

CHAPTER I

INTRODUCTION

GROWTH OF MULTINATIONAL COMPANIES IN INTERNATIONAL PHARMACEUTICALS INDUSTRY:

The current century observed domination trends and concentration of economic power in every sphere of world economy. Multinational companies have emerged as giant exponents of this new type of "Corporate Capitalism", which is sometimes referred as "neo-colonialism".¹ Despite the fact that drugs and pharmaceutical industry is comparatively smaller than the other world industries, but it is one of the most internationalised industries in its character, structure and operations

The origin of modern global pharmaceutical industry has its roots in the 16th century when the increasing complexity and variety of drugs and chemicals and the attendant skills required for their production resulted in the establishment of specialist apothecaries and chemists as dominant manufacturers and distributors of drugs. The famous apothecary of F.J.Merck started manufacturing drugs in 1618 under the new name of Merck, Sharpe & Dohme.² In the next two centuries many of these chemists and druggists developed into wholesalers and afterwards started their own manufacturing operations.³ Twenty-three of the major drug manufacturing multinationals existing today started as pharmaceutical supply houses out of which 13 were from United States, 5 from F.R.G and 3 from U.K⁴

Chemical industry also played an important role in the development of pharmaceutical industry. The famous discovery of 'Salvarsan', the 'Magic Bullet' by Paul Ehrlich in 1904 was based on the use of aniline dyes to kill bacteria. Ehrlich is also credited for discovery of chemotherapy, which originated from R&D in chemical industry.⁵

The medical science and its modern Allopathic therapy made big strides during the therapeutic revolution period (1900-1950) and simultaneously boosted the rapid growth of pharmaceutical industry. Beside Salvarson-discovered by Ehrlich and Barbitone, Bayer of Germany also marketed Aspirin and Phenacetin.⁶ The therapeutic revolution took a big leap when the German scientist Dr. Gerhard Domagk discovered a new substance named "Brontosil" in 1935 while testing germs killing properties of a red dyestuffs. It took more than a quarter of century to find the first effective treatment for a variety of bacterial diseases Prontosil, the red dye was effectively used against pneumonia, urinary infection, childbed fever and scarlet fever But later on French-scientists of Pasteur Institute soon found that the active ingredient of Prontosil was not the red dye but a component named ' sulfanilamide' May & Baker Ltd. discovered M & B- 693 in 1938 improving the efficacy of Protosil These discoveries soon paved the way for the development of " sulfa drugs" for the control of infectious desease.⁷.

The discovery of Penicillin by Alexander Fleming in 1928 started the antibiotic revolution World War-II gave a fillip to the pharmaceutical industry when penicillin was used on a large scale. ⁸ Penicillin proved to be a great boon to heal the wounds of millions of soldiers. Many other great discoveries followed the introduction of sulpha drugs and penicillin. Waksman invented streptomycin in 1943, which was effective against tuberculosis (T.B) Chloramphenicol and Neomycin were discovered in 1949, Oxytetracycline in 1950, Reserpine in 1952 and Tetracycline in 1953 were the other new drugs which flooded the world market boosted by effects of second world war.⁹

After 1950, pharmaceutical research and development (R&D) was centered around mental, heart and cardiovascular diseases. In 1960's Swiss drugs companies introduced Librium and Valium, famous tranquilizers still dominating the world market. In 1965 Americans added Nardil and Parnate. In the last three decades many other important drugs like- Anti depressants, Dueretics, Corticorteroids, oral contraceptives and antihistamines were discovered, developed and produced by drug companies to alleviate human ailments ¹⁰

ORIGIN OF MULTINATIONAL PHARMACEUTICAL INDUSTRY:

In the beginning of the 19th century the edifice of pharmaceutical industry was completely different from its current position as a multinational industry. The drug companies of that era were hesitant to occupy it in therapeutic research. Due to the absence of major R&D activities the pace of launching new drugs was very slow. The sales promotion of drug firms was centered around assuring quality and efficiency of their products. Promotion of drugs to doctors was very little and mostly advertisements were given in the press.

The revolution in the procedures of treatment during 1930-50 changed the structure of pharmaceutical industry. The major break-through in medical therapy forced the big drug firms to specialize their functioning in certain areas instead of manufacturing full-line commodity items. The pharmaceutical industry and its business was forced to become R&D and advertising intensive. The discovery of chemotherapy and its subsequent growth attracted worldwide attention and created great hopes for the suffering humanity. The sick and wounded soldiers fighting in the world wars also required effective drugs to heal and cure them. These factors were responsible for pushing the industry in the world market. According to Barrie G. James, " the pharmaceutical industry moved into the world market due to a

combination of the university of need and usage of ethical drugs, the economic necessity of amortizing heavy research investment as widely as possible and the lack of any one country's monopoly on inventions". ¹¹

The doorway of pharmaceutical companies in to the world market accompanied high rate of earnings But it drastically changed the structure and internal organisation of the companies Full line commodity firms were required to change themselves in to specialised firms with " vertically integrated operations and combining research, production and marketing functions into an integrated company" ¹² The new type of internal organisation not only gave economy of scale, division of labour and brand loyalty but also the operational strength at the world level

New drugs are obtained through pharmaceutical R&D, which is generally a complex, lengthy and costly affair. Its magnitude can be imagined from the fact that " roughly one compound in 10000 which enters the screen ultimately emerges as a drug, the rest being discarded". ¹³ The increased R&D expenses incurred by these firms necessitated the expansion of their markets so as to spread cost as well as the risk The high investment in R&D can be recovered only if the production is aimed for global requirements. The recovery of large investment expected to be attained in a short span to time as patent protection for products gets limited by time

While tracing the earliest history of the giant drug multinational companies of today, it is found that although most of the big drug firms have turned to drug manufacturing from pharmaceutical supply business, many of today's leaders in pharmaceutical industry were earlier chemical and dyestuffs producers. The table I 1 gives the list of some of the existing pharmaceutical multinational companies, which were suppliers and chemical/dyestuff manufacturers during the last century.

TABLE I - 1

ORIGINAL BUSINESS OF SOME PHARMACEUTICAL

Pharmaceutical Supply Houses	Founding Year
E. Merck	1618
Glaxo	1715
Smithkline	1828
Parke-Davis	1866
Richardoon-Merrel	1880
Boots	1888
Searle	1888
Dye- Stuff Producers	
Cıba-Giegy	1758
Hoechst	1812
Sandoz-Warder	1886
Chemical Manufacturers	
Pfizer	1849
Bayer	1863
Abbot	1888
Hoffman-Ia-Roche	1896

MULTINATIONAL COMPANIES

(Source: Barrie G. James opcit., p.10)

The brief history of major drugs multinational companies reveals that search for diversification was primarily responsible to motivate the firms of allied industries to take initiative in pharmaceutical industry. Their thrust for maximizing profit was also pushing them to increase the size of production so that economies of large scale could be utilised

The global pharmaceutical industry is presently dominated by around 100 multinational companies. Of these, leading 25 multinational companies account for around 50% of the total market share. ¹⁴ The table no 1 -2 give the list of the top 15 pharmaceutical companies in 1995 calculated on the basis of prescription sales.

The table clearly shows the extent of domination by multinational drug and pharmaceutical companies. Initially the basic motive behind many of these companies entry into pharmaceutical sector was diversification from the core chemical background, which is brought out by the percentage of sales of these companies coming from pharmaceutical sector. It can be noted that only 2 of the top 15 companies are concentrating exclusively on the pharmaceutical industry.

RANKS	COMPANIES	PHARMA SALES	PHARMA SALES AS
		(\$ MILLIONS)	(% OF TOTAL SALES)
1	Glaxo Wellcome	12568	100
2	Novartis	10593	49
3	Merck & Co.	10521	63
4	Hoechst-Marion- Rousell	9100	100
5	BMS	7811	57
6	Pfizer	7072	71
7	AHP	7005	52
8	Roche	6814	55
9	Smithkline Beechem	6603	60
10	Johnson & Johnson	6274	33
11	Lilly	6242	92
12	Pharmacia & Upjohn	5235	75
13	Astra	4950	98
14	Rhone-poulenc-Rover	4731	89
15	Bayer	4629	15

TABLE NO. I - 2 TOP 15 PHARMACEUTICAL COMPANIES IN THE WORLD

(Source: Scrip. No. 2115 March 29, 1996)

MULTINATIONAL DRUG COMPANIES IN INDIA:

Multinational drug and pharmaceutical companies have been dominating the Indian pharmaceutical industry since their inception in India and have gained importance after 1990-91. Almost all important nations with their well-developed pharmaceutical industry have contributed in one form or other in the massive development of this industry in India. Thus today we have pharmaceutical units with American, British, Swiss, German, French, Dutch, and Italian collaboration This is because medicines and diseases know no national boundaries in character.¹⁵

The real beginning of the modern pharmaceutical industry in India can be traced only after Independence, though its foundation was already laid down early in 1901 by Acharya P.C.Ray with the establishment of the Bengal Chemical & Pharmaceutical Works, Calcutta. At the time of Independence 28 multinational drugs and pharmaceutical companies comprised a guarter of the total investment and 38 % of sales.¹⁶ Shortly after India became independent, most of the leading multinational drugs companies established themselves as trading concerns.¹⁷ The first industrial policy and statement on foreign capital declared by the then Prime Minister Pt Jawaharlal Nehru in the Parliament on April 8, 1948 was instrumental in inviting multinational pharmaceutical companies of Britain, America, West Germany and Switzerland. The salient features of the policy statement on foreign capital provided liberal remittance facilities for profits, dividend, royalty, technical fees and non-discriminatory treatment for multinational companies. This congenial atmosphere provided excellent opportunities for these multinational pharmaceutical companies to establish themselves as trading concerns with meagre investment.¹⁸ During a short span in the first 4 years of Independence (1947-50), 19 multinational drug companies started their business in India.¹⁹ Their trading activities were confined to importing the finished drug formulations from their parent companies and market them. When the demand for the drugs increased rapidly they took further steps and started to import the formulations in bulk and then packaging it in

India. Later on the Government of India persuaded these foreign companies to further their indigenous activities.²⁰ During the first three Five Year Plans, the Government of India gave every facility to foreign firms to expand their business as fast as possible. Permission letters to manufacture 364 items were given to 15 leading Multinational companies.²¹ Barring 4 bulk drugs, remaining 360 items were 'money-spinner' formulation. The multinational drug companies were now importing the bulk drugs and getting them processed into formulations on "Job-work" basis by Indian companies.²² For all these activities the foreign companies were not required to invest large amounts in factories, employment and R & D. instead they were earning fabulous profits with multiple growth in their assets and reserves. The case of 5 major multinational pharmaceutical companies in support of the above is cited below:

TABLE I - 3

ORIGINAL EQUITY AND GROWTH OF FOREIGN FIRMS (1973-74)

(Rs. In lakhs)

Firms	Original	Total Paid up	Foreign	Turnover	Reserves
	Equity	Capital	Equity		
1. Anglo-French	0.10	0.10	0 08	227.69	49
2. Richardson Hindu.	0.02	70.00	38.50	546.00	93
3. Geoffrey Manners	0 01	96.00	43.20	1536.69	218
4 Glaxo	1.50	720.00	540.00	3639.00	758
5. Ciba	3.00	487.50	316.87	3122.00	403

(Source: Hathi Committee's Report 1975, Chapter V Annexure-I, Page 108)

It can be observed from the above given table that within two decades of their business the multinational pharmaceutical companies built up huge reserves thousand times more than the original equities. Meanwhile the Indian public sector also came into picture and started their production with the support and

collaboration of U.S.S.R., H A L., at Pimpari in 1955 and IDPL in 1968. The entry of public sector in the production of these essential drugs provided new thrust and strength to Indian Pharmaceutical Companies in the private sector. The Indian sector of the industry, which mostly comprised of companies from Maharashtra, Gujarat and West Bengal at that time, was developing rapidly to compete with the foreign sector. But the Indian sector could not find much time to develop and sooner it had to face heavy onslaught from the foreign drug companies through their "high pressure sales promotion technique"23 History of pharmaceutical industry in India clearly reveals that " more than resources and products, it was the management policy, the high streamlined recruitment and training procedures for medical detailers, the area of super expertise that was created, the technique employed by foreign companies to persuade doctor to prescribe their drugs and meticulous cost and economic studies of all operations carried out by them beat the Indian companies completely and left them for being in the race".²⁴ As observed by the Lev Raj Kumar Committee the multinational companies spent several times more on sales promotion than on R & D.²⁵ Thus the multinational pharmceutical companies attained a position of dominance in the drug industry. From a base of Rs 10 crores of turnover in 1947, the industry had grown to Rs. 370 crores in 1973 This high growth industry was controlled for all practical purposes, by foreigners and the structure of control on production and capital was again pyramidical.²⁶ In 1973 sixtysix multinational companies controlled 80% of the total production and their annual repatriation of profits was more than 50% of their initial investment. The growth of the top six multinational companies- Glaxo, ACCI, CIBA, Pfizer, Hoechst and Bayerwas even more spectacular. ²⁷The Hathi Commission Report (1975) shows that their assets increased by 111 times between 1952 and 1973. In fact the top six multinational firms enjoyed decisive power as indicated by their share in the industry's production and capital. They truly dominated and controlled India's drugs and pharmaceutical industry and had profound influence on the country's hospitals doctors and medical care in general ²⁸

With the implementation of Foreign Exchange Regulation Act (FERA) in 1973, the multinational companies were compelled to reduce holding in their Indian ventures to 40% or else comply with export obligation to retain a maximum 51% stake. As a result some multinational companies curtailed the scope of their operations. The Drugs Price Control Order (DPCO) was also introduced in 1970 by the Indian Government. This further deterred the multinational companies as selling their products at much lower prices in India meant global repercussions and possible uproar in their home countries. Thus the multinational companies curtailed the launching of new products giving further scope to Indian players. The Indian Patent Act (IPA) introduced by the Indian Government had been one of the single most important factors to spur the domestic pharmaceutical industry. Under the IPA only process patents were allowed for a period of 5 years from the date of patent grant or 7 years from the date of filing for patent whichever was earlier With the IPA the cost of local manufacture reduced, as also, the absence of royalty payments on reverse engineered drugs. This all strengthened the position of the local pharmaceutical companies ²⁹ Thus in 1970's and 1980's due to the growth of the domestic pharmaceutical companies, the dominance of multinational firms declined Multinational firms felt stifled by the combined weight of the Monopolies & Restrictive Trade Practices Act and the Foreign Exchange Regulation Act. Protectionist policy introduced by the Indian government in 1970 hit profits hard and the multinational pharmaceutical companies were further deterred by the lack of

intellectual property. In spite of all this they found India attractive because of its large size market, and relatively larger demand for drugs, milder drug control measures and the absence of local competition. In addition, the government's policy of industrialization by way of import substitution, especially from the second plan onwards, provided a sellers market protected by high tariff walls and other import restrictions.³⁰ Because of the heterogeneous nature of the industry, multinationals could dominate specific market niches through extensive promotion and established brand names. One study shows that for companies like Glaxo and Cyanamid more than 10% of their foreign sales were generated in India.³¹ Thus the status of multinational companies in drugs and pharmaceutical industry slipped from dominant to a major partner but it still continued to be an important part of the industry by virtue of its technological, managerial and financial resources.

In 1990-91, a new economic policy laid many policy changes, which allowed multinational companies to increase their foreign equity from 40% to 51%. The Foreign Exchange Regulation Act of 1973 was amended and restrictions placed on foreign companies and multinational enterprises by FERA were lifted.³² The MRTP Act being amended, custom duties and corporate taxes being lowered, relief concessions and facilities were extended to the multinational companies as well as to the Indian companies. These steps towards globalisation favoured the multinational pharmaceutical companies while having an adverse effect on the indigenous drug industry.³³ According to a study made by S Ganesh in 1995, the share of the multinational drugs and pharmaceutical companies share in the total sales of drugs & pharmaceutical sector was significant and it worked out to 30% Thus the presence of multinational drugs and pharmaceutical products was deeply felt. He further concludes that in the three key sectors covering engineering goods,

electrical equipments, drugs and pharmaceuticals, multinational companies had considerable influence.³⁴ The restructuring process which took place in the multinational pharmaceutical companies improved their position very well. The profits of the multinational pharma companies' grew by an average of 20% over the last three years. As against this the profit of local formulation companies grew by an average of 14.5% and bulk drugs manufacturers actually saw a 40% fall in profits ³⁵ The present scenario is that the multinational drugs and pharmaceutical companies in India are still leading due to backing of their global Research and Development. High cost for basic research deterred local players in the private sector. The global R&D expenditure of one multinational company is equivalent to 70% of the total domestic turnover of the entire Indian pharma industry. ³⁶

Today in the anticipation of the WTO, (World Trade Organisation) agreement multinational drugs and pharmaceutical companies are strengthening their ranks in India - either by setting up new 100% subsidiaries or marketing tie-ups with major domestic players.³⁷ Until recently India has so far has recognised patents only on processes. But with the implementation of WTO agreement, the product patent regime will be put into practice beginning from 1st January 2005. As per WTO, from the year 2005 India will grant product patent recognition to all new chemical entities i e. bulk drugs developed then onwards. This leaves few more years of Multinational Company's research output open to process piracy. But the long-term prospects for multinational companies are good. The transition phase in the preparation of WTO has commenced. The multinational pharmaceutical companies have started strengthening their position Most companies have already restructured their operations and focused on the pharma business. Parent companies are reassessing India's market potential and have accordingly increased their stakes in the existing ventures and set up new subsidiaries.³⁸ In the post product patent era the growth of multinational companies could be significantly different. They will be able to freely introduce top of the line, new products i.e. those patented after 2005 in the domestic market. However, these are expected to be priced at a significant premium in line with the multinational companies global policy of earning return on their R& D investment. Thus new launches by multinational pharmaceutical companies will be high margin but low volume products and will be mostly imported from overseas bases and only marketed in India. Multinational companies, which do not have a base in India, will enter into tie-ups with local player to license their new products. Local players in India will continue to make and market in India the popular generic and also those pre-WTO products, which may still be under, patent overseas. They will take up franchise manufacturing and marketing for overseas multinational companies. Local player may also enter into research tie-ups with multinational companies to leverage on their relatively low-cost, efficient skill base of trained pharmacist and chemists.³⁹

STRUCTURE OF INDUSTRY:

Pharmaceutical Industry is at the forefront of India's science based industries with wide ranging capabilities in the complex field of drug manufacture and technology The pharmaceutical industry of India consists of four sectors viz., Public Sector, Foreign Sector (foreign controlled companies) Large Indian Sector and Small-Scale Sector (SSI units) ⁴⁰ The organised sector of the pharmaceutical industry has played a key role in promoting and sustaining development in this vital field Multinational companies associated with this sector have stimulated, assisted and spearheaded this dynamic development and helped to put India on the global map The organised sector units accounts for 70% of the industry's total value of

production.⁴¹The total number of units producing bulk drugs and formulations were 1752 in 1952-53. These units increased to 2257 in 1969-70, 16000 units in 1989-90, and 20053 units in 1999-00. ⁴² Among the 20053 firms engaged in the production of drugs and pharmaceuticals about 250 units are on the list of the Directorate General of Technical Development (D.G.T.D) generally known as the organised sector of the Industry. Out of 250 units some of them have a foreign equity. ⁴³ Pharmaceutical industry ranks top among all the industries in terms of the number of companies. The fact that there are 20053 firms operating in this industry itself is evidence enough to prove the statement. It has grown to be the 6th largest in terms of volume and 20th in terms of value.⁴⁴ Consequently the capital investment has also increased over the years especially in the last two decades. The investment in the industry was Rs. 225 crores in 1973, which increased to Rs. 800 crores in 1988. It further increased to Rs 2500 crores in 1999 As per 9th Five-Year Plan projections, the investments in industry are expected to be of Rs. 2800 crores.⁴⁵

From an indigenous production of hardly Rs. 10 crores in 1948 ⁴⁶ and depending mainly on imported formulations, the Indian Pharmaceutical production of bulk drugs and formulations in 1990-91 increased to 4570 crores and in 1999-00 has risen to around Rs 19737 crores Table no. I - 4 gives detailed information and statistics related to the production of bulk drugs and formulations during the last five decades. Till 1970, the base of bulk drug manufacturing industry was very small. But thereafter, the rise in production of bulk drugs and formulations has remained significant and touched a new height of Rs 3777 crores and Rs. 15960 crores in 1999-00 respectively The average trend in the rate of growth of production per annum over a period of 10 years i e. from 1990-91 to 1999-00 was 19 49% for bulk drugs and 16 73% for formulations, while it was 17.20% for the total production.

working group set up by the government to prepare projections for the Ninth Five Year Plan has estimated that the production of bulk drugs will be Rs. 5439 crores and that of formulation Rs. 21104 crores. This indicates the future growth potential of the industry. ⁴⁷Though India has emerged as the largest producer among the developing countries, its share in world production is still insignificant at 1.6% though it account for 15% of the world's population. ⁴⁸

TABLE NO. I - 4

PRODUCTION OF BULK DRUGS AND FORMULATIONS

			Rs. In Crores)	
YEARS	PRODUCTIONS			
	BULK DRUGS	FORMULATIONS	TOTAL	
1947-48		10	10	
1952-53	-	35	35	
1962-63	15	95	110	
1970-71	35	360	395	
1980-81	240	1200	1440	
1989-90	640	3420	4060	
1990-91	730	3840	4570	
1991-92	900	4800	5700	
1992-93	1150	6000	7150	
1993-94	1320	6900	8220	
1994-95	1518	7935	9453	
1995-96	1822	9125	10947	
1996-97	2186	10494	12680	
1997-98	2623	12068	14691	
1998-99	3148	13878	17026	
1999-00	3777	15960	19737	

(Source: 1. Indian Drug Manufacturers Association 2. OPPI Annual Reports 1999-2000)

The Pharmaceutical sector achieved noteworthy success in the field of exports in 1990's In 1990-91 the total exports of bulk drugs and formulations were

Rs. 784.80 crores, which increased to Rs. 6631 crores showing an increase of 7.5 times. Bulk drugs form a major portion of these exports though the share of formulations is now increasing. Table no. I -5 gives detailed information and statistics related to the export of bulk drugs and formulations for a period of ten years. The exports of pharmaceuticals consist of basic drugs, intermediates and fine chemicals (including quinine salts exported exclusively by the Government) and finished formulations.

TABLE NO. I - 5EXPORTS OF BULK DRUGS AND FORMULATIONS

		<u> </u>			(Rs. In Crores)
YEARS	FINISHED FORMULATIONS	% OF TOTAL	BULK DRUGS	% OF TOTAL	TOTAL
1990-91	371.40	47	413.40	53	784.80
1991-92	558.50	44	722.60	56	1281.10
1992-93	965.50	70	409.50	30	1375.00
1993-94	1310.80	71	530.80	29	1841.60
1994-95	1505 50	66	760.10	34	2265.60
1995-96	2044 80	64	1132.90	36	3177.70
1996-97	2509 20	61	1581.10	39	4090.30
1997-98	3180.00	59	2173.00	41	5353.00
1998-99	3194 90	54	2764.10	46	5959.00
1999-00	NA	N.A	N.A	N.A	6631 00

(Source: OPPI Annual Report 1999-2000)

The imports of bulk drugs and formulations of the pharmaceutical industry were lower as compared to exports As depicted in table no 1-6 the imports were Rs 604 crores in 1990-91, which increased to Rs 3441 crores in 1999-00 showing an increase by 5 69 times. As against this the exports increased by 7 5 times during the same period. Thus, it indicates that in 1990's the country was a net exporter of the pharmaceutical products ⁴⁹This had positive impact on the balance of payment position and foreign exchange reserves of the country.

TABLE NO. I - 6

IMPORTS OF BULK DRUGS AND FORMULATIONS

(Rs. In Crores)

YEARS	BULKDRUGS	FORMULATIONS	INTERMEDIATES, CHEMICALS SOLVENTS & OTHERS	TOTAL
1990-91	322.57	84.94	196.49	604.00
1991-92	458.51	96.12	252.75	807.38
1992-93	508.39	119.51	509.48	1137.38
1993-94	612.74	138.33	415.46	1166.53
1994-95	811.43	173.02	384.27	1368.72
1995-96	1630 00	270.00	505.00	2405.00
1996-97	1705.00	345.00	555.50	2605.50
1997-98	1827.00	430.00	611.00	2868.00
1998-99	1918.00	540.00	670 00	3128.00
1999-00	2025.00	680.00	736.00	3441.00

(SOURCE: OPPI ANNUAL REPORT 1999-2000)

The pharmaceutical industry provided direct employment to approximately 4,60,000 people comprising of various categories of personnel including managerial, technical, skilled and unskilled in organised sector and small-scale units. The industry provided indirect employment to almost 28,60,000 people in ancillary and distribution trade. ⁵⁰

The pharmaceutical industry is among the most highly Research and Development intensive industries on account of rapid obsolescence products, interdisciplinary character of the research needed for new drug discovery and continuous social pressure to reduce the cost of drugs.⁵¹ R&D expenditure was Rs.10 50 crores in 1976-77, increased to Rs 125 crores in 1993-94 and further increased to Rs 320 crores in 1999-00 Usually Indian pharmaceutical firms spend about 1 to 2 % of their turnover on R&D as compared to 15 to 20% which

multinational companies of foreign origin spend.⁵² The amount of R&D expenditure of the industry was high as compared to other industry. There are several reasons that compel the industry not to spend more on research and development. The most important factor that is responsible for the indifference towards R&D by Indian pharmaceutical industry is the presence of Drugs and Price Control order (DPCO). The provision of DPCO compelled the firms to keep the selling price within the prescribed limits. Therefore the firms had to resort to cost cutting as a major competing element. Due to price control raw material comprised of almost 70 to 80% of the total cost of production and about 55-60% of the net selling price.⁵³ This in fact used to leave little margin for the firms to invest in basic R&D. Therefore, the Indian firms were engaged in producing the drugs introduced in the developed market through reverse engineering. It must be noted here that process developed by reverse engineering is valid and entitled for availing patent protection under Indian Patents Act 1970. R&D expenditure as a percentage of Gross National Product in India is 0.44% as against 3.4% in U.S.A., 2 3% in U K., 1.6% in France, 1.5% in Japan and 1% in Canada. As compared to these developed countries the R&D expenditure of India was proportionately very less 54

The per capita consumption of drugs in India is only \$3 per year compared to \$412 in Japan, \$222 in Germany, \$191 in the US, \$7 in China & Pakistan and \$5 in Indonesia ⁵⁵

The Government has introduced several legislations to control the manufacture, distribution and sale of drugs and medicines. At present there are several acts related to manufacture and sales and to other related aspects of drugs in India. There are also rules framed under provisions of these laws, which govern the production and sales. The following laws operate in the country: ⁵⁶

- 1. The Drugs and Cosmetic Rules of 1945.
- 2. The Drugs and Cosmetic Amendment Act 1964.
- 3 The Drugs and Cosmetic Amendment Act 1972.
- 4 The Drugs and Cosmetic Amendment Act 1982.
- 5. The Drugs and Cosmetic Amendment Act 1986.
- 6 The Pharmacy Act 1948
- 7. The Drugs and Medicines Remedies Act of 1954.
- 8. The Narcotic Drugs and Psychotropic Substances Act 1985.
- 9. The Poisons Act 1919.
- 10. The Medicinal and Toilet Preparation (Excise and Duty Act) 1956.
- 11. The Drugs and Price Control Order 1995.

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

- 1. The Industries (Development and Regulation) Act of 1951.
- 2. The Trade and Merchandise Mark Act 1958.
- 3 The Indian Patents and Design Act of 1970.

According to a renowned pharmaceutical consultant Dr, Raja Smarta, the pharmaceutical industry remained under the influence of the Government for about four decades after the Independence.⁵⁷ The Government of India played a vital role in building pharmaceutical industry in India Immediately after Independence, the government envisaged the health care sector to be the most important sector for the overall growth and development of Indian economy. Therefore the government had accorded "Core Sector" status to the healthcare sector and set priorities for its development.

Patents Act of 1970. Thereafter it issued a DPCO in order to regulate and control the price of pharmaceuticals especially life saving drugs so that the people could afford the medicines. Despite all efforts, multinational companies of foreign origin largely dominated Indian pharmaceutical scenario. In 1990-91 a new economic policy brought about many changes, which allowed multinational companies to increase their foreign equity from 40% to 51%. It is guite obvious that the post industrial policy regime scenario that will emerge after 2005 will be significantly influenced by the government's stand through policy framework. It is quite unlikely that DPCO will be done away with. In the interest of public at large, government will definitely continue to impose price control on life saving drugs. Thus in the Indian context, one cannot afford to ignore the government or the legal forces since they have a significant impact on the industry and in such changing environment the multinational pharmaceutical companies do operate. In India the multinational companies in general and drugs and pharmaceutical companies in particular have faced a continuously changing environment and especially more so after 1990-91 In recent times there have been many changes in the policies towards these companies. From the point of view of multinational pharmaceutical companies, the amendments in the legal framework and other changes in the host country governments' attitude and policies have added new dimensions to their operating performance. Although multinational pharmaceutical companies play a significant role in industrial sector as well as in the economic development of India, its performance has not received due attention of the researchers in India Thus the appraisal of these companies forms the theme of the present study. The rationale of the study is discussed out in the following section.

RATIONALE OF THE STUDY:

Management of a business concerns is interested in every aspect of financial management. It is their overall responsibility to see that the resources of the firm are used most effectively and efficiently and that the firm's financial condition is sound. The effective and efficient utilisation of the funds leads to higher operating efficiency. A higher operating efficiency will help the concern to earn an expected higher rate of returns. Similarly, if the firm is financially solvent, it will be in a position to meet its short term and long-term obligations as and when they become due for payment. A lower operating efficiency and financial insolvency will not only lead to decline in the profit but also to an ultimate downfall of the business concern. Thus efficient use of the funds will assist in cost savings and in maximising financial return on the total capital employed The operating efficiency and solvency of the business can be judged by the management only through the appraisal of data contained in the financial statements. The purpose of financial appraisal is a detailed cause and effect study of the profitability and financial health of a business concern. The rationale of the study is emphasised by the fact that the appraisal of the financial statements is important to examine the financial health of a business enterprise. To improve the financial health, each business concern should have a periodical appraisal of its financial results. This will enable the management to measure the effectiveness of its own policies and will help them to take corrective actions to improve the business position. If financial appraisal is not initiated, the management may not be in a position to analyse the performance of business. Sometimes it may lead to close down of the business activities. Thus an in-depth understanding of the importance of financial appraisal helps management to take steps towards improving its performance in adverse conditions

The need for financial appraisal varies according to the type of users The users of the financial information contained in the financial statements include Management, Bankers, Investors, Creditors, Employees, Government, Researchers, etc. Each of these users has different needs and accordingly each tends to concentrate on particular aspects of the company's financial position. Careful appraisal of the financial statements by the users clarifies many points regarding the performance of any business undertaking.

For the management, financial appraisal serves as a means of self-evaluation i.e. a report of its managerial skill and competence. It also helps the management in planning and controlling the affairs of the business.

A banker can judge the liquidity position of the business enterprise through appraisal of financial statements. ⁵⁸

Appraisal of financial statements is also very useful to creditors because it act as a magic eye.⁵⁹ Creditors of a firm may consist of short-term and long-term creditors. The former are concerned with the firms ability to meet its obligations when due, while the later are interested in the conditions of the firms earnings over a long-term period Thus Creditors can establish the credit rating through financial analysis of the financial statements.

An investor can plan buying, and selling of shares on the basis of the safety of its principal and capital appreciation as warranted by the past earning records Like creditors investors are also interested in debt paying ability of the business because, if maturities are not satisfied when due, the firm will face bankruptcy.

A debenture holder can ascertain whether the income generates sufficient margin to pay the interest, whether the cost is adequate, will the company have enough funds to redeem debentures at maturity? Answers to such different questions are provided by financial appraisal. By using the technique of financial appraisal an economist can study the extent of concentration of economic power and pitfalls in the financial policies pursued, while a planner can ascertain if the pattern of investment follows the aims of planning.

To labour leaders, financial appraisal reveals how the company's stands in relation to labour and its welfare.

Legislation concerning licensing, control of costs, fixing of prices ceiling of profits, dividend freeze, tax subsidy and other regulations desirable in the socioeconomic interest may be based on statement analysis.

The financial appraisal of the financial statements enables the research scholars and the financial analyst to study the financial policies pursued by the managements and on the basis of their studies can offer constructive suggestions to overcome any flaw disclosed therein

From the above discussions it is very clear that appraisal of financial statements is of interest to many users which helps in clarifying many points regarding the performance of any business undertaking. The pharmaceutical industry is an interesting case for such a study because of its contribution in the growth of national economy

Many research studies have been undertaken on different industries including pharmaceutical industries highlighting different facets of financial management. Specific research exclusively on the performance of multinational drugs and pharmaceutical is very scanty. The financial appraisal of multinational pharmaceutical companies is altogether an ignored area of research. This is evident from the various studies reviewed briefly in Chapter II Not a single in-depth doctoral study concerning financial appraisal has been undertaken, though number of small studies have been carried out on various aspects of financial management. However some research studies on multinational companies have included pharmaceutical companies as part of a much larger sample involving companies from many industrial sectors

For instance, Richman and Copen ⁶⁰ have studied the transferability of management know-how developed by American Multinational Companies, to their subsidiaries in India. The company chosen for this study belonged to the pharmaceutical, chemical, and engineering industries. The emphasis in this study was on analysing the management process in a group of companies rather than in individual companies.

A study conducted by Lall and Streetan ⁶¹ on various aspects of the operation of 159 transnational companies in 6 developing countries included 32 pharmaceutical companies. The country-wise distribution of these 32 pharmaceutical companies was: 20 from Columbia, 6 from Iran, 4 from India, and 2 from Kenya The practices of these companies, which were analysed on the basis of the inter-country comparisons, and comparison of transnational companies with non-transnational companies within each industry.

Another study conducted by Sengupta ⁶² examines the structure, growth and working of European Multinational Companies in India. The sample of this study includes subsidiaries of multinational companies belonging to several industrial sectors including pharmaceuticals The study confines itself to analysing the growth and structure of multinational companies of European origin although some reference was also made about their research and development practices.

A study conducted by Mehra ⁶³ is directly related to the pharmaceutical industry wherein he analyses the pricing policies amongst multinational and wholly owned Indian drug companies

Research by Johri⁶⁴ studies Multinational Drug Companies in India wherein he analysed the various functional policies adopted by them.

None of the earlier studies deal with an overall financial appraisal of multinational drugs and pharmaceutical companies in India. Keeping this in view and the remarkable performance of multinational drugs and pharma companies, the present study viz., "Financial Appraisal of the Selected Medium and Large Size Multinational Drugs and Pharmaceutical Companies in Mumbai" is undertaken.

STATEMENT OF PROBLEM:

The present study is titled "Financial Appraisal of Selected Medium and Large Size Multinational Drug and Pharmaceutical Companies in Mumbai"

With a view to have conceptual clarification, it is essential to define important terms used in the proposed study.

The term 'Financial Appraisal ' refers to a process of scientifically making a proper and comparative evaluation of the profitability and financial health of medium and large size multinational drugs and pharmaceutical companies in Mumbai.

The term 'Multinational Drugs and Pharmaceutical Companies ' refers to Indian subsidiaries of multinational drugs and pharmaceutical companies.

The medium and large size refers to those selected multinational drugs and pharmaceutical company with a paid up capital of Rs. 1 crore and above

The drugs and pharmaceutical companies refer to those companies of whose the main activity is manufacturing drugs and pharmaceuticals and those having more than 50% production of allopathic medicines. Companies engaged solely in trading, producing exclusively ayurvedic, homeopathic and unani medicines are excluded. Moreover their registered Offices are located at Mumbai and are listed on Bombay stock exchange The term bulk drugs refers to the basic drugs used in manufacturing ethical drugs over the counter drugs. Ethical drugs are drugs advertised and promoted mainly to physicians, pharmacists and allied professionals usually requiring a doctor's prescription. Formulations refer to combinations of drugs in finished form for final consumption of the patient

Mumbai refers to the place and city where 76% of the total multinational drugs and pharmaceutical companies in India are located.

OBJECTIVES OF THE STUDY:

The main objective of the study is to appraise financial performance of the selected medium and large size multinational drugs and pharmaceutical companies in Mumbai. In order to appraise the financial performance, the profit and loss account and balance sheet of selected companies has been analysed for the period between 1990-91 and 1999-2000

The main objectives of the study are as follows:

- 1 To appraise the financial performance of selected medium and large multinational drugs and pharmaceutical companies in Mumbai.
- 2. To evaluate the profitability position and operating efficiency.
- To assess the capital structure and examine its relationship with profitability.
- 4 To appraise effectiveness of Working Capital Management
- 5. To analyse the investment pattern and utilisation of fixed assets.
- 6 To examine the components of sources of funds and its prolific utilisation.
- 7. To suggest measures to improve financial performance of selected multinational drug and pharmaceutical companies in Mumbai.

CHAPTER SCHEME OF THE STUDY:

The present study comprises of five chapters.

The **First** chapter is the introductory one dealing with the background of study, the structure of study, the rationale of study, specification of problem, objectives of study, limitations of study, and the chapter scheme of study.

The Second chapter reviews related literature and researches.

The **Third** chapter deals with the methodology adopted for the present study, i.e. selection of sample, sources of data, collection of data, methods of analysis and statistical techniques used and specific ratios followed.

The **Fourth** chapter deals with the analysis and interpretation of the data It is divided in to five sections.

Section I has been devoted to Appraisal of Profitability. Significant profitability ratios are calculated in relation to sales and investments and the profitability position of the selected medium and large size multinational drugs and pharmaceuticals companies is interpreted.

Section 2 deals with Appraisal of Capital Structure. The long term financial strength of the selected medium and large size multinational drug companies in Mumbai has been judged by the analysing of capital structure through leverage ratios.

Section 3 deals with the Appraisal of Working Capital of the multinational drug companies in Mumbai Through various liquidity ratios, an attempt has been made to analyse the liquidity position and short-term financial strength of sample companies The financing of working capital has also been analysed Section 4 deals with the Appraisal of Fixed Assets. The section has also been devoted in measuring the efficiency of fixed assets and in analyzing the financing of fixed assets

Section 5 gives a detailed Analysis of Sources & Application of Funds.

The **Fifth** chapter presents the findings, conclusions, suggestions and recommendations for further research.

LIMITATIONS OF STUDY:

Following are certain limitations of the present study.

- 1. The scope of the study is limited only to the appraisal of profitability, liquidity, working capital management, long term financial strength, capital structure and appraisal of funds position of selected sample companies. It excludes probing into other financial problems such as capital budgeting, impact of economic and political environment of the pharmaceutical industry, impact of government policies etc.
- 2. The study is based on secondary data collected from the annual audited balance sheets, profit and loss account, directors and auditors report of the multinational drugs and pharmaceutical companies. The other data used for comparing the results of pharmaceutical companies are taken from various journals and periodicals. So the inherent limitations common to secondary data and to the company's financial statements are self evident in this study The limitations of the secondary data along with the limitations of the financial statements for the purpose of analysis are well known Despite these limitations, financial statements continue to be a major source of data for analysing of the company's performance
- 3. The limitations of the small sample are also applied here, as the size of the sample is restricted. In the present study, out of 22 multinational drugs and pharmaceutical companies having their registered office in Mumbai on or before 1990-91, only 11 of them are selected on the basis of judgement

sampling method. The rest of the companies are not included in the sample companies either due to non-availability of data or on account of their being small or because they produce allopathic drugs and pharmaceuticals less than 50% of the total production.

- The inherent limitations of the financial and statistical techniques used for analysis could not be avoided.
- 5. The accounting year is not same for all the sample companies as a result of which uniform financial statements could not be obtained. Out of 11 sample companies covered in this study, 6 of them followed financial year, 4 followed calendar year and 1 followed November ending as their accounting year. Thus, in order to facilitate the analysis, the data has been arranged in a manner that it pertains to the accounts closed during the twelve months ending on 31st March of the concerned year.
- 6. The companies are grouped according to their main activity; hence combined data for a particular company would include figures related to the subsidiary activities Studies related to sample companies are, however, bound to suffer from this sort of limitation irrespective of the source of data.
- As multinational companies in pharmaceutical industry operate world wide, it is very difficult to compute the volume of profit charged through transfer pricing

The present research has been undertaken considering all the above listed limitations Thus one should carefully and judiciously use the findings of the study.

The research methodology and the sampling procedure has been discuss in detail in chapter no III

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