When Mrs. Indira Gandhi returned to power in January, 1980 she moved rightwards by initiating a trend towards the liberalization of economy. A number of factors contributed to this change.\(^1\) India's industrial growth had slowed down from 7-8\% in pre-mid 1960's period, to about 5\% per annum over the later fifteen years. The 1979 was particularly a bad year. Within the government, reports brought out by bureaucrats and specialists since the 1970's had recommended liberalization of the economy in one aspect or the another. The Janata Government had taken some measures in the economy in 1979 that could be interpreted as liberalizing measures. Industrial growth had jumped back to over 8\% in 1980.

The issue of a sluggish industrial performance was in any case at the forefront. New policies were needed. Various alternative policy measures were suggested. Whatever their economic merits, some alternatives clearly suited Indira Gandhi's political design better than others. It was clear to Mrs. Gandhi by now that socialism was not working. Anti-

poverty programmes had not been very successful. Apart from this, the full force that business communities had thrown behind Morarji Desai's Government left her vulnerable. In order to regain her support among the business communities, a movement toward liberalizing the economy, while maintaining some rhetoric of socialism and some of the anti-poverty programmes was initiated. Besides these overtly political considerations, other factors probably also played some part in pushing India toward economic liberalization. The World Bank had also been periodically keeping pressure on the Indian Government to decontrol and open up the economy.

While Indira Gandhi initiated liberalization in the economy, the extent of change was not significant enough to raise too many political fallouts. It was during the first six months of Rajeev Gandhi's rule (1985) that a genuine attempt at a new beginning was made in the economic policy. An attempt was made to make a decisive shift from the state controlled and import substitution model to a liberal model of development. Soon after 1985 (June) elections, Rajeev Gandhi Government promised new economic policies. Rajiv Gandhi summed up his government's economic approach as involving a "judicious combination of deregulation, import
liberalization and easier access to foreign technology". This involved a fairly sharp break from Nehru and Indira Gandhi's rhetorical emphasis on "socialism, planning and self-reliance". Rajeev Gandhi's economic advisors included individuals such as Montek Ahluwalia, Abid Hussain, Bimal Jalan and Manmohan Singh; most of them were known for their decontrol and pro-liberalization proclivities. If one contrasts Rajeev Gandhi and this group of India's new elite with Nehru and his band of seasoned, left leaning nationalist leaders and advisors, then the image of a sharp break with the past is clearly discernible.

Indian Drug Policy, 1986

The 1978 Drug Policy had imposed a number of controls on the drug industry. The prices of a large number of drugs were under Government control. The policy provided for sectoral reservations for Indian Sector (Private and Public) in the production of drugs. As a consequence of this, large Indian owned companies had diversified their base and consolidated their position. By early eighties, multinational drug companies were joined by the large private sector Indian companies in demanding a review of the 1978 Drug policy. Mrs. Gandhi's Government to begin with delicensed a

2. Times of India, 6 January 1986.
number of drugs. Subsequently in 1983, her Government set up the National Drugs and Pharmaceutical Development Council (NDPDC),\(^3\) to review the 1978 policy in which the representation of the drug industry overwhelmed the others. The 1986 Drug Policy entitled "Measures for Rationalisation, Quality control and Growth of Drugs and Pharmaceutical Industry in India", announced by the Government on 18 December 1986, was largely based on the NDPDC Report.

One of the major objectives of the 1986 Drug Policy, promulgated under Rajeev Gandhi, was to deregulate the drug industry. The Government had initiated a policy of delicensing even before the 1986 policy. Government delicensed 12 bulk drugs in March 1983 and 82 bulk drugs in June 1985.\(^4\) This allowed any company including multinationals to manufacture these 94 bulk drugs, hitherto, reserved for Indian sector. This scheme of delicensing covered all anti-cancer drugs. The 1986 policy further extended the scheme of delicensing to all the bulk drugs whose imports were allowed on Open General Licence (OGL). Further, in the case of all new

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bulk drugs and related formulations developed in the coun-
try, the delicensing scheme was now made available to all
drug firms, including FERA companies. 5

A large number of formulations had been under produc-
tion since sixties and seventies with industrial approvals
which were questionable. Majority of these drugs were
claimed to be covered under registration certificate issued
under section 10 of the Industries (Development and Regula-
tion) Act. These registration certificates, however, did not
mention individual items and capacities but merely permitted
production of "drugs and pharmaceuticals". Another major
category comprised of items claimed to be covered under
notification issued in the 1960's and 1970's, under Section
298 of the IDR Act, announcing exemption from industrial
licensing, subject to some conditions. However COB
(Carry-on-Business) licences could not be issued in many
cases because of non-fulfilment of one or more of the condi-
tions subject to which the exemptions were granted. The 1986
Drug Policy regularised 6 the production of all such formu-
lations and surgical aids, without going into the merits of

5. Document, Indian Drug Policy 1986, Department of
Chemicals and Petrochemicals, Ministry of Industry,
GOI, p.10.

6. ibid.
The 1986 Drug Policy brought a number of changes in the system of price control of drugs. The new policy reduced the span of price control from 347 bulk drugs to 166 drugs. It decreased the number of controlled categories to two and the MAPE (Maximum Allowable Post-manufacturing expense incurred from the stage of manufacturing to retailing and manufacturer's margin) allowed in these was increased to 75 and 100 percent for category I and II respectively. Drugs under category I were those required for National Health Programmes and the list was prepared by the Department of Chemicals and Petrochemicals in consultation with Ministry of Health. Drugs under category II, i.e., other essential drugs were identified by an Expert Committee (Kelkar Committee) by applying certain exclusion criteria, viz consumption not significant, new drugs for which process developed indigenously, drugs whose availability is far more important than the price, drugs

7. ibid., p.7.

8. The 1978 Drug Policy, had for the first time introduced a comprehensive price control in the drug industry (though some price control measures had been in force since 1970). The DPCO, 1979, categorised drugs into four categories - category I (life saving), category II (essential), category III (less essential), and category 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.
having adequate market competition etc. There was to be no price control for the remaining drugs. In respect of imported formulations, selling and distribution expenses including interest and importers margin, was not to exceed 50 percent of the landed cost.⁹

The 1986 policy provided a uniform norm of pricing for all bulk drugs falling in the controlled category I and II. The manufacturers were given the following three options:¹⁰ (i) 14 percent post tax return on net worth; or (ii) 22 percent on capital employed; or (iii) long term marginal costing with 12 percent internal rate of return in the case of new plants.

The 1978 Drug Policy had set up Drug Price Equalisation Account (DPEA) essentially to encourage the domestic production of bulk drugs through a system of retention pricing. Under the 1986 policy, this system of retention and pooled pricing was discontinued. Protection, henceforth, to the indigenous production of bulk drugs was to be provided, through the tariff mechanism.¹¹

⁹. ibid., p.8.
¹⁰. ibid., p.7.
¹¹. ibid., p.8.
Assessment

The 1978 Drug Policy, despite being based on the partial acceptance of Hathi Committee Report, had, nevertheless, many significant provisions. Some of these provisions were as under:

(a) Sectoral Reservation in the production of essential drugs by the public sector and Indian sector companies;
(b) lower mark up on category I and II drugs to make them relatively cheaper;
(c) of the total turnover of each manufacturer, at least 20 percent must be made up of essential drugs;
(d) for those engaged in manufacture from imported raw materials and penultimates, manufacture from the basic stage to be ensured in two years;
(e) there should be a profitability ceiling of 12-14 percent post-tax on individual manufacturers; and
(f) a certain percentage of turnover be spent on R&D.

The 1986 Drug Policy, based as it was on the Report of National Drugs and Pharmaceutical Development Council (NDPDC) (dominated by the interests in the drug industry), marks a clear departure from the earlier accepted policy of self-reliance. It further diluted the objectives set out by
the Hathi Committee by liberalizing the economy. It in-creased the prices of controlled drugs in the absence of any unbiased study on the profitability of drugs. The study¹² used by the Government in the area of pricing was done by National Council of Applied Economic Research (NCAER), sponsored and financed by the OPPI, the Organisation of foreign companies in the Pharmaceutical Industry. Further, the drugs which remained under price control were presumably essential drugs. As multinational companies produced very few essential drugs, they remained unaffected by price control measures. Thus, the MNCs could reap super profits under the New Drug Policy (1986). Apart from this, the 1986 policy left enough scope for intensive lobbying and manipulations by the manufacturers to keep their products outside the price controlled categories, since the list of drugs to be under the span of price control was to be drawn up later on.

The pricing mechanism under the 1986 policy (as also under the earlier policy) was through the so-called MAPE (Maximum Allowable Post-Manufacturing Expenses) formula which provided for differential mark-ups (lower mark-up for category I and II drugs). Apart from the problems of decline

in production of essential drugs that this led to, there was another anomaly in this "Cost plus" pricing structure with regard to formulations. MAPE is calculated taking into account, among other factors, material costs. Thus for a formulator, the volume of MAPE automatically went up when he dealt with costlier materials (costlier bulk drugs and additives), though the manufacturer had not actually contributed to their production. In addition, there has been a tendency to using costlier packaging material. It led to a situation where formulators were more interested in pushing higher priced drugs in fancier packings.

It may be pointed out here that drug companies argue for an increase in MAPE on formulations on the grounds that a lower mark-up has been leading to a shortage of essential drugs. However, increase in profitability of formulations has no direct bearing on the availability of bulk drugs. Actually it is in the area of bulk drug production that there has been shortages and dependence on imports in a large number of cases. Therefore, there is a need to look into the system of differential mark-ups. A modified MAPE which excludes raw material and packaging material costs and

is based only on conversion costs and packing costs should be worked and an independent cost study needs to be carried out for a correct MAPE percentage.

Table I

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</tr>
</thead>
<tbody>
<tr>
<td>Pencillin</td>
<td>MMU</td>
<td>370</td>
<td>360.32</td>
<td>305.97</td>
<td>330</td>
<td>255.79</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Streptomycin</td>
<td>T</td>
<td>270</td>
<td>247.87</td>
<td>276.32</td>
<td>180</td>
<td>167.98</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chloramphenicol</td>
<td>T</td>
<td>300</td>
<td>111.46</td>
<td>98.12</td>
<td>200</td>
<td>107.02</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ampicillin</td>
<td>T</td>
<td>200</td>
<td>258.17</td>
<td>456</td>
<td>360.58*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin-A</td>
<td>MMU</td>
<td>77</td>
<td>52.00</td>
<td>93.64</td>
<td>110</td>
<td>77.19</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>INH (anti-T.B.)</td>
<td>T</td>
<td>250</td>
<td>288.40</td>
<td>57.84</td>
<td>333</td>
<td>25.45*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chloroquine</td>
<td>T</td>
<td>200</td>
<td>194.57</td>
<td>140.10</td>
<td>200</td>
<td>196.22</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dapsone</td>
<td>T</td>
<td>200</td>
<td>86.90</td>
<td>51.50</td>
<td>58</td>
<td>13.30</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diphtheria</td>
<td>MU</td>
<td>800</td>
<td>653.57</td>
<td>136.00</td>
<td>na</td>
<td>na</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note*: Major production in small-scale sector which is not reflected here


The drug manufacturers primarily involved in formulations do not have an important role to play in the industry; they are essentially traders. It is they who have been demanding higher prices and decontrol. It was to discourage such trends that ratio parameters for the manufacture of bulk drugs and formulations was stipulated in the 1978 and
1986 policies. But these ratio parameters have never been strictly enforced and hence need is to evolve mechanisms to encourage basic (bulk) drug production.

The Government initiated scheme of delicensing in eighties inspite of repeated observations made by the Government appointed Committees that the system of sectoral reservation had paid good dividends towards increase of production. It was as a result of restrictions on the multi­
nationals and the entry of public sector into the manufac­
ture of bulk drugs from basic stage that the real production of bulk drugs started in India. A number of FERA Companies had to rethink their options and were forced to dilute their equity to below 40 percent. The number of FERA Companies declined from 45 in 1978 to only eight by 1986. During this period, the national companies had shown improved perform­ance. The National Drugs and Pharmaceutical Development Council (NDPDC) had observed :- small scale units now ac­count for more than 50 percent of the production of a number of bulk drugs like Chloramphenicol amoxicillin, doxycycline, sulphamethoxazole, tinidazole, caffeine, piperazine and its salts. Similarly, Indian non-MRTP companies account for a significant share of bulk drugs like sulphamethoxazole,
trimethoprim, metronidazole etc. 14

The Working Group of NDPDC had observed further that in order to meet the increased demands of drugs for national programmes to control/eradicate T.B. leprosy, blindness, malaria etc., - that production of bulk drugs required for these programmes would have to expand manifold because of the proposed expansion of these programmes by the Ministry of Health. However, there is no need for relaxation of any of the present policy parameters in regard to industrial approvals of these bulk drugs and formulations. 15

The 1986 Drug Policy offers de-licensing and de-control of prices as panacea for all the problems in the drug industry. It pre-supposes that multinationals would produce bulk drugs and bring in new technology. However, as pointed out by Hathi Committee, the multinationals in the drug industry are engaged, primarily in the formulation business. Before the 1978 policy, there wasn't any sectoral reservation for Indian sector in the production of drugs, but even then bulk drugs were imported in large quantities. It was to overcome such crisis situation that sectoral reservation was adopted.

14. ibid., n.3, p.16.
15. ibid., n.3, p.24.
With the delicensing,\textsuperscript{16} Indian companies have been exposed to unequal competition with the MNCs who can procure raw materials at cheaper price from the international market or from their own establishments abroad which makes the production cost cheaper. This apart, the scope of using large reserve capital, transfer pricing and sales promotion network of the MNCs are in no way comparable to that of the Indian drug companies.

Delicensing has virtually led to an anarchy in the production of bulk drugs. MNCs have rushed to obtain capacity registration. The total amount of capacity registered for the delicensed drugs in most cases, surpassed the Seventh Plan (1985-90) targets several times over. This abnormally high capacity registration show that the MNCs will market these drugs either in single dosage form or through a most irrational combination formulation even if the need is saturated by creating artificial demands, generated by their

\textsuperscript{16.} The following 22 drugs were delicensed, the technology for which were already developed by the Indian sector companies: (i) Ampicillin, (2) Chloramphenicol (3) Chloroquin Phosphate (4) Clofazimine (5) Chlopropamide (6) Dexamethazone (7) Diazepam (8) Doxycyline (9) Erythromycin (10) Ethambutol (11) Ethinyl estradiol (12) Frusemide (13) Glybenclamide (14) Ibuprofen (15) Mebendazole (16) Metronidazole (17) Norethisterone (18) Propranolol (19) Pyrazinamide (20) Sulphamathoxazole (21) Trimethoprim and (22) Griseofulvin.

(Source: Compiled from the "Drug Statistics of India, 1984-85").
high pressure sales technique.

Table II

Capacity Registration by MNCs After June, 1985

<table>
<thead>
<tr>
<th>Bulk Drug</th>
<th>Unit</th>
<th>Capacity Registered</th>
<th>7th Plan Target</th>
<th>Excess over the Target (per cent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Ibuprofen</td>
<td>Mt.</td>
<td>1359</td>
<td>140</td>
<td>940</td>
</tr>
<tr>
<td>2. Procan</td>
<td>Mt.</td>
<td>415</td>
<td>98</td>
<td>423</td>
</tr>
<tr>
<td>3. Diazepam</td>
<td>Mt.</td>
<td>41</td>
<td>5</td>
<td>820</td>
</tr>
<tr>
<td>4. Cephalexin</td>
<td>Mt.</td>
<td>430</td>
<td>18</td>
<td>2389</td>
</tr>
<tr>
<td>5. Methyldopa</td>
<td>Mt.</td>
<td>374</td>
<td>68</td>
<td>450</td>
</tr>
<tr>
<td>6. Pyrazinamide</td>
<td>Mt.</td>
<td>159</td>
<td>35</td>
<td>354</td>
</tr>
<tr>
<td>7. Chlopheniramine</td>
<td>Mt.</td>
<td>77</td>
<td>21</td>
<td>267</td>
</tr>
<tr>
<td>8. Mebendazole</td>
<td>Mt.</td>
<td>174</td>
<td>63</td>
<td>176</td>
</tr>
<tr>
<td>9. Dapsone</td>
<td>Mt.</td>
<td>298</td>
<td>30</td>
<td>893</td>
</tr>
<tr>
<td>10. Amodiaquin</td>
<td>Mt.</td>
<td>137</td>
<td>47</td>
<td>191</td>
</tr>
</tbody>
</table>

(Source: EPW, 3-10 January 1987, p.18.)

Delicensing would encourage the MNCs to abandon the production of essential drugs from the basic stages and would destroy even what has already been achieved towards self-reliance in the production of drugs. With this scheme, MNCs have full freedom to increase production of their formulations, based on imported bulk drugs. The scheme of delicensing, is thus against one of the principal aim of our industrial policy, i.e., attainment of self-reliance.

In spite of almost total de-control in the production of drugs, there has been severe fall in the production
of those drugs that were de-licensed. In 1985-86, out of 90 monitored bulk drugs, there was slight improvement in the production of 13 bulk drugs only. All others were under produced. In most cases, production levels went down below the installed capacities of 1983. Similarly, no improvement in the production of essential drugs was achieved.

Table III

<table>
<thead>
<tr>
<th>Direct Imports &amp; Indigenous Production of Some Bulk Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>------</td>
</tr>
<tr>
<td>Ibuprofen</td>
</tr>
<tr>
<td>Production</td>
</tr>
<tr>
<td>Hydrocortisone</td>
</tr>
<tr>
<td>Production</td>
</tr>
<tr>
<td>Cephalexin</td>
</tr>
<tr>
<td>Production</td>
</tr>
<tr>
<td>Chloramphenicol (L Base)</td>
</tr>
<tr>
<td>Production</td>
</tr>
<tr>
<td>Ephedrine</td>
</tr>
<tr>
<td>Production</td>
</tr>
<tr>
<td>Pseudoephedrine</td>
</tr>
<tr>
<td>Production</td>
</tr>
</tbody>
</table>

(Source: "Drug Statistics of India", 1985-86, quoted in, *EPW*, 3-10 January 1987.)
The situation has been further aggravated by liberalization of the import policy. The liberalization of import of bulk drugs and penultimates has either reduced or totally stalled the production of bulk drugs from the basic stages. There is no logic in scheduling drugs which are supposed to be manufactured by multinationals under Open General Licence (OGL). Thus, the opportunity for direct imports of bulk drugs provides the multinational drug companies a large scope to utilize transfer pricing. The study of eight such bulk drugs are as in Table above.

In a study by Sandhya Gautam,\textsuperscript{17} where she analysed import of 42 bulk drugs which were shifted to OGL from restricted items, it was found that only 6 of the 42 drugs were life-saving and essential (category I and II, old DPCO); 26 were under category III (higher mark-up - 100 percent) and the rest 10 drugs were not under any price control and hence had unlimited potential for profit. Bulk drugs like Ibuprofen, Pyrazinamide, Tinidazole, Amoxicillin, Ampicillin, Corticosteroids, Ephedrine, Methyldopa, Chloroquin, Sulphamethoxazole, Chloramphenicol, etc. are

\textsuperscript{17} Sandhya Gautam, "Impact of Import Liberalization on Bulk Drug Production", paper presented at the seminar of Indian Medical Association, New Delhi, 29-30 November 1986.
produced indigenously and also allowed to be imported. The multinational companies (MNCs) having a market monopoly of these drugs have shifted to import while their own production capacities are underutilised. This created a situation where even when there was a glut of sulphamethoxazole in the market, its import was allowed.

The import of rifampicin has been allowed in large quantities and is exempted of import duty. The technology for production of rifampicin was developed by CDRI but its production has not been feasible as 105 percent duty was imposed on its raw materials. The import of Chloroquin was exempted from duties while its intermediates bore a duty of 25 percent. This indicates that the import policy has been discouraging not only production but research and development of indigenous technology as well.

Customs duty for intermediates/raw materials were often higher than those on the bulk drug import. This led to substantial drainage of foreign currency by way of direct import of bulk drugs.
Table IV

<table>
<thead>
<tr>
<th>Bulk Drug</th>
<th>Duty (%)</th>
<th>Intermediate/ Raw Materials</th>
<th>Duty (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trimethoprim</td>
<td>100</td>
<td>3,4,5 Trime-thoxy-benzaldehyde</td>
<td>134</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>Nil</td>
<td>Raw Materials</td>
<td>105</td>
</tr>
<tr>
<td>L-Dopa</td>
<td>Nil</td>
<td>Vanillin</td>
<td>135</td>
</tr>
<tr>
<td>Sulphadiazine</td>
<td>100</td>
<td>Intermediate</td>
<td>135</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>100</td>
<td>Intermediate</td>
<td>135</td>
</tr>
<tr>
<td>Chloroquin</td>
<td>Nil</td>
<td>Ethoxymethylene diethylmalnate</td>
<td>25</td>
</tr>
</tbody>
</table>

(Source: EPW, 3-10 Jan. 1987.)

Given the framework of 1986 Drug Policy, the above situation was unavoidable. The new policy that almost completely reversed the earlier (1978) policy is a total capitulation to MNCs lobby in drug industry. On June 30, 1990, Minister of Chemicals and Petro-Chemicals, Mr. M.S. Gurupadaswamy in a meeting with the drug industry associations, chemists and druggists, and consumer and health workers, said the following which is worth reproducing here: "There is a strong view that the earlier review of the policy in 1986 was more from the point of view of manufacture and that the preamble of the 1986 policy was to ensure remunerative returns to the manufacturers instead of according priority to the health needs of the people. Therefore, the feeling is
that the very objective of the 1986 policy was misplaced...."\textsuperscript{18} The demand estimation of essential drugs cannot be a merely arithmetical excercise. It must take into account the disease patterns of the country.

To conclude, the 1986 policy was \textit{dangerously} silent about the health needs of the people. The Government totally capitulated to the unreasonable demands of the pharmaceutical industry. The changes articulated in the policy pertained only to pricing and licensing. The shifts in these areas were in accordance with the demands of the industry lobby from time to time, while the interests of consumers and indigenous sector were totally ignored. No National Drug Policy can have its foundations in pricing and licensing policies. Health authorities were not even consulted before formulation of the policy. The policy had no provision for phasing out hazardous drugs and irrational for mulations. No attempts were made either to formulate an "Essential drug list. Thus, while the Government had moved with speed to satisfy industry lobby, the health of the people was totally ignored.

\textsuperscript{18} \textit{Economic Times} (New Delhi), 25 August 1991.
New Drug Policy 1994

During the 1980's, India's economy had grown at a rate of about 5 percent. Despite this a crisis situation developed in the economy in 1991. The domestic rate of inflation was up to 17 percent, foreign exchange reserves had plummeted to $1.2 billion, barely sufficient to pay for two weeks imports; the Central Government's fiscal deficit as percent of GDP (Gross Domestic Product) touched the all time high of 8.4 percent; and the current account deficit widened to almost 8 billion US dollars (2.6 percent of the GDP). This crisis situation provided the new Government which came into office in June 1991, the rationale for further liberalization of the economy. Mr P.V. Narasimha Rao, Government which announced the New Industrial Policy Statement (NIPS) in June, 1991 marks a clear departure from the earlier policies. The changes in industrial policy since 1991, has led to a dismantling of most of the industrial controls and regulations that had remained in place since the process of deregulation and delicensing had started in 1970's. The basic objective behind economic liberalization has been to reduce the discretionary role of Government with respect to economic matters and thereby increase the space for market forces to operate.
The new drug policy (1994), may be looked as a part of the new economic policy that have been initiated by the Government since 1991. The aim of the new drug policy as spelt out by the Government is two fold: 19

(a) to bring changes in the drug policy to bring it in consonance with the spirit and philosophy of the New Industrial Policy (1991);

(b) to deregulate the drug prices, in view of complains received from the drug industry. The new drug policy seeks to bring policy changes in licensing, pricing and in foreign investment.

The new drug policy, 1994, marks a major shift from the earlier ones, since changes have been made in the light of New Economic Policy, to essentially free the industry from Government regulations and giving freer climate to the foreign companies to operate in the Indian drug industry without any concommitent commitment in matters of technology transfer, and production of essential drugs from basic stages.

Licensing

The earlier drug policies (1978 and 1986) had restricted the activities of foreign companies (foreign equity above 40 percent) to 66 bulk drugs/intermediates and their formulations. Under FERA (Foreign Exchange Regulation Act), companies with foreign equity up to 40 percent were treated at par with Indian companies. In consonance with the New Industrial Policy, the 1994 drug policy abolished industrial licensing for all bulk drugs, their formulations, and for intermediates. The new policy reduced the number of drugs reserved for public sector from 15 in 1986 to just five. The new drug policy, further, allows 51 percent foreign equity participation automatically in all sectors of bulk drug production and will be treated at par with wholly Indian owned companies.

The new drug policy (1994) has abolished many other restrictions on the MNCs. The FERA and MRTP companies were required (under the earlier policy) to supply 50 percent of their bulk drug productions to non-associated formulators. This mandatory provision has been abolished. Similarly the compliance of ratio parameters limiting consumption of imported bulk drugs to 50 percent has been abolished. Now
the MNCs are free to import bulk drugs and market them through formulations.

**Pricing**

The Government has reduced the number of drugs under price control from 142 to 73 bulk drugs only. By this measure, 69 drugs have been brought out of price control, most of which are essential and life-saving. This reduces the span of control from 72 percent (DPCO, 1987) to around 50 percent.\(^{20}\) The new policy has created single list of price controlled drugs, with MAPE (Maximum Allowable Post-Manufacturing Expenses) of 100 percent for all drugs under price control. For selecting drugs price control, a criteria based on a minimum turnover of Rs. 4 crores annually has been adopted. The drugs in which there is sufficient market competition, that is, there are atleast five bulk drug producers and atleast ten formulators with none having more than 40 percent of the market share in retail trade (as per ORG), will, however be kept outside the price control.\(^{21}\)

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21. In the case of bulk drugs having an annual turnover of Rs 1 crore or more, if there is a single formulator having 90 percent or more of the market share in the retail trade (as per ORG), a monopoly situation shall be assumed to prevail and hence appropriate measures (not spelt out in the policy) are to be taken to keep the price movement in view.
The new policy has provided for speedier revision of drug prices. National Pharmaceutical Pricing Authority (NPPA), an independent body of experts, is to be setup, to decide price revisions within a time frame of two months for formulations and four months for bulk drugs.

The new policy has proposed to set up a National Drug Authority (NDA). A one percent cess has been levied on the production of drugs and pharmaceuticals. The funds so collected is to be made available to the proposed NDA, for use in upgradation and augmentation of the existing infrastructural facilities as well as for enhanced R&D.

Assessment

The 1994 Drug Policy, as it is, has been made from the point of economic liberalization. The policy does not make any distinction between drug industry and other consumer industries. This situation is at variance with special treatment being given to the drug industry in view of its importance to the nations well-being. The 1994 policy is likely to have grave consequences for the self-reliant growth of the Indian drug industry. The "Background Note" to the review of 1986 policy show a positive trade balance achieved by the drug industry. However it conceals the fact
that the import of bulk drugs as percentage of indigenous production has increased from 43 percent in 1980-81 to 93.2 percent in 1989-90. The import of bulk drugs was of Rs. 597 crores in 1989-90. Though a part of the import of bulk drugs is being used for export market, the growing trend in import is a matter of concern. This tendency has appeared as multinationals are increasingly relying for bulk drugs on import from their parent Concern.

The "Background Note" claims that the country is self-sufficient in the production of formulations. This is not the true indicator of self-reliance in drugs. True indicator of self-reliant development of the drug industry is the self-reliance in bulk drug production. The new policy allowing automatic approval for foreign equity participation up to 51 percent, together with the policy of import liberalizations, may hamper the self-reliant growth of indigenous capabilities in drug production. Let us remember what Hathi Committee had to say on the operation of MNCs in Indian drug industry. To quote: "The multinational units operating in India produce only a small fraction of bulk drugs. The main thrust of the multinational units continues to be towards

capitalizing on drug formulations and non-drug items like cosmetics and luxury goods where technology and capital inputs are much lower and which permits promotion of aggressive salesmanship and brings in much higher returns on investments.  

Nothing much has changed since then, Infact the situation has worsened. The foreign sector is the worse offender in the matter of production of irrational and hazardous drugs and the non-production of essential drugs. The small-scale sector produces more bulk drugs than the foreign sector. The measures in the 1978 drug policy restricting this sector, has been the single most important factor responsible for the rapid growth of the Indian drug industry in general and the Indian sector in particular. The foreign sector has never in the past brought in new technology and is not likely to do so in the future. In 1992-93, a study has shown that three out of five Indian Companies spent more than 2 percent of sales on R&D, while only one in ten foreign companies was willing to do so. Several multinational companies spent less than one percent of sales on R&D.  

The new drug policy of 1994 seeks to dismiss the positive role played by the public sector drug units in the past in the production of bulk drugs and wants to reduce its role further by reducing the number of drug reserved for production by it from fifteen to just five only. Further, the new policy has not spelt out any measures to revitalise the public sector units which has been passing through a phase of deliberate neglect, mismanagement, corruption and sabotage at various levels. Let us remember that it was due to the entry of public sector in drug production that the production of vital drugs like anti-biotics in this country started, which forced the multinational firms to reduce their prices by as much as 60 to 70 percent.

In the absence of any production control in the 1994 policy, it is very much likely that a major share of investment would be in the production of non-essential drugs. More liberalization in the absence of concomitant policy of production may lead to more production of hazardous, irrational and inessential drugs. The new policy proposes tariff mechanism to ensure manufacture of bulk drugs from basic stage. However this is likely to be ineffective in the phase of liberal import policy. The 4 percent higher rate of return for bulk drugs manufacture may encourage some produc-
tion of bulk drugs from basic stage. Even this may not work in a more open economy. Companies producing from the intermediate stage onwards may earn higher profits by making use of cheaper imports. The removal of import restrictions, abandoning of ratio parameters linking bulk drug manufacture to formulation activity, abolishing of ratio parameter limiting consumption of imported bulk drugs to 50 percent and doing away the condition stipulating mandatory supply of a percentage of bulk drug production to non-associated formulators - may put the Indian drug industry on the path of regression. This tendency is already visible as import of bulk drugs are increasing. The measure of reducing the number of bulk drugs under price control from 142 to 73 drugs, together with higher MAPE of 100 percent will raise the prices of essential drugs beyond the means of Indian consumers.

The proposed setting up of NDA is a good step. However, the role suggested for it is too restricted. The policy proposes two objectives for it, firstly to monitor standard practices in drug promotion and use, and secondly, to look after the effective implementation of the provisions of the Drugs and Cosmetics Act. Also it is not clear in the policy whether the power of NDA would be mandatory or advisory. The setting up of National Pharmaceutical Pricing Authority
(NPPA) would most likely over-come the problems associated with price fixation. The ceiling on prices of commonly marketed standard pack sizes of price controlled formulations under the new drug policy is a good measure and may help in achieving uniformity in prices of widely used formulations. However, since most of the drugs are outside the price control, its effect would be confined to only few drugs under the span of price control. This price ceiling should have been extended to all the essential and life-saving drugs, including those outside the price control.

To conclude, the 1994 drug policy is entirely based on the new economic policy (NEP) and has nothing much to commend. The new drug policy has subjugated the health of the nation and is a part of the new industrial policy that dismantles the control on the industries. Because of its special nature, the drug policy should be an integral part of the health policy. The liberalization of import of drugs may thwart the self-reliant growth of drug industry. The new policy seems to be relying on the MNCs for the availability of life saving and essential drugs in the country. Excessive dependence on them, however, would lead to many serious consequences. In future, drug prices is likely to rise beyond the capacity of consumers to pay. India, being a
developing country, the modern drugs are already beyond the reach of a large number of people. The new drug policy, will, further deprive a sizeable section of population, the benefits of modern drugs.