NEW DRUG POLICY AND THE PROSPECTS OF SELF-RELIANCE

A STUDY OF THE DRUG AND PHARMACEUTICAL INDUSTRY IN INDIA (1974-79)

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It is certified that the dissertation entitled "New Drug Policy and the Prospects of Self-Reliance: A Study of the Drug and Pharmaceutical Industry in India (1974-79)" submitted by Mr. J. Manohar Rao in fulfilment of eight credits out of the total requirement of 24 Credits for the degree of Master of Philosophy of the University, is his original work to the best of my knowledge and may be placed before the Examiner for evaluation.

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PREFACE

For the proper functioning of the health-care system of a country, it should be adequately supplemented by a compatible level of the pharmaceutical production. The drug and pharmaceutical industry, therefore, constitutes one of the vital sectors of the socio-economic set up of a country, and is a decisive factor in the healthy growth of population. Most of the health care systems in the developed as well as the developing countries are sponsored and managed by the State. The government policy and supervision, therefore, becomes an important factor in maintaining the quality and safety of the drug products as they are mainly produced by private companies all over the world. In the developing countries, where even the essential drug products are out of reach of a common-man due to the lack of purchasing power, it also becomes the responsibility of the government to see that the prices of drugs are properly regulated and distributed in adequate quantities.

The Hathi Committee has examined several problems of the Indian pharmaceutical industry and has submitted its report in 1975. The Committee's wide ranging criticism of the foreign companies in the drug industry has ensued in substantial debates inside the Indian Parliament and outside it has drawn the attention of the general public as well,

to the domination of MNCs. Thereafter, the stress has been increasingly laid on the necessity to reduce the multinational domination in the drug industry and to promote indigenous efforts through technological self-reliance. The Janata Government has announced an exhaustive new drug policy in 1978, which claimed to have incorporated majority of the Hathi Committee recommendations.

The present study examines the Indian drug and pharmaceutical industry against this backdrop. Chapter I brings out certain features of the world pharmaceutical industry and locates the status of the Indian pharmaceutical industry in the international context. The government's policy, particularly the new drug policy has been discussed in Chapter II, in the light of the Hathi Committee's recommendations. Chapter III evalutes the roles of the multinational, the Indian private and the public sector companies in order to assess the progress towards achieving self-reliance in the drug industry. The intensity of research and development in various sectors of the drug industry has been traced out in Chapter IV and the progress towards technological self-reliance has been explained. Conclusions and findings are summed up in Chapter V.

I have incurred many debts of gratitude in the process of writing this thesis. First and foremost, I am greatly indebted to Dr Prabhat Patnaik, my supervisor of research, who has gone through an earlier draft with meticulous care

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J. Manohar Rao

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CHAPTER I

CHAPTER I

THE INTERNATIONAL CONTEXT OF THE INDIAN PHARMACEUTICAL INDUSTRY

Introduction

'Pharmaceuticals' consist of products ranging from phytochemicals (made out of plant material) to complex chemical substances like antibiotics, steroids, hormones, vitamins etc, used in the modern system of medicine. The term 'pharmaceutical industry' refers to the industrial scale manufacture of drugs based on substances of either vegetable, organic or synthetic origin. The 'ethical drugs' are the consumer products which can be sold only on a prescription by a doctor and hence the actual consumer neither determines the demand, nor does he choose the products he will use or purchase. In the matter of choosing drugs, doctors should be concerned, first with the relative performance, benefits and risks associated with the use of non-use of particular drug products.[1] The introduction of synthetic chemicals in medicine has led to a drastic change in the production and distribution structure of the pharmaceutical industry.

1.1 World Production and Consumption

A structural break occurred in the worldwide pharmaceutical production and consumption with the advent of

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1. Competitive Problems in the Drug Industry, Summary and Analysis: Select Committee on Small Business; United States Senate Sub-Committee on Monopoly (Hereafter Kefauver Committee), U.S. Govt. Printing Office, Washington D.C. 1972.

sulpha-drugs in the late 1930s and with the introduction of penicillin in the mid-1940s. Not only have synthetics replaced drugs of natural origin, but mass-scale production methods have also been adopted for natural products. This phenomenon has led to the concentration of pharmaceutical production, based both on vegetable and synthetic origin. Physicians started showing preference for ready-made synthetic drugs which are less troublesome and pose lesser problems in compounding.

The therapeutic revolution, so to say, in drugs has stimulated two fundamental changes in the manufacturing firms. First, the major companies were transformed from full-line commodity houses, which manufactured and sold a complete range of all the medicaments the pharmacist needed to compound the doctor's multi-ingredient prescriptions, into vertically-integrated research based manufacturers by the 1950s.[2] The research based on production gave rise to new product innovations, protected by patents, promoted by brand names resulting in domination of the market by a few large companies. The second change at the firm level was that nationally based companies became multinationally organized. Sales, production and other activities were increasingly carried out by affiliates located in countries other than those in which the parent companies were domiciled.

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2. See, William Breckon, Drug Makers, Eyre Methuen, London, 1972.

Data on the worldwide production and consumption of pharmaceutical products are difficult to find except for the advanced OECD countries (Switzerland does not publish even such information). A large number of less developed countries (LDCs) do not maintain any data at all, and some of them which do, give less-reliable or outdated estimates. Sanjaya Lall's figures,[3] for example, show production and consumption of pharmaceuticals in 1973 for 48 market economy countries. The excluded countries would not affect the totals significantly.

Table 1.1 indicates that the developing countries account for nearly 85 per cent of the world production[4] of drugs and for a somewhat smaller per centage of their consumption: the LDCs as a whole, while containing over three-fourths of the world's population account for 10 per cent of production and 13 per cent of consumption.

Estimates for growth rates are even less precise, but a comparison of 1973 figures with the similar ones for 1971,[5] suggests that output is growing, in current prices, at about 20 per cent per annum for the world as a whole, at 18 per cent for developed countries, 31 per cent for South European countries and 22 per cent for LDCs.

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3. See S. Lall and S. Bibile, " The Political Economy of Controlling Transnationals: The Pharmaceutical Industry in Sri Lanka (1972-76)", Economic and Political Weekly (Hereinafter EPW), August 1977.

4. Hereafter the terms 'world', LDCs and DCs refer only to the capitalist economy countries and the countries with centralized economies are excluded.

5. S. Lall, Major Issues in Transfer of Technology to Developing Countries: A case Study of the Pharmaceutical Industry, UNCTAD, Geneva, 1975.

TABLE 1.1

ESTIMATED PRODUCTION AND CONSUMPTION OF PHARMACEUTICALS 1973

Country group	No. of countries	Production		Consumption[a]	
		Million dollars	Per centage	Million dollars	Per centage
Developed market economies	17	24,919	84.4	23,372	80.8
Southern European[b]	4	1,534	5.2	1,798	6.2
Less developed[c]	27	3,113	10.4	3,767	13.0
Total	48	29,566	100.0	28,937	100.0

Source: S. Lall, The Growth of the Pharmaceutical Industry in Developing Countries: Problems and Prospects, New York, (UNIDO), 1978.

Notes: a) Defined as production plus imports minus exports.
b) Spain, Portugal, Greece and Turkey.
c) Including Yugoslavia.

Within the developed world, the six leading producers, France, Germany, Italy, Japan, UK and US contributed $22 billion, or 88 per cent of the output of the group (74 per cent of the total world output). The seven leading exporters viz., France, Germany, Italy, Netherlands, Switzerland, UK and US exported $3.6 billion worth of pharmaceuticals in 1973, which comes to 84 per cent of total exports by developed countries and 77 per cent of total world exports (excluding, of course, the centralized economy countries.[6]

6. S. Lall, loc. cit., Annexure I, Table 7.

Within the developing and South European group, the five more industrialized countries, Brazil, India, Mexico, Spain and Yugoslavia account for $2.9 billion of production, which is 61 per cent of the total for the group and 10 per cent of the world total.[7]

It has become clear that on the one hand the world-wide production, consumption, and trade is confined to a few advanced countries and on the other a few large companies carry out these activities. The market and product concentration, apart from geographical concentration by those companies which were operating nationally and later on turned to global operations are to be examined in detail.

1.2 Global Operation of Pharmaceutical Multinationals

The pharmaceutical multinationals, as in other industries, apparently are motivated by the profit maximization objective, and concentrate on expansion of market shares through increased sales turnover and a more rapid introduction of new products on a world-wide basis to obtain quicker returns on heavy research investment. The pharmaceutical multinational corporations (MNCs) have adopted a fairly wide range of business strategies to enter overseas markets in an attempt to develop substantial foreign income.

The strategies vary from export of finished pharmaceutical product to direct investment in an overseas sub-

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7. Ibid.

sidiary or even to the setting up of a branch. However, the multinationals do follow some alternative strategies in order to cope with the increasing protectionist tendencies in the underdeveloped countries. Among the major alternative entry strategies of pharmaceutical companies 'licensing' has been a widely practised phenomenon alongwith 'marketing agreements' and 'joint-ventures'.[8]

A cross-sectional study of major pharmaceutical multinationals would show that they have been following either, or all the three entry strategies mentioned above to expand their operations and increase their sales turnover. The evidence provided in Table 1.2 suggests that the world-wide sales of pharmaceutical products are concentrated in a small number of firms. The world's 25 largest privately owned companies account for nearly 40 per cent of total pharmaceutical sales. The US companies account for 48 per cent of the total sales out of these 25 companies (see Table 1.2a).

West Germany shared the second largest amount with 20 per cent of total pharmaceutical sales of these top 25 multinational companies, followed by Switzerland with 16 per cent. The degree of sales concentration was high for individual German firms followed by Swiss, both together accounting for around 36 per cent of the total sales.

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8. Under 'licensing', a company grants the right to manufacture, distribute and sell together with the technical knowhow in a specific country or countries for a certain time period, to a second company; Marketing agreements involve the 'host' company taking on the sales management of products from the 'initiator' and 'joint-venture' differs from both as it involves the legal establishment

TABLE 1.2

THE TOP 25 MULTINATIONALS OF 1977

Company	Domicile	Millions of dollars[a]
1. Hoechst	FRG	1,572.9
2. Merck and Co.	USA	1,446.4
3. Bayer	FRG	1,273.4
4. Ciba-Geigy	Switzerland	1,150.0
5. Hoffmann La Roche	Switzerland	1,145.0
6. American Home Products	USA	1,116.0
7. Warner-Lambert	USA	1,024.8
8. Pfizer	USA	1,016.0
9. Sandoz	Switzerland	934.8
10. Eli Lilly	USA	911.1
11. Upjohn	USA	744.0
12. Boehringer Ingelheim	FRG	734.6
13. Squibb	USA	668.4
14. Bristol Myers	USA	666.2
15. Takeda	Japan	645.6
16. Rhone Poulenc	France	613.9
17. Schering-Plough	USA	606.1
18. Glaxo	UK	594.3
19. Abbot Laboratories	USA	581.0
20. Beecham	UK	523.8
21. Johnson and Johnson	USA	518.3
22. Montedison	Italy	486.9
23. Cynamid	USA	484.0
24. Schering	FRG	456.2
25. AKZO	Netherlands	441.5

Source: From Transnational Corporations and the Pharmaceutical Industry, Annexure I, Table 4, United Nations, New York, 1979.

a) Corresponds to corporate fiscal year, 1977.

TABLE 1.2a

PHARMACEUTICAL SALES OF THE MAJOR PHARMACEUTICAL MNCs, BY SIZE AND NATIONALITY, 1977

Domicile (Top 25 companies)	No. of MNCs	Value of sales (million dollars)	Per centage
United States	12	9,782.6	48
West Germany	2	4,037.1	20
Switzerland	3	3,339.8	16
Japan	1	645.6	3
United Kingdom	2	1,118.1	5
France	1	613.9	3
Others	2[a]	928.4	5
Total	25	20,355.5	100

Source: Same as Table 1.2

a) Sweden and Panama

The market power of these dominant multinationals is often derived from the sales of a select category of therapeutic product group (or groups) which generally have a high profitability. There are a dozen or so major therapeutic product groups,[9] for example, vitamins, analgesics, barbiturates, contraceptives, etc., which are economically distinct, in that the products of one group cannot generally be substituted for those of any other since their medical properties are quite different. Some

8. contd.
of a jointly owned company through capital expenditure. See, Barrie G. James, The Future of the Multinational Pharmaceutical Industry to 1990, Associated Business Programmes, London, 1977, pp.25-28.

9. A list of important therapeutic categories grouped as product sets is given in Douglas L. Cocks and John R. Virts, "Pricing Behaviour of the Ethical Pharmaceutical Industry", The Journal of Business, Vol.47, No.3, 1974, pp. 349-362.

20 or so major multinational companies have dominated in a dozen or so major therapeutic areas in 1973, covering a major share of pharmaceutical products.[10] While the operation in select therapeutic areas has remained a major strategy of multinationals as a source of market concentration, they also follow some other distinct and well-established methods to wield their influence in other related areas. One such widely practised strategy is 'diversification' out of the pharmaceutical industry into related areas.[11] The major areas for the diversifying companies have been over-the-counter drug products, cosmetics and toiletries, biologicals and animal health products.[12] Diversification into even technologically unrelated industries like ultrasonics and motion picture production is not uncommon.[13]

1.2.1 The Pharmaceutical MNCs and Competition

In spite of the high concentration in therapeutic markets, competition in the pharmaceutical industry does exist and often in an intense form. The research and

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10. B.James, Op. cit., p.37.
11. The diversification methods of MNCs in India are given in Chapter III below; a detailed account of strategies and patterns of 'diversification' into and out of the pharmaceutical industry is given in H. Henry, "Corporate Strategy, Marketing and Diversification", in A Handbook of Strategic Planning, Taylor and Hawkins (Eds.), Longman, London, 1972; Igor Ansoff et al., "Planning for Diversification Through Merger", California Management Review, Vol.1, No.4, 1959 and Igor Ansoff, Corporate Strategy, Penguin, London, 1968.
12. B. James, Op. cit., pp. 47-51.
13. Ibid.

innovation based production of pharmaceuticals alongwith the brisk patenting of products gives rise to a unique form of product, pricing and promotional competition, which is by and large different from other industries. Hence the technology, patents, the brand names and the government policy play an important role in determining the level of competition among the companies in the industry.

Product competition, however is widely existent among pharmaceuticals. An important characteristic of product competition in pharmaceuticals is that each of the large drug companies depends on a small number of its products for the major part of its sales. Schwartzman has provided a comparison of sales concentration in individual United States companies by products for 1973 and 1960.[14] His figures suggest that only one of 10 leading United States manufacturers (Abbott) required more than eight products to account for 50 per cent of its total sales. Six other companies, viz., Lilly, Upjohn, Smithkline, Merck, Squibb and Pfizer, made half of their sales on five products or less.[15] A comparison, also, of the five leading products in each area out of some nine selected therapeutic areas in the United States in 1960 and again in 1973 showed that frequently three or more of the five leading products in

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14. David Schwartzman, Innovation in the Pharmaceutical Industry, The John Hopkins University Press, Baltimore, 1976, Tables 6-14, pp.120-128.

15. Ibid.

1973 were not among the top products in 1960, and for that matter, in many cases the 1973 leading products had not yet appeared on the market in 1960.[16] Another important feature of product competition in this industry and generally adopted by large firms is to invest huge amounts in innovations and research in order to reduce the extent of price competition by patenting new products. But, this type of investment, it is argued, often tends to waste scarce scientific and other resources on trivial product changes, which generally result in duplicative drugs designed to bypass the patents protecting major new discoveries.[17] It is also pointed out that a large company Squibb, for example, devoted 25 per cent of its research funds on 'worthwhile' projects, and 75 per cent to the development of 'duplicative' drugs, and most of the top companies do not deviate from this pattern.[18] Here, it is important to note that competition by innovation limits price competition in two ways: (a) it gives the drug manufacturer a basis for claiming superior quality over several products and helps in shifting attention from price on to product and (b) despite large research expenditures, firms introduce a few large selling drugs, usually not more than four

16. Ibid., p.9, Table 2.

17. Milton Silverman and Philip R. Lee, Pills, Profits and and Politics, University of California Press, Berkeley, 1974, p.38.

18. Statement by a former Director of Research at Squibb, in Ibid., p.40.

or five which account for a major share of the total sales.[19] Because of this high degree of market concentration and company dependence on new products, price competition is not an attractive alternative for the leading firms in the industry.

This product competition is followed by intense promotional competition in the pharmaceutical industry. Both are closely linked by the workings of the patent and brand-name systems which act as insulators in preventing rival companies from price competition.[20] The amount of money spent on promotional competition in the pharmaceutical industry is remarkably high. Approximately 20 per cent of all drug sales at the manufacturer's level goes for promotion, which in 1978 amounted to over $1.9 billion for the United States alone.[21] The brand-name system has an advantage over the patent system, since the brand names can be operative even in products whose patents have expired, or in products which cannot be patented or in products which are freely licensed.[22] The brand-name system gives rise to an array of different names for the same drug. Some 700 different drugs available in the United States have around 20,000 brand names,[23] at an

19. David Schwartzman, Op. cit., p.5.
20. See, Stuart St. P. Slatter, Competition and Marketing Strategies in the Pharmaceutical Industry, Croom Helm, London, 1977.
21. Pharmaceutical Manufacturers Association, Annual Survey Report: Ethical Pharmaceutical Industry Operations, 1977-78, Washington, D.C., 1978.
22. M. Silverman and P. Lee, Op.cit., p.17.
23. Ibid., p.19.

average of 30 names for each prescription product. In India, for example, the pharmaceutical companies spend around 18 per cent of their total sales for promoting some 15,000 products.[24] The large pharmaceutical companies do obtain immediate returns on their product-promotion expenses as physicians generally show preference for branded products. By 1965, for instance, about 90 per cent of the total number of prescriptions written in the United States were for drugs which had trade marked brand names.[25]

Price competition, as noted earlier, is limited by innovational competition backed by promotional activities for branded products. However, price competition also exists among pharmaceuticals, generally in multiple-source drugs, or unpatented generic-products which are sold by more than one company. But, taking into consideration the oligopolistic situation that exists within the therapeutic sub-markets and the lack of product standardization which is further aided by the low elasticity of demand for ethical drugs and the high rate of product innovation, Cooper[26] maintains that the pharmaceutical industry never has been and never will be competitive in the exact sense

24. See S. Lall, Op. cit., (n.5).

25. Lawrence H. Wortzel, Technology Transfer in the Pharmaceutical Industry, UNITAR (Report No.14), New York, 1971, p.15.

26. Michael H. Cooper, Prices and Profits in the Pharmaceutical Industry, Pergamon Press, London, 1966, p.41.

of the term. However, it is pointed out that in the United States the antibiotics market is now ripe for price competition.[27] This might have been due to the large market for antibiotics and secondly to the fact that the patents on many antibiotics have now expired resulting in a large number of suppliers. Where identical substitutes are marketed by powerful companies at lower prices than the original innovator after patent lapse, considerable changes in sales volume can occur. Reekie[28] cites the case of ICI's brand of tetracycline, Imperacin, entering the UK market in 1966 to compete with Pfizer's Terramycin, and causing considerable fall in the latter's sales volume.

With the increasing cost consciousness of health care systems in the developed markets, generic competition for drugs off-patent may possibly force the major companies to enter into aggressive price competition in the future, but it is not likely to be the case with the underdeveloped markets of the third world countries at least till the next decade.

1.2.2 Transfer Pricing[29]

Transfer pricing has been one of the widely practised techniques among the pharmaceutical multinationals all over

27. See, Paul A. Brook, Resistant Prices: A Study of Competitive Strains in the Antibiotic Markets, Council on Economic Priorities, New York, 1975.

28. W.D. Reekie, The Economics of Innovation with Special Reference to the Pharmaceutical Industry, Ph.D. Thesis, University of Strathclyde, 1969; See also Reekie, The Economics of the Pharmaceutical Industry, Macmillan, London, 1975.

29. For a detailed account, see S. Lall, "Transfer Pricing by Multinational Manufacturing Firms", Oxford Bulletin of Economics and Statistics, Vol.35, No.3 (August 1973);

the world. Transfer pricing technique is common to many industries, particularly chemicals, oil and electronics where basic ingredients or components or other raw materials are produced in one country and sold to a subsidiary or an off-shoot in another country at a price which is higher than cost plus normal profit additions.[30] While this can be proximately explained by reference to exchange rate changes, tax regulations, transport cost and the like,[31] the basic underlying reasons behind the higher prices are lack of market information on the part of the buying country or the technological monopoly enjoyed by the seller.[32]

One of the well-known examples of inter-company transfer pricing is that of Hoffmann-La Roche. Roche's two products Librium and Valium were priced very high and this was justified by the company on the plea that it passed on the research and corporate overheads on worldwide operations to its UK subsidiary.[33] However, the UK Monopolies Commission rejected this in 1973 and concluded that the

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29. Contd.
J.S. Schulman, "Transfer Pricing in Multinational Firm" European Business, January 1969, p.46; C.V. Vaitsos, Intercountry Income Distribution and Transnational Enterprises, Clarendon Press, Oxford, 1974.

30. B. James Op. cit., p.140.

31. See, M.H. Cooper and A.J. Cooper, International Price Comparisons, National Economic Development Office, London, 1972.

32. S. Lall, Op. cit., (n.6), p.14.

33. The Monopolies Commission, Report on the Supply of Chloridiazepoxide and Diazepam (Librium and Valium), Her Majesty's Stationery Office (HMSO), London, 1973.

company reduce its selling prices by 60 per cent for Librium and 75 per cent for Valium.[34] In 1974, the prices of Librium and Valium in the UK were one quarter and one sixth respectively of average world price for the products.[35]

An important and often cited case in point is Sri Lanka, where the government invited worldwide tenders for several drugs and this apparently resulted in considerable reduction of the extent of transfer pricing.[36] A substantial amount of savings has been achieved, it is stated, after intervention by the State Pharmaceutical Corporation (SPC) in Sri Lanka. A clear savings of 92.5 per cent and 80.1 per cent was achieved respectively on chlorpropamide and tetracycline formulated locally by Pfizer.[37] In two other intermediate chemicals, Aspirin and chlorpheniramine, formulated by Glaxo, a substantial savings of 14.7 per cent and 87.3 per cent respectively was achieved.[38]

Whilst it may not be possible to conduct investigations into transfer pricing on all the products, the healthcare systems funded by governments either fully or partially,

34. Ibid.

35. The Economist, 14 April 1975.

36. See, S. Bibile, The State Pharmaceutical Corporation of Sri Lanka, Colombo, 1976.

37. S. Bibile in S. Lall and S. Bibile, Op. cit. (n.3).

38. Ibid.

might focus attention on individual products with large sales volume. This is likely to follow the Librium and Valium example in the UK and in other countries.

1.3 Pharmaceutical Multinationals and the Third World Countries

The pharmaceutical MNCs have been criticized heavily for their discriminatory approach towards the third world countries, whether it is pricing or in research aimed at discovering tropical drugs. The World Health Organization (WHO) had waged a relentless campaign, ever since it took up the program in 1957 to increase pharmaceutical awareness among the peoples and national governments of both the developing as well as the developed countries, in order to pressurise the companies to invest in research for new tropical therapy.[39] It is cited, for example, that there has been no advance in drug therapy for tropical diseases, since diethylcarbamazine in 1948 to cure Filariasis affecting over 250 million people.[40] Not much research has taken place even on some of the widely prevalent tropical diseases such as Malaria, Cholera, Yellow Fever, Ascariasis, Ancylostomiasis and Schistosomiasis.[41]

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39. See, for example, The Work of the World Health Organization, 1976-77, biennial Report of the Director-General, WHO, Geneva, 1978; and see also, WHO Chronicle, various issues.

40. See, for example, Chemotherapy of Malaria and Resistance to Anti-Malarials, WHO (Technical Report Series, 515), Geneva, 1973.

41. See, WHO, Technical Report Series on the respective diseases.

Criticism of the pharmaceutical multinationals intensified and an increasing awareness on the part of the public occurred during the 1960s after the multi-country Thalidomide disaster.[42] This led to the setting up of various committees and panels by national governments and the public also started keeping a closer vigil over the pharmaceutical industry. The UK Kefauver-Harris hearings of 1959-61 highlighted the reasons for the Thalidomide disaster and the hearings produced a considerable amount of positive reaction from the press, a number of books too appeared as a result.[43] Subsequently a number of aspects, apart from drug safety, viz., pricing, profits, promotional techniques etc., have also been examined by the committees set up by various national governments. The US Senate Sub-Committee on Monopolies and Small Business,[44] as well as the Sainsbury Committee[45] in the UK had arrived at some important conclusions which have even more far reaching implications for the third world countries than for the advanced countries. The phenomenon of probe into

42. Thalidomide is a chemical intermediate which was administered on pregnant women till the 1960s. It was then discovered that the substance had, apart from high toxicity, given rise to structural deformities in the embryos and even the destruction of foetus, and had resulted in the occurrence of a number of deaths of prospective mothers in various countries.

43. The most notable book being H. Sjostrom and R. Nilsson, Thalidomide and the Power of the Drug Companies, Penguin London, 1972.

44. Kefauver Committee, On. cit.

45. Report of the Committee of Enquiry into the Relationship of the Pharmaceutical Industry with NHS 1965-67 (Sainsbury Report), HMSO, London, 1967.

the pharmaceutical industry is not limited to the US and the UK and has occurred virtually in all countries in varying degrees. In India, for example, a Committee[46] was set up in 1974 to look into various problems of the domestic pharmaceutical industry.

Apart from the governmental probings, some non-profit social organisations have also brought into light, several aspects of pharmaceutical multinationals' operations in the third world. Haslemere Group,[47] for example, pointed out that the prices for drugs paid by the developing countries was 'near criminal'. A case in point was India, which had to pay nearly $10 per kilo of vitamins whereas Britain paid American firms only $2.40 per kilo.[48] The study also pointed out that the multinationals were selling virtually ineffective and obsolete drugs in the third world markets. In India,again, one of the sulphonamide drugs, sulphapyridine, now considered obsolete in the West, is not only still sold but is the most expensive drug of its kind.[49] This has been confirmed by a recent study[50] for a later period. Mother Jones a US magazine

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46. Report of the Committee on the Drugs and Pharmaceutical Industry, Government of India, New Delhi, 1975 (Hereafter Hathi Committee Report or HCR).

47. Haslemere Group, Who needs the Drug Companies? Haslemere Group, London, 1976.

48. Ibid.

49. Ibid.

50. Report of Mother Jones published in Economic Times, 15 October 1979, New Delhi.

of investigative journalism, accused that the US and European drug companies have been "systematically dumping in developing countries unsafe products ranging from contraceptives to pesticides to baby pacifiers" and termed this as the "corporate crime of the century".[51]

A number of measures have been initiated by national governments to offset the strategies of multinationals particularly high pricing. Pakistan and India, for example, attempted to limit the use of brand names.[52] In India, the policy applies solely to essential drugs, though exceptions are made for patented and imported products. Pakistan banned trade names entirely in 1972, but this was not successful for long due to major quality control problems; she ultimately revoked the 1972 Drug Act and replaced it with the 1976 legislation which allowed some use of brand names.[53] The Pakistan case is often cited by the multinationals to support their argument for continuation of brand names. It is very difficult to implement a policy like abolishing brand names without a proper investigation of the therapeutic equivalence of various

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51. Mother Jones cited a number of examples in its report; notable among them are, the dumping of Depo-Provera an injectable contraceptive which caused malignant tumours and the Dalkon Shield a contraceptive device which caused deaths and were subsequently banned in the US. The dumping, it is alleged, is done with the assent of the US Agency for International Development (USAID), see, Ibid.

52. Review of Major Developments in the Area of Restrictive Business Practices, UNCTAD (TD/BC.2/159), New York, 1975, p.20.

53. "Assessment of the Pharmaceutical Industry in Developing Countries: its Potential and National and International Action Required to Promote its Development", UNIDO (ID/WG.292/2), Vienna, 1978, p.29.

drugs and without proper quality control measures to prevent the spawning of spurious drugs. In these circumstances the third world countries with their limited resources can move forward only with more cooperation among themselves and with the help of various supranational organizations to counter the operations of the drug multinationals. The Sri Lanka case is already a pointer in this direction.

1.4 Indian Pharmaceutical Industry: Historical Perspective

Indian systems of medicine such as Ayurveda, Unani and Siddha enjoyed wider public confidence and were largely in use prior to the colonial rule[54] and still continue to be used in most of the rural areas even now. The Allopathic system of medicine has been a late starter in India. A beginning was made in the production of allopathic medicines and drugs with the establishment of Bengal Chemicals and Pharmaceutical Works in 1901 by Prof. P.C. Ray, in Calcutta. Until the 1940s, however, the Indian pharmaceutical industry was largely an adjunct of the British industry and concentrated on the selling operations of imported finished drugs. The World War II gave a fillip to the production of pharmaceuticals through increased demand all over the world. The Indian drug industry was not in a position to keep pace with wartime needs due to

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54. See, Report of the Pharmaceutical Enquiry Committee (Bhatia Committee), Government of India, New Delhi, 1954.

its meagre size in terms of capital investment and sales volume. With the rapid developments in the pharmaceutical field during the 1940s and with the introduction of sulpha-drugs, antibiotics, steroids and various other synthetic drugs, the research and innovation based large pharmaceutical firms started dominating the pharmaceutical markets across the national boundaries. Thus the multinationals made their headway into Indian markets, a phenomenon which was readily accepted by the colonial government and successfully continued even after Independence.

The early post-independence years (1948-53) proved to be a turning point in the history of the Indian pharmaceutical industry. It was during this period that the foundations of a truly modern pharmaceutical industry in this country were laid. A programme of development was launched, which was phased in Five Year Plans and had specific goals in different fields including the progressive achievement of self-sufficiency. In 1953, the Union Ministry of Commerce and Industry, set up a Pharmaceutical Enquiry Committee[55] to recommend the lines on which the pharmaceutical industry could be developed as an integrated industry. To ensure that the industry would achieve the required pattern of growth it was placed within the purview of Industries (Development and Regulations) Act of 1951, and put under the guidance of Directorate General of Technical

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55. Ibid.

Development (DGTD). The pharmaceutical industry is classified among the core industries for the purposes of licensing under the Industries (D&R) Act and is one of the 65 priority industries for the purposes of raw material allocation. The Industrial Policy Resolution of 1956 grouped this industry in Schedule B, where both public and private industries could operate.[56] However, the emphasis of the Industrial Policy was to increase the role of public sector and to reduce progressively the hold of foreign companies, an emphasis which was equally applicable to the pharmaceutical industry as well. As a sequel to this policy the public sector unit Hindustan Antibiotics Limited was strengthened and another unit Indian Drugs and Pharmaceuticals Limited was set up to manufacture the synthetic drugs.

However, the setting up of HAL and IDPL in itself did not achieve the object of reducing multinational domination in the pharmaceutical industry; on the contrary the profits of multinationals rose substantially. Sixty pharmaceutical multinationals in India shared between themselves 70 per cent of total drugs sales in 1973-74.[57] The product concentration is also very high among the multinationals; each large company concentrates on a few product groups while a few large companies together dominate all the major

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56. See, Industrial Policy Resolution, Government of India, New Delhi, 1956.

57. Hathi Committee Report, Op. cit.

therapeutic areas and products, thereby edging out relatively smaller Indian competitors. While Merck, Sharp and Dohme in India, for example, control the products of sulphathiazole and phthalyl sulphathiazole, Parke-Davis monopolises the production of bulk amodiaquin and bulk chloromycetin.[58] Geoffrey Manners, Hoechst and CIBA dominate the productions of meprobamate, tolbutamide and sulphasomidine respectively.[59]

The price variations for various drugs are very common in the Indian pharmaceutical multinationals. Indian Schering and Nicholas, both associates of an English multinational, which manufacture a life-saving drug Neomercazol used for the treatment of thyrotoxicosis, price it at Rs.16 whereas the manufacturer's cost is just 10 paise.[60] The Tariff Commission has brought out a number of other examples too of transfer pricing by multinationals in India, which is a part of their global tax-minimization strategy. Hoechst, for instance, sold 50 tolbutamide tablets at Rs.14 in European countries, and at Rs.27 in India; Pfizer sold 60 tablets of chlorpropamide at Rs.10.68 in Italy, and at Rs.30.30 in India; Cynamide sold Aureomycin in Argentina at Rs.9.01 for 16 capsules, while its associate in India, Lederle sells the same for Rs.52.42. The same firm sold tetracycline (Acromycin) at Rs.9.01 for 10 capsule in Argentina, and at Rs.49.39 in India.[61]

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58. See, Report of the Tariff Commission, Government of India, New Delhi, 1970.
59. Ibid.
60. Ibid.
61. Ibid.

These and various other practices of multinationals such as non-production of tropical drugs, heavy remittances to their parents domiciled abroad in the form of royalties, technical fees etc., are still not stalled through effective checks at various ends. However, increased consciousness of the costs involved in the health-care system among the government circles and a growing awareness among the public as a result of revelations of various committees inside India and abroad led to the setting up of the Hathi Committee in 1974 which examined different aspects of the Indian drug industry.

Scope of the Present Study

In a country like India, where the degree of economic and technological backwardness is still relatively high, there is a tendency towards dependence on foreign multinationals. In the pharmaceutical industry this becomes still more important since the production of various drugs is innovation oriented and the products internationally patented, generally by a few large privately owned multinational corporations. In such a situation long-term policy is called for in order to achieve self-reliance at a faster pace in both production and technology, keeping in view the dominance of multinationals in both the fields. In India a clear policy on drugs did not emerge till the Hathi Committee came out with certain concrete suggestions; prior to that there were only certain ad hoc measures like the

Industrial Policy and Drug Price Control orders or Drugs and Cosmetics Acts. A coherent and comprehensive drug policy emerged only in 1978, on the basis apparently of the Hathi Committee recommendations.[62]

In this background the present study approaches the problems of self-reliance and the contribution of various sectors viz., the multinational, the Indian private and the public sectors towards achieving the set targets in the production of various drugs. First, an attempt has been made to trace out the activities of pharmaceutical multinationals in India including their financial performance. The profit ratios and the remittances abroad by foreign firms are examined in detail since these parameters can considerably affect the economy in general and the pharmaceutical industry in particular. Some of these aspects are compared with the Indian private sector in order to identify the status of private Indian pharmaceutical companies and their role in achieving self-sufficiency.

The present study also examines the role of the public sector which forms the major sector in terms of capital investment and which has been assigned a prominent role by the Hathi Committee. In a drive towards progressive self-sufficiency the pricing policy of the public sector calls for a balanced approach and should have a stabilizing effect on maintaining the price-line, particularly in a

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62. Discussed at length in Chapter II below.

market dominated by large multinational companies. This aspect has been dealt in detail and the price discrepancies of various products manufactured by different sectors have been brought out.

The question of self-sufficiency is analyzed in terms of capacity utilization and production targets set up by the Task Force of the Planning Commission on the basis of the suggestions of the Hathi Committee. This has been done for all the three sectors.

The indigenous efforts to gear up innovational output will be fruitful only if the investment in R&D as a percentage of either the sales turnover or the total capital employed is adequately high. The examination of R&D expenditures of various firms according to their sizes, in the present study, should give a fair idea of indigenous efforts toward technological self-reliance.

Whilst attempting to trace out the importance of R&D a number of fundamental questions regarding the nature of pharmaceutical research (capital-intensive or labour-intensive) and the resource cost of technology transfer from capitalist and socialist countries are raised.

Sources

A variety of sources have been made use of in the present study. However, the general paucity of source material about the pharmaceutical industry continues to be the major drawback. Hence, the study mostly depends

on the company annual reports, the Annual Reports of the Ministry of Petroleum, Chemicals and Fertilizers, the CCTD Manuals and the Parliament proceedings (including the papers laid on the table) etc. The private companies, mostly multinationals still do not disclose much of the vital information, which allegedly is kept secret for trade purposes. These serious constraints have limited the scope of the present study to a few aspects. Descriptive statistical methods alone are employed in much of the analysis of data; statistical techniques, however, are adopted in a few instances.

CHAPTER II

CHAPTER II

GOVERNMENT'S POLICY TOWARDS THE DRUG AND PHARMACEUTICAL INDUSTRY IN INDIA

Since policy decisions with regard to any given sector of the industrial economy are taken within the overall context of the industrial policy, the government's drug policy cannot be examined in isolation. The pharmaceutical industry in India, which is mostly dominated by the foreign multinational companies financially and technically, raises some specific questions in regard to equity participation, choice of technology and so on. Hence, a policy for this sector must involve a judicious approach of bringing together of the national industrial and science policies, particularly when the government's objective is one of achieving self-reliance through progressive reduction of foreign control and substantial increase in indigenous efforts both in technology and in production.

2.1 Drug Policy in relation to Industrial Policy

A clear and well defined policy towards the pharmaceutical industry, in comprehensive terms, did not emerge in India until recently, when some of the Hathi Committee's recommendations were apparently incorporated into the drug policy. The general guiding principles laid down in the industrial policies and the Drugs and Cosmetics Acts alongwith the Price Control orders used to determine the policies

toward the quality control, levels of production, pricing of products and the foreign participation in the drug industry.

The Government of India announced its first Industrial Policy Resolution (IPR) in 1948, entailing the maximum utilization of indigenous resources, the equitable distribution of goods and services and achievement of higher standard of living as the main objectives.[1] It also recognized the important role of indigenous technology on the one hand, and the participation of foreign capital and enterprise on the other, for achieving rapid industrialization in the country.[2] The policy in regard to foreign investments was further explained in the First Five Year Plan, where it was considered desirable that foreign investments "should be channelized into those spheres which were in urgent need of development"[3] and probably the pharmaceutical industry was considered one of those, since a free flow of foreign capital and technology was entertained in this sector. However, the basic framework of Indian policy toward foreign participation in domestic industries was laid down in the Second IPR announced in 1956, though there was no direct reference to the import of technology nor about the establishment of in-plant R&D in indigenous industries.[4] During the Second Five

1. Government of India, Industrial Policy Resolution, April 6, 1948, New Delhi, para 8.
2. Ibid., paras 8-10.
3. Government of India, First Five Year Plan, New Delhi, 1952, p. 412.
4. See, Industrial Policy Resolution, April 30, 1956, Government of India, New Delhi, 1956.

Year Plan period, there was a shift in the pattern of investment and greater emphasis was laid on the growth of the public sector absolutely and relatively to the private sector.[5] Private capital (including foreign), however, was not against the increased investments in the public sector, which went largely into areas like infrastructure and machine building which involve high risks and long gestation periods and hence are not very attractive for private capital to initiate development in.[6] Nevertheless, the pharmaceutical industry was not entirely a state monopoly, according to the IPR of 1956, but was put in Schedule B, in which category both the public and the private (including foreign) enterprises could operate in harmony.[7]

The second IPR states:

> Industries in the second category will be those listed in Schedule B. With a view to accelerating their future development, the State will increasingly establish new undertakings in these industries. At the same time, private enterprise will also have the opportunity to develop in this field, either on its own or with State participation.[8]

This leads to a clear suspicion that the development of the public sector in general and in the pharmaceutical industry in particular was not aimed specifically at con-

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5. Jagdish Bhagwati and Padma Desai, India: Planning for Industrialization, Oxford University Press, London, 1970, pp. 86-87.

6. The authors of the Bombay Plan, however, expressed the idea that private capital could take over the more profitable public investments at a later date and also hoped to buy up some of the enterprises which were to be created in the public sector. See, The Bombay Plan, New Book Company, 1944.

7. See, IPR 1956, op. cit.

8. Ibid., paras 10-14.

trolling private capital, the outlook was one of co-existence of private and public investments with the intention of promoting the interests of private capital in the long run.

The new Industrial Policy announced by the Janata Government in 1977 also has the avowed objective of creating an industrial base in India mostly with the help of indigenous technology.[9] The stress of the new policy was to develop small-scale and medium-scale sectors by aiding them through various state and other autonomous financial institutions. Insofaras the pharmaceutical industry is concerned, a new policy with a definite shape was announced a year later in 1978.

2.2 The Pre-Hathi Committee Drug Policy

Whilst the general guidelines set in the various industrial policies used to govern the overall approach towards the pharmaceutical industry the specific problems were tackled on a legal rather than the policy plane. The Indian government had adopted from the British, the Drugs Cosmetics Act of 1940 and amended it at regular intervals. This act governed the manufacture, sale and distribution of various drug products used in the allopathic, Ayurvedic and Unani systems of medicine practised in India. The Drugs and Cosmetics Act of 1940 was first amended in 1955 as Drugs (Amendment) Act followed by further amendments in /

9. See, IPR, December 23, 1977, Government of India, New Delhi, 1977.

1960 and in 1962. This Act was replaced by the Drugs and Cosmetics (Amendment) Act of 1964 with subsequent additions in 1972 and in 1979.[10] The Act entrusted the government with the power to prevent the emergence of spurious drugs, to maintain quality in production and to provide for the import of drugs wherever necessary. The prices of drugs were however controlled from time to time by the promulgation of various statutory orders. The first such order was the Drugs (Display of Prices) Order in 1962 and later the Drugs (Control of Prices) Order in 1963 which were promulgated under the Defence of India Act. However, their impact was minimal and prices continued to rise despite the statutory measures. The drug price index calculated on the basis of the prices of a static group of Drugs had risen by 41.9 points by 1970-71 with 1961-62 as base.[11] A Tariff Commission study was also conducted during 1965-66 to determine the prices of 18 basic drugs and their 69 formulations which led to the announcement of Drugs (Prices Control) Order in 1970, later.[12] Strangely, the highest annual increase of 12 points occurred in 1970-71 with the declaration of DPCO.[13] The drug prices were regulated under DPCO 1970 until it was replaced by a new order in March 1979, which was a result of the new drug policy in 1978.

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10. See, The Drugs and Cosmetics Act and Rules, Government of India (Department of Health), New Delhi, 1979.

11. P.S. Agarwal, P.K. Ramachendran and B.V. Ranga Rao, "Anomalies in Drug Price and Quality Control", EPW, Vol.7, Nos. 46 and 47, 1972, pp. 2285-92.

12. See, V.L. Mote and H.N. Pathak, "Drug Price Control: An Evaluation", EPW, Vol.7, July 15, 1972, pp.1469-79.

13. P.S. Agarwal et al., ibid.

The questions concerning joint-ventures, technological collaborations and foreign participation in the pharmaceutical industry were more or less governed by the general guidelines set by the Reserve Bank of India and later on by the Foreign Exchange Regulations Act, etc., till recently.

2.3 New Drug Policy

The Hathi Committee which delved into various questions concerning the drugs and pharmaceutical industry submitted its voluminous report to the government in April 1975. It took almost three years for the government to come out with a clear and coherent policy on drugs, which apparently incorporated the Hathi Committee recommendations into it. This policy was announced in March 1978.[14]

The broad objectives laid down in the new drug policy are as follows:

i) to develop self-reliance in drug technology;
ii) to provide a leadership role to the public sector;
iii) to aim at quick self-sufficiency in the output of drugs with a view to reduce the quantum of imports;
iv) to foster and encourage the growth of the Indian private sector;
v) to ensure that drugs are available in abundance;
vi) to promote research and development by providing special incentives to those firms which are engaged in it; and
vii) to provide other parameters to control, regulate and rejuvenate this industry as a whole, with particular reference to containing and channelizing

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14. The present study does not take into account the political change and its impact on the economy due to the change in the government in 1977. However, it can be seen from section 2.1 whether it was the Indira Congress or the Janata, the essence of economic philosophy was mainly derived from the second IPR.

the activity of the foreign companies in accord with national objectives and priorities.[15]

The objectives listed above were quite comprehensive and well-defined, since they were framed along the lines suggested by the Hathi Committee. The first objective is clearly interlinked with the rest and to assess to what extent the objective of self-reliance is achieved a closer examination of at least items (ii), (vi) and (vii) is called for.

2.3.1 Multinational (Foreign) Sector

The foreign multinational companies in the pharmaceutical industry were to be more or less guided by the FERA and other regulations, since a very specific policy in regard to this sector cannot be laid down which would be very different from the general industrial policy. The drug and pharmaceutical industry is listed in Appendix I of the Industrial Licensing Policy of 1973, where a preferential treatment is given for the allocation of raw materials. The Hathi Committee, however, felt that for the purpose of administering section 29 of FERA guidelines the foreign companies should be directed to bring down their equity to 40 per cent and further reduce it progressively to 26 per cent. This, however, is without depriving them of other concessions to which they are eligible as a result of being grouped in Appendix I of ILP.[16]

15. Government Decisions on Report of the Hathi Committee, Economic Intelligence Service, Centre for Monitoring Indian Economy, Bombay, April 1978. (Hereinafter referred as New Drug Policy or NDP).

16. Hathi Committee Report, Op. cit., Chapter V, para 21.

The suggested reduction in equity participation does not appear to be an effective instrument for controlling foreign capital. The RBI practice of taking a 40 per cent share in the equity of a firm as a threshold of control is arbitrary enough. It becomes intolerably rigid when a firm has large non-controlling interests in complementary units in an industry; or when a controlling interest in one part of industry is coupled with consultancy interest elsewhere.[17] Effective foreign control could be exerted also when the holder of a majority interest is an industrial giant, very much larger than its majority partner, as has happened time and again in India.[18] Even the Hathi Committee's suggestion of progressive reduction of equity to 26 per cent may also be ineffective since it is pointed out that most of the matters that affect the affairs of a company require three-fourths majority vote; because of this several foreign investors have found it unnecessary to take more than 26 per cent of the share in the equity, as this gives them an effective veto.[19]

The Hathi Committee appears to have considered this point when it suggested that equity should not be shared in a dispersed form by Indian nationals, but should be purchased by the public sector undertakings which are con-

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17. Michael Kidron, Foreign Investments in India, Oxford, London, 1965, p.188.

18. Ibid.

19. Ibid., p. 287.

nected directly or indirectly with the manufacture of drugs, chemicals or by public financial institutions or by the government itself.[20]

The government, however, did not go this far with the Hathi Committee, when it incorporated the Committee's recommendations. It directed such foreign companies which are engaged purely in formulation activity to bring down their direct foreign equity to 40 per cent, those engaged in the manufacture of bulk drugs from basic stage which involve high technology and of formulations made out of such drugs are not required to bring down their equity at all.[21] Such companies were provided with an incentive of a post-tax profit of 14 per cent on 'net worth'.[22,23] A 14 per cent post-tax profit on net worth would mean about 35 per cent post-tax profits on paid-up capital. Hence, the foreign companies would gain much out of this incentive, their ratio of paid-up capital to reserves being generally of the order of 2:3.[24]

Since a number of suggestions came from many quarters and particularly since the Hathi Committee recommended that multinationals should not be allowed to manufacture in

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20. Hathi Committee Report, Ch. V, paras 22-23.
21. NDP, Op. cit., paras 15 and 16.2.
22. Ibid., para 44.
23. 'Net worth' means the 'share capital' (equity) of a company plus 'free reserves', if any, and a free reserve is created by appropriation of profits. For detailed definitions in the context of the drug and pharmaceutical industry in India, See Drugs (Price Control) Order 1979, Government of India, New Delhi, 1979.
24. See, Economic Times, 26 August 1977, New Delhi.

abundance the less useful nutrients and household tonics, the government took a decision in this regard. It announced in its new policy that any further expansion in capacity for the manufacture of household remedies will not be allowed and for this purpose redefined the term "drugs and pharmaceuticals" listed under item 14 of Appendix I of ILP.[25] The new definition includes only those drug intermediates from the basic stage for the manufacture of high technology bulk drugs and formulations based on them;[26] consequently it has the effect of making foreign companies which are subject to ILP to confine their production to the bulk drugs only. Hence, an ambiguity arises at this stage, since the FERA regulations appear not to be applicable to those who are engaged in manufacturing the "drugs and pharmaceuticals" in the sense of the new definition.

Herein also lies the question of identifying whether a firm is involved in the manufacture of bulk drugs with or without high technology, which is very difficult to determine. To take a case in point, the Ministry of Petroleum, Chemicals and Fertilizers suggested that almost all the multinational drug companies except two should be treated as high technology units, a suggestion which was rejected by the Reserve Bank of India and the FERA Committee on the

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25. Ibid., para 13.

26. The new definition is as follows: "(a) Drug intermediates from basic stage 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 drugs consumption (from own manufacture) to formulation from all sources of 1:5." Ibid., para 14.

grounds that this would defeat the basic purpose of amending the definition of "drugs and pharmaceuticals".[27] It should also be noted that so far only eight foreign companies out of the 45 foreign companies listed by the government which were identified as engaged only in the pure formulation activity and were directed to reduce their non-resident interest to 40 per cent.[28]

2.3.2 Indian (Private) Sector

The Indian private sector, is comparatively smaller than the foreign multinational sector. The Hathi Committee recommended that a more liberal policy should be adopted to encourage the Indian companies to make their contribution to the production of bulk drugs and formulations.[29] It even recommended that such items as are manufactured by the Indian companies need not be imported.[30] The new drug policy apparently considered these aspects and announced that the small scale sector would be a prohibited area for foreign firms.[31] The Hathi Committee had recommended that the foreign companies should provide 50 per cent of their total bulk drug production to non-asso-

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27. The Ministry had argued that all the bulk drugs could be treated as high technology items, and hence all the units manufacturing such items make the 'core sector'. See, IDMA Bulletin, Indian Drug Manufacturers Association, Bombay, Vol. XI, No.8, February 29, 1980, pp.88-89.
28. Answer to Unstarred Question No.1817, Lok Sabha Debates, December 1978.
29. HCR, Ch.v, para 13(h).
30. Ibid., Ch.v, para 13(q).
31. NDP, para 23.

ciated Indian formulators.[32] But the government's decision permitting it to be given to any non-associated formulator,[33] would invariably result in one foreign company giving the material to another foreign company, nullifying the intended effect of the provision.

The government, while declaring its intention to favour the Indian private sector in the drug industry in the matter of capacity regularisation, in fact formulated a policy which only favoured the multinationals. The criterion of regularisation of production in excess of licensed capacity was the following: "the highest production actually achieved in any year during the three year period ending March 31, 1977"[34] was to be treated as regular capacity. In fact the Hathi Committee felt that any regularisation of excess capacities should not be allowed, particularly in the foreign companies. But, the government's decision to consider upto the year 1977, would amount to legalisation of the unauthorised capacities of most of the multinationals since the bulk of the illegal capacity built up prior to 1977 belonged to the multinationals.

2.3.3 Public Sector

The case for a strong public sector gained momentum since the second IPR, as it was believed that state owner-

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32. HCR, Ch.V, para 22.
33. NDP, paras 27.2 and 28.
34. Ibid., para 27.3

ship in the industry would off-set the undue profits to the private companies, particularly to the multinationals. The Hathi Committee's recommendations had reaffirmed this faith in the context of the drug and pharmaceutical industry and suggested that the public sector be given a leadership role.

The new policy, in order to achieve the country's objective of self-reliance and self-sufficiency in the production of drugs and pharmaceuticals, assigned a big role to the public sector.[35] The public sector was also given a major role for the production of capital and technology-intensive bulk drugs which were needed in high quantities and where large scale production was economical. The new policy also laid the responsibility for the distribution of life-saving drugs with the public sector and suggested that all the public sector units should have greater coordination among themselves to meet the demands of the public health services.[36]

The Hathi Committee had identified 117 essential drugs and reserved 34 drugs exclusively for production by the public sector. The new policy, however, reserved 25 drugs for the public sector and 23 for the Indian private sector and about 66 were open for all the sectors.[37] Most of the antibiotics and life saving drugs appear to have been allotted to the public sector with the expectation that it should bring about some positive achievements.

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35. Ibid., para 12.
36. Ibid.
37. Ibid., Annexure I.

The public sector's target, in the new policy, to produce bulk drugs worth Rs.300 crores per year by 1983-84 appears to be an ambitious task, when compared with the present bulk drug production of around Rs.50 crores by the public sector,[38] and demands gigantic and well organized efforts to achieve the target. The Hathi Committee had suggested that the public sector should also take up the production of some specific synthetic drugs which were being imported and whose production was essential. The new policy, however, seems not to have considered this seriously.

The new policy while attempting to put the public sector in a leadership role in the bulk drug production, had no provision to ensure that the public sector does not become a servicing sector for the private industry. The formulation industry of the private sector, dominated by the multinationals which derive their main source of profits through formulation activity depends on the bulk drugs produced by the state owned companies. Hence, it would have been a better proposition for the public sector to start its own formulation activity instead of selling the drugs in bulk form to the private formulators.

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38. For a detailed analysis, see Chapter III below.

2.3.4 Technology and R and D Policy

This area calls for a closer coordination between the national science policy and the sectoral technology policy with a view to promoting in-plant R and D in the industrial units. A national body like the National Committee on Science and Technology (NCST) should govern the overall programme of indigenous research efforts in various sectors with a close collaboration of national laboratories. The Hathi Committee's recommendations are adopted in the new policy in this regard, which announced that with the involvement of the National Chemical Laboratory, the Central Drug Research Institute and the Regional Research Laboratories, the development of indigenous technology would be taken up.[39]

In order to reduce dependence on import of technology in general and in the pharmaceutical industry in particular, the new policy laid down that the public sector units and the national laboratories would be equipped with pilot plants so that they have a strong design and engineering component in their R and D structure.[40]

Since the foreign companies show little interest in tropical drug-research, the new policy accorded highest priority to centrally directed research aimed at discovery of new drugs for treatment of tropical diseases, viz.,

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39. NDP, para 86.

40. Ibid., para 86.

anti-malarials, enthelmintics and so on.[41] The public sector is supposed to set an example, in this respect by investing 5 per cent of its net turnover on R and D activity.

With regard to foreign drug companies, the government decided that the right to determine the import of technology for new bulk drugs by such companies should be vested in the hands of the government and directed the foreign companies even to undertake transfer of technology to the public sector units where national interests justify.[42] This, however, may not cut much ice as the past record suggests. When Hindustan Antibiotics Limited entered into an agreement with Merck of U.S. for the manufacture of streptomycin, it was found that Merck was getting higher 'titre yield' than the HAL (titre refers to the quantity of solution required to convert a compound into another form). Later, the US company was found using a strain very different from that supplied to the HAL and the reason given was that Merck had obtained that strain from Glaxo and the HAL was not entitled to its use.[43] But the fact is that it was Merck's responsibility, according to the terms of the agreement to see that the entire yield in HAL was as that of the original manufacturer. A pertinent question

41. Ibid., para 81.

42. Ibid., para 40; the statements in paras 86, 81 and 40 of the new policy are based on the recommendations contained in the HCR, Ch.V, para 13(t) and Chapter VII paras 22, 36, 37 and 39.

43. See for some more details, C.V. Gopalakrishnan, 'What Role Multinationals?', The Hindu, 23 July 1977, Madras.

can also be raised: if Merck itself was on the look out for another source for improved strains, then how could it undertake to provide improved technology for the HAL? Hence it appears that the multinationals are capable of even defying the terms of agreement and resorting to misleading and dubious practices.

Another policy directive suggests that the foreign companies whose turnover in drugs is in excess of Rs.5 crores per annum should have R and D facilities within the country on which capital investment should be at least 20 per cent of their net block and that they should additionally spend at least 4 per cent of their sales turnover as recurring expenditure on R and D facilities.[44]

2.3.5 Pricing Policy

The pricing policy of drugs as explained in section 2.2 took the form of various control orders since the 1960s, but those could not arrest the price rise effectively. The Hathi Committee which went into the question of pricing of drugs in detail, had recommended that the mark up[45] for the essential drugs should be cut drastically, while more liberal mark up should be allowed for drugs which are not essential. The Hathi Committee had also suggested the identification of a 'leader product' and the fixation of a

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44. A close examination of R and D expenditures by various multinationals shows that some of the large companies, too, do not spend much on R and D. See Chapter IV below.

45. 'Mark up' includes distribution cost, outward freight, promotional expenses, manufacturer's margin and the trade commission. See DPCO 1979, Op. cit., para 11.

'leader price' to such products in different groups.[46]

The new policy which claims to have based itself on an exhaustive examination of these recommendations, announced that all the bulk drugs which are used in the production of price-controlled formulations would be subject to price control. The important drug formulations currently marketed are grouped into four categories. The pricing of formulations in categories I and II are worked out on the basis of product groups of equivalent therapeutic value and makes use of the leader product and leader price concepts. In category III formulations, though separate pricing for each product is adopted, application of the leader price technique is not totally ruled out. The mark ups have been 40 per cent, 55 per cent and 100 per cent respectively for categories I, II and III. Category IV formulations are not subject to price control and hence there is no control over this mark up.

There is no convincing rationale behind the categorisation of formulations, since both life-saving and non-essential drugs are there in all the first three categories. The manufacturers who suffer due to a relatively lower mark up in categories I and II are amply compensated by marketing products in category III. Another important

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46. The criterion of identifying a 'leader product' is on the basis of 60 per cent of the sales, of a product in a therapeutic group, accounted between different manufacturers. Maximum prices may be prescribed on that basis and units may fix prices anywhere within that ceiling. See, Hathi Committee Report, Ch.VIII, paras 36 and 37.

point to be noted here is that almost all the items included in the first two categories are well known and very little promotional expenditure is required for their sale. Category IV formulations are exempted from price control but the price worked out by the manufacturer has to be stated on the label. An average consumer may not know which formulations are controlled and which are not. Hence, the consumer does not have any choice except paying the price stated on the label since it is more than likely that he would proceed on the assumption that it is a controlled price which appears on the label. The government, perhaps, has the intention of subjecting the formulations to competitive forces of the market by removing the price controls. However, this argument does not hold good since almost all the formulations are sold under brand names and hence only the product competition exists, edging out price competition, thus implicitly amounts to a cartel type operation.

While the general pricing policy in the pharmaceutical industry decides the level of multinational domination through market sales a specific policy is required for the public sector since it is a decisive factor in holding the price line in the market. Unless the public sector is in a position to offer competitive prices, it is very difficult to reduce the domination of multinationals, particularly in an industry like the pharmaceuticals.

The Hathi Committee had recommended that the public sector should make drugs available to the large masses at cheaper prices. Some studies had suggested that the pricing policy of the public sector has a rationalizing and stabilizing effect on prices in the drug and pharmaceutical industry.[47] However, the evidence provided in Table 2.1 suggests quite a different picture. A group of seven important products have been selected on the basis of price discrepancies between the public sector and the private (including foreign) sector companies. It is found that the prices of two antibiotics, viz., benzyl penicillin and fortified procaine benzyl penicillin produced by both HAL and IDPL, were higher than those charged by Glaxo by 54 per cent and 50 per cent respectively. Chloramphenicol, another important drug produced by IDPL, is priced 32 per cent higher than the same drug produced by May and Baker. IDPL's price of phthalyl sulphathiazole is exorbitantly high and is 83 per cent more than Dey's Chemicals', an Indian firm. Hence it appears that the public sector pricing policy, instead of having a rationalizing effect,[48] rather helped the MNCs to continue their domination.

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47. P.S. Agarwal et al., Op. cit.

48. Agarwal and others have based their analysis on the retail price differentials of 19 drugs and found that multinational selling prices were 100 to 300 per cent higher than the public sector's. However, this should not lead to any generalization, as suggested above.

TABLE 2.1

PRICE COMPARISONS OF SOME FORMULATIONS PRODUCED BY PUBLIC AND PRIVATE SECTORS.

Sl. No.	Name of the product	Name of the Mfg. unit	Pack Size	Retail price allowed (Rs.)
1.	Benzyl Penicillin inj. Penicillin G. Sodium	IDPL	5 lac' vial	1.05
		Alembic	-do-	0.87
		Glaxo	-do-	0.70
		HAL	-do-	1.08
		IDPL	10 lac' vial	1.55
		Alembic	-do-	1.42
		Glaxo	-do-	1.42
		HAL	-do-	1.58
2.	Fortified Procaine Benzyl Penicillin inj.	IDPL	4 lac' vial	0.88
		Alembic	-do-	0.77
		Pfizer	-do-	0.77
		HAL	-do-	0.93
		IDPL	20 lac' vial	3.38
		Alembic	-do-	2.46
		Pfizer	-do-	2.66
		HAL	-do-	2.75
3.	Streptomycin Sulphate inj. 1 gm	IDPL	1 vial	1.22
		Sarabhai	-do-	1.18
		Pfizer	-do-	1.13
		HAL	-do-	1.23
4.	Chloramphenicol caps. 250 mg.	IDPL	100 Bottle	40.88
		Alembic	109 -do-	32.10
		May and Baker	100 -do-	30.15
		Smith Stanistreet	100 strip	37.67
5.	Thromycin tablets Erythromycin Estolate	IDPL	10s strip	14.80
		Thenis	-do-	13.11
		Anglo French	-do-	15.52
6.	INH tablets 100 mg.	IDPL	1000's tin	33.05
		Pfizer	-do-	30.41
		Sarabhai	-do-	25.99
7.	Phthalyl Sulphathiazole tablets 5 gm.	IDPL	1000's tin	133.78
		May and Baker	-do-	96.20
		Dey's	-do-	72.99

Source: Compiled from answer to USQ No. 1188, by Surendra Bikram, Lok Sabha Debates, August 1979.

Public sector drugs are mainly distributed through government concerns and State agencies and organisations throughout the country. Most of the drugs are not backed by promotional techniques for obvious reasons. Hence, it is difficult for them to compete with the branded products except through competitive prices. It also becomes imperative for the public sector to have a more realistic pricing policy in the light of the declared objectives of providing drugs in plenty at cheaper prices, and loosening the multinationals' stronglehold on the price system.

2.3.6 Abolition of Brand Names

The generic versus brand names controversy has been a long drawn out one in the pharmaceutical industry ever since a case for generic names of drug products arose. The government had partially implemented the Hathi Committee suggestions, by abolishing the brand names of five drugs, viz., Analgin, Aspirin, Chlorpromazine, Ferrous sulphate, Piperazine and its salts such as adipate, citrate and phosphate. The detractors of generic names have always advanced the argument that Pakistan had resiled from its earlier decision to abolish brand names on an ostensible plea that this resulted in a glut of spurious drugs in the market. However, there are so many examples of successful operation of marketing generic drugs, even in advanced countries such as the USA and Canada, that this argument has little validity.

2.4 Centralized Buying

A number of policy measures have been suggested by various supra-national organizations such as OECD, UNIDO, UNCTAD and UNITAR, to reduce the degree of influence of multinationals. One such policy measure which is considered to be significant is centralized buying on a national scale. The case for centralized buying[49] became popular with the experiment by the State Pharmaceutical Corporation (SPC) in Sri Lanka, which is believed to have successfully reduced MNC domination.

A similar measure is adopted in India by the Chemicals and Pharmaceutical Corporation (CPC) of India Limited which is a subsidiary of the State Trading Corporation. It is pointed out that after canalising the drugs through CPC, there were substantial savings in the buying of indomethacin, trimethoprim, gentamycin, doxycycline and metronidazole in 1977.[50] Table 2.2 shows the savings achieved after the CPC had bought the drugs through world-wide tenders. These drugs were further canalized to the individual manufacturers through the CPC itself. However, this had not resulted in any lowering of the retail prices. This might be because of high mark-ups by the CPC and due to the operations of other middle-men.

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49. See, Sanjaya Lall and Senaka Bibile, Op. cit., also in World Development, July 1977.

50. See loc. cit.

TABLE 2.2

SAVINGS DUE TO CANALIZATION OF DRUGS IN INDIA, 1978

Sl. No.	Name of the Drug	Quantity of imports 1977-78 (Tonnes)	CIF Price before canalization (Rs./Kg.)	CIF Price after canalization (Rs./Kg.)	Amount saved (Rs./Kg.)
1.	Indomethacin	1	4320.00	364.83	3955.17
2.	Trimethoprim	2	2060.00	561.34	1498.66
3.	Gentamycin	0.1	70180.00	35378.00	34802.00
4.	Doxycycline	1	2037.00	1608.00	428.12
5.	Metronidazole	20	250.00	152.00	98.00

Source: Answer to Unstarred Question No.1821, by Motibhai R. Chaudhury, Lok Sabha Debates, November 1979.

There is no doubt that the establishment of a nationalised wholesale monopoly might result in substantial savings but this does not always necessarily lead to lower retail prices. Hence a still more comprehensive policy measure is called for in this regard.

2.5 Summary

A coherent drug policy was not in existence till the announcement of the new drug policy. The general guidelines were derived mainly from the Industrial Policy Resolution of 1948 and the Industrial Policy Resolution of 1956. During the Second Five Year Plan period a greater emphasis was laid on the public sector in order to prevent the emergence of monopolies and the concentration of production in a few private industries. The pre-Hathi Committee drug policy was more in the form of legal statutes, price controls rather than in the

shape of a specific policy approach towards achieving self-reliance in production and technology. The questions concerning the foreign participation and transfer of technology were determined by the guidelines set by the RBI and the FERA in the drug industry. Despite the importance given to the public sector and various controls aimed to contain the dominance of multinationals, little was achieved. The Hathi Committee went into different aspects of the drug industry and came out with valuable recommendations in its report in 1975. The Janata government which came to power in 1977, announced the new drug policy in 1978, apparently after the inclusion of some major recommendations of the Hathi Committee.

The new drug policy was definitely a positive outcome in the sense that it contained specific, long-term prescriptions for the pharmaceutical industry. It laid down some important guiding principles, though ambiguous, to reduce foreign domination in the drug industry through assigning a big role to the public sector, providing incentives for the Indian private sector and encouraging indigenous R and D activity. However, a number of loopholes exist in the new policy which may ultimately defeat its objective. The provisions regarding the manufacture of drugs involving high technology, for example, would be thoroughly used by the big private capital (MRTP companies) and the foreign capital for manipulating the RBI guidelines and FERA regu-

lations in regard to equity participation and the setting up of illegal capacities, to the detriment of the declared objectives. The pricing policy in the new drug policy is most arbitrary and gives ample scope for the Indian private companies as well as the foreign companies to take enough advantage out of it. The approach of the public sector towards prices of drugs is in no way better, and indirectly helps the multinationals in maintaining their lead in the market. Abolition of brand names of five important drugs is one positive and bold step of the present policy. However, this may not have much impact since the brand named drug products rule the roost in the entire drug market and the share of the drugs devoid of brand names is very less. Another step which should have had a positive effect is the buying of drugs through global shopping around; this where it has been adopted, has led to lower import costs without any reduction of the retail prices, however.

CHAPTER III

CHAPTER III

ECONOMIC PERFORMANCE AND THE PROSPECTS OF SELF-RELIANCE

A number of studies since the early 1960s,[1] have brought out the oligopolistic structure of the pharmaceutical industry. The basic approach of these studies, generally, is to examine the structure, conduct and performance of the industry. The structure includes such characteristics as seller concentration, barriers to the entry of new firms (such as economies of scale and product differentiation), the conditions of demand and buyer concentration. The market structure determines the conduct of firms in the industry, and that conduct in turn determines the quality of industry's performance.

Probably the most often mentioned element of market structure is industry concentration. Since a market may contain many small sellers having only a small aggregate share of the market and therefore little influence on price; the number of sellers is not important in determining the degree of concentration, some other criterion like the share of the market held by a few top sellers should be used instead. Some of these studies, emphasising oligopolistic structure have brought out that when there are only a few large sellers of a product, each will be

1. See, Michael Cooper, Op. cit.; W.D. Reekie (1975), Op.cit.; G. Teeling Smith (Ed.), Economics and Innovation in the Pharmaceutical Industry, Office of Health Economics, London, 1972; and in the Indian context, see, Sanjaya Lall, Op. cit. (n.5).

reluctant to provoke retaliation by cutting prices. In the place of price competition, firms thus turn primarily to product competition and promotional competition.

Concentration in an industry is itself determined by other elements of market structure. Chief among these factors in the drug industry is a series of barriers to the entry of new firms, such as the role of patents, and R and D based innovational techniques, which result in the monopoly of market by a particular branded drug edging out the smaller firms. Hence the degree of concentration by a few large sellers becomes obvious in such a situation. Another important structural feature in the drug industry is the unique nature of consumer demand, where the consumer cannot make his own choice of the product, but is decided by somebody else, namely, the physician. All these elements of market structure are capable of influencing firm behaviour, and hence industry performance, as would become clearer in the subsequent analysis of the Indian pharmaceutical industry.

3.1 Growth

The total capital investment in the industry increased from Rs.24 crores in 1952 to Rs.200 crores in 1972 and to nearly Rs.450 crores in 1979-80. The production rose from Rs.35 crores to Rs.250 crores and to around Rs.1150 crores in

the respective years.[2] In 1971, 2442 units were engaged in the production of drugs and it rose to 2935 units by the end of 1975 and to more than around 3200 units in 1979. As of May 1978, there were about 136 organized sector units of which 45 were foreign,[3] as compared to 66 foreign units out of 118 in 1975. The reduction in the number of foreign units may be explained in terms of some of the stringent measures taken by the government in reducing the foreign holding. There are 14 companies holding more than 74 per cent foreign equity, 11 companies with above 51 and upto 73 per cent and 13 units with 40 to 51 per cent. Besides these 38, there are 7 more companies in the organized sector, out of which there are branches of foreign companies and the equity break up for the rest is not available. The break up of these 45 companies countrywise is given in Table 3.1.

TABLE 3.1

FOREIGN DRUG COMPANIES IN INDIA

Name of the country	No. of firms
1. USA	18
2. United Kingdom	13
3. Switzerland	6
4. FRG	4
5. Others	4
Total	45

Source: Economic Intelligence Service, Op. cit.

2. Government of India, Annual Reports (various), Ministry of Petroleum, Chemicals and Fertilizers, New Delhi.

3. The term 'foreign' is used in the same sense as defined in the FERA, and as followed by the government for granting licenses and other purposes. Hence, 'foreign' here does not necessarily indicate the degree of foreign control either in technology or in the organisation of a

Though the reduction in the number of foreign companies took place as a result of the government's directives to some foreign companies which were engaged in only formulation activity, the multinational domination still continues to be significant in the industry.

3.2 Assessment of progress towards self-reliance

The assessment of progress towards self-reliance in the pharmaceutical industry is a difficult task, since it involves a number of problems ranging from determining the levels of production to evaluating product and process technologies in particular therapeutic groups, and their total net effect in the drug industry as a whole.

The present study attempts to assess progress towards self-reliance in the Indian pharmaceutical industry on the lines suggested by the Hathi Committee, which were later on incorporated in the new drug policy. The evaluation is taken up in the light of domestic drug production and imports, and the assessment is made at three levels:

(a) the role of multinational companies (foreign sector) in the drug industry in India and their share in the production of bulk drugs and formulations; this is examined in terms of their overall profit ratios, concentration of activity in specific product groups and the amount of repatriation to their principals;

(b) the Indian private sector in the drug industry, its present status and growth in comparison with the foreign sector; a comparison is also made for both the sectors in their market shares and profit ratios; and

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3. contd.
company, except that these 45 companies have an outside equity higher than 40 per cent. Since the data obtained is mostly from the governmental sources further analysis of multinational companies is also carried out in this sense of the definition.

(c) an evaluation of the public sector is made to examine how far it has achieved its assigned task of reducing the quantum of imports and the dependence on foreign companies; through the bulk drug production and the indigenous technological efforts.

The examination of overall performance of the three sectors will throw some light on the degree to which progress towards self-reliance has been made and on the future prospects.

3.2.1 Domestic Production and Imports

One of the important suggestions of the Hathi Committee was that the foreign multinationals were engaged only in producing low-tonnage, high-value drugs and hence they should be directed by the government to see to it that they produce a considerable percentage of bulk drugs alongwith the formulations. This, in the Committee's opinion, could prevent MNCs from extracting enormous profits out of manufacturing only formulations and also would lead to the production of more life-saving drugs. The foreign multinationals have already been producing bulk drugs in larger quantities at least after they had faced the threat of being taken over by the State on the recommendations of the Hathi Committee. Table 3.2 shows the share of various sectors in bulk drug production. The table clearly shows that the foreign sector has complied with the Hathi Committee's recommendations by sharing in a larger measure in bulk drug production.

TABLE 3.2

SHARE OF VARIOUS SECTORS IN BULK DRUG PRODUCTION
(Rupees in Crores)

Year	Public Sector	Foreign Sector	Indian (private) sector	Total production
1975-76	42.77 (32.8)	52.00 (40.0)	35.30 (27.2)	130
1976-77	48.63 (32.4)	63.00 (42.0)	38.37 (25.6)	150
1977-78	46.70 (28.5)	75.44 (46.0)	41.86 (25.5)	164

Source: Calculated from the Annual Reports, 1975, 1976, 1977, 1978 and 1979, Ministry of Petroleum, Chemicals and Fertilizers, Government of India, New Delhi. Figures in brackets show percentage to the total production.

The bulk drug production, however, was not very satisfactory and heavy imports have been resorted to during 1975-79. It has been alleged that some of the drugs imported were also being manufactured by the firms in India and the government's policy was not one of expanding capacities of foreign firms in India but to import directly from abroad.[4] Table 3.3 shows the production of bulk drugs and formulations and imports from 1975 to 1979. It has been indicated in the table that the position in regard to the bulk drugs is far from satisfactory.

4. See, 'Drugs: Are we planning for shortages?', an OPPI release, December 28, 1979.

TABLE 3.3

PRODUCTION AND IMPORTS OF DRUGS DURING 1975 TO 1979
(Rupees in Crores)

Year	Bulk Drugs			Formulations			CIF value of total imports	Total indigenous production
	Indigenous	Imported	Total	Indigenous	Imported	Total		
1975-76	130	39.36	169.36	560	0.74	560.74	40.10	690
1976-77	150	47.03	197.03	700	0.69	700.69	47.72	850
1977-78	164	74.29	238.29	900	1.25	201.25	75.54	1064
1978-79 (estimated)	180	-	-	950-1000	-	-	-	1130-1180

Source: Same as Table 3.2.

While the indigenous production of bulk drugs showed a rise of 38 per cent from Rs.130 crores to Rs.180 crores between 1975 and 1979, the imports increased by about 83 per cent by 1978 itself. The situation becomes more serious when the fact that the responsibility of bulk drug production lies mainly with the public sector is taken into consideration. The public sector has shown a decline even in absolute terms in the production of bulk drugs from 1976-77 to 1977-78, let alone a decline in percentage terms. Equally unimpressive is the record of the Indian private sector with a progressive decline in its percentage share though it has gained in absolute terms during the same period. When we bear in mind the government's plan to extend medical facilities to the countryside, and the projection that by 1983-84 the demand for drugs is expected to go upto Rs.2,100 crores, three times that in 1975-76 and double that of the production estimated in 1978-79 (see Table 3.3) the actual performance hitherto appears even more disappointing.

As the expected demand in 1983-84 is put at Rs.2,100 crores by the Ministry of Petroleum, Chemicals and Fertilizers, the bulk drug requirements in that period will be between Rs.650 and 700 crores worth. This is divded between different sectors as follows: public sector 300 crores; foreign sector Rs.200 crores; and Indian sector (including

small scale) Rs.150 to Rs.200 crores. These targets, however, would appear impracticable to achieve within the next five years and hence more imports will have to be resorted to, but even so the industry must be apprised of what is the minimum expected of it.

In this context it becomes important to analyse the production targets in detail, set by the Task Force of Planning Commission, and the achieved levels of production. Table 3.4 shows select groups of various drugs with their licenced capacities, and the production levels achieved in the period between 1975-and 1979 against the demand targets set by the Task Force.

The general trend of production levels against the set targets provides a grim picture. Of the 18 products shown in the table, production was below 50 per cent of the target set for 1978-79 in products. The production of the product group analgesics and antipyretics (amidopyrin, analgin, phenacetin and paracetamol) in 1978, averaged at 40 per cent below their licenced capacities and 56 per cent below their production targets of 1978-79. The production of sulpha-drugs in the same year was only 34.2 per cent of the production targets. Among antituberculars, one of the important product groups and significant to tropical countries, particularly India, where the degree of undernourishment is high, PAS sodium

TABLE 3.4

LICENSED CAPACITIES, PRODUCTION OF VARIOUS DRUGS IN PUBLIC SECTOR AND THE TARGETS SUGGESTED BY TASK FORCE

(in tonnes)

Sl. No.	Name of the Product	1975[3] lic. cap.	1975[3] Pdn.	1976[3] lic. cap.	1976[3] Pdn.	1977[3] lic. cap.	1977[3] Pdn.	1978[3] lic. cap.	1978[3] Pdn.	Demand Target by[2] 1978-79	Demand Target by[2] 1983-84
1.	Amidopyrin	40	7	40	-	40	7	40	16	20	40
2.	Analgin	260	206	500	278	500	287	500	274	400	800
3.	Phenacetin	412	198	462	163	462	201	475	190	500	800
4.	Piperazine salts	50	92	115	118	166	112	165	74	118	230
5.	Diethyl Carbamazine Cit.	56	7	56	12	56	18	56	23	45	95
6.	Phenocarbitone/Na	15	11	30	16	50	15	50	23	34	70
7.	Sulphacetamide/Na	50	36	-	68	50	35	-	14	80	160
8.	Sulphadimidine/Na	500	425	-	502	500	422	-	261	1010	2020
9.	Sulphaguanidine	250	222	-	195	250	261	250	47	133	145
10.	Sulphanilamide	150	48	150	97	-	-	-	17	-	-
11.	Folic Acid	4	3.42	7.5	4.32	7.5	4.48	7.5	3.62	7.5	15
12.	Vitamin B1	60	29	120	33	120	33	120	29	100	200
13.	Vitamin B2	15	5	24	7	24	7	24	7	24	48
14.	Paracetamol	431	153	543	176	653	222	650	157	400	800
15.	PAS Sodium	860	620	1110	700	1170	560	1290	558	1000	1200
16.	Sulphamethizole	7	Nil	7	Nil	7	1	7	6	12	23
17.	Thiacetazone	133	17	153	17	153	25	153	13	153	140
18.	Sulphaphenazole	50	65	153	179	-	126	-	92	180	350

Sources:

[2] = Taken from Hathi Committee Report (Annexure VI, Ch.III).

[3] = Compiled from Annual Reports, 1976, 1977, 1978 and 1979. Ministry of Petroleum, Chemicals and Fertilizers, Government of India, New Delhi.

registered 22 per cent and thiacetazone, somewhat better with 55.8 per cent of their production targets in the same period. Anthelmintics, vitamins, tranquillizers (ataractics) showed no better progress. With these facts, it appears that the achievements of the targets set for 1983-84 by the Task Force, which are just twice the size of the targets set for 1978-79, will be a formidable task, if not an impossible one.

Having brought to the fore certain general trends in pharmaceutical production and imports, we have to examine a number of questions concerning the patterns of production by various sectors and their contribution towards the self-reliance drive.

3.2.2 Multinational (Foreign) sector

The foreign sector, as has been said earlier, had shared a fair percentage in bulk drug production. Does this alone indicate a progressive trend? This has to be examined in detail. There are 45 major foreign multinational pharmaceutical companies operating in India. The countrywise break up is already provided in Table 3.1. These multinationals follow more or less the same behaviour regarding production, market sales and R and D in a majority of the underdeveloped countries throughout the world. Table 3.5 shows the top 25 foreign companies rankwise according to their sales turn over in India. The

TABLE 3.5

THE TOP 25 PHARMACEUTICAL MNCs IN INDIA, 1976[1]

Rank	Company's Name	Domicile	Net sales (Rs. in lakhs)	
1.	Glaxo	UK	4,748	(6,749)[2]
2.	Ciba-Geigy	Swiss	3,319	
3.	Pfizer	USA	2,992	(4,155)[2]
4.	Hoechst	FRG	2,536	(5,435)[2]
5.	Sandoz	Swiss	2,217	(3,360)[2]
6.	Suhrid-Geigy	Swiss	2,090	
7.	Geoffrey-Manners	USA	1,839	
8.	Cynamid	USA	1,629	
9.	Parke-Davis	USA	1,341	
10.	Abbott	USA	1,325	
11.	Smith, Kline and French	UK	1,102	
12.	Burroughs Welcome	UK	1,040	
13.	Richardson-Hinduetan	USA	1,001	(1,176)[2]
14.	Boots	UK	959	(1,282)[3]
15.	Roche	Swiss	955	
16.	Merck, Sharp and Dohme	USA	928	
17.	May and Baker	UK	876	
18.	Warner-Hindustan	USA	825	(1,432)[2]
19.	German Remedies	FRG	756	(1,052)[ε]
20.	Bayer	FRG	640	
21.	Boehringer-Knoll	FRG	632	
22.	E. Merck	FRG	625	
23.	Johnson and Johnson	USA	615	
24.	Raptakos Brett	UK	612	
25.	Organon	Netherlands	505	

Source: Company Annual Reports, Economic Times 26-8-1977, New Delhi, EPW, 1978, 1979, 1980 (various issues).

1 = Refers to fiscal 1975-76
2 = Figures in brackets correspond to 1979
3 = Figures in brackets correspond to 1978
ε = Figures in brackets correspond to 1977

precise measure of size of the firms has been provided by the sales volume of ethical drugs. Sales volume appears to be the most practical parameter since the industry is not overtly capital intensive in structure and assets lie mainly in intangibles such as patents, and capability of research teams to innovate rather than in plant machinery and land. Due to the structure of the industry where no company derives all revenues exclusively from the sales of ethical drugs, overall profitability is an impractical measure of size. Among the top twenty transnationals Glaxo laboratories (UK) could successfully maintain its lead since 1975 in India. In 1979, Hoechst (FRG) had forced Ciba-Geigy and Pfizer to third and fourth positions respectively while itself taking second position. Hoechst however, maintained the largest net sales turnover in the world market with 1,572.9 million US dollars (in 1977) while Merck (US), Bayer (FRG), Ciba-Geigy (Swiss) and Hoffman-La Roche (Swiss) followed in the descending order (in the same year). Glaxo the topper in India could secure only the eighteenth position in the world market, despite the fact that the company specializes in a larger number of product lines than other companies.[5] The United States accounted for the largest share of total sales in the Indian drug market as it did in the world pharmaceutical

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5. See, for details, Table 1.2 above.

market. Interestingly the contrywise shares of the multinationals in India are almost similar to the situation prevailing in the world market; that is, the US takes the largest share followed by Swiss, German and English companies, though the English do not figure prominently in the international pharmaceutical market.

According to one estimate,[6] the pharmaceutical market share held by domestic firms in India, in 1975 was 25 per cent whereas the remaining 75 per cent was held by the foreign firms. The foreign companies continued to enjoy almost a similar status even after the submission of the Hathi Committee Report and the consequent measures taken by the Government. Their major activity continued to be formulations, though occasionally it is balanced with bulk drug production, earning enormous profits and a substantial amount out of these profits has been repatriated abroad resulting in the loss of foreign exchange to the national exchequer. Data are available for some 28 foreign companies regarding the amount of remittances abroad in the fiscal year 1976; these are furnished in Table 3.6, alongwith foreign holdings of these 28 companies. The other details such as equity, total capital employed, gross fixed assets, not fixed assets, cash flows, interest, etc., have been avoided in order to focus attention mainly on the activity and performance rather than on the financial balance sheets of the companies.

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6. Leif Schaumann, Pharmaceutical Industry Dynamics and Outlook to 1985, Stanford Research Institute, California 1976, Table 3, p.13.

TABLE 3.6

REMITTANCES ABROAD TO THEIR PRINCIPALS BY FOREIGN FIRMS IN INDIA, 1976

Sl. No.	Name of the firm	Foreign holding (%)	Remittances abroad as dividends, royalty, technical fees, etc. (Rupees in lakhs)
1.	Pfizer	75	94.86
2.	Glaxo	75	86.44
3.	Cyanamid	65	77.14
4.	Alkali and Chemicals Corpn	60	54.30
5.	Parke Davis	83.33	49.67
6.	Smith, Kline and French	Branch	47.83
7.	Ciba-Geigy	65	34.18
8.	Burroughs-Wellcome	100	33.20
9.	Roche	89	30.67
10.	Bayer	53	23.28
11.	Hoechst	50	20.36
12.	Geoffrey-Manners	45	20.32
13.	Warner-Hindustan	50	19.92
14.	Abbott	100	16.36
15.	Richardson-Hindustan	55	14.14
16.	Johnson and Johnson	75	13.97
17.	Merck, Sharp and Dohme	60	12.26
18.	Sandoz	60	11.46
19.	Wyeth	74	11.13
20.	Boots	58	6.75
21.	Organon	49	5.57
22.	Beecham	100	3.79
23.	E. Merck	60	3.18
24.	Indian Schering	88.6	1.97
25.	Anglo-French Drug	80	0.90
26.	Suhrid Geigy	47.5	0.45
27.	Carter Wallace	49.46	0.36
28.	Whiffens	50	0.21

Source: Compiled from answer to Unstarred Question No.1231, Lok Sabha Debates, July 1979.

The 28 companies listed in the table have repatriated Rs.695.67 lakhs in 1976, to their principals abroad and data for the rest of the companies are not available. The gross remittance is the highest for Pfizer (Rs.94.86 lakhs) followed by Glaxo (Rs.86.44 lakhs). But the amount of remittances as a per centage of sales turnover would reveal a different trend of repatriation. Cynamid with 65 per cent foreign holding had remitted 4.5 per cent of its sales turnover to its principal abroad followed by Smith, Kline and French (UK) which is a branch, with 3.8 per cent. The other companies which followed in the descending order were Burroughs-Welkome 3.25 per cent, with 100 per cent foreign holding, Parke-Davis 3.1 per cent, with 83 per cent foreign holding, Roche 2.7 per cent with 89 per cent foreign holding and finally Glaxo with 75 per cent foreign holding has repatriated only 1.3 per cent. The 28 companies together have repatriated, generally, between 1.5 and 3.5 per cent of their sales turnover approximately.

Profitability has been very high for the foreign companies compared to the Indian private and the public sector companies. Their gross profits rose from Rs.45 crores to Rs.53 crores in 1976. Profitability as measured by gross return on total capital employed also stood higher at 23.4 per cent in 1975-76 as against 20.7 per cent in the previous year (see Table 3.7). The multinationals maintained higher profit margins due to adjustments in overhead costs

TABLE 3.7

PROFITABILITY OF FOREIGN COMPANIES IN INDIA, 1976-79

Sl. No.	Name of the Company	Year	Gross profit (Rupees in lakhs	Net Profit (Rupees in lakhs)	Profit as percentage of gross sales	Net profit as percentage of total capital employed
1	2	3	4	5	6	7
1.	Warner-Hindustan	1976	154	55	17.26	15.54
		1977	213	72	20.46	19.68
		1978	254	77	20.03	21.69
		1979	291	83	20.32	20.85
2.	Searle (India)	1976	56	26	20.59	21.85
		1977	62	22	20.60	16.54
		1978	65	23	17.76	21.67
		1979	95	42	20.13	20.69
3.	Sandoz (India)	1976	415	79	15.13	14.42
		1977	556	112	16.55	17.47
4.	Richardson-Hindustan	1976	145	41	14.54	11.03
		1977	206	53	19.00	25.23
		1978	220	45	17.96	20.55
		1979	118	25	10.03	11.06
5.	Glaxo Laboratories	1976	552	206	12.21	9.07
		1977	784	301	15.35	16.74
		1978	923	326	15.80	12.64
		1979	1107	383	16.40	13.88
6.	Boots (India)	1976	127	32	13.20	22.09
		1977	167	55	15.06	18.08
		1978	216	73	16.84	21.10
7.	Duphar-Interfran	1976	52	15	9.14	13.59
		1977	71	20	12.91	13.00
		1978	97	35	14.92	19.66
8.	Boehringer-Knoll	1976	91	36	13.00	17.80
		1977	90	31	12.26	17.32
		1978	73	21	9.46	11.11
		1979	59	17	7.18	8.76
9.	Hoechst	1976	281	123	11.07	17.39
		1977	-	-	-	-
		1978	232	79	4.58	17.80
		1979	258	86	4.73	17.16
10.	Pfizer	1976	727	232	20.26	23.23
		1977	722	291	21.03	14.55
		1978	799	264	20.54	13.86
		1979	758	271	18.24	13.52
11.	Cynamid	1976	526	149	32.28	41.08
		1977	-	-	-	-
		1978	494	175	27.06	18.83
		1979	444	154	22.67	16.09

contd.

1	2	3	4	5	6	7
12.	Ciba-Geigy	1976	381	220	11.46	13.50
13.	Suhrid-Geigy	1976	255	50	12.21	6.75
14.	Geoffrey Manners	1976	190	78	10.31	22.56
15.	Parke-Davis	1976	192	56	14.33	14.37
16.	Roche	1976	161	55	16.91	12.54
17.	Merck, Sharp and Dohme	1976	106	27	11.39	9.70
18.	German Remedies	1976	159	44	17.41	22.11
		1977	180	54	17.11	22.88
19.	Anglo-French	1976	11	1	3.73	2.00
20.	Ethnor	1976	52	13	18.54	25.67
21.	Indian Schering	1976	52	13	11.92	14.21
22.	Johnson and Johnson	1976	133	31	16.38	19.05
23.	Roussel	1976	32	7	8.83	9.21
24.	Wyeth Laboratories	1976	116	28	25.86	21.00
25.	Curewell	1976	11	5	21.96	7.76
26.	Orgenon	1976	95	23	18.74	16.10
27.	US Vitamin	1976	25	5	10.42	12.45
28.	Wander	1976	19	4	12.00	12.08
29.	Raptakos Brett	1976	32	(-) 1	5.27	(-) 0.99
30.	Dental Products	1976	10	3	30.71	16.42

Source: Same as Table 3.5.

of production aided by price revisions. Shortages of vital bulk drugs and the resulting scarcity of some medicines provided a convenient opportunity to assess the market potential with a view to concentrating on high pay-off formulations. The recent price revisions which were based more on the movement of prices of bulk drugs rather than on other costs of production also helped the foreign units considerably. It needs to be pointed out that although profit margins of the 'market leader' as identified by the Hathi Committee, have fallen steadily since 1971-72, they still rule high. The profitability of some companies, it is shown in Table 3.7, had levelled off and even declined steeply in certain cases during the earlier years of the current decade. However, this was only a short-term phenomenon and most of the drug multinationals recovered considerably in the later period, i.e. since 1974-75 onwards. Among the 30 foreign units, 17 units were able to show improved results during 1974-79. A few units such as Cynamid, Dental Products and Wyeth Laboratories could perform better than many other companies. In fact the branches and subsidiaries of foreign companies had higher profit margins than the regular joint-ventures and foreign equity firms. The gross return on total capital employed for the foreign sector was 23.1 per cent in 1975-76, 22.8 per cent in 1976-77 and 22.3 per cent in 1977-78.

The foreign companies obtained higher profitability ratios through product differentiation, certain companies being monopolistic in some specific branches of production. The drug industry as a whole had lower profit margins than the foreign sector alone. The profit ratio for all the three sectors together in the drug and pharmaceutical industry has been fluctuating between 15.9 and 16.4 per cent during 1976-79.

The high returns for the foreign companies were also attributed to the diversified nature of some units. The strength of the affiliates of MNCs in India lies in the broad product diversification. For those companies that want to diversify out of pharmaceuticals, cosmetics, household products, and general health-care products and services have been the most common routes. However, few companies obtain the majority of their income from more than three to four therapeutic groups. This is possible due to the fact that foreign drug companies have both the resources and the expertise available to cover specific therapeutic groups through intensive research.

Diversification patterns in the pharmaceutical industry are extremely complex. Every form of diversification — horizontal, vertical, forward and backward or concentric has been used as a definite strategy to enter, leave and consolidate positions within the pharmaceutical industry.[7]

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7. B. James, Op. cit., p.37.

It should be emphasized that the majority of companies which have diversified into the pharmaceutical industry from both technologically related and unrelated areas, have used the acquisition of a going concern as a major entry strategy, the classic examples in India being ICI, Alkali and Chemicals Corporation, Carter Wallace and so on.

Another major strategy of the multinationals in India, apart from diversification, has been for each one of them to concentrate on no more than three or four major therapy areas; each therapy area therefore tends to be dominated in both sales volume and new product innovation by a small group of multinational companies. Table 3.8 shows the major multinational pharmaceutical companies dominating selected therapeutic areas in India. Some twenty major multinationals dominated the twelve important therapeutic areas in 1978.

The MNCs' main concentration continues to be formulation activity, inspite of the Hathi Committee's recommendation that they should produce important bulk drugs for tropical diseases, particularly to suit Indian conditions. Table 3.9 shows that only seven of the current fortyfive foreign companies contribute to this production and that too only a meagre share.

TABLE 3.8

MAJOR MULTINATIONAL PHARMACEUTICAL COMPANIES IN INDIA DOMINATING SELECTED THERAPEUTIC AREAS, 1978

Therapy Area	Name of the Company
1. Analgesics	Roche Bayer Burroughs-Wellcome
2. Anthelmintics	Ciba-Geigy Abbott May and Baker
3. Cardiovascular agents	Boehringer-Knoll Ciba-Geigy Hoechst Merck Sandoz
4. Antibiotics	Pfizer Lederle Parke-Davis Hoechst Cynamid
5. Dermatologicals	Ciba-Geigy Glaxo Indian Schering May and Baker
6. Hormones	Lederle Merck Roussel Searle
7. Non-steroidal anti-inflammatory agents	Boots Ciba-Geigy Merck
8. Oral contraceptives	Parke-Davis Organon Searle Warner-Hindustan
9. Psycho therapeutics	Roche Pfizer Merck Johnson and Johnson
10. Respiratory agents	Boehringer-Knoll Glaxo Richardson-Hindustan
11. Vitamins	Roche Merck Dumex

Source: Worked out by the author on the basis of B.James, Op.cit., Chap.3.

TABLE 3.9

BULK DRUGS FOR TROPICAL DISEASES PRODUCED BY MNCs IN INDIA

Name of the drug	Name of the producer	Production during 1976-77 (in tonnes)	1977-78 (in tonnes)	1978-79 (in tonnes)	Estimates for full year
(a) Fatidysentery and Anti-Amoebic					
1. Phthalyl Sulphathiazole	May and Baker	6.15	8.34	NA	-
2. Indochloro-hydroxy quinoline	Synbiotics	1.99	0.25	0.79	-
3. Di-iodo-hydroxy quinoline	May and Baker	2.65	0.15	NA	-
	Synbiotics	Nil	0.45	NA	-
4. Metronidazole	May and Baker	4.58	7.65	7.34	12.00
5. Intestopan substance	Sandoz	40.66	34.18	29.97	35.00
(b) Antimalarials					
1. Chloroquin Phosphate	Bayer	24.25	30.29	22.52	30.00
2. Amodiaquin	Parke-Davis	21.27	18.20	12.48	24.00
(c) Antifilarials					
1. Diethyl carbamazine citrate	Burroughs Wellcome	10.10	13.11	11.70	14.00
	Uni-UCB	5.18	5.40	5.45	8.50
(d) Anti-leprotic					
1. Dapsone	Burroughs Wellcome	13.59	13.75	8.44	15.00

Source: Answer to Unstarred Question No.7289, by Jyotirmoy Bose, Lok Sabha Debates, July 1979.

3.2.3 Indian (private) sector

The Indian private sector assumes a preferential position in the government policy, since the Hathi Committee recommendations are taken into consideration. However, the Indian companies are much behind the MNCs whether in terms of sales turnover or in terms of total capital employed. The capital assets of Indian owned private units excluding the MRTP companies constitute less than 25 per cent assets than the foreign sector.[8]

Table 3.10 details the data relating to 10 wholly Indian-owned units. These companies do not have any foreign tie-ups, technical, financial or otherwise. While the foreign multinationals flourished with high levels of profitability ratios Indian companies lag far behind them. Though profitability for the Indian companies had not been as high as for MNCs, some of them had certainly offered a stiff competition in product-promotion and sales turnover. Alembic Chemicals, for example, was the fifth largest firm in the industry, measured by its sales turnover, which was Rs.2,217 lakhs in 1976 (compare with Table 3.5). Other Indian firms which also had a respectable standing in terms of sales turnover, are Unichem Laboratories with Rs.780 lakhs (15th), Standard Pharmaceuticals with Rs.734 lakhs (17th), East Indian Pharmaceuticals with Rs.692 lakhs (18th) and Ranbaxy Laboratories with Rs.532 lakhs (21st).

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8. See, The Bombay Stock Exchange Directory 1978, Vol.14, Bombay.

TABLE 3.10

SALES AND PROFITABILITY OF TEN MAJOR INDIAN PHARMACEUTICAL FIRMS, 1974-76

Name of the Company	Year	Net sales (Rupees in lakhs)	Gross profit as percentage of sales	Net profit as percentage of net worth
1. Alembic Chemical Works	1974-75	1,907	6.87	4.75
	1975-76	2,217	9.42	8.58
2. Amrutanjan	1974-75	219	8.05	9.63
	1975-76	335	15.78	21.61
3. Bengal Immunity	1974-75	272	- 2.61	- 37.41
	1975-76	266	- 4.05	- 135.06
4. Cipla Labs	1974-75	206	6.15	6.54
	1975-76	237	8.05	8.59
5. Chemo-Pharma	1974-75	225	-11.80	-
	1975-76	205	6.91	-
6. East India Pharmaceuticals	1974-75	583	6.38	10.54
	1975-76	692	6.83	10.54
7. Ranbaxy Labs	1974-75	410	7.83	8.86
	1975-76	532	10.46	15.36
8. Standard Pharmaceuticals	1974-75	643	5.48	- 7.70
	1975-76	734	6.02	1.65
9. Unichem Labs	1974-75	674	5.98	8.21
	1975-76	780	8.21	6.12
10. Zandu Pharmaceuticals	1974-75	186	5.76	6.54
	1975-76	205	6.36	5.10

Source: Same as Table 3.5.

Some of the Indian companies' product-promotion techniques and sales network are in no way inferior to MNCs. Alembic's 'Glycodin' has been the most advertised cough syrup and offers tough competition to Richardson-Hindustan, Parke-Davis, Abbott, Pfizer and Bayer, which have similar products with various brand names and varied syrup-bases. Unichem's 'uni-enzyme' and Ranbaxy's 'Garlic Pearls' have set examples in business management. 'Roscillin' manufactured by Ranbaxy has been priced higher than some of the MNCs in the similar range and still could sustain the market with impressive sales. The product-promotion expenditure (advertising, publicity, detailing, etc.) is higher for those Indian units which manufacture household remedies, tonics, nutrients, etc. Amrutanjan's advertising expenditure as a percentage of net sales income in 1976 was 7.7 per cent, next only to 8.9 per cent of Richardson-Hindustan, which was the highest in that year. Other Indian companies, Alembic Chemicals, East India Pharmaceuticals and Ranbaxy Laboratories spent 2.2 per cent, 1.5 per cent and 1.5 per cent respectively of their sales income.[9]

When compared with Table 3.5, it can be seen that the largest increase of 52.7 per cent in sales income in 1976, was recorded by Amrutanjan, an Indian company followed by Roussel (33.8 per cent), Indian Schering (32.5

9. See, Company Annual Reports, 1977.

per cent) and Ranbaxy another Indian firm (9.5 per cent). In terms of conventional parameters like profit ratios, whether on sales or on net worth (paid up capital plus reserves), or as gross return to total capital employed, some of the Indian units fared well. However, it should not be inferred from this that the general performance of the Indian private units was better than the foreign units as such; it only shows that some individual large firms in the Indian private sector did obtain higher profit margins. While considering the drug industry as a whole the performance of the foreign sector is much ahead of the Indian private sector. Taking both tables 3.7 and 3.11 into account, Cynamid recorded the largest profit ratio of 41.1 per cent on total capital employed in 1976, followed by Ethnor (40.7 per cent), Dental Products (36.9 per cent) and Amrutanjan (36.2 per cent). One of the oldest Indian units Bengal Immunity registered a negative profit of -135.06 on net worth.

The small-scale companies have been acting only as feeder links to large Indian companies and/or to foreign multinationals. Most of the small scale firms manufacture only household remedies, cosmetics, creams with petroleum-jelly base, dermatologicals, purgatives and laxatives. In the majority of cases they supply only drug intermediates to large Indian or foreign companies. Since the formulation activity does not require much capital and technology,

the Indian private sector, whose performance, though not yet comparable to the multinationals, has shown an appreciable improvement, should be able to meet the demand for formulations to a major extent. The large units with foreign holdings should get involved in more capital intensive and technology intensive projects in the long-term interests of the drug industry as a whole.

3.2.4 Public Sector

The setting up of Hindustan Antibiotics Limited (HAL) in 1954 at Pimpri and the subsequent establishment of Indian Drugs and Pharmaceuticals Limited (IDPL) at Rishikesh and at Hyderabad in 1962, was meant to challenge the multinationals' domination of the drug industry and their continued monopoly of technological innovations in production process; it represented the government's determination to achieve self-reliance through participation in production. The HAL was assisted by the World Health Organization and the UNICEF in the formative stages. Later on it turned towards American Home Products for technical assistance to produce semi-synthetic penicillins in India. Pfizer and Glaxo also provided technical knowhow in the subsequent periods. The IDPL also entered into an agreement with the USSR to manufacture synthetic drugs and the production of such drugs commenced from 1968. The HAL and the IDPL together with the Kerala State Drugs and Pharma-

ceuticals had a paid up capital of Rs.55.20 crores in 1975-1976 and their gross profits amounted to Rs.4.29 crores and net profits to a meagre of Rs.0.21 crores in the same year.[10]

The Hathi Committee assigned a big role to the public sector by reserving three antibiotics and 34 synthetic drugs, out of the 117 essential drugs, exclusively for the public sector. However, the new drug policy reserved only 25 out of 114 drugs in favour of the public sector. Out of the total target of Rs.168 crore worth of bulk drugs by the end of the Fifth Five Year Plan period, the Committee recommended production of Rs.78 crore worth of bulk drugs by the public sector. The main operations of the IDPL centre on four areas: bulk drugs, formulations, marketing imported bulk drugs and surgical instruments. Of the total turnover of Rs.58.5 crores during 1975-76, Rs.29.6 crores worth of formulations and Rs.18.0 crores of bulk drugs were produced, whereas the sale of surgical instruments amounted to Rs.0.6 crores. The remaining Rs.10.3 crores was accounted for by the import of bulk drugs.[11] A close scrutiny of the working results of the IDPL during 1975-76 showed a higher profit amounting to Rs.3.54 crores compared to 1974-75 when the profits were Rs.3.41 crores.[12] The increased profits during 1975-76 were attributed to an improvement in the performance of the Rishikesh plant which recovered from a loss of Rs.2.67 crores in 1974-75 to a Rs.12 lakh profit in 1975-76.

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10. Director's Reports, IDPL and HAL, 1977.
11. Ibid.
12. Ibid.

The HAL obtained meagre profits until the 1970s and later on it has been continuously incurring negative net-profit after tax.[13] This trend is shown in Table 3.11 below.

TABLE 3.11

TREND OF LOSSES IN HAL

Year	Loss (Rs. lakhs)
1973-74	148.21
1974-75	327.96
1975-76	291.75
1976-77	67.74
1977-78	222.25
1978-79	260.78 (estimated)

Source: Answer to Unstarred Question No. 46, by Vijaykumar N. Patil, Lok Sabha Debates, September 1979.

The reason for continued losses in that unit, apart from underutilized capacities, could not be traced to any specific factor as such.

The low turnover ratio witnessed for the public sector as a whole is partly due to over-capitalization necessitated by the high cost of capital goods. The more important question relates to the choice of technology, choice of investment in right product mix, and cost of importing technology to obtain the optimum benefits to the economy.

13. Some could not visualise this tendency and continued to argue that the profitability in HAL was high. See, for example, B.V. Ranga Rao, Indian Drug Industry: Its Status and Perspectives, Centre for Studies in Science Policy, JNU, New Delhi, 1975, pp. 9-10.

For instance, investments made in chlorotetracycline hydrochloride of the IDPL turned out to be infructuous. Probably there was some resistance by the medical profession against the use of chlorotetracycline hydrochloride for human treatment.

3.2.5 Utilization of Capacities

Optimal utilization of capacities and judicious selection of production items, is the key factor to achieve self-reliance at a faster pace in any industry. Ironically, the Indian drugs industry suffers from two basic maladies: excess capacity utilization in less demanded formulations; and under-capacity utilization of life-saving bulk drugs.

The MNCs have earned the notoriety of resorting to various unhealthy practices to extract undue profits. In India one of their well known strategies, has been to produce drug intermediates in excess of their licensed capacities, which can later on be used in manufacturing high-value formulations. Table 3.12 clearly brings out this aspect and shows that some nine prominent foreign companies have produced around some 14 drugs and intermediates in excess of their licensed capacities. Some of the drugs produced in excess are vitamins and intermediates used in topic preparations.

While multinationals thrive on excess capacity utilization, just the opposite phenomenon can be witnessed in

TABLE 3.12

EXCESS PRODUCTION OF CERTAIN DRUGS BY MNCs, 1976-77

Sl No.	Name of the Company	Items	Unit	Permissible capacity	Actual production	Excess production
1.	Burroughs Wellcome	1. Biphenium Hydroxynaphthoate	Kgs	6250	13407	7157
		2. Diethyl Carbamazine Citrate	,,	2500	6034	3534
2.	May and Baker	1. Promethazine HCl (Base pure)	,,	1250	1351	101
		2. Promethazine 8-Chlorothiophyllinate	,,	750	906	156
3.	Pfizer	1. Tetracycline	Tonnes	17.5	46.26	28.76
		2. Protein Hydrolysate (for Protinex)	,,	137.5	239.7	102.2
4.	Bayer	1. Chloroquin Phosphate	,,	15	24.23	9.23
5.	Cynamid	1. Tetracyclines	,,	12.5	21.17	8.67
6.	Roche Prdts.	1. Dihydroemetine dihydrochloride	Kgs	118.75	395.00	276.25
7.	Ciba-Geigy	1. Antrenyl	,,	518.75	769.00	250.25
		2. Nepresol	,,	623	1138	513
8.	Wyeth Labs	1. Corticosteroids (Prednisolone)	,,	900	1186.6	286.6
		2. 17-Alpha Hydroxy Progesterone Caproate	,,	337.50	525.65	188.15
9.	Sandoz	1. Calcium Gluconate etc.	Tonnes	200	226.75	36.75

Source: Answer to Unstarred Question No.1332, by Jyotirmoy Bosu, Lok Sabha Debates, October 1979.

the public sector. Tables 3.13a and 3.13b bring out the details of installed/licensed capacities for various drugs and actual production from 1975-76 to 1978-79 in the IDPL and the HAL. A scrutiny of both the tables gives a grim picture of the public sector performance in production. The IDPL Rishikesh did not achieve full capacity utilization in any of the drugs and it is very difficult to fulfil this task, as is evident from the gradual decline of production figures from 1975-76 onwards. The performance of the IDPL Hyderabad is somewhat better. The Synthetic Drugs Plant could produce near installed capacities in some of the drugs; and in vitamins, analgesics and psychotherapeutics it even exceeded the capacity. But the overall performance remains disappointing, in the year 1978-79 the production of drugs was nowhere near their licensed capacities and some drugs were not even in production either at the IDPL or at the HAL. The production of aureofungin and hamycin the outcome of indigenous research and development is yet to commence at the HAL.

The reasons for under-utilization of capacity in the industrial sector as a whole are very difficult to establish and they vary from industry to industry and sector to sector. A Federation of Chamber of Commerce and Industry study[14] enlisted the factors contributing to under-

14. See, for details, IDMA Bulletin, Vol.6, No.20, May 1975, Indian Drug Manufacturers Association, Bombay.

TABLE 3.13a

INSTALLED CAPACITY AND OUTPUT OF BULK DRUGS AT IDPL

S.No.	Name of the drug	Installed capacity (in MMU units)	Actual production during 1975-76 (in MMU Units)	1976-77 (in MMU Units)	1977-78 (in MMU Units)
	IDPL Rishikesh				
1.	Potassium Penicillin (saleable)	32.200	4.297	23.750	8.119
2.	Sodium Penicillin	53.000	37.324	20.980	37.435
3.	Procaine Penicillin	52.000	17.552	19.392	30.699
4.	Streptomycin Sulphate	85.000	45.615	44.924	39.051
	IDPL Hyderabad				
1.	Sulphanilamide	...	58.920	12.10	14.05
2.	Sulphaguanidine	250.000	183.050	244.00	185.70
3.	Sulphadimidine	500.000	472.935	471.00	309.75
4.	Vitamin B1	30.000	27.725	33.05	34.94
5.	Vitamin B2	5.000	5.000	6.88	7.81
6.	Folic Acid	2.500	3,633	4.42	4.61
7.	Analgin	200.000	225.282	281.02	302.85
8.	Amidopyrine	...	4.367	2.46	10.93
9.	Nicotinamide	20.000	...	...	...
10.	Phenobarbitone	10.000	10.221	12.55	18.51

Source: Answer to Unstarred Question No.286 by Govinda Munda, Lok Sabha Debates, June 1979.

TABLE 3.13b

LICENSED CAPACITY AND OUTPUT OF IDPL AND HAL

Sl. No.	Name of the drug	Annual licensed capacity (in tonnes)	Production during 1978-79 (in tonnes)
A.	IDPL		
1.	Sulphenilamide	150	18.14
2.	Sulphaquanidine	250	90.40
3.	Acetazolamide	25	1.47
4.	Amidopyrine	40	10.79
5.	Vitamin B1	120	29.28
6.	Vitamin B2	24	6.45
7.	Folic Acid	7.5	3.23
8.	Sulphamethizole	12	4.85
9.	Sulphadimethoxine	30	Not in production
10.	Diallybarbitone	10	-do-
11.	Sulphamethoxy-pyridazine	20	-do-
12.	Griseofulvin	6	560.85 kgs
B.	HAL		
1.	Hamycin	250 kgs	Not in production
2.	Aureofungin	5	-do-

Source: Answer to Unstarred question No.8271 by Shankersinghji Vaghela, Lok Sabha Debates, August 1979.

utilization of capacity in various industries. Some of the general and common constraints are shortage of power, inadequate supply of raw materials, irregular supply of coal, transport bottlenecks, adverse industrial relations and credit squeeze. The slackening of demand and consequent accumulation of stocks (stock-piling) are also other reasons. None of these reasons, however, seem to be the main factor for underutilized capacities in the public sector pharmaceutical units. Most of these factors viz., power supply and coal supply are unlikely to have meant much in the context of the pharmaceutical industry as they do not by and large figure prominently in the production process of drugs and pharmaceuticals except in the manufacture of some important antibiotics, sera and vaccines.

The public sector policy in regard to the bulk drug production and their subsequent disposal to the private formulators, invited wide ranging criticism. It has been argued that many of the policies of individual public sector pharmaceutical units are such as to consign the public sector to playing the role of servicing the private sector units, including multinational companies.[15] The Eightieth Report of the Committee on Public Undertakings (Fifth Lok Sabha) brought out how the HAL had deliberately restricted its own production of formulations so as to be

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15. 'Public sector at Private Sector's Service', EPW, Vol.11, No.19, May 8, 1976, p.678.

able to sell as large a proportion of its output in bulk form to private companies as possible, even though it is more profitable for the HAL to sell its output as formulations than in bulk form. The Committee summed up its findings as follows:

> The Committee are constrained to conclude that by showing excessive concern for the requirements of private viallers and by keeping HAL's formulation capacity underutilized through this period, the administrative Ministry as well as HAL have not acted as the guardian and promoter of the interests of the public sector but have rather helped the private firms, particularly the foreign firms, to earn huge profits at the expense of the public sector and national interest.[16]

Hence it appears that despite the assigned objectives and massive capital support from the State, the public sector did not rise upto the expectations detailed in either the Second Plan or in the Hathi Committee Report.

3.3 Summary

The growth of the pharmaceutical industry in India is characterised mainly by (a) the domination of multinationals whose main interest is to maximize profits through the production of less relevant high value medicines and to repatriate a large part of the profits abroad, and (b) a tiny less capable Indian private sector alongwith a non-performing public sector whose emphasis on the bulk production was taken advantage of by the multinationals.

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16. Ibid. (Emphasis added).

Despite the impressive record of the bulk drug production by the public sector and the foreign sector did not result in reduction of quantum of imports. Contrarily the imports increased by about 83 per cent during 1978 itself. In such a dismal state of performance, it is not surprising that the drug industry lagged much behind the production targets set by the Task Force and the Hathi Committee, in such specific products groups as, anti-tuberculars, anthelmintics, vitamins and so on.

The foreign units with their advanced sales techniques backed by sophisticated equipment and machinery accounted for a major share, more than 70 per cent, of the total sales of the pharmaceutical products in India during 1975-79 period. The multinationals therefore had a higher profitability ratio of around 18 per cent during this period, higher than the Indian private companies and the public sector companies. The Indian private companies had a lesser standing than the foreign companies with some of the oldest drug houses incurring even negative profits in 1976.

While on the one hand multinationals with their monopoly in some specific product groups had resorted to diversification strategies taking them into related areas, on the other the public sector concentrated mainly on bulk drug production. The performance of the IDPL was far from satisfactory; the HAL has been consistently incurring losses since 1973-74 till now. The over capitalization of the public sector units was also another reason for this phenomenon, since large overheads

and sizeable depreciation provisions erode into the net profits after tax. Whilst the foreign multinationals thrived on excess production of high pay-off medicines than the licensed capacity, the public sector units did not show signs of reaching anywhere near their licensed capacities for many bulk and synthetic drugs. The research efforts made by the public sector units, which, unlike the multinationals, arrived at the discovery of new drugs relevant for tropical diseases, were not fully utilized. This can be seen in the absence of production of two drugs aureofungin and hamycin.

Hence, the overall picture of the performance of the drug industry as a whole gives the impression that it is unlikely to achieve self-sufficiency in drug production at least till the next five years; self-reliance of course is even more of a far cry.

CHAPTER IV

CHAPTER IV

TECHNOLOGICAL PERFORMANCE AND RESEARCH AND DEVELOPMENT

The classical economists argued that technological inventions and innovations were frequently, even predominantly, made possible by increasing specialization and differentiation of functions in the process of production. Marx in particular has distinguished sharply between two different organizational processes, viz., the increasing division of labour and the introduction of specialized machinery which resulted directly in higher labour productivity, and which went of hand in hand.[1]

These two interlinked processes also had the indirect effect of making the process of production more amenable to the application of scientific principles and consequently widened the scope for technical innovation. The processes of specialization have enormously increased the capacity to produce, and no doubt also the rate of innovation in industry. However, specialization particularly specialization in the creation of innovations, has another aspect. It opens the way to appropriation of knowledge by individual firms. The knowledge used in any particular innovation tends to be so highly specialized that it may remain specific to the innovating firm for a

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1. See, Karl Marx, Grundriese, Penguin, London, 1973, Chapter on Capital (Note book VII), pp. 699-882.

long time. In fact as Ricardo, Marx and Schumpeter so clearly recognized, the possibility of appropriating knowledge-technology to be more precise, is the mainspring of innovation, under capitalism. Innovation needs scarce resources of skill which have high opportunity cost. Firms will not invest in these resources unless they are sure of getting a return on them. They will not get a return if their innovations are immediately imitated by their competitors. Consequently, the appropriation of technological innovations is not simply a perverse outcome of increasing specialization. It is a necessary condition for innovation to happen at all in a market economy. By corollary, firms innovate in expectation of the commercial advantages they will get from monopolistic control over the new technology.[2]

With this perspective, the question of technological innovations and Research and Development (R and D) is approached in order to trace out the underlying strategy and practice of various firms in the drug industry in India.

4.1 Elements of Technology

Technology as a specific 'factor of production' connotes the appearance, first, at the level of social division of

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2. The definitions in this paragraph are drawn from UNCTAD, Handbook of the Acquisition of Technology by Developing Countries, Report by UNCTAD Secretariat, United Nations, New York, 1978 and Frances Stewart, Technology and Underdevelopment, London, Macmillan, 1977.

labour, of determined forms of production - the production of knowledge and technologies with a view to production - together with the corresponding categories of workers, researchers and engineers, and secondly, of trade in the results of this production.[3] This is the significance of the definition of technology adopted by UNCTAD. In general, technology consists of the package of 'skills, knowledge, and procedure (SKP) for making, using and doing useful things'.[4] Technology transfer, then, is the process by which this package gets from one person to another, or from one place to another or from one firm to another.[5]

Drug making involves superposition of various stages of technological requirements. In the drug industry, a distinction may be made between three types of technology: product technology, process technology and packaging technology.[6] Product technology included the discovery of new drugs - the most difficult, expensive and lengthy part of technological innovation in the industry; process technology comprises improvements or adaptations in the production methods for given drugs; whereas innovations in dosage

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3. UNCTAD, Guidelines for the study of technology to developing countries, UNCTAD (TD/B/AC.11/9) UN, New York, 1972, p.1.

4. R.S. Merril, 'The Study of Technology', International Encyclopaedia of the Social Sciences, D.L. Sills (Ed.) Macmillan, New York, 1968, p.576.

5. Lawrence H. Wortzel, Op. cit., p.2.

6. The Growth of Pharmaceutical Industry in Developing Countries: Problems and Prospects, Op. cit., p.33.

forms, packaging, storage etc. form packaging technology. These three packages can be called the specific sub-packages of technology in the pharmaceutical industry.[7]

A brief examination of these subpackages of technology would help trace some basic features of drug manufacturing. Firstly, the active ingredient(s) must be made available by recourse to natural substances, chemical synthesis or other processes. Secondly, active ingredients must be purified and made suitable for application to human beings and/or animals without risk of unacceptable hazards. Thirdly, the drug must be given the physical shape most suited to the purpose for which it is intended. The control of technical processes and quality are the other stages which are important. Drug-making in the final analysis, is to give to active ingredients a form which makes possible their absorption by the human or animal body, so ensuring that the desired action is achieved in the most safe and rapid manner. Thus the main technology elements in drug making are the active ingredients - the so called 'raw materials'.

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7. The distinction of technologies is for analytical purposes only. In fact, Lawrence Wortzel had a different classification of subpackages viz., (a) technology related to the identification, formulation, purification and synthesis of new drugs, (b) technology related to drug manufacture, and (c) technology related to the use of drugs for therapy. See, Lawrence Wortzel, Op.cit. p.2ff. But technology (c) lies with the physicians and is beyond the scope of present study. Hence, the present classification sufficiently qualifies for the further examination.

4.2 R and D Performance

The research consciousness in the Indian industry is yet to catch roots. The first R and D laboratory in industry was started in 1928, but the commitment to R and D in the industry is a post-independence phenomenon. The government has also contributed sufficiently to generate R and D potential for the drug industry in India by encouraging research departments and divisions at the universities and research organizations supported by the government.

There are around 25 R and D centres in India which are currently carrying on research activities both in the public and the private (including foreign) sectors (see Table 4.1). These are fullfledged institutions contributing to the advancement of technological innovations and indigenous R and D. Among the foreign multinationals Ciba, Hoechst, Glaxo, Pfizer and Sandoz have large centres with well organized facilities which range very widely in their activities. A few of them like Ciba, Alembic and Sarabhai's have facilities for basic research as well.

The research and development activities of pharmaceutical industry in India are located in three classes of organizations:

(a) In-house R and D in private sector;
(b) R and D in the public sector; and
(c) public funded R and D institutions.

TABLE 4.1

R AND D CENTRES IN PHARMACEUTICAL INDUSTRY

Sl. No.	Name of the Company	R and D Centre
1.	Sandoz (India) Ltd.	Bombay
2.	Searle (I) Ltd.	-do-
3.	Organon (I) Ltd.	-do-
4.	Ciba of India Ltd.	-do-
5.	Indian Organic Chemicals Ltd.	-do-
6.	Hoechst Pharmaceuticals Ltd.	-do-
7.	Excel Industries Ltd.	-do-
8.	Chemical Industries and Pharmaceutical Laboratories Ltd.	-do-
9.	The Nitson Laboratories	-do-
10.	Raptakos and Borett and Co. Ltd.	-do-
11.	Unichem Labs Ltd.	-do-
12.	Richardson Hindustan Ltd.	-do-
13.	Glaxo Labs (I) Ltd.	-do-
14.	The Fairdeal Corporation (P) Ltd.	-do-
15.	Cadila Labs Ltd.	-do-
16.	Wyeth Labs Ltd.	-do-
17.	Bengal Immunity Co. Ltd.	Calcutta
18.	Dey's Medical Stores (Mfg) P. Ltd.	-do-
19.	Sarabhai Research Centre	Baroda
20.	Synbiotics Ltd.	-do-
21.	Ranbaxy Lab (P) Ltd.	New Delhi
22.	IDPL (Synthetic)	Hyderabad
23.	IDPL (Antibiotic)	Rishikesh
24.	Haffkine Institute	Pune
25.	Suneeta Labs (P) Ltd.	Indore

Source: IDMA Bulletin, Vol.6, No.20, 31 May 1975, p.273.

4.2.1 In-house R and D in Private Sector

The in-house R and D activity among the Indian private companies, barring a few like Alembic, Sarabhai, Unichem, etc. is almost insignificant. Even the drug multinationals, which are supposed to be primarily oriented towards innovation through high levels of investment in R and D activity aimed at the discovery of new drugs, do not invest considerable amounts in R and D in India. It is not to suggest that large companies do not pool their resources to finance research, and attempt at minimizing costs of research. American firms are already relocating their activities in Western Europe, notably in the United Kingdom, in order to economise from the differences in salary paid in the two countries, or clinical trials of some drugs are carried out in Latin America, because government rules there are less strict.[8] Pfizer's research activities are mainly carried out in the United States, the United Kingdom, Germany and France. Another American Company, Wyeth, on the other hand, has selected the United States, the United Kingdom and also India.[9] India was included because of the availability of trained personnel and also because a certain amount of research had earlier been undertaken. This relocation by

8. A. Cilingiroglu, Transfer of Technology for Pharmaceutical Chemicals, OECD, Paris, 1975, p.26.

9. Ibid.

some firms should not lead to the conclusion that a decentralization of geographical concentration in R and D is taking place. Not many pharmaceutical multinational giants have chosen third world countries for their research activities. The reasons given for not conducting R and D in local units range from lack of skilled, trained manpower, and of infrastructural facilities to the absence of conducive technological atmosphere. But the Indian case itself would be sufficient to dismiss this argument. In fact, India had been placed in 'Stage IV' of UNIDO classification, where countries have reached considerable level of self-sufficiency, oriented towards full integration into their economy of at least the main sectors of the pharmaceutical industry.[10] However, this did not give much encouragement for the multinationals to carry out either basic or applied research activity in India. Most of the multinationals do not deem it fit to invest in research aimed at producing drugs for tropical diseases.

Out of 45 identified FERA companies only 7 companies perform R and D in the manufacture of basic drugs (see Table 4.2). Out of the 14 companies shown in the Table, 7 multinationals, 4 Indian private, and three public sector units are taking part in R and D activity of basic drug manufacture. The common place tropical drugs antifilariale

10. UNIDO, The Pharmaceutical Industries in the Second Development Decade, UNIDO Secretariat, Vienna, 1969, p.19.

and antimalarials are manufactured by Unichem and Bengal Immunity, both Indian companies, whilst the foreign units concentrate their research efforts on high-value drugs like cardiovasculars and diuretics.

TABLE 4.2

MANUFACTURE OF BASIC DRUGS BY THE 14 FIRMS CARRYING OUT R AND D

Therapeutic category	Firms
1. Anaesthetics	Alembic, Hoechst
2. Antacids	Geoffrey Manners
3. Anthelmintics	IDPL, Glaxo
4. Anti-amoebic	Sandoz, Alembic, Sarabhai
5. Antibiotic	Geoffrey Manners, Hindustan Antibiotics, IDPL, Alembic, Cynamid, Pfizer
6. Antidiabetic	Bengal Immunity, Pfizer, Hoechst, Unichem
7. Antifilarial	Unichem
8. Antimalarial	Bengal Immunity
9. Anti T.B.	Sandoz, Pfizer, Hoechst, Bengal Immunity
10. Cardiac Drugs	Sandoz
11. Diuretic	Glaxo
12. Steroids	Glaxo
13. Sulpha Drugs	IDPL, Ciba
14. Vitamins	Glaxo, IDPL, HA
15. Tranquilizers	Geoffrey Manners, Ranabaxy
16. Hormones	Glaxo

Source: CSIR, Towards Self-Reliance: Problems of Technological Development - A Case Study of Drugs and Pharmaceutical Industry in India, (Unpublished project report), New Delhi, 1979.

4.2.1.1 Intensity of Innovative R and D in Private Sector

The larger companies in the industry in general and in the multinational sector in particular are supposedly highly R and D intensive. Not many studies

exist in India showing the R and D intensity in terms of per centages of sales, net income, and cash income (net income after taxes) invested by pharmaceutical companies. A review of R and D expenditure in 1974 (see Tables 4.3a and 4.3b) for drugs industry in India reveals that the total expenditure on R and D was 2 per cent of turnover, which was far above the R and D expenditures of many other industries, e.g. textiles (0.1 per cent), rubber products (0.6 per cent) chemicals and chemical products (0.1 per cent), and engineering and machine building (0.08 per cent). The average R and D expenditure of all the industries is 0.06 per cent of the turnover. Compared to this, in the US, expenditure on pharmaceutical R and D in 1975 was as high as 4.7 per cent of sales volume and in excess of 50 per cent of profits, which was surpassed only in the ratio of total R and D expenditure to sales volume by the office equipment and computer industry with 5.6 per cent, and instrumentation industry with 5.4 per cent.[11]

TABLE 4.3a

R AND D EXPENDITURE IN THE DRUG INDUSTRY, 1974

Total Industry	...	80.00 (Rs. in millions)
R and D as per centage of turnover		2.00

Source: President's speech, Eleventh Annual General Meeting of Organization of Pharmaceutical Producers of India, 27 April 1977.

11. Business Week, 28 June 1976, New York.

TABLE 4.3b

R AND D EXPENDITURE - A COMPARISON

Industry	R and D as percentage turnover
Textiles ...	0.1
Rubber products ...	0.6
Chemicals and chemical products	0.1
Engineering and machine building	0.08
All industries (average)	0.06

Source: President's speech, Eleventh Annual General Meeting of Organization of Pharmaceutical Producers of India, 27 April 1977.

A number of studies have been made by economists in an attempt to determine the economics of innovative activity in the pharmaceutical industry at the international level. The strong association between research and the introduction of new drugs is well established by now.[12] However, there are questions like what is the optimal size of R and D unit for a firm of given capacity, and whether the performance of the R and D unit is proportional to the size of the firm, or what is the effect of diversification in research on risk of R and D investment and so on that are still areas of dispute.

12. See, for example, J.D. Cooper, The Economics of Drug Innovation, American University, Washington, D.C., 1970; G. Teeling-Smith, 'Comparative International Sources of Innovation', Paper at the II Seminar of Dynamics of Pharmaceutical Innovation and Economics, Washington, D.C., October 1973.

In studies of R and D spending during the 1945-62 period for the U.S. pharmaceutical industry, Mansfield and Grabowski both concluded that the largest drug firms did not spend more on R and D, relative to sales, than did somewhat smaller firms.[13] On the other hand Schwartzman rejected these earlier conclusions on the basis of his study of the 1965-70 period. Using laboratory employment data in the place of R and D spending data to measure research effort, Schwartzman found that research effort increases more than proportionally with size.[14]

Whether there exist significant economies of scale has been examined by several investigators. Comanor studied economies of scale in drug research by relating the new drug product output to firm size for the 1955-60 period. He concluded that there were substantial diseconomies of scale in R and D which were associated with large firm size.[15] In a separate study of the most important pharmaceutical innovations introduced between 1935 and 1962, Schnee found that the largest drug firms did not produce a disproportionately large share of the

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13. Edwin Mansfield, Industrial Research and Technological Innovation, New York, W.W. Norton, 1968, pp.38-40; and Henry G. Grabowski, 'The Determinants of Industrial Research and Development: A Study of Chemical, Drug and Petroleum Industries', Journal of Political Economy, March/April, 1963, pp.292-305.

14. David Schwartzman, 'Research Activity and Size of the Firm in the U.S. Pharmaceutical Industry', Regulation, Economics and Pharmaceutical Innovation, (Ed.) J.D. Cooper, American University, Washington, 1976.

15. William S. Comanor, 'Research and Technical Change in the Pharmaceutical Industry', Review of Economics and Statistics, May 1965, pp.180-82.

innovations. The pharmaceutical firms that contributed the most innovations relative to their size, were not the largest firms but somewhat smaller ones.[16]

More recent investigations of technical change and firm size refute the Comanor and Schnee conclusions. For the 1965-70 period, Vernon and Gusen found that larger pharmaceutical firms appeared to have decided advantages over smaller ones in accomplishing technical changes. They disprove Comanor's 'diseconomies of scale' hypothesis.[17]

Not many rigorous studies of similar nature have been conducted in India. A conventional parameter - the R and D effort as a function of firm size, which is measured by the per centage of sales turnover devoted to research - is applied to Indian pharmaceutical industry in the present study. Data of R and D investment as per centage of sales turnover is presented for the major multinational pharmaceutical companies in India in Table 4.4. The serial number of the company shown in the table indicates their rank accordingly based on their sales turnover in fiscal 1976. The R and D expenditure of these firms normally ranged between 1.5 and 2.5 per cent of their sales turnover during 1974 and 1975 period,[18] whereas the major drug multinationals

16. Jerome E. Schnee, 'Innovation and Discovery in the U.S. Ethical Pharmaceutical Industry', in E. Mansfield, Research and Innovation in Modern Corporation, W.W. Norton, New York, 1972, Chapter 8.

17. In fact, Vernon-Gusen have employed the data relating to laboratory personnel and so on to measure the effort of R and D, see, John Vernon and Peter Gusen, 'Technical Change and Firm Size: The Pharmaceutical Industry', Review of Economics and Statistics, August 1974, pp.294-302.

18. OPPI has put the average R and D expenditure in 1974 at 6.45 per cent of its turnover for its member companies.

TABLE 4.4

PERCENTAGE OF INCOME INVESTED ON R AND D TO SALES TURN-OVER, 1973-75

Sl.No./ Rank	Name of the firm	Percentage of income invested on R and D based on sales turnover		
		1973	1974	1975
1	2	3	4	5
1.	Glaxo	3.00	3.00	3.00
2.	Ciba-Geigy	7.00	6.70	6.80
3.	Pfizer	2.00	2.00	2.00
4.	Hoechst	3.90	4.40	3.10
5.	Sandoz	2.20	3.00	1.40
6.	Suhrid-Geigy	0.21	0.23	0.63
7.	Geoffrey Manners	1.30	1.00	1.00
8.	Cynamid	0.75	0.82	0.80
9.	Parke-Davis	0.06	0.07	0.10
10.	Abbott	1.00	0.40	0.40
11.	Smith, Kline French	0.40	0.60	0.70
12.	Burroughs Wellcome	0.43	0.42	0.33
13.	Richardson-Hindustan	0.40	0.37	0.40
14.	Boots	0.50	2.00	1.90
15.	Roche	0.55	0.45	0.50
16.	Merck, Sharp and Dohme	0.72	0.80	0.90
17.	May and Baker	6.47	6.41	6.35
18.	Warner-Hindustan	1.50	1.40	1.20
19.	German Remedies	N.A.	N.A.	N.A.
20.	Bayer	Nil	Nil	Negligible

1.	2.	3	4	5
21.	Boehringer-Knoll	2.50	2.00	0.50
22.	E. Merck	0.51	0.81	0.55
23.	Johnson and Johnson	0.80	1.00	1.00
24.	Organon	1.00	1.00	1.70
25.	Wyeth	4.95	4.71	4.13
26.	Indian Schering	2.45	2.11	1.65
27.	Duphar Interfren	N.A.	N.A.	N.A.
28.	Roussel	0.80	1.10	0.80
29.	Anglo French	1.70	1.70	2.30
30.	Ethnor	2.60	2.59	1.85
31.	Searle	3.00	3.00	3.00
32.	U.S. Vitamin	0.30	0.60	1.30
33.	C.E. Fulford	0.30	0.25	0.45
34.	Wander	Negli-gible	Negli-gible	Negli-gible
35.	Beecham	Nil	Nil	Nil
36.	Curewell	0.5o	0.75	0.84
37.	Uni-Sankyo	Nil	11.80	10.65

Sources: (a) Rank based on sales turnover of Fiscal 1976, calculated on the basis of Table 3.5.

(b) R and D investment data compiled from 'Paper laid on the table of Lok Sabha', LT-1196/77, Lok Sabha Secretariat, 1977.

N.A. = Not available.

in the world spend typically between 5 per cent and 15 per cent of their annual turnover on R and D.[19] However, this is not the case with pharmaceutical multinationals in India.

Research expenditure of an individual firm, in principle should vary with the size of the firm in terms of total capital or sales volume or the number of employees, at least in the large units, which are supposedly involved in basic research. But in our examination, only sales volume criterion is used to measure the size of the firm and subsequent investment in R and D as a per centage of sales volume. It is found that the rank correlation coefficient of R and D expenditure and the size of the firm in 1975 worked out to a meagre 0.07497 for the 32 foreign companies,[20] representing a marginal relationship between the two.

Given the size of the firm as measured by its sales turnover, a direct relation between R and D expenditure as a percentage of sales and firm's size is difficult to establish as is evident from the table. Ciba-Geigy with a sales turnover of Rs.3319 lakhs has the second highest investment in R and D at 6.8 per cent, but strangely May and Baker with a sales turnover of Rs.805 lakhs in 1975 made

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18. contd.
See, the President's Speech, OPPI, Op. cit. Incidentally the companies analyzed here too, are all members of OPPI.

19. B. James, Op. cit., p.63.

20. Data for the remaining five is either not available or so negligible that it would not affect the result.

an almost equal investment of 6.35 per cent. While the other two top MNCs Glaxo, and Pfizer which had sales turnover of Rs.4748 lakhs, and Rs.2992 lakhs respectively lagged far behind with 3.0 per cent and 2.0 per cent respectively. An interesting paradox has been that of Uni-Sankyo, a Japanese firm with sales turnover of a mere Rs.39 lakhs in 1975 which invested 10.65 per cent in R and D, the highest in the whole industry for that year.[21] The present evidence and discussion, whilst it need not confirm Comanor and Schnee 'diseconomies of scale' hypothesis, might appear close to the Mansfield and Grabowski conclusions for the US pharmaceutical industry.[22] However, it can safely be concluded that the multinational investment in R and D does not reflect the same pattern in Indian context as it does in the context of advanced market economies. This may be due to the fact that MNCs earn more profits through direct transfer of patents from their principals abroad to the underdeveloped countries.

4.2.2 R and D in Public Sector

With the objective that drugs which are most commonly needed and used in India should be produced locally and that further developments should be based on indigenous efforts,

21. This paradox needs to be probed further; lack of information preempted further analysis.

22. Since Vernon-Gusen variables are also significant in determining the levels of R and D of individual firms, an examination of these could be taken up but for lack of data on Indian companies.

without dependence on multinational corporations, the government had adopted the policy that basic drugs should be in the public sector at least partly, if not totally. However, the paradox of underdevelopment is that there is a great urge to be independent but all actions are directed towards dependence. The general belief that the nature of majority ownership of firms determines the degree of dependence is not true. It has been argued, for example, that majority ownership of a company is not necessarily of great significance and that the necessary control can be exercised with a very small percentage of the equity owned.[23] Furthermore, joint ventures are frequently joint in name only; they are becoming increasingly popular with the multinational corporations. Experience shows that MNCs can successfully exercise a control, even, if the collaborating firm is a state owned unit; the terms of transfer of technology may be such as to lend a commanding position to the foreign collaborator rather than strengthening the domestic firm.[24] Hence, the state participation in technical collaboration should be approached with discrimination, avoiding uncritical import of technology, which might create

23. Handbook on the acquisition of Technology, Op.cit., p.28.

24. Gulati and Bansal have shown that in a technical collaboration between a public sector electronics unit and a MNC (which they call fictitiously as Indionics and Multionics respectively, to avoid embarrassment for these firms), the terms of transfer were such as to keep the foreign collaborator in a dominating position. See, I.S. Gulati and Swaraj K. Bansal, 'Export Obligation, Technology Transfer and Foreign Collaboration in Electronics', EPW, Vol.15, Nos.41, 42 and 43 (Special number), 1980, pp.1846-56.

problems of technological assimilation and hamper local technological efforts.

However, it appears that these factors are paid little attention to or are totally neglected, while approaching for technological collaborations among the public sector drugs units. The collaboration spree started in the public sector right from the setting up of the plants, Hindustan Antibiotics at Pimpri and the IDPL's one at Rishikesh and another at Hyderabad. All the three units have well established R and D units to carry on in plant research activities, while another IDPL unit at Madras has only a surgical instruments plant.

The HAL started its collaboration first with American Home Products and Pfizer for manufacture of antibiotics and later on turned to British-owned Glaxo for improved strains.[25] It is estimated that the HAL research establishment has a capital expenditure of Rs.4.8 million and a recurring expense of nearly Rs.1.9 million. This unit at present employs more than 100 people, including 60 scientists, technologists, technicians and others. Approximately 20 per cent of the total inputs of the research unit staff is devoted to basic research. Some of the problems tackled are: biosynthesis of chlorotetracycline, carbohydrate metabolism, requirements of antibiotic producing organisms, etc.

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25. How Glaxo had cheated the public sector undertaking by providing inferior quality strains, has already been explained in Chapter II above.

Both the IDPLs started in 1962 with the collaboration of a Russian concern, 'Technoexport' of Moscow.[26] The collaboration was in regard to manufacture of the following antibiotics at Rishikesh:

> Sodium penicillin, Procaine penicillin, Streptomycin sulphate, Tetracycline hydrochloride, Oxytetracycline hydrochloride, Nyostatin, Chlorotetracycline;

and the following synthetic drugs at Hyderabad:

> Phenacetin, Sulphaguanidine, Sulphadimidine, Sodium sulphacyl, Vitamin B1, Folic Acid, Vitamin B2, Analgin, Amidopyrine, Piperazine and salts, Diethyl carbamazine citrate, Nicotinamide, INH, Phenobaritone, Acetazolamide.

More recently, the IDPL entered into collaboration with Farmafin,[27] of Italy for achieving higher yields per lower consumption of raw materials in the manufacture of various antibiotics. The agreement for Adoxycycline was made in June 1976 and for potassium penicillin, tetracycline, niacinamide and others was made in December 1976. The basic engineering was obtained from a Swedish firm, A.B. Bofors at the cost of 2 million Swedish Kroners.[28]

Now this raises some very important questions as these drugs were manufactured under Russian collaboration also.

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26. See, answer to unstarred question No.286, by Govinda Munda, Lok Sabha Debates, June 1979.

27. Farmafin is a consortium of six Italian pharmaceutical companies, formed in 1974 under the control of Montedison to promote Italian drug activities in the underdeveloped markets of the third world. See, B. James, Op. cit., p.28.

28. See, answers to unstarred question Nos. 752 by M.V. Chandra, P.M. Sayeed and 7340 by Motibhai R. Chaudhury in Lok Sabha Debates, July 14 and July 19, 1979.

It is very important to examine also the rationale behind switching over to Italian technology from Russian collaboration. Is it that the Russian collaboration did not provide sufficient technical knowhow, skills, procedures so as to promote self-reliance? Or, was it costlier than the present technology available from Italy, in which case the much publicised cheaper and best technology from Russia is not true? A clear suspicion arises here that the government has not attempted to answer these questions effectively through comparative evaluation of cost-benefits of various technological collaborations, which perhaps would have averted frequent shifts in collaboration.

With so many technical collaborations, the public sector units appear to have little to their credit in terms of the outcome of R and D and basic research. This is despite the fact that the public sector R and D investment amounted to around 2.5 - 3.00 per cent of its total turnover during the 1975-79 period. However, the HAL had made two historic discoveries in antifungal preparations viz., hamycin and aureofungin, for which the international patents have been obtained. Despite this the HAL continued to incur losses, and all the public sector units produced much below their capacities in almost all the drugs and some of the drugs supposed to be produced did not see production at all.[29] The HAL unit is also responsible for the

29. This point has already been discussed at length in Ch. III above and it has also been noted that the production of hamycin and aureofungin has not commenced in this country yet.

discovery of the enzymatic process for the production of 6-APA from penicillin G, first crystals, which is used as an intermediate for preparation of ampicillin.

These achievements appear less-impressive before the long collaboration ordeal that has been going on. The fact that it is the government or a state organization, which becomes the partner, should improve the bargaining strength of the importing country, but in practice a lessening of technological dependence has not necessarily followed. In Sri Lanka in recent years an increasing proportion of total industrial investment has been in the state sector, including the government to government investment with Eastern European partners. There has so far, however, been little lessening of technological dependence; the same problems of absorption and assimilation of technology arise in the state as in the private sector and whether the source of technology is a multinational corporation or a state organization in a socialist country,[30] when there is a lack of adequate technological effort to carry forward the acquired technological processes and skills. Hence a mere state partnership in technical collaborations may not be very fruitful, at times even counter-productive in the absence of a sound technological base to absorb, assimilate and indigenise the acquired technology from the outside partners.

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30. See UNCTAD, 'The Transfer and Development of Technology in Sri Lanka: Report by an UNCTAD Mission', UNCTAD/TT5), paras. 20-22.

For India, data has been compiled on 233 foreign collaboration agreements with government companies covering the period 1953 to 1970.[31] The sources of technology were found to be broadly the same as in the private sector, as was the problem of asset transfer. As in the private sector, the payment of royalties increased, relative to technical fees. Restrictive features of agreements and reliance on foreign technicians were greater for public sector than in the private sector. The proportion of State companies with R and D as a percentage of those with foreign collaboration agreements was only 7 per cent, compared with 46 per cent for foreign subsidiaries in the private sector and 33 per cent for minority participation companies. This has limited the ability of the state companies to absorb, adapt and assimilate imported technology, has led to repetitive imports and tends to make technology transfer and dependence self-perpetuating. This precisely is also the reason why the public sector companies in the pharmaceutical industry have been switching so frequently over from one technology to the other and from one foreign company to another, let it be from Pfizer (American) to Technoexport (Russian) or to Farmafin (Italy). The basic character of technological dependence has continued in different guises rather than get reduced. Finally, when it comes to the question of controlling technology, "there is

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31. P. Mohanan Pillai, Foreign Collaboration in the Public Sector and Economic Development, Sardar Patel Institute of Economic and Social Research, Ahmedabad, 1977.

no exaggeration in saying that the foreign collaboration wielded more influence in state sector ventures through supply of technology than pure collaboration agreements in the private sector.''[32]

4.2.3 Public Funded Research Institutes

The Indian Council of Medical Research is the main body which funded research projects at various medical colleges and research institutes. The Ministry of Health, has a number of Pasteur Institutes, which manufacture vaccines of various types and also engage themselves in research work connected with vaccine development. The Council for Scientific and Industrial Research has two research institutes totally devoted to drugs and their development. They are: the Central Drug Research Institute, Lucknow and the Indian Institute of Experimental Medicine, Calcutta. Besides these, the National Chemical Laboratory, Poona and the Regional Research Laboratories at Hyderabad, Jorhat and Jammu also tackle problems connected with the manufacture of intermediate compounds or basic pharmaceuticals.

4.3 Coordination of Research

One of the complex problems in India is coordination of research or internal technology transfer. The depend increasingly on indigenous R and D and technological competence

32. Ibid., p.23.

demands three sources of internal technology transfer: (a) In-house R and D activity and the inplant technology transfer; (b) technological diffusion between firms within and outside the particular industry, i.e. intra-industry and inter-industry technology transfer; and (c) national laboratories and public sector laboratories should have well organised exchange of information system. In a vital sector like health, there is very little coordination of R and D activities and if the national laboratories and the industry are working in isolation, it is indeed a waste of national resources. Very often there is an avoidable duplication of work, because of lack of coordination. However, it may be mentioned, here, that lack of coordination between various systems is a universal phenomenon but its impact in developing countries is more deleterious.

4.4 Pharmaceutical R and D: Capital Intensive or Labour Intensive?

Before we conclude this chapter, an important but complex question needs to be answered. Most of the multinationals come out with the theory that pharmaceutical industry itself is a capital intensive industry and more so the pharmaceutical R and D; hence the developing countries need not make ventures into this field.

The entire processes and stages involved in drug making have been laid down in section 4.1 and in the Appendix. A cursory glance at these sections gives us an idea that the present location pattern of the pharmaceutical industry is

not at all in conformity even with the economic theory which holds that each nation should make what they are good at. The industrialised countries, although realising that the packaging stage of the pharmaceutical industry requires unskilled and in many cases female workers, have tried to increase automation in order to save labour, whereas there are millions of workers available for this type of work in developing countries. The pharmaceutical industry is labour intensive at the stage of formulating, labelling and packaging. Since in addition the drug industry's skill requirements are not very high, it is an industry well suited to developing countries.[33]

In basic research, the development of a drug is a very time-consuming activity, because, even if it is theoretically known that a particular product could be used to cure certain illnesses, it must first be tested on animals before being used in clinical trials. It has to undergo various disciplines, tests by chemists, toxicologists, pharmacologists, physicians, working on it jointly or successively. But still the outcome may not be guaranteed. In other words, basic research is risky, more uncertain and demands long gestation periods before the exact results and returns start accruing. Cilingiroglu has argued that the cost of R and D in pharmaceuticals is high, not because costly equipment is needed but because it requires the work of different people over a long period.[34] To sum up in his

33. See, 'The steps involved in establishing a pharmaceutical industry in developing countries', UNIDO, (UN/W.G. 267/3), Vienna, 1978.

34. A. Cilingiroglu, Op. cit.

own words:

> Although a large number of people are involved in pharmaceutical tests and trials, it is not necessary for them to be very highly specialized. ...We may even define pharmaceutical research as labour intensive activity or labour intensive research.[35]

Hence, the underdeveloped countries can accomplish the vital task of pharmaceutical production to aid their national health services, at least by taking up formulation activity. They can also venture into the field of pharmaceutical research. Moreover, pharmaceutical research and therefore formulation activity both being basically labour intensive, the entry into these fields by the underdeveloped countries which have abundant unemployed labour can avoid undue automation. Countries like India which are endowed with sufficient trained manpower, technical skills and significant state sector can even venture into the field of bulk drug production.

4.5 Summary

Technological innovations and specialization in specific process technologies continue by and large to be a monppoly of a few drug multinationals in the world. Hence, their off-shoots in India too enjoy a similar monopoly. The R and D in India is carried out in three major sectors (a) In-house R and D in private sector, (b) R and D in public sector, and

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35. Ibid., p. 26.

(c) public funded R and D institutes. There are around 25 R and D laboratories in all the three sectors, which are currently engaged in the development of indigenous technology.

The geographical concentration of R and D is high among the multinationals. They generally do not perform R and D in their foreign subsidiaries and the main strategy of MNCs is to directly transfer the patents to their overseas subsidiaries obtaining huge profits. Some foreign units in India do invest considerable amounts in their local R and D units, but it is generally confined to the research of high-value drugs, while the commonplace tropical drug research is undertaken by either Indian private firms or the public sector units. The Unichem, Bengal Immunity provide an example in this case.

The R and D intensity in terms for instance of the percentage of sales devoted to R and D is supposed to be high in the pharmaceutical multinationals. But this is not generally the case in the drug multinationals in India. The general belief that the larger the size of the firm the more the investment in R and D does not hold good with the foreign drug firms in India. The top 37 firms ranked according to their sales turnover in fiscal 1976 showed a minimal correlation with their respective investments in R and D taken as a proportion of sales. The rank correlation coefficient for these companies showed a meagre 0.07497.

The public sector should set an example in R and D by pooling the resources toward centrally directed research aimed at the discovery of new drugs for tropical use, according to the Hathi Committee. It also suggested that the public sector should spend on R and D at least 5 per cent of its total turnover till at least 1980. However, the current public sector expenditure on R and D ranges typically between 2.5 - 3.00 per cent. The switch over of technical collaborations in the public sector is too frequent and often resulting in the problems of assimilation of new technology and of repetitive collaboration agreements. The coordination of research efforts between various sectors of the industry and the national laboratories is not too encouraging. Lack of such coordination often tends to encourage duplicative research.

A close examination of the packages of technology involved in drug making suggests that the underdeveloped countries can take up at least, formulation activity to start with, which is labour-intensive. Countries like India with sufficient trained technical personnel and skill can take to high technology bulk drug production too. The general belief that the pharmaceutical research is capital intensive involving trivial product innovations, with long gestation periods, cannot be advanced as an argument to discourage the underdeveloped countries to venture into the field of research as well.

CHAPTER V

CHAPTER V

CONCLUSION

The domination of multinationals on an international scale has been on increase in various spheres through control over technology. The third world countries, more often, are dependent on the advanced industrialized countries for, new technical knowledge and skills. Of late, many third world countries have expressed great concern about the domination of MNCs and realized the need to move towards self-reliance through building indigenous technological capability. However, the unevenness of which characterises the international economy, and persists as a tendency, acts as a major hurdle against the success of such attempts.

Thus a major share of world-wide pharmaceutical production - 84.4 per cent - and of consumption - 80.8 per cent - is confined to a few advanced capitalist countries like the US, the UK, France, Germany, Italy, Japan and Switzerland. The third world countries on the other hand shared only 10.4 per cent of world's drug production and about 13 per cent of consumption.[1] The world pharmaceutical market shares are also controlled by the multinational corporations, of these few countries. World's twentyfive leading MNCs alongwith their off-shoots all over the world account for nearly 40 per cent of total drug sales.[2]

The third world countries became more alerted by the continued presence and domination of MNCs in their domestic pharmaceutical markets and concentrated efforts to gear-up the indigenous drug production. The Hathi Committee Report in India, in fact, is an expression of concern about such a dominance of MNCs in the drug production in India. The Hathi Committee, has delved into various problems of the Indian pharmaceutical industry and came out with wide ranging recommendations.

The Hathi Committee Report, which was submitted to the government in 1975, brought forth the necessity of reducing the multinational domination in the Indian drug industry through various measures. The HCR suggested that the proportion of foreign equity in the Indian subsidiaries of MNCs should be reduced to 40 per cent forthwith and progressively to 26 per cent.[3] The new drug policy (NDP) which claimed to have incorporated the recommendations of the HCR, however, did not initiate any action in that direction. The government has identified some 45 companies as foreign, which have non-resident equity more than 40 per cent. The government however, directed only eight companies, to reduce their foreign equity to 40 per cent which were supposed to have engaged in the pure formulation activity. First, it is altogether a different question that whether foreign equity of 40 per cent as a threshold of control is an effective criterion in reducing the domination of MNCs;

experience shows that foreign companies could effectively exercise control even with 26 per cent equity. Second, it is seen in the foregoing analysis, that the drug multinationals in India maintained higher profit margins due to concentration on high pay off formulations and the production of non-essential low-tonnage high value drugs.[4] Therefore, to say that only eight companies were engaged in formulation activity is a gross understatement of the facts.

In fact, the drug multinationals obtained a 23.1 per cent gross return on total capital employed in 1975-76, 22.8 per cent in 1976-77 and about 22.3 per cent in 1977-78, due to their formulation activity in particular. This phenomenon is also attributed, however, to product differentiation, and monopolistic hold over the production of some specific drugs by certain companies. The off-shoots of multinationals in India, as their principals elsewhere, resort to unethical practices of pricing, sales techniques and concentration of production of some specific therapeutic groups to attain high profits.[5] The strength of the affiliates of the drug multinationals in India is derived mainly from the domination of select therapeutic areas by a small number of companies; some twenty major drug multinationals dominated among themselves some twelve important therapeutic areas in 1978.[6]

The NDP has provided a convenient alibi for the multinationals to continue their domination by allowing those foreign companies to retain the foreign equity even upto 74 per cent which are engaged in the production of 'high technology' bulk drugs and of formulations based on them. But the process of identification of these companies which are engaged in the production of so called 'high technology' bulk drugs and formulations based on them, has proved to be a complicated and erratic one; the government itself has attempted to pass on the majority of foreign companies as 'high technology' units, an attempt which was resisted by the FERA and the RBI committees.[7]

While the NDP on the one hand, claims to have adhered to the policy of fostering self-reliance by stepping up the production of bulk drugs and intermediates in the country, it has on the other hand provided convenient opportunities to the multinationals to manipulate the provisions regarding the production of bulk drugs and imports thereof. Of late the imports of bulk drugs have increased rapidly; a part of the explanation behind this no doubt lies in the fact of the above off shoots resorting to inessential imports from their principals, as well as to imports at inflated prices which help to conceal repatriation of profits. The total production of bulk drugs in 1977-78 was Rs.164 crores which made possible a turnover of Rs.900

crores in terms of formulations, a ratio of around 1:5.5. The ₨.164 crores of bulk drug production in turn was made up from raw materials available in the country as well as from imported bulk drugs and intermediates. The landed cost of total imported bulk drugs and intermediates in 1977-78, was no less than ₨.147 crores, a part of which went into domestic bulk drug production and another part directly, into formulation activity. The landed cost of imports of bulk drugs had shot up from ₨.82 crores in 1976-77 to ₨.147 crores in 1977-78. The proportion of imported bulk drugs to the total output of pharmaceutical formulations went up from 11.7 per cent in 1976-77 to 16.3 per cent in 1977-78. And the proportion of incremental imports of bulk drugs to incremental output of formulations was as high as 32.5 per cent in 1977-78. The production of specific product groups during 1975-79, vis-a-vis their targets set by the Task Force of the Planning Commission, also shows a grim picture. In most of the products the production was below 50 per cent of the target set for 1978-79.[8]

This trend, however, is in total contrast to the suggestion of the Hathi Committee, and the claim of the NDP that its aim is to achieve 'quick self-sufficiency in the output of drugs with a view to reducing the quantum of imports.'[9]

The Hathi Committee's suggestion regarding capacity regularisation was that any excess capacity of the pharma-

ceutical companies, particularly of MNCs should not be regularised. The NDP did not take into account this suggestion and allowed the regularisation of excess capacities. This was more favourable to the multinationals than the Indian private companies, because most of these unauthorised capacities belonged to MNCs, as shown in Table 3.11 in Chapter III. The criterion for regularisation is also not on the basis of whether the drugs are life saving or not, but on the superficial basis of a bulk drug to formulation ratio. Therefore, excess capacity for the production of even household remedies and non-essential drugs like, vitamins, tonics, tranquilizers and so on will be allowed to be regularised, so long as the ratio of production of bulk drugs to that of formulations is less than 1:5 in the case of foreign firms and 1:10 in that of Indian companies. This, however, will keep the hold of multinationals in tact as the actual ratio of bulk drugs to formulations production of foreign companies at present will conform to 1:5.

The government's decision of attaching export obligation to firms also implies removal of virtually all constraints upon capacity regularisation by the MNCs. The NDP says that if the company undertakes to export any excess production of drugs than licensed capacity for a period of five years, it will be regularised without any grudge. Regularisation of excess capacity of the private firms, including MNCs, on the ostensible plea of augmenting exports, will mean in practice a virtual abolition of any

control on private capacity creation and also an unfettered regularisation of capacities already installed illegally.

Since the foreign companies have shown little interest in tropical drug research, the Hathi Committee's suggestion, which was apparently incorporated in the NDP, was to accord the highest priority to centrally directed research aimed at the discovery of new drugs for treatment of tropical diseases, namely, antimalarials, anthelmintics and so on. The NDP also suggested that the foreign companies should spend at least 4 per cent of their sales turnover as recurring expenditure on R and D facilities.

Only seven companies out of 45 foreign companies enlisted by the government so far have undertaken the production of bulk drugs for tropical diseases and even their share is not very impressive.[10] As far as R and D expenditure is concerned, the MNCs in India do not spend sufficient amounts on R and D as a percentage of their sales income. Some 37 drug MNCs in India have spent between 1.5 and 2.5 per cent of their sales turnover on R and D during 1974 and 1975. The rank correlation coefficient between R and D expenditure as a proportion of turnover and the size of these companies, in fact, was only 0.07497 during 1975.[11] Hence, it is clear that the foreign firms do not make sufficient efforts toward discovery of new drugs for tropical diseases through increased R and D expenditure; it is not at all certain, moreover that increased R and D expenditure

alone will ead to successful adaptation and assimilation of technology and skills and will thereby reduce dependence.

In this situation of continued dependence on foreign multinationals the Hathi Committee's recommendation of providing a leadership role to the public sector, and of encouraging the Indian private sector is a well intentioned step. The Hathi Committee assigned a major role for the public sector in the bulk drug production and reserved 34 drugs exclusively for it, out of a total of 117 drugs identified as essential ones. The NDP, however, has reserved only 25 drugs in favour of the public sector, and classified only 114 drugs as essential.

The performance of the public sector in the production of bulk drugs as well as in reducing the technological dependence, has not lived upto expectations. While the IDPL at Rishikesh produced much below its licensed capacity during 1975-78, another IDPL at Hyderabad was somewhat better during the same period. The production of some newly discovered drugs did not commence at all at the HAL, for which international patents are obtained. The public sector units showed a poor performance in terms of profit margins as well. The HAL and the IDPL together with the Kerala State Drugs and Pharmaceuticals obtained gross profits amounting to Rs.4.29 crores, and net profits amounting to a meagre Rs.0.21 crores, whereas their total paid up capital was of the order

of Rs.55.20 crores during 1975-76. In fact, the HAL has been continuously incurring negative net profits after tax ever since 1973. This trend is due among other things to the over capitalization of the public sector units.[12]

The public sector policy in regard to the bulk drug production and the subsequent disposal of such drugs to the private sector also seems highly questionable. Since the formulation activity of the private companies (including MNCs) depends on the bulk drugs produced by the public sector, there is no mechanism to ensure that the public sector does not become a servicing sector of the MNC dominated private sector.[13] In fact, it would have been a better proposition for the public sector to start its own formulation activity.

The Hathi Committee and subsequently the NDP have formulated that the public sector should set an example in R and D by investing at least 5 per cent of its net turnover on R and D activity. It is also a policy objective that efforts should be made to reduce dependence on foreign companies for technology, through indigenous technological efforts. However, in actual practice the public sector has belied the hopes on both counts.

The public sector R and D expenditure amounted to around 2.5 - 3.00 per cent of its total turnover during 1975-79 period. The public sector technological efforts also present an equally disappointing picture of progress

towards self-reliance. The public sector units depended on foreign technology, and knowhow since their inception right upto the present. Frequent shifts in collaborations from one country to another and from one technology to another have created the problems of adaptation and assimilation of imported technology to the local conditions and also hampered the indigenous technological efforts. The only credit of indigenous technological efforts so far has been the discovery of antifungal preparations, hamycin and aureofungin at the HAL.[14]

The public sector's pricing policy also was erratic, from both a doctrinal as well as a practical point of view. The pricing policy of the public sector only helped the MNC dominated private sector. This policy instead of having a rationalizing and stabilizing effect on the general price line of the pharmaceuticals, provided a convenient leeway for the multinationals to justify their prices in general.[15]

The Indian private sector (excluding MNCs), too did not perform any better either. Some of the companies fared well in formulations, but they were mostly MRTP companies. The private Indian companies as such, put up a poor show. Whatever be the government's intention on the question of showing preference to the Indian private companies whether in the provision of bulk drugs to non-associated formulations, or in the regularisation of capacity, the NDP contains sufficient loopholes, which the MNCs are capable of successfully manipulating in their favour.

Why Does the Dominance of MNCs Continue?

The continuation of multinational dominance in the Indian pharmaceutical industry raises some fundamental questions in the political economy of development and needs to be answered at that level. In every fresh formulation of the government's policy, one of the objectives particularly emphasised was that of fostering self-reliance. The dependence continued with reinforced vigour with every successive declaration of such policy. The important question which needs to be examined is, whether India is capable of making her own technological and economic decisions in a situation in which external economic links wield considerable influence on her programme of development.

Indian planning ever since its inception has been dependent heavily on external borrowings and foreign aid. There was of course, a reduction in aid inflows in the early 1970s, but of late, large scale borrowings has once again been resumed. This year in particular, the worsening balance of payments have forced the government to borrow heavily from the IMF and the Euro-currency markets apart from Aid-India Consortium.

Thus, the government to tide over its balance of payment difficulties, generally resorts to borrowings from international organizations as well as from advanced economies, and when the payments difficulties worsen, the scale of borrowing is larger. Hence it is not surprising that the government has borrowed Rs.540 crores from the IMF's Trust Fund and

total borrowings from the IMF have amounted to Rs.815 crores in 1979-80 alone. The government also took credit for a borrowing of $2.4 billion in 1978-79 and $3.4 billion in 1979-80, from the Aid-India Consortium of which the World Bank is the main sponsor.

It has since long been established that foreign aid whether it is directly from a government, or from an international agency, invariably affects the politico-economic outlook of the aid-recipient.[16] It is also pointed out that the World Bank has not simply remained a provider of development loans, but over the past few years it has become a major force in shaping the economic policies of various countries.[17]

The general aid-dependence has created a suitable climate for continuation of MNCs, and furtherance of technological dependence. Besides, policies like 'export-led' growth and export-orientation have gained momentum in the recent past.[18] Economic Survey, 1980, clearly states that a broad based strategy for rapid export growth in the coming decade should be adopted, 'with a system of incentives which makes exports profitable and encourages export growth in areas of dynamic comparative advantage'. It further says that it is necessary to keep industrial policy under review so as to remove 'undue restrictions on production and capacity expansion in areas with export potential.'[19]

The new drug policy has to be seen in this context, where the 'export-led' growth caught on in the upper

echelons of the Indian policy making. This policy is in clear conformity with the policy of regularisation of illegal capacities of the MNC dominated private sector companies in the drug industry.

The export led growth strategy and the export obligation on a firm could place a domestic firm in a weak bergaining position vis-a-vis its foreign collaborator. This weakness might even impinge on the domestic firm's ability to secure access to contemporary technology and knowhow that is initially purchased under the collaboration agreement.[20] Hence, the export obligation in turn leads to continued dependence on foreign collaborator, and also implies the uncritical import of technology by the aid-recipient, country, since her access and choice for technology is limited by week-bargaining position.

Another built-in drawback in this strategy is that the technological collaboration is prone to frequent shifts on the basis of temporary gains through newly found collaborator. This results in complex problems of absorption and assimilation of imported technology and skills. In fact, the lack of indigenous technological base, and of efforts, creates problems of adaptation of technology, which in turn results in further import and continuation of technological collaboration. Hence, a long technological collaboration hampers the local technological capability of the technology receiving country and might result in the process of self-perpetuating dependence.

Hence, any search for self-reliance must aim at reducing such a self-perpetuating dependence through basic changes in the techno-economic structure. In the Indian context a still broader examination of the Indian bourgeoisie and its evolution under colonialism, its ability to manipulate the political and state apparatus, the nature of state capitalism and its contradictions and compromises with imperialism,[21] can only explain as to why the technological choice in India has been in favour of foreign technology. The Indian bourgeoisie after independence, devoid of earlier strength, had to compromise with the existing semi-feudal set up.[22] They had to ally with MNCs for technology; and import of technology has provided them an opportunity to establish and maintain monopolistic positions in the domestic market. This in fact has become an obstacle to both development and utilization of indigenous technological potentialities and hence dependence has become a self-perpetuating process. Any genuine policy of self-reliance, in the pharmaceutical sector or for that matter in any sector of the economy, must aim at doing away with such technological dependence, to the extent possible, and for this purpose must set about altering the underlying course of socio-economic development itself.

Notes and References

1. Chapter I, p.3.
2. Chapter I, p.6.
3. In fact, the majority opinion of the Hathi Committee, was for a government takeover of the Indian drug industry. See, Chapter II, pp.35-36.
4. Chapter III, pp.72-74.
5. Chapter I, pp.10-12 and Chapter III, p.74.
6. Chapter III, p.75 (Table 3.8).
7. Chapter II, pp.38-39.
8. Chapter III, pp. 59-65.
9. Chapter II, p.34.
10. Chapter III, Table 3.9, p.76.
11. Chapter IV, pp. 105-108.
12. Chapter III, pp. 81-83.
13. Chapter II, p.42 and Chapter III, pp.89-90.
14. Chapter IV, pp.112-115.
15. Chapter II, pp.48-50.
16. See, in this context, P.J. Eldridge, Politics of Foreign Aid in India, Vikas, New Delhi, 1969; Teresa Hayter, Aid as Imperialism, Harmondsworth, Pelican, 1971, and Cheryl Payer, The Debt Trap: The IMF and the Third World, Pelican, 1974.
17. See, Joseph Collins and Frances Moore Lappe, 'Whom Does the World Bank Serve?', EPW, Vol.14, No.19 (1979), pp.853-856.
18. See, for example, K.K. Subrahmanian and P. Mohanan Pillai, 'Implications of Technology Transfer in Export-led Growth Strategy', EPW, Vol.11, No.44 (1976).
19. Economic Survey, 1979-80, Government of India, New Delhi.
20. I.S. Gulati and Swaraj K. Bansal, Op.cit.

21. See in this context, Charles Bettleheim, India Independent, MacGibbon and Kee (Indian Reprint), New Delhi, 1977; also see, Prabhat Patnaik, 'Imperialism and the Growth of Indian Capitalism', in Mathew Kurian (Ed.), State and Society, Orient Longmans, 1976.

22. Charles Bettleheim, Ibid., p.62.

APPENDIX

APPENDIX

PHARMACEUTICAL R AND D AND ITS COMPONENTS[+]

Research and experimental development may be defined as creative work undertaken on a systematic basis to increase the stock of scientific and technical knowledge and to use this stock of knowledge to devise new applications. In the context of pharmaceuticals, R and D concerns primarily with the discovery of new prescription medicines.

For analytical purposes, pharmaceutical R and D can be divided into two broad categories: (a) Direct R and D for the drugs, and (b) supportive R and D or infrastructure.

(a) Direct Components

(i) Basic Research: Basic research is original investigation undertaken in order to gain new scientific knowledge and understanding. It is not primarily directed towards any specific practical aim or application.

Basic research yields new hypotheses, theories and general laws. It involves the analysis of the properties, structures and interrelationships of substances and phenomena of all types with a view to organizing the findings into general laws using explanatory outlines and interpretative theories. The investigation has no immediate specific practical application in view but may be oriented towards an area of interest to the performing organization.

[+] Excerpts organized from: Christopher Freeman, The Economics of Industrial Innovation, Penguin, London, 1974, pp.313-14; K.D. Sharma, C.V. Swaminathan et al., Op.cit. and American Chemical Society, Chemistry and Medicine, (1976) in B. James, Op.cit., pp.59-60.

(ii) Applied Research: Applied research is the practical application of knowledge derived from basic research and covers product and process researches including the problems concerning production, maintenance and so on. This can be further divided into (a) product research on existing lines, which includes new combinations of active ingredients and products of purely imitative nature; (b) product research on new lines consisting of single chemical entities which have not been introduced previously in the Indian industries; and (c) process improvement, either in reduction in number of stages in production or replacement of costly or imported material by cheap and indigenous material or increase in yield/reduction in cost and efficient utilization of inputs.

(iii) Development: Concerns the definition of the optimum dosage form for the substance, transferring the compound into a medical preparation, such as tablets, to establish the most effective, stable, palatable and well tolerated form of administration.

(iv) Therapeutic Research: This is primarily concerned with the clinical testing of new and existing compounds in humans.

Generally clinical testing is carried out in four phases. Phase one is concerned with determining how normal persons metabolize a drug and human safety aspects. In phase two, the drug is tested on a limited number of sick people to assess the drug's effectiveness against a disease

and the dosage ranges of a product. Expanded studies are carried out in phase three to statistically confirm phase two findings and detect rare adverse effects and check interactions with other drugs. Phase four studies are directed towards expanding the therapeutic claims of a product as well as monitoring long term effects.

(b) Supportive R and D or Infrastructure

A special feature of infrastructure or supportive R and D in the drug industry is that many components could have an independent status of research areas by their own merit. However, they have been included here only to indicate their relationship with direct components. Secondly, no chemical - even if its therapeutic value has been established - could be expected to become an accepted drug unless it passes through the various stages of supportive research.

(i) Animal House: This is a vital aspect of the drugs and pharmaceutical industry. This facility is an absolute necessity for development of new drugs, for testing existing ones for quality control during and after production. Many species of animals like mice, rats, hamsters, guinea-pigs, rabbits, dogs and monkeys in various stages of growth are required. Physiological and genetic norms of these animals have to be consistent and known in order to have a good animal house.

(ii) Fermentation Research: This could be considered both as an infrastructure activity as well as primary acti-

vity. Fermentation research is mainly concerned with problems of production of antibiotics and some other types of drugs which are products of fermentation. Raw materials, strain and medium improvement, better control of pit, variation of atmosphere in which the fermentation is conducted, etc. are the fields in which investigations are carried out.

(iii) Equipment, Machinery and Import Substitution: The main plank of this is the development of equipment and machinery required for production of a drug. Drug-making is often a multi-step process. So substitution at any stage will be beneficial not only for the economy, but also for establishing production competence within the country.

(iv) Packaging: This activity could hardly be considered as part of any research activity. Labelling, amount of material to be packed or bottled in containers, upkeep of the quality of the formulations against temperature, humidity, transportation etc. are part of this activity. The problem of high illiteracy and low health and drug consciousness among the general public makes this type of research important.

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