CHAPTER II
CONTROLS ON PRODUCTION AND CONSUMPTION OF DRUGS

Mandate in the Directive principles of Indian Constitution has laid stress on the improvement of public health and prohibition of drugs injurious to health as one of the primary duties of the State. Taking thread from these constitutional provisions, the Supreme Court in *Vincent v. Union of India*, explained the scope of this primary duty of the State. It pointed out:

"Maintainance and improvement of public health have to rank high as these are indispensabla to the very physical existance of the community and on the betterment of these depends the building of the society of the constitution makers envisaged. Attending public health, in our opinion, therefore, is of high priority - perhaps the one at the top."

The Supreme Court of India expressed the view that such drugs which are found necessary should be manufactured in abundance and

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1 Constitution of India, Article 47. It reads: "The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and in particular, the state shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and drugs which are injurious to health."

3 *Id.* at p. 995
4 *Id.* at p. 996
availability to satisfy every demand should be ensured. According to the Court undue competition in the matter of production of drugs by allowing too many substitutes should be reduced as it introduces unhealthy practice and ultimately tends to affect quality. The State’s obligation to enforce production of qualitative drugs and elimination of the injurious ones from the market must take within its sweep an obligation to make useful drugs available at reasonable price so as to be within the common man’s reach. The Court also held the view that for every illness which can be cured by treatment, the patient must be in a position to get medicine.

These are the objectives set and the responsibilities imposed by the Constitution on the State. In the light of these objectives and responsibilities it is intended to study the policy guidelines on the production and consumption of drugs. These guidelines must ensure rational production and consumption in the light of the provisions of the Constitution, directions of the Supreme Court and the recommendation of the Hathi Committee and the World Health Organisation. The study also underlines the need for preparing an essential drugs list on lines recommended by the report of the Hathi Committee and the World Health Organisation. The need to discourage production of irrational and hazardous combination of drugs and to encourage the production and sale of generic drugs and drugs which are

\[5 \text{ Ibid.}\]
essential to the large sections of the society is underlined in this part of the study.

**A profile of drug industry and production**

The drugs and pharmaceutical industry in India is one of the most important sectors of the Indian economy. It is of crucial significance to the public health of the nation. Since independence, the industry has expanded considerably and India today has wide-ranging capability in production of basic drugs and formulations. There are about 8000 pharmaceutical companies in India. They include some of the well known multi-national giants. They produce approximately 70,000 drug formulations. The production pattern of the industry in general indicate that pharmaceutical industry produces much more formulations than bulk drugs. The break up of production of bulk drugs and formulations by various sectors of the industry clearly shows that only public sector undertakings are using their capabilities to produce bulk drugs and formulations on equal proportion.

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The table showing comparative production of bulk drugs and formulations in India during 1985-86 to 1992-93

<table>
<thead>
<tr>
<th>Year</th>
<th>Bulk Drugs (Rs. in crores)</th>
<th>Formulations (Rs. in crores)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1985-86</td>
<td>416</td>
<td>1945</td>
</tr>
<tr>
<td>1986-87</td>
<td>458</td>
<td>2140</td>
</tr>
<tr>
<td>1987-88</td>
<td>480</td>
<td>2350</td>
</tr>
<tr>
<td>1988-89</td>
<td>550</td>
<td>3150</td>
</tr>
<tr>
<td>1989-90</td>
<td>640</td>
<td>3420</td>
</tr>
<tr>
<td>1990-91</td>
<td>730</td>
<td>3420</td>
</tr>
<tr>
<td>1991-92</td>
<td>900</td>
<td>4800</td>
</tr>
<tr>
<td>1992-93</td>
<td>1045</td>
<td>5520</td>
</tr>
</tbody>
</table>

The foreign drug manufacturing firms and Indian owned private sector are concentrating mainly on formulations\(^7\).

It would be interesting to review the share of various drugs according to the different therapeutic groups in their sales through the trade channels. From the data\(^8\) worked out on purchase records maintained by 532 chemists spread all over India, it is seen that 22% of the market share is enjoyed by Vitamins, Tonics, health restorers and haematinics while about 20% of the market share is enjoyed by the antibiotics.

The Indian Government's enquiry\(^9\) into the drug and pharmaceutical industry concluded that the transnational drug companies are interested in carrying out research only on products which will have a global demand.

<table>
<thead>
<tr>
<th>(Rs. In Crores)</th>
<th>Bulk</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) Public Sector</td>
<td>48</td>
<td>47</td>
</tr>
<tr>
<td>(ii) Foreign Sector</td>
<td>63</td>
<td>293</td>
</tr>
<tr>
<td>(iii) Indian Private Sector including small scale sector</td>
<td>39</td>
<td>361</td>
</tr>
<tr>
<td>Total</td>
<td>150</td>
<td>200</td>
</tr>
</tbody>
</table>


\(^7\) Percentage share of different groups of drugs in the market during 1985.

<table>
<thead>
<tr>
<th>Drug Group</th>
<th>Sales Rs.in crores</th>
<th>Percentage of total market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systemic Antibiotics</td>
<td>249.02</td>
<td>21.15</td>
</tr>
<tr>
<td>Vitamins and Tonics</td>
<td>187.78</td>
<td>15.95</td>
</tr>
<tr>
<td>Cough &amp; Cold preparations</td>
<td>55.40</td>
<td>4.70</td>
</tr>
<tr>
<td>Anti - parasites</td>
<td>46.78</td>
<td>3.97</td>
</tr>
<tr>
<td>Analgesics</td>
<td>44.29</td>
<td>3.76</td>
</tr>
<tr>
<td>Antacids</td>
<td>38.17</td>
<td>3.64</td>
</tr>
<tr>
<td>Anti-inflammatory &amp; Anti-rheumatics</td>
<td>53.06</td>
<td>4.50</td>
</tr>
<tr>
<td>Anti T.B. Drugs</td>
<td>30.39</td>
<td>2.50</td>
</tr>
<tr>
<td>Enzymes</td>
<td>24.69</td>
<td>2.10</td>
</tr>
<tr>
<td>Sex Hormones</td>
<td>23.61</td>
<td>2.00</td>
</tr>
</tbody>
</table>


such as tranquillisers, anti-histaminic and anti-hypertensives and not on
drugs for treatment of tropical diseases such as T.B. and Malaria which are
common in India. The Country’s pharmaceutical industry is more committed
to selling medicine rather than promoting health. It has concentrated on
production of money spinning, non-essential and often irrational and
hazardous products.\textsuperscript{10} Studies\textsuperscript{11} after Hathi Committee report also revealed
the same. The shortage of essential drugs necessary to cure diseases like
T.B. and other local diseases when compared to their demand is clearly
revealed in the data provided by the Department of Chemicals and
Fertilisers.\textsuperscript{12}

\textsuperscript{10} \textit{Indian Express}, October 24, 1990.
\textsuperscript{11} Arun Bal, “Distortions in Drug Policy: Who is to be blamed?” \textit{Economic and

\textsuperscript{12} TABLE 1

\begin{tabular}{|c|c|c|c|}
\hline
\hline
SIM Tons & 302.0 & 227.3 & 320 & 225.4 & 320 & 266.0 \\
\hline
INH Tons & 154 & 129.2 & 140 & 110.4 & 158 & -128.0 \\
\hline
Thiacetzone Tons & 20.0 & 8.4 & 16.4 & 14.4 & 21 & -25.0 \\
\hline
Ethambutol Tons & 33.0 & 24.9 & 32.0 & 66.9 & 54 & -85.0 \\
\hline
\end{tabular}

\textit{TABLE 2}

\begin{tabular}{|c|c|c|c|c|c|}
\hline
\hline
Target Production & 66.0 & 59.8 & 66.6 & 52.6 & 77.0 & 52.0 & 90.0 & 60.23 & 105.0 & 41.92 \\
\hline
\end{tabular}

Source: Government of India, “Indian Pharmaceutical Industry: Problems and Perspectives”,
contained in Department of Chemical and fertilisers, performance Budget, 1982-83, pp. 250-253.
This shortfall in the production cannot be attributed to limited production capacities. The installed capacities are underutilised for obvious reasons. Thus artificial demand has been created by the pharmaceutical industry. The real reasons are evident from the fact that certain essential generic drugs are not available where as their formulations and combinations are made available. For example, streptomycin is not available but it is possible to get injections of streptomycin in combination with penicillin. The fact is that these combination are more expensive though more profitable for the manufacturer.

Formulation activity represents the high pay-off sector of the pharmaceutical industry and the bulk drugs manufacture gives comparatively low profits. Inevitably therefore, entrepreneurs who enter the pharmaceutical industry usually prefer formulation activity. An analysis\(^\text{13}\) of the working of a number of drugs manufacturing units in this country has revealed that the ratio of capital invested to sales turnover in the formulation sector averages out at about 1:2.6 with an upper limit of as high as 1:7.75. It is estimated that purely formulation unit recovers the entire invested capital in 2-4 year period. On the other hand, in bulk drug production, under the best circumstances, sales turnover to capital ratio does not usually exceed the 1:1 figure and in many cases in the early development stages this ratio is considered much lower\(^\text{14}\).

It is evident that a manufacturer whose basic philosophy is materially trade oriented, would usually try to remain in the formulation sector and keep the less paying basic drug manufacture at the lowest level of production priority.

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\(^{13}\) See for details Report of Hathi Committee (1975), para 12.55.

\(^{14}\) *Ibid.*
It is interesting to note that Indian owned small scale sector is producing more share of the total bulk drugs when compared to the foreign and foreign majority units owned by the multinationals. The total production of bulk drugs by small scale units was estimated to be at about 500 tonnes including synthetic bulk drugs. Out of this only about 3 percent was produced by the small scale units of foreign and foreign majority units and about 97 percent by the Indian units. At the same time these multinational have concentrated their effort in the production of formulations. They accounted for over 24 percent of the total turnover in formulation.

These figures both for bulk drugs production and formulation lead to the inescapable conclusion that the multinationals have concentrated their effort in the high value formulations.

This was the state of affairs in the production of drugs inspite of the norms laid down by the Government as part of its production policy of the drugs. The policy guidelines issued by the Government appeared to have lacked the necessary teeth to bite the erring producer. However, the analysis of these norms may reveal the nature of drugs and quantities they are required to produce depending upon the capability of each sector.

**Norms imposed upon production of drugs under 1978 Drug Policy**

Different norms were imposed on public sector, Indian private sector and foreign sector for production of drugs. Public sector was given untill recently the leading role to manufacture certain drugs exclusively to enable it to meet substantial healthcare needs of the Country. Approved production policy for Indian manufactures of drugs in private sector was that they were

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15 *Id.* at Paras 17.56, 19.56 and 20.56.


17 The Statement of Drug Policy 1978, para.10, see supra. *n.*7. It may be noted that these guidelines have been substantially altered by the new drug policy 1994. See *infra* text carrying footnote 63 for details.
allowed for formulation licence upto ten times of the value of their bulk drug production\textsuperscript{18}. But out of the total bulk drugs used by such firms for manufacture of formulation, fifty percent must be consumed from the indigenously produced bulk drugs. This condition was imposed to encourage the consumption of indigenously produced bulk drugs. There was power to review whether Indian companies should be allowed to expand formulation capacity freely if it is based on consumption of indigenous bulk drugs and whether the restriction on expansion of formulation capacity should be imposed when the Indian companies are seeking imported bulk drugs\textsuperscript{19}. Hence the policy appeared to be that Indian companies should be encouraged even in the formulation activity provided they use substantially the indigenously produced bulk drugs. The policy was to discourage the production of formulations based on imported bulk drugs.

**Norms for foreign companies**

Several measures of control were included to direct the activities of the foreign drug companies to subserve the national objectives and interests. It was insisted that at least twenty percent of their total production must be high technology bulk drugs from the basic stage of production\textsuperscript{20}. They were asked to bring down the foreign equity to 40 percent if the foreign companies engage themselves only in manufacture of formulations or bulk drugs not involving high technology\textsuperscript{21}. It was also part of the approved policy that the foreign companies engaged in the manufacture of household remedies should not be granted any expansion\textsuperscript{22}. The existing foreign companies producing drug formulation based on imported bulk drugs or producing bulk drugs from penultimate stage were compelled to produce

\textsuperscript{18} Id. at para 12 (xi).
\textsuperscript{19} Id. at para 12 (xiii).
\textsuperscript{20} Id. at para 14 (b).
\textsuperscript{21} Id. at para 15.
\textsuperscript{22} Id. at para 20.
bulk drugs from basic stage\textsuperscript{23}. Extention of formulation licence to the existing foreign companies was linked with the production of high technology bulk drugs from the basic stage\textsuperscript{24}. Foreign companies were prohibited from entering into the area of small scale sector and no foreign company was to be given loan licence\textsuperscript{25} for operating in drugs field\textsuperscript{26}.

All this was well. But there was no plan of action to support these policy guidelines. Hence, it has thoroughly failed in implementing these control measures. Hence they stood as standing statutory advises which these firms never bothered to oblige.

Because of the production pattern adopted by the pharmaceutical industry, it is estimated\textsuperscript{27} that the modern drugs reach only about 20 percent of our people. This would imply that the majority of the people, particularly in the rural areas and economically weaker sections of the society derive little advantage from the modern systems of medicine and to that extent their suffering remains unabated. This immediately throws into focus the magnitude of inadequacy of our national effort in this vital area of not only social but also economic consequences of our people. It is thus clear that production of allopathic drugs in terms of the magnitude of the needs of the country has barely begun in India.

The findings of the Foundation for Research in Community Health\textsuperscript{28} showed that though drug industry has the knowhow, the drugs which are most necessary in India are either not produced or produced in small

\textsuperscript{23} Id. at para 21.

\textsuperscript{24} Id. at para 22.

\textsuperscript{25} Loan licence means a licence which a licensing authority may issue to an applicant who does not have own arrangements for manufacture but intends to avail himself of the manufacturing facilities owned by another licensee. See Drugs and Cosmetics Rules, 1945. \textit{Explanation} to Rule 69-A.

\textsuperscript{26} Supra n. 17 at paras 23 & 24.

\textsuperscript{27} Report of Hathi Committe (1975), para 8.55.

\textsuperscript{28} See Andrew J. Rebello, "Drugs Policy needs to be changed", The Hindu, Oct. 25, 1989.
quantities. The most essential drugs are those intended to fight infection, parasitic respiratory diseases such as T.B., malaria, dysentery, diarrhoea, cholera etc. Even drugs which are available, such as streptomycin which is basic drug to cure T.B. is made use of and manufactured in wasteful combinations and sold under brand names such as Chlorostrep, Enterostrep, Intestrep thus reducing its use for T.B. 29

Indian Council of Medical Research also point out that India is producing and marketing hazardous, non-essential and useless drugs much more than it is producing essential, necessary and life saving drugs 30. Much concerned citizens in this field were reported to have said that topsy turvey planning, poorly developed health management and imbalances in the provision of access to channels of health care are largely responsible for our failure to achieve the goal as stated in India’s commitment to the UN pledge of “Health for all by 2000 A.D.” The Drugs Controller of India admitted that he is helpeless and can’t guarantee safe drugs since the “existing machinery is inherently incapable of doing so.” It may be shocking to everyone but it is a truth. That something needs to be done about the drug condition in India is

29 Ibid.
30 For example, Novalgin (Manufactured by Hoechst) an over the counter (OTC) drug which needs no prescriptions from a doctor in India, has recorded a 94 per cent increase in sales in India. It, however, has been banned in 15 countries as being hazardous and resulting in a fatal disease if taken often. For details see Arewrthanur, “National drug policy: Basic Desiderata” Mainstream, January 17, 1987, pp 23-25. Also see N Battacharya, "Distorted Drug Policy 1986” Mainstream, January 17, 1987, p.27.
evident not merely from this admission by the Drug Controller, but from the various reports that come up so often.\(^{31}\)

In order to make the production and consumption of drugs rational, one of the alternatives to be considered is to limit the production and consumption as far as possible to certain essential drugs that will meet the needs of large section of the people of the country. Some developing countries are already experimenting this under the active guidance of the World Health Organisation.

**Meaning of essential drugs**

An ‘essential drug’ has not been defined by law. But generally ‘essential drugs’ mean a number of rational drugs and their dosage pattern that satisfy the healthcare - preventive, curative, symptomatic and rehabilitative needs of the large majority of the people\(^{32}\). All drugs are rational but all rational drugs are not essential. When several drugs of the same pharmacological groups are rational, one of them will be chosen as essential drug based on such criteria as most favourable chemical outcome, quality including bio-availability, total cost for treatment, local availability and stability in the local situation. Therefore, The essential drugs are those that are basic, indispensable and necessary to meet the health needs of the

\(^{31}\)“Adulterated anaesthesia claims lives at AIIMS” - read one news report; “Over 50 kids paralysed after inoculation” - read another; “ESIS faces shortage of essential drugs” - says a third; “Banned drugs still freely available” - said yet another. Quoted in supra n.28.

people. The limited list of essential drugs is said to have some advantages. It would reduce the number of drugs to be manufactured, purchased, stored and distributed, there will be improvement in the quality of management, control and information monitoring and utilisation. It also reduces the cost.

**Need for preparation of essential drugs list**

The list should be meant to include only those drugs which our country considered necessary to treat the diseases which are afflicting our people. The quantum of essential drugs may vary from country to country depending upon the health conditions prevailing in that country. At present, if we compare with what we consider as needed with those what was actually circulated in the country there is a vast discrepancy. About 70000 varieties of drugs were being sold whereas all that we needed were approximately 200. Hathi Committee had drawn up its list of 116 drugs for

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33 Cuba, with one of the most advanced health care systems in the world, has 610 drugs only. The second (1980) edition of Mozambique’s national formulary has just over 500 items with 343 therapeutic substances. Zambia allows only 376 essential drugs to be used in its health system. A report from Mexico says that number of drugs available has been reduced to 329, in 583 combinations. A survey of the diseases prevailing in Bangladesh showed that only 150 drugs can cover all the major ailments affecting their masses. See Shahidulla, Secretary General of Bangladesh Association of Pharmaceutical Industry (BAPI) is reported to have accepted to abide by the list. See supra n.28. See also S.V. Joga Rao, “Legal Dimension of Drugs Vis-a-Vis Consumer Justice: Thrusts and Contradictions” (Supreme Court Journal Mimeo) Quoted by the same author in “Economic Reform, Pharmaceutical Industry and Right to Health” a paper presented in Commonwealth Legal Education Association Conference held in Bangalore during June, 4-6, 1993

34 Staff Reporter of The Hindu quoting speakers of a National Seminar Organised by (VHAI) Voluntary Health Association of India, Rajasthan Chapter, reported in The Hindu, January 22, 1991.
the purpose\textsuperscript{35}, while the World Health Organisation (WHO) maintained in 1985 that 250 drug combinations are sufficient to cover all ailments. In the absence of such a list there would be no way to ensure the production, distribution or availability of the needed drugs can be ensured. If much care is not taken in preparing the essential drugs list, it might do the just reverse of its objectives.\textsuperscript{36}

The consumers are being bombarded with misleading advertisements of a variety of brand names. For example, there might be ten or more varieties of chloroquine in the market. All these are marketed as malaria therapies under different brand names. The general public do not know that all these drugs are in reality the same thing and since they were advertised as if they are different drugs, people are understandably confused. If they had malaria they would often buy one brand and so on without understanding that they are in fact buying the same pharmaceutical substance.

**Rational consumption of drugs**

Preparation of essential drugs list is of no benefit unless it is made use of by doctors for their prescription. Rational consumption of drugs implies the prevention of self medication not only of overthecounter drugs but also of the prescription drugs. The present arrangement in our system in the area of prescription is the self regulation not backed by any form of protection to the victims of over prescription. Free enterprising model is not

\textsuperscript{35} Hathi Committee Report, (1975)

\textsuperscript{36} Indian Express, Oct. 30, 1991.
convincing in the case of prescription drugs because the market behaviour is not influenced by the principle of demand and supply. This is because, the purchaser is not free to choose the drug as he has to buy what has been prescribed to him and prescribing doctor is insulated from the considerations of cost.

Need to regulate prescribing habits of the doctors

Two thirds of all visits to the doctor end up in the writing of a prescription. Often these prescriptions are justified on medical and psychological grounds. But it is also true that the doctors while prescribing are under intense sales promotional pressures of drug manufacturing companies. There is definite possibility that in good number of instances where drugs are prescribed and purchased not based on the need but in response to such promotional pressures. Association of British Pharmaceutical Industry long before estimated approximately £4800 as the cost of promotion for every doctor in Britain37. Some studies have suggested that doctor’s prescribing habits can be strongly influenced by sales representatives who constitute their primary source of information38. Even though the free hospitality, gifts and samples are usually of trivial financial

37 The Times, February 22, 1983.
value, they help to create a relationship that is not necessarily conducive to the best interest of patients.

**Objections in regulating prescription habits**

Attempts to regulate the prescribing habits of the doctors may have to meet stiff resistance on the ground that it would constitute undue interference with the clinical freedom of the doctors. Doctors may argue that the concepts such as ‘safety’ and ‘efficacy’ are open-ended and the quantum of drug to be prescribed to a patient has to be calculated in the light of such considerations as the seriousness of the illness, the condition of the patient and the proposed length of treatment. According to them, the issue of what constitutes ‘efficacy’ for the drug can’t be satisfactorily determined. Similarly they contend that it is artificial to assess the drug’s ‘efficacy’ without considering the relative effectiveness of the various determinants of a ‘healthy life’. And these yardsticks, according to them, vary in each individual patient’s case. They argue that it is sufficient to have strong pre-market controls on drugs and the society can afford to keep faith on the doctors prescribing habits.

**Need to regulate**

But the legal regulations on prescriptions as a means of lessening the consumers’ vulnerability in the face of dubious marketing techniques of

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39 *Id.* at p.314
40 *Id.* at pp.308-309.
both manufacturers and importers seems necessary for obvious reasons.\textsuperscript{42} Competition among various manufacturers of the same drug persuades doctors or in the case of household remedies persuade the consumers to patronize a particular brand of drug. The use of brand names as opposed to generic names enables the drug industry to sell essentially similar drug formulations at widely varying prices. Quite often it is difficult for the doctor and almost impossible for the patient to have at their disposal information which would enable them to compare prices of drugs which are virtually identical.

Throughout the world and in our own country as well, a medical student receives his training on drugs under generic names. In fact in all textbooks of therapeutics as well as pharmacology drugs are always mentioned by generic names. In the interest of rational practice of medicine, therefore, it is in the fitness of things that medical practitioners are advised to prescribe only a drug under generic name so that they are fully conscious of the type of the therapy prescribed for their patients. More often the practising physician is likely to be unaware of the active ingredients of a drug prescribed under brand name. Two brand names containing the same or

similar active ingredients may be prescribed to patients resulting in overdosage and consequent toxicity or damage to the patient’s health.

**Need to substitute generic drugs**

It has been alleged that the branded products containing the same ingredients differ to a very great extent in their prices and the products bearing generic names are decidedly cheaper\(^{43}\). In fact, in the larger context this is not in the best interest either of the manufacturer or the patient. Brand names have been responsible for putting up a larger number of unnecessary and often irrational formulation in the market. This has resulted in excessive use of drugs particularly under the name ‘tonics’ containing vitamins in excessive quantities. Multiple drug combinations containing excess of medicines than what is required result in not only colossal national wastage of drugs but also lead to harmful consequences to the patients.

The brand names have a corrupting influence on the profession. A doctor more often patronises branded product and unwittingly therefore, makes his patient pay more than what is necessary. This is a matter which the medical profession should think over seriously.

It is often argued that the quality of a product is assured because of its brand name and substitution of generic name will result in lowering of standards. Maintainance of quality is the responsibility of the manufacturer and it does not go with the brand name. A scrutiny of the total number of

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\(^{43}\) Hathi Committee report (1975), para 10-253.
substantial misbranded and spurious products reported by various drugs control organisations and drug testing laboratories of Government of India revealed that there are more instances of branded products being misbranded or spurious. There has been no instance where a product marketed under generic name has ever been reported to be spurious. Thus, branding of products promotes a tendency to prepare misbranded or spurious products.

The changeover from brand name to generic be brought about in phased manner. A beginning was already made with few drugs identified and kept in a separate Schedule. But it provides for only five names of the drugs which are considered inadequate. There is need to expand the list provided under the Schedule. Non-proprietary names as recommended by WHO from time to time should be adopted. In order to keep the medical profession, particularly the general practitioners, well informed about new drugs and also to popularise the generic names it is essential to take the following steps immediately as recommended by the Hathi Committee:

1. To revise the Indian Formulary and make it up-to-date.
2. To publish journals on the lines of Prescriber’s Journals, U.K., Medical Letter, USA, or Formulary Notes of Sri Lanka. Such publications will have to be under the control of an editorial board comprising of the leaders of medical profession in the country. From the legal point of view, there

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44 Id. at para 18-254.
45 See Drugs and Cosmetics Rules 1945, Schedule ‘W’. This includes 5 drugs namely Analgin, Aspirin and its salts, Chlorpromazine and its salts, Ferrus Sulphate and Piperazine and its salts which should be marketed only under generic names.
should be no difficulty in abolishing the brand names. Abolishing of brand names will entail first the amendment of the Trade and Merchandise Marks Act 1958 and subsequently the Drugs and Cosmetics Rules. An undertaking from all the members of Indian Medical Association must be obtained to the effect that they would not prescribe any drug outside such list.

Government need to regulate very stringently the import, manufacture, sale or distribution of any drug outside the essential drugs list. In the meanwhile, drugs have to be advertised and sold under generic names so that when the pharmacists labels their drugs, the generic name must appear very boldly under the brand name. It should be at least three quarters of the size of the brand name.\(^4\) There should be an independent department with all the financial support to monitor every aspect of this policy.

**Considerations of a drug policy:**

**Need for production oriented to the poor**

Though it is necessary to develop our own essential drugs list because we know, better than anybody else, our patterns of disease, it will be most useful to all the developing countries to keep in view of the guidelines of the WHO in preparing the list. None can deny the WHO’s valuable work in this area. But at the same time, needs of the national consumers should be the upper most concern in preparing the list. A large majority of Indian

\(^4\) For example, the advertisement for “Panadol” must immediately mention ‘Paracetamol’ under it. After the brand name is given it has to be followed by the words “brand of” followed by the generic name.
population live in rural areas. Their needs for drugs are no less pressing than those of urban dwellers. But because of logistical and other problems, it is relatively easy to underserve the rural communities while the urban ones are overserved.

In a more general manner, the problem of product appropriateness is of special relevance in developing countries when a consumption pattern, originating in the developed countries is forced on consumer in developing countries by means of extensive sales promotions, without due regard to the real needs of these consumers. Products originally developed with regard to standards of living, climatic and racial needs in developed countries may have characteristics that do not fit into the consumption patterns and needs of the developing countries. There is also a possibility that firms from developing countries will choose to direct their attention to the market segments in a developing country where the demands are similar to those in the developed countries while the vast majority of the consumers - poor and inarticulate as they are remain unsupplied.

**Legal support to producers and distributors of generic drugs**

Generally, generic drugs are cheaper when compared to the brand name formulations. There is no dispute that we need more generic drugs so that consumers are free to choose between the costlier brand name and cheaper effective generic drugs. It is good news for the consumer to know

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that at least there are pharmaceutical companies and chemist's shops, though very few, set up solely to produce and sell generic drugs. That the prices are cheap can be seen from a comparison of some of the more common and often used medications. How these forms can sell these drugs at rates much below than what the rest of the drug manufacturers? Would their quality be bad or substandard? Clearly, it is not so because all these drugs are doubly tested for quality in reputed laboratories and proved that their quality control is 100 per cent. This experiment proves that it is possible to ensure high quality drugs at low cost. So consumers can see that low cost can also be best and not what most advertisers propagate that cheap necessarily means poor or substandard. Therefore, what is required is the socio-legal effort to encourage such firms and popularise the generic drugs. In order to reduce the cost of advertisement for such firms, voluntary consumer organisations must canvass for these firms. State should

49 See for details Andrew J. Rebello, “Effort to make popular generic drugs,” Indian Express, July 28, 1989 (Consumer Notes). The Druggists are the Lok Swasthya, Situated at Ahmadabad, SEVA and LOCOST, a drug manufacturing voluntary agency was set up at Baroda as collective effort to promote rational drug therapy.

50 For Example Aspirin, which is the generic name for brand name tablets like Apadin, Disprin, Capramin, Majoral, etc., is available at this shop at only 50 paise for ten tablets, while the brand name production sell at, on average Rs. 2.50 per ten tablets. Paracetamol, which more people stock in houses and which is available under the brand names of Crocin, Metacin etc., which we may have brought at about Rs. 2.50 for ten, is available for 90 paise for ten. Ibuprofen, a drug used mostly by those suffering from musculoskeletal disorders, such as backpain gout, rheumatoid arthritis, etc., is available at Rs. 1.95 for ten of 200 mg potency, as against the cost of brand name products such as Brufen, Ibudex, Sugafen etc., which cost on an average about Rs. 5.50 a strip of ten tablets of similar potency. For more details see ibid.

51 Ibid.
encourage such firms by reducing or avoiding all kinds of taxes and duties on the production of such drugs.

The above consideration indicate a need for the selection of drugs, and for their procurement, storage, distribution and utilisation to be determined by well thoughtout principles which should be scrupulously executed. Only then, can we be sure that problems of drug supply would not constitute an impediment to the achievement of our national health policy, which is "health for all Indians." This necessitates the clear formulation of our national goals with respect to drugs and the strategies by which the goals are to be achieved, which together constitute our national drug policy.

Need to reconcile the interests of industry and consumers

Any drug policy has to make a right endeavour to retrieve pharmaceutical industry from the cobwebs of bureaucratic control ensuring at the same time basic requirements of the national health policy are met. The complaints\(^{52}\) that the soaring prices of many drugs in the delicensed category have made a mockery of the policy of safeguarding consumer interests. The essence of any national drug policy lies in the effectiveness with which the domination exerted by the multinational corporations (MNCs) is mitigated. This apart, there cannot be any disagreement over the necessity to synthesise the interest of the consumers with those of manufacturers who are inevitably bound up with the expansion of capacity.

modernisation, reduction of costs, enhancement of quality and quantity and also building up of export competitiveness. After all the preferred object of ensuing abundant availability of essential life saving and prophylactic medicines of good quality and at reasonable prices cannot be attained merely through repeated affirmation of concern for consumers. There is a widespread criticism\(^{53}\) that the policy makers, over the years, have found it extremely difficult task to recognise that pharmaceutical industry as one which obeys the economic law of investment being governed by a reasonably competitive rate of return. Therefore, there is a need to encourage the pharmaceutical industry which is genuinely committed to expansion, modernisation, quality and cost reduction. To achieve this, the industry needs to invest reasonable sums on research and development. But reports reveal that support for research and development is so patently negligible in the industry. Enormous potential of the indigenous pharmacopoeia remains largely unutilised. Therefore, the whole range of decisions dictated by the priorities of national health policy as well as by the legitimate commercial interests of those who provide the investment in the industry have to be brought into interaction.

**Need for allocation of more funds to healthcare and rationalisation of taxes**

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Hathi Committee and World Health Organisation reports revealed that modern medicine do not reach 80 percent of the population in India and other developing countries. The consumption capacity can be enhanced only by strengthening the public healthcare system. Primary health centres are to be supplied with adequate supply of essential drugs. All these measures can be effected only when plan outlay for this purpose is considerably enhanced. At the same time taxes on essential drugs are to be reduced substantially. It seems\(^\text{54}\) that taxes add much more to drug prices than industry’s profits. If the government is genuinely interested in protecting the consumer interest they can do it well by lowering the burden of taxes and duties on the industry. According to the estimates these levies account for about one third of drug prices\(^\text{55}\). Excise duties, customs duties, sales taxes and other imports on raw materials, intermediates and finished products account for nearly 35 per cent of the price paid by the consumer.\(^\text{56}\) The purchasing power of an overwhelming majority of Indian consumers is far too low. The Government can greatly improve the situation by raising the plan outlay\(^\text{57}\) on health and reducing, if not abolishing taxes on medicines. The committee on health survey and planning popularly known as the

\(^{54}\) Ibid.

\(^{55}\) Ibid.

\(^{56}\) See the discussion by Assocham at the workshop on “Drugs and pharmaceuticals: Protection of consumer interest” organised by it in association with the Council of Fair Business Practices in Bombay during September, 1989 quoted in Editorial, Finance Express Sept.9, 1989.

Mudaliar Committee had recommended more than two decades ago that at least a tenth of the plan outlay should be earmarked for health. Unfortunately, even now the allocation for the health sector is less than two per cent of the total outlay. No less disconcerting is the fact that Union and state governments treat medicines as a source of revenue. It is bad enough that the government is tardy in lowering the incidence of taxes on medicines. What is worse is that, the state governments are still to aim for uniformity in the rates of sales tax and octroi. As the maximum retail price is fixed under the drugs price control orders which is exclusive of local taxes, retailers get an opportunity to defraud consumer by inflating local taxes. Therefore, there is a need to levy local taxes at uniform rates throughout the country for protecting consumers. The Union Government has been advising the state governments to exempt drugs from the turnover tax and other local taxes since drugs are controlled. Unfortunately, the advise fell on deaf ears. Like the state governments, Union Government too is reluctant to sacrifice revenue yielded by imposts on this industry. This will lead to unhealthy consequences like shortage of essential drugs. Because of the price regulation industry is not permitted to sell drugs beyond

59 Ibid.
60 State of Andhra Pradesh reimposed turnover tax on all goods including medicines on the ground that other States are collecting. See Eenadu, June 25, 1996 and also see Eenadu, Nav. 9, 1993, p.6.
61 See the 1996 Central Budget Reports.
a particular price and the producers are unlikely to intensify their efforts to raise production of those drugs whose prices are not remunerative. The prices can only be controlled without affecting supply of drugs if production costs are contained and there is free play of the forces of demand and supply.

Major health needs in developing country like India arise firstly from environmental deficiencies, which lead to poor or non-existing sanitation secondly from poverty which, in turn, largely accounts for malnutrition and thirdly from endemic diseases. Clearly the first of these two problems can not be overcome by using drugs. Only endemic diseases like helminthiasis malaria, tuberculosis and other non sexually communicable diseases could be treated on a piece meal with drugs. In any case it would clearly be better to prevent and eradicate these conditions once and for all. But it can only be done by radical political and economic solutions.

Need for proper co-ordination

The policy statement should also ensure that negotiations would be under taken with the departments of customs and excise to ensure that duties and levies on raw materials and excipients for manufacture of essential drugs are minimised or removed and substantial duties be levied on imported finished products which are also manufactured locally.

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Many countries still lack adequate supplies of drugs appropriate for their health needs and the irrational use of drugs pose problems in both developed and developing countries. The reasons for this are complex and are not merely the result of financial and budgetary constraints, lack of infrastructure and human resources. But it is also due to the attitude and behaviour of the government, prescribers, dispensers, consumers and the drug industry. National drug policy as an integral part of the health policy should aim to ensure an adequate supply of safe and effective drugs of good quality at an affordable price.

All the concerned need to participate in the process of framing the policy since its success depend on the interest and wholehearted endorsement of these agencies at all levels. Endorsement by sectors like planning, finance, health, industry and commerce are also of particular importance since decision regarding licensing, import of drugs, foreign exchange, tariffs, marketing and human resources development may all have a significant effect on drug procurement, manufacture, distribution and use.

A policy is a guide to action and a commitment to a goal. A primary goal will be to make essential drugs available to the entire population and to assure the safety, efficacy and quality of the medicines provided to the public. The regular availability of drugs and health facilities increases the credibility and acceptance of health workers, and facilitates the recognition of their important role in preventive medicine. As already pointed out, other
health related goals include improving prescribing and dispensing practice and promoting the correct use of medicines by the public.

A national drug policy also has economic goals of which the principle will be to lower the cost of drugs to both the public and government and also to reduce the foreign exchange drain from drug imports through wiser purchasing. It will need to consider the inter-relationship between the public and private sector since most of the drugs are prescribed and purchased from the private and public sectors. It will also need to consider the fact that self-medication accounts for a substantial portion of the drugs consumed in the country. And finally, the policy will have to include national development goals, such as an improved infrastructure, increasing human resource skills in pharmacy and medicine or promoting the local production of drugs.

Every country has to take up the challenge to develop comprehensive national drug policy. In doing this all the sectors must be involved in this complex area. The cornerstone of a national drug policy will be legislation to ensure the safety, responsible market with adequate enforcement measures so that resources spent on modern pharmaceuticals are not wasted but make a positive contribution to the health of the population. Legislation should be accompanied by a plan of action for implementation. This may have to be in a phased manner, since it will not always be possible to implement all components simultaneously. The exercise of formulating a national drug
policy provides a unique opportunity to evaluate the present, identify problems and plan for the future.

**New drug policy of 1994: A critique**

In the light of what has been said about factors to be considered for a rational drug policy, one should analyse the provisions of the modified drug policy. It may lead us to the conclusion that the present policy guidelines have negated the objectives of the 1986 policy and are also against to the spirit of the Hathi Committee recommendations. In effect it would go against the directives of the Constitution.

The main objective of the drug policy 1986 was “ensuring abundant availability, at reasonable prices of essential and life saving and prophylactic medicines of good quality”. Because of the production pattern of the pharmaceutical industry and their record in producing only profit spinning formulations and their disinclination to concentrate on bulk drugs and essential drugs and the consequent inadequacy of bulk drugs, Hathi Committee was of the opinion that “a large number of bulk drugs are still required to be imported to meet the present demands”. According to it, progress attained so far is not commensurate, with the increasing needs of

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64 Ibid.

65 Hathi Committee (1975) Part II para 19.20.
the country particularly in respect of bulk drugs. Committee held the view that the response of the multinationals for the persuasive efforts of the Government of India to produce bulk drugs has been "negative or poor".

As against this background and without taking cognizance of these facts into account the new policy document says that the "conditions stipulating mandatory supply of percentage of bulk drug production will be abolished". This will lead to large scale import of bulk drugs while the pharmaceutical industry in India will decide to concentrate only on formulations. The policy also states that the "ratio parameters linking bulk drugs and formulation production and limiting the use of imported bulk drugs will stand abolished".

Hathi Committee was of the opinion that in the case of licensing for the manufacture of new drugs developed abroad, the main consideration should be that the proposed new drug must have distinct advantages over the existing range of drugs. The Committee further recommended that the therapeutic character of such new drugs should be scrutinised by a Committee of experts. Whereas the revised policy seeks to abolish all licensing for formulations except in cases of specific cell or tissue targeted formulations.

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66 Id. at para 17-20.
67 Id. at Part III, para 60.60.
68 See supra n. 63 at para. 22.1.2.
69 Id., at paras 22-1-4.
70 Supra., n. 63 para 22.1.3.
and thereby the government denied itself the opportunity to scrutinise the application for licence to a new formulations and screen out if they are found to be irrational. It is clearly against the reasoned recommendations of the Hathi Committee. This is considered to be unwarranted in the light of the fact that multinationals have a tendency to introduce newer products of similar activities with marginal differences. Since such products are patented, they are usually priced high.

Hence by its new policy the state has openly abandoned its primary constitutional obligation to monitor the production of essential and qualitative drugs. The problem thus is not that India do not have the knowhow or not that she do not have the capacity but that it has a very lopsided policy and implementation procedure which does not help the poor consumer who needs quality life-saving drugs at cheaper price.

The approval process of new drugs is to be studied in the context of the drug policy discussed above.