OPPORTUNITIES FOR THE DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY OF INDIA

by

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STATEMENT BY AUTHOR

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FOREWORD

The Problem

As indicated by data in this text, life expectancy for the average person in India is now about forty-two years. In 1900, this expectation of life was about twenty-three years. Thus, today people in India can look forward to a life of nineteen more years than they could have expected sixty-one years ago. This, however, is still far below an adequate span of life such as is cherished in the U. S. A. where it is about seventy years.[1]

If people of India on the average enjoyed a longer span of life, it would yield them a longer opportunity for productive employment. This should permit the development of a much higher productivity rate with more stable growth. The output of essential goods would become cumulatively larger and this, in turn, should give added support to a further rise of life expectancy and would contribute to a rising standard of living.

The pharmaceutical industry in India occupies a key position in bringing about longer life expectancy. It has grown but apparently not at a sufficient rate to serve the interests of the people adequately.

The problem envisaged in this study is to reveal opportun-

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[1]Philip M. Hauser, Population Perspectives. New Jersey: Rutgers University Press, 1960, p. 169

ities for a higher rate of growth of this important industry in India.

Objectives

Our specific aims are to probe these questions:

(1) In what areas might the pharmaceutical industry have a basic opportunity for expanding the flow of proven pharmaceutical products at prices within the reach of the masses in India?

(2) Can the rate of innovation of new products be improved to meet local health needs?

(3) What means might be employed to achieve these ends?

Scope and Method

Both primary and secondary data have been employed in exploring the above possibilities.

Original inquiry was made among a selected list of authorities in both the United States and India by mail. The co-operation obtained from those contacted was very high. It was clear, however, that personal contacts would have been more fruitful but these were beyond the range of practicability - both time and expense, for purposes of this study. Consequently, secondary data was relied upon heavily.

Original information was received from the following:

(1) Some authorities in the field such as Dr. B. Shah, Secretary of Development Council for Drugs, Ministry of Commerce and Industry, Government of India; Mr. P. R. Gupta, Deputy Development Officer (Drugs), Government of India.

(2) Executives of pharmaceutical manufacturing establishments in India (see Technical Appendix for complete list).

(3) Executives of pharmaceutical manufacturing establishments in the U. S. A. (see Technical Appendix for complete list).

Secondary data was assembled from the following:

(1) Reports of certain Commissions and Committees appointed by the Government of India (see Technical Appendix for complete list).

(2) Authoritative books and journals obtained from India.

(3) Literature available at the National Library of Medicine, Washington, D. C. and at the libraries of University of Arizona, Tucson; University of Illinois, Urbana; Stanford University, Palo Alto; and University of California, Los Angeles.

The data assembled from the above sources are believed to provide the facts within sufficient reliability for purpose of this study.

Due to the scarcity of data it was found necessary to draw conclusions largely on a qualitative or judgmental basis.

S. Prakash Sinha

GLOSSARY OF TERMS

Ayurved: An indigenous system of medicine in India.

Rupee: Unit of Indian currency. (Re. 1.00 = $0.21)

Swadeshi Movement: A political movement started by Mahatma Gandhi in 1905, which boycotted British manufactured goods and encouraged indigenous manufactures.[1] (The Sanskrit word "Swadeshi" means "of one's own country".)

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[1]John Cumming, Political India, 1832-1932, London, Oxford University Press, 1932, p. 53

H. T. Maxumdar, Gandhi Versus Empire, New York, Universal Publishing Co., 1932, pp. 133-135

P. A. Wadia and K. T. Merchant, Our Economic Problem, Bombay, Vora and Co., 1957, p. 421

CHAPTER I

SUMMARY

The Objectives

The aims of this study are to explore the areas in which the pharmaceutical industry in India might have a basic opportunity for expanding the flow of proven pharmaceutical products, to probe if the rate of innovation of new products can be improved to meet the local health needs and to suggest some means which might be employed to achieve these ends.

Findings

The study reveals the following:

1. The pharmaceutical production in India has appreciably grown in the past ten years. However, it has not grown enough to provide an adequate amount of pharmaceuticals for the people of India. The pharmaceutical industry of India makes available to the people of India products which amount to only 12 per cent of what the U. S. pharmaceutical industry makes available to the people of the U. S. A.
2. The active demand for pharmaceuticals has been rising in India. It is now nearly twice of what it was in 1952. Besides, there is a great latent demand for such products in India.

3. The productive structure is composed of both public and private enterprise. Most of the producing units seem to be inadequately equipped and their facilities appear to be limited.
4. There is a great number of indigenous drugs which have been used in India for centuries and which have proven therapeutic value. However, their development has not been consistent with the development of modern medicine.
5. Pharmaceutical research in India is conducted by government institutions, universities, medical colleges and manufacturing concerns. However, their facilities seem to be so limited that inadequate product innovation is the consequence especially when compared with pharmaceutical research done in the U. S. A.
6. The problem of spurious drugs affects the utility of an already short supply of drugs and medicines in India.
7. The marketing of pharmaceuticals in India does not seem to follow any well organized pattern.

CONCLUSIONS AND RECOMMENDATIONS

Opportunities for expansion are visualized for the pharmaceutical industry of India, particularly in the areas of organic intermediates, sulpha drugs, iso-nicotinic hydrazides, penicillin, streptomycin, anti-dysentery drugs, para-aminosalicylics and phyto-chemicals.

By organization of intensive pharmaceutical research the rate

of innovation can be improved to meet the local health needs. Drug and pharmaceutical research has a very wide scope in India and may extend from systematic scientific study of the crude drugs that have been used in the indigenous systems of medicine for centuries, on one hand, to the highly developed field of synthetics and antibiotics on the other.

In order to achieve the desired expansion of the Indian pharmaceutical industry, it is suggested that manufacture of drugs and pharmaceuticals starting from the basic chemicals within the country should be encouraged. Further, it is believed that if the government operations are conducted on commercial basis and increasing initiative is permitted to the private enterprise, it will impart a flexibility to the industry whereby it can keep pace with advance of science of medicine and meet the growing human needs. Greater encouragement of foreign technical and financial assistance might prove fruitful for keeping in tune with new discoveries and promoting the expansion of the industry. The marketing task can be made more effective by organizing it along the lines of specialized functions.

If these means are pursued with vigor, greater volume of production will be the result which will supply a larger amount of pharmaceutical products for consumption and would provide wider distribution of these products to a greater mass of people in India. This, it is believed, would help raise the average life expectancy in India.

CHAPTER II

AVAILABILITY AND CONSUMPTION OF PHARMACEUTICAL PRODUCTS IN INDIA

In terms of human need, the volume of pharmaceutical products manufactured by the pharmaceutical industry of India appears to be relatively small. The first systematic effort to measure this volume was made by the Pharmaceutical Enquiry Committee appointed by the Government of India in 1953. According to this Committee's Report, the value of output of Indian pharmaceutical industry was Rs. 346,813,983 in 1952, as revealed by data given in Table I below:

Table 1

Capital Invested in the Pharmaceutical Industry of India in 1952 and the value of Output

Characteristics of Pharmaceutical Industry		Units
Number of pharmaceutical producers		1,643
Capital Invested:	Rupees	236,439,340
	Dollar Equivalent	49,652,261
Value of Output:	Rupees	346,813,983
	Dollar Equivalent	72,830,936
Population of India in 1952		365,000,000
Value of Output per capita:	Rupee	0.95
	Dollar Equivalent	0.20

Sources: (1) Report of the Pharmaceutical Enquiry Committee, 1954,

Ministry of Commerce and Industry, Government of India, p. 21.

(2) Government of India Planning Commission, Third Five Year Plan, A Draft Outline, Planning Commission, Government of India, June, 1960, p.5.

Thus, the products which the Indian pharmaceutical industry made available in 1952 amounted to Re. 0.95 per capita.

Since the 1952 survey, both pharmaceutical output and the population of India have grown. By 1961, the value of pharmaceutical production has risen to Rs. 735,700,000, an estimated increase by 112 per cent of 1952 levels, based on the growth of chemical production as analysed below.

Table 2 presents the index of industrial production as published by the Government of India.

Table 2

Index of Industrial Production

Commodities	Year			
	1951	1955	1956	1959
All commodities	100	122.4	132.6	151.1
Cotton Textiles	100	111.9	117.5	111.5
Iron and Steel	100	113.3	119.4	163.1
Machinery	100	163.9	215.0	424.3
Chemicals	100	159.0	171.1	214.0

Source: Government of India Planning Commission, Third Five Year

Plan, A Draft Outline, Planning Commission, Government of India, June, 1960, p. 18.

Indices for the components of the above four classifications of commodities are not provided in the above publication. However, the classification "chemicals" includes pharmaceuticals, according to correspondence. It is realized that the growth rate for all classes of chemicals conbined including pharmaceuticals, conceals the precise growth rate for individual classes. Nevertheless, based on discussions with several authorities, it is assumed that the growth of pharmaceutical products is roughly the same as the growth for all classes of chemicals. Pharmaceutical production in India is estimated in Table 3 below.

Table 3

Estimate of Pharmaceutical Production in India

Year	Index Number	Value in Rupees
1951	100.00	304,000,000
1952	114.25	346,800,000
1959	214.00	692,800,000
1961	242.00	735,700,000

Thus, the estimate of pharmaceutical production in India for 1961 is Rs. 735,700,000. It increased by 112 per cent of the 1952 level.

As evidenced by data in following Table 4, the population of India grew from 365 million in 1952 to 431 million in 1961, a rise of 66,000,000 or 18 per cent.

Table 4

Growth of Population in India

Year	Population (in millions)	Annual Growth in percent of 1951
1951	362	100
1956	391	108
1961	431	119
1966	480	133
1971	528	146
1976	568	156

Source: Government of India Planning Commission, Third Five Year Plan, A Draft Outline, Planning Commission, Government of India, June, 1960, P. 5.

The population estimate for 1961, as indicated in Chart I, is 431 million. Therefore, the per capita pharmaceutical production in India amounts to Rs. 1.70 in 1961 as compared with Re. 0.95 in 1952. Thus, it has increased by 79%. Nevertheless, this is far below an adequate amount of pharmaceutical products available for the people of India when compared with the United States of America where the pharmaceutical production per capita amounts to $13.92. This is evidenced by data contained in Table 5.

Chart I GROWTH OF POPULATION IN INDIA

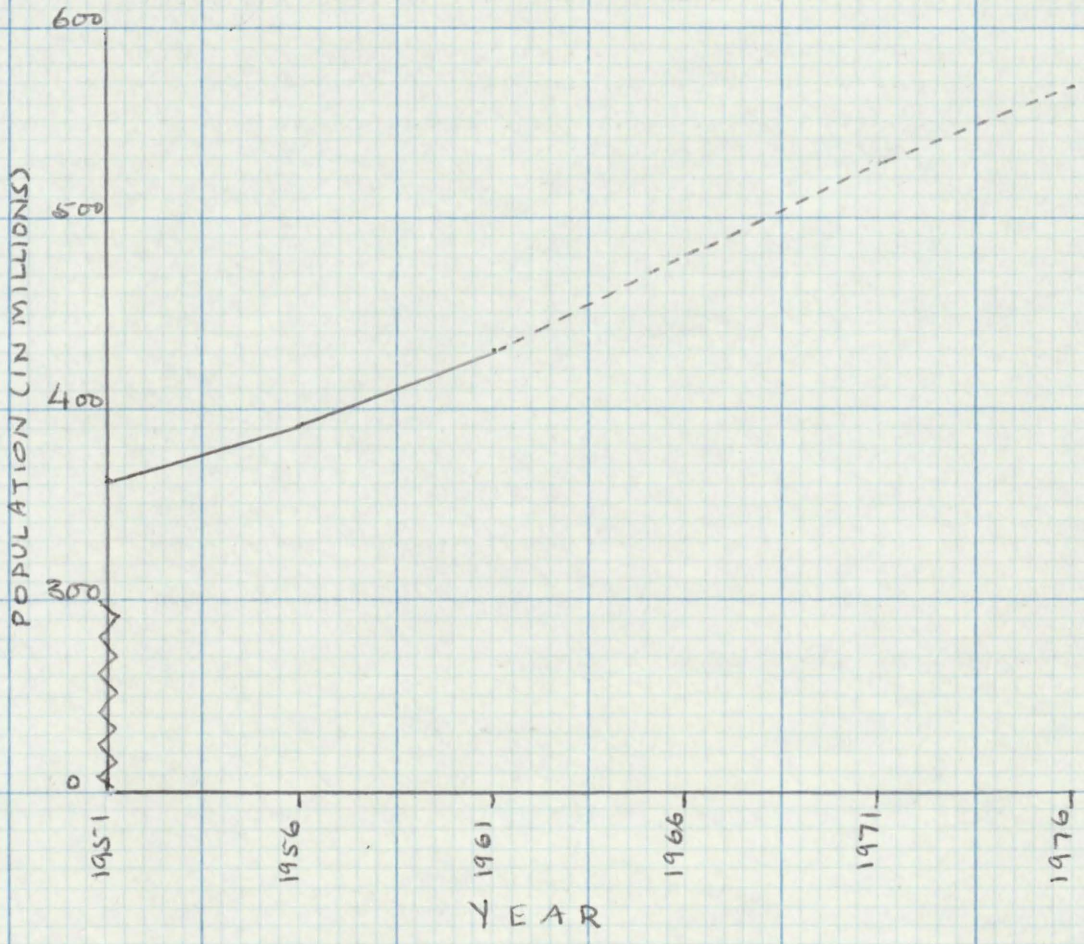

Table 5

Inventory, Shipment, and Production of U. S. Pharmaceutical Industry for the year 1957

Inventory of finished products at the end of year 1956	$ 157,178,000
Add	
Value of Shipments during the year 1957	2,375,102,000
	2,532,280,000
Less	
Inventory of finished products at the end of year 1957	161,718,000
Value of production during the year 1957	2,370,562,000
U. S. Population for the year 1957	170.293 million
Value of per capita pharmaceutical production	$13.92

Sources: (1) U. S. Department of Commerce, Bureau of Census, Annual Survey of Manufacturers, 1957, Washington, D.C., Government Printing Office, p. 20, 98, 118, 136.

(2) U. S. Bureau of Census, Current Population Reports, series p25, nos. 171, 191, 195.

On the basis of above analysis, the per capita pharmaceutical production amounts to Rs. 1.70 in India and $13.92 in the U. S. A. The purchasing power of a rupee in India is almost equal to that of a

dollar in the United States.[1] Therefore, the ratio of pharmaceutical products available per capita in India and in the U. S. A. is 1.70 to 13.92. In other words, the Indian pharmaceutical industry makes available for the people of India products which amount to 1/8th of what the U. S. pharmaceutical industry makes available for the people of the United States. Thus, to fight his disease an Indian, on the average, has access to only 12 per cent of the medicines that are available to an average American. This may be a significant reason why the expectation of life in India is only 42 years, as demonstrated by Chart II. The death rate, as illustrated in Chart III, is as high as 19.8 per thousand for 1961. Further, a high incidence of deaths prevails largely on account of diseases as is evident from Table 6 which shows general death rates in India.

Thus, the incidence of deaths on account of diseases in India was 61.09 per cent of the general death rate in 1959 and as read from Chart IV, it is 57.5 in 1961. The decline is significant. Nevertheless, the incidence of deaths due to sickness is very high since more than half of the deaths still occur on account of diseases.

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[1]This is a matter of general experience. For example a cotton shirt may be bought in India for Rs. 3-4. In the U. S. one can buy it for $3-4. A pair of shoes may be had for Rs. 10-15 in India. Its price in the U. S. is $10-15.

Chart II EXPECTATION OF LIFE AT BIRTH

IN INDIA AND THE U. S. A.

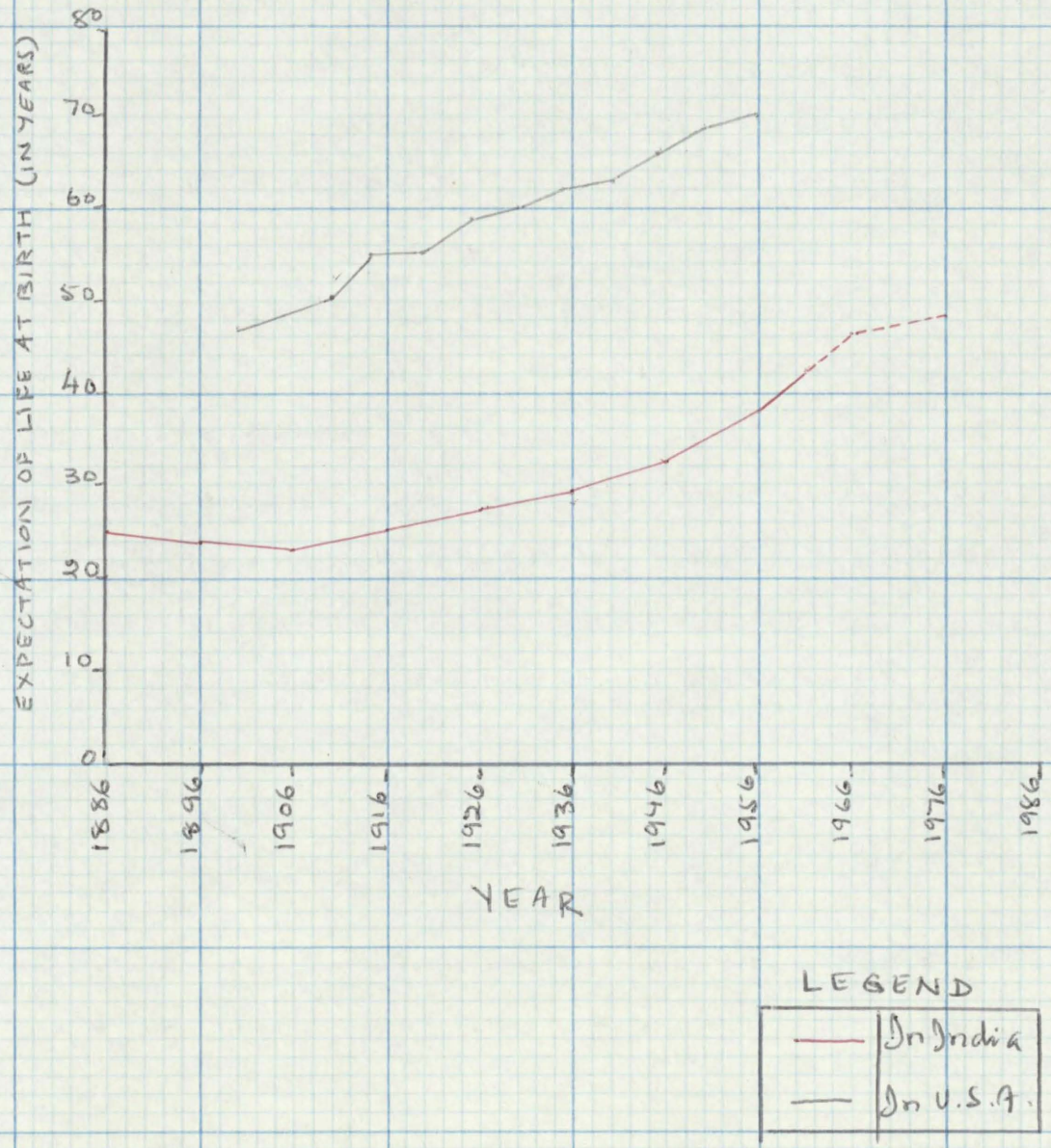


Chart III DEATH RATE IN INDIA

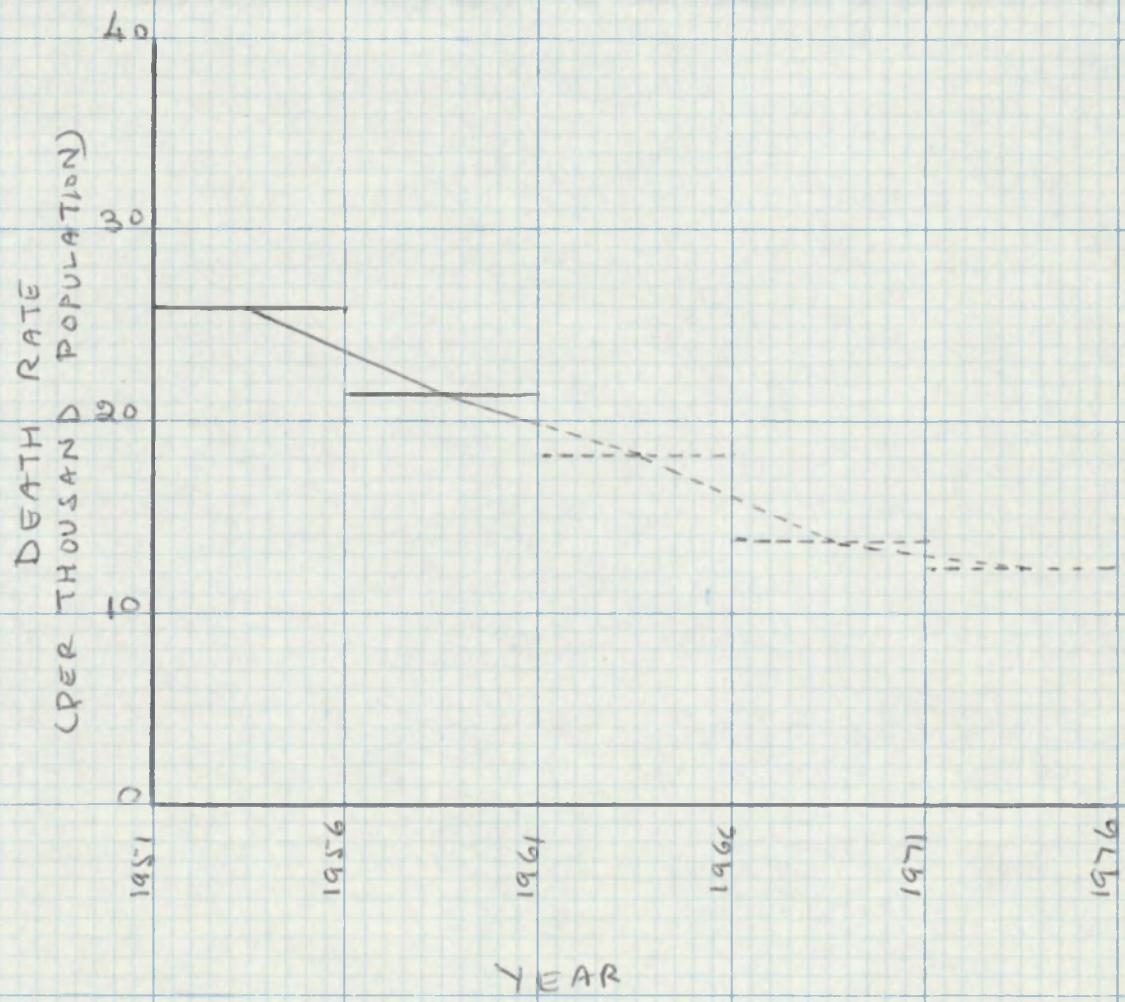


Table 6

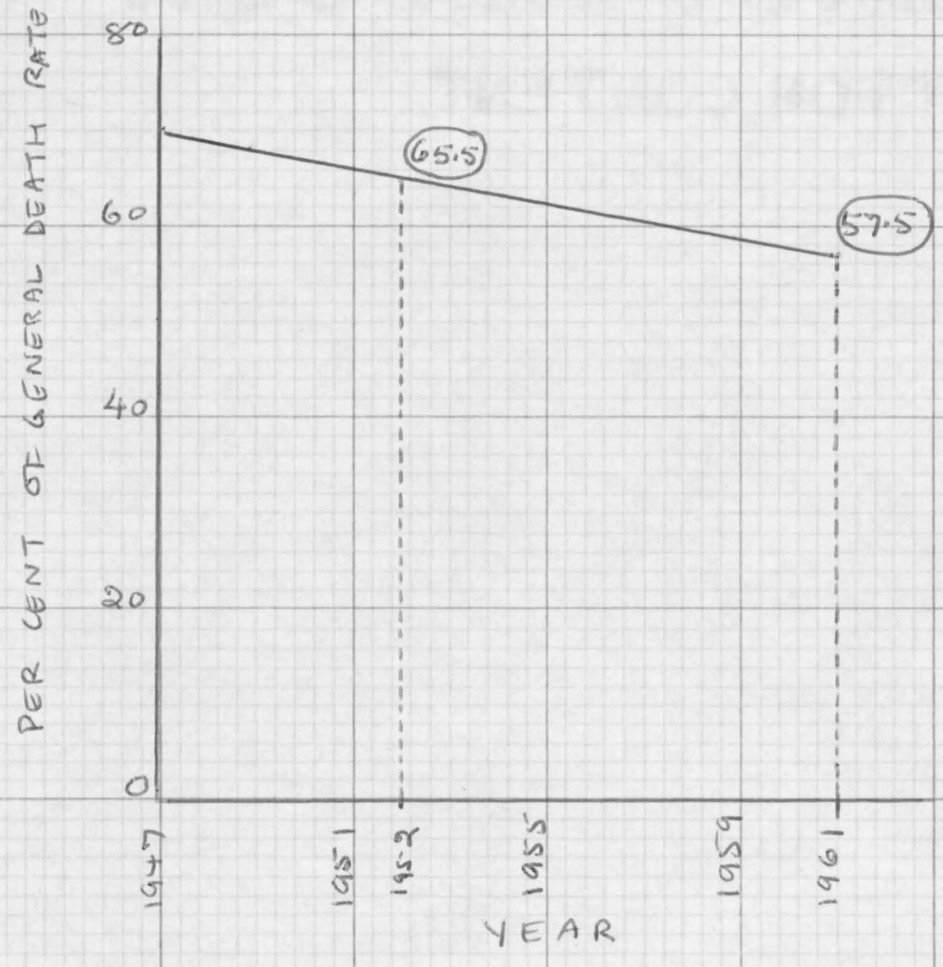
Deaths in India

		1947	1957
General Death Rate per Thousand of Population		19.7	11.1
Incidence of Deaths per Thousand on account of diseases:		13.9	6.7
(i)	Fevers	10.8	4.8
(ii)	Small Pox	0.1	0.16
(iii)	Plague	0.3	0.0
(iv)	Cholera	0.4	0.16
(v)	Dysentary & Diarrhea	0.8	0.5
(vi)	Respiratory Diseases	1.5	1.1
Incidence of deaths per thousand due to other causes		5.8	4.3
Percentage of total deaths due to diseases		70.06	61.09

Source: India 1960, A Reference Manual, Research and Reference Division, Ministry of Information and Broadcasting, Government of India, New Delhi, Publications Division, Government of India, 1960, p. 139.

Chart IV INCIDENCE OF DEATHS IN INDIA

ON ACCOUNT OF DISEASES



CHAPTER III

ESTIMATES OF DEMAND AND AREAS OF EXPANSION

Estimates of Demand

In monetary terms, the value of pharmaceutical products consumed in India for 1961 is estimated at Rs. 735,700,000 based on the volume of sales as shown in Chapter II, Table 3. This is compared to the volume of sales in 1952 which amounted to Rs. 346,000,000. Since that year, the price level in India has risen by 20 per cent.[1] Therefore, after being adjusted by the inflation factor, the real output for 1961 amounts to Rs. 685,560,000, which is 98 per cent above the 1952 level.

The estimates of sales of pharmaceutical products in India for 1961 are revealed, in terms of quantity, in Table 7. These estimates are based on the real rise in production of pharmaceuticals in 1961.

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[1]Government of India Planning Commission, Third Five Year Plan, A Draft Outline, Planning Commission, Government of India, June, 1960, p. 45.

Table 7

Annual Sales of Pharmaceutical Products in India

	Product	Unit	1952 Estimates	1961 Estimates
1.	Antibiotics	lb.	44,155,000	87,427,000
2.	Sulpha Drugs	lb.	1,330,000	2,633,000
3.	Anti-malarials	lb.	320,000	634,000
4.	Vitamins:			
	Cod Liver Oil)			
	Shark Liver Oil)	gls.	100,000	198,000
	Others	lb.	1,310	2,600
5.	Endocrines	m/u	125	250
6.	Heamatinics:			
	Liver extract oral	lb.	700,000	1,386,000
	Crude Liver extract injectibles	ccs.	22,500,000	44,550,000
7.	Anaesthetic and Analgesics	lb.	281,000	556,000
8.	Anti-syphilitics	lb.	2,500	5,000
9.	Anti-leprosy	lb.	32,000	63,000
10.	Anti-tuberculosis	lb.	125,900	249,000
11.	Vaccines, sera and Anti-toxins	ccs.	110,000	218,000
12.	Drugs of vegetable origin	lb.	21,000	42,000
13.	Other Drugs	lb.	2,578,000	5,104,000

Scource: Report of the Pharmaceutical Enquiry Committee, Ministry of Commerce and Industry, Government of India, 1954, pp. 125-130.

Generally speaking, therefore, the active demand for pharmaceutical products in India is now nearly twice of what it was in 1952.

Areas of Expansion

Possibilities of expansion are visualized in eight categories of pharmaceutical products. These are organic intermediates, sulpha drugs, anti-tuberculosis drugs, penicillin, streptomycin, anti-dysentery drugs, I. N. H., and phyto-chemicals. The pharmaceuticals are classified in nine categories by the Third Five Year Plan of the Government of India. This classification includes the above products and the insecticides. The Plan sets forth the targets of production for these nine classes, to be achieved by 1966 which is the end of the Third Plan period. The Plan also lays down the 1961 production figures for these classes. The scope for expansion is disclosed by comparing targets with present production for every class.

Table 8 below presents the quantitative measurement of the scope for expansion in production of the various classes of pharmaceutical products in India. It also reveals the percentage of increase required in the present level of production in order to meet the targets.

A sound opportunity appears to exist for additional production of organic intermediates. Manufacture of sulpha drugs can be expanded by five and a half times that of the present level. Anti-

tuberculosis drugs offer a potential for 300 per cent increase. Production of penicillin can be tripled. Output of streptomycin, anti-dysentry drugs and iso-nicotinic hydrazides (I.N.H.) can be raised by about one and a half times that of the present volume. Scope also exists for increasing the production of phyto-chemicals. No further expansion in the manufacture of insecticides seems to be visualized by the Government of India's Third Five Year Plan. However, upon the basis of personal observation of the use of insecticides in Indian homes, it is felt that a large scope exists for additional consumption of insecticides in India.

Table 8

Targets, Production and Scope for Expansion

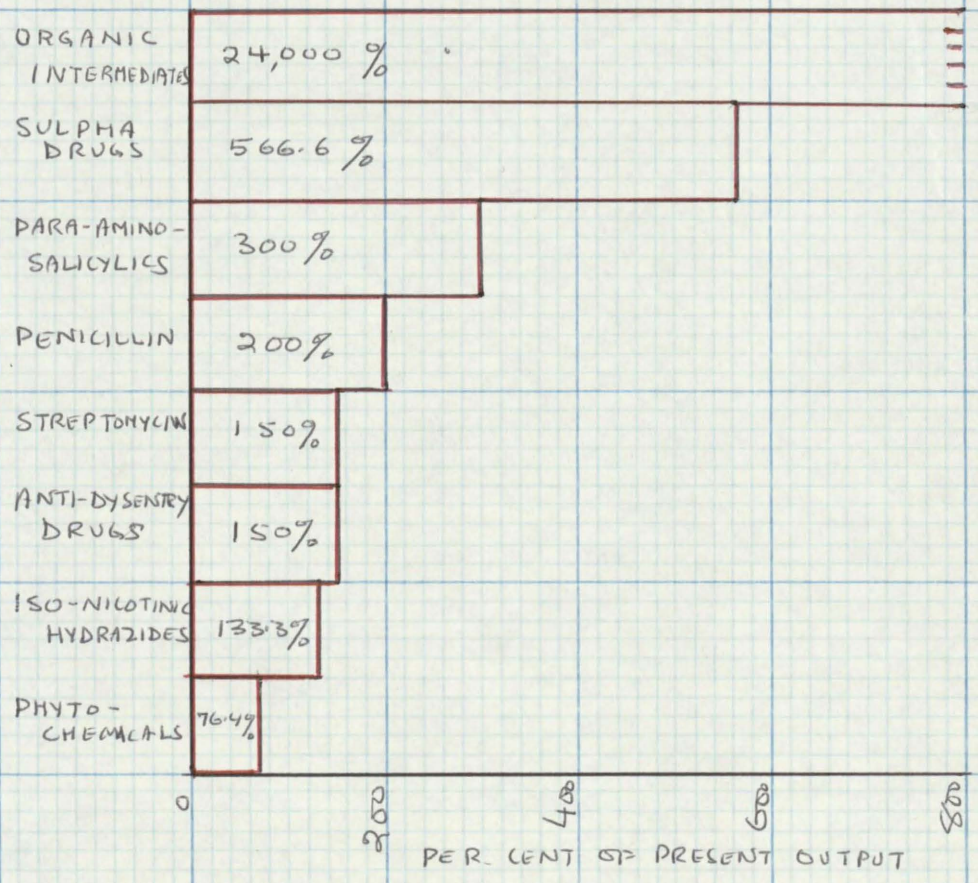
in the Manufacture of Pharmaceutical Products in India

Product classification	Units	Target of production for 1966	Production for 1961	Additional production needed to meet the target	Percentage increase required in present volume of production to meet the target
Sulpha Drugs	tons	1,000	150	850	566.6
Penicillin	milli-mega-units	120	40	80	200.0
Streptomycin	tons	150	-	150	Infinite
Para-amino-salisylics	tons	400	100	300	300.0
Iso-nicotinic-hydrazides	tons	100	30	70	133.3
Anti-dysentry Drugs	tons	75	30	45	150.0
Organic intermediates	tons	24,000	-	24,000	Infinite
Phyto-chemicals	tons	76.4	-	76.4	Infinite
Insecticides	tons	2,800	2,800	-	0.0

Source: Government of India Planning Commission, Third Five Year Plan, A draft Outline, Planning Commission, Government of India, June, 1960, pp. 238-239.

Chart V AREAS OF EXPANSION IN THE

PHARMACEUTICAL INDUSTRY OF INDIA



CHAPTER IV

THE PRODUCTIVE STRUCTURE

The productive structure of the Indian pharmaceutical industry may be divided into the following four classes:

(A) State enterprise

(B) Large scale private enterprise under foreign control

(C) Large scale private enterprise under Indian management

(D) Small scale private enterprise

(A) STATE ENTERPRISE

Both Central and State Governments have set up factories which participate in the manufacture of pharmaceutical products in India.

Flexibility is of particular importance in the production of pharmaceuticals due to the rapid advances being made in the science of medicine. By its nature, however, the social method of production of pharmaceuticals appears as somewhat inflexible. Their production under private enterprise promises the flexibility needed to expand output consistent with growing science and human needs. Instead of undertaking manufacturing activities, the government may find better results by conducting research and recommending production of new products.

Attempt is made hereunder to analyze the activities of state enterprise in the field of pharmaceutical production. Although changes might be made to bring the operations up to date, a reversion

to former status is feared due to their inflexibility.

The government factories are distinguished as:

(i) Medical Store Depots; and

(ii) Other Factories.

(i) Medical Store Depots

The Government Medical Stores were set up in 1870 to store medical supplies for the army. Of these, the Stores now left in the country are located at Madras, Bombay and Calcutta.[1] Originally these depots were merely storages for drugs, medicines and surgical instruments for military and semi-military organizations. These supplies were either received from abroad or purchased from Indian market. In course of time, however, these depots commenced preparation of pharmaceuticals up to the British Pharmacopoeia Standard at prices at which the European market could not supply.[2] An enquiry instituted in 1910 by the officers of these Depots recommended continuance of their manufacturing activity as being necessary to meet the demand. The demand on the resources of the Medical Stores Depots grew considerably during the World War I due to sinking of the ships carrying medical supplies to India and because of the Government of India's decision in 1917 that all schools, colleges, laboratories and scientific institutions should obtain their supplies from these depots. The Drugs Enquiry Committee set up by the Government of

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[1]Government of India, Ministry of Commerce and Industry, Report of the Pharmaceutical Enquiry Committee, New Delhi, 1954, p.25

[2]Ibid., p. 25

India in 1930 appraised the manufacturing activities of these Depots. The Committee received strong protests from the representatives of pharmaceutical manufacturing firms in Calcutta and Bombay according to whom the government manufacturing activities hindered the growth and expansion of the pharmaceutical industry in India. The Committee, however, came to the conclusion that Medical Store Depots were no great rivals to the drug trade because the quantities prepared by them were very small compared to the volume of production of the rest of the factories. State enterprise in this direction was recommended to provide stand-by in case of war or sudden stoppage of imports and to provide a deterrent to profiteering by private firms.[3]

By the creation of the Armed Force Medical Store Depots during World War II, the Medical Store Depots were confined to supplying the civil medical requirements of the Central and State Governments. They were also brought under the control of the Health Ministry. Due to the general shortage of supply of drugs and medicines in the world during this period, the Medical Store Depots were able to supply only 45 per cent of the demand from its restricted group of buyers.[4] In 1950, the Health Ministers' Conference was convened to discuss this shortage following which vigorous steps were taken to improve the situation by altering the provisioning methods. By the year 1951-52,

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[3]Government of India, Report of the Drug Enquiry Committee, 1930-31, Delhi, 1931, pp. 21-34.

[4]Government of India Ministry of Commerce and Industry, Report of the Pharmaceutical Enquiry Committee, New Delhi, 1954, p.26

the supply position against demand rose to 90 per cent.[5]

The activities and facilities of the Medical Store Depots were thoroughly examined by the Pharmaceutical Enquiry Committee which reported in 1954 that

> "the equipment used is out of date and the products made consist of common items which are also produced by private manufacturers. The procedure employed in obtaining raw materials and equipments is very cumbersome and not conducive to the efficient running of the factories... The production of these Depots is in no way larger than that of other private concerns to accrue the advantage of bulk purchase of raw materials and economies of large scale production. Added to these, the antiquated equipment, cumbersome procedure of obtaining raw materials, increase their inefficiency and cost of production."[6]

The Committee did not consider it advisable to discontinue these Depots. It, however, recommended that the manufacturing activities in these depots should be reorganized and method of management changed to conform to commercial practices. The antiquated equipment should be replaced by modern equipment.

Discussion with authorities reveals that the Government has adopted these recommendation. The process of rationalization of these Depots is, however, not fully completed yet. It is submitted that steps be taken to implement a thorough re-organization of these Depots on a commercial basis. Also, their manufacturing activity should be restricted to the production of essential items such as fine chemicals and glandular products which are not being produced adequately by the private sector.

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[5] Ibid., p. 26

[6] Ibid., p. 28

(ii) Other Factories

The other factories run by the Government include the penicillin factory, the D.D.T. factories, the opium factory, the quinine factories and the shark liver oil factories.

Penicillin Factory

The Government Penicillin Factory was started as a result of an agreement concluded on July 24, 1951 between the Government of India, World Health Organization and the United Nations International Children's Emergency Fund. The management of the factory is vested in the Hindustan Antibiotics Limited, a state enterprise with an authorized capital of Rs. 40 million.[7] The production commenced in August, 1955. Since then, the factory has been meeting its annual production targets.[8]

As noted in Chapter III, Table 8, an expansion of 200 per cent of the present production is visualized in the manufacture of penicillin in India. It is not known whether this factory will be capable of meeting this demand. However, it is believed that encouragement of private enterprise in this field might render better assured results.

D.D.T. Factories

A factory for the production of D.D.T. was established in Delhi by the Government of India following an agreement entered by

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[7]S. C. Sarkar, Hindustan Year Book, Calcutta, M. C. Sarkar and Sons Publishing Ltd., 1960, p. 434.

[8]Ibid., pp. 434-435

it on July 19, 1952, with the World Health Organization and the United Nations International Children's Emergency Fund. At present, this factory is producting 1,400 tons of technical D.D.T. per annum.[9] The Government of India has started another D.D.T. factory in Alwaye which went into production in 1960. The Alwaye factory has a capacity to produce 1,400 tons of D.D.T. per annum.[10] Both these factories are being managed by the Hindustan Insecticides Private Limited, a government owned company.

As indicated in Chapter III, the latent demand for insecticides in India is more than 2,800 tons per annum and this demand is expected to grow with the rise in the standard of living of the people in India. Obviously, production in the government factories will not be able to match this growing demand.

Opium Factory

Factories for production of opium were opened by Government of India in 1820 after the State monopoly in the field was introduced in 1797 in the interest of government revenues.

Opium is obtained by incision from the unripe capsules of poppy and poppy is purchased by the Government from the individual cultivators. A quality bonus for high morphine content is the only step taken by the Government to induce cultivation of better grades of poppy. It is recommended that the Government should set up experi-

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[9] S. C. Sarkar, op. cit., pp. 426-450

[10] Ibid., p. 435

mental plantations in order to increase the yield of opium, render technical service and advice, supply better grades of seeds and demonstrate improved methods of cultivation to help the private cultivators to improve their produce.

There is hardly any mechanization in the plant,[11] and recommendations have been made to mechanize operations involved in the factory. This, it is believed, would reduce the cost per unit of production by improving the efficiency of production.

Medicinal use of opium will increase with the growth of pharmaceutical industry in India. Manufacturing activity under private enterprise promises flexibility which would assure adequate supply to meet the increasing demand. Government Factory may be improved and its operations may be mechanized but it will soon revert to former status due to the inherent inflexibility of public enterprise. The Government can very well have controls over the use of opium as narcotic without undertaking its production.

Quinine Factories

Factories for manufacture of quinine were started in 1871. They were originally set up for extraction of the total alkaloids from Cinchona plant which is the source of quinine. Later, these factories began producing quinine sulphate. At present these factories are located at Madras, Naduvattam in the Nilgiris, Anamalai and Mungpoo in Bengal.

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[11]Government of India, Report of the Pharmaceutical Enquiry Committee, op. cit., pp. 30-35

For the past few years the sales of natural quinine have declined sharply in the country due to a fall in the incidence of malaria and the appearance of a number of synthetic anti-malarials. The Government of India's Special Cinchona Committee, therefore, recommended no new planting towards expanding the total area of cinchona cultivation.[12] Even in re-planting areas normally vacated by uprooting of the trees, the Committee recommended that the Government should exercise a degree of caution.

It is, however, believed that through the use of commercial ways of marketing and distribution, the market for anti-malarials in India could be extended so that the demand for quinine, either natural or as a component to synthetic anti-malarials, would grow.

Shark Liver Oil Factories

The factories for extraction of shark liver oil were started by the Governments of Madras and Bombay during World War II. These factories were established as a result of investigations undertaken to reveal opportunities for development of sources of vitamin A within the country. It was discovered that shark liver oil containing a high vitamin A concentration could be extracted on a commercial scale and used for medicinal purposes. The Governments of Madras and Bombay established the factories for its extraction.

The Panel on Fine Chemicals, Drugs and Pharmaceuticals, appointed by the Government of India in 1944-45 stressed the need for

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[12]Government of India, Report of the Special Cinchona Committee, New Delhi, 1953, pp. 29-35

putting the industry on a sound and permanent footing and suggested the formation of a permanent Advisory Board whose functions would be (a) to indicate steps for securing adequate supplies of sharks, (b) to study and fix seasons during which fishing should be carried out to safegard the proper breeding of sharks, (c) to devise proper methods for the extraction of shark liver oil and utilization of by-products, and (d) suggest other measures for improving the industry.

A later study reveals that no attempts have been made to implement the above suggestions.[13] The two Government factories compete with each other for the sale of their products and fishing still remains unregulated. There is also a lack of co-ordination between the manufacturing and marketing activities of the two Government factories. The Central Government should look into this situation to see that the State Governments take the necessary steps to conserve this important source of vitamin A and to co-ordinate the activities of the two factories.

There is a great latent demand for vitamin A in India and the demand will grow with spread of education and rise in the standard of living. It does not appear that the two government factories will be able to meet this demand and be flexible enough to keep pace with the advance of science and human needs. It is, therefore, recommended that private enterprise should be permitted initiative in this sphere.

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[13] Report of the Pharmaceutical Enquiry Committee, op. cit., p. 55

(B) LARGE SCALE PRIVATE ENTERPRISE UNDER FOREIGN CONTROL

The pharmaceutical concerns under foreign control are either branches of foreign firms within the country or Indian subsidiaries of foreign firms. Some are mainly engaged in imports while others have undertaken manufacturing activities.

The Government of India has given the following assurances to the investments of foreign capital in Indian industry:[14]

1. No discrimination between foreign and Indian undertakings in application of general industrial policy.
2. Reasonable facilities for the remittance of profits and repatriation of capital consistent with the foreign exchange position of the country.
3. Fair and adequate compensation in the event of nationalization.

This policy has been "faithfully honored since the time it was adopted".[15]

The Planning Commission of the Government of India has laid out a broad principle that foreign investment should be permitted in so far as new lines of production are to be developed, or where special types of experience and technical skill are required, or where the volume of domestic production is small in relation to de-

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[14]Government of India, Industrial Policy Resolution, New Delhi, 1948.

[15]Selig S. Howson, ed., India and the United States, New York, The MacMillan Company, 1961

mand and there is no reasonable expectation that the indigenous industry can expand at sufficiently rapid pace.

A majority of the pharmaceutical firms under foreign control process imported bulk pharmaceuticals into compounded preparations, tablets, ointments, injectibles, etc.[16] Similar processing work is also carried on by a large number of Indian firms. Therefore, their activities do not really come under the category of providing new lines of products. At present, neither does the majority of processing work involve special types of experience and skill which indigenous industries cannot undertake. Protests, therefore, have been made by the Indian manufacturers against this activity of foreign firms processing bulk pharmaceuticals. Once a foreign firm has been allowed to establish itself in the country, no discrimination can be made as regards its activities and the suggestion that they should be restricted to production of bulk pharmaceuticals is untenable. However, while there should be no objection to the foreign firms producing pharmaceuticals to meet established markets, they should not be restricted only to this sphere, making the country dependent on foreign imports of bulk pharmaceuticals. They should be permitted to progressively extend their manufacturing activities to include the production of bulk pharmaceuticals starting from basic chemicals and intermediates as near the basic chemicals as possible.

Besides the firms mentioned above, some of the Indian firms

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[16] Report of the Pharmaceutical Enquiry Committee, op.cit., pp. 61-66.

have also undertaken production of pharmaceuticals under agreement with foreign firms.

The agreements for such collaboration are broadly of four types:

1. Agreements with foreign concerns and their Indian subsidiaries embodying royalty terms.
2. Agreements between foreign firms and their branches in India embodying royalty terms.
3. Agreements between foreign firms and Indian firms in which capital is partly foreign and partly Indian, with royalty payments to foreign firms.
4. Agreements between foreign firms and Indian firms in which capital is entirely Indian, with royalty payments to foreign firms.

The agreements include a variety of terms which were examined by the Pharmaceutical Enquiry Committee of the Government of India. The Committee concluded that there were no definite guiding principles that appeared to have been followed while drawing these agreements.[17] The Committee recommended that foreign collaboration should be allowed only when a firm agrees to commence with the manufacture of basic drugs from primary raw materials. This kind of activity would provide a sound foundation for expansion of the industry.

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[17] Report of the Pharmaceutical Enquiry Committee, op. cit., pp. 66-71

(C) LARGE SCALE PRIVATE ENTERPRISE UNDER INDIAN MANAGEMENT

Based upon the nature of pharmaceuticals they produce, the Indian managed large scale private enterprises may be classified as under:

1. Manufacturers and processors of drugs.
2. Manufacturers of disinfectants, insecticides and their formulations.
3. Manufacturers of surgical dressings.

i. Manufacturers and processors of drugs

The manufacture of galenicals is the most common activity of these firms. The next common activity is the manufacture of biological products, especially liver extracts, vaccines and sera. The manufacture of fine chemicals such as ether, chloroform, calcium lactate etc., and synthetic drugs have also been undertaken by these firms.

As observed by an Enquiry, many of the factories make glandular products and vaccines which are not up to the standard required.[18] Furthermore, many of the factories are able to utilize only 50 per cent or even less of their installed capacity.

ii. Manufacturers of disinfectants and insecticides

Disinfectants and insecticides are produced by private industry to a very limited extent and the most common disinfectant made is

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[18] Report of the Pharmaceutical Enquiry Committee, op. cit., p. 75

phenyl from coal tar fractions for sanitation work. The main producer is Government of India which has started two factories in this field.

As observed earlier in this chapter, it is doubted if the government factories would be able to meet adequately the growing need for disinfectants and insecticides in India. Encouragement, therefore, should be accorded to the private enterprise to undertake and expand manufacture of these products.

iii. Manufacturers of surgical dressings

Production of surgical dressings was well expanded during World War II and immediately after the War some products were exported. However, due to poor quality, these export markets were lost.

A very unhealthy competition exists and the quality is being constantly sacrificed. But the need for these products is general throughout the country and is expected to rise as modern medicine becomes increasingly popular with the mass and is brought within their means through greater production and better marketing.

(D) SMALL SCALE PRIVATE ENTERPRISE

A number of small establishments came into existence in the country following the World War II, for making galenicals and processing drugs into tablets, capsules, etc. A count was made in 1954 and of a total number of 1,642 pharmaceutical manufacturers in India, 1,568 were found to be small scale manufacturers who, on the average, had a capital investment of Rs. 110,000 and employed 20 persons.[19]

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[19] Report of the Pharmaceutical Enquiry Committee, op. cit., p. 80

These small scale factories are situated in insanitary places and use obsolete machines without adequately qualified staffs. Due to the cut-throat competition, the manufacturers are working on a very small margin of profit. Very few of them have resources to obtain better equipment or buy better raw materials. There is not much promise for these factories if they continue in the present state. They might work on a co-operative basis as larger and better equipped units by pooling their resources.

Thus, both private and public sectors participate in manufacture of pharmaceutical products in India. Most of the producing units seem to be inadequately equipped and the facilities are limited. Social method of production does not seem suitable for producing drugs and medicines since it is not flexible enough to keep pace with advance of science and growing human needs which characterize the pharmaceutical industry. There is a great latent demand for pharmaceuticals in India. The existing productive structure, however, is inadequate to exploit it and meet it. Indian pharmaceutical industry, as noted in Chapter II, makes available for the people of India products which amount to only 12 per cent of what the pharmaceutical industry makes available for the people of the United States. This may be significant reason why the expectation of life in India is only 42 years.

CHAPTER V

AN APPRAISAL OF MANUFACTURE OF INDIGENOUS DRUGS IN INDIA

Nature of drugs used in indigenous medicine

Many of the effective remedies of the indigenous systems of medicine in India have been lost during the course of time since their origin and a number of uncertain ones have sprung with the result that, at the present, almost every plant and shrub growing in the country has been ascribed some medicinal virtue. Remedies have multiplied without proof and in many cases no correct notion seems to prevail as to their uses and properties.

A thorough and complete research into all these drugs would constitute life-long work of innumerable chemists, pharmacologists and physicians. The method adopted for practical purposes has been to make use of the experience of indigenous practitioners and to take up for investigation those drugs which have a great local reputation[1] before examining the less reputed remedies. A number of those drugs have also been clinically tried by medical men practising western medicine.

Many of the remedies mentioned in the old books defy recognition and one cannot be certain from the description whether the specimens obtained are of a particular drug described. The identi-

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[1]Chopra, Ram Natha, Indigenous Drugs of India, Calcutta, U. M. Dhur & Sons, 1958, p. 18

fication of drugs will remain a problem until the characteristics of each drug become established. Their verbal description given in the books does not enable the botanists to identify some plants. Confusion has been the result so that many drugs are being sold under various names and different drugs under the same name.[2] Even the learned indigenous practitioners cannot say with certainty which is the authentic specimen meant in the old texts. As a result of vague and confusing descriptions some of the important drugs of Ayurveda are not available at all.[3]

There are no chemical or biological standards laid down anywhere to evaluate the properties of indigenous drugs. Since there is no pharmacopoeia of indigenous drugs where standards are laid to judge the quality of drugs, the drug dealers take full advantage of this and sell to their customers anything that resembles or may be made to resemble the genuine drug.

Attempts at revival of indigenous systems of medicine

The Government of India has decided to recognize only the modern system of medicines, because it is international in scope and has attained highest standards of development. However, the well settled policy of the Government is to give all possible help and encouragement to the indigenous systems of medicine and incorporate from them contributions of approved value in the existing system of

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[2] Indigenous Drugs of India, op. cit. p. 23

[3] Indigenous Drugs of India, op. cit., p. 26

medicine. A committee under the chairmanship of D. T. Dave made various recommendations for the improvement of indigenous systems of medicine such as a five and half year degree course[4], but the Central Council of Health held that it was not possible to lay down a uniform policy[5] and recommended that state governments should take practicable and desirable steps in this matter. The Government of India has established a Central Institute of Research in Indigenous Systems of Medicine and a Post-Graduate Training Center in Ayurveda at Jannagar in 1953. In 1955 the Government of India approved a five-year degree course in homeopathy. In 1959 the Government of India constituted a Central Council of Ayurveda Research under the Ministry of Health. The Second Five-year Plan (1956-1961) made a provision of Rs. 10 million for the development of indigenous systems of medicine.[6] Rs. 52 million were provided in the States' Plan for the same purpose and a sum of Rs. 22 million was earmarked for the improvement of existing colleges and the establishment of new colleges in indigenous systems of medicine. The Third Five-year Plan (1961-1966) allocates Rs. 80 million for the development of indigenous systems of medicine.[7] The programs include training, research,

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[4]S. C. Sarkar, Hindustan Year Book, Calcutta, M. L. Sarkar & Sons Publishing Lab., 1960, p. 396

[5]Ibid, pp. 396-397

[6]Government of India Planning Commission, Second Five-year Plan, A Draft Outline, New Delhi, Planning Commission, Government of India, Feb. 1956, p. 155

[7]Government of India Planning Commission, Third Five-year Plan, A Draft Outline, New Delhi, Planning Commission, Government of India, June 1960, p. 116

standardization and improvement of products. It is proposed to establish herbaria with a few selected herbs locally available in individual development blocks.

Why should research be carried on in indigenous drugs?

The question is very appropriate in the light of the rapid strides and remarkable progress made in the fields of chemistry and modern medicine. The group of antibiotic drugs have revolutionized the treatment of many bacterial and rickettsial diseases and even virus diseases.

The diseases which were considered incurable a while ago are now treated successfully by modern medicine. What is, therefore, the necessity for going on with research on indigenous drugs? The wise and experienced clinician never spurns an "old wife's tale" until he has good evidence for doing so. The lore of the countrymen is built upon the experience of generations--often centuries-- and the data upon which it is based have often been obtained at a price of human lives which no modern research worker would ever dream of considering. At the present moment, when the pharmaceutical companies of the world are emitting an increasing flow of new synthetic drugs, it is appropriate that attention should be turned to the possible remedies that may be found among indigenous herbs of India and other countries. Much remains to be learned from a close study of indigenous herbs. It may well be that here lies one of the major contributions that countries such as India can make to the advancement of world health. Synthetic processes for which a chemist requires enormously high degrees of heat and pressure are being quickly carried on by

nature in plants at ordinary conditions of temperature and pressure. Chemists synthesised such alkaloids as quinine after intensive work extending over half a century whereas cichona plant does it every day. Many active anti-biotics occur in plants and this is yet an unexploited field. What is in store, nobody knows. Only research can reveal it.

CHAPTER VI

RESEARCH WORK

Pharmaceutical research in India is carried on by the following bodies:

A. Government Institutions and Universities.

B. Medical Colleges.

C. Manufacturing Concerns.

A. Research work by Government Institutions and Universities

The Indian Council of Medical Research and the Council of Scientific and Industrial Research have sponsored a number of research projects in drugs and medicines in India. The special features of these projects has been their concentration on the indigenous drugs of India.[1] These researches have been undertaken with the following objectives:

(1) To make India self-supporting by enabling her to utilize the drugs available to the country and manufacture them in a form suitable for administration.

(2) To discover effective remedies from the claims of indigenous systems of medicine.

(3) To discover the means of effecting economy, so that

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[1]Government of India Ministry of Commerce and Industry, Report of the Pharmaceutical Enquiry Committee, New Delhi, 1954, p. 175

these remedies would fall within the reach of the masses.

As a result of these investigations, the utilization of a large number of drugs which grow wild and in great abundance in India, has become possible. A number of pharmacopoeial drugs which did not naturally grow in the country, have been introduced and found to thrive well when cultivated under proper conditions. A large number of plants, which grow in India, and which can form excellent substitutes for the imported remedies, have been made available for use. Frequently, these are allied species which are pharmacologically as active as the imported varieties. A considerable amount of work has been undertaken to determine the active ingredients of these drugs, their composition and pharamacological action, by various university laboratories in the departments of chemistry and pharmaceutics. Pharmaceutical preparation of active principles from these sources are now being manufactured by most manufacturing concerns.[2] Data with regard to 180 items has been published by the Ministry of Health of Government of India as the first Indian Pharmacopoeial list. It is a book of standards for Indian drugs and has the same status in India as the British Pharmacopocia. From this list, the Ministry of Health has compiled the first Indian Pharmacopocia. An Indian Pharmaceutical Codes has been prepared which provides 193 monographs[3] and a Formulary has been developed which gives pharmacognostic, chemical, pharmacological and therapeutic data on indigenous drugs with their preparation

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[2] Ibid, p. 176

[3] Ibid, p. 176

and dosage for the use of medical and pharmaceutical profession. Efforts are being made to bring them into use in the treatment of minor maladies.

The work of discovering remedies from the claims of the indigenous systems of medicine in India has been a very difficult task due to the fact that many of the effective remedies have been lost in the course of time and increasingly replaced by many useless substitutes. Almost every plant and shrub grown in the country has been ascribed some medicinal virtue. The remedies have multiplied without proof. Therefore, before a crude drug is used in rational scientific medicine, it undergoes a systematic program for evaluation which includes (1) botanical indentification, (2) chemical examination, (3) pharmacological and toxicological assay, (4) chemotherapeutic trials and (5) clinical trials. These steps are demonstrated in the following figure:

Systematic Program for Evaluation of Indigenous Drugs

Crude drug used empirically

Botanical identification and Pharmaceutical Standard section	Chemical analysis
	Determination of active principals
Bioassay	
Pharmacological evaluation	Synthesis of chemically related substances
Experimental therepeutics	

Rational clinical use

Source: Report of the Pharmaceutical Enquiry Committee, Government of India, Ministry of Commerce and Industry, New Delhi, 1954, p. 177

These investigations require team-work by several groups of scientists, each an expert in his own field. The facilities for such team-work are not easily available in the country. Another difficulty that comes in the way of investigating Indian drugs is the problem of correct identification. Many of the remedies mentioned in the old texts cannot be easily recognized and identified as the descriptions given are not very complete. This has resulted in a great deal of confusion and even experienced workers are not able to recognize with certainty the authentic specimen mentioned in old texts.

Indiscriminate exploitation of medicinal plants which grow wild in India, has been reported. Steps should be taken to regulate the cultivation and use of such plants. Experimental farms should be set up to determine the best seasons for cultivation and collection of medicinal plants. Based upon the results of the experimental farming, large scale farms may be established to insure regular supply. The improvement of economic plants for better yield of active principles remains a largely unexplored field in India which should be encouraged for improving the varieties that are now being cultivated.

Several universities are conducting research in pharmaceutical and related biological subjects. Notable among them are the universities of Andha, Benaras, Bombay, Calcutta, Dehli, Gujrat and Madras. The veterinary Research Institute of Izzetnagar, Central Research Institute of Kassants, King Institute of Guindy, Haffkine Institute at Bombay and Pasteur Institutes located in different parts of the country are doing very useful research work in the field of biologicals although their main concern relates to sera and vaccines.

From the above it can be concluded that a number of trained personnel and some tradition for pharmaceutical investigations have been obtained in the field of pharmaceutical research in India. However, what has been achieved is not by any means adequate for the needs of the country and the development of the industry.

(B) Research work by Medical Colleges

Only 62 per cent[4] of the medical colleges in the country undertake research in pharmacology. A few medical colleges also undertake research in biochemistry. Lack of adequate equipment for undertaking satisfactory pharmacological and biological investigations of drugs in most of the medical colleges has been a serious handicap in way of promotion of research. More adequate personnel, equipment and finances should be provided to overcome the situation.

The number of pharmacological research papers published in India is almost negligible compared to the corresponding number in the U.S.A. To overcome the lack of equipment and funds for research in pharmacology in the medical colleges, it is recommended that these institutions should be given substantial grants by private pharmaceutical manufacturers in India. Examples may be drawn from the pharmaceutical industry of the United States where the pharmaceutical manufacturers, apart from having their own research wings, grant substantial sums of money to the Universities and Medical Schools for conducting basic research.

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[4] Ibid, p. 178

(C) Research work by manufacturing concerns

Among the fields research activities carried out by the pharmaceutical manufacturing firms, the following may be mentioned most prominently:

(1) Sulpha drugs and related organic chemicals

(2) Active principles of plant drugs

(3) Medicaments related to treatment of leprosy

(4) Liver extracts

The large manufacturing concerns in the country have established special research laboratories for carrying out investigations on problems arising during the manufacture of their products. In recent years, some amount of original research has also been undertaken by these firms in the United States and Europe, maintaining their own research laboratories where a great deal of scientific investigation of high quality is carried out. This stage in India is still far off. However, there are indications that the research activities of manufacturing concerns in India are likely to increase in the near future.

The volume of research work done in these Indian units is not keeping pace with the growing needs of the pharmaceutical industry.[5] The majority of the smaller pharmaceutical concerns are not even properly equipped with testing laboratories for either chemical or biological control.

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[5] Ibid, p. 180

Some of the concerns are financing research in University laboratories and other research institutions. This is a desirable feature serving the interest of both parties. To the industrial concerns it is more economical than having their own research laboratories. For the universities, it helps them to expand their activities and provide students with opportunities of getting trained in this type of work.

There is one important aspect of research to which the industry has not paid much attention. This is the pilot plant study of the manufacture of drugs which the firms have been investigating. A pilot plant study of processes intended to be adopted is necessary in order to arrive at an accurate estimate of the cost of production and to obtain the necessary chemical and chemical engineering data for designing and setting up regular plant for the commercial production of the concerned drug.

Research is of particular importance for the pharmaceutical industry due to the advances which the science of medicine is making. In advanced countries, research bodies are increasingly making contributions of improved and more effective ways of controlling disease thereby increasing the span of human life. In India, very little research activity is noticed in this field. The facilities appear to be very inadequate. This may be a reason why sufficient pharmaceutical products are not made available to the people of India.

CHAPTER VII

CONTROL OVER QUALITY OF DRUGS IN INDIA

The quantity of drugs consumed is not by itself sufficient to control disease. Their quality is a significant factor in determining their effectiveness.

Machinery for control of quality of drugs in India

The machinery for control over quality of drugs in India was enacted in the Drugs Act, 1940, according to which the following responsibilities have been imposed on the Central Government:[1]

(1) Constitution of a Statutory Board, called the "Drugs Technical Advisory Board", to advise the Central and State Governments in technical matters relating to the Act.

(2) Establishment of Central Drugs Laboratory.

(3) Constitution of a Drugs Consultative Committee consisting of two representatives of the Central Government and one each of the State Governments in matters tending to bring about uniformity in the administration of the Act.

(4) Establishment of adequate machinery for administration.

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[1] Drugs Act, an Act of 1940, New Delhi, Government of India Publications Division, 1940

(5) Control of standards of imported drugs and making rules for regulating the import.

The Sta te Governments are responsible for the performance of the following functions with respect to effecting control over quality of drugs:[2]

(1) To control manufacture, sale and distribution of drugs by establishing an adequate machinery consisting of licensing authorities, inspectors and Government analysts.

(2) Establishment of State Drug Control Laboratories.

(3) To make rules in consultation with the Drugs Technical Advisory Board for giving effect to the above.

The Central Government established the Drugs Technical Advisory Board and drafted Rules to give effect to the provisions of the Drugs Act. In order to secure uniformity, the Central Government Drugs Rules are adopted by the State Governments.

The Biochemical Standardization Laboratory, now known as the Central Drugs Laboratory, carries out the following main functions:

(1) To test samples of imported drugs sent to it from ports.

(2) To grant certificates of registration in respect of patent or proprietary medicines, which do not have their composition disclosed on the label.

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[2] Drugs Act of 1940, New Delhi, Government of India Publications Division, 1940

(3) To test samples of drugs referred to it by courts of law in disputed cases.

(4) Any other function assigned to it by the Government.

Control over quality of imported drugs

The control over import of new drugs has been progressively tightened and now there are practically no cases where new drugs are allowed to be imported unless their therapeutic efficacy and pharmacological standards are well established and approved by the Licensing Authority. Further, before permission to import new drugs is given, evidence must be produced by the importer to the effect that such drugs are allowed free sale by the Health Authorities of the country of origin. This precludes the possibility of the import of new drugs without clinical trials having been made in the country of origin. The standards of new drugs manufactured in India have to be approved by the Central Government before they are allowed manufacture on a commercial scale.

In order to regulate import of drugs, the Central Government has declared ports of Bombay, Madras, Calcutta and Cochin as the only ports of entry for import of drugs. Drugs can only be imported at these points by sea and certain other specified air ports and land frontiers. At the Centre, in the Directorate General of Health Services, the Government of India has appointed a Drugs Controller who is also the licensing authority. The Drugs Controller is assisted by an Advisory Chemist and an Assistant Drugs Controller. At each of the ports of Bombay, Madras, Calcutta and Cochin an Assistant Drugs Controller has been appointed whose functions are:

(1) to control the quality of drugs;

(2) to ensure that the labelling and other provisions of the Drugs Act are followed by importers; and

(3) to ensure that the importer of drugs requiring licenses possesses the requisite storage facilities and takes samples periodically to a prescribed laboratory for test and report.

These Assistant Drugs Controllers work in close liaison with the customs authorities. The drugs which are found sub-standard are re-exported to the country of origin or, alternatively, destroyed if the defects cannot be remedied. These officers have also been empowered to inspect periodically the premises where imported drugs are stored and take samples from there to ensure that they have maintained their potency. Batches of drugs which are found to have lost their potency are forced to be withdrawn from the market. The Assistant Drugs Controllers also advise the Customs Collectors, as well as the importers, on the provisions of the legislation and the necessity for maintaining storage facilities.

Facilities for testing drugs

Drugs are tested for quality at Central Government Laboratories, State Government Laboratories, Manufacturers' Laboratories and Public Analytical Laboratories.[3]

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[3]Government of India Ministry of Commerce and Industry, Report of the Pharmaceutical Enquiry Committee, New Delhi, 1954, p. 44

Central Government Laboratories

There are two laboratories maintained by the Central Government for testing of drugs. These are the Central Drug Laboratory of Calcutta and the Central Research Institute at Kassauli, These laboratories appear to be sufficiently equipped and adequately staffed for carrying out the duties entrusted to them at present. However, a great increase in the work of these laboratories is visualized in the future and steps should be taken to supplement the staff and testing facilities as and when the need arises.

State Government Laboratories

Laboratories have been set up by the State Governments and staffed by Drugs Inspectors to carry on the work of testing drugs. The existing laboratory facilities for testing samples of drugs drawn by Drugs Inspectors are very inadequate in all the State Government Laboratories and result in inordinate delays. It is not uncommon to receive reports of analysis nine months after drawing the samples.[4] It is thoroughly impractical to take action on stocks from which samples were drawn after a lapse of such a long period of time. The inadequacy of Government Laboratory facilities also restricts the number of samples drawn and analysed.

Manufacturers' Laboratories

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[4] Ibid., p. 46

A large number of drug manufacturers have their own testing laboratories. While some of these are well-equipped and adequately staffed, a number of these are far from being satisfactory. To increase laboratory facilities for small scale manufacturers it is suggested that groups of small sized manufacturers in various localities should get together and set up joint laboratories on a co-operative basis. Medical profession and pharmaceutical industry should join hands in setting up testing laboratories for the purposes of certifying the products made by the industry. This will create confidence among the public in the products manufactured.

Public Analytical Laboratories

At present there are a small number of Public Analytical Laboratories approved by Drugs Controllers of different States where a large number of drugs are tested on behalf of those manufacturers who have no testing facilities of their own. These laboratories serve a very useful funcion and deserve to be encouraged.

CHAPTER VIII

PROBLEM OF SPURIOUS DRUGS

Trade of spurious products in place of genuine ones is a serious handicap in making available to the people of India drugs and medicines of desired effectiveness. This is a problem which effects the utility of their present already short supply.

The problem of marketing spurious drugs for genuine products began in India during the first world war when the country had to depend on other countries for its supplies of drugs and unscrupulous elements took advantage of the scarcity of essential drugs. The problem still exists.[1]

Causes:

The spurious drug trade thrives due to several causes:

(1) The first and foremost cause is the greed for making cheap money and taking advantage of the popularity of a drug by selling clever imitations as genuine products.

(2) The second cause is the tendency of the public to buy cheap drugs. The public in this country have yet to learn to buy their supply of drugs from licensed chemists and druggists who are required to keep their establishments in compliance with various laws and who

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[1] Report of the Pharmaceutical Engineering Committee, 1954, Ministry of Commerce and Industry, Government of India, p. 161

buy their supplies from the manufacturers directly or from the authorized stockists and distributors. Other shops dealing in drugs buy their drugs usually from the middlemen or commission agents or, as they are called, "walking chemists", who have no premises of their own and have no establishments to maintain. These are the persons who are mainly responsible for the spurious drug trade because they sell these drugs at a rate which is much lower than that supplied by genuine manufacturers to the general provision merchants and grocers.

(3) The third cause is the shortage of medicines of established reputation. This shortage may be real, caused by restrictions in imports, or it may be artificial, created by hoarding large stocks of drugs with the expectation that some day prices will rise further and benefit the hoarders.

(4) Another important cause is the high retail price of certain drugs such as the anti-biotics which are so much in demand due to their life saving property that the average public does not hesitate to buy their imitations when offered at lower prices.

Mode of operation

Generally speaking, the mode of operation in the manufacture and trade of spurious drugs follows the pattern described below.

The genuine containers of drugs are collected by "Old Bottle Collectors" and are supplied in lots to the main shops dealing in old

bottles. The drug fakers obtain their supply from these dealers at regular intervals. The containers are purchased in bulk and deposited at some place. It is not an offense to have in possession any number of old containers. As soon as an order for spurious drugs is received, the containers are taken to the place where the filling of the spurious drugs is carried out. If a person manufactures these types of drugs, he is not liable under the Indian Penal Code nor under the Trade Marks Act nor under the Drugs Act because he does not keep with him the instruments for counterfeiting the labels. His usual defense in a prosecution is that he is not manufacturing any faked drugs, but he is having these for his own personal use as empty containers.

Labels of genuine drugs are also printed with the help of printing press owners who print these labels knowing fully well that the person who has ordered them is not the genuine representative of the firm. Blocks for printing are destroyed on the spot as soon as the order is executed. Thousands of labels are printed at one time so that the question of printing afresh does not arise immediately. Thus, the chief evidence of counterfeiting is lost. The counterfeited labels are then stored with some relative or friend of the drug faker. Just sufficient number of labels are taken to the place of manufacture wherever required. If the printing block is not destroyed, it is also depositied in safe custody with some friend or relative. Manufacture of spurious drugs is carried out in unit operations. The raw materials which are used in these drugs are stored at one place and the place where actual filling operation is carried out is different from all the above three places.

These drugs, in turn, are passed on to the public through hawkers and walking chemists who go from shop to shop and especially to grocers, restaurants, provision merchants and the unscrupulous chemists and druggists. The hawkers carry with them some fictitious cash memos which are tendered to the buyer. The buyer thinks that he will be protected if the cash memo is produced. These walking chemists sell the goods with the plea that some firm has just gone into liquidation or that there is a general fall in prices.

Remedies

The existing legislation is inadequate to fight the menace of spurious drugs and this is one of the main reasons why spurious drugs are marketed on a large scale. The profit earned by the faker is so enormous compared to the penalty imposed, when convicted, that it is always an attractive proposition to manufacture spurious drugs.[2] During the course of this investigation, the writer came across a case reported from Bombay where a person who was prosecuted for manufacturing spurious drugs jumped the bail and during the absconding period, he was again arrested for alleged manufacturing of spurious drugs. Evidently, the existing provisions of the law are not sufficient deterrent to the drug fakers. The penalties under the existing legislation should be increased. A strick and uniform enforcement of the Drugs Act will help to minimize this menace to a

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[2]Report of the Pharmaceutical Engineering Committee, 1954, Ministry of Commerce and Industry, Government of India, p. 162

large extent.

Checking of spurious drug trade in India is very necessary for the success of any proposals for the pharmaceutical industry to supply adequate amounts of standard pharmaceutical products towards raising the expectancy of life in India.

CHAPTER IX

MARKETING OF PHARMACEUTICAL PRODUCTS IN INDIA

Generally speaking, the marketing phase of Indian pharmaceutical industry does not follow an organized pattern of a nature as is noticed in the U.S.A. Concepts such as market research and organized product planning which are regarded as necessary marketing functions in the U.S.A. are considered too fanciful in India in which only a few big firms may indulge. Following is an analysis of marketing institutions and functions employed in distribution of pharmaceutical products in India.

Institutions

In effecting transfer of pharmaceuticals from their producers or importers to ultimate consumers no uniform system of distribution is being followed. The importers and manufacturers supply the products through their branch offices located in big towns. Retail traders are also appointed as distributors on a contract basis, the contract being that they should buy a fixed amount during a year for which they are given an extra discount. The discounts allowed to the trade vary over wide limits from 6¼ per cent to 25 per cent[1] and additional discount allowed to those who work on contract vary from

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[1]Government of India Ministry of Commerce and Industry, Report of the Pharmaceutical Enquiry Committee, New Delhi, Ministry of Commerce and Industry, 1954, p. 187

5 to 10 per cent.[2] The diversity in the discounts allowed and the low margins of profit are not conducive to an efficient system of distribution. Apparently most all business is transacted with reference to price alone and not with reference to quality. A competition in price rather than in quality has resulted in the demoralization of the trade. Adulteration, trickery, short-weight and even sale of spurious drugs are being resorted to in order to exist with the low margin of profit.

There is a need to restore healthy competition. In India, specialized channels like the physician supply houses as existing in the U.S.A., are lacking. It is, therefore, necessary that a system should be evolved which, while protecting the existing channels of distribution, would help in placing them in a sound position. The experts of the Pharmaceutical Enquiry Committee have suggested the following scheme:[3]

(a) Normally, no manufacturer should be allowed to set up in the trade as a distributor, but should utilize the existing channels. The established traders should be encouraged to act as distributors.

(b) No trader should be allowed to trade both as a wholesaler and retailer in the same premises.

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[2] Ibid, p. 187

[3] Report of the Pharmaceutical Enquiry Committee, on. cit., p. 189

(c) The wholesale establishments should be further divided into:

(1) Regional distributors handling the products of a limited number of manufacturers and importers.

(2) General wholesalers dealing in all types of drugs and medicines from all manufacturers and importers.

(d) Dispensing of drugs should ordinarily be done by a pharmacist or a medical practitioner, but not both. Medical practitioners, however, may be allowed to dispense drugs to their own patients. The medical practitioners, as far as possible, should employ qualified persons to do the dispensing work. It should be considered necessary for them to maintain equipment and requisite storage arrangements and adequate maintenance of proper records on the lines of those provided under the drugs rules.

An objection to this scheme may be raised in so far as it insists on continuation of existing set up and prohibits establishment of new channels of distribution. However, as noted above, the existing set up is very inadequate and, at times, even demoralized.

Functions

Product Planning

Product planning is a rare element among the pharmaceutical manufacturing concerns in India. Most of them decide on their product

and volume of production through a priori judgment rather than through study of market requirements as to type of product, volume and price. This is one reason why they have not been able to supply sufficient amount of marketable products in India.

Marketing Research

In India, studies of market, marketing institution, function, cost and policy seem to be scarcely undertaken by the pharmaceutical units. Marketing decisions are based on guess work rather than knowledge obtained through research. A contrast may be made with the U. S. pharmaceutical industry where market research department is asked at a very early stage of product development to determine probable sales potential for the product and the degree of competition in the market.[4] In a number of leading pharmaceutical firms in the U. S. studies of this type are becoming concurrent with the product idea.[5] Activity of this type is rarely attempted in India. Therefore, full knowledge of the actual and potential market and how to reach it is not made available. This may be a reason why the Indian pharmaceutical industry makes available to the people of India products which amount to only 12 per cent of what the U. S. pharmaceutical industry makes available for the people of the U. S.

Selling

In India, the importers or manufacturers of pharmaceutical

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[4]Health News Institute, Facts about Pharmacy and Pharmaceuticals, New York, Health News Institute, 1958, p. 40

[5]Ibid, p. 40

products supply their products direct to the wholesalers, retailers and physicians.[6] Some manufacturers distribute their products through their branch offices situated in big towns. Retail traders are also appointed as distributors on a contract basis which provides them extra discount upon the sale of certain quota.

Transportation

The situation with regard to the movement of drugs in India is very unsatisfactory at present. Considerable delays occur due to shortage of wagons.[7] A high priority should be given to the transport of pharmaceutical products, which are vital to the well-being of the public. Consignments of medicines should be provided with special rush labels so that even small packages could be moved at a faster rate.

Storage

Under the Drugs Act and Rules of India, biologicals and other heat sensitive drugs are to be kept in cold storage so that they nay not lose their potency. But during transit from one part of the country to another, no cold storage facilities have been provided on the railways[8] with the result that they are likely to deteriorate during transit and the consumer does not get the requisite response after their use.

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[6] Report of the Pharmaceutical Enquiry Committee, op. cit., p. 187

[7] Ibid, p. 190

[8] Ibid, p. 190

Hence it is necessary that the railway authorities should provide cold storage facilities both in the wagons and the storage houses for storing heat sensitive medicinal products.

Advertising

The ethical products sold through the medical profession in India are advertised as follows:

(1) by medical representatives who call periodically on medical practitioners and leave with them clinical reports, literature and samples of the products for trial;

(2) by direct mailing service giving latest trial reports and discussions as to composition, therapeutic dosages, etc; and

(3) through advertisements in scientific and technical journals.

Thus, it would appear that the marketing of pharmaceutical products in India does not proceed along any well organized pattern. The marketing institution seems to be inadequate and marketing functions such as product planning and marketing research are rarely performed. This might be a reason why the industry is not able to adequately reach the mass and supply them sufficient products within their means.

CHAPTER X

SOME GENERALIZATIONS ON THE INDIAN PHARMACEUTICAL INDUSTRY

The pharmaceutical industry in India has not yet attained sufficient size and strength to generate out of its own earnings the additional capital required for the expansion of the industry. Home capital is not adequately available for efforts, the returns on which are long deferred. Plans for expansion, therefore, will have to include policies which will set in motion external forces favorable to the industry. Development will depend largely on the preservation of a reasonable profit outlook. A vigorous expansion would be ensured by a more constructive attitude towards capital, either home or foreign.

The industry in India is witnessing a strong trend towards the development of new product lines. However, the details and the time schedule are still in a state of flux.

Expansion will eventuate without an economic and political setting that will encourage enterprise. Suitable economic conditions have, by and large, been achieved and further progress is in prospect. As for political conditions, the Government of India's Industrial Policy Resolution of 1948 is clearly the answer. Subject to operations in some specialized segments, private enterprise has full opportunities for expansion. Authority has offered to assist. A Development Council has been formed which would consider, inter alia, stimuli capable of setting in motion and sustaining a variety of efforts.

Planning has been rather a recent phenomenon with the industry in India. The pharmaceutical manufacturing units have grown unplanned. The factories were built where their product could be sold, so that viewed regionally, there is either an agglutination or an absence of producing units, and a concentration in cities. Hygienic requirements were scarcely considered. Relocation now is difficult.

The units are at various stages of growth, from those highly advanced to those barely under way. Consequently, in both size and phase, they are susceptible in different degrees to the impact of economic forces. The bigger ones are well organized. While the large units have brought the advantages of massive effort and integration to the problems of carry through to the markets, the small one have contributed diversity. Many local merchants perform the retail function.

The structure of the pharmaceutical industy is a mixture of State and private enterprise. Both are subject to a complex system of State regulation; and between them the relationship is obscure and indeterminate. On the pattern of enterprise to be developed, views vary. The divergence, however, relates largely to the means rather than ends. Almost all agree on ultimate objectives; national welfare, advancing living standards and progress. No economic criteria, however, have yet been established to determine the course most likely to lead to the desired goal. State operation, of course, has many proponents and has the advantage of conforming to the political convictions of large numbers of people.

Given time and favorable conditions, its achievement may be noteworthy. Even so, some doubts obtrude. As a system it possesses certain inherent mechanical and economic drawbacks, which, notwithstanding the knowledge and skill of the managerial personnel, can be overcome only with difficulty. It is slow in application and, therefore, wastes that invaluable ingredient, time. Hence, unless operations are conducted on a commercial basis, the expected economies may not materialize. Taking Government Medical Stores and Government Opium Factory for instances, the enterprise has to be subsidized out of the internal economy. Consequently, there is a large avoidable diversion of economic energy worthy of more rational use. In addition, attempting to develop through an arm of the State involves in some cases the principle of monoply. While the monopolistic system can achieve results of a sort, competitive activity, if deliberately sought and encouraged, is a dynamic force for which no adequate substitute has yet been found. Moreover, in planning for the future, this mixed pattern of governmental and private effort raises difficult problems of adjustment. A conscious effort to enter only fields not yet taken up by private sector is discernible. Nonetheless, it involves a responsibility to ensure that the industry's position either at home or abroad is not thereby weakened and that there is no squandering of diverted funds on purely short-term objectives.

The output has marked a general increase. Manufacture from a basic material, distinguished from mere processing work such as tabletting, vialling or ampouling, from imported drugs, is being

encouraged. However, there is much duplication. It is hoped that with the more intelligent implementation of the powers taken by the Government under the Industries (Development and Regulation) Act, the situation will improve by taking into account existing capacity, the level of demand, and the pattern of development planned before licences are issued for the establishment of new undertakings.

A peculiar feature of this industry, where it differs from several others, is that it needs to keep pace with a stream of discoveries. Medical science is advancing fast; new drugs are rapidly replacing old ones. It may soon be necessary to review targets. No developing country seeking to promote pharmaceutical production within its borders can exclusively confine itself to its own efforts for best results notwithstanding its increasing competence in the field of industry. Foreign technical and financial assistance seem very significant.

Prejudice prevails against the Indian product. The situation calls for a careful and impartial investigation. Carlessness and dishonesty are nowhere more obviously short-sighted than in this promising industry whose reputation can be built up only by scrupulous adherence to standards.

Funds allotted for research are generally small in both the public and private sectors. Much could be done if manufacturers agreed on a co-operative effort and enlisted the assistance of finance corporations.

The policy has been to allow only such imports as will supplement, not substitute, home production. Notwithstanding a

higher home production, imports have shown a steady increase.

Statistics in the pharmaceutical industry are in a deplorable state. Those relating to production and imports present only a part of the picture. For consumption, there are virtually no figures available. This renders an economic analysis very difficult.

Active demand for pharmaceutical products has been increasing very rapidly for the past few years and shows a tendency of faster rise.

Distribution leaves much to be desired. Abundance and scarcity alternate with areas. As a rule, cities are well served; rural areas are invariably short of requirements.

The Drugs Act has been very helpful in enforcing control over quality of drugs. There, however, is need for stricter enforcement of the Act.

Exports have been on the increase. The bulk of the export trade is with countries in South East Asia. As demand expands in this area and in African countries, India will doubtless be among the chief contestants for the increase in her exports. Investment and cost of production will assume a decisive role in determining the rate of expansion. Much will depend upon whether the country maintains a competitive status or permits itself to become a marginal source of supply subject to the second choice of customers.

Indian ändigenous medicine is a highly challenging field and pursuing its progress is desirable not only because it offers a rich mine for scientific investigation but also because it has vast economic possibilities in the country.

CHAPTER XI

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

Due to the increasing rate of rise in demand for pharmaceutical products in India and their comparatively limited availability to the masses, opportunity exists for an expanding pharmaceutical industry in India. In particular, the Indian pharmaceutical industry has a basic opportunity for expanding the flow of proven pharmaceutical products at prices within the reach of the masses in the areas of organic intermediates, sulpha drugs, P.A.S., penicillin, streptomycin, anti-dystentry drugs, I.N.H., and phyto-chemicals. Also the indigenous drugs offer potentialities that need to be explored.

If India is to solve her difficulties in the field of health and sanitation and thereby increase the span of life of the people, it is imperative that intensive drug research should be organized in a way similar to that in the U. K., U. S. A., Germany and Switzerland. Drug and pharmaceutical research has a very wide scope in India. It will extend from systematic scientific study of the crude drugs that have been used in the indigenous systems of medicine for centuries, on one hand, to the highly developed field of synthetics and antibiotics, on the other. Much of India's drug resources are still unexplored and unexploited. By organized intensive research the rate of innovation can be improved to meet local

health needs.

Recommendation

Following are the means that may be employed to achieve these ends:

1. Efforts should be made by each manufacturing concern to increase the production of pharmaceuticals and drugs starting from the basic chemicals within the country itself.
2. Import controls should be geared with the development of the industry so that firms under foreign control or collaboration would extend their activities to include the production of bulk pharmaceuticals starting from basic chemicals.
3. Preservation of the reasonable profit outlook might be a helpful factor in attracting capital for expansion.
4. Reduction in customs and excise duties on raw materials might prove conducive to increasing the Indian output of fine chemicals.
5. The railway freight on raw materials should be reduced.[1]
6. Plant and equipment should be classified as "capital goods" for the purposes of calculation of import duty.
7. Import duty on scientific and research apparatus may be abolished.

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[1]Railways in India are nationalized and are operated by the Ministry of Railways, Government of India.

8. Transport restrictions on Indian made spirituous medicinal preparations should be lessened.

9. Favorable revision of taxation laws is believed to be helpful in promoting the development of the industry.

10. Vigilance and intelligent implementation of powers taken under the Industries (Development and Regulation) Act is urged so that existing capacity, level of demand and pattern of development planned are taken into account before issuing licences for the establishment of new undertakings and for the manufacture of new articles, in order to prevent much duplication.

11. The administration of the Drugs Act and the Industries (Development and Regulation) Act might be co-ordinated in order to increase their effectiveness.

12. Government operations are recommended to be conducted on commercial basis.

13. Study should be made as to how to reach rural areas through commercial methods of marketing.

14. Co-ordination among the producing units, particularly in the pooling of resources, might promote efficiency and cost reduction.

15. For extension of resources, development of the fine chemical industry is recommended.

16. The problem of paucity of funds for research may be approached in the following ways:

(a) Joint co-operating drug-testing laboratories.

(b) Expansion of research wing in universities and firms.

(c) Co-ordination between public and private sectors in therapeutic research.

17. Co-ordination should also be attempted between the medical profession and thepharmaceutical industry in setting up laboratories.

18. A stricter enforcement of the Drugs Act is recommended for improvement in quality of drugs sold.

19. In order to prevent manufacture of sub-standard drugs, it is suggested that a scrutiny be made of equipment and staff of all the producting units and the manufacturing licences granted under the Drugs Act should be withdrawn wherever the required minimum equipment and staff do not exist.

20. The efforts of State Governments, Indian Council of Agricultural Research and the Council of Scientific and Industrial Research might be linked into a co-ordinated scheme for cultivation of medicinal plants.

21. Foreign technical and financial assistance should be promoted in order to keep tune with new discoveries. A developing country cannot exclusively rely on its own efforts for best results notwithstanding its increasing competence in the field of industry.

22. Co-operation between the medical profession and industry seems to be necessary in order to create confidence in

the drugs made in the country.

23. There has been a lot said and written on prejudice against the Indian product. An impartial investigation should be undertaken of this situation. Reputation can be built only by scrupulous adherence to standards.

24. Facilities for training for technical skill should be augmented.

25. Efforts of Government as well as the manufacturing concerns should be directed towards establishment of adequate facilities for the manufacture and inspection of drugs of standard quality.

26. The Government might deem it fruitful to take up market research for export of Indian drugs and pharmaceuticals and advise the industry.

27. Possibilities of export of galenicals, biologicals and alkaloids whose production is surplus to local requirements, might be investigated.

28. Co-ordination may be effected within the industry for obtaining requirements of tank wagons for the transport of coal-tar.

29. A co-ordination of activities of West Bengal and Bihar Governments might make alcohol more readily available for operations.

30. The Governments of Bombay and Madras might find it helpful to co-ordinate their efforts in prescribing proper courses of study and providing training facilities in the manufacture and marketing of shark liver oil.

31. The producting units should place increasing reliance on marketing research for product planning and istribution. It is believed that the firms will find that the fruits of marketing research would outweigh the cost.

32. In order to reach the masses, investigation is recommended in the ways of achieving widespread distribution of pharmaceutical products in India. Larger distribution would lead to greater mass production which will result in lower prices within the reach of the masses in India.

33. As to indigenous drugs:

(a) A careful scrutiny of the claims for the various drugs is suggested so that useful drugs might be separated from useless ones.

(b) Each indigenous drug should be properly identified and its attributes precisely defined.

(c) Chemical or biological standards should be laid down to evaluate quality of crude drugs.

(d) Stricter Governmental control should be exerted over the sale of adulterated and spurious drugs.

(e) Research need be promoted in the indigenous drugs. Facilities and outlay should be provided for establishing sufficient number of laboratories with adequate staff.

(f) Facilities might be improved for the cultivation of medicinal plants for indigenous drugs.

(g) Cost studies of manufacturing indigenous drugs would help in the efforts to make effective remedies

available within the reach of the public through cost reduction.

(h) If more chairs in indigenous pharmacology are established in various universities and medical colleges, it would help promote the interest in ingigenous medicine.

(i) A more complete pharmacopoeia of Indian indigenous drugs might be compiled.

34. Statistics seem to be very inadequate. It is strongly recommended that serious attempts be taken to compile various statistics for the industry. An economic analysis is very difficult without such statistics.

APPENDIX I

PRIMARY SOURCES IN INDIA

The following letters addressed to the author have been the primary source for information:

Name of Firm	Date of the Letter	Letter No.
Alembic Chemical Works Co. Ltd., Baroda	Sept. 6, 1960	8096
Asian Chemical Works, Bombay	Sept. 2, 1960	
Ayurvedashram Pharmacy Ltd., Ahmednagar	Aug. 25, 1960	
Beecham (India) Prvt. Ltd., Bombay	Aug. 23, 1960	TD/50
Boehringer-Knoll Prvt. Ltd, Bombay	Aug. 24, 1960	
British Drug Houses (India) Prvt. Ltd., Bombay	Aug. 25, 1960	
Capsulation Services Prvt. Ltd., Bombay	Sept. 2, 1960	G/I/8304
Ciba Pharma Prvt. Ltd., Bombay	Oct. 19, 1960	BP/5/6211
G.D.A. Chemicals Ltd., Calcutta	Aug. 22, 1960	R-GF/ 1/96/60
Glaxo Laboratories (India) Prvt. Ltd., Bombay	Aug. 19, 1960	PD/1112
Government of West Bengal, Directorate of Cinchona, Calcutta	Aug. 31, 1960	4452(c)

Haffkine Institute, Bombay	Sept. 14, 1960	CAO/59280
Hind Chemicals Ltd., Kanpur	Aug. 26, 1960	42091
Hindustan Insecticides Ltd., New Delhi	Aug. 19, 1960	T-1/15/980
Hoechst Pharmaceuticals Prvt. Ltd., Bombay	Aug. 22, 1960	AC/3
International Franchises Private Ltd., Bombay	Sept. 15, 1960	
James Wright Ltd., Calcutta	Aug. 19, 1960	I.X.I./JW/863
Lederle Laboratories (India) Prvt. Ltd., Bombay	Aug. 23, 1960	JM/8/20
National Chemical Laboratory, Poona	June 17, 1960	52/21-2/D/1034
Oriental Pharmaceutical Industries Ltd., Bombay	Sept. 8, 1960	1895/60
Park Davis (India) Prvt. Ltd., Bombay	Aug. 22, 1960	WD/DS
Pharmed Private Ltd., Bombay	Sept. 7, 1960	HRN/MG/697
Raptakos, Brett & Co. Private Ltd., Bombay	Oct. 13, 1960	
Reckitt and Colman of India Ltd., Calcutta	Aug. 20, 1960	JCMC-BT:627
Sanitex Chemical Industries Ltd., Baroda	Oct. 10, 1960	15/SEC/29291
Sarabha Chemicals, Baroda	Aug. 29, 1960	PVK
Suhrid Geigy Prvt. Ltd., Baroda	Aug. 31, 1960	G/1428
Therapeuti Pharmaceuticals, Bombay	Aug. 24, 1960	TP:NUK:60/2556
Zandu Pharmaceutical Works Ltd., Bombay	Aug. 29, 1960	39419

AND OTHERS

APPENDIX II

PRIMARY SOURCES IN U. S. A.

A. Letters addressed to the author

B. Manuels sent to the author

A. Letters

Name of Firm	Date of Letter
Abbott Laboratories, Chicago	Oct. 28, 1960
American-British Chemical Supplies Inc., New York	Nov. 1, 1960
Armour Pharmaceutical Co., Kankakee, Ill.	Nov. 7, 1960
Bristol Laboratories, Inc., Syracuse	Dec. 8, 1960
Commercial Solvents Corporation, New York	Oct. 24, 1960
The Cudahy Laboratories, Omah, Nebr.	Oct. 19, 1960
Cutter Laboratories, Berkeley	Oct. 18, 1960
The Dow Chemical Company, Midland, Mich.	Oct. 19, 1960
Eli Lilly and Company, Indianapolis	Oct. 26, 1960
Fort Dodge Laboratories, Fort Dodge, Iowa	Oct. 26, 1960
Hoffmann-La Roche Inc., New Jersey	Oct. 26, 1960
Hollister-Stier Laboratories Spokane, Wash.	Nov. 1, 1960

Lederle Laboratories, Pearl River, N. Y.	Oct. 25, 1960
Mallinckrodt Chemical Works, St. Louis	Nov. 30, 1960
Meade, Johnson & Co., Evansville, Ind.	Oct. 24, 1960
Merek & Co. Inc., New Jersey	Oct. 14, 1960
Monsanto Chemical Company, St. Louis	Oct. 20, 1960
Novocol Chemical Manufacturing Co., New Jersey	
Rexall Drug and Chemical Co., Los Angeles	Oct. 28, 1960
Dr. Salsbury's Laboratories, Charles City, Iowa	Oct. 20, 1960
R. P. Scherer Corporation, Detroit	Nov. 7, 1960
Smith Kline & French Laboratories, Philadelphia	Nov. 15, 1960
E. R. Squibb & Sons, New Jersey	Oct. 19, 1960
Standard Brands Incorporated, New York	Oct. 19, 1960
Strong Cobb Arner, Inc., Cleveland	Jan. 6, 1960
Sunkist Growers, Ontario, Calif.	Nov. 10, 1960
U. S. Industrial Chemicals Co., New York	Oct. 20, 1960
The Upjohn Company, Kalamazoo, Mich.	Nov. 10, 1960
Warner-Chilcott, New Jersey	Oct. 20, 1960
William F. Rorer, Inc. Philadelphia	Oct. 14, 1960

Winthrop Laboratories, New York	Oct. 21, 1960
Wyeth Laboratories, Philadelphia	Oct. 21, 1960

B. MANUALS

Name of Firm	Manual
E. R. Squibb and Sons, New Brunswick, New Jersey	Production Control Manual
Warner-Chilcott Laboratories, Morn's Plains, New Jersey	Production Control Manual

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