CHAPTER III

HATHI COMMITTEE REPORT¹ AND ITS IMPLEMENTATION:
DILUTION OF THE NATIONALIST PERSPECTIVE

During 1960's, several problems were visible with regard to the functioning and growth of drugs and pharmaceutical industry in India. In 1965, the Government of India announced certain liberalization of its licensing policies in respect of all industries, including drugs and pharmaceuticals, in order to overcome the shortages which were developing. Subsequently, after devaluation of the rupee and the liberalization of import policy, two further notifications were issued - one in 1966 and other in 1967 - Permitting manufacturers to diversify production into the manufacture of 'new articles', and to expand production of licenced or registered capacities up to 25 percent without any amendment to the licences under the Industries (Development and Regulation) Act, 1951.² The application of this in respect of all the industries including the drugs and pharmaceuticals, however, came under review in 1970 because it

1. The report of the Committee on drugs and pharmaceutical, constituted in 1974 under the chairmanship of shri Jaisukhlal Hathi will hence forth be refered to as Hathi Committee Report, in short, H.C.R.

was felt that under the policy permitting diversification, foreign units and those belonging to large houses were likely to expand their activities to high profit areas and not to the high priority areas as desired by the government keeping in view the social objectives before the country.

In February 1970, certain changes were made in the licensing policy on the basis of recommendations made by the Industrial Licensing Policy Inquiry Committee (ILPIC), the Administrative Reforms Commission and the Planning Commission. Measures to regulate the licensing of foreign firms and large Industrial Houses were taken. The concession of permitting diversification, was withdrawn, and such diversifications as had taken place prior to that date, was required to be regularised by specific applications for "Carrying-on-Business" (COB) licenses. The Government also revised the diversification policy of 1966 in July, 1970. This policy prohibited foreign firms from effecting diversification without an industrial license and also stipulated that C.O.B licences should be obtained in cases where diversification was effected earlier on the basis of 1966 policy.

A press note issued on February 2, 1973 summed up

3. ibid., p.87.
Central Government's basic philosophy on the development of the drug industry (and other industries), taking into account the growth priorities envisaged under the Fifth Five Year Plan (1974-75 to 1977-78). We reproduce below the relevant portions from the Press Note: 4

"Government have carefully reviewed their policies relating to industrial development in the light of the experience gained in the implementation of the Industrial Licensing policy of 18 February 1970 and in the context of the approach to the fifth five year plan. The Industrial Policy Resolution of 1956 has laid down the basic principles that govern Government's approach towards industrial development. These principles have been derived from the Directive Principles of State Policy contained in the constitution and from the adoption by Parliament in December 1954 of the socialist pattern of society as the objective of social and economic policy. The Industrial Policy Resolution of 1956 will continue to govern Government's policies for achieving the objectives of growth, social justice and self-reliance in the industrial sphere."

In the context of the approach to the Fifth Plan, the core industries of importance to the national economy in the future, industries having direct linkages with such core industries, and industries with long term export potential were all regarded as basic and of critical strategic importance for the growth of the economy. The industries included in Schedule A of the Industrial Policy Resolution, 1956

4. ibid., p.88.
were to be reserved for the public sector. Larger Houses were to be eligible to participate in and contribute to the establishment of industries provided that the item of manufacture was not one reserved for production in the public sector or in the small scale sector. Their investments were to be subject to the "guidelines on the dilution of foreign equity" and were to be examined with special reference to technological aspects, export possibilities and the over-all effect on the balance of payments. 5

Keeping in view the Industrial Policy Resolution of 1956, which had identified the Drugs and Pharmaceutical industry as one of the core industries of importance to the national economy, a large expansion was envisaged in the production of pharmaceuticals during the Fifth Five Year Plan. The Task Force (Planning Commission) on Drugs and Pharmaceuticals, which was set up to draw up programmes for the Fifth Plan, had estimated that the value of production of formulations would rise to about Rs. 600 crores by 1978-79 as compared with the level of Rs. 300 crores in 1971-72. A four-fold increase was envisaged in the production of bulk drugs during the above period. A high powered committee under the chairmanship of Shri Jai Sukhlal Hathi was ap-

5. ibid., p.88.
pointed in February 8, 1974 to suggest a rational policy that would meet the growth of the industry outlined in the Fifth Plan. The need of such a Committee was also voiced by the members of the Parliament to thoroughly enquire into the performance of public sector drug units, the role of multinational companies, licensing policy and the prices of the drugs in the country. The committee consisted of 15 members and included in it eminent scientists like Dr. M. L. Dhar of Central Drug Research Institute, Lucknow, Dr. B.D. Tilak of National Chemical Laboratory, Poona, and social scientist Dr. B.V. Rangarao, Centre for Studies in Science Policy, Jawaharlal Nehru University, New Delhi, apart from three influential Congress MPs, Yashpal Kapur, Vasant Sathe and C. M. Stephen. Later on Dr. B.B. Gaitonde, Director Haffkine Institute, Bombay was co-opted by the Committee. 6

The terms of reference of this committee were as follows: 7

1) To enquire into the progress made by the industry and the status achieved by it.

2) To recommend measures necessary for ensuring that the public sector attains a leadership role in the

6. ibid., p. 1.
7. ibid., pp. 1-2.
manufacture of basic drugs and formulations, and in research & development.

3) To make recommendations for promoting the rapid growth of the drugs industries, and particularly of the Indian and small scale industries sector. In making its recommendations the committee will keep in view the need for a balanced regional dispersal of the industry.

4) To examine the present arrangement for the flow of new technology into the industry, and make recommendations therefor.

5) To recommend measures for effective quality control of the drugs, and for rendering assistance to small-scale units in this regard.

6) To examine the measures taken so far to reduce the prices of drugs to the consumer, and to recommend such further measures as may be necessary to rationalise the prices of basic drugs and formulations.

7) To recommend measures for providing essential drugs and common household remedies to the general public, especially in the rural areas, and.

8) To recommend institutional and other arrangements to ensure equitable distribution of basic drugs and raw materials especially to the small-scale sector.
The Report of the Committee submitted to the Government in April 1975, was tabled in both the Houses of Parliament in May, the same year for its consideration. The government initiated the process of taking action soon. For this, a series of discussions were held with the representatives of the drug industry. A series of inter-ministerial consultations were initiated. After going through all this process, the Cabinet Committee, designated for it, put its views to the Cabinet for a final consideration in February 1977. However, it could not be considered by the cabinet because of impending elections. The Janata Party Government which took over at the Centre after 1977 General Elections, however, took the matter on a priority basis. The Minister of Petroleum, Chemicals and Fertilizers, held several discussions with the Indian Medical Association (IMA), Indian Drug Manufacturers Association (IDMA), Organisation of Pharmaceutical Producers of India (OPPI), All India Manufacturers Organisation (A.I.M.O.), Indian Pharmaceutical Manufacturers Association (IPMA), Pharmaceutical and Allied Manufacturers Association (PAMDAL) and All India Chemists and Druggists Associations. A series of Inter-Ministerial meetings at high level also held to review several points of

8. ibid., p.9.
view. A special meeting of the Consultative Committee of the Ministry of Chemical and Fertilizers convened in November 1977 discussed exclusively the recommendations of Hathi Committee at length. The draft recommendations which emerged from all these deliberations were directed by the Cabinet to be considered by a Cabinet Committee on drugs. The Cabinet considered the conclusions of this Committee and took a final decision on various recommendations at their meeting held on March 28, 1978. It was put before the Lok Sabha the very next day on March 29, 1978.

Before we go for an examination of the new drug policy (1978), let us make a brief outline of some general observations of the Committee contained in the report. This will enable us to put the 1978 Drug Policy in a clear perspective.

Some Observations

The Hathi Committee, after an extensive study noted with satisfaction that the Drugs and Pharmaceutical Industry had grown considerably out of a state of non-existence at the time of independence. However, structurally the industry
was dominated by multinational Companies. The production pattern of drugs did not match the disease profile of our country. Thus, while there was shortage of several essential drugs required for treatment of malaria, tuberculosis, leprosy etc, there was abundant availability of drugs of irrational combinations and of little therapeutic value such as Vitamins, tonics, health restorers, haematinics (22 percent of the total share).

The Committee found that the foreign drug Companies were mainly engaged in formulation activities which yielded high profits. Their production of basic drugs (bulk) were negligible. Their research priorities were limited to the products which had global demands such as tranquilizers, anti-histaminics, anti-hypertensives etc. Their research on drugs for treatment of tropical diseases and those endemic in India such as Malaria, Tuberculosis Filaria, Leprosy,

9. (i) About 70 percent of the total sales turnover of drugs in the country, namely Rs.370 crores belonged to foreign sector in 1973-74 [H.C.R, p.89].

(ii) Out of the total turnover of Rs 370 crores in 1973-74, the value of tonics, household remedies, Vitamins and minerals etc came to about Rs. 70 crores. (ibid)

(iii) In 1973-74, foreign companies manufactured bulk drugs worth about Rs 19 crores (ibid, p.90).

10. ibid., p.25.
11. ibid., p.95.
Amoebiasis, Helminthiasis, Malnutrition, Iron deficiency, Anaemia, Trachoma, Scabies and various types of infections was negligible. The expenditure on Research and Development in the drugs and pharmaceutical industry in India was grossly inadequate, a mere 1.1 percent of the total turnover, as compared to 12-15 percent of the total turnover in other countries.\textsuperscript{12}

The Committee noted the fact that public sector units, in the drugs and pharmaceutical sector had played a key role in the manufacture of bulk drugs in the country. Prior to their entry into drug sector, most of the bulk drugs were imported. It is a credit to them that after their entry in the field of production of synthetic bulk drugs in 1968, they successfully modified the production technologies to conform to economic compulsions of a competing economy.\textsuperscript{13} They had also worked out new technologies for production of several drugs. Thus, they were able to achieve an overall production of substantial capacity, particularly of synthetic drugs and demonstrated their capacity to handle the growing needs of the country in this highly technology-

\textsuperscript{12} ibid., p.25.

\textsuperscript{13} ibid., p.61.
intensive area of drug production.\textsuperscript{14}

The Committee noted the importance of quality control for the growth of this industry. Effective quality control would infuse a sense of confidence among the medical profession and the consumers in this country and abroad and would encourage them to patronize these drugs. According to the Committee, while the quality control measures were quite satisfactory in some states, this was not to the required level in many states. The Drug Control Organisation should attempt to rectify this mess.\textsuperscript{15}

Brand names, according to the Committee, had undesirable consequences for the Indian drug industry. It had led to proliferation of numerous unnecessary and often irrational formulations in the market. The Committee felt that the Organised Sector was able to continue their dominance in the Indian drug market because of their brand products containing multiple ingredients.\textsuperscript{16} Many new drugs were introduced in the market under brand names without even obtaining necessary licences for their production. Brand names ena-

\textsuperscript{14} Basic drugs were being produced in the Indian sector, including the public sector, to the extent of about 90 per cent in tonnage terms, (H.C.R., p.96).

\textsuperscript{15} ibid., p.190.

\textsuperscript{16} ibid., p.253.
bled many drugs with expired patents to continue reap high profits. Also, it was found that the quality of drugs and their bio-availability did not necessarily depend upon formulation.¹⁷

The committee was of the view that pricing of drugs was an issue of social relevance, firstly, because it would adversely affect the consumers' capacity to get treatment, and secondly, because it would adversely affect the capacity of public hospitals, already in a dire financial need, to serve the poor and needy patients. However, the existing price control system, which allowed lower mark-up for essential drugs, had led to an undesirable effect on the industry, wherein, foreign companies diversified their drug output in non-essential drugs where the price control was inoperative. Production of essential drugs were either cut down or stopped altogether leading to their shortage in the market.

All over the World and in every country, the drugs and pharmaceutical market was found to be under the control of multinational firms. The drug market was quite heterogenous, consisting of a large number of products each differentiated from the other and often protected by patents. As a result

¹⁷. ibid., p.254.
The industry was found to be highly competitive particularly in the matter of formulations in the form of persuading doctors or in the case of house-hold remedies, consumers, to patronize a particular brand of drug formulation. The competition, however, did not translate in terms of prices of drugs (as it happens in other commodities) since one who prescribes does not have to pay. It is not the consumers, but the doctors, who decide for the former.

The drug industry is characterized by a quick product change or product adaptation which is only partly based on proven improvements in effectiveness of production combinations. In most of the cases, the product adaptation or innovation is essentially a marketing technique with a view to retaining or increasing one's share of the market for a particular pharmaceutical product group. This marketing technique involves a substantial selling cost which in turn leads to price escalation of drugs. The use of brand names (instead of generic names), also enables the industry to sell essentially similar drug formulations at widely varying prices. It is just impossible for the doctors and consumers to compare prices of numerous brands which are virtually

18. ibid., p.173.
identical.\textsuperscript{19}

Price control measures had helped in preventing excessive profits by drug manufacturers. But in the view of Committee, it had failed to contribute to the emergence of a product or price pattern which is in harmony with social needs or national objectives.\textsuperscript{20} To evolve an effective price control, the need is to identify its main objectives.\textsuperscript{21} The Committee observed that any scheme of price/production regulation should ensure that the country's dependence on imports of basic drugs is reduced sooner by encouraging an economically viable domestic production of such drugs.\textsuperscript{22} To obviate the need for competitive product adaption or aggressive selling, which add to the costs of drugs, efforts should be made to promote generic names of drugs.

In addition, the Committee felt that administrative regulation and licensing should be geared to ensure that greater emphasis be laid on production of the 117 essen-

\begin{itemize}
  \item \textsuperscript{19} ibid., p.173.
  \item \textsuperscript{20} ibid., p.179.
  \item \textsuperscript{21} ibid., p.174.
  \item \textsuperscript{22} ibid., p.180.
\end{itemize}
tial medicines, as pointed out by it.

Recommendations of H.C.R

The major recommendations of the Hathi Committee, were as follows:

Essential Drugs list - The Committee recommended a list of 116 medicines, drawn up by a panel of eminent physicians and some members of the Committee, labelled as "essential drug list", for their production and availability to the general public, under the supervision of the government.

Public sector - With a view to streamlining the operations and achieving the basic objectives of producing and distributing essential drugs to the largest number of people as economically as may be possible, the Committee recommended the establishment of a National Drug Authority (NDA) which will also lay down and co-ordinate the policies. In order to achieve the above objectives, the Committee felt that leading role for production and distribution of drugs and pharmaceutical should vest with the state. The public sector should be given the major role for the production of capital and technology intensive bulk drugs such as are

23. ibid., p.180.
24. ibid., p.54.
needed in high tonnage quantities and where large scale production would be economically preferable. Public sector units should between themselves divide the responsibilities for the production of individual items so that they may attain the required level of specialisation and sophistication in their respective lines of effort. At least 60 percent of the bulk drugs produced by the public sector should be formulated by the Public sector industry itself. In the disposal of the remaining 40 percent, first preference should be given to the Indian sector, particularly the small scale sector units. Public sector should set an example in respect of R & D activity in the drugs field and to begin with should set aside at least 5 percent of their net turn-over for this purpose. In addition to these, the Committee felt that the existing structure of the public sector needed substantial changes so as to enable them to achieve the objectives set for it in terms of our socio-economic goals. The working of the public sector plants at all levels should be carefully re-organised. The Committee felt the need to attend immediately to removing all deficient-

25. ibid., p.61.  
26. ibid., p.63.  
27. ibid., p.65.
cies in the plants. It felt that each unit should operate strictly on economic basis.28

**Foreign Companies** - The majority in the Hathi Committee strongly recommended that the multinational units in drugs and pharmaceuticals should be taken over by the Government and managed by the proposed National Drug Authority (NDA). However, the Committee was of unanimous view that the drug industry should not be eligible to preferential treatment as specified in the guidelines of Foreign Exchange Regulation Act, 1973 (FERA) and Appendix I of the Industrial Licensing Policy of February 1973. Further, the Committee recommended (unanimously) that the foreign drug units operating in this country should be directed to bring down their equity to 40 percent forthwith and further reduce progressively to 26 percent. The dilution of foreign equity as suggested above, should not take the form of dispersed holding of the shares by large number of Indian nationals. This is because such widely dispersed holdings will not, in any way reduce the effective control of the foreign equity holders. In order to serve national objectives, it would be desirable for Government to purchase these shares either by public sector undertakings which are directly or indirectly

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28. ibid., p.64.
connected with the manufacture of drugs chemicals or by public financial institutions or by Government itself. 29

In no case, Foreign Companies should be allowed hereafter to manufacture household remedies, such as alcohol based tonics, other types of tonics, Vitamins preparations, ointments for cold, burn, sprains, etc, cough mixtures, grippe mixtures, aspirin tablets, pain relieving tablets etc beyond the capacity mentioned in the Industrial Licence or application for registration. Foreign units which are already engaged in the manufacture of these household remedies etc should not be granted any expansion of capacity. 30

With regard to the capacities approved for the manufacture of bulk drugs against permission letters and Carry-on-Business (COB) licences, the Committee felt that they may be regularised on the condition that: a) all bulk drugs are manufactured from the basic stages, and (b) 50 percent of the production of basic drugs be made available to non-associated Indian formulators. As regards formulations covered by COB licences or permission letters, the foreign firms should be required to switch over within one year to the manufacture of bulk drugs and formulations to the extent

29. ibid., p.98.
30. ibid., p.99.
of 50 percent of the production of bulk drugs, and the balance 50 percent be supplied to non-associated Indian formulators.

**Pricing** - The Committee recommended a return post-tax between 12 to 14 percent\(^{31}\) on equity, i.e. paid-up capital plus reserves, as the basis for price fixation, depending on the importance and complexity of the bulk drug. In the case of formulations, the Committee felt that the principle of selectivity should be introduced in terms of (a) the size of the units, (b) selection of items, and (c) controlling the prices only of market leaders, in particular, of products for which price control is contemplated. The Committee felt that units (other than MRTP units) having only turnover of less than Rs. 1 crore may be exempted from price control. Alternatively, all formulations (others than those marketed under generic names) which have an annual sale in the country in excess of Rs. 15 lakhs (inclusive of excise duty) may be subject to price control, irrespective of whether or not the total annual turnover of the unit is in excess of Rs. 1 crore. The ceiling price will be determined taking into account the production costs and a reasonable

\(^{31}\) ibid., p.181.
return for the units which are the market leaders.\textsuperscript{32}

Yet another variant of selectivity, according to the Hathi Committee, would be to identify product groups which individually are important and which collectively constitute the bulk of the output of the industry. In respect of each item of this list, it would be possible to identify the leading producers who account for about 60 percent of the sales between them. On the basis of cost analysis in respect of these units, maximum prices may be prescribed and all other units may be free to fix their prices within this ceiling. On the whole, the Committee felt, that the later variant of selectivity may be administratively simpler.\textsuperscript{33}

The Committee felt that the recommendations of the Working Group on pricing of formulations under the alternative scheme of pricing could be adopted with the revised rates of ceilings on profits ranging from 8 to 13 percent on sales turnover-listing the firms under large, medium and small groups. It further suggested that as an alternative criterion, the ceiling on profit may also be specified between 10 and 12.5 percent post-tax on net worth i.e paid

\textsuperscript{32} ibid., p.182.

\textsuperscript{33} ibid., pp.181-82.
Brand names, quality control etc. - The Committee recommended for setting up of a National Drug Authority (N.D.A), an autonomous body which should handle all matters concerning the future expansion of the drug industry - licensing, imports, exports, technological development etc. It also recommended for the abolition of brand names in favour of generic names, in 13 cases\(^{35}\) with immediate effect and in phased manner, at least for essential drug list of 117 items. The Committee noted that for the country was to be self-reliant and progressive in the drugs sector, intensive R & D activity would have to be emphasized. It felt that public sector should play a leading role in this by earmarking 5 percent of their turnover for R & D to begin with.\(^{36}\)

Irrational drugs - The Committee noted the existence of numerous multiple drugs combinations in the market, most of which were irrational and of doubtful therapeutic value. Hence it suggested that these multiple ingradient drug

\(^{34}\) ibid., p.184.

\(^{35}\) The list of drugs recommended to be sold under generic name to begin with is given in Annexure III, p.271 of H.C.R.

\(^{36}\) ibid., p.65.
formulations should be banned from being marketed.\(^{37}\)

To conclude, the Hathi Committee appointed in 1974 brought out a landmark report and based on a scientific analysis of the industry recommended radical measures for restricting the activities of the multinational companies, on the one hand, and on the other, the revitalisation of the public and Indian private sector so that in the long run the complete control of the industry would rest with the latter. Along with the basic structural shift within the industry, it recommended orientation of the industry towards producing necessary and quality drugs at cheap prices.

**1978 DRUG POLICY**

The Government announced the 'New Drug Policy (NDP) in March 1978, supposedly based on Hathi Committee recommendations. The stated objectives of the NDP (1978) were:

- To develop self-reliance in drug industry
- To provide a leadership role to the public sector
- To aim at quick self-sufficiency in the output of drugs.
- To foster and encourage the growth of the Indian sector
- To ensure that drugs are available in abundance in the country to meet the health needs of the people.

\(^{37}\) ibid., p.253.
To make drugs available at reasonable prices.
To keep a careful watch on the quality of drugs produced and prevent adulteration and other malpractices.
To offer special incentives to firms which are engaged in research and development; and
To provide other parameters to control, regulate and rejuvenate this industry as a whole, with particular reference to containing and channelising the activity of foreign companies in accord with national objectives and priorities.

The Janata Party Government announced the 1978 Drug Policy supposedly based on the recommendations of Hathi Committee. The various provisions in the policy regarding production, role of public sector and foreign sector, pricing, licensing, brand names etc. were as follows.

Policy on Production Planning and Role of the Public Sector

The 1978 policy divided the drugs into three groups (sectoral reservation) to serve as an indicative list of lines of production for public sector, Indian sector and open for all sectors (including foreign sector). Table I gives the items which were open to licensing for production by the public sector. Table II gives the list of drugs open
to licensing and production only by the Indian Sector. Table III gives the items open for licensing and production to all sectors including the foreign sector.38

In considering industrial licence applications preference was to be given to Indian Companies over MRTP units and foreign companies, and in that order. Economy of scale, technology and pricing of products, however, were to be the deciding factors.

The public sector was to be assigned a leading role in the production and distribution of drugs and pharmaceuticals. Adequate outlays was to be provided to achieve this objective. The public sector was to be permitted to obtain the best technology available to improve productivity. The new policy sought to encourage earmarking of a suitable percentage of the net turnover by public sector for R & D activities. Their production was to be planned to meet the major requirements of drugs for public health services.

The Indian drug manufacturers was allowed formulation licences upto 10 times of the value of their bulk drug production. In order to encourage consumption of indigenously produced bulk drugs, such formulation capacity was to be

38. Document (Indian Drug Policy, 1978), Department of Chemicals and Fertilizers, Ministry of Petroleum, Chemicals and Fertilizers, GOI.
sanctioned provided the formulation turnover is based on a ratio of 2:1 between consumption of indigenous bulk drug and imported/canalised bulk drugs. However, a case-by-case approach was to be adopted in applying these ratios where Indian Companies had made substantial investments for production of bulk drugs but actual production was yet to be achieved, because of the gestation periods, time span for perfection of technology etc.

Certain units in the Organised sector had been exempted from obtaining industrial licences, but were required to register their activities with the DGTD (Director General of Technical Division). With a view to ensuring the implementation of the entire complex of decisions on licensing etc in the drugs industry, the new policy proposed that all units which were carrying on so far with DGTD registration only, would be required to obtain industrial licences and the registration scheme cease, in so far as the drug industry was concerned.

Role of Foreign Companies

In order to direct the activities of foreign companies to subserve national objectives and interests, the Government decided to redefine "drugs and pharmaceuticals" listed
at 14 of Appendix I of Industrial Licensing Policy of 1973 in a comprehensive manner. The new definitions is as follows: 39

"a) Drug intermediates from the basic stage for production of high technology bulk drugs; and

b) High technology bulk drugs from basic stage and formulations based thereon with an overall ratio of bulk drugs consumption (from own manufacture) to formulation from all sources of 1:5".

The new policy further decided that in as far as foreign companies engaged in the manufacture of formulations and/or bulk drugs not involving high technology were concerned, they would be required to bring down their foreign equity forthwith to 40 percent so that 60 percent of the balance equity currently in the hands of foreign shareholders is disinvested in favour of Government financial or public sector institutions and the rest in favour of Indian investors, preference in the latter case being given to Indian employees of such Companies.

For the purpose of identifying foreign companies engaged in the manufacture of bulk drugs not involving high

39. ibid.
technology detailed exercises were to be carried out through a high level committee consisting of Secretaries to the Government in the Department of Chemicals and Fertilisers, Industrial Development, Technical Development, and Science and Technology assisted by experts.

For the purpose of FERA, a drug company was to be deemed to be a foreign company if the direct foreign equity in it was above 40 percent. The FERA guidelines and dilution formula applicable to all other industries were to be applicable to the drugs and pharmaceuticals industry also.

Foreign companies engaged in the manufacture of household remedies were not to be granted any expansion in capacity nor were to be allowed to take up such activity as additional items hereafter. Existing foreign companies were to be given formulation licences in future only if they were linked with the production of high technology bulk drugs from the basic stage. The small-scale sector was a prohibited area for foreign companies. No foreign company was to be given loan licence for operating in the drugs field. The turnover of the foreign companies based on the existing loan licences were now to be treated as a purely trading activity.
Applications for Industrial Licences (including expansion of capacity over the level existing on 31.12.1977) by foreign drug companies for the manufacture of high technology lines of bulk drugs was to be considered, under the new policy, subject to the overall condition of their supplying 50 percent of their production of such bulk drugs to non-associated formulators and subject further to their restricting their overall ratio of bulk drug consumption (from own manufacture) to formulation from all sources to 1:5. The condition of release to non-associated formulators, in similar circumstances in respect of Indian Companies the public sector and MRTP companies were to be 30 percent, 40 percent and 50 percent respectively. 40

Regularisation of Capacity

The 1978 policy sought to regularise production in excess of licenced capacity or capacity based on COB licences, permission letters, registration certificates, no objection certificates etc, the criteria being highest production actually achieved in any year during the three-year period ending March 31, 1977. In the case of foreign drug companies regularisation of excess production on the

40. ibid.
above criterion was to be done (a) subject to their making over to non-associated formulators, 50 percent of their total production of such bulk drugs (including that regularised), and (b) subject further to their restricting the value of their formulations to five times the value of their total bulk production.

In the case of Indian sector, Public sector and MRTP companies, regulation of excess production on the above criterion would be done on the condition that they make available 30 percent, 40 percent and 50 percent respectively of their total production (including that regularised) to non-associated formulators and subject to further condition that they restrict production of their formulations to ten times the value of their bulk drug production.\(^{41}\)

Excess production in formulations which fell with in the decontrolled category was not to be regularised and the companies were required to reduce their production in this category to the level of authorised capacity within a period of six months from the promulgation of policy.

The excess production in household remedies produced by the foreign sector was not to be regularised. However, in

\(^{41}\) ibid.
the case of foreign companies which had a ratio of bulk to formulation of less than 1:5 (or 1:10 in the case of Indian Companies), regularisation of excess production of decontrolled formulations and household remedies was permitted upto the ceiling of these ratios.

Excess production in any category was to be regularised if the Company undertook to export such excess for a period of five years from the promulgation of the policy.

No unauthorised production (i.e. production not authorised by industrial licence, COB licence, Permission letter or DGTD registration) was to be regularised.

**Pricing Policy**

The NDP (1978), for the first time, introduced a comprehensive system of price control in the drug industry (though some price control measures had been in force since 1970. The new DPCO categorised drugs into four categories-I (life saving), II(essential), III (less essential) and IV (non-essential/simple remedies). Of these, the first three categories were price controlled with mark up (profits allowed) of 40 percent, 55 percent and 100 percent respectively. The idea behind this graded system of price control was to make more essential drugs cheaper.
All the bulk drugs which were used in the production of price controlled formulations were subject to price control. The post-tax return on bulk drugs required for production of category I and II formulations (highly essential and life-saving) was kept at 14 percent and on other bulk drugs, at 12 percent on networth — i.e. equity plus free reserves. The prices of new bulk drugs introduced in the market after the promulgation of the new policy were also to be governed by the above criterion. The new policy provided that at least 20 percent of the turnover of an individual drug company shall be in categories I and II formulations.

In the case of entirely new or original bulk drugs developed through indigenous R&D efforts and which had not been produced elsewhere, there was no price control on the bulk drug and its formulations for a period of five years. The condition of supply of a part of the production to non-associated formulators was not also applied to such bulk drugs during the period.

Abolition of Brand Names, Quality Control etc.

Instead of setting up of a National Drug Authority (NDA), as recommended by Hathi Committee, the 1978 policy

42. ibid.

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provided for setting up of a high-level Committee on Drugs and Pharmaceuticals called "Policy and Planning Committee for Drugs Industry (PPDIC)" to advise the Department of Chemicals and Fertilizers from time to time. The Development Council for Drugs and Pharmaceuticals was to be activised under the chairmanship of the Minister of Petroleum, Chemicals and Fertilizers.

The brand name was to be abolished in respect of the following five drugs - Analgin, Asprin, Chlorpromazine, Ferrous Sulphate, Piperazine and its salts such as adipate, citrate and phosphate. All single ingredient dosage forms of the above drugs was to be marketed only under generic names. Drugs to be exported were to be allowed to bear brand names. Drug formulations marketed under generic names was also subject to price control.

A quality control of drugs was to be the responsibility of the Ministry of Health & Family Welfare. The Ministry of Health and Family Welfare was asked to strengthen the organisational set up with the aim of ensuring that spurious or substandard products were not manufactured or marketed by drug manufacturers.

43. ibid.
The Hathi Committee recommendation which provided for setting apart five percent of net turnover of the public sector for R&D activity was to be implemented in the new policy, subject to the availability of funds for such investment.

Foreign Companies whose turnover in drugs was in excess of Rs. Five Crores per annum was required (a) to have R&D facilities within the country on which capital investment should be at least twenty percent of their net block, and (b) to spend at least four percent of their sales turnover as recurring expenditure on R&D facilities.

The new policy sought to impose export obligation on foreign companies, wherever existing industrial licences did not prescribe it. Foreign Companies were asked to offer quality control facilities to the small scale sector on a no-profit no-loss basis.

Assessment

The 1978 Drug Policy, announced by the Government after a lapse of more than three years of submission of the Hathi Committee Report, had many positive features. The new policy sought to encourage the development and growth of the Indian sector of the drug industry. In the aftermath of the 1978
policy, the Organised Indian private sector created a solid base for itself in the drug industry.

The new policy provided a leading role to the public sector in the production and distribution of drugs in the country. It introduced for the first time the concept of sectoral reservation in the matters of production of drugs in the country. A total number of 25 basic drugs were reserved for manufacture by the public sector. Similarly, the list (Annexure I of 1978 Drug policy) also indicated the drugs reserved for Indian private sector and open to all sectors.

The new policy contained several provisions to encourage the production of bulk drugs in the country. The Indian sector was allowed manufacture of formulations ten times the value of their bulk drug production. However, this liberal attitude of the Government with regard to the manufacture of formulations (itself to encourage the Indian Sector companies), was subject to the condition that the consumption of indigenous bulk drug was twice that of their consumption of imported/canalised bulk drugs, i.e. in the ratio of 2:1. Further, the policy, required that the manufacturers engaged in the manufacture of formulations from imported raw materials and penultimates, should manufacture bulk drugs from
basic stage within a period of two years.

The new policy (1978), also sought to direct the activities of foreign companies in to the high priority area of bulk drug production. It redefined the "drugs and pharmaceuticals" listed at 14 of Appendix I of Industrial Licensing Policy of 1973. The new definition limited its scope to the production of high technology bulk drugs from basic stage and those of formulations based thereon in the ratio of 1:5 and those of drug intermediates from the basic stage for the production of high technology bulk drugs. Further the 1978 policy prohibited the future expansion of the foreign drug companies in the manufacture of household remedies. Their industrial licences in the future with regard to formulation activities was linked to their production of high technology bulk drugs. Further, the foreign drug companies could apply for industrial licences or for the expansion of existing capacity, subject to the overall condition that they supply 50 percent of their production of bulk drugs to non-associated formulators and subject further to their restricting overall ratio of bulk drug consumption (from own manufacture) to the formulations from all sources to 1:5. Further, foreign companies were prohibited from entering into small-scale sector. No loan licensing facility
was to be provided to the foreign companies.

The new policy directed the foreign companies not engaged in the manufacture of bulk drugs and formulations involving high technology to bring down their equity to 40 percent, the rest to be disinvested in favour of Government financial institutions or public sector institutions and the Indian investors; preference in the latter case to be given to the Indian employees of such companies. There were 31 FERA companies with direct foreign equity exceeding 40 percent in March 1978 on the eve of the announcement of drug policy. Since then, 25 of them diluted their foreign equity to 40 percent or below.

The NDP (1978) and the Drug Price control order (DPCO), 1979 introduced for the first time a comprehensive system of price control. It provided a graded system of price control, wherein the drugs were divided into four categories. The life saving and essential drugs (I & II) were allowed lower mark-up, the idea being to make these drugs cheapest. The new policy further provided that at least 20 percent of the turnover of an individual drug company should be in categories I and II formulations. This measure was to increase the production of life-saving and essential drugs.
The new policy sought to stimulate R & D activities and stipulated that a certain percentage of turnover be spent on R & D. Foreign companies whose turnover was in excess of Rs 5 crores per annum were required to invest at least 20 percent of their net investment in R & D facilities and were further required to spend at least 4 percent of their sales turnover as recurring expenditure on R & D facilities. To encourage indigenous development of new drugs, the policy provided for total decontrol in prices on the bulk drug and its formulations for a period of 5 years, provided the bulk drug so developed was entirely new or original which had not been produced elsewhere.

The NDP sought to abolish brand names. A beginning was made by abolishing brand names in respect of five drugs to begin with, to be progressively extended for all the drugs in essential drug list. The new policy also wanted to check reckless profits by the drug manufacturers and therefore imposed a profitability ceiling of 12-14 percent post-tax returns for individual manufacturers.

Notwithstanding several commendable provisions in the 1978 policy such as sectoral reservation, equity dilution, mandatory bulk drug-formulation ratio etc, the new policy was at best, albeit partially based on the recommendations
of Hathi Committee. Its major recommendations were not accepted by either the Congress Government or its Janata successor. Without making any efforts towards restructuring of the industry, the new drug policy sought to implement the recommendations of the Committee in a piecemeal manner. This led to the perpetuations of the strangle hold of the multinational drug companies in India.

One of the major recommendations of the Hathi Committee was to give leading role to the public sector units in the production and distribution of drugs in the country. While twenty five bulk drugs were identified and reserved for production by the public sector, no attempt were made to address to the problems being faced by these units. No steps were taken to overhaul their management or to make them available raw materials, power supply etc, so as to enable them to fulfill the major tasks assigned to them. Deliberate neglect, mismanagement, corruption and sabotage at various levels has brought the public sector drug units to its present pass.

The Hathi Committee had felt the need for an independent body on drugs and pharmaceuticals to handle all matters concerning the future expansion of the drug industry. Therefore, it suggested for the setting up of a National Drug
Authority, an autonomous body. The Government, however, didn't accept this important recommendation and instead set up an advisory body under the Department of Chemicals and Fertilizers. However, such a body cannot be a substitute for the NDA. Thus the matters concerning the development and regulation of the drugs industry continued to be looked at an adhoc basis.

Another important concern of the Hathi Committee was the question of regulation and control of foreign drug companies operating in India. In view of the fact that these companies preferred to operate in the high profitable formulation activity, the Committee by a majority recommended for their nationalisation. However, the Government refrained from nationalising the drug industry. Instead, it directed only the foreign companies not engaged in high technology bulk drug and formulation activities, to bring down their quity to 40 percent. Even the equity dilution as proposed by Hathi Committee was diluted. The Committee had unanimously recommended that foreign drug units should not only "be directed to bring down their equity to 40 percent forthwith... but (should) further reduce it progressively to 26 percent ". Moreover, it further recommended that the dilution of foreign equity should not take the form of
dispersed holdings by a large number of Indian nationals because such widely dispersed holdings will not, in anyway, reduce the effective control of the foreign equity shareholders.

The manner in which the new policy proposed equity dilution was in effect a dilution of the Hathi Committee recommendation. The 1978 drug policy required only such foreign Companies as had engaged only in formulation or in the manufacture of a few basic drugs not involving high technology, and that too mostly for captive use, to bring down their direct foreign equity to 40 percent. Others who were engaged in the manufacture of bulk drugs from the basic stage which involve high technology and of formulations made out of such drugs, need not by inference, bring down their foreign equity to 40 percent. Most FERA companies readily complied with as it is always possible to control a company with 40 percent block holding of shares provided the other shares are widely dispersed. This is precisely how equity dilution was done by most FERA companies. This gave them added advantage of being treated at par with Indian Companies (under FERA).

To identify the Companies producing high technology bulk drugs and hence to be eligible for concession of re-
taining more than 40 percent of foreign equity, a high level Committee was appointed by the Government. It submitted its report in October 1979. The main criteria adopted by the Committee in the definition of "high technology" were the following.44

1) Isolation and extraction involving sophisticated processes such as counter current liquid extraction, repeated chromatography or narrow cut fractionation.
2) Fermentation processes, use of enzymes for chemical transformation.
3) The steps of operations involved in a Chemical synthesis.
4) Reaction pressures of 10 atmospheres and above.
5) Use of potentially explosive materials.
6) High temperature vapour phase catalytic processes.
7) Reaction pressures above 250°C or below (-) 30°C.
8) Use of toxic materials.
9) Purification and separation by different types of sophisticated techniques.
10) Careful on-line process controls.

11) Degree of sophistication employed to ensure health, safety and quality.

12) New drugs discovered in India involving detailed pre-clinical laboratory and clinical trials.

It is evident from points number (8), (9), (10) and (11) that any drug producing company can be considered to be a "high technology" company. Further, the Government declared that "the need and scope for review of the findings of the Committee ..... will be considered in the light of representations received from the individual companies concerned". In other words, only representations from the concerned drug manufacturers could initiate, and determine the scope of the review. Views of scientists, doctors and consumers were considered irrelevant.

45. ibid.

46. The carte blanche given to drug companies by the Committee on high technology led to some piquant situations. For instance, while the Deputy Director, National Chemical Laboratory, Pune had stated that in the production of salbutanol, the process involved low technology, the Committee concluded on the basis of the extremely generous definition given above, that the process involved high technology. On the basis of the Committee's unscientific classification, the Government permitted Hoechst, leading foreign concern, to manufacture drugs already being manufactured in the small-scale sector. (ibid; J.S Majumdar, quoted in Nagesh Kumar & K.M.Chenoy, "MNCs and self-reliance : A Case study of the Drugs and Pharmaceutical Industry", Social Scientist, April 1982, p.18.)
The Hathi Committee had recommended that those foreign Companies producing in excess of their licensed capacity should be made to part with 50 percent of this production to non-associated Indian formulators. The 1978 policy, however, allowed the foreign companies to share this 50 percent of their excess produce to any non-associated formulators. This invariably resulted in one foreign sector undertaking giving the material to another foreign sector undertaking. This not only nullified the intended effect of such a provision but also gave an opportunity to foreign Companies, in their collusive strategy of denying some critical items to the Indian sector.

The 1978 policy had stipulated that the criteria for regularisation of capacity in excess of licensed capacity or based on COB licenses, permission letters, registration certificates, no objection certificates etc, would be the highest production actually achieved in any year during the three-year period ending March 31, 1977. However, due to sustained lobbying by pro-MNC groups led to substantial modifications in the already liberal new drugs policy, with further concessions to the drug MNCS. The Government decided to regularize liberally all existing installed capacities as of 4 september 1980, in disregard to the earlier stated
The new policy divided the price controlled drugs into four categories with graded pricing structure. However, there seems to be no rationale for this categorisation and probably was drawn arbitrarily. All the first three categories contained drugs which could be called life-saving. They contained also drugs used for mass diseases. Further, all the three categories contained drugs that were high priced and low priced. Category 3 contained, among others, drugs intended for use in diabetes, tuberculosis, hypertension, angina etc. All these are chronic diseases and a patient is required to be under medical treatment the rest of his life, excepting in the case of tuberculosis where the treatment lasts for 2 to 3 years. The mark-up of 100 percent for this category (III), that is 100 percent of the ex-factory cost of formulation, inflated the price of formulation to the consumer to a prohibitive level.

The Hathi Committee had recommended a list of 117 essential and life-saving drugs, drawn by a panel of experts, for their production in the country on a priority basis. The 1978 policy, however, had no production control

47. Indian Express (New Delhi), 18 October 1981, cited in Nagesh & Chenoy (ibid.).
measures, to compel manufacturers to produce these drugs. This when coupled with graded pricing structure proved to be disastrous. Companies reduced their production of category I and II drugs, where the mark-up permitted was relatively lower. Table below illustrates this point. The essential drugs (I & II) production in the country declined from 21.2 percent in 1978 to 16.8 percent in 1980.

### Drug Production in Response to Pricing Policy

(Percent)

<table>
<thead>
<tr>
<th>DPCO category</th>
<th>1978</th>
<th>1979</th>
<th>1980</th>
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<tbody>
<tr>
<td>I (Life saving)</td>
<td>4.5</td>
<td>4.2</td>
<td>3.6</td>
</tr>
<tr>
<td>II (Essential)</td>
<td>16.7</td>
<td>14.8</td>
<td>13.2</td>
</tr>
<tr>
<td>III (Marginal)</td>
<td>67.1</td>
<td>67.0</td>
<td>68.6</td>
</tr>
<tr>
<td>IV (Decontrolled)</td>
<td>11.7</td>
<td>13.0</td>
<td>14.6</td>
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To encourage the production of basic drugs in the country, the 1978 policy provided incentives where in bulk drugs so produced was allowed a post-tax profit of 14 percent on net worth. Although this incentive was provided to all manufacturers of such bulk drugs, foreign or Indian, the maximum benefit was derived by the foreign sector whose ratio of paid up capital to reserves was in the order of 2:3. A 14 percent post-tax profit on net worth thus amount-
ed to 35 percent post-tax on paid-up capital. The Indian sector could not benefit to this extent as their reserves were insignificant. In the case of formulations, the return provided was pre-tax 10 percent on sales turnover for those units that had a turnover of Rs. 6 crores and over per annum, who made bulk drugs from basic stage and who had installed R & D facilities. As in the case of bulk drugs, here too the foreign sector had an edge over the others, as their quality control department which is usually of a very high order, can be made out to be their R & D division. Data published in Economic Times of August 27, 1977 worked out the pre-tax return of over 35 foreign companies as 9.1 percent and 9.2 percent respectively in the years 1974-75 and 1975-76. The 10 percent profit permitted by the Government was too liberal and was more by 2 percent than the recommendations of the Wanchoo Committee.

Hathi Committee had recommended abolition of brand names in 13 cases with immediate effect and in a phased manner, at least for essential drug list of 117 items. The 1978 policy accepted this only in case of five drugs. The notification for the same was issued on Jan 17, 1981.48

almost three years after the policy decision. Even this hesitant step of the Government was blocked by drug lobbies, especially OPPI, through Court injunction. Hoechst, the manufacturers Novalgin and Pfizer, the manufacturer of piperazine went to Delhi High Court and the order was stayed.\textsuperscript{49} This indicates a weakness in the legislation with regard to control and regulations of drugs and pharmaceuticals.

In the 1978 policy, no serious attempts were made to remove irrational and hazardous drugs from the market. Their share in the total drug production has been rising. The number of formulations at present in the market number more than sixty thousand. The responsibility of quality control was vested in the Ministry of Health & Family welfare, despite the fact that the Ministry has no executive power to license drug manufacturers or suspend or cancel their licenses in case of detection of spurious or sub-standard drugs. This Ministry has been vested with responsibilities without concomittant power. Even otherwise, no serious efforts were made to strengthen the organisational set up needed for quality control measures.

\textsuperscript{49} Economic Times, July 30, 1981.
Hathi Committee had pointed out lack of research and development activities in the private sector in India despite the fact that R&D was backbone of this industry. To remedy this situation, it recommended that the drug policy should ensure a minimum investment by drug manufacturers in their R&D. Further, public sector was asked to ensure a minimum investment of 5 percent of their turnover in R&D.

The 1978 policy, however, diluted the above recommendations. Public sector was to be allowed a 5 percent allocation to R&D subject to availability of funds. This in practice proved ineffective. While some fiscal incentives were provided for R&D investment (for instance, the expenditure on scientific research was allowed full deduction under the Income Tax Act, etc), the private sector investment in R&D has not been forthcoming. In fact, in many private sector companies, the R&D staff generally performs the job of quality control. This has been true of drugs and pharmaceuticals as well. Foreign sector R&D engage their R&D staff only in preliminary stages of screening of local microbes, herbs and plants for their medicinal properties, the promising ones so found being sent to their principals so that patents could be obtained in their principals name. Similar picture emerges in the case of synthetic drugs too. The R&D staff in India is asked to synthesize a large number of
alternatives and derivatives around active groups. After a preliminary screening or even without it, the promising ones or anticipated ones—possessing superior activity or action, are being sent to their principals for final screening, activity measurement and toxicity studies even though facilities for such investigations have been created in India.

The Hathi Committee referred to the section 100 of the Indian Patents Act, 1970, which empower the Central Government and any person authorized in writing by it, to use a patented invention for the purposes of the Government. Government, therefore under the powers vested in it, permit the public sector undertaking to use the inventions for the purposes of the Government. However, the 1978 policy scuttled this suggestion on a vital issue, referring it to Department of Science and Technology, to be taken up separately in consultation with Ministry of Law and Controller General of Patents, Designs and Trade Mark.

Meanwhile, there have been instances wherein foreign sector acted as impediment in fructification of indigenously developed technology, what to say of patented ones. For instance, Pfizer lodged litigation against Bengal Chemicals and Pharmaceuticals Works, when the latter wanted to patent
the manufacture of chlorpropamide, an anti-diabetic. The case in Calcutta High Court dragged on for 8 years, and finally it was found that the patent to which Pfizer had a claim, did not relate to chlorpropamide.50 Thus, during 8 years, Pfizer was able to continue holding monopoly on Tolbutamide - a brand name for chlorpropamide. Another case of preventing others to compete is that of Franco India Pharmaceuticals. This firm produces haemoglobin from the blood collected from slaughter houses. Its total capacity for producing haemoglobin can be met with only one slaughter house, but the company reserved all the slaughter houses of the country for blood collection.51

. An analysis of the quality of production technology employed and the R&D undertaken, was provided by analysis of the qualifications and training of the high income employees specially in a country like India where the availability of qualified people, unemployment and under-employment are quite high. In an analysis of seven leading foreign pharmaceutical Concerns, Kumar and Chenoy reported that out of a total of 1885 high income employees (Rs 3000/ per month or more), in 1978-79, 435 (25.7 percent) did not have any

50. ibid., n.43.

university degree. As many as 1,300 (76.7 percent) had first university degree or less qualification. Further, 28 p.c and 1.6 percent of their high income employees were employed in marketing and R&D respectively. The comparable figures for National sector were 15.4 and 10.8 percent respectively. Thus, it is obvious where the emphasis lay in foreign sector companies. The Indian sector, inspite of limitations of resources, seems to have relatively better performance in this regard.

To conclude, 1978 drug policy, was a policy aimed at preserving the public sector and hence it was nationalist in intent and orientation, but did not go far enough in this regard. The nationalisation of drug industry, one of the major recommendations of the Hathi Committee was not accepted. It also diluted effectiveness of Hathi Committee report by not plugging loopholes and making concessions to foreign Companies. However, compared to drug policy elsewhere, it protected the home industry. It contained many provisions to encourage the production of bulk drugs in the country. Some of the important provisions in the 1978 policy were, however, never implemented. For instance, the provision which required the manufacturers to produce at least 20 percent of essential drugs was not adhered to. The 1978
policy was a step further towards self-reliance as compared to earlier policies in 1950's and 1960's. The restrictions on the MNCs had a salutory effect on the growth of organised indigenous sector and on production of bulk drugs in our country.