CHAPTER I

INTRODUCTION

Health and human development form integral components of the overall socio-economic development of a nation. For no nation can hope to develop fast economically, if majority of its people are poverty stricken, undernourished, afflicted by diseases of all kinds, and the death rate at all levels is very high. Development of a country, therefore, should first and foremost mean ensuring the good health care of its people; and hence public health care is now recognised as a basic and fundamental right of the people. Its attainment has become very much a social responsibility.

An essential element of health is that medicines, particularly the essential and necessary drugs, are made available to the poor easily at reasonable prices, so that these people and others can easily care for their health needs without undue stress and financial burden. However, supply of medicines remains nearly exclusively today in most countries including India in
the hands of private industry. There is thus a conflict of interests between the social interests of governments, very much intent on providing health care services to all the people at costs they can afford and those of the drug industry pursuing all the time the goal of increasing drug sales, market sales and profits. In this context, it is incumbent on every country to formulate drug policies such that they combine the economic goals of drug manufacturers and its own social objectives. The present study wishes to evaluate the Indian drug policy and examine how far the twin objectives have been achieved in India.

Global Focus on Drug Policies

Drug policies have been the subject of continued concern to governments and international organisations, as evinced by the actions and deliberations of the World Health Organisation (WHO) and United Nations Conference on Trade Organisation (UNCTO). Till 1950, the World Governments were mainly concerned with ensuring the quality of drugs and the drug industries' compliance with specifications and methods for the analysis of active components of drugs. In the early 1960's, public attention focussed on the study of drugs and on the possibility of unforeseen interactions between drugs and human body. In the early 1970's, the socio-economic aspects of pharmaceuticals gained importance with the increasing expenditure on drugs and pharmaceuticals.
In due course, Governments became involved in issues such as over prescription and over consumption of drugs and fair prices of pharmaceutical products, and there was a search all over the world for ways and means of making the most essential drugs available to people with low purchasing power. Thus evolution of drug policies moved from technical and clinical aspects of pharmaceuticals to economic and social aspects, including social justice in drug production, distribution and marketing and appropriate allocation of resources for pharmaceutical expenditure.\(^2\)

The aim of developing national drug policies is to improve the efficiency of the pharmaceutical supply system through clear definition of objectives and the coordination of its different components. And the main objective of a national drug policy should be to render accessible to people most effective and safe pharmaceutical products of established quality at fair prices. There is, therefore, the need to plan and review the pharmaceutical supply system as a whole in the light of this objective.\(^3\)

Drug Policies

Drug policies vary from country to country. It is not uncommon to find drug policies being directed mainly towards industrial and trade development. In some countries, a strong domestic pharmaceutical industry is an important national asset
because it not only constitutes a vital component of the health care system, but is also a source of revenue and of foreign exchange. In most countries the greatest concern is the social objective of providing drugs for all, and at prices within the reach of the poor who form the bulk of the population. And so, a multi-sectoral approach to drug policy formulation and cooperation is required because while one aspect of national drug policy would concern itself with the regular and steady supply and distribution of quality and low cost pharmaceutical products, another aspect would concern with the production and export of drugs and also with technological advancement and development of the pharmaceutical field. 4

A significant development took place in 1977. The 30th World Health Assembly adopted a resolution proclaiming that the main social target of the World Government and WHO should be the attainment of 'Health for All' by the year 2000, at a level which would permit them to lead socially and economically productive lives. The provision of essential drugs was thus recognised as a vital component of the global strategy to achieve 'Health for All by the Year 2000'.

This ambitious goal was to be achieved through Primary Health Care, as discussed by the International Conference on Primary Health Care held in Alma-Ata in 1978. The conference strongly reaffirmed that
health is a state of complete physical, mental and social well being . . . it is a fundamental human right . . . the existing gross inequality in the health status of the people, particularly between developed and developing countries as well as within countries, is politically, socially and economically unacceptable and is, therefore, of common concern to all countries.\textsuperscript{5}

To achieve the goal of health for all by the year 2000, a strategy need to be incorporated in the policy. Those drugs and vaccines which have the potential to ensure enormous health benefits for a large number of people, need to be supplied in adequate quantity; they should be of good quality, available at prices which are within the reach of the poor and common people. The policy strategy should contain the above elements in it. And so Fattorusso rightly remarked

many essential drugs which are largely the result of drug research and development within the pharmaceutical industry are at present beyond the reach of a high proportion of potential consumers. . . . Success cannot be achieved by the health technicians alone, nor by the industry alone, nor by regulatory action alone . . . tangible advances can be made if the commitment is accepted.\textsuperscript{6}

Thus there are two major considerations in drug policy for developing countries. One is the access issue, which is to say that people of those countries should have access to
essential drugs. Such access requires that drugs are available, in appropriate quantity, at costs those countries can afford and that there is a distribution system that ensures availability at the social and geographical periphery. The second major issue concerns the role of industry in pursuing research and development of drugs needed in less developed countries; making essential drugs available at reasonable prices and assisting developing countries in instituting the necessary quality control and establishing logistic distribution systems.

As Bryant points out that there are many important aspects to a drug policy—social, technical and political, it is socially important in the context of WHO's goal of "Health for All by the Year 2000," already referred to above. It is technically important as the range of technology involved is very wide, from research and development on pharmaceuticals to the management of infrastructures to ensure the distribution of essential drugs. And it is politically important as decisions by governments to extend services to entire populations call for shifts in resources and power within their countries that can only be accomplished through political commitment. There are other aspects to the same question. According to Mahler, a former Director-General of the World Health Organisation, the question was not merely technical and political but also ethical, on involving governmental
responsibilities as well as the global social responsibility of the pharmaceutical industry with regard to both the availability of existing essential drugs and the development of better ones.  

The Indian Context

The present study concerns the Indian Drug Policy and so the Indian context and policies need to be briefly reviewed. The Constitution of India envisaged the establishment of a new social order, based on equality, freedom, justice and the dignity of the individual. It aimed at the elimination of poverty, ignorance and ill-health and directed the State to regard the raising of nutritional standard of living of people and the improvement of public health as among its primary duties and securing the health and strength of workers, specially ensuring that children are given opportunities and facilities to develop in a healthy manner. The successive Five Year Plans provided the framework within which the Centre and States developed their health services infrastructure. Central legislations had been enacted to regulate standards in the manufacture and sale of certified drugs. However, it is felt that an integrated, comprehensive approach towards the future development of health services needs to be established to serve better the actual health needs and priorities of the country. This is the context and background of India's National Drug Policy.
After extensive deliberations, the Planning Commission concluded that provision of basic health is fundamental to progress in any sphere in India. In terms of resources for economic development, nothing is considered of higher importance than the health of the people, which is a measure of their energy and capacity. Various plan documents had continued to emphasise the primacy of providing basic health needs to the people and this was required for the full development of the country and its people.

In spite of this emphasis, the expenditure on health care in India as also in many developing countries had been below two percent of the GNP. Annual Government budget allocation for health care remained generally very meagre as it was mostly directed towards control of specific diseases, unrelated to the total environment of the country. Production of pharmaceuticals in India is sufficient to meet the needs of just one-fifth of its population. The vast rural population is left untouched by modern medicines and it is forced to rely mostly on the traditional and often unsafe methods of medicine. What is more, the prevailing price control has failed not only to ensure reasonable prices for the poor, but also reasonable returns on investments for the industry.
In the Indian pharmaceutical field there are both private and public sector units, the former consisting of indigenous, and foreign and multinational corporations. Among the indigenous industries, some of them are engaged in producing indigenous medicines. The industry is very much controlled by various policy enactments after the independence of India. As Divatia points out, it is necessary that this industry should be given a special status and consideration instead of treating it like any other industry. Management of the pharmaceutical industry requires not only business skill, but also a good amount of professional skill in taking correct decisions to ensure the availability of drugs at the right time, at the right place and of the right quality.\textsuperscript{12}

The Focus

As an attempt to ensure this question, the present study proposes to evaluate the success of Indian Drug Policies with special attention to the two recent policy enactments viz., one announced by the Government of India in 1978 on the basis of the recommendations made by the Hathi Committee of 1975, and a revised Drug Policy enactment of 1986. These two policy enactments were meant to regulate and govern the pattern of production in the country. The first policy was based on the Industrial Policy Resolution of 1956 which set the tempo for industrialisation,
with emphasis on self-reliance. Briefly stated the main provisions were--

i) self-sufficiency in the output of drugs;

ii) reduction of the quantum of drugs imported;

iii) ensuring availability of drugs in abundance; and

iv) ensuring reasonable prices for consumers so that the health needs of the people are met adequately.

The 1986 policy had the following main provisions--

i) to increase the availability of essential and life-saving drugs of high quality at reasonable prices;

ii) to strengthen the quality control and promotional system;

iii) to create a favourable climate to attract new investments and to introduce new technologies into the industry; and

iv) to increase the capacity of indigenous production.

Thus, the thrust of the two policies is to encourage the growth of the pharmaceutical industry, with such regulations as to serve the social objectives of quality control, adequate supply and reasonable prices of drugs. How far this aim has been realised? An attempt to answer this question warrants an impact analysis which would mean an objective evaluation of the performance of the policies. In other words, it is a study to understand the extent to which the policy output has accomplished its stipulated goals. The present study is such an attempt.
Objectives

Therefore, overall objective of this study is to evaluate the impact of Indian Drug Policies on the performance of the pharmaceutical industry of the country. Specific objectives are:

i) to analyse in depth the philosophy and content of the two drug policy statements (of 1978 and 1986) to delineate their goals;

ii) to examine the trends and the pattern of drug production over the period from 1975-76 to 1989-90;

iii) to investigate whether the performance of the industry conforms with the goals of the policy; and

iv) to identify constraints if any in implementing the policy with a view to suggesting changes if any needed to improve the impact of the policy.

Hypotheses

In the context of the above objectives, it is hypothesised that a public policy could influence the production, supply, demand and the price of pharmaceuticals only under certain helpful conditions. These pre-conditions include a clear statement of goals and objectives, a sound strategy for achieving them, a positive commitment of all parties concerned, namely government, producers and distributors to implement the policy. It is also essential to have an appropriate administrative mechanism to direct and monitor the working of the policy and substantive rewards (incentives) for implementing the policies, and punishments for violating the policies. More specifically the hypotheses are:
1. The two Policy statements of Government of India in 1978 and 1986 provide consistency between the social objectives of the government and interest of the drug industry. Therefore, profit motive of the producers does not work against social objectives.

2. The trend in the production of drugs in India from 1975-76 to 1989-90 is sufficient to keep pace with the growing demand for the drugs.

3. There is fairly reasonable control over prices for essential drugs to keep them within the reach of the poor.

Scope

The study makes first an objective review of provisions of the Drug Policy of 1978 and 1986 covering criteria of production, adequacy of pharmaceutical products, prices and definitions of related concepts.

Secondly, the study presents a review of drug policies and their relevance for the 15-year period from 1975-76 to 1989-90. The study of production, sales and price of all pharmaceutical products in the country assesses the trend in supply and its adequacy.

Thirdly, an attempt is made to compare the two drug policies and analyse their implications for successful implementation.
Finally, the thrust of the study would be to help policy makers rectify the deficiencies, if any, so as to best serve the interests of socio-economic and physical well-being of the people. Through a close understanding of the limitations and constraints of the present drug policy, it should be possible to plan result-oriented policies which would be compatible with the nation's declared policies.

Limitations

Since the unit of analysis is the pharmaceutical industry, which itself is an organised industry, institutional data has been depended on. The researcher has not much control over the quality, and veracity of the data. The findings and conclusions should be viewed in the light of this limitation which is stated explicitly to place this study in its proper perspective. However, this does not restrict a detailed in-depth analysis of the problems covered by the study. An important limitation concerns published data. While value of production is readily available for 30 or 40 years, data on quantity produced is not easily available. With some difficulty, the researcher was able to search and find data for 15 years only.

Plan of the Thesis

The thesis is organised in nine chapters as follows:

Chapter I General introduction, global focus, statement of the problem, objectives and hypotheses of the
study, the scope and limitation of the study.

Chapter II Concepts used in the present study along with an overview of previous studies.

Chapter III The profile of the Indian drug industry

Chapter IV Methodology

Results of analysis are presented and discussed in the next four chapters.

Chapter V Drug Policy Content Analysis

Chapter VI Drug Production and Prices

Chapter VII Trends and Projections

Chapter VIII Other Performance Measures

Chapter IX Conclusion and Implication
NOTES


4. Ibid., p. 1.


