which can be produced indigenously but the flow still continues"[202] Thus, while the drug policy had talked about a leadership role for the public sector in both the production and sale of drugs, the implementation occured in an absolutely opposite direction.

In 1983 the Government decided to review various aspects of the 1978 Drug Policy. In May, of the same year the National Drugs and Pharmaceuticals Development Council was constituted. The Council at its very first meeting constituted three working groups to study and report about

various aspects of 1978 Drug Policy, the need to review or revise the existing policy and to recommend changes wherever necessary. The working groups submitted their report in 1984 and a Steering Committee was appointed to consolidate the recommendations of the earlier groups. The Steering Committee submitted its Report in 1985. The major recommendations of the Committee related to the reduction in the span of price control, an increase in the mark up for fixation of drug prices and free licencing procedures for the industry.[203] The bent of the recommendations of the Steering Committee towards trade and industry was not surprising as the Committee and the working groups had substantial representation of the industry. The Chairman of the Committee Mr. Mahendra Prasad, M.P. Congress -I who himself had substantial interests in Aristo Pharmaceuticals and the Managing Director of Hoechst and E Merck were influential members of the Committee.[204]

Based on the recommendations of the Steering Committee the Government, via a press Note dated 6th March, 1985 delicenced 12 bulk drugs and intermediates (these included rifampicin, dapsone, clofazimina, primaquine, BMME, Nevaldamine, insulin, anticaneer drugs, vitamin $B_6$ and nergestrol, and drugs developed through indigenous research.[205] In June 1985 this list

was increased to include 95 drugs totally, with 82 more drugs being delicenced. Delicencing, it was claimed, through stimulation of industrial growth and simplification of industrial licencing procedures, would result in increased availability of essential and life saving drugs.[206] The irony of the situation however was that of the drugs delicenced, 79 were from the priority drug list prepared by the Steering Committee This list consisted of only 22 from categories I & II, 68 from category III and 5 drugs from category IV of D P C O 1979. The delicenced drugs in a similar pattern consisted of 7 drugs from category I and II (which according to the DPCO 1979 contained essential and life saving drugs) 54 from category III and 8 from category IV. 15 drugs on the priority list which had not been delicenced were mainly from the public sector.[207] As to how the delicencing of non-essential drugs was likely to increase production of essential drugs was questionable. Though it is true that licencing does mean a lot of unnecessary bureaucratic interference and licencing procedures are too cumbersome resulting in the harassment of individual manufacturers and other citizens for their own corrupt practices, it must be remembered that licencing is a major tool in the hands of the State whereby it can regulate the industry by stopping, reducing or encouraging the production of certain drugs, delicencing takes this initiative away from the State.

Therefore, more efficient licencing rather than delicencing would have been a bettermove. Further, problems at the level of licencing have not been the major limiting factors affecting the low production of essential drugs. The crux of the issue actually being the extent to which investment in the production of such drugs may lead to profit maximization in this industry which continues to be dominated by private enterprise ruled by the logic of the market place.

## DRUG PRICE CONTROL ORDER (1979) IMPLEMENTATION

A major crib of the industry was that the Drug Price Control Order (1979) had offered such low mark ups that the industry did not find it possible to produce essential drugs. That this was not true was visible from the comments of the economic times dated 30th July, 1984 "the financial performance of 33 pharmaceutical companies improved substantially during 1982-83"[208]. The net sale, income, gross profit and net profits of these companies increased during the year. Again on the 7th August 1984 the Financial Express reported,

"the pretax profits of major wholly Indian private sector firms have risen substantially during the first three years of the current decade. The impressive results

assume special significance in the light of repeated allegations made by wholly Indian drug firms that foreign equity firms have been reaping profits. What is more, these results have been achieved under the much maligned 1978 Drug Policy"[209]

The economic times of the Ist July, 1986 further reported that the "pharmaceuticals companies in the private corporate sector witnessed an all round improvement in their financial performance during 1984-85 ... enabled pharmaceutical companies to achieve higher profits, impressive cash flow and an improvement in major profitability ratios during 1984-85 as compared to 1983-84."[210]

What had actually happened was in no way different from the situation in the area of licencing even upto 1986. The Government had not succeeded in implementing major provisions of the Drug price control Order 1979. While on onehand, the industry refused to cooperate in the implementation of certaim provisions of the Drug Price Control Order, 1979, e.g. the prices fixed for bulk drugs under the order and the abolition of brand names and the banning of hazardous and irrational drugs as already stated, on the other hand, the Government itself did not implement certain provisions of the Drug Price Control

Order. In fact, the Government was not even successful in conductingthe price fixation exercise as per the Drug Price Control Order, successfully as was accepted by the Minister himself,

"We had the price control on more than 300 bulk drugs, and more than 4000 formulations, on more than 20,000 formulation packs. Because of the big span of control ... the Government was paralysed, we could not fix prices of all these that I have mentioned in proper time."[211]

According to para 59 of the Policy, the Government had said that it would ensure 20% of turn over of an individual manufacturer in category I and II drugs. As against fhis, theproduction and sales of essential drugs in fact fell considerably from 1978-79 to 1985-86.[212]

Further, the Drug Price equalization account created by the Government under the Drug Price Control Order, 1970 was not worked by the Government despite the issue being repeatedly raised at the Parliament and the Press. The total recovery of the Government, in this fund, was only Rs. 2.28 crores from four firms while according to a four member committee appointed by the Department of Chemicals and Ferlizers illegal profits of Rs. 13.61 crores were payable by six companies and that too for the period ending December 31st, 1983.[213]

## FROM THE HATHI COMMITTEE TO THE MEASURES FOR RATIONALIZATION, QUALITY CONTROL AND GROWTH OF DRUG AND PHARMACEUTICAL INDUSTRY (1986 ONWARDS)

In view of the progressive liberalization in policy that occured from 1980 onwards, the "measures ..... were only a culmination of the strategy to subvert the Drug Policy of 1978.

Not surprisingly, the Measures for Rationalization, Quality Control and Growth of Drug and Pharmaceutical Industry announced in December 1986, focussed mainly on a reversal of the licencing and pricing policy provisions of the earlier policy, which had aimed at placing a certain degree of restraint on the chaotic growth of the industry. The measures aimed at

- Ensuring abundant availability of essential drugs at reasonable prices;
- strengthening the system of quality control over drug production and promoting the rational use of the drugs in the country.
- Creating an environment more conducive to channelizing new investment into the pharmaceutical industry;
- strengthening indigenous capability of production of drugs.[214]

The transformation of the economy of shortages to one of surpluses was to occur through progressive extension

of the delicencing strategy already adopted by the Government, broadbanding of industrial licencing for bulk and formulations, (whereby a company that got permission to manufacture/formulate a particular drug could then without getting a separate licence produce all associated and related drugs) and through reduction in the span of price controls coupled with increased profit margins for the industry.

While delicencing was not likely to result in the increased production of essential drugs broadbanding especially in the case of formulations provided an excellent opportunity to the industry to proliferate increasingly into the production of non-essential, irrational which were already flooding the market.

The reduction in the span of price control to only 166 bulk drugs as against 347 under the Drug Price Control Order, 1979, and reduction of price controlled formulations to only 40% as against 85% in the Drug Price Control Order 1979, also served the purpose of the industry which was free to charge exorbitant price on the decontrolled items in the Drug Price Control Order 1987.[215] The new Drug Price Control Order further divided drugs into two categories each with much higher mark ups than under Drug Price Control Order 1979.

These are drugs needed for national health programme with a mark up of 75% and drugs essential for health needs 100%. The Drug Price Control Order 1987 further stipulates price fixation based on 27 bulk drugs by the Government where the prices of the rest of the formulations based on 139 bulk drugs were to be calculated by the Indian manufacturers (Despite the 1970 Drug Price Control Order experience)[216] The new policy further envisages a liberalised import policy both for technology, and bulk drugs and intermediates. A number of drugs whose imports were so far restricted have been placed under Open General Licence with total disregard of the impact of these policies on the indigenous production and sales of drugs.[217]

As far as the public sector is concerned, the policy has restricted its role from a 'leadership role' to an important role in the production of bulk drugs for National Health Programmes.[218]

The drug price equalization account which had been set up with the intention of encouraging indigenous production of bulk drugs has been abolished under the plea,

'in actual practice the operation of Drug price Equilization Account (DPEA) is giving rise to intractible

administrative problems with anticipated acruals to the DPEA, being thwarted by disputes and claims on the DPEA put forward promptly'.[219] This decision has been taken despite the fact that the estimated amount due from the industry to the Government stood at Rs. 200 crores (mostly from the multinational companies) and the Supreme Court ordering drug companies to pay back huge amounts to the Government due to over pricing of their bulk drugs or lower prices of imported drugs.[220] The impact of this decision is definitely negative for the public sector drug industry as through the system of retention and pooled prices, the D.P.E.A. funds were to be used to pay back to indigenous producers, the differences between retention prices and import prices.[221]

As far as the issue of Brand name is concerned the new policy in a reversal of its 1978 policy decision as decided to allow drug companies to market new single ingredient formulations under Brand names on the conditions that the generic names shall be displayed in double the size as the trade (brand) name. No mention is however made in the policy of more important issues related to stopping disinformation to doctors, banning prescriptionsunder brand names or keeping a strict check on unethical marketing practices of the industry.

## PATENT LEGISLATION 1970 AND BEYOND

The new patents Act of 1970 is a progressive piece of legislation. That the public sector has benifited considerably by the passing of the 1970 legislation is obvious from the considerable R and D effort in these companies, since the passing of 1970 law. Let us take IDPL for e.g. IDPL Rishikesh has been able to improve productivity levels of all industrial culture by 10 - 15% . The improved technologies of Oxytetracycline and Streptomycin have been scaled up in the main plant. The technology for preparation of Erythromycin, Ethyl-succinate and Erythromycin Stearate has been developed. Imported lard fat specified with Italian technology has been successfully substituted by Groundnutoil for tetracycline manufactured reducing inputs by Rs. 1000/- per batch. Dextrose has been substituted with cane sugar in Penicillin fermentation and has resulted in reduced input worth Rs.1750/- per fermentor.[222]

IDPL Hyderabad similarly has been able to improve the process for Para Aminobenzoyl Glutamic acid. A process for manufacture of Methyldopa has been developed starting from a lower raw material to a higher raw material. Ampicillin has been made by the Company at a

lower cost and considerable work has been done on Nifedipine and Ibuprofen.[223]

The law reduced the term of the patent for food and drugs to 7 years from the date of filing of the patent. For the above products the Act gives protection to process patents only explicitly excluding "product by process protection".[224] It makes provisions not only for compulsory licences which may be applied for at any time after the expiry of three years of the ceiling of the patent. In the case of medicines, food and chemicals it is further declared that after the expiry of three years these shall automatically be endorsed with the words "Licences or rights" i.e. any interested person on payment of royalty is entitled to a licence under such patents. The royalty is further restricted to 4% of the net exfactory price in bulk of the patented article. The most important provision of the new Act relates to the Government use of patented inventions in Section 100 of the patents Act. The Central Government and any person authorised by it in writing may use a patented invention for the purposes of the Government. Use for the purpose of the Government is defined in section 99 of the said Act to include making use exclusively or vending for the purposes of the Central Government, a

State Government or a Government undertaking. The Government may therefore, under the powers vested in it permit the public sector undertakings to use the inventions for the purpose of the Government. The effect of the above would be that the mere fact that a patent has been filed or a patent has been granted will not debar public undertakings from manufacturing and distributing the products so patented. The committee on the Drugs & pharmaceutical Industry (1975) stated in this regard,

> "the Committee feels strongly that allowing the freedom to the public sector unit to use desirable patent would not only constitute an exciting challenge to the scientist and technologist, to innovate and establish production technologies ordinarily forbidden to them by patent laws but also would obviate payments of high royalities for really worth-while patents"[225]

the Government is yet to implement the above recommendation. Further, while under the provisions of the 1911 patents act appeals from decision of the Controller were to lie in the majority of cases with the Central Government, under the new Act all the cases appeals from decisions, orders and directions

of the Controller will lie only with the High Court which is the highest court in each state in India. The normal judicial process in accordance with the rule of law is thus assured to all parties under the Act.[226]

With regard the reciprocal or convention arrangements too the new Act has removed limitations that restricted such arrangements to only the United Kingdom and Commonwealth Countries. The Government may conclude bilateral or multilateral arrangements or treaties with any other country or countries for mutual protection of inventions.[227]

In the recent years International interest in the Indian patent laws has once again increased. The Indian patents Law has achieved rich dividents for India. By not recognising product patent in the case of drugs the Act provides a viable and solid basis to Indian R & D to develop technologies for substituting the import of patented products and to prevent their unhindered access to the Indian market. In view of increasing import substitution, as a result of the law the multi-national lobby is once again feeling threatened. No surprisingly, therefore, there is frantic lobbying by International drug firms to drag

India into the Paris Convention,[228] "as an effective determent to international trade in goods where there is an infringement of international property rights".[229] They are demanding that for patent protected products, the production of identical products should be prohibited, that the life of the patent be increased to 20 years that the patent may not be revoked for non-working that the burden of proof should be reversed from the patent holder to the infringer to prove that he is not guilty and where for justified, legal technical or commercial reasons the patent is not worked, but importation is authorised the requirements of working of the patents should be treated as satisfied.[230]

Pressure has been brought to bear in the above context on the Indian Government by the USA, European Countries and Japan. The US offensive is a part of its global initiative on the subjects of international property rights. Attack on India was first mounted in 1982 when she was negotiating for the Science & Technology initiative. It was renewed three years later at the Uruguay Round Negotiations of the General Agreement on Tariffs and Trade (GATT) and the Montreal Meeting held in December, 1988, and through pressure to sign the controversial Paris Convention on patents

which is overseen by the World Intelectual Property Organisation (WIPO).[231]

After withstanding pressure from the above lobbies for a considerable period of time, the Rajiv Gandhi Government in April, 1989 finally gave in, agreeing to negotiate substantive norms and standards relating to Intellectual Property Rights under the General Agreement on Trade and Tariff (GATT).[232] With India agreeing to negotiate the issue at GATT there is now every possibility of the western proposal being wirtten into GATT dispute settlement mechanism being applied in case of any violation. According to an official source,

> "the situation is now ten times more ominous for India than if she Joint the Paris Convention."[233]

The above decision of the Indian Government shall work against the indigenous industry including the public sector, which had made considerable progress in the area of developing process technologies for bulk drug as a result of the patent Act of 1970.

The above resume is a comment on the seeming lack of concern of the Indian Government for the growth

of indigenous industry specially in the face of pressure from private enterprise both Indian and Foreign, Government priorities seem to have mostly been decided on the basis of pressures and interests of multi-national corporations of advanced capitalist countries or indigenuous manufacture rather than the needs of the public sector industry.

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# CHAPTER - III

# PUBLIC SECTOR PROFILE AND CONSTRAINTS ON GROWTH

## CHAPTER - III

## PUBLIC SECTOR PROFILE AND ARISING CONTRADICTIONS

Public undertakings in India were expected to serve the goals of public policy and were established in accordance with the industrial policy of the Government embodied in the two Resolutions issued in April, 1948 and April, 1956.

The Resolution of 1948 stressed the need for "the State to play a progressively active role in the development of industries[1]", while the Resolution of 1956 widened the scope of public enterprises stating "the adoption of the socialist pattern of society as the national objective as well as the need for planned and rapid development, require that all industries of basic and strategic importance or in the nature of public utility services should be in the public sector. Other industries which are essential and require investment on a scale which only the State in the present circumstances could provide, have also to be in the public sector. The State therefore has to assume direct responsibility for the future development of industries over a wider area.[2]"

While the two Resolutions on industrial policy did make it abundantly clear that public undertakings were to help further the national objective of " attaining a socialist pattern of society by acting as counterweights

to the abuses of economic power and helping to usher in a more 'just and equitable social order', while simultaneously serving as levers of public authority guiding the economy into planned directions. They did not, however especially in view of the wide scope of possible interventions identify the specific nature, capacity, and role of state intervention and its determinants in specific industries. The recognition of the hetrogenous nature of public enterprises growing in various sectors of the economy brought in, early enough the realisation of the need for a clear ennunciation of the objectives of public undertakings. Observations in this regard were first made by the Estimates Committee, on the National Coal Development Corporation.[3] This recommendation was reiterated in 1965 by the Committee on Public Undertakings in its 7th Report (Third Lok Sabha).[4] The Administrative Reforms Commission also, in October, 1967 recommended that the Government should make a comprehensive and clear statement on objectives and obligations of public undertakings. The above recommendations however resulted in no action on the part of the Government for a considerable period. It was in fact seven years after the Estimate Committee made its recommendations that the Bureau of Public Enterprises issued relevant instructions in November, 1970 asking all Government companies to initiate action to formulate a statement

of their objectives and obligations and have them approved by the Ministry. Action, was however still not taken!

The Committee on public undertakings in its 40th Report (5th Lok Sabha) was constrained to note that the Government "had not laid the financial, economic and social objectives of public enterprises so far".[6] The Committee further emphasised that as a result of this delay, the performance of public undertakings continued to be judged by a variety of vague objectives and considerations affording scope for uninformed criticism which made for dilution managerial accountability.[7]

The Committee asked the Government to present before the Parliament a white paper containing a framework of principles of the Governments general, economic, financial, and social strategy for public undertakings, micro objectives both financial and economic for each undertaking providing for a review from time to time and a qualification of social objectives and obligations and issue of Government directives in appropriate case.

The story did not however end here, the Bureau of Public Enterprises again in 1979 sent out circulars asking public enterprise to spell out their micro objectives consistent with the broad objectives spelt

out in the industrial policy statement in 1977. In the case of the public undertakings in the drugs and pharmaceutical industry itas only then that Hindustan Antibiotics got its macro and micro objectives approved. In line with the industrial policy of 1977, IDPL had yet to get its objectives approved in 1986-87. One of the reasons given for this state of affairs being that the Ministry had 'misplaced' the file containing IDPL macro objectives which the company had sent to the Ministry for approval in 1974, while the under-taking had not finalised its macro objectives as it was caught in the larger question of its survival. The Committee on public undertakings in its 29th Report stated in this regard,

"the Committee are pained to say that both the undertaking and the Ministry have shown scant respect to the recommendations of this Committee as is evidenced by the fact that in response to recommendations made by the Committee in 1973-74 ....."

Thus despite repeated reiteration the Government did not find it necessary to clarify the macro and micro objectives of the public sector so that even four decades after independence public enterprises continued to run in the absence of clearly enunciated objectives.

While their performance may only be evaluated on the basis of objectives and the role envisaged the lack of

precise and clear objectives for the Public Sector Undertakings, in the drugs and pharmaceutical sector has resulted in the evaluation of the performance of these undertakings largely on the basis of the profit yardstick.

Since, according to the Report of the Administrative Reforms Commission, the performance of Public Enterprises may be evaluated only after accounting for the 'social and non-commercial obligations laid on them'[8]. We shall first attempt to define public sector achievements in relation to their social orientation and obligations as per health needs of the people.

The 22nd Report of the Committee on Public Undertakings said with regard to objectives behind the establishment of I.D.P.L.,

"The setting up of drug manufacturing units and surgical instruments factory in the public sector was intended to serve the tripple 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 a 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."[9]

I.D.P.L. similarly in its general objectives formulated for approval by the Bureau of Public Enterprises states,

"It shall be the constant endeavour of I.D.P.L.:

(i) to undertake basic manufacture of essential bulk drugs, chemicals, basic intermediates and formulations in adequate quantities to meet increasing demand for them in context of :

(a) State taking over increasing responsibilities for provision of medical relief in the country;

(b) necessity of bringing down prices of essential medicines"[10].

Bulk VS Formulation Production

In the direction of meeting this first objective public sector undertakings have constantly undertaken production of drugs from basic stages. Analysing the bulk drug production, in the country the Hathi Committee[11] found that of a total bulk production of 5300 tonnes in the organised sector, the public sector produced 1500 tonnes of bulk drugs valued at 24 crores, the Indian and the Indian majority units manufactured 3200 tonnes of bulk drugs valued at Rs.27 crores while the foreign majority equity units produced only 600 tonnes of bulk drugs valued at Rs.19 crores.

These figures are of special significance as the foreign equity holding units in the organised sector amounted for 80 % of the total turn over of the industry. The public sector production of formulations on the other hand was worth only 20 crores.

Bulk Drugs produced by the Public Sector units interestingly were given preferentially to non-associated formulators as against being formulated by the companies itself despite this leading to considerable underutilization of the formulation capacities of these undertakings. The Committee on Public Undertakings in its 80th report, 5th Lok Sabha on H.A.L. stated in this regard,

"The Committee note that the major portion of the total production of different products of H.A.L. is sold in bulk form to private viallers although sale in vialled formulations was more profitable than sale in bulk. They are unable to understand why the Government thought that they " had also an obligation to supply bulk drugs to private viallers, " even though the bulk sales has been a substantial factor contributing towards losses which the Company has been sustaing lately."[12]

though the production of formulations increased soon after the 1978 Drug Policy was announced. It however continues to be much lower than the recommended 60 % stated by the Committee (Table -1, Appendix-3)[13].

Essential Drugs Production

The concept of essential drugs was arrived at on the following basis,

" It is clear that for the optimal use of limited financial resources 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, these 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#.[14]

The first comprehensive list of essential drugs for India was produced by the Hathi Committee (1975). Based on this list the Drug Policy of 1978 further categorised these drugs into category one and two formulations i.e. highly essential and life saving drugs. The Public Sector product mix lies most in category one and two of this list.(Table-2, Appendix-III).[15]

Drug Prices, Sales and Marketing

Another major objective of Public Undertakings in the country has been to bring down the prices of essential drugs.

H.A.L. infact from its very inception brought about reductions in the prices of antibiotics manufactured, starting from 1958 when the first revisions were made. (Table-3, Appendix-III). Further as already discussed in detail in the Chapter on Policy, the Public Sector, time and again as per the Directives of the Government did not bring about price increases allowed to other manufacturers.[16]

In a study by Agarwal, Ramchandran and Rao (1972) retail prices of four widely used drugs of I.D.P.L. were compared with the price of the same product in the Indian Private Sector, the Foreign Sector and the four drugs

chosen for the study had the prices of the bulk drugs fixed by the public sector at a common price for the imported and indigenously produced products. Despite pooled bulk drug prices, the prices of the formulations produced and sold from these bulk drugs were found to vary considerable. The prices of all I.D.P.L. products were found to be much lower than either the Branded or Generic products of the foreign firm and the same product formulated by the indigenous manufacturers (Table-4, Appendix-III). The study concluded that public sector prices were lower than prices for the same product in the private sector and further stated that the system of pooled prices had considerably reduced the prices of bulk drugs in the country. Jagjit Singh further found that prices of drugs had reduced considerably in the market since the emergence of I.D.P.L.[17] (Table-5, Appendix-III). The price of tetracycline capsules which used to be around Rs.106 to Rs.118 per 100 capsules prior to the public sector, I.D.P.L. coming into production were reduced to Rs.60 to Rs.63 after the emergence of IDPL, merely because the prices in the Trade fixed by the Public Sector were lower. Similarly, oxytetracycline capsules which used to be around Rs.115 per 100 capsules dropped to Rs.63 merely because I.D.P.L. was supplying the product in the market at Rs.58 per 100 capsules.

Further in consonance with their social orientation and aims to meet the health needs of the larger masses the public sector units opted for a preference to hospital sales as against trade sales. H.A.L. for example, did not have any significant trade sales upto 1975-76 (these stood at Rs.4 lakhs as against total sales figures for the company for that year of Rs.103.075568 lakhs)[18] though, the company had since improved its trade sale considerably, recent figures still were in favour of Hospital and Central Government Organizations. In 1979-80 for example, Government vs Private sales were Rs.8.45 crores and Rs.2.58 crores respectively.In 1980-81 similarly, the figures remained Rs.9.71 crores and Rs.3.22 crores respectively and in 1981-82 they were Rs.14.47 crores and Rs.3.24 crores respectively.[19] I.D.P.L. similarly gave preference to sales to Central Government institutions and hospitals, with sales to Govt. Departments constituting 70 to 80 % of its total sales. In 1970-71 for example, 78.6 %; in 1971-72, 80.5 % ; in 1972-73, 80.6 % and in 1973-74, 72.3 % of the total sales of the company were constituted by Government sales.[20]

In additional to the above measures both H.A.L. and I.D.P.L., since their inception followed the practice of giving discounts of about 15 % to Government institutions on narrow spectrum antibiotics i.e. penicillin, streptomycin, combination of penicillin and streptomycin and 28 % on tetracyclines. Dealers were given discounts of 7½ %[21], the

rates of supply to Government institutions in 1971-72 were so low that they remitted in a loss of Rs.164 lakhs to the company during that period.[22]

Import Substitution and R & D Efforts

The Public Sector through venturing into the production of bulk drugs which were otherwise being largely imported also resulted in considerable foreign exchange savings for the Government. The Secretary of the Ministry of Petroleum and Chemicals stated regarding the role of public sector,

"Some years ago all the drugs now manufactured in the public sector were formulated by others, including foreign companies then in existance but the basic drugs were imported from abroad that was not good enough. As you know, the formulations are the really profitable items in the drug industry therefore, the private sector would not like to elect for the manufacture of bulk drugs, or the basic drugs but only for formulating basic drugs and making profit, therefore we decided to manufacture bulk drugs instead of importing them."

Further, as we saw in Chapter-II, the nature of technology available to the public sector initially was more often than not the 'second best' and in considerable need of improvement. Both I.D.P.L. & H.A.L. in this direction have conducted successful R & D efforts. While H.A.L. not only developed a new antifungal antibiotic

Hamycin and improved upon the existing technologies, role of I.D.P.L. in this regard has been reasonally good. While it did improve technologies in seven cases and developed better processes, in 15 cases (mostly antibiotics- the imported technology could not be improved upon. Moreover it is producing 22 new bulk drugs from all four categories, and 13 intermediates based on the indigenously developed technologies. It has also perfected pilot scale technologies for another 14 drugs. It is also important to note that both I.D.P.L. and H.A.L. and Bengal Immunity are engaged in basic research to develop new drugs[24]. Sectorwise study shows that the public sector is extremely well placed with regard to its technological status on bulk drug production (Table-6, Appendix 3)[25].

Generic Vs. Brand Names

A drug has three names, a chemical name, a generic or non-proprietory name and a brand name. In India an overwhelming majority of drugs are sold by their brand names. However on grounds of clarity, of drug class of lower prices and of generic drugs / the elimination of irrational combination and the fact that Doctors in India are educated in the use of generic names, it is considered in public interest that drugs be sold under generic rather than brand names. The public sector undertaking in accordance with their social orientation, sold products mostly under their generic names[26].

Sites For Construction of Public Sector Units

The Public Sector in accordancewith the Government Policy to develop backward areas and provide them with sources of employment were established at considerable distances from the town/adjecent city. These sites have been developed into beautiful townships and provide all facilities to their employees.[27]

Sick Units

In consonance with Government Policy, with a view to maintaining employment of people and optimum utilization of production assets the public sector units in the drugs and pharmaceutical industry have taken over the management of sick units and also eventually the units themselves as desired by the Government. I.D.P.L. was authorised as per the notice of the controller from 8-5-72 to take over the management of Smith Stanistreet Co. Ltd. This was extended again in 1974-75 and again in 1976-77 for periods of two years each. On the 30th of September, 1977 the Government decided to nationalise the undertaking. Under I.D.P.L. management the firm was able to improve both its production and sales figures substantially. A tableting and encapsulating section was introduced while the product mix was extended to chloramphenical, furazone ointment and tollbutamide.[28]

Another sick unit Bengal Immunity Ltd. was taken over on 18th May, 1978 for two years under the I.D.R. Act and board of management constituted. The management offer was extended upto 17th May, 1982. The firm was nationalised

under the I.D.R.A. 1951, on Ist October, 1984 as a new company under the style of Bengal Immunity Ltd. The Company has two manufacturing units at Baranagar in West Bengal and Dehradun in U.P. engaged mainly in the production of vaccines and sera. The Government today under rehabilitation plan drawn up by the Company is planning to extend production to other areas also.[29]

A third sick unit the Bengal Chemical and Pharmaceutical Works was also nationalised by the Government in 1980. The firm with production units at Maniktala and Panihati in West Bengal, and in Kanpur and Bombay has been allowed expansion to produce Sulphuric Acid and Caffeine and Dapsone.[30]

The takeover of sick units was interestingly, despite the recommendations of the Committee on Public Undertakings which in its 40th Report, 5th Lok Sabha in Role and Achievement of Public Sector Undertakings stated,

"The Committee are compelled to observe that Government should not allow themselves to be saddled with the problem of mills which are contrived into sick condition because of mismanagement".[31]

Arising Constraints

The above social/public policy oriented aspects of the Indian Public Sector Drugs and Pharmaceutical industry have in context of the larger milieu of the prevailing market economy, however resulted in giving rise to constraints on effective generation of surplus by these units and are today threatening their very survival.

It is quite obvious for example that a unit which concentrates on the production of bulk drugs in a market situation where the sales turn over to capital ratio for bulk does not exceed the 1 : 1 figure and in many cases in the earlier stages of development is still lower is not likely to earn any profit while a firm which in negation of national priorities produces formulations whose capital invested to sales turn over ratio averages at 1 : 2.6 with an upper limit of 1 : 7.75 makes massive profits.[32]

Similarly, a company which attempts to sell its product under generic names faces considerable resistance from branded products on account of the creation by large firms of brand loyalties among doctors who in the absence of any other source of information regarding product quality rely on brand names to prescribe drugs. Further not only does a generic product face competition from the branded products produced by organised private enterprise, it also has to cope with competition from small scale manufacturers (these firms in view of their small size and lack of stress on quality control are often able to produce a cheaper product than the public sector) who are also selling the product under generic names. The C.M.D., I.D.P.L. stated in this regard,

" We have a problem being a part of the Government and being a public sector company we have to do business according to Government policy. One of the policies which

the Government have laid down is not supporting the brand names. ..... But the reality, as far as trade is concerned, is that if my product has got a brand name and if the trade prescribes my product I do not have to fight with anybody in the market. If the product is sold with generic names then I have to fight with the small scale industries that at whatever prices they sell them, We have to match those".[33]

The preferance for hospital vis-a-vis trade sales has also similar in view of the system of discounts offered effectively reduced I.D.P.L. ability to generate surpluses. In this connection, it is important that the public sector units have received no cooperation from the Government, thus while I.D.P.L. and H.A.L. preferred hospital sales over trade sales the Government was not even able to assure the public sector companies, a maximum price preference upto 10 % and guarantee that for products under the product mix of these companies, the Government department and public enterprises would buy their requirements from the public sector undertakings in the drugs and pharmaceutical industry. A recommendation to the above effect was made to the Govern-ment by the Committee on Public Undertakings in its 46th Report. The Government had as a result issued instructions in June, 1971/ May, 1972, these were however not being followed by some of the State Government and D.G.S.D.'s who also entered into parallel contracts with private firms.[34] Even Government Medical Stores Depots under the Department of

"Family Planning" did not give effect to the recommendations of the Government to accord a 10 % preference to I.D.P.L. The price Preference for the public sector was implemented only in 1978 when the Ist Drug Policy was announced. This was however, again withdrawn in the year 1980.[35]

Another major problem faced by the public undertakings as a result of their late entry to the market, their higher initial costs of production in relation to those of private producers (due to obsolete technology and high raw material and equipment costs) and the absence on the emphasis here on sales promotion and high pressure marketing tactics ( as used by the private sector) was their inability to meet their sales targets except where they held a monopoly over both indigenous production and import of the product. The problem was faced with considerable intensity between 1968-69 and 1973-74[36] by both I.D.P.L. & H.A.L. in view of the foreign exchange crisis and rising raw material costs. In order to overcome the problem in the area of sales and to reduce competition between existing public undertakings in the pharmaceutical sector, the Committee on public undertakings in its 40th Report on the Role and Achievements of Public Sector Undertakings (1973-74) had recommended that the Government should evolve a common sales and marketing organization for the public sector in each type of industry.[37] No action was

however taken by the Government on this recommendation. Recalling the above recommendation, the C.P.U. on H.A.L. 1975-76 reiterated the above recommendation.[38] Action is yet to be taken on the above recommendation.

The fact that sites for location of Public Sector Undertakings are determined on the basis of their economic feasibility but on the policy of the Government which caters to the development of industrially backward areas by setting up new industries and thus providing the population with employment opportunities has had adverse effects on the public sector. An excellent case is the Antibiotics Plant at Rishikesh, the site is at considerable distance from the main centres of drug production and sale remitting in considerable portion of transport of raw-materials and end products and further, as Rishikesh was an industrially backward area the plant suffered considerably on account of inadequate supply of electricity and power breakdowns.[39]

The takeover of sick units by the public sector similarly is a much criticised policy of the Government whereby the mismanagement by the private sector is endorsed by the Government at the cost of a drain on public sector resources and their managerial expertise.

While on one hand the public sector today finds its survival threatened by its attempt at fulfilling the objectives for which it was created, political interference

in the guise of public accountability of the enterprise as affected efficient functioning of these enterprices and added to their woes. Regarding the issue of Accountability Mohammed Fazal states,

" the public sector has been so systematically fettered from all sides, that there is very little to encourage a sense of involvement among the managers of public sector projects. One has to be a very brave Chief Executive who can undertake measures for the operations of an enterprise for the overall good of the undertaking without hinderance ". There are innumerable interference from various quarters of the Government including the Ministers, where the intention is more a backseat driving on the part of these interfering agencies without taking formal responsibility for the consequences of such interferences. Most of the public sector managements have a real fear of being in position of being wrongly blackmailed and thus are forced to toe the line.[40]

An excellent case of political interference that back fired came from the Drugs and Pharmaceutical Industry. An interview with some high I.D.P.L. officials revealed that, it was on the insistence of Mr. George Fernandes the then Minister of Chemicals and Fertilizers that Muzaffarpur was finalised as the site of the I.D.P.L. Plant.[41] The plant was set up at an estimated cost of Rs.83 lakhs to produce Nicotinamide, Nicotinic Acid, Methyl ethyl pyridine, Acetaldehyde and all chemicals and intermediates.

The Plant since its commissioning has been in a constant state of crisis (March 1979 and October 1979). In 1981 the Plant closed for 53 days because of a shortage of power and alcohol. It was closed again in 1984 and worked intermittently only to be closed again in October 1984. This was despite the fact that the plant is said to be located in the heart of the alcohol belt of the country and the State Governments at the time of the establishment of the Plant had promised all required facilities. The General Manager of the Unit of I.D.P.L. said to India Today that he had decided to,

"Keep the plant closed as it is uneconomical to run the plant with such meagre quantities of alcohol and then shut it down again..... when the Bihar Government had assured adequate supply of alcohol but the Government has backed out. We don't know what to do now".[42]

The Plant requires two million bulk litres of alcohol every year to keep it running full steam. The nine distillaries produce 10 million litres using raw materials supplied from the two sugar mills in North Bihar. The State had assured that the firm would get its full requirement on a priority basis. According to Syed Raza Imran Rizvi, Additional Secretary,

"Our Distillaries are closed when we ourselves are facing a problem how can we think of I.D.P.L."[43]

The truth of the matter however was that the distillary got much higher prices from alcohol sold as liquor.

A new element of uncertainty has also crept in during the last few years in the public sector, this relates to the selection and tenure of the Chief Executive and Functional Directors of these undertakings. In the case of I.D.P.L. for example five managing directors were changed from 1980 - 1985,[44] the appointment of the present Chief Executive of I.D.P.L also being shrouded in controversy,

"It is being pointed out that the Chief Executive who was inducted in the Organisation in revocation of certain well defined rules may be rough shod over his collegues because of his unfamiliarity with the norms of the Public Sector, the present encumbent to the Office of Chief Executive, before joining I.D.P.L. in the latter half of 1986 did liasion work for a multinational company.

As the public attention rivets to I.D.P.L. the concerned people will have to expalin how could the Public Enterprises Selection Board (PESB) interview only one outsider. It is beside the point that some senior public sector members were called for the post of Chief Executive without inviting applications from the public, through advertising, the appointment committee of the Cabinet was reportedly told that the post was not advertised".[45]

New Trends in the Public Sector

Increasing emphasis by all quarters on the lack of profit of the public sector undertakings in the Drugs and

Pharmaceutical Industry has resulted in the Chief Executives of the Public Undertakings in this sector slowly shifting towards commercialization. Caught within the web of conflicting Government Policies, the Public Sector today in a bid to survive has diverged from the retionale behind its institution. They have been driven towards joining hands with the private sector in the collective loot of the masses. The I.D.P.L. Chairman said very succintly in this regard,

".....if we have to protect our interest, we cannot be fed with conflicting directives that on one hand we have to become efficient, economically viable and profitable and keep our head over water and on the other say that we must do things that will undermine this position"[46].

In this direction both H.A.L. & I.D.P. L. have taken a number of steps. Encouraged by the Government in certain cases to move in the direction of profit maximization H.A.L. and ID.P.L. are slowly reducing their institutional sales while building up trade sales. Both companies are strengthening their market organizations and increasing the number of representatives with them. According to a witness from H.A.L.

"..... we took a phased programme of increasing the representatives, we had to take a second step if trade sales had to go up , we should also have brand names, but we did not have them then, we must also have literature for our representatives. For this we started a Medical Services Department. Our production range was very narrow only a few

years ago we had them only in D category viz. Category I. We developed 60 new products. We made a three phased programme, Phase I of marketing was to increase efforts in that direction , our aim was to concentrate on growth , our sales had gone up by 100 % in 5 years. The 2nd phase known before use is to continue growth, and to cut inventories and outstandings. Phase III will come after one to two years in which we have to excell in terms of our growth inventories and outstandings."[47]

I.D.P.L. similarly has decided to go ahead with brand names much to the dislike of the Government.[48] Further it is also strengthening its marketing effort while at the same time reorient its pribrities.

The CMD , I.D.P.L. said :

First of all we have completely reoriented our priorities.In trying to make the productivity of money we have re-arranged priorities of all production, the basis of the money generating turned it around fastest not only taking into account the generation of money but the speed of generation of money. It just happens that one product which gives me maximum and fastest generation of money is penicillin"[49].

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# CHAPTER - IV

# DISCUSSION

# CHAPTER - IV

# DISCUSSION

## A RESUME ON PRECEDING CHAPTERS LEADING TO ISSUES

The creation of the public sector in India had a weak ideological base.[1] Though the attainment of the 'Socialist pattern of Society' through progressively active State intervention, visualizing a dominant role for this sector was a much espoused goal of State policy, no more than lip service was paid to it. The State continued to rely implicitly on market forces as against altering the process of income generation or property distribution. State policy too was implemented basically at the level of incentive/disincentives operated through tax concessions, subsidies price controls, quotas and restrictions on licencing and other procedures.[2] The growth of public sector in the above scenario was necessarily full of problems which we a enhanced by the objective contradiction between the transnational sector and the public sector.[3]

In view of the orientation of the State towards the market and the limitations of technology, a largely dependant growth of the private sector through increasing foreign collaborations was initiated in the Ist plan period.[4] The decade of the 60's to early 70's, in view

of the importance of the socialist support to the congress well marked by a degree of growth in the public sector; the Prime Minister at her speech at the conference of heads of public sector undertakings on July 19, 1969 said :

> "The public sector occupies a pivotal role in our economic strategy. From the beginning it has been recognised that the public sector would necessarily have to venture into difficult and capital intensive fields of basic industry which the private sector had shunned for long. This has been done boldly and sometimes in the teeth of opposition. I think we can say with justifiable pride that the sinews of our strength though it may be modest by the standards of the Western countries, lie largely in our public enterprises."[6]

Developments that occured were also fraught with problems from the very word go, India in an attempt perhaps to keep both the USSR and USA at bay went in for technological collaborations with both, for the establishment of the largest State promoted Public Sector Drug and Pharmaceutical Organisation in the country and expansion of the only other public sector undertaking

in India.[7]

By the time these units overcame their teething problems and settled down to manufacture they found that markets had already been captured by Transnational Corporation, the strength of the Public Undertakings however lay in their ability to produce bulk drugs from basic stages. Further both undertakings attempted to develop export markets (IDPL was infact quite successful).

Government policy towards the undertakings was largely directed towards the growth, through the public sector, the drug manufacture, in those areas, where the private sector was not ready to intervene. Working within the strong grip of market forces, in context of the failure of Government Controls to either bring down drug prices, or orient production to areas of national priority, obviously put the public sector, bound in the cloak of social orientation at a disadvantage. In the absence of Government policies conducive to its growth and unable to hold substantial markets (in view of the high pressure sales and marketing tactice used by the private sector) the public sector started nose diving in the direction of losses.[8]

Increasing public dissatisfaction with the dominance of the transnational over the drug industry led in 1974 to the establishmentof the Hathi Committee (1975).[9] The recommendations of the Committee however were 'sat on' by the Government till 1977-78 when as a part of the anti-Congress wave of measures introduced by the new Janata leadership and the 1978 Drug Policy came into being. Again in view of the larger structure of the State the recommendations of the Hathi Committee (1975) were only partially incorporated in the Policy and even less was eventually implemented.[10]

The period following the comeback of the Congress Government in 1980 was infact characterised by an overt rejection of the Government controls and regulation procedures infavour of opening up the economy to the free play of market forces. In this context the public sector already struggling to fight for its survival was made the brunt of considerable criticism while it was exhorted to improve management and efficiency leading to increasing profitability.[11]

"The world Bank multi national increasingly pressurised the Government for Policy measures such as watering down the planning process; over emphasising growth rather than self reliance and social commitments

import liberalization of both technology and equipment".[12]

It was in this direction that public sector undertakings were encouraged to shift priorties to business lines as against 'Government lines' through a new arms length relationship with the Government.

Caught between the need to survive and at the same time meet the social obligations the public sector seems to be giving in to pressures for increasing the profitability of these enterprises. To do this the public sector is necessarily abandoning its social orientation and accepting all what it had negated in private enterprise as'unjust to the masses' The mood of the public sector is clarified in the difference between the statements made by CMD's of IDPL in 1978 when thepublic section was being ushered in as the leader in the industry, and today when it is being castigated. I quote,

Statement by L.K. Behl CMD, I.D.P.L. (1978)

"The I.D.P.L. complex was created not to add another drug manufacturing unitto the already existing 2,500 firms engaged in the production of drugs and pharmaceuticals. IDPL was not the least 2,500 drug firms plus one. It was infact established to meet a national commitment where these firms were inherently not

capable to come up to the national expectations".[12]

Statement by CMD, IDPL (1986-87)

"We have a problem. Being a part of the Government and being the public sector company, we have to do the business according to Government Policy."[13]

## ISSUES

The issues that arise from the above liberalization in the economy relate largely to the priorities of the state and those of the people and existing contradiction in purpose between the two. The same State which is today propogating privatization in the name of masses had propagated State regulations and control in the name of the welfare of the same groups 4 decades ago. Today the very same representative of public policy which the State had created in the form of public sector in the name of masses is being thrown out unceremoniously to usher in a free market economy". ..

The State therefore despite its assertions to the contrary concerns itself largely with the needs and aspirations of the more powerful section of society, who will actually benefit from the 'opening up' of the Indian economy (to some degree or the other). The repercussions however of the increasing volume of production

(determined by market strategies as against needs) the increased amount of imports of (and set back to self reliance) and the impact on the growth of the Indian Economy as a result of increasing in roads by both multinationals and large Indian private sector enterprise will be born by another class of people, "the masses".

If the priorities of the Indian State therefore are more than just increasing profitability of a few to the despair of the rest then, the present moves towards liberalization in the Indian Economy and Commercialization of the Public Sector has to be stopped.

In view, however, of the minimal impact of the Public Sector so far despite its constant endeavour to direct the growth of the Indian Drug and Pharmaceutical industry in consonance with national priority and its ability to meet the health needs of the people, it would still be pertinent to ask if the public sector undertakings as they exist within the present societal framework are of any significance to thehealth status of the masses, who are living at a very low level of purchasing power. The answer to that question obviously in regulation of the industrial sector being accompanied by more fundamental structural

changes leading to a larger socio-economic transformation, the nature of which would necessarily reduce inequalities of income and power.

A role for the public sector in meeting the health needs of the people does exist, it only needs the right socio-economic and political milieu to make itself apparent.

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# CHAPTER - V

# CONCLUSIONS

# CHAPTER - V

## CONCLUSIONS

The Public Sector Drugs and Pharmaceutical industry has come a long way in the 4 decades that have elapsed since independence. It has, despite the unsupporture nature of State Policy and ineffective State controls pioneered the production of bulk drugs in the country which was neglected by the Private Sector in view of the higher investment involved and the low initial profitability.

The present status of the Public Sector in this Industry is largely and outcome of State Policies and priorities. The lack of State interest in the development of this sector except as a vehicle to launch private enterprise in the direction of greater profitability has been a major factor in the down fall of the Public Sector.

The social orientation of the public sector is in distinct contradiction to the motive of profit maximization in the private sector. It is not surprising therefore that public sector units in this country in the absence of strict Government controls disciplining private enterprise are running at considerable losses.

If State priorities are to be directed towards meeting the objective of Health for All by the year 2000 A.D. we shall have to re-think and reorganise our policies in the direction of a much wider scope for the public sector accompanied by socio-economic changes of a transforming nature for the economy.

# APPENDICES

Appendix-1

## Table - 1

Direct foreign equity holding companies in the Pharmaceutical Sector.

| S.No. | Name of the Company | % Foreign Equity | | Remarks |
|---|---|---|---|---|
| | | Present | Permissible | |
| 1 | 2 | 3 | 4 | 5 |
| 1. | M/s. Anglo French | 40 | 40 | - |
| 2. | M/s. Indian Schering (merged into one) | 39.95 | 40 | - |
| 3. | M/s. Nicolas of India(i.e. Nicholas Labs) | - | - | - |
| 4. | M/s. Carter Wallace | 40 | 40 | - |
| 5. | M/s. C.E.Fulford | 40 | 40 | - |
| 6. | M/s. Abbott Laboratories | 40 | 40 | - |
| 7. | M/s. Eskayef Ltd. | 40 | 40 | - |
| 8. | M/s. Suhrid Geigy | NIL | * | - |
| 9. | M/s. Geoffery Manners | 40 | 40 | - |
| 10. | M/s. Parke Davis | 40 | * | - |
| 11. | M/s. Warner Hindustan | 40 | * | |
| 12. | M/s. Hindustan Ciba Geigy of India Limited | 40 | * | |
| 13. | M/s. Infar India Ltd. | 40 | * | |
| 14. | M/s. May & Baker(I) Ltd. | 40 | 40 | - |
| 15. | M/s. Glaxo Laboratories | 40 | 40 | - |
| 16. | M/s. Hoechst Pharmaceuticals | 40 | * | - |
| 17. | M/s. Whiffens India Ltd. | Since merged into Rallis | | |
| 18. | M/s. Merind | 40 | * | |

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| 19. | M/s. Burroughs Wellcome & Co. | 40 | 40 | |
| 20. | M/s. Richardson Hindustan | 40 | 40 | |
| 21. | M/s. Uni-Sankyo | 39.99 | 40 | |
| 22. | M/s. Bayer India Ltd. | 51 | 51 | |
| 23. | M/s. Johnson & Johnson Ltd. | 75 | 51 | Representation |
| 24. | M/s. Cyanamid India Ltd. | 55 | 55@ | |
| 25. | M/s. Alkali & Chemicals | 51 | 51 | Amalgamated in IEL. |
| 26. | M/s. Pfizer Ltd. | 60 | 51@ | |
| 27. | M/s. Boots Co.(India) Ltd. | 40 | * | - |
| 28. | M/s. Sandoz (India) Ltd. | 60 | 60 | - |
| 29. | M/s. Wyeth Laboratories | 74 | 74 | - |
| 30. | M/s. Roche Products | 74 | 74 | - |
| 31. | M/s. E. Merck (I) Ltd. | 51 | 51 | - |

* Voluntary dilution

@ Offer of voluntary dilution to 40 % is under process.

Source : The Drug Policy 1987-88 by S.K.Jain
Published by India Investment Publication
pp.174-175.

Table - 2

Growth of India's Pharmaceutical Industry

| S.No. | Item | 1952-53 (Rs. crores) | 1987-88 (Rs. crores) |
|---|---|---|---|
| 1. | Investment | 24 | 750 |
| 2. | Production | | |
| | (a) Bulk Drugs | N.A. | 480 |
| | (b) Formulations | 35 | 2350 |
| | Total | 35 | 2830 |

Source: (i) Indian Drug Statistics, 1975

(ii) 27th Annual Publication January, 1989 IDMA.

## Table - 3

### AVAILABILITY OF TECHNOLOGY

A. PRODUCTION FROM BASIC STAGE

I. TECHNOLOGY AVAILABLE

ANTIBIOTICS

1. Ampicillin
2. Amoxicillin
3. Tetracycline
4. Oxytetracycline
5. Doxycycline
6. Kanamycin

SULPHA DRUGS

7. Sulphamethoxazole
8. Sulphadimidine
9. Sulphacetamide/Sod
10. Sulphamethizole
11. Phthalyl Sulphathiazole
12. Phthalyl Sulphacetamide
13. Sulphazonidine
14. Sulphagnamidine
15. Sulphanilamide
16. Sulphamoxole
17. Sulphaphenazole
18. Sulphadiazine

VITAMINS

19. Vitamin C

20. Vitamin E

21. Vitamin K

22. Vitamin P

ANALGESICS ETC

23. Analgin

24. Aspirin

25. Phenylbutazone

26. Oxyphenbutazone

27. Paracetamol

28. Pethidine

29. Probenecid

30. Ibuprofen

31. Baralgan Ketone

32. Dextropropoxyphene

33. Phenyl Isopropyl-Pyrazolone

STERIODS & HARMONES

34. Betamethazone

35. Predinisolone

36. Hydrocortizone

37. Cortisone

38. Predinisone

39. Hydroxy Progesterone Caproate

40. Hydroxy Progesterone Acetate

41. Methyl Testosterone

42. Testosterone & its esters

ANTI TB

43. PAS & its salts

44. Isoniazed (INH)

45. Thiacetazone

ANTI-AMOEBIC

46. Iodo chloro hydroxyquinoline

47. Di-Iodo hydroxyquinoline

48. Broxyquinoline

49. Brobenzoxaldine

50. Metronidazole

51. Tinidazole

52. Diloxanide Furoate

53. Dehydroemetine

54. Emetine

55. Furazolidone

ANTHELMINTIC

56. Mebendazole

57. Bephenicumhydroxy Naphthoate

58. Tetramisole

ANTI-FILARIAL

59. Diethyl carbamazine citrate

ANTI-HISTAMINIC

60. Pheniramine Maleate

61. Buclizine

62. Cyclizine

63. Meclozine

64. Chlorcyclizine

ANTI-DIABETIC

65. Insulin

66. Chlorpropamide

67. Tolbutamide

68. Glybenclamide

ANTI-ASTHAMATIC

69. Salbutamol

70. Theophylline

71. Aminophylline

CARDIO VASCULAR

72. Propranolol

73. Xanthinol Nicotinate

74. Digoxin

75. Methyl Dopa

76. Clonidine

77. Clofibrate

78. Clopamide

DIURETICS

79. Frusemide

80. Acetazolamide

81. Sprionolactone

82. Hydrochloro Thiazide

ANAESTHETICS

83. Xylocaine

84. Procaine

85. Benzocaine

86. Ether

87. Ethyl Chloride

TRANQUILIZER

88. Diazepam

ANTI-MALARIAL

1. Pyrimethamine

2. Phanquone

ANTI-HISTAMINICS

3. Diphenhydramine

4. Methadilazine

5. Mepyramine

CARDIO-VASCULAR

6. Dihydrallazine

7. Guanethidine

DIURETIC

8. Cyclopenthiazide

C. TECHNOLOGY NOT AVAILABLE & REQUIREMENT MET THROUGH IMPORTS.

ANTIBIOTICS

*1. Ampicillin Sodium

*2. Cloxacillin Sodium

*3. Carbenicillin Sodium

*4. Cephalexin

5. Cephaloridine

*6. Cephradine

7. Neomycin

*8. Bacitracin/Zinc Bacitracin

9. Oleandomycin

*10. Polymixin

SULPHA DRUGS

11. Sulphadoxine

12. Sulphadimethoxy pyridazine

13. Sulphadimethoxine

VITAMINS

*14. Pantothenates

ANALGESICS ETC.

*15. Indomethacin

*16. Naproxen

STERIODS & HORMONES

17. Drydrogesterone

*18. Norethisterone

19. Fluocinolone

20. Fluo cortolone

*21. Norgestrel

*22. Triamcinolone

ANTI-T.B.

23. Ethionamide

ANTI-AMOEBIC

*24. Loperamide

ANTI-HISTAMINIC

25. Dimethindone Maleate

ANTI-CANCER

26. Bulsulphan

27. Cyclophosphamide

28. 5-Flyorouracil

29. Mitomycin

30. 6-Mercaptopurine

31. Melphalan

ANTI-ULCERANT

*32. Cimetidine

*33. Ranitidine

DIURETIC

34. Benzthiazide

35. Hydroflumethazide

CARDIO-VASCULAR

36. Dipyridamole

37. Oxyfedrine

*38. Verapamil

TRANSQUILIZER/SEDATIVE/HYPNOTICS

39. Doxeprine

40. Fluphenazine

41. Hydroxyzine

42. Pyrithyldone

43. Thioridazine

OTHER MISCELLANEOUS DRUGS

44. Amitryptiline (Antidrepressant)

45. Carisoprodol

46. Chlorozoxazona — Skeletal muscle Relaxants

47. Propantheline — Antispasmodic

48. Cyclandelate

49. Dicyclomine

*50. Dextromethorphan (Antitussive)

51. Hydantoin derivatives (Anti-epileptic)

52. Naphazoline Nitrate (Nasal decongestant)

| | | |
|---|---|---|
| *53. | Phenyl ephrine | |
| *54. | Oxytocin | |
| 55. | Alkaloids of Ergot | Oxytocics) |

* Industrial Approvals granted yet to be implemented.

II. TECHNOLOGY AVAILABLE BUT NEEDS IMPROVEMENT

ANTIBIOTICS

1. Penicillin
2. Streptomycin
3. Chloramphenicol
4. Erythromycin
5. Gentamycin

VITAMINS

6. Vitamin A
7. Vitamin $B_1$
8. Vitamin $B_2$
9. Vitamin $B_6$
10. Vitamin $B_{12}$
11. Folic Acid

ANTI-LEPROTICS

12. Dapsone
13. Clofazimine

ANTI-ASTHAMATIC

14. Ephedrine

SEDATIVE

15. Phenobartitone

B. CURRENT PRODUCTION FROM INTERMEDIATE STAGE

I. Technology for basic production desirable

ANTIBIOTICS

1. Rifampicin
2. Framycetin

ANTI-GOUT

3. Allopurinol

STERIODS & HARMONES

4. Dexamethasone

5. Megestrol Acetate

ANTI TB

6. Pyrazinamide

ANTI MALARIAL

7. Chloroquine

8. Amodiaquine

ANTI AMOEBIC

9. Furazolidone

ANTHEIMINTIC

10. Piperazine salts

11. Pyrantel

OTHER ANTIBACTERIALS

12. Trimethoprim

ANTI-ASTHAMATIC

13. Terbutaline

14. Pseudo-ephedrine

CARDIO-VASCULAR

15. Isoxsuprine

ANAESTHETIC

16. Halothane

II. LOW REQUIREMENT THEREFORE BASIC PRODUCTION NOT NECESSARY

VITAMIN

1. Vitamin D3

Appendix-1

## T a b l e - 4

### Percentage Deaths due to Major Diseases, 1985

| S.No. | Disease | % of Deaths |
|---|---|---|
| 1. | Tuberculosis of the lungs | 5.8 |
| 2. | Pneumonia | 5.7 |
| 3. | Anaemia | 3.5 |
| 4. | Gastroenteritis | 2.5 |
| 5. | Typhoid | 1.9 |
| 6. | Malaria | 1.6 |
| 7. | Dysentery | 1.6 |

Source: Twenty Seventh Annual Publication January, 1989. IDMA pp.9-10.

Appendix-1

Table - 5

Production of some Essential Drugs in Relation to Requirement.

| S.No. | Item | Production (Present) | Import (Present) | Projected requirement by 1990 | Estimated Shortfall |
|---|---|---|---|---|---|
| 1. | Chloroquine ( M.T. ) | 80.82 | 198.25 | 500 | 220.92 |
| 2. | Amodiaquin ( M.T. ) | 30.15 | Nil | 100 | 69.85 |
| 3. | Primaquin ( Kg. ) | Nil | 100.00 | 400 | 300.00 |
| 4. | Streptomycin ( M.T. ) | 239.4 | 8.27 | 500 | 152.13 |
| 5. | Aspirin (M.T.) | 1325.35 | 74.24 | 2000 | 600.41 |
| 6. | I.N.H. (M.T.) | 199.01 | Nil | 400 | 200.99 |
| 7. | Dapsone (M.T.) | 30.94 | 34.70 | 250 | 184.36 |
| 8. | Pencillin(M.T.) | 358.00 | 20.00 | 500 | 122.00 |
| 9. | Vitamin A | 52.00 | 20.00 | 150 | 78.00 |

Source: Essential Drugs and Public Policy by Dr. Naresh Banerjee pp.217-218, in 'A Decade After Hathi Committee' Edited by Dr.B.Ekbal.Publ.KSSP May, 1988.

Appendix-1

## T a b l e - 6

Sales of Different Groups of Drugs as percentage of total market. (1985)

| S.No. | Drug Group | Sales (Rs. in crores) | Percentage of total market |
|---|---|---|---|
| 1. | Systemic Antibiotics | 249.02 | 21.15 |
| 2. | Vitamin & Tonics | 187.78 | 15.95 |
| 3. | Cough and Cold preparations | 55.40 | 4.70 |
| 4. | Anti Parasites | 46.78 | 3.97 |
| 5. | Analgesics | 44.29 | 3.76 |
| 6. | Antacids | 38.17 | 3.64 |
| 7. | Anti-inflamatory and Anti Rheumatics | 53.06 | 4.50 |
| 8. | Anti T.B. Drugs | 30.39 | 2.50 |
| 9. | Enzymes | 24.69 | 2.10 |
| 10. | Sex Hormones | 23.61 | 2.00 |

Source : ORGMAT - 1985.

Appendix-1

## Table - 7

### Public Sector Profit/Losses

| Year | Nett Profit/Losses (Rs. in crores) | | | | |
|---|---|---|---|---|---|
| | I D P L * | H A L** | B C P L*** | B L**** | SSPL***** |
| 1978-79 | (+) 0.01 | (-) 1.61 | N.A. | N.A. | N.A. |
| 1979-80 | (-) 7.02 | (-) 2.98 | N.A. | N.A. | N.A. |
| 1980-81 | (-)16.82 | (-) 6.39 | (-) 0.42 | (-) 2.18 | 2.18 |
| 1981-82 | (-)27.44 | (-) 5.69 | (-) 0.36 | (-) 2.13 | 2.10 |
| 1982-83 | (-)24.01 | (+) 0.24 | (-) 0.27 | (-) 3.83 | 1.45 |
| 1983-84 | (-)19.43 | (-) 1.71 | (-) 0.12 | (-) 3.20 | 3.68 |
| 1984-85 | (-)26.25 | (-) 5.80 | (+) 0.02 | (-) 3.96 | 1.99 |
| 1985-86 | (-)32.21 | (-) 8.12 | (-) 1.35 | (-) 4.38 | 4.38 |
| 1986-87 | (-)50.87 | (-) 0.81 | (-) 2.12 | (-) 6.65 | 4.09 |
| 1987-88 | (-)30.22 | (+) 1.64 | (-) 2.21 | (-) 7.71 | 5.03 |

* I D P L - Indian Drugs & Pharmaceuticals Ltd.

** H A L - Hindustan Antibiotics Limited

***B C P L - Bengal Chemicals and Pharmaceuticals Ltd.

****B L - Bengal Immunity Ltd.

*****S S P L - Smith Stanistreet Private Ltd.

Source : Relevant Annual Reports of the above Undertakings.

Appendix-II

## T a b l e - 1

### PHARMACEUTICAL FIRMS IN INDIA (1952)

| S.No. | Type of Firm | Numbers |
|---|---|---|
| 1. | Number of Large Scale Concerns | 75 |
| 2. | Number of Small Scale Concerns | 1568 |
| 3. | Number of Concerns Under Foreign Control | 28 |
| (a) | Firms with Manufacturing Departments | 19 |
| (b) | Firms without Manufacturing Departments. (Products processed by other firms in India) | 9 |

Source : Compiled from Table No.3 and Table No.20 of the Report of the Pharmaceutical Enquiry Committee (1954) Ministry of Commerce & Industry. p.19 and p.62 respectively.

Appendix-II

T a b l e - 2

## Financial Status of Foreign Firms in India

(in Rs.million)

| Name of Firm | Equity | | Net Profit including tax 1970-71 | Total remittance |
|---|---|---|---|---|
| | Original | Present | | |
| Abbot Lab | 0.10 | 0.10 | 10.14 | 2.27 |
| Alkali Chemical | 3.53 | 43.40 | 23.78 | 3.45 |
| Anglo French | 0.01 | 0.01 | 3.35 | 0.06 |
| Anglo Thai Corpn | N.A. | N.A. | 6.73 | 1.54 |
| Bayer India | 0.40 | 30.00 | 16.48 | - |
| Beecham Ltd | 0.10 | 0.60 | 2.40 | 0.66 |
| Bochringer Knoll | 1.50 | 6.00 | 1.95 | 0.14 |
| Boots | 1.00 | 7.50 | 6.11 | 0.61 |
| Burroughs Wellcome | 0.50 | 5.00 | 3.65 | 0.76 |
| Chesbrough Pond | - | - | 9.12 | 2.29 |
| Ciba of India Ltd | 0.30 | 48.75 | 15.87 | 3.59 |
| Cooper Ltd | - | - | 0.20 | N.A. |
| Cynamid | 0.15 | 7.01 | 27.70 | 2.41 |
| Dental Products | 0.50 | 0.34 | 0.31 | - |
| Ethnor Ltd | 0.50 | 0.50 | 0.90 | - |
| C.E.Fulford | 0.40 | 0.50 | Loss | - |
| G.W.Garnick | N.A. | N.A. | N.A. | - |
| German Remedies | 0.01 | 4.00 | 2.82 | 0.14 |
| Glaxo Labs | 0.15 | 72.00 | 30.71 | 2.41 |

| Name of Firm | Equity | | Net Profit including tax 1970-71 | Total remittance |
|---|---|---|---|---|
| | Original | Present | | |
| Grimault Lab | 0.20 | 0.20 | 1.49 | - |
| Indian Schering | 0.84 | 0.60 | 3.16 | - |
| Johnson & Johnson | 2.00 | 3.60 | 6.97 | 0.51 |
| John Whyeth | N.A. | N.A. | 5.55 | - |
| May & Baker Br | N.A. | N.A. | 12.54 | 1.31 |
| Merck, Sharp & Dohme | 18.00 | 18.00 | 15.21 | 2.12 |
| E.Merck Ltd | 2.00 | 6.69 | 0.55 | N.A. |
| Nicholas of India | N.A. | N.A. | 2.47 | - |
| Parke Davis | 3.75 | 10.50 | 23.46 | 1.65 |
| Pfizer Ltd | 0.20 | 56.00 | 41.95 | 6.83 |
| Reckitt Coleman | 3.00 | 25.00 | 10.66 | 0.93 |
| Richardson Hindustan | 2.75 | 7.00 | 4.85 | 0.39 |
| Roche Products | 5.00 | 10.00 | 11.94 | 1.68 |
| Roussel Pharma | 0.20 | 0.65 | N.A. | N.A. |
| Sandoz India Ltd | 1.00 | 15.00 | 10.00 | 0.93 |
| Searle Ltd | 6.00 | 6.00 | Loss | - |
| Smith & Nephew | 0.75 | 1.13 | 1.60 | 0.09 |
| Smith, Kline & French | N.A. | N.A. | N.A. | 2.73 |
| Wyeth Labs | 3.37 | 7.50 | 1.35 | 0.42 |

Source: Lok Sabha proceedings, December, 1973.

## Table - 3

List of Drugs Identified by the Hathi Committee for Sale under Generic Names.

1. Chloramphenicol
2. Tetracycline
3. Ferrous Sulphate
4. Aspirin
5. Chlorpromazine
6. Reserpine
7. Tolbutamide
8. Analgin
9. Piperazine
10. Crystalline Pencillin G
11. Streptomycin
12. INH Tablets
13. Tablets INH - Thiacetazone

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Source: The Report of the Committee on Drugs & Pharmaceutical Industry, Ministry of Petroleum and Chemicals, Govt. of India, 1975, Chapter X Appendix-II.

Appendix-II

## Table - 4

### Criteria for High Technology Drugs-4th Oct,1982

The criteria adopted by the Committee on High Technology for the purpose of identification of bulk drugs involving high technology produced/proposed to be produced by foreign companies.

| S.No. | Criteria |
|---|---|
| 1. | Isolation and extraction involing sophisticated processes such as counter liquid extraction, repeated chromatography or narrow cut fractionalisation; |
| 2. | Fermentation processes; use of enzymes for chemical transformation; |
| 3. | The steps of operations involved in a chemical synthesis; |
| 4. | Reaction temperatures above 250°C or below (-)30°C; |
| 5. | Reaction pressures of 10 atmospheres and above; |
| 6. | Use of potentially explosive materials; |
| 7. | High temperature vapour phase catelytic processes; |
| 8. | Use of toxic materials; |
| 9. | Purification and separation by different types of sophisticated technique; |
| 10. | Careful on-line process controls; |
| 11. | Degree of sophistication employed to ensure health safety and quality; |
| 12. | New drugs discovered in India involving detailed pre-clinical, laboratory and clinical trials. |

Source: Jain S.K. Drug Policy 1986-87. India Investment Publications, Annexure 5L.

Appendix-II

## T a b l e - V

List of 22 Foreign Companies Employing High Technology according to the Ramanathan Committee.

| | Company | Equity (%) |
|---|---|---|
| | **Foreign Equity 41 % to 49 %** | |
| 1. | Geoffray Manners & Co.Ltd. | 45 |
| 2. | Suhrid Geigy | 47.5 |
| 3. | Organon (India) Ltd. | 49 |
| 4. | Uni-Sankyo Ltd. | 49 |
| | **Foreign Equity 50 % - 59 %** | |
| 5. | Hoechst Pharmaceuticals Ltd. | 50 |
| 6. | Warner-Hindustan Ltd. | 50 |
| 7. | Alkali & Chemical Corpn. of India Ltd. | 56.15 |
| 8. | Bayer (India) Ltd. | 51.37 |
| 9. | Cyanamid India Ltd. | 55 |
| 10. | Boots Company (India) Ltd. | 53 |
| | **Foreign Equity 60 % - 100 %** | |
| 11. | E. Merck (India) Pvt.Ltd. | 60 |
| 12. | Merck Sharp & Dohme of India Ltd. | 60 |
| 13. | May & Baker (India) Ltd. | 60 |
| 14. | Sandoz (India) Ltd. | 60 |
| 15. | Ciba-Geigy of India Ltd. | 66 |
| 16. | Wyeth Laboratories Ltd. | 74 |
| 17. | Johnson & Johnson Ltd. | 75 |

| | | |
|---|---|---|
| 18. | Glaxo Laboratories (India) Ltd. | 75 |
| 19. | Pfizer Ltd. | 75 |
| 20. | Parke-Davis (India) Ltd. | 83.33 |
| 21. | Roche Products Ltd. | 89 |
| 22. | Burroughs Wellcome & Co.(India) Pvt. Ltd. | 100 |

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Source: Bhagat Mukkaram (1982) Aspects of the Drug Industry in India, CMIE.

Appendix-II

## T a b l e - 6

### Voluntary Dilution by Foreign Equity Holding Companies

| | Company | Present | Permissible | |
|---|---|---|---|---|
| 1. | Geoffray Manners & Co. Ltd. | 40 | 40 | |
| 2. | Suhrid Geigy | Nil | * | |
| 3. | Organon (India) Ltd. | Nil | * | |
| 4. | Uni-Sankyo Ltd. | 39.9 | 40 | |
| 5. | Hoechst Pharmaceuticals Ltd. | 40 | * | |
| 6. | Warner-Hindustan Ltd. | 40 | * | |
| 7. | Alkali & Chemical Corpn. of India Ltd. | 51 | 51 | Amalgamated with IEL. |
| 8. | Bayer (India) Ltd. | 51 | 51 | |
| 9. | Cyanamid India Ltd. | 55 | 55 | |
| 10. | Boots Company (India) Ltd. | 40 | 53 | |
| 11. | E. Merck (India) Pvt. Ltd. | - | 60 | |
| 12. | Merck Sharp & Dohme of India Ltd. | 51 | 60 | |
| 13. | May & Baker (India) Ltd. | 40 | 60 | |
| 14. | Sandoz (India) Ltd. | 60 | 60 | |
| 15. | Ciba Geigy of India Ltd. | 40 | 66 | |
| 16. | Wyeth Laboratories Ltd. | 74 | 74 | |
| 17. | Johnson & Johnson Ltd. | 75 | 75 | |
| 18. | Glaxo Laboratories (India) Ltd. | 40 | 75 | |
| 19. | Pfizer Ltd. | 60 | 75 | |

| | | | |
|---|---|---|---|
| 20. | Parke-Davis (India) Ltd. | 40 | 83.33 |
| 21. | Roche Products Ltd. | 74 | 89 |
| 22. | Burroughs Wellcome & Co.(India) Pvt. Ltd. | 40 | 100 |

Source: Bhagat Mukkaram (1982) Aspects of the Drug Industry in India, C M I E.

Appendix-II

## Table - 7

Number of Industrial Licences Granted Sectorally between 1978-79 & 1984-85

| S.No. | Sector | Number of Licences granted | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | 1978-79 | 1979-80 | 1980-81 | 1981-82 | 198 -83 | 1983-84 | 1984-85 |
| 1. | Public Sector/ Joint Sector | 4 | 17 | 14 | 9 | 8 | 1 | 17 |
| 2. | Indian Sector | 39 | 23 | 40 | 17 | 36 | 17 | |
| 3. | Foreign Sector | - | 1 | 1 | 2 | 14 | 5 | 3 |

Source : Relevant Annual Reports of the Ministry of Chemicals and Fertilizers.

Appendix-III

## T a b l e - I

Sectorwise Value of Production of Bulk Drugs and Formulations During the period 1975-76 to 1987-88.

(Rs. in crores)

| Sector | 1975-76 | 76-77 | 77-78 | 78-79 | 79-80 | 80-81 | 81-82 | 82-83 | 83-84 | 84-85 | 85-86 | 86-87 | 87-88 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. Public Sector | 43 | 48 | 47 | 49 | 59 | 62 | 67 | 67 | 61 | 64 | | | |
| 2. Foreign Sector | 52 | 63 | | 56 | 53 | 56 | 72 | 72 | 65 | 68 | | | |
| (including Ex-FERA companies ) | | | 105 | | | | | | | | | | |
| 3. Indian Organised Private Sector | 25 | 29 | | 75 | 90 | 95 | 120 | 121 | 155 | 166 | | | |
| 4. Small Scale Sector | 10 | 10 | 12 | 20 | 24 | 27 | 30 | 65 | 74 | 79 | | | |
| Total Bulk Drugs | 130 | 150 | 164 | 200 | 226 | 240 | 289 | 325 | 355 | 377 | 416 | 458 | 480 |
| | | | | | FORMULATIONS | | | | | | | | |
| 1. Public Sector | 35 | 47 | 53 | 60 | 72 | | | | | | | | |
| 2. Foreign Sector (including Ex-FERA comapnies) | 300 | 292 | | | | | | | | | | | |
| | | | 697 | 800 | 778 | | | | | | | | |
| 3. Indian Organised Private Sector | 225 | 241 | | | | | | | | | | | |
| 4. Small Scale Sector | | 120 | 150 | 190 | 300 | | | | | | | | |
| Total Formulations | 560 | 700 | 900 | 1050 | 1150 | 1200 | 1430 | 1600 | 1760 | 1827 | 1945 | 2140 | 2350 |

Source: 29th Annual Report, January, 1989.

APPENDIX III

TABLE - II

BULK DRUGS IN THE PUBLIC SECTOR
PRODUCT MIX USED FOR CATEGORY
I AND II FORMULATIONS

| | HAL | IDPL |
|---|---|---|
| CATEGORY I | Penicillin G<br>Procain Penicillin<br>Benzathine Penicillin<br>Penicillin V Potassium<br>Penicillin G Potassium<br>Streptomycin | Potassium Benzyl Penicillin<br>Procain Benzyl Penicillin<br>Sodium Benzyl Penicillin<br>Streptomycin Sylphate<br>Sodium P.A.S. |
| CATEGORY II | | Analgin<br>Tetracycline<br>Piperazine Salts<br>Phenobarbitone<br>Chloroquine Salts |

Source : Compiled from Indent mix literature of IDPL and HAL

Appendix-III

## T a b l e - 3

Price Reduction of Some Products brought about by H.A.L. in 1958-59.

| Drug | Oct:58 | 1-11-58 | 1-4-59 | 1-8-59 |
|---|---|---|---|---|
| Streptomycin 1 gm. | 1.25 | 1.00 | 0.90 | 0.75 |
| Dihydro-Streptomycin 1 gm. | 1.25 | 1.00 | 0.90 | 0.75 |
| Streptodicin 1 gm. | - | 1.00 | 0.90 | 0.75 |
| Streptopenicillin 1 gm. | 1.75 | 1.50 | 1.40 | 1.30 |
| Streptopenicillin ½ gm. | 1.25 | 1.00 | 0.90 | 0.90 |
| Penicillin V Tablets | | | | |
| 12 Tablets | 2.50 | 2.25 | 2.25 | 2.25 |
| 24 Tablets | - | - | - | 4.00 |
| 36 Tablets | - | - | 6.00 | 6.00 |

Source : Annual Report H.A.L. 1958-59.

Appendix-III

## Table - 4

### Retail Prices in Paise per Tablet

| Drug | Year of Introduction in clinical use | Wholesale fixed price | Active ingredient per tablet in mg. | Standard Retail Price | Public Sector | Brand name product of foreign firm | Generic name product of foreign firm | Indian Private Sector | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Large Units | Small Units |
| Phenobarbitone | 1912 | 170 | 30 | 1.19 | 1.08 | 8.29-2.55 | 1.54 | 1.72 | 2.2 to 0.65 |
| | | | 60 | 2.04 | 1.80 | 3.4 | 2.4 | 2.58, 3.50 | 2.68 to 1.12 |
| Analgin | 1943 | 137 | 500 | 15.97 | 13.2 | 19.38 | - | 17.4, 12.65 | 21.00 to 9.00 |
| Diethyl Carbamazine Citrate | 1947 | 190 | 50 | 2.22 | 2.69 | 7.48 | - | 3.68 | 3.75 to 2.13 |
| Sulphanilamide | 1938 | 30 | 500 | 3.5 | not marketed | no brand name | 3.5-3.6 | 4.5 - 1.8 | 6.0 - 2.7 |

Source : Anomalies in Drug Prices and Quality Control by P.S.Agarwal, P.K.Ramachandran, B.V.Rangarao.

Appendix-III

## T a b l e - V

Reductions in Prices charged by Private Drug Companies following the emergence of I.D.P.L.

| Product | Company | Prices charged before emergence of IDPL | Prices charged at present |
|---|---|---|---|
| Oxytetracycline Caps. | M/s. Deys Medicals | 44.00 for 100 caps. | 33.90 per 100 caps. |
| Analgin Tablets | M/s. Hoechst | 115.00 for 100 tablets | 79.90 per 100 tablets |
| Streptomycin Sulphate 1 gm. | M/s. Merck Sharp Dhome | 68.40 per 100 vials | 58.50 per 100 vials |
| Streptopenicillin ½ gm. DCC Tablets | M/s. Sarabhai | 72.74 per 100 vials<br>13.15 per 500 tablets | 68.50 per 100 vials<br>6.50 per 500 tablets |
| Piperazine Adipate 300 mg. tablets. | M/s. Glaxo | 22.50 per 1000 tabs. | 18.20 per 1000 tabs. |
| | M/s. Burroughs Wellcome | 21.70 per 1000 tabs. | 20.00 per 1000 tabs. |
| Phenobarbitone tablets 60 mgs. | M/s. Martin & Harris. | 22.66 per 1000 tabs. | 15.57<br>16.50 per 1000 tabs. |

Source: National Convention on Economic Independence and Perspective of Drug Industry, Essential Drugs and the Common Man by JAGJIT SINGH.P.6.

Appendix-III

## T a b l e - 6

Sectorwise Technological Status of Bulk Drug Production by the Top 10 Companies in (1978-1982).

| Sector | Cat. I | | | Cat.II | | | Cat.III | | | Cat.IV | | | Grand Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | I | T | B | I | T | B | I | T | B | I | T | |
| Public (4) | 8 | 1 | 9 | 9 | 0 | 9 | 22 | 5 | 27 | Nil | | | 45 |
| Indian private | 3 | 1 | 4 | 3 | 0 | 3 | 19 | 6 | 25 | 0 | 2 | 2 | 32 |
| Foreign | 5 | 2 | 7 | 3 | 3 | 6 | 12 | 11 | 23 | 0 | 2 | 2 | 36 |
| Small Scale(All) | - | NA - | 7 | | -NA- | 8 | | -NA- | 27 | 0 | 1 | 1 | 44 |

B - Basic, I - Intermediate, T - Total

Sources of Data

1. Indian Drugs Statistics 1982-83
2. Company records and Annual Reports
3. DGTD Reports
4. Answers to Parliament Questions.