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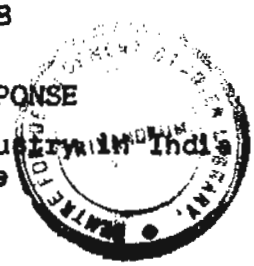
POLICY INTERVENTION AND RESPONSE

A Study of the Pharmaceutical Industry in India during the Last Decade



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The pharmaceutical industry in India has provoked much debate and sharp criticism, on account of its insensitivity towards the health needs of the Indian people. The vulnerability of the industry towards the manipulations of multinational corporations, has added another dimension to the discussion. The Government has been interfering with the working of the industry from time to time. Through regulation and control, it hoped to effect national control on the internally oriented product structure in the industry. This paper attempts to make an enquiry into the response of the industry under the impact of major policy interventions, following the Hathi Committee report which was released a decade back. An attempt is also been made to examine the likely impact of the New Drug Policy announced by the Government recently.[1]

The report of the Hathi Committee constituted, perhaps, the first ever scientific attempt to understand the deep seated structural maladies affecting the Indian pharmaceutical industry. It made recommendations of a radical nature, so as to synchronise the production of the industry, with the health needs of the people. The committee looked into the entire drug scenario - production pattern, ownership control, pricing, quality control etc. The major recommendation of the committee was to evolve a system which would (1) develop self-reliance in drug technology

(2) provide a leadership role to the public sector (3) aim at quick self-sufficiency in the output of drugs (4) foster and encourage the growth of the Indian Sector (5) ensure that drugs were available in abundance and at reasonable prices and (6) keep a careful watch on the quality of drugs produced.

In an attempt to remove the structural maladies afflicting the industry and to realise the objectives it had outlined, the committee recommended restrictions on the activities of the foreign sector in the short run and the nationalisation of that sector in the long run. Thereby, it hoped to pave the way for the complete control of the industry by the public and the domestic, private sectors.

Since the Hathi Committee went against the vested interests of the Multi National Corporations and their Indian collaborations, there was intense lobbying for about three years, not to implement its recommendations. However, the New Drug Policy which is claimed to have been based on the Hathi Committee report was announced in 1978. It is significant that the Government did not accept the report in its totality; the incorporation of the Committee's recommendations in the new policy was in bits and pieces and in a somewhat diluted form. A review of the major recommendations of the Hathi Committee and an appraisal of the extent to which they have been incorporated in the policy framework viewed against the response of various segments of the industry to these measures would hence be timely.

The Increasing Dependence

One of the primary concerns of the Hathi Committee had been the pharmaceutical industry's external dependence. It is natural for us to expect that the overall dependence of the industry should have reduced after the implementation of the New Drug Policy and other measures. Unfortunately, the facts belie this expectations. The dependence is no lower now, than a decade ago. This point can be illustrated with reference to the import dependence of bulk drugs. The ratio of bulk drugs import to domestic production was continued to grow unabated (see Table 1).

Table 1

Sector-wise Pattern of Bulk Drug, formulation Production, Import content, Bulk drug used for the formulation of essential drugs etc. since Hathi Committee

(Rs.crores at current prices)

Year	Sectoral share in total production (%)			Total (Rs. crores)	Import of bulk drugs (at C.I.F prices)	Import as % of production	Total formulation	Of which formulation of essential drugs
	P.S.	I.S.	F.S.					
1975-76	33.08	26.92	40.00	130	46	35.38	560	n.a.
1976-77	34.28	20.71	45.00	140	84	60.00	700	n.a.
1977-78	28.66	31.71	39.63	164	81	49.39	900	n.a.
1978-79	24.50	47.50	28.00	200	95	47.50	1050	n.a.
1979-80	26.11	50.44	23.45	226	87	38.49	1150	n.a.
1980-81	26.25	51.67	22.08	240	105	43.37	1260	360
1981-82	25.51	52.38	22.11	294	115	39.12	1430	400
1982-83	26.80	65.20	17.00	325	123	38.00	1660	430
1983-84	26.00	57.20	16.80	345	178	51.59	1660	466
1984-85	-	-	-	405** (816)	n.a.		1840** (2450)	

P.S. Public Sector; I.S. Indian Sector including small scale sector; F.S. Foreign Sector.

Source: Ministry of Petroleum, various reports. For Recent data on bulk drug production and other major indicators here taken from Naresh Banerjee, Essential Drugs and Public Policy, Paper submitted in K.S.S.P. Seminar, A Decade After Hathi Committee, Nov.1985, Trivandrum.

** Estimated figures in the bracket indicate targeted production by the end of Sixth Plan.

A very interesting aspect emerging from the Table 1 is that of the Rs.1660 crores worth of formulation produced in the country by 1983-84 only 28 per cent was used for formulating essential drugs. The rest went for the preparation of non-essential formulations. Another point to be considered is that the industry's performance falls behind by one half the targeted output of the Sixth Plan.

Table II gives the details of the growth rate of output patterns (basic drugs and formulations) between the period 1973-83. The growth of bulk drug production after the introduction of the New Drug Policy, 1978, fell to a bare [illegible] from 12% at constant prices. The performance of the formulations sector was, however, better, leaving far behind the production of the bulk drugs sector. The increasing gap is depicted in the graph.

Table 2

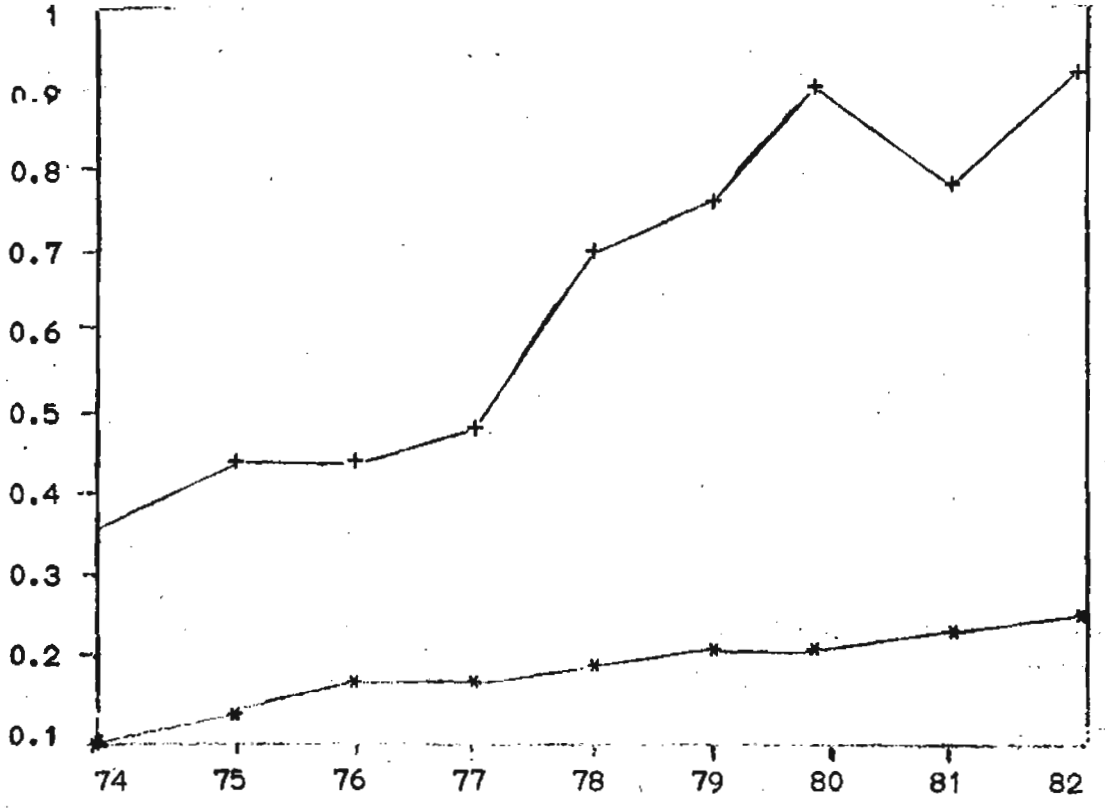
Annual Average Compound Growth of Domestic Production of Bulk Drugs and Formulations in Percentage at current and Constant Prices

Period	Bulk Drugs at current prices	Bulk Drugs at constant prices	Formulations at current prices	Formulations at constant prices
1	2	3	4	5
1973-74 } 1977-78 }	22	12	25	18
1978-79 } 1982-83 }	13	1	11	4
1973-74 } 1982-83 }	18	8	18	12

Note: The prices were deflated by using Chandok Wholesale price Index - bulk drug price (1970=100) formulations (1970=100)

The aggregate bulk formulation ratio does not reveal in full the extent of dependence. It is significant to note that the dependence is ever increasing in respect to essential therapeutic categories like antilepratics and antimalarias. We are importing several times more than domestic production in certain

Growth of Production of Bulk druqs and Formulations at Constant prices (deflet or base 1970-71 = 100)



* Bulk drugs (const.price) + formulation (constant price)

essential categories of medicine.[2] It is evident that the restructuring of the industry, in terms of the 1978 Drug Policy (though it was based on certain recommendations of the Hathi Committee), was incapable of making the industry compatable with the health needs of the Indian people.

The reasons are not far to seek. The Committee had demonstrated in its report, that the pharmaceutical industry in India, will only perpetuate human suffering unless the MNCs who promote their global business interest are cut to size. Therefore, the Committee had recommended that the MNCs in the field of drugs and pharmaceuticals, should be taken over and managed by the National Drug Authority — a proposed statutory body which would take on the responsibility of large scale production and distribution of drugs. The NDA would assess the national needs of essential drugs and plan and co-ordinate responsibilities with individual production units. But this critical element in the planning process of the pharmaceutical industry was set aside by the Government. Instead, the emphasis was mostly on interim measures like equity reduction, without providing a support system to ensure that such measures add to the ultimate objective of self-reliance. Even these interim measures suggested by the Committee were diluted, thereby defeating their very purpose. For example, take the case of reduction in the equity share capital on according to the New Drug Policy announced by the Government in 1978. The recommendations of the Hathi Committee in this regard were diluted. The Hathi Committee had wanted the equity holding of foreign companies to be reduced to 40 per cent forthwith and a further progressive reduction to 26 per cent. But, as per the 1978 Drug Policy, foreign companies, which are engaged purely in formulation activity, only need to bring down their equity to 40 per cent. It further add that those companies engaged in the manufacture of high technology bulk drugs and their formulations

could retain a higher equity share. As a result, the foreign sector continue to exercise its control over the industry notwithstanding the dilution process.

The Foreign Sector

It is doubtful if the dilution of foreign equity leads to a dilution of foreign control. This is a different question which we shall discuss later. The administrative procedures defining exemption on the basis of 'high technology' took such a long time (as long as five years) that it rendered greater manoeuvrability to the bureaucrats and technocrats who were influenced by the tempting arguments and lobbying of the foreign companies. The outcome was that out of 44 majority owned foreign companies, 32 were exempted from the dilution of equity upto 40 per cent by 1981-82. (See Table 3). But interestingly enough, the recent trend is towards dilution of equity on their own. This trend indicates the advantages of indigenisation which we shall discuss later.

Regarding the settlement of high equity, it is interesting to note that the criterion of 'high technology' is dubious,[3] for, the products identified as high technology, are already being produced by fully owned Indian companies with indigenous technology. Interestingly, such bulk drugs constitute only a small proportion of their production. As a result, even those companies involved mostly in making bandages or calcium compounds of dubious value or tableting imported tranquillisers have been permitted to retain higher than 40 per cent foreign equity.[5] Having 'become' high technology, the MNCs throttled the very vitality of the

pharmaceutical industry by cutting back the production of bulk drugs in the guise of unremunerative prices. This resulted in the heavy import of bulk drugs from parental sources, thereby increasing the scope for transfer pricing and other unethical practices. The case of Hoechst is illustrative of this point.

The imported Baralgan Keton was selling at Rs.23,625/kg. till 1977. The government later fixed the price of this at Rs.1810-20/kg. with effect from 31st December 1980. Before the prices of various formulations, based on the revised prices of drugs as announced by the government, could be fixed, the Delhi High Court granted a stay to the company, by virtue of this, it was able to maintain a pre-revised price for bulk drugs, under the Drug Price Control order of 1979. The government has filed a special leave petition and application for a stay against the Delhi High Court judgement in the Supreme Court. Meanwhile, the company had made a total of bulk and associated imports to the tune of Rs.3.13 crores between 1980 and 1984 and remitted Rs.2.08 crores during the above period.[6]

No wonder then, that the stipulation regarding the manufacture of bulk drugs made by the Hathi Committee, remains a far cry even after a decade. The Committee was of the opinion that a foreign undertaking producing formulations, should start and complete manufacture from the basic stage, within a period of three years, failing which it should not be allowed to continue marketing the formulations. And, those foreign companies producing more than their licensed capacity, should be made to part with 50% of this production to non-associated Indian formulators.

Table 3

Pattern of Share Holding of Foreign Companies Since Hathi Committee

Company Type	Non-resident share in foreign equity	1975-76*		1981-82**		1984***	
FERA companies	1. Above 74	20	41	5	32	3	14
	2. 50 to 74	11		14		10	
	3. Above 40 and upto 49	10		13		1	
Non FERA Companies	4. Between 26 to 40	10	20	13	26	30	42
	5. Below 25	10		13		12	
Total		61		58		56	

* Drug Prices and costs of production, Economic Times, November 15-16, 1977.

** Indian drug Statistics, Ministry of Petroleum, 1978, 1982.

*** Compiled from various issues of Assochem Parliamentary Digest.

In the New Drug Policy of 1978 the 'high technology' qualifications was more or less an excuse to the first stipulation of manufacturing from the basic stage. Not only did the foreign companies keep the bulk production from the penultimate stage, but the Government also subsequently permitted them to make use of the import of bulk drugs, even under concessional duties.[7] (also see Table 4) The Government by the Drug Policy of 1978 also permitted the foreign companies to share half their unauthorise drug production with any non-associated firms. This only helped the collusive strategy of the MNCs in the pharmaceutical industry! Therefore, the original intention of the Hathi Committee to check the strength of the MNCs in the Indian formulation market was defeated by the new policy.

Table 4

Names of the Multinational Drug Companies Operating in India along with the Drugs being Manufactured by each of them from Penultimate/intermediate stages

Sl.No.	Bulk Drug Produced from Penultimate Intermediate stage
I. M/s. Alkali Chemicals Corporation (P) Ltd.	1. Primidone
	2. Halothane
	3. Chlorohexidine
II. M/s Bayers	1. Chloroquin Phosphate
	2. Rosotreu Substance (Chloquinate)
	3. Detigon Substance (Chlorphedianol base)
	4. Incidal Substance (Mebhydrotin)
	5. Badional
	6. Uvilon (Piperazine Phosphate)
III. M/s Pfizer Ltd.	1. Chlorpropamide
IV. M/s Roche Products	1. Vitamin E Acetate
	2. Chlordiazepoxide
V. M/s Sandoz (I) Ltd.	1. Intestopan Substance
VI. M/s Wyeth Laboratories	1. Ethopheptazine Citrate

Source: Assochem Parliamentary Digest, April 1985.

Again in 1980 and 1982 decisions were taken according to the new industrial policy to regularise the "excess capacity" of formulations produced by foreign companies. Although, the Government, by the drug policy of 1978, fixed a very liberal bulk formulation ratio of 1:5, the ratio was 1:12 as on 1982-83 (See Table 5).

Table 5

Ratio of Bulk Drugs to Formulations

Sectors		Ratio as on 1974-75	Ratio as on 1980-81	Ratio as on 1982-83
I	Foreign Sector	1:6	1:12.53	1:12
II	Indian Sector	1:8	1:2.6	1:3.44
III	Public Sector	1:0.8	1:1.26	1:1.12

Source: Same as in Table I

Foreign Sector in Disguise

We were discussing above those companies which did not undergo the Indianisation process of 40% and below. It is true that there is no magic in the rule-of-thumb formula of direct non-resident ownership upto 40 per cent, which will reduce the extraterritoriality of control. In fact, it is not possible to fix precisely any particular ownership proportion as the criterion of measuring the actual control exercised by foreign companies in Indian enterprises. It all depends on who holds the rest of the 60 per cent shareholding and how widely this is held. Above all the precise terms of the contract for technology are important. The Hathi Committee, in fact, considered this aspect and indicated

that equity should not be shared widely among Indian nationals, but should be purchased by, public sector institutions which are connected directly or indirectly with the manufacture of drugs and chemicals or by public financial institutions or by the government. But, contrary to this stipulation, no safeguard was taken while dispersing the equity of foreign companies and hence, they dispersed it as widely as possible, to subserve their main interest of retaining control in their own grip. According to the latest figures, there are 43 companies, whose equity is 40% and below. More firms are likely to dilute to 40 per cent.

Indianised thus, the government made them immune to the basic requirements stipulated by the Hathi Committee, which said that (1) foreign companies should be allowed to manufacture household remedies such as alcohol based tonics, vitamin preparations, ointments for colds, burns, aspirin tablets etc. (2) foreign units which were already engaged in the manufacture of these household remedies should not be granted any expansion of capacity and (3) remittances of money outside this country would be permitted subject to certain conditions like the fulfilment of export obligation and other commitments imposed in the licence by a body created specially for this purpose. The Hathi Committee hoped that these restrictions coupled with indigenisation would bring foreign firms within the ambit of the overall strategy for increased production and would prevent a further foreign exchange drain from the country.

But a mechanical view of the process of indigenisation without monitoring led to diastrous consequences to the industry. Having escaped from FERA's grip these companies have expanded

their formulation capacities[8] into low technology areas. This kind of expansion has been in contrast to the Hathi Committee recommendation that additional formulation capacity, if necessary, should only be permitted either to public sector units, units sponsored by state governments or in the purely Indian sector to units run by technocrat entrepreneurs.

That the expansion of capacity has not taken place in desirable areas, tells upon the scarcity felt in essential categories of formulations in recent years. We shall go into this issue later. One only has to look at the high remittances to parent companies which reflect upon the high profitability of their operations out of new expansions. We have compared the remittance pattern (at current prices) of these companies before and after the dilution of equity. Clearly some companies have managed to send out eight times more to their parent companies than they could before Indianisation. (Table VI). Overall, with the lapse of seven years, the remittances have more than doubled. Table 5 clearly brings out the cost to the country due to unwanted "expansion" in the guise of Indianisation. There are indications that the foreign companies retaining more than 40 per cent at present will further reduce equity to enjoy the advantages of Indianisation.

Control on Production

Did the pervasive influence of the MNC's diminish in the pharmaceutical market over a period of time by the so called structural transformation in the form of indigenisation of the industry? As the production statistics relate only to majority

Table 6

Remittances of Indianised Companies

Company Code	Average outflow on account of profit, technical fees, royalty etc. (Rs.lakhs)				Percentage increase
	Foreign equity before dilution	Annual average outflow (71-73)	Foreign equity after dilution	Annual average outflow (80-82)	
A	63	50.72	40	150.38	196
B	72	63.90	40	135.58	112
C	53	54.89	40	108.77	98
D	62	25.49	40	105.81	315
E	70	72.12	40	102.10	30
F	56	8.30	40	40.21	303
G	49	4.32	40	40.10	828
M	45	3.12	39	14.23	356
I	52	2.12	35	10.32	386
J	48	4.10	39	20.82	407
Total		295.03		728.22	147

Source: For 1971-73 Hathi Committee, 1980-82 Answers to Parliament questions which appeared in Assochem Bulletin, various issues.

owned foreign companies, we cannot estimate the full production share of the foreign sector (including Indianised foreign companies). Even the practice of giving sector-wise production figures by official sources was discontinued since 1980-81. Attempts at sectoral estimates showed that in the dynamic expansion of the market for pharmaceuticals, foreign companies could carve out a disproportionate share from the other sectors.[9] At the time when the Hathi Committee submitted its reports, the 34 majority owned foreign companies had a share in the formulation production

to the extent of 40.17 per cent. By 1983-84, around 14 companies could control 39% of the formulation market (615/1600). This does not include the share of another 20 companies have foreign equity upto 40 per cent. They added 25 per cent more to the foreign control. Thus 64 per cent of the formulation market clearly belonged to foreign companies.[10] If the share of companies having above 10 to 15 per cent equity is also added it may not be surprising if the total share of the entire foreign sector in formulation production exceeds 75 per cent. It is interesting to contrast this to the estimates of the Government in 1978. Assuming a 1:5 bulk formulation ratio for the foreign sector, the share of formulation production was expected to increase only by 47% of the total formulation market by 1982-83.[11] Ironically enough, by 1981-82 when the total bulk production lagged behind by half (Rs.275 crores against 500 crores projected for Rs.1983) the foreign sector nearly achieved its targets by 1980-81 with a bulk drug formulations ratio of almost 1:12. The real control over the formulation market can be studied by the MNC's domination in the therapeutic categories. The information on this available from ORC estimates of 1977-78 of retail sales showed a high degree of concentration.[12] This changing dimension may be another area of interesting study.

The Indian Private Sector

It is clearly evident that the MNCs did not contribute on any significant scale to the development of basic drug manufacture. It was the Indian sector that took the challenges to the industry. As observed by the Hathi Committee, and further

established by later studies[13] the Indian sector has over a period of time built up its technological capability. As it stands today, except in the case of a few drugs in the category of antibiotics and steriods, the Indian sector has established its technological competence. In fact, it is reported in a recent study that the Indian sector is capable of producing at least 76.8 per cent of the bulk drugs and 97.5 per cent of the value of formulations.[14] But, the environment since the introduction of the 1978 Drug Policy has been such that, it could not make a dent in the industrial output due to the high pressure-selling tactics followed by the MNCs. As the Lev Raj Kumar Committee also observed the MNCs spent several times more on sales promotion than on any genuine R & D.[15]

It is important to mention in this context, certain behavioural characteristics of Indian sector. This sector has a better R & D allocation than the MNCs.[16] It produces more drugs from the basic stage rather than the penultimate stage and over a period of time has developed technologies for 28 new bulk drugs.[17] It also could export and effectively compete in the export market against the MNCs. The point of emphasis is that the internal environment continues to be unfavourable to this sector. Many product areas involving light technology one becoming exclusive preserves of 'Indianised' foreign companies. A warning signal to this effect had already been conveyed by the Hathi Committee when it said that if the foreign companies are left uncontrolled, Indian companies would face the 'full blast'.

The Fa ling Public Sector

In so far as the production of a drug is basically interwoven with that of basic chemicals, it is the public sector enterprise which imparts a fair amount of capability to the industry by downstream manufacture of important antibiotics and synthetic drugs. The Hathi Committee, therefore, assigned a leading role to the public sector. Of the identified 177 essential drugs, the committee recommended the reservation of 34 drugs exclusively for production by the public sector enterprises. But the government diluted this recommendation. It only reserved 25 drugs for the public sector enterprises, 23 for the Indian private sector enterprises and about 69 were open to all sectors. The Hathi Committee wanted at least 60 per cent of the bulk drugs to be formulated by the public sector itself. The record of public sector enterprises with relation to their target is a dismal one. There was a short fall of around 50 per cent in the targeted bulk production by 1982-83. The reasons for the shortfall are complex, the major problem plaguing these enterprises is the failure to upgrade their technology. Instead of a systematic effort to upscale the technology by investing heavily in R & D through pilot plants and proto-type large scale production as the Hathi Committee had suggested, most of the time they relied on easy options like the import of technology. The experience of HAL with Merck of U.S. is a case in point.[18]

Another major failure arose from the non-implementation of the Hathi Committee recommendation regarding the formulation of the bulk drugs. The formulation activity of the public sector enterprises remains low. Therefore these enterprises

have not been able to generate a sufficient surplus for expansion. The failure of the public sector enterprises has provided on, alibi for the MNCs to slow down the bulk drug production. But, the fact is that the public sector enterprises have been continuing the role of fuelling the growth of the MNCs and the private sector units by not formulating the bulk drugs they produce. There is credence in the argument that the light technology, high profit areas are thus reserved for other sectors. The involvement of the public sector in high cost areas rendered it unable to generate surplus for further expansion. This has had a backlash effect in the form of shortages and cutbacks.

In discussions on the role of the public sector in the pharmaceutical industry, the above aspect is often forgotten. Instead of subsidizing foreign companies, why did not these enterprises go into the formulation area on a large scale? The answer is to be sought in the political economy, for in a developing country like India, the public sector is interconnected with the underlying political process.

Technology Development

The overwhelming emphasis of the Hathi Committee had been on the upgradation of technology through R & D activities. The Committee wanted the proposed National Drug Authority, to plan and supervise the development of indigenous technology and to act as a sole importer of technology in order to ensure the horizontal transfer of technology. The NDA was to be funded with a 2% levy on the sales of all the units of the industry.

The Committee also wanted a suitable machinery to be evolved to screen the import of knowhow, to check the type of knowhow imported, the fees paid, the contribution made by foreign technology, and the conditions fulfilled by the foreign companies before payment was made. The first recommendation was incorporated in the new drug policy of 1978 by involving the NCST with public sector research institutions and national laboratories. A heavy investment of the public sector in R & D was embarked upon. But the other recommendations were however given only a peripheral treatment. There was no check on the payments for the imported technology and remittances on other accounts by foreign firms. On the average, the foreign firms' remittances had been increasing from Rs.1,98 crores (at current prices) during 1961-74 to Rs.6.45 crores during 1975-82. As rightly remarked by the Hathi Committee, the drain of foreign exchange by the MNCs has to be viewed in the context of their import bill in relation to their own export of drugs and not in terms of their own sales, inclusive of formulations. When worked out, bearing this in mind, it was found that between 1979-81, 23 foreign companies drained off around Rs.6,854 lakhs (see Table VII). Another specific recommendation of the Hathi Committee was that those foreign firms whose turnover was in excess of 5 crores per annum should additionally spend at least 5 per cent of their sales turn over on recurring R & D. But by 1982-83, there were 25 firms of foreign origin who had yet to have a registered R & D unit. Those companies which have spent more money on R & D, help their parent companies in analysing thousands of chemical compounds, as such expenditure is lower in India than in research centres abroad.[19]

Table 7

Foreign Exchange Drain by MNCs* in India (Rs.lakhs)

Years	Total inflow (exports and other earnings)	Outflow due to imports	Trade balance	Outflow on account of dividend, royalty, technical fees etc.	Total foreign exchange drain
1	2	3	4	5	6 (3+5 - 2)
1970	2298.05	4533.74	1552.69	762.48	2298.17
1980	2632.28	4290.27	1657.99	748.40	2442.39
1981	2660.01	3939.08	1278.57	834.99	2113.56

* Relates to only 23 foreign companies

Source: Assochem Parliamentary Digest, dated 9.5.1983.

In contrast to the Hathi Committee's verdict on technology development, by giving emphasis to upgradation and rationalisation of available technology, the import of technology was increasingly allowed. It is important to note that following the recommendation of the Hathi Committee, a high dose of foreign technology was injected into the industry by around 45 collaborations between 1976 and 1984. In a single year 1984, 24 collaborations were allowed in the name of modernisation, most of them of repetitive types. It is a matter of concern that we are importing even today technologies for sweetners, aspirin, adhesive tapes and surgical dressing etc. (See Table 8).

Price Policy

The committee was of the view that technological dependence can be effectively attacked by a multi-pronged strategy.

The major elements of the strategy were (1) a rational price policy which assures that prices are fair to the producer and consumers and (2) the abolition of brandnames. The Hathi Committee which went into pricing recommended that the markup for essential drugs should be reduced and that of non-essential drugs should be given a liberal margin. This recommendation was accepted by the government in a distorted manner, subjecting all bulk drugs to price control instead of a leader price formula as suggested by the Hathi Committee. Formulations were grouped into four categories whereas category IV was not subjected to any price control, a separate pricing of each category of production was accepted allowing a markup of 40,55 and 100 per cent respectively for the other three categories. The rationale of this decision is not clear, for, essential drugs appear in all the three categories. The pharmaceutical industry, crying hoarse

Table 8

Some examples of Repetitive Collaboration in Pharmaceutical Industry Approved during 1983-84

Name of the Drug	Name of the Collaborator
1. Salicylic acid, Salicylated including aspirin	Industrial Export/Import - Romania
2. Sweet 'N' Low (sweetner)	Comberland packing Corpn. U.S.A.
3. Refompicin	Chong Kum Corporation South Korea
4. Timed release of Pharmaceutical formulation	Sidmak Laboratories India, U.S.A.
5. Adhesive tapes and surgical dressing	S.A.Isoplast, Switzerland.
6. Vitamin C	Foster Wheeler, Italy
7. Plaster of Paris bandages	IVF Machine Fabrik, Switzerland.

Source: Reply by the Minister of Petroleum & Chemicals (L.S. as Q.6483 (14.5.1983).

over 'unremunerative' margins responded by cutting down the categories of low markup and expanded the decontrolled items.

Table 9 with a sample of 22 firms, indicates the output behaviour of firms in response to price policy. As seen in Table 9, while the products in category I and II are systematically curtailed those in category IV and decontrolled items increase.

Table 9

Output Behaviour of Firms in Response to Price Policy

(Amount Rs. lakhs)

DPCO Category	1978		1979		1980	
	Amount	Share (%)	Amount	Share (%)	Amount	Share (%)
I	1384	4.5	1477	4.2	1376	3.6
II	5159	16.7	5169	14.8	5041	13.2
III	20720	67.1	23756	67.8	26134	68.6
Decontrolled	3630	11.7	4613	13.2	5547	14.6

Source: NCAER, The Indian Pharmaceutical Industry Problems and Prospects, NCAER, 1984.

Interestingly enough, the price reduction was easily shifted to non-controlled high margin items. Morever, regarding the essential categories the Multinationals have successfully challenged the provisions of price controls in the court and systematically lobbied the bureaucrats and decision makers, practically rendering them ineffective. Also, the prices of imported intermediates and raw materials remained largely outside the price controls. This gave ample scope for the MNCs to resort to transfer pricing and offset the loss, if any, by price controls. We have seen in

Table 6 that the incidence of imports has already assumed a higher proportion with the MNCs. The ineffectiveness of price controls is pretty clear from the notice issued by the government recently for the recovery of unintended profits running into several crores. An unintended profit is a profit in excess of what the law allows under the Drug Price Control Act 1979.[20] On account of the higher prices charged for an anti-TB drug Refampicin the government has to recover from the companies around Rs.3 crores!

This is one side of the picture. On the other hand, there has been a frequent upward revision of drug prices of all the three categories by Government to nullify the effect of cost escalation. For example, the price of Refampicin, an anti-TB drug was revised six times after 1980. Such examples can be multiplied.[21]

Again, in 1984, the prices of 17 bulk drugs and 47 packs of leader formulations have been increased and those of 9 bulk drugs and 29 packs of leader formulations in 1985. The percentage increase in the case of upward revision is given in Table 10 A & B.

The uncontrolled category which was meant to compensate for the off loss of the controlled catogory has turned out to be a profit spinner. The extent of price rise in the category of drugs of common use is given in Table 11.

We have tried to show above, that contrary to the complaint of the industry that the controls are insensitive to cost, it has actually been responsive to the cost escalation.

Tabl 10-A

The Percentage increase in the Case of Upward Revision of prices of Some basic drugs in response to cost escalation

Sl. No.	Bulk Drugs	% increase	Sl. No.	Bulk Drugs	% increase
1.	Aspirin	9.30	8.	Chloroquin phosphate	7.01
2.	Bengocaine	31.26	9.	Doxyegeline	47.25
3.	Boric Acid IP Granules	12.81	10.	Procaine HCL	63.70
4.	Boric acid (Powder)	12.47	11.	Salyicyche acid	59.14
5.	Boric acid (crystal)	12.16			
6.	Chlorophenecol(Powder)	13.67	12.	Menthol	27.18
7.	Chlorophenecol powder	6.93			

Table 10-B

The percentage increase in the price of formulations in response to cost escalations

Sl. No.	Formulations	% increase	Sl. No.	Formulations	% increase
1.	Aspirin(300)mg.tab	24.94	7.	Thiopentone sid.inj. 0.5 gram acid	30.38
2.	Chloroquin phosphate (mg.)	22.76	8.	Thiopentone sod inj. 1.0 gm.	29.48
3.	INH tablets (300 mg)	26.05	9.	Vitamin C Tab.100 mg tab.	
4.	Doxyregetine Caps 100 mg/base/cap	34.66	10.	Vitamin C.injection	18.68
5.	Kanamycin capsules 250 mg/cap	21.78	11.	Vitamin C. drops 100 mg/ml.	19.71
6.	Morphaginanide tablet 500 mg/tab.	19.28			

R.S. Uns. 123 (21.1.85)

Parliamentary Digest No.2, Jan. 1985.

Table 11

Increase in the Prices of Drugs of Common Use

A Statement showing the prices before Drugs (price control) Order 1979 as well as current price along with percentage of increase is given below

Sl. No.	Name of the Formulation	Pack size	Price before PCO, 1979	Current Price	% increase
(1)	(2)	(3)	(4)	(5)	(6)
1.	PROLUTION DEPOT INJ				
	125 mg/ml	10 Amps	42.00	64.00	54.05
	250 mg/ml	10 Amps	76.00	116.30	53.03
	500 mg/ml	5 Amps	70.00	107.25	53.21
2.	TESTOVIRON DEPOT INJ				
	100 mg/ml	10 Amps	51.00	91.00	78.43
	250 mg/ml	10 Amps	95.00	161.90	70.42
3.	ELTROXINTABS	100s	2.72	5.98	119.85
4.	CALMPOSE, TABS 5 mg.	10s	0.93	2.09	124.71
5.	Vicks Cough Drops	2 Dozs	0.25	0.39	56.00
		4 Dozs	0.29	0.89	175.86
		10 Dozs	1.68	2.80	66.60
6.	Halls Lozenges	10s	1.19	2.09	75.63
		250s	30.11	58.28	93.56
7.	Water bury compound red label	250 ml.	5.71		
8.	Panzy Normtabs	100s bottle	38.00	68.00	78.95
9.	Dulcobax Tablets	5 mg.	10.30	14.60	41.75
10.	Algipan Cream	90 grams	5.06	9.31	83.99

Source: Same as 10A and 10B

The Brand name Issue

One of the major recommendations of the Hathi Committee as a measure to check the high pressure sales techniques and thereby control the price was to abolish brandnames in a phased manner. To begin with the Committee listed 13 drugs whose brand-names should be abolished and should be replaced by generic names. But the new drug policy stipulated the abolition of brandnames of only 5 drugs. The organisations representing the interests of foreign companies opposed the government policy by a vigorous campaign against distributing medicines by generic names. The argument had been that in Pakistan withdrawing brandnames led to the multiplication of spurious drugs. But the examples of Afghanistan, Bangladesh and advanced countries like the U.S. were deliberately withheld from public knowledge. Meanwhile, four companies (Hoechst, pfizer, Cyanamid, and Costume Farma) challenged the government action in the court and the court cancelled the government decision on brandnames in 1982. Now, brandname in the pharmaceutical industry has become a non issue!

The industry continues to dump spurious and substandard drugs into the market inspite of brandnames continuing to exist (around 25 per cent). Many such drugs belong to foreign companies. One of the major recommendations of the Hathi Committee to check the problem of spurious drugs, was to strengthen the existing system of drug inspection in all stages. The cost of this was to be borne by the Central Government. This recommendation, along with several others, to check the existence of spurious drugs, has not been given serious attention. This is clear from the inadequate infrastructure to test medicine. Only nine

states have any drug testing laboratories. There are only 600 drug inspectors whereas the workforce needed is around 8000.[22]

New Drug Policy

The new drug policy announced on 18th December 1986, after long deliberations and hectic lobbying by the Multinational Corporations had further frustrated the attempt to generate an appropriate product structure at appropriate prices. This is because, instead of seeking a solution to the stagnation of the industry brought about by structural distortions, the new policy had sought a market solution and allowed a price hike to the extent of 25% for essential drugs! Surprisingly, this hike has been permitted without undertaking any home work. This testifies the success of lobbying by the MNCs for the relaxation of price controls. Instead of simplifying the procedures and keeping a strict watch on the implementation of price control on essential medicines, the new policy has reduced the existing three categories into two the number of drugs falling in each category has also been reduced. For example, the first category now consists of only 40 drugs.[23] The mark up has been increased to 75 per cent to 100 per cent in place of the existing 40 and 55 per cent respectively for the first two categories. The number of drugs to be included in the second category are to be announced later after consultation with the industry.

It is a matter of great concern that the New Drug Policy does not appear to have taken seriously the need for a product and price pattern in consonance with social needs.

It thereby violate the assurances given regarding the implementation of an integrated health policy which would assure access to essential drugs at reasonable prices.[24] The New Drug Policy had moved towards a market solution by delicensing drug manufacturing and broad banding around 31 drugs. This approach of privatisation of drug production, without doubt, is at the expense of public sector enterprises which have built up large capabilities in the production of basic drugs. Though they have been ailing for years for various reasons, no commitment is made in the new policy to rejuvanate them or to supply them with essential formulations. It appears that public sector enterprises are expected to supply the basic drugs to the formulating Multinational enterprises and remain as their servicing units!

The new policy, while relaxing the price controls, also relieved the Indianised foreign firms of the responsibility of integrating the production of formulations with the manufacture of basic drugs. The Hathi Committee report and subsequently the Drug Policy of 1978 wanted such integration of critical bulk drugs. There was also a kind of reservation of certain other critical drugs for the public sector and the Indian Private Sector. The new policy does not insist on any such integration or reservation. The Hathi Committee and Drug Policy of 1978 insisted on reservation and integration, for, it thought that price control along with the lifting of Trade Marks may induce the foreign firms to confirm to the social needs. Now that all these controls have gone, it is likely that foreign firms and 'Indianised'

foreign firms will consolidate the formulation market with vigorous sales campaigns. Then involvement in the production of basic drugs will perhaps remain minimal.

With regard to the fixing of the bulk/formulation ratio, the new policy has totally abandoned the norms followed in the previous approach based on foreign control. The new policy propose a gradual basis depending upon the turnover.[25] This measure of treating the Indian firms and "Indianised" foreign firms on an equal footing undermines the very spirit of the policy of protecting the indigenous firms, As the Hathi Committee rightly remarked! "The Committee feels that in our anxiety to produce more drugs, we should not adopt a policy which places the Indian manufacturers at a disadvantage. On the contrary, if the choice were between a foreign company and an Indian company, encouragement should be given to Indian Companies which are technically competent. Somehow or the other there seem to be exaggerated notions about the capabilities of foreign companies vis-a-vis Indian units". The policy which induce unequal competition between the MNCs and Indian firms is likely to put the latter at a disadvantage. The New Drug Policy has also abandoned the question of brand names, It only pay lip service to the problems of quality control and manufacture of hazardous and irrational drugs. We have discussed the magnitude of the problem elsewhere. That new strategy does not realise the seriousness of the issues involved is evident from the fact that such issues are left to be decided by the newly created apex body. Ironically, this 'apex' body will be 'adequately' represented by the industry

and since the major interest of the industry is represented by foreign firms - it is anybody's guess what the likely outcome of such a body will be!

Need for Multipronged Action

We have demonstrated above how the recommendations of the Hathi Committee to make the pharmaceutical industry more meaningful in terms of health needs, when embodied in a haphazard manner as in the 1978 Drug Policy, did not lead to the expected results. In fact, the way in which they were implemented gave enough scope to foreign firms to manipulate their sales strategies further sharpening the contradiction between their profit motive and the health needs of the people. To break the stagnation in the industry, the government announced the New Drug Policy recently and resorted to a market solution for the health needs of the people by offering all sorts of incentives to the foreign sector. If history is any guide, such a step is unlikely to deliver the goods.

The importance of the Peoples Science Movement needs hardly any emphasis in this regard. It is encouraging that an organisation like the Kerala Sastra Sahitya Parishad has already taken up the drug issue and has launched a big campaign exposing the anti people exploitative tactics of the MNCs, the question of essential versus non-essential drugs, the rising prices of life saving drugs, the non-implementation of the Hathi Committee recommendations etc. The aim of the campaign is to sensitise the medical profession to issues and to launch a People's

Health Movement for the formulation of a People's Drug Policy with the following major elements: (1) essentiality (2) efficacy (3) safety (4) low cost (5) Case of administration (6) easy availability. A number of non-governmental organisations in India, interested in drug and related issues have joined together and formed a drug action network.[26] All these efforts are significant steps towards arousing conscientiousness against the prevailing exploitative drug policies in the country.

[This is a slightly revised version of the paper presented at the All India Conference on Pharmaceutical Industry, A Decade After Hathi Committee organised by the Kerala Sastra Sahitya Parishat between November 24-25, 1985 at Trivandrum, The author is thankful to K.K.Subrahmanian, I.S.Gulati and S.J.Patel for comments in revising this in the light of recent drug policy announcement]

Notes

1. In the context of renewed demand inside and outside the parliament for more national control of the pharmaceutical industry in the early 70s, the Hathi Committee was appointed in February 1974. The Committee was asked to outline measures for promoting the growth of the industry with self-reliance in order to make available essential drugs at reasonable prices. See Ministry of Petroleum and Chemicals (1975).

2. For example, the 1981-82, the import percentage of production was 87% for antibiotics, 40% for analgesics, 282% for anti-malarials, 38.33% for antileprotics. See, for details, NCAER (1984).

3. The identification of 'high technology' products is solely on the basis of the answers received to a questionnaire circulated among the MNCs. Some of the elements that make a product high technology are a reaction temperature at above 250 centigrade, a pressure of ten atmospheres, the number of steps in chemical analysis. These elements are common to most of the products in this industry. If these criterion are applied, almost all the products in this industry, may qualify to be in the high technology category.

4. Choudhari S. (1985).

5. See Bidwai P.(1983)

6. Reply to a question to the Minister for Chemicals and Fertilizers (Qn. No.262 dated 18.3.1985) reproduced in Asschem Parliamentary Digest, August 1985. Interestingly the company in question is going to dilute its equity to 40 per cent.

7. See Gopalakrishnan, C.V. (1983).

8. They have been registering fresh projects and booked huge additional capacities. Searle India has registered itself for the production of 37 new items in three years. Duphar Interfran for 40 items in just one year, German Remedies for 19 items and Borhringer-Knoll, for 24 different drugs, see India Today, June 15, 1985.

9. Pillai P.M. (1984).

10. Worked out from the balance sheet of Indianised companies.

11. See, New Drug Policy, Economic and Political Weekly, May 27, 1978.

12. UNCTAD, (1979),

13. Choudhari S. (1984).

14. The Report of the Lev Raj Kumar Committee quoted in Mehrotra N.N. (1984).

15. Ibid.

16. Ibid.

17. NCAER (1984).

18. It was found that the type of technology for manufacture of streptomycin that HAL got from Merck was inferior and during the period of collaboration there had been cases of blatant refusal by the collaborator to honour the terms and conditions of collaboration, see for details Gopalakrishnan C.V. (1977).

19. See Man Mohan, (1985).

20. See Collapse of Price Control, Economic and Political Weekly, September 8, 1984.

21. To quote another example, after a systematic study by the Bureau of Industrial Costs and Prices, the Price of Ibuprofen was reduced from Rs.1044.35 per kg. to Rs.828.25 on November 1984 and increased to Rs.845.25 on November 5, 1984 and increased to Rs.845.60 on September 25, 1985. The price of the bulk drug metrondiazole was also reduced from Rs.497.98 to Rs.363.00 on November 14, 1984 but increased to Rs.450 on September 25, 1985. See Economic Times, January 1, 1986.

22. See Drugs, Paper Standards, Economic and Political Weekly, March, 1984.

23. The price control order 1979 covered almost 80% of the drug formulations produced in the category.

24. See, The Draft Seventh Five Year Plan, Planning Commission, New Delhi, 1984.

25. Upto Rs.10 crores the ratio will be 1:10, for production in excess of Rs,10 crores and upto Rs.35 crores, the ratio would be 1:7, and production in excess of Rs.25 crores the ratio would be 1:5.

26. Some of these groups are voluntary Health Association of India, Medico Friend Circle Arogya Dakshata Mandal, Delhi Science Forum, Society of Young Scientists, Lok Vignyan Sargathana, etc.

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