CHAPTER II

CONCEPTS AND REVIEW OF LITERATURE

CONCEPTS

In any scientific work, an important pre-requisite is that the concepts used in the work are made clear. Such clarification would make understanding and discussion easier. And so in this section, concepts which are unfamiliar and difficult are explained.

Drug Policy

Policy is a statement of intention and direction only. A national drug policy is part of the health policy of a country because it is dependent on the health situation of the country, the status and future of medical education, the situation of the medical care system, the possibilities for drug research and development, manufacturing of drugs and the possibilities for importation, possibilities for the objective evaluation of the quality and efficacy of drugs, determination of drug demand, basic principles of drug supply and the system of drug supply.
'Policy outputs' are tangible and symbolic manifestations of public policy; they are observable indicators of what governments in fact do. 'Policy impact' refers to performance, that is, the extent to which a policy output has accomplished its stipulated goals. As Nachimias has pointed out, "no longer do we assume that once we pass a law, establish a bureaucracy, and spend money . . . the purpose of these acts will be achieved and the results will be what we expected them to be."\textsuperscript{2}

Drugs

The definitions of 'drugs', 'medicines', 'pharmaceutical products', and 'medicinal products' vary from country to country. However, the terms usually mean substances and/or products for preventive, diagnostic, and creative purposes. These include substances of synthetic or natural origin, biological substances, vaccines and sera. The concept of drug, as used in this study, refers to any substance, other than food, intended for use in the diagnosis, cure, mitigation treatment or prevention of disease in man or other animals.\textsuperscript{3} Any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient.\textsuperscript{4} In the present study, the word 'drug' is common to all sorts of phrases like drug production, drug pricing, drug adequacy, drug distribution, per capita drug consumption. The meaning of the word is the same in all of them.
Essential Drug

Drugs are of different categories, one of which is 'Essential Drug'. The WHO defines 'essential drugs' as those that satisfy the health care needs of the majority of the population. Essential drugs are selected on the basis of scientific information on their efficacy and safety. Essential drugs are basic, simple drugs, needed for primary health care programmes in developing countries. Availability of essential drugs is a fundamental element of any comprehensive health care system. WHO has identified 200 drugs as essential to any nation's health. But experts hold a different view as many among them agree that as few as a dozen or so vital drugs are sufficient to cater to the most pressing needs of poor communities.

The set of essential drugs depends on many factors, such as the pattern of prevalent diseases; the treatment facilities; the training and experience of the available personnel; the financial resources; and genetic, demographic, and environmental factors. Because of the great difference between countries, the preparation of a drug list of uniform, general applicability and acceptability is not feasible or desirable. Therefore, each country has the direct responsibility of evaluating and adopting a list of essential drugs, according to its own policy in the field of health.

Medicine and Bulk Drugs

A medicine is a product intended for external or internal
use in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals. Thus it refers to ready-to-use form of drugs, while the latter include 'bulk drugs which refer to basic formulations, not yet made into medicine. Medicines are made in different dosage forms, that is, form in which a medicine is made available to the user. It differs by the route of administration of a medicine and the dosage to be used. Routes of administration are oral, parenteral (injectable), topical or external on skin, ophthalmic and miscellaneous. Four systems of medicines are practised in India, viz., (i) Allopathy, (ii) Ayurveda (including Siddha), (iii) Unani, and (iv) Homeopathy. This study confines itself to allopathy medicines only.

**Antibiotics**

In recent years, 'antibiotics' are the most commonly used drug in the world of medicines. Antibiotics refer to any of a large class of substances produced by various micro-organisms and fungi that have the power of arresting the growth of other micro-organisms and are of value in the treatment of certain infectious diseases. The development of antibiotics is to attack life-threatening infections without the patient suffering ill-effects. Anti-bacterial drugs have made it possible to save lives on a massive scale, by eradicating serious diseases such as anaemia, typhoid and TB of India.
Drug Formulations

'Drug formulations', another important related concept, are the finished products which are directly consumed and contain in addition to the active drug compound, other ingredients such as diluents, binders, flavouring, colouring agents (as in tablets), gelatin shells (capsules), chemical bases and waxes, preservations (ointments) and so on. The Indian Pharmaceutical Industry was dependent on the multi-national corporations for the supply of bulk drugs which were then fabricated into dosage formulations. The Hathi Committee observed that formulation activity represented the high pay-off sector and recommend its domestic growth.

Rational Drugs

Pharmaceutical products which, when administered to the same individual in the same regimen, have essentially the same efficacy and/or toxicity are called 'rational drugs'. They are accepted world wide and included in the standard textbooks of medicine and pharmacology and medical journals. There is no controversy about their efficacy and safety.

In contrast, 'irrational drugs' are those which have not been proved to be effective or safe. A combination of two or more rational drugs may become irrational because of increased chances of drug interaction, reducing their controlling quality and information about different ingredients is either not given.
or is not specific. Many drugs have become irrational either because a new product has appeared or it turns out to be toxic or better substitutes have become available. But many drug companies continue to market such drugs for years together even after medical authorities have declared them to be irrational. They include Analgin, Amidopyrine, Butazones, Clioquinols, and Anabolic steroids. If essential drugs are to be made available to the needy, the production of irrational drugs and irrational drug combinations should be stopped.

Generic Name

In the pharmaceutical field, a frequently used concept is 'Generic Name'. It pertains to a genus or a class of related things. The 'generic name' is the official name of a drug regardless of manufacturer. This generic or medical name is generally the international non-proprietary name established by the WHO. Generic names usually indicate the therapeutic or chemical class to which the drug belongs. A basic recommendation is establishing rational essential drug policies is to use drugs by their generic names, which are understood worldwide. However, only in a few countries generic prescribing is required by law.

The Hathi Committee of 1975 recommended phased abolition of brand names as one aspect of the comprehensive new drug policies.
The Committee suggested that initially generic names should be made compulsory for 13 drugs. It was not until 1980 that the Indian Government moved to ban brand names for five drugs.

Drugs are generally cheaper when purchased under generic names. Drug companies charge inordinately high prices for their brands on account of their vast promotional and marketing techniques. Marketing medicines under their generic names will check promotion of several brands having the same drug in various combinations: For example,

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Brand name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td>Disprin, Equigenic, Mecopyrin, Optalidon</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>Paramet Palgin, Norgesic, Ibugosic</td>
</tr>
</tbody>
</table>

Brand names are the trade names of drugs and their combinations given by the drug companies to their products. There is a great variation in the prices of drugs sold under brand names as the promotional expenditure and administrative overheads are added on to the costs of the final products. For example, the generic drugs metronidazole and mebendazole are sold under different brand names at different rates in 1989.
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metronidazole</td>
<td>Ambvan-200 mg</td>
<td>Rs2.41</td>
</tr>
<tr>
<td></td>
<td>Flagyl-200 mg</td>
<td>Rs2.84</td>
</tr>
<tr>
<td></td>
<td>Aristogyl-200 mg</td>
<td>Rs3.76</td>
</tr>
<tr>
<td>Mebendazole</td>
<td>Mendazole</td>
<td>Rs2.13</td>
</tr>
<tr>
<td></td>
<td>Mobazolo</td>
<td>Rs3.60</td>
</tr>
<tr>
<td></td>
<td>Meber</td>
<td>Rs4.88</td>
</tr>
<tr>
<td></td>
<td>Sugandazole</td>
<td>Rs5.08</td>
</tr>
</tbody>
</table>

While only 200 drugs are advised by the WHO to cover most illness, but the country has over 60,000 formulations (brand names) of drugs produced by 8000 pharmaceutical companies in the country. The results of this situation are that the world market is flooded with what Senator Edward Kennedy described as 'myriad of competing drug products'. The inevitable consequences of this variety of competing brands is that manufacturers must spend heavily on product promotion to convince doctors that their products are superior to that of their competitors. These marketing costs can add up to as much as 20 percent of sales turnover. Inevitably the costs of innovation and advertising have to be paid for in higher drug prices. As a result, actual production costs account only for as little as 20 percent to 30 percent of the research based companies prices. Grebmer explains that "between 70 percent and 80 percent of the sales price figure goes towards general costs and profits."
Pharmaceutical Industry

'Pharmaceutical industry' is one engaged in the production of drugs. The term pharmaceutical industry is defined to include firms producing bulk drugs by the process of germination and firms producing formulations. It is rightly considered a 'life-line' industry and is in the front rank of India's science based industries. Recognising its crucial role, it is included in the 'core sector'. Hence the growth of the industry was subject to detailed planning. Each plan fixed targets of production after a careful assessment of the demand for drugs and domestic capabilities to produce these with the objective of achieving self-sufficiency (see Appendix 1). To ensure that the industry progresses along the desired path of growth, it was brought under the purview of the Director General of Technical Development (DGTD). A Development Council was also constituted to advise the government on matters relating to its growth so that the targets fixed in different Five year Plans are achieved.

The responsibilities of the pharmaceutical industry are to provide complete information on pharmaceutical products to governments, prescribers, and consumers; to observe good manufacturing practices; to comply with established drug promotional criteria; to respond to the country's need for low-cost drugs of acceptable quality; and to develop badly needed new drugs.
in neglected fields, particularly to solve the health problems. Thus the industry is expected to serve the goals of the drug policy. The average per capita availability of drugs in India is Rs34 per annum (Rs8 in rural areas) at present. If the Eighth Plan production targets are achieved, it may increase to Rs54. It is lowest as compared to some countries (as of 1984).  

<table>
<thead>
<tr>
<th>Country</th>
<th>Per Capita Consumption (Rs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>34 (Rural Rs8)</td>
</tr>
<tr>
<td>Pakistan</td>
<td>43</td>
</tr>
<tr>
<td>Indonesia</td>
<td>42</td>
</tr>
<tr>
<td>Nigeria</td>
<td>70</td>
</tr>
<tr>
<td>Philippines</td>
<td>95</td>
</tr>
<tr>
<td>Thailand</td>
<td>159</td>
</tr>
<tr>
<td>Turkey</td>
<td>165</td>
</tr>
<tr>
<td>Egypt</td>
<td>190</td>
</tr>
<tr>
<td>South Korea</td>
<td>346</td>
</tr>
<tr>
<td>Japan</td>
<td>1650</td>
</tr>
</tbody>
</table>

The Organisation of Pharmaceutical Producers of India

The Organisation of Pharmaceutical Producers of India (OPPI hercafter) represents companies that produce 70 percent of India's pharmaceuticals and account for 70 percent of the
industry's exports. Its membership consists of large, medium and small scale units made up of Indian companies as well as companies with international organisation. OPPI identifies itself with the country's national health objectives and seeks to coordinate the activities of its member companies and to direct this efforts into more urgent and deserving areas of activity.

Drug Price Control Order

High price and consequent large profit encourage production. But the drug manufacturer has the ability to mark the prices up as high as possible to squeeze maximum profits on account of a monopoly sales manipulated through drug prescribing agents, while the consumer is just a helpless price taker.

Drug is an integral part of health care of an individual. And therefore, it plays a unique role in the market when compared to other consumer goods. In the case of all other consumer goods, the choice and the payment are done by the consumer and hence demand is a function of income and relative prices. In the case of drugs, the decision-maker is the physician and the choice is not guided by the patients' income and product prices. This situation between the decision maker and the consumer creates a strong imperfection in the market which renders the demand for life saving drugs completely price inelastic. These peculiarities make the consumer more vulnerable to high drug prices.
which the producers could charge in the absence of any price control. The situation is still worse because of imperfections on the supply side; for fifty percent of the world sales of pharmaceuticals lies in the hands of twenty largest transnational corporations. In such a situation, price control on drugs would not only protect the consumer but also act as a check on the undue profits of the drug companies.  

Hence, to protect the consumers' interests, the Government passed the Drug Price Control Order (DPCO) periodically to control and direct drug prices. There have been four such orders in 1962, 1970, 1979 and 1987, but the goal of making the essential drugs available to poor Indians at reasonable prices seems still a mirage.

Drug Pricing

Drug pricing has always been a sensitive issue in India. Drugs are sold in four different forms: finished drugs ready for use, bulk drugs in final dosage form ready for packaging, pharmaceutical chemicals for dosage formulations, and chemical intermediates requiring further chemical processing. Prices may vary markedly from one category to the next depending on the value added, patent and trade mark protection, degree of
substitutability, extent of price competition, purchasing methods and, more generally, the nature of the market.

Price competition tends to be most intense for multiple source products, i.e., those sold by more than one supplier; and in the form of product differentiation when supported by heavy promotional expenditures. For drugs which are protected by patents and which are generally produced by only one or a few firms, price competition is considerably less pronounced or does not exist. This occurs both in domestic and international markets.26

The drug industry is characterised by intensive product competition among the giant companies. The major drug companies of the world give maximum emphasis to the continuous development of new products in their Research and Development (R and D) efforts. No doubt, people all over the world have greatly benefitted from these innovations. However, product competition has given rise to two major disadvantages.27

i. It largely eliminates price competition whereby the consumer is deprived of the important benefit of lower drug prices.

ii. It adversely affects the composition of R and D outlays by the large firms with substantial sums
being spent on superficial product changes with a view to enhancing saleability.

It is in the context of these specific characteristics of the drug industry that the Indian Government has evolved elaborate price and profit controls with a view to attaining a better harmony of private profit and social good. The Hathi Committee had explained that the main objective of the policy was to secure better convergence of commercial considerations and social needs and priorities. The emphasis was to be on increasing the social utility of the industry particularly in the context of extreme poverty and the urgent need for extending as rapidly as possible certain minimum facilities in terms of preventive and curative medicines to the large mass of people both urban and rural. Conceptually speaking, price control is perfectly valid. However, whether it is effective in practice depends much on the manner in which the Government attempts to implement it and on the response of the industry.

Cost of Drug

Cost of drug is a concept very much relevant here. The 'ex-factory cost' is the sum of material cost (MC), conversion charges (CC), cost of packing materials (PM), and packing charges (PC). The material cost of a formulation includes the cost of
bulk drugs and other pharmaceutical aids used (including overages, if any); process losses thereon in accordance with such norms as specified by the government. The conversion and packing charges are required to be worked out according to the norms notified by the government. Packing material costs are allowed to be charged on an actual basis, but the process losses thereon are to be calculated in accordance with the norms announced by the government from time to time. The DPCO 1979 listed the following expenses that are supposed to be met out of the prescribed mark-ups: distribution, promotion, trade commissions and outward freight.

**Patent Right**

Patent right is an exclusive authority granted by a government to the inventor of a new machine or process. The inventor in this case reserves the privilege for a number of years, specified by the government, to make, sell and use his invention. The possession of patent rights, thus, gives the owner a certain degree of monopoly power. Patent rights are of vital importance in the case of pharmaceutical products and may occur in the following forms: (a) patents on the composition of matter, (b) process patents, (c) product patents, and (d) in some countries as in France, application of usage patents. All the leading
drug firms have their patents registered in one of these forms either in their home country or in the host country where they operate. The period for which patent rights are allowed differ from country to country. 31

Research and Development

Research and Development (R and D hereafter) are extremely important for pharmaceutical firms in maintaining growth and competitive advantage. Investment in R and D has to generate products that can be sold in large markets at reasonable prices. In the drug industry, R and D in the initial years would concentrate on product stabilisation. 32 Gradually, the focus would shift from product modification to process modification; adopting the production processes to local raw material and factor input availability to cut down costs and to become competitive. Finally, the industry would develop the ability to generate innovative products and processes on its own in an independent manner.

MultiNational Corporations

MultiNational Corporations (MNCs) play a key role in the pharmaceutical industry of developing countries. Even in the most industrialised developing countries where local production can satisfy most of the local demand, these corporations continue to hold a leading position through direct investment, licensing and management agreements, and as a source of raw materials and
intermediate chemicals. By virtue of their enormous resources and technological skills, the leading pharmaceutical firms can make a significant contribution to the developing countries' urgent need to improve the health care of their populations. Such a contribution can take a variety of forms such as a reallocation of R and D resources in favour of the major tropical diseases, the sale of low-priced essential drugs and the provision of the necessary technology under reasonable conditions for the manufacture of essential drugs by indigenous enterprises.33

In order to bring the operations of the multinational drug companies in line with national needs and priorities, the Government of India outlined its policy towards the foreign companies, with equity participation exceeding 40 percent in the New Drug Policy of 1978. The 1986 policy has brought down the equity participation to 40 percent and below and there are only five foreign companies operating in India at present.

Health for All

Jointly sponsored and organised by WHO and UNICEF, "Health for All by the Year 2000" realises that the health status of hundreds of millions of people in the world is unacceptable. More than half of the population of the world do not have the benefit of adequate health care. There is a wide gap between the developed and developing countries in their levels of health
and in the resources they are devoting to the improvement of health—within individual countries and between different groups of population.

Therefore the Constitution of WHO and numerous Health Assembly resolutions have reaffirmed that health is a basic human right and a worldwide social goal; that it is essential to the satisfaction of basic human needs and the quality of life; and that it is to be attained by all people. In 1977, the Thirtieth World Health Assembly decided (in Resolution WHA 30.43) that the main social target of governments must be "the attainment by all citizens of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life."

Following this, the Declaration of Alma-Ata, adopted on 12 September 1978 by the International Conference on Primary Health Care, clearly stated that primary health care is the key to attaining the target of health for all by the year 2000 as part of overall development and in the spirit of social justice. The Declaration called on all governments to formulate national policies, strategies and plans of action to launch and sustain primary health care as part of a comprehensive national health
system and in coordination with other sectors. In January 1979, in resolution EB 63.R21, the Executive Board of WHO endorsed the report of the International Conference on Primary Health Care, including the Declaration of Alma-Ata, and suggested to the Thirty-Second World Health Assembly that it invite Member States to consider using the present document individually as a basis for formulating national policies, strategies and plans of action, and collectively as a basis for formulating regional and global strategies for attaining an acceptable level of health for all by the year 2000.34

India is a signatory to the 'Alma-Ata Declaration' adopted by the World health Assembly in 1978 which gave the call "Health for All by 2000 A.D." It is now the aim of the Government to ensure that every citizen has the universal provision of comprehensive health care service, including essential and life saving drugs of proven quality, and they must be made available and accessible to the whole population. This implies that in just eight years from now, the country has to extend the drug coverage from 25 percent of the population to 100 percent. The Government of India has already set the goals for Health and Family Welfare Programmes in terms of "Health for All by 2000 A.D." (see Appendix 2).
Adequacy

Another important concept is adequacy which means sufficiency in terms of quantity. In this study, it means whether the availability of drugs in a country is sufficient to meet the total requirements of the population. To meet this requirement, a national drug policy should identify the therapeutic needs of the country, select the drugs and estimate the quantities required for each need. For this, a drug supply system has to be set up, covering procurement, storage, inventory control, distribution and training. Prescribers and consumers have to be educated to use the drugs properly. Quality control has to be ensured.

Much of the problem of people not getting health care or drugs is straight economics, which is to say that entire populations of those countries should have adequate quantities to meet the drug requirements. Such adequacy requires that the drugs be available in appropriate quantity, at costs those countries can afford, and that there is a distribution system ensuring availability at the social and geographical periphery. The supply of drugs must be uninterrupted. The out-of-stock situation could be a matter of life and death with drugs. Products must be distributed consistently to convenient dispensing points throughout a complex network. Furthermore, a high degree of accessibility
must be maintained. Prescription drugs must be available 24 hours a day for emergency purposes, and the wider the availability of home medicines, the more efficiently they can play their role.

Governments of poor countries lack resources not just to buy medicines, but to balance all the conflicting demands generated by under-development. This lack of resources is of course a major stumbling block to making health care available to the mass of the people. It is important to bear in mind that the industrialised countries have not only to meet their own drug needs but also to endeavour to meet those of the developing countries. As far as developing countries are concerned, the question remains to be the allocation of scarce resources among alternative uses. Any economy in which resources are scarce in relation to human wants, must have some mechanism to produce decisions on the problem of resource allocation.

**Affordability**

It means to bear the expenses or of having the necessary money or resources to purchase a commodity. Therefore, the aim of a national drug policy is to ensure that drugs of acceptable quality, safety and efficacy are available at affordable cost to all who need them, to combat the diseases or maintain the health of its inhabitants. Such a policy needs a strong political will and commitment and Governments would have to make sure that
the resources are available to meet the drug needs of the country. This requires the coordinated action of the sectors involved, such as planning, finance, industry, trade, communications and education. Such an infrastructure will vary according to the social and economic conditions of each individual country. Governments could consider the most appropriate measures to ensure that drugs cost as little as possible consistent with acceptable quality and ensured availability. This could be achieved with a Keynesian combination of free market forces and government interaction. 38

To ensure the availability of good quality low-priced drugs for the vast sections of population in the country, pharmaceutical manufacturers might agree to mass produce essential drugs and market them at prices that people could afford. This applies to national and multinational companies, and the research-based industry as well as generic manufacturers. Since industry cannot be expected to sell at a loss, governments might consider fiscal measures favouring low prices for the consumer, for example, exemption from import taxes, relief on company turnover taxes, and the price discrimination in favour of essential drugs.

The price people could pay for products depends not on the costs of production but on an appreciation of the benefits
that the product confers, in companies with the rest of the range of available preparations. When price is the only difference between products, then there is always a close relationship between the cost price and the selling price. The greater the specific benefit conferred by the product, the less the relationship will be apparent.
Having clarified the important concepts used in the study, an attempt is made to survey some important literature relating to the present study. Since Independence, two drug policies were announced, one in 1978 and the other in 1986. These two policies attempted to reveal the magnitude and dimensions of the problems faced by the pharmaceutical industry in India and thereby contributed richly to the definition and discussion of several related conceptual issues. A review of these studies will, therefore, help place the present study in its proper perspective. Most of the studies on drug policy in India relate to the period after 1978. This review would cover the following areas: First there would be a review of studies on pharmaceutical industry in general. This would be followed by reviewing studies on Drug Policy in general. The third review would be of studies on the New Drug Policy of 1978; followed by review of studies on the Drug Policy of 1986. The next review would be of studies on Drug Pricing. The sixth review would be of studies on Drug Price Control Orders of 1979 and 1987. An important review would be of studies on Social Objectives of Drug Policies. And lastly, the review would be of studies on the availability of essential drugs. Thus the survey of studies would cover all aspects of drug production, pricing and distribution.
On Pharmaceutical Industry

The first review would be of studies on pharmaceutical industry in general. Public health is now recognised as a fundamental right. Its attainment has become a social responsibility. There is a conflict of interests between the social objectives of government wishing to provide health care services to all the people at costs they can afford and those of the industry geared to increasing sales market shares and profits. Therefore, Fryers in his analysis says, "the principal function of the industry can most simply be stated as the supply of the products. The supply of drugs must be uninterrupted and the products must be distributed consistently to convenient dispensing points throughout a complex network."  

The UNCTC in its study has brought out clearly the challenges and problems of the pharmaceutical industry in developing countries and says that the pharmaceutical industry in developing countries represents a formidable challenge to policy makers. In the absence of adequate sanitation, nutrition and primary health care facilities for the bulk of their population, developing countries must rely on pharmaceuticals as the first line of defence against a wide range of diseases. However, these countries continue to face a number of problems in meeting their health objectives. In the pharmaceutical sector, expenditures on drugs tend to be very high relative to available
resources; indigenous production capabilities are generally low while dependence on imports is subsequently high; and large transnational corporations continue to play a strong or dominant role in the manufacture and trade of pharmaceutical products. In this situation, Governments and international organisations have been engaged in an intensive search for policies which would ensure an adequate supply of reasonably priced drugs and encourage the growth of indigenous pharmaceutical industries in the developing world.

Norgeolet in his observations has said that the indis­pensable role of the pharmaceutical industry in the control of disease makes them the servants of man and thus distinguishes them from consumer goods, which are subject only to the laws of supply and demand. Although drugs are of considerable economic importance in industry and commerce, it is their role in relations to health and society that sets them apart. The overall objective of the pharmaceutical industry remains everywhere the same; to make available, in sufficient quantities and at acceptable prices, drugs that are of excellent quality and as safe and effective as possible.

Phadke puts the problem of pharmaceutical produc­tion forcefully and says,
the drug industry, like any other industry, produces only to the extent that drugs can be sold at a reasonable profit in the market, irrespective of the needs of the people. The majority of the population is very poor. These people do not have money to buy the drugs. The industry neglects this section of the populace. . . . This happens because the logic of the present day society is such that production is geared to the demand in the market, irrespective of the needs of the people. 42

The IFPMA commenting on the code of pharmaceutical process said that scientists and managers within the industry were aware that poor people were deprived of vital drugs. 43 Poverty was the main constraint and drug producers were in no position to end poverty. The pharmaceutical industry, however, acknowledged that it had special obligations arising from its involvement in public health.

The OPPI studied the nation's health indicators and the profile of the pharmaceutical industry during the period 1947-1976, 44 and concluded that health was fundamental to progress in any sphere and it was more than a problem in India. The success of the government's efforts in meeting the challenge can be measured by the remarkable improvement that has been brought about in the health of the nation.

Jayaraman has observed that the imbalance in the production and distribution of drugs in the industry, was
mainly due to foreign monopoly which, through its control of production, technology and the market, not only affected the growth of indigenous productions within the country, but also deprived the common man of essential drugs at cheap prices. In this situation, the argument went on, even if production of drugs and pharmaceuticals in the country were to be doubled, there would be no guarantee that the common man would reap the benefits of modern drugs at cheap prices, so long as the existing imbalances in the production technology and distribution of drugs as between the different sectors of the industry were not set right.

According to Fryers, there are five important functions of pharmaceutical industry. They are (a) supply of the products, (b) product development and manufacture, (c) communication, (d) innovation, and (e) research and development. It is necessary to consider the functions to understand the interactions between the pharmaceutical industry and national drug policies.

The ICSSR-ICMR and the National Committee on Science and Technology and Task Force appointed by the Planning Commission made a critical study about the pattern of drug production by the pharmaceutical industry in India. These two studies
revealed that the pattern of drug production did not conform to the real social needs of the country. For instance, the production of INH for tuberculosis and of Dapsone for leprosy was only one-third and one-fourth respectively of minimal requirements. On the other hand, tonics and vitamins, most of which were alcoholic preparations and 'spin' money were produced in abundance.

Bhagat attempted to highlight some of the central issues involved in the important areas of health and drugs in the developing world, primarily in the context of Indian experience. This report examined the role of drugs and the drugs industry in the context of "Health for All by the Year 2000 A.D." and concluded by raising some fundamental economic and political issues involved, and the likely trends and prospects in the near future, in the operation of the 'mixed' industrial economy of India characterised by extreme inequality and poverty on the one hand and an abysmally low rate of growth on the other.

In 1984, Narayana made a study on the Indian pharmaceutical industry and its problems and prospects and observed that pharmaceutical products were vitally important for human welfare. According to him, the demand for pharmaceutical products was expected to rise further as India had adopted
the goal of "Health for All by 2000 A.D." This study was designed to comprehensively analyse the past trends and future prospects of the Indian pharmaceutical industry. As Government regulates the growth of the industry as well as its prices respectively through New Drug Policy and Drugs (Prices Control) Order, these policies received special attention in the study. The study covered a wide range of subjects like pharmaceutical technology, future demand for drugs, development policies, cost and profitability trends in the industry. The study concluded that--

a. the availability of drugs had made a significant contribution to the mitigation of several diseases and virtual eradication of some others;

b. in the first two years that followed the announcement of the 1978 policy, production of both bulk drugs and formulations increased at a slower rate as compared with the growth maintained during the sixties and seventies;

c. to make up the shortfall in domestic production, considerable quantities of bulk drugs were imported;

d. an essential part of improving health standards was to ensure adequate supply of medicines to the needy persons;

e. a large mass of technology was imported into India during the post-independent period. The imported technology was adapted to the local conditions and in many cases improved upon by Indian scientists and technologists, thereby placing India in the position of leadership in the Third World Countries next only to Brazil.
f. In the production of ordinary range of pharmaceutical formulations, India had a firm base for self-reliance. But in the production of bulk drugs, there was a definite need for the induction of modern technology.

g. The manufacturing costs of individual bulk drugs were very much higher in India in relation to imported bulk drugs. The main reasons for this were the high cost of drug intermediaries, uneconomic plant sizes, use of obsolete technology and low labour productivity.

The NISTADS, as a pilot study in 1984, made an attempt to investigate the nature and level of Research and Development and its relationship with the production of five essential drugs, namely, Chloroquine, Primaquine, Tetracycline, Oxytetracycline and Piperazine. The first two drugs are used in the treatment of malaria, tetracycline and oxytetracycline in the treatment of respiratory infections, and piperazine is used in the treatment of helminthiasis.

The study concluded that all these drugs were in short supply and were being imported. In the case of piperazine and chloroquine, the capacity utilisation had been below the registered/licenced capacity. By and large, all the companies in the Indian private or multi-national sector had chosen to concentrate their research efforts only on the development of
processes for the production of known drugs or improvements in known processes. None of them had mounted an effort towards basic research for the development of new drugs.

Smith while analysing the pharmaceutical progress said that the pharmaceutical progress and therapeutic innovation did not just happen out of nowhere. They had to be created by the use of resources that were expensive in terms of both money and manpower. And as a background to this discussion of the costs and benefits of pharmaceuticals in the health services, it was important to remember that in practical terms, these resources had come almost entirely from the free enterprise, research-based pharmaceutical industry of the Western World.

Multinational corporations have emerged as one of the most remarkable phenomena of the post-World War II era. Satwinder Singh has made a modest attempt to study the various dimensions and characteristics of multinational corporations and the economics of pharmaceutical industry in India including an assessment of the Drug Prices and Drug Price Control (DPCO) Orders in India. Drawing on a number of resources, he has concluded that the manifold activities of these corporations would ensure that their activities promote and not hinder national development.
The Delhi Science Forum and Federation of Medical Representatives Associations of India in 1986 analysed the role of drug industry and the health conditions of the Indian people. Like anyone else, the Indian poor mass want an effective and affordable solution to their health problems. Cheap and quick relief is an economic necessity of the poor people. Loss of a working day can add to the misery and even bring disaster if the disease persists for a few days longer than they can really afford. According to them, it was for this economic reason that drugs and curative medicines which otherwise constituted only a small part of the overall health care system, became the most urgent, essential and hence a priority needed for our country. This would continue to be so, so long as the basic elements of health care such as food, shelter, healthy and safe environment were not made available universally to all the Indian people. From the industry's angle, a competition market system is the basis for innovations and growth of the industry. Supporting this point, House says:

Proponents of a free and competitive market maintain that the standard economic approach is to rely on signals sent by market forces. Consumers are expected to have well-defined preferences and are assumed to be able to choose from a variety of suppliers of the goods and services they need. In doing so, they will choose the lowest cost supplier. Suppliers will produce their goods at the minimum possible
cost and offer a range of qualities from which consumers may purchase; otherwise another supplier may take his business away. If there is an inefficient group of suppliers in an industry, it is assumed that firms outside the industry will enter the market in pursuit of profits thereby ensuring that those goods consumers most wish to purchase with their incomes are produced at minimum cost.

Jayasuriya while dealing with the legal issues and approaches for the regulation of pharmaceuticals in developing countries is of the view that the formulation and implementation of pharmaceutical policies are now being accorded high priority by almost every developing country. His work provided a much-needed introduction to some of the legal issues relevant to the regulation of pharmaceuticals and described some of the possible approaches to the establishment of a regulatory framework. It dealt mainly with the aspects of immediate concern to administrators in establishing modest control systems to facilitate the availability of safe and effective drugs of acceptable quality of reasonable prices.

The World Health Organisation in its report on "The World Drug Situation," has analysed the nature and functioning of the pharmaceutical industry in 1988. The report says that India is characterised by a strong pharmaceutical industry capable of manufacturing nearly all the drugs needed in the
country. According to UNIDO, India is in category 4 that is
technologically developed enough to be totally self-reliant,
with research capability for the discovery of new chemical
entities.

Balasubramanian is of the view that an 'ideal' drug industry would be one where there would be convergence of commercial considerations and social needs and priorities. For Third World countries, this 'ideal' could be achieved by the following strategy:

a. To provide a leading role for the public sector in pharmaceutical production;
b. to encourage national entrepreneurs to set up and/expand their activities;
c. to allow foreign investors, joint ventures and subsidiaries to set up manufacturing companies on specified terms, so that their activities can be controlled by the government;
d. to provide tax and fiscal benefits for indigenous research and development carried out either in-house or in a research or academic institutions in the country;
e. to allow imports of technology after careful scrutiny and reference to national research and development institutions;
f. to organise pooled imports of selected drugs and chemical intermediates to avoid transfer pricing.
Agarwala, while pleading for a natural cooperation between the government and the industry, says that the pharmaceutical industry has a key role to play in the economy and health of the nation. The Indian industry today accounts for 2 percent of the world production of pharmaceuticals although we have 15 percent of the world’s population. He goes on to add that there has been a perceptible and progressive shift in government policy towards the pharmaceutical industry. From rigid controls and regulations, the policy focus has changed to liberalisation and pragmatic measures for promoting growth and development.

He further says that our country is poised for a great leap forward into the 21st century. The pharmaceutical industry too should leap with the nation and not limp along. The future of the pharmaceutical industry is bright and promising. And therefore, the government and the industry must work together in a spirit of cooperation and mutual trust so that the industry can effectively play the role the nation expects it to play in order to make available drugs of the highest standards of quality and safety, in adequate quantities and at reasonable prices to our people.

From the industry’s side, the joint report submitted by the IDMA-OPPI reveals that the pharmaceutical industry is
relatively a small industry in terms of investment and production. But its importance lies not so much in its size, but in the vital role it plays in the nation's health program. The country's requirements of drugs are met by indigenous production. Import of finished formulations is negligible and the present level of import is confined only to certain specialised drugs such as anti-cancer drugs. From a net importer of drugs, the country has now emerged as a net exporter. The availability of wide range of drugs is reflected in the trend of health indicators—birth rate, death rate and infant mortality. It has also created an excellent record in technology development and has introduced several new drugs also in the recent past.

The Export-Import Bank of India, while analysing the functioning of pharmaceutical industry, observes that India is considered to be the largest producer of pharmaceuticals among the developing countries. Production of drugs and formulations in 1988-89 increased by 30% over the previous year. Production of pharmaceuticals has shown an encouraging growth rate of approximately 14 percent per annum during the last five years with output of drugs and formulations in 1989-90 reaching Rs610 crores and Rs3360 crores respectively. The per capita consumption of drugs in India is the lowest in the world. It is about US $2 per capita against US $40 in the developed countries.
This gives an indication of further growth potential for this industry. The study further notes that drug prices in India are the lowest in the world. On account of rigid price controls, escalating cost of raw materials, packing materials, wages and salaries, the profitability of the industry fell from 15.47% in 1969-70 to 3.4% in 1986-87. Subsequent to Drug Price Control Order of 1987, it improved to 5.6% in 1988-89 and currently, it has fallen down to 3.5% in 1989-90.

Divatia felt that there were three major challenges, namely, innovation, pricing policy and licensing policy facing the pharmaceutical industry in the decade of 80s and strongly appealed to the authorities that the pharmaceutical industry should be completely exempted from price regulations and licensing regulations. Jayaraman studied how the stringent regulatory measures retarded the growth of the pharmaceutical industry on the basis of individual case studies of the six selected countries (India, Brazil, Mexico, Pakistan, South Korea and Argentina) by the Pharmaceutical Manufacturers Association of India in respect of production and sales of pharmaceutical products during 1975-80. This study clearly brought out the fact that a shift to more stringent regulation of pharmaceuticals, chiefly in the form of price controls, had been self-defeating. It had curtailed the new investment; hampered the development of the domestic sector of the industry; increased the imports and
resulted in shortages of critical medical supplies. Those affected most were the consumers in these countries. In contrast, governments that adopted less restrictive policies had stimulated international and domestic companies to increase their investments and the production of medicines needed by their people.

Nair in his analytical study about the industry's dilemma said that the Indian pharmaceutical industry had the capability—technological, financial and managerial—to meet the country's requirements of medicine estimated at Rs160,000 million in the year 2000. However, this capability could be translated into more investment, more production of high quality drugs for the people at reasonable prices, if we removed the bottlenecks and developed a new perspective and a new approach to this vital industry. Suresh Thakur Desai observed that the recent decision to bring additional 21 drugs under the price control had been termed by the drugs and pharmaceutical producers as an arbitrary step and it would retard the future growth by diversion of fresh investment to non-pharma activity.

Sharma feels that government regulations of the past three decades have been systematically unreasonable enough to render this industry sick—through price controls, profitability ceilings, ever increasing levies and dearer imports of critical inputs and machinery. These units spread across
the country have been operating, as a result, at low efficiency levels. The capital formation in this industry is by far the lowest, lower even than in core sector industries like aluminium, steel, cement and sugar.

Sundaram, while pleading for pragmatic policies, observed that the manufacturers of medicines in this country had a long-standing grouse against the Government of India, that it had pegged down the prices of pharmaceuticals for too long with the result that their profitability had been considerably eroded and they were being forced to seek avenues of business in other sectors of the economy.67

The current scenario of the pharmaceuticals has been summarised in Yojana.68 It says that the pharmaceutical industry in India is one of the largest and most advanced among the developing countries. It is capable of manufacturing most bulk drugs and formulations of all dosage forms. Over the past decade, the pharmaceutical industry has shown a steady growth of about 10 percent per annum and this growth rate continues to be maintained both in the field of production as well as in exports. The total production of bulk drugs and formulations have been calculated to be of Rs640 crores and Rs3,420 crores respectively for 1989-90 and the total exports are Rs836.90 crores.
Thus there is growing recognition of importance of pharmaceutical industry and its pivotal place in the economy not so much for its contribution to Gross National Product but to its capacity to improve the health status of the population. For, a healthy industry and a healthy trade are a must for a healthy nation; and progressive use of modern drugs has enabled the government to effectively control several diseases and eradicate others. The government on its part committed to providing the sick, the poor and the under-privileged with drugs at cheap prices.

Secondly, pharmaceutical industry in India has shown tremendous progress, with present production covering a wide range of basic drugs including antibiotics, vitamins, sulphonamides, analgesics and a host of other synthetic drugs, phytochemicals and biological products and formulations. The total production in 1984-85, the base year for the Seventh Plan, was Rs377 crores for bulk drugs and Rs827 crores for formulations. And for the year 1989-90, it has been calculated that the production of bulk drugs at Rs640 crores and formulations of Rs3,420 crores.

Despite its impressive growth, the drug industry still suffers from many deficiencies. The industry feels that price controls, profitability ceilings, ever-increasing levies and costlier imports are factors causing sickness in the industry. The operational efficiency of most units continues to be low and the gap between the target and the actual in the case of bulk drugs continues to be high. The basic problem facing the drug industry is the lack of incentive to produce because of reduced profit margins.
On Drug Policy in General

The present study chiefly refers to Drug Policy. In this section review of studies on drug policy in general would be attempted. Fattorusso of WHO writing on aims and objectives of Drug Policy says that the aim of developing national drug policies was to improve the efficiency of the pharmaceutical supply system and to render accessible to the whole population the most effective and safe pharmaceutical products of established quality at reasonable cost. He further adds that multi-sectoral approaches to policy formulation, and mechanisms for coordination and cooperation were required because, while one aspect of national drug policy concerned delivery of optimal care in terms of quality, cost, and distribution of pharmaceutical products, another aspect concerned national economy, export and technological development.

Moulopoulas expressed almost identical views and said that the formulation and implementation of national drug policies were aimed mainly at optimising the benefits, minimising the dangers, and reducing the cost of drug use in the treatment and prevention of diseases. In addition, he stated that formulating drug policy was a complex task. It required cooperation between the various groups concerned, namely representatives of the consumer (government and non-governmental agencies) the drug control agencies, the industry, and the officials dealing with the economic aspects.

Faller found that the formulations and implementation of a country's drug policy were dependent on certain national characteristics. They were--
- the health situation of the country;
- the pharmacotherapeutic practice in the country and its historical development;
- the status and future of the education and postgraduate training of physicians, pharmacists and other health specialists;
- the situation of the medical care system (hospitals, clinics, pharmacies);
- the possibilities for drug research and development;
- manufacturing of drugs and the possibilities for importation;
- possibilities for the objective evaluation of the quality and efficacy of drugs and the extent to which drug safety requirements had been met;
- determination of drug demand;
- basic principles of drug supply; and
- the system of drug distribution (factory, wholesale trade, pharmacies, and other commercial outlets).

According to Nargeolet, the overall objective of Drug Policy remained everywhere the same: to make available, in sufficient quantities and at acceptable prices, drugs that were of excellent quality and as safe and effective as possible. Clearly, this did not imply that any government policy in regard to drugs should be concerned solely with their industrial and commercial development. The country's social situation and
its economic policies had to be taken into account. In fact, the economic policies might even be decisive in this field.

The World Health Organisation in its another report stated that the aim of a national drug policy, was to ensure drugs of acceptable quality, safety and efficacy were available at affordable prices to all who needed them, where and when they needed them, to combat and to improve or maintain, people's health. Such a national drug policy needed a political will on the part of the government, together with a strong commitment to formulating the policy and carrying it through, and the government must ensure that resources were available to meet the growing needs for drugs in the country. This required the coordinated action of various administrative governmental agencies dealing with planning, finance, industry, trade, communications, and education. Controls were required to alleviate the marketing of pharmaceutical products of unacceptable quality, safety, and efficacy, and to ensure that promotion of those products meets ethical criteria.

It was necessary, therefore, in a national drug policy to identify the therapeutic needs of the country to select the drugs and estimate the quantities required for each need. A drug supply system had to be set up, covering procurement,
storage; an appropriate information system had to be set up to provide objective information on drugs, and ethical criteria for promoting drug use must be defined; and appropriate legislation for drug policy had to be enacted. Besides, manpower requirements for administering a national drug policy has to be estimated and personnel trained and a financial master plan had to be drawn up.

The World Health Organisation in its latest guidelines for national drug policies prepared a working group of experts says that the goal of health for all by the year 2000 has been accepted by most countries. To achieve it, a strategy needs to be framed and incorporated in a written policy. Such a strategy must include a satisfactory health care system. The prevention and treatment of disease require an adequate health care delivery infrastructure and appropriate education, and high priority must be given to ensure adequate sanitation, safe water supplies, and nutrition.

Many countries have frequently lacked adequate supplies of drugs, not only on account of financial and budgetary constraints, but also chiefly on account of the attitude and behaviour of the government, prescribers, dispensers, consumers, and the drug industry. To ensure an adequate supply of safe and effective
drugs of good quality, every country should have a national drug policy as an integral part of its health policy. A vital requirement is that governments should exert the political will necessary to formulate and implement a drug policy.

New Drug Policy of 1978
The review would next cover specifically drug policies of 1978 and 1986. The first policy statement of 1978 and its practice had been examined by Jayaraman. He observed that the 1978 Drug Policy statement was really an unhappy compromise between doctrinaire economics on the one hand, and the pulls of different sectoral interests on the other, and full of contradictions, ambiguities, constraints and restraints, disincentives and discriminations, sectorally and industry-wise. In the process, the common man in whose interest the policy was avowedly made and who had a vital stake in the continued availability of essential drugs of the highest quality and safety, in adequate quantities and at reasonable prices, appeared for all practical purposes, to have been left high and dry.

According to Gopalakrishnan, the government failed to spell out the aims of the policy clearly and as a result, the 1978 policy had not achieved the intended results. The policy according to him classified drugs into three major categories:76
Category I  Life saving drugs
Category II  Major essential drugs
Category III  Other drugs

The 'mark-up' on categories I and II was not to exceed 40 percent and 55 percent respectively of the ex-factory cost. For category III, the mark-up can go up to 100 percent (the mark-up includes margin and trade commissions). Naturally, anti-TB drugs should be included in Category I for which the mark-up was the lowest. Ethambutol, an anti-TB drug was not listed even under category II. If this drug had been put under category I, the price advantage of the TB patients would have been much greater.

The study conducted by the ICSSR-ICMR revealed that the 1978 policy which aimed at 'self-reliance' and 'abundance of drugs' to meet the health needs showed that it did not accord special emphasis on the pattern of drug production. It also emphasised that it was not enough to see that drugs were produced by Indian manufacturers and in abundance; it was even more important to see what drugs were produced and for whom.

The National Committee on Science and Technology (NCST) and Task Force appointed by the Planning Commission on the above
policy observed that,

the pattern of drug production in the country did not conform to the real social needs of the country. Out of a total production of Rs700 crores in 1976, 25 percent was accounted for by vitamins, tonics, health restoratives and enzyme digestants, mostly consumed by the well-to-do urban population. Twenty percent was covered by antibiotics, only 1.3 percent by sulphonamides (a very cheap and useful anti-infective) and 1.4 percent by anti-tuberculosis drugs for a disease, the incidence of which had been computed to be of the order of nearly 1.8 percent of urban and rural population. Dapsone, the basic drug for leprosy costing only Rs5 for a year’s treatment was always in short supply.

The study conducted by the ICSSR-ICMR and others also found fault with the policy. They all observed that the pattern of drug production in the country should be oriented closely to the disease pattern. The drugs required by the poor should be produced in adequate quantities and at the cheapest prices.
possible. Similarly, a list of basic essential drugs should be prepared and the requirements of these drugs should be estimated on the basis of the prevailing disease pattern.77

In his analytical study on "Health-Drug Policy Contradictions" Jayaraman has pointed out that drug policies were and continued to be linked with industrial trade development, influenced by factors other than health considerations.78 What was more, 'large chunks of health budget' were spent on buying non-essential and high-priced drugs, while a major segment of the population continued to be denied the most necessary drugs. Funds available for health care in less developed countries was 1 and 2 percent of the GNP, and only 15 to 30 percent of these funds may be spent on drugs.

According to Jayaraman, shortages of essential drugs and pharmaceuticals appeared to be assuming almost alarming proportions due to inordinate delays in the grant of licenses, serious slippages in the implementation of projects, especially by the public sector units, and ideologically constraints against multinationals, which had all the capabilities, resources and technology to produce the very same drugs in required quantities and quality which were being imported from abroad at great cost.
to the nation. As a result, production of a large number of life-saving drugs, especially drugs for the treatment of tropical diseases like malaria, leprosy, worm infestations, etc., which the country could produce in abundance at no extra cost to the nation, could not be done, thus leaving the sick and suffering millions afflicted with no hope of relief so far.

Narayana observed that in the years that followed the announcement of the New Drug Policy of 1978 and Drug Price Control Order of 1979, the production of bulk drugs and formulations increased at a slower rate as compared with the growth maintained during 1960s and 1970s. In 1981-82, which was the second year of the Sixth Plan, production of bulk drugs and formulations registered a sharp increase; but the same tempo of growth could not be maintained in 1982-83. The All India Drug Action Network and Voluntary Health Association of India concluded that though the Hathi Committee Report provided the inspiration for formulation of Bangladesh's National Drug Policy, yet, not a single recommendation of the Hathi Committee had been implemented in India.

**New Drug Policy of 1986**

New Drug Policy of 1986 which was an improvement on 1978 policy statement identified four major thrust areas for action namely licensing, pricing, quality control and rational use
of drugs, and considered that a limited number of drugs could still be reserved for the public sector, and the small-scale sector Indian companies would be eligible for industrial approvals for the manufacture of all other bulk drugs and formulations.

Lall evaluating this policy concludes that the overall effect would be that the industry was in grave danger of losing its long-term commercial viability. Shiva and Alvaro have found that the new policy had not gone into the basic issues of a national health programme and that it was unduly concerned with the health of the industry and not with that of the consumer.

Gandhi on the other hand took up the defence of the pharmaceutical industry and suggested a system of overall profitability control, rather than of individual product price control. He argued for a uniform post-tax return of 16% on net worth instead of the existing return of 14% for essential bulk drugs and 12% for other bulk drugs. In a similar vein, Langrana also agreed that the Seventh Plan targets of investment and production could not be achieved unless the drug policy, particularly the pricing policy was suitably changed. The Plan envisaged a more than doubling of the production of bulk drugs and formulations from Rs377 crores and Rs1827 crores in 1984-85 to Rs808 crores and Rs3,775 crores respectively in 1989-90. The additional investment envisaged to achieve this target was Rs455 crores, an increase of 70% over the current investment.
The industry had the capability to achieve those targets provided appropriate changes were made in the drug policy and the pricing scheme.

Nair also took the side of drug industry and said that the new drug policy of 1986 had failed to cheer the industry. Nair also criticised the 1986 policy statement on the ground that the actual policy was counter to the stated objectives of 1986 Drug Policy. For the prices of formulations of 26 additional bulk drugs brought under price control were slashed even without calling for cost data from manufacturers. According to Choudhuri, 1986 policy was directed mainly for the growth of the industry and there was likely to be an all-round increase in drug prices, and companies with less than 40 percent foreign equity would be treated on par with wholly Indian companies.

Gupta in his critical analysis said that the New Drug Policy of 1986 had come as an unpleasant surprise to many. The government had totally capitulated to the unreasonable demands of the pharmaceutical industry. He felt that the government had rushed through piecemeal change in the 1978 policy while many important issues had been kept in abeyance. The changes articulated in the policy statement pertained only to pricing and licensing. The shifts in these areas were in accordance with the demands being made by the industry, while
the interests of the consumers and the indigenous sector had been totally ignored.\textsuperscript{89}

The World Health Organisation report provides a systematic description of what has happened in India in the last twenty years.\textsuperscript{90} It is evident from the report that it is not always possible to reconcile economic and health goods. India provides a paradoxical example of over-production of drugs existing simultaneously with shortage of essential drugs for major diseases. Although attempts have been made by the Hathi Committee to elaborate a policy geared to meeting the health needs of the people, this policy has not been followed completely and economic priorities have often taken precedence over health priorities. The new policy of 1986 is an attempt to redress the situation and ensure availability of essential drugs for every one.

The survey of the above studies shows that all have been critical of the two policy statements. Some authors have viewed that these policy statements have not protected the interests of the consumers and that the prices would shoot up. Still others found fault with the policy statements for not being more favourable to the industry. Generally, the social responsibility of the industry and the interests of the consumers were neglected by the authors.

On Drug Pricing
Pricing is a complex issue, not least because of all the
external factors that influence prices, including the size of the market, the degree of competition between similar products, the extent of government controls, taxes and the margins added by wholesalers and retailers. There are striking differences in drug prices from one market to another, between different manufacturers and in the prices that the same producers charge different buyers. An important factor underlying different prices between both developed and developing countries is the degree of government price control.

A study conducted by the UNCTAD reveals that in the Philippines, where the government exercises few controls on the market, prices are generally much higher than elsewhere. The World Health Organisation in a report indicates that drug prices are determined as much by market factors as the actual costs of production and supply. The conclusion reached by some of the earlier studies of the UNCTAD confirmed that manufacturers appeared to charge what the commodity will bear. Jayaraman is of the opinion that external market forces alone do not account for all the price discrepancies; but the structure within the industry makes it inevitable that identical drugs are sold at very different prices. There are exceptions; but as a rule, the research-based companies charge one set of prices and non-research based producers another.
Inevitably the costs of innovation and advertising have to be paid for in higher drug prices. The costs of Research and Development now are truly astronomical in nature. To discover, to develop and to market a new drug today, it costs over $100 million (against $70 million a few years ago) and a time span of 10 to 12 years. As a result, actual production costs can account for as little as 20-30% of the research-based companies prices. Klaus Von Grebmer explains that "between 70% and 80% of the sales figure goes towards general costs and profit." The Third World's heavy reliance on the market leaders means that the poor are helping to foot the heavy bill for research and promotion. According to him,

Owing to the special nature of the costs structure in the research-based pharmaceutical industry, the only economically reasonable accounting procedure to adopt is to calculate for each product a so-called "contribution margin" (= price minus directly chargeable costs) which includes an extra percentage to cover general costs. However the price discrepancies we have described make it clear that this "contribution margin" cannot be distributed evenly. Lall observes that this system of adding a premium to the actual production cost of all drugs is so advantageous that a few of the best-selling drugs effectively subsidise the cost of drugs for rarer diseases. (Commonly 50% of a company's sales are made up by only about 5% of their
product range). Third World patients do of course benefit, because rich world purchasers are helping to pay for drugs for tropical diseases that might otherwise be even more prohibitively expensive as their sales volume is low.97

While supporting the case of the drug industry, Ball says that the drug prices are controlled by the Drug Price Control Order, there is no such control whatsoever on costs of raw materials and packing materials.98 Their costs have also been increasing. The industry's main arguments supporting its actions for the increase in drug prices are: (i) unremunerative prices of final products, (ii) no control over prices of raw materials, (iii) uncertain environment for business, and (iv) lack of automatic price hikes. However, the argument of the industry is that the Indian drug prices are lower than anywhere in the world.

The OPPI puts forth the problems of the industry forcefully and says that the stresses and strains of the general economy were reflected in the operations of the pharmaceutical industry too.99 The cost of almost all locally procured raw materials, packing materials, utilities and services continued to rise relentlessly. The Gulf conflict and the consequent sharp increase in prices of all petroleum-based products gave a further push to cost escalation. The cost of raw and packing
materials increased by an estimated 40 percent to 100 percent, depending upon the import content and when the price was last fixed. On top of this, the imposition by the Reserve Bank of India of a 200 percent cash margin for imports (price controlled drugs were subsequently exempted from the cash margin requirement) devaluation of the rupee and substantial hike in interest rates further added to the inflationary spiral. It is time that the authorities realised that unremunerative prices would discourage production in the long run and as a result, the consumers would be hurt very much. It was possible that rigid price control had discouraged investment at a time when it needed to be stepped up for stimulating production.

**Drug Price Control Orders.**

Drug prices have been under government control since 1962. The monitoring of drug prices by the Government of India started 28 years ago in 1962 as an emergency measure in the wake of the Chinese Aggression. The Drugs (Display of Prices) Order, 1962 was issued mainly to contain inflationary forces as a consequence of the War and the Drugs (Control of Prices) Order 1963 was promulgated freezing the sale prices of drugs at the levels obtaining on 1 April 1963. Both these orders were issued under the Defence of India Act. On 30 January 1966, the government issued the Drugs (Display and Control) Order replacing the two separate orders with certain additional provisions
by which no new product or formulations could be marketed without prior price approval. This invited some criticism of the manufacturers and therefore a "Drug Advisory Committee" was constituted to work out a mechanism for determining the price structure of drugs from the stage of manufacturing to the stage of consumption. The Committee submitted an interim report on 27 April 1966.

In August 1966, the Tariff Commission was requested to review the cost structure of 18 essential bulk drugs and 69 formulations. Based on the Tariff Commission's Report, the Drug (Prices Control) Order 1970 was issued.

Then the government referred the cost and price structure of 25 more bulk drugs and formulations not covered by the Tariff Commission to the Bureau of Industrial Costs and Prices. The Drug Price Control Order (DPCO) 1970 provided for a 15% pre-tax return on capital employed in respect of bulk drugs and a mark-up of 75% to 150% on the manufacturing cost of formulations, which were broadly divided into two categories, essential and non-essential. Apart from price control, a profit ceiling (at 5% on the turnover of formulations) was also provided for the profits earned in excess of this ceiling being required to be funded separately. The immediate impact of the DPCO 1970 was to bring about a reduction in the prices of life-saving drugs, even while the manufacturers were able to make up for the reduction in profits by raising the prices of other established drugs within the 75% to 150% mark-up provided for.
Drug Price Control Order 1979

The DPCO 1979 was based largely on the recommendations of the Hathi Committee 1975. It provided for a three-tier system of control:

i) control on the prices of bulk drugs;

ii) control on the price and profit margin of each and every formulation based thereon; and

iii) an overall ceiling on profits.

The basis of return provided for bulk drugs was on net worth (equity plus reserves); return was fixed at 12-14% of net worth, depending upon the importance and complexity of drugs. Formulations were divided into four considerations of essentially and separate mark-up levels for the different categories were provided for:

- Category I: 40% mark-up
- Category II: 55% mark-up
- Category III: 100% mark-up
- Category IV: free mark-up or decontrol for the rest

Jayaraman in his study of the above order explained that it was important to note that mark-up was not the profit margin as such, but covered trade commission, outward freight,
administration, selling and distribution expenses, interest on borrowings, Research and Development expenditure, etc., besides a reasonable margin to the producer. Formulation prices in categories I, II and III were again subjected to control through the concept of what is known as 'leader prices', which were 'the prices of efficient, major manufacturers' whose names had been separately notified. Prices which were higher than the 'leader prices' were to be reduced to the level of the leader prices and those lower than the leader prices were to stay frozen at such lower levels, till an upward revision was approved by the government. Thus, the prices of 85% of drugs marketed in India were fixed by the government under the DPCO 1979 leaving the remaining 15% of drugs out of price regulation.

According to Singh, a careful reading of the DPCO 1979 reveals many drawbacks. The main assumption is that the loss suffered by drug companies due to low mark-ups in category I could be made good by introducing products from the remaining three categories. This argument, according to Singh, did not hold good for many firms, especially those in the small sector which had little control over the market. As regards the licensing of capacities, the capacities for bulk drugs or formulations was not specified. This criterion would certainly have worked in favour of large companies, especially the foreign companies. The DPCO 1979 had also been subjected to criticism from industry side. The All India Manufacturers'
Organisation criticised this order from industry's angle. They objected to the lower mark-ups of 40 percent and 55 percent allowed on category I and II drugs. In fact many recommendations of this Organisation were incorporated into 1979 DPCO. The Organisation is of the view that the break-even mark-up for any size of industry should be 80 to 90 percent; for the sales promotion cost had greatly increased due to certain governmental regulations, increased salaries, travelling, printing and administrative costs. The average expenses were about 45 percent out of the mark-ups allowed for the manufacturers. And so, the mark-ups allowed on category I and II drugs in the Order would discourage drug companies from undertaking production of medicines falling under these categories. And this could result in a shortage of many essential and life-saving drugs.

In practice, the pricing mechanism has remained irresponsible to those changes made under the DPCO 1979. There were disturbing trends in drug prices. The index of drug prices (1970-71 = 100) stood at 191.7 in 1984-85 against 135.2 in 1979-80 an increase of 41% in five years. The average annual increase in the index of wholesale prices of drugs and pharmaceuticals during the Fifth Plan was 5.6 points which had gone upto 11 points in the Sixth Plan. It appeared that the production pattern and drugs prices in the industry did not reflect the genuine needs of the people.
The Drugs (Prices Control) Order: 1987

To correct the mistakes of the earlier drug orders, the government announced a New DPCO on 27 August 1987, replacing the DPCO of 1979. The new DPCO was intended to boost production of essential drugs, encourage domestic sector and curtail profits of the multi-nationals. In all, only 166 bulk drugs would be controlled. This decontrol followed from the government's conviction that a greater importance to market forces would result in higher production at lower costs.

The new DPCO 1987 permitted three options: 14% on net worth or 22% capital employed or in the case of new units; an internal rate of return of 12% based on marginal costing. The order also cleared the doubts about the concept of capital employed so as to remove the legal wrangles that might ensue later on.

The above review shows that various Drug Price Control Orders were responsive to the demands of both the industry and the consumers and so orders were changed and modified as and when needed. The result was that the prices of drugs were kept under reasonable control, without affecting adversely production.

Social Objectives of the Policy

An important aspect of Drug Policy has been to fulfil the social objectives of the country. Over the past few years, all governments have been expressing their commitment to extend health
care services to cover their entire population. The World Health Organization in its Alma-Ata Declaration has set the ambitious target of "the attainment by all people of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life."\footnote{106} The Alma-Ata Declaration defined primary health care as "essential health care . . . made universally accessible to individuals and families in the community . . . through their full participation and at a cost that the community and country can afford. It is within the framework of these primary health care services that medicines could be used most effectively as a part of a wider preventive strategy. The WHO in another report says that the overall social goal of health for all had to be broken down into more concrete social policies aimed at improvement of the quality of life and maximum health benefits to all.\footnote{107} If the gap between 'haves' and 'have-nots' was to be reduced, then it would imply the preferential allocation of health resources to those in greatest social need as an absolute priority, as a step towards attaining total population coverage.

The National Academy of Sciences observed that pharmaceuticals were an important component of modern medical technology and the majority of the low income population in rural areas and semi-urban areas did not have access to an adequate personal health services system or to the pharmaceuticals they needed.
Only a limited number of existing pharmaceuticals was appropriate for use and even those supplies were not available. The First Five Year Plan document has outlined its broad objective on health and said health is fundamental to progress in any sphere. In terms of resources for economic development, nothing can be considered of higher importance than the health of the people, which is a measure of their energy and capacity as well as of the potential man-hours for productive work in relation to the total number of persons maintained by the nation. For the efficiency of industry and of agriculture, the health of the worker is an essential consideration.

The ICMR-ICSSR in its study spelt out what was wrong with the drug production and what should be done to remedy it. The main recommendation of the report was that drugs required by the poor from social and economic angles, should be produced in adequate quantity and at the cheapest price possible. There was also need to prevent the production of high-priced useless drugs which were put on the market for making profits. They had a demonstration effect which involved the poor also and became an additional channel for their exploitation. The UNCTAD study concluded that in the planning of drug production in India, the pattern of diseases was not given enough attention. This had occurred because those 'patent protected' and 'branded' products earned a much higher profit margin than the generic products required by the poor.
Narayana in his study said that the pharmaceutical products were vitally important for human welfare and in the absence of adequate supply of medicines, the suffering of human beings afflicted by various diseases could not be effectively controlled. It was, therefore, described as a life-line industry, whose products could not be replaced or substituted. The World Health Organisation in its report observes that the pharmaceutical industry should provide complete and unbiased information on pharmaceutical products to consumers to respond to the need of developing countries for low-cost drugs of acceptable quality; and to the development of badly-needed new drugs in neglected fields, particularly to solve the health problems of developing countries.

According to Banergee, the health of the people was the basic input for national progress, economic, cultural and social development through productive mandays. Without taking into account the dismal socio-economic and health background, our deliberations on "Health Disease and Drugs" as a part of "National Drug Policy" or "National Health Policy" or "Health for All by 2000 A.D." could not achieve the desired results.

The National Health Policy statement has expressed the view that it was necessary to secure the complete integration
of all plans for health and human development with the overall national socio-economic development process. The contours of the National Health Policy has to be evolved within a fully integrated plan for framework which sought to provide universal, comprehensive health care services, relevant to the actual needs and priorities of the community at a cost which the people could afford to. Jayaraman explains that India's biggest problem was poverty and unemployment and their consequences—hunger, lack of personal and social hygiene, illiteracy, low per capita income, lack of adequate health care infrastructural and personnel, and of availability of modern drugs of proven efficacy and safety to the masses. It was in the last area that the drug industry was really involved.

Shiva and Alvares seem to feel that drugs were no solution to our problems of disease. For the majority of our population were suffering from malnutrition, unsafe drinking water and unhealthy living conditions. For the right to health to be real, these issues had to be tackled first. The country should change its priorities with more investment in supplying the population with clean drinking water, and we get increasingly involved in a curative system of medicine whose effectiveness decreased every year.

Duke's expectations are that the pharmaceutical industry has not only to be physically healthy but also socially
healthy by 2000 A.D.; a lot of changes need to take place. The industry should not expect to please all the people all the time; but at least some sections of the industry should be seen to be trying harder than they had done so far to please the weaker and needy sections. At the very least, people working in the industry should be as open as possible about their motives, activities and faults. This industry was a high-risk industry, which must deliver a high rate of return on investment, if that investment was to continue to be attracted and not directed into other fields of industrial endeavour; the return was currently and often higher and sometimes much higher than it needed to be. We had to strike a balance. If such a balance could be assured by the year 2000, we should have come a long way.

From the above review, we gather that the pharmaceutical industry could be spiritually and socially healthy only if it fulfils the following social criteria:

i) it should provide products which the community has a right to expect from it;

ii) it should provide these products at fair prices;

iii) it should avoid exerting an undue or unwanted influence on society;

iv) it has to be honest about itself;
v) it should be honest about its products;
vi) it should build a solid future for itself with new products and services; and
vii) it should maintain a healthy self-confidence and a clear conscience.

Availability of Essential Drugs

The World Health Organisation in its technical report says, "Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts." Fryers opines that prescription drugs must be available 24 hours a day for emergency purposes, and the wider the availability of home medicines, the more effectively they can play their role.

The choice of such drugs to be made available depends on many factors such as the pattern of prevalent diseases, the treatment facilities, financial resources, and genetic, demographic and environmental factors.

Jayasuria referring to the prevalence of common diseases in India says that the pattern of diseases varies from country to country. Appendix 3 shows the prevalence of some common diseases in India. For this reason, it is neither practicable nor feasible to have any kind of uniform list of drugs applicable to all countries. What is possible, however, is to prepare a
model or guiding list of essential drugs, on the basis of which countries can determine the minimum number of drugs they require. These lists need to be periodically reviewed and drugs added to or deleted from them, as necessary. The availability of drugs can be restricted by a mix of strategies rather than by a single method. In the past, most drugs laws provided for one or two methods, such as registration or import restrictions. But present trends in some countries indicate a move towards viewing the problem from a broad perspective with intervention at several different points.\textsuperscript{122}

Banerjee observes that in 1984, only 5 to 6\% of the people could afford modern drugs needed for their health care; another 25\% had access to modern drugs marginally or usually. About 70\% of people living in rural areas and urban slums, who are the principal victims of endemic and epidemic diseases had got no or only marginal access to treatment with modern drugs. This view has been supported by Iyer.\textsuperscript{124}

The Indian Drug Manufacturers' Association in its study "The Indian Drug Industry (1980-2000)" has analysed the level of consumption and the requirements of drugs in the country. The report says that the per capita drug consumption in India is expected to increase from Rs14.30 in 1980 to Rs76 by the
year 2000. To meet this increase in requirements, the industry will need to invest a total of Rs7,500 crores over the next 20 years. With the population expected to reach 960 million by the end of the century, drug consumption is anticipated to rise to Rs13,500 crores by then, assuming a 3% annual inflation rate, compared with Rs1,000 crores in 1979-80. Bulk drug requirements are likely to be at least 8 times greater than they are at present. The value of drug production will be Rs5,000 crores by 2000 compared with Rs200 crores in 1978-79, Rs325 crores in 1982-83; and Rs640 crores in 1989-90.

Shiva and Alvares, writing on the situation in India regarding availability of drugs, observe that there are over 60 million people with endemic goitre because of iodine deficiency and the drugs produced could meet only 20% of our actual requirements. There were 10 million TB patients in the country, out of which 2.5 million were actively infectious and 50,000 died every year. We produced only one-third of our minimum requirements of our anti-TB drugs and the production of cheaper anti-TB drugs is declining. While 1.5 million children died of diarrhoea in India each year, the availability of simple oral rehydration therapy was woefully insufficient. The target for cheaper drugs had gone up from 140 tonnes (1981-82) to 158 tonnes (1982-83), but the target for costly drugs like ethambutool
increased from 32 tonnes to 154 tonnes. In 1980, the production of vitamins, tonics, cough and cold remedies amounted to 23.5 percent of the market, whereas anti-microbials were a mere two percent and essential vaccines seven percent.

Above review reveals that the Government of India has tried, during the past four decades, to make essential drugs available to the people at prices which the poor can afford. But the actual situation is far from being satisfactory, in spite of some significant achievements.

Estimating the Future Requirements for Drugs

There are three studies which have attempted to estimate the future requirements for drugs. They are:

i) IDMA Estimates, 1980
   (Indian Drug Manufacturers Association)

ii) NCAER Estimates, 1983
   (National Council of Applied Economic Research)

iii) AFF Estimates, 1987
    A. F. Ferguson & Co; Government of India)

(i) IDMA estimates. The Indian Drug Manufacturers Association in its study on "Indian Drug Industry (1980-2000 A.D.)" estimated the growth of the industry during the next 20 years. The study provided two types of scenarios, namely, the "Trend Scenario" and "Preferred Scenario".
The "Trend Scenario" studied the future growth of the industry by 2000 A.D. based on the past trends making an allowance for certain constraints which are likely to persist. The assumptions are that the population would reach 960 million mark, and the ratio of urban and rural will be 26:74. The average life expectancy would be 58 years. National income would grow at a rate of 4% per annum and the per capita income would be Rs1,806. Rural health services would be inadequate with one primary health centre for every 40,000 population and one sub-centre for every 4,000 persons. The doctor-to-population ratio in urban areas would be 1:680 and 1:3400 in rural areas. Safe drinking water supply would be available in 50% of the villages and sanitation in 30% of the villages. Immunisation would cover 30 to 40% of rural population and 75% of urban population. On the basis of these assumptions, the demand estimates would be as under:

- the value of drug production (at constant 1977-78 prices) may reach Rs7,300 crores;
- the per capita consumption of drugs would be Rs76. The figures for urban and rural will be Rs176 and Rs40 respectively.

The assumptions made for the 'Preferred Scenario" are that the population would reach 880 million as family planning methods will be accepted by both rural and urban population.
The urban and rural ratio will be 30:70 and the average life expectancy will be 66 years. The national income will grow at a higher rate of 6% with the gradual removal of price controls and other restrictions on the growth of industries. The per capita income would be Rs3000. Rural health services will cover most of the rural areas, with one primary health centre for every 20,000 population and one sub-centre for 2000 persons. Immunisation will cover at least 90% of urban and 66% of rural population. Sanitation will be provided in 90% of the urban and 60% of rural areas. Based on these assumptions, the demand estimates would be:

- the industry would increase at a faster rate of 13% per annum by volume of production;
- the output of formulations would reach Rs13,000 crores at 1977-78 constant prices;
- the per capita consumption of drugs and formulations would increase to Rs190 in rural areas and Rs446 in urban areas.

The investment requirements of the drug industry would be Rs4,010 crores for bulk drugs and Rs3,560 crores for formulations. Appendix 3 would show the requirements of some selected bulk drugs as estimated by the IDMA.

(ii) NCAER estimates. The National Council of Applied Economic Research, on the basis of various assumptions and taking
into account three critical variables, viz., per capita income, per capita outlay on health and the employment in the organised sector, has estimated the demand for drugs in 2000 A.D. Data for these were assembled from various sources for the period 1960-61 to 1979-80 and deflated into 1970-71 constant prices with the help of wholesale price index for drugs and medicines. Based on the projected values of the variables and the coefficients obtained from the demand model, two alternative levels of demand for drugs were estimated by the NCAER as given below.

<table>
<thead>
<tr>
<th>Year</th>
<th>Alternatives I</th>
<th>Alternatives II</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980-81</td>
<td>1238.8</td>
<td>1217.5</td>
</tr>
<tr>
<td>1984-85</td>
<td>2162.0</td>
<td>2123.0</td>
</tr>
<tr>
<td>1989-90 (VII Plan)</td>
<td>4112.2</td>
<td>4030.7</td>
</tr>
<tr>
<td>1990-95 (VIII Plan)</td>
<td>8300.0</td>
<td>8132.0</td>
</tr>
<tr>
<td>1995-2000 (IX Plan)</td>
<td>15996.1</td>
<td>15667.8</td>
</tr>
</tbody>
</table>


It is evident from Table 1 that the production of medicincs has to increase at a cumulative rate of 14.4 percent per annum till 2000 A.D., if self-sufficiency in drugs is to be achieved.
(iii) AFF estimates. The Department of Chemicals and Petrochemicals of the Government of India carried out a study in 1987 covering 147 bulk drugs by Ferguson in terms of quantity and value by 2000 A.D. The long-term demand projections were made for each group and for each drug within the group. The requirements were estimated on the basis of the past consumption, availability of alternative drugs and advent of new drugs. Basing on these data, the study used a Regression Model and End Use Approach. The study had chosen 1984 as the base year and projected the consumption for the year 1990 and 1995 taking into account varying growth rates from 1984-1990; and 1990-1995. The targets for the base year 1988-89 were arrived at for 147 bulk drugs covering 24 therapeutic groups.

The demand projections of bulk drugs for the Eighth Plan Period were worked out on the basis of prices prevailing in 1979-80. Total value of demand for the VIII Plan was estimated to be Rs5,280 crores. Particulars for various years were as given in Table 2.

No country can become self-sufficient because of the greater degree of obsolescence of existing drugs and advent of new drugs. Imports are likely to continue even with the higher
### Table 2 Demand for Bulk Drugs

<table>
<thead>
<tr>
<th>Year</th>
<th>Value (in crores)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990-91</td>
<td>880</td>
</tr>
<tr>
<td>1991-92</td>
<td>960</td>
</tr>
<tr>
<td>1992-93</td>
<td>1045</td>
</tr>
<tr>
<td>1993-94</td>
<td>1140</td>
</tr>
<tr>
<td>1994-95</td>
<td>1,255</td>
</tr>
<tr>
<td>Total</td>
<td>5,280</td>
</tr>
</tbody>
</table>


Technological inputs available in the country. Therefore, the projected requirements for the Eighth Plan period would necessarily have to be supplemented by imports. The past trend and imports (Cif values) as percentage of total production of formulations in the country has been about 8 percent. Table 3 indicates the values of formulation production for respective years based on the landed cost of imported bulk drugs and the anticipated indigenous production.
<table>
<thead>
<tr>
<th>Year</th>
<th>Produced Cif</th>
<th>Produced Landed</th>
<th>Imported* Cif</th>
<th>Imported* Landed</th>
<th>Total</th>
<th>Anticipated value of formulation production</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990-91</td>
<td>625</td>
<td>255</td>
<td>510</td>
<td></td>
<td>1135</td>
<td>3405</td>
</tr>
<tr>
<td>1991-92</td>
<td>675</td>
<td>285</td>
<td>570</td>
<td></td>
<td>1245</td>
<td>3735</td>
</tr>
<tr>
<td>1992-93</td>
<td>730</td>
<td>315</td>
<td>630</td>
<td></td>
<td>1360</td>
<td>4080</td>
</tr>
<tr>
<td>1993-94</td>
<td>800</td>
<td>340</td>
<td>680</td>
<td></td>
<td>1480</td>
<td>4440</td>
</tr>
<tr>
<td>1994-95</td>
<td>880</td>
<td>375</td>
<td>750</td>
<td></td>
<td>1630</td>
<td>4890</td>
</tr>
</tbody>
</table>

*excludes the value of intermediates/chemicals.

NOTES

8 Marckwardt, op. cit., p. 388.
9 Mukkarram Bhagat, op. cit., p. 57.
10 WHO, op. cit., p. 50.
11 VHAII, The Rational Use of Medicines, p. 5.
12 Ibid., p. 12.
13 Marckwardt, op. cit., p. 526.
17 Ibid., pp. 10-11.


30. Ibid.


33. UNCTC, Transnational Corporations in the Pharmaceutical Industry of Developing Countries.


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46 Fryers, op. cit., p. 78.


48 Mukarram Bhagat, op. cit.

49 Narayana, op. cit.

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ICSSR-ICMR, op. cit., pp. 177-178.


Ibid., p. 11.


Mira Shiva and Claude Alvares, Health, Voluntary Health Association of India (1983).


Langrana, op. cit., p. 47.


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96 Ibid., p. 7.


100 Government of India, Ministry of Industry, Drugs (Prices Control) Orders, 1970.
103 Satwinder Singh, op. cit., p. 168.
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