PREFACE

The work on "Legal Protection for Consumers of Pharmaceutical Products" is undertaken to study the legal framework that is existing for this purpose and the functioning of regulating mechanism that is envisaged under it. The purpose of the study is to analyse how far these measures are effective in adequately protecting various aspects of consumer interest. Methodology adopted for the study is analytical. The statutory provisions, rules framed and case law under these provisions have been examined. Wherever it is necessary, a comparative study of the provisions of developed countries like the United Kingdom and the United States of America is also made.

The provisions of relevant international conventions and agreements such as European Convention on Human Rights in Bio-Medical Research on human beings, Helsinki declarations, guidelines of World Health Organisation and provisions of Trade Related aspects of Intellectual Property Rights agreements have been studied. The data provided by the government departments and enquiry commissions appointed by the government is also analysed. The reports of the enquiry committees like Hathi Committee on pharmaceutical products and industry and Lentin Committee which enquired into the incidents of J.J. Hospital Bombay have been studied for the purpose of this study. The whole study is devided into various chapters in the following manner.

At the outset, it is thought appropriate to study the assumptions of freedom of contract since the roots of any consumer protection lie in the law of contract which is based on freedom of contract. The historical background of the legal
controls on drugs and the meaning of the "Consumer of Pharmaceutical Products" is also projected in the introduction chapter i.e. Chapter I.

An attempt has been made to study production pattern of the pharmaceutical industry and the needs of its average consumer in the Chapter II. The need to prepare and use the essential drugs list on the guidelines of World Health Organisation and Hathi Committe report is underlined. The legal incentives for those who produce, sell and prescribe are stressed.

There is need to ensure that new drugs are marketed at the earliest to save those suffering from terminal diseases like AIDS and Cancer. At the same time it is also necessary to protect the public from unsafe drugs being marketed by over ambitious manufacturers. Chapter III, deals with the regulations on marketing of new drugs. Clinical trial procedure of the U.S. are also examined here. The need for legal protection to the clinical trial subjects in the light of international conventions are also underlined.

The impact of the patent system on interests of consumers of pharmaceutical products is studied in Chapter IV. The Provisions of Patents Act 1970 and its predecessor legislation dealing with drugs have been analysed in this context. Impact of the present globalisation process particularly of the TRIPS agreement in GATT on the pharmaceutical consumer is studied. Provisions of Patents Bill 1995 are also studied in this chapter.

Pharmaceutical Products involve complex mixture of ingredients. It is very difficult for a consumer to judge their quality. The Drugs and Cosmetics Act 1940 and rules framed under it provide for quality control measures. The Act sets standards of safety, potency and efficacy. It defines what is misbranded, adulterated
and spurious and provides powers for the regulatory authorities to enforce those standards. The Act mainly relies on penal provisions for this purpose. Chapter V deals with all these aspects. The need for provisions for civil liability for the manufacturer and compensatory mechanism for the victims of drug injury is also probed in this chapter.

The price of any commodity is an important concern for any consumer. The price controls on drugs have been made from time to time through drugs price control orders framed under Essential Commodities Act. Chapter VI deals with the study of these provisions. The study noted the advantages of these provisions to the consumer in controlling the prices of the drugs and deficiencies in its approach. The formulae envisaged under the provisions was considered to be cumbersome, complex and inadequate to meet the purpose. The possibilities of other means to control the prices of the drugs are also probed in this chapter.

Advertising is a means of communication between seller and buyer. It is supposed to be factual, informative, honest in content and clear in presentation. A phenomenon known as 'high pressure' sales advertising has born out of keen competition among manufacturers of goods of same utility. Chapter VII is a study of the legal provisions providing for the control of advertisements in pharmaceutical business. Drugs and Magic Remedies (Objectionable) Advertisements Act 1954 and rules framed under it is the main legislation dealing with drug advertisements. In addition to this, there are provisions in Drugs and Cosmetics Rules, 1945 which deal with labelling and other information to be supplied by the manufacturer. Provisions in MRTP Act, 1969 and Consumer Protection Act, 1986 dealing with unfair trade practices also intend to govern advertisements in general. The study in
this chapter covers all these areas. With the support of little case law available, an
attempt is made to understand the concept of misleading advertisement in this
chapter.

Drugs are not like ordinary commodities whose sales can take place anywhere
where and can be effected by any person. The sale, purchase and compounding of
medicines are activities subject to regulations in public interest. The general
framework of law for this purpose of regulation lies in the system of licensing. It is
administered by the regulatory agencies under Drugs and Cosmetics Act 1940 and
rules formed under it. The chapter VIII of this work deals with the study of these
provisions. The liability aspect of the seller for injuries arising from the sale and
distribution of drugs is also studied in this chapter. The safety measures in
procuring, storing and facilities to be provided in blood banks also examined since
the ‘blood’ and ‘blood products’ are also included under the control system In this
context, a recent Supreme Court decision, Common Cause v. Union of India,
dealing with safety measures in blood banks is also studied in this chapter.

Basing on the study conducted, certain conclusions are drawn. These
conclusions are summarised in the last chapter, that is chapter IX. Some
suggestions and observations are also made here basing on the whole study.

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