CHAPTER I
INTRODUCTION

A premier research organisation in the field of medicine had reported that “India is producing and marketing hazardous, non-essential and useless drugs much more than it is producing essential, necessary and life saving drugs\(^1\). In India, there is an over consumption and misuse of drugs on the one side and blatant lack of even few life saving drugs in slums and rural areas on the otherside\(^2\). According to one report, the Indian market is flooded with more than 60,000 drug formulations and combinations. Many of them are identified to be irrational and hazardous\(^3\). World Health Organisation stated that approximately half the World’s population still lacks regular access to the most needed essential drugs. It is estimated that over 60 percent of the developing world does not have regular access to basic drugs\(^4\).

A newspaper reported that fungus, that can cause instantaneous death was found in a drug and glucose was found contaminated at the two

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\(^1\) Statement of Indian Council for Medical Research quoted in Indian Express, Oct. 25, 1989.


\(^3\) Irrational drug is not defined. It generally means a drug that has more ingredients than are strictly necessary. When these extra ingredients have a harmful impact, the drug is hazardous. These superfluous ingredients are added to impart an additive value and usually pander to the consumer’s notion that a “strong” drug is the most effective one. See Indian Express, (Bombay) Oct 23, 1989.

most reputed medical institutes in the capital city of India. Manufacturers of drugs are involved in indecently aggressive marketing activity. They are said to have been rigging up prices to levels which have no relation to the costs of production. And still worse is the statement issued by the drug control administration. It says:

"The drug control organisation at the central and state levels...is woefully inadequate to monitor the quality and regulate the production and sales of the rational and safe drugs...".

All the above reports and statements are made by the organisations or individuals who are most concerned in the field of drugs and medicines. These actually reflect the problems faced by consumers of pharmaceutical products. These statements reveal the stark realities about production, distribution, pricing, and marketing of drugs. Helplessness in which drug control authorities are placed in the country is also reflected. The focus of attention will naturally be on these and other related aspects in any study on the 'protection for consumers of pharmaceutical products'.

'Legal Protection for Consumers of Pharmaceutical Products' is a study of the legal framework that is available for this purpose and the functioning of regulating mechanism that is envisaged under it. The

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7 Dr. P.K. Gupta. Drug Controller of India, in a circular issued by him on 22-4-1989 quoted in *supra* n.5, at p. 9.
effectiveness of these measures in adequately protecting the various interests of the consumer in this area is also probed.

It is appropriate in this context to study the relevancy of various assumptions of freedom of contract in protecting consumers. The historical background of the legal controls on drugs is also examined here. An attempt is also made to identify the meaning of the term, ‘consumers of pharmaceutical products’ in this chapter.

The prime object of consumer law is to protect the weak from the strong and the individual from the organisation. An individual is by definition weak compared with the combination of individuals who make up an organisation. More so if such organisation is a trading company. Even in his dealings with another individual who happens to be a trader, like a shopkeeper, the individual consumer is in a weaker position. He generally lacks the expertise of the trader who, day in and day out, consistently does the same job.

The law relating to consumer protection was considered to be a branch of private law and in particular a part of contract law. Contract law is based on individualistic philosophy of the 19th century. Assumptions of freedom of contract are offsprings of this philosophy. An analysis of these assumptions may enable us to understand the need for protection of consumer in general and pharmaceutical consumer in particular.
An analysis of the assumptions of freedom of contract theory

Because of the fact that most contracts originate in an agreement, the essence of contract was said to be the meeting of the wills of the parties and agreement was the outcome of the free and consenting minds. The reasons for this doctrine are many. One such reason was the great emphasis that had been placed in the political philosophy of the 18th century on the concept of human liberty.

According to this philosophy every man should be free to pursue his own interests in his own way. It was considered to be the duty of the law to give effect to the wills of the parties as expressed in their agreement. It was asserted that, as few restrictions as possible should be placed upon 'freedom of contract'. This view finds expression in Adam Smith's Wealth of Nations.8

Freedom of contract on whatever terms might seem most advantageous to the individual became the cornerstone of 19th century laissez faire economics. Henry Maine's postulation that 'the movement of progressive societies had hitherto been a movement from status to contract' was considered as a victory statement of the champions of individualist social philosophy9. Therefore, it was considered as the requirement of the public policy that men of full age and competent understanding shall have

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the utmost liberty of contracting and that their contracts when entered into freely and voluntarily shall be held sacred and shall be enforced by the courts of justice. Their assumptions are that man is a rational maximiser of satisfaction and free market provides sufficient competition among the producers to the advantage of the consumer. It is said that consumers can discipline the producers by rejecting bad quality, high priced and dangerous goods and to survive competition, producers will come with good quality, low price goods with proper design and mark. They argued that consumers are the best judges, not the Government, of the quality and efficacy of the goods.

 Limitations of the theory

This analysis is subject to strong qualifications\(^\text{10}\). Generally speaking, it fails to take adequate account of the severe deficiencies in the operation of market and bargaining capacities of consumers. Based on questionable premises, the conclusions drawn by this theory are considered demonstrably inaccurate\(^\text{11}\).

The legal protection for consumers does not work in the abstract or in a vacuum. It must relate to the reality of the market in which it is meant to operate. One has to have regard to the economic environment in which the


\(^{11}\) *Ibid.*
protection operates. It is a fact that many economists in the 19th century itself recognised oligopoly as a prevalent form of market organisation.  

(a) Consumer sovereignty: A myth

Many consumer products are complex and it is unreal to think that consumers can protect themselves. The technicalities of the products are such that it is often impossible to ascertain the quality of the product. The industrial revolution has primarily been responsible for proliferation of human needs in respect of goods and services. Today few of us will opt for firewood in place of gas or bullock-cart for a car or a motor cycle or traditional ayurvedic treatment or nature's cure in place of allopathic treatment. With the emergence of technical goods with unknown components, the assumption of caveat emptor became unreal in most cases.

(b) Market imperfection:

Another assumption of the free market is that competition among sellers generates product information for consumers. This assumption, however, fails in the face of the current advertising practices. Modern advertising does not function in a competitive manner. It rather, in a superficial way, presents only the advantages of a product and not the disadvantages of those marketed by competitor. It frequently excludes or

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distorts information which consumers need, such as useful information about value and performance. Competitors may fail to publicize damaging information about another partly due to fear of retaliation.

(c) Market not unbiased:

Another false assumption of the ‘free market’ theory is that it assumes that market is unbiased. It failed to take into account the distribution of wealth and power. In fact, market is not unbiased. Quite often it favours the powerful and wealthy\(^4\). It treats unequals equally by putting business on the same footing as the consumers. It allows the stronger to dominate the weaker. The reality of standard form of contracts is not of competing sellers offering favourable terms to consumers but of consumers being forced to accept contracts with disadvantageous terms.

Therefore, the concept of ‘freedom of contract’ is to be seen in a different perspective. ‘Freedom of contract’ is a reasonable social ideal only if there is equality of bargaining power between contracting parties, and no injury is done to the economic interests of the community at large. In the more complicated social and industrial conditions of a collective society, it has ceased to have much idealistic attraction. It is now realised that economic equality often does not exist in any real sense. Individual interests have been made to subserve those of the community. Hence, there is a

perceived change both in the social outlook and in the policy of legislature
towards contracts. Hence the law today rightly interferes at numerous points
with the freedom of the parties to make what contract they like.

The need for State’s intervention for protection of the weak

The purpose of this interference is obviously, to offer protection to
the weak and to provide some balance. Thus the relations between employer
and employed have been regulated by statutes\(^\text{15}\) designed to ensure that
employees’ conditions of work are safe, he is properly protected against
redundancy; he gets due remuneration and other benefits and that he knows
his terms of service. The public has been protected against economic
pressures such as high rents, unreasonable prices, and unfair trade practices.
Separate legislation\(^6\) were enacted and rules were framed under these
enactments to protect the weak against such pressures.

This interference is necessary especially today when most contracts
entered into by ordinary people are not the result of individual negotiations.
It is not possible for a private person to negotiate and settle the terms of his
agreement with Indian Railways, Electricity Boards, Gas Board Authority,
or with a Multinational Pharmaceutical Company. In all the contracts with
any of these and other entities, the standard form of contract is the rule. He
must either accept the terms \textit{in toto} or go without. Since it is not feasible to

Restrictive Trade Practices Act, 1969, etc.
deprive oneself of such necessary goods and services, the individual is compelled to accept those terms. In view of these facts, it is quite clear that freedom of contract is now largely an illusion.\(^{16}\)

**Court's intervention**

Courts in India have also made their contribution in this progressive path to help the weak against the strong. They supported and sustained those progressive legislation when they were attacked on the ground that the legislation were nothing but unreasonable restrictions on the freedom to carry on trade and business. For instance in *Diwan Sagar and General Mills v. Union of India*,\(^ {17}\) the sugar control order empowered the Central Government to fix the maximum price at which sugar might be sold. Several factors were to be taken into account by the Government before fixing ex-factory price of sugar on the ground that it would not bring about inequitable distribution of this essential commodity at a fair price. With regard to the reasonableness of price fixation procedures, the Court observed that if all the relevant economic factors were taken into account and the price fixed was not less than actual cost of production, it could not be struck down as unreasonable restriction on the freedom to carry on trade and business.

\(^{16}\) It may be noted that with the introduction of new liberal economic policy from 1992, there is a scope for resurgence of the principles of freedom of contract. Legislation framed subsequent to the introduction of the new economic policy reveal that the state is disinclined to interfere into the contractual relation of the parties thereby giving impetus to the freedom of contract theory.

\(^{17}\) A.I.R. 1959 S.C 627.
Again in *Shree Meenakshi Mills v. Union of India*, the Court disapproved the tendency of keeping the profit and producer's return in the forefront on fixation of a fair price at which an essential commodity would be made available to the consumer. Chief Justice Ray concluded that fixing of controlled price was not aimed at giving a fair price to the producer but to hold the price line and make available the essential commodity to the consumers at fair price. He further observed that it was not shown here that the controlled price was so grossly inadequate that it not only resulted in huge losses but also a threat to the supply position of the commodity.

Instances of Court interference are also available when the Court struck down the unreasonable clauses in the standard form of contract again either to protect the employee in a contract of employment or a consumer in a contract of sale of goods. Courts adopted many devices to enable itself to come to the rescue of the weak contracting party. Where the parties are not economically on equal footing and there is a wide gap in the bargaining power of the parties, and one of them is in a position to exploit the other, the contract made with that other is often considered apparently unfair. For example the Supreme Court in *Central Inland Water Transport Corporation v. B.N. Ganguly*, held that a corporation imposing upon a needy employee a term that he can be removed just by three months notice or pay in lieu of

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notice and without any grounds was an exploitation. According to the Court
every ruthless exploitation is against public policy\(^{20}\).

Judiciary adopted many techniques for the purpose of effectively
protecting the consumers. These include relaxation of the *locus standi* rule\(^{21}\)
purpose interpretation of the Constitution and beneficial interpretation of the
existing legislation\(^{22}\). The above discussion reveals that the Courts are not
lagging behind in its endeavour to protect the weaker one under law whether
he is consumer or party to the contract in a weak bargaining position.

**Relevance of freedom of contract to consumer of Pharmaceutical
Products**

The consumer of a pharmaceutical product is weak when compared to
its manufacturer and distributor. He is in a still disadvantageous position
because of the complexity of the medical product and lack of choice for him
to buy the medicine of his choice. Medicines are complex mixture of
chemical ingredients. Only the experts in the field can ascertain its quality
and usefulness. Apart from this, he has to buy the medicine prescribed by
the doctor in most occasions. Hence the scope for 'free will' and 'rational
judgement' as contemplated under principles of freedom of contract are
conspicuously absent in the case of consumers of pharmaceutical products.

\(^{20}\) *Id.*, p. 1615.

\(^{21}\) See *Vincent v. Union of India, A.I.R. 1987 S.C. 990*; *Common Cause v. Drug Controller of

\(^{22}\) See Dr. A.M. Varkey, "Judicial Activism to Promote Consumer Protection", (1997) C.U.L.R.
In a perfect market condition the price of a commodity is to be determined by the principle of demand and supply. There is no possibility for such price variations depending upon the demand and supply here, because the purchase is made based on the prescription. The question of abstaining from buying the product does not arise because the prescriber is insulated from the cost or price of the medicine as he is not paying from his pocket. Hence there is no wonder if the price of the medicine do not come down inspite of the sufficient supply and low cost of production. Hence, free market theory may not be of much help to the consumers of pharmaceutical products.

In addition to this the socio-economic conditions of most of the consumers make them more vulnerable to their counterparts in this area. Almost three-fourths of the population live in villages. They live in poverty and environmental deficiencies like poor sanitation facilities. Poverty in turn largely accounts for malnutrition. They confront with endemic diseases like malaria, tuberculosis and non-sexually communicable diseases. Because of their immobility and low literacy rate, this rural consumer is not exposed to tricks of the trade so that he could protect himself from the manipulative techniques of the trader. In a setting of this kind it is not surprising to find that widespread adulteration of food and drugs and sale of spurious drugs take place. Because of illiteracy, they indulge in self-medication or become easy prey to quacks without knowing the serious consequences on their health.
Hence the need for separate legislative measures to protect the gullible consumer in this area. Any such legislation framework should ensure safety of the medicines produced or marketed by import, rational selection in the production and distribution of the drugs, availability at reasonable prices, and responsible marketing or advertising procedures. The legislation should be accompanied by a plan of action for implementation with adequate enforcement measures. The policy on intellectual property protection must also be seen in conjunction with this comprehensive outlook of the subject.

In this background it is appropriate to study the drug control legislation from its historical perspective so as to understand these provisions in a better manner.

**History of legal controls on drugs**

Drugs are subject to control all over the World since these directly concern the health of people, especially the ill and ailing. Legislations have therefore been made to regulate their import, production, distribution, pricing and advertisement in public interest in developed as well as developing countries.

**Development of legislation in England**

In England, a Select Committee of the House of Commons considered the evidence about abuses in the preparation of drugs, their poor quality, incompetence of many pharmacists and the insufficiency of powers given to
the authorities to authorise the destruction of adulterated drugs in 1847. In 1856 another Select Committee found that the public health is endangered by the use of several of these compounds. It recommended the registration of chemists and druggists. Pharmaceutical chemists were already registered under the Pharmacy Act, 1852, which provided for examinations for those wishing to register and prohibited persons who were not duly registered from assuming the title of pharmaceutical chemist. Legislation in 1868 extended the examination and registration requirements to those who compounded the prescriptions of medical practitioners.

Apart from these requirements there were few restrictions on the sale of drugs. There were broad provisions of Food and Drugs Acts that drugs were not to be injurious to health and were to be of the nature, substance and quality expected by the normal consumer. Adulteration of Food and Drugs Act, 1872 made it an offence to sell food and drugs which contained injurious material and which was adulterated or not pure. All counties and boroughs were required to appoint analysts while market inspectors were given powers to enable samples of food and drugs to be acquired from suspected traders. There were, however, weaknesses in the legislation and numerous disputes between traders and public analysts concerning what

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24 Ibid.
constituted an adulterant and what was an acceptable ingredient. In 1874 a Select Committee was established to examine the Act in detail and to make suggestions for change. The outcome of the Select Committee report was a new Act called the Sale of Food and Drugs Act 1875. This Act was generally recognised to be the first substantial legislation. This law provided for criminal sanction and imposed strict liability.

However, the Act was only concerned with adulteration and gross contamination. In 1928, the Sale of Food and Drug Act 1875 was repealed by consolidation with other measures into the Food and Drugs (Adulteration) Act, 1928. But the main provision of the 1875 Act remained unaltered.

The next significant step came in 1938 when public health measures were combined with food and drugs legislation in Food and Drug Act 1938. This Act strengthened the drugs regulation. It introduced penalties for false or misleading labels and advertisements. The provision was especially important because there was a significant problem of false labelling. It introduced powers to the ministers to make regulation to control both composition and labelling of food and drugs.

Before enactment of the Medicines Act 1968, the legislation dealing with therapeutic substances and medicinal products fell into four classes. The first category included those substances, the purity and potency of which cannot be tested by chemical means. Part I of the Therapeutic

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26 Ibid.
Substances Act, 1956 and regulations made under it controlled the manufacture, importation and sale of these substances. These activities relating to such substances were generally prohibited except under licence. Pencillin and other therapeutic substances constituted the second category. These are capable of causing danger to the health of the community if used without proper safeguards. Part II of the Act of 1956 controlled the sale, supply and administration of these substances and were in general prohibited except by qualified person or other persons under their direction. The third category concerned substances used for veterinary purposes. The purity and potency of these substances cannot adequately be tested by chemical means. Their manufacture, importation and sale were controlled by part II of the Diseases of Animals Act, 1950 and orders made under it. These activities were in general prohibited except under licence. The fourth category included radioactive substances regulated under the Radioactive Substances Act, 1948. The Secretary of the State had powers to control the sale and supply of radioactive substances intended to be taken internally by or injected into human beings and to control the use of certain irradiating apparatus for therapeutic purposes.

**Present position**

This distinction between four classes of therapeutic substances and medicinal products was sought to be removed by a separate legislation. The control would be replaced by one complex overall framework provided under the Medicines Act, 1968 which has not come into force fully. At
present, the veterinary products are still governed by the Animal Health Act 1981 in parallel with provisions of the Medicines Act 1968.

Scope of control under Medicines Act 1968 and 1971

These Acts provide a framework for regulation and control of all dealings in medicinal products. The manufacture, assembly, sale, supply, import and export of a medicinal product in the course of business is generally prohibited except under licence. There are exemptions in favour of professionals in this field. The Ministers' act as the licensing authority and the Act provides a scheme for grant, refusal or renewal of licences. The sale or supply of a medicinal product for the purpose of a clinical trial or a medicinal test on animals is also regulated.

Part III of the Act makes further arrangements for regulating the sale or supply of medicinal products. It provides for the establishment of a general sale list of medicinal products which can safely be sold without supervision of a pharmacist. It restricts the retail sale of medicinal products which are not included in general sale list only to sales by registered pharmacies. There are also exemptions to these provisions. The sale of medicinal products from automatic machines is also regulated. Provisions are made for the establishment of a list of medicinal products which may be sold or supplied by retail only in accordance with a prescription given by a practitioner.

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Contravention of the provisions of the Act or any regulation made under it is in general, a criminal offence.

**Regulations on drugs in the U.S.**

In United States, drug laws give the federal Government the right and duty to prevent the manufacture of an unsafe or ineffective drug. The Food and Drug Administration (FDA) is the federal agency responsible for the enforcement of drug laws. At the beginning of the 20th century, many physicians in the United States became concerned about the increasing degree to which preservatives, some of which were harmful, were being added to food, and about the rising extent to which patent medicines of the questionable value were being sold. They also worried that even proven medicines were being marketed in an adulterated or even decomposed state so that their potency and therapeutic efficacy were unreliable. Many pure food and drug Bills were therefore introduced in Congress. The movement culminated, in the passage of the Pure Food and Drug Act 1906, which made it illegal to manufacture or introduce an adulterated or misbranded food or drug anywhere in the United States.

The 1906 law represented a major step forward and ensured the purity of the drugs, but it did not, surprisingly guarantee that drugs were safe to use. A disaster, in which over a hundred people died as a result of

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29 9 Encyclopedia Americana 413.
consuming an elixir of sulfonamide dissolved in highly toxic diethyl glycol, resulted in the passage of the Food, Drug and Cosmetic Act 1938 which required manufactures to test their new drugs for safety and to report the test findings to the Food and Drug Administration. Although this Act required new drugs to be proved safe, it still did not require proof of therapeutic efficacy. Worried by the ever-increasing consumer drug bill, Congress passed the Drug Amendments Act in 1962. This Act requires a manufacture to demonstrate the efficacy of a drug as well as its safety. This law and subsequent amendments apply not only to new drugs but to all drugs introduced since 1938. Through these laws, drugs found to be too dangerous in proportion to their therapeutic worth can now be removed from the market.

**History of drug legislation in India**

The purity and efficacy of drugs was considered as a matter of public concern since 1861 when the Indian Penal Code was drafted. Legislature realised that purity and efficacy of the drugs should not be compromised since any tampering with drugs may have serious consequences upon those whom they are administered. Hence, adulteration was made punishable under the Penal Code. It also punishes the sale as well as distribution of adulterated drug from any dispensary for medicinal purpose. Provisions were also made to punish any one selling a medicinal substance or article by

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30 See Indian Penal Code, 1861, S. 274
31 See id., S. 275.
substituting the one required by the customer\textsuperscript{32}. The object of these provisions is to protect public health by penalising the sale of adulterated, inefficacious, and noxious drugs. But the enforcement of these provisions was found difficult. There being no standard prescribed under law, it was pointed out\textsuperscript{33} that there can be no test and until a standard is fixed, the provision is likely to remain a dead letter.

Therefore, separate drug control legislations were required providing for standard of purity, safety and efficacy so that it would be possible for the enforcement agencies to test whether the drugs produced, sold, and distributed are of the standard prescribed by the law.

**Drug legislation in India**

The first law to regulate the import of drugs into British India was introduced in the legislative Assembly in 1937. The Select Committee appointed to consider this bill was, however, of the opinion that there was a need for a comprehensive measure which would deal with manufacture and distribution of drugs in addition to their import. After the Provincial Legislatures passed resolutions empowering the Central government to pass a law regulating drugs, the Central Legislature passed the Drugs Act 1940. When the Constitution of India came into force, regulation and control of manufacture, sale and distribution was included in the Concurrent List\textsuperscript{34}.

\textsuperscript{32} See id., S. 276.


\textsuperscript{34} Constitution of India, , List III, Entry 19.
Consequently under the Constitution it is the Central Law which prevail\textsuperscript{35}. In view of the importance of the subject the law has been amended from time to time to ensure that uniform standards are maintained throughout India. The amendments of 1960 empowered the Central Government to control the manufacture of drugs, to appoint inspectors for taking samples and inspecting manufacturing units and to appoint Government analysTs. The Amendment of 1962 brought within its fold regulation of cosmetics. The Drugs Act was renamed as the Drugs and Cosmetics Act 1940.

Further amendments have been made to establish regulatory system for medicines prepared in accordance with the Ayurvedic or Unani system of medicine\textsuperscript{36}, to prevent adulteration of drugs and production of injurious and substandard drugs by imposing stringent penalties\textsuperscript{37}. Consumer organisations have also been empowered by a recent amendment to initiate action in CourtS against the wrongdoer under the Act\textsuperscript{38}. To enable consumers to buy medicines at a fair price, use is being made of the Essential Commodities Act by framing Drugs Price (Control) Orders under it. To prevent the misleading and exaggerated claims in advertisements of pharmaceutical products Drugs and Magic Remedies (Objectionable Advertisements) Act\textsuperscript{39} has been enacted. The rules framed under the Drugs

\textsuperscript{35} Id. at Article 254.
\textsuperscript{36} Act 13 of 1964.
\textsuperscript{37} Act 68 of 1982.
\textsuperscript{38} Drugs and Cosmetics (Amendment) Act, 1986.
\textsuperscript{39} Act 21 of 1954.
and Cosmetics Act called Drugs and Cosmetics Rules 1945 go into every
details of controls on drugs.

**Advisory bodies**

Under the provisions of the Act, the Drugs Technical Advisory Board
has to be consulted before any rule is amended or introduced. The Drugs
Technical Advisory Body (DTAB) is a technical body with the Director
General of Health Services as the chairman and Drugs Controller of India as
the member-secretary.°°

State level Drugs Advisory Committees have been constituted by the
respective State Governments with the secretary to the Health, Medical and
Family Welfare department as its chairman. The members of the
committee include officials and non-officials representing trade, industry and
medical profession. Trade include both retail as well as whole sale chemists.
Similarly representatives from industry include large scale, small scale and
government undertakings. The main objective of the advisory committees is
to ensure availability of essential drugs in rural areas and to examine
suggestions and complaints from the public.

°° Drugs and Cosmetics Act, 1940. Section5 provided for the establishment of the Board. The
Board includes, *inter alia*, President of the Medical Council of India, President of the Pharmacy
Council of India, Representatives of the Indian Medical Association, Indian Pharmaceutical
Association, Pharmaceutical Industry, as well as State Drug Controllers and Government
Analysts.

° See brochure published by Directorate of Drugs Control Administration, Government of A.P.
Administrative measures

India has a federal structure of government and as already pointed out, drugs fall in the concurrent list. Both Central and State Government have therefore power to enact legislation relating to drugs. Although Drugs and Cosmetics Act is a central legislation, the responsibility for enforcing the provisions of the Act is divided between the Central and State Governments. The Central Government is concerned with control over quality of imported drugs, laying down regulatory measures and standards for drugs, granting approval for import or manufacture of new drugs. The State Governments are responsible for exercising control over drugs manufactured, sold and distributed in their respective states.

For giving effect to the above responsibilities under the Act, Government of India, has established a Central Drug Control Organisation which is headed by Drugs Controller of India. Offices of their department are established in limited parts of the State\textsuperscript{42} for controlling quality of the drugs imported into the country by sea. The organisation has also established Central Drug Laboratories at various places for testing of drugs. The Drug Control agencies in the respective states are headed by drug controller. He is the licensing authority for all manufacturing concerns in the state. He may designate his deputies as the licensing authorities. Drug inspectors in each district inspect the licensed premises of manufacture and

\textsuperscript{42} For example such departments are established presently at Bombay, Madras, Calcutta and Cochin.
sale and draw samples of drugs for test and analysis which are tested in State Drug Control Laboratories.

**Redressal machinery**

Redressal of consumer grievances under these laws is made available in the ordinary civil courts established in the country. Prosecutions can be initiated against the wrongdoers in the criminal courts. But the brief survey of the decisional law in the post-independence era indicates that the consumers have, by and large, not been making use of ordinary courts in consumer disputes due to long drawn technical, expensive and time consuming character of these processes.

Instead a demand has been made for setting up of quasi-judicial agencies with simple procedures for providing speedy relief. The Consumer Protection Act 1986 meet these demands. According to the statement of Objects and Reasons of this Act, it seeks, *inter alia*, to promote some basic rights of consumers, namely the right to safety, to be informed of quality, potency and purity of the products, to access to variety of goods at competitive prices, to redressal of grievances and to consumers education.

Provisions have been made for setting up of quasi-judicial authorities for redressal of common disputes. The apex authority, the National Consumer Dispute Redressal Commission, has also been constituted. There are provisions for setting up of State Commissions and the District Formulas. The Act provides for appeal to the Supreme Court against an order made by the National Commission.
In this context it may be noted that the consumer organisations have also been empowered by an amendment to the Drugs and Cosmetics Act to initiate action in any of these forums or in ordinary courts for redressal of consumer grievances.

**Meaning of consumer of pharmaceutical products**

In the widest sense of the term, a consumer is a person who buys goods or avails services provided by traders for satisfaction of his needs and demands. In this sense consumer includes any individual, group of individuals or entity. It may be noted that the discussion here is confined only to the consumer of goods. Consumer of goods has been defined under the Consumer Protection Act 1986. Some of the attributes of consumer as per this definitions are:

a) The person must have bought or agreed to buy and paid consideration for the goods. It is not necessary that the whole or part of the consideration has been paid. Even promise of payment for goods bought or to be bought is sufficient to meet the requirement of law.

43 Drugs Cosmetics (Amendment) Act, 1986.

44 Consumer Protection Act 1986. Section 2(1)(d) reads:

(d) "consumer" means any person who -

(i) buys any goods for a consideration which has been paid or promised or partly paid and partly promised, or under any system of deferred payment and includes any user of such goods other than the person who buys such goods for consideration paid or promised or partly paid or partly promised, or under any system of deferred payment when such use is made with the approval of such person, but does not include a person who obtains such goods for resale or for any commercial purpose; or
b) The status of the consumer is not restricted to buyer of goods. It is extended in favour of a person who uses the goods with the approval of the original buyer of goods.

A person who obtains goods for resale or commercial purpose is excluded from the definition of consumer.

A few points are worthy to be mentioned. First the definition avoids the controversy relating to requirement of privity in contractual transaction. It is well known that a contract confers rights and imposes obligations on parties to the contract only and not on third parties. Second, the remedies under the Act are available to persons who buy the goods under the system of deferred payment. Thirdly, even though the law does not state to whom the consideration should have been paid and for whom the goods have been bought, yet it may be inferred that there are no limitations, express or implied, in the Act in this regard.

Inspite of the above positive aspects of the definition, it may be stated that definition is heavily based on the concept of 'consideration'. This may exclude a large segment of consumers of pharmaceutical products who are eligible to get free medical care from government hospitals. Free medical care also includes free medicines to the eligible patients. The definition also do not cover consumers of free sample medicines given to them by the medical practitioners which in turn were supplied to them by the pharmaceutical industry through their local sales personnel. In the same way
consumers of investigational new medicinal product in the bio-medical
research may not be covered.

Hence, there is a need to broaden the scope of consumer with respect
to pharmaceutical products so as to enable a large section of the people to be
brought under the protective umbrella of the law. In fact in all the above
instances the user of the medicine is within the foreseeability of the producer
or supplier of the medicine. In addition to this, recent decisions of the
Supreme Court will lead us to conclude logically that the persons who are
eligible for free medical aid from government or non government hospitals
are treated as 'consumers' for the purpose of the Act.

In Indian Medical Association v V.P. Shantha45, this idea has been
partially accepted. The Court refused to accept the argument that even the
government hospitals, where services are rendered free of charge to all
patients should come under the provisions of the Act. But it conceded that
services rendered by such institutions will come under the Act if they collect
charges from any section of the patients who can afford to pay and render
free services to other sections of people who cannot afford to pay. The
Court said:

"To hold otherwise would mean that the protection of
the Act would be available to only those who can afford to pay
and such protection would be denied to those who cannot so
afford, though they are people who need the protection more\textsuperscript{46}.

The court was of the view that the legislature did not intend such consequences which would restrict the protection of the Act to persons who can afford to pay for services. It would also lead to different standards of quality of service to different sections of the patients depending upon their capacity to pay in the same hospital. Such consequence would defeat the object of the Act. The Court categorically said that all persons who avail of the services in such hospitals are required to be treated on the same footing irrespective of the fact that some of them pay for the services and others avail of them free of charge\textsuperscript{47}. To circumvent the argument that government hospitals cannot be equated with the commercial institutions the Court said,

\begin{quote} 
"We are of the view that in such situation, the person belonging to “poor class” who are provided services free of charge are the beneficiaries of the service which is hired and availed of by the “paying class”\textsuperscript{48}.
\end{quote}

Therefore, the court took the view that in such hospitals where “poor class” and “paying class” are treated simultaneously, such of those who are rendered free services are “beneficiaries” and as such come within the definition of ‘consumer’.

\begin{footnotes}
\item[46] Id. at 676, \textit{per} S.C.Agrawal, J.
\item[47] Ibid.
\item[48] Ibid.
\end{footnotes}
The Supreme Court has attempted to further widen the scope of the meaning of ‘consumers’ in *Pachim Bengal Kheth Mazdoor Samithi v. State of West Bengal* 10. In this case a mazdoor who met with an accident and who was eligible for free medical care in government hospitals was denied emergency medical aid by the government hospitals on the plea that facilities were not available. He took treatment in a private nursing home. The question before the Court was whether he is entitled to claim reimbursement and compensation for the ‘deficiency’ of services. The Court held that the expression consumer as defined in the Act includes persons getting or eligible for medical treatment in government hospitals and that expression ‘services’ also defined in the Act includes services provided in the government hospitals also. In the process Court said that the financial constraints on the part of the Government cannot be a ground for not providing services or for providing deficient services. Court opined:

“It is no doubt true that financial resources are needed for providing these facilities. But at the same it cannot be ignored that it is the constitutional obligation of the State to provide adequate medical services to the people. Whatever is necessary for this purpose he has to be done.”

In this context the Supreme Court referred to its own decision in *Kathi I I v. State of Bihar* 51 wherein it held that the constitutional obligation to provide free legal aid to the poor accused cannot be avoided by the State


50 *Id*, at p. 48.

on account of financial constraints. It held that these findings would apply
with equal, if not greater, force in the matter of discharge of constitutional
obligation of the state to provide medical aid to preserve human life.

The Court said,

"In the matter of allocation of funds for medical
services, the said constitutional obligation of the state has to be
kept in view."

The Court ordered the state to pay Rs. 25,000 to the claimaint as a
compensation.

The observations made by the Supreme Court in the above two cases
relating to medical services would equally apply to the medicinal products.
Hence, a person who received medicines from a government hospitals free
of cost and found to be defective and one who could not get required
medicines in adequate quantity because of non-availability of the same in the
government hospital though he is eligible for such medicines are persons
who can be considered as consumers. This is the logical fallout of the
findings of the above two Supreme Court decisions. Even the financial
constraints of state may not be allowed as grounds of excuse for the inability
of the State to provide safe, efficacious and adequate quantity of medicines
in such hospitals.
Meaning of pharmaceutical product

The word 'pharmaceutical product' is deliberately used with a view to exclude Ayurvedic, Unani and Sidha systems of medicine from this study. The word 'drug' during the course of last few decades has assumed another meaning and currently, when we use the term drug, the usual cannotation is to a 'dangerous narcotic drug'. However, in this work the term drug whenever is used would mean only 'pharmaceutical preparation'.

A drug is a chemical agent that is used therapeutically to treat disease. More broadly, a drug may be defined as any chemical agent that affects living protoplasm. The term drug is usually used in its narrower sense to refer to a chemical whose specific purpose is the treatment of a disease.

Meaning of drug under English Law

Medicines Act 1968 (England) defines medicinal product as one which is used wholly or mainly in either of the two ways (1) administration in human beings or animals for medicinal purposes. (2) The other way is use as an ingredient in the preparation of a substance or article to be administered to a human being or animal for a medicinal purpose. However for this second way to operate, a product is to be used in pharmacy

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\[54 \text{Encyclopedia Americana} 404.\]

\[55 \text{Section 130(1)}\]

\[56 \text{Such a purpose being for the treatment or prevention of disease or providing information as to a physiological condition, contraception, inducing anaesthesia, or anyhow preventing or interfering with the normal operation of a physiological function. See Medicines Act 1968 (U.K.) Section 130 (2)}\]
or hospital, by a doctor, veterinary surgeon or practitioner\textsuperscript{56}. The Act clearly excluded an instrument, apparatus or appliance used for medicinal purpose.

However, ‘medicinal product’ does not include any substance or article which is manufactured for use wholly or mainly being administered to one or more human beings or animals for research purpose. It is not to be considered as medicinal product if the person who manufactured it in the course of business of a laboratory or research establishment carried on by him or anyone under him and used solely by way of test for ascertaining what effect it has when so administered and in circumstances where the manufacturer has no knowledge of any evidence that those effects are likely to be beneficial to those human beings or animals. But if such product having been manufactured, is sold, supplied or exported for use, it may amount to medicinal product. Under English law medicinal product must also be taken not to include substances used in dental surgery for filling dental cavities, bandages and other surgical dressings except medicated dressings where medication has a curative function which is not limited to sterilising the dressings\textsuperscript{57}.

\textbf{Drug under the U.S. law}

The Federal Food, Drug, and Cosmetic Act\textsuperscript{58} of the United States provides that the term “drug” means (1) articles recognised in the official


\textsuperscript{57} Ibid.

\textsuperscript{58} See 25 Am Jur (2nd) 284.
United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National formulary, or any supplement to any of them, (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, (3) articles other than food, intended to affect the structure or any function of the body of man or other animals, (4) and articles intended for use as a component of any articles specified in the above clauses. But the term 'drug' does not include devices or other components, parts or accessories in United States.\(^59\)

**Meaning under Indian law**

In India under the Drugs and Cosmetics Act\(^60\) a "drug" includes- (i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes, (ii) and Substances other than food intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, (iii) all substances intended for use as components of a drug including empty gelatin capsules, and (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of

\(^59\) 21 U.S.C. 321(g).

\(^60\) Drugs and Cosmetics Act 1940, Section 3(b).
diseases or disorder in human beings or animals as may be specified from

time to time by the central Government after consultation with the Board\textsuperscript{61}.

The narrow definition given by the U.S. law permits escape from legal

control of all therapeutic or curative devices like electric belts. It also

permits the escape of preparations which are intended to alter the structure

or serve the function of the body, like preparation intended to reduce or

minimise body weight. Fortunately in India all such devices and even

devices like disposable syringes can also be included in the definition of

drug\textsuperscript{62}.

An analysis of the differences between the definition of drug in

these three countries is not attempted here. However it is worth observing

that the definition under Indian law makes an attempt at widening the scope

of the meaning of drug by including devices also under it which have been

expressly excluded in the U.S. and English laws. But for these minor

differences, all the definitions are very clear on the fundamental concept of

drug and in particular even the language used in the U.S. and Indian law is

almost identical.

Thus, the definition of drugs is only inclusive and not an exhaustive

one. The above definition of ‘drug’ as interpreted by the Courts is

comprehensive enough to take into its fold not only medicines but also

substances. The Supreme Court interpreted the word substance to include

\textsuperscript{61} Ibid.

such devices and things used in the treatment such as gauze, absorbent cotton wool, and roller bandages. In *Chimanlal Jagjivandas v. State of Maharashtra*\(^6\), it was held that the definition does not introduces a distinction between medicines and substances which are not medicines strictly so called. The expression 'substances' therefore must be something other than medicines but which are used for treatment. The appropriate meaning of the expression substances in the section is 'things'. It can not be disputed that absorbent cotton wool, roller bandages and guaze are substances within the meaning of the said expression. If so the only question is whether they are used for or in 'treatment'. The said articles are sterilised or otherwise treated to make them disinfectant and then used for surgical dressing. The Court said,

"They are essential materials for treatment in surgical cases. Besides being aseptic, these articles have to possess those qualities which are utilised in the treatment of disease. Thus, for instance 'gauze' has to confirm to a standard of absorbency in order that it might serve its purpose. Otherwise the fluid which oozes is left to accumulate at the site of the wound or sore\(^6\)."

The legislature designedly extended the definition of 'drugs' so as to take in substances which are necessary aids for treating surgical or other cases. The substances intended to affect the body such as legature or suture were considered as substances under the subclause.

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\(^6\) *Id.* at p 666 *per* K. Subba Rao, J.
‘Water’ meant to be used for dissolving other medicines for injection into human body was held as drug within the meaning of the section\textsuperscript{65}. Similarly ‘Boroline’ which is recommended to be used by the makers for beautifying or promoting attractiveness is also recommended to be used for preventing infection in case of minor cuts. From the formula as mentioned in the carton, the Calcutta High Court held that Boroline contain certain medicine. It was, therefore, as a drug\textsuperscript{66}.

The products like dust powder was considered to constitute a drug. The products that claim to cure baldness or a skin disease and hormone creams and antibiotic deodorants are in fact drugs because their ingredients affect the function of the human body. The term ‘drugs’ embraces patent or proprietary remedies that possess or are reputed to possess curative or remedial properties sold or used as medicines. And it is true regardless whether they are purchased with or without prescription. Drug has also been construed to include aspirin, laxatives, tincture of iodine, spirits of camphor, and tincture of arnica but not to include tobacco or borax. Although whisky is not generally considered to be a drug, it may be regarded as such in certain circumstances where it is used and sold as drug. A vitamin preparation, otherwise deemed a food product, is to be considered as a drug where it is administered or used as a medicine.

\textsuperscript{65} Ramachandra Sundarka v. State of West Bengal, 1971 Cr.L.J. 1369 (Cal.).

For the purpose of regulating its collection, storage and supply, "blood" is treated as a 'drug' under the Act. Already claims have been made in respect of 'contaminated blood' and blood products supplied by blood banks. Claims were also been made in respect of defective heart-valves, infra-uterine devices and breast implants. It would be difficult to think of other products which could provoke litigation. It is not clear whether donated human organs, contaminated or defective donated sperm can be regarded as products for the purpose of claiming remedy under defective products. There will be difficulty in such claims especially when law prohibits sale of such organs. Commodification of human organ is objected on moral ground that 'society's moral values mitigate against regarding body as a commodity. But potential possibility of some form of payment for human organ has been seriously discussed. According to them payment for organs would generate a large supply of cadaveric organs than does under the current voluntary system.

Thus 'consumer of a pharmaceutical product' means anyone foreseeably harmed by the defective medicinal product. This includes user...
of the product, a member of the purchaser's family including foetus *in utero* or an employee of the purchaser. It may also include persons such as donee of blood or human organ. Hence the need to widen the notion of consumer so as not to restrict the beneficiaries and this has got value for the general application of all the consumers and in particular to those of consumers of pharmaceutical products.

The foregoing discussion shows that the legislative and judicial attempts in India and elsewhere had been to widen the concept of Consumers of Pharmaceutical Products. The scope of protection provided may vary. But in every country attempts have been made to control pharmaceutical industry in the manufacture, sale and supply of medical products.